IAS2017

9TH IAS CONFERENCE ON HIV SCIENCE
PARIS, FRANCE – 23-26 JULY 2017

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The Abstract Mentor Programme provides an opportunity for early-career investigators to receive feedback from more experienced researchers on their draft abstracts.
The programme links mentees to mentors within the same track to maximize the use of the mentors' expertise. Participants are required to take part in an online e-course on conference abstract writing in order to submit to the programme.

This year, 117 mentors reviewed 204 draft abstracts submitted by 156 researchers. One hundred and twenty-eight of them were submitted to IAS 2017 and the following were selected:

- 2 Oral Abstract
- 1 Poster Discussion Session
- 26 Poster Exhibition

We would like to thank all volunteer abstract mentors, listed below, who supported early-career HIV researchers improve the quality of their abstracts.

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The 9th IAS Conference on HIV Science received more than 4,300 abstract submissions, which went through a blind, peer-reviewed process carried out by an international panel of reviewers who play a critical role in designing a strong scientific programme.

More than 800 specialists from around the world volunteered their time and expertise to serve as peer reviewers, helping to ensure that the abstracts presented were selected on the basis of rigorous review and were of the highest scientific quality.

We extend our special thanks to the large pool of abstract reviewers for the time they dedicated to the success of the conference:

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IAS 2017 ABSTRACT CODING

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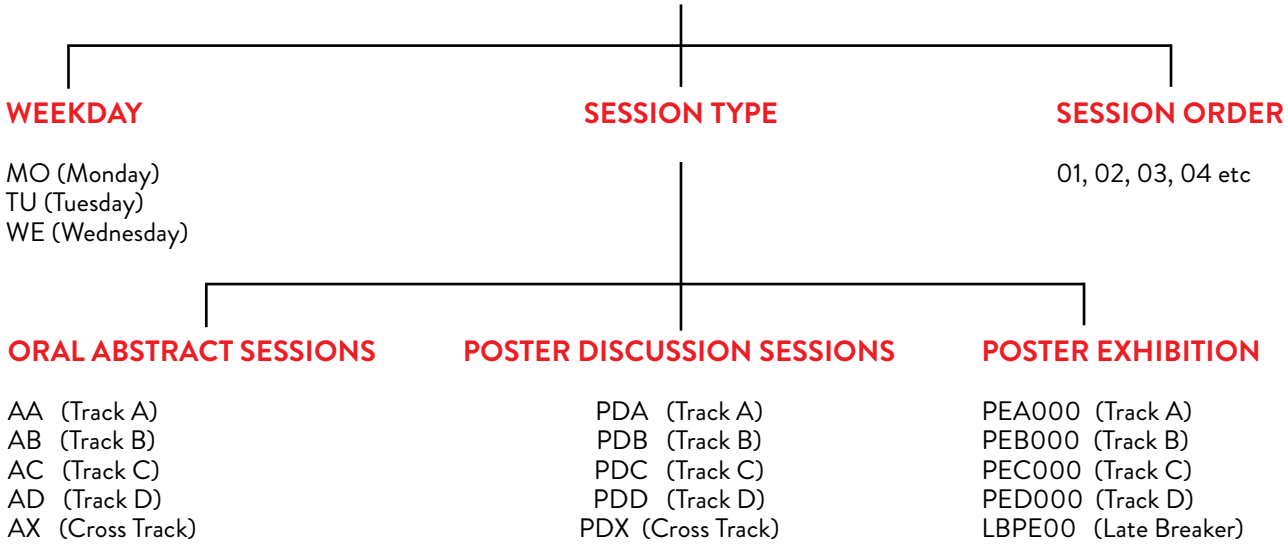
Example 2: **MOAA0105LB** = **MO** (weekday) – **AA** (session type) – **01** (session order) - **05** (abstract order) – **LB** (late breaker abstract)

Example 3: **MOPEA001** = **MO** (poster presentation day) – **PE** (presentation type) – **A** (track) – **001** (abstract order)



Monday 24 July

Oral Abstract Sessions

MOAA01 Hide and Seek: Biology of Reservoirs

MOAA0101

Assessing individual viral reactivations of the latent reservoir using a novel barcoded virus

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Background: An overwhelming obstacle to HIV cure is the presence of long-lived viral reservoirs that can reignite viral infection after removal of cART. Yet, our knowledge of the mechanisms of reservoir maintenance and persistence remains incompletely understood. Therefore, in this study, we generated a novel virus model for evaluating individual reactivation events following cART interruption to better understand key aspects of reservoir biology in vivo.
Methods: A genetically tagged virus (SIVmac239M) was generated with a 34-base molecular barcode stably inserted between vpx and vpr of SIVmac239. Rhesus macaques were infected intravenously and combination antiretroviral therapy (cART) administered, beginning either on day 6 for 82 days (n=4) (study 1), or day 4 for 305, 374, or 482 days (n=6) (study 2). Next-generation sequencing was used to evaluate the number of genetic variants in the stock and in plasma before and after treatment.
Results: In the viral stock, 9,336 individual barcodes, or clonotypes, were identified. During acute infection, an average of 1,247 barcodes were identified in each of the 10 animals. Plasma viremia was reduced to 15 vRNA copies/mL during treatment, and virus rapidly rebounded following treatment interruption. Between 87 and 136 distinct clonotypes were detected in plasma at peak rebound viremia in animals from study 1, and between 4 and 7 clonotypes in animals from study 2. Because the growth rate of each clonotype is equivalent once the virus reaches systemic infection, the measured relative proportions of each clonotype at rebound reflect the time between when each clonotype achieved systemic infection. The viral growth rate and the relative abundance of each clonotype in plasma during acute recrudescence was used to estimate a reactivation rate of 22.7 and 0.54 events per day in studies 1 and 2 respectively.
Conclusions: We conclude that identifying rebounding clonotypes may be used as a direct measurement of the latent reservoir that can successfully contribute to rebound viremia. Furthermore, the results confirm that the size of the post-cART recrudescence-competent viral reservoir is influenced by the timing of cART initiation and duration of treatment, enabling manipulation of these parameters to establish reservoirs of desired size for specific experimental purposes.

MOAA0102

Accumulation and persistence of deleted HIV proviruses following prolonged ART

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Background: HIV persistence during antiretroviral therapy (ART) is a substantial obstacle to HIV cure. HIV infected cells can undergo clonal expansion and specific clones may be highly expanded. We previously reported one provirus integrated in the HORMAD2 gene that accounted for 20-40% of all proviruses in one patient. Mechanisms by which clones emerge and persist over time are uncertain. To investigate the dynamics of HIV clonal expansion, we developed multiplexed droplet digital approaches (ddPCR) to quantify HIV proviruses, including specific integrants, prior to and following prolonged ART.
Methods: HIV infected ART-naïve individuals (N=11) underwent ART and were followed for a median of 13.7 years (range 4.3-16.4). Cell associated DNA (CA-DNA) from peripheral blood lymphocytes pre-ART, during first and second phase viral decay, and after prolonged ART was quantified using multiplexed ddPCR assays targeting HIV gag, LTR, and tat/rev regions, as well as a host gene (CCR5). We designed a specific ddPCR primer set overlapping the host-HIV junction to quantify the HIV integrant in HORMAD2.
Results: All patients had successful suppression of HIV RNA on ART to < 50 c/mL plasma within 5 months; HIV DNA copies/million CD4+ cells decreased for gag (average 15-fold), LTR (average 9.3-fold), and tat/rev regions (average 20-fold). In 10/11 patients the LTR:gag and LTR:tat/rev ratios increased progressively after second phase decay (average 6-fold and 6.4-fold respectively, p<0.01, paired T-test) demonstrating loss of full length proviruses; in 1/11 patients, LTR:gag and LTR:tat/rev ratios remained stable. The HORMAD2 integrant was undetectable at pre-ART, 1 month, and 2 months on ART (< 1 copy in 500,000 infected cells). After 1 year on suppressive ART, however, the HORMAD2 integrant was present at a frequency of 30% of all infected cells and persisted for 6 years on ART.
Conclusions: Progressive appearance of deleted proviruses is detectable in most, but not all patients undergoing ART. Substantial deletion did not appear during first or second phase viral decay, but only after 1-4 years during suppressive therapy. Clonal expansion of HIV infected cells can be rapid, and sustained at stable levels during prolonged ART, suggesting that both antigen-induced clonal expansion and homeostatic proliferation maintain HIV populations.

MOAA0103

A subset of extreme HIV controllers is characterized by a small HIV blood reservoir and a weak T cell activation level

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Background: HIV controllers (HICs) form a heterogeneous group of patients with regard to formal definitions, immunologic characteristics and changes over time in viral load.
Methods: HICs with undetectable viral load (uHICs, i.e. for whom a viral load had never been detected with routine assays, n=52) were compared with 178 HICs with blips during the follow-up (bHICs). Clinical characteristics, ultrasensitive HIV-RNA and HIV-DNA loads, HIV1-Western blot (WB) profiles and immune parameters were analyzed.
Results: Relative to bHICs, uHICs had significantly lower ultrasensitive plasma HIV-RNA loads (median < 4 copies/ml [IQR < 2-< 4] vs. 21 [7-84] copies/mL, p<0.0001) and HIV-DNA levels in PBMC (< 10 copies per million PBMCs [< 10-11] vs. 21 [< 10-52], p=0.0004), higher CD4+ T cell count (790 [638-1038] vs. 711 [520-920], p=0.04) at enrolment, and lower T cell activation levels.
Half the uHICs were characterized by having a protective HLA allele (-B57/58/B27), a weak CD8+ T cell response and very small HIV-DNA reservoir. Between diagnosis and inclusion in the cohort, the CD4+ T cell count had not changed in uHICs but had significantly decreased in bHICs (-5.16 CD4/µL/year, p=0.001). 21% of the uHICs lacked specific anti-HIV IgG antibodies. These individuals also had very low levels of HIV-DNA, and 83% of these patients had both undetectable HIV DNA and us HIV RNA, compared with 40% of uHICs with full anti-HIV IgG responses.
Conclusions: We suggest that an optimal HIC phenotype combines protective HLA alleles, low level of HIV blood reservoirs and reduced immune activation. Such patients may have limited benefit from antiretroviral therapy.

MOAA0104

HIV integration sites in CD4 T cells from virally suppressed individuals show clonal expansion but no preferential location in oncogenes

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Background: Assessing HIV integration site location and frequency in latently infected cells can inform how HIV persists on antiretroviral therapy (ART). We aimed to characterise HIV integration sites in CD4 T-cells from blood and tissue from HIV-infected individuals on suppressive ART.
Methods: Genomic DNA from 1 million CD4 T-cells obtained from blood, lymph node (LN) or rectal tissue from virologically suppressed participants on ART was enzymatically cut to random sized fragments, tagged and amplified by nested PCR with barcoded primers before Miseq sequencing. Chromosomal alignment was determined using Blat-UCSC Genome Browser (GRCH38/hg38). Clonal expansion of HIV integration sites was defined if identical HIV integration sites differed >2 base pairs in PCR-product length and ≥3 length polymorphisms were present.
Results: We assessed 1794 integration sites from 7 participants receiving ART for a median [range] of 14 [7-19] years with an undetectable viral load for 6 [4-16] years. Integration was enriched in genes vs non-genes (78 [58-87]% vs 23 [13-42]%, p<0.001). The majority of integration sites into genes were intronic (median 86 [72-97]% vs 13 [3-18]% exonic, p<0.001) and demonstrated preferential insertion in the opposite orientation relative to gene transcription (median 60 [47-68]% vs 40 [32-52]% same orientation, p=0.007). In blood we observed a median of 54 [25-70]% clonally expanded integration sites.
Interestingly, the frequency of clonal expansion was different in blood and tissue. In matched samples of 2 participants, the frequency of clonal expansion in LN was similar to blood, whereas rectal tissue showed the least amount of clonal expansion (table). Integration sites in expanded compared to non-expanded clones were enriched in genes (84% vs 69% respectively, p=0.04) but there was no enrichment in oncogenes (median 22% vs 25% respectively, p=0.74).

	CD4 count	HIV DNA /10^6 CD4 cells	% Clonal expansion in blood	% Clonal expansion in LN	% Clonal expansion Rectal tissue
Participant 6	578	1500	32	38	17
Participant 7	521	494	25	-	10

[Clonal expansion of HIV integration sites]

Conclusions: Expanded clones of infected cells in blood and tissues are common. HIV integration is preferentially detected in intronic regions but not oncogenes with orientations that are usually in opposite direction. The relative contribution of expanded clones to HIV persistence may differ in different tissue sites but analysis of further tissue samples are needed.

MOAA0105

The impact of treatment duration on defective and expanded identical HIV genomes in T cell subsets from peripheral blood and tissues

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Background: Understanding the impact of antiretroviral therapy (ART) duration on HIV-1 reservoirs is critical for implementing effective curative strategies. We studied the distribution of defective viral genomes in T cell subsets within blood and tissues over 3-18 years of effective ART. We also examined expansions of identical HIV-1 DNA sequences (EIS) to assess the contribution of cellular proliferation to viral persistence during ART.
Methods: Using single-genome/proviral sequencing, we performed inter-patient analysis of 479 HIV-1 p6-RT RNA sequences from pre- and early-ART plasma; and 2329 HIV-1 DNA sequences from naïve (N), central (CM), transitional (TM), effector (EM), gut homing and lymph homing memory CD4+ T cells sorted from peripheral blood (PB), lymph node (LN) and gut tissues from 14 participants who initiated ART during chronic infection (3-18 years on ART). Defective viral sequences had hypermutation, premature stops, frameshifts and large deletions. EIS were determined as ≥2 identical intact or defective HIV-1 DNA sequences across all cell types from all anatomic sites.
Results: Defective HIV-1 DNA sequences did not appear to accumulate substantially over 3-18 years of ART in any anatomic site (odds ratio=0.90-1.02/year, p=0.14-0.98). The viral sequences derived from pre- and early-ART plasma samples were more often genetically intact than sequences derived from PB and LN after several years of therapy (p≤0.004). The odds of an HIV-1 DNA sequence belonging to EIS increased in PB by 1.09-fold/year of ART (p=0.003). In tissues, the increase of the proportion in EIS during each additional year of ART was not statistically significant (p=0.15-0.25). Of note, 37-71% of identical HIV-1 DNA sequences were in EM sorted from PB and tissues. The odds that a viral sequence is part of an EIS in PB-derived EM increased by 1.11-fold/year (p=0.007), whereas other cell types showed no statistically significant trend (p=0.12-0.46).
Conclusions: The proportion of proviruses that were defective did not increase during effective therapy, suggesting that they are established in cells prior to viral suppression. Our data suggests that proliferation of HIV-infected T cells increased the proportion of sequences in EIS within peripheral blood over 3-18 years of therapy, and the EM cells were the major contributor.

MOAA02 Kill Me or Neutralize Me

MOAA0201

Sequential receptor-induced conformational states of native membrane-embedded HIV-1 Env

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Background: To fulfill its function of mediating virus attachment and entry, the HIV-1 envelope glycoprotein (Env) trimer undergoes a sequence of conformational changes. Due to their unstable nature, entry intermediates remain challenging to study, leaving several aspects of the entry process unresolved. This includes effects of CD4 and coreceptor engagement on the formation of successive Env intermediates and the stoichiometry of receptor and coreceptor binding. Knowledge on the different conformational states of native Env during the entry process is however crucial to understand its antigenic landscape and vulnerability to neutralization. While Env-directed broadly neutralizing antibodies (bNAbs) are thought to recognize Env preferentially in its closed, unliganded form, we currently lack information on their activity across different entry steps. As activity across intermediate Env conformations could increase the window of action, an antigenic profile of receptor-bound Env needs to be defined to select the best bnAbs for therapy and vaccine design.
Methods: We have developed a flow cytometry-based assay to assess and compare antigenic properties and conformational stability of fully native, cell surface-expressed Env trimers using an array of Env directed Abs and compounds. HIV-1 pseudovirus neutralization activity of a panel of NAbs was determined to explore links between open Env conformation and neutralization sensitivity.
Results: Our analysis provides a fine mapping of sequential exposure of shielded Env epitopes upon exposure to increasing doses of soluble CD4 (sCD4). Conformational changes induced by sCD4 binding proved consistent with a model where occupation of a protomer alters conformation of all three simultaneously. Increasing protomer occupancy by sCD4 promoted transition through intermediate, progressively more open Env conformations. According to our data, exposure of the coreceptor binding site may require at least two CD4 molecules to be bound per trimer. Most intriguingly, upon saturation of CD4 binding sites the trimer adopts a pre-hairpin conformation even in the absence of coreceptor interaction.
Conclusions: We provide here novel insights on antigenic characteristics of unliganded and receptor-bound conformations of native Env, that offer means to decipher critical steps of the entry process with high relevance for Env immunogen selection and design.

MOAA0202

Optimized Env trimer immunization parameters amplify onset, magnitude and consistency of autologous Tier 2 neutralizing antibody development in nonhuman primates

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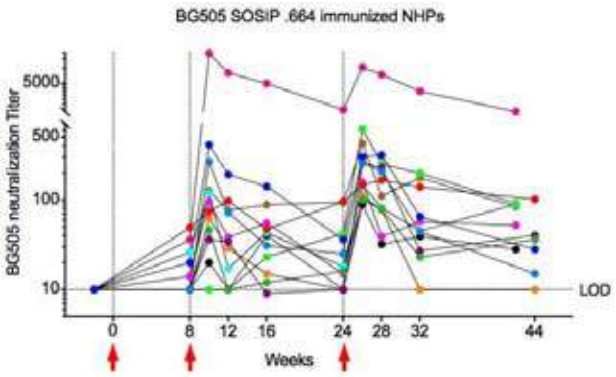
Background: The development of soluble native-like HIV Envelope trimers has reinvigorated hopes for protein-based vaccination strategies to induce protective antibody responses to HIV. However, unlike in rabbits, immunogens of this class have thus far induced only modest and inconsistent autologous neutralizing antibody (NAb) titers in rhesus macaques, raising concerns regarding the translatability of this approach. Moreover, Tier 2 NAbs have generally taken 6 months to develop in macaques.
Methods: Here, we investigated the effects of immunization schedule, route, dose and delivery on quantity, quality, and rapidity of NAb development in head-to-head comparisons, using 6-12 macaques per group. All 78 animals in the cohort were tightly matched for age, weight and gender.
Results: Major effects were observed. We identified strategies in which 100% of animals developed mean Tier 2 NAb titers of over 1:100 by wk 10. Geometric mean titers at wk 26 following two boosts were consistently higher than 1:200 (Figure 1). Effects of trimerization strategy (SOSIP vs. NFL) and immunization dose (100µg vs. 20µg) on autologous NAb titers were not significant. We further evaluated and compared novel SOSIP stabilization techniques (SOSIP v4.1, v5.2, Olio6), some of which significantly ($p < 0.001$) reduced induction of Tier 1 NAbs over previously reported strategies, while maintaining strong Tier 2 NAbs. Germinal center, T cell, and Ab responses were extensively analyzed in all animals through fine needle aspirates (FNAs), particularly those with BG505 NAb titers of 1:1000-1:20,000. Finally, high autologous Tier 2 neutralizing macaques also developed some neutralization breadth on a global Tier 2 viral panel.



[BG505 SOSIP .664 immunized NHPs]

Conclusions: In summary, this study provides a framework for preclinical and clinical vaccine studies targeting the elicitation of neutralizing antibodies by trimer immunization. We identified the when, where, and how of trimer immunogen delivery to maximize NAb titer induction in vivo.

MOAA0203

Germinal centers monitored by lymph node fine needle aspirates correlate with and predict HIV Tier 2 neutralizing antibody responses after HIV trimer immunization

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Background: The discovery of HIV broadly neutralizing antibodies in HIV+ individuals has re-galvanized efforts to develop a protective, antibody-based HIV vaccine. However, generation of neutralizing antibody (nAb) responses to clinically relevant strains of HIV (Tier 2) by immunization remains a challenging problem. Furthermore, the immunological barriers to induction of such responses by Env immunogens are unclear.
Methods: To directly study the germinal center (GC) responses induced after immunization, we have now performed over 1000 lymph node fine needle aspirates (LN FNA) of draining LNs in rhesus macaques immunized with native-like HIV-1 Env trimer proteins, such as BG505 SOSIP. LN FNA sampling captured GC cells and was highly representative of whole LN biopsies. Greater than 95% of samples provided sufficient cells for identifying the major cell types of the GC, GC B cells and GC T follicular helper (Tfh) cells. LN FNAs also afforded an opportunity for gene expression analysis of antigen-specific GC Tfh cells by RNAseq and longitudinal BCR sequencing to track evolution of the Env-specific B cell response.
Results: A majority of immunized animals developed autologous Tier 2 neutralizing antibodies. Tier 2 nAb development was most strongly associated with the magnitude of the GC response in an initial study ($p = 0.007$). In a subsequent study, the GC responses predicted Tier 2 nAb development ($p = 0.014$). Notably, Tier 2 nAbs did not correlate with BG505 SOSIP Ab binding titers. Thus, the GC responses distinguish between nAb responder and nAb non-responder monkeys, but ELISA binding titer does not.
Conclusions: Longitudinal LN FNA sampling has provided strong evidence that GC B and GC Tfh cell responses are central to generating HIV Tier 2 nAbs by immunization.

MOAA0204

Rapid elicitation of broadly neutralizing antibodies to HIV by immunization in cows

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Background: No immunogen to date has reliably elicited broadly neutralizing antibodies (bnAbs) to HIV in humans or animal models. Recent advances in the design of immunogens (BG505 SOSIP) that antigenically mimic the HIV envelope glycoprotein (Env) have improved the elicitation of potent isolate-specific Ab responses in rabbits and macaques, but so far failed to induce bnAbs. One possible contributor to this failure is that the relevant antibody repertoires are poorly suited to target occluded conserved epitope regions on Env relative to exposed variable epitope regions. The antibody repertoire of cows contains long third heavy chain complementary determining regions (HCDR3) with an ultralong subset that can reach nearly 70 amino acids in length.
Methods: Here we show that immunization of cows with BG505 SOSIP results in the rapid elicitation of broad and potent serum antibody responses. Four cows were immunized in total. Serum were collected over the course of immunization and evaluated for neutralization breadth and potency. Single memory B cells were then antigen-sorted with BG505 SOSIP and heavy and light chain variable genes were amplified by PCR.
Results: All immunized cows developed broad and potent neutralizing serum responses. Longitudinal serum analysis for one cow showed the development of neutralization breadth (19%, n = 114 cross-clade isolates) in 42 days and peak breadth (100%, n = 12 global isolates panel) at 217 days. A monoclonal antibody was isolated from this cow which harbored an ultralong HCDR3 of 64 amino acids and was able to recapitulate 69% of neutralization breadth with a potent median IC50 of 0.03 µg/ml. The antibody epitope mapped to the CD4 binding site of HIV Env.
Conclusions: Despite the inherent difficulty of eliciting broad and potent responses to HIV in most test animals, immunization with a trimer mimic in cows was able to show rapid responses in only 42 days, supporting the notion that the frequency of long HCDR3s is a critical factor in the ability to elicit HIV bnAbs. The results further suggest that immunization of cows may provide an avenue to quickly generate antibody prophylactics and therapeutics to address disease agents that have evolved to avoid human antibody responses.

MOAA0205

Killing of HIV-1-infected cells by neutralizing antibodies

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Background: Anti-HIV-1 non-neutralizing antibodies (nnAbs) capable of antibody-dependent cellular cytotoxicity (ADCC) have been identified as a protective immune correlate in the RV144 vaccine efficacy trial. Broadly neutralizing antibodies (bNAbs) may also mediate ADCC and rely on their Fc region for optimal efficacy in animal models.
Methods: Here, we selected 10 bNAbs and 9 nnAbs, targeting various epitopes and conformations of the gp120/41 complex, and analyzed the potency of the two types of antibodies to bind and eliminate HIV-1-infected cells through NK engagement in culture. We tested their activity against 18 HIV-1 strains, including primary viruses.
Results: The landscape of Env epitope exposure at the surface and the sensitivity of infected cells to ADCC vary considerably between viral strains. The most potent bNAbs, and not the nnAbs, bound to reactivated infected cells from HIV-positive individuals and mediated effective ADCC against those cells. The nnAbs also modestly recognize cells infected with 8 different transmitted founder (T/F) isolates. Efficient ADCC requires sustained cell surface binding of bNAbs to Env proteins, and combining bNAbs allows a potent killing activity. Addition of a synthetic CD4 mimetic enhanced the binding and killing efficacy of some of the nnAbs in an epitope-dependent manner, without reaching the levels achieved by the most potent bNAbs.
Conclusions: Our study reveals important qualitative and quantitative differences between bNAbs and nnAbs, delineates the parameters controlling ADCC activity of bNAbs, and supports the use of the most potent antibodies to clear the viral reservoir.

MOAA0206

Allosteric regulation in human anti-HIV-1 Env ADCC-mediating antibodies upon immune complex (IC) formation enhances the binding to FcγRs for the activation of cytotoxicity against HIV-1 virus

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Background: The field of HIV-1 vaccine research is in rapid development and a deeper knowledge of the mechanisms of defense against HIV-1 infection is urgent. In this regard, key insights about antibody-mediated immune response were provided by the RV144 vaccine trial that showed moderate protection correlating with Fc-effector functions. Historically, the activation of antibody-dependent cellular cytotoxicity (ADCC) has been considered dictated by two distinct and critical steps: optimal binding of viral antigens and engagement of FcγRs, respectively occurring in two distinguished mAbs regions (Fab and Fc domains). Only recently, few studies suggested a functional connection of Fab and Fc regions within the IgG.
Methods: Utilizing multiple approaches, such as ELISA, FCS (Fluorescence Correlation Spectroscopy), H/DX MS (Hydrogen/Deuterium Exchange Mass Spectroscopy) and crystallography, we studied whether the immune complex formation by antigen (Ag)-binding may impact the ability of IgG to consequently engage FcγRs and, in turn, activate the cytotoxic immune response against HIV-1 sensitized targets.
Results: Here we demonstrate a reciprocal allosteric regulation in anti-HIV gp120 Cluster A mAbs resulting from IC formation with a gp120-CD4 chimera antigen. We establish that the formation of ICs dramatically increases the efficiency of mAbs interaction to low affinity FcγRs compared to free IgG. Moreover, antigen-binding reverses the effect of FcγRs binding-attenuating LALA mutations in the Fc region, resulting in residual ADCC activity. HDX-MS analysis reveals an allosteric increase in conformational dynamics in the Fc domain of wildtype IgG upon Ag-binding, highlighting a putative mechanism for effective Fc receptors-engagement. In line with crystallographic data, H/DX MS showed a higher flexibility in the LALA mutant. However, antigen-binding further stabilized Fab and Fc regions of LALA mAbs, maintaining an adequate level of flexibility in the same crucial residues observed in the wt-IgG-Ag complex. Of note, the more mobile residues map to non-contact regions for FcγRs, but include residues that indirectly affect the IgG-FcγRs affinity and the induction of IgG-multimerization.
Conclusions: Collectively, these findings provide unique insights into reciprocal allosteric regulation between Fab and Fc domains, as IgG intrinsic factors that dictate the ability to tune selective Fc-effector functions, such as ADCC, in vaccine regimens or HIV-1 passive treatments.

MOAB01 Antiretroviral Therapy - ART: Season One

MOAB0101

Immunodeficiency at the start of combination antiretroviral therapy in low-, middle- and high-income countries

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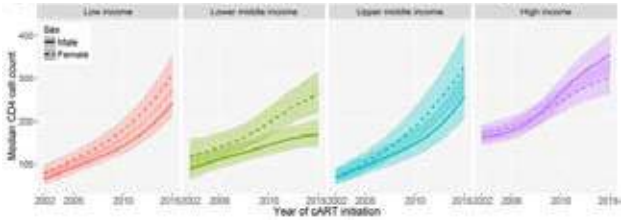
Background: Early initiation of combination antiretroviral therapy (cART), at higher CD4 cell counts, prevents disease progression and reduces sexual transmission of HIV. Changes in guidelines are expected to result in increased CD4 cell counts at cART start. We describe temporal trends in the median CD4 cell count at cART start in adult men and women.

Methods: We used data from the International epidemiology Databases to Evaluate AIDS (IeDEA) sub-Saharan Africa, Latin America, Asia-Pacific and North America regions and from the Collaboration of Observational HIV Epidemiological Research in Europe (COHERE). We included all HIV-positive adults (≥16 years) initiating cART between 2002 and 2015. We aggregated data by calendar year, country and sex, and calculated median CD4 cell counts for each of the data cells. We used additive mixed models to analyze temporal trends in median CD4 cell counts. Sex, country income group and their interaction were included as fixed effects, and yearly trends were smoothed by sex and country income group.
Results: We included 652,728 adults from 14 low-, 11 lower middle-, 6 upper middle-, and 17 high-income countries. The Figure shows the modelled median CD4 cell count (cells/μL): from 2002-2015 there was an increase from 66 to 243 (+268%) in low-, from 88 to 170 (+93%) in lower middle-, from 69 to 257 (+272%) in upper middle- and from 163 to 355 (+118%) in high-income countries in males; and from 78 to 309 (+296%) in low-, 118 to 264 (+124%) in lower middle-, 70 to 328 (+369%) in upper middle- and 170 to 302 (+78%) in high-income countries in females.
Conclusions: Median CD4 cell count at cART start increased in all income groups, but generally remained below 350 cells/μL. Substantial additional efforts are needed to increase testing coverage with the aim of achieving earlier diagnosis, linkage, and initiation of cART globally.



[Figure. Modelled trends in CD4 cell count (cells/μL) at the start of cART, by sex and country income group]

MOAB0102

ANRS 146 - GeSIDA 7211 OPTIMAL phase III trial: maraviroc plus cART in advanced HIV-1-infected individuals

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Background: Late HIV diagnosis is associated with an excess risk of AIDS-Defining-Events (ADE) and mortality. We hypothesized that -due to its immunomodulating effect- the addition of maraviroc (MVC) to cART in naïve patients with low CD4 cell counts will decrease the risk of disease progression and death.
Methods: The ANRS 146 OPTIMAL trial (NCT01348308) was an European, multicentre, randomized, double-blind, phase III trial, in France, Spain and Italy, in ART-naïve HIV1-infected adults with CD4+ count < 200/μL or an ADE. Participants were randomized (1:1) to receive cART plus placebo or MVC for 72 weeks. The primary composite endpoint was any new ADE, serious non-AIDS-defining event, IRIS, or death from any cause. The primary endpoint and its components were compared using Kaplan-Meier estimates and Cox proportional-hazards models. In a post-hoc analysis, a Poisson regression model was used to analyse occurrence of all events and the interaction between the study period (0-24 versus 24-72 weeks) and the treatment effect.
Results: Between October 2011 and November 2014, 409 patients were included. At baseline, median HIV viral load was 5.39 $\log_{10}$ copies/mL, median CD4+ count 80 cells/μL and 42% of participants had an ADE. No difference was seen in CD4 cell increase (+258.3±8.9 vs +254.2±9.2/μL) (p=0.746). 74 events occurred in 53 participants: 42 events in 27 participants in the placebo group and 32 events in 26 participants in the MVC group. The incidence of the first event was 11.2 events per 100 person-years in the placebo group versus 11.1 events per 100 person-years in the MVC group with a hazard ratio of 0.97 (95% confidence interval [CI], 0.57-1.67). Poisson regression analysis showed that the incidence-rate-ratio (IRR) of the two groups differed significantly between periods 0-24 and 24-72 weeks with respective IRR of 0.61 (95% CI: 0.33-1.08) and 2.90 (95% CI: 0.86-12.49) (p=0.016).
Conclusions: The results of this large randomized trial showed that adding MVC to cART does not impact the occurrence of serious disease or death in advanced HIV1+ patients. However, post hoc analysis showed a trend for a beneficial effect of the addition of MVC in the first 24 weeks that disappeared thereafter.

MOAB0103

Safety, efficacy, and dose-response of GSK3532795/BMS-955176 plus tenofovir/emtricitabine (TDF/FTC) in treatment-naïve (TN) HIV-1-infected adults: week 24 primary analysis

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Background: This Phase 2b study investigated the safety, efficacy and dose-response of GSK3532795 (formerly BMS-955176), a novel second generation MI, relative to Efavirenz (EFV) in treatment-naïve (TN), HIV-1-infected subjects.
Methods: AI468038 (205891) is a global, randomized, doubled blind, active-controlled trial. TN adults, with HIV-1 RNA ≥ 1000 c/mL and susceptibility to commercially available study medications, were randomized 1:1:1:1 to 60 mg, 120 mg or 180 mg of GSK3532795, or EFV 600mg once-daily with TDF/FTC. The primary endpoint was the proportion of subjects with HIV-1 RNA < 40 c/mL at Week 24 using the FDA Snapshot algorithm.
Results: A total of 210 subjects were randomized and 206 were treated. The mean age was 33.7 years; 85.4% were male. The mean baseline HIV-1 RNA and CD4+ T-cell counts were 4.3 log10 c/mL (17% >100,000 c/mL) and 444 cells/μl (5.8% < 200 cells/μl), respectively. At Week 24, 76-82.7% of subjects across the GSK3532795 arms (60, 120, and 180 mg) and 77.4% in the EFV arm achieved a HIV-1 RNA < 40 c/mL (mITT, FDA snapshot). More EFV (17%) than GSK3532795 (2-8%) subjects reported AEs leading to discontinuation. Few subjects reported SAEs on EFV (9%) or GSK3532795 (2-4%). The rates of GI AEs, predominately diarrhea and abdominal pain (all grades, regardless of relationship), in the GSK3532795 arms were 52-72.5%; the EFV rate was 24.5%. The rate of treatment emergent NRTI resistance in the GSK3532795 arms was 6.5%. The EFV arm did not contain any treatment emergent NRTI/NNRTI resistance.

Parameter, n (%)	GSK3532795 60 mg + TDF/FTC QD	GSK3532795 120 mg + TDF/FTC QD	GSK3532795 180 mg + TDF/FTC QD	EFV 600mg + TDF/FTC
Week 24 Snapshot (mITT)	(N = 50)	(N = 52)	(N = 51)	(N = 53)
HIV-1 RNA < 40 c/mL	38 (76.0)	43 (82.7)	42 (82.4)	41 (77.4)
HIV-1 RNA ≥ 40 c/mL	10 (20.0)	7 (13.5)	4 (7.8)	3 (5.7)
No virologic data at Week 24	2 (4.0)	2 (3.8)	5 (9.8)	9 (17.0)
Week 24 (Observed Data)	(N = 46)	(N = 47)	(N = 45)	(N = 44)
HIV-1 RNA < 40 c/mL	38 (82.6)	43 (91.5)	42 (93.3)	41 (93.2)

[Week 24 Efficacy Data]

Conclusions: The Week 24 primary endpoint showed similar efficacy results across GSK3532795 treatment arms relative to EFV when combined with TDF/FTC in TN HIV-1 infected adults. However the GSK-3532795 arms showed a higher rate of GI intolerability and treatment emergent resistance to the NRTI backbone relative to EFV.

MOAB0104

48-weeks efficacy of a third-line based on darunavir plus raltegravir regimen in HIV-infected adults who failed second-line protease inhibitor-based regimen in sub-Saharan Africa, ANRS 12269 THILAO study

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Background: Tolerance and efficacy data on third-line treatment are scarce in Sub-Saharan Africa, in a context where viral load and genotype test are limited. This study aims to assess the effectiveness of 48-week third line therapy after 3-month adherence reinforcement in HIV-infected adults who failed second-line ART.
Methods: Thilao is a cohort study conducted in Burkina Faso, Côte d'Ivoire, Mali and Senegal. HIV-1-infected adults with virological failure on a second-line protease inhibitor based regimen after a first-line non-nucleoside reverse transcriptase inhibitor were included.
Adherence reinforcement measures were proposed at baseline (V0). After 3 months (V3), a viral load (VL) was performed. The second-line therapy was maintained if VL from baseline to V3 decreases by more than 2 log or below 400 copies/ml and a switch to a third-line Darunavir/r 600/100 mg BID (DRVr) and Raltegravir 400 mg BID (RAL) regimen in case of virological failure without knowing genotypic resistance test results. Each patient was followed 64 weeks (W64) and 48 weeks (W48) after third-line initiation. We describe the virological outcomes at W48 for those initiated third-line therapy.
Results: 201 patients were included.
Women: 69%, median age: 41 years old [35-48]. Median CD4 count and VL at pre-inclusion were 242/mm^3 [113-400] and 4.5 log/ml [3.0-5.0]; median duration since ART initiation: 8 years [6-10] including median 3 years [2-6] of second-line protease inhibitor. The median of medication possession ratio between W0 and W64 was 97.1 [91.4-100.2].
After V3, 34% have initiated third-line ART. Among them, 64% received TDF 3TC/FTC-NNRTI regimen. At W48: 4 are deceased and 0 were lost-to-follow up. 62% had a VL < 50 copies/ml. The median of those with a detectable VL was 896 copies [176-24500].
The probability of eventually initiating a third-line therapy during follow-up at W64 was 39%.
No severe adverse event related to third line therapy were notified. Among patients who failed DRVr and RAL regimen (n=11), only one mutation E157q to RAL was detected.
Conclusions: Sequencing of third line regimen such as recommended by WHO based on Darunavir/r, Raltegravir and recycled NRTI, is well tolerated and efficient as salvage therapy.

MOAB02 Children and Adolescents: Issues in the First and Second Decade

MOAB0201

Maximizing targeted testing to improve HIV yield among children and adolescents in Rwenzori region, Uganda

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Background: Ugandan national Anti-retroviral therapy (ART) coverage among children (< 15 years) is low, at 42% (61,642/147,394) compared with the target of 90%. This arises from the low identification of HIV infected children and adolescents through HIV Testing Service (HTS) models, such as routine counselling and testing. In Rwenzori region, HIV testing yield is low for children (0.7%) and adolescents (1%). Baylor-Uganda implemented targeted HTS models to improve HIV yield among children and adolescents and thus close the ART gap in the Rwenzori region. We determined the HIV yield from these models.
Methods: In the period March-June 2016, we provided HTS to children and adolescents 18months -19 years using the following models: HTS outreaches to dwelling homes of orphans and vulnerable children (OVC); Know your child Status Campaigns (KYCS); HTS outreaches to children of female sex workers (FSWs), fisher folks (FFs) and tea plantation workers; and evening HTS points targeting adolescents after work/school hours. We summarized the HIV yield for the different models in proportions and frequencies.
Results: Of the 4,091 children and adolescents tested, 2,135 (52%) were females and 2,030 (50%) adolescents (10-19 years). The overall HIV yield from all models was 53/4,091(1.3%). The HIV yield among adolescents, children (5-9 years) and those under 5 years was 30/2,030(1.5%), 20/1,234(1.6%) and 3/824(0.4%) respectively. It was highest through outreaches at OVC dwelling homes 7/271 (2.6%) and lowest through outreaches to children of tea plantation workers 0/214(0%). The HIV yield through outreaches to children of FSWs, children of FFs, KYCS campaigns and evening HTS points was 10/610(1.6%); 3/283(1.1%) ; 16/836 (0.9 %) and 14/815 (1.7%) respectively.
Conclusions: A relatively high HIV yield was achieved through HTS at OVC dwelling homes, children of FSWs, FFs and Evening HTS; and a low yield through outreaches to children of tea plantation workers and KYCS campaign. Therefore, deliberate efforts should be made to scale up HTS to OVC dwelling homes, children of FSWs and fisher folks, and evening HTS for adolescents; and consider to discontinue HTS outreaches to children of tea plantation workers and scale down or modify KYCS campaigns.

MOAB0202

Impacts of vitamin D and calcium supplementation on bone mineral density among perinatally HIV-infected adolescents: a 48-week randomized clinical trial

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Background: This study aimed to identify the impacts of vitamin D and calcium (VitD/Ca) supplementation on bone mineral density (BMD) and bone metabolism among perinatally HIV-infected Thai adolescents.
Methods: An ongoing, randomized, open-label trial has been conducted. Adolescents aged 10-20 years who were stable on ART (HIV RNA< 400 copies/ml) were randomly assigned to receive either "high-dose": VitD/Ca (3200 IU/1.2 g daily) or "normal-dose": VitD/Ca (400 IU/1.2 g daily) supplementation for 48 weeks. Lumbar spine BMD and bone metabolism-related markers were evaluated at baseline and 48 weeks. BMD was measured by dual-energy X-ray absorptiometry, of which z-score ≤ -2 was defined as low BMD. Bone metabolism-related markers included 25-hydroxyvitamin D (25OHD), intact parathyroid hormone (iPTH), alkaline phosphatase (ALP), C-terminal telopeptide (CTX-bone resorption marker),

and procollagen type I amino-terminal propeptide (PINP-bone formation marker). An interim analysis, stratified by baseline BMD z-score ≤-2 (low BMD) vs. >-2 (normal BMD), was performed using the intention-to-treat analysis.

Results: Between April 2015 and October 2016, 166 adolescents were enrolled. The median age and ART duration were 16.0 and 10.0 years, respectively. The median baseline BMD z-score was -1.5 and 67 adolescents (40%) had low BMD. Overall adherence to VitD/Ca supplementation was 80%. At week 48, there was a significant increase in BMD z-scores in participants with low baseline BMD, particularly among those receiving "high-dose" compared with "normal-dose" supplementation (+0.74 vs. +0.49) (Table1). The increased 25OHD, and the declined iPTH, ALP, CTX and PINP levels were also observed in both treatment groups (P<0.001). No between-group differences in changes from baseline for BMD z-scores and all bone biomarkers (P>0.05), except for iPTH (P=0.007).

Parameters	Treatment group	Change from baseline to week 48*		Overall P†
		Low baseline BMD (n=67)	Normal baseline BMD (n=99)	
BMD z-score	High-dose	0.74 (0.31 to 1.14)‡	0.10 (-0.25 to 0.67)	0.07
	Normal-dose	0.49 (-0.4 to 1.19)‡	-0.07(-0.51 to 0.43)	
25OHD, ng/ml	High-dose	5 (-3 to 12)‡	5 (1 to 11)‡	0.81
	Normal-dose	6 (3 to 12)‡	6 (2 to 10)‡	
iPTH, pg/ml	High-dose	-10 (-21 to -2)‡	-6 (-22 to 1)‡	0.007
	Normal-dose	-16 (-23 to -6)‡	-13 (-22 to -3)‡	
ALP, U/l	High-dose	-24 (-128 to -14)‡	-45 (-83 to -11)‡	0.12
	Normal-dose	-65 (-95 to -27)‡	-49 (-119 to -21)‡	
CTX, ng/l	High-dose	-180 (-420 to 30)‡	-330 (-790 to 10)‡	0.09
	Normal-dose	-480 (-780 to -160)‡	-270 (-600 to 30)‡	
PINP, µg/l	High-dose	-49 (-193 to 13)‡	-87 (-208 to 11)‡	0.23
	Normal-dose	-170 (-331 to -36)‡	-71 (-225 to 16)‡	

*Data is presented as median change from baseline (interquartile range).
†P-value evaluates the overall difference in median change from baseline to week 48 between the two treatment groups (between-group difference), using Wilcoxon rank-sum test.
‡Indicates the median change from baseline to week 48 within the treatment groups (within-group difference) is a statistical significant (P <0.05), by Wilcoxon signed-rank test.

[Table 1. Changes of bone mineral density z-scores and bone metabolism-related biochemical markers from baseline among 166 perinatally HIV-infected Thai adolescents over the 48-week study follow-up.]

Conclusions: With the preliminary results, BMD were significantly ameliorated in adolescents with low baseline BMD who received VitD/Ca supplementation, regardless of dose, over 48-week follow-up. A prospective study with longer follow-up is warranted to confirm our findings.

MOAB0203

Inequality in mortality and access to antiretroviral therapy in adolescents living with perinatally-acquired HIV in sub-Saharan Africa: a Collaborative Initiative for Paediatric HIV Education and Research (CIPHER) cohort collaboration analysis

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Background: Eighty percent of adolescents living with perinatally- and behaviourally-acquired HIV live in sub-Saharan Africa (SSA), a continent with marked economic inequality. Extending our previous global description of adolescents living with perinatally-acquired HIV (APH), this analysis aimed to describe APH outcomes in SSA by country income group (CIG).
Methods: Through the CIPHER cohort collaboration, individual retrospective data from 12 cohort networks across 5 continents were pooled; 7 networks representing SSA were included here. APH included were HIV-infected children with entry into care at age <10 years (proxy for perinatally-acquired HIV), and follow-up at age >10 years. CIG was classified according to World Bank classification at median year of first visit by country.
Cumulative incidence functions were calculated by competing risks analysis for mortality, transfer-out and loss-to-follow-up.
Results: 30,296 APH were included; 75.7% resident in low income countries (LIC), 4.6% in lower-middle income countries (LMIC) and 19.8% in upper-middle income countries (UMIC). 64% of APH were born ≥2000. Median (interquartile range [IQR]) age at antiretroviral therapy (ART) start (8 [6;9] years) and at last follow-up (12 [11;14] years) were equivalent across CIG. 26,018 (85.9%) ever started ART and 3,352 (12.5%) started at age >10 years, both significantly different between CIG (p<0.001) (Table 1).
Individual CD4 count improved between ART start and last visit in all CIG (p<0.001). Half of APH had height-for-age Z-score (HAZ) <-2 at ART start that improved by last visit in LIC (p<0.001) and UMIC (p<0.001) but not LMIC (p=0.18). Mortality between age 10-15 years was lowest in UMIC however loss-to-follow-up was highest in UMIC.

	LIC N=22,925	LMIC N=1,386	UMIC N=5,985
Ever started ART - n (%)	19,114 (83.4)	1,207 (87.1)	5,697 (95.2)
Started ART age >10 years - n (%)	2,829 (14.8)	141 (11.7)	382 (6.7)
CD4 count (cells/µl) at ART start - median [IQR] (N=15,254)	310 [165; 520]	292 [174; 417]	318 [162; 558]
CD4 count (cells/µl) at last visit - median [IQR] (N=24,223)	668 [434; 945]	735 [532; 985]	729 [513; 971]
HAZ at ART start - median [IQR] (N=16,181)	-2.01 [-2.97; -1.08]	-2.08 [-2.95; -1.33]	-2.02 [-2.86; -1.17]
HAZ at last visit - median [IQR] (N=25,333)	-1.77 [-2.60; -0.95]	-2.02 [-2.77; -1.30]	-1.54 [-2.31; -0.77]
Cumulative incidence of mortality - % (95%CI)	3.5 (3.1; 3.8)	3.9 (2.7; 5.4)	1.1 (0.8; 1.4)
Cumulative incidence of transfer-out - % (95%CI)	17.5 (16.8; 18.3)	27.5 (24.2; 31.0)	23.7 (22.4; 25.1)
Cumulative incidence of loss-to-follow-up - % (95%CI)	13.1 (12.4; 13.8)	8.3 (6.3; 10.6)	14.0 (12.9; 15.3)

[Table 1: APH characteristics by CIG (N=30,296)]

Conclusions: Despite starting ART late, improvements in height and CD4 count were observed in most APH surviving to adolescence. Mortality rates are likely under-estimated. However, results highlight inequalities in mortality and access to ART according to CIG in SSA.

MOAB0204

Evaluation of the risk of birth defects among children exposed to raltegravir *in utero* in the ANRS-French Perinatal Cohort EPF

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Background: Raltegravir is an integrase inhibitor, largely used in the recent years, but tolerance data in pregnancy is scarce. Potential teratogenicity has not yet been evaluated for this molecule in a clinical context. We aimed to describe the rates and types of birth defects among children exposed to raltegravir in utero and to study the association with trimester of exposure.
Methods: EPF is a multicenter national cohort, which prospectively enrolls pregnant HIV-infected women delivering in 90 centers throughout France. Children are followed by pediatricians until two years of age. All births exposed to raltegravir were included. Birth defects were defined using the EUROCAT classification. Rates of birth defects were compared according to timing of exposure to raltegravir (1st trimester vs 2nd and 3rd trimester) using χ^2 tests.
Results: We included 479 fetuses born between 2008 and 2015, exposed to raltegravir, among which 6 stillbirths (1.3%) and 2 late miscarriages (0.4%). There were no terminations of pregnancies for birth defects. Rates of birth defects were 4.2% for all births (20/479, [95% CI 2.4%-6.0%]), and 4.2% among live births (20/471 [2.4%-6.1%]). This incidence was similar to that reported in a previous study in EPF for live births exposed to any ARV (4.4% [4.0%-4.7%]). Birth defect rates did not differ significantly between first trimester exposure to raltegravir (5.7%; 8/140) and 2nd or 3rd-trimester exposure (3.5%; 12/339; p=0.32). The anomalies did not follow any pattern and concerned various organs: 7 heart defects, 5 polydactylies, and 8 other defects. Other notable adverse outcomes were preterm births (14.2%), and 2 cases of HIV perinatal infection (0.4%). The follow-up was complete to 24 months for 63% of children. For 15% of children, only the birth questionnaire was available.
Conclusions: This is the largest prospective cohort of children exposed in utero to raltegravir with homogenous evaluation of birth defects. We did not find a significant association between 1st trimester exposure to raltegravir and birth defects. This finding is quite reassuring as this molecule is often prescribed to women of child-bearing age, and thus many children may be exposed in the first trimester of pregnancy.

MOAB0205

High prevalence of respiratory non-tuberculous mycobacteria respiratory infections in children living with HIV in South-East Asia

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Background: Data on burden of Non Tuberculous Mycobacteria (NTM) and related Pulmonary Diseases are limited in HIV-infected children in developing countries. We investigated NTM respiratory infections (RI) prevalence, species distribution, and associated factors in HIV-infected children with a suspicion of tuberculosis in four countries in South-East Asia and Africa.
Methods: From 2011 to 2014, HIV-infected children ≤13 years with a suspicion of tuberculosis were included in the ANRS 12229-PAANTHER 01 study in Burkina-Faso, Cambodia, Cameroun and Vietnam after parental consent. Children underwent respiratory and stool samples for mycobacterial culture and molecular identification of species. Children with ≥1 analyzable sample in culture were included. NTM-RI was defined as ≥1 sample culture-positive for any NTM. Logistic regression models were used to identify factors associated with respiratory NTM or Mycobacterium avium complex (MAC) infections.
Results: Of 438 children enrolled, 427 had ≥1 analyzable sample. Median age was 7.3 years, with 212 (49.7%) male, 245 (57.4%) Asian, 267 (63.9%) underweight, 212 (51.1%) severely immuno-depressed, and 258 (60.4%) ART-naïve. Prevalence of culture-confirmed tuberculosis was 13% (55/427), including 5 co-infections tuberculosis/NTM. Prevalence of NTM-RI was 10.8% (46/427), 16.7% (41/245), and 2.8% (5/177), in all, Asian, and African children, respectively. MAC were isolated in 21/427 (5%) children overall and 17/125 (13.6%) children from Asian origin with severe immune-depression (CDC classification 2014). Majority of NTM patients with severe immune-depression were infected by MAC (n=17/19). In contrast, Mycobacterium fortuitum, scrofulaceum, interjectum, and gordonae were the most frequent species in non or moderately immuno-depressed children. Overall, South-East Asian origin (OR 7.2; 95%CI 2.5-21.1), age 5-9 yo compared to 0-2 yo (OR 10.1; 95%CI 2.3-44.8), and severe immune-deficit (OR 3.3; 95%CI 1.5-7.2) were factors independently associated with NTM-RI. CD4-T Lymphocytes count <50/mm^3 (OR 9.8; 95%CI 3.6-26.5), and Asian origin (OR 16.5; 95%CI 2.2-126.1) were independently associated with MAC infection.
Conclusions: NTM-RI are frequent in HIV-infected children with presumptive tuberculosis in South-East Asia, not only as opportunistic infection in severe immuno-deficiency. NTM contribution to lung disease is unclear in a tuberculosis suspicion context. Empiric treatment for both tuberculosis and MAC may be relevant in most severely immuno-depressed HIV-children suspected of tuberculosis in South-East Asia.

MOAB0206

High-risk vaccine-specific HPV infection in HIV-infected and HIV-uninfected, vaccine-naïve Asian female adolescents

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Background: Adolescents in resource limited countries have limited access to human papillomavirus (HPV) vaccination. We assessed the prevalence of 7 high-risk vaccine-specific HPV types (HRVS-7) in the nonavalent vaccine and identify factors associated with oral and anogenital HRVS-7 infection in perinatally HIV-infected female adolescents (PHIVA), and HIV-uninfected females (controls).
Methods: Sexually active PHIVA were enrolled in a prospective study in Thailand and Vietnam from 2013 to 2015. Controls were matched by age and lifetime number of sexual partners. All participants were naïve to HPV vaccination. HPV genotypic assay were performed on oral, anal, cervical and vaginal samples using the Roche Linear Array, and serum neutralizing antibodies (NAb) to HPV type 16 and 18 were measured. An audio-computer-assisted self-interview (ACASI) was performed to assess behavioral risks. Screening for sexually transmitted infections (STI) included Chlamydia trachomatis, Neisseria gonorrhea, herpes simplex virus-2 (HSV2) and syphilis. Multiple logistic regression analysis was used to assess factors associated with presence of any HRVS-7 genotypes (16, 18, 31, 33, 45, 52, 58) at any body sites.
Results: A total of 93 PHIVA and 99 controls were enrolled; median (IQR) age 19 (18-20) years, with 2 (1-3) lifetime sexual partners. At enrollment, median CD4 among PHIVA was 593 (392-808) cells/mm^3, and 62% had HIV-RNA < 40 copies/mL. HRVS-7 genotypes were found in 43 (46%) PHIVA and 39 (39%) controls (P=0.3). NAb were detected in 19 (22%) PHIVA and 26 (28%) controls (P=0.3). For the complete cohort, 20/33 (61%) adolescents 13-16 years, 50/105 (48%) 17-19 years, and 28/54 (52%) 20-24 years were positive for HRVS-7 DNA or NAb. A history of ≥3 lifetime partners (vs. 1; OR 3.34 [1.59-7.04]), and having any non-HPV STI (OR 3.39 [1.56-7.39]) were independently associated with increased risk of infection with an HRVS-7 genotype. Among PHIVA, HIV-RNA >40 copies/mL and having any non-HPV STI were independently associated with increased risk of infection with HRVS-7.
Conclusions: Half of Asian PHIVA and HIV-uninfected female adolescents in our cohort had high-risk HPV infection. Greater access to HPV vaccination is needed in the region to reduce future HPV-related cancer risk.

MOAB03 HIV and the Liver: Co-Infection and Complications

MOAB0301

Hepatitis C care cascade for people living with HIV in the country of Georgia

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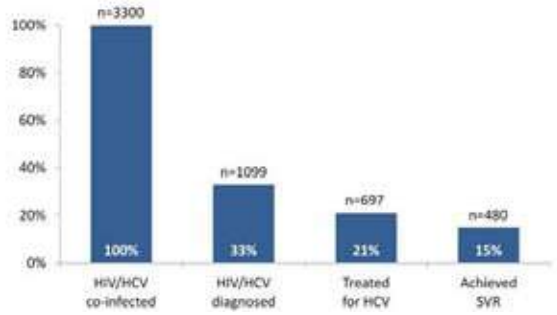
Background: Georgia made significant progress in addressing high burden of hepatitis C virus (HCV) infection among people living with human immunodeficiency virus (HIV). During 2011-2015 with the support of the Global Fund HIV positive persons in Georgia had access to free HCV treatment with pegilated interferon and ribavirin (PEG/RBV). In April 2015 in partnership with the U.S. CDC and Gilead Sciences the country launched a national hepatitis C elimination program, which provides free treatment with modern direct acting antivirals (DAAs).
Methods: The following steps of HCV care cascade were quantified:
1) HIV/HCV co-infected,
2) Diagnosed for both HIV and HCV,
3) treated for HCV infection,

4) achieved sustained virologic response (SVR).
Number of HIV/HCV co-infected persons was estimated using modeling and observed HCV prevalence. Data on diagnosed persons were extracted from the national AIDS health information system as of September 1, 2016.
Results: Among estimated 3300 persons living with HIV/HCV co-infection in Georgia, 2201 (67%) were not aware of their HIV status and 1099 (33%) were diagnosed both with HIV and HCV. Of those 1099 diagnosed persons 697 (63%) were treated for hepatitis C with either PEG/RBV or DAA-based regimen. 480 (69%) of those treated achieved SVR. Rates of SVR were 44% with PEG/RBV and 89% with DAA. Overall, because of gap in diagnosis stage only 15% of estimated number of HIV/HCV co-infected persons were cured.



[Hepatitis C care cascade]

Conclusions: The major gap in the HCV care cascade is at the stage of diagnosis resulting from deficiencies in HIV diagnosis. Reducing the number of people living with undiagnosed HIV/HCV co-infection will be critical for achieving population level impact of free HCV treatment program.

MOAB0302

Trends in cause-specific mortality in HIV-hepatitis C (HCV) co-infected patients in Canada (2003-2016): early impact of HCV therapy

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Background: Hepatitis C treatment and an aging population may contribute to shifts in mortality, allowing other causes of death to emerge. We aimed to examine cause-specific mortality among HIV-HCV co-infected patients, evaluating changes in mortality trends over time.
Methods: The Canadian Co-infection Cohort is a prospective multicentre cohort of 1695 co-infected patients from 19 sites in Canada. All reported deaths, classified using a modified "Coding of Cause of Death in HIV" (CoDe) protocol, were analyzed from April 2003 to July 2016. Event rates per 1000 person-years before (2003-2009) and after (2010-2016) the availability of effective treatment stratified by age (20-50; 50-80) were calculated. Comparison of trends between periods was performed using Poisson regression. Multinomial regression was used to estimate the cause-specific hazard ratios (HR) and 95% confidence intervals (CIs) of time and age on cause of death.
Results: Overall, 1477 participants (72% men) contributed 6675 person-years of follow-up. Of the 203 (14%) patients who died (152 with assigned causes), end-stage liver disease (ESLD; 20%), smoking-related (17%) and drug overdose (16%) were the most common causes of death. All cause mortality decreased in both age groups over time (Table 1), while HCV treatment increased 2.8 times. Deaths due to ESLD declined by approximately 2-fold and were no longer the most common cause of death in the 2010-2016 time period for either age category. In contrast, smoking-related deaths increased with time and, among those aged 50-80, accounted for the greatest proportion of deaths from 2010-2016 (cause-specific HR 2.8; 95% CI, 1.5 - 5.4). Drug overdose accounted for the greatest proportion of deaths among individuals aged 20-50 from 2010-2016.
Conclusions: Increased HCV treatment uptake has coincided with decreased liver-specific mortality in HIV-HCV co-infected patients. However, these gains may be thwarted if modifiable risk factors (tobacco and drug use) are not addressed.

Outcome	Age	2003-2009	2010-2016
All cause	20-50	26.04 (13.91, 48.75)	19.29 (11.59, 32.11)
	50-80	56.61 (28.09, 114.1)	41.97 (28.2, 62.46)
ESLD	20-50	5.21 (1.52, 17.85)	3.64 (1.3, 10.2)
	50-80	14.15 (4.13, 48.49)	7.72 (3.42, 17.43)
Smoking			
All	20-50	3.72 (0.96, 14.48)	2.18 (0.63, 7.55)
	50-80	6.07 (1.05, 35.04)	9.65 (4.89, 19.03)
CVD	20-50	0	0.73 (0.11, 4.95)
	50-80	6.07 (1.27, 29.02)	3.38 (1.21, 9.41)
Lung cancer	20-50	2.23 (0.48, 10.34)	0
	50-80	0	3.38 (1.24, 9.21)
Pneumonia	20-50	1.49 (0.2, 11.25)	1.46 (0.35, 6.09)
	50-80	0	2.89 (0.9, 9.31)
Other			
All	20-50	11.16 (4.36, 28.55)	7.28 (3.23, 16.42)
	50-80	26.28 (9.58, 72.09)	14.47 (7.45, 28.12)
AIDS	20-50	2.23 (0.86, 5.8)	0.36 (0.07, 1.9)
	50-80	0	0.96 (0.3, 3.11)
Suicide/Trauma/Accident	20-50	0.74 (0.05, 10.37)	1.46 (0.39, 5.44)
	50-80	0	2.89 (0.99, 8.49)
Drug overdose	20-50	7.44 (1.67, 33.15)	4.37 (1.12, 17.09)
	50-80	14.15 (2.37, 84.41)	1.45 (0.09, 22.14)
Cancer (non-liver, non-HIV, non-esophageal/lung)	20-50	0.74 (0.06, 9.97)	0.73 (0.12, 4.56)
	50-80	8.09 (2.21, 29.6)	3.38 (1.27, 9.01)
Infection	20-50	0	0.36 (0.02, 6.99)
	50-80	4.04 (0.5, 32.67)	3.86 (1.36, 10.97)
Unknown	20-50	5.95 (1.25, 28.38)	6.19 (2.12, 18.07)
	50-80	10.11 (1.4, 72.9)	10.13 (3.86, 26.57)

CVD, cardiovascular disease; ESLD, end-stage liver disease

[Table 1. All cause and cause-specific event rates (95% CI) per 1000 person-years by age group and time period]

MOAB0303

Efficacy and safety of glecaprevir/pibrentasvir in patients co-infected with hepatitis C virus and human immunodeficiency virus-1: the EXPEDITION-2 study

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Background: Pangenotypic, once-daily glecaprevir (identified by AbbVie and Enanta)/pibrentasvir (G/P) has demonstrated high rates of sustained virologic response at 12 weeks post-treatment (SVR12) in patients with hepatitis C virus (HCV) genotype (GT) 1-6 infection.
This phase 3 study evaluated the efficacy and safety of G/P in patients with chronic HCV GT1-6 infection and HIV-1 co-infection, including patients with compensated cirrhosis.
Methods: EXPEDITION-2 (NCT02738138) is a phase 3, multicenter, open-label study evaluating G/P (300 mg/120 mg) treatment in HCV/HIV-1 co-infected adults without or with compensated cirrhosis for 8 or 12 weeks, respectively. Patients were either HCV treatment-naïve or experienced with interferon (IFN), pegylated IFN ± ribavirin, or sofosbuvir + ribavirin ± pegylated IFN. GT3 treatment-experienced patients were excluded. The primary endpoint was the proportion of patients with sustained virologic response (HCV RNA < lower limit of quantification) 12 weeks post-treatment (SVR12).
Results: In total, 153 patients were enrolled, including 16 (10%) with cirrhosis. Baseline demographics are shown in **Table 1**. In patients with available data, rates of response at end of treatment and post-treatment week 4 were 98.7% (151/153) and 98.6% (144/146) respectively. To date, there is one (1/153; 0.65%) virologic failure: a breakthrough in a patient with GT3a infection and cirrhosis. The most common adverse events (AEs) were fatigue (16/153; 10%) and nausea (13/153; 8%).

Three patients (2%) had serious AEs, and one serious AE of stroke led to treatment discontinuation on Day 23 in one patient with cirrhosis; all were unrelated to G/P. All patients maintained HIV-1 suppression (< 200 copies/mL) during treatment.

Characteristic	Without Cirrhosis 8 Weeks N = 137	With Cirrhosis 12 Weeks N = 16
Male, n (%)	113 (83)	15 (94)
Genotype 1/2/3/4/5/6, n	84/12/22/16/0/3	10/1/4/1/0/0
Age, median (range), years	45 (23-74)	50 (35-62)
HCV treatment-experienced	26 (19)	2 (13)
HCV RNA, media (range), log_{10} IU/milliliter	6.2 (4.0-7.4)	6.1 (4.4-7.0)
Antiretroviral therapy-naive	9/137 (7)	0
Raltegravir anchor ARV, n (%)	39 (29)	6 (38)
Dolutegravir anchor ARV, n (%)	62 (45)	5 (31)
Rilpivirine anchor ARV, n (%)	27 (20	5 (31)
CD4+ cell count ≥500 cells/mm^3, n (%)	92 (67)	9 (56)

[Table 1. Baseline Demographics & Disease Characteristics]

Conclusions: G/P for 8 weeks in non-cirrhotic and 12 weeks in cirrhotic patients is a well-tolerated and highly efficacious pangenotypic treatment for HCV/HIV-1 co-infection, regardless of baseline HCV RNA or treatment experience. Full SVR12 rates and prevalence of baseline NS3 and NS5A polymorphisms will be presented.

MOAB0304

Metabolic syndrome and obesity are the cornerstones of liver fibrosis in HIV-monoinfected patients: results of the METAFIB study

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Background: Metabolic syndrome (MetS) has become a common finding in HIV-infected patients. However the severity, risk factors and pathogenesis of liver fibrosis in this population have been poorly documented.
From a matched cohort of HIV-monoinfected patients with and without MetS, this study aimed 1) to assess the impact of MetS on the prevalence and severity of liver fibrosis and 2) to analyze the association between liver fibrosis and markers of adipose tissue, insulin resistance and macrophage activation.
Methods: Patients with immune-controlled HIV-1 infection under antiviral therapy (ART) were enrolled in the following exposed-unexposed study. The exposure was defined by the presence of MetS according to international criteria after exclusion of all other causes of chronic liver disease. Fibrosis was assessed using transient elastography (Fibroscan). Adipokines, HOMA index and soluble CD163 and CD14 were measured as markers of fat mass, insulin resistance and macrophage/monocyte activation, respectively.
Results: 468 HIV-monoinfected individuals were enrolled (male (89%), mean age 53 (9) years, mean BMI 24.6 (5.3) kg/m^2); 246 with MetS and 222 without MetS. Patients with MetS were older and 49% of them had insulin resistance i.e HOMA-IR≥2.5 (compared to 8.5% in patients without MetS). The mean value (SD) of LSM was 5.6 (2.2) kPa with a minimum and maximum value of 2.4 and 17.1 kPa. Mean LSM was higher in patients with MetS compared to those without MetS [6.3 (2.6) versus 4.9 (1.5) kPa, p<0.0001]. In multivariable analysis, obesity (OR: 3.9 (IC95% 2.1-7.1)) and insulin resistance (1.1 (1.06-1.2)) were independent factors of significant fibrosis (≥F2) and remained associated after adjustment on MetS. Serum levels of adipokines and sCD163 were significantly associated with the degree of liver fibrosis. When adjusted on MetS leptin and sCD163 remained strongly associated to fibrosis. HIV parameters and ART regimen were not associated fibrosis.
Conclusions: In HIV-monoinfected patients, MetS is an important risk factor of liver fibrosis. Obesity and insulin resistance are key factors in the development of liver fibrosis independently of HIV infection parameters. Adipose tissue and macrophage activation certainly play an important role in the development of fibrosis in HIV monoinfected patients but the exact mechanisms need to be elucidated.

MOAB0305

Predictor factors associated with liver fibrosis and steatosis by transient elastography in HIV-monoinfected patients under long-term combined antiretroviral therapy: the PROSPEC-HIV study

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Background: Liver disease remains one of the main causes of non-AIDS mortality in HIV-infected individuals. Transient elastography (TE) is an accurate imaging method to estimate liver fibrosis and steatosis. We aimed to evaluate the risk factors associated with liver fibrosis and steatosis in HIV mono-infected patients under long-term combined-antiretroviral therapy (c-ART).
Methods: This cross-sectional study prospectively included HIV-infected adult patients under c-ART (PROSPEC-HIV; NCT02542020). Liver stiffness measurement (LSM) and Controlled Attenuation Parameter (CAP) by TE were used to estimate liver fibrosis and steatosis, respectively. Exclusion criteria were hepatitis coinfection and c-ART naïve. Patients with an unreliable M probe LSM or CAP were excluded from the liver fibrosis and steatosis analyses, respectively. Clinical evaluation, fasting blood tests and TE were performed at the same day. TE exams were performed by a single experimented operator blinded to clinical and laboratory data. Metabolic factors were defined according to the International Diabetes Federation criteria. Alcohol consumption was quantified using the AUDIT score. Presence of liver fibrosis and steatosis were considered when LSM ≥ 8.0kPa and CAP ≥250dB/m, respectively. Age and gender-adjusted multivariate logistic regression was performed.
Results: A total of 348 HIV mono-infected patients [61% female, median (IQR) age=44 (34-52) years, BMI=25.4 (23.0-29.3) kg/m^2] were included. Median (IQR) time under c-ART and under the current c-ART regimen were 7.3 (4.1-12.8) and 4.3 (1.9-7.5) years, respectively. LSM and CAP were unreliable in 6% and 12%. Liver fibrosis and steatosis prevalence were 9% (n=30/326) and 33% (n=102/305). In age and gender adjusted multivariate analysis, factors associated [OR (95%CI)] with liver fibrosis were: age >45 years [2.91 (1.19-7.15); p=0.020]; CD4 count <200 cells [5.00 (1.38-18.21); p=0.014] and type-2 diabetes [3.04 (0.97-9.55); p=0.056]. Male gender [5.69 (2.68-12.04); p<0.001]; dyslipidemia [2.86 (1.46-5.60); p=0.002]; type 2 diabetes [6.00 (2.08-17.28); p=0.001] and central obesity [10.24 (4.11-25.50); p<0.001] were independently associated with liver steatosis.
Conclusions: Non-communicable diseases (NCD) can play a major role in the development of liver fibrosis and steatosis. NCD prevention and care services need to be integrated to HIV care to decrease the burden of hepatic events in HIV-infected individuals.

MOAB04 Tuberculosis in a Time of HIV

MOAB0401

Gaps and opportunities in policy and practice in 20 countries with the highest burden of HIV-associated TB

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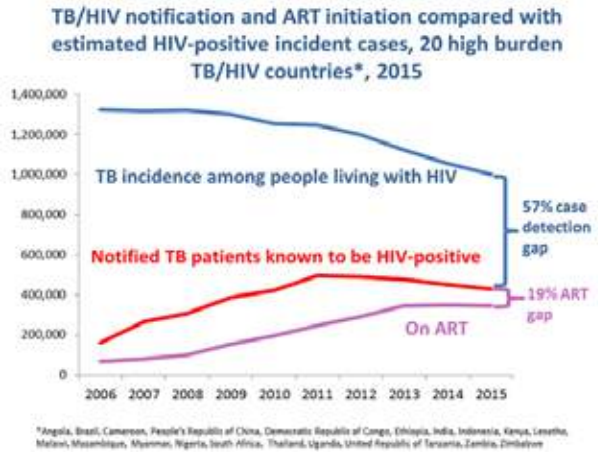
Background: Despite impressive scale-up of collaborative TB/HIV activities since 2004, TB is still the major cause of morbidity and mortality among people living with HIV (PLHIV). In June 2016 Member States adopted the UN Political Declaration on HIV and AIDS, including a target to reduce TB deaths among PLHIV by 75% by 2020. In order to achieve this, gaps in policy, implementation, and recording and reporting need to be identified and urgently addressed.
Methods: 20 countries were selected with the highest estimated burden of HIV-positive incident TB in 2015. Data on collaborative TB/HIV activities were extracted from the Global TB Programme Database and the UNAIDS online GARPR tool, and trends and progress analysed. Reviews were further conducted of the latest available policy documents, programme reviews, epidemiological assessments, Global Fund Concept Notes and GARPR reports to identify gaps and opportunities in policy and implementation.
Results: Cascade analysis revealed a 57% gap in notification of TB patients living with HIV, compared with estimated cases, and a 19% gap of ART started among notified HIV-positive TB patients (Figure 1). Half of countries did not report Isoniazid

preventive therapy (IPT). Case fatality among TB patients living with HIV was at least 3 times higher than HIV-negative TB patients in seven reporting countries. Document review revealed the following gaps and barriers: misalignment of policies on ART and IPT; poorly implemented TB screening and IPT; centralized or underuse of Xpert MTB/RIF; centralized ART provision; stock-outs in IPT, HIV testing kits and ART; and separate planning, supervision, health management information systems, and procurement and supply.
Conclusions: Considerable gaps and opportunities were identified in this analysis. Countries need to seek ways to resolve barriers, be they policy, implementation or health system-related to ensure access to evidence-based HIV-associated TB care and to end HIV-related deaths from this preventable disease.



[Figure 1]

MOAB0402

Genomic epidemiology of extensively drug-resistant tuberculosis in KwaZulu-Natal, South Africa: demographic expansion and genetic determinants of epidemiologic success in a high HIV prevalence setting

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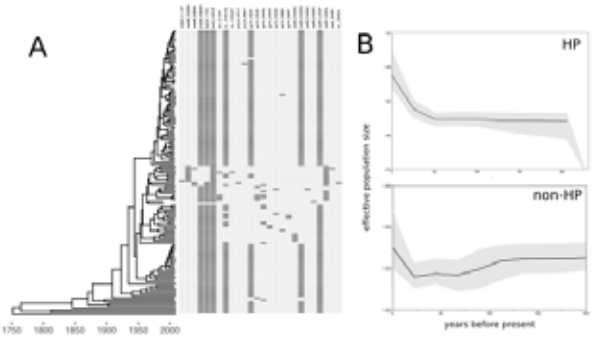
Background: Extensively drug-resistant tuberculosis (XDR-TB) has emerged over the last decade as a significant public health threat worldwide, particularly among people with HIV. South Africa first reported XDR-TB in 2005 and now has among the highest burden of XDR-TB worldwide, with >1000 cases diagnosed in 2015. The bacterial evolutionary determinants behind the rise of XDR-TB in South Africa are not well understood.
Methods: We enrolled persons with newly-diagnosed, culture-confirmed XDR-TB from 2011-2014 in KwaZulu-Natal province and performed whole genome sequencing of their Mycobacterium tuberculosis (Mtb) isolates. Lineage 4 isolates were selected for phylogenetic reconstruction, dating of drug-resistance mutations, and estimates of prior demographic history using Bayesian Markov chain Monte Carlo Methods (BEAST v1.8.3).
Results: Among 160 participants with XDR Mtb isolates included in this analysis, 127 (79%) were HIV co-infected. Half (51%) of XDR-TB cases were attributable to a single predominant clade of highly monomorphic isolates (Restriction Fragment Length Polymorphism type HP). There were no significant differences between the proportion of participants with HIV or with CD4 counts < 200 cells/µl in the HP vs. non-HP isolates. Both HP and non-HP Mtb populations exhibit evidence of rapid population expansion beginning 25-30 years ago (Figure, B). The emergence of key drug resistance mutations occurred near the historical dates of introduction for their corresponding antibiotics (Figure, A).



[IAS1]

(A) Dated phylogenetic tree for HP isolates annotated with known drug resistance mutations; (B) Bayesian Skyline reconstruction for HP and non-HP isolates
Conclusions: Mtb isolates from the predominant HP clade and from less prevalent XDR-TB strains underwent demographic expansion following the onset of the HIV epidemic in South Africa. Endemic strains in KwaZulu-Natal acquired drug resistance mutations across diverse strain groups and genetic backgrounds, corresponding to the introduction of new antituberculosis medications. The impact of HIV coinfection on pathoadaptive evolution in Mtb remains an important area for further investigation.

MOAB0403

Incidence of tuberculosis in the first year of antiretroviral treatment in West-African HIV-infected adults

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Background: Despite evidence that isoniazid preventive therapy (IPT) reduces tuberculosis incidence and mortality, its uptake remains very limited in West Africa. Our objective was to assess tuberculosis incidence during the first year of antiretroviral therapy (ART) and identify associated factors in HIV-infected adults in West Africa to support policy decisions in these countries.
Methods: We conducted a retrospective observational cohort analysis using data collected in three HIV outpatient centers from Côte d'Ivoire, Burkina Faso, and Senegal participating in the IeDEA West Africa Collaboration. We included HIV-infected adults (≥16 years) initiating ART between 2010 and 2014, without tuberculosis diagnosis at ART initiation and with ≥1 follow-up visit. None of them received IPT. Tuberculosis new diagnoses were documented according to national recommendations. We analyzed incidence of tuberculosis and identified associated factors using Poisson regression models.
Results: Of 4,154 patients who started on ART, 3,404 had ≥1 follow-up visit after ART initiation. Of those, 191 (5.6%) had ongoing tuberculosis at ART initiation. Thus, we enrolled 3,213 patients in our analysis. Median age was 38.5 (IQR 32.0-45.4) years, 67.1% were female, and median CD4 count at ART initiation was 211 (IQR 95-343) cells/mm^3. Overall 170 new tuberculosis cases were reported for 2,360.5 person years (PY) at risk. The crude tuberculosis incidence rate during the first year on ART was 7.2 (95% CI 6.12-8.28) cases per 100 PY. The adjusted tuberculosis incidence rate was 1.42 (95% CI 0.55-3.20) per 100 PY in women, aged 16-30 years, without prior tuberculosis history, with CD4 ≥500 cells/mm3, and hemoglobin ≥11 g/dL, followed in Burkina-Faso. A higher tuberculosis risk was significantly associated with male gender (RR 1.87; 95% CI 1.28-2.74), previous history of TB (RR 4.22; 95% CI 2.70-6.42), hemoglobin < 9 g/dL (RR 2.26; 95% CI 1.61-4.31) and follow-up in Côte d'Ivoire (RR 4.32; 95% CI 2.90-6.50).
Conclusions: Tuberculosis incidence remains high during the first year on ART in the West African context in the absence of IPT. It is crucial to reinforce implementation of IPT in all HIV-infected adults starting ART especially in this part of the world.

MOAB0404

Time to treatment initiation for drug-resistant tuberculosis is delayed in a South African prospective cohort

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Background: Drug-resistant tuberculosis (DR-TB) is a growing threat to TB management and elimination globally. Early initiation of DR-TB treatment is critical to successful treatment outcomes (cure) and to prevent transmission. The South African National TB Program (NTP) recommends initiating treatment within five days of diagnosis. This study examined time to treatment initiation and its relationship with patient age among a prospective cohort of individuals living with DR-TB in South Africa.
Methods: Patients included subjects, age 13 years or older, enrolled in a DR-TB cluster-randomized trial in two South African provinces. Outcomes were treatment initiation within five days of DR-TB diagnosis and days from diagnosis to treatment initiation. Hierarchical mixed-effects models were employed to examine the association between age and these outcomes, adjusted for patient (sex, TB history, HIV coinfection) and site (rural/urban, province) characteristics and random effects of treatment center.
Results: Of 521 patients, there were 55% male, 75% with HIV coinfection, and 53% with prior history of TB. Only 82 patients (16%) received DR-TB treatment within five days of diagnosis. The median time to treatment was 11 days (range=0 to 180). Age was not associated with treatment initiation within five days (F=0.07, df=1,495, p=0.794) or days to treatment initiation (F=1.42, df=1,489, p=0.233). Individuals coinfected with HIV tended to have a greater likelihood of receiving treatment within five days relative to those without coinfection (17% vs 12%, p=0.104; Odds Ratio=1.749, 95% Confidence Interval=0.891-3.433).
Conclusions: Delays in DR-TB treatment increase harm to the patient and risk of disease spread. Only one in six patients with DR-TB received treatment within five days of being diagnosed as recommended by South African NTP guidelines. Further research is needed to examine what modifiable factors decrease treatment delay and how to most effectively implement treatment guidelines.

MOAB0405

High uptake of antiretroviral therapy among HIV-positive TB patients receiving co-located services in Swaziland

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Background: Swaziland has the highest adult HIV prevalence, the third highest tuberculosis (TB) incidence, and the highest rate of TB/HIV coinfection globally. In recent years, the Ministry of Health and partners have increased integration and co-location of TB and HIV services, but the timing of antiretroviral therapy (ART) initiation relative to TB treatment - a marker of program quality and predictor of outcomes - is unknown.
Methods: We conducted a retrospective review of programmatic data from 11 purposefully-sampled facilities to evaluate provision of timely ART for adult (≥15 years) HIV-positive TB patients seen and retained in care between July and September 2014. Timely ART was defined as initiated within two weeks of TB treatment initiation for patients with CD4< 50/µL or missing, and within eight weeks for others. Descriptive statistics were estimated and logistic regression was used to assess factors independently associated with timely ART.
Results: Of 466 HIV-positive TB patients, 51.5% were male, median age was 35 (interquartile range [IQR]: 29-42), and median CD4 was 137/µL (IQR: 58-268). 189 (40.6%) were on ART prior to, and five (1.8%) did not receive ART within, six months of TB treatment initiation. Median time to ART initiation after TB treatment initiation was 15 days (IQR: 14-28). Almost 90% started ART within eight weeks. 25 of 55 patients (45.5%) with CD4< 50/µL started within two weeks. Of 44 (16.1%) patients without a documented CD4, 47.7% began ART within two weeks, and 93.2% within eight. Patients with CD4 50-200/µL or ≥200/µL had significantly higher odds of receiving timely ART than patients with CD4< 50/µL, with adjusted odds ratios of 11.3 (95% confidence interval [CI]: 5.0-25.8) and 10.38 (95% CI: 4.89-22.03), respectively. 71.2% achieved TB cure or treatment completion at six months, but this was not associated with timely ART.
Conclusions: This study demonstrates the relative success of integrated and co-located TB/HIV services in Swaziland and shows that very high levels of timely ART uptake for HIV-positive TB patients can be achieved in integrated but resource-limited TB/HIV settings. However, gaps remain in getting patients with CD4< 50/µL to receive ART within the recommended two weeks post TB treatment initiation.

MOAB0406

Feasibility of using determine-TB LAM test in HIV-infected adults in programmatic conditions

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Background: We assessed the feasibility and described the operational aspects of using the Determine-TB LAM (LAM) test for diagnosis of tuberculosis (TB) in adult HIV infected patients.
Methods: This multi-centric study was conducted in Malawi and Mozambique from 2014 to 2016. LAM was used as a rule in screening tool for hospitalized adult HIV infected patients (Malawi) and for ambulatory patients with CD4 < 100 /µl (Mozambique), and as an additional diagnostic tool for adult HIV infected TB suspects with CD4 < 200 /µl (Malawi and Mozambique). Standard questionnaires were used to assess user acceptability of LAM; electronic databases used to calculate reader agreement between LAM users, and health centre registers to calculate workload. Supervision notes, minutes of meetings, training reports, and personal observations were used to assess training required, patient flow changes after LAM introduction, strengths and challenges of using the LAM test.
Results: Training of LAM users was performed in approximately 1.5 hours in Malawi and 4 hours in Mozambique. All users found the test easy to perform. Reader agreement for test interpretation was excellent: 98.9%, kappa=0.97, and 98.3%, kappa=0.94 for Malawi and Mozambique respectively. Time to results when LAM was performed in the consultation room was 2 to 7 times lower than when performed in the laboratory. LAM positive patients were started on TB treatment on same day. Introduction of LAM did not require additional space or staff. Strength of LAM was that overall, 98.7% and 99.6% of patients received a LAM result compared to 69.5% and 67.2% receiving a sputum result, and 31.7% and 46.0% receiving a chest X ray result in Malawi and Mozambique respectively. A challenge in Mozambique was the need for CD4 prior to the LAM test to identify LAM eligible patients.
Conclusions: Using the LAM test to diagnose TB among hospitalized or severely immune-suppressed ambulatory HIV patients was feasible, well accepted, and required minimal training. The LAM was a useful additional test for TB in this group because of the ease of providing the urine sample and the rapidity of the results which allowed immediate TB treatment for LAM positive patients.

MOAD01 What's Different about Differentiated Care and Service Delivery?

MOAD0101

Readiness for antiretroviral therapy: implications for linking HIV-infected individuals to care and treatment

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Background: ART readiness is a key predictor of ART initiation. However, there is a paucity of data on ART readiness among individuals at the time of HIV-diagnosis and ART eligibility assessment. Under a test-and-treat approach, understanding

factors associated with ART readiness can inform strategies to support early engagement in care and thereby maximize the benefits of ART. This study examined demographic and psychosocial factors associated with ART readiness and potential barriers to linkage to care among individuals referred for treatment from a mobile health clinic.
Methods: Between April 2015 and May 2016, 87 individuals (18 years and older) in a resource-limited setting in Cape Town, South Africa, completed a face-to-face survey immediately after referral for ART. ART readiness was assessed using key components of this concept identified in the literature (1) an awareness that treatment will be beneficial; (2) motivation to initiate treatment; and (3) the intention to start treatment soon. Multiple logistic regression analysis, controlling for age, gender and education, identified factors associated with ART readiness.
Results: Most participants were very ready (84%) and motivated (85%) to start ART, but 28% reported some uncertainty regarding ART initiation. Treatment readiness was lower among those surprised by their diagnosis (aOR:0.26,p< 0.05) and among healthier individuals (aOR:0.44,p< 0.01). In contrast, higher readiness was associated with better ART knowledge (aOR:4.31,p< 0.05) and knowing someone who had experienced positive health effects from ART (aOR:2.65,p< 0.05). The three most common self-reported barriers to linking to care were: (1) not wanting to be seen at the clinic (31%); (2) no money for transport (29%); and (3) not being able to get time off work (20%).
Conclusions: Results indicate that post-test counselling will need to be designed to deal with surprise at HIV diagnosis, and that health messaging needs to be carefully crafted for HIV-positive but healthy individuals to improve ART readiness and to increase likelihood of further linkage to treatment and care. Further research is needed on effective post-test counselling approaches (e.g., motivational-interviewing) and effective framing of health messaging to increase awareness of the positive benefits of early ART initiation and corresponding motivation to engage in treatment.

MOAD0102

Factors associated with loss to follow-up in a primary healthcare HIV clinic practising test and treat

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Background: World health organisation (WHO) currently recommends all people diagnosed HIV positive to start antiretroviral therapy instantly (T&T) regardless of CD4 cell count and WHO stage. Currently however, a myriad of HIV treatment programs are plagued with the challenge of patients' loss to follow up. We set out to study factors associated with loss to follow up (LTFU) in a primary healthcare facility practising T&T.
Methods: We retrospectively drew and analysed a sample of patients from routine patients' data for HIV clients enrolled into HIV care from January 2012 to December 2014 at Masaka regional referral hospital -Uganda Cares clinic. We defined loss to follow up as failure of the client to show up at the Masaka clinic for at least 91 days from the date of their last appointment taking 31st December 2014 as the reference. We determined cumulative incidence of loss to follow up at differing time intervals and used multivariable cox proportional hazards regression model to determine factors associated with time to LTFU.
Results: We included 600 patients in the sample, 64.7% were females and the median (IQR) age at enrollment of 30.4 (23.8-37.1). The median (IQR) CD4 cell count at start of ART was 373 (204-570), and 15.2% were in WHO stage 3 or 4. By 31st December 2014, 55 cases of LTFU were observed, and the cumulative incidence of LTFU was 8.48% (95% CI=6.26-11.12) at 12 months into HIV care. In multivariable analysis, T&T (aHR=2.49, 95% CI=1.07-5.78), WHO stage 3&4 (aHR=3.78, 95% CI=1.70-8.41) TB suspect (aHR=3.42, 95% CI=1.19-9.81) were associated with an elevated risk of LTFU; whereas access to mobile phone (aHR=0.56, 95% CI=0.36-0.88) duration on ART 1-3 months (aHR=0.21, 95% CI=0.08-0.59), 3-6 months (aHR=0.03, 95% CI=0.01-0.11) and ≥6months (aHR=0.003, 95% CI=0.001-0.01) were independently associated with reduced risk of LTFU.
Conclusions: This study identified testing and initiating on ART instantly being associated with elevated risk of LTFU and as well TB suspicion and advanced disease at enrolment. In a bid to achieve the 90-90-90 campaign therefore, steep ART initiation should be backed by intensive pre-initiation and adherence counseling for better long term retention of patients.

MOAD0103

Pilot study of a multi-pronged intervention using social norms and priming to improve adherence to antiretroviral therapy and retention in care among adults living with HIV in Tanzania

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Background: Interventions incorporating insights from behavioral economics and psychology have been successfully used in the private sector and have the potential to enhance HIV ‚treatment as prevention' (TasP). This approach recognizes that decisions are influenced by emotions, contexts, and decision-making shortcuts outside of conscious awareness. To test this hypothesis, we evaluated an intervention to improve antiretroviral therapy (ART) adherence and retention in care based on concepts of social norms and priming.
Methods: We used patient-centered design to develop a combination intervention using social norms and priming, which is when a stimulus subconsciously or indirectly influences another behavior. The intervention included visual feedback about clinic-level retention in care (social norms), a self-relevant prime, and useful take-home items with the priming image (calendar, pill box). The intervention was implemented at two HIV primary clinics in Shinyanga, Tanzania in 2-week intervals for six months.
We conducted a quasi-experimental pilot study (Clinicaltrials.gov: NCT02938533) by reviewing the medical records of a random sample of 438 adult patients living with HIV infection (PLHIV, 320 exposed and 118 unexposed) to compare retention and the proportion of patients achieving a medication possession ratio (MPR) ≥95% after six months. Intervention acceptability was determined through an in-person survey with a convenience sample of 405 PLHIV at baseline (n=189) and endline (n=216).
Results: In adjusted analyses, PLHIV exposed to the intervention were significantly more likely to be in care after 6 months (87% vs. 79%, adjusted odds ratio (OR_a)=1.73, 95% CI: 1.08, 2.78, p<0.05) and were more likely to achieve MPR≥95% (70% vs. 59%, OR=1.51, 95% CI: 0.96, 2.37, p=0.07). The intervention was associated with increases in staff support of treatment goals (100% vs. 95%, p=0.01) and life goals (66% vs. 50%, p<0.01), the perceived likelihood of other patients' adherence (54% vs. 32%, p<0.01), support from other patients (71% vs. 60%, p=0.03), and being very satisfied with care (53% vs. 35%, p< 0.01).
Conclusions: This novel intervention has the potential to improve the clinic experience, short-term retention in care, and ART adherence. Future studies are needed to expand the generalizability of the approach and evaluate effectiveness on clinical outcomes.

MOAD0104

Multi-month refills of antiretroviral drugs for stable patients in Malawi: assessing accuracy in the application of eligibility criteria at the health facility level

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Background: The provision of three-month antiretroviral (ARV) refills, or multi-month scripting (MMS), for stable HIV patients on antiretroviral therapy (ART) can increase service efficiency and decrease congestion. Since 2008, Malawi has offered MMS to patients that are 18 years or older, have been on ART at least six months, are on first-line ART, have no adverse drug reactions or opportunistic infections, have a viral load less than 1000 copies/mL, and have good adherence according to pill counts. We assessed the extent to which patients are accurately differentiated as eligible or ineligible for MMS and explored potential causes of inaccurate patient differentiation.
Methods: Data were collected from 30 purposefully selected ART facilities in 2016. Participation and eligibility for MMS were determined based on 75,364 patient clinical records, which were analyzed using Stata version 13. Results were weighted and clustered by facility. The reasons for inaccurate patient differentia-

tion were explored using structured surveys with 136 health workers and 32 qualitative interviews with clinic management. Interviews were audio recorded, transcribed and thematically coded.
Results: A majority of patients (86.4%, 95% confidence interval [CI] 84.0-88.6) were eligible and 68.7% of patients (95% CI 62.5-74.6) were receiving MMS. Among patients eligible for MMS, 72.9% (95% CI 66.3-78.6) received MMS. However, 42.3% (95% CI 33.1-52.0) of ineligible patients (amounting to 5.7% of all patients) also received MMS. Results were similar based on sensitivity analyses using different eligibility criteria scenarios, but variation in the application of criteria existed across facilities. Among ineligible patients receiving MMS, 77% had viral load greater than 1000 copies/mL, and 39% had been on ART less than six months. Inaccurate patient differentiation was suggested to result from lack of health worker knowledge of the criteria for MMS, patient requests, health worker attempts to reduce workload, and perceived challenges with low stocks of medications.
Conclusions: MMS is being widely implemented in Malawi, but patient differentiation in many facilities is not happening according to the agreed upon definition of eligibility. Simplification of guidance, improvements in health worker mentorship, patient counseling, and alignment of patient record forms against eligibility criteria would improve patient differentiation in Malawi.

MOAD0105

Multi-month prescription of antiretroviral therapy and its feasibility: experiences from the Baylor International Pediatric AIDS initiative (BIPAI) in six southern African countries

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Background: To improve antiretroviral coverage (ART) and help reach the 90-90-90 treatment targets, differentiated approaches to care are necessary, including reduced frequency of clinic visits for stable patients. Given the paucity of data regarding the impact of differentiated care models on pediatric outcomes, BIPAI conducted a retrospective analysis of clinical outcomes, comparing monthly (MS) with multi-monthly (MMS) ART prescription schedules for children and adolescents in Botswana, Lesotho, Swaziland, Malawi, Uganda and Tanzania.
Methods: MMS was introduced in each country in line with national policy. Patients were transferred to MMS when clinically stable and ART adherent, after 6-9 months of monthly prescriptions. For analysis patients were allocated to the MMS group after three consecutive visits at intervals of greater than 56 days. Adherence, lost-to-follow up rates, CD4 counts and viral load were compared between MS and MMS patients by two-sample tests for binomial proportions. Mortality was compared by log rank test. To avoid bias against the MS groups, deaths in the first 6 months of MS therapy were excluded, given the known, high early rates of mortality. To avoid immortal time bias, MMS patients contributed person-time to the MS group between ART initiation and the start of MMS. The analysis was conducted according to an IRB approved protocol.
Results: There were 11,421 MS and 18,137 MMS patients aged between 0 and 19 years. Comparison of clinical outcomes is displayed in table 1.

Variable	MS patients	MMS patients	p value
Mean interval between visits (SD)	39 days (27.5)	61 days (34.9)	
% of patients with good adherence by pill count (95 to 105%)	68.7% (7,846/11,421)	78.5% (14,238/18,137)	< 0.0002
Lost-to-follow up (%)	7.1% (811/11,421)	1.8% (326/18,137)	< 0.0002
Mortality (deaths per 100 patient years)	2.9	0.4	< 0.0001
CD4 counts (% reaching >350 or >25 % for under age 5	78.0% (8,312/10,653)	92.8% (16,767/18,067)	< 0.0002
Viral load (% undetectable)	63.3% (2,976/4,703)	78.9% (10,787/13,678)	< 0.0002

[Table 1: Clinical outcomes of MS and MMS patients]

MMS patients had statistically lower mortality and lost-to-follow up rates, as well as superior ART adherence rates and response to ART by CD4 counts and viral load measurements.

Conclusions: This study, representing data from six African countries, provides reassurance that patients 0-19 years of age who are clinically stable and ART adherent, can do well with reduced clinical visits via MMS. The consequent reduction in visits can yield additional benefits by decreasing the burden on health systems and patient time.

MOAD02 Unlocking the Epidemic with Key Populations

MOAD0201

Why don't key populations access HIV counselling and testing centres in Nepal? Findings based on national surveillance survey

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Background: UNAIDS proposed the 90-90-90 targets, i.e., that by 2020, 90% of PLHIV will know their HIV status, 90% of PLHIV who know their HIV status will receive HIV treatment, and 90% of PLHIV on ART should be virally suppressed. It is estimated that three million new HIV infections and three million AIDS-related deaths could be averted if these targets are achieved. HIV Testing and Counselling (HTC) is the entry point for HIV care services in Nepal and is provided free of cost to all. This study assesses the demographic, psychosocial and structural factors associated with non-utilization of HTC by female sex workers (FSW) and men who have sex with men/ transgender (MSM/TG) in Nepal.
Methods: We analysed data from the national surveillance survey which included 610 FSW and 400 MSM/TG recruited from 22 and three districts of Nepal respectively. Adjusted prevalence ratio (PR) using modified Poisson regression was used to assess the association between independent and outcome variables (non-utilization of HTC in last year).FSW was recruited using two-stage cluster sampling whereas MSM/TG was recruited using respondent driven sampling.
Results: Non-utilization of HTC in last one year was 54% for FSW and 55% for MSM/TG. The prevalence of depression among study populations was very high (≥50%). About 2 of every 10 FSW experienced forced sex in the last 12 months. The significant factors for FSW related to non-utilisation of HTC were: depression[PR=**1.4(1.1-1.6)**], injection of drugs (ever)[PR=**1.4(1.1-1.8)**],episode of forced sex in previous year [PR=**1.1(1.0-1.3)**], presence of dependents in the family [PR=**1.1(1.0-1.3)**], andparticipation in HIV awareness programmes(ever) [PR=**1.2(1.0-1.4)**]. Non-utilisation of HTC among MSM/TG had significant association with age 16-19 years [PR=**1.4(1.1-1.7)**],physical assault in previous year [PR=**1.6(1.3-2.0)**], condom use [PR=**1.2(1.0-1.4)**],experience of forced sex [PR=**0.5(0.3-0.9)**]and participation (ever) in HIV awareness programs [PR=**1.6(1.3-2.0)**].
Conclusions: HIV prevention programmes in Nepal need to go beyond condom promotion. Creative strategies should be envisaged for effective behavioural change communication. Psychosocial and structural interventions should be integrated with HIV prevention programmes to support key populations.

MOAD0202

Feasibility and acceptability of immediate ART initiation in MSM in West Africa (CohMSM ANRS 12324 - Expertise France)

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Background: Since September 2015, the World Health Organization (WHO) has recommended to initiate antiretroviral treatment (ART) in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count. In Africa, few programs focused on men who have sex with men (MSM). We therefore assessed the feasibility and acceptability of immediate ART initiation in MSM in four West African countries.
Methods: A prospective cohort study has been conducted since June 2015 in community-based clinics in Bamako (Mali), Abidjan (Côte d'Ivoire), Lomé (Togo) and Ouagadougou (Burkina Faso). MSM eligibility criteria were as follows: aged 18 years or older, reporting at least one episode of anal intercourse with another man within the previous 3 months, and either HIV-seronegative or discovering their HIV infection at study enrolment. HIV-seronegative MSM were offered a quarterly follow-up including clinical examinations, screening for HIV, screening and treatment for sexually transmitted infections, individualised peer-led support for prevention, condoms and lubricants. MSM who discovered their HIV infection at study enrolment and those who seroconverted during the follow-up were offered ART initiation immediately after HIV diagnosis.
Results: As of January 16, 2017, 679 MSM were enrolled in the study. Of them, 120 were HIV-seropositive at study enrolment and 35 seroconverted during follow-up. The median age of these 155 HIV-infected MSM was 24.5 years (interquartile range [IQR]: 21.8-28.1). A total of 134 (86.5%) MSM initiated ART. The median time from HIV diagnosis was 7 days (IQR: 3-16). Only 15 (11.2%) MSM initiated ART more than 1 month after HIV diagnosis, and 6 (4.5%) MSM after 3 months. The median CD4 cell count at ART initiation was 433 cells/µL (IQR: 324-535). Few discrepancies were observed between the study sites. MSM mainly received EFV+TDF+3TC (85.1%) or EFV+TDF+FTC (13.4%). Of 57 MSM with available data, 5 were resistant to EFV, of which 2 were also resistant to 3TC/FTC.
Conclusions: These preliminary results indicate that immediate ART initiation is feasible and well accepted by MSM in West Africa, strengthening the recent WHO-recommendation.

MOAD0203

Don't get lost: how peer navigation can link HIV-positive key populations to care and treatment and re-engage those lost to follow-up

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Background: Linking key populations (KP), including men who have sex with men (MSM) and sex workers (SW) to HIV care and treatment programs, and ensuring they adhere to treatment to reach viral suppression is a challenge in many developing countries. The peer navigation system in Cameroon was initiated to support enrollment and retention of HIV-positive KPs in the HIV service cascade and to remain adherent to treatment. Peer Navigators (PN) are HIV-positive, medication-adherent role models who understand and can convey clearly how to access and utilize key services for people living with HIV and their partners, loved ones, and children.
Methods: Through the USAID- and PEPFAR-funded LINKAGES and CHAMP projects, we pilot tested the peer navigation system in Yaoundé, Cameroon. Working with two community-based organizations, twenty-four PN were trained to provide quality support to HIV-positive KP. PN are usually HIV positive, may be a member of the KP community, trained and full-time staff. Programmatic data collected between November 2015-July 2016 before PN was introduced was compared to data collected between August-December 2016 after PN initiation. For the analysis, linkage to HIV treatment before and after PN was reviewed.
Results: A total of 838 HIV-positive FSW and 557 HIV-positive MSM accessed services from the two CBOs between November 2015 to December 2016. Preliminary data showed increases in client linkage to care and treatment, which went from roughly 39% of newly diagnosed HIV-positive clients before PN to as high as 82% after PN was introduced. Also, 38% of MSM and 71% of SWs living with HIV that were lost to follow-up before PN were recovered in just four months of PN implementation and linked to treatment.
Conclusions: While data are preliminary, they demonstrate the potential effectiveness of Peer Navigation programs that are being initiated in sixteen countries where LINKAGES is working. More widespread implementation of PN with high risk populations could accelerate progress toward 90-90-90 goals.

MOAD0204

HIV treatment cascade analysis for people who inject drugs in Ukraine: identifying the correlates of continuum

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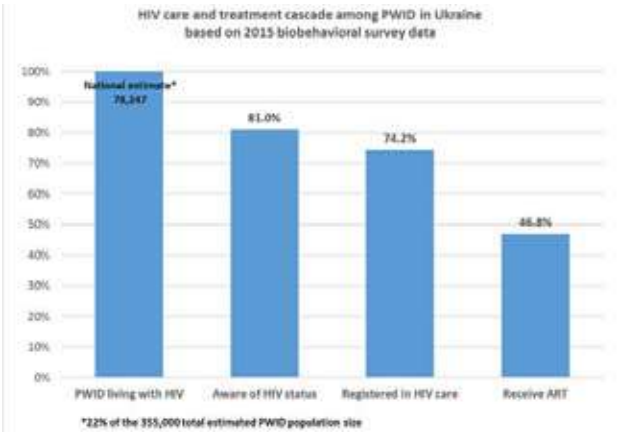
Background: PWID constitute over 50% of PLWHIV and continue driving HIV incidence in Ukraine, but data on HIV care continuum are scarce. Integrated bio-behavioral surveys (IBBS) among PWID are conducted biannually since 2007 to evaluate the effectiveness of HIV response. The aim of this study was to identify gaps in the HIV treatment cascade among PWID and identify correlates of receiving HIV care and ART.
Methods: This is a secondary analysis of 2015 IBBS data collected in all 27 regions of Ukraine using RDS. Results of rapid HIV testing and self-reported data on HIV status awareness, enrollment into HIV care and treatment were used to construct the cascade. Socio-demographic variables, drug use patterns, risk behaviors, receiving of prevention and other interventions were evaluated as potential correlates of being registered in HIV clinic and receiving ART. Logistic regression was used to test significance of association.
Results: 9,405 PWID were recruited (25% females), 22% tested positive for HIV. Of those, 81% reported being aware of their status. Among PWID who agreed to disclose HIV+ status, 74.2% were registered in HIV care and 46.8% received ART (see Figure).



[PWID Cascade]

Being female (aHR=1.9, 95%CI 1.02-3.33), age>35y.o. (aHR=4.05, 95%CI 1.95-8.41), being a harm reduction client (aHR=2.03, 95%CI 1.19-3.46) were positively associated with HIV care registration. Age>35y.o. (aHR=2.54, 95%CI 1.49-4.32), being a harm reduction client (aHR=1.68, 95%CI 1.26-2.24), current case-management (aHR=1.75, 95%CI 1.04-2.97) were positively associated with receiving ART. Past history of case-management was negatively associated with both outcomes (aHR=0.09, 95%CI 0.04-0.2 and aHR=0.44, 95%CI 0.22-0.88, respectively). Opioid agonist treatment, drug and alcohol use, risk behaviors were not associated with either outcome.
Conclusions: The study confirmed existence of significant gaps in HIV cascade among PWID in Ukraine, especially in access to ART. Services provided at harm reduction programs, including case-management, are important interventions that may improve access to care and treatment.

MOAD0205

Effectiveness of comprehensive HIV and stimulant use prevention intervention with Cambodian female entertainment and sex workers

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Background: HIV prevention services for female entertainment and sex workers (FESW) could serve as a platform for targeting key risk factors for HIV infection, including amphetamine-type stimulant (ATS) use and economic distress. We examined sequentially delivered interventions to decrease ATS use and improve economic well-being to boost HIV risk reduction with FESW.
Methods: This cluster randomized stepped-wedge trial in 10 Cambodian provinces enrolled 1,198 FESW to test the effectiveness of a comprehensive HIV and ATS use prevention package leveraging SMARTGirl, an existing HIV prevention platform for Cambodian FESW. The intervention included a conditional cash transfer with cognitive-behavioral aftercare (CCT+AC) intervention to reduce ATS use followed by a microenterprise (ME) opportunity. The co-primary outcomes assessed in 600 FESW purposively targeted for the 18-month follow-up were: 1) self-reported number of sexual partners (past three months); and 2) positive urine toxicology results for ATS (ATS Tox+). After baseline, FESW with problematic patterns of ATS use were allocated to receive a 4-month CCT+AC intervention. All FESW who were abstinent from ATS at six months were allocated to receive a ME opportunity.
Results: At six months, relative to baseline participants had 60% lower odds of ATS Tox+ (Adjusted Odds Ratio [AOR]=0.40; 95%CI 0.25-0.65; p<0.001) and non-significant decreases in number of sexual partners (Adjusted Risk Ratio [ARR]=0.65; 95%CI 0.38-1.11; p=0.11). At 12 months, FESW reported 50% fewer sexual partners (ARR=0.50; 95%CI 0.25-0.95; p=0.035) and non-significant reductions in the odds of ATS Tox+ (AOR=0.58; 95%CI 0.30-1.14; p=0.11). Although FESW continued to display reductions in both primary outcomes at 18 months, these were not statistically significant (p's< 0.09).

	# of Sexual Partners (3 Mo)	ATS Tox+
	ARR (95% CI)	*AOR (95% CI)*
Follow-up Assessment		
6 Months	0.65 (0.38 - 1.11)	**0.40 (0.25 - 0.65)***
12 Months	**0.50 (0.25 - 0.95)***	0.58 (0.30 - 1.14)
18 Months	0.45 (0.18 - 1.14)	0.44 (0.18 - 1.07)

[Intent-to-treat analyses (N = 1,198 at Baseline)]

Conclusions: Findings support the robust, short-term effectiveness of the sequentially delivered CCT+AC and ME interventions for optimizing HIV prevention services for Cambodian FESW. Further implementation science research is needed to inform the scale up and improve the durability of this comprehensive approach to boost HIV risk reduction with FESW in Southeast Asia.

MOAD0206

Viral suppression at the first integrated methadone and antiretroviral therapy program for people who inject drugs in sub-Saharan Africa

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Background: The prevalence of HIV among people who inject drugs (PWID) in Dar es Salaam is 42%, compared to 7% in the general population. In 2011, an opioid treatment program (OTP), using methadone, was established in Tanzania to reduce HIV risk behaviors and transmission. Enrollment of PWID into the OTP program surged, but linking and sustaining HIV-positive, eligible OTP patients in antiretroviral therapy faced many obstacles. We report the results from the first integrated methadone and antiretroviral therapy (IMAT) program to improve sustained ART access for PWID in sub-Saharan Africa.
Methods: A community engagement process with patients, providers, and government stakeholders helped us to collaboratively define an integrated model, including: opt-out HIV screening, OTP providers trained in HIV clinical management and monitoring, multiple ART dispensing models from the OTP clinic, and intensive case management for people who were not virally suppressed. We assessed viral suppression 6 and 12-months after implementation of the integrated model, and used logistic regression to assess predictors of viral suppression (< 1,000 copies/mL) at 12 months.
Results: Of the 126 people receiving HIV treatment at OTP, the median age was 35 years old, and 17% were female. Overall, 72% (95% Confidence Interval (CI): 60-82%) of patients had achieved viral suppression after 6 months of receiving HIV care at the OTP clinic, and after 12 months, 81% (95% CI: 69-88%) had achieved viral suppression. Regarding ART dispensing models, 79% received monthly supplies while 21% received directly administered ART (DAART) at the pharmacy or by a nurse. Age (p=0.323), sex (p=0.814), time in treatment (p=0.683) and ART regimen (p=0.263) were not significantly associated with viral suppression. Intensive case management was associated with a 16% (95% CI: 1-32%; p=0.0362) increase in viral suppression within 3 months of the case management session.
Conclusions: Our findings show a high level of viral suppression among people accessing HIV treatment within the IMAT program. The success of IMAT was driven by early engagement of OTP patients and providers. Future work will develop differentiated models of care for people receiving ART to achieve sustained viral suppression among HIV-positive PWID without overburdening the region's health system.

MOAX01 Just Do It Yourself: Preferences and Performances of HIV Self-testing

MOAX0101

Self-testing: an effective means of increasing HIV-testing and status awareness

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Background: HIV self-testing (HST) could potentially improve HIV testing uptake and awareness of serostatus, especially if targeted towards patients who refuse routinely-offered facility-based HIV counselling and testing (HCT) due to privacy concerns. We conducted a pilot study of HST at two health facilities in Khayelitsha, South Africa, among patients who refused HCT, and assessed their HST uptake and linkage to care.
Methods: Patients who refused HCT were offered HST using OraQuick ADVANCE HIV1/2. Participants were asked to report their HST result by pre-paid text message (SMS), or by returning to the facility. Participants who did not report their result within 7 days were contacted telephonically.
Results: From 1 March 2016 to 31 October 2016, 537 patients were offered HST, of whom 422 (78%) accepted. Those who accepted HST, had a median age of 28 years; 409 (97%) were female; and 313 (74%) reported their HST result. Of the 422 participants, 245 (58%) reported their result within 7 days, and the median time to reporting the result was 1 day. Of those who reported their result, 269 (86%) reported by SMS. Reporting of results varied by facility, being 60% at the facility where many patients did not carry a cell phone due to security concerns, compared to 83% at the other facility. Among participants who reported their HST result, 19 (6%) were positive, compared to 7% HCT at same facilities. Of the 19 participants reporting a positive HST result, 10 (53%) returned for confirmatory testing. Of the 294 participants who reported a negative HST result, 53 (18%) returned for confirmatory testing. All confirmatory tests agreed with the reported HST results.
Conclusions: Offering HST in public-sector clinics is an effective way of increasing HIV testing uptake among those who refuse HCT, but ensuring that those with positive HST results return for confirmatory testing is challenging. As the majority of patients attending clinics are female, the effectiveness of providing HST in other settings needs to be assessed as a means of increasing HIV testing uptake among males.

MOAX0102

HIV self-testing: feasibility and acceptability of a large scale national service delivered by a community organisation

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Background: The UK needs a dramatic increase in HIV testing to reduce undiagnosed HIV and late diagnoses. HIV self-testing offers the potential to significantly increase the number and frequency of tests.
Methods: : We piloted a national HIV self-testing service, which was delivered online to men who have sex with men (MSM) and Black Africans living in the UK. A dedicated website was created and the service was promoted through social media. Participants provided demographic information, contact details and answers to HIV risk assessment questions. An HIV self-testing kit was then posted to them. Service users were asked to log onto a secure page on the website to inform us of their result. Anyone with a reactive result was called for support or advice and to ensure access to care for confirmatory testing. An online satisfaction survey was sent to everyone who gave consent.
Results: The pilot ran from 24th June - 5th Aug 2016. A total of 4,879 kits were ordered. 3,021 people (62%) informed us of their result. 19% had never had an HIV test before and a further 37% had last tested >1 year ago. 68% reported condomless anal sex in the previous 3 months with 28% reporting this with 2 or more partners. 28 people (0.92%) reported a reactive result. 3 (10.7%) people already knew they were HIV positive and one result was confirmed as a false positive. Of the remaining 24 all were MSM. 15/24 (62.5%) identified as white British. Contact was made with 22 (92%) all of whom had accessed confirmatory testing and HIV services. 602 people responded to the survey. 98% would use the service again, 91% felt self testing encouraged them to test and 91% were happy with the support they received.
Conclusions: We have demonstrated the feasibility and acceptability of HIV self-testing in the UK. It also demonstrated a high percentage were willing to report their results which allowed for confirmation of linkage to care. We believe that an investment in HIV self-testing will compliment existing options and provide a cost-effective way to scale up our approach to testing.

MOAX0103

The impact of HIV self-testing among internet-recruited MSM, eSTAMP 2015-2016

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Background: Knowledge of HIV status is essential for accessing antiretroviral therapy and effective prevention services. Providing HIV rapid diagnostic tests (RDTs) for self-testing to persons at risk of HIV infection, such as men who have sex with men (MSM), could increase frequency and timeliness of HIV testing. The "Evaluation of HIV self-testing among MSM Project" (eSTAMP) is a 12-month randomized controlled trial (RCT) that evaluates the impact of this strategy.
Methods: MSM in the US were recruited online from March through August 2015 and enrolled into eSTAMP. Participants were asked to complete online surveys at baseline, 3, 6, 9, and 12 months. The intervention group was mailed 4 RDTs at baseline with the option of replenishing the ones used after interim assessments. At the end of the study, all participants who completed the 12-month survey were mailed 2 RDTs and a dried blood spot (DBS) card. We compare the percentage of participants who tested ≥ 3 times, mean number of all HIV tests, percentages who accessed clinic-based HIV testing services, mean number of sex partners over 12 months, and newly identified cases of HIV infection by intervention and control groups.
Results: We randomly assigned 2665 MSM to the Intervention (n=1325) and Control (n=1340) arms. Mean age was 30.4 years; 58% were white, 10% black, 23% Hispanic, and 9% other or mixed race; 17% had never been tested for HIV. 72% completed at least one follow-up survey; retention rate at 12 months was 58%. There was significantly more HIV testing in the intervention group. 42 cases of HIV infection were identified, 21 were linked to care.

Results over 12 month follow-up period	Intervention	Control	P value
Number of newly identified HIV cases*, n/N (%)	25**/966 (2.6%)	11**/958 (1.2%)	0.03
MSM reporting ≥3 HIV tests, n/N (%)	761/965 (79%)	217/958 (22%)	< 0.01
Number of HIV testsa, mean (SD)	5.3 (3.6)	1.5 (1.8)	< 0.01
MSM reporting clinic-based HIV tests, n/N (%)	395/966 (41%)	614/958 (64%)	< 0.01
Number of sex partners, mean (SD)	9.1 (17.0)	9.7 (19.7)	0.57
*includes RDT and clinic-based testing among study participants. **Additional cases (Intervention: n=3, Control: n=3) were identified from the DBS testing after the 12 month survey.			

[Table 1]

Conclusions: Implementing internet-based HIV screening programs with free HIV RDT increased HIV testing and diagnosis among MSM, including those who have not previously accessed traditional HIV testing services.

MOAX0104

Feasibility of HIV self-test programming among female sex workers in Zimbabwe

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Background: Female sex workers (FSW) are disproportionately affected by HIV, yet their engagement in HIV services does not reflect this heightened risk. Increasing HIV testing is the first step towards prevention and care services. There is little research on HIV self-testing (HIVST) among FSW, which may be particularly appropriate for this population. We conducted a pilot study offering HIVST for 6 months to FSW in Zimbabwe to evaluate programmatic feasibility.
Methods: Adult FSW of unknown HIV status presenting for testing at a dedicated FSW clinic were given the option of provider-delivered testing or HIVST. Those opting for HIVST and who had a mobile phone were invited to enroll. Participants received self-test kits and validated instructions. They were contacted after 2 weeks to complete a questionnaire about their experience.
Results: 607 FSW presented for testing and 325 (54%) opted for HIVST (p< 0.01). Among self-testers, mean age was 29 years (range 18-62). Most (94%) had previously tested for HIV. 100% reported the test was not difficult to use, and 98% were comfortable learning their result without a provider present. 30% had a reactive result, and of those, 99% had attended post-test services by the 2-week post-test questionnaire. 100% indicated they would want HIVST to be available to them, and would recommend HIVST to family/friends. 81% would recommend HIVST to their clients. Though no participants were forced to self-test, 38% thought coercive testing might happen if HIVST became more widely available. FSW thought HIVST distribution should be via clinic (62%), pharmacy (18%), peer (14%) and/or workplace (13%). FSW indicated they would be willing to pay $0.50-$25 for self-tests, with 35% willing to pay $1 and 30% $5.
Conclusions: FSW found HIVST highly acceptable, and wanted HIVST to be available to them. A high proportion had a reactive self-test, and importantly, virtually everyone had linked to post-test services by the 2-week follow-up questionnaire. Some expressed concern about potential for coercive testing. FSW were willing to pay for HIVST, and provided useful insight into how to distribute and promote HIVST during future implementation research. HIVST represents a promising strategy to promote regular re-testing among FSW in Zimbabwe.

Monday 24 July

Poster Discussions

MOPDA01 Getting to the HAART of Immune Activation

MOPDA0101

A higher fraction of drug resistant proviruses express unspliced HIV RNA during ART compared to the archival wild-type proviruses that comprise the HIV-1 reservoir

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Background: The fraction of proviruses persisting during ART that are latent vs. transcriptionally active has not been determined. To address this question, we investigated the expression of unspliced HIV RNA in vivo in single cells carrying either wild-type (WT) proviruses or those with drug resistance (DR) mutations.
Methods: PBMC were analyzed from Patient #1 in Maldarelli, et al., 2014. The fraction of the proviruses expressing HIV RNA was determined by single-genome sequencing of cell-associated HIV RNA and DNA from single cells. Intact proviruses, capable of infectious virus production, were identified using viral outgrowth assays (VOA). The levels of viral RNA present in infected cells were determined for the archival drug sensitive population, the recently infected DR population, and for clones carrying intact and defective proviruses.
Results: We analyzed a total of 77 million PBMC, of which 10,450 contained HIV pro-pol sequences: 7137 were WT, 1714 were DR, and 1599 were defective (contained stop codons). The median fraction of proviruses that expressed RNA in cells more recently-infected with DR virus was 25%, whereas in cells with WT or hypermutant proviruses, it was 14% (p=0.0008). Levels of expression in single cells with DR proviruses were higher than in cells with WT proviruses (p=0.002). The median fraction of cells in apparent clonal populations carrying intact proviruses (N=3) expressing HIV RNA was 2.3% (1.2%-8.8%). For clones carrying defective proviruses (N=5), the median fraction expressing was 3.5% (0.9%-7.0%), and for clones carrying proviruses that did not have obvious defects in the pro-pol region but were not recovered in the VOA (N=26), the median was 6.6% (1.3%-66.7%).
Conclusions: A small fraction of the proviruses in clones of HIV infected cells expressed HIV RNA. The fraction and levels of proviral expression were significantly higher in more recently infected cells than in those that persisted during long-term ART. These findings show that ART can select both for cells infected before ART initiation that either do not express HIV RNA or express at low levels and for cells infected recently with drug-resistant viruses that express higher levels of HIV RNA.

MOPDA0102

Evidence of production of HIV-1 proteins from "defective" HIV-1 proviruses in vivo: implication for persistent immune activation and HIV-1 pathogenesis

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Background: Greater than 95% of proviruses detected in circulating PBMCs are referred to as "defective" and are unable to encode intact viruses. They have been thought to represent a silent graveyard of viruses with little contribution to HIV-1 pathogenesis. We have recently shown that these "defective" proviruses are capable of transcribing novel mRNA species. In the present study, we demonstrate that these "defective" proviruses are also capable of producing HIV-1 proteins.
Methods: CD4+ T cell clones were obtained from an HIV-infected individual who had recently been placed on suppressive combination antiretroviral therapy (cART). The CD4+ T cells were initially plated in 96-well cell culture plates at a cell density of 100 cells/well and expanded for 2 weeks in the presence of autologous feeder cells. Positive wells by HIV-DNA PCR were further expanded in 48-well plates for another week. The identification of single-cell clones harboring "defective" proviral DNA was confirmed by combining 5´LTR-to-3´LTR single-genome amplification and direct amplicon sequencing of the genomic DNA. Cellular expression of HIV-1 proteins was analyzed by western blot and flow cytometry.
Results: Two months after suppression of plasma viremia to <40 copies/ml, the estimated frequency of CD4+ T cells containing HIV-DNA was 1%. Multiple cell lines harboring defective proviruses ranging from 6.5-8.2 kb in length were derived from the CD4+ T cells. Most prominent among these were cells containing an identical 6.5 kb provirus. Sequencing of this 6.5 kb provirus revealed a 2.4 kb internal deletion affecting the region encoding the HIV-1 accessary proteins and the gp120 portion of Env protein. The Gag, Pol and Nef regions remained intact in the 6.5 kb provirus. Consistent with the DNA data, western blots revealed the presence of the Gag and Nef proteins.
Conclusions: These data indicate that "defective" proviruses in successfully treated HIV-infected patients are not silent dead-end products but rather capable of producing HIV-1 proteins in vivo. The proteins encoded by these defective "zombie" proviruses may be responsible for persistent seropositivity and immune activation in most patients with controlled HIV-1 infection during suppressive cART.

MOPDA0103

HIV reservoirs in the brain and association with sex and neurocognition

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Background: Although antiretroviral therapy (ART) reduces plasma HIV-RNA below the detection limit, HIV reservoirs persist in anatomic compartments, as the central nervous system. The clinical and biological factors that influence HIV reservoirs in brain are unknown.
Methods: Paired autopsy tissues from frontal cortex [FC, N=61], occipital cortex [OCC, N=60], basal ganglia [BG, N=31] and peripheral lymphoid tissue (N=37) from 63 HIV+ adults were selected from the National NeuroAIDS Tissue Consortium. All participants died with virologic suppression on ART (< 50 or 400 copies/ml, assay-dependent) without evidence of CNS opportunistic disease, between 1999-2014. Genomic DNA was extracted by magnetic beads; HIV-DNA levels were measured by ddPCR and normalized by RPP30. Neurocognitive (NC) functioning was assessed at the last visit (median 3 months before death) by Clinical Rating based on 7 neuropsycological abilities. Bayesian hierarchical regression model was used to evaluate the relationship between brain regions, sex and NC functioning. The model used a zero-inflated negative-binomial family with a logit link function.
Results: The study cohort consists of 12 females and 51 males (median age: 55 years). Median CD4+ at the last visit was 164 [IQR: 80-390] and median estimated duration of infection was 14 years [IQR: 10-19]. HIV-DNA was detected in 62.5% of brain and 100% of lymphoid tissue. Lymphoid tissue has higher HIV-DNA levels than brain (85.6 vs. 14.2, p<0.001). BG has higher HIV-DNA levels (20.3 copies/10^6 cells) compared to FC (13, p=0.018) and OCC (9.3, p=0.005). Female sex and younger age are associated with higher HIV-DNA in brain (p=0.026, p=0.06, respectively), but not in lymphoid tissue (p=0.31). When evaluating NC sub-domains, higher HIV-DNA (any brain region) was associated with worse speed of information processing (p=0.012) and better verbal fluency (p<0.05). No sex-differences in Clinical Rating was observed.
Conclusions: HIV-DNA was detected in most of brains despite virologic suppression. While levels of HIV-DNA were comparable in lymphoid tissue, women had higher brain HIV-DNA levels than men. Higher brain HIV-DNA levels negatively affected the speed of information in both sexes. The negative association between HIV-DNA and verbal fluency requires more investigation.

MOPDA0104

Monocyte-derived reactive oxygen species impair CD4+ T cell restoration in HIV-1 patients under therapy

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Background: Antiretroviral therapy is highly efficient at suppressing viral replication in over 90% of HIV-1-infected patients. However, 5-25% of these virologic responders do not restore correctly their CD4 count. This suboptimal immunologic response is often correlated with a persistent hyperactivity of the immune system. However, the molecular mechanisms linking residual immune activation to impaired CD4 cell recovery remain to be identified. We tested the hypothesis that periph-

eral blood mononuclear cells (PBMC) from aviremic HIV adults might induce DNA damage in CD4+ T cells resulting in their apoptosis.
Methods: We probed by immunofluorescence the presence of g-H2AX, 53BP1 and 8-hydroxy-2-deoxyguanosine, markers of genostress, DNA double-strand break and oxidation, respectively, in primary fibroblasts co-cultured in transwells with PBMC from virologically suppressed patients. PBMC subpopulations were sorted using magnetic beads. The amount of reactive oxygen species (ROS) expressed in the monocytes and CD4+ T cell apoptosis were measured by flow cytometry using dichloro-dihydro-fluorescein diacetate and fluorescent Annexin V, respectively. DNA-dependent protein kinase (DNA-PK) and p53 phosphorylation was analyzed by western blot.
Results: PBMC of 56 out of 103 virologic responders (54%) induced g-H2AX nuclear foci in cocultured fibroblasts. Cell sorting and inhibition of this phenomenon by a ROS scavenger and an NADPH oxidase-inhibitor established that this genostress, characterized by DNA oxidation and double-strand break, was due to ROS released by monocytes. In cocultured CD4+ T cells, this resulted in DNA-PK as well as p53 phosphorylation, and finally in apoptosis. Patients with PBMC able to damage DNA, a phenotype that we found stable over time, presented with lower CD4 recovery than patients whose PBMC did not induce DNA damage ($p = 0.003$). Patient CD4 slopes were inversely correlated with the intensity of DNA damage induced by their PBMC ($r = -0.419$, $p = 0.006$).
Conclusions: ROS are persistently produced by monocytes in half of virologic responders, inducing DNA damage, cell death in CD4+ T cells, and impaired CD4 restoration. This phenomenon could pave the way for oncogenesis and could be an important driver of CD4 loss in non-treated persons. ROS inhibitors deserve to be tested in non-immunologic responders.

MOPDA0105

HIV-1-mediated induction of Hypoxia Inducible Factor-1 alpha activity in CD4+ T cells modifies immunometabolic phenotype and decreases cell survival

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Background: Chronic T cell activation and dysfunction are hallmarks of HIV infection. Taking into consideration that T cell metabolism influences T cell functionality, we hypothesized that CD4+T cell dysfunction during HIV infection could be associated to virus-induced metabolic alterations. A critical transcription factor in the coordination of T cell metabolism, differentiation and effector function is Hypoxia Inducible Factor-1α (HIF-1α). Herein, we analyzed the expression, activity and function of HIF-1α in CD4+T cells.
Methods: CD4+T cells isolated from the blood of healthy donors were activated with anti-CD3/CD28 antibodies and infected in vitro with HIV. HIF-1α activity was evaluated by using a reporter cell line, expressing GFP under the control of the Hypoxia-Responsive-Element. Cytokine production was evaluated by CBA kit. Cell viability was evaluated by 7-AAD staining and Annexin V binding. Silencing of HIF-1α expression was achieved by transduction with lentivirus-encoded shRNAs. To analyze ex vivo the relationship between HIF-1α levels and cell death in CD4+T cells a total of 7 HIV-1-infected patients on cART and 6 healthy donors were recruited.
Results: We show that HIV-1 infection triggers HIF-1α expression and activity, promoting aerobic glycolysis and the production of proinflammatory cytokines in CD4+T cells infected in vitro. We also observed that the promotion of aerobic glycolysis by HIV is associated with a higher rate of CD4+T cell death. Remarkably, silencing HIF-1α expression in CD4+T cells reverted the promotion of cell death and production of proinflammatory cytokines induced by HIV-1 infection. Finally, we also analyzed HIF-1α expression in samples from HIV-1-infected patients on cART. Interestingly, these patients also exhibit higher levels of HIF-1α expression compared to healthy donors. Moreover, the expression levels of this transcription factor presented a negative correlation with CD4+T cell counts.
Conclusions: In conclusion, we show that HIV infection induces the activity of HIF-1α in productively infected cells promoting glycolytic activity, a proinflammtory phenotype and cell death. These results pave the way to explore the possibility of targeting HIF-1α and/or T cell metabolism to restore CD4+T cell physiology in HIV-1 infected individuals.

MOPDA0106

Toll-like receptor activation modulates inflammation and HIV-1 infection in the female reproductive tract (FEMINIVI study)

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Background: The female reproductive tract (FRT) mucosae are the main sites of exposure and entry of sexually transmitted infections (STIs) including HIV-1. The Toll-Like receptors (TLRs), widely expressed in the FRT, recognize pathogenic motifs and modulate immune responses. TLR stimulation induces an immune activation and/or a local production of inflammatory markers. This inflammation has a controversial impact on the antiviral activity. The aim of this project is to determine in vitro the impact of the TLR activation in the control of HIV-1 infection and on the inflammation in the major mucosal sites of the human FRT
Methods: Samples from different compartments of the FRT (vagina, cervix and uterus) were obtained from HIV-1 negative non-menopausal women who gave their written informed consent. To test the potential antiviral effect of the TLRs, mononuclear cells isolated from the samples were stimulated by TLR agonists 72h prior to HIV-1 infection: PolyI:C (TLR3), LPS (TLR4), R848 (TLR7/8) and the CpG ODN (TLR9). Viral production was measured in cell culture supernatants by p24 Ag ELISA. Prior to HIV-1 BaL infection, the modulation of cytokine production was quantified by Luminex assay and evaluated by confocal microscopy in tissue sections of TLR pre-stimulated biopsies
Results: Each compartment of the FRT presents a specific composition in immune cells. Among CD45+ cells, CD3+ T cells (30-56%), and CD14+ cells (9-16%) are the major populations in the FRT. The NK cells (CD56+) are more abundant in the uterus (4%). The stimulation of TLR3, 7/8 and 9 controls more efficiently HIV-1 infection in the uterus than in other compartments, while TLR4 stimulation does not have a major impact. TLR stimulation also modulates the production of pro and anti-inflammatory cytokines such as IL-6, IL-8 and IL-10
Conclusions: Our results show that the TLR stimulation modulates the cytokine expression and impacts the HIV-1 infection according to compartments in the FRT. Our aim is now to determine if a synergetic effect is obtained by stimulating more than one TLR at the time. The effect of induced inflammation on HIV-1 infection in the FRT is under investigation. Our findings will give clues for developing novel strategies against STIs

MOPDB01 Comorbidities in an Ageing Era

MOPDB0101

More and earlier cardiovascular events (CVE) and shorter overall survival (OS) in HIV-positive patients (HIV+) compared to the general population differ by sex

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Background: The OS of HIV+ should be adapted to the general population by antiretroviral treatment. But in the aging HIV+ CVE and strokes became more frequent.
Methods: We compare CVE, stroke and OS of HIV+ outpatients of the HIV HEART study (HIVH) and of HIV-negative controls of the population-based Heinz Nixdorf Recall study (HNR), both recruited from the German Ruhr area. HIVH cases with HNR controls are matched in a 1:2 ratio by sex and age. CVE are defined

by myocardial infarction and sudden cardiac death. Cox proportional hazard models are used to investigate the impact of study affiliation on OS, CVE and stroke with time from study start to event or last contact. We adjust for age, active smoking and for men additionally for diabetes.
Results: Descriptions are shown in table 1. We observe adjusted Hazard ratios (HR) of 3.5 (95%-CI: 2.2; 5.5) for CVE for male HIVH vs. HNR and for stroke of 1.8 (0.8; 3.9) for male and 2.2 (0.1; 42.9) for female HIVH vs. HNR. The OS in male and female HIVH vs. HNR has an HR of 3.9 (2.5; 6.1) and 1.7 (0.2; 12.3), respectively. The smoking status is different in male subjects (p< 0.0001) and the Framingham Risk score (FRS) is different in female subjects (p< 0.0001). Men differ highly in variables related to blood fats and BMI, women differ in terms of blood pressure and heartrate which is also displayed in the highly different FRS.

	HNR male	HIVH male	p-value	HNR female	HIVH female	p-value
N (%)	950 (66.7)	475 (33.3)		124 (66.7)	62 (33.3)	
Age mean±SD	54.5 ± 6.7	54.5 ± 6.7		51.3 ± 6.1	51.3 ± 6.1	
Cardiovascular events N (%)	40 (4.2)	47 (9.9)	<0.0001	0	2 (3.2)	0.0443
Stroke N (%)	16 (1.7)	12 (2.5)	0.2803	1 (0.8)	1 (1.61)	0.6152
Deceased N (%)	49 (5.2)	52 (11.0)	<0.0001	2 (1.6)	2 (3.2)	0.4747
Never smoker N(%)	278 (29.3)	111 (23.4)		51 (41.5)	22 (36.1)	
Former smoker N(%)	371 (39.1)	126 (26.5)		38 (30.9)	10 (16.4)	
Active smoker N(%)	299 (31.5)	238 (50.1)	<0.0001	34 (27.6)	29 (47.5)	0.0157
FRS mean ± SD	12.6 ± 7.3	11.8 ± 3.1	0.0295	5.5 ± 5.6	14.6 ± 4.7	<0.0001

[Description of the matched study population of 537]

Conclusions: HIV+ males had an increased incidence of CVE compared with HIV-negative controls in spite of similar FRS at baseline in contrast to HIV+ females with higher FRS than controls but comparable rates of CVE. HIV+ males had the highest mortality rate and a higher risk to die or to get CVE at younger age than the general population.

MOPDB0102

Incidence of renal Fanconi syndrome in patients taking antiretroviral therapy including tenofovir disoproxyl fumarate

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Background: Fanconi syndrome (FS) is a well recognised complication of use of the antiretroviral agent of tenofovir disoproxyl fumarate (TDF).
Despite millions of patient years of TDF use, the incidence and predictors of FS are not known. The aim of this study was to determine the incidence and predictors of FS in a clinic cohort of patients taking TDF.
Methods: Clinical records and laboratory investigations from patients receiving ART between January 2002 and March 2016 at the Melbourne Sexual Health Centre, Australia, were extracted. FS was defined as new onset normoglycaemic glycosuria and proteinuria and at least one other marker of renal dysfunction. Kaplan-Meier survival curves were performed using duration of exposure to ART: not containing TDF, or containing TDF, with or without ritonavir co-administration. Cox regression analysis was performed on TDF exposures with using the covariates ritonavir co-administration, age, sex, co-morbidities (hypertension, hyperlipidemia, diabetes, viral hepatitis), CD4 cell count nadir and baseline eGFR.
Results: 1537 patients received ART, including 1260 who received TDF, of whom 398 patients received TDF co-administered ritonavir, representing 10401 patient years (PY) of ART, 5327 PY of TDF and 1641 PY of TDF ritonavir co-administration. 13 cases of FS were identified. All cases were taking TDF and the mean duration of exposure was 55 months (12-98) before developing FS. The incidence of FS was 1.09/1000PYs (95% CI 0.54-1.63) of TDF exposure (without ritonavir) and 5.48/1000PYs (3.66-7.33) of TDF-ritonavir co-administration (p=0.0057). The adjusted hazards ratio for ritonavir co-administration was 4.71 (1.37-16.14, p=0.014). Known risk factors for chronic kidney disease were not associated with an increased risk of FS.
Conclusions: In this first published study of the incidence of Fanconi syndrome, we find that ritonavir co-administration but not other factors is associated with a greater risk of FS. FS developed late. Out study supports ongoing renal monitoring in long term supressed patients with twice yearly urinalysis, particularly if serum laboratory monitoring is not available.

MOPDB0103

Higher HDL, better brain? Higher HDL cholesterol is associated with better cognition in a cohort of older persons living with HIV infection

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Background: Despite effective combination antiretroviral therapy (ART), neurocognitive impairment (NCI) remains prevalent in persons living with HIV (PLWH). The contribution of cardiovascular comorbidities to NCI may increase as PLWH age. We investigated the association of cardiovascular risk factors with prevalent NCI in a prospective cohort of older PLWH at entry into the AIDS Clinical Trials Group A5322 study.
Methods: Participants who underwent a brief neurocognitive screen (Trailmaking Tests A and B, HVLT-R, Digit Symbol) at entry into A5322 were eligible. Primary outcomes were overall cognitive performance summarized by mean z-scores of the 4 tests (NPZ-4) and presence of NCI, defined as ≥1 SD below the mean on 2 or more tests or ≥2 SD below the mean on 1 test. We used linear and logistic regression models to determine the association between cardiovascular risk and the primary outcomes.
Results: Of 988 participants (30% black, 21% Hispanic/Latino, 20% women), mean age was 52 years and education 14 years. Median ART duration was 8 years, mean CD4 count 661 cells/mm^3, and 90% of participants had viral load < 40 copies/mL. Current smoking (26%), statin (27%) and anti-hypertensive (36%) use were common, while stroke (2%), myocardial infarction (3%) and injection drug use (< 1%) were uncommon. Mean LDL and HDL cholesterol were 109 and 49 mg/dL, respectively, and systolic blood pressure was 126 mmHg. 180 participants (18%) had NCI. In demographics and education-adjusted models, higher HDL was associated with better NPZ-4 (+0.04, p=0.040) and lower odds (OR 0.88, p=0.043) of NCI per 10 mg/dL higher HDL, as was statin use (+0.15 NPZ-4, p=0.037). An association between smoking and worse NPZ-4 (-0.15, p=0.053) became non-significant after controlling for anti-depressant use and hepatitis C. In a multivariable model including factors significant at p< 0.10 in demographics and education-adjusted analyses, older age, female sex, Hispanic/Latino ethnicity, high school education or less, and anti-depressant use were associated with worse NPZ-4. Longer ART duration and higher HDL were associated with better NPZ-4.
Conclusions: Among older PLWH with well-controlled cardiovascular risk factors, higher HDL was associated with better cognition. Investigation into the impact of modifying HDL cholesterol on cognition in PLWH is merited.

MOPDB0104

The combination of Tai Chi, cognitive behavioral therapy and motivational text messaging improves physical function, reduces substance use and improves pain in older HIV-infected adults

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Background: Chronic pain is common among older HIV-infected (HIV+) adults and contributes to substance use, reduced physical function and disability. We designed a pilot randomized controlled trial of cognitive behavioral therapy (CBT) + tai chi + motivational texting vs standard of care to reduce pain, disability and substance use in older HIV+ adults.
Methods: Evidence-based chronic pain and substance abuse CBT protocols were adapted and combined with group tai chi and motivational text messaging (EXP). HIV+ adults ≥50 years of age with chronic pain and substance use (n=55) were randomized to EXP (n=18), support group control (cINT, n=19) or no intervention (noINT, n=18) for 8 weeks plus a 4-week post-study follow-up. All participants also completed daily diary assessments. Effects were compared within and between groups. Linear regression models assessed factors, including treatment assignment, associated with physical function, pain, substance use and quality of life.

Results: Participants had mean age 55, 17 years HIV+, 11 years chronic pain; 84% were non-white, 76% male and 9% transgender women. Approximately 1/3 each reported alcohol, marijuana and stimulants as their preferred substance. At baseline, all participants had physical and mental health (SF-12) scores below population means, and 87% had reduced physical function (short physical performance battery [SPPB] ≤10). After 8 weeks, only EXP participants had significantly improved SPPB scores (+31%, within-group p<0.001, between-group p=0.04) and physical function (60% less reduced physical function) that persisted at the post-study follow-up visit and after controlling for age, education, HIV and baseline pain severity. After 12 weeks, both EXP (-55%, p=0.04) and cINT (-120%, p=0.03) participants demonstrated reduced 30-day preferred substance use. However, only EXP participants experienced reduced overall substance use (-51%, p=0.02) and improved percent pain relief (-76%, p=0.03).
Conclusions: An 8-week combined CBT, tai chi and motivational text messaging intervention significantly improved physical function in older HIV+ adults with chronic pain and substance use. After 12 weeks, substance use decreased and achievable pain relief also improved, possibly reflecting delayed onset of improvement in these outcomes. Further study will determine whether CBT + tai chi + motivational texting can provide sustained improvements in this vulnerable population.

MOPDB0105

Capacity to screen and manage mental health disorders at HIV treatment sites in low- and middle-income countries

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Background: Mental disorders are prevalent among people living with HIV (PLWH) and are associated with inferior HIV treatment outcomes, including poor adherence to antiretroviral therapy and lack of viral suppression. Integrating interventions to treat mental disorders into HIV care is a key strategy to improve HIV treatment outcomes in low- and middle-income countries (LMIC), but data on HIV treatment sites' capacities to screen and manage mental disorders is limited.
Methods: We report preliminary findings from an ongoing survey among a stratified random sample of 142 HIV treatment sites in 36 LMIC that participate in the International epidemiologic Databases to Evaluate AIDS (IeDEA). This analysis focuses on depression, posttraumatic stress disorder (PTSD), and substance use disorders (SUD) screening and management in the 53 adult HIV treatment sites that have completed the survey so far.
Results: Most sites (n=40, 75%) were in urban areas. Although 34 sites (64%) reported screening for depression, only 14 (26%) sites had guidelines for screening. Screening for depression and PTSD was more common in low-income countries than middle-income countries. This trend was reversed for SUD screening (Table). Depression, PTSD, and SUD were managed on site (defined as having services provided at the HIV clinic or the same health facility) in 62%, 43%, and 36% of sites, respectively. Selective serotonin reuptake inhibitors (SSRIs) were available in all sites from upper-middle income countries, but only in 22% and 35% of low-income and lower-middle income countries, respectively.

	Low Income Countries N=18 n(%)	Lower middle income countries N=23 n(%)	Upper middle income countries N=12 n(%)	Total N=53 n(%)
Depression screening	13(72)	14(61)	7(58)	34(64)
Guideline available for depression screening	8(44)	3(13)	3(25)	14(26)
Depression management on site	10(56)	12(52)	11(92)	33(62)
PTSD screening	8(44)	2(9)	2(17)	12(23)
Guideline available for PTSD screening	7(39)	2(9)	1(8)	10(19)
PTSD management on site	8(44)	5(22)	10(83)	23(43)
Substance use disorders screening	8(44)	18(78)	8(67)	34(64)
Guideline available for substance use disorders screening	6(33)	4(17)	4(33)	14(26)
Substance use disorders management on site	6(33)	5(22)	8(67)	19(36)

[Screening and management of mental disorders]

Conclusions: Interim findings suggest that most of the HIV treatment facilities surveyed have integrated some mental health services and that screening for depression is commonly reported in low-income countries. However, on site management of depression is less common in these settings. Additional research is needed to understand individual, organizational, and contextual factors that may influence availability of mental health interventions in LMIC.

MOPDC01 Anti-virals and Pregnancy

MOPDC0101

Methods of gestational age (GA) assessment influence the observed association between ART exposure and preterm delivery (PTD): a prospective study in Cape Town, South Africa

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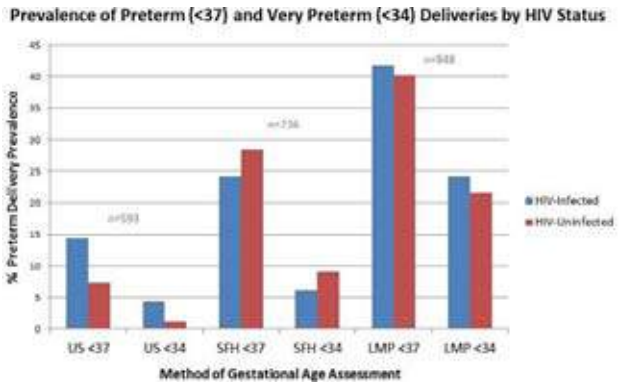
Background: The association between antenatal ART and PTD in HIV+ women is controversial and has not been reliably quantified. Measuring GA is challenging in resource-limited settings; different methods could explain heterogeneous findings. We examined impact of GA estimation methods on observed PTD deliveries rates, by maternal ART.
Methods: Between 4/2015-10/2016 we enrolled women regardless of HIV status attending a large primary care antenatal clinic. Midwives estimated GA by last menstrual period (LMP) and symphysis-fundal height (SFH); separately, obstetric ultrasound was performed by a research sonographer blinded to midwife GA assessment if clinical GA was < 24w. Analyses compared GA estimated by ultrasound, SFH and LMP; the association between HIV/ART status and PTD was examined by GA assessment method using multivariable logistic regression.
Results: Of 1060 women (median age 28y; 46% HIV+ of whom 48% initiated ART pre-conception vs 52% during pregnancy), 82% had LMP-based GA, 71% SFH-based GA, 58% ultrasound-based GA and 54% (n=576) had GA based on ultrasound and at least one other method. At first ANC visit, estimated median (IQR) GA was 18w (12-23w) by LMP, 23w (18-28w) by SFH and 17w (13-21w) by ultrasound. Overall PTD < 37w was observed in 41% by LMP, 27% by SFH and 12% by ultrasound. In 1037 live-singleton births (mean birthweight 3124g; 10% SGA < 10th centile), PTD risk was doubled for HIV-infected compared to uninfected women for ultrasound-based GA (OR=2.01, 95%CI=1.15-3.51); but for LMP/SFH-based GA the association was not significant (Figure). These differences between GA assessment methods persisted after adjustment for age, parity, height and previous PTD; PTD risk did not vary by ART initiation timing for any GA method.
Conclusions: Findings for an association between HIV/ART and PTD are substantially influenced by GA assessment method. With growing scientific interest in this association, future research efforts should seek to standardize optimal measures of gestation.



[Figure]

MOPDC0102

Pregnancy outcomes and infant survival in the era of universal HAART in Africa: the POISE study

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Background: In the era of universal HAART, concerns remain that triple-therapy may increase adverse pregnancy outcomes. We compared low birth weight (LBW), preterm birth (PTB), and survival in infants born to ART-experienced women and to uninfected women in Blantyre, Malawi, where first-line ART includes tenofovir, lamivudine, and efavirenz.
Methods: We enrolled HIV-infected and uninfected women and their babies at delivery into a one-year prospective study at four health-facilities. Eligibility included confirmed HIV status, consent, singleton births, CD4>350 cells/mL^3, and no stage 3/4 HIV. We documented sociodemographic data, clinical and reproductive history, maternal and infant survival, birth weight and gestational age using Ballard score. We applied logistic regression to measure the association between HIV and LBW and PTB. Odds ratios and 95% CIs are presented.
Results: We enrolled 459 HIV-uninfected and 335 HIV-infected women on ART from January to December 2016; 1.4% were virally suppressed at baseline (< 40 copies per/ml). Rates of LBW among HIV-infected and uninfected women were 4.2% and 3.4%, respectively; p=0.69. 11.9% of HIV-infected women and 12.0% of uninfected women delivered PTB; p=0.99. In multivariate analyses for LBW and PTB (Table 1), there was no association between HIV status and adverse outcomes. Among all women, having more than one pregnancy (OR=0.36, 95% CI (0.18, 0.73)) or more than one birth (OR=0.39, 95% CI (0.19, 0.82)) was protective against LBW. PTB was 8.9% among women starting ART before or during first trimester; 15.5% among those starting in second trimester; and 17.9% among women starting in third trimester (p=0.06 for trend). Two infants died: one HIV-exposed and one HIV-unexposed. No maternal deaths were observed.

Baseline Characteristics		Low Birth Weight		Gestational Age	
		OR (95% CI)	Adjusted OR (95% CI)	OR (95% CI)	Adjusted OR (95% CI)
HIV Status (reference = HIV-, n=408)	HIV+ (n=310)	1.23 (0.57, 2.66)	2.08 (0.88, 4.90)	0.99 (0.63, 1.57)	1.18 (0.69, 1.98)
Maternal age	Per year of age	0.96 (0.89, 1.03)	0.95 (0.88, 1.03)	0.98 (0.95, 1.02)	0.99 (0.94, 1.03)
Body Mass Index at delivery (kg/m2) (reference = 18.5-24.9, n=426)	<18.5 (n=15)	1.83 (0.23, 14.78)	2.12 (0.25, 17.83)	1.92 (0.52, 7.05)	2.26 (0.59, 8.63)
	≥25 (n=267)	1.00 (0.45, 2.25)	0.99 (0.43, 2.32)	1.05 (0.65, 1.68)	1.11 (0.67, 1.82)
Estimated work load during pregnant (reference = In house only, n=569)	In house + outdoor (n=43)	0.63 (0.83, 4.79)	0.71 (0.09, 5.58)	1.10 (0.42, 2.91)	1.33 (0.49, 3.63)
	Moderate to heavy (n=92)	0.27 (0.04, 2.00)	0.24 (0.03, 1.84)	0.62 (0.28, 1.40)	0.54 (0.22, 1.29)
Electricity at home (reference = Yes, n=337)	No (n=382)	1.29 (0.59, 2.82)	1.33 (0.59, 2.99)	1.13 (0.72, 1.78)	1.30 (0.80, 2.12)
Hemoglobin (reference = ≥10 mmHg, n=522)	<10 mmHG (n=151)	2.28 (0.68, 7.71)	2.81 (0.81, 9.75)	1.20 (0.67, 2.14)	1.33 (0.72, 2.46)

[Table 1: Adverse Pregnancy Outcomes by HIV Status]

Conclusions: It is reassuring to observe that adverse outcomes were not different between healthy HIV-infected women and HIV-uninfected women. It appears that near-universal ART can eliminate mother-to-child transmission of HIV without significant negative impact on other pregnancy outcomes.

MOPDC0103

ARV drug concentrations in breastmilk, viral load, and HIV transmission to the infant

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Background: Concentration of antiretroviral (ARV) drug found in plasma, as well as the amount of drug excreted into breastmilk, may affect the rate at which ARVs suppress viral replication, and/or the duration of viral suppression, affecting HIV viral load and potentially HIV transmission from mother to infant.
Methods: A case cohort study was conducted using data from the Breastfeeding, Antiretrovirals and Nutrition study to 1) examine correlation between plasma and breastmilk ARV drug concentration, 2) estimate associations between ARV drug concentration and HIV viral load, and 3) compare time to breastmilk HIV transmission by plasma drug concentration status. We included mothers randomized to 28 weeks of postpartum maternal ARVs or infant nevirapine who had ≥1 plasma or breastmilk (maternal ARV arm only) specimen available 2-24 weeks postpartum. Among these, we included all mothers who transmitted HIV to their infants between 2-28 weeks and 15% of mothers who did not (n=27 and 227, respectively). Plasma and breastmilk drug concentrations for nevirapine, nelfinavir, and lopinavir were dichotomized using the median effective concentration (EC50) as a cutoff (>EC50 vs ≤EC50). Plasma and breastmilk viral load were dichotomized as detectable (plasma: >40 copies/ml, breastmilk: >56 copies/ml) or undetectable. Spearman correlation coefficients were used to assess correlation between plasma and breastmilk ARV concentration. Associations between drug concentration and viral load cutoffs were assessed using mixed effects models. Cox models were used to estimate the association between plasma drug concentration and breastmilk HIV transmission between 2-28 weeks.
Results: All ARV compounds exhibited substantial correlations between maternal plasma and breastmilk concentrations (rho: 0.85-0.98, p-value < 0.0001). Having plasma drug concentration above the EC50 was associated with lower odds of having detectable HIV RNA (plasma OR 0.69, 95%CI 0.49-0.98; breastmilk OR 0.23, 95% CI 0.15-0.37) and a reduced rate of breastmilk HIV transmission (HR 0.42, 95% CI 0.18-0.98). Having breastmilk drug concentration above the EC50 was also associated with lower odds of having detectable HIV RNA (plasma OR 0.65, 95%CI 0.47-0.89; breastmilk OR 0.44, 95% CI 0.31-0.62).
Conclusions: Ensuring adequate drug concentration in both plasma and breastmilk is important for reaching and maintaining viral suppression, and preventing breastmilk HIV transmission.

MOPDC0104

Stillbirth in HIV-infected women delivering in UK/Ireland between 2007 and 2015

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Background: Stillbirth (SB) has multifactorial and incompletely understood causes. We aimed to assess the SB rate and associated risk factors in HIV-infected women delivering in UK/Ireland between 2007-2015.
Methods: We analysed data from singleton deliveries and defined a SB as a baby delivered at ≥24 gestational weeks (GW) showing no signs of life. We performed multivariable logistic regression of SB risk factors, adjusted for maternal age and country of origin (grouped, see Table), year, IDU history, parity, first antenatal CD4 count ≤350cells/μL, antenatal ART regimen, late antenatal care start (≥13GW) and newborn gender with random effect for repeated pregnancies in the same mother.
Results: There were 10157 pregnancies (in 7951 mothers) and 87 (0.9%) SB; MTCT was reported in 41 (0.4%) cases. Compared to live births (LB) SB were more likely to be male (58.7% vs 50.6%), delivered pre-term (median 33.5GW vs 39GW) and be SGA (55.2% vs 20.4%); 7/87 (8.1%) SB had congenital abnormalities versus 295/10070 (2.9%) LB. Compared to mothers delivering a LB, those delivering a SB were more likely to be primiparous (46.5% vs 32.7%), older (56.3% vs 47.2% of age ≥33yrs), from Eastern Africa (47.1% vs 41.4%), more likely to book antenatal care at ≥13GW (93.1% vs 86.8%), have first antenatal CD4 count ≤350cells/μL (50.8% vs 34.5%) and more likely to receive no antenatal ART (5.8% vs 1.6%). Multivariate analysis suggested that significant risk factors associated with SB were antenatal CD4 count ≤350cells/μL and delivering a male newborn; women whose country of origin was not Europe or Africa were also at higher risk (Table).

Maternal age (per 1year increase)	1.04 (0.98, 1.10)
Area of origin: Europe	1.00
Eastern Africa	1.63 (0.55, 4.80)
Western Africa	1.35 (0.40, 4.57)
Middle/South Africa	2.24 (0.68, 7.39)
Other	4.33 (1.31, 14.26)
CD4 cells/µL: ≤350	1.00
>350	1.96 (1.09, 3.53)
Newborn : Female	1.00
Male	1.95 (1.06, 3.58)

[Adjusted OR (95%CI) for stillbirth]

Conclusions: SB rate in HIV-infected women in UK/Ireland was 0.9% in 2007-2015, around twice that in the general population (< 0.5%). Further research is needed to understand circumstances around SB in this population in order to identify possible interventions.

MOPDC0105

Usefulness of HBV rapid tests to identify pregnant women at high-risk of HBV mother to child transmission: the pilot ANRS 12328 study in Cambodia

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Background: Mother-to-child transmission (MTCT) of HBV is mainly associated with high maternal HBV DNA viral load (VL) levels. International guidelines recommend the use of antiviral drugs (such as tenofovir [TDF]) during pregnancy if maternal VL is >200,000 IU/mL. In Southeast Asia (SEA), many pregnant women are not screened for hepatitis B surface antigen (HBsAg) and VL testing is not accessible for those who are HBsAg-positive. Here, we report among pregnant women from Cambodia, the performance of a serial algorithm using two HBV rapid diagnostic tests (RDTs), in which samples reactive for HBsAg were further tested for hepatitis B e antigen (HBeAg), as a surrogate marker for HBV replication.
Methods: In 2015, we prospectively collected plasma samples of 250 pregnant women from the Calmette Hospital (Phnom Penh), including women with a known positive HBsAg status. All specimens were initially tested with the SD BIOLINE HBsAg RDT (Standard Diagnostics), and results were compared to the Murex HBsAg ELISA v3.0 (Diasorin) (gold standard). HBeAg status was then blindly assessed among all ELISA HBsAg-positive samples using the SD BIOLINE HBeAg RDT, and results were compared to HBV DNA levels (PUMA HBV kit, Omunis) (gold standard). Analysis was done according to thresholds of 200,000 and 2,000,000 IU/mL.
Results: Overall, 128 pregnant women tested positive for HBsAg with ELISA (51.2%). The sensitivity and specificity of the HBsAg RDT, compared to ELISA, were 99.2% (95% confidence intervals, 95.7-99.9) and 100% (97.0-100), respectively. Among the 128 ELISA HBsAg-positive samples, 29 (23%) tested positive with the HBeAg RDT, 34 (26%) showed HBV viremia >200,000 IU/mL and 29 (23%) >2,000,000 IU/mL. The sensitivity and specificity of the HBeAg RDT in detecting HBV replication were 76.5% (60.0-87.6) and 96.8% (91.0-98.9) for VL > 200,000 IU/mL and 89.7% (73.6-96.4) and 97.0% (93.6-100.0) for VL >2,000,000 IU/mL.
Conclusions: Our results strongly suggest that a combination of HBsAg and HBeAg RDTs in a serial algorithm is an efficient strategy to identify highly viremic HBV-infected pregnant women in need of TDF to prevent HBV MTCT. RDTs-based strategies can significantly improve HBV screening coverage among pregnant women, notably in SEA where HBV is highly prevalent.

MOPDD01 Getting on with #Adolescents

MOPDD0101

HIV treatment and care services for adolescents: a situational analysis of 218 facilities in 23 sub-Saharan African countries

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Background: In 2013, 2.1 million adolescents (age 10-19 years) were living with HIV globally. The extent to which health facilities provide appropriate treatment and care was unknown. To support understanding of service availability in 2014, Paediatric-Adolescent Treatment Africa (PATA), an NGO supporting a network of health facilities across sub-Saharan Africa, undertook a facility-level situational analysis of adolescent HIV treatment and care services in 23 countries.
Methods: Two hundred and eighteen facilities , responsible for an estimated 80,072 HIV-infected adolescents in care, were surveyed. Sixty percent of the sample were from PATA's network, with the remaining gathered via local NGO partners and snowball sampling. Data were analyzed using descriptive statistics and coding to describe central tendencies and identify themes.
Results: Respondents represented three sub-regions: West and Central Africa (n=59; 27%), East Africa (n=77, 35%) and Southern Africa (n=82, 38%). Half (50%) of the facilities were in urban areas, 17% peri-urban and 33% rural settings. Insufficient data disaggregation and outcomes monitoring were critical issues. A quarter of facilities did not have a working definition of adolescence. Facilities reported non-adherence as their key challenge in adolescent service provision, but had insufficient protocols for determining and managing poor adherence and loss to follow-up. Adherence counselling focused on implications of non-adherence rather than its drivers. Facilities recommended peer support as an effective adherence and retention intervention, yet not all offered these services. Almost two-thirds reported attending to adolescents with adults and/or children, and half had no transitioning protocols. Of those with transitioning protocols, 21% moved pregnant adolescents into adult services earlier than their peers. There was limited sexual and reproductive health integration, with 63% of facilities offering these services within their HIV programmes and 46% catering to the special needs of HIV-infected pregnant adolescents.
Conclusions: Results indicate that providers are challenged by adolescent adherence, and reflect an insufficiently targeted approach for adolescents. Guidance on standard definitions for adherence, retention and counselling approaches are needed. Peer support may create an enabling environment and sensitize personnel. Service delivery gaps should be addressed, with standardized transition and quality counselling. Integrated, comprehensive sexual reproductive health services are needed, with support for pregnant adolescents.

MOPDD0102

Factors associated with viral suppression among adolescents living with HIV in Cambodia

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Background: Adolescents living with HIV on antiretroviral therapy (ART) have poorer rates of treatment adherence and viral suppression as well as higher mortality rates compared to their adult counterparts. This study investigated factors associated with viral suppression among adolescents living with HIV in Cambodia.
Methods: A cross-sectional study was conducted in August 2016, among adolescents living with HIV aged 15-17 years randomly selected from 11 ART clinics in the capital city and 10 provinces, utilizing a structured questionnaire. The most recent viral load test result was retrieved from medical records obtained from the ART clinics. Adolescents were categorized as having viral suppression if the viral load count was < 1,000 copies/ml. Multivariate logistic regression analysis was performed.
Results: This study included 328 adolescents with a mean age of 15.9 years (SD= 0.8); of whom, 48.5% were female. Mean duration on ART was 97 months (SD= 40.2). Proportion of adolescents with viral load suppression was 76.8%. In bivariate analyses, viral suppression was significantly associated with older age, duration on

ART, higher CD4 count, better family socio-economic status, living with parents, parental education, having parents as main caregivers, no experience of negative attitude from healthcare providers, being aware that they were receiving ART, knowing that HIV is transmitted through unprotected sex with people living with HIV, understanding that there is no cure for AIDS, receiving treatment from a pediatric clinic and type of ART (first or second line). After adjustment, viral suppression remained significantly associated with longer duration on ART, higher CD4 count, receiving treatment from a pediatric clinic, being aware that they were receiving ART and better HIV-related knowledge including knowing that HIV is transmitted through unprotected sex with people living with HIV and understanding that there is no cure for AIDS.
Conclusions: Viral load suppression rates among adolescents living with HIV in this study were considerably high, but fall short of the global target of 90% viral suppression among people living with HIV on ART. Our findings indicate the need to strengthen treatment literacy and understanding of HIV among adolescents as they prepare for transition from pediatric to adult HIV care.

MOPDD0103

Evaluating the implementation and impact of the adolescent package of care at health facilities in former Nyanza province, Kenya

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Background: Youth represent 40% of new HIV infections worldwide including in sub-Saharan Africa. Young people respond better to HIV and sexual health services tailored for their developmental stage. In 2015, Kenya's National AIDS and STD Control Program (NASCOP) introduced an adolescent package of care (APOC) to provide standardized adolescent services to HIV infected adolescents. We conducted this evaluation to assess the impact of APOC on: visit adherence, family planning (FP) uptake, and viral load (VL) suppression.
Methods: Beginning in November 2015, staff at Family AIDS Care & Education Services (FACES)-supported sites were trained in APOC, which included utilizing adolescent checklists and adolescent tailored services i.e. support groups, home re-fills, adolescent clinic days. At 16 sites utilizing electronic medical records, data for adolescents (9-19 years) was extracted on demographic characteristics, clinic appointments, FP, and VL from November 2015-December 2016. At these same sites, chart audits were conducted on a random sample of encounters per site every quarter to assess APOC checklist utilization (0-10) as a proxy for APOC implementation. Generalized estimating equations for logistic regression, accounting for repeated measures, were used to assess effect of checklist utilization on outcomes from November 2015-Decemeber 2016.
Results: We assessed visit adherence and FP uptake in 19,301 encounters for 2,739 HIV-infected adolescents and 1,372 VL tests for 1,305 adolescents. Median age was 13 years (IQR 11, 17). Females comprised 60% (n=1,646) and 61% (n=794) of the clinical encounters and VL tests, respectively. FP uptake (aOR=1.50; 95% CI: 1.19-1.89) and VL suppression (aOR=1.54; 95% CI: 1.09-2.20) increased over time, as did APOC checklist utilization (aOR=2.18; 95% CI: 1.54-3.08). Increased APOC checklist utilization was not associated with change in visit adherence and was inversely associated with FP uptake (aOR= 0.93; 95% CI: 0.89-0.98) and VL suppression (aOR=0.87; 95% CI: 0.89-0.95) over time.
Conclusions: We observed increased FP uptake and VL suppression during scale-up of the APOC. However, increased utilization of the APOC checklist was not associated with these improved outcomes. The checklist is only one element of APOC. Further investigation of additional elements are needed to assess full implementation and impact of APOC on adolescent outcomes.

MOPDD0104

Economic context and HIV vulnerability in adolescents and young adults living in urban slums in Kenya: a qualitative analysis-based on scarcity theory

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Background: Urban slum adolescents and young adults have disproportionately high rates of HIV compared to rural and non-slum urban youth. Yet, few studies have examined youth's perceptions of the economic drivers of HIV. This study applied principles from traditional and behavioral economics, in particular the theory of scarcity as defined by Mullainathan & Shafir (2013), in understanding the duality that impoverished youth face in making sexual decisions both in response to direct money shortages and under the cognitive load of financial distress.
Methods: Twenty focus group discussions were conducted with 120 adolescents, aged 15 - 17, and young adults, aged 18 - 22, living in one of two urban slums in Nairobi, Kenya. Using a semi-structured discussion guide, we asked youth to describe how their economic scarcity, in the form of financial, material, and physical deprivation, contributed to sexual risk behaviors and influenced their capacity to prevent HIV acquisition. All discussions were conducted in Kiswahili and translated and transcribed into English. Data were then coded and analyzed using interpretive phenomenology.
Results: Results indicated that slum youth made many sexual decisions considered rational from a traditional economics perspective, such as acquiring more sex when resources were available, maximizing wealth through sex, being price-sensitive to costs of condoms or testing services, and taking more risks when protected from adverse sexual consequences. Youth's engagement in sexual risk behaviors was also motivated by scarcity phenomena explained by behavioral economics, such as compensating for sex lost during scarce periods (i.e., risk-seeking), valuing economic gains over HIV risks (i.e., tunneling, bandwidth tax), and transacting sex as an investment strategy (i.e., internal referencing). When scarcity was alleviated, young women additionally described reducing the number of sex partners to account for non-economic preferences (i.e., slack). These findings further revealed two implications for prevention interventions relating to gender-specific economic interests and reduced perceived costs of HIV infection.
Conclusions: Scarcity theory draws attention to the role of financial insecurity in altering how individuals and couples approach sexual decision-making. Combination prevention interventions, including biomedical technologies relying on adherence, should not ignore traditional and behavioral economic drivers of sexual decisions in urban poor settings.

MOPDD0105

The effectiveness and cost-effectiveness of community-based support for adolescents receiving antiretroviral treatment in South Africa

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Background: Adolescents receiving antiretroviral treatment (ART) in sub-Saharan Africa are at particular risk of suboptimal adherence, inadequate viral suppression and high loss to follow-up (LTFU). Sub-Saharan Africa also has critical shortages of professional healthcare workers. Community-based support (CBS) programs

are task-shifting interventions to address these shortages. Effectiveness and cost-effectiveness data of interventions improving ART outcomes amongst adolescents are very limited. We measured the effectiveness and cost-effectiveness of a large CBS program in South Africa, the country having the highest HIV burden globally.
Methods: A cohort study including ART-naïve adolescents and youth (ages 10-24 years) who initiated ART at 47 facilities. CBS workers conducted regular home visits providing ART-related and adherence education, psychosocial support, symptom screening for opportunistic infections and traced patients defaulting clinic appointments. Outcomes were compared between adolescents who received CBS plus standard clinic-based care vs. adolescents who received standard care only. Cumulative incidences of LTFU, mortality, CD4 count increases, viral suppression, and pharmacy refill data using the medication possession ratio (MPR) were analysed using multivariable competing-risks regression, generalized estimating equations and multilevel mixed-effects models over five years of treatment. Costs of CBS were compiled and incremental cost-effectiveness ratios (annual cost per additional patient retained in care for patients receiving CBS vs. not receiving CBS) were calculated.
Results: Of 6706 patients included, 2100 (31.3%) received CBS. 5523 (82.4%) were female and 1810 (27.0%) were aged 10-19 years. LTFU was 36% lower amongst adolescents who received CBS; being 29.9% vs. 39.0% amongst adolescents with and without CBS after 5 years, respectively; adjusted subhazard ratio (asHR)=0.64 (95% CI: 0.55-0.76); P<0.0001). Mortality was 32% lower amongst adolescents with CBS, asHR=0.68 (95% CI: 0.53-0.88; P=0.004). Virological suppression (adjusted risk ratio=1.04 [95% CI: 0.94-1.16]), annual CD4 count increases (coefficient=11.7 [95% CI: -13.0 to 36.6; P=0.35]) and mean MPR (81.9% vs. 82.7%; P=0.16) were not significantly different. The average cost of CBS was US$49.54/patient/year. The cost per additional patient retained due to CBS was US$828 and US$594 after one and two years, respectively.
Conclusions: CBS for adolescents receiving ART is a low-cost intervention associated with substantially reduced LTFU and mortality, and can be scaled-up in low income countries.

MOPDD0106

HIV risk behavior, risk perception and experiences in accessing HIV and sexual reproductive health (SRH) services among adolescent key populations in Kenya: a situational analysis

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Background: Men who have sex with men, sex workers, and people who inject drugs are considered key populations (KPs) due to their high risk of HIV infection and transmission. Adolescent KPs (less than 19 years) are at higher risk of HIV than their older counterparts yet programs have not prioritized them. Legal barriers affect their access to SRH and HIV services. A study was conducted to identify risk perceptions and experiences that heighten risk of HIV among adolescents aged 10-19 years who engage in either sex work, same sex relationships or intravenous drug use and their uptake of SRH services.
Methods: A qualitative exploratory study was conducted between October 2015 and April 2016 in Nairobi, Mombasa and Kisumu Counties. Nine (9) focus group discussions and 18 in depth interviews were conducted with 37 adolescent girls reporting sex work, 36 adolescent boys in same sex relationships, and 35 adolescents involved in intravenous drug use. The participants were purposively selected from various KP community based organizations. Data were coded thematically and analyzed using Nvivo 10. Ethical approval was obtained from AMREF ESRC.
Results: 108 adolescent KPs (51 female and 57 male) ranging from 10 to 19 years were interviewed. They reported similar experiences that placed them at heightened HIV risk; being forced to have "condomless" sex for more money, selling sex to sustain themselves and their dependents (22 of the 37 adolescent FSWs had children), sexual abuse and physical abuse from clients and police. Self-perceptions of HIV risk were mixed; those practicing sex work and had multiple sexual partners perceived themselves to be at high risk while those having one partner perceived themselves at low risk. All groups preferred accessing SRH services in private unlike public facilities due to stigma and discrimination.
Conclusions: The findings demonstrate the challenges faced by the often forgotten adolescent KPs highlighting the need for adolescent KP friendly policies, services and structural interventions to address poverty, legal barriers to service access, violence, stigma and discrimination. HIV prevention interventions should address knowledge of and self-perception of HIV risk to prevent HIV acquisition and transmission.

Monday 24 July

Poster Exhibition

The Virus and its Transmission

MOPEA0001

Evidence of substantial HIV-1 genetic evolution in vivo during suppressive therapy

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Background: Although antiretroviral therapy (ART) suppresses HIV to undetectable levels in plasma, it is unclear if treatment fully suppresses viral replication. We aimed to determine if current ART is fully suppressive by investigating HIV genetic diversification during therapy as a proxy for ongoing viral replication.
Methods: Peripheral blood cells from 30 HIV-infected individuals were evaluated immediately before starting therapy and after four years of continuous ART with undetectable viral loads. Ultra-deep sequencing of the gp41 and C2V3 regions of HIV gp160 was performed. Low-frequency viral variants were filtered based on an error rate of 0.5% derived from misincorporations in the HIV BAL plasmid, which was amplified and sequenced with the samples. HIV divergence and diversity at each time point were calculated using average pairwise distance. Genetic compartmentalization analyses between time points based on tree topologies and pairwise distance were also performed. Correlations between genetic divergence and elapsed time between sampling points were evaluated using linear regression, implemented using TempEst software (root-to-tip analysis).
Results: There was no correlation between read depth and the number of viral variants recorded (p=0.74). gp41 sequences after four years of ART demonstrated significant increases in viral genetic divergence from the most recent common ancestor sequence as compared to baseline sequences from the same individual (p=0.0004). Viral divergence values exhibited significant negative correlations with the CD4/CD8 ratio (p=0.02). No difference was observed in viral diversity between time points. Compartmentalization analyses indicated the presence of distinct virus populations emerging at each time point in 20 out of 30 individuals based on both tree topologies and pairwise distance analysis tests. Root-to-tip analyses yielded R^2 values ranging from 0.01 to 0.96 at gp41 and 0.15 to 0.74 at C2V3 region, indicating high correlation between genetic divergence and time and therefore viral evolution.
Conclusions: Ongoing viral genetic evolution was detected in the majority of individuals on continuous ART. These results suggest that current ART regimens do not completely suppress viral replication. Residual replicating virus may replenish the viral reservoir and sustain inflammatory responses, especially in sanctuaries. These findings suggest that ART intensification should be considered as part of HIV eradication strategies.

MOPEA0002

CRF19_cpx variant emergence in a cluster in naive patients of Southern Spain

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Background: HIV CRF19_cpx has been described as a highly pathogenic recombinant from Cuba. We describe the emergence of this CRF19_cpx variant in southern Spain, clustering in MSM.
Methods: The study was undertaken at the Hospital Virgen de la Victoria (Málaga, Spain) a reference center for the analysis of HIV-1 genotypic drug resistance. The subtype for each FASTA sequence provided was assigned through REGA v3.0. Sequences consigned as a CRF19_cpx variant were confirmed by phylogenetic analysis with other 195 reference sequences retrieved from LANL. Protease and reverse transcriptase (RT) genes were aligned by ClustalX and the phylogenetic reconstruction inferred by maximum likelihood method (RAxML). The reliability of the clades was supported on bootstrapping, with 1,000 replications. For analysis of RT and protease resistance mutations Stanford algorithm v7.1.1 was used. Epidemiological, clinical and immunological data were collected.
Results: Genotypic test was performed in 2340 naive patients from four hospitals during 2011-2016, finding the CRF19_cpx variant in 52 (2.2%). These recombinants, except one, were clustered together (bootstrap=88%), with phylogenetic relation to CRF19_cpx from Israel, Bulgaria and Cuba. Seven well-supported subclusters with different number of patients were also found: A (n=9); B, C, D and G (n=2); E (n=10); and F (n=4). Non-nucleoside RT inhibitor G190A resistance mutation was found in 26 patients (50.0%), among them, clades C, D, E and F. All the patients were MSM, twenty-two of them (42,3%) had a prior negative HIV test, with a median time of seroconversion of 15,7 months. All were Spanish, except one patient from Argentine and one from France. The median age was 32.5 years, baseline CD4 count was 369/µL and VL 5.05 Log (4.4-5.5), being lower in patients with G190A mutation (4.6 vs 5.1, p=0.02). Three cases of AIDS (5,7%) and one death occurred (acute myocardial infarction). All the patients treated with first-line combination ART responded
Conclusions: CRF19_cpx variant has emerged affecting MSM naive patients from southern Spain; all cases but one are related to a local cluster. Half of patients showed the G190A resistance mutation. Unlike previous studies, the variant from Malaga seems less pathogenic, with few cases of AIDS and excellent response to ARV.

MOPEA0003

Impact of HLA-associated HIV adaptation on disease progression in Mesoamerica

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Background: Transmission of HIV pre-adapted to HLA class I-restricted CD8+ T cell responses can accelerate disease progression. HLA-associated adaptation of circulating HIV can vary significantly in populations with different immunogenetic backgrounds. We assessed the impact of HLA-associated HIV adaptation in Mesoamerica.
Methods: We estimated HLA-associated autologous, heterologous and circulating HIV adaptation distributions in gag and pol sequences from 3,208 HLA-typed, antiretroviral treatment-naïve individuals from Mexico, Guatemala, Belize, Honduras, El Salvador, Nicaragua and Panama using a published probabilistic framework.
Results: Autologous and heterologous HIV adaptation distributions overlapped substantially in Mesoamerica compared to other cohorts, suggesting a relatively high degree of pre-adaptation of the circulating virus to HLA alleles in the population. CD4 counts were significantly lower in individuals harboring HIV displaying high adaptation to the autologous HLA profile (p<0.0001 1st vs. 4th quartile). This effect was observed when considering adaptation to HLA-A (p=0.0012) and -B (p< 0.0001), but not -C alleles. Moreover, autologous adaptation could partially explain HLA-specific effects on plasma viral load (pVL): individuals with protective HLA alleles with non-adapted viruses showed lower pVL than individuals with highly adapted viruses (p=0.0482). Interestingly, HLA-specific circulating adaptation positively correlated with HLA-specific pVL (r=0.3276, p=0.0018) and HLA frequency (r=0.2990, p=0.0025), consistent with a general detrimental effect of HIV pre-adaptation on viral control in the Mesoamerican epidemic. Notably, risk HLA alleles showed significantly higher median circulating adaptation than protective alleles (p<0.0001). When considering only protective and risk HLA alleles, we observed a positive correlation between viral replicative capacity and HLA-specific circulating adaptation (r=0.4543, p=0.0442). Additionally, we identified pairs of same-locus HLA alleles with high adaptation similarity and observed that individuals with more compatible HLA pairs had significantly higher pVL (p=0.0386).
Conclusions: Our observations corroborate the negative impacts of HLA-associated HIV adaptation on HIV disease progression. We also provide evidence that adaptation of circulating viruses to frequent HLA alleles negatively impacts viremia control. Moreover, allele-specific circulating adaptation could explain some differential HLA effects on HIV disease progression in different populations. These observations underscore the importance of considering HIV adaptation in vaccine design in a population-specific manner.

MOPEA0004

Heterogeneous age and genetic distribution of within-host HIV-1 reservoirs revealed by a novel phylogenetic dating strategy

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Background: HIV's ability to persist within latent cellular reservoirs represents a major barrier to cure. Since HIV reservoir establishment begins early following transmission, and HIV evolves continually within a host, viral reservoir sequences sampled during chronic infection should range in both age and divergence from the founder virus. However, methods to infer these parameters from HIV reservoir sequences remain limited. We developed a phylogenetically-informed regression method to date HIV sequences sampled within-host, and apply it to infer the ages of reservoir sequences sampled from the blood of an individual after nearly 10 years of suppressive cART.
Methods: The method involves inference of a maximum-likelihood phylogeny from longitudinal within-host plasma HIV RNA sequences, followed by optimal rooting of the tree using root-to-tip regression. Root-to-tip distances of presumed latent reservoir sequences are then mapped to the optimal regression line to estimate their establishment (integration) dates. The method was first validated on simulated and published HIV sequences. Then, it was applied to empirical data from a single participant comprising 65 Nef sequences isolated by single-template amplification from 14 archived pre-cART plasma samples spanning 1996-2006, and 16 unique putative reservoir sequences isolated in 2016 from PBMC during suppressive cART.
Results: Our phylogenetically-informed regression approach reliably recovered sampling dates from simulated longitudinal sequence datasets with and without latent lineages. Validation on published HIV RNA sequences was similarly successful and provided more realistic error estimates. Application of the method to „date" published HIV DNA sequences from phylogenies inferred from longitudinal datasets of paired HIV RNA and DNA sequences yielded age estimates consistent with latency. Application of the model to the study participant yielded a realistic estimated Nef evolutionary rate of 2.0 X 10^{-5} substitutions/base/day. Reservoir sequences were genetically diverse with estimated establishment dates ranging from 1999-2013, consistent with a heterogeneous reservoir pool.
Conclusions: Dates of establishment of individual HIV reservoirs can be recovered from phylogenetic analysis of within-host HIV RNA sequence variation. Our novel method illuminates HIV reservoir dynamics and contributes to the ongoing debate surrounding the extent of HIV evolution on suppressive cART.

MOPEA0005

Subtype-specific constraints on HIV-1 adaptation to host cellular immunity revealed through statistical and functional analyses

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Background: The extent to which viral genetic context constrains HLA-driven immune escape pathways in HIV remains incompletely understood. We combine phylogenetically-informed statistical analyses with in vitro functional assessments to investigate HLA-driven adaptation in a host population where multiple HIV-1 subtypes co-circulate (Uganda).
Methods: HLA-associated polymorphisms in HIV-1 Gag, Pol and Nef were identified in 200 antiretroviral-naive individuals infected with subtype A1 and 135 infected with subtype D. Their strengths of selection were then compared across HIV-1 subtypes using a phylogenetically-informed logistic regression approach to identify instances of differential selection between subtypes. Multiple testing was addressed using q-values. Infectious molecular clones expressing consensus and mutant subtype A1 or D gag/protease sequences in an HIV-1 NL4.3 backbone were constructed using Gibson Assembly and used to produce VsVg-pseudotyped virus stocks. In vitro replication of these viruses was assessed using a 7-day GFP-reporter-based assay.
Results: A total of 83 Gag, 198 Pol and 105 Nef HLA-associated polymorphisms were identified in subtype A and/or D at q< 0.2 (all p< $9x10^{-4}$). Of these, 34% (Gag), 39% (Pol) and 27% (Nef) exhibited significant differential selection between subtypes (p< 0.05; q< 0.1). For example, HLA-B*57:03 strongly selected Gag-T242N in subtype D (Odds Ratio [OR]=250; p=$2x10^{-10}$), but not subtype A1 (OR=1.8; p=0.8)(inter-subtype comparison p=$8x10^{-6}$; q=0.001). This raised the hypothesis that the subtype A1 consensus proline at adjacent Gag codon 243, which differs from the consensus leucine observed in subtype D, is incompatible with T242N. Indeed, a subtype A1 virus carrying 242N/P243 exhibited >10-fold poorer in vitro replication compared to consensus A1, confirming HIV-1 subtype-specific constraints on immune escape at this position.
Conclusions: Statistical analyses applied to linked HIV-1/HLA datasets can illuminate HIV-1 codons where mutational immune escape pathways may be constrained in certain HIV-1 subtypes. Functional validation of these incompatible mutation combinations may help identify subtype-specific mutationally-constrained viral regions for vaccine design.

MOPEA0006

Pre-existing tuberculosis infection and associated immune reconstitution inflammatory syndrome affects the HIV-1 reservoir

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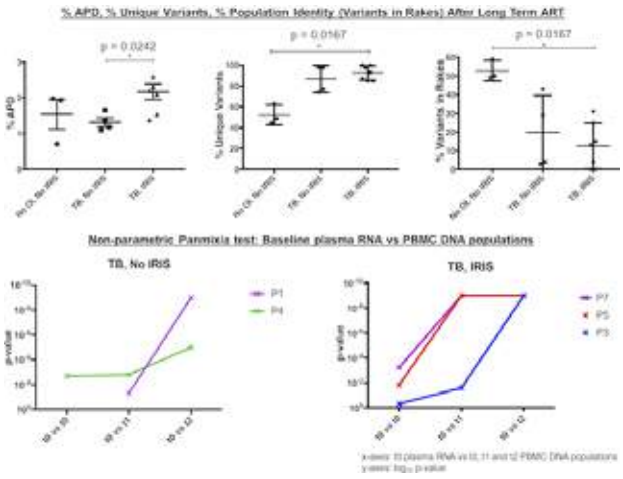
Background: Tuberculosis (TB)-associated immune reconstitution inflammatory syndrome (IRIS) is an aberrant inflammatory response of TB patients starting antiretroviral therapy (ART), especially with severe CD4 lymphopenia or disseminated TB. Previous studies show TB-IRIS driving rapid expansion of activated TB-specific CD4+ T-cells. We hypothesized that pre-ART (baseline) TB and IRIS in HIV-1 infected patients have long-term effects on viral reservoirs.
Methods: A single copy assay measured HIV viremia in baseline lymphopenic (BL) patients +/-IRIS to assess if IRIS affected HIV replication after long term ART (1-2y). CD4+ T-cell associated (CA) gag RNA:DNA ratios quantified the CD4+ reservoir of patients +/-TB and IRIS. Single genome sequencing (SGS) of HIV-1 p6-pol (1.3kb) characterized proviral populations of peripheral blood mononuclear cells at baseline, 2-8w of ART, during IRIS; and after long-term ART as well as pre-ART viral plasma RNA.
We measured genetic diversity as percent average pairwise distances (%APD), %unique population variants, and determined %population identity. Non-parametric panmixia tests assessed shifts between populations and intra-population neutrality was computed. Mann-Whitney p-values< 0.05 were indicative of statistically significant observations. Patient characteristics - Table 1.

TB, IRIS	7 patients	57% Male; 43% Female	Median = 41 years old	Median CD4 count = 49c/mm3	1040 sequences
TB, No IRIS	4 patients	75% Male; 25% Female	Median = 35 years old	Median CD4 count = 50.5c/mm3	661 sequences
No TB, No IRIS	3 patients	67% Male; 33% Female	Median = 40 years old	Median CD4 count = 23/mm3	427 sequences

[Table 1 - Patient Characteristics]

Results: After long-term ART, there was no difference in viremia between patient groups. TB patients without IRIS had lower ratios of CA gag RNA:DNA than those without TB or IRIS (p=0.02). TB-IRIS patients had higher %APD and more unique variants than TB patients without IRIS (p=0.02), and less population identity than patients with no TB or IRIS (p=0.02). Preliminary analyses revealed shifts in HIV populations during ART in TB infected patients. Graph 1 - Sequence Analyses.



[Graph 1 - Sequence Analyses]

Conclusions: TB-IRIS patients had higher frequencies of HIV infected cells, higher HIV genetic diversity, less population identity and less evidence of panmixia after long term ART, suggesting that IRIS may alter the HIV reservoir permanently.

MOPEA0007

Evolution of HIV-1 groups M and O: genetic comparative analysis of 19 HIV-1/MO inter-group recombinant forms

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Background: HIVs are characterized by a high genetic diversity, due to their simian origins and their replication mode, enhanced by recombination events. Despite the great genetic divergence between pandemic HIV-1/M and HIV-1/O (endemic in Cameroon), dual infections between the two groups can generate HIV-1/MO inter-group recombinants. Only three cases were described before 2004. The consequences of the emergence of these forms on diagnosis and treatment are currently unknown, but the presence of group O fragments in their genome may have a strong impact due to the strong divergence between these variants. The aim of this work was to analyze the recombination patterns and genetic peculiarities of all HIV-1/MO recombinants currently characterized.
Methods: Between 2006 and 2016, the implementation of a sero-molecular algorithm in Cameroon and the exploration of atypical HIV-1 infection profiles in France allowed the description of new HIV-1/MO infections. In addition to the first three cases described, 16 new recombinants or putative forms, all found in patients of Cameroonian origin, were identified in Cameroon and France. Recombination and phylogenetic analysis covered 19 distinct HIV-1/MO recombinants, partially or completely sequenced.
Results: The results showed the complexity of screening and molecular characterization of these forms, but also that these recombinants could be detected with a suitable sero-molecular strategy or following discordances between detection and/or follow-up of results. The genetic diversity of the mosaic fragments matched the molecular epidemiology in Cameroon, with a clear predominance of HIV-1/M CRF02_AG (48%) and of HIV-1/O sub-group H (84 %). Phylogenetic analysis showed that the 19 recombinant forms corresponded to 19 URFs. Analysis of the genomic profiles and of the breakpoints frequency revealed hotspots in the „central" accessory genes (vif, vpr, vpu), reverse transcriptase and gp41, and no recombination event in protease, gp120 and nef. This work also highlighted a variable degree of complexity in profiles, with on average two to three breakpoints per recombinant genome.
Conclusions: In conclusion, this work allowed us to describe and analyze a unique series of HIV-1/MO recombinants, highlighting a greater diversity and complexity than originally supposed, and offering new research perspectives on the conditions of emergence and virological properties of these recombinant forms.

MOPEA0008

Proposal for an improved classification of the HIV-1 M subtype A sub-subtypes

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Background: The extensive genetic diversity of HIV-1 subtype A has let, to date, to the description of 6 sub-clades comprising 4 sub-subtypes (A1 to A4), a putative A5 and a distinctive cluster from former Soviet Union (FSU). The current classification only retains A1 and A2 as official sub-subtypes and does not reflect the real diversity of HIV-1 A, leading to classification difficulties for subtyping tools. We aimed to re-analyse subtype A diversity and propose a more accurate classification.
Methods: Pairwise genetic distances between all HIV-1 A near full genome sequences available in the LANL database were calculated, excluding clonal, sequential or potential recombinant sequences (n=201). A maximum of likelihood phylogenetic tree (FastTree 2.1) was reconstructed and compared to clades and distances observed between previously established and candidate sub-subtypes. These analyses were also done on the pol, gag and env genes separately.
Results: Based on the tree topology and the genetic distance analysis of A subtype and previously well-established sub-subtypes, a full genome minimal mean genetic distance of 0.10 substitution/site was necessary to distinguish between major A clades, hence to define sub-subtypes. This proposal maintained most of previous sub-subtype candidates still not including in the extant classification system. Two new sub-subtypes are added, A6 (the FSU cluster) and A7. Another potential sub-subtype was rejected as only one full genome sequence is available and no partial sequences clustered with it in our separate-genes analysis. The A5 sub-subtype, whose existence is only supposed from the CRF26 analysis but was never retrieved outside this recombinant virus, was not retained in this proposal to avoid any potential confusion.
Conclusions: This proposal provides a more accurate view of subtype A diversity and will allow a more precise and rapid identification of emergence or diffusion of these particular subtype A variants, the cornerstone of HIV classification.

MOPEA0009

High frequency of non-subtype B infections and clustering in new HIV-1 diagnoses in Spain

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Background: HIV-1 sequences generated for analysis of drug resistance and tropism, combined with epidemiological data, contain valuable information to be used for molecular epidemiologic surveillance of HIV infection. Since 1999, we have phylogenetically analysed samples from 10,257 HIV-1-infected individuals attended at Spanish hospitals. Here, we update molecular epidemiological data of new HIV-1 diagnoses in Spain in 2016.
Methods: We have analysed 439 HIV-1 infections diagnosed in 2016 in 38 Spanish hospitals from 13 regions. Sequences of protease-reverse transcriptase, integrase and env V3 region were analysed with phylogenetic trees using FastTree, including all sequences generated in our laboratory since 1999 and similar sequences retrieved from databases through BLAST searches. Recombination was analysed by bootscanning with SimPlot
Results: 80% subjects were men. Geographic origin, available for 80% individuals, was Spain in 70%, Latin America in 14%, Africa in 10%, Europe in 4%, and other in 2%. Transmission route in men, available for 71%, was 49.6% men who have sex with men (MSM), 20.8% unspecified sexual, 25.6% heterosexual, 3.6% parenteral, and 0.4% mother-to-child transmission (MTCT); and in women, available for 67%, was 96.6% heterosexual, 1.7% parenteral, and 1.7% MTCT.
The distribution of HIV-1 genetic forms was 64% subtype B, 8.7% CRF02_AG, 5.7% subtype F, 4.1% subtype A1, 3.2% subtype G, 3% subtype C, 1.4% CRF47_BF, 0.9% CRF01_AE, 3.4% other CRFs, 2.3% unique BF recombinants, and 3.6% other unique recombinant forms. Non-subtype B infections (36%) were more frequent among non-Spaniards (49.6% vs 27.8% in Spaniards).
187 (42.6%) infections grouped in 89 transmission clusters (TCs) of ≥4 individuals. 93% individuals belonging to clusters were men, among which transmission route, available for 75.9%, was 56.1% MSM, 19.7% unspecified sexual, 22.7% heterosexual, and 1.5% parenteral. Among women, 7% belonged to TCs, and transmission

route, available for 76.9%, was heterosexual in all cases. Geographic origin in TCs, available for 85%, was Spain in 84.6%, Latin America in 9.9%, Africa in 2.5%, and Europe in 2.5%.
Conclusions: New HIV-1 diagnoses in Spain are dominated by sexual transmission in men, with 42.6% infections clustering in TCs and 36% corresponding to infections with non-subtype B genetic forms, including 27.8% in Spaniards.

MOPEA0010

Relative resistance of HLA-B for downregulation by Nef is a fundamental property across lentiviral lineages

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Background: HLA-B plays a dominant role, compared to HLA-A and HLA-C, in immune control of HIV-1 infection. Such differential roles have been shown to be attributable to relative resistance of HLA-B for downregulation by primary HIV-1 Nef sequences. However, the previous study was performed with only subtype B Nef clones and thereby it remains elusive whether this Nef property is conserved across various lentiviral lineages.
Methods: The Nef's ability to downregulate HLA was analyzed using Jurkat T cells engineered to express HLA-A*02:01 or chimeric HLA-A*02:01 molecule whose cytoplasmic tail was replaced with HLA-B*35:01. A panel of diverse Nef sequences (N=270 in total) across lentiviruses including SIVs, HIV-2 and a pandemic group M (subtypes A, B, C and D) as well as a relatively rare group O of HIV-1 was tested for HLA downregulation functions.
Results: Despite a diverse genetic diversity, all lentiviral Nef clones tested exhibited reduced downregulation activity to the HLA-B, compared to the HLA-A ($p<0.001$). Specifically, Nef clones from HIV-1 subtypes (A, B, C, and D) were comparably resistant to HLA-B for downregulation. However, although the amino acid residue at Nef-202 in subtype B was important for this phenomenon, the pairwise analysis of HIV-1 subtype C Nef sequences revealed that the amino acid at Nef-9, but not Nef-202, was solely associated with resistance to HLA-B, a finding corroborated by Nef mutational studies for downregulation of various HLA alleles.
Conclusions: Taken together, these results indicate that, though mediated by different Nef residues among viral lineages, relative resistance to HLA-B, compared to HLA-A, for downregulation is a fundamental functional property among naturally occurring Nef sequences of diverse lentiviruses.

MOPEA0011

Characterization of a novel dolutegravir monotherapy-associated S230R Mutation in HIV

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Background: The integrase strand-transfer inhibitor (INSTI) Dolutegravir (DTG) has a higher barrier to resistance than other approved INSTIs. In treatment-experienced individuals and in vitro, DTG can select for several primary mutations that have not been observed in patients undergoing first-line triple therapy, possibly due to the fact they significantly impair viral replicative capacity. DTG monotherapy has been considered as a possibility for HIV-infected patients. We report the emergence of a S230R substitution in two patients who experienced virological failure after switching to DTG monotherapy from triple therapy and the effects of S230R on integrase (IN) activity, viral infectivity and drug resistance.
Methods: IN-resistance associated mutations were evaluated by sequencing both prior to and at the time of virologic failure. Strand-transfer and tissue culture assays were performed to characterize enzyme activity, viral infectivity and to measure resistance to different INSTIs.
Results: The first case of S230R was found in the DOMONO study (NCT02401828) in a patient who experienced virologic failure at week 30 (HIV-1 RNA was 1570 copies/mL). The patient had a CD4 nadir of 330cells/mm^3 and had been virologically suppressed on EFV/TDF/FTC for 25 months before switching to DTG 50 mg once daily. A second case involved a patient who had been virologically suppressed on DTG/ABC/3TC for 8 months before switching to DTG monotherapy. Viral load remained < 20 copies/mL but increased to 700 copies/mL with the presence of S230R in IN at week 29.
The results of cell-free assays showed that, compared to the WT-IN (Km = 8.8 ± 0.95), the S230R-IN had a 2.22-fold increase in Km (19.9 ± 2.3). In the presence of DTG, the S230R-IN had a 2.6- fold decrease in DTG susceptibility (Table 1). A slight decrease in susceptibility to other INSTIs was observed in S230R-IN compared to WT-IN (Table 1). The infectivity of S230R virus was also impaired by about 50% compared to WT.

Recombinant enzyme	DTG - Ki (mean ± SD nM)/Fold change	CAB - Ki (mean ± SD nM)/Fold change	BIC - Ki (mean ± SD nM)/Fold change	RAL - Ki (mean ± SD nM)/Fold change	EVG - Ki (mean ± SD nM)/Fold change
WT	1.27 ± 0.13 - 1	1.76 ± 0.4 - 1	1.84 ± 0.30 - 1	6.40 ± 0.5 - 1	2.30 ± 0.13 - 1
S230R	3.33 ± 0.22 - 2.62	3.38 ± 0.55 - 1.92	2.70 ± 0.49 - 1.47	13.8 ± 5.5 - 2.16	7.34 ± 0.47 - 3.19

[Table 1. Susceptibilities of recombinant integrase]

Conclusions: Virological failure involving DTG monotherapy can occur due to replication of a virus containing a novel S230R substitution that confers modest-level resistance to DTG and other INSTIs.

MOPEA0012

HIV-1 resistance to dolutegravir is modulated by epigenetic signals

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Background: Integrase strand transfer inhibitors (INSTIs) act by inhibiting the HIV integrase enzyme (IN). The INSTI raltegravir (RAL) selects for drug resistance substitutions within the catalytic site of IN. The R263K dolutegravir (DTG) INSTI resistance substitution, however, is located in the C-terminus of IN and has an unknown resistance mechanism. The C-terminus is post-translationally modified by the acetylation of three lysine residues by the histone acetyltransferase enzyme (HAT) p300. We hypothesized that the R263K substitution interferes with some function of IN through dysregulation of the acetylation of nearby residues.
Methods: TZM-bl cells were infected with NL4.3 viruses in the presence of INSTIs, with or without the addition of HAT inhibitors (HATi) or histone deacetylase (HDAC) inhibitors (HDACi) 2 or 12h post-infection. PM1 cells were infected with NL4.3 viruses produced under different conditions (HATi or HDACi) and followed for 14 days post-infection. Co-IP was performed with 293T cells transfected with pACGFP-1C$_{IN}$ constructs and western blots to detect KAP1 were performed.
Results: Treatment of cells with HATi resulted in a decrease in the IC$_{50}$ for DTG and Cabotegravir for NL4.3$_{WT}$ but not NL4.3$_{R263K}$. However, no change in IC$_{50}$ was seen for RAL or Lamivudine and experiments are currently underway with the novel INSTI Bictegravir. NL4.3$_{WT}$ and NL4.3$_{R263K}$ produced in the presence of HATi or HDACi displayed different parameters over the course of infection. HDACi reduced the peak of replication for NL4.3$_{WT}$ but not NL4.3$_{R263K}$, whereas HATi had no effect on NL4.3$_{WT}$ but greatly enhanced the peak replication for NL4.3 $_{R263K}$. Using Co-IP, we were also able to show that IN$_{R263K}$ binds with a higher affinity to KAP1 (a component of the HDACI complex) as compared to IN$_{WT}$.
Conclusions: This is the first report of the influence of post-translational modifications on HIV drug resistance. Both the replication and resistance to DTG of NL4.3$_{WT}$ and NL4.3$_{R263K}$ are differentially affected by acetylation, likely through altered interactions with the HDACI complex. Many "shock and kill" strategies to eradicate HIV employ HDACi to reactivate latent HIV; however our results suggest that some drug resistant viruses may differentially respond to HDACi, which may complicate the advancement of this concept.

MOPEA0013

Impact of immune-driven sequence variation in Pol on viral replication capacity and disease progression in HIV-1 subtype C infection

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Background: CD8+ T cell responses to epitopes, particularly conserved Gag epitopes, in which immune escape mutations result in lower viral replication capacity is a hypothesised mechanism of protection in HIV-1 infected individuals with certain clinically favourable HLA class I alleles. Therefore, a possible vaccine strategy is to direct immune responses to vulnerable HIV regions, aiming to limit immune escape

due to fitness constraints or slow virus replication. Substantial replication costs and clinical relevance of several immune escape mutations in the HIV-1 Gag have been demonstrated, however, less is known about consequences of immune-driven mutations in other proteins. We investigated the impact of immune-driven sequence variation in Pol, a highly conserved and immunogenic protein essential for viral replication, on viral replication capacity and disease progression in a large population of individuals chronically infected with HIV-1 subtype C, the most prevalent subtype world-wide.
Methods: 414 patient-derived RT-integrase NL4-3 recombinant viruses were generated by electroporation of a green fluorescent reporter cell line (GXR cells) with plasma-derived RT-integrase PCR products and pNL43ΔRT-integrase and RT-integrase sequences were generated for 369 of these thus far. The replication capacities of recombinant viruses were determined by calculating the slope of increase in percentage infected cells, as measured by flow cytometry, from days 3-6 following infection.
Results: The mean replication capacity of these viruses, normalised to the growth of wild-type NL4-3, was 0.92 (interquartile range; 0.87 to 0.97). RT-integrase driven replication capacity correlated significantly with log viral load (r= 0.2571 p=< 0.0001) and CD4 count (r= -0.2580 p= < 0.0001). A preliminary sequence analysis of RT-integrase HLA-associated polymorphisms previously described to reduce replication capacity of subtype B viruses, showed that the HLA-A*33 restricted polymorphism G163E in integrase was associated with significantly reduced replication capacity in subtype C viruses (p=0.02).
Conclusions: The data suggest that RT-integrase-driven replication capacity is clinically relevant. Preliminary sequence analyses suggest that immune-driven mutations in Pol may significantly attenuate HIV. Further comprehensive sequence analysis may inform which Pol epitopes are the most vulnerable for an attenuation-based vaccine.

MOPEA0014

High-resolution mapping and phasing of HIV diversification in humanized mice

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Background: The extensive HIV diversification throughout infection complicates effective antiretroviral treatment and facilitates immune escape. Both viral (e.g., reverse transcriptase) and host factors (e.g., APOBEC3G restriction factor) contribute to viral evolution in vivo. The advent of humanized mouse models combined with powerful next generation sequencing approaches provides new opportunities to dissect the dynamics and mechanisms driving HIV evolution with unprecedented precision.
Methods: We generated isogenic HIV molecular clones that differed in their ability to counteract APOBEC3G (A3G) due to point mutations in Vif (HIV-WT: 100%; HIV-45G: 10%, HIV-SLQ: 1%). Humanized mice were infected with HIV-WT, HIV45G and HIV-SLQ. One month post-infection, some of the mice were treated with the RT inhibitor, lamivudine (3TC) (HIV-WT+3TC, N=11; HIV-45G+3TC, N=11; HIV-WT no treatment, N=12; HIV-45G no treatment, N=7, HIV-SLQ no treatment, N=4). Plasma viremia was quantified throughout the infection by RT-qPCR.
Using molecular barcodes (UMID) in conjunction with deep sequencing, we determined the viral quasi-species at single-molecule resolution in plasma and tissue compartments. Custom bioinformatics pipelines were developed to generate consensus sequences and analyze viral diversity over time within individual animals and across groups.
Results: Both HIV-WT and HIV-45G resulted in robust infection of humanized mice, but over time the fitness of HIV-45G was significantly reduced compared to HIV-WT (p=0.0039). In contrast, in the presence of 3TC, replication of HIV-45G was superior to that of HIV-WT (p=0.0045). We sequenced a total of 146,781 single HIV genomes, 24,606 single HIV transcripts and 2,293 single HIV proviruses. We found that the 3TC drug-resistance mutation RT-M184I appeared at a 10-fold faster rate than RT-M184V in HIV-45G infected, 3TC treated mice (p=0.0008). Of note, the proviral pool of both HIV WT and HIV 45G infected mice, revealed extensive mutagenesis, suggestive of A3G deaminase activity.
Conclusions: We show in this study that A3G accelerates emergence of 3TC drug resistance in vivo using deep sequencing on the Illumina platform. Furthermore, while HIV population dynamics between plasma and tissue transcripts were comparable, the HIV proviral pool in tissues was highly divergent due to extensive A3G driven mutagenesis.

MOPEA0015

Learning evolutionary pathways of HIV-1 subtype C under lopinavir treatment

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Background: HIV-1 infection can be clinically managed using combination antiretroviral therapies (cART). However, accumulation of drug resistance mutations leads to treatment failure in a subset of patients, necessitating changes of therapy. Emergence and accumulation of resistance mutations follow certain patterns, which have been mostly studied on the basis of HIV-1 subtype B infections. Also, most therapeutic strategies are based on research and clinical studies of this subtype, although non-B subtypes represent the majority of global HIV infections. Clinical research on the basis of subtype B may not generalize to other subtypes, as host and environmental factors may be confounding. Here, we used a probabilistic model to describe the temporal progression of drug resistance mutations in a large cross-sectional dataset of South African individuals infected with HIV-1 subtype C, which accounts for nearly half of all HIV infections worldwide, under the selective pressure of lopinavir (LPV) boosted cART with low-dose ritonavir (LVP/r).
Methods: We collected and genotyped virus populations from 1065 South African individuals infected with HIV-1 subtype C. We used the continuous time conjunctive Bayesian network (CT-CBN) model for analyzing the accumulation of LPV-associated mutations. In addition, we contrasted our results on HIV-1 subtype C with a dataset of 254 HIV-1 subtype B genotypes from patients treated with LPV, obtained from the Stanford HIV Drug Resistance Database.
Results: We focused on 22 LPV-associated mutations according to the Stanford HIV Drug Resistance Database. We found 4 major protease inhibitors resistance mutations with high abundance in both datasets, namely M46I, I54V, L76V and V82A. Furthermore, we identified I54V as an early event in HIV-1 subtype C infections, whereas L24I, I50V and V82C were consistently identified as genetic changes occurring at later times. For subtype B, on the other hand, the early events consist of mutations M46I and I54V, with I84V being a later event. Differences in the inferred progressions of subtypes B and C suggest different evolutionary pathways.
Conclusions: CT-CBNs provide insights on the evolution of drug resistance in HIV-1 subtype C infections and allow comparisons to other subtypes.

MOPEA0016

High prevalence of CXCR4-using virus in long lived latently infected naïve and central memory CD4+ T cells in individuals on ART

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Background: Persistent HIV can be found in a range of CD4+ T cells such as long lived naïve and central memory (CM) cells; as well as short lived transitional (TM) and effector memory (EM) cells in individuals on combination antiretroviral therapy (ART). These cells express vastly different viral receptor levels and we sought to determine if the envelope protein (Env) was genotypically and phenotypically different amongst the subsets which would indicate adaptation to these different environments.
Methods: HIV-infected 8 individuals on ART for at least 3 years with a plasma HIV RNA< 50 c/ml were studied. Single genome amplification for the env gene was performed on genomic DNA extracts from CM, TM, effector memory (EM) and naïve CD4+ T cell subsets. 10-30 envs were selected, sequenced and any variants containing hypermutation removed. Phylogenetic trees were created based of the V1-V5 region of env. Coreceptor usage was predicted using the geno2pheno prediction algorithm based on V3 amino acid sequence.

Results: The cohort was male with a mean age of 58 years, mean CD4 count of 607 cells/ul and nadir CD4 of 275 cells/ul. A total of 535 env sequences with intact reading frames were generated from 8 individuals. Phylogenetic analysis showed envs did not cluster based on the CD4+ T cell subset from which it was derived, however envs did form phylogenetically distinct clusters based on coreceptor tropism. CXCR4-using variants were detected in 5 of 8 individuals ranging from 34-62% of envs. Where CXCR4 usage was detected, it was most prevalent in envs derived from naïve (CXCR4 prevalence; mean 87.47% ± 2.5% SEM) and central memory CD4+ T cells (60.0% ± 7.9%); whilst less prevalent in transitional (34.8% ± 4.5%) and effector memory CD4+ T cells (16.8% ± 3.1%).
Conclusions: There is distinct compartmentalisation of viruses in short and long lived cells on ART as determined by co-receptor use and CXCR4-using strains appear to replace CCR5-using strains in the long lived but not short lived viral reservoir. Our results suggest direct infection of each individual cell type helps form and maintain the viral reservoir.

MOPEA0017

HIV-1 transfer by T cell-macrophage fusion triggers multinucleated giant cell formation for virus spreading

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Background: Macrophages are cellular targets of HIV-1 and participate in virus dissemination and establishment of persistent virus reservoirs in host tissues, but the mechanisms of virus cell-to-cell transfer to macrophages remain largely unknown.
Methods: An experimental approach was developed to investigate the mechanisms of virus cell-to-cell transfer from infected T cells to macrophages. 36 h after infection, infected T cells were co-cultured for a maximum of 6 h with macrophages derived from primary monocytes, and virus transfer and dissemination in macrophages was then analyzed by flow cytometry, ELISA, immunofluorescence, live-cell imaging and transmission electron microscopy.
Results: We reveal a very fast and efficient mechanism involved in cell-to-cell transfer from infected T cells to macrophages and subsequent virus spreading between macrophages. We show that tight contacts between infected T lymphocytes and monocyte-derived macrophages lead to cell fusion for transfer of viral material to macrophage targets. This cell-to-cell fusion transfer is very efficient, restricted to CCR5-tropic viruses, and mediated by viral envelope-receptor interactions. Transferred viruses can then accumulate in cytoplasmic compartments of newly formed lymphocyte/macrophage fused cells. Moreover, early viral assembly and budding events, resulting from the merge of viral material between infected T cells and macrophages, are also observed at the plasma membrane of the lymphocyte/macrophage fused cells. These cells thus acquire the ability to fuse with neighboring non-infected macrophages for virus dissemination. Together, these two-sequential envelope-dependent cell fusion processes lead to the formation of highly virus-productive multinucleated giant cells.
Conclusions: These two-step cell fusion processes reveal the mechanisms for virus transfer and dissemination in macrophages and the formation of the infected multinucleated giant macrophages detected in vivo in lymphoid organs and the central nervous system of HIV-1-infected patients and SIV-infected macaques. These mechanisms contribute to a better understanding of virus dissemination from infected T cells toward macrophages and formation of long-lived macrophage viral reservoirs in host tissues during HIV-1 infection.

MOPEA0018

Investigation of tandemers activities against cell-associated HIV-1 and against viruses with decreased sensitivity to griffithsin

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Background: The lectin griffithsin (GRFT) is a homodimer and each of its monomers has three binding sites for glycans on HIV-1 envelope. GRFT showed potent and broad anti-HIV-1 activity and is one of the leading microbicide candidates. Tandemesrs 2MG, 2MG3, 3MG and 4MG are GRFT derivatives made of arrays of two, three and four monomeric units, respectively. Since the bond between monomers in GRFT is rigid while being flexible in tandemers, also given that some tandemers have more than two monomers, we hypothesized that these derivatives will be more active than GRFT against HIV-1.
Methods: We evaluated HIV-1 subtype A, B and C against 2MG, 2MG3, 3MG, 4MG and GRFT using the TZM-bl neutralization assay. GRFT derivatives were also tested for their inhibition of the cell-to-cell transmission of HIV-1. The 234 and 295 glycans, shown to be important in GRFT binding to HIV-1, were introduced in the virus by site directed mutagenesis, and their effects on 2MG, 2MG3, 3MG and 4MG binding studied. GRFT resistant viruses were generated by culturing HIV-1 under escalating concentrations of the lectin. These resistant viruses were then tested for sensitivity to 2MG, 2MG3, 3MG and 4MG.
Results: In general 2MG and 2MG3 were as potent as GRFT against all the viruses tested while 3MG and 4MG were more potent against HIV-1 subtype A and C. GRFT was also less potent than these two derivatives in the inhibition of cell-to-cell transmission of HIV-1. Similar to GRFT, the introduction of the 234 and 295 glycans affected HIV-1 sensitivity to 2MG and 2MG3; while it did not affect 3MG and 4MG neutralization of the virus. Lastly, GRFT resistant viruses showed sensitive to 3MG and 4MG.
Conclusions: We found that 3MG and 4MG were more potent than GRFT. Also viruses that showed resistance to GRFT remained sensitive to these compounds. It is possible that 3MG and 4MG binding sites on the viral envelope are different from that of GRFT given that GRFT resistant viruses remained sensitive to these tandemers. Our study suggests that linking GRFT monomers into arrays of more than two units increases potency against HIV-1.

MOPEA0019

Host microRNAs-221 and -222 inhibit HIV-1 entry of macrophages by targeting the CD4 viral receptor

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Background: Macrophages are heterogeneous and functionally important immune cells that contribute to HIV pathogenesis by promoting viral spread, forming viral reservoirs and mediating neurological disorders. Macrophage phenotype and function vary depending on their location and tissue of origin, and these conditions influence also their susceptibility to HIV infection. Indeed, GALT macrophages are relatively resistant to HIV infection, whereas lung macrophages are relatively more susceptible. While these different phenotypes can be recapitulated in vitro with monocyte-derived macrophages (MDMs) (susceptible) or the M1- or M2- polarized macrophages exposed to pro- or anti-inflammatory cytokines (more refractory), the host factors responsible for these varying phenotypes are not entirely defined. Herein, we investigated the role of microRNAs in regulating the susceptibility of macrophages to HIV infection.
Methods: MDMs were infected with GFP-encoding HIV-1; infected (GFP+) and bystander (GFP-) cells were sorted by FACS and microRNA expression profiles determined using RNA-seq. The effect of miR-221/222 on CD4 expression was assessed by Q-RT-PCR and flow cytometry, while the impact on viral entry was analyzed by viral fusion assay. Myeloid cells from gut biopsies and blood from healthy volunteers were isolated by FACS and miR-221 levels determined by Q-RT-PCR.
Results: We examined the microRNA expression profile of over 400 microRNAs in HIV-infected MDMs and compared their expression profile in HIV non-producing bystander and uninfected cells. Among these microRNAs, we identified miR-221 and miR-222 as two negative regulators of the CD4 viral receptor expression, which are up-regulated in the bystander population. Functional analyses of miR-221/miR-222 in MDMs revealed that these microRNAs, which are efficiently induced by the pro-inflammatory cytokine TNF-α, inhibit HIV entry by down-regulating CD4. Inhibition of miR-221/miR-222 enhanced HIV replication and spread in infected macrophage cultures by limiting TNFα-mediated up-regulation of miR-221/222 in non-infected bystander cells. Consistent with a role of these microRNAs in the resistance of GALT macrophages to HIV infection, we found that miR-221 was significantly enhanced in myeloid cells from the gut as compared to those of peripheral blood.
Conclusions: MiR-221/222 represent pivotal host factors activated during inflammation that are capable of modulating permissiveness to HIV infection by restricting viral entry via CD4 down-regulation.

MOPEA0020

HIV-1 can enter and integrate the human male germ line, revealing potential for endogenization

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Background: Endogenization of SIV was demonstrated in lemur primates, suggestive of infection of the germinal lineage, and HIV/SIV nucleic acids detected in situ within testicular germ cells (TGCs) from men and macaques. In this context, we aimed to decipher the nature of the interactions between primary human TGCs and HIV-1.
Methods: TGCs isolated from normal human testes comprised haploid spermatids, tetraploid primary spermatocytes and diploid spermatogonia/ secondary spermatocytes. TGCs preparation purity (>94%) was assessed by flow cytometry using specific germ cell markers (DDX4, MAGEA4) as well as leukocyte/somatic markers (CD45, HLA class I, vimentin). HIV receptors and co-receptors expression was measured by flow cytometry. R5-, X4-tropic and Denv HIV-1 binding to TGCs was assessed by p24 ELISA. Viral entry, early steps of replication and viral proteins expression were investigated upon cell-free or cell-associated infection of primary TGCs and testicular germ cells T-cam2 using wild type HIV, or HIV-1 nef-ires-gfp infected Jurkat as donor cells. Viral entry was detected by confocal microscopy while new viral protein expression was evaluated by microscopy, FACS and ELISA. Integrated HIV-1 DNA was measured by PCR on FACS sorted TGC populations (CD45-DDX4+MAGEA4+).
Results: TGCs expressed the alternate HIV-1 receptors CD206, galactocerebroside and heparan sulfate proteoglycans, as well as CCR3. R5- and X4- tropic HIV-1 bound to isolated TGCs in a dose dependent manner, and this binding was inhibited by inhibitors/competitors for heparan sulfate proteoglycans, CD206 and HIV gp120. HIV-1 entry was more efficient with cell-associated HIV than with free virus. Integrated HIV-1 DNA was found in both TGCs and Tcam2 cells following cell-associated infection, as well as in T-cam2 cells exposed to cell free HIV pseudotyped with VSV-G.
Conclusions: Our results indicate that HIV-1 can enter testicular germ cells and integrate into the human germ line genome. The close proximity within the testis of stem germ cells to HIV-infected leukocytes, along with their high daily generation rate, may favor such events. These findings imply that HIV has the potential to integrate into the male gamete genome, which might ultimately lead to HIV nucleic acids endogenization in the progeny.

MOPEA0021

Regulation of CCR5 conformational states and export by homo-dimerization

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Background: The chemokine receptor CCR5 is the main coreceptor for entry of R5 HIV-1 strains into target cells. It plays a prominent role during HIV transmission, progression of infection, and evolution to AIDS. One allosteric non-peptidic inhibitor targeting CCR5, maraviroc, has already been approved for treatment of HIV infection. Like other G-protein coupled receptors, CCR5 forms homo-dimers at the cell surface, which could affect receptor physiology and HIV pathogenesis. However, the structural properties and dynamics of CCR5 homo-dimers are still unknown.
Methods: We combined computing approaches with cross-linking, energy transfer, and a new functional assay (based on the RUSH system) to characterize residues involved in CCR5 dimerization interface.
Results: We show that unliganded CCR5 exists in two dimer conformations, involving residues of the transmembrane helix 5. Binding of maraviroc stabilizes a third dimeric conformation that has not yet been described in a GPCR crystal structure. Functionally, we show that CCR5 dimerization occurs in the endoplasmic reticulum and regulates receptor cell surface targeting.
Conclusions: This study supports that dimerization contributes to the conformational diversity of CCR5. The three dimer models of CCR5 described constitute an essential step for future exploration of the role of CCR5 dimerization in HIV infection. Their involvement in receptor export also offers a new possibility to inhibit HIV entry by playing directly on CCR5 dimerization and cell surface expression.

MOPEA0022

HIV-1 subtype C may possess extended coreceptor utilization in peripheral blood and the central nervous system of patients experiencing cryptococcal meningitis

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Background: Limited evidence suggests that HIV-1 clones obtained ex vivo without culture may have expanded coreceptor utilization. However, it is widely reported that for HIV-1 subtype C (HIV-1C), the predominant genotype in the global epidemic, the switch to coreceptors other than CCR5 is infrequent. Here, we sought to determine the entry phenotype of uncultured HIV-1C circulating in plasma and cerebrospinal fluid (CSF) of patients with late stage HIV infection and cryptococcal meningitis co-infection.
Methods: Matched plasma and cerebrospinal fluid (CSF) was collected from eight antiretroviral therapy naive HIV-infected South Africans (median CD4 count of 17 cells/μL), experiencing cryptococcal meningitis. Following RNA extraction and cDNA synthesis, HIV-1C envelope gene fragments were amplified, sequenced and cloned into the pSVIII-Env expression vector. Pseudoviruses capable of single-round replication were produced in 293T cells and serial dilutions of these were used to infect NP2-CD4 or U87-CD4 cells expressing CCR5, CXCR4 or CCR3. Pseudovirus entry into target cells was quantified by assaying luciferase activity in cell lysates. Background (culture medium), negative and positive (lab-strain) controls were included in the assays.
Results: From eight study participants, 28 unique (median of 3 per participant) plasma-derived and 29 (median of 1.5 per participant) CSF-derived pseudoviruses were produced. Four of eight participants had exclusive CCR5-utilizing variants only in plasma and CSF, and one had a CCR5-utilizing variant that also utilized CCR3 in plasma and CSF. Notably, three other participants had variants which utilized CXCR4 in plasma and not CSF, but one had a CXCR4-utilizing variant in both plasma and CSF.
Furthermore, CCR3-utilization in combination with CXCR4 or CCR5 was identified in the plasma and CSF of these three participants.
Conclusions: Uncultured HIV-1 subtype C circulating in plasma and CSF is capable of utilizing more than one coreceptor for entry in advanced disease. CCR5 alone or in combination with CCR3 was frequently utilized in plasma and CSF of study participants. CXCR4 usage by CSF-derived clones was infrequent. Our study shows that coreceptors other than CCR5 may be important for cell entry in the central nervous system in late stage disease. We will next explore the importance of CCR3-utilization in ex vivo models.

MOPEA0023

Alternative splicing of human APOBEC3G in HIV infection

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Background: We recently identified two individuals seemingly cured of HIV. Indeed, they exhibit confirmed HIV-seropositivity since 30 and 5 years, respectively, but kept normal LT-CD4-counts and had no HIV-related illness despite they never received antiretrovirals. In addition, they persistently displayed undetectable plasma HIV-RNA and PBMC HIV-DNA with standard assays, while HIV culture was negative. Scarce short PBMC HIV-DNA sequences were only laboriously obtained using hundreds of nested-PCR and next-generation sequencing. These sequences showed a high level of gene inactivation by G-to-A mutations generating stop-codons. As this is a signature of deamination by human-APOBEC3G, we se-

quenced APOBEC3G-mRNA from the blood of these two patients to gain a better understanding of their infection outcome.
Methods: RNA was extracted from plasma using the EZ1-Virus Mini kit (Qiagen). Reverse transcriptase-PCR amplification and Sanger population sequencing were performed by in-house protocols. Next-generation sequencing was performed on two HIV-DNA fragments overlapping APOBEC3G gene exons 2-6 and 2-7 using Illumina paired-end technology on MiSeq instrument.
Results: Sequences corresponding to APOBEC3G-mRNA obtained from the two patients showed presence of the complete form (1,132 nucleotides generated from 8 exons). Strinkingly, three truncated isoforms were identified by Sanger sequencing, one from patient#1 (isoform1) and two from patient#2 (isoform2, isoform3). Isoform1 contained only five exons;exons 3-4-5 lacked. Isoform2 and isoform3 contained only 6 exons; exon3 and exon6 were truncated and of different lengths. Importantly, isoform1 lacked exon3 region encoding amino-acids targeted by HIV-Vif protein that triggers APOBEC3G degradation, whereas exon6 region encoding the deamination active site was present. Regarding isoform2 and isoform3, they both lacked the Vif-interacting site-encoding region. Preliminary analysis of sequence-reads obtained by next-generation sequencing confirmed isoforms 1-3 presence and identified several additional putative APOBEC3G-mRNA isoforms.
Conclusions: These results indicate an alternative splicing of APOBEC3G gene in these two patients in whom no live HIV and no full-length HIV-DNA with untruncated genes were retrieved. This could be notably related to APOBEC3G resistance to Vif-triggered degradation and enhanced APOBEC3G activity. This deserves additional studies of APOBEC3G gene alternative splicing and further characterization of sensibility to Vif and activity of these APOBEC3G isoforms.

MOPEA0024

The role of CCR5 structural diversity in HIV infection

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Background: CC chemokine receptor 5 (CCR5) plays a key role in innate immunity and HIV infection. It acts as a CD4-associated coreceptor for entry of R5-tropic strains of HIV-1 into CD4+ T-lymphocytes and macrophages. CCR5 interacts with the CD4-bound form of the HIV-1 envelope glycoprotein gp120, leading to fusion between the viral and host cell membranes. R5 strains of HIV-1 are preferentially transmitted and predominate in the asymptomatic stage of infection. Recent data identified that CCR5, similarly to other G protein-coupled receptors (GPCR), exists in an ensemble of structurally diverse forms at the cell surface, but how this affects the functional properties of the receptor and its role in HIV infection is not known.
Methods: We performed binding assays of envelope glycoproteins (gp120) from ten different R5 HIV-1 strains to CCR5-expressing cell lines and primary cells. Virus-cell fusion experiments were also carried out to characterize whether a link exists between the cellular tropism of R5 HIV-1 isolates and their ability to recognize specific CCR5 populations. Finally, competition experiments of gp120 binding by anti-CCR5 monoclonal antibodies and site directed mutagenesis of CCR5 were set up to identify factors contributing to multiplicity of the CCR5 populations.
Results: Results revealed that distinct subsets of the CCR5 molecules differentially bind distinct envelope glycoproteins isolated from different primary HIV-1 isolates. The divergent binding levels of gp120 to CCR5 do not result from impaired binding to CD4 or incorrect folding when they are bound to CD4. The distinct binding capacities of these envelope glycoproteins to CCR5 are related to differential recognition of antigenically distinct populations of CCR5 and sensitivity to CCR5 homodimerization. Finally, the nature/quantity of the CCR5 populations to which the HIV-1 envelope glycoproteins may bind differs between different target cells and critically controls the cell tropism of R5 viruses.
Conclusions: This study sheds light on the relationship between CCR5 structural diversity and physiopathology of HIV-1 infection and provides important clues for developing future CCR5 entry inhibitors against HIV-1.

MOPEA0025

Loss of SUN2 impairs CD4 T cell proliferation and alters sensitivity to HIV-1 infection in a cyclophilin A-independent manner

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Background: Linker of nucleoskeleton and cytoskeleton (LINC) complexes bridge the nucleus and the cytoskeleton in eukaryotic cells. Previously, we demonstrated that overexpression of the inner nuclear membrane protein and LINC complex component, SUN2, inhibits HIV infection between reverse transcription and nuclear import, and that this depends on the viral capsid. We also showed that in several cell lines, SUN2 silencing does not alter HIV infection. SUN2 silencing in primary CD4 T cells was recently reported to decrease HIV infection, which was suggested to result from modulation of Cyclophilin A (CypA)-dependent steps of HIV infection.
Methods: To better understand the role of SUN2 in HIV infection, we used lentiviral shRNA transduction to silence SUN2 in primary CD4 T cells from many donors, in which cell proliferation and health were monitored. Several HIV strains (lab-adapted, transmitted/founder, and non-lab-adapted) were used for spreading infections in these cells. Single-round infections in the presence of Cyclosporin A were performed to address the potential role of CypA. Analysis of viral gene expression levels was performed by flow cytometry.
Results: Consistent with previous data, we found that HIV infection of primary CD4 T cells is reduced upon SUN2 silencing, and we extend these results to additional viral strains. However, we found that endogenous SUN2 was dispensable for the well-documented positive effects of CypA during HIV infection. Conversely, CypA was not required for the reduction in HIV infection observed in the absence of endogenous SUN2. In contrast, primary CD4 T cells lacking SUN2 exhibit a striking proliferation defect, as well as lower expression of activation markers and decreased viability. Furthermore, we found that levels of viral protein expression were reduced in SUN2-silenced CD4 T cells that did become infected. Future work will determine whether SUN2 might also act directly on the virus.
Conclusions: Our results suggest that SUN2 does not promote CypA-dependent steps of HIV replication. Rather, we demonstrate that SUN2 is required for efficient activation and proliferation of primary CD4 T cells. Therefore, disruption of these processes can explain the role of endogenous SUN2 in HIV infection of primary lymphocytes.

MOPEA0026

Insights into the domains of IFITM3 involved in the negative imprinting of HIV-1 viral particles infectivity

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Background: The Interferon-induced transmembrane proteins 1, 2 and 3 (IFITMs) are innate defense proteins that inhibit a broad range of viruses, including HIV-1. Thus far, IFITMs have been associated to two distinct mechanisms of viral inhibition, at least in the case of HIV: the endosomal trapping of incoming viral particles by the pool of IFITM molecules present in target cells; the interference with the production of infectious HIV-1 viral particles in virus-producing cells.
In the latter, we and others have demonstrated that IFITMs coalesce with the structural protein Gag during virion assembly, leading to the production of virion particles that package IFITMs and that display a consistent infectivity defect. At present, it is unclear whether the physical incorporation of IFITMs into virions can be dissociated from the negative effects on the viral infectivity, and the domains(s) of IFITMs driving this defect remain poorly characterized.
Methods: Using IFITM3 as a paradigm for the IFITM family, we have examined a panel of point mutants spanning the entire length of the protein and we have determined the effects of these mutants on both HIV-1 assembly and virion particle infectivity.
Results: In so doing, we have identified domains that enhance the antiviral effects of IFITM3, as well as domains that relieve the infectivity defect. We have then measured and correlated several parameters as quality and quantity of Envelope incorporated into virions, intracellular localization of IFITM mutants, cholesterol level changes etc to the infectivity data, to pinpoint to key parameters at the basis of the antiviral role of IFITMs against HIV-1.

Conclusions: Overall our results indicate that changes in envelope maturation and processing are unlikely to be major determinants of the antiviral effects of IFITM3 and that cholesterol modifications are similarly not involved in these effects. These and other results on the characterization of the action of IFITM3 on the production of infectious HIV-1 virion particles will be presented.
With the support of ANRS and Sidaction.

MOPEA0027

Apolipoprotein E is an HIV-1-inducible restriction factor of HIV-1

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Background: Apolipoprotein E (ApoE) is a secretory protein that plays an important role in various biological processes, including lipid metabolism, cardiovascular diseases, Alzheimer's disease, immunoregulation and HCV infection. ApoE has three major isoforms, ApoE2, ApoE3 and ApoE4 with isoform-specific functional properties and is produced by liver and macrophages. Notably, we noticed that HIV-1 infection specifically and strongly induces endogenous ApoE expression in primary human monocyte-derived macrophages by micro array and Western blot analysis. Therefore, ApoE might affect life cycle of HIV-1.
Methods: To test this possibility, we first analyzed the HIV-1 kinetics in ApoE knockdown primary human macrophages. Then, we performed the overexpression study of ApoE. 293T cells were co-transfected with ApoE-expressing plasmid and HIV-1 molecular clone (R9, NL4-3, JR-FL, and AD8) and we examined the HIV-1 replication and HIV-1 infectivity in their culture supernatants. Furthermore, we observed subcellular localization of HIV-1 proteins and ApoE.
Results: We observed that HIV-1 production is enhanced in the ApoE knockdown primary human macrophages, indicating that ApoE restricts HIV-1 life cycle. In contrast, overexpression of ApoE significantly reduced the expression levels of both HIV-1 capsid and envelope (Env) proteins. In this context, the HIV-1 production was strongly suppressed in the ApoE-overexpressing cells. Indeed, all three different isoforms of ApoE could suppress the HIV-1 infectivity.
Furthermore, ApoE failed to suppress the expression level of HIV-1 capsid protein from HIV-1ΔEnv, an HIV-1 molecular clone lacking Env. As well, all isoforms of ApoE unable to suppress the expression of other virus envelope glycoprotein like vesicular stomatitis virus (VSV-G), suggesting that ApoE specifically targets the HIV-1 Env. In fact, ApoE colocalized with HIV-1 Env in cytoplasm and immunoprecipitation result showed that both proteins bind each other, indicating an interaction of ApoE with HIV-1 Env.
Moreover, we also observed that ApoE sequesters HIV-1 Env in early (Rab5) and late (Rab7) endosomes. Finally, ApoE hijacked HIV-1 Env into lysosome, a protein degradation site, resulting in degradation of HIV-1 Env.
Conclusions: Altogether, ApoE seems to be a novel HIV-1-inducible restriction factor of HIV-1 in macrophage. These findings have important implications for further understanding of HIV-1 life cycle as well as development of novel antiretroviral strategies.

MOPEA0028

A structural study of UNG2 and its interaction with the HIV protein Vpr

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Background: Antiretroviral treatments cause the emergence of resistances and side effects that prompted us to look for new therapeutic targets against HIV. Vpr controls the integration of viral DNA into the genome of the host cell, the activation of the transcription of the LTR (long terminal repeat) and the cell cycle arrest in G2 phase of the host cell, which are essential steps for viral multiplication. UNG2 is involved in DNA repair and reduces the viral genome mutations enabling it to evade the immune system. Vpr, by interaction with UNG2, appears to facilitate its ubiquitination and its degradation by the proteasome. The interaction between the uracil DNA glycosylase (UNG2) and the HIV-1 viral regulatory protein (Vpr), which has no equivalent in humans, is a potential target against HIV replication. Our first objectif is to understand the factors governing that interaction at the atomic level. Our second objective is to target that interaction with ligands that have been identified against Vpr.
Methods: We expressed the UNG2 in E. coli and synthesized Vpr and several of its fragments in order to characterize their interaction by NMR, crystallography, circular dichroism, and other physico-chemical methods. Peptides containing the WxxF motif and chemical compounds have been selected by screening against Vpr.
Results: First NMR experiments allowed us to confirm in vitro, the mode of interaction between these two proteins. The same experiments carried out on the fragment of Vpr (containing W54) and a fragment of UNG2 (containing the WxxF pattern) showed similar results. Peptides containing the WxxF pattern or WW motif were studied by the two-hybrid system. One of these peptides interacts with Vpr and by biochemical tests, we have shown that it disrupts the interaction between Vpr and UNG2. On the other hand, a primary screening of a small molecules library was used to select chemical compounds, potential Vpr inhibitors and a secondary NMR screening will identify those disrupting the interaction between Vpr and UNG2.
Conclusions: The interaction between the two proteins was demonstrated by NMR and pool down, and one of the peptides containing the WxxF motif (the petide P6) we tested, can totally inhibit this interaction.

MOPEA0029

Regulation of retroviral integration by RNA polymerase II associated factors and chromatin structure

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Background: HIV-1 integration occurs in highly Pol II transcribed and spliced regions of the chromatin thanks to the interaction between the retroviral intasome and the cellular tethering factor LEDGF/p75. These regions of the host genome are enriched in transcription and remodeling factors that are expected to modulate the chromatin access to the incoming intasome and its functional association with the targeted nucleosome.
Methods: This final step has been shown to be regulated by both intasomes and chromatin structure we investigated these regulation processes focusing on the analysis of the IN/nucleosome interaction and on the role of the cellular proteins associated with the Pol II transcription apparatus.
Results: We show here that histone tails are required for optimal association between HIV-1 IN and the nucleosome and efficient integration on it. Interactions between IN and the amino-terminal tail of human histone H4 was reported in vitro. Structure/function studies enabled us to identify HIV-1 IN amino-acids important for this interaction in the carboxy-terminal domain (CTD) of the viral protein. Functional analyzes confirmed the importance of this interaction for efficient replication and integration of the virus. Additionally the analysis of the role of Pol II associated remodeling factors on this functional association led us to found that FACT (facilitates chromatin transcription) complex, a chromatin remodeler associated with Pol II and recently reported to bind LEDGF/p75, can regulate the access to the nucleosome and histone tails to the incoming intasomes. Mechanistic studies indicate that FACT generates partially dissociated nucleosomes structures that are highly favored substrates for HIV-1 integration. This partial nucleosome dissociation decreases the chromatin density in the vicinity of the integration site and, thus, allows the final association between intasomes and the targeted nucleosome.
Conclusions: Consequently, our work highlights new host/pathogen interactions that could constitute novel and attractive targets for future potential therapeutic applications in addition to provide a better understanding of this crucial integration step of the retroviral replication.

MOPEA0030

Autophagy does not influence HIV replication in productively infected dendritic cells (DCs)

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Background: Macroautophagy, thereafter referred to as autophagy, is a lysosomal degradation process essential for the maintenance of cellular homeostasis. Since few years, autophagy is emerging as an important factor of immunity. Indeed, autophagy can directly degrade intracellular pathogens but it is also involved in the regulation of both innate and adaptive immune responses. To escape from autophagy degradation, several viruses have evolved strategies to inhibit or even hijack autophagy. In this work, we focused on Human Immunodeficiency Virus (HIV-1) which targets cells from the immune system such as CD4 T lymphocytes, macrophages and dendritic cells (DCs). Whereas interactions between HIV and au-

tophagy have been studied in CD4 T cells and in macrophages, it is less described in DCs. We previously reported that during viral entry in DCs, incoming HIV particles could be degraded by autophagy and that HIV-1 induces a rapid shutdown of autophagy. However, involvement of autophagy during viral replication was unknown.
Methods: In this study, we analysed the impact of autophagy modulation by drugs or shRNA on HIV replication in productively infected DCs.
Results: We show that in DCs, the HIV Gag protein does not colocalize with the protein LC3, a marker of autophagosomes, suggesting that newly-produced HIV-1 particles are not sequestrated into autophagosomes. Moreover, the induction of autophagy using drugs, CD46-trigerring or TLR ligands does not lead to a targeting of Gag in autophagosomes. The use of HIV-1 mutants lacking Env or Nef proteins (that have been shown to impact early and late steps of autophagosome formation, respectively) suggest that the absence of Gag uptake into autophagosomes is not the result of an escape mechanism developed by HIV-1. Interestingly, we also demonstrate that the HIV Env protein does not colocalize with autophagosomes. Moreover, shRNA-mediated inhibition of autophagy in DCs does not impact HIV-1 replication and propagation.
Conclusions: Our work reveals, in DCs, two distinct phases in HIV and autophagy interactions: whereas viral incoming particles are targeted to autophagosomes during viral entry contributing to the induction of cellular responses, HIV does not interact with the autophagy pathway after the establishment of a productive infection.

MOPEA0031

p21 restricts HIV-1 replication in dendritic cells through the synergistic reduction of dNTP biosynthesis and the regulation of SAMHD1 antiviral activity

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Background: Dendritic cells (DCs) play a key role in the induction of immune responses against HIV. Immature myeloid DCs allow HIV-1 replication, but mature myeloid DCs are strongly resistant to HIV infection. $p21^{cip/waf}$, a cyclin-dependent kinase inhibitor involved in cell cycle regulation and monocyte differentiation and maturation, and SAMHD1 are cellular factors that regulate the size of the dNTPs pool and can block HIV replication in myeloid cells. We used the different HIV-1 susceptibility of immature and mature DCs to shed light on the intermingled antiviral activities of p21 and SAMHD1 and their impact on the intracellular dNTP pool.
Methods: Dendritic cells were obtained after differentiation of freshly isolated primary human monocytes in the presence of GM-CSF and IL-4. Monocytes derived to DCs were then cultured in the absence (immature) or the presence (mature) of IFNγ, CD40L with a His-tag and His6x. mRNAs of the genes of interest were quantified by qRT-PCR and proteins by western blot under different experimental conditions. Intracellular dNTP concentrations were measured with a single-nucleotide incorporation assay.
Results: We found that the inhibition of HIV-1 replication in mature DCs was related to a strong increase in the expression of p21. p21 decreased the size of the intracellular dNTP pool by suppressing several enzymes involved in dNTP synthesis (i.e., RNR2, TYMS, and TK-1). In parallel, we show that p21 prevented SAMHD1 phosphorylation and promoted SAMHD1 antiviral activity. Both activities were complementary and differently contribute to block HIV-1 replication. The antiviral activity of SAMHD1 in our primary cell model appeared to be, at least partially, independent of its dNTPase activity. The reduction in the pool of dNTPs in DCs was rather due to p21-mediated suppression of dNTP biosynthesis.
Conclusions: This study shows that p21 expression resulted in conditions that allowed the effective inhibition of HIV-1 replication in DCs through complementary/synergistic mechanisms affecting differently dNTPs synthesis and the phosphorylation of SAMHD1. Overall our results point to p21 as key regulator of HIV infection in myeloid cells.

MOPEA0032

Expression of native HIV-1 antisense protein (ASP) in chronically infected T cells (ACH-2) following stimulation with TNF-α

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Background: HIV-1 Antisense protein (ASP) is an antisense (-2) open reading frame encoding for a highly hydrophobic protein of 20 kDa encompassing Env at the junction of gp120-gp41. Existence of ASP was initially suggested by Miller in 1988 and ASP transcripts demonstrated shortly thereafter. Expression of recombinant ASP has been widely shown in various cell lines, although its cellular localization remains controversial. In this study we report expression of native ASP in the membrane fraction of TNF-α-stimulated ACH2, a T cell line chronically infected with $HIV\text{-}1_{HXB2}$.
Methods: ACH2 cells and their uninfected counterpart A301, were stimulated with recombinant TNF-α at intervals of 12h and up to 72h. Cells were lysed and the proteins from the membrane and cytoplasmic cell fractions separated by SDS-PAGE and analyzed by Western blot using ACH-2-derived anti-ASP polyclonal antibody. Western blot competition assay was performed with synthetic ASP peptide in the membrane fraction of both ACH2 and A301 at 48h post TNF-α stimulation.
Results: A band similar in size to ASP (20 kDa) was reproducibly observed in the membrane fraction of TNFα-stimulated ACH2 using anti-ASP polyclonal antibody. In contrast, no band was observed in A301. The intensity of the 20 kDa band increased in a time-dependent manner up to 48h post TNF-α stimulation. In ASP peptide competition assays, the 20 kDa band was specifically competed out by free, soluble ASP peptide. In contrast, it could be clearly observed in ACH2 in absence of competition. No band could be observed in A301 with or without competition.
Conclusions: Our data indicate that anti-ASP antibodies recognize a band of 20 kDa, the ASP expected molecular weight. Detection of this protein by anti-ASP antibodies and its presence only in ACH2 clearly indicate its specificity for HIV, whereas its finding only in the membrane fraction is in good agreement with the hydrophobic nature of the ASP protein as predicted by bioinformatic analysis. Finally, the 20 kDa band was inhibited by free ASP peptide, suggesting that this protein is indeed ASP. Further experiments to formally prove the identity of the 20 kDa band and its cellular localization are on the way.

MOPEA0033

Inhibition of HIV-1 gene transcription by KAP1: a new CTIP2 interactant

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Background: HIV-1 post-integrative latency generates reservoirs which prevent the eradication of the virus with the current therapies. We have demonstrated that the transcriptional co-repressor CTIP2 recruits multi-enzymatic complexes to promote the establishment and the persistence of HIV-1 latency in microglial cells (Marban et al., 2007), the major viral cellular reservoir in the central nervous system. The control of the HIV-1 Tat transactivator is crucial to the persistence of these long-life reservoirs (Cherrier et al., 2013).
Methods: In the present work, the protein partners of CTIP2 were investigated. Nuclear protein extracts from HEK cells expressing Flag-CTIP2 were submitted to immunoprecipitation using an anti-Flag antibody. Co-immunoprecipitated proteins were identified by quantitative mass spectrometry. KAP1, a newly identified partner of CTIP2, has been studied for its function on the control of HIV-1 gene transcription by classical methods: Luciferase assays, co-immunoprecipitation assays, SDS-PAGE and Western blot analysis.
Results: 888 proteins interacting with CTIP2 ($p < 0.05$) were identified, including the transcriptional regulatory factor, KAP1 / TRIM28. KAP1 has been shown to control viral gene expression and viral latency of KSHV, Murine Leukemia Virus (MLV) and human T-cell lymphotropic virus-1 (HTLV-1) (Chang et al., 2009; Wolf et al., 2008a, 2008b).

We found that the transcriptional repressor KAP1 contributes to HIV-1 gene silencing by repressing the initiation and the Tat-dependent steps of the viral gene transcription.
Moreover, we report that KAP1 cooperates with CTIP2 to silence HIV-1 gene transcription and the viral expression. KAP1 functions are closely linked to SUMO-mediated post-transcriptional regulations. Our results suggest that KAP1 induces Tat degradation via a SUMO-sensitive pathway. Indeed, favoring SUMOylations promotes Tat association with KAP1 and the resulted degradation. Logically, over-expressing the SUMO protease SENP1, abrogates KAP1-mediated degradation of Tat.
Conclusions: Altogether, our results suggest that KAP1 contributes to the establishment and the persistence of the latently infected HIV-1 reservoirs. Nevertheless, these results suggest that targeting the SUMO pathways may be a new field of investigation to develop new classes of Latency Reversing Agents for cure strategies.

MOPEA0034

Translational regulation of APOBEC3G mRNA by Vif requires its 5'UTR and contributes to restoring HIV-1 infectivity

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Background: The HIV-1 requires the concerted contribution of many cellular factors to achieve efficient replication. Similarly, mammalian cells express a set of proteins called restriction factors to suppress viral replication. Among these factors, the family of APOBEC3 (A3) proteins and in particular A3G and A3F are the most efficient against HIV-1. They belong to a large family of cytidine deaminases that catalyze the deamination of cytidines to uridines during retrotranscription. The antiviral activity of A3G/F is counteracted by the HIV-1 Vif protein. Vif significantly reduces their expression in cell and their incorporation into viral particles by
1) recruiting an E3 ubiquitin ligase complex to induce their degradation by the proteasome, and;
2) regulating their translation. Up to now, mechanisms by which Vif regulates the translation of A3G are unknown.
Methods: We tested the importance of the untranslated regions (UTRs) of A3G mRNA in the translational inhibition. HEK293T cells were transfected with wild-type and mutated constructions of A3G mRNAs in presence or absence of Vif. These experiments were also performed with proteasome inhibitors in order to distinguish the proteasomal degradation from the translational inhibition.
Results: Although the translation of wild-type A3G mRNA is significantly reduced by Vif, the deletion of its 5'UTR suppressed its regulation by Vif, suggesting the importance of this region for translational repression. Moreover, its replacement by heterologous 5'UTRs prevents translation inhibition. Within this 5'UTR, the two distal stem-loops are required for the inhibition. Interestingly, we found that A3G is also translationally regulated by Vif in HIV-1 chronically infected lymphoid cells (H9). This effect of Vif on A3G translation is conserved amongst HIV-1 isolates, whereas CBF-b an essential factor in Vif-induced A3G proteasomal degradation does not seem to be required. Finally, we observed a strong correlation between the level of A3G protein translation in cell, their incorporation into viral particles, and the infectivity of released virions.
Conclusions: Experiments are in progress to identify with precision the mechanisms and partners of A3G translational regulation. Regulating the translation of A3G could thus be considered as a new target to restore a functional expression of A3G and viral restriction.

MOPEA0035

TILRR is a potential enhancer of inflammation and HIV-1 vaginal infection through interacting with NFκB signaling pathway

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Background: TILRR (Toll like IL1 Receptor Regulator), a transcript variant of FREM1, is a novel regulatory component, which stimulates host defense against infection through binding to IL-1R1 and TLR complex and enhancing the recruitment of MYD88 in the Ras-dependent NFκβ signal transduction pathway. Our previous study identified FREM1 as a novel candidate gene in correlation with HIV-1 resistance/susceptibility in the Pumwani Sex worker cohort. In this study, we investigated the effect of TILRR on the global gene expression profile of the NFκB signaling pathway by over-expressing it into human cell lines.
Methods: TILRR was overexpressed in HeLa and VK2 cells using eGFP tagged plasmid construct. Transfection efficiency was confirmed by Confocal microscopy and Flow cytometry. TILRR RNA overexpression was confirmed by qRT-PCR and Western blot analysis. The effect of TILRR on the expression of 84 genes linked to NFκB pathway was subsequently investigated by qRT-PCR. Conditioned media were also tested for the protein level expression of important pro- and anti-inflammatory cytokines/chemokines using Bioplex multiplex cytokine/chemokine bead assay.
Results: Overexpression of TILRR significantly up-regulated 32- and 52-genes, as well as down-regulated 15- and 4-genes in IL-1β treated and non-treated cells, respectively. We observed that most of the pro-inflammatory cytokine/chemokine encoded genes, like IL-1β, IL-6, TNFα, and IL-8 (chemokine) were significantly increased at mRNA level expression. We further noticed that cytokines/chemokines, those were assessed for mRNA level expression by qRT-PCR, were also increased at the protein level expression in conditioned media using multiplex bead assay. Data described here are the representative of three independent experiments using female genital tract cell lines, which suggest a potential link of TILRR in HIV-1 vaginal infection through enhancing the NFκB and inflammatory responses.
Conclusions: Although how TILRR influence the expression of these genes needs to be further studied, our study is the first to show that TILRR may influence the expression of genes directly involved in HIV-1 infection in addition to its role in enhancing NFκB and inflammatory responses. NFκB and inflammatory response pathways are extremely important in HIV-1 transmission; therefore, further study of the role of TILRR may identify novel intervention targets and strategies against HIV-1 vaginal infection.

MOPEA0036

HIV-1 Vpr counteracts CTIP2-mediated cellular response to viral infections

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Background: Mammals have developed innate and acquired immune responses to combat infections. Several host factors such as APOBEC3G, Tetherin, TRIM5a or SAMHD1 have been described to restrict HIV-1 expression. Interestingly, none of them targets the transcription step of the viral life cycle. We have previously reported that the cellular transcription factor CTIP2 contributes to the establishment and the persistence of HIV-1 post-integration latency. CTIP2 restricts HIV-1 gene transcription by recruitments of multi-enzymatic complexes at the viral promoter. Since CTIP2 is widely expressed in HIV-1 target cells, we investigated how the virus counteracts this transcriptional block to allow its expression in permissive cells.
Methods: Microglial and T cell lines have been used to study the molecular mechanisms underlying the HIV-1 counteractions of CTIP2 functions. Classical but focused and complementary methods have been used to investigate the functional and biochemical interplays between the response of the host cells and the role of the viral factors.
Results: We report that CTIP2 expression is favored by interferon treatments making this transcription factor a contributor of the innate cellular response against viral infections. HIV-1 infection induced a biphasic control of CTIP2 expression. CTIP2 was overexpressed at early time points and reduced during the productive phase of the viral expression. Since the overexpression of CTIP2 resulted from an interferon sensitive increase of CTIP2 mRNA, the reduced expression of CTIP2 resulted from a degradation of the protein through the proteasome pathway. We report that the viral accessory protein Vpr promoted this degradation through the association of CTIP2 with the CULL4-DDB1-DCAF1 complex. Vpr induced the degradation of CTIP2 and of its associated-chromatin modifying enzymes at the HIV-1 promoter. These events favor an efficient HIV-1 gene transcription and the subsequent viral replication.
Conclusions: Our results suggest that the transcriptional repressor CTIP2 contributes to the cellular response against HIV-1 infections. In HIV-1 permissive cells, the virus counteracts this cellular restriction through a Vpr-mediated degradation of CTIP2. Through modulations of CTIP2 expression, the transcription step of the HIV-1 life cycle is for the first time targeted by host factors to restrict the viral expression and by the viral factors to counteract this restriction.

MOPEA0037

BRD4 inhibitor, JQ1, but not HDAC inhibitors, stimulate accumulation of spliced HIV RNA

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Background: Understanding HIV transcription is critical to developing new strategies to eliminate latency. HIV Tat protein augments transcriptional transactivation by facilitating viral RNA elongation and splicing. Tat proteins are highly acidic and undergo different posttranslational modifications on lysine residues which modify the behaviour of Tat. We aimed to determine the effects of these lysine residues on HIV transcription and splicing in the presence and absence of latency reversing agents (LRAs), including histone deacetylase inhibitors (HDACi).
Methods: Wildtype (WT) Tat101 (AD8) was mutated by site-directed mutagenesis to generate K28A, K50A, K50/51A, K71A, and R53A. Expression of these mutants was confirmed by Western Blot. TZM-bl cells were used to measure the effect of each mutant on transcriptional transactivation compared to WT Tat and luciferase expression was quantified. Effects on splicing were quantified by flow cytometry using a fluorescent splicing reporter system, where unspliced transcripts expressed green fluorescent protein (eGFP) and spliced transcripts expressed dsRed. We transfected HEK293T cells with the reporter constructs in the presence of WT and mutant Tat using a panel of LRAs (vorinostat, panobinostat, JQ1, chaetocin, and disulfiram), DMSO and PMA.
Results: In TZM-bls, transfection of the Tat mutants K28A, K50A and K50/51A, and to a lesser extent, R53A, significantly reduced luciferase expression compared to WT, while there was no difference between K71A and WT. In the splicing reporter system, the impact of Tat mutations on eGFP expression (unspliced product) was similar to our findings in TZM-bl cells, and the addition of HDACi and JQ1 but not chaetocin or disulfiram, resulted in increased expression of eGFP compared to DMSO for all Tat mutants. In contrast, only JQ1 significantly increased the level of dsRed (spliced product) compared to DMSO. Finally, in the absence of Tat, JQ1 was the only LRA to significantly increase dsRed to levels similar to wildtype Tat.
Conclusions: JQ1, a BRD4 inhibitor that promotes pTEF-b formation, drives accumulation of spliced HIV RNA, even in the presence of Tat mutants while HDACi, only increased the levels of unspliced HIV RNA. JQ1 may have increased potency as an LRA in latently infected resting T-cells where Tat levels are low.

MOPEA0038

Generation of HIV latency reporter cell lines by targeted genome engineering to explore effects of proviral integration site choice

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Background: Infection with Human Immunodeficiency Virus (HIV) leads to non-random integration of proviral sequences into the human host genome. Irrespective of antiretroviral therapy, this results in a genomic burden of virus-derived sequences. It is thought that only a small proportion of these sequences code for intact, replication-competent HIV genomes. They have been claimed to be the source of a latent reservoir in infected and treated individuals. In such individuals, recent reports highlight the existence of preferred genomic integration sites for provirus-derived sequences. These findings prompt the question of whether the site of genomic proviral integration impacts on proviral activity or indeed if there is an effect vice versa.
Methods: T cell-derived Jurkat cells were targeted using CRISPR/Cas9 technology to introduce an HIV-derived reporter cassette. The workflow for targeting and screening of clonal lines will be demonstrated.
Results: In this study, we have used targeted genome engineering to generate T cell-derived lines that carry an HIV-derived fluorescent reporter at defined genomic loci. These defined loci have been reported as preferred integration sites in HIV-infected subjects under therapy. We demonstrate thorough characterization of the novel reporter lines by Southern blotting, qPCR and flow cytometry and show how stimulation with various latency reversing agents (LRAs) affects LTR-dependent reporter expression.
Conclusions: Our study shows how genome engineering techniques can be exploited to generate new in vitro models for HIV latency. Focusing on recurrent proviral integration sites found in vivo, these reporter models provide unique tools to study the link between genomic integration site and provirus activity.

MOPEA0039

HIV-1 Gag interaction with Dicer and consequences on the miRNA processing and binding to the RNA interference complex

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Background: RNA interference (RNAi) is a post-transcriptional gene process in eukaryotes that controls cell differentiation, development, and immunity. RNAi in mammals occurs via micro RNAs (miRNA), which are small ~22 base pair non-coding double-stranded RNAs that hybridize to a specific target mRNA for cleavage or translational repression. This process requires the RNA Induced Silencing Complex (RISC), which is composed of Dicer, TRBP and Ago2. We and others have shown that HIV-1 does not shut off the RNAi pathway but, HIV-1 proteins and RNAs act at discrete steps. Here, we identify an interaction between the HIV-1 structural protein Gag and Dicer and analyze its impact on Dicer activity and miRNA selection in the RISC.
Methods: We identified an interaction between Gag and Dicer by indirect immunofluorescence, Proximity Ligation Assay (PLA) and co-immunoprecipitation (co-IP). In addition, we determined the cleavage capacity of Dicer using a catalytic activity assay with miRLet7-c and mir29a. Finally, we evaluate miRNAs bound to Dicer by using RNA immunoprecipitation and sequencing (RIP-seq).
Results: We show that Gag co-localizes with Dicer by confocal microscopy. We show that Dicer co-IPs with Gag in an RNA-independent fashion. By PLA we quantify ($P< 0.001$) and determine that Gag-Dicer interaction occurs mainly in the cytoplasm. Additionally, we developed a catalytic assay for Dicer to evaluate its function. Our results show that Dicer catalytic activity is not impaired by Gag for the amount or size of two produced miRNAs, Let7-c and miR29a. We are on the process of acquiring results from ongoing RIP-seq analyses to evaluate the miRNAs produced by Dicer in the presence of Gag.
Conclusions: We have demonstrated HIV-1 Gag interacts with Dicer. The importance of this discovery relies on the fact that pre-miRNAs must pass through Dicer to complete their function whether they have been produced by a canonical or non-canonical pathway. Subtle modifications by Gag could affect miRNAs binding and processing by Dicer and consequently the mRNA expression.

MOPEA0040

Microglial cells that are latently infected by HIV are activated by inflammatory stimuli and induce neuronal damage

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Background: The major reservoirs for HIV in the CNS are in the microglia, perivascular macrophages, and to a lesser extent, astrocytes. We hypothesized that toll-like receptor (TLR) responses to inflammatory conditions by microglial cells induce latent HIV proviruses and that these activated microglial cells, in turn, are responsible for the neuronal damage seen in HIV-associated neurodegeneration.
Methods: Primary human cells, including cells obtained from adult brain tissue, were transformed with lentiviral vectors expressing a combination of SV40 T antigen and hTERT. These newly developed human microglial cell lines (hμglia) were used to generate latently infected cells using a single-round HIV virus carrying a green fluorescence protein (GFP) reporter (hμglia/HIV, clones HC01 and HC69). Neuronal viability was assessed through time-lapse digital images recording of live cells, MAP-2 immunohistochemistry, and Western blot analysis.
Results: The immortalized cells have microglia-like morphology, demonstrate the expected migratory and phagocytic activity, express key microglial surface markers (CD11b, TGFβR, and P2RY12), and have RNA expression profiles characteristic of primary microglial cells. The inflammatory cytokines TNF-α and IL-1β stimulated HIV transcription. Surprisingly, two TLR3 agonists, poly (I:C) and bacterial ribosomal RNA (rRNA) also potently reactivated HIV in hμglia/HIV cells using a previously unreported mechanism mediated by IRF3. The selective induction of IRF3 by poly (I:C) was confirmed by chromatin immunoprecipitation (ChIP) analysis. LPS (TLR4 agonist), flagellin (TLR5 agonist), and FSL-1 (TLR6 agonist) reactivated HIV to a lesser extent through transient NF-κB induction. Pam3CSK4 (TLR2/1 agonist) and HKLM (TLR2 agonist) only weakly reversed HIV latency. When LUHMES cells or mouse primary neurons were co-cultured with HIV infected microglia, extensive neurodegeneration was observed as shown by the significantly reduced MAP-2 staining of neuronal axons (dendritic damage), decreased level of synaptophysin, GluR1 AMPA and synaptophysin (synaptic damage), and increased levels of phosphor-Tau (neuronal microtubules damage).

Conclusions: The cell lines developed and rigorously characterized will provide an invaluable resource for the study of HIV infection in microglial cells. Since HIV patients characteristically have chronic inflammation due to the release of microbial components into the circulation, the TLR responses that we have documented are likely to contribute to CNS-disease progression.

MOPEA0041

A single-cell method to detect early activation of the latent HIV provirus

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Background: The reservoir of latently infected cells is the main obstacle to cure HIV. The cellular mechanisms that are responsible for the initial activation and transcriptional elongation of the latent provirus remain unclear. To better understand the factors that affect the proviral activation in the heterogenous population of the latent reservoir, there is a need for new tools.
Methods: We have developed a technique to identify early proviral activation in single cells. The technique relies of detection of proximity of a single viral Tat protein to the HIV promoter in an engineered Jurkat-derived cell model.
Results: We are able to detect early activation in a sensitive and robust manner without increasing the background signal relative to standard assays. The results were compared to a J-lat model, 5A8, with a latent reporter HIV-GFP contruct. Up to three-fold higher activation were observed using our technique compared to the GFP signal in the same cell. The signal for activated provirus could be detected a few hours after stimulation of T-cell receptor signaling.
Conclusions: This technique can be used to delineate the cellular pathways that promote or restrict proviral activation.

MOPEA0042

The nuclear pore orchestrates HIV-1 nuclear import and sculpts the chromatin landscape near integration sites

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Background: Nuclear pore complexes (NPCs) are dynamic structures embedded in double lipid layer of the nuclear envelope, which act as guardians of nucleocytoplasmic transport, genome organization, genome stability and gene expression regulation. Some of these cellular functions orchestrated by NPCs are usurped by viruses that replicate in the nucleus. In recent years, research regarding multiple aspects of the early steps of HIV-1 life cycle highlights dynamic and concerted mechanisms between viral components, NPC, chromatin state. Recently, we unraveled the distinct roles of two nuclear basket Nups, Nup153 and Tpr, in HIV-1 infection. We observed that Nup153 participates in HIV-1 nuclear import, while Tpr maintains a chromatin environment favorable for HIV-1 replication.
Methods: We generated stable knockdown cells using lentivectors carrying shRNA specific for a single nucleoporin and using HIV-1 mutants. We analyzed HIV-1 integration sites by high throughput pyrosequencing and RNA sequencing. Functional enrichment analysis has been performed using DAVID and ToppGene Suite, both including defined gene sets for Gene Ontology categories and biological pathways like KEGG.
Results: We investigate how critical is the passage through the NPC for HIV-1 replication and if the pore is the exclusive pathway used by the virus to reach the chromatin. To understand whether HIV-1 integration sites in particular chromatin regions depends on the NPC passage we performed high throughput pyrosequencing in different viral conditions. We observe divergences in the distribution of integration sites in host chromatin regions and in particular chromatin features. Bioinformatics analysis show changes in cluster of genes involved in cell cycle, DNA repair and transcription. We previously observed that cells depleted for Tpr have a defect in HIV genes expression. In order to identify cluster of genes that could be involved in viral silencing due to the absence of Tpr, we compare the transcription level of 36,064 genes on Tpr depleted Jurkat cells vs control cells infected and not with HIV-1.
Conclusions: Taken together these results could help the comprehension of how Nups, chromatin factors and genes are concerted to orchestrate HIV-1 replication. Nucleoporins may be another "cellular code" for specifying HIV-1 fate through the underlying chromatin.

MOPEA0043

Host factors associated to control of HIV-reservoir in elite controller patients

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Background: Latency remains the biggest barrier to HIV eradication. Elite controller (EC) patients, who are able to spontaneously control viral replication, could have molecular mechanisms against HIV-reservoir. In this study, we seek for correlates of HIV reservoir control in the CD8-T cells and resting memory CD4-T cells (TRM) transcriptional profile of these patients.
Methods: Thirty HIV-patients were included according to plasma viral load (pVL) and cART status: 10 EC (pVL< 50 without cART); 10 TX (pVL< 50 on cART); 10 TP (pVL>50 without cART). Ten healthy controls (HC) were also included. HIV reservoir size was analyzed measuring cell-associated total HIV-DNA by digital droplet PCR in TRM cells. Transcriptional profile of purified CD8 and TRM cells was analyzed with human whole genome Agilent microarray platform. Limma test was used for the analysis of genes with differential expression; genes were considered significant with false discovery rate (FDR) below 0.05 (P< 0.05).
Results: The smallest HIV reservoir size was seen in EC among HIV-patients (p< 0.0001). CD8 T-cells transcriptional profile revealed that HIV induces deregulation of 5153 genes in TP patients; viral suppression with cART (TX patients) led to a normalization with only 24 genes differentially expressed compared to HC. Surprisingly, EC had 368 genes differentially expressed compared to HC, many of these related to immune response. Otherwise, TRM cells transcriptional profile revealed 256 genes differentially expressed in EC but not in TX compared to TP. Again, many of these were related to immune system, and interestingly some were associated to infection control: MICA (fold change 3.38 EC vs. TP; p=0.04) a NK cell-activating ligand, and CD96 (fold change 4.39 EC vs. TP; p=0,006) a T cell-specific receptor.
Conclusions: EC patients present a better control of proviral HIV-DNA in TRM cells, the main component of cellular HIV reservoir. Interestingly, both CD8 T-cells and TRM cells transcriptional profiles reveal molecular mechanisms specifically associated to the status of EC and potentially involved in the better control of reservoir size observed in these patients, and different to those potentially associated to control throughout treatment. These data provide important findings to improve clinical strategies that could help to achieve HIV remission.

MOPEA0044

Peripheral T follicular helper cells make a difference in HIV reservoir size between elite controllers and patients on successful ART

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Background: HIV latency is the main barrier to HIV eradication. At cellular level, long-term persistent virus has been mainly described in resting memory CD4+ T-cells. Recently, peripheral T follicular helper (pTfh) cells have taken a prominent role in HIV persistence.
Herein, we analyzed the HIV reservoir size in memory CD4+ T-cell subsets in patients with HIV replication control.
Methods: Twenty HIV-infected patients were included according to plasma viral load and ART status: 10 elite controller (EC) and 10 treated (TX) patients. Size of HIV reservoir was analyzed by ultrasensitive digital droplet PCR assay to measure total cell-associated HIV-DNA in resting memory CD4+ T-cells, peripheral T follicular helper cells and non-peripheral T follicular helper cells. Inter-group and intra-group differences were tested using non-parametric tests.

Results: Compared to TX patients EC patients had lower reservoir size in resting memory CD4+ T-cells (p=0.059) and in pTfh cells (p=0.025), but not in non-pTfh cells (p=0.17). Moreover, pTfh and non-pTfh cells harbored similar levels of HIV reservoir both in EC (p=0.60) and in TX patients (p=0.17).
Conclusions: Our data shows that compared to patients on successful ART, Elite Controller patients have a lower HIV reservoir size in memory CD4+ cells, and this is consequence of the HIV-DNA content in pTfh cells, a population of memory cells with a pivotal role in anti-viral immune response, suggesting a potential link between low level of infection of pTfh cells and ability of EC to spontaneously control HIV replication.

MOPEA0045

HIV-1 integration sites reveal heterogeneity in the latent population and explain the limited induction of latent proviruses

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Background: Current antiretroviral therapy (ART) does not allow for the eradication of the human immunodeficiency virus (HIV) due to the presence of latent proviruses in rare, long-lived resting CD4+ T cells. The main research efforts to eliminate the viral reservoir are focused on the use of latency reversing agents (LRAs) to force the reactivation of the latent provirus, while maintaining ART to prevent de novo infections. Subsequently, reactivation of HIV expression would kill reservoir cells via viral cytopathic effects and/or immune clearance ("shock and kill" strategy). So far, no LRAs tested in clinical trials have succeeded in reducing the viral reservoir.
Methods: We used an improved dual-fluorescent HIV reporter (GKO), which distinguishes productively infected cells from the latent population, to investigate the efficacy of the "shock and kill" strategy. In addition, GKO provides a unique opportunity to:
(1) explore the impact of HIV integration site specificity on the fate of the infection, and to;
(2) characterize the inducible subpopulation of latently infected cells, since it allows the isolation of inducible latent and non-inducible latent populations from the productively infected majority.
Results: We first showed that our patients' data was consistent with previously published studies. However, we found that at most 5% of GKO latent proviruses were reactivated, and that these reactivated cells were resistant to virus-induced cytopathic effects, thus preventing their elimination. Moreover, the analysis of HIV-1 integration sites from productively, non-inducible and inducible latently infected populations reveals heterogeneity within the latent infections. In contrast to non-inducible latent infections, the integration sites of inducible latent proviruses have similar features to those of productive proviruses, thus demonstrating a prominent role for the site of integration and its chromatin context for the fate of the initial infection as well as for latency reversal.
Conclusions: Our study shows an important roadblock for the "shock and kill" approach to reservoir eradication. Differences between reactivatable and permanently latent reservoir cells suggest that complete reservoir reactivation and eradication with LRAs may prove impossible, and that a multipronged "functional cure" approach may be necessary.

MOPEA0046

HIV reservoir size and composition, after antiretroviral treatment initiation, is related to HIV-specific CD8+ T-cell responses developed during primary HIV infection

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Background: The persistence of latently infected T-cells remains the major obstacle to cure HIV. Understanding the early events that occur after infection and establish HIV latency will be fundamental for potential eradication. We aimed to determine the relationship between CD8+ cytotoxic T lymphocyte (CTL) function and HIV persistence on antiretroviral therapy (ART).
Methods: Twenty-one individuals were enrolled during acute/early HIV infection (median 2 month post-infection, mpi) and started ART within 12 mpi. Blood samples were obtained at enrollment (baseline sample, pre-ART) and every 3 months (on-ART) during 2 years. Cell-associated HIV DNA and unspliced (US) RNA were quantitated by real-time PCR, in samples on-ART. HIV-specific CTLs were identified based on cytokines/CD107 production upon peptide stimulation. Phenotypic (CD45RO, CCR7, PD-1) markers were studied in baseline samples on bulk and HIV-specific CTLs by flow cytometry. Data was analyzed using non-parametric statistics
Results: HIV DNA and US RNA rapidly diminished after ART initiation, reaching a plateau by 30 weeks post-ART (median total HIV DNA 159 copies/10^6 cell equivalents; unspliced (US)-RNA 14 copies/10^6 18S copies). HIV-specific CTLs profile at baseline was: 52% terminal effectors (T_{TE}); 20% naïve-like; 13% effector memory (T_{EM}) and 5% central memory. PD-1+ HIV-specific CTLs were 24.7%. Also, high intensity PD-1 (PD-1^{High}) expression was measured in 1.2% CTLs.
Spearman's correlations showed that the proportion of baseline naïve CTLs was inversely correlated with levels of cell-associated US-RNA measured at 12 month post-ART (mp-ART) (r=-0.6321, p=0.005). A higher proportion of bulk and HIV-specific CD8+ T_{EM} cells at baseline correlated with higher levels of US-RNA measured at 12 mp-ART (r=0.6746, p=0.002 and r=0.5752, p=0.017; respectively). The percentage of HIV-specific CD8+ T_{TE} cells positively correlated with total HIV DNA levels at 12 mp-ART (r=0.6888, p=0.011).
Finally, a strong positive correlation was observed between the proportion of bulk and HIV-specific PD-1^{high} CTLs measured at baseline and total HIV DNA levels at 12 mp-ART (r=0.5005, p=0.034 and r=0.7349, p=0.006; respectively).
Conclusions: Results suggest that higher proportion of terminally differentiated CTLs and higher CTL exhaustion are related to higher HIV reservoir size. Thus, the quality of early CTL immune responses may serve as a predictor of HIV persistence on ART.

MOPEA0047

Urethral tissue macrophages are genuine viral reservoirs in HIV-1-infected individuals under suppressive antiretroviral therapy

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Background: HIV-1 eradication, or at least functional cure, requires the elimination/reduction of the HIV-1 reservoir pool. The best-characterized HIV-1 reservoir resides within peripheral blood resting memory CD4+ T-cells. Yet, residual viremia in HIV-1-infected HAART-suppressed individuals originates not only from T-cells

but also from macrophages, which could therefore comprise an additional long-lived HIV-1 reservoir. Indeed, macrophages are tissues-resident cells that resist the cytopathic effects of HIV-1 infection, survive for long periods, have the capacity of self-renewal, and accumulate infectious virus in intracellular virus-containing compartments (VCCs). Moreover, latency-reverting agents (LRAs) re-activate HIV-1 production in-vitro from both latently infected CD4+ T-cells and macrophages. Currently, a clear demonstration that macrophages actually comprise genuine HIV-1 reservoirs is lacking, as no studies showed that tissue macrophages recovered from HIV-1-infected HAART-suppressed individuals produce infectious virus only following re-activation.
Methods: Using whole penile tissues, obtained upon transgender surgery, from HIV-1-infected HAART-suppressed individuals with undetectable plasma viral loads, we evaluated whether urethral macrophages serve as a yet unrecognized cellular reservoir for HIV-1. Such assumption was based on our previous results showing that urethral macrophages are the first cells targeted by HIV-1 during sexual transmission.
Results: We found that urethral macrophages, but not urethral T-cells, contain HIV-1 proteins, intact virions in VCCs, RNA and R5-tropic integrated DNA. Moreover, in a sensitive quantitative viral outgrowth assay (sQVOA), urethral cells release infectious HIV-1 following stimulation with the macrophage-specific activator lipopolysaccharide (LPS), but not the T-cell-specific activator phytohaemagglutinin (PHA). HIV-1 reservoirs form preferentially in a newly identified subset of polarized urethral macrophages we term transitional M1/M2. Such cells highly express IL-1-receptor, CD206 and IL-4-receptor, but lack CD163, and are increased in urethral tissues from HIV-1-infected HAART-suppressed individuals. Finally, HIV-1 in urethral macrophages does not result from phagocytosis / internalization of T-cells.
Conclusions: Our results show for the first time that despite suppressive HARRT, HIV-1 persists in urethral macrophages, which can be re-activated to release infectious virus. Hence, urethral macrophages are genuine HIV-1 reservoirs. These findings are determinant for therapeutic strategies aimed at HIV-1 eradication.

MOPEA0048

Stimulation of the HIV T-cell reservoir leads to expression of genetically intact but functionally impaired Env glycoproteins

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Background: The HIV T-cell reservoir harbors only a small percentage of intact HIV genomes, but little is known of the functional capacity of viral proteins expressed by these sequences. We have focused here on the HIV envelope glycoprotein, a major target for the host immune response and a strong effector of HIV cytopathicity.
Methods: Resting CD4+ T-cells were collected from 4 HIV-infected subjects in whom viral replication had been fully suppressed by ART for more than 4 years. After in vitro T-cell stimulation, Env sequences were obtained from two sources : clonal replicative virus isolated by qVOA, and cell-associated Env mRNAs isolated by limiting-dilution PCR. Env sequences were cloned in a Rev-independent expression vector. Env expression was examined quantitatively by FACS flow cytometry and Western Blotting. Env function was tested using both a quantitative cell-cell fusion assay and a pseudotype infectivity assay.
Results: All qVOA-derived Envs were intact, while 26% of mRNA-derived Envs carried lethal mutations. Only clones with intact sequences were tested. As expected, clusters of identical sequences were seen in all 4 patients. Env diversity was widest in patients with longest HIV history. Env fusogenicity was highest in qVOA viruses, with 90% of them expressing fusion values above 50% of that of NLAD8 control. By comparison, among mRNA-derived Envs, only 41% reached fusogenic levels above 50% of control, 31% had fusogenic levels below 25% of control, and 14% had no detectable fusion activity. Similar findings were made when Env sequences were expressed and tested in a pseudotype infectivity assay, with a significant correlation between results from the two assays. Flow cytometry and Western-Blot analyses revealed that defects in Env function were essentially related to defects in Env expression, maturation and/or stability.
Conclusions: The discovery of apparently intact, yet functionally defective, Env sequences in the HIV reservoir has two implications. First, Env fusogenicity and cytopathicity could be one important factor driving selection of defective HIV genomes in the reservoir. Second, the presence of poorly expressed and poorly functional Env sequences in the reservoir could preclude elimination of cells harboring these sequences in « kick and kill » HIV eradication attempts.

MOPEA0049

Early initiation of antiretroviral treatment post SIV infection does not resolve lymphoid tissue activation

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Background: Germinal center (GC) resident follicular helper T (TFH) cells in lymphoid follicles are a potential sanctuary for HIV/SIV replication. But the dynamics of GCs upon early initiation of antiretroviral therapy (ART) and their potential role in the formation of viral sanctuaries post SIV infection are not fully understood.
Methods: Sequential lymph node biopsies (n=10) were collected from SIVmac239-infected rhesus macaques at time points corresponding to pre infection, 5 weeks post infection/pre ART, 6 and 12 weeks after ART initiation time points for frequencies of TFH cells and the evaluation of GC scores.
Results: Post-acute SIV infection (wk 5/pre ART), modest but significant increases in TFH cells and hyperplastic follicles with large GCs were noted. In contrast, 6 weeks after ART initiation, substantial increases in GC TFH cells, hyperplastic follicles with large GCs and abundant local IL-21 production were observed, while levels of SIV RNA and DNA of lymph nodes had decreased to barely detectable values, as well as circulating SIV antibody producing plasmablasts. An additional 6 weeks of ART did not appreciably decrease GC TFH numbers or GC scores.
Conclusions: Thus, early ART rapidly control SIV replication, but not lymphoid activation, which may be potentially dictating the seeding and magnitude of viral reservoirs.

MOPEA0050

A humanized mouse-based HIV-1 viral outgrowth assay with higher sensitivity than in vitro VOA in detecting latently infected cells from patients on ART with undetectable viral loads

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Background: With the current emphasis on achieving a complete cure for HIV/AIDS it is important to develop assays that can verify full viral clearance. Currently, in vitro viral out growth assays (VOA) are the gold standard compared to PCR based-tests which cannot distinguish between defective and replication competent viruses. However, the VOAs failed to detect latent virus in cases such as the Boston patients prior to treatment interruption during which virus rebounded. Thus more sensitive latent viral detection methods are needed.
Methods: With a goal of developing a potentially more sensitive in vivo-based VOA, we employed humanized mice shown to be permissiveness for HIV infection, latency and viral reactivation. Purified resting CD4 T cells were obtained from patients on long term ART and no detectable viral loads. These cells were first tested by the standard in vitro quantitative VOA (qVOA). Patient samples that gave negative viral outgrowth by this method were injected i/p into hu-mice and these mice were followed for 8 weeks to detect any viral outgrowth.
Results: Of the five in vitro VOA negative patient samples tested, four showed viral outgrowth in the hu-mouse based viral outgrowth assay (hmVOA) indicating its higher sensitivity. In positive samples, those injected with higher numbers of cells became virus positive sooner and in some, only mice receiving the largest numbers of cells showed viral outgrowth consistent with the distribution of minute levels of latent cells present in aviremic patients on effective ART.
Conclusions: Our results suggest that in vivo-based hmVOA is more sensitive than the standard in vitro qVOA in detecting the latently infected cells. The reasons for better sensitivity are attributed to a more physiological in vivo environment in present in hu-mice versus in vitro culture for the longer term cell survival as well as potent xenograft reaction possibly resulting in better viral induction. These findings set the stage for further improvement and refinement of the hmVOA in HIV latency and cure research.

MOPEA0051

Suppressive myeloid cells of the human testicular interstitium: implication for HIV-1 persistence

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Background: Despite viral control in antiretroviral therapy (ART)-treated individuals, HIV persists in anatomic reservoirs. We demonstrated the presence of HIV DNA in the testes of individuals receiving ART. In animal models, the testis is described as a site of immune privilege where immune responses are suppressed, notably through the expression of indoleamine 2,3-dioxygenase (IDO) in macrophages and dendritic cells (DCs). Herein, we characterized human testicular myeloid cells and evaluated their immunosuppressive properties that may contribute to HIV persistence.
Methods: Matched testis and blood samples were collected from 9 uninfected individuals undergoing sex reassignment surgery. Peripheral blood mononuclear cells (PBMCs) were isolated by ficoll gradient density centrifugation and testicular cell suspensions were obtained by enzymatic digestion. Myeloid (mDCs), plasmacytoid (pDCs) dendritic cells and myeloid-derived suppressor cell (MDSCs) were assessed using multicolor flow cytometry. In situ localization of testicular immune cells was evaluated by immunostaining of frozen sections. IDO mRNA expression was quantified by qPCR.
Results: Testicular cell suspensions contained 9% of leukocytes, of which 30% were myeloid cells. Testicular myeloid cells harbored a higher expression of MHC class II molecules than their peripheral counterparts (p=0.004). Immunosuppressive macrophages (lin$^-$ HLA-DR$^+$ CD14$^+$ CD163$^+$) represented 20% of the testicular leukocytes.
The majority of testicular DCs (lin$^-$ CD14$^-$ HLA-DR$^+$) were mDCs (CD11c$^+$), contrasting with rare pDCs (CD123$^+$). MDSCs were not detected in the testis while representing 0.5% of PBMCs. IDO-secreting macrophages and mDCs as well as T cells were detected in the testicular interstitium but not pDCs. Importantly, IDO mRNA levels were remarkably higher in the testis than in PBMCs (p<0.001).
Conclusions: Our results show for the first time the existence of an immune privilege mediated by immunosuppressive myeloid cells in the human testis, which creates a „safe harbor" for HIV. Such findings will contribute to orient tissue-specific viral eradication strategies.

MOPEA0052

Analysis of microRNA differential expression patterns during HIV-1 reactivation to identify new molecules involved in HIV-1 latency

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Background: Despite antiretroviral treatments, HIV-1 remains integrated in reservoir cells. Non-productive expression after viral integration may result from insufficient levels of transcriptional activators, chromatin silencing, and specific microRNA activity etc. Indeed, some data show that microRNAs could contribute to the establishment of latency. Several therapeutics approaches are investigated to achieve HIV-1 eradication from the reservoirs by using latency-reversing agents (LRAs) to disrupt the latency. The use of LRAs, targeting multiple pathways combined with anti-retroviral therapy may accelerate viral reservoirs exhaustion. To find markers and new targets of HIV-1 latency, we have analyzed microRNA/mRNA expression patterns during HIV-1 reactivation.
Methods: We used a HIV-1 latent model in lymphocytes, monocytes and macrophages that expresses HIV-1 Gag protein fused with the Green Fluorescence Protein (GFP). By using Western-blot, fluorescence, cell viability assay, flow cytometry and RT-qPCR we have set up and characterized the conditions for HIV-1 reactivation. We used several LRAs including Histone deacetylase inhibitors, Histone Methyltransferase inhibitors, Bromodomain inhibitors, and Akt/PKC agonists. Reactivated cells were sorted by FACS and the RNA expression profiles were analyzed by RNA Sequencing.
Results: We set up and characterized the HIV-1 latent model by using different LRAs. We showed that the drugs: JQ1, HMBA, Chaetocin, SAHA, prostratin and Disulfiram reactivate viral expression by different mechanisms. The reactivation patterns are different for each LRA and also for each cell type (lymphocytes, monocytes and macrophages). Based on the reactivation and the cell viability, we determined the best days of reactivation for each LRA and each cell type. We also observed that the combination of two LRAs, Prostratin and SAHA, was the best reactivator treatment. We then decided to use these treatments to analyse the RNA expression profiles. In this model, we can distinguish reactivated cells by the expression of GFP. We isolated the reactivated and the non-reactivated cells after the reactivation treatments and then purified RNAs. We are currently analyzing the microRNA expression profiles of the reactivated and non-reactivated cells.
Conclusions: We expect to identify novel microRNA-based latency mechanisms. These results will help to identify strategies to eliminate the virus from the reservoirs.

MOPEA0053

Intact HIV-1 provirus is enriched in effector memory and HLA-DR$^+$ memory CD4$^+$ T cells

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Background: The proportion of replication-competent HIV-1 genomes in memory CD4$^+$ T cell subsets, including cells considered resting or activated, during antiretroviral therapy (ART) is unclear. To address this issue, we used a novel full-length HIV-1 sequencing assay to examine the distribution of intact proviruses within memory CD4$^+$ T cell subsets during ART.
Methods: Naïve, central (CM), transitional (TM) and effector (EM) memory CD4$^+$ T cells, as well as CD45RA$^-$HLA-DR$^+$ and CD45RA$^-$HLA-DR$^-$ CD4$^+$ T cells, were sorted from the peripheral blood of six participants who initiated ART during either acute (n=3) or chronic (n=3) infection. Cellular DNA was subjected to nested PCR, using LTR-specific primers at the limiting dilution, to isolate near complete individual genomes. The resulting 30-40 amplicons per cell subset were subjected to next-generation sequencing, and proviruses were characterized as defective (containing INDELs, stop codons or APOBEC3G hypermutation) or intact (lacking defects).
Results: All cell subsets contained intact proviruses except for the CM subset, which contained only defective proviruses (0/125 isolated sequences intact). The number of HIV-1 positive cells varied significantly across T cell subsets ($p < 0.001$), with the highest infection frequency in HLA-DR$^+$ cells. The proportion of intact provirus was also significantly different across the cell subsets ($p = 0.001$), with HLA-DR$^+$ and EM cells containing the highest proportion of intact genomes. The HLA-DR$^+$ subset contained the highest frequency of cells infected with a genetically intact provirus (48 versus < 10 infected cells/million cells in HLA-DR$^+$ versus all other subsets).The proportion of genetically intact virus isolated from participants treated during acute (5.6 ± 2.4 %) or chronic (3.8 ± 0.90 %) infection was similar ($p = 0.73$).
Conclusions: The HLA-DR marker identifies cells containing a high frequency of intact HIV-1 genomes, therefore assays quantifying the HIV-1 reservoir should include cells expressing HLA-DR. The lack of observable replication-competent proviruses in CM indicates that the majority of rebound virus is not derived from these cells. Similar proportions of intact genomes in participants treated during acute or chronic infection indicates that the replication-competent HIV-1 reservoir is established during acute infection, further supporting the need to initiate ART as early as possible.

MOPEA0054

Inhibition of HIV-1 replication in macrophages by the neuropeptides VIP and PACAP: analysis of the inhibitory potential and mechanisms

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Background: VIP and PACAP are high similar members of Secretin/Glucagon family of peptides, sharing immunoregulatory functions, besides other systemic actions. We have reported that VIP and PACAP treatment of HIV-1-infected macrophages reduces viral production (Temerozo et al, 2013). Here, we show their potential to confer resistance to HIV-1 infection and identify molecular mechanisms engaged in macrophages.
Methods: Monocyte-derived macrophages (MDM) from healthy donors were infected with HIV-1, exposed to VIP or PACAP under different conditions, and viral replication was assessed by ELISA to p24 antigen. Statistics were done using One or Two-way ANOVA, with Bonferroni's or Sidak post test, respectively.
Results: VIP or PACAP (10 nM) inhibited HIV-1 replication (38% inhibition) when added to MDMs before infection, likewise neuropetide treatment after infection (51% inhibition). Viral replication was also inhibited in infected macrophages exposed to multiple sub-optimal input (1 nM) (47% inhibition for VIP and 66% inhibition for PACAP), comparable with a single optimal dose (58% for VIP and 45% for PACAP). Upon sequencing the provirus, we found that treatment with neuropeptides promoted mutations, similar to those induced by IFN-α. VIP and PACAP receptors were identified in both infected and uninfected macrophages by immunofluorescence. We detected, in signaling studies, that VIP effect was impaired by PKA or PKC inhibition, whereas PACAP effect diminished only with PKC blockage. Through immunoblotting, we observed that VIP induced activation of PKA and PKC, and that PACAP activated only PKC. Next, VIP and PACAP induced CREB activation and inhibition of NF-kB, and down modulated the levels of Cyclin D1 in HIV-1-infected macrophages.
Conclusions: Our study shows that VIP and PACAP render MDM more resistant to HIV-1 replication in different treatment protocols, and promote mutations in the provirus, indicating that these neuropeptides can modulate key regulators of HIV-1 replication. We found that HIV-1 inhibition by VIP and PACAP is mediated by PKA and PKC, and some of the molecular mechanisms could involve the activation of CREB and the down modulation of NF-kB activity and Cyclin D1. The action on transcription factors and its regulators implicates that, at some level, mechanisms related to HIV-1 proviral transcription/latency could be involved in our model.

MOPEA0055

Major contribution to HIV reservoirs of peripheral blood T follicular helper cells in HIV treated patients with low HIV reservoirs

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Background: Recently two minor peripheral blood subsets of memory-stem cells (SCM) and T follicular helper CD4 T-cells (TfH) have been shown to harbor HIV provirus. While low levels of HIV-reservoir achieved in some treated patients appears to be necessary, though probably not sufficient, to reach functional cure, the relative contribution of SCM and TFH to these low HIV-reservoirs remains unknown. The Resachron study aims to decrypt the contribution of SCM and TfH subsets to these low HIV-reservoirs compared to major memory CD4 T cell subsets.
Methods: The Resachron cross-sectional study enrolled 17 patients under-cART with CD4 counts >400/mm^3, pVL< 50 copies/mL and low HIV-DNA< 200 copies/10^6 PBMCs. The CD4 T-cells were sorted as total naïve cells (TN) and TN depleted of CD95+SCM (TN-SCM), total central-memory (CM) and CM depleted of CXCR5+TfH (CM-TfH), transitional-memory (TM) and effector-memory (EM) subsets. HIV-reservoirs were quantified as total HIV-DNA in PBMCs and sorted subsets using ultrasensitive PCR and analyzed for correlation with cell activation. Results were expressed as subset contribution to total HIV-reservoirs and blood concentrations of subsets reservoirs.
Results: The total CM and TM subsets were the major HIV-reservoirs by contributing up to 50.8% and 19.9%, respectively to the total blood HIV-reservoirs. The total CM reservoir concentration in blood was 76 copies/mL. After CM depletion in TfH (TfH represented 32% of total CM), the CM-TfH reservoir dropped down to 19 copies/mL (p=0.03) with a CM-TfH contribution to HIV-reservoirs falling down to 11.7% (p=0.01 vs total CM). In total TN, HIV-DNA was below limit of detection (< 66 copies/10^6 PBMCs) in 65% cases and TN contributed only to 6.6% of reservoirs. After TN depletion in SCM (SCM represented 2.5% of TN), changes in undetectable reservoir levels were not interpretable. Finally, proportions of CD4+ CD25+ activated T-cells correlated with HIV-DNA levels in CM (r=0.732, p=0.004).
Conclusions: In virologically-suppressed cART-treated patients with low HIV-reservoirs, TfH represent a major reservoir for HIV, at least equivalent to the reservoirs contained in bona fide CM cells. These results point to the key contribution of TfH issued from lymph nodes to these low HIV-reservoirs, opening new perspectives for strategies towards HIV remission.

MOPEA0056

Contribution of peripheral blood and colon myeloid cells to HIV persistence during ART

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Background: Antiretroviral therapy (ART) controls HIV-1 replication to undetectable levels; however, HIV eradication is not achieved. The persistence of HIV reservoirs during ART is well established in CD4+ T-cells, but the contribution of myeloid cells remains controversial. While monocytes are resistant to HIV, monocyte-derived dendritic cells (MDDC) and macrophages (MF) are well-established HIV targets. Herein, we investigated the contribution of myeloid cells obtained from the blood and colon to HIV persistence during ART.
Methods: Total monocytes, CD16+/CD16- monocyte subsets, and/or CD1c+ DC were isolated from leukapheresis (n=2-12), while matched myeloid cells (lineage-HLA-DR$^+$) and CD4+ T-cells were isolated from sigmoid biopsies of ART-treated individuals (HIV+ART) (n=13), using magnetic and/or flow cytometry sorting. The presence of early (RU5), late (Gag), and integrated HIV-DNA was measured by nested real-time PCR in 3-10 replicates of 10^5 cells / test. Co-cultures of monocytes (10^6) with TCR-activated CD4+ T-cells (10^6) from HIV-uninfected individuals allowed detection of replication-competent HIV.
Results: RU5 but not Gag/integrated HIV-DNA was detected in total monocytes of 3/12 HIV+ART individuals. Low/undetectable levels of HIV replication were detected upon co-culture of monocytes of HIV+ART individuals with heterologous activated uninfected CD4$^+$ T-cells, indicative of low levels of replication-competent HIV persistence in monocytes. CD16+ but not CD16- monocytes sorted from 1/2 individuals carried Gag HIV-DNA (63 HIV-DNA copies/10^6 cells), while RU5 but not Gag/integrated HIV-DNA was detected in blood CD1c+ DC of 1/2 individuals (341 HIV-DNA copies/10^6 cells). Finally, in sigmoid mucosa biopsies, Gag HIV-DNA was detected in myeloid cells of 1/13 individuals (1562 HIV-DNA copies/10^6 cells), while CD4+ T-cells from 11/13 donors tested carried high levels of Gag HIV-DNA (303-7124 HIV-DNA copies/10^6 cells).
Conclusions: These results support a minor role played by myeloid cells from blood and colon to HIV reservoir persistence during ART relative to CD4+ T-cells. However, CD16+ monocytes and CD1c+ DC from blood of certain individuals may fuel viral reservoirs considering their tissue recirculation potential. Assessment of lymphoid tissues and other anatomic sanctuaries will be required to consider or not myeloid cells as relevant cellular reservoirs for HIV.

MOPEA0057

Ultrasensitive HIV-1 p24 detects single infected cells and differences in reservoir induction by latency-reversal agents

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Background: The existence of HIV reservoirs in infected individuals under cART represents a major obstacle towards cure. Viral reservoirs are assessed by quantification of HIV nucleic acids, which does not discriminate between infectious and defective viruses, or by viral outgrowth assays, which requires large number of cells and long-term cultures.
Methods: Here, we used an ultrasensitive p24 digital assay, which we report to be 1000 fold more sensitive than classical ELISA in the quantification of HIV-1 Gag p24 production in HIV-infected individuals samples. Results from ultrasensitive p24 were compared to conventional viral RNA RT-qPCR based assays, and outgrowth assays readout by flow cytometry.
Results: Using serial dilutions and flow-based single cell sorting, we show that viral proteins produced by a single infected cell can be detected by ultrasensitive p24. This unique sensitivity allowed the early (as soon as day 1 in 49% of cases) and more efficient detection and quantification of p24 in PHA-stimulated $CD4^+$ T cells from individuals under effective cART. When testing seven different classes of latency reversal agents (LRA) in resting $CD4^+$ T cells from HIV-infected individuals, ultrasensitive p24 revealed differences in the extent of HIV reactivation. Of note, HIV RNA production was infrequently accompanied by p24 protein production (19%). Among the drugs tested, prostratin showed a superior capacity in inducing viral protein production.
Conclusions: In summary, the ultrasensitive p24 assay allows the detection and quantification of p24 produced by single infected-$CD4^+$ T cells and provides a unique tool to assess early reactivation of infectious virus from reservoirs in HIV-infected individuals.

MOPEA0058

The mammalian target of rapamycin is a druggable key regulator of HIV-1 permissiveness in gut-homing CCR6+ Th17 cells

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Background: Gut-associated lymphoid tissues (GALT) are enriched in CCR6+ Th17-polarized CD4+ T-cells that orchestrate immunity against pathogens but also support HIV-1 replication and reservoir persistence during antiretroviral therapy (ART). Th17 cell frequency/functions are not restored by ART, thus raising the need for additional Th17-targeted therapies. In an effort to identify mechanisms governing HIV-1 permissiveness in gut-homing Th17 cells, we analyzed the transcriptome of CCR6+ versus CCR6- T-cells exposed to retinoic acid (RA), a gut-homing inducer, and performed functional validations in colon biopsies of HIV-infected individuals receiving ART.
Methods: Memory (CD45RA-) CCR6+/CCR6- T-cells were sorted from PBMCs using magnetic beads (Miltenyi) and FACS (BDAriaII). Cells were stimulated via CD3/CD28 in the presence/absence of RA and RNA was extracted for microarrays analysis (Illumina). Validations of microarrays were performed using RT-PCR and/or FACS. HIV replication was monitored in the presence/absence of mTOR inhibitors by HIV-DNA real-time PCR and ELISA/FACS HIV-p24 quantifications. HIV reactivation from T-cells of ART-treated individuals was measured using a RA-based viral outgrowth assay. Levels of CCR5, integrin β7 and phosphorylated mTOR expression were monitored by FACS on CCR6+/CCR6- T-cells from matched blood/colon biopsies of ART-treated individuals (n=7).
Results: Although both CCR6+ and CCR6- T-cells responded to RA in terms of RA-induced gene 1 and integrin α4β7 up-regulation, the modulation of unique sets of genes coincided with preferential HIV-1 replication in RA-treated CCR6+ T-cells. The RA-induced transcriptional signature in CCR6+ versus CCR6- T-cells included the up-regulation of HIV-dependency factors and the down-regulation of transcripts involved in viral restriction acting via entry/post-entry mechanisms. Noteworthy, the PI3K-Akt-mTORC1 signaling pathway and the mTOR expression/phosphorylation were selectively modulated by RA in CCR6+ T-cells. The mTOR inhibitors rapamycin and INK128 counteracted the effect of RA on HIV replication/reservoir reactivation by mechanisms independent on CCR5-mediated entry but depended on RORγt activity. Finally, higher CCR5 and integrin α4β7 expression, as well as mTOR phosphorylation, were observed in CCR6+ versus CCR6- T-cells infiltrating the colon of ART-treated individuals.
Conclusions: Together, our results identify mTOR as a druggable key regulator of HIV permissiveness in gut-homing CCR6+ T-cells and propose the use of mTOR inhibitors for mucosal immunity restoration during ART.

MOPEA0059

Massive full-length, next generation sequencing identifies clonally-expanded, genome-intact replication-competent HIV-1 in Th1 cells

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Background: HIV-1 remains an incurable disease due to long-lasting reservoirs of infected cells that are unaffected by suppressive antiretroviral therapy. However, the mechanisms that maintain long-term stability of such viral reservoirs are not well understood. Here, we used a near-full-genome deep sequencing approach to characterize HIV-1 DNA content in highly purified CD4 T cell subsets with distinct functional polarization.
Methods: Highly purified CD4 T cells secreting IFN-g (Th1), IL-4 (Th2), IL-9 (Th9), IL-17 (Th17), cytokine-negative control cells and unstimulated autologous CD4 T cells were sorted or enriched from ~500million PBMC obtained from chronically-infected ART-suppressed patients; these were matched with autologous longitudinally archived PBMC. Total DNA extracted from each sample/population was subjected to ddPCR HIV-1 DNA quantification (5'LTR-gag 127bp) and/or to single-template near-full-genome nested PCR (HXB2 coordinates 638-9632) followed by Illumina MiSeq deep sequencing. Viral outgrowth assays were performed according to standard protocols, followed by near-full length HIV-1 sequencing of MOLT cells co-cultured in transwells.
Results: Little variation was found between total HIV-1 gag DNA levels among the different polarized
T cell populations in ten study subjects. In subsequent full-genome sequencing assays from three patients, 1378 HIV-1 DNA amplicons were obtained; only 5% (70/1378) were genome-intact. Of these, 622/1378 were from polarized CD4 T cell populations; 26 (4%) were sequence-intact. The proportion of genome-intact sequences relative to the pool of all viral species was highest in Th1 cells 11% (17/158), followed by cytokine-negative-Th 3% (6/171), Th2 2% (2/85), Th17 1% (1/78), and Th9 0% (0/120) (Fisher $p=1x10^{-5}$, Th1 vs non-Th1). In seven distinct cases, groups of two to nine genome-intact viruses that shared 100% sequence identity over ~9000bp were detected from autologous polarized Th1 cells and/or unfractionated CD4 T cells and/or archived total PBMC, suggestive of clonal expansion of cells harboring intact provirus. Viral replication competence of an eight-member clonal cluster was confirmed by the detection of a 100% homologous sequence from viral outgrowth assays.
Conclusions: Th1-polarized cells seem to represent an important reservoir of cells harboring genome-intact and replication-competent HIV-1 sequences during antiretroviral therapy. Proliferation of such cells may contribute to maintaining and expanding the HIV-1 infected cell pool.

MOPEA0060

Role of peroxisome proliferator activated receptor-gamma in regulating inflammatory signalling in HIV-1 associated brain inflammation

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Background: Despite the use of combination antiretroviral therapy for the treatment of HIV-1 infection, cognitive impairments remain prevalent due to persistent viral replication and associated brain inflammation. Primary cellular targets of HIV-1 in the brain are microglia and astrocytes which in response to infection release inflammatory markers, viral proteins [i.e., glycoprotein 120 (gp120)] and exhibit impaired glutamate uptake. Peroxisome Proliferator-Activated Receptors (PPARs) are members of the nuclear receptor superfamily of ligand-activated transcription factors.
Compelling evidence suggests that PPARs exert anti-inflammatory properties in neurological disorders. The goal of this study was to examine the role of PPARgamma in the context of HIV-1 gp120 induced inflammation in vitro, in primary cultures of rat astrocytes and in vivo, in a rodent model of HIV-1-gp120-associated brain inflammation.
Methods: Primary mixed cultures of rat astrocytes and microglia were treated with PPARgamma agonists (rosiglitazone or pioglitazone) and exposed to $gp120_{ADA}$. Inflammatory and oxidative stress markers (TNFalpha, IL-1beta, iNOS) were measured using qPCR and glutamate transporter (GLT-1) was quantified by immunoblotting. In vivo, rats were administered an icv injection of gp120 and an intraperitoneal (ip) injection of PPARgamma agonist (rosiglitazone) or co-administration with PPARgamma antagonist (GW9662). qPCR and immunoblot analysis were applied to measure inflammatory markers, GLT-1 and PPARgamma.
Results: In primary mixed cultures of rat astrocytes and microglia, $gp120_{ADA}$ exposure resulted in a significant elevation of inflammatory markers, and a decrease in GLT-1 expression which were significantly attenuated with rosiglitazone or pioglitazone treatment. Similarly, in vivo, treatment with rosiglitazone reversed the gp120 mediated inflammatory response and downregulated GLT-1 in the rodent brain. Co-administration with PPARgamma antagonist (GW9662) abolished the anti-inflammatory effects of rosiglitazone.
Conclusions: To date, we have established an acute in vivo rodent model of $gp120_{ADA}$ induced brain inflammation and demonstrated the role of PPARγ activation in reversing this effect. Our data suggest that targeting PPARγ signaling may provide a therapeutic option for preventing/treating HIV-associated brain inflammation.

MOPEA0061

Factors associated with increased number of unique integration sites during early ART

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Background: Asymptomatic replication of Cytomegalovirus (CMV) and Epstein Barr Virus (EBV) is frequent during HIV-infection and is associated with chronic inflammation and slower decay of HIV DNA during antiretroviral therapy (ART). We investigated the frequency and distribution of unique integration sites (UIS) of HIV DNA within the human genome in the setting of CMV and EBV replication.
Methods: We evaluated 25 longitudinal PBMC samples from 5 CMV/EBV-seropositive, recently HIV-infected men. Participants started ART within 5 months from estimated date of infection (EDI) and sustained viral suppression for >4 years thereafter. Levels of HIV, CMV and EBV DNA were measured by ddPCR at each time-point. Genomic DNA was fragmented by sonication, amplified by ligation-mediated PCR targeting the HIV 3LTR and sequenced using the MiSeq Platform. Individual reads were mapped to the human genome using BLAT and RefSeq.
For IS located within a gene, we determined annotation and enrichment of biological functions using the DAVID Functional Annotation Tool. The effect of EBV and CMV replication on the number of UIS was evaluated using mixed-effect regression analyses (R statistical software). Additional covariates were current and nadir $CD4^+$ counts, EDI, time from EDI to ART start, HIV DNA and peak HIV RNA.
Results: We identified 459 UIS among all participants (median: 4, IQR [1-12]). HIV DNA was enriched into genes associated with biological processes, e.g. alternative splicing, ATP and nucleotide binding proteins, intercellular organelles, transcription, and protein kinases. Higher numbers of UIS during ART were significantly associated with (i) higher levels of HIV DNA, (ii) higher levels of EBV, (iii) lower current and nadir $CD4^+$ T-cells, (iv) shorter EDI (v) lower levels of CMV (all $p<0.001$). In a multivariate analysis, higher levels of EBV ($p<0.001$), lower CD4 Nadir ($p=0.008$) and shorter EDI ($p<0.001$) remained significantly associated with increased UIS ($P<0.001$) after adjusting for HIV DNA, while CMV and current CD4 did not ($p>0.2$).
Conclusions: Presence of EBV replication, lower Nadir $CD4^+$ and shorter time from EDI were associated with higher frequencies of UIS during suppressive ART. How these factors may be associated with HIV integration or clonal expansion should be investigated further.

MOPEA0062

Characterization of the active viral reservoir by a novel single cell RNA FISH-flow method in samples from HIV-infected individuals

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Background: Latently-infected cells have been postulated as the main barrier to fully eliminate HIV-1 from the human body. The "active viral reservoir" has been found in both, treated and untreated HIV-infected patients, and encompasses cells actively transcribing HIV-RNA, representing a portion of the entire HIV reservoir. Here we have validated and used a novel single cell FISH methodology that detects intracellular HIV-1 RNA molecules by flow cytometry with the aim to characterize the cell subpopulations actively transcribing HIV. Moreover, we used the RNA FISH/flow method to assess viral reactivation of primary $CD4^+$ T cells from antiretroviral treated HIV-infected patients.
Methods: The Human PrimeFlow® RNA Assay (eBioscience) was performed with a high sensitivity target-specific set of 50 probes targeting the Gag-Pol HIV-mRNA sequence. The proportion of cells expressing HIV-RNA was quantified in 15 millions of unfractionated PBMCs samples from untreated and treated HIV-infected patients. Viral reactivation was evaluated after stimulation of primary $CD4^+$ T cells with PMA/Ionomycin. Quantification of HIV-DNA and intracellular HIV-RNA was performed by qPCR using genetic material obtained from purified $CD4^+$ T cells.
Results: Effector memory $CD4^+$ T cells were identified as the main subset supporting HIV-RNA transcription during treated and untreated HIV infection. In patients with high viral load, HIV-RNA transcription was also detected in central memory cells. There was a direct correlation between the proportion of cells expressing HIV transcripts and either, plasma viral load, proviral DNA and intracellular HIV-RNA measured by qPCR. On the contrary, an inverse correlation was observed with absolute $CD4^+$ T cell counts, percentage of $CD4^+$ T cells and CD4/CD8 ratio. In addition, this novel RNA FISH/flow assay detected increased numbers of primary cells expressing viral transcripts and protein after ex-vivo viral reactivation with an activating stimulus.
Conclusions: This study identifies effector memory CD4+ T cells as the main cellular source of the "active viral reservoir" during both untreated and treated HIV-infection. Furthermore, this technique might be useful to evaluate the effectiveness of different latency-reversing agents in primary HIV-infected samples.

MOPEA0063

The lungs as anatomical reservoirs of HIV: enrichment in HIV-infected cells and skewed T-cell distribution in the lungs of HIV-infected adults under suppressive ART

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Background: Despite the success of antiretroviral therapy (ART), HIV reservoirs remain the primary impediment to HIV eradication. The lungs represent important but almost neglected HIV reservoirs in the ART era. Here, we characterized pulmonary T-cells and their contribution to HIV reservoirs compared to blood in ART-treated adults.
Methods: Bronchoscopies were performed to obtain bronchoalveolar lavage (BAL) fluid and matched blood samples were drawn from 15 ART-treated individuals (suppressed viral load for ≥3 years and CD4 count ≥350 cells/mm^3) without any active respiratory symptoms. Pulmonary mucosal cells were purified from BAL and the frequency of T-cell subsets, the expressions of immune activation and senescence markers were assessed using multicolor flow cytometry. The frequency of cells harboring total and integrated HIV DNA was measured by real-time PCR in total BAL cells and PBMCs.
Results: Participants with detectable levels of total HIV DNA in both PBMCs and BAL cell pellets displayed greater frequencies of infected cells in the lung compared to blood (p=0.04). A substantial decrease in naïve and central memory T-cells and a massive increase in effector-memory CD4 and CD8 T-cell subsets were observed in lungs vs. blood (p<0.001, p≤0.03, p<0.001, respectively). Importantly, total, central and effector memory pulmonary CD4 T-cells expressed higher levels of the activation marker HLA-DR when compared to their circulating counterparts (p<0.01 for all comparisons). Interestingly, the lungs were enriched in senescent CD4 T-cells (CD28-CD57+, p=0.003) and double negative T-cells, previously proposed as potential cellular reservoirs for HIV (CD4-CD8α-CD8β- and CD4-CD8α-TCRαβ-TCRγδ-; p<0.001, p=0.008, respectively). No difference in the frequencies of regulatory T-cells and Th17 cells was noted between the 2 compartments. However, a higher frequency of two recently described HIV reservoirs, Th1/Th17 and CXCR3-CCR4+CCR6+ T-cells, was observed within the lungs (p=0.004, p=0.003, respectively).
Conclusions: Compared to blood, higher HIV burden within the lungs is accompanied with a higher CD4 T-cell immune activation and greater frequencies of various T-cell subsets known as cellular reservoirs of HIV including effector memory CD4 T-cells, double negative T-cells, Th1/Th17 and CXCR3-CCR4-CCR6+ cells. Our results suggest the potential contribution of distinctive T-cells distribution in lungs as anatomical reservoir for HIV during ART.

MOPEA0064

Memory CD4$^+$CD45RO$^+$SAMHD1^{low} cells exhibit distinct genes profile and contain the highest level of HIV-1 DNA with segregated HIV-1 populations

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Background: c-ART cannot fully eradicate HIV-1 due to persistence of the reservoir. We have reported the presence of memory CD4$^+$ T-cells that display low levels of SAMHD1 (SAMHD1^{low}), are enriched in T-regulatory, Th17 and T-follicular helper cells and are productively infected in vitro (Ruffin et al. AIDS, 2015). Here we investigated whether SAMHD1^{low} cells are characterized by a distinct gene expression profile and contain high levels of HIV-1 DNA with distinct HIV-populations.
Methods: Patients (pts; n=36) on c-ART (median: 7y) with median CD4+ counts and nadir of 549 cells/ul and 210 cells/ul, respectively and 6 elite-controllers (HIC) (CD4+: 900 cells/ul) were studied. Memory CD4$^+$CD45RO$^+$SAMHD1^{low} and CD45RO$^+$SAMHD1^{high} together with naive CD45RO$^-$SAMHD1^{high} cells were sorted. Gene expression analyses were performed using Illumina Human-HT-12 V4-BeadChips. Cell-associated HIV-1 DNA levels were quantified (HIV-DNA Cell, Biocentric) and ultra-deep-sequencing (UDS, 454/Roche) of partial env (C2/V3) HIV-1 DNA was performed. Sequenced reads were quality-filtered and assembled using an in-house data processing-pipeline to characterize the HIV-DNA populations in sorted subsets.
Results: Memory SAMHD1^{low} cells exhibited a distinct gene profile with significant up-regulation (Fold change 3; p< 0.03) of activation, proliferation and phagocytosis pathways. Memory SAMHD1^{low} from c-ART pts showed high levels of DNA compared to SAMHD1^{high} cells (Median: 4.5 [3.1-6.2] vs 3.8 [2.9-5.7] log/10^6 cells, respectively, p=0.02), while naïve CD45RO$^-$SAMHD1^{high} showed lower levels (3.1 [1.6-4.4]). HIC exhibited low HIV-1 DNA in both SAMHD1^{low} and SAMHD1^{high} cells (1.6 and 2.3 log/10^6 cells, respectively, p>0.05). Naïve CD45RO$^-$SAMHD1^{high} from HIC showed lower DNA compared to naïve CD45RO$^-$SAMHD1^{high} from c-ART pts (1.6 and 3.1 log/10^6 cells, respectively, p=0.01). Phylogenetic analyses of UDS data revealed well segregated HIV-DNA populations between subsets. FST and Slatkin Maddison approaches confirmed significant compartmentalization between SAMHD1^{low} and SAMHD1^{high} cells in all but 2 participants (p< 0.001) with limited viral exchange, predominantly directed from CD45RO$^-$SAMHD1^{high} toward CD45RO$^+$SAMHD1^{high}.
Conclusions: Our data contribute to characterize the landscape of HIV reservoir. We show that memory SAMHD1^{low} cells exhibit distinct genes profile which segregates them from the SAMHD1^{high} counterpart, and contain the highest level of HIV-DNA. Moreover, we reveal distinct/well-segregated HIV DNA populations in both subsets, suggesting minimal viral exchange.

MOPEA0065

2LTR circle dynamics during integrase inhibitor monotherapy in the presence and absence of CD8$^+$ cells

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Background: 2LTR circles are extrachromosomal products generated upon failed integration of HIV/SIV into the host genome. It is predicted that 2LTR circle levels will increase during therapy including integrase inhibitors, but little is known about fluctuations of these isoforms during integrase inhibitor monotherapy (INT). To this end, we explored the effects of raltegravir (RAL) monotherapy on SIV-infected rhesus macaques (RMs) in the presence or absence of CD8$^+$ T cells.
Methods: Twenty RMs were intravenously-infected with SIVmac251 and were given the CD8$^+$ T-cell depleting antibody M-T807R1, RAL monotherapy, or a combination of both, with RAL treatment interrupted after 23 days. Blood was routinely sampled and lymph nodes (LNs) were biopsied. Plasma viral loads (VLs) and 2LTR circles from PBMCs and lymphocytes from LNs were measured with qRT-PCR, with 2LTR circles normalized by co-quantifying CCR5 expression.
Results: The CD8 depletion group had an immediate 1 log increase in VLs and a slower increase in PBMC 2LTR levels following depletion, with a noticeable increase in 2LTR circles 30 days after complete CD8$^+$ T-cell suppression. The INT group had an overall sharp decline in VLs (between 0.5-2.5 logs) upon RAL initiation but did not exhibit a change in 2LTR levels in PBMCs. The RAL + CD8 depletion group exhibited a similar increase in VLs following CD8$^+$ T-cell depletion and a weaker decline following RAL initiation, but showed a strong increase in 2LTR circles immediately following RAL initiation that remained elevated throughout RAL treatment and after CD8$^+$ T-cells recovered. Interestingly, only the RAL + CD8 depletion group exhibited a strong increase in 2LTR circles in the LNs following RAL treatment, while the other two groups' LNs maintained steady 2LTR levels.
Conclusions: We have shown for the first time that INT does not significantly increase levels of 2LTR circles in PBMCs or in LNs, likely due to the rapid decrease in VLs and subsequent infection events following INT initiation. However, CD8$^+$ T-cell depletion increases 2LTR levels, which are enhanced in the presence of INT. This data suggests a potential role of CD8$^+$ cells in controlling the levels of 2LTR isoforms during HIV/SIV infection.

MOPEA0066

HIV reservoirs in developing countries: implication for HIV CURE strategies

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Background: We measured the size of HIV RNA and DNA reservoirs in lymphatic tissue (LT) before and during ART in a group of HIV chronically infected Ugandans.
Methods: Cross-sectional and longitudinal quantification of HIV RNA/DNA (vRNA & vDNA) positive cells was done by in situ-hybridization with probes specific for HIV clades A & D in tissues from lymph node(LN) and rectal biopsies from HIV-infected Ugandans at the Joint Clinical Research Centre (JCRC), Uganda before and during prolonged ART.
Results: We enrolled 20 HIV+ people, mean age 32years, 50% were women, and mean CD4 T-cell count was 174 cells/mm^3(range 30-309 cells/mm^3). The mean plasma viral load was 81,827 copies/ml(range 736-908,930 copies/ml). A subset of 14 participants were followed for a mean of 4years (range 2-6years) after starting ART with multiple repeat LN and rectal biopsies. The mean frequency of vRNA+ cells in LN prior to ART was 9.4x10^4 cells/gram (range 6.3x10^3-3.5x10^5 cells/gram) and 2.0x10^5 cells/gram(range 2.3x10^4-9.6x10^5 cells/gram) in the rectum, similar to measures made in Clade B HIV infection. Before ART, the mean frequency of vDNA+ cell in LN was 6.2x10^7 cells/gram LT(range 8.3x10^6-1.3x10^8) vDNA+ cells/gram. The impact of ART on the LT reservoir in subjects who had been treated for >2 years (range 2-6 years) was surprisingly modest. ART only reduced the mean frequency of vDNA+ cells by about 1 log, to 2.3x10^6 cells/gram (range 1.1x10^5-7.3x10^6 cells/gram). This decrease is substantially less than we previously documented after six months of ART, albeit in a patient population from the US with a mean CD4 T-cell count of 467 cells/ul at entry. However, in gut tissues we did not document any decrease in the size of the vDNA reservoir. Prior to ART the frequency of vDNA+ cell was 3.8x10^5 cells/gram LT(range 1.8x10^5-8.4x10^5) and after >2 years of ART (range 2-6 years) the mean was 2.6 x 10^5 cells/gram (range 1.0x10^5-4.5x10^5 cells/gram).
Conclusions: ART had modest effect on the viral reservoir in this Ugandan cohort. The large size and stability of the DNA reservoir underscores the challenges to eradicating chronic HIV infection with current approaches, especially in the developing world.

MOPEA0067

In vivo massive expansion of a T-cell clone carrying a defective HIV genome: implication for the measurement of the HIV reservoir

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Background: HIV persists as an integrated genome in memory CD4$^+$ T cells during ART. Infected cells have the ability to survive and to proliferate, thereby ensuring the long-term stability of the viral reservoir. Here we report the unique case of an HIV-infected individual on suppressive ART with a massive expansion of an HIV infected T-cell clone.
Methods: The participant (57 year-old African American man) received suppressive ART for more than 3 years at the time of leukapheresis.
Results: Measurement of HIV DNA in isolated CD4$^+$ T cells by Alu-qPCR revealed that an unusually high frequency of cells carrying integrated genomes (31,070 copies per million cells). In contrast, the frequencies of CD4$^+$ T cells harbouring inducible HIV RNA by TILDA and replication competent virus by mQVOA were in the normal ranges of virally suppressed individuals (45 and 0.87 cells per million respectively), suggesting that the vast majority of the proviruses detected by Alu-PCR was defective. Circulating CD4$^+$ T cell subsets (Naïve, Central, Transitional, Effector memory and Terminally differentiated cells (N, CM, TM, EM and TD, respectively)) were sorted by flow cytometry. Strikingly, 44% of EM cells harboured integrated HIV DNA, representing 97% of all integrated viral genomes in the blood of this participant. Single-genome sequencing of the envelope gene revealed a unique sequence in the EM subset. This was consistent with the identification of the massive overrepresentation of a specific integration site in chromosome 14, gene RPS6KA5. The massive expansion of a defective provirus suggested proliferation of a particular clone of EM cells, which was confirmed by TCR sequencing, with 60% of EM cells sharing the same rearranged TCR.
Conclusions: These results indicate that massive clonal expansion of defective genomes can occur in vivo, leading to a >35,000 fold difference between PCR and QVOA measurements. These proliferation events may contribute to the weak association between DNA measurements and replication competence in some individuals.

MOPEA0068

Inhibition of HIV-1 infection by bi-specific immunoadhesin-IgA in humanized mice

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Background: Human immunodeficiency virus type one (HIV-1) is mainly a sexually transmitted virus. However, there is no effective vaccine to prevent HIV-1 mucosal transmission. IgA antibody may play a determinant role in mucosal protection yet few broadly neutralizing antibody (bNAbs)-IgA have been reported thus far.
Methods: In this study, we generated two bi-specific immunoadhesin-IgAs, BiIA-IgA$_1$ and BiIA-IgA$_2$, trying to improve their breath and potency against HIV-1 mucosal infection by combining single-chain variable fragment(ScFv) of bNAbs. They were characterized in vitro by ELISA, FACS and neutralization assays. Moreover, we evaluated their efficacy in humanized NSG mice against HIV$_{JR-FL}$ challenge. Viral load and p24+ T cell were measured in mouse blood by Q-PCR and FACS. P24$^+$ T cells in spleen, lung, intestine and rectum were stained by immunohistochemistry.
Results: BiIA-IgA$_1$ and BiIA-IgA$_2$ were successfully expressed as soluble antibodies after transfection into human 293 T cells. Both of them were able to bind their corresponding target antigens specifically. They displayed anti-HIV activities yet the potency was slightly weaker than the parental BiIA-IgG$_1$. The half-life was similar between BiIA-IgA$_1$ and BiIA-IgA$_2$ but was shorter than that of BiIA-IgG$_1$ after intramuscular injection in mice. Interestingly, intramuscular BiIA-IgA$_2$ resulted in mucosal distribution and displayed more potent protection against intraperitoneal challenge by HIV$_{JR-FL}$ when compared with BiIA-IgA$_1$.
Conclusions: Our findings indicated that BiIA-IgA$_2$ is effective against systemic HIV-1 infection, which warrants ongoing investigation for mucosal prophylaxis.

MOPEA0069

The male organs source of AIDS virus in semen uncovered through phylogenetic analysis

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Background: Semen remains the main vehicle for HIV-1 dissemination. HIV-1 strains in semen differ from those in the blood (i.e., compartmentalized) in over 50% of infected men, and HIV-1 can persist in this body fluid despite suppressive antiretroviral therapy, indicating local viral production. In this study, we aimed to identify the tissue sources of HIV/SIV in semen and decipher the factors involved in virus compartmentalization and excretion within the male genital tract.
Methods: Five chronically infected Asian macaques were screened for viral compartmentalization in semen and testis, epididymis, vas deferens, seminal vesicle, prostate and urethra using single genome amplification of full HIV env gene and genetic analyses [phylogenies, tree-based (AI, S-M, r and rb) and Fst]. In order to investigate parameters associated with compartmentalization and excretion, the infection levels of genital organs and their expression of a range of molecules (cytokines, cell markers, antiviral/restriction factors) were assessed by quantitative PCR. Infected cells nature and localization was determined by immunohistochemistry and in situ hybridization.

Results: Compartmentalized SIV populations were identified in testis, epididymis, vas deferens, seminal vesicles and urethra from two macaques displaying compartmentalized virus in semen. We found genetic sequence similarities between viral strains present in semen and in epididymis, vas deferens or seminal vesicles from these individuals, thus highlighting the genital organs responsible for virus shedding in semen. The excretion of compartmentalized virus in semen was not associated with male organs' infection or inflammatory levels nor with the nature of infected cells within those organs.
Conclusions: This study uncovers for the first time the specific male genital organs which are source of HIV/SIV in semen. The factors involved in the compartmentalization and excretion from those organs are yet unclear and under further investigation. These data have important implications for our understanding of systemic virus shedding and persistence in semen, and provide a new basis for innovative targeted strategies to prevent and eradicate HIV in the male genital tract.

MOPEA0070

HIV cell-associated transmission in the colo-rectal mucosa *ex vivo* and its modulation by seminal plasma

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Background: It was recently shown that intra-rectal inoculation of SIV-infected cells is more effective in initiating infection than cell free virus in macaques. To date, cell-associated (CA) transmission has been largely overlooked, especially in the colo-rectal mucosa. Since the molecular events underlying CA transmission differ from those involved in cell-free virus transmission, improving our knowledge on HIV CA transmission in human mucosa, notably the nature of the infected seminal cell types involved and the influence of seminal plasma (SP), has important implications for vaccine and microbicide development. In this context, we aimed to decipher the seminal cell types involved in CA infection of the colo-rectal mucosa, the impact of SP and the mechanisms involved.
Methods: A polarized ex vivo explant model of human colo-rectal mucosa was developed, along with an in vitro model of colonic epithelial Caco2 cells. The apical epithelium of these models was exposed to the leukocytes which are known to be infected by HIV-1 in semen (CD4 T lymphocytes and monocytes/macrophages, CFSE-labeled), in the presence or absence of 10-50% of seminal plasma (SP). The integrity of the epithelial barrier before and after exposure was evaluated by permeability measure (Dextran leaking and trans-epithelial resistance) and by junction/adhesion molecules staining. Adhesion and transmigration of leukocytes through the colonic epithelium were evaluated by fluorescence microscopy.
Results: Transmigration of both T lymphocytes and monocytes/macrophages was observed through the intact epithelium of the colon mucosa as early as 1h post-exposure, with or without SP. SP did not modify the colon mucosal barrier integrity, nor the expression pattern of the adhesion molecules E-cadherin and JAM-A. The presence of activated T lymphocytes underneath the epithelial barrier increased leukocytes transmigration, as did the pro-inflammatory cytokines TNFa and IL-1b on the apical side.
Conclusions: This is the first demonstration of active and rapid transmigration of both T lymphocytes and monocytes/macrophages across the intact colorectal barrier. Our results suggest that seminal plasma has no effect on the colorectal barrier integrity nor on the ability of leukocytes to adhere and transmigrate through this barrier.

MOPEA0071

Vaginal bacteria modify HIV pre-exposure prophylaxis efficacy in African women

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Background: Pre-exposure prophylaxis (PrEP) to prevent HIV infection has shown inconsistent results in women. We investigated whether the vaginal microbiome modulated PrEP efficacy in the CAPRISA 004 tenofovir gel trial.
Methods: Cervicovaginal lavage (CVL) samples were collected during the CAPRISA 004 trial at quarterly study visits when pelvic examinations were performed. The last HIV-seronegative CVL available from the 62 HIV seroconvertors and a randomly selected CVL sample from the 626 HIV-negative women that were assigned to either the tenofovir or placebo gel, were analyzed by mass spectrometry and 16S rRNA sequencing. Lactobacillus dominant (LD) women had vaginal Lactobacillus proteins at >50% abundance. Tenofovir concentrations in CVLs and bacterial cultures were assessed by validated mass spectrometry methods. We used an in vitro culture system to assess biodegradation of tenofovir by major bacterial species identified.
Results: Two major bacterial community state-types were identified in the 688 women profiled; one of low diversity where Lactobacillus iners and crispatus were the most common (Lactobacillus-dominant (LD), 59.2%), and the other with high ecological diversity where Gardnerella vaginalis predominated, co-dominant with Prevotella, Mobiluncus, and other anaerobic bacteria (non-Lactobacillus-dominant (non-LD), 40.8%). Women with LD had three-fold higher protection than women with non-LD; HIV incidence rates in the tenofovir and placebo gel arms were 2.7 and 6.9 per 100 women-years in LD women (Incidence rate ratio (IRR)=0.39 (95% Confidence Interval) (CI) 0.16, 0.89, P=0.013), compared to 6.4 and 7.8 per 100 women-years in non-LD women, respectively (IRR=0.82; CI: 0.37,1.77; P=0.644). Detectible mucosal tenofovir was considerably lower in non-LD women (P=0.008), despite similar adherence, and negatively correlated with G. vaginalis abundance. Bacterial cultures demonstrated that tenofovir is rapidly metabolized and depleted 64.5% by G. vaginalis in 24 hours (P< 0.001) but not L. iners or L. crispatus. Prevotella, Mobiluncus, and other anaerobic bacteria also significantly depleted tenofovir compared to abiotic controls (P=0.007).
Conclusions: Our study provides new evidence linking vaginal bacteria to PrEP efficacy in women, and proposes a putative mechanism of tenofovir depletion by bacteria which may be a factor contributing to the variable effectiveness of topical tenofovir-containing PrEP.

MOPEA0072

Human seminal plasma from HIV-1-infected patients induces migration of mucosal dendritic cells and alters integrity of intestinal epithelium

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Background: The mechanisms involved in the early stages of HIV-1 infection have not yet been elucidated. Human seminal plasma (HSP) from HIV-1 infected patients represents a source of virions rich in pro-migratory and/or pro-inflammatory factors, thus could contribute in spreading the infection and activating mucosal cells. Here we investigate the HSP capability to affect gut epithelial integrity both ex-vivo and in vitro, and characterize the migration of mucosal cells to uptake virions.
Methods: Ex-vivo and in vitro previously optimized models were applied. Ex-vivo colorectal mucosa tissue culture was apically treated with HSP from characterized HIV-1 infected, therapy naïve patients. Structural epithelial integrity and mucosal cells migration was investigated by confocal microscopy identifying molecules involved in the epithelia immunological barrier function. In vitro co-culture of polarized Caco-2/monocyte -derived Dendritic Cells (DCs) was apically treated with

HSP. Changes in the distribution of either epithelial surface antigen or junctions molecules and DCs migration were evaluated at confocal microscope. Migrated DCs were quantified by morphometry. Uptake of HIV-1 expressing mCherry was evaluated. The concentration of pro-migratory and pro-inflammatory factors in HSP was determined by ELISA.
Results: Ex-vivo experiments showed that HSP induced the migration of CD11c+/CD64- DCs but not of CD11c-/CD64+ macrophages towards the apical region of the colonic mucosa. The in vitro co-culture system demonstrated a DCs migration through the Caco-2 monolayer in response to HSP comparable to that observed with HIV-1. These effects induced by HSP were paralleled by changes in the epithelial barrier antigens in both models. The observed changes may be HIV-1-related as suggested by in vitro detection of mCherry-expressing virions in the proximity and inside $CD11c^+$ DCs.
Conclusions: These are the first results showing HSP involvement in mucosal barrier alteration and DCs migration, in relationship with penetration of HIV-1 through the colorectal epithelium. Data highlight the role of DCs in the early stages of infection. Better understanding of these mechanisms will be of importance for the development of new therapies.

MOPEA0073

A combination of broadly neutralizing antibodies prevents *in vitro* $SHIV_{162P3}$ cell-free transmission more efficiently than cell-to-cell transmission

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Background: HIV transmission from cell-to-cell is a common way for viral dissemination. Indeed, it has been suggested that transmission through infected cells is more efficient and more difficult to neutralize than cell-free virus. Nevertheless, most therapeutic and preventive vaccine candidates towards HIV-1 have been evaluated pre-clinically for efficacy against cell-free viral challenges. We previously reported a protective effect of a combination of three NAbs, 2G12, 2F5, and 4E10, against simian/human immunodeficiency virus (SHIV) vaginal transmission in macaques in vivo (Moog et al., 2014).
However, to date, there is no evidence that strategies that can efficiently prevent macaques exposed to cell-free SHIV, like the use of bNAbs, are also able to protect from cell associated-SHIV exposure. Here we aimed to determine in vitro the extent to which bNAbs inhibit cell-free and cell-to-cell $SHIV_{162P3}$ transmission.
Methods: We developed a cell-to-cell transmission assay and evaluated antibody-mediated virus neutralization using both TZM-bl and human PBMC as target cells and in vivo $SHIV_{162P3}$- infected spleen cells as donor cells. We used the anti CD4-binding site IgG1b12, the gp120-directed antibody 2G12, and the two gp41-directed antibodies, 2F5 and 4E10 against the two transmission route. The bNAbs were used either alone or in combinations of 3 (2G12+2F5+4E10) and 2 (2G12+4E10, 2G12+2F5, 4E10+2F5).
Results: Our results demonstrated that cell-to-cell $SHIV_{162P3}$ transmission was less sensitive to neutralizing antibodies compared to cell-free $SHIV_{162P3}$. The triple bNAb combination showed decreased potency in the TZM-bl assay than in the hPBMC assay. Moreover, inhibition of cell associated transmission was achieved only when 2G12 was present in the bNAbs combination in the TZM-bl, whereas in the hPBMC assay the double combination is more potent to neutralize the infection when 2F5 is present. In the TZM-bl assay, none of individual 2F5, 2G12 and 4E10 can inhibit cell-to-cell transmission while 2F5 can efficiently block it in the hPBMC assay. Interestingly the IgG1b12 was very efficient to inhibit cell-to cell transmission in both assays.
Conclusions: Therefore, our findings support the use of antibody combinations against cell-associated virus in future candidate therapeutic regimens.

MOPEA0074

Intestinal dendritic cells and macrophages play a different role in the early events of HIV-1 transmission

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Background: Sexual transmission of HIV is the main route for HIV acquisition. Infection frequently occurs through colorectal mucosa where mononuclear phagocytes (MP), comprising dendritic cells (DC) and macrophages (Mf), are among the first target cells.
We showed that human colonic lamina propria CD11c+DCSIGN+CD68- cells sample luminal R5 HIV in an ex vivo model, a mechanism exploited by HIV to bypass the intact epithelial barrier. However, little to nothing is known about resident DC and Mf in the lower intestinal tract, the extent to which different subsets exist, and their role in HIV acquisition.
Methods: We used multicolor flow cytometry, immunofluorescence and ex vivo explant culture of colorectal mucosa obtained from healthy human donors and Cynomolgus macaques, to define MP distribution and their susceptibility to HIV/SIV infection.
Results: CD64 allowed to differentiating colonic DC (CD11c+CD64-) and Mf (CD11c+CD64+). Three major DC subsets were identified on the basis of CD103 and the fractalkine receptor (CX3CR1) expression. The totality of colonic Mf was CX3CR1+ while about 50% expressed the M2 marker CD163. Cells were further characterized for the expression of the CD172a and CD11b.
At steady state, CD11c+CD103+ DC were detected underneath the luminal epithelium and at cript level. Following ex vivo R5 HIV-1 stimulation, both CD11c+CD64+ and CD11c+CX3CR1+ cells penetrated the intestinal epithelium, whereas an increase in CD11c+CD103+ cells migration was not observed.
Interestingly, CCR5, that we showed to drive CD11c+ cells migration toward the intestinal lumen, was preferentially expressed by the CD11c+CD64+CX3CR1+ cells, which support their involvement in active sampling of HIV and in transmission of infection in situ.
Conclusions: In conclusion we have unravel a previously underestimated complexity in the phenotype and function of the intestinal MP in human and NHP and discuss the relative contribution of different subsets of DC and Mf in the early events of HIV transmission at mucosal sites.

MOPEA0075

Virological synapses formed between HIV-1-infected $CD4^+$ T-cells and mucosal epithelium promote macrophage infection followed by reservoir formation in reconstructed urethral tissues

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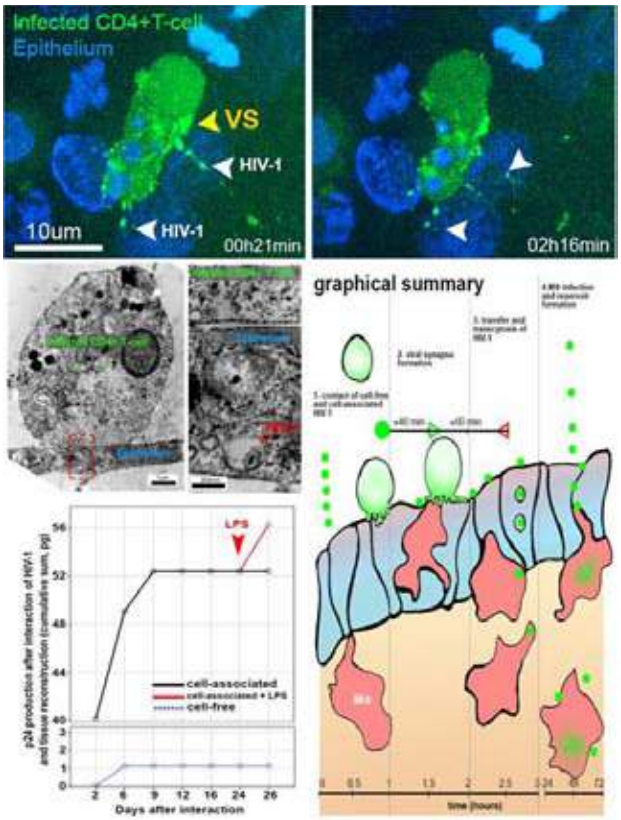
Background: During sexual intercourse HIV-1 cross epithelial barriers composing the genital mucosae, a poorly understood feature which requires an HIV-1-infected cell vectoring the entry. We have demonstrated that the adult penile urethra is an HIV-1 entry site and that, in contrast to poorly infectious cell-free virus, efficient HIV-1 penetration in the mucosa depends on infection driven by HIV-1 infected cells.
Methods: Viral synapses (VS) are the basis of HIV-1 cell-to-cell transmission and, due to their dynamic nature, require live imaging techniques to be adequately approached. Thus, we have developed immunocompetent urethral tissues reconstructed in vitro based on penile cells, and comprizing a tight epithelium overlaying a lamina propria, suitable for imaging the interaction of live CD4+T-cells, that produce infectious and fluorescent R5-tropic gag-iGFP HIV-1, and human urethral epithelial cells.
Results: We demonstrate that HIV-1 infected cells contact the epithelium, leading to virus production at the surface of urethral epithelial cells. VS are established during the first hour of interaction between infected CD4+T-cells and epithelium, resulting in virus budding that is transported across epithelium and stroma. Gp41-envelope specific IgA inhibit this contact, resulting in a reduction of HIV-1 translocation across reconstructed mucosa.
Following VS, viral transfers are detected for ≈1 hour and transcytosis of HIV-1 through mucosal epithelial cells are detected in regions where VS occurred. Efficient macrophage targeting following VS initiation results in viral production for 9 days before production halting, suggestive of macrophage reservoir formation within mucosa reconstructed in vitro. Additonally, treatment of LPS restores viral production from latency.

Conclusions: Altogether, VS formed between a donor immune cell infected with HIV-1 and a target epithelial cell in the context of reconstructed immunocompetent mucosa will potentially reveal novel aspects of HIV-1 transmission, helping to design better targeted antiviral strategies including gp41-specific IgA.



[Figure]

MOPEA0076

HIV and biologic sex differences in the risk of mother to child transmission in Cameroon

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Background: Previous studies reported that girls were more at risk of in utero and perinatal mother to child transmission (MTCT) of HIV-1. We looked at the data collected in Cameroon to verify this observation. The hypothesis is that this is not true as several other factors will hinder the biologic sex effect on the MTCT of HIV-1.
Methods: We investigated biologic sex and HIV transmission among infants born to HIV infected mothers. The infants were tested by polymerase chain reaction (PCR) for HIV proviral DNA. All infants whose PCR1 was positive on two different testings were considered HIV infected. The results were analyzed using Stata software and the pearson chi 2 and Fisher exact tests.
Results: A total of 15,404 infants aged 6 weeks to 18 months were recruited (Mean age 16.7 weeks) and 34.8% were breastfed. A portion of 9.4% was infected. Generally, biologic sex was not associated to HIV transmission, but was combined to other factors. According to the type of twins´ pairs (161 twins sets) more HIV infected children were found in boy-girl twins´ sets ($p = 0.037$) and more girls were infected in this type of twins´ sets compared to girl-girl pairs ($p = 0.043$). Girls were more likely to be infected when mothers underwent treatment or prophylaxis ($p = 0.037$), and more likely to be infected in the age group of 6.1-24 weeks ($p=0.034$). Younger mother (≤25) transmitted more ($p = 0.049$). Delivery order did not impact transmission.
Conclusions: In our setting, biologic sex was associated to vertical transmission in specific conditions. More transmissions occurred in boy-girl twins´ sets, in girls when mother on ART. Many parameters may be associated to impact MTCT of HIV-1. Mechanisms underlying these associations should be further investigated. Interventions through family planning and pre natal consultation, especially for twin pregnancies should be re-enforced.

MOPEA0077

Properties of ENV derived from transmitted HIV-1 issued from transmission clusters

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Background: Recent studies suggested that during sexual transmission of HIV-1, a single transmitted/founder (T/F) virus among numerous viral variants present in the donor is transmitted most often. The result is a genetically restricted viral population at the beginning of infection. The aim of our study was to investigate if this bottleneck event is a stochastic process or if it selects viral variants with particular biological properties that predispose them to more effectively establish new infections. To that aim, we examined the antigenic and phenotypic properties of transmitted viruses that have a common origin, derived from the same transmission cluster. Our hypothesis was that if the transmitted variants have a selective advantage, they should share some biological properties.
Methods: Between 2006 and 2013, 8 clusters of at least 3 patients infected by subtype B or CRF02-AG viruses were included in the early phase of infection in the ANRS Primo Cohort. We produced Env-pseudotyped viruses derived from the viral population infecting each patient and compared their neutralization sensitivity to a panel of broadly neutralizing antibodies targeting major epitopes of the envelope glycoprotein.
Results: We found that neutralization profiles are conserved within 7 clusters of transmission, indicating a strong antigenic conservation of the transmitted viruses. Secondly, we studied the sensitivity of pseudotyped viruses to various entry inhibitors. We observed similar sensitivities to T20 (fusion inhibitor) and Maraviroc (CCR5 inhibitor) within each cluster.
Conclusions: Together, these results support the hypothesis of a selective restriction of transmitted variants during the transmission event.

MOPEA0078

Gut-homing Δ42PD1$^+$Vδ2 T cells promote innate mucosal damage via TLR4 during acute HIV-1 infection

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Background: Acute HIV-1 infection leads to vigorous innate immune responses and rapid CD4$^+$ T cell depletion in intestinal tissues. Innate immune cells underlying mucosal responses remain incompletely understood.
Methods: Δ42PD1 expression on γδ-T cells was examined in following HIV-1 infection in acute (n=57) and chronic (n=50) patient cohorts and healthy controls (n=22) in correlation with serum cytokine levels. A humanised mice model was used to determine if Δ42PD1+ γδ-T cells migrate to the gut, and tissue sections of small intestine was examined.
Results: Δ42PD1 expression was significantly up-regulated on Vδ2 subset of γδ-T cells in acute (~20%) compared to chronic HIV-1 patients (~11%) and healthy controls (~2%). Frequency of Δ42PD1$^+$Vδ2 cells and pro-inflammatory cytokines levels positively correlated in acute patients. We found that HIV-1 infection rapidly induced Δ42PD1$^+$Vδ2 cells in vitro, which also expressed high levels of gut-homing receptors CCR9/CD103, and triggered small intestinal inflammatory damages after adoptive transfer into humanized mice. The innate receptor for Δ42PD1 was discovered as TLR4/MD2 that induces pro-inflammatory cytokines by using antibody/small molecule blocking, binding affinity and co-immunoprecipitation assays. By fluorescence immunohistochemistry, co-localization of Δ42PD1$^+$Vδ2 cells and TLR4 or IL6 was evident primarily in mice small intestines. The mucosal damage was reduced when Δ42PD1-specific antibody was administered before and during adoptive transfer of HIV-induced Vδ2 cells into humanized mice.
Conclusions: In summary, this study uncovered a novel Δ42PD1/TLR4 pathway exhibited by infection-induced gut-homing Vδ2 cells that may contribute to innate immune activation and intestinal pathogenesis during acute HIV-1. Δ42PD1$^+$Vδ2 cells may serve as a new target for the investigation of diseases with gut inflammation.

MOPEA0079

In depth sampling of high-risk populations to characterize HIV transmission epidemics among young MSM using PrEP in France and Quebec

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Background: The ANRS IPERGAY trial was a double-blind, randomized trial of pre-exposure prophylaxis among high-risk men conducted in France and Quebec. We reconstructed HIV transmission networks from recently infected individuals enrolled in the IPERGAY trial in combination with French and Montreal primary infection Cohorts to identify and characterize active clusters of transmission.
Methods: HIV pol sequences were generated from 31 IPERGAY participants (2012-2014). Phylogenetic and network analyses were performed to infer putative relationships between these participants and 1,352 unique HIV pol sequences from individuals enrolled in the French PRIMO ANRS Cohort (1999-2014) and 490 individuals enrolled in the Montreal PRIMO Cohort (1996-2016). We applied a logistic growth model to estimate the maximum expected size of the largest active cluster.
Results: All 31 participants from the IPERGAY trial were predominantly infected with HIV-1 subtype B (64.5%) and CRF02_AG (22.6%). At diagnosis, the median age was 34 years (IQR:27-44), the median HIV RNA and CD4 counts were 5.5 Log_{10}cp/mL (IQR:4.5-6.7) and 464 cells/mL (IQR:390-661) respectively. Fifteen individuals (48.4%) were involved in 12 clusters sampled over a median period of 2 years (IQR:0.3-7.8) including 6 dyads and 6 larger clusters ranging from 3 to 62 individuals. All clustering individuals were male and all clusters but 2 involved subtype B. All but 3 clustering sequences were identified in Paris, France while two were from Quebec. The Quebec cluster with 7 Montreal Cohort and one IPERGAY participants (surrounded in Figure) was part of a previously identified cluster with 45 MSM infected in Montreal (n= 32), Sherbrooke (n=7) and Quebec (n=6) diagnosed between 2012 and 2014.The largest cluster included 62 CRF02_AG sequences (4 IPERGAY) sampled between 2000 and 2015 with an expected maximum size of 72 by 2030. Of the 31 IPERGAY sequences, one harbored the NNRTI K103N mutation and was linked to 6 French sequences with the same mutation diagnosed between 2009 and 2012.
Conclusions: These results demonstrate high rates of HIV transmission clustering among young high-risk MSM enrolled in the IPERGAY trial. In-depth sampling of high-risk populations may help to uncover unobserved transmission intermediaries and improve prevention efforts that could be targeted to the most active clusters.

MOPEA0080

Very early treated acute HIV patients have high naïve-CD4+Tregs recovery with a decreased immune activation

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Background: ARV treatment (ART) administered during acute HIV-infection presents several immunological benefits leading to a better CD4+ T cell recovery. In a prospective, observational cohort of patients with acute HIV-infection, immunologic markers and clinical characteristics were evaluated. We present here T-cell-immune-phenotypic characteristics at baseline and 2 months after ART initiation.
Methods: Patients with acute HIV-infection are being followed-up in 5 sites across Mexico. Clinical, demographic data and blood samples are collected in all patients. In a sub-set of patients, we collected fresh whole blood for flow cytometry analysis. Naïve-(Nv), central memory- (CM), effector memory (EM) and terminally differentiated- T-cells (TMRA), as well as activation markers were determined using CD3, CD4, CD8, CD45RA, CCR7, CD38 and HLA-DR markers. We used Fox-P3, CD25, CD127 and CD45RA to identify T-regs and their subsets. To assess changes over time, Wilcoxon matched-pairs signed rank test was used for each value between baseline and month 2.
Results: We included 10 patients with complete flow-cytometry data and at least 2 months of follow-up. All subjects were male infected by sexual transmission; mean age was 32 y.o. Mean CD4+ T cell count was 439 cells/uL and median viral load was 1.2 million copies/ml (23379-10x10^6 copies/ml) at the baseline. According to Fiebig criteria, patients were distributed as follows: 2 patients in Fiebig II;
4 patients in Fiebig IV and 4 patients in Fiebig V. All patients received treatment immediately. TDF+FTC+EFV were prescribed in 8 subjects (80%).
At 2 months, CD4+ T cell increased from 439 cells/uL to 609 cells/uL (p=0.1). Immune activation markers (HLA-DR, CD38) decreased from 4.55% to 2.22% (p=0.03) in T-CD4+ and from 43.25 to 8.97 (p=0.006) in T-CD8+. The proportion of T-CD4+ or T-CD8+ subsets (Nv, Cm, EM, TMRA) at 2 months did not change from baseline. Concerning T-regs, they increased from 4.8% to 7.8% (p=0.01) and this difference was mainly due to a recovery of the naïve T-regs subset (from 4.2 to 6.1, p=0.01).
Conclusions: Early total T-regs recovery driven mainly by naïve-T-reg and a decrease in immune activation markers precede the T CD4+ recovery observed in patients with acute HIV-infection treated immediately after diagnosis.

MOPEA0081

Low frequencies of HIV-infected cells in blood, colon and lymph node at the earliest stage of acute infection (Fiebig I)

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Background: A small pool of HIV-infected cells is established early in the blood of recently infected individuals. However, little is known about the frequency of infected cells in tissues during the earliest phase of HIV infection. Here we quantified infected cells in blood, colon and lymph node from acutely infected individuals.
Methods: We measured the frequency of cells harbouring total HIV DNA in total cells obtained from the blood (n=105), colon (n=53) and lymph nodes (n=25) from recently infected Thai participants (Fiebig stages I-V) not receiving antiretroviral therapy. Samples from chronically infected Thai individuals were used as controls.
Results: Blood, colon and lymph node displayed similar frequencies of HIV-infected cells in participants from a given Fiebig stage. In contrast, lymph node from chronically infected individuals displayed slightly higher levels of infected cells compared to blood. Fiebig I individuals were unique as they displayed extremely low frequencies of infected cells in blood, colon and lymph node (median: 1.0, 0.0 and 0.9 Log10 HIV DNA copies per million cells), which were all statistically lower than any other group. Fiebig II-V participants displayed similar levels of HIV DNA as chronically infected participants in blood (2.7 vs 2.7), colon (3.0 vs 2.8) and lymph node (3.0 vs 3.2 median Log10 HIV DNA copies per million cells in Fiebig II-V vs chronic, respectively). Overall, the frequency of infected cells in blood strongly correlated with the frequencies measured in colon (p<0.0001, r=0.6) and lymph node (p<0.0001, r=0.8). Finally, HIV plasma viral load was correlated to the frequencies of infected cells in the blood (p<0.0001, r=0.4) and lymph node (p=0.001, r=0.5), but not in the colon.
Conclusions: Fiebig I individuals display lower frequencies of HIV-infected cells in blood, gut and lymph node than any other acutely infected participants. Strikingly, the frequencies of infected cells typically measured in blood and tissues from chronically infected individuals are already reached as early as Fiebig II stage. These results suggest that ART initiation at the Fiebig I stage may significantly limit the frequency of infected cells in blood and tissues.

MOPEA0082

T follicular helper cells are preserved by ART and correlate with reservoir size in early HIV infection

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Background: Evidence suggests a key role for T follicular helper cells (Tfh) in HIV antibody responses and reservoir. The impact of ART during Primary HIV infection (PHI) on Tfh is unclear. We compare early (ART-48) versus no ART (SoC) initiated in PHI, and explore the association with HIV reservoir and antibody responses.
Methods: Using longitudinal samples (baseline and week 48) from the SPARTAC RCT, 12 individuals from the ART-treated (ART-48) arm and 21 from the untreated (SoC) were studied. Expression of CXCR5, PD-1, TIGIT, Tim-3, HLA-DR, Bcl-6 and IL-21 was assessed by flow cytometry. Tfh were defined by coexpression of CXCR5 and PD-1. HIV DNA was measured by qPCR. Total, HIV specific anti-gp120 and specific anti-p24 IgG and IgA antibody responses were measured by ELISA. Mixed-effect models were used to assess the impact of ART on Tfh and CD4+CXCR5+T-cells.
Results: At baseline, using samples from all 33 individuals, expression of Tfh associated markers: PD-1 (p=0.009), TIGIT (p<0.0001), Bcl-6 (p<0.0001) & IL-21 (p=0.03) was significantly higher on CXCR5+CD4+T-cells compared to CXCR5-T-cells. There was an inverse correlation between the baseline absolute number of Tfh and both total (r=-0.4,p=0.03) and integrated HIV DNA (r=-0.5,p=0.01). In addition, a positive correlation was observed between Tfh and both CD4/CD8 (r=0.62, p<0.001) and frequency of B Cells (CD19+) (r=0.49, p=0.003).
Absolute Tfh and CXCR5+CD4+T-cell numbers at week 48 were significantly higher in ART-48 compared to SoC. Mixed effect models showed significantly increased numbers of both Tfh and CD4+CXCR5+T-cells at week 48 (p=0.001) in the ART-48 arm compared to the SoC arm.
In the ART-48 arm, expression of exhaustion (PD-1, TIM-3) and activation (HLA-DR) markers on CXCR5-CD4+T-cells decreased significantly (p<0.05 for all) between baseline and week 48; no difference was seen in the SOC arm. No difference in expression of activation and exhaustion markers was noted on CXCR5+CD4+ T-cells in either arm.
Specific-gp120 IgG/IgA ratio was higher in the SoC arm at 48 weeks compared to baseline, while specific-p24 IgG/IgA was greater in the ART-treated group.
Conclusions: These data show dynamic changes in the Tfh compartment in PHI, which correlated with reservoir size and was impacted by ART.

MOPEA0083

Evidence of fast normalization of inflammation biomarkers after ART started during acute, but not in early chronic HIV infection

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Background: HIV-1 infection leads to chronic immune activation and systemic inflammation. We investigated the impact of early antiretroviral treatment (ART) on inflammation biomarkers and immune cells activation during acute and early chronic HIV infection.
Methods: Blood samples were obtained from HIV-uninfected (HIVneg), late chronically ART-treated HIV-infected (LcART-HIV), early chronically ART-treated HIV-infected (EcART-HIV, Fiebig VI) and acutely ART-treated HIV-infected (aART-HIV, Fiebig I-V) patients from Rio de Janeiro, Brazil.
Plasmatic levels of inflammation biomarkers (IP-10, IL-18, CRP and IL-6) were measured before the start of ART (D0) and six (M6) months after. The $CD8^+CD38^+HLA\text{-}DR^+$ T cells frequencies were evaluated by flow cytometry in D0 and M6. The Mann-Whitney test and Spearman correlation were used for statistical analyses.
Results: Among the plasmatic biomarkers analyzed, only IP-10 and IL-18 were significantly elevated at D0 in both aART-HIV and EcART-HIV infected patients. The levels of IP-10 and IL-18 reduced significantly between D0 and M6 in aART-HIV individuals, reaching values similar to HIVneg. Among the EcART-HIV patients, IP-10 levels between D0 and M6 were reduced, but remains higher than in HIVneg and no significantly reduction of IL-18 levels was observed. The $CD8^+$ T cell activation levels in aART-HIV and EcART were elevated at D0 and reduced significantly on M6, but remain higher than in HIVneg.
We found a positive correlation between IP-10 and CD8+ T cell activation in D0 in aART-HIV and EcART, this positive correlation was also found on M6 in aART-HIV patients.
Conclusions: Starting ART early during HIV infection is able to reduce systemic inflammation, but it only normalizes when ART is initiated in acute phase. T cell activation was reduced, but remains elevated in both aART-HIV and EcART-HIV patients.

MOPEA0084

IL-7 is UP-regulated in the ileal mucosa during hyperacute siv infection in Chinese rhesus macaques, triggering local chemokine expressions and immune cell migrations

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Background: The intestinal barrier, one of the first targets of HIV/SIV, is subjected to major changes during acute infection. We previously demonstrated that pharmaceutical injection of interleukin-7 (IL-7) triggers chemokine expression leading to massive T-cell homing, in particular to the intestine. We here explored mucosal IL-7 expression as part of the cytokine storm occurring during the acute phase of SIV infection in rhesus macaques.
Methods: Gut tissues were analyzed after necropsy in healthy (n=5) and acutely SIV-infected macaques (n=9). Uninfected macaques were also sacrificed following IL-7 injection (80µg/Kg, n=4). The levels of mRNA coding for IL-7 and 13 chemokines involved in lymphoid and myeloid cells homing as well as viral DNA and RNA were quantified by (RT)-qPCR. IL-7 protein was quantified in whole gut samples by ELISA. Confocal imaging after immunostaining was used to evaluate immune cell counts and distribution in large ileum sections (25 mm^2). Circulating T-cell subsets and chemokine receptors expression on these cells were followed-up over 3 weeks, by flow cytometry.
Results: Concomitant with viral detection, IL-7 expression progressively increased in the ileum of SIV-infected macaques, with a peak expression at day 10. In macaques showing enhanced ileal IL-7 mRNA/protein expression, 7 out of 13 chemokines were overexpressed in intestinal tissue. Among these, the macrophage and/or T-cell attractant chemokines CCL4, CCL25, CCL28 and CXCL8 correlated to gut IL-7 expression and were also enhanced in the ileum of IL-7-treated uninfected macaques. $CD8^+$ T-cell counts increased by day 3 in the lamina propria (LP), reaching a maximum at day 10 post-infection.
In contrast, $CD4^+$ T-cell counts were not affected in the ileum, suggesting replenishment. $CD4^+PM\text{-}2K^+$ macrophage numbers augmented at day 3 in the LP and inversely diminished in the submucosa. In the blood, absolute numbers of all T-cell subsets transiently decreased up to day 10, with a marked drop in the proportion of gut-homing $CCR9^+\beta7^+$ T-cells.
Conclusions: These findings suggest a role for IL-7 in the initiation of early mucosal immune responses to lentiviral infections. However, IL-7 triggered $CD4^+$ T-cells and macrophages localization at viral replication sites could also participate to viral spread and establishment of viral reservoirs.

MOPEA0085

Deep sequencing reveals viral evolution in Gag within protective HLA alleles B*57:02, B*58:01 and B*7 supertype individuals acutely infected with HIV-1 subtype C in Durban, South Africa

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Background: Transmission of cytotoxic T cell escape variants, timing and frequency of CTL-mediated viral escape following acute HIV-1 infection can profoundly influence disease course but comprehensive analysis of CTL epitopes restricted by protective HLA class I alleles is lacking. We evaluated the transmission of CTL immune escape variants and immune selection over one-year following acute HIV-1 infection for epitopes restricted by the B*7 supertype and protective HLA-B*57 and HLA-B*58:01 alleles.

Methods: HIV-1 uninfected women were screened twice weekly for HIV-1 RNA by finger prick blood draw. Six females were identified possessing the HLA-B*7 supertype [HLA-B*07 (n=2), HLA-B*39:01 (n=2), HLA-B*42:01 (n=1) and HLA-B*42:02 (n=1)] while six women possessed the protective HLA-B*57:02 (n=1) and HLA-B*58:01 (n=5) class I alleles. Plasma samples were available at baseline (Fiebig I-III) and at 2-6 subsequent time points thereafter over one year of infection. Deep sequencing of gag was performed using the Illumina MiSeq platform. Amplicons were molecularly bar-coded, pooled and sequenced resulting in >250-fold coverage. A subset of limiting-dilution full-length HIV-1 genome amplicons were also sequenced by PacBio at ~1000-fold coverage. Sequence analysis was performed using Geneious v8.1.8 (Biomatters Ltd).
Results: In transmitted/founder viruses, the four known Gag CTL epitopes presented by HLA-B*57/B*58:01 were wild type in two of the six participants, with the remaining four participants showing evidence of CTL-mediated pre-adaptation in at least one epitope. By one-year post infection, de novo CTL-mediated selection was observed in all 6 subjects, but never in all 4 epitopes. 5 of 6 participants experienced escape within the immunodominant TW10 epitope. Of the five known Gag epitopes presented by the HLA-B*7 supertype, all six participants showed evidence of a CTL variant in at least 3 epitopes within the transmitted virus sequence. The TL9 epitope remained wild type in 5 of 6 participants with no evidence of CTL escape up to one-year post infection. Transmitted escape variants remained virtually unchanged throughout the follow up period except in one participant who showed evidence of slow reversion in the HLA-B*57/58 ISW9 epitope.
Conclusions: Deep sequencing reveals extensive transmission of pre-adapted CTL variants and slow immune selection within immunodominant epitopes restricted by protective HLA class I alleles.

MOPEA0086

NKp30 and its ligands: emerging players in HIV-2-infected patients

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Background: HIV-2 infection progresses more slowly to AIDS, and subjects survive longer than those with HIV-1 infection. It is well established that natural killer (NK) cells are the critical antiviral effectors of the innate immune system. They distinguish their targets from healthy cells via a panel of activating and inhibitory receptors that recognize ligands specifically induced on "stressed" cells. It has been reported that their activities (cytokine production and cytotoxic functions) prevent HIV-1 transmission and viral replication. Due to the scarcity of data in HIV-2 infection, knowledge about the differentiation and function of NK cells is critical to better understand their role in the evolution of the disease.
Methods: Twenty-two untreated HIV-2-infected patients (19 controllers and 3 progressors), included in the ANRS HIV-2 cohort, were compared to LTNP or controllers HIV-1 patients from the ANRS ALT cohort, and healthy controls. Extensive phenotypic and polyfunctional NK cell assays were performed by flow cytometry. Cytolytic function and expression of ligands for NK cell receptors were assessed on CEM T cells infected with HIV-2 or HIV-1 strains.
Results: HIV-2+ patients displayed altered NK cells, highlighted by a profound down-modulation of the activating NKp30 receptor ($p<0.0001$), as compared to HIV-1 patients and healthy controls. NKp30 expression was positively correlated with both NKG2A and Siglec7 ($r=0.65$ and $r=0.60$, respectively), and negatively with HLA-DR and CD57 ($r=0.68$ and $r=0.60$, respectively), suggesting a major impact on NK cell differentiation. $NKp30^{low}$ phenotype was also associated with reduced NK-cell polyfunctionality, even toward stimulation with HIV-2-infected target cells. To determine the mechanism leading to NK-cell dysfunction in HIV-2, expression of cellular ligands for major NK-cell receptors was analyzed. As previously observed for HIV-1, NKp44L was specifically upregulated on bystander non-infected cells in HIV-2, whereas NKG2D ligands were slightly more expressed on both bystander and infected target cells. Importantly, a higher frequency of HIV-2-target cells (up to 70%) expressed NKp30 ligands, as compared to uninfected and HIV-1-infected cells.
Conclusions: Taken together, these data suggest that constitutive expression of NKp30 ligands on HIV-2-infected cells could provoke decreased NKp30 expression by NK cells, eventually leading to their functional impairment.

MOPEA0087

Prevalence and risk factors associated with HIV/viral hepatitis B and C co-infections among people who inject drugs in Mozambique, 2013-2014

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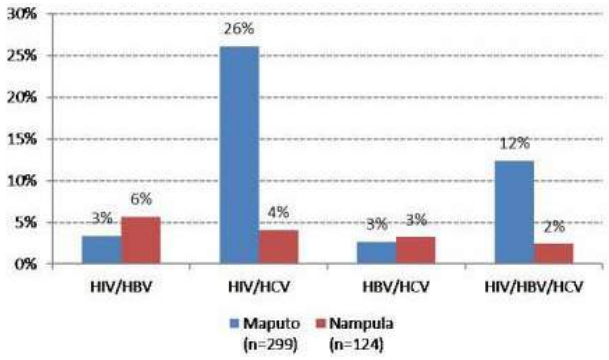
Background: While the high burden of HIV in the general population of Mozambique is well documented, no data exist on HIV, Hepatitis B (HBV) and C (HCV) virus among People Who Inject Drugs (PWID). The first Integrated Bio-Behavioral Surveillance (IBBS) Survey among PWID took place in 2013-2014 to address this gap in knowledge. The present analysis assesses the prevalence of HBV and HCV infection among PWID and describes associated risk factors.
Methods: Using respondent-driven sampling, PWID aged 18 years and older were recruited in Maputo and Nampula/Nacala, two large urban centers of Mozambique. Rapid screening of HIV, HBV (HBsAg) and HCV was performed on site. We pooled data from both sites to conduct unadjusted bivariate analysis using chi-square where HIV/HBV and HIV/HCV coinfections were separate outcomes.
Results: Among the 492 eligible PWID, 94% were male and median age was 32 years. The prevalence of HIV/HBV and HIV/HCV co-infections among survey participants was 4.0% and 19.6%, respectively. Figure 1 illustrates the burden of disease among participants. HIV/HBV co-infection was independently statistically associated ($p<0.01$) with older age, prior history of needle sharing and drug injection in the last month. HIV/HCV co-infection was independently statistically associated with older age, prior history of needle sharing, drug injection in the last month, needle sharing in the last month and history of arrest. There was no association of sexual risk behaviors with either HIV/HBV or HIV/HCV co-infections.
Conclusions: There is a high burden of HBV and HCV among HIV-infected PWID in two urban areas in Mozambique. Our results highlight the need for targeted harm reduction interventions that include needle exchange programs and integrated services for diagnosis and treatment of HIV,HBV and HCV in Mozambique to address these epidemics among PWID. Efforts should be made to assess the feasibility of introducing HBV vaccination in this high-risk population.



[Hepatitis B & C Infection among HIV-infected PWID]

MOPEA0088

A New HIV/HBV co-infection model: hepatocytic expression of human sodium taurocholate cotransporting polypeptide (NTCP) enables hepatitis B virus infection of macaques

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Background: HIV/HBV co-infected patients exhibit increased liver dysfunction and fibrosis, but the mechanisms contributing to this differential pathology remain poorly understood, and an animal model of HIV/HBV co-infection is needed. Rhesus macaques are regularly utilized as models for HIV infection, but no endogenous HBV strain has been discovered in this species. We hypothesized that the block to HBV replication in rhesus hepatocytes is due to failure to gain cell entry. To test this hypothesis, we expressed the HBV receptor -- human NTCP (hNTCP) -- on rhesus hepatocytes both in vitro and in vivo. We show for the first time that macaques expressing hNTCP can be infected with HBV, paving the way for a physiologically relevant animal model of HIV/HBV co-infection.
Methods: We generated helper-dependent adenovirus (HDAd serotype 5) and adeno-associated virus (AAV serotype 8) vectors expressing hNTCP and transduced freshly isolated rhesus and baboon primary hepatocytes (PH) in vitro. We then challenged these PH with HBV and monitored in vitro infections by supernatant HBsAg/HBeAg ELISA, HBV DNA qPCR, and electron microscopy. For in vivo studies, macaques were injected with HDAd and AAV vectors expressing hNTCP and challenged with HBV. We monitored in vivo HBV infections by HBV DNA and alanine transaminase concentrations in the serum, HBV DNA and RNA levels in isolated hepatocytes, anti-HBV humoral and cellular immunity, and expression of HBcAg in the liver.
Results: Rhesus and baboon PH expressing hNTCP supported high levels of HBV infection, evidenced by increasing supernatant concentrations of both HBsAg and HBeAg. In addition, covalently-closed circular DNA (cccDNA) qPCR and electron microscopy revealed the formation of cccDNA and the release of Dane particles, respectively. These results indicate that all stages of HBV replication are present in rhesus hepatocytes. Expression of hNTCP in vivo facilitated HBV infection, evidenced by detection of serum HBV DNA, HBV DNA/RNA in isolated hepatocytes, anti-HBV humoral and cellular immunity, and HBcAg expression in the liver.
Conclusions: We have built a physiologically relevant HBV infection model using rhesus macaques. Given the long history of HIV research in this species, our new data portend the future use of rhesus macaques in HIV/HBV co-infection research.

MOPEA0089

Hepatitis B virus infection in HIV-1 negative and positive pregnant women in Botswana, implications for HBV vertical transmission

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Background: Mother to child transmission (MTCT) of hepatitis B virus (HBV) is a major health problem, as infections acquired in early childhood are more likely to lead to chronic infections. High rates of HBV MTCT have been reported in HBV surface antigen (HBsAg) and HBV e antigen (HBeAg) positive mothers despite universal HBV vaccination of infants. Higher rates of HBV transmission (8-12%) have also been reported among infants born to mothers with high HBV viral loads. We determined the prevalence of HBsAg and of HBeAg, and compared HBV viral loads, in HIV-negative and -positive pregnant women in Botswana.
Methods: We enrolled and followed 443 HIV-infected and 451 HIV-uninfected mothers in a prospective observational study in Botswana (Tshipidy cohort). A total of 752 maternal plasma samples collected at delivery from this cohort were available for screening for HBV infection using Murex HBsAg ELISA. HBsAg-positive samples were screened for HBeAg using the Monolisa™ HBe Ag-Ab PLUS ELISA, and HBV viral loads were determined using the COBAS® AmpliPrep COBAS® Taqman®. HBV genotyping was conducted by amplifying a 410bp fragment of HBsAg which was sequenced using Big-Dye sequencing chemistry. Sequences were edited and compared to reference sequences to determine the HBV genotypes.
Results: Of the 752 pregnant women, 368 were HIV-negative and 384 were HIV-positive. Overall, 16 (2.1%; 95%CI 1.08 - 3.12%) were HBsAg-positive. Among HIV-positive women, 12 were HBsAg-positive (3.1%; 95%CI 1.37 - 4.83%) and in HIV-negative women, 4 were HBsAg-positive (1.1%; 95% CI 0.03 - 2.17%) p=0.04. Of the 16 HBsAg-positive samples, 13 were tested for HBeAg and 3 were positive and were all from HIV-negative women. HBV viral loads were higher among HIV-negative women than HIV-positive women, (452 IU/mL [Q1,Q3: 166, 2250] vs >1.7 x 10^8 IU/mL, p= 0.02). Of the 8 samples successfully genotyped, 6 were genotype D and 2 were genotype A.
Conclusions: HBV seroprevalence was higher among HIV-positive pregnant women compared to HIV-negative pregnant women. However, HIV-negative HBV positive pregnant women were all seropositive for HBeAg and had higher HBV viral loads than HIV-positive women. The impact of higher HBV viral loads and HBeAg seropositivity among HIV-negative women warrants further investigation.

MOPEA0090

Burden of HCV mono-infections and HCV/HIV co-infections in four provinces in Cambodia

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Background: The knowledge of hepatitis C virus (HCV) burden in Cambodia is essential for evidence informed policy development and for the mobilization of resources, including improving access to HCV cure with direct acting antivirals. The objectives of this study were to assess the prevalence and genetic diversity of HCV and to identify associated risk factors with hepatitis C mono-infection or with HCV/HIV co-infection.
Methods: Between March and April 2016, we conducted a cross-sectional survey on HCV in four geographical areas in Cambodia: Phnom Penh, Battambang, Siem Reap and Preah Sihanouk province. Subjects were randomly selected among HIV-uninfected pregnant women attending public antenatal care clinics and among HIV-infected subjects who were followed-up in the national HIV program. HCV Ab testing was done with the HCV Bio-Rad enzyme-linked immunosorbent assay (ELISA). All HCV Ab-positive subjects were tested for HCV RNA viral load (VL) with the Omunis PUMA HCV kit. HCV genotyping was performed in the NS5B region.
Results: A total of 935 participants were enrolled, including 510 (54.6%) pregnant women and 425 (45.4%) HIV-infected individuals, with median age of 27 years (IQR, 24-31) and 42 years (IQR, 37-49), respectively. Overall, HCV Ab prevalence was 3.6% (34/935) and significantly higher in HIV-infected individuals, compared to pregnant women (6.8% vs 0.9%) (p< 0.001). Of the 34 anti-HCV-positive individuals, 24 (70.6%) showed detectable HCV RNA VL results, leading to an overall prevalence of active HCV infection of 2.6%. Active HCV infection rate was higher in HIV-infected subjects than in pregnant women (23/425, 5.4% vs 1/510, 0.2%) (p< 0.001). HCV RNA median was 6.29 $\log_{10}$ IU/mL (range, 2.47-7.08). Predominant HCV genotypes were 1b (55%), 6 (40%), and 2 (5%). In multivariate analysis after adjustment on HIV status and provinces, HCV infection was significantly associated with older age (OR:4.54, 95%CI: 1.62-12.72, p=0.004), having a family member positive for HCV (OR:3.49, 95%CI: 1.47-8.25, p=0.004), reporting a history of testing for hepatitis infection (OR:2.53, 95%CI: 1.14-5.58, p=0.021), and having received intravenous medication in the last past 5 years (OR:8.26, 95%CI: 1.10-61.99, p=0.040).
Conclusions: In Cambodia, active HCV infection is common among HIV-infected subjects, and is associated with history of intravenous medication.

MOPEA0091

Dysregulation of IL-7/IL-7 receptor signaling pathway in memory CD8 T cells predicts cryptococcosis-associated immune reconstitution inflammatory syndrome

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Background: Up to 50% of individuals with HIV-associated cryptococcal meningitis (CM) experience paradoxical clinical deterioration, known as cryptococcosis-associated immune reconstitution inflammatory syndrome (C-IRIS), weeks after initiation of combination antiretroviral therapy (cART). The immunological mechanisms underlying C-IRIS are incompletely understood and no reliable biomarkers to predict C-IRIS exist.
We investigated whether C-IRIS could be predicted by plasma or cerebrospinal fluid (CSF) levels of cytokines and, for those that did, we examined aspects of related T cell function.
Methods: CM individuals that experienced C-IRIS upon cART initiation (n=27) were compared to CD4 T-cell count-matched patients without C-IRIS in a 1:1 ratio. Plasma and CSF cytokine levels were quantified using a high-sensitivity Luminex kit. IL-7 receptor (CD127) expression on various T cell subsets was measured by flow cytometry. All parameters were measured from samples obtained at baseline following antifungal therapy and immediately prior to cART initiation; and at the time of the C-IRIS event post-cART initiation for the C-IRIS group.
Results: Of 17 cytokines analyzed, plasma levels of IL-7 and IL-5 pre-cART were higher in C-IRIS patients compared to controls after Bonferroni correction (both p< 0.001). In a multivariate Cox proportional hazard-regression analysis, high IL-7 (HR=9.30 [95% CI, 1.96-44.0]; p=0.005) and IL-5 (HR=5.76 [95% CI, 0.77-43.0]; p=0.088) were predictive of C-IRIS. Median cytokine levels were up to 100-fold higher in CSF compared to plasma except for IL-7, but no differences were noted between those with and without C-IRIS. Pre-cART, we observed lower percentages of $CD127^+CD27^+$ $CD8^+$ T cells in C-IRIS patients (median=3.32%, [IQR] 1.87-4.42%) compared to non-C-IRIS (5.88% [2.57-7.89%) (p=0.053) (Mann-Whitney); but no differences in the $CD4^+$ T cell compartment. At the time of the C-IRIS event, there was a significant increase in both $CD127^+CD27^+$ $CD8^+$ and $CD4^+$ T cells compared to baseline (both p<0.05, Wilcoxon signed ranks).
Conclusions: High plasma IL-7 levels and decreased percentage of IL-7 receptor expressing memory $CD8^+$ T cells in patients who develop C-IRIS suggests that dysfunction in the IL-7/IL-7-receptor signaling pathway is associated with the immunopathogenesis of C-IRIS. Further studies to investigate the specific involvement of this pathway in the pathogenesis of C-IRIS are warranted.

MOPEA0092

Impact of minority variants on the virological response to a rilpivirine-based first-line regimen

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Background: Minor resistant variants of HIV-1 could influence the virological response to treatments using non-nucleoside reverse transcriptase inhibitors but data on minor rilpivirine-resistant variants are scarce. Next-generation sequencing (NGS) can detect and quantified minor variants (less than 20% of a virus quasispecies).
The objective of the study was to identify patients harbouring minority variants that have rilpivirine-resistance mutations and to assess the impact of this resistance on the virological response.
Methods: The 541 HIV-1-infected patients studied were from 24 French virology laboratories (members of the ANRS HIV-1 resistance group). They started their first line regimen (rilpivirine, tenofovir and emtricitabine) between 2012 and 2015. NGS was performed retrospectively on the GS FLX platform (Roche) using the XL+ kit to obtain long reads (724 base pairs) of the reverse transcriptase gene. The sensitivity threshold for detecting minor variants was < 1%.
Results: The median patient age was 36 years and 79% were men. The mean virus load at treatment initiation was 4.5 log copies/mL and the mean CD4 cell count was 494 cells/mm^3. Virological success was achieved in 90.6% of patients after a median follow up of 24 months. Virological failure occurred in 16 patients (3.3%) while 30 patients were lost to follow-up. Baseline NGS found resistance-associated mutations (IAS list) that accounted for 1-5% of variants in 17.2% of samples, for 5-20% in 5.7% of samples, and for >20% in 29% of samples. We identified 35 patients who harbored rilpivirine-resistant variants (7%) before treatment initiation. Also, 15 samples contained variants resistant to tenofovir and/or emtricitabine. Thus, the regimens of 12% of patients contained fewer than 3 active drugs according to the ANRS algorithm (threshold: 1%). The frequencies of variants resistant to rilpivirine in patients whose antiretroviral treatment failed (6.2%) and in patients with virological success (7%) were similar.
Conclusions: NGS identified rilpivirine-resistant variants in 7% of patients with a 1% sensitivity threshold. We found that minor resistant variants had no impact on the virological response of our 541 treatment-naive patients to a rilpivirine-based regimen.

MOPEA0093

Primary HIV-1 drug resistance by massive parallel sequencing among treatment naïve HIV-infected blood donors

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Background: Drug resistance mutations (DRMs) in human immunodeficiency virus (HIV) is one of the main reasons for treatment failure. Sanger sequencing is currently the routinely used assay to perform genotyping analysis of therapy resistant variants in HIV-1 protease (PR) and reverse transcriptase (RT). However, this assay has the capacity to detect only mutant variants present at levels above 20% in the viral quasispecies. This drawback was tackled by the introduction of the massive parallel sequencing (MPS) approach, which allows generation of thousands of sequences from the viral population. Here, we used both the Sanger and massive parallel sequencing data to simultaneously detect DRM associated with the inhibitors of the PR, nucleoside reverse transcriptase (NTRI) and non-nucleoside reverse transcriptase (NNTRI) in plasma specimens of 18 drug naïve blood donors.
Methods: The viral nucleic acid were extracted, amplified and successfully sequenced by Illumina paired-end protocol. The conventional Sanger data of the HIV-1 PR and RT nucleotide sequences of the same samples were obtained from the database.
Results: Analysis of DRMs of the 18 plasma samples demonstrated that 4 Sanger and 18 MiSeq samples possessed one or more major resistance mutations based on the list of 2015 IAS-USA. The sensitivity and specificity of the MPS was 100% in detecting DRMs identified by Sanger sequencing. NRTI resistance mutations were only detected in all 18 (100%) samples sequenced by MPS. On the other hand, NNRTI resistance mutations were observed in 4 samples (22.2%) and 17 samples (94.4%) sequenced by Sanger and MPS, respectively. The F77L and M230I were the most common NTRI and NNTRI resistance mutations detected in 88.9% and 77.8% of samples sequenced by MPS, respectively. Minority variants with major DRMs to a lower limit of 1% were detected by MPS in all subjects. No variants with major DRMs were identified in the PR gene either by Sanger or MPS assays.
Conclusions: The majority of HIV variants with DRMs that became undetectable by Sanger sequencing were detected by MPS. The significance of these variants and how they will influence the future therapeutic decisions remains to be determined.

MOPEA0094

A bioinformatic approach to determining HIV-1 drug resistance profiles in next-generation sequencing datasets

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Background: Next generation sequencing technologies are widely used to study the genetics of HIV-1 populations. Although software is available for processing large scale sequence data, no pipelines include an automated analysis of HIV-1 drug resistance mutations. Therefore, we developed a pipeline that constructs high quality consensus sequences from reads with identical primer IDs as reported previously (Jabara CB, et. al. PNAS, 108: 20166) and reports drug resistance mutation profiles for each consensus by interacting with the Stanford HIV database (https://hivdb.stanford.edu/hivdb/by-sequences/).
Methods: We developed a pipeline that, after binning sequence reads generated by paired-end Illumina Miseq technology according to their common primer IDs, applies a super-majority rule which requires ≥80% agreement at each nucleotide position in order to detect and eliminate PCR-based errors. Consensus sequences are subsequently generated from each group of primer IDs and are automatically processed in the Stanford HIV database. The pipeline is written in Perl.
Results: Our new bioinformatics pipeline produces high quality consensus sequences that have error rates equivalent to the gold-standard single-genome sequencing assay and generates an automated excel spreadsheet that reports each HIV-1 genome that contains drug-resistant mutations. The final report produced from the pipeline includes the frequencies of each HIV-1 drug resistance mutation in the total dataset, the frequencies of linked drug resistance mutations, and the characterization of the genetic backbones on which linked mutations occur.
Conclusions: Our new pipeline allows for the rapid profiling of drug resistance mutations in targeted, HIV-1 next-generation sequencing datasets and is a reliable and easy tool for highly sensitive HIV-1 genotyping.

Course of HIV Disease

MOPEB0239

Potency of CXCR4-tropic HIV-1 on mortality is mitigated in the era of ART: 18 year follow-up in a women´s cohort

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Background: Emergence of CXCR4(X4)-tropic HIV-1 strains in infected individuals often heralds CD4 cell depletion and accelerated disease progression, as demonstrated during the pre-HAART and early HAART eras. To investigate whether long-term ART mitigates the deleterious effect of X4 strains, we examined the relationship of HIV-1 tropism to CD4 count and mortality due to AIDS in 529 women followed for 18 years in the Women's Interagency HIV Study (WIHS).
Methods: Participants in the Bronx and Brooklyn WIHS sites were interviewed, examined, and had lab studies performed semiannually (1994-2012). We determined tropism of plasma-derived HIV-1 at 1-3 visits per subject using a heteroduplex tracking assay.
Results: X4 strains were detected, either exclusively or in a mixture with R5 strains, in 39% of participants. We compared CD4 counts over time in subjects with X4's to those with CCR5(R5) strains only, controlling for HIV-1 load. Although CD4 counts rose in both groups, the X4 group displayed significantly diminished counts throughout the entire follow-up period compared to those with R5 strains only (P=0.026).
To examine mortality in relation to tropism, we categorized subjects according to reported visits on HAART after initiation: 1) ≤3 visits on HAART, 74% of whom reported no HAART; 2) < 70% of visits on HAART; 3) >70% of visits on HAART; 4) Viral suppression for ≥3 years on HAART.
Analyses controlled for CD4 count and viral load. AIDS mortality rates in each category for subjects with X4 strains vs those with R5 strains only, respectively, were as follows: Group 1) 63% vs 18% (P< 0.0001); Group 2) 23% vs 21% (NS); Group 3) 6% vs 12% (NS); Group 4) 0 vs 2.5% (NS). Logistic Regression revealed that complete HIV-1 suppression for 10 visits, or 25% of visits after initiation of HAART (for those with fewer than 10 visits), was sufficient to mitigate the deleterious effect of X4 strains on mortality.
Conclusions: In a women's cohort studied for 18 years, long-term HAART mitigated the potency of X4 strains on AIDS mortality. The reduction in mortality, however, was correlated with duration of HAART and viral suppression, supporting HIV-1 suppression as a crucial treatment goal.

MOPEB0240

HIV-RNA CD4/CD8 ratio and HDL concentration in a cohort of HIV + ART-naive patients

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Background: HIV infection is associated with dyslipidemia marked by low levels of high-density lipoprotein (HDL), low-density lipoprotein, total cholesterol and increase of triglycerides. To maximise lipid rafts and virus budding, HIV Nef protein downregulates ATP cassette binding transporter A1 (ABCA1), reducing cholesterol efflux from macrophages and the generation of nascent HDL.. To analyse the correlation between HDLs level, HIV viremia and CD4/CD8 ratio in a group of ART-naive HIV-positive patients and to evaluate its role in HIV replication and disease progression.
Methods: We included ART-naïve HIV-infected people in the ICONA Foundation cohort. We considered persons for whom ≥2 viral load (VL) measurements prior to ART initiation were available. The viral set point (VLset) was defined as the mean of the first two VL and the date of the 2nd value chosen as the index date for this cross-sectional analysis. We then included people without statin therapy and with a value of HDL over 3 months of the index date. We performed correlation unadjusted and gender/age, HCV status, BMI and AIDS diagnosis adjusted linear regression analyses. VLset and CD4/CD8 ratio were fitted in the $\log_{10}$ scale, HDL distribution in the raw scale.
Results: We included 2,596 individuals; median age was 36 (range: 18-81). Thirty-nine (1.5%) were aviremic (VLset ≤50 copies/mL), 20% female, 12% PWID and 48% MSM. We observed a negative correlation between HDL and VLset (R^2=0.03, from fitting a linear regression model -3.2 mg/dl per $\log_{10}$ higher VL, p<0.0001), and a positive correlation between HDL and CD4/CD8 ratio (R^2=0.02, +8.9 mg/dl per $\log_{10}$ higher ratio, p<0.0001). There was a dose-response relationship between HDL levels and VLset strata independent of age, gender and CD4/CD8 ratio which was no longer significant after controlling for other factors such as HCV status and BMI. In contrast, greater values of CD4/CD8 ratio were independently associated with higher HDL levels.
Conclusions: Our data show that HDL level is associated with VLset (negative correlation) and CD4/CD8 ratio (positive correlation), suggesting that the change in lipid metabolism caused by HIV is an important step in its life cycle and should confirm the close relationship between HIV infection and CVD.

MOPEB0241

Association between inflammatory/coagulation biomarkers and mortality in HIV-infected adults with high CD4 counts in Côte d'Ivoire, West Africa (TEMPRANO ANRS 12136)

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Background: Several inflammatory and coagulation biomarkers have been previously associated with clinical outcomes in untreated or treated HIV-infected patients in high-income countries. We analyzed the association between ten biomarkers and mortality in HIV-infected adults who participated in a trial of early antiretroviral therapy (ART) and 6-month IPT in Côte d'Ivoire, West Africa.
Methods: In the Temprano trial (ANRS 12136), HIV-infected adults were randomly assigned to immediate ART or deferred ART. The trial follow-up (TFU) was 30 months. Participants who completed the TFU were invited to participate in a post-trial phase (PTP). The PTP endpoint was all-cause death. Serum/plasma samples were collected and frozen at baseline. We used these samples to measure IL-6, IL-1RA, sVCAM-1, sCD14, sCD163, IP-10, D-dimer, hsCRP, fibrinogen, and albumin in patients assigned to deferred-ART. We used Cox proportional models to analyse the association between all-cause mortality and each marker from inclusion in Temprano (March 2008) to the end of the PTP phase (January 2015). Markers significantly associated with death in univariate analysis were included in a step-by-step ascending multivariate analysis. Analyses were adjusted for sex, HIV-RNA, total HIV-DNA, CD4 count, and IPT. Marker concentrations were treated as categorical (< vs. ≥ 3rd quartile).
Results: 1,023 patients (77% women, mean baseline CD4 count 459/mm^3) were randomized to deferred ART and followed for 4,657 patient-years (median 4.8, IQR 3.3-5.8 years). A total of 49 deaths were observed. In univariate analysis, the hazard ratio of death was 2.16 (95%CI 1.21-3.85) for IL-6, 1.09 (0.56-2.15) for IL-1RA, 2.83 (1.58-5.05) for sVCAM-1, 3.96 (2.16-7.27) for sCD14, 2.02 (1.13-3.60) for sCD163, 2.70 (1.49-4.87) for IP-10, 1.84 (1.01-3.34) for D-dimer, 1.50 (0.79-2.83) for hsCRP, 1.15 (0.62-2.14) for fibrinogen, and 0.74 (0.33-1.66) for albumin. In multivariate analysis, sVCAM-1 and sCD14 remained independently associated with mortality (adjusted HR [aHR] sVCAM-1=2.07 [95%CI 1.06-4.03, p=0.03]; aHR sCD14=3.26 [95%CI 1.74-6.13, p< 0.001]).
Conclusions: In these West African adults with high CD4 counts, sVCAM-1, an endothelial activation marker, and sCD14, a marker of monocyte activation, were independent predictors of all-cause mortality. While the latter association was previously reported, to our knowledge this is the first report of the association between sVCAM-1 and mortality.

MOPEB0242

Blood HIV-1 DNA level strongly predicts mortality in HIV-infected adults with high CD4 counts in Côte d'Ivoire, West Africa

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Background: In sub-Saharan Africa, high HIV-1-DNA levels in PBMCs have been previously associated with a higher risk of severe morbidity and a faster decline in CD4 count. Here we report the association between HIV-1-DNA and mortality in HIV-infected adults who participated in a trial of early antiretroviral therapy (ART) in West Africa.
Methods: In the Temprano ANRS 12136 trial, untreated HIV-infected adults with < 800/mm^3 and no WHO criteria for starting ART were randomly assigned to start ART immediately or defer ART until WHO criteria were met. The trial follow-up (TFU) was 30 months. Participants who completed the TFU were invited to participate in a post-trial phase (PTP). The PTP endpoint was all-cause death. PBMCs were frozen at -80°C at baseline. HIV-1-DNA in PBMCs was measured using a real time PCR method (Biocentric, Bandol, France). We used a multivariate Cox proportional model to analyse the association between all-cause mortality, PBMC HIV-1-DNA (≥3 vs. < 3 $\log_{10}$copies/million PBMCs) and plasma HIV-1-RNA (≥5 vs. < 5 $\log_{10}$copies/ml) from inclusion in Temprano (March 2008) to the end of the PTP phase (January 2015) in patients assigned to deferred-ART. The multivariate analysis included baseline HIV-1-RNA, baseline HIV-1-DNA, sex, baseline CD4 count, time-updated ART status, and isoniazid preventive therapy status (received/not received).
Results: 1,023 patients (77% women) were randomized to deferred ART and followed for 4,657 patient-years (median 4.8 years, IQR 3.3-5.8). At baseline, median CD4 count was 459/mm^3 [IQR 362-567], median plasma HIV-1-RNA 4.6 $\log_{10}$copies/ml [IQR 4.0-5.2], and median HIV-1-DNA 3.0 $\log_{10}$ copies/million PBMCs [IQR 2.5-3.3]. During follow-up, 49 participants died. In univariate analysis, the hazard ratio [HR] of death was 2.97 (95%CI, 1.58-5.60) for patients with HIV-1-DNA ≥3 $\log_{10}$ copies/million PBMCs vs. others, and 2.08 (95%CI, 1.19-3.64) for patients with HIV-1-RNA ≥5 log10copies/ml vs. others. In multivariate analysis, PBMC HIV-1-DNA ≥3 remained strongly associated with the risk of mortality (adjusted HR=2.55, 95%CI 1.26-5.15, p=0.009) while the association between plasma HIV-1-RNA and mortality was not significant (adjusted HR=1.37, 95%CI 0.74-2.54, p=0.32).
Conclusions: In these sub-Saharan African adults with high CD4 counts, HIV-1-DNA level ≥ 3 $\log_{10}$ copies/million PBMCs was a strong independent predictor of death.

MOPEB0243

Socioeconomic status and time trends associated with early ART initiation following primary HIV infection in Montreal, Canada: 1996-2015

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Background: Guidelines regarding ART initiation in HIV infection have varied over time, with 2015 recommendation by the World Health Organization to initiate ART at the time of diagnosis regardless of CD4 T cell counts.
Herein, we investigated the influence of sociodemographic and clinical factors in addition to time trends on early ART initiation among participants of the Montreal Primary HIV Infection Study.
Methods: The Montreal Primary HIV Infection Study is a prospective cohort established in three community medical centres and two university medical centres. Recently diagnosed HIV-infected adults were categorized as receiving early (vs. delayed) ART if ART was begun within 180 days of the baseline visit. Associations between early ART initiation and sociodemographic, socioeconomic and behavioral information were examined. Independent associations of factors linked with early ART initiation were determined using multivariate binary logistic regression analysis.
Results: A total of 348 participants had a documented date of HIV acquisition of <180 days. The median (IQR) age of participants was 35 (28; 42) years and the majority were male (96%), having paid employment (63%), men who have sex with men (MSM) (78%) and 1-4 sexual partners in the last three months (70%). Participants presented with a median (IQR) HIV plasma viral load of 4.6 (3.7; 5.3) $\log_{10}$ copies/mL, CD4 count of 510 (387; 660) cells/µL and were recruited in community medical centres (52%) or university medical centres (48%). Early ART initiation was observed in 47% of the participants and the trend followed a V-shaped curve with peaks in 1996-97 (89%) and 2013-15 (88%) with a dip in 2007-09 (22%). Multivariate analyses showed that having paid employment (aOR: 2.43; 95% CI: 1.19, 4.95), lower CD4 count (aOR per 50 cell increase: 0.93; 95% CI: 0.87, 0.99) and care at university medical centres (aOR: 2.03; 95% CI: 1.06-3.90) were independently associated with early ART initiation.
Conclusions: Early ART initiation during primary HIV infection was associated with poorer biologic prognostic factors and calendar time mirroring evolution of treatment guidelines. In addition, despite universal access to care in Canada, sociodemographic factors such as no employment may be a barrier in accessing early ART.

MOPEB0244

Long-term outcome of patients after HIV-1 primary infection in the ANRS PRIMO cohort

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Background: French guidelines recommend universal treatment of HIV infection, since primary infection (PHI) and regardless of CD4 cell count. However many patients are still diagnosed during chronic infection. To determine the consequences of delayed diagnosis, we compared long-term immunovirological and inflammatory outcomes according to whether patients were treated since PHI (immediate ART - iART, N=77) or not (differed ART - dART, >12 months after PHI, N=73).
Methods: We selected patients from the ANRS French PRIMO Cohort treated for >3 years, with a sustained HIV-RNA <50cp/mL and available frozen samples. CD4 and CD8 cell counts and plasma HIV-RNA were measured locally; total cellular HIV-DNA, plasma usHIV-RNA and inflammation markers (IL-6, IL-1α, TNFα, MCP-1, IP-10, sCD14, sCD163, IL-10, LAP and iFABP; FlowCytoMix or ELISA assay) were measured centrally. We compared between iART and dART patients inflammation markers levels at PHI, before ART initiation, at 36 months of ART and at the last follow-up visit on ART. We modelled CD4 count, CD4/CD8 ratio and HIV-DNA dynamics with mixed models.
Results: Patients were mostly Caucasian men (79%), median age 37 years. ART was initiated within a median time of 1 and 29 months after PHI in the iART and dART groups, respectively, mostly with protease inhibitor-containing regimen (82%). At PHI, median CD4 and HIV-RNA levels were 414 cells/mm3 and 5.5 log10cp/mL in the iART group and 539 and 4.6 in the dART group. In both groups, IP-10, MCP-1, sCD163, IL-6 levels decreased on ART while TNFα and sCD14 levels remained stable. IL-1α levels remained higher in the dART vs. iART group at 36 months of ART. At the last follow-up visit on ART (iART: 91.0 months, dART: 73.5 months), no difference in inflammation markers and usHIV-RNA levels were observed between groups. Modelling showed a sustained lower HIV-DNA level in the iART vs. dART group (between -0.3 and -0.6 log10cp/106PBMC). On the other hand, the benefit in CD4 and CD4:CD8 ratio observed with iART gradually diminished overtime and no longer differed after 45 months on ART between the groups.
Conclusions: These results strongly argue for an immediate ART initiation during PHI, to optimize long-term viral reservoir level.

MOPEB0245

Prevalence of non-B subtypes and trends in transmission of primary drug resistance in patients with primary HIV-1 infection during the last 10 years (2005-2015) in Marseille university hospitals, Southeastern France

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Background: Transmitted HIV-1 drug resistance (TDR) remains a public health problem and requires a sentinel national surveillance at the country-scale. In addition, non-B HIV-1 subtypes are increasing in developed countries. We assessed the prevalence of transmitted drug resistance (TDR) and the frequency of non-B subtypes in patients with acute HIV-1 infection in Marseille university hospitals, Southeastern France, during the period 2005-2015
Methods: Between 2005 and 2015 (10 years), all patients with a genotypic test performed at the time of primary HIV-1 infection (PHI) in Marseille University hospitals were enrolled. HIV-resistance-associated mutations (RAMs) to reverse transcriptase and protease inhibitors were characterized using both the 2009 WHO list of mutations and the French ANRS Algorithm V.26. Subtypes were determined by phylogenetic analysis of the reverse transcriptase gene.
Results: 115 patients diagnosed with PHI were analyzed. According to the ANRS algorithm v.26, the prevalence of protease, nucleoside/nucleotide reverse transcriptase, 1st generation nonnucleoside reverse transcriptase inhibitor and ETV/RPV-associated RAMs were 27%, 5.2%, 7.8% and 5.2%, respectively. Among resistant viruses the proportion of those resistant to 2-3 classes was 15.3%. Men having sex with men (MSM) were more frequently infected with resistant viruses than were other transmission groups (26% vs 7%, p=0.011). RAMs frequency did not differ in patients infected with B compared with non-B subtypes. Non-B subtypes were identified in 31% of patients. Non-B strains were diverse and included 4 subtypes (3 A; 1 C; 5 F; 1 J; and 4 circulating recombinant forms (CRFs) including 23 CRF_AG; 1 CRF06_cpx; 1 CRF30; 1 D/K). The proportion of non-B subtypes increased significantly over time in particular during the 2011-2013 period vs the 2005-2011 period (p= 0.03, Kendall's rank correlation tau). Of note, CRF02_AG largely predominated in the 2005-2013 period, whereas rare recombinant D/K, CRF06-cpx and CRF30_0206 emerged only recently (2014-2015).
Conclusions: These data highlight two tendencies in southeastern France: (1) the spread of resistant HIV strains among MSM; (2) the recent increase of rare CRF/cpx of HIV. This should be taken into account when implementing suitable prevention strategies particularly in MSM and in starting combined antiretroviral therapy in this setting.

MOPEB0246

HIV transmission and disease progression are linked to the frequency of α4β7+ CD4+ T cells

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Background: The α4β7 integrin is one of the major gut-homing receptors involved in the migration of a variety of lymphocytes, including CD4+ T cells, into the gut associated lymphoid tissue (GALT). α4β7 expressing lymphocytes are involved in the pathogenesis of a number of human diseases that involve GALT, including graft-versus-host disease, and inflammatory bowel diseases such as Crohn's disease and ulcerative colitis. More recently, a role for α4β7-expressing cells has been described in the non-human primate (NHP) model of SIV infection in which, during the early stages of disease, the GALT is a major target of infection. Of note, in a NHP model, SIV-infected macaques, when treated with a combination of antiretroviral therapy (ART) and an anti-α4β7 mAb, were able to maintain low to undetectable viral loads and normal CD4+ T-cell counts in plasma and gastro-intestinal tissues for over 2 years, even after all treatments were withdrawn.
Methods: We compared $\alpha_4\beta_7$ integrin levels on $CD4^+$ T cells in blood of study participants who remained HIV uninfected versus those that acquired HIV infection in the CAPRISA 004 tenofovir vaginal gel study conducted in South Africa.
Results: We found that increased frequencies of α4β7 CD4+ T cells in blood are associated with an increased likelihood of acquiring infection and a more rapid disease course following infection. We also find that at the earliest stages of HIV infection, CD4+ T cells expressing α4β7 are rapidly depleted, particularly from the gut, and are not restored by early initiation of ART.
Conclusions: This is the first study to link pre-HIV α4β7 expression with HIV susceptibility and clinical outcomes in humans. These results further substantiate the central role of α4β7 in HIV transmission and pathogenesis.

MOPEB0247

Long-term non-progressors and factors associated to immunological progression among HIV-2-infected individual in West Africa

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Background: The low pathogenicity of HIV-2 infection leads to consider the majority of these patients as long term non progressors (LTNP) which are therefore out of the scope of therapeutic guidelines. Despite the long asymptomatic phase of the infection, all HIV-2 infected patients may progress to AIDS and to death in ab-

sence of holistic care. There is limited data on the prevalence of LTNP and the time to immunologic progression among people living with HIV-2 in West Africa. This study aimed at estimating the prevalence of LTNP among HIV-2 infected patients followed in the HIV-2 cohort of the IeDEA West Africa collaboration (WADA-HIV-2).
Methods: A cross-sectional survey was conducted from February to December 2014 in Burkina Faso and Côte d'Ivoire, within the WADA-HIV-2 cohort. All HIV-2-infected patients, aged 18 years and above, attending the HIV clinic for a follow-up visit were invited to participate. A dedicated questionnaire was used to collect clinical and biological characteristics of patients. We defined LTNP in this study as ART-naïve patients with CD4 count >500 cells/mm^3 at HIV diagnosis and who maintained high CD4 count (>500 cells/mm^3) during at least five years. We defined progression as the fact of having at least one measure of CD4 count < 500 cells/mm^3. We performed survival analysis to estimate the probability of staying LTNP over the time.
Results: Among the 631 patients who participated in the study, the median age was 49 (IQR [42-55]) years, 381 (60.6%) were women, 470 (77.9%) were receiving ART and 18 were identified as LTNP. The prevalence of LTNP was estimated to 2.8% (95%CI [1.6-4.2]). All LTNP had undectable plasma HIV-2 viral load at the time of screening, 6 (33.3%) of them had CD4 count >750 cells/mm^3. Initial CD4 count >750 cells/mm^3 was the only factor associated with long term non progression among HIV-2 patients (aOR=5.8; 95%CI [3.2-10.8]; p=0.003). The probability of staying LTNP was declining over the time, 20% after 5 years to 10% after 10 years.
Conclusions: The low proportion of HIV-2 long term non progressors sheet light on the necessity to revisit the therapeutic guidelines, specifically toward universal treatment.

MOPEB0248

Gender differences, impact of violence exposure on drug use, and HIV risk behaviors among young adult African Americans in Washington DC

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Background: This presentation provides baseline preliminary analysis of data collected in a longitudinal study from 440 African Americans young adults ages 18-25 living in Washington. One component of the study is designed to test the effects of social and environmental stressors, such as exposure to violence, on alcohol, tobacco and other drug (ATOD) use, and on sexual risk behaviors that may render African American young adults more vulnerable to contracting HIV/AIDS. The objective here is to understand how exposure to violence impacts ATOD use and HIV risk behaviors, and to determine if the strengths of the associations vary based on violence type and gender.
Methods: We conducted a factor analysis of the exposure to violence scale items to identify domains or types of violence. We then conducted a series of regression analyses to measure how various violence types affect the dependent variables representing ATOD use, and knowledge and perception of HIV risk factors.
Results: Women and men differed in the types of violence to which they were likely to have been exposed. Women were significantly more likely to have been exposed to personal violence and attacks, which explained 65.8 percent of the total variance explained in the model for behaviors that obviate a need to worry about HIV. Exposure to drug sales or physical violence explained 70.1 percent of the total variance explained in women's knowledge of HIV transmission risks. Exposure to gun use or seeing violent deaths explained 76.5 percent of the total variance explained in women's attitudes towards condom practices, and 79.9 percent of the total variance in their perceptions of condom users. Among men, exposure to gun use or seeing violent deaths explained a much smaller 38.2 percent of the total variance explained in attitudes towards condom practices, and exposure to childhood sexual abuse explained 36.5 percent of the total variation explained in worrying about contracting HIV.
Conclusions: The results suggest that a large percentage of young African American adults are exposed to violence, that violence has a strong impact on ATOD use and HIV risks behaviors, and that African American women and men are exposed to different kinds of violence.

MOPEB0249

Social behavioural determinants of early HIV infection in young South African women

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Background: New incidents of HIV are high among Black South African women 15 to 24 years. We adopt a lifecourse approach we test whether early adverse life circumstances such as parental HIV, orphanhood, physical and sexual abuse and extreme poverty in childhood predict sexual behaviors (e.g., early sexual debut) which place women at risk for HIV exposure.
Our hypotheses are that (1) childhood history predicts sexual experiences, gender-based violence and partner characteristics; (2) that partner characteristics such as age difference and antisocial behaviour will be associated with HIV infection.
Methods: Findings derive from a 2016 case-control interview study of 869 women outpatients (M age = 23) who reside in informal settlements surrounding Pretoria in Gauteng, South Africa. Women outpatients were recruited in waiting rooms from hospitals and clinics and interviewed for one hour in SeSotho, Setswana, isiXhosa and English. Their HIV status was confirmed through medical records (HIV+=450; HIV-=419). The interview included mainly standardized instruments. Approval was granted from five different ethics review boards. Data entry was completed in December 2016 and SPSS used as the statistical program.
Results: Findings reveal that there is a strong intergenerational risk for HIV, with 65% of HIV+ patients recounting HIV+ relatives in contrast to controls (25%). Parental death from any cause predicted HIV status. Sexual behaviors were inconsistently related to HIV and HIV+ women were no more likely to have multiple sexual partners.
The most significant proximal risk indicator for early onset HIV was a long-term union before the age of 19, typically with a man at least four years older; risk was heightened if he was violent or drank to excess. Departure from secondary school was associated with long-term unions at an early age.
Conclusions: To avert the rise in new incidence among girls in South Africa immediate interventions are needed for teenage girls who recall child abuse or whose mothers are absent or deceased. Furthermore, efforts must be intensified to retain girls in school and discourage early live-in relationships.

Diagnostic and Monitoring

MOPEB0250

Provider initiated testing and counseling uptake in Wum District hospital (Nord-West Cameroon): a hospital-based cross sectional study

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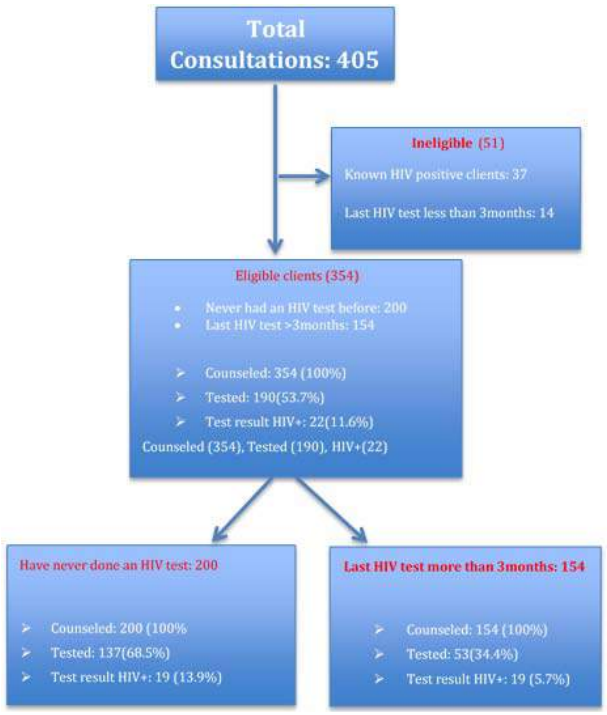
Background: An estimated 1.6% of Cameroonian adults are HIV positive, of which 85.6% have never done an HIV test. To achieve the UNAIDS goal of 90-90-90, the Cameroon Ministry of Health mandated that all clients who have never done an HIV test and clients whose last HIV test was negative and dates more than three months should be systematically proposed an HIV test at all medical visits. However, there is no data on the acceptability of this test by the population in Cameroon.
Our main goal was to determine the proportion of patients who finally get to do the HIV test after recommendation and counseling.
Methods: We carried out a cross sectional descriptive study over a three months period in the outpatient consultation clinic of the Wum District hospital. During this time, HIV testing was recommended to clients who had never had an HIV test, or whose prior negative test had been more than three weeks earlier. For those who consented, rapid (Determine) and confirmation (BISPOT) tests were administered and results reported to the prescribing physician. Data were entered into a spreadsheet and analyzed using SPSS.
Results: About 50% of persons consulting at the Wum district hospital still do not know their HIV status. Despite routine recommendation and counseling for testing, only about half of the persons who received counseling did not do the test, figure 1.
Conclusions: Acceptability of testing for HIV despite routine recommendation and counseling is a barrier to achieving the 90-90-90 goals in this setting. We recommend that a large-scale study be carried out to determine the reasons why persons decline getting tested for HIV.



[Figure 1. Flow Chart Showing Study Population and Results]

MOPEB0251

Performance of alere HIV combo test in established and acute HIV infection

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Background: Rapid anti-HIV test is highly preferred for busy laboratories and mobile VCT settings. Most of the commercially available rapid tests are 3rd Generation kits. We evaluated the performance of Alere HIV Combo (AlereCOMBO), the newly available 4th Generation anti-HIV test.
Methods: Three sets of an overall 250 stored plasma samples [(1) HIV positive, N = 100 as defined by positive Abbott Architect 4th generation Ag/Ab test (Test 1) and confirmed by both immunochromatography (Determine) (Test 2) and gel particle agglutination (Test 3); (2) HIV negative, N = 100 as screened by Test 1; (3) acute HIV infection, N=50 as defined by positive Test 1 but negative both Test 2 and 3 whereas HIVRNA by Aptima was positive] from the Anonymous Clinic of the Thai Red Cross AIDS Research Centre were used to evaluate AlereCOMBO. Sample/cut-off (S/CO) ratio of the test and the viral load (VL) of each sample were used for analysis.
Results: AlereCOMBO correctly detected all the confirmed positive and negative samples gaining 100% sensitivity and specificity. The overall sensitivity and specificity of the entire 250 samples were 91.3% and 100% respectively. Of particular interest was on the 50 acute HIV infection samples, AlereCOMBO could detect 37/50 (74%): 5 anti-HIV positive only (R1), 26 p24 antigen positive only (R2), and 6 both p24 Ag and anti-HIV positive (R3). S/CO ratios of R1/R2/R3 were 21.55/148.38/72.97 respectively as compared to 7.57 for the non-reactive (NR) acute HIV samples**.** R2 and R3 had significantly higher S/CO than NR or R1 ($p<0.001$).. The corresponding $\log_{10}$ HIVRNA of NR/R1/R2/R3 were 5.55/5.64/6.74/6.30 respectively. HIVRNA in R2 and R3 were significantly higher than NR ($p<0.001$).
Conclusions: AlereCOMBO detected mainly p24 Ag in acute HIV infection as seen in 32/50 (64%) subjects, supported by the highest S/CO in the p24 Ag only group (R2), followed by the Ag+Ab group (R3). For antibody detection, AlereCOMBO could detect 11/50 (22%) more samples than the two 3rd Generation anti-HIV tests used in our testing algorithm, Therefore, AlereCOMBO is a preferred rapid test in a setting with high incidence and is more sensitive than the commonly used 3rd Generation tests.

MOPEB0252

HIV self-test: perception and intention to use in a French nationwide study

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Background: It is considered that 28,000 undiagnosed HIV-infected people live in France. This unawareness should be reduced, as it fuels HIV transmission, and leads to late-stages of HIV infection. Since fall 2015, HIV self-test is available in French pharmacies without prescription. We aimed to explore perceptions toward this new testing tool, and whether people most at risk of HIV infection intent to use it, particularly MSM.
Methods: An anonymous online questionnaire was diffused between November 2015 and January 2016 by different means, targeting the general population and MSM population. The questionnaire explored gender, age, sexual partner gender, self-perceived HIV exposure, the use of condom in case of sexual intercourse with penetration with another partner than the usual partner (if any), the knowledge and perceptions concerning of HIV self-test, and past and planned future use.
Results: 1336 participants filled the questionnaire (male 67.1%, female 32.4%, other 0.5%; age 32.8±12 years), including 889 who completed it. 44.8% were MSM. 33.5% considered they were not exposed to HIV; 41.5% declared they did not always use or make use a condom in case of sexual intercourse with penetration with another partner than their usual partner (if any)(participants "objectively at risk"). 9.9% had already used the self-test, this proportion being higher in multivariate analysis in those with a monthly income above 1000€, and those who declared being very/rather well informed on HIV. 38.5% declared they plan to use the self-test in the forthcoming month or year, this proportion being lower in male and in MSM in multivariate analysis, and higher in those "objectively at risk". 68.4% under-estimated the delay after an HIV exposure to rule out the infection with a self-test (12 weeks). The 3 issues with self-test more frequently cited were that it does not test for other sexually transmitted infection (49.5%), that you have to pay to get tested (44.4%), and that one is alone with his/her result (41.0%).
Conclusions: HIV self-test is identified as an interesting tool by different at-risk populations, and may help reducing the proportion of undiagnosed infections. Communication should insist on the delay for reliability. A much lower price may enhance its use.

MOPEB0253

Non-reactive HIV-1 self-tests after sustained viral suppression following early antiretroviral therapy

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Background: Early antiretroviral therapy (ART) during primary HIV-1 infection (PHI) is now recommended to improve clinical outcome and prevent sexual transmission. Early ART may also impact HIV-specific serological response due to the rapid control of viral replication. Our aim was to assess the sensitivity of different HIV screening tests after a prolonged successful ART among patients treated during PHI.
Methods: Among HIV-infected patients enrolled at time of PHI in the ANRS PRIMO cohort, we selected those who received immediate ART and presented an undetectable viral load for ≥36 months afterwards. Frozen serum samples were tested using the CE-certified self-test Autotest VIH® (self-test), two point-of-care immunoassays (INSTI® HIV-1/HIV-2 Rapid Antibody Test [INSTI] and VIKIA® HIV1/2 [VIKIA]), and the 4th-generation ARCHITECT® HIV Ag/Ab Combo immunoassay (4thG ELISA).
Results: Patients (N=44) were mostly male (82%), median age was 40 years. At diagnosis, median CD4 cell count, plasma HIV-RNA and cell-associated HIV-DNA were 372/mm^3, 5.3 $\log_{10}$ copies/ml and 3.6 $\log_{10}$ copies/10^6 PBMC, respectively. ART was initiated at a median of 43 days (range 20-115) after estimated date of infection, corresponding to Fiebig stage II (5%), III (2%), IV (36%), V (21%) or

VI (36%). HIV-specific serological response was evaluated after a median of 84 months (range 36-204) of successful treatment. Non-reactivity was found to be 30% for self-test, 9% for INSTI test and 7% for VIKIA test. All participants remained positive with 4thG ELISA (median index=48 [range:1.9-491]) but 7/44 had an index value < 10. We did not find any baseline- or on-treatment immunogical or virological factor associated with non-reactivity of self-test, except the 4thG ELISA index measured at the same time which was weaker for patients with non-reactive self-test (index: 23 vs 60, p=0.003). Cell associated HIV-DNA level at time of self-test was not associated with non-reactivity; of note it remained detectable for 9 of 13 patients (69%) with negative self-test.
Conclusions: The HIV-specific antibody response is stopped and declines when ART is initiated during PHI. Several years of successful ART may lead to seronegativity of HIV self-test in 30% of patients. Particular caution should be given in case of HIV self-retesting.

MOPEB0254

Detection and confirmation of HIV-2 presence in Brazil: surveillance algorithm in indene area

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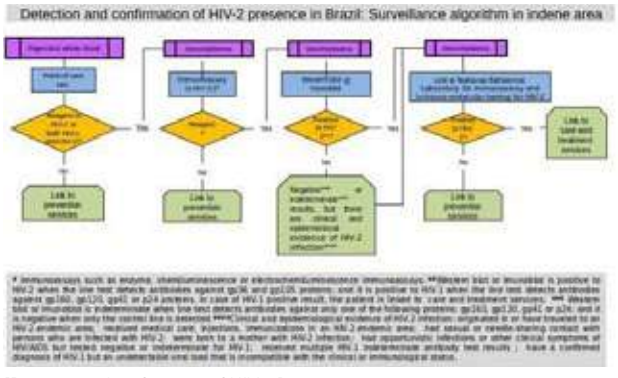
Background: Despite Brazil being an indene transmission area for HIV-2, the Brazilian Ministry of Health (MoH) established in 2010 surveillance measures for HIV-2 detection and diagnostic confirmation in view of the intense flow of people throughout Brazil and the endemic areas.
Methods: The surveillance algorithm suggests the use of point-of-care tests (POCT) in health facilities. The POCT are able to distinguish HIV-1 and HIV-2 antibodies that are present in whole blood samples (fingerstick). Whenever HIV-2 or both HIV-1 and HIV-2 are detected in the test line, a sample is submitted to immunoassay. In case of reagent result, a Western blot/Imunoblot (WB) is performed in order to detect antibodies against gp36 and gp105, HIV-2 specific proteins. If the WB is positive, a sample is sent to the National Reference Laboratory (NRL) for immunoassay and in-house molecular testing for HIV-2. If the WB is negative or indeterminate, a sample is sent to the NRL only in the event of strong epidemiological and clinical evidence of HIV-2 infection. If the HIV-2 infection is confirmed by the NRL, the patient is referred to start treatment; otherwise, the person is directed to the prevention service
Results: From 2010 to 2016, forty-three cases were investigated for HIV-2 infection. The HIV-2 infection was confirmed in two Brazilians, whose both partners were from Guinea Bissau. Other cases occurred in foreigners from Senegal, Costa do Marfim and Guinea Bissau.
Conclusions: The algorithm ensures early diagnosis, thereby minimizing transmission risk and providing opportunities for appropriate treatment. All HIV-2 confirmed cases related to epidemic countries. The MoH aims to expand the use of POCT in health facilities regardless the type of the virus.The HIV diagnosis in Brazil seeks to reach every Brazilian citizen or resident foreigner in Brazil.



[Detection and confirmation of HIV-2]

MOPEB0255

Comparison of home-based oral fluid rapid HIV self-testing vs. mail-in blood sample collection or medical/community HIV testing by young adult black, Hispanic, and white MSM: results from a randomized trial

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Background: A primary goal for home-based oral fluid rapid HIV self-testing is to encourage people at higher risk for HIV infection and those with reduced access to traditional medical/community testing facilities to be tested for HIV, such as young white and ethnic minority men-who-have-sex-with-men (YMSM). We aimed to determine if black, Hispanic and white YMSM were more likely to complete home-based oral fluid rapid HIV self-testing than either mail-in blood sample collection or medical facility/community organization-based HIV testing.
Methods: This randomized trial included 125 black, 150 Hispanic, and 150 white HIV-uninfected 18-24-year-old YMSM recruited through eight social media platforms across the US. Within each race/ethnicity stratum, participants were randomly assigned to use a free home-based oral fluid rapid HIV self-test (n=142), use a free mail-in blood sample collection HIV test (n=142), or be tested at a medical facility/community organization of their choice (n=141). Test completion, time to test completion, and legitimate referrals of other YMSM to use the same HIV test were compared by study arm using summary statistics with 95% CIs.
Results:

	Assigned HIV testing group		
	Home-based oral fluid rapid HIV self-test	Home-based mail-in blood sample collection HIV test	Medical facility or Community organization HIV test
	n=142	*n=142*	*n=141*
Completed assigned HIV test, % (95% CI)	66.2 (58.4, 74.0)	40.1 (32.1, 48.2)	56.0 (47.8, 64.2)
Days to complete assigned HIV test, median (95% CI)	14.0 (11.0, 17.0)	17.0 (15.0, 22.0)	17.0 (11.0, 26.0)
Agreed to refer, % (95% CI)	35.9 (28.0, 43.8)	19.7 (13.2, 26.3)	26.2 (19.0, 33.5)
Made at least one legitimate referral, % (95% CI)	28.9 (21.4, 36.3)	18.3 (11.9, 24.7)	22.0 (15.1, 28.8)

[Main results]

As shown in the table of the main results, completion of the assigned test and willingness to refer other YMSM to use the same assigned test were greater in the oral fluid rapid HIV self-test arm than the mail-in blood sample collection HIV test arm, but not significantly greater than the medical facility/community testing arm. Time to testing and legitimate referrals were similar across study arms. In additional analyses, there were no differences in these measured outcomes by race/ethnicity.
Conclusions: Although free home-based oral fluid rapid HIV self-testing showed moderate promise in facilitating HIV testing, it was not associated with greater HIV testing than directing these black, Hispanic, and white YMSM to medical facility/community HIV testing venues. Providing testing through multiple venues and strategies appears necessary to optimize testing for this higher HIV risk population.

MOPEB0256

Men who have sex with men (MSM) acute HIV infection (AHI) detection at CheckpointLX, Lisbon, Portugal

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Background: CheckpointLX (community-based HIV testing site) study, Lisbon MSM Cohort (Meireles et al, 2015), followed 804 MSM for a total of 893.37 person-years between April 2011 and February 2014: overall incidence of 2.80 per 100 person-years (95% CI:1.89-4.14). The median time between participant visits was 0.57 years (≈7 months) and among those who seroconverted 0.79 years

(≈9 months): showing the existence of primary infections (< 6 months) and the opportunity to target for AHI detection. This study aims to study the impact of two screening algorithms in the detection of AHI at CheckpointLX.
Methods: Between November 2016 and November 2019, MSM seeking for HIV screening are tested with Alere™ Determine HIV-1/2 Ag/Ab Combo (algorithm one, rapid Ag test) and those with AHI symptoms and non-reactive Ag are tested with Alere™ q HIV-1/2 Detect (screening algorithm two, point-of-care HIV-RNA test). All positive Ag and/or HIV-RNA confirmed cases are assessed with Alere™ Pima for CD4 count. Primary HIV infection case definition (acute or recent) according with EACS guidelines 8.1. Those with AHI are linked to care in 48 hours. Study protocol was approved by both the Ethics Committee of the Lisbon Medical Academic Centre and the National Commission for Data Protection.
Results: In the first two months of enrollment, 9 MSM with recent primary HIV infection (Ab negative to positive in the last 6 months) and 1 MSM with acute primary infection (presence of p24 or HIV-RNA in the absence of Ab) were found.
Conclusions: Preliminary data shows that at CheckpointLX recent primary HIV infection are frequent and targeted AHI screening programs enable rapid linkage to the clinical benefit of the individual and the HIV prevention benefit of the public.

MOPEB0257

Rapid oral testing improves acceptance and diagnosis of HIV in a hospital outpatient dental clinic: a case-control study in Yuxi county, China

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Background: To compare the outcomes of the routine provider-initiated HIV testing and counselling (PITC) and rapid oral HIV testing for dental clinic outpatients in a hospital.
Methods: We recruited dental outpatients into routine serum-based and rapid oral testing groups. The acceptance rate, completion rate, and result notification rate were compared between groups using descriptive statistics.
Results: A total of 758 and 816 participants were enrolled into routine and rapid oral testing groups, respectively. The percentage of participants willing to receive routine HIV testing was 28.1% (24.9-31.3%) and 96.1% (94.8-97.4%, $\chi2$=186.4, p<0.01) for the rapid testing. Among accepted participants, the percentage of who finally received HIV testing was 26.8% (20.9-32.7%) in the routine group versus 100.0% in the rapid testing group ($\chi2$=77.5, p<0.01). About 93.0% of routine testers returned for the test results in the next day, whereas all rapid testers received their test results ($\chi2$=34.6, p<0.01). These correspond to an overall completion rate of 7.0% (5.2-8.8%) and 96.1% (94.8-97.4%, p<0.01), respectively. Among the 545 patients who declined routine serum-based HIV testing, the main reasons include, an unnecessary hassle (254/545, 46.6%), having been previously tested (124/545, 22.8%) and self-perceived low risk of HIV infection (103/545, 18.9%). In contrast, only 32 individuals declined rapid oral testing, and having received a previous test is a primary reason. Three patients in the rapid testing group were later confirmed HIV-positive, yielding an HIV prevalence of 0.38%.
Conclusions: Rapid oral HIV testing is a feasible and efficient approach in a clinical setting.

MOPEB0258

Fast tracking the HIV response in Nairobi city by targeted HIV testing of key populations, Kenya, 2015

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Background: Nairobi City has the largest proportion of key populations in Kenya. The County has an estimate of 29,494 female sex workers(FSWs), 11,042 men who have sex with men(MSMs) and 6,216 people who inject drugs(IDUs).The HIV prevalence in Nairobi for FSW is 11.1%, 18.2% for MSM and 18.7% for IDUs. Program data shows that only between 11% to 21% of key populations had received a HIV test in the first quarter of 2015.We therefore carried out a HIV testing and linkage to treatment campaign with an aim of increasing the number of key populations who knew their HIV status.
Methods: Key population hot spots were mapped within the city and HIV testing services offered for free to all MSMs, FSWs and IDUs operating within those hot spots from 27th November to 7th December 2015. The target was to test 5,000 key populations and the strategies used were snowballing, moonlighting and outreaches at drop in centers (DICs) and sex dens. All KPs who tested positive were linked for free treatment services at the KP trained health facilities. Data on KPs tested was collected using standardized government HTS data registers and analyzed using MS Excel 2007.
Results: A total of 6602(132% of target) key populations were tested with 5061(77%) being FSWs, 1255(19%) MSMs and 286(4%) IDUs. Mean age was 27.3 years (range 16-57 years). Of those tested, 192(2.9%) tested HIV positive and all were successfully linked to care. The highest positivity rates were seen in Embakasi (6%),Langata (5.5%) and Dagoretti (5.5%). In addition to testing, 180,000 condoms were distributed to the key populations tested and their clients.
Conclusions: The strategies used to target the key populations worked and we were able to surpass our targets and identify HIV positives who we successfully linked to care. This activity also presented us with an opportunity for targeted condom distribution for this vulnerable group. Given the recommended guidance on testing of KPs, the city intends to carry out targeted outreaches to the key populations every quarter.

MOPEB0259

Implementing routine HIV testing in the emergency department using electronic health record modifications at University Hospital, Newark, NJ

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Background: The prevalence of HIV infection in Newark, NJ is >1%. Therefore, all persons presenting to care in the Emergency Room (ER) at University Hospital (UH) should be tested, yet only 9% were being tested. We implemented a routine HIV testing program in the ER using electronic health record (EHR) prompts and a patient navigator (PN) to help with connection to care (CTC).
Methods: This was a retrospective study of patients seen in select areas of the ER from April 2015 to November 2016 to see the proportion of eligible patients getting tested for HIV. The triage nurse would ask patients about HIV diagnoses or recent HIV test and an automatic order was placed if indicated unless the patient declined the test. We collected following information on HIV+ patients: age, gender, race, HIV risk factor, baseline CD4 count and HIV viral load (VL) and CTC.
Results: A total of 34,158 patients were seen in Main and Mid-Trak areas of the ER. Of these, 26,610 (78%) were eligible for HIV testing, 9,911 (37%) had the test ordered and 8,812 (89%) had the test performed. Monthly HIV testing rate increased from 9% to 75%.
Of those tested, 165 (1.9%) were found to be HIV positive (2 acute, 112 newly diagnosed, 51 previously known). The demographics of the HIV+ patients were: mean age - 48, Male 96 (58%), Race- Black 126 (76%), Hispanic 23 (14%), White 9 (6%), and Other 7 (4%). The HIV risk factors were: MSM (9%), Injection drug use (8%), heterosexual (69%) and other (20%). The Median CD4 count was 389 (range 3-1,804 cells/cu.mm) and median HIV VL was 132,352 (range < 20-2,752,888 copies/ml). 107 (65%) were either connected or are in the process of being CTC. Of the 58 not CTC, 46 (89%) were diagnosed prior to having a PN. The CTC since the PN was hired is over 70%.
Conclusions: We successfully implemented routine HIV testing in a busy ER with effective modification of the EHR and increased our monthly testing rate from 9% to 75%. However, PN navigators are essential for effective CTC especially in busy clinical settings.

MOPEB0260

Increasing testing and diagnosis for men who have sex with men using social networks for HIV self-test distribution

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Background: As the HIV epidemic continues to disproportionately impact men who have sex with men (MSM) globally, novel strategies are needed to increase testing uptake. We implemented a peer network HIV self-test distribution strategy to reach African American and Latino MSM who do not regularly test for HIV. We assessed the efficacy of the program by comparing HIV-related testing outcomes to those attained through the local public health department's targeted HIV testing program.

Methods: African American and Latino MSM and Transgender women (N=31), between 18 and 45 years old were engaged and trained as peer recruiters on the basics of HIV infection, proper use of the OraQuick® In-Home HIV test (OraSure Technologies), and supporting a friend through the testing process. Each peer was given five *self-test* kits to distribute to MSM friends thought not to have tested for HIV in at least 6 months. Those receiving the self-test kits were asked to complete an online survey after completing their test. Chi-squared tests were used to compare the number of *first time* testers and new HIV *diagnoses* through the peer network testing and amongst African American and Latino MSM who tested in a geographically overlapping contemporaneous government supported traditional community-based HIV testing program.
Results: Peers distributed self-test kits to 143 social and sexual network members, of whom 110 completed the online survey. Compared to MSM who utilized the government sponsored testing programs, individuals reached through the peer-based self-testing strategy were significantly more likely to have never tested for HIV (4.0% vs. 0.5%, p<0.01) and to report a positive test result (3.7% vs 1.5%, p<0.01), though 6 people in the peer-based strategy (5.5%) declined to provide a result.
Conclusions: These findings suggest that a network-based strategy for self-test distribution is a promising intervention to increase testing uptake and reduce undiagnosed infections among African American and Latino MSM.

MOPEB0261

Use of FACSPresto™ for measurement of CD4 and haemoglobin in resource-limited settings

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Background: Haemoglobin and CD4 T-cell counts are important prognostic markers in HIV infection, where decline in the two is often associated with HIV disease progression.
As a result, accurate and reliable data in monitoring CD4 and haemoglobin (Hb) levels is of critical importance to patient management. Conventionally, BD FACSCalibur and the Mindray hematology analyser are some of the equipment used in measuring CD4 and Hb respectively. However, with up to 50% of HIV patients still in need of life-saving ARV medications, alternative CD4 testing platforms are warranted. FACSPresto™ machine is a point of care testing (POCT) device for both CD4 cell count and haemoglobin. In Kenya, medical devices need to be verified before use in health care facilities. Verification of the BD FACSPresto™ machine was carried out at the National HIV Reference Laboratory (NHRL).
Methods: A total of 103 consenting patients were enrolled. Fresh whole blood (matched capillary and venous) samples from HIV positive patients were collected from Mbagathi Hospital clinical laboratory by trained staff. Laboratory testing for CD4 and haemoglobin levels was done on BD FACSCalibur, BD FACSPresto (Becton Dickinson, East Rutherford, NJ, USA) and Mindray Haematology Analyzer BC-5380 following manufacturer's instructions.
Laboratory analysis entailed the absolute and percent CD4 counts, and total haemoglobin concentration in the whole blood from HIV-infected patients. Statistical analysis entailed calculation of Pearson´s correlation and Bland Altman analysis for mean bias.
Results: The mean CD4 absolute count from the Presto was 805.89 compared to 889.49 from Calibur. Correlation at 0.93 was near perfect and the results were substantially equivalent. The mean difference between the reference method (Facscalibur) and test method (Facspresto) absolute CD4 counts was 76.3 which is within the 28% acceptance criteria.
Average Hb reading from venous sample was 12.65 compared to 12.56 from capillary sample. Correlation at 0.94 was near perfect. The mean difference between venous and capillary Hb reading was 0.091 and was not statistically significant.
Conclusions: The results obtained from the BD FACSPresto™ machine were comparable to the two reference equipments.
BD FACSPresto™ can utilize both venous and capillary blood thus it can be used as a point of care device.

MOPEB0262

Multicenter evaluation of CD4 T-cell counts on the new BD FACSVia™ system using BD Tritest™ and BD Multitest™ reagents

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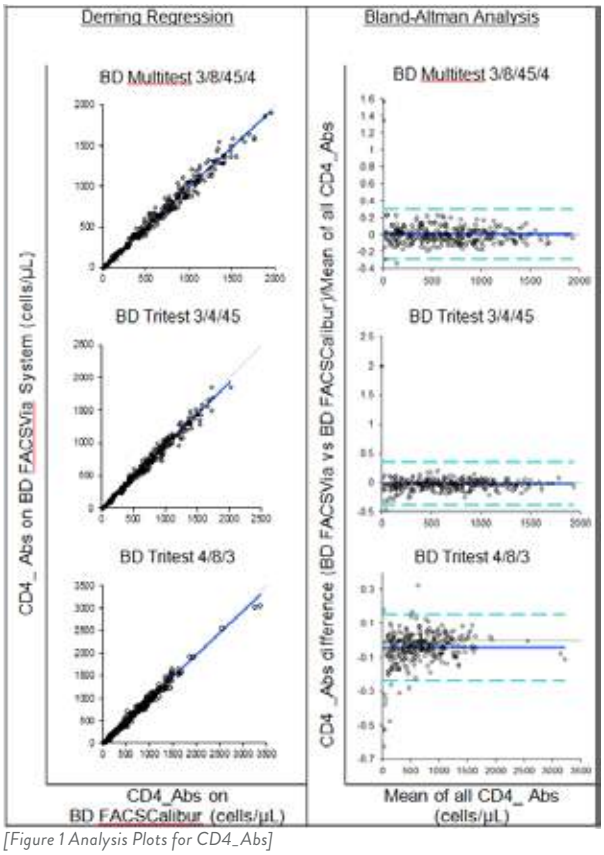
Background: $CD3^+CD4^+$ T-lymphocyte count remains one of the most important laboratory indicators in HIV/AIDS diagnosis/staging, treatment initiation, monitoring of regimen effectiveness and patient risk management, for example, using a CD4 cell count at or below 350 to initiate treatment for HIV patients (WHO 2016 guidelines). To meet global health needs, BD has developed a simple-to-use, affordable flow cytometer, the BD FACSVia™ System.* It features novel designs that provide workflow efficiency and high throughput in clinical laboratories. We evaluated CD4 absolute counts (CD4_Abs) on the BD FACSVia System vs the predicate BD FACSCalibur instrument at three study centers using BD Tritest™ (CD3/CD4/CD45 and CD4/CD8/CD3), BD Multitest™ (CD3/CD8/CD45/CD4) reagents.
Methods: De-identified venous blood specimens from HIV+ patients (n = 204), immune reconstitution patients (n = 51) and normal donors (n = 50) were enrolled in the study. Each specimen was stained using the two BD Tritest and the BD Multitest reagents in BD Trucount™ tubes, followed by acquisition on the BD FACSVia System and BD FACSCalibur instrument. CD4_Abs results were compared between the two systems using Deming regression and bias analysis. A two-by-two contingency table was used to assess agreement about a CD4 clinical cutoff, at 200 cells/µL and 350 cells/µL.
Results:

Reagent	Deming regression on CD4_Abs			Bland-Altman analysis on CD4_Abs	Percent agreement about CD4 clinical cutoff (95% LCI, 95% UCI)	
	Slope (95% CI)	Intercept	R^2	Bias% with 95% Limits of agreement	Cutoff ≤ 200 cells/µL	Cutoff ≤ 350 cells/µL
BD Multitest 3/8/45/4	0.99 (0.98, 1.00)	2.70	0.99	0.9% (-28.8%, 30.7%)	N** = 55, 98.6 (96.5, 99.5)	N = 80, 98.3 (96.0, 99.3)
BD Tritest 3/4/45	0.97 (0.95, 0.98)	1.19	0.99	-1.8% (-38.7%, 35.1%)	N = 50, 98.3 (96.1, 99.3)	N = 78, 99.7 (98.1, 99.9)
BD Tritest 4/8/3	0.98 (0.96, 1.00)	-5.89	0.99	-4.3% (-23.8%, 15.2%)	N = 52, 99.7 (98.1, 99.9)	N = 78, 98.7 (96.6, 99.5)
**note: N is the number of samples at or below cutoff as measured on the BD FACSCalibur instrument						

[Table 1 Analysis results for CD4 absolute count]



[Figure 1 Analysis Plots for CD4_Abs]

Conclusions: The BD FACSVia System demonstrated equivalent results in the accessed range of CD4 T-cell absolute count, as well as around CD4 clinical cutoff compared to the BD FACSCalibur instrument. Since CD4 count remains an important parameter in the management of HIV patients, the BD FACSVia System provides an easy-to-use, affordable solution to clinical laboratories.
*This product was CE Marked (EU IVD Directive 98/79/EC).

MOPEB0263

Outcomes of routine viral load monitoring in Namibia's national antiretroviral treatment program

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Background: Namibia antiretroviral treatment (ART) guidelines recommend the use of viral load (VL) testing to monitor HIV treatment as recommended by WHO. VL testing is recommended at 6 months after ART initiation. The guidelines defines VL suppression as HIV RNA < 1000 copies/ml, and recommends switch to second-line ART following failure of VL suppression with two consecutive tests performed at 6 and 9 months. We assessed timing of VL testing and suppression rates for patients newly initiating ART.
Methods: A retrospective cohort analysis of patients initiating ART between January 2014 and March 2015 at public ART facilities in Namibia. Clinical and laboratory records were matched from two non-interfaced, client-based electronic systems used for patient management and laboratory services. Matching was performed using probabilistic record linkage (Link Plus v3.0 software) using patient surname, first name, and date of birth. VL results were described by age, sex, baseline CD4 cell count.
Results: Out of 8366 adult and pediatric patients with matched laboratory and clinical records, 2536 (30%) received a first VL test within 6-9 months of ART initiation. VL suppression was achieved among 97.3% adults (95% CI: 96.6-97.9) and 92.4% children (95% CI: 86.7-95.8). An additional 3528 (42%) patients received a first VL test >9 months after ART initiation and lower suppression rates were observed for both adults (94.0%, 95% CI: 93.2-94.8) and children (81.1%, 95% CI: 75.6-85.6), p=< 0.05. Out of the 315 who failed to suppress the first VL test, only 26 (8.3%) follow-up VL tests were performed 3-6 months later, of which 15 (57.7%; 95% CI: 38.9-74.5) achieved suppression. Clients who failed initial VL suppression had lower baseline median CD4 cell counts (148 vs. 292, p <0.01), compared to those achieving suppression.
Conclusions: Though suppression at 6-9 months was high among patients who had VL testing after ART initiation, overall there was low compliance to timely VL monitoring. VL suppression declined for patients not monitored within the recommended interval after starting ART, especially in children. Improved recording and compliance to routine VL monitoring guidelines in Namibia is urgently needed to better detect early treatment failure and minimize development of ART resistance.

MOPEB0264

A pilot evaluation of whole blood finger-prick sampling for rapid and convenient point-of-care HIV viral load measurement: the UNICORN study

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Background: Antiretroviral therapy treatment interruption (TI) is the only test for HIV remission or cure in the absence of a validated laboratory biomarker. Clinical studies incorporating TI within their protocols require frequent plasma viral load (pVL) monitoring - up to every 2-3 days - to identify rebound viraemia and inform recommencement of ART. Such regular blood draws are a substantial inconvenience to participants and may impact recruitment. We present the first study of a simple whole blood finger-prick pVL analysis using an off-label protocol for GeneXpert Cepheid cartridges.
Methods: The UNICORN study is an analysis using two point-of-care (PoC) assays of 40 HIV+ve participants, 20 with detectable viraemia and 20 with undetectable pVL (<20 copies/ml). Using 100µl finger-prick whole blood samples, the Cepheid GeneXpert HIV Viral Load and HIV Qual cartridges were compared with formal laboratory pVL assessment from plasma (TaqMan, Roche). Samples were diluted and tested with and without a three minute spin using a benchtop microcentrifuge in the clinic room. Results were available within 90 minutes.
Results: At the 50% recruitment stage, for those participants with undetectable viraemia (< 20 RNA copies/ml) by TaqMan Roche, only 63.6% were ‚undetectable' using the GeneXpert VL assay and 33.3% ‚not detected' using the Qual assay, likely reflecting detection of cellular HIV nucleic acid. However, after a 3 minute spin, 100% of samples were undetectable using either assay, showing full concordance with formal pVL testing.
All participants in the ‚VL detectable' group (pVL range 33-500,000 copies/ml) were identified as detectable by both assays without incorporating a spin. On comparing sensitivity including the spin, only two detectable samples (both ≤158 copies/ml by Roche) were reported as ‚not detected' by both PoC assays. After correcting for volume, values of pVL by Roche and GeneXpert post-spin were closely correlated (p=0.0006; rho=0.97).
Conclusions: Finger-prick whole blood sampling is a specific, sensitive, quick, convenient and acceptable method for screening for detectable plasma HIV viraemia using either quantitative pVL or binary qualitative PoC approaches. This method has significant potential for use in TI studies exploring HIV cure strategies, but also in resource-limited regions with minimal access to certified diagnostic laboratories.

MOPEB0265

Evaluation of the Cepheid GeneXpert HIV-1 Qualitative molecular assay in patients with early primary HIV-1 infection and on antiretroviral therapy

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Background: The Cepheid GeneXpert HIV-1 Qual kit is a single-sample rapid molecular assay for the qualitative detection of HIV-1 in whole blood samples. It is used for the diagnosis of HIV-1 infection in newborns in the South. Our objective was to assess the performances of this assay in HIV-1-infected patients at the time of primary HIV infection (PHI) and on antiretroviral therapy (ART).
Methods: HIV-1 Qual is a qualitative endpoint RT-qPCR assay, thus potentially detecting both viral RNA and DNA from blood samples. This study was conducted in Hôpital Saint-Louis, Paris, France. We tested 59 banked frozen whole blood samples obtained from 24 PHI patients and 23 ART patients (of which 4 were followed for 72 weeks), accounting for a wide quantitative range of plasma HIV-1 RNA (Roche Cobas TaqMan HIV-1 v.2, threshold=1.3$\log_{10}$copies/ml) and of blood HIV-1 DNA (Biocentric Generic HIV-1 DNA Cell, threshold=1.3$\log_{10}$copies/10^6 cells). Negative/Positive results and threshold cycles (Ct) were recorded. Correlations were tested by the Wilcoxon signed rank-test and longitudinal changes of Ct values by Friedman´s non-parametric test.
Results: Median HIV-1 RNA was 1.8 $\log_{10}$copies/ml (range ≤1.3-7.7), including 23 samples ≤1.3 $\log_{10}$copies/ml. Median HIV-1 DNA was 2.6 $\log_{10}$copies/10^6 cells (range ≤1.3-4.21). Amplification with GeneXpert HIV-1 Qual yielded a Ct value in 47/59 samples (median Ct was 34.7, range (22.1-43.3). All tested PHI samples were assessed HIV-1 positive by HIV-1 Qual. Detection Ct was inversely correlated with viral RNA and DNA loads: R^2= 0.78 and R^2=0.60, respectively. Amongst 4 HIV-infected patients followed for 72 weeks after treatment initiation, all 4 patients originally tested HIV-positive at W0 but only two remained positive by HIV-1 Qual after 72 weeks of suppressive ART. Out of the total 12 HIV-1 blood samples which did not yield a detection Ct, 11 were aviremic samples and 1 RNA load was 2.06$\log_{10}$copies/ml. In these blood samples HIV-1 DNA load ranged from ≤1.30 (4 samples) to 2.70 $\log_{10}$copies/10^6 cells.
Conclusions: Detection Ct was correlated with HIV-1 RNA and DNA viral load and GeneXpert HIV-1 Qual assay tested positive for all viraemic blood samples ≥200 RNA copies/ml of plasma.

MOPEB0266

Performance evaluation of Xpert® HIV-1 viral load assay for rapid quantification in plasma specimens

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Background: Durable control of HIV-1 replication forms the basis of antiretroviral therapy (ART) medication. Thus, accurate quantification of HIV-1 viral load has become an essential factor in monitoring the effectiveness of ART. Longer turn-around-time (TAT), batch testing and technical skills are major drawbacks of standard Real Time PCR assays. Hence, accurate and reliable assays which require very minimal technical skills and rapid TAT in quantifying HIV-1 plasma viral load are always in demand.
Methods: In this study, Xpert HIV-1 viral load assay was evaluated against Abbott Real Time PCR, m2000rt system. A total of 96 specimens that were tested by Abbott Real Time PCR as part of patient care services and the remaining specimens stored in freezer at -75 ± 5°C were utilized for this performance evaluation. Two plasma specimens were tested 5 times each, to check assay precision. Mean difference and linear relationship were calculated by Bland-Altman analysis and Pearson correlation coefficient (r), respectively. GraphPad Prism, Ver5.0 (San Diego, USA) was used to perform statistical analyses.
Results: Compared to Abbott Real Time PCR, m2000rt system, Xpert HIV-1 viral load assay showed a mean difference of 0.27 log_{10}copies/mL (95% CI, -0.41 to 0.96 log_{10} copies/mL; SD, 0.35 log_{10} copies/mL) with good correlation (Pearson r=0.81; p< 0.0001). Assay sensitivity was 96.3% in quantifying plasma specimens with viral load of ≤ 3.5 log_{10} copies/mL, while it was 100% in plasma specimens with viral load of ≤ 3.7 log_{10} copies/mL. In both the specimens tested for precision, the results were excellent with a coefficient of variation (CV) of 1.9% and 1.07%, respectively.
Conclusions: Comparable to the standard assay, shorter TAT (less than 2 hours) and ease of testing individual specimens could make Xpert HIV-1 viral load assay as an efficient alternative method for ART monitoring in clinical management of HIV disease. Rapid testing results of this assay could help in making immediate clinical decisions, which strengthens the patient care in resource-limited settings.

MOPEB0267

Risk factors for viral failure among HIV patients on antiretroviral therapy (ART) at the Infectious Diseases Institute Kampala Uganda

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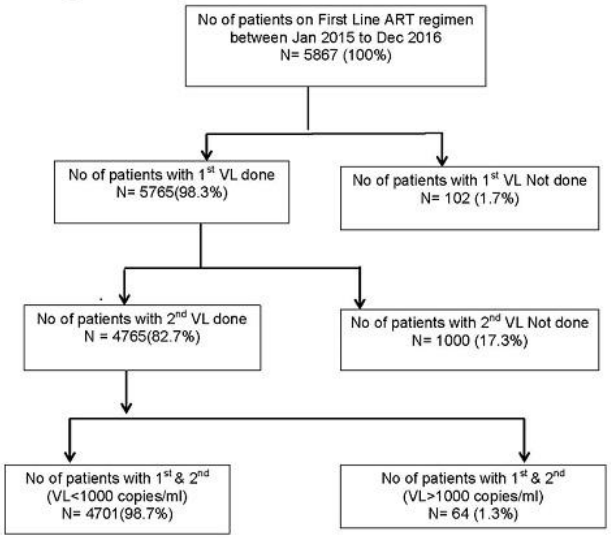
Background: Globally the UNAIDS targets that by 2020; 90% of patients on ART will have viral suppression. Despite studies assessing this objective, little is known about risk factors hindering the achievement. We assessed the risk factors for viral failure among HIV patients on ART at the Infectious Diseases Institute, Uganda.
Methods: We performed a retrospective data review of patients on first line ART between January 2015 and December 2016 who started ART before 31st December 2015.Virological failure was defined as two consecutive VL>1,000 copies/ml with in at least 6 months from ART start.We used frequencies and logistic regression to determine the characteristics associated with virological failure.
Results: 5867patients were on first line ART by 31st December 2016. Of these, 4765 (82.7%) had at least two viral loads done (Figure1). 2951 (61.9%) were female, median age 41 (IQR: 35-48) and median CD4 count 491(IQR: 358-655) cells/μL. 2831(61%) had WHO stage 3 and 4. Majority 2905 (61%) were on Efavirenz based regimen. Patients with viral failure were 64(1.3%). At multivariable analysis, being older (>45 years), being on Nevirapine and having a CD4>500 copies were protective of viral failure (OR< 1). (Table 1)

Patients characteristics	Unadjusted OR(95 CI)	P Value	Adjusted OR(95 CI)	P Value
Gender Female Male	1.00 1.04(0.62-1.72)	0.869		
Age(years) <45 >45	1.00 0.27(0.13-0.54)	<0.001	1.00 0.26(0.13-0.54)	<0.001
Baseline regimen Efavirenz Nevirapine	1.00 0.43(0.23-0.79)	0.006	1.00 0.46(0.26-0.86)	0.013
BaselineCD4(cells/μL) <500 >500	1.00 0.33(0.18-0.59)	<0. 001	1.00 0.31(0.17-0.56)	<0.001
WHO stage 1&2 3&4	1.00 0.89(0.54-1.47)	0.666		

[Table 1 Regression estimates of viral logic failure]



[Figure 1: Showing Viral loads (VL) done for patients on first line ART regimen]

Conclusions: Close monitoring for younger patients and those with lower CD4 is required to achieve better virological out comes in patients on first line ART. Further investigation is required to ascertain possible cause of viral failure among patients on Efavirenz based regimen.

MOPEB0268

No substantial sex differences in tenofovir exposure after directly-observed dosing of TDF/FTC as assessed via hair concentrations

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Background: Pre-exposure prophylaxis (PrEP) with tenofovir (TFV) disoproxil fumarate (TDF)/ emtricitabine (FTC) is highly efficacious, although several studies in sub-Saharan Africa demonstrated lower effectiveness in women than men. This difference was attributed to poor adherence, although relatively lower TFV levels in vaginal versus rectal mucosa could have contributed. Hair concentrations reflect cumulative adherence and exposure, both of which can impact PrEP effectiveness. We sought to evaluate whether TFV hair concentrations differ between men and women receiving directly observed dosing of TDF/FTC.
Methods: We compared TFV hair concentrations in low-risk, HIV-uninfected volunteers on directly observed TDF/FTC in Denver and San Francisco (DOT-DBS, NCT02022657). Participants were randomized to two of the following 12-week dosing regimens: 100%, 67%, or 33% of daily dosing. Hair samples were collected at dosing weeks 4, 8, and 12 and every 3 weeks during a 12-week washout. TFV concentrations in the proximal 1.5 centimeters of hair (representing 6 weeks of exposure) were analyzed using a validated liquid chromatography/tandem mass spectrometry (LC-MS/MS) assay. Linear regression models with random-person effects modeled TFV hair concentrations in terms of sex, doses taken over the prior 6 weeks, and number of days since last dose.
Results: Hair was collected from 46 individuals (52% female): median age 29 years; 57% white, 15% African American; 28% Hispanic ethnicity. Female participants had similar TFV hair concentrations to males (fold-difference 0.95, 95% CI 0.78-1.15, p=0.6). The estimated fold-difference in TFV levels for female versus male participants did not appreciably change when age (0.96, CI 0.79-1.17), weight (0.90, CI 0.73-1.12), or race (0.97, CI 0.79-1.18) were added to the model.
Conclusions: Under directly-observed dosing, TFV hair concentrations in women were similar to those in men. This observation remained constant regardless of race, age and weight. As pharmacokinetic metrics are increasingly used to monitor PrEP, these findings provide guidance for assessing adherence-response relationships via hair concentrations in men and women.

MOPEB0269

Transmitted drug resistance in treatment-naïve HIV-Infected VCT clients in southern Taiwan, 2013-2016

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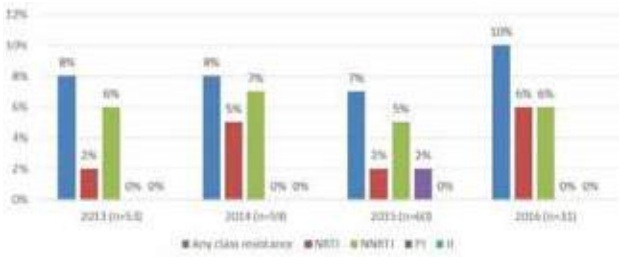
Background: The use of antiretroviral therapy has reduced the mortality and morbidity of patients with HIV/AIDS. However, Transmission of drug-resistant (TDR) strains poses a challenge for the control of the HIV-1 epidemic. The aim of this study was to monitor the prevalence of TDR in Taiwan, where free highly active antiretroviral therapy (HAART) was provided since 1997.
Methods: A prospective study on TDR was conducted in antiretroviral treatment-naïve HIV-1-infected voluntary counseling and testing (VCT) clients from 2013 to 2016 in southern Taiwan. Genotypic drug resistance was determined by ViroSeq™ system, CCR-5 tropism and integrase strand-transfer inhibitor (INSTI) resistance were determined by the in house population sequencing.
Results: From 2013 to 2016, a total of 18615 clients received a VCT. The positive rate for HIV-1 infection was 2.5%. Sequences were obtained from 184 individuals, of whom 96.7% were infected by MSM, and 3.3% were infected by heterosexually. Ten percent (19/183) of the patient had hepatitis B and 33.3% (61/183) had syphilis infection. Subtype B HIV-1 strains were found in 96.1% of the individuals, and subtype CRF01_AE in 3.9%. Fifteen patients (8.4%, 15/178) were found to harbor NRTI/NNRTI/PI resistance. CCR-5 coreceptor usage was found in 71.4% (130/182) of the patients. No one had INSTI resistance, But 17 patients had INSTI polymorphic substitution. Those who had INSTI polymorphic substitutions were more likely have higher HIV viral load (p=0.039) and CCR-5 coreceptor usage (p=0.043).



[HIV drug resistance in 2013-2016]

Conclusions: Although the implementation of early treatment in HIV infected patients, the rate of TDR to PI and INSTI were low in these 4 years. Further monitor trend of TDR in our community is needed with the increase use of integrase strand-transfer inhibitor in the future.

MOPEB0270

Usefulness of proviral HIV-1 DNA resistance testing in virologically suppressed HIV-infected patients candidate for maintenance therapy

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Background: Switch of antiretroviral therapy (ART) in virologically suppressed patients is frequent, to prevent toxicities or for simplification or convenience reasons. Pretherapeutic genotypic resistance testing (GRT) on plasma RNA can be lacking in these patients before switching because of a long period since ART introcuction. For patients with history of virological failure resistance information provided by GRT on proviral DNA is less informative than the cumulative history of standard plasma RNA genotypic results. In patients virologically controlled with no history of virological failure few data are available on the concordance of current proviral DNA GRT and pre-therapeutic plasma RNA GRT.
Methods: Monocentric, cross sectional study including virologically suppressed patients on ART with no history of virological failure. Proviral DNA GRT was compared with pre-ART plasma RNA genotype. Mutations described in the V.24 ANRS algorithm were considered as resistance-associated mutations (RAMs), and the others as polymorphism mutations (PMs).
Results: Sixty nine pair-wised sequences from plasma RNA and blood DNA compartments 47 months apart were compared. A stop codon was evidenced in 23% of proviral DNA sequences. These strains were considered as defective and non-replicative. There was a high concordance rate between plasma RNA and non-defective proviral DNA both on protease (88%) and reverse transcriptase (76%) genes. Presence of RAMs only in DNA but not in pretherapeutic RNA was evidenced in 8 % on protease and 19% on reverse transcriptase sequences. When considering RAMs to nucleoside reverse transcriptase inhibitors, all mutations detected on RNA were also detected on provirus DNA. In 5 cases, RAMs were detected only on proviral DNA (M41I, E44K, V75A, K219Q, K219R). Concerning non-nucleoside reverse transcriptase inhibitors, 2 minor mutations (K101R and V179I) were detected only on RNA, while 2 others (V106I and M230V/I) were detected only on proviral DNA. In all other cases, mutations were present both on RNA and provirus DNA. The phylogenetic analysis showed that the DNA and RNA sequences were linked with a bootstrap score >99% for each patient.
Conclusions: Proviral DNA GRT might be an informative tool before switching ART in virologically suppressed patients, especially when pretherapeutic GRT is lacking, but interpretation should be restricted to non-defective viruses.

MOPEB0271

Trends of transmitted drug resistance among HIV-positive people who use drugs, Vancouver, Canada

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Background: Transmitted drug resistance (TDR) may compromise response to antiretroviral treatment (ART) among HIV-positive individuals. However, there is limited data on TDR among people who use illicit drugs (PWUD). We sought to characterize TDR patterns among HIV-positive PWUD in Vancouver between 1996 and 2015.
Methods: Data was drawn from ACCESS, a community-recruited longitudinal cohort of HIV-positive PWUD in Vancouver, Canada, linked to comprehensive ART dispensation and clinical monitoring records. TDR was defined according to the WHO 2009 list for surveillance of drug resistance mutations. We estimated the prevalence and correlates of TDR among ART-naïve PWUD and evaluated trends over time.
Results: Among 573 ART-naïve PWUD (65% male, 95% with a history of injection drug use, 18% recent seroconverters), the overall prevalence of TDR was 9.8% (95%CI 7.3-12.2). TDR-associated mutations were more common for non-nucleoside reverse transcriptase inhibitors (NNRTI, 5.4%, 95%CI 3.5-7.3), followed by nucleoside reverse transcriptase inhibitors (NRTI, 3.0%, 95%CI 1.5-4.4), and protease inhibitors (PI, 1.9%, 95%CI 0.7-3.1). TDR prevalence was significantly lower among PWUD with recent HIV seroconversion (AOR = 0.39, 95% CI 0.15-0.87). We observed an increasing trend of TDR over the study period, from 8.5% (95%CI 3.4-13.8) in 1996-1999 to 21.1% (95% CI 10.9-31.3%) in 2010-2015 (p=0.003), mainly driven by resistance to NNRTI.
Conclusions: Between 1996 and 2015, the prevalence of TDR increased significantly among PWUD in this setting, mainly driven by increases in NNRTI-mutation K103N. These results suggest that ART-naïve PWUD may be an important source of TDR. Lower rates of TDR among recent seroconverters may be partially explained by limited exposure to ART among PWUD in the earlier years, when most seroconversions were documented. Our findings support current recommendations for baseline resistance testing to guide ART selection, as well as for early initiation of ART to limit the spread of TDR.

MOPEB0272

Multivariate longitudinal HIV drug resistance analysis in ART naïve patients to validate a point-of-care assay

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Background: The main obstacle to successful antiretroviral therapy (ART) is the emergence of HIV drug resistance mutations (HIVDRM); the detection of HIVDRM relies on genotyping assays, however their use is limited in resource-constrained settings (RCS). Hence the need to develop an affordable and reliable point-of-care resistance testing assay for RCS is warranted.
Methods: ART naïve HIV-1 infected patients from Cameroon were subjected to a multivariate HIVDR analysis using Amplification Refractory Mutation System (ARMS)-PCR (a PCR-based point mutation assay), Standard sequencing (Sanger) and longitudinal Next-Generation Sequencing (NGS, MiSeq Illumina), to determine their mutation profiles for K103N, Y181C, K65R, M184V and T215Y/F. Subtyping was performed using phylogenetic methods (MEGA5.2 and FigTree).
Results: We processed 29 ART-naïve HIV-1 infected patients and generated pol sequences with the prevalent subtypes CRF02_AG (73%), F2 (14%), D (3%), A1G (3%), CRF11_cpx (3%) and CRF37_cpx (3%), confirming the predominance of CRF02_AG and the increasing rate of F2 in Cameroon. Pol sequences further served to identify HIVDRM and to validate ARMS-PCR. We compared three resistance testing methods for 29 patients, 5 mutation sites each (145 patient/mutation data sets). Using standard sequencing, the overall prevalence of HIVDR mutations was 4.8% (7/145) and included all studied mutations except K65R. Comparing ARMS-PCR with Sanger sequencing as reference, we obtained a sensitivity of 100% (7/7) and a specificity of >97% (135/138), caused by three false positive calls with ARMS-PCR. With NGS as reference, we observed one additional mismatch made up by minority variants (7%) that might not be clinically relevant. Longitudinal NGS analyses revealed changes in HIVDRM in four subjects that could not be attributed to treatment or superinfection.
Conclusions: The high sensitivity and specificity of the cost-effective ARMS-PCR method suggest it as a potential point-of-care assay to monitor transmitted HIVDRM in RCS. ARMS-PCR assay can guide the choice of more successful ART regimens; therefore, help improve ART programs in RCS. Longitudinal changes in HIVDRM should be considered even in the absence of treatment.

MOPEB0273

RNA and DNA sanger sequencing versus ultra-deep sequencing for HIV-1 drug resistance testing in treatment-naive patients

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Background: HIV-1 drug resistance testing is recommended in patients at entry into care. Sanger sequencing on plasma RNA is the standard method used in clinical laboratories, but is limited by the non-detection of resistance associated mutations (RAMs) with prevalence below 20%. We compared RNA and DNA Sanger sequencing (RSS and DSS) to RNA ultra-deep sequencing (UDS) for RAMs detection in HIV-1 reverse transcriptase (RT), protease (PR), and integrase (IN) genes.
Methods: Sanger sequencing was performed on RNA and DNA, following recommendations of the French Agency for AIDS Research (ANRS). UDS was performed on RNA using the HIV-1 Drug Resistance Assay - v3.0 (Roche) on the 454 GS Junior sequencer. The IAS-USA list (2015) was used to identify RAMs in the different HIV-1 genes. ANRS, Rega and Stanford algorithms were used for drug resistance interpretation.
Results: The study included 54 ART-naive patients. The median age was 38.5 years old and patients were mainly male (87%). The number of patients with a least one major RAM was 3, 5, 5, 10 and 20 when using RSS, DSS, UDS 20%, UDS 5% and UDS 1% respectively. The highest number of major mutations was observed in the RT gene. UDS allowed detection in 2 patients of N155H mutation in the integrase gene, while no major mutation was found with RSS and DSS. Numerous minor mutations were detected in patients, especially in the PR gene. A very good agreement in RAMs detection was observed between RSS, DSS and UDS 20%, and drug resistance interpretation overall yielded high rates of susceptibility to antiretrovirals. Significant differences were observed between algorithms. ANRS algorithm was clearly the most stringent tool regarding PR inhibitors, while Stanford algorithm interpretations highly impacted IN inhibitors. Patients received mainly PR inhibitors and IN inhibitors based ART, and no impact of the minority RAMs detected by UDS was found on the virological outcome, six months after treatment initiation.
Conclusions: DSS does not clearly improve the detection of RAMs in ART-naive patients, as compared to RSS. UDS allows detection of minority RAMs; however their impact on the different drug classes and the clinically relevant threshold require further investigation.

MOPEB0274

Atypical mutations for RAL resistant clinical isolates, and associated integrase strand transfer inhibitor susceptibility with public algorithms

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Background: We previously evaluated INSTI resistance for 705 RAL-resistant isolates (RAL fold change in IC50 (FC) >1.5, Monogram biological cutoff). IN resistance substitutions H51Y, L74I/M, E92Q/V, T97A, G118R, E138A/K/T, G140A/C/S, Y143C/H/R, S147G, Q148H/K/R, V151I, S153F/Y, N155H, G163K/R, G193E, and R263K were originally available. We evaluated full-length integrase sequences for 48 of 85 isolates without RAL resistance mutations Y143C/H/R, Q148H/K/R, and N155H. We searched for additional substitutions associated with higher INSTI resistance, and compared FCs with predicted susceptibilities using publically available interpretation algorithms.
Methods: IN substitutions were enumerated by IAS 2015 **major** and minor mutations: **T66I, E92Q, F121Y, S147G, Y143C/H/R, Q148H/K/R, N155H,** T66A/K, L74M, E92G, T97A, E138A/K, G140A/S, R263K or non-IAS substitutions at positions V151I, E157Q, G163E, G193E, and V260I. Atypical substitutions are standard font. Comparison of HIV-1 genotypic resistance interpretation algorithms (HIVdb, REGA, ANRS), was performed using Stanford HIV Drug Resistance Database web tool HIValg, version 7.0.1, using the option to normalize algorithm interpretations to Susceptible (S), Intermediate (I), Resistant (R).
Results: For each 48 full length sample, all IN substitutions observed were summarized at each position with n= number of sequences with any listed substitution at that position; counts for atypical substitutions are also given: T66A/**I**/N/R (n=5; 2 with N/R), L74I/M (n=20; 6 with I), E92L/**Q**/V (n=7; L=1,V=1), T97A (n=33), F121**Y** (n=1), E138D/K (n=4; D=2,K=2), Y143A/G/S (n=13; G=7,A=1,S=2,A/S=3), V151I (n=8), N155S (n=2), E157Q (n=5), G163E/K/R/T (n=9), G193E/N/R (n=8), and V260I (n=1). Comparison of FC data with predictions from resistance databases ANRS, HIVDB, and REGA showed a substantial number of isolates with apparent higher FC than would be algorithm predicted.

Algorithm - Prediction	DTG FC Med. (Range) [#pts]	EVG FC Med. (Range) [#pts]	RAL FC Med. (Range) [#pts]
ANRS - S	1.0 (0.2 - 4.3) [48]	9.2 (1.2 - 71) [21]	4.45 (1.1 - 64) [25]
ANRS - I	NA [0]	NA [0]	NA [0]
ANRS - R	NA [0]	55 (6.1 - 144.7) [27]	100.2 (2.0 - 170.6) [23]
HIVDB - S	1.0 (0.2 - 4.3) [43]	7.8 (1.2 - 43) [15]	1.6 (1.1 - 14) [4]
HIVDB - I	1.4 (1.0 - 3.9) [5]	37.5 (3.2 - 131.9) [22]	8.7 (1.4 - 131.5) [29]
HIVDB - R	NA [0]	76 (11 - 144.7) [11]	100.7 (29 - 170.6) [15]
REGA - S	1.0 (0.2 - 4.3) [38]	17 (1.2 - 132.7) [37]	4.2 (1.1 - 137.3) [24]
REGA - I	1.0 (0.3 - 3.0) [9]	40 (40 -40) [1]	58.5 (1.7 - 170.6) [22]
REGA - R	3.9 (3.9 - 3.9) [1]	76.5 (11 - 144.7) [10]	13 (13-13) [2]

[Resistance Database Predictions]

Conclusions: Higher FCs were observed for EVG and RAL than expected in predicted Intermediate and Susceptible categories. This may be associated with a relatively high frequency of T97A (33 of 48) and atypical substitutions at positions previously associated with INSTI resistance.

MOPEB0275

HIV drug resistance among adults initiating antiretroviral therapy in Namibia

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Background: Knowledge of pre-treatment HIV drug resistance (PDR) can assist countries to monitor effectiveness of first-line antiretroviral therapy (ART) and minimize spread of HIV drug resistance (HIVDR). We present preliminary results from the first national PDR survey among adults initiating ART in public health facilities in Namibia.
Methods: Twenty-three clinics were randomly selected from among 74 ART clinics. Adults (≥18 years) initiating treatment were consecutively enrolled based on 2014 WHO PDR survey methodology. Consenting patients self-reported prior ART exposure and provided finger-prick dried blood spots (DBS) for HIVDR testing. HIVDR testing was performed at the CDC-Atlanta laboratory using ATCC HIV-1 genotyping kits. HIVDR mutations (DRMs) from quality-assured sequences were determined using the Stanford HIVDR interpretation algorithm. Significant DRMs (SDRMs) were defined as those predicted to cause low-, intermediate-, and high-level of resistance to drugs used in Namibia and recommended by WHO, including (NNRTIs [NVP & EFV], NRTIs, and PIs (DRV/r, LPV/r & ATV/r) for first-line ART.
Results: Overall, 509 patients were enrolled (67.8% females and 32.2% males) and 83 (16.3%) indicated prior ART exposure (15.2% males; 16.8% females). Samples from 387 DBS (76.0%) were successfully genotyped; DRMs were identified in 34.3% (95% CI: 29.8%-39.2%) and SDRMs in 13.0% (95% CI: 10.0%-16.8%). SDRM rates were 93.9%, 24.5% and 12.2% to NNRTIs, PIs, and NRTIs, respectively.
The most prevalent DRMs were K103N/S (9.0%), T74S (8.8%), E138A/D/E/G/K/N/Q (7.5%), and K20I/M (3.4%). Patients with prior ART exposure were more likely to have PDR than those without (30.4% v 9.2%; OR=4.3; 95% CI: 2.3-8.3). Viral load (VL) data were available for 116 survey patients on ART for 9-12 months since survey enrollment.
The viral suppression rate (VL <1000 copies/ml) was lower among patients with ART exposure (76.2%; 95% CI: 54.9%-89.4%), compared to those without (97.8%; 95% CI: 92.6%-99.4%).
Conclusions: Our unweighted results showed a moderately high level of PDR among adults initiating ART. Patients with prior ART exposure had more PDR and a lower probability of VL suppression after treatment. Alternative, non-NNRTI-based, first-line regimens need to be considered for patients reporting previous ART exposure to maximize the benefit of first-line treatment and minimize risk of HIVDR in Namibia.

MOPEB0276

HIV multi-class resistance in patients failing to first and second-line ART in resources limited setting, Mali

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Background: Antiretroviral treatment (ART) has been widely implemented in resources constraint setting. Second-line ART has become more and more available but the biological monitoring is still limited. In order to achieve the goal of the three 90 of UNAIDS it will be interesting to know the resistance profile of the patients failing to ART. The objective of this study is to determine the prevalence of HIV multi-class resistance viruses and their impact the virological outcome.
Methods: All patients with virological failure on first or second-line ART in our routine genotyping system were included. The pol gene was sequenced by using viroseq or in house ANRS method.
Results: We identified 342 patients with genotypes available: 273 (79.9%) and 69 (20.1%) were on first and second-line ART, respectively. The median viral load (VL) was 69,740 copies/mm^3 and median CD4 was 276 cells/mm^3 at failure. The main first-line regimen was TDF/3TC/EFV and second-line was AZT/3TC/LPVr. Among the 342 patients, 21 (6%) had a wild-type virus and 321 (94%) with multi-class resistant virus. The prevalence of resistance mutations was: M41L (37%), A67G/N (42%), M184V (100%), T215F/Y (68%), K219E/Q (37%) and Q151M (16%) for the nucleoside. For non-nucleoside: K103N (32%), K101E/H/P (11%), Y181C/I/V (37%) and H221Y (21%). For PI: L76V (42%), V82A/F/T/S (21%) and I84V (37%). Patients were resistant to NRTIs in 83%, NNRTIs in 94% and PIs in 42%. Among the second-line ART failures, 19% were resistant to darunavir. After 6 and 12 months of ART, 63% and 76% of patients had suppressed HIV RNA less than 40 copies/ml.
Conclusions: Our results show a high level of resistance after first and second-line ART failure in Mali. Thus, resistance genotypic testing is crucial for patient failing to ART in resources limited setting to achieve the goal of the three 90.

MOPEB0277

Transmission of a primary integrase inhibitor resistance mutation identified in a Bronx, NY ambulatory clinic

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Background: Primary integrase inhibitor (INI) resistance transmission is rare. However, INIs are now recommended as a first-line therapy for HIV infection. This report describes an antiretroviral -naïve individual who acquired an integrase mutation at primary infection.
Methods: Retrospective chart review of a patient followed by primary care providers at a clinic in the Bronx, NY. Clinical history and results of resistance testing were obtained through chart abstraction.
Results: A 17-year-old man reported to have a negative HIV test in February 2013. He and his male sexual partner tested negative for HIV with the expressed intention of having sex without use of a condom. In July 2013, after his partner screened HIV positive, the patient presented with disseminated lymphadenopathy and had a reactive 4th generation HIV screening test. His viral load (VL) was 100,234 copies/mL and CD4 count was 237 cells/µL. Resistance testing performed in August 2013 identified the reverse transcriptase (RT) mutation D67N and protease (PR) mutations M36M/I, D60E, I62V and A71T. No phenotypic resistance was reported. Integrase resistance testing was not performed. Further testing in December 2013 reported the same mutations, except M36M/I, and low levels of phenotypic resistance to unboosted atazanavir (fold-change [FC] 2.4) and nelfinavir (FC 3.9). Darunavir/ritonavir/tenofovir/emtricitabine was initiated in January 2014; however, complicated psychosocial issues led to incomplete adherence. In May 2015 the patient restarted the same regimen, when his VL and CD4 were 125,164 copies/mL and 258 cells/µL, respectively. Subsequent adherence was sporadic and, although his VL initially did not decline, by November 2015 the VL and CD4 were 744 copies/mL and 334 cells/µL, respectively. Genotypic testing at that time reported the M184M/V NRTI mutation and integrase mutations E92K and R263K, despite never having been prescribed an INI. R263K is a rare non-polymorphic mutation selected in patients receiving raltegravir (RAL) and dolutegravir (DTG). It reduces RAL, DTG, and EVG (elvitegravir) susceptibility by 2-4 fold.
Conclusions: This is the first report of integrase mutation R263K transmission in an antiretroviral-naïve patient with concurrent RT and PR resistance mutations. Since INIs are now recommended as first line therapy, baseline INI resistance testing should be considered in high-risk demographic settings.

MOPEB0278

Trends in HIV resistance to integrase inhibitors in Newark, New Jersey, USA

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Background: Integrase strand transfer inhibitors (INSTIs) are a relatively new and growing class of antiretroviral (ARV) drugs active against human immunodeficiency virus (HIV). Raltegravir (RAL) was the first INSTI approved in October 2007 followed by elvitegravir (EVG) as part of a fixed drug combination in August 2012. Most recently dolutegravir (DTG) was FDA-approved in August 2013 and has a high genetic barrier to resistance. DTG resistance has not been reported in clinical trials in those naïve to INSTIs.
The aim of our study was to identify the incidence of INSTIs resistance in our community and determine the likelihood of developing treatment-emergent INSTI resistance.
Methods: A retrospective chart review from October 1st, 2013 and October 31st, 2015 was performed in HIV-positive patients on INSTIs attending an outpatient HIV clinic in Newark, New Jersey. Four hundred and thirty-four patients were enrolled and clinical plus demographic data were obtained. Failure of ARV therapy was defined as a confirmed detectable viral load (VL) (VL >200 copies/ml) in patients previously controlled (defined as VL <20 copies/ml). Genotypic resistance testing was performed to determine the frequency of major mutations associated with the various ARVs.
Results: There were 253 male patients (58.3%). Two hundred and fifty-one patients (n=251, 57.8%) were on EVG for a total of 15,687.5 patient-week weeks. Fifty-eight (13.4%) were on RAL for 10,266 patient-week weeks and 125 patients (28.8%) on DTG for 2,750 patient-week weeks. Of the total 433 patients, only 13 developed resistance while on therapy. Eight patients were receiving EVG while 5 patients were on RAL. However, none receiving DTG developed resistance. Of these 13 patients, 5 (38.5%) had dual or triple class resistance.
Conclusions: The use of INSTI-based therapy has steadily increased as these agents have been proven safe and efficacious in the treatment of HIV. Resistance to first generation INSTIs RAL and EVG was rarely encountered, and DTG resistance was not identified in our patient population. However, this may be due to DTG's recent introduction. We propose that additional real world data is needed to determine how best to use INSTIs in efforts to preserve their utility.

MOPEB0279

The clinical utility of Cystatin C in assessing renal function among HIV-positive patients on antiretroviral therapy at Mildmay Uganda

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Background: In clinical practice, measurement of glomerular filtration (GFR) rates is the gold standard for assessing renal function. Extra renal factors affecting creatinine concentration, the most widely used molecule in GFR estimation limit its efficiency. Use of exogenous substances e.g. inulin to measure GFR is not possible due to cost and complexity. Cystatin C has been proposed as a potential renal function marker but its use in HIV-Positive patients has not been well evaluated. The study was carried out to assess the clinical utility of Cystatin C based prediction equation in determining renal function among HIV-positive infected individuals.
Methods: A cross sectional study was carried out on 914 HIV-positive adults (≥18 years) on ART attending Mildmay Uganda for care and treatment between January to March 2015. Serum Cystatin C was measured by a quantitative sandwich enzyme immunoassay using the particle enhanced immunoturbidimetric assay. Creatinine was analyzed using enzymatic Creatinine PAP method. Using the results of the eGFR by creatinine as reference method, the sensitivity, specificity and positive/negative predictive values and likelihood ratios of Cystatin C were calculated.
Results: Of the 914 participants 626 (68.5%) were females and 288 (31.5%) were males. Median age in the study was 38.4years (IQR 31 - 45). Median weight was 61.5 (IQR 52 - 70). Mean Cystatin C (mg/L) concentration was 0.8mg/L. Means and standard deviation of the main blood chemistries were Serum Creatinine 77(31.8), Serum Cystatin C 0.8(.02), Potassium 4.4(0.6), Sodium 140(7.9), and Urea 3.1(1.6). The sensitivity of Cystatin C was 15.1% (95% CI= 8.4, 24) with specificity 99.3% (95% CI=98- 99.7). Positive and negative predictive values were 70.0% (95% CI 45.7-88.1) and 91.2% (95% CI 98.11-92.94) respectively. Positive likelihood ratio was 18.81 and negative likelihood ratio was 0.85. Cystatin C had diagnostic accuracy of 90.7 and area under curve was 0.768.
Conclusions: Cystatin C exhibited a high specificity and a high positive likelihood ratio in diagnosis of kidney disease among HIV-positive patients.

MOPEB0280

Management of cryptococcal meningitis in sub-Saharan Africa: still a long way to go

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Background: Cryptococcal Meningitis (CM) is one of the leading causes of mortality in HIV patients. Current WHO recommendations include screening with cryptococcal antigen (CrAg) test if CD4 baseline below 100 cells and initiation of treatment in symptomatic patients with CrAg positive when no immediate access to lumbar puncture (LP). Many African countries have adopted this approach but there is little evidence on how it is implemented. Here we analyze program data from facilities supported by the AIDS Healthcare Foundation (AHF) in Uganda, Kenya and Lesotho.
Methods: Data from HIV positive patients enrolled in facilities where CrAg test was available between January 2013 and July 2016 were included in the study. Six months retention in care after a positive CrAg test was calculated using Kaplan-Meier survival methods. Cox proportional hazards model was used to identify predictors of attrition in patients with CM.
Results: Twenty two health facilities met the inclusion criteria and 3985 clients had a CrAg test done during the study period. 222 of those tests were positive (5.6%). Out of those positive with complete data (74%), 45% were women, median age was 33 years and median CD4 was 45 cells. Overall 6 months retention after the CrAg positive result was 79%. 96 patients (58%) had symptoms suggestive of CM at the time of the CrAg result and 22% of them had an LP done. Out of those with positive CrAg in Cerebrospinal fluid (CSF) 53% received Amphotericin B as part of the antifungal treatment. Among the clinical suspects with CrAg positive where LP was not done, 12% received Amphotericin B and 80% received a regimen containing just Fluconazole (9% received the one recommended by WHO).
Conclusions: We identified several gaps in the implementation of WHO recommendations for diagnosis and management of CM, especially the low percentage of diagnosis confirmed with LP and patients treated with Amphotericin B. It is also concerning that just a small percentage of patients treated only with Fluconazole received the regimen recommended by WHO. National programs need to make an effort to increase access to LP and Amphotericin B and ensure clinicians are updated in the new protocols.

MOPEB0281

Comparison of two immunoassays for simultaneous detection of HCV Antigen and antibodies among HCV/HIV co-infected patients in dried serum spots

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Background: Hepatitis C virus (HCV) antigen and antibody combination assays have been launched as a cost-effective alternative to nucleic acid testing (NAT) for early diagnosis by reducing the window period. This study evaluated the clinical performance of HCV antigen/antibody combination assays during window period using HCV seroconversion panels followed by NAT for ELISA reactive samples.
Methods: The performance of the Monolisa HCV antigen-antibody Ultra (Monolisa, Bio-Rad) and the Murex Ag/Ab test (Murex, Abbott) were compared by using two sets of serially diluted commercial HCV seroconversion panels [Genotypes (Gt) 1a & 2b]. Moreover, both assays were used to screen HCV co-infection in filter dried serum spots (DSS) of newly diagnosed HIV-cases (n=1683). All samples positive for both tests were evaluated in the quantitative RT-PCR (qRT-PCR) developed to amplify the 5´ non-coding region of HCV genome.
Results: For lower dilutions of HCV seroconversion panels, the Murex detected HCV infection 9 (Gt 1a) and 2 (Gt 2b) days earlier than the Monolisa. However,

Murex showed fluctuating and lower OD values below the cut-off for higher dilutions until days 28 (Gt 1a) and 135 (Gt 2b) compared with the Monolisa which showed a progressive increase in the OD value for all dilutions in each panel. Accordingly, 219/1683 (12.9%) and 193/1683 (11.4%) DSS samples were found positive in the Murex and Monolisa, respectively. Further testing of ELISA reactive samples by qRT-PCR revealed 167 NAT positive results. Of these, 74 (44.3%) were also positive for both, the Murex and Monolisa. Moreover, 10/167 (5.9%) of samples positive in the HCV RNA assay were only positive in the Monolisa while 5/167 (2.9%) were only positive in the Murex ELISA.
Conclusions: The Monolisa provides more reliable results for the detection of HCV infections in all dilutions compared to the Murex indicating its potential use for HCV screening in DSS. However, with its reactivity at earlier days of HCV infection, the Murex may serve as an additional diagnostic tool in HIV/HCV co-infected patients to narrow the window period. Moreover, the application of NAT on ELISA positive samples can be used to confirm early infections and to distinguish between active/chronic and resolved HCV infections.

MOPEB0282

Detecting mild HIV-associated neurocognitive disorders in multi-ethnic Malaysia

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Background: The Montreal Cognitive Assessment (MoCA) is commonly used to screen for HIV-associated neurocognitive disorder (HAND), primarily in Western countries, however, studies have found medium to adequate sensitivity for mild forms of HAND. Outside these regions, the validity of the MoCA is uncertain, especially when using the recommended cut-off score (≤ 26).
This study determines the optimal sensitivity of the MoCA to cognitive impairment in HIV-positive individuals on cART with viral suppression, and community-based controls in Malaysia.
Methods: A cross-sectional study of 350 HIV-positive (median CD4=106 cells/μL) from an infectious disease clinic at University of Malaya Medical Center, and 286 HIV-negative persons was completed between September 2014 and July 2016. All participants completed the MoCA and Lawton Instrumental Activities of Daily Living (IADL) to assess cognitive impairment and functional decline. The MoCA was scored according to the recommended cut-off, and regression based normative formula accounting for demographic variables and first order interactions were developed for the total score. The formulas were applied to the HIV-positive group, and impairment was defined using the Global Deficit Score (GDS) method. The Frascati criteria were used to determine HAND.
Results: The mean age was 44.3 ± 11.7 years, 72.7% were male, 42.6% had completed less than 12 years of education, and 24.3%, 65.3%, 9.9% were of Malay, Chinese and Indian ethnicity. When using a MoCA cut-off value of ≤ 26, the rate of impairment was 59.4% (HIV-negative) and 64.3% (HIV-positive). After establishing norms based on demographic characteristics, 40 (14.1%) HIV-negative and 78 (23.4)% HIV-positive persons were considered impaired. Of the 78, 65 (83.3%) and 13 (16.7%) were classified with asymptomatic neurocognitive impairment (ANI), and mild neurocognitive disorder (MND), respectively. HIV-associated dementia (HAD) was not detected in this population.
Conclusions: Normative corrections are needed when using the MoCA to detect cognitive impairment in Malaysian populations. Without normative corrections, there is not only poor sensitivity to HAND in the HIV-positive sample, but also considerable overestimation of cognitive impairment in healthy populations. When using norms, the MoCA is sensitive to mild HAND, similar to previous studies in different regions of the world. Criterion validity against more extensive neuropsychological testing is required.

ART

MOPEB0283

Dolutegravir use during pregnancy and birth outcomes: data from the Antiretroviral Pregnancy Registry (APR)

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Background: There are no well-controlled studies evaluating safety of dolutegravir (DTG) in pregnant women. The Antiretroviral Pregnancy Registry (APR) is an ongoing international, voluntary, prospective exposure-registration cohort study, that monitors for early warning signal of major teratogenic effects of antiretroviral (ARV) therapy and collects data on pregnancy and neonatal outcomes.
Methods: Using APR data on prospectively reported pregnancies, this analysis describes maternal demographic and clinical characteristics, pregnancy outcomes and frequency of birth defects among neonates with prenatal exposure to DTG.
Results: As of 31 January 2016, 61 pregnancies with exposure to DTG were prospectively reported to the APR with initial DTG exposure occurring among 32 pregnancies during 1st trimester, 7 pregnancies during 2nd trimester and 22 pregnancies during 3rd trimester. At enrolment, 23 (37.7%) women had a CD4 count ≥ 500 cells/μL, 19 (31.1%) had a CD4 count of 200-499 cells/μL, 16 (26.2%) had a CD4 count of < 200 cells/μL and unknown for 3 (4.9%).
Of 61 pregnancies, 51 (83.6%) resulted in live births (22 with 1st trimester and 29 with 2nd/3rd trimester DTG exposure), 3 (4.9%) resulted in induced abortions (all with 1st trimester DTG exposure), and 7 (11.5%) resulted in spontaneous abortions (all with 1st trimester DTG exposure). There were no stillbirths reported. Two of 51 live births (3.9%) reported birth defects - a bilateral polydactyly, post-axial to both hands with 1st trimester DTG exposure; and one Hypoglossia Hypodactylia Syndrome with 3rd trimester exposure to DTG.
Five of 51 live births reported non-defect adverse outcomes: 2 Preterm (<37 weeks of gestation), 1 low birth weight (LBW<2500 grams), 1 Preterm + LBW, and 1 Preterm + Very LBW (<1500 grams).
Conclusions: This analysis of birth defects includes the largest number of prenatal exposures to DTG to date. While limited in sample size to reach definitive conclusions, APR data do not demonstrate an increased risk of congenital anomalies with DTG use above the population expected rate of defects (2.72 - 4.17/ 100 live births from MACDP and TBDR respectively). Continued monitoring of prenatal DTG exposure and outcomes is needed. Clinicians are urged to continue reporting ARV exposures to the APR.

MOPEB0284

Simplified dual therapy (LPV/r plus 3TC) for ART-naïve patients is a viable alternative in resource-limited settings in China: 48-week results from a randomized, open-label, non-inferiority trial

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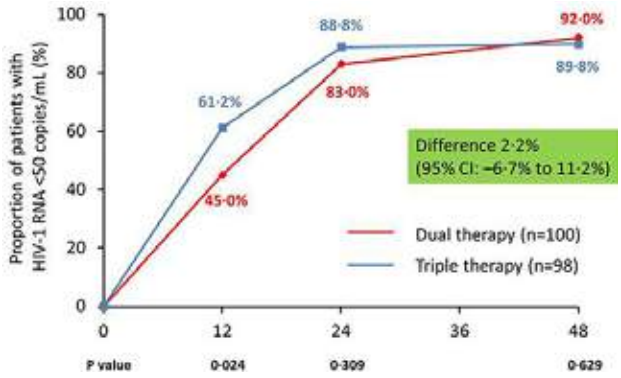
Background: The evidence supporting dual therapy as a viable HIV treatment strategy for ART-naïve HIV-infected patients is increasing, driven by improvements in toxicity, costs and future options. However, there are very few reports from China where triple-therapy containing efavirenz (EFV) is recommended as the first-line regimen.
We evaluated the efficacy and safety of dual-therapy [lopinavir and ritonavir (LPV/r) plus lamivudine (3TC)] in Chinese ART-naïve HIV-infected patients, as compared to triple-therapy containing tenofovir (TDF), 3TC plus EFV.
Methods: This was a randomized, controlled, open-label, non-inferiority trial conducted in China. ART-naïve HIV-1-infected patients were randomized 1:1 to receive a dual-therapy regimen of LPV/r plus 3TC or a triple-therapy regimen of TDF, 3TC plus EFV. All patients were followed-up for 48 weeks after receiving ART. The primary endpoint was the proportion of patients with plasma HIV-1 RNA <50copies/mL at week 48, assessed with the US FDA snapshot algorithm.
Results: 274 patients were screened, of which 198 were found eligible and randomized into the dual-therapy group (DT group, n=100) or triple-therapy group (TT

group,n=98). 92 patients(92%) in the DT group and 88(89.8%) in the TT group achieved plasma HIV-1 RNA< 50copies/mL at week 48(difference 2.2%, 95%CI-6.7% to 11.2%,p=0.629).



[Proportion of patients with HIV-1 RNA <50copies/mL]

Among patients with baseline HIV-1 RNA100,000copies/mL,13 of 14 achieved primary endpoint in the DT group, as compared to 9 of 9(100%) in the TT group(p=1.000). No virological resistance was found in both groups. Mean changes in CD4 count from baseline through 48 weeks were similar in both groups (+203.2cells/mm^3 in the DT group vs. +174.8cells/mm^3 in the TT group,p=0.114). The safety profile was similar between the two groups. The majority of adverse events were mild and only one serious adverse event occurred in the DT group, which was unrelated to the study drugs.

Conclusions: Dual-therapy of LPV/r plus 3TC is effective, safe and comparable to the first-line triple-therapy regimen containing TDF,3TC plus EFV in China, even in patients with high baseline viremia.

MOPEB0285

Cost-effectiveness of the introduction of dolutegravir in first or second-line ART regimens in sub-Saharan Africa

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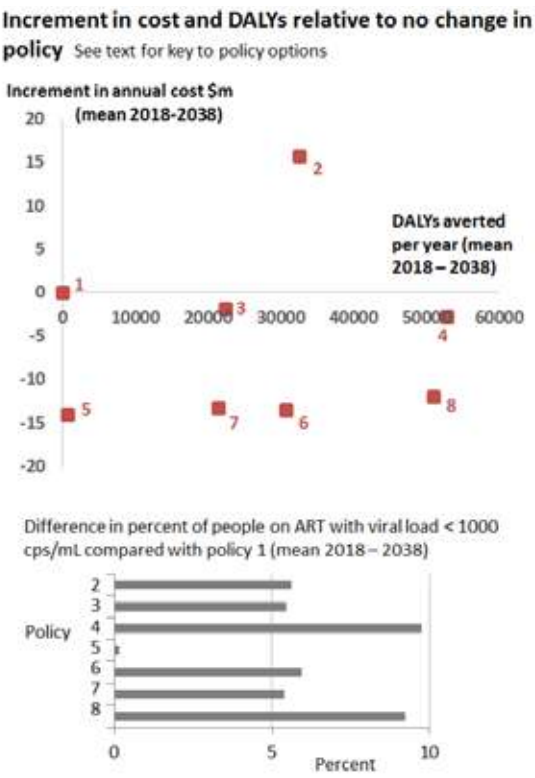
Background: While current ART regimens are highly successful there is potential for improvement in cost effective regimen choice with the introduction of the integrase inhibitor dolutegravir, which has a higher barrier to resistance, appears to be associated with reduced toxicity, although potential issues over pregnancy, people with TB and IRIS remain. .

Methods: We synthesized existing evidence in the framework of a dynamic, individual-based model and estimated the cost effectiveness of various policies involving use of dolutegravir-based regimens in the context of sub-Saharan Africa starting in 2018. Policy options considered were:

1. No change;
2. Increase rate of switch to 2nd-line (atazanavir-based);
3. All ART initiators: dolutegravir-based 1st-line;
4. All on first line ART: move from efavirenz to dolutegravir;
5. Transition of 2nd-line regimen to dolutegravir-based rather than atazanavir-based;
6. Transition of 2nd-line regimen to dolutegravir-based rather than atazanavir-based, plus an increase in rate of switch to 2nd line;
7. Dolutegravir 1st-line regimen for all new ART initiators, no switching to 2nd- line in those on dolutegravir, replacing atazanavir with dolutegravir in those on 2nd line already;
8. Dolutegravir-based regimen for all on 1st-line, no switching to 2nd-line in those on dolutegravir, replacing atazanavir with dolutegravir in those on 2nd-line already.

Dolutegravir cost $44, efavirenz $38, atazanavir $213; health systems perspective, 20 year time horizon, 3% discount rate.

Results: The figure shows the predicted increment in cost and DALYs averted for the alternative policies in the context of a country of population 10 million adults.



[Figure]

Dolutegravir introduction is predicted to lead to substantial DALY benefits, and a large reduction in costs if atazanavir is replaced in 2nd-line.

Conclusions: Dolutegravir introduction will likely bring health benefits and may well be cost saving, with various options for its use. However we should proceed with caution and current studies and possible future trials of dolutegravir are important to inform future use of the drug.

MOPEB0286

Patient reported outcomes (PROs) in HIV-infected adults enrolled in the NEAT001/ANRS143 trial comparing first-line ART regimens with darunavir/ritonavir (DRV/r) in combination with tenofovir DF/emtricitabine (TDF/FTC) or raltegravir (RAL)

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Background: There are few data comparing patient reported outcomes (PROs) in HIV-infected individuals receiving first-line antiretroviral therapy (ART) with either a standard PI/r-based triple combination or a dual combination. We present results from a substudy of the NEAT001/ANRS143 trial.

Methods: The randomised trial demonstrated non-inferiority of first-line DRV/r 800/100mg once daily plus RAL400mg twice daily compared with DRV/r plus TDF/FTC 245/200mg once daily. Changes in PROs were assessed at 4, 12, 24, 48 and 96 weeks from baseline. PROs recorded were as follows: the EuroQoL 5

domains questionnaire (EQ-5D) and Visual Analogue Scale (VAS), the Centre for Epidemiologic Studies Depression scale (CES-d), and the HIV Treatment Satisfaction Questionnaire (HIVTSQ). Major Depressive Disorder (MDD) was defined as CES-d≥16. General estimating equations were used to model change over time in PROs form baseline. Cohen's d measuring effect size was calculated to compare arms in change from baseline for EQ5D.

Results: Of the 805 participants, 797 (99%) contributed to the substudy: 683/797 (86%) at baseline, 611 (77%) at W96, and 526 (66%) at both visits. Baseline PROs data were similar for the two treatment groups for all the variables. Participants reported health improvements over time (mean increase in VAS score of 7.98 by W96 (95%CI 6.5-9.4; p<0.001)). There were no statistically significant differences between the arms on EQ-5D during the study (VAS p=0.77, Cohen's d<0.2 for all EQ-5D domains). In addition, there was no significant difference between treatment groups on CES-d p=0.87, or odds of MDD during follow-up, adjusted for baseline MDD (OR=0.98, 95%CI 0.82-1.18). Satisfaction with treatment was lower in the RAL+DRV/r arm (Table 1) (median score: 53 RAL/r+DRV/r vs 55 TDF/FTC+DRV/r (p=0.001)).

Treatment Satisfaction Question at Week 96	RAL + DRV/r (% very satisfied)	TDF/FTC + DRV/r (% very satisfied)	X ² p-value
HIV well controlled	250/268 (93%)	277/287 (97%)	0.08
Satisfied with extent of unwanted side effects	234/267 (88%)	250/287 (87%)	0.85
Satisfaction with how demanding treatment is	180/267 (67%)	220/286 (77%)	0.01
Convenience	209/268 (78%)	249/287 (87%)	0.007
Flexibility of treatment	176/271 (65%)	217/285 (76%)	0.004
Satisfaction with understanding of HIV	232/266 (87%)	252/287 (88%)	0.84
Extent with which treatment fits into lifestyle	203/264 (77%)	250/287 (87%)	0.002
Recommendation to a friend	230/266 (86%)	267/288 (93%)	0.02
Continuation of treatment	230/266 (86%)	252/286 (88%)	0.56

[Table 1: HIVTSQ results]

Conclusions: PROs improved in both arms after starting ART, but with no statistically significant difference between arms. The lower level of convenience, flexibility and lifestyle suitability of RAL+DRV/r, may be explained by twice-daily drug administration.

MOPEB0287

Dolutegravir-lamivudine as initial therapy in HIV-infected, ARV naive patients: 96 week results of the PADDLE trial

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Background: Based on the results of the GARDEL trial, we designed a proof of concept study to evaluate the antiviral efficacy, safety and tolerability of a dual therapy regimen with Dolutegravir (DTG) 50m mg QD plus Lamivudine (3TC) 300 mg QD as initial HAART among ARV-naïve patients. Week 48 analysis was presented at AIDS 2016 (90% (18/20) reached the primary end point of a pVL <50 copies/mL. Week 96 results are reported here.

Methods: Pilot study including 20 HIV-infected ARV-naïve adults. Eligible participants had no IAS-USA defined NRTI resistance, HIV-1 RNA <100.000 copies/mL at screening and negative HBsAg. Viral load (pVL) was measured at baseline, on days 2, 4, 7, 10, 14, 21, 28 and on weeks 6, 8, 12, and thereafter every 12 months up to 96 weeks. Primary endpoint was the proportion of patients with HIV-1 RNA <50 copies/mL in an ITT-exposed analysis at 48 weeks and week 96(FDA-snapshot algorithm).

Results: Eighteen patients completed 48 weeks and were included in the extension phase. Fifteen patients completed week 96, 100% maintained plasma HIV-1 RNA below 50 copies/mL. Three patients are virologically suppressed at week 84. Their week 96 results will be reported at the conference. Mean CD4+ increase between baseline and week 96 was 271 cell/mm^3, without change between 48 and 96 weeks. No new virologic failures, no new AIDS defining illnesses, or SAEs (related/possibly related to study drugs) were observed. No Treatment discontinuations were reported through the extension phase. Two grade 3 laboratory abnormalities were reported (high cholesterol, and proteinuria) but considered unrelated to study drug.

Conclusions: In this pilot study, dual therapy with DTG+3TC has demonstrated efficacy, safety, tolerability and durability through 96 weeks of treatment. This strategy is being explored in a large randomized trial.

MOPEB0288

Adults with renal impairment switching from tenofovir disoproxil fumarate to tenofovir alafenamide have improved renal and bone safety through 144 weeks

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Background: Elvitegravir, cobicistat, emtricitabine, and TAF (E/C/F/TAF) was associated with high efficacy and improved bone and renal safety in HIV-1 infected adults with mild to moderate renal impairment at Weeks (W) 48 and 96. We now report long-term (W144) efficacy and safety outcomes.

Methods: Virologically suppressed adults with stable renal impairment (eGFR$_{CG}$ 30 to 69 mL/min) switched from TDF- and non-TDF-containing regimens to open-label E/C/F/TAF. We report efficacy (HIV-1 RNA <50 c/mL FDA snapshot algorithm), renal and bone safety endpoints overall, and stratified by pre-switch TDF use.

Results: Of 242 participants switched to E/C/F/TAF [mean age 58 years (range: 24 - 82), 18% Black, 39% HTN, and 14% DM], 65% were on TDF pre-switch. At W144, virologic suppression was 83.1% (90% CI 77.7%, 87.7%). We observed significant improvements in median eGFR$_{CG}$ overall and by pre-switch TDF use, while those not on TDF pre-switch had no change (Table). No new participants discontinued study drug for renal adverse events after W96. There were no cases of proximal renal tubulopathy or Fanconi syndrome through W144. Participants had significant improvements in total proteinuria, albuminuria, and tubular proteinuria, with particularly marked improvements in pre-switch TDF takers (p<0.001 for all) (Table). Clinically significant proteinuria (UPCR >200 mg/g) and albuminuria (UACR ≥30 mg/g) at baseline resolved for 69% and 47% of all participants, respectively. Both hip and spine BMD increased significantly overall and more markedly for pre-switch TDF takers (p<0.001 for both); spine BMD increased significantly in non-TDF takers (p=0.030).

Conclusions: Through W144, HIV-infected adults with mild and moderate renal impairment who switched to E/C/F/TAF had high rates of virologic suppression, stable renal function, and significant improvements in proteinuria and BMD, with benefits particularly marked for pre-switch TDF users. These long-term data support switching from TDF-containing regimens to E/C/F/TAF in those with mild to moderate renal impairment.

	With Pre-Switch TDF Use (N=158)	P-value*	Without Pre-Switch TDF Use (N=84)	P-value*	Total (N=242)	P-value*
Change in eGFR, median (mL/min)	+3.1	<0.001	-0.1	0.33	+1.5	0.020
Changes in Renal Biomarkers, median (%)						
UPCR	-57.0	<0.001	-8.5	0.76	-45.7	<0.001
UACR	-58.6	<0.001	-4.1	0.27	-35.1	0.003
RBP: Cr	-85.1	<0.001	15.0	0.023	-63.8	<0.001
β2M: Cr	-90.3	<0.001	5.6	0.023	-81.9	<0.001
Changes in BMD, mean (%)						
Spine	+3.75	<0.001	+0.60	0.030	+2.76	<0.001
Hip	+2.28	<0.001	+0.99	0.098	+1.99	<0.001

*P-values for within group differences (baseline vs Week 144) were based on the two-sided Wilcoxon signed rank test

[Table. Key safety outcomes at week 144]

MOPEB0289

Switching from TDF to TAF improves bone and renal safety independent of age, sex, race, or 3rd agent: results from pooled analysis (N=3816) of virologically suppressed HIV-1-infected adults

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Background: Five randomized trials evaluating switching from a tenofovir disoproxil fumarate (TDF)-containing regimen to a tenofovir alafenamide (TAF) regimen demonstrated improved bone and renal safety.

Methods: We pooled data at Week (W) 48 from five trials of HIV-infected, virologically suppressed individuals who switched from a TDF-containing to a TAF-containing regimen to assess outcomes in subgroups at risk of bone and renal complications: age, sex, race, baseline eGFR, and 3rd agent prior to switch (PI, integrase, or NNRTI).
Results: Of 3816 participants, 2205 (58%) switched to TAF and 1611 (42%) remained on TDF. 48 weeks after switching to TAF, there were statistically significant improvements in hip and spine BMD, eGFR, and total and tubular proteinuria overall and in all subgroups (Table 1). Of note, greater magnitude benefits were seen in those at greater bone and renal risk. Significant improvements in mean BMD % change were seen after switching to TAF vs TDF in women (hip: +1.4% vs +0.1%, spine: +2.3% vs -0.4%) and adults ≥50 years (hip: +1.1% vs -0.3%, spine: +1.9% vs -0.1%). Those on TAF with baseline eGFR < 90 mL/min had greater improvements in median eGFR (+6.2 vs +1.0 mL/min), significant median % declines in total (UPCR: -30.2% vs +14.8%, UACR: -25.1% vs +22.4%) and tubular proteinuria (RBP:Cr: -45.4% vs +43.7%; B2M:Cr: -62.6% vs +45.3%) compared with increases with TDF. Black participants who switched to TAF had improvements in both bone (hip: +1.2% vs +0.1%, spine: +1.9% vs -0.3%) and renal (UPCR: -15.6% vs +8.5%) safety. Improvements in bone and renal safety were independent of 3rd agent.
Conclusions: For >2200 individuals who switched to TAF, those at greater bone and renal risk had more benefit. These data support switching from TDF to TAF, in particular in TDF-treated individuals at high risk for low BMD or renal disease.

Subgroup		Treatment	Mean % change in BMD: Spine	Mean % change in BMD: Hip	Median eGFR$_{CG}$* change (mL/min)	Mean % change in renal biomarkers: UPCR	UACR	RBP: Cr	β2M: Cr
Overall		TAF	+1.64	+1.37	+3.6	-20.7	-13.6	-26.7	-43.6
		TDF	-0.20	-0.19	0.0	+6.3	+12.2	+22.4	+17.7
Age	<50 years	TAF	+1.52	+1.47	+3.1	-19.6	-14.1	-25.8	-43.0
		TDF	-0.25	-0.14	0.1	+3.3	+9.9	+20.6	+16.4
	≥50 years	TAF	+1.90	+1.14	+4.8	-23.0	-10.1	-30.4	-46.2
		TDF	-0.10	-0.28	-0.1	+8.8	+16.0	+27.7	+21.2
Sex	Male	TAF	+1.50	+1.36	+3.4	-20.2	-14.0	-26.6	-44.8
		TDF	-0.17	-0.24	+0.3	+5.1	+11.7	+22.2	+17.3
	Female	TAF	+2.33	+1.42	+4.8	-24.2	-8.9	-27.6	-38.4
		TDF	-0.59	+0.13	-1.8	+7.4	+15.7	+22.6	+21.7
Race	Black	TAF	+1.87	+1.22	+4.3	-15.6	-6.2	-18.9	-29.8
		TDF	-0.28	+0.08	-0.5	+8.5	+14.0	+21.5	+12.6
	Nonblack	TAF	+1.57	+1.41	+3.6	-22.1	-15.0	-29.4	-49.1
		TDF	-0.18	-0.27	+0.1	+4.6	+11.8	+22.7	+19.6
Baseline eGFR$_{CG}$	<90 mL/min	TAF	+2.03	+1.34	+6.2	-30.2	-25.1	-45.4	-62.6
		TDF	-0.25	-0.43	+1.0	14.8	+22.4	+43.7	+45.3
	≥90 mL/min	TAF	+1.49	+1.38	+1.8	-17.0	-9.7	-21.9	-38.3
		TDF	-0.18	-0.10	-0.5	+2.4	+8.5	+17.6	+11.4
Prior treatment	INSTI	TAF	+1.32	+1.11	+3.1	-15.8	-15.6	-25.9	-42.8
		TDF	-0.32	-0.27	+0.1	+12.9	+2.5	+20.6	+19.6
	PI	TAF	+2.13	+1.68	+2.7	-22.8	-15.1	-35.6	-55.4
		TDF	-0.43	-0.19	-1.2	+9.4	+16.3	+18.1	+22.8
	NNRTI	TAF	+1.42	+1.26	+5.4	-21.8	-11.5	-22.9	-37.0
		TDF	-0.04	-0.16	+1.2	+0.8	+12.6	+24.4	+14.6

eGFR = estimated glomerular filtration rate; UPCR = urine protein to creatinine ratio; UACR = urine albumin to creatinine ration; RBP:Cr =retinol binding protein to creatinine ratio; B2M:Cr = beta-2-microglobulin to creatinine ratio
* P-values for BMD were calculated using the ANOVA model including study and treatment as fixed effects. P-values for renal safety data were calculated using the van Elteren test including study as a stratification factor.
† Excludes participants who received EFV/FTC/TDF as prior treatment.

[Table 1. Changes from baseline in BMD and renal biomarkers at week 48 (p≤0.001 for all treatment differences)]*

MOPEB0290

Limited impact of first-line drug resistance mutations among patients receiving second-line therapy in Uganda

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Background: Most ART programs in low-income countries in Africa still have limited access to routine viral load (VL) testing. Concerns have arisen that delayed detection of treatment failure among patients in these settings may lead to sub-optimal response to second-line therapy due to accumulated drug resistance mutations (DRMs) on first-line ART.
Methods: Beginning in June 2012 we followed participants who had been on NNRTI-based first line ART for ≥4 years and had a measured VL ≥1000 copies/mL at enrollment. Participants were switched to protease inhibitor- (PI) based regimens and followed every six months until September 2016. We collected clinical and behavioural data by an interviewer administered questionnaire and measured VL at study exit. We conducted DRM testing on VL samples ≥1000 copies/mL collected at enrollment and study exit. We compared factors associated with virologic failure(VF) using Wilcoxon Rank Sum, Chi-square and Fisher's Exact Test.
Results: We enrolled 137(64.3% female) participants who had VL > 1000 copies/mL with a median age of 44 years(Q1-Q3= 4-7) and median duration on ART of 6 years(Q1-Q3=38-48). In a median of 2.8years(Q1-Q3=2.6-3.2) of follow-up, 7 (5%) died, 5(3.6%) voluntarily withdrew and 2 (1.5%) became lost-to-follow-up. Of 116 participants with a VL result at study exit, 20 (17.2%) had VL> 1000copies. Virologic failure was associated with a lower BMI both at baseline and 36 months (p=0.007) and (p=0.009) respectively and sub-optimal adherence (P=0.028). Of 105 patients with drug resistance data at enrollment, 103 (98%) had at least one drug resistance mutations, Participants with thymidine analogue mutations (TAMS) at enrollment were less likely to develop virologic failure on PI-based therapy (11% vs. 36%; p=0.007).
Of 18 patients with drug resistance testing at study exit 14(77%) had mutations, with M184V being most common (11/4 or 78%). A total of 4 participants developed PI resistance mutations and 1 had K65R.
Conclusions: Even in the presence of multiple DRMs at enrollment, virologic failure at nearly 3 years of follow-up on PI-based ART was infrequent. Sub-optimal adherence to ART was associated with virologic failure, but no DRMs found at enrollment were positively associated with failure.

MOPEB0291

Efficacy and safety of switching from RPV/FTC/TDF or EFV/FTC/TDF to RPV/FTC/TAF in Black adults

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Background: Black adults are disproportionately affected by HIV and chronic kidney disease. We report the efficacy and safety of switching from either emtricitabine/tenofovir disoproxil fumarate plus rilpivirine (RPV/FTC/TDF) or efavirenz (EFV/FTC/TDF) [TDF group] to the single-tablet regimen rilpivirine/emtricitabine/tenofovir alafenamide (RPV/FTC/TAF) in Black individuals.
Methods: We conducted a post-hoc subgroup analysis in Black adults using the Week (W) 48 efficacy and safety data pooled from 2 phase 3, double-blinded, randomized, active-controlled studies in virologically suppressed HIV-infected participants. Viral suppression (HIV-1 RNA <50 copies/mL) rates by FDA snapshot analysis at W48 were compared, and percent change in bone and renal measurements are reported.
Results: Of 1505 treated participants, 357 self-identified as Black (RPV/FTC/TAF n=183, TDF n=174). Baseline characteristics among Blacks were generally balanced between treatment groups; the median (range) age was 47 (21-76) years, 5% had diabetes and 34% hypertension. At W48, rates of virologic success were 87.4% RPV/FTC/TAF vs. 91.3% TDF (difference -3.9%, 95% CI -10.5% to 2.7%; p=0.30); the lower rate of success was primarily driven by study drug discontinuation (10.9% RPV/FTC/TAF vs. 6.5% TDF) due to reasons other than AEs, rather than by virologic failure. There was no emergent resistance with RPV/FTC/TAF. Lumbar spine and total hip BMD increased with RPV/FTC/TAF and minimally declined with TDF; differences in BMD change were statistically significant at W48 (p<0.001, Table 1). Assessment of renal safety using estimated glomerular filtration rate (eGFR) and protein:creatinine and albumin:creatinine ratios favored RPV/FTC/TAF, with similar trends observed for renal tubular biomarkers (Table 1). Switching to RPV/FTC/TAF from either EFV/FTC/TDF or RPV/FTC/TDF had minimal impact on fasting total cholesterol to HDL ratios.
Conclusions: Virologically suppressed Black adults who switched to RPV/FTC/TAF experienced improvements in proteinuria, albuminuria and BMD while maintaining high rates of viral suppression through Week 48.

	Blacks: RPV/FTC/TAF (n=183)	Blacks: TDF group (n=174)	P-value
Change in eGFR, median (mL/min)	-4.8	-0.6	0.028
Percent Changes in Renal Biomarkers, median (%)			
Urine Protein: Creatinine Ratio	-19.1	+2.8	0.007
Urine Albumin: Creatinine Ratio	-6.7	+15.4	0.004
Urine Retinol Binding Protein: Creatinine Ratio	-19.0	+23.6	1.00
Urine Beta-2-Microglobulin: Creatinine Ratio	-27.5	+13.5	0.29
Percent Changes in BMD, mean (%)			
Lumbar spine	+1.76	-0.12	<0.001
Total hip	+1.00	-0.16	<0.001

[Table. Changes from baseline in measures of renal and bone safety parameters at week 48]

MOPEB0292

Efficacy and safety of tenofovir alafenamide vs tenofovir disoproxil fumarate in HIV-infected virologically suppressed older adults: 96-week subgroup analysis of a randomized switch study

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Background: As the HIV-infected population ages and has increasing prevalence of co-morbidities, efficacy and safety of antiretrovirals in older participants is of heightened importance. Tenofovir alafenamide (TAF) has a potential to benefit older individuals, as it has previously demonstrated an improved renal and bone safety profile compared to tenofovir disoproxil fumarate (TDF).
Methods: We conducted a 96-week subgroup analysis in those ≥50 years old for efficacy (pre-specified) and safety (post-hoc) from a randomized, double blind, active-controlled study in virologically suppressed HIV-infected participants on ARV regimens composed of emtricitabine/TDF (FTC/TDF) plus third agent, who either switched to FTC/TAF or remained on FTC/TDF, while maintaining their third agent.
Results: Of 663 treated, 294 were ≥ 50 years (FTC/TAF n=150, FTC/TDF n=144). Baseline viral load, CD4 counts, renal laboratory parameters, and bone mineral density (BMD) were similar between the two arms within those ≥ and < 50 years, respectively. For participants ≥50 years, virologic success by FDA snapshot algorithm at Week 96 was FTC/TAF 92% vs. FTC/TDF 92%; for those < 50 years, it was 86% vs 87%. Few participants discontinued study drug due to adverse events in either subgroups (≥50 years, FTC/TAF 3.3% vs. FTC/TDF 2.1%; < 50 years, 1.6% vs. 0.5%). The assessment of renal and bone safety using estimated glomerular filtration rate (eGFR), renal biomarkers, and BMD had significant differences between the two arms that consistently favored FTC/TAF over FTC/TDF (Table 1). No cases of Fanconi syndrome or proximal renal tubulopathy were reported with FTC/TAF (vs one participant ≥50 years in FTC/TDF group).
Conclusions: At 96 weeks, virologically suppressed adults ≥50 years who switched to FTC/TAF had comparable efficacy and improved bone and renal safety to those remaining on FTC/TDF. These findings of improved safety with TAF relative to TDF in older individuals are of particular importance as the population living with HIV ages and experiences more renal and bone-related comorbidities.

	Age ≥50 years			Age <50 years		
	FTC/TAF (n=150)	FTC/TDF (n=144)	P value	FTC/TAF (n=183)	FTC/TDF (n=186)	P value
Change in eGFR, median (mL/min)	+7.8	+3.7	<0.001	+10.6	+4.2	<0.001
Changes in Renal Biomarkers, median (%)						
Urine Protein: Creatinine Ratio	-21.2	+7.7	<0.001	-30.2	-1.4	<0.001
Urine Albumin: Creatinine Ratio	+5.8	+29.4	0.002	-1.0	+22.0	<0.001
Urine Retinol Binding Protein: Creatinine Ratio	-6.3	+57.8	<0.001	-3.5	+36.9	<0.001
Urine Beta-2-Microglobulin: Creatinine Ratio	-29.7	+54.7	<0.001	-29.8	+41.8	<0.001
PRT or Fanconi Syndrome	0	1		0	0	
Changes in BMD, mean (%)						
Spine	+2.69	+0.15	<0.001	+1.49	-0.41	<0.001
Hip	+1.59	-0.78	<0.001	+1.81	-0.08	<0.001

PRT = proximal renal tubulopathy

[Table. Key safety outcomes at week 96]

MOPEB0293

Which antiretroviral as first regimen? Evolution over the last 10 years in France

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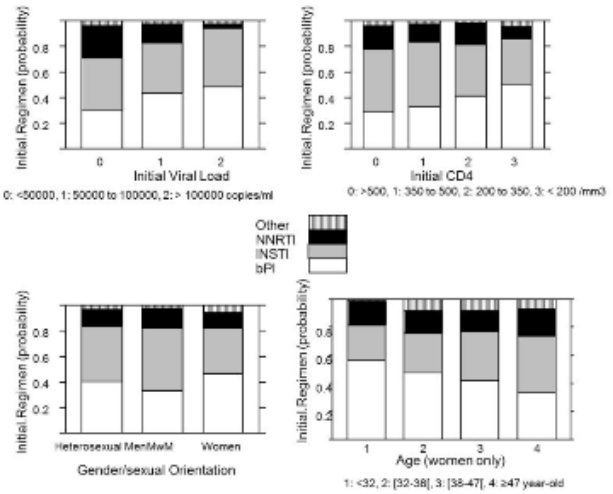
Background: To describe the evolution of initial ART regimens between 2005 and 2015 and the patients´ characteristics related with the choice of the regimen in 2015.
Methods: Patients starting ART between 2005 and 2015 were selected from a large prospective French cohort. Regimens were classified as three nucleos(t)ide reverse transcriptase inhibitors (NRTI); 2 NRTIs with a boosted protease inhibitor (bPI), with a non-nucleoside reverse transcriptase inhibitor (NNRTI), or with an INSTI; or other. A multinomial logit model was fitted to analyze characteristics related with the choice of the regimen in 2015.
Results: We analysed 15 897 patients, median age 38 years (stable across the study period), 63% men in 2005 to 73.8% in 2015 (p< 0.001). CD4⁺ cell count at initiation increased, from a median of 232 in 2005 to 390/mm³ in 2015 (p< 0.001) with no change in initial median viral load (VL) (4.7 log_{10}.copies/ml). Proportion of patients starting with: a bPI decreased from 60% before 2014 to 38.1% in 2015; a NNRTI decreased from 30% in the past years to 17.8% in 2015; an INSTI increased to 39.4% in 2015. In 2015, patients with an initial VL greater than 5 log.copies/ml were less prone to receive NNRTI (β=-2.46, SE=0.33) or INSTI regimens (β=-0.37, SE=0.15) than bPI, patients with initial CD4⁺ T cell count below 200/mm³ were less prone to receive NNRTI (β=-1.26, SE=0.25) or INSTI (β=-0.85, SE=0.18) than bPI, and women were less prone to receive an NNRTI (β=-0.23, SE=0.24) or an INSTI regimen (β=-0.33, SE=0.18) than a bPI, although for women age was also related with initial ART choice. The figure shows the probability of the initial regimen according to these factors and to age for women.



[Probability of initial regimen]

Conclusions: Choosing a first ART regimen in France is evolving. Forthcoming data in some patients' specific populations may lead to greater modifications.

MOPEB0294

A fixed dose combination of elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate for the initial treatment of HIV-2 infection: 48 week results from Senegal, West Africa

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Background: There is an urgent need for safe and effective ART for HIV-2 infection. HIV-2 treatment is complicated by intrinsic resistance to many FDA-approved HIV-1 drugs, and multidrug-resistance is common in individuals failing ART. There are limited options for 1st- and 2nd-line ART for HIV-2 in resource-limited settings. An increasing body of data suggests that integrase inhibitor-based regimens may be of utility for the treatment of HIV-2. We have undertaken the first clinical trial of a once-daily fixed-dose combination pill containing elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (E/C/F/TDF) to assess the effectiveness of this regimen in HIV-2-infected individuals in Senegal, West Africa.
Methods: HIV-2-infected, ART-naïve adults with WHO stage 3/4 disease or CD4 counts below 750 cells/mm³ were eligible for this open-label trial (NCT02180438), with planned enrollment of 30 subjects and follow-up for 48 weeks. We analyzed: HIV-2 viral load, CD4 counts, adverse events, mortality and loss to follow-up.
Results: We screened 35 subjects and 30 subjects started ART with E/C/F/TDF. 26 subjects have achieved at least 48 weeks of follow-up. The majority were female (80%), with a median age of 49 years at enrollment. There were no deaths, 1 loss to follow up/withdrawal and no new AIDS-associated clinical events. Median baseline CD4 count was 422 cells/mm³ (IQR: 317-530) and increased to 507 cells/mm³

(IQR: 413-604) at week 48. 25 subjects had baseline HIV-2 viral loads (VL) of fewer than 50 copies/ml of plasma, including 15 subjects who had viral loads below the limit of detection (10 copies/ml). In those with detectable HIV-2 VL, the median was 41 copies/ml (IQR: 22-57). Using a mITT analysis (FDA snapshot method), 24 of 25 (96%) had viral suppression at 48 weeks. E/C/F/TDF was generally well tolerated; there were three grade 3-4 adverse events, none were deemed study related. Adherence was good by self-report and pill count.
Conclusions: Long-term outcomes of HIV-2 infected patients on ART in West Africa are suboptimal and new therapeutic options are needed. Initial data suggest that E/C/F/TDF, a once-daily single-tablet regimen, is safe, effective, and well-tolerated in this population. Our findings support the use of integrase inhibitor-based regimens for HIV-2 treatment.

MOPEB0295

Comparison of 2 versus 3 fully-active drugs regimen in long-term virological success after first-line NNRTI failure. The key question: is three a crowd?

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Background: After virological failure HIV treatment guidelines recommend that a new ARV regimen should contain at least two, and preferably three, fully active drugs. Nevertheless, there are increasing data showing that an active boosted PI (PI/r) plus one active NRTI may effectively reduce viral load in some patients. The aim of our study was to evaluate in a real-life setting the long-term virological outcome of a PI/r-based therapy containing 2 or more active drugs after a first-line NNRTI treatment.
Methods: Retrospective study. HIV-1 infected patients who had virological failure to a first-line NNRTI regimen that started a PI/r-based regimen after genotyping test (TRUGENE HIV-1 Genotyping Assay) were included from the Outpatient Care Unit Muñiz Hospital cohort (MHOBA), Buenos Aires, Argentina (2002-2014). Number of active drugs was defined using the REGA genotypic sensitivity score (GSS): GSS 2.5: two active drugs; GSS ≥3: three or more active drugs. Sustained virological suppression was defined as HIV viral load (VL) < 50 copies/ml at week 96. Patients with PI resistance were excluded.
Results: A total of 164 patients were included. Male: 66%. Median age: 40 years. Median baseline CD4+ T-cell count: 210 cells/mL; baseline VL: 10.496 copies/ml. Fifteen percent of the patients had previous PI/r exposure and switched to a NNRTI-based therapy due to toxicity. Based on GSS, 30.4% of the patients started a PI/r plus 1 active drug (GSS 2.5) and 69.6% started a PI/r plus ≥2 active drugs (GSS ≥3). No significant differences were observed in both groups except for higher baseline HIV-VL in the GSS 2.5 group (p=0.03). The proportion of VL< 50 copies/ml at week 96 was: GSS 2.5 group: 48%; GSS ≥3 group: 49%; (p=0). No differences were observed between both groups stratifying by gender, age, VL, CD4+ T-cell < 200 cells/mL, and PI-experience.
Conclusions: After first-line NNRTI virological failure, a 2 fully-active drug regimen including a PI/r was as effective as a 3 or more fully-active drug regimen at week 96. The use of fewer active drugs in this setting could reduce toxicities and costs without affecting the long-term virological efficacy.

MOPEB0296

Prevalence of viral suppression in persons living with HIV on antiretroviral treatment in 30 facilities in Botswana

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Background: Viral suppression (VS) is the third component of the UNAIDS 90-90-90 targets for HIV epidemic control. The Botswana Combination Prevention Project (BCPP) offers a unique opportunity to evaluate rates of VS in Botswana. The baseline household survey (BHS) component of BCPP found that 96.5% of HIV-infected persons on ART in 30 BCPP communities had VS defined as a viral load (VL) HIV-1 RNA ≤ 400 copies/ml. This report provides additional information on rates of VS from clinics providing ART in BCPP communities.
Methods: Data on VL testing and other clinical and demographic information are routinely captured in national electronic medical record systems for all persons currently on antiretroviral therapy (ART). Botswana national guidelines call for VL testing 3 and 6 months after ART initiation and every 6 months thereafter. We used clinical and VL data from patients receiving ART in 30 communities taking part in the ongoing community-randomized BCPP. Using the most recent VL, rates of VS were determined for all persons living with HIV (PLHIV) currently on ART in one of these 30 community clinics, with at least one VL reported between January 13, 2016 and January 12, 2017.
Results: Of the 21,920 PLHIV designated as currently on ART for ≥ 6months, 18,856 (86.0%) had a VL recorded in the prior 12 months with 18,194 (96.5%) having VS. Assuming that PLHIV with missing VL are not suppressed, then overall 83.0% of PLHIV on ART for ≥ 6 months were found to have VS.
Conclusions: Analysis of program data from 30 community clinics participating in BCPP reveals very high levels of VS consistent with prior reports of rates of VS derived from the BHS. However, PLHIV with missing VL data may be less likely to have VS and therefore there is uncertainty as to whether the 3rd 90 (90% of persons on ART with VS) has been achieved in these communities. Factors associated with high rates of VS noted in two different modalities of evaluation, a household survey and a clinic record review within these 30 communities, along with the impact of missing data should be further explored.

MOPEB0297

Real-world comparative 48-week outcomes of switching to 2 nucleoside reverse transcriptase inhibitors and an integrase inhibitor

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Background: Switching to integrase inhibitor (INI) based ART can reduce toxicities and drug interactions. There is a lack of comparative data between the three current INIs to guide use.
Methods: Multicentre retrospective evaluation of patients on ART with HIV VL< 50c/mL switching to a dual-NRTI backbone with the INIs dolutegravir (DTG), cobicistat-boosted elvitegravir (EVG) or raltegravir (RAL) in the UK and Ireland from 1/1/15-31/8/15. The main outcome was 48-week viral suppression (VL< 50c/mL): (i) those without 48-week VL excluded (M=E; S=I); (ii) those without 48-week VL considered as VL>50c/mL (M=F; S=I); (iii) those without 48-week VL or who switched from INI considered as VL>50c/mL (M=F; S=F; NRTI changes ignored).
Results: 12 centres provided data on 359 individuals. 105 (29%) switched to RAL; 218 (61%) DTG; and 36 (10%) EVG. At switch, there were no significant differences in gender (male: RAL-70%, DTG-75%, EVG-72%), median age (46, 47, 48 years), white ethnicity (61%, 65%, 64%) or main HIV risk being sex between men (58%, 61%, 53%). There were differences in percent with CD4< 200 cells/µl (0%, 6%, 3%; P=0.03). 64%, 60% and 44% switched from PI/r-based ART respectively (p=0.0048).
At 48 weeks, comparable proportions achieved VL< 50 c/mL (table, M=E; S=I); however when considering INI switch and missing VL as failure significant differences were observed.
By 48 weeks, 25/105 (24%) discontinued RAL, 27/218 (12%) DTG and 8/36 (22%) EVG (P=0.023). VL was detectable at switch in 2/25 (8%) taking RAL, 1/27 (4%) DTG and 0/8 (0%) EVG. No genotypes or resistance development was reported for anyone discontinuing initial INI. Side effects/toxicity was the most common indication for stopping INI (37/60, 62%). Switch for simplification was common for RAL (9/25, 36%).

Outcome	RAL (n=105)	DTG (n=218)	EVG (n=36)	P (b)
M=E, S=I	69/73 (95%)	159/162 (98%)	26/28 (93%)	0.19
M=F, S=I	69/105 (66%)	159/218 (73%)	26/36 (72%)	0,40
M=F, S=F	51/105 (49%)	140/218 (64%)	23/36 (64%)	0.023
(a) on initial INI with VL<50 (b) chi-squared test				

[Viral load outcomes (VL<50c/mL) at 48 weeks]

Conclusions: Those switching to INI+2NRTI had high rates of viral suppression, with discontinuations driven mainly by side effects/toxicity. Twice daily dosing of RAL seemed to prompt a small number to switch again for convenience.

MOPEB0298

Impact of social determinants on antiretroviral therapy access and outcomes entering the era of universal treatment for HIV-infected people

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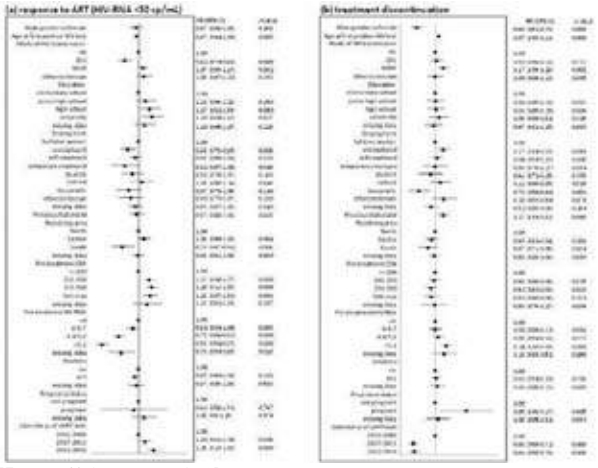
Background: Social determinants are known to be a driving force of health inequalities, even in high income countries. Aim of our study was to determine if these factors can limit ART access, outcome and retention in care of people living with HIV (PLHIV).
Methods: All ART naïve PLHIV of Italian nationality enrolled in the Icona Cohort from 2002 to 2016 were included. The association of socio-demographic characteristics (age, sex, risk factor, education, occupational status and residency area) with time to ART initiation from 1st-positive anti-HIV test, 1-year probability of HIV-RNA <50 cp/mL, and 1-year risk of 1st-ART regimen discontinuation were evaluated by Cox regression, Kaplan Meier and log-rank test. Three study periods were compared: 2002-2006; 2007-2011; 2012-2016.
Results: A total of 8,023 PLHIV (82% males, median age at first positive anti-HIV test 36 years, IQR: 29-44) were included, of whom 6,214 (77.5%) started ART during the study period. Females, pts aged >50 years, unemployed vs employed, and people with lower educational levels presented the lowest CD4 count at ART initiation. The overall median time to ART initiation was 0.6 years (IQR 0.1-3.7), with a significant decrease over time [2002-2006=3.3 yrs (0.2-9.4); 2007-2011=1.0 yrs (0.1-3.9); 2012-2016=0.2 yrs (0.1-2.1), p<0.001]. By multivariate analysis, females (p<0.01), IDUs (p<0.001), retired patients (p<0.001) and housewives (p=0.18) presented a longer time to ART initiation, while older people (per 10 yrs increase) (p<0.001), subjects with higher educational levels (p<0.001), unemployed (p=0.02) and students (p<0.001) were more likely to initiate ART. Factors associated with
(a) virological response to ART (HIV-RNA < 50 cp/mL) and with
(b) treatment discontinuation for any cause are shown in Figure 1.



[Figure 1. Multivariate analysis]

Conclusions: Despite median time to ART start decreased dramatically from 2002 to 2016, socio-demographic factors still contribute to disparities in ART initiation, outcome and durability.

MOPEB0299

Efavirenz use and risk of depression and suicidal ideation in HIV-infected adults receiving antiretroviral therapy in Southwestern Uganda

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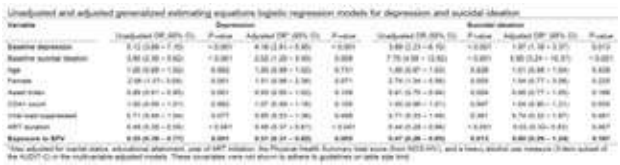
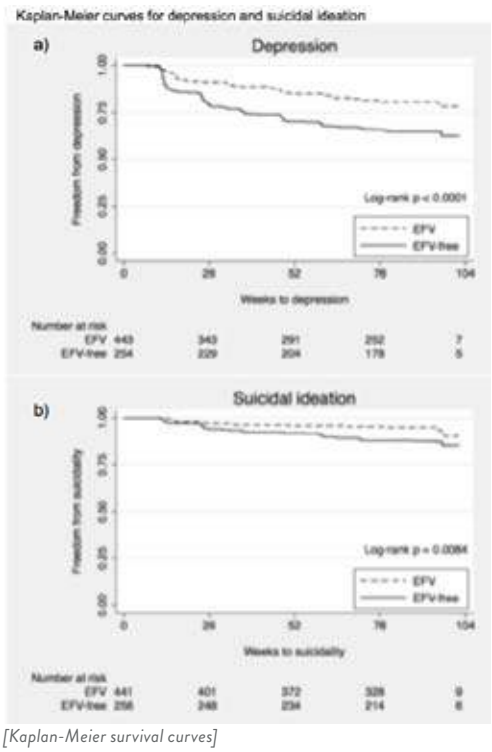
Background: There is conflicting evidence on the morbid neuropsychiatric effects of efavirenz and limited data in sub-Saharan Africa, where efavirenz remains commonly used.
Methods: We analyzed data from 704 participants in the Uganda AIDS Rural Treatment Outcomes Study, a cohort of adults in southwestern Uganda observed every 3-4 months from 2005-2015. The primary exposure was efavirenz use, defined as a prescription including efavirenz for seven consecutive days and >60/90 days prior to a visit. Outcomes of interest were: 1) depression, defined by a score >1.75 on the Hopkins Symptom Checklist; and 2) self-reported suicidal ideations (SI). We fitted generalized estimating equations (GEE) logistic regression models and graphed Kaplan-Meier curves to examine the association between efavirenz and risk of depression and SI, accounting for baseline depression and SI, demographics, CD4 count, viral suppression, ART duration, year of ART initiation, quality of life, and heavy alcohol use.
Results: There were no differences at ART initiation in depression or SI among those receiving efavirenz versus other regimens (P>0.5). In multivariable-adjusted models, use of efavirenz was paradoxically associated with a lower risk of depression (GEE AOR 0.51; 95% CI, 0.31-0.82) and was not associated with SI (GEE AOR 0.60; 95% CI, 0.29-1.24). Results were robust to exclusion of baseline suicidal and depressed patients.



[GEE logistic regression models]



[Kaplan-Meier survival curves]

Conclusions: We did not identify an association between efavirenz use and an increased risk of depression or SI in southwestern Uganda. Future analyses should assess for the possibility of time-varying confounding to corroborate this finding and to support efavirenz as a first-line agent in the region.

MOPEB0300

Durability of rilpivirine- and integrase inhibitor-based first-line regimens in HIV-infected patients starting antiretroviral therapy with a viral load < 100,000 copies/mL: data from the ICONA Foundation Study

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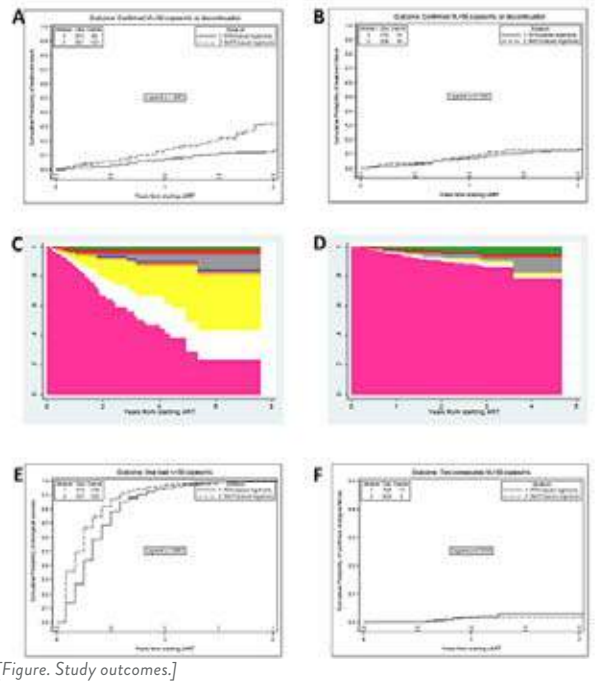
Background: Aim of the study was to compare the durability of rilpivirine (RPV) and integrase inhibitor (InSTI)-based first-line regimens in HIVinfected patients starting antiretroviral therapy (ART) with < 100,000 HIV-RNA copies/mL.
Methods: Patients enrolled in ICONA Cohort who started ART since January 2012 with HIV-RNA < 100,000 copies/mL, RPV or one InSTI, ≥1 follow-up visit thereafter, were included in this analysis.
Primary endpoint: cumulative probability of treatment failure (TF=confirmed virological failure >50 copies/mL or discontinuation of ≥1 drug in the regimen), as assessed by Kaplan-Meier method and log-rank test; independent associations were investigated by Cox regression.
Results: 1476 patients, 18% females, 4% in stage C, 10% with a CD4+ nadir < 200/µL, included in the analysis. 815 and 661 started RPV and InSTI (38% elvitegravir/cobicistat, 42% dolutegravir, 21% raltegravir), 96% and 73% with tenofovir/emtricitabine, respectively.
Over a median (Q1-Q3) follow-up of 17 (7-28) and 8 (2-15) months in the RPV and in the InSTI group, the cumulative probability of TF was higher in the InSTI group (p< .0001, Figure, panel A), but there was no difference when considering only patients who started a single table regimen (STR, Figure panel B).

Figure. A) cumulative probability of treatment failure in the overall population; B) cumulative probability of treatment failure in patients who received a single tablet regimen; C) cumulative probability of discontinuation of an integrase inhibitor-based regimen according to reason(*); D) cumulative probability of discontinuation of a rilpivirine-based regimen according to reason(*); E) cumulative probability of attaining <50 HIV-RNA copies/mL; F) cumulative probability of virological failure (two consecutive HIV-RNA values >50 copies/mL).
*(Green = failure; Red = Intolerance; Grey = Toxicity; Orange = Non-Adherence; Yellow =Simplification; White = Other reason; Pink= Never stopped)



[Figure. Study outcomes.]

The main reason for discontinuation in the InSTI group was treatment simplification (43/114=38%). After adjusting for age, gender, nation of birth, mode of HIV transmission, hepatitis coinfection, stage C, tenofovir/emricitabine vs. abacavir/lamivudine as backbone, baseline CD4+ count and HIV-RNA and year of starting ART, risk of TF was independently associated with treatment with InSTI (AHR [95%CI]=2.41 [1.75-3.31]; p< .001).
Conclusions: In patients starting ART with < 100,000 HIV-RNA copies/mL, the risk of TF was lower in patients starting a RPV-based treatment compared to those initiating InSTIs, but there was no longer a difference when restricting to STR regimens. A STR seems to be a key factor for the durability of initial antiretroviral treatment.

MOPEB0301

Similar reduction of blood HIV-1 DNA reservoir with raltegravir and efavirenz in HIV-infected patients co-infected with tuberculosis

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Background: Faster viremia control is obtained on integrase inhibitor (INI)-based compared to non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimens. The respective effects of INI and NNRTI on HIV DNA reservoir are unknown. We studied the evolution of HIV-1 DNA quantification over the first year of treatment with efavirenz or raltegravir-based regimens.
Methods: The ANRS REFLATE I phase 2 study was a non-comparative, open-label, randomized trial including antiretroviral-naive patients with HIV-1 infection and tuberculosis to receive raltegravir 400mg (RAL400), raltegravir 800mg (RAL800) or efavirenz (EFV) with tenofovir and lamivudine. Total HIV-1 DNA load in TCD4+ cells was quantified using Biocentric Generic HIV DNA Cell kit in blood samples obtained at week 0 (W0), week 24 (W24) and week 48 (W48). HIV-1 DNA levels and changes over time in the 3 treatment groups were compared with a linear mixed model including random effects on intercept and slope.
Results: Blood samples (including at least W0 baseline sample) were available for 126 participants (RAL400, n=40; RAL800, n=41; EFV, n=45), mostly men (71.4%) and a median (IQR) age of 36 (30-44) years. Baseline median (IQR) plasma HIV-1 RNA was 4.9 (4.4-5.5) $\log_{10}$copies/ml and median CD4+ count was 140 (61-305) cells/mm^3. Treatment led to plasma HIV-1 RNA < 50copies/ml in RAL400 (79% at W24 and 91% at W48), RAL800 (89% and 85%) and EFV (76% and 90%) arms. Respective median TCD4+ increases from inclusion to W24 and to W48 were 195 (76-370) and 214 (161-372) in the RAL400 arm, 134 (76-233) and 222 (108-395) in the RAL800 arm, and 170 (88-268) and 216 (87-328) in the EFV arm. Median (IQR) HIV-1 DNA ($\log_{10}$copies/10^6 CD3+CD4+ cells) at inclusion was 4.7 (4.2-5.1) in the RAL400 arm, 4.6 (4.2-5) in the RAL800 arm and 4.9 (4.4-5.1) in the EFV arm (Kruskall-Wallis p=0.28). Estimated HIV-1 DNA decreases ($\log_{10}$copies/10^{6}CD3+CD4+ cells) per one year were -0.91 in the RAL400 arm, -0.90 in the RAL800 arm and -0.93 in the EFV arm (p=0.98).
Conclusions: In AIDS patients with tuberculosis, HIV-1 DNA decrease in blood was estimated as 1 $\log_{10}$ copies/10^{6}CD3+CD4+ cells over 1 year, with either dose of raltegravir and efavirenz in combination with TDF/3TC.

MOPEB0302

Treatment of acute HIV with elvitegravir, cobicistat, emtricitabine and tenofovir

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Background: Prompt diagnosis and treatment of Acute HIV Infection (AHI) may have important clinical and public health benefits. This study sought to determine if integrase inhibitor (InSTI)-based antiretroviral treatment (ART) initiated during AHI suppresses HIV replication more rapidly than efavirenz-based ART.
Methods: This is a prospective, multicenter, single arm, 48-week open-label study of co-formulated elvitegravir (EVG), cobicistat (COBI), emtricitabine (FTC), and tenofovir disoproxil fumarate (TDF) initiated within 30 days of AHI diagnosis. The primary endpoint is the proportion of participants with HIV RNA < 200 copies/mL (c/mL) by week 24 and < 50 c/mL at week 48. We compared the time to viral suppression in this study population to that of a previously studied cohort of patients treated within 30 days of AHI with co-formulated FTC/TDF/Efavirenz (EFV) using the Wilcoxon-Mann-Whitney test.
Results: Between September 2012 and April 2015, 33 participants with AHI started InSTI-based ART. Their median age was 26 years (range 18-54), 64% were black, and most (76%) were MSM. Three participants discontinued early, leaving 30 study participants for analysis. In a previous study, 90 acutely infected participants were treated with EFV-based ART between January 2005 and December 2011, and 89 remained on ART and included in time to suppression analysis. Demographic data was similar in both groups, as was time to ART initiation, median pre-treatment CD4 count and peak HIV RNA. Of those treated with InSTI-based ART, 29/30 (97%) achieved HIV RNA < 200 copies by week 24, and 26/30 (87%) to <50 copies/mL by week 48, compared to 92% at week 24 and 80% at week 48 of participants treated with EFV-based ART. The median time from ART initiation to viral suppression was significantly more rapid for InSTI-based ART patients (HIV RNA <200 copies/mL at 26 days (range 7-132) and <50 copies/mL at 54 days (range 12-251) compared to EFV-based ART [65 days (range 7-523) and 105 days (range 14-523)] respectively (p<0.0001).
Conclusions: Once daily InSTI-based ART with EVG/COBI/FTC/TDF in acute HIV infection achieves rapid HIV suppression, potentially limiting infectivity during a period of high infectiousness. These results support the use of integrase inhibitor-based treatment for AHI.

MOPEB0303

Long-term outcomes in antiretroviral naïve patients starting efavirenz- vs. boosted protease inhibitor-based ART in the Caribbean, Central, and South America network for HIV epidemiology (CCASAnet)

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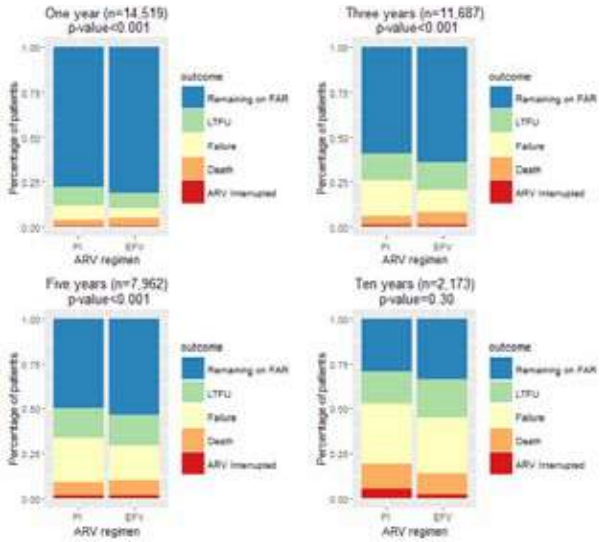
Background: Efavirenz (EFV) and boosted Protease Inhibitors (PI) are preferred options for the third component of first-line antiretroviral regimens (FAR) in Latin America. Clinical trials and meta-analyses have shown comparable short-term efficacy between both. Long-term follow-up could provide additional information on clinical outcomes, especially considering expected long-term use and increasing life-expectancies of people living with HIV (PLWH). We assessed the durability and long-term outcomes of patients receiving EFV or PI as the third component of FAR in our region.
Methods: ART-naïve PLWH ≥18 years old, enrolled in CCASAnet, and starting EFV- or PI-based FAR (Lopinavir/ritonavir or Atazanavir/ritonavir) between 2000-2016 were included. Outcomes were: Time on FAR and events ending FAR (i.e., virologic failure(VF), treatment interruptions >180 days (TI), death, and/or loss to follow-up (LTFU)). Events were compared between groups at 1, 3, 5, and 10 years of follow-up. Kaplan-Meier estimators for median times were generated and stratified by baseline CD4 (> or ≤200 cells/μL).
Results: We included 14,519 patients: 12,898 (89%) started EFV and 1,621 (11%) a PI. Median time on EFV was 5.2(IQR: 5.0-5.4) and on PI was 4.1 (IQR: 3.6-4.5) years; p-value <0.001. There were differences in median time on FAR among patients starting ART with >200 cells/μL (5.52 years for EFV vs. 3.77 years for PI; p-value <0.01). Differences between outcomes were found at 1, 3 and 5 years of follow-up (Figure 1).
Including the first event during all the follow-up there were 6,474 (50%) first-line-ending events in the EFV group: 854 (13%) deaths, 3,185 (49%) LTFU, 2,235 (34%) VF and 200 (3%) TI. In the PI group, we observed 843 (52%) first-line-ending events: 84 (10%) deaths, 364 (43%) LTFU, 372 (44%) VF and 23 (3%) TI (p-value <0.001).



[Figure 1. Distribution of outcomes by FAR at first, third, fifth and tenth year of follow-up]

Conclusions: In this ART-naïve cohort, duration of FAR was longer with EFV than PI. These differences were observed only in those with >200 CD4 cells/μL and were explained mostly by differences in rates of VF.

MOPEB0304

Psychological and social implications of initiating antiretroviral therapy (ART) in the Spanish CoRIS Cohort patients from the perspective of patients, clinicians, and representatives of nongovernmental organizations (NGOs)

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Background: We aim to assess the impact of initiating ART on patients' Health-Related Quality of life (HRQoL) from the perspective of clinicians, community representatives and patients.
Methods: Qualitative research with 2 focus groups (FG) with clinicians (n=9/n=8), 2 in-depth interviews with NGO's representatives and 9 with patients from CoRIS. We selected patients who had recently started ART. A specific script containing main themes was used for each profile. FG and interviews were registered, transcribed, codified and a content analysis was performed.

Results: ART initiation is reported as a turning point where HIV+ patients consider themselves as "sick persons". Before ART initiation, patients' fears of side effects, largely lipodystrophy and other visible signs because of HIV stigmatization. Patients also report anxiety related to ART and the impact on their professional life. Upon ART initiation, there is no consensus regarding the timing or who should be responsible for taking the decision to initiate ART. Clinicians consider themselves as the most qualified to make this decision, while NGOs favor empowering patients, and among patients, there are not agreement. The choice of ART is not entirely up to the clinicians, but is based on hospital guidelines, varying by Spanish Autonomous Communities, and cost of ART is key in the decision-making process. Of available ARTs, the choice of treatment by clinicians is driven by patients' lifestyles, resistance tests and drugs interactions. Once ART is initiated, side effects are uncommon but have important implications on patients' HRQoL. Psychological implications of treatment are linked to the anxiety of involuntary disclosure of HIV status. Patients often hide their pills and worry about being seen collecting the medication at the hospital pharmacy. Patients relate their ART with the feeling of being ill and often report non-adherence to ART as "escaping" from the disease. Clinicians, patients and NGOs agree that nonadherence often occurs when patients find it difficult to maintain a routine.
Conclusions: ART has important social cost as psychological charge of feeling sick and anxiety derived from be discovered with HIV. These feelings have important implications on adherence and thus, on virological failure that may increase treatment costs for the Health National System.

MOPEB0305

Faster immune-virological response following initiation of first line NNRTI- and INI-based antiretroviral therapy compared to boosted PI-containing regimens: a real life cohort study (2010-2015)

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Background: We aimed to evaluate viro-immunological response in untreated HIV-positive patients starting a boosted-PI-, NNRTI- or INI-based cART.
Methods: Cohort study on antiretroviral-naive patients starting a triple boosted-PI-, NNRTI- or INI-based cART (01/01/2010-31/12/2015). Time to virological success (VS:confirmed HIV-RNA< 40 copies/mL) and time to immunological response (IS1, increase of >100/mmc CD4+ from baseline; IS2, increase to >500/mmc CD4+ in patients starting≤350/mmc; IS3, increase to ≥1 CD4/CD8 in patients starting with ratio< 1) were evaluated (Kaplan-Meier,Cox analyses, intention-to-treat).
Results: We enrolled 427 patients:

	PI-based cART (N 180)	NNRTI-based cART (N 159)	INSTI-based cART (N 88)	p values
Age, median (IQR)	38 (33-45)	37 (30-42)	44 (35-51)	0.0001
Female, %	18.7	13.3	18.4	0.4
Caucasian, %	76.3	86	85.2	0.15
MSM, %	53.8	68.3	58.9	0.11
CD4+ nadir(cells/mmc), median (IQR)	277 (143-381)	385 (285-439)	385 (179-417)	0.0001
Baseline Log10 HIV-RNA copies/mL, median (IQR)	4.8 (4.1-5.3)	4.2 (3.7-4.7)	4.7 (4.1-5.2)	0.552
Antiretroviral backbone, %	TDF/FTC 90.2; ABC/3TC 5.8; ZDV/3TC 4.0	TDF/FTC 94.4; ABC/3TC 5.0; ZDV/3TC 0.6	TDF/FTC 75.6; ABC/3TC 24.4; -	-
Antiretroviral third drug, %	DRV/r 60.7; ATV/r 29.5; LPV/r 9.8	EFV 52.2; RPV 45.3; NVP 2.5	RAL 28.4; EVG/cobi 40.9 DGT 30.7	-

[Demographic and immuno-virological characteristics]

After a mean follow-up of 5.9 months (95%CI 5.2-6.6), the 6-month probability of VS was 61.8% (95%CI 54.4-69.2) for boosted-PI, 79.9% (95%CI 73.5-86.3) for NNRTI and 72.6% (95%CI 61.8-83.4) for INI (p=0.0002). A higher probability of VS with NNRTI and INI was confirmed after adjustment for baseline HIV-RNA and CD4+; the other predictive factor of VS was lower HIV-RNA. The 12-month probability of IS1 was 75.7% (95%CI 69.1-82.3) for boosted-PI, 82.6% (95%CI 76.6-88.6) for NNRTI and 81.3% (95%CI 68.5-94.3) for INI (p=0.03); no difference in IS2-IS3. Predictors of IS1 were: NNRTI, younger age, lower CD4+ and higher HIV-RNA. Higher CD4+ was the strongest predictor of long-term immunological reconstitution (IS2-IS3), younger patients showed an increased probability of IS2.

	VS		IS1		IS2		IS3	
	AOR (95%CI)	P	AOR (95%CI)	P	AOR (95%CI)	P	AOR (95%CI)	P
Age (for add year)	1.0 (0.9-1.0)	0.9	0.9 (0.9-1.0)	0.04	0.9 (0.9-1.0)	0.1	0.9 (0.9-1.0)	0.01
Female (vs male)	1 (0.6-1.4)	0.9	0.8 (0.6-1.3)	0.5	0.9 (0.5-1.7)	0.8	1.5 (0.8-2.3)	0.2
Eterosex MSM TD ex-TD	1 1.2 (0.9-1.6) 0.7 (0.3-1.4)	 0.2 0.3	1 1.3 (0.9-1.7) 0.6 (0.4-1.1)	 0.07 0.7	1 1.2 (0.8-1.8) 0.4 (0.1-1.4)	 0.3 0.2	1 0.8 (0.5-1.5) 1.0 (0.3-3.1)	 0.6 0.9
Baseline CD4+ count (for add 100 cells/mmc)	1.0 (0.9-1.1)	0.5	0.8 (0.8-0.9)	0.001	2.3 (1.8-3.0)	<0.001	1.3 (1.2-1.5)	<0.0001
Baseline Log_{10} HIV-RNA copies/mL (for add log_{10})	0.8 (0.7-0.8)	0.0002	1.1 (1.0-1.3)	0.005	1.1 (0.9-1.3)	0.2	0.9 (0.7-1.1)	0.4
PI NNRTI INSTI	1 1.6 (1.2-2.1) 1.5 (1.2-2.1)	 0.0002 0.01	1 1.3 (1.0-1.5) 1 (0.7-1.5)	 0.03 0.8	1 1.1 (0.7-1.6) 1.3 (0.6-2.9)	 0.4 0.4	1 0.7 (0.5-1.2) 1.1 (0.5-2.4)	 0.2 0.7

[Probability of VS/IS by Cox analyses]

Conclusions: In this observational setting patients given first-line NNRTI or INI, compared to boosted-PI, displayed a faster virologic response. In NNRTI the earlier virologic suppression seems to drive a rapid immunological recovery, suggesting T-cells redistribution from lymphoid compartment. Conversely, adequate immune reconstitution is predicted by higher baseline CD4+, independently by cART regimen, confirming the role of an early cART initiation.

MOPEB0306

Can WHO guidelines use observational data? An empirical comparison of three methods for adjusting observational data and a meta-analysis of randomized controlled trials (RCT)

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Background: RCTs provide the strongest evidence for efficacy of an intervention. Observational studies can inform clinical guidelines when RCT data are lacking. Using data from IeDEA and a meta-analysis of RCTs, we compared how closely three different strategies for adjusting observational data approximated RCT results approximated RCT results.
Methods: We compared two initial regimens, TDF+XTC+EFV with all other two-drug NRTI combinations + EFV. We calculated RR and 95% CI for 96-week all-cause mortality and 48-week retention in care on initial regimen in ART-naïve HIV-infected adults ≥16 years old IeDEA participants in six regions using three separate adjustment techniques: (1) propensity scores for receiving TDF+XTC+EFV based on sex, age, country and baseline CD4 count with each individual matched to one individual receiving 2NRTIs + EFV with a similar propensity score (within 0.001); (2) a multivariable regression model controlling for the same variables as the propensity score; and (3) a meta-analysis by IeDEA region using a random effects model. We compared these estimates to those from a systematic review of seven RCTs.
Results: For the propensity score-matched analysis and the multivariable regression model we evaluated 19,470 IeDEA participants. For the regional meta-analysis, we evaluated 58,232 for retention and 47,985 for mortality. For mortality, all three methods overlapped with the 95% CI of the RCT meta-analysis; propensity scoring and multivariable regression estimates produced results closer to the RCT RR than the meta-analysis by region. For retention, all three estimates overlapped the 95% CI of the RCT meta-analysis; again propensity score matching and multivariable regression produced results closer to the RCT RR.

	96-week mortality RR (95% CI)	48-week retention on initial regimen RR (95% CI)
Propensity score matched	0.99 (0.89-1.10)	1.13 (1.12-1.15)
Multivariable regression model	1.01 (0.92-1.12)	1.12 (1.11-1.14)
Meta analysis by IeDEA region	0.84 (0.61-1.16)	1.09 (1.03-1.16)
Systematic review of RCTs	1.00 (0.14-7.07)	1.14 (1.01-1.30)

[Comparison of outcomes from IeDEA ob]

Conclusions: The effectiveness of initial ART regimen estimated from IeDEA data analysed using propensity scoring and multivariable regression closely approximates efficacy as measured by meta-analysis of RCTs, but not the regional meta-analysis. Future guidelines may consider using IeDEA and other large cohort data to explore questions of effectiveness of different ART regimens overall and in specific patient subsets. We recommend propensity score matching if numbers of subjects are sufficiently large.

MOPEB0307

Demographic correlates of survival in adult HIV-infected patients initiating first-line antiretroviral therapy in Nigeria: a 7-year prospective cohort study

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Background: USAID Nigeria through PEPFAR supports the provision of Antiretroviral Therapy (ART) to eligible HIV-infected persons in Nigeria since 2004. Universal access to ART has been the program focus. Complementary to this work is attention to survival outcomes of the ART program. This study assesses survival and associated demographic correlates among HIV-infected patients on ART in the six geographic regions of Nigeria.
Methods: A cohort of 10,278 adult patients who initiated first-line ART between January 2009 and December 2010 at 17 ART centers was followed-up for seven years. Follow-up time was calculated from the date of ART initiation to date of death or censoring. The censor date included date patient stopped ART or date of last visit. Data from patient medical records were extracted and mortality rate (per 1000 person-years [PY]) calculated. Kaplan-Meier method was used to estimate probability of survival and Cox regression applied to assess predictors of mortality by adjusted-age and sex; and lost to follow-up (LTF) accounted for using competing risk regression.
Results: The 69.1% of the cohort was female, and 3,243 were LTF. Median age at ART initiation was 33 years (IQR:28-40). Of the total 341 deaths, 60% were females, and 39% of deaths occurred within 12 months of commencing ART. The estimated mortality per 1000 PY at 12, 24, 36, 48, 60, 72 and 84 months was 2.83, 0.97, 1.18, 1.03, 0.70, 0.36 and 0.13 respectively. In Kaplan-Meier analysis, the one-year survival probability was 0.98 (95%CI, 0.96-1.00); seven-year survival probability was 0.94 (95%CI: 0.91-0.97). Males were associated with lower risk of death than females, which was similar for Cox regression (adjusted hazard ratio [AHR]: 0.72; 95%CI: 0.57-0.90,p< 0.004) and competing risk regression (ASHR: 0.87; 95%CI 0.81-0.94,p< 0.001). The hazard for age groups of 50-59 years (AHR: 1.25,p< 0.015), 60-69 years (1.69,p< 0.0001) and over 70 years (AHR: 2.11,p< 0.001) were associated with mortality.
Conclusions: In this study, mortality among HIV-infected patients on ART was highest within first year of commencement of ART and declined over time. Mortality was independently associated with female and older age groups. Findings can inform better design of differentiated care approaches for these patient populations.

MOPEB0308

Assessment of the impact of persistent low-level viremia on the subsequent risk of virologic failure in a cohort of people living with HIV after 7 years of observation in Mauritania

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Background: The prognosis of people living with HIV has improved consistently in developed countries since the advent of antiretroviral therapy (ART) in 1996.
The current goal of antiretroviral therapies (ART) is to maintain HIV virologic suppression below limits of assay detection. When viral loads remain in low-level viremia (LLV), especially between 50-200 copies/mL, the best management and clinical consequences remain unknown.
Our objective was to study the long-term impact of persistent LLV on subsequent risk of virologic failure (>1000 copies/ml) in a cohort of people living with HIV in Mauritania.
Methods: We used data from an opened cohort of 605 HIV infected patients of the Ambilatoire Treatment Centre (CTA) and oriented in Nouakchott virology laboratory of the National Institute for Research in Public Health (INRSP) for biological monitoring.
We compared the cumulative incidence of subsequent virologic failure (HIV RNA >1000 copies/mL) in patients under ART for at least 12 months, following 4 persistence status (< 50, 50-199, 200-499 and 500-999 copies/mL) for 6, 9 or 12 months using Kaplan-Meier analysis. The association between subsequent virologic failure and persistence status were estimated using Cox proportional hazards model.
Results: it was about 314 women (52 %) and of 291 men (48 %). The median age was of 36 years.
The cumulative incidence of virologic failure one year after having maintained a LLV for 6 months was 19 % (95%CI: 10.5- 30.6) for 50-199 copies/mL, 27.4%(95%CI: 14.9-33.6) for 200-499 copies/mL and 45.3%(95%CI:39.2-70.3) for 500-999 copies/mL, compared to 5.7% (95%CI:4.3-7.2) when remaining undetectable. Even after adjustment for potential confounders, persistent LLV of 50-199 copies/mL for 6 months doubled the risk of virologic failure (Hazard Ratio=2.22, 95%CI:1.60-3.09) when compared to undetectable viral loads for the same duration. Similar results have been found for persistent LLV of 9 or 12 months.
Conclusions: In this cohort, all sub-categories of persistent LLV between 50-999 copies/mL were associated with an increased risk of virologic failure. The results shed new light for the management of patients with LLV, especially with regards to LLV of 50-199 copies/mL.

MOPEB0309

Efficacy and cost-effectiveness of reducing drug burden in patients with cART ≥ 4 drugs regimen in the Infectious Disease Department of Pitié-Salpêtrère Hospital: the Ecovir study

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Background: Patients with experience of virological failure (VF) have accumulated drugs to achieve viral suppression (VS). New drugs offer opportunity to reduce drug burden in patients suppressed a multi-cART.
Methods: ECOVIR is a prospective, single center, intervention study aiming at evaluating whether drug reduction in virologically suppressed patients, could maintain VS over 48 weeks. Patients were included with a cART ≥ 4 drugs regimen (4-DR) for ≥24 weeks, a pVL ≤ 50copies/ml for ≥12 months. Intervention based on a multidisciplinary expert advice consisted in discontinuation of genotypically less susceptible drugs (based on the ART history, cumulative drug resistance (ANRS-algorithms), intolerance and drug-drug interactions) to reach a final optimized antiretroviral treatment (OAT) with ≤ 3-DR for a Genotypic Susceptibility Score ≥2. Primary end point was maintenance of viral suppression at W24. The study was designed to show an efficacy >80% assuming a success rate of >92% with a power of 90%.
Results: From 146 individuals with cART ≥4-DR, 89 were enrolled. OAT was proposed in 82 (92%) patients, 11 patients did not switched (physician decision 9/11, patient decision 2/11) leaving 71 (80%) patients switching to OAT. Baseline characteristics (median, IQR) were: age: 57(51-63) years, CD4: 584(416-758)/mm^3, duration of treatment: 20.8(18.2-23.0) years, viral suppression: 5.4(2.8-8.1) years. Cumulative resistance profile showed full/intermediate resistance: lamivudine/emtricitabine (92%), abacavir (76%/14%), tenofovir (41%/32%), efavirenz/nevirapine (72%), rilpivirine (54%), etravirine (20%/18%), atazanavir (72%/4%), darunavir-QD (42%/6%), raltegravir (13%), dolutegravir-QD (0%/7%). Intervention led to decrease the use of NRTI (from 93% to 21%, p<0.001), PI (from 75% to 52%, p<0.001) and maraviroc (from 32% to 17%, p<0.001). Use of INI raised from 66% to 76% (p=0.020). Overall, 24% of patients switched from ≥4-DR to a 3-DR and 76% to a 2-DR. Success rate of OAT at W24 was 93.9% (95%CI: 84.4-97.6, Kaplan-Meier estimate). Four patients experienced VF (at W4, 8, 12 and 24), all with VL <600cp/ml and no emergence of resistance mutations and were subsequently resuppressed. ART monthly cost decreased from 1745.00€ to 1120€ (-36%, p<0.001).
Conclusions: Even in multi-cART treated patients with high level resistance, individualized strategies can offer 2-DR options with a significant economic impact and ensure virological success.

MOPEB0310

Dual therapy with dolutegravir plus darunavir/cobicistat as salvage therapy regimen. Results at 24 weeks

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Background: HIV-1 infected patients with suspected or confirmed resistance to one or more families of antiretroviral drugs receive complex and expensive salvage regimens. Dual therapy with dolutegravir (DTG) plus darunavir/cobicistat (DRV/c) is especially attractive as a salvage regimen due to the absence of analogues, high genetic barrier and simplicity. The aim of this study was to evaluate the efficacy and safety of this dual therapy in pretreated HIV patients with virological failure (VF) or suppressed under other antiretroviral salvage therapy.
Methods: Retrospective study of HIV-1 infected patients on treatment with DTG-DRV/c for at least 24 weeks. We describe baseline characteristics, treatment history, and reasons for the change. Efficacy, tolerability and durability of this therapy were analyzed, as well as economic impact.
Results: We analyzed 44 patients (72.2% males), mean age 50.73 years, with a mean length of HIV infection of 18.6 years. Most of them had a nadir CD4 cell count below 200 cells/mm3 and 24 patients (54.5%) had experienced a CDC Class C event. All patients had received NRTI, 35 (79.5%) NNRTI, 41 (93.2%) protease inhibitors and 25 (56.8%) ISTI, and 18 patients had confirmed resistance to one or more families. Thirty-one patients (70.4%) received salvage regimens with more than 4 drugs or 2 families. The reasons for switching were: empiric salvage regimen in 16 patients with VF or low-grade viremia, and simplification of salvage regimen in 28 virologically suppressed patients. At 24 weeks, out of 28 patients who switched for simplification, 26 remained with undetectable viremia. Patients who started DTG-DRV/C as a salvage regimen (n=16) were all undetectable or showed an appropriate decline at 24 weeks. Mean duration of therapy is currently 13.8 months. No adverse effects have been observed. Regimen was only changed in two patients, due to potential interactions. Cost savings were a mean of 1687 euros/patient per year. Considering only simplification cases, cost savings rise to 2468 euros.
Conclusions: Dual therapy with DTG plus DRV/c seems efficacious and well-tolerated as an empiric salvage regimen or simplification of more complex therapies, sparing NRTIs and allowing a substantial reduction of the number of pills per day and cost savings.

MOPEB0311

Switch to 3TC+Darunavir/ritonavir (DRV/r) dual therapy. Subgroup analysis of DUAL clinical trial (GESIDA-8104-RIS-EST45)

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Background: Dual Therapy (DT) with 3TC+DRV/r could be as efficacious as triple therapy based on DRV/r to maintain viral suppression in selected patients.
Methods: DUAL is a multicenter, open label, randomized, 48 weeks clinical trial comparing the efficacy and safety of switching to 3TC+DRV/r in patients with HIV-RNA < 50 c/ml for > 6 months while on TDF/FTC (or ABC/3TC)+DRV/r. A subgroup analysis is presented. Multivariate linear or logistic regression were used to calculate p-values for interactions.
Results: 249 patients (75% TDF/FTC, 25% ABC/3TC) were randomized to switch to DT (n=126) or continue TT (n=123). In the primary analysis (snapshot, ITT-exposed, 48 weeks) DT was non-inferior to continuing triple therapy (TT): 89% (112/126), vs. 93% (114/123), difference -3.8; 95%CI -11% to 3.4%. There were no significant differences in efficacy when different subgroups were analyzed: time with viral load < 50 c/ml > or < 12 months; Age > or < 50 ys; CD4+ nadir > or < 200; baseline CD4+ > or < 500; HCV seropositivity; HCV replication; and baseline nucleosides (TDF/FTC or ABC/3TC).
In the whole population, switching to DT was not associated with significant changes in e-GFR and TC/HDL ratio relative to maintaining TT. At baseline, patients treated with TDF/FTC had significantly lower total-cholesterol (tC): 178 vs 202 mg/dl, LDL-cholesterol: 109 vs 122 mg/dl, triglycerides (Tg): 127 vs 146 mg/dl, but similar tC/HDL ratio: 4 vs. 4. In those patients switching from TDF/FTC, there was a non-significant trend towards higher increases in tC, LDL and Tg, without changes in Tc/HDL ratio. Changes in the estimated glomerular filtrate, or the proportion of patients with proteinuria, or pathologic uric acid or phosphate excretion between arms were not different when patients with TDF/FTC or ABC/3TC at baseline were compared.
Conclusions: Switching to 3TC+DRV/r dual therapy in patients with suppressed viral load for > 6 months maintains similar efficacy to triple therapy irrespective of the length of undetectability, age, nadir or baseline CD4+ count, HCV coinfection or baseline nucleosides. No differences were seen in changes of lipids or renal function between patients switching from TDF/FTC or ABC/3TC.

MOPEB0312

Viral and immune effects of a dose-reduction strategy in suppressed HIV+ patients

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Background: Dose-reduction strategies in HIV patients with long-term virological suppression are of interest to avoid toxicity, to improve quality-of-life and to reduce cost. We aimed to comprehensively compare virological and immunological impact at 24 weeks of a reduced dose schedule (3-days a week; Mo/We/Fr) (n=30) relative to daily antiretroviral therapy (ART) (n=31) in HIV-1-infected patients. All of them treated with the fixed-dose combination efavirenz/emtricitabine/tenofovir with suppressed plasma viral load (VL) for more than 2 years.
Methods: VL (ultrasensitive RT-PCR), HIV-1 reservoir dynamics (measured as Total and Integrated DNA in CD4 T cells) and immunological profiles of activation (CD38 and HLA-DR), senescence (CD57 and CD28), apoptosis (annexin V), and the proportions of naive, Tscm and effector memory (CCR7, CD45RA, CD95 and CD27) T cells (flow cytometry) were measured at baseline, at 24 weeks, and in selected patients also at 48 weeks. Changes at 24 and 48 weeks and correlations between virological and immunological changes were assessed.
Results: From the immunological point of view no differences between arms were observed on activation, senescence or apoptosis of both CD4 and CD8 T cells during the 24-week follow-up. Only proportion of naïve CD4 T cells showed a significant decrease in the 3-days group (mean (SD); 24.6 (13.7) to 20.5 (12.9);**p=.002). VL levels and HIV-reservoir did not change in both arms during the 24-weeks follow-up. In-depth review of clinical data revealed a higher VL zenith (5.5 vs 5.0 log10 copies/ml;**p=.0048) and a tendency toward lower CD4 nadir (mean (SD); 203 (134) vs 246 (90) cells/µl) in the 3-days ART relative to daily ART. Correlations between virological and immunological parameters showed that CD4 Tscm levels in the 3-days group correlated with basal integrated DNA and in an additional sample after 48 weeks. Nevertheless, no differences were detected in the daily ART group.
Conclusions: A reduced-dose strategy with the fixed-dose combination efavirenz/emtricitabine/tenofovir did not significantly affect immunological or virological parameters. Only small differences, probably related with a bias in basal characteristics between groups, were observed. These data are reassuring and support the need of future clinical trials with longer follow-up.

MOPEB0313

Efficacy and safety of darunavir dose reduction from 800 to 400 mg daily with ritonavir and TDF/FTC or ABC/3TC in virologically suppressed HIV-1-infected adults: an open-label study (ANRS-165 Darulight)

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Background: Protease inhibitors are key antiretroviral drugs but their high price limit their availability. Reducing their dose while maintaining efficacy could yield significant cost savings and improve access. The optimum dose of darunavir (DRV) in patients without resistance-associated mutations (RAMs) has not been established.

Methods: HIV-1 infected adults with a plasma HIV RNA level < 50 cp/ml for at least 12 months, receiving a combination of 2 NRTIs + DRV 800 mg/ritonavir (r) 100 mg once daily for at least six months, with no prior virologic failure (VF) and a pre-treatment genotypic resistance test with no DRV or NRTI RAMs, were enrolled in this multicenter phase II single-arm open-label study and switched to once daily DRV 400/r with the same NRTIs. The primary study endpoint was the proportion of patients with a plasma HIV RNA level <50 cp/ml at 48 weeks without any change in the study regimen, in a modified intent-to-treat analysis.
Results: From March to October 2015, 113 patients (pts) were screened, 100 were enrolled and started the reduced DRV dosing regimen. At baseline, most patients were male (78%), with a median age of 44.3 years, a median duration of antiretroviral therapy of 43.6 months and a median CD4 T-cell count of 633 cells/mm^3. 76% received TDF/FTC and 24% ABC/3TC. Three pts with major violations of entry criteria were excluded from the analysis.
During follow-up, 1 pt withdrew consent (not considered a failure), 3 pts discontinued the study regimen, and 6 experienced VF (confirmed HIV RNA level > 50 cp/ml). The overall rate of virologic success at week 48 was 90.6% (87/96; 95% CI: 82.9-95.6). No RAM was detected in 3 amplifiable genotypes. Sixty-four pts (66%) presented a total of 213 adverse events, with only 14 (6.5%) grade 3 and 4 AEs, and a single AE (grade 2 osteoporosis) deemed to be drug-related.
Conclusions: In HIV-infected patients virologically suppressed with DRV/r (800mg/100mg) and 2 NRTIs, a reduction of the DRV dose to 400 mg/d maintained virologic efficacy. This reduced dose now deserves to be assessed in a randomized trial.

MOPEB0314

Raltegravir/etravirine as maintenance strategy in HIV-1-infected virologically suppressed individuals aged over 45 years on prior boosted protease inhibitor containing regimen: results at W48 of the ANRS163-ETRAL study

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Background: ART individualization with reduction of ARV drugs to minimize toxicity is a clinical challenge in aging HIV population. Dual therapy combining integrase (INI) and non-nucleoside inhibitors (NNRTI) is an interesting approach in long-term experienced patients.
Methods: The ANRS163-ETRAL trial (NCT02212379) is a 96-week multicentre, single-arm study designed to evaluate the capacity of the dual raltegravir(RAL)/etravirine(ETR) regimen to maintain viral suppression in patients over 45 years, on a stable boosted PI-containing regimen, RAL and ETR naïve, with HIV fully susceptible to these 2 drugs. All enrolled participants switched to RAL/ETR (400/200 mg) BID. The primary endpoint was the proportion of participants maintaining plasma viral load (VL) ≤50 copies/mL up to week 48, estimated with the Kaplan-Meier method.
The study was designed to show an efficacy >90%, assuming a success rate >95%, with a power of 80% and a 5% type-one error.
Results: Overall, 170 participants were enrolled out of 219 screened in 20 sites; 5 who never took RAL/ETR were not analyzed. Baseline characteristics for the 165 analyzed participants were (median values; IQR): male (71%), age: 52 years (48-58), duration of ART: 16.8 years (11.1-19.3), viral suppression: 6.9 years (3.4-9.3), CD4: 700/mm^3 (525-904), CD4 nadir: 209/mm^3 (93-286), ART consisted in PI/r monotherapy (21%), NNRTI+PI/r (7%), 2NRTIs+PI/r (65%) as QD (73%) or BID (27%) regimen and 26.7% were on lipid lowering agents.
At W48, by ITT analysis, the rate of maintaining viral suppression was 99% (95%CI: 96-100). One patient, with previous K103N mutation, experienced virological failure at W24 (VL: 11,607 and 18,472 cp/mL) with additional NNRTI-resistance (K101E+Y181C+G190A) but no resistance to RAL, and re-suppressed on resumption of baseline ART. Seven participants discontinued the RAL/ETR regimen for AE, leading to a strategy success rate of 95% (95%CI: 91-98) and one participant discontinued with no AE. 18 SAE occurred in 17 participants of whom 4 were study drug-related. All lipid fractions and eGFR significantly improved at W48 (p<0.02).
Conclusions: RAL/ETR showed a potent and robust antiretroviral activity in virologically suppressed ageing patients, with an excellent safety profile. Longer follow-up including bone, fat tissue, and inflammation markers evaluations is on going.

MOPEB0315

HIV-1 DNA ultra-deep sequencing analysis at initiation of the dual-therapy DTG+3TC in the maintenance DOLULAM pilot study

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Background: DOLULAM study assessed a dual-therapy, dolutegravir+lamivudine, to maintain virological suppression in treatment-experienced patients. In this substudy, we assessed the prevalence of M184I/V mutations at time of dual-therapy initiation using historical DNA/RNA genotypes and baseline DNA genotype obtained by next-generation sequencing (NGS).
Methods: HIV-1 reverse transcriptase (RT) sequences were obtained from DNA and/or historical RNA with Sanger technology by using ANRS procedures. HIV-1 DNA RT and integrase NGS was performed using Illumina® technology (cut-off=1%). Resistance mutations were identified using the ANRS resistance algorithm.
Results: Among the 27 patients enrolled in the DOLULAM study, HIV-1 DNA sample was available at initiation of the dual-therapy in 25, and NGS was successful in 22 and 19 for RT and integrase regions, respectively. Historical HIV-1 DNA and RNA Sanger sequences were obtained in a median time before dual-therapy initiation of 2.8 years (IQR=1.0-4.0) and 9.8 years (IQR=6.6-11.0), respectively; and were available in 14 and 18 patients, respectively. Baseline DNA NGS genotypes showed that 10 (45%) and 5 (26%) patients harbored minority resistant variants (MRV) in RT and integrase, respectively.
Combining all available genotypes data, a M184I/V was observed in 16/27 patients (59%). Most M184V were detected in historical RNA genotypes (n=8/10), whereas M184I were exclusively detected in DNA genotypes (n=10, including 7 as MRV). Ten patients displayed defective viral genomes in cellular reservoirs with stop codons, all including M184I, an APOBEC G-to-A induced mutation. M184V was observed in baseline DNA NGS in 4 patients, including one as MRV.
No difference was observed in the prevalence of integrase MRV between patients pre-exposed to RAL and INI-naïve patients (p=0.62).
No impact of M184I/V on the virological outcome could be assessed, since no virological failure (2 consecutive viral load >50 c/mL) occurred during the first two years of the dual-therapy.
Conclusions: These first NGS data on HIV-1 DNA at initiation of a switch study showed: (i) a high proportion of patients harboring defective viral genomes, whose mutation M184I is a marker, (ii) a low number of patients in whom M184V remains detectable in PBMC. These elements most likely contribute to the limited impact of the M184I/V on maintenance of virological suppression.

MOPEB0316

High virological suppression rates regardless to the genotypic susceptibility score after switching to a dolutegravir-based regimen: W48 results in a prospective cohor

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Background: To assess, in virologically-suppressed patients, based on the genotypic susceptibility score (GSS), the virological response after switching ARV-treatment to a dolutegravir (DTG)-based regimen.

Methods: A prospective observational single-center cohort enrolling all patients with a plasma viral load (pVL)< 50 c/mL initiating a DTG-based regimen between September and December 2015. pVL were performed using CobasTaqman HIV-1 V2.0 assay. GSS of the ARV regimen was calculated using the ANRS algorithm including DTG, translating the interpretations „susceptible", „possible resistance" and „resistance" into scores of 1, 0.5 and 0, respectively.
Results: Among 254 patients who switched to a DTG-based regimen, 212 (83%) had historical available genotypes. Among them, 196 (92%) have a one-year follow-up, and taking into account all historical genotypes, 27 (13%), 75 (35%) and 110 (52%) had a total GSS equal to 1 or 1.5 (group 1), 2 or 2.5 (group 2) and 3 (group 3), respectively. Median time since the last genotype was 9 (IQR=4-11), 8 (IQR=4-12) and 5 (IQR=2-8) years in groups 1, 2 and 3, respectively. History of infection differed between the groups regarding duration of prior cART or CD4 cell count nadir. Twenty patients (9.4%) discontinued DTG-based regimen in relation with occurrence of neuro-psychological adverse events (n=7), pregnancy (n=3), renal toxicity (n=2), headaches (n=1), cutaneous adverse events (n=1), virological failure (VF) (n=1), patients´ decision (n=2) and others (n=3). No VF occurred in patients of groups 1 and 2. In group 3, one patient out of 110 (0.9%) experienced a VF. It was a highly pre-treated patient who had a previous history of VF under RAL without selection of integrase mutations. Overall, 8.0% (17/212) of the patients experienced a viral blip with no difference between the three GSS groups.
Conclusions: In this observational cohort, we showed a high level of virological suppression maintenance in the first year following the switch to DTG-based regimen, regardless to the baseline GSS. These data suggesting that DTG remains potentially able to maintain viral suppression when combined with fully or incompletely active drugs in these long-term virologically-suppressed patients need to be confirmed in clinical trials.

MOPEB0317

HIV-1-infected patients under successful less-drug regimens have similar genital shedding and residual viremia than those under triple therapy

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Background: There is a growing interest for less-drug regimens (LDR) to decrease side effects, toxicity and interactions of antiretrovirals. Although avoiding sexual transmission is a crucial issue in this setting only few small studies have evaluated the impact of LDR (with protease inhibitor monotherapy only) on genital shedding.
Methods: HIV-1-infected adults with plasma HIV-RNA (pVL) < 50 copies/mL receiving one among four evaluated LDR (cases) or a classic triple therapy (controls) were prospectively enrolled. Concomitant genital (i.e. sperm or cervico-vaginal lavage) and blood samples were taken to assess HIV-RNA and HIV-DNA levels using ultrasensitive assays adapted from Roche and Biocentric kits. Residual concentrations (C_{24h}) were measured in both compartments by using liquid chromatography-tandem mass spectrometry. The primary objective was to determine the proportion of patients with undetectable (versus detectable or quantifiable) HIV-RNA and/or HIV-DNA in genital secretions according to the strategies. We also looked for residual viremia.
Results: 56 patients (30 males; 26 females) were included and treated as follow: dolutegravir (DTG) monotherapy, n=14; tenofovir + emtricitabine, n=10; DTG + unboosted atazanavir (uATV), n=11; uATV + two nucleoside inhibitors, n=11; triple-therapy, n=10.
Overall, cases and controls shared similar characteristics (median): age (47), sex-ratio, CDC staging, duration with pVL < 50 copies/mL (5.8 years), duration with current strategy (0.9 year), current CD4 (701/µL) and nadir (294/µL), highest pVL, HIV-DNA in PBMC.
The LDR group had similar proportions of patients with undetectable genital HIV-RNA (88%), HIV-DNA (76%), both items (67%) and no residual viremia (34%) than the triple-therapy group (90%, 80%, 80% and 50% respectively; all p-values >0.4).
In the LDR group, no factor was predictive to find HIV-RNA and/or HIV-DNA in the genital tract whereas, in a logistic-regression analysis, a high HIV-DNA in PBMC was positively correlated (per increased quartile) with the frequency of residual viremia (OR = 2.6; 95%CI: 1.2-5.6, p=0.01). Neither the number of drugs nor C_{24h} were predictive of viral control in both compartments.
Conclusions: In our study, patients under various LDR with sustained viral suppression had similar genital shedding and residual viremia than those under a classic triple-therapy. These conclusions have to be validated in larger groups.

MOPEB0318

Analysis and impact of ultra sensitive viral load on virological failure in 3 protease inhibitor monotherapy trials as simplification regimen (ANRS and IMEA Studies)

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Background: Protease inhibitor monotherapy is a potential approach to antiretroviral treatment simplification. Using 3 randomized studies: Kalesolo (LPV/r 200/50mg bid versus 1NRTI/3TC/PI or NNRTI), Dream (LPV/r 200/50mg bid versus EFV/FTC/TDF) and Monoi (DRV/r 600/100mg bid versus DRV/r + 2NRTIs), we performed a pooled-analysis. Our objective was to determine in PI monotherapy and standard tritherapy : 1) distribution of ultrasensitive viral load (USVL) at week 96 (W96); 2) virological and clinical characteristics associated with virological failure (VF) at W96 and 3) impact of baseline USVL on VF.
Methods: VF was defined as 2 consecutive measurements of HIV-1 RNA viral load>50 copies/mL and analysed in Intention-To-Treat. Patient's characteristics were defined as median and interquartile range for continuous variables and as percentages for categorical variables. A logistic model was used to investigate which variables were predictive of a VF. Fisher test was used to investigate differences in USVL at W96.
Results: Among 637 patients, 71% were male and the median age was 44.6 years (IQR 40.3-52.3), treatment duration was 4.1 years, (IQR 2.4-7.8), baseline CD4/CD8 ratio was 0.78 (IQR 0.56-1.10), baseline CD4 was 564/mm3 (IQR 422-707) and 60% presented a baseline USVL< 1 copy/mL. At W96, the proportion of USVL< 1 copy/mL was significantly different between PI monotherapy and standard tritherapy in pooled-analysis (65% versus 74%; p=0.04) with significant difference in Dream and Kalesolo but no difference in Monoi. Overall, baseline USVL< 1copy/mL and tritherapy regimen were associated with USVL< 1 copy/mL at W96 (p=0.0003 and 0.05). In PI monotherapy receiving DRV/r rather LPV/r was associated with USVL< 1 copy/mL at W96 (p=0.002). Factors associated to VF at W96 were baseline CD4/CD8 ratio< 0.6 (p<0.0001), baseline USVL>1 copy/mL (p=0.0004) and to receive PI monotherapy rather than tritherapy (p=0.04).
Conclusions: Pooled-analysis of 3 PI monotherapy trials showed better efficacy of tritherapy in terms of USVL at W96. Furthermore regarding USVL at W96, to receive LPV/r seems to be more deleterious than DRV/r. To be on PI monotherapy and to have a lower baseline CD4/CD8 ratio were associated with VF at W96. Baseline USVL impacts VF at W96 in PI monotherapy and tritherapy.

MOPEB0319

TDF-associated tubular dysfunction might not be reversible after discontinuation

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Background: Use of TDF will phase out because of the advent of TAF in resource-rich settings. However, whether kidney tubular dysfunction (KTD) due to TDF is reversible after discontinuation of TDF is unknown.
Methods: This cross-sectional study enrolled 943 HIV-infected patients to investigate the association between KTD and duration of TDF exposure, regardless of current TDF use. Tubular function was comprehensively examined and KTD was predefined as the presence of at least two abnormalities in the following five biomarkers: urine β2-microglobulinuria, high urinary N-acetyl-beta-glucosaminidase, fractional excretion of phosphate, fractional excretion of uric acid, and non-diabetic glycosuria. Logistic regression model was used to examine the association between KTD and duration of TDF exposure.
Results: 94% of study patients were male (median age 45, median eGFR 75 ml/min/1.73m^2). 99% were on antiretroviral therapy (median CD4 575 cells/mm^3). 64% had history of TDF use and 39% was currently using TDF. 29% used TDF for >5 years. 114 (12%) patients met definition of KTD. In adjusted multivariable model, compared to patient without history of TDF exposure, patients with >5 years of TDF exposure and current TDF use (OR4.3, 95%CI2.39-7.65), >5 years of TDF

exposure and no current TDF use (OR2.4, 95%CI1.08-5.26), <5 years of TDF exposure and current TDF use (OR2.5, 95%CI1.24-4.86), <5 years of TDF exposure and no current TDF use (OR2.4, 95%CI1.23-4.66) were all significantly associated with KTD (Table).
Furthermore, in another model, longer exposure of TDF was significantly associated with KTD (per one year of exposure, OR1.1, 95%CI1.04-1.19) whereas in the same model, current TDF use was not associated with KTD.

	Adjusted OR	95% CI	*P-value*
Without history of TDF exposure	ref	ref	ref
>5 years of TDF exposure and current TDF use	4.28	2.39-7.65	<0.001
>5 years of TDF exposure and no current TDF use	2.38	1.08-5.25	0.010
<5 years of TDF exposure and current TDF use	2.46	1.24-4.86	0.031
<5 years of TDF exposure and no current TDF use	2.39	1.23-4.66	0.010
Age (per one year increment)	1.05	1.03-1.07	<0.001
Body weight (per one kg increment)	0.97	0.95-0.99	0.001
CD4 cells (per one/mm^3 increment)	1.00	1.00-1.00	0.038
eGFR (per one ml/min/1.73m^2 increment)	0.99	0.97-1.00	0.094
Hypertension	1.44	0.89-2.35	0.140

OR: odds ratio CI: confidence interval eGFR: estimated glomerular filtration rate

[Table. The association between kidney tubular dysfunction and duration of TDF exposure: multivariate analysis]

Conclusions: Regardless of current TDF use, TDF exposure is associated with KTD, and for patients with longer exposure of TDF, the association is more robust. KTD may be irreversible for patients with history of TDF exposure even after discontinuation of TDF.

MOPEB0320

Successful switch to once-daily single-tablet regimen (STR) containing elvitegravir (EVG) or dolutegravir (DTG) in virologically suppressed HIV-1-infected patients despite archived resistant quasispecies

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Background: The main objective of this study was to assess switches with integrase strand-transfer inhibitor (INSTI)-based regimen STR therapy in ARV-treated patients with undetectable HIV-1 viral load (VL).
Methods: A retrospective analysis was conducted on 75 HIV-1 infected, treatment-experienced adults from 2 French centers (Rennes, Saint-Malo). The inclusion criteria were:
i) treatment-experienced,
ii) VL≤ 50 copies/mL at baseline and
iii) switch to an INSTI-based STR.
Patients were divided into two groups: previous genotypic(s) test(s) performed on plasma HIV RNA and/or cellular HIV DNA (group 1; n=51, 68%) and no historical genotypic test available (group 2; n=24, 32%). Following data were collected: demographic, treatment prior to STR, reasons for STR switch and immuno-virological data. Virological failure (VF) was defined by 2 consecutive VL >50 copies/mL. Antiretroviral susceptibility and genotypic susceptibility scores (GSS) were determined according to the ANRS v26 algorithm.
Results: Seventy-five patients were included, mostly men (n=47, 63%), median age of 52 years. EVG or DTG-based STR were prescribed in 38 and 37 patients, respectively. Patients were heavily pre-treated for a median duration of 18 years and virological success since a median of 7 years. Main reasons for switch were simplification (n= 47, 63%) and tolerability (n=26, 35%). Patients were followed-up for a median period of 13 months [range 1-84] after switching. Median CD4 count remained stable (701 vs 681 cells/mm^3) at month 12. Seven patients discontinued the new regimen due to side effects (EVG; n=3, DTG; n=2), death (hepatocellular carcinoma; DTG) and VF (EVG), one patient each.
Twenty-seven out of 50 patients (54%) in group 1 displayed virus with ≥1 drug resistance substitution on reverse-transcriptase gene (M184V; n=22, K65R; n=4, L74I/V; n=5, ≥2 TAMs; n=13) and 3 out of 14 on integrase gene (T97A).
All patients, except one, remained virologically suppressed. VF was observed at month 28 in one patient (group 1), with a baseline GSS =2 and N155H substitution selected at VF.
Conclusions: This study reflecting routine clinical practice confirms the efficacy of INSTI-based STR in virologically suppressed, ARV-experienced patients, with a low prevalence of viral failure despite archived resistant quasispecies.

MOPEB0321

No increase in HIV-1 reservoir and inflammation markers in four days a week short-cycles maintenance therapy: the ANRS162-4D trial

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Background: After the randomized BREATHER study demonstrating efficacy of a 5 days-a-week maintenance therapy in children/young adults, the ANRS-162-4D trial has demonstrated the feasibility of a maintenance short-cycles 4 days-on/3 days-off regimen in adults with controlled HIV infection under a PI/r or NNRTI-based antiretroviral therapy (ART). The aim of the present analysis is to assess the impact of this strategy on inflammation markers and the size of the viral reservoir.
Methods: Patients included in the ANRS162-4D trial were HIV-1 infected adults with controlled viral load (VL< 50 c/ml) for more than 1 year under ART with 2 nucleoside analogs and either a PI/r or a NNRTI. Maintenance therapy used the same regimen, taken 4 consecutive days of each week, evaluation was conducted up to 48 weeks. Success was defined as VL< 50c/ml at each visit until W48. Viral reservoir measured by total HIV-1 DNA in PBMCs, and plasma inflammation markers (CRPus, IL-6, CD14s, IP-10, MIG-1) were assessed at D0, W24, and W48. Plasma ARV drug concentrations (Ctrough) were measured at all time-points to assess adherence to the study strategy.
Results: 100 participants were enrolled in the study, aged 47 years [IQR:40-53], receiving ARV therapy since 5.1[IQR:2.9-9.3] years with VL< 50 since 4.1[IQR:2.3-6.4] years, and median CD4 count =665/mm^3 [IQR:543-829]. Current regimen included tenofovir-DF+FTC (n=89) or abacavir+3TC/x (n=11), combined with a PI/r (n=29) or a NNRTI (n=71). Overall success rate was 96% [Kaplan-Meier 95%CI: 90-98]. Residual ART concentrations showed a good adherence (>90%) to the study strategy. No significant difference was shown for total HIV-1 DNA, stable between D0 (2.4±0.7 $\log_{10}$.copies/10^{6}PBMCs), W24 (2.4±0.7 $\log_{10}$.copies/10^{6}PBMCs) and W48 (2.4±0.7 $\log_{10}$.copies/10^{6}PBMCs) (p=0.765), and for inflammation markers with stable values for CRPus, IL-6, MIG-1, IP-10. A decrease in CD14s was observed between D0 (1019±749ng/mL) and W48 (820±393ng/mL)(p=0.004).
Conclusions: Over 48 weeks, maintenance ARV therapy with 4 days a-week regimen was effective in these adults with suppressed VL under ART, resulting in a success rate of 96%. The intermittent short-cycles therapy was associated neither with increase in viral reservoir nor with increase in inflammatory markers.

MOPEB0322

Dual regimen with dolutegravir and lamivudine maintains virologic suppression even in heavily treatment experienced HIV-infected patients: 96 weeks results from maintenance DOLULAM study

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Background: Novel antiretroviral combinations may be needed for HIV-infected patients with long term toxicity. We aimed to assess the efficacy and safety of dual therapy with dolutegravir (DTG) and lamivudine (3TC).
Methods: DOLULAM is a prospective cohort study. Patients on a stable antiretroviral regimen with HIV RNA <50 copies/ml for >12 months, with problems of toler-

ability and without resistance to integrase inhibitors, were given the opportunity to switch to dolutegravir 50 mg plus lamivudine 300 mg once daily.
Visits and laboratory tests including plasma HIV-1 RNA levels (VL)(Roche Cobas Ampliprep / Taqman HIV-1 v.2.0.; limit of detection, 20 copies/mL) were scheduled at baseline (BL), W6, W12, W24, W36, W48, then every 12-24 weeks.
Results: We enrolled 27 patients (20 men, 7 women, median age: 59 years, plasma HIV-1 RNA zenith > 100 000 copies/ml: 56%, median nadir CD4:167/mm^3, median baseline CD4: 601/mm^3).
Before switching to dual therapy, patients had been taking antiretroviral therapy for a median of 215 (range 22-329) months and the last HAART (TDF: 48%, PI/r: 81%, RAL: 26%) for a median of 51 (13-108) months. Ten (37%) patients had a history of genotypic test prior swich with M184V mutation.
After a median of follow up of 96 weeks (2362 patients-week) no patient experienced virologic failure (defined as confirmed VL > 50 copies/ml) or severe clinical or laboratory adverse event, or was lost to follow-up. Two patients experienced one blip (52 and 66 copies/mL at week 12 and 36). Three patients wanted to discontinue DTG+3TC combination (2 at week 16 and week 24 for fatigue, one at week 18 after blip at W12 visit).
There was a small decrease from baseline in estimated glomerular filtration rate (eGFR) at first on-treatment assessment (median BL-W6 evolution: - 9 mL/min/1.73m2) but remained stable over the 96-week follow-up (median BL-W96 evolution: -6).
Conclusions: These results suggest that, in this population of heavily treatment-experienced patients without or with history of M184V mutation, dolutegravir plus lamivudine dual therapy is an attractive strategy of maintenance.

MOPEB0323

CD4/CD8 ratio in patients who switch cART therapy: triple drug regimen could be better than mono/dual?

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Background: A low CD4/CD8 ratio has been associated to AIDS and non-AIDS associated events. Long-term side effects have led to non-conventional NRTI-sparing regimens. Aim of the study was to evaluate if the switch to mono/dual therapy could determine a change in CD4/CD8 ratio.
Methods: naïve patients from Icona cohort who started a triple cART regimen and switched to another triple regimen or to dual- or mono-therapy and maintained it till 12 months during virological suppression. End-points: patients who at 12 months increased 1) CD4/CD8 ratio of at least 10% and 2) CD8 of at least 25% respect to baseline value. Logistic regressions were used to evaluate associated factors.

a)	AOR	95% CI		P	b)	AOR	95% CI		P
Male gender vs female	0.67	0.44	1.02	0.061	Male gender vs female	1.50	0.82	2.44	0.104
Age (10 yrs older)	0.99	0.98	1.01	0.348	Age (10 yrs older)	0.99	0.97	1.01	0.268
Mode of HIV transmission					Mode of HIV transmission				
heterosexual	1.00				heterosexual	1.00			
IVDU	1.11	0.57	2.15	0.753	IVDU	0.80	0.37	1.74	0.575
homosexual	0.88	0.60	1.30	0.516	homosexual	0.74	0.46	1.19	0.210
Other/unknown	0.87	0.50	1.90	0.921	Other/unknown	0.70	0.30	1.68	0.417
migrants vs natives	1.16	0.68	1.98	0.587	migrants vs natives	0.72	0.38	1.37	0.321
previous aids event	0.63	0.39	1.03	0.064	previous aids event	1.75	1.03	3.01	0.043
years of infection (1 year more)	0.97	0.94	1.00	0.089	years of infection (1 year more)	1.01	0.98	1.06	0.439
HCV co-infection					HCV co-infection				
no	1.00				no	1.00			
yes	1.19	0.68	2.14	0.563	yes	1.05	0.53	2.07	0.887
not known	2.31	0.88	5.96	0.064	not known	0.67	0.25	1.86	0.465
CD4 pre cART, cell/mm3					CD4 pre cART, cell/mm3				
<200	1.00				<200	1.00			
201-350	0.59	0.38	0.93	0.023	201-350	1.98	1.15	3.40	0.013
351-500	1.04	0.62	1.74	0.884	351-500	2.35	1.26	4.38	0.007
500+	1.36	0.83	2.23	0.191	500+	1.83	0.78	3.90	0.184
missing	1.23	0.40	3.77	0.721	missing	1.39	0.48	5.30	0.448
HIV-RNA pre cART, cp/mL					HIV-RNA pre cART, cp/mL				
<20.000	1.00				<20.000	1.00			
20.000-100.000	1.02	0.70	1.48	0.937	20.000-100.000	0.67	0.42	1.07	0.091
100.000-250.000	1.13	0.71	1.78	0.607	100.000-250.000	0.90	0.53	1.55	0.712
250.000+	1.04	0.63	1.71	0.883	250.000+	1.04	0.58	1.87	0.896
missing	0.74	0.33	1.65	0.462	missing	1.62	0.67	3.94	0.288
CD4 at switch, cell/mm3					CD4 at switch, cell/mm3				
<350					<350	1.00			
350-500	0.60	0.36	0.99	0.045	350-500	0.57	0.34	0.96	0.035
500+	0.66	0.39	1.11	0.116	500+	0.32	0.18	0.58	0.000
years of viral suppression	0.99	0.98	1.00	0.009	years of viral suppression	0.99	0.91	1.07	0.749
CD4/CD8 ratio at switch	0.22	0.14	0.36	<0.001	CD8 at switch (100 cells increase)	0.83	0.80	1.07	<0.001
mono/dual vs triple	0.39	0.24	0.61	<0.001	mono/dual vs triple	2.06	1.23	3.46	0.006

[Table. Multivariable logistic regression models to estimate the probability of: a) CD4/CD8 and b) CD8 increase respect to baseline value.]

Results: 905 patients included, 104 switched to mono/dual regimen (51 monoPI, 53 dual), while 801 switched to triple regimen. 76.1% males, mean age: 43 years, 9.9% migrants, 17.2% HCV positive, median time of viral suppression of 20 months (range 10-37). Patients who switched to mono/double therapy were more frequently MSM, HCV-Ab negative. At switch, there were no difference concerning duration of viral suppression and CD4, while CD4/CD8 ratio was lower in those who switched to triple therapy (0.65 vs 0.77; p< 0.013). At 12 months patients on triple regimen showed a median ratio increase +0.10(+0.01;+0.20) vs +0.05(-0.03;+0.14) (p=0.007) in triple and mono/dual respectively.
The difference was not due to CD4 increase: median increase 63 vs 99 cells/uL at 12 months (p=0.45), but to CD8 change. Indeed, at 12 months the median change was -20 cells/uL (-172;+127) in the triple and +28(-98;+166) (p=0.018) in double/mono. At multivariable (tab) pts on mono/dual therapy were independently associated with reduced probability of ratio gain and higher probability of CD8 increase at 12 months.
Conclusions: Patients who switch to a dual/mono therapy, despite viral suppression, could not completely benefit of immune-reconstitution as those who remained on a triple regimen.

MOPEB0324

Switching to rilpivirine from first-line regimens is safe and effective in resource-limited settings

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Background: Life-long suppressive therapy is required for HIV-infected patients. Maintaining success in the long term is facilitated by avoiding long-term toxicities and convenient regimens. There are a limited number of studies looking at switching to RPV-based regimens in resource-limited settings. This study assessed the efficacy and safety of switching from a first-line NNRTI or boosted protease inhibitor (PI)-based regimen to RPV-based regimens in virologically suppressed patients living in an Asian resource-limited setting.
Methods: From January 2011 to December 2015, we conducted a prospective cohort study in Bangkok, Thailand. Participants without history of NNRTI failure with current plasma HIV-RNA <50 copies/mL and receiving PI- or NNRTI-based regimens were switched to RPV-based regimens. The primary endpoint was the proportion of patients with plasma HIV-1 RNA level <50 copies/mL after 12 months of RPV treatment.
The secondary endpoint was safety profile, defined by changes in the kidney function and lipid results from baseline to the12-month time point.
Results: A total of 170 participants switched NNRTI or boosted PI to RPV. 7 participants stopped RPV within 3 months due to adverse event (rash, and hepatitis). Only 136 who completed 12 months of follow-up were included in this analyses. Baseline regimens were NNRTI 79 (58%) or PI-based 57(42%). The rationale for switching to RPV was due to toxic adverse-effects (63%) or simplification of cART (35%). Ninety-five (56%) participants were male with a median age of 45 (IQR 40-50) years. At 12 months, 134 (98%) participants maintained virological suppression (HIV RNA <50 copies/ml) and another 2 participants had viral loads <100 copies/mL. Significant improvements from baseline to month 12 were seen for total cholesterol (median change -18.7 (IQR -41 - 7) mg/dL; p<0.001) and triglycerides (-40.3 (IQR -73.5 - 11.5) mg/dL; p<0.001).
There was no difference in the reduction of the lipid profiles between PI- and NNRTI-pre-treated groups. And a small increase in serum creatinine 0.03 mg/dL (p<0.001) was also found.
Conclusions: RPV-based regimen is a viable switching option from other first-line therapy for maintaining virological suppression and improving the lipid profile for HIV-positive people living in a resource-limited setting.

MOPEB0325

MONODO: peripheral blood and cerebrospinal fluid viremia of 24-weeks MONOtherapy of DOlutegravir in HIV-1 virologically suppressed patients

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Background: Current recommendations for the treatment of HIV infection are based on a combination of antiretroviral drugs (cART). Simplified HIV treatment maintenance regimen is strategical to ease retention of care, to improve treatment satisfaction and to reduce healthcare costs.
We aim to assess the feasibility and efficacy of dolutegravir maintenance monotherapy in patients who were virologically suppressed with conventional triple cART for at least 24 months prior to baseline by confirming that viral load is undetectable(HIV-RNA < .50 copies/ml) in peripheral blood and HIV reservoirs, including cerebrospinal fluid (CSF) and sperm.
Methods: Interventional, open label, single arm, 24-week pilot study. Eligible patients were virologically suppressed (HIV-RNA < .50 copies/ml) for at least 24 months and had no history of previous ART failure nor documented antiretroviral drugs resistance.
Primary outcome: Number of patients completing 24 weeks of dolutegravir monotherapy without experiencing virological failure defined as plasma HIV-1 RNA ≥ 200 copies/ml on two consecutive measurements or positive HIV-1 RNA level in CSF at week 24.
Results: Eight patients were enrolled, including two women. Mean age was 47 years (range 36-66 years), mean follow up since HIV diagnosis was 12 years (range 2-26 years), mean nadir CD4 count was 301/µl (range 21-555/µl) and, mean CD4 count at baseline was 800/µl (range 345-1511/µl). Three patients so-far had a lumbar puncture at baseline and at week 24. HIV-RNA in the peripheral blood and in the CSF was< 50 copies/ml in all tested samples. Results of HIV-RNA in the sperm at baseline and week 24 will be available at the end of the study. Seven patients reached week 12, all with HIV-RNA below the detection level of 20 copies/ml.
Conclusions: Treatment maintenance with dolutegravir monotherapy seems to be feasible in rigorously selected HIV-suppressed patients and presents good penetration in the CSF compartment. However closer follow-up is needed and results from larger randomized clinical trials are expected.

MOPEB0326

Pharmacokinetics of dolutegravir and darunavir qd in HIV-patients: the DUALIS study

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Background: With successful antiretroviral therapy (ART) life-expectancy of HIV-patients has substantially increased, but ART-related long-term toxicities have led to the emergence of novel treatment strategies. The combination of the integrase inhibitor dolutegravir (DTG) and the boosted protease inhibitor darunavir (DRV/r) may play a key role in this setting. However, pharmacokinetic (PK) data is sparse to date.
Methods: Prospective, randomized, non-blinded pharmacokinetic sub-study of the DUALIS study (Eudra-CT: 2015-000360-34). Virologically suppressed HIV infected patients under ART were randomized and either kept on DRV/r plus NRTI backbone or switched to DTG 50 mg qd in combination with DRV/r 800/100 mg qd. Samples for PK analysis were obtained 4 weeks after switch at a single day (before and 1, 2, 4, 8 and 12 hours after intake of DTG plus DRV/r with food) and plasma levels were determined using HPLC.
Results: A total of 10 patients (pts) (7 male, 3 female) with a median (IQR) age of 46 (37-50) years, a Body Mass Index of 24.6 (23.2-25.2), HIV RNA of 39 (19-44) cps/ml and a CD4-count of 715 (450-860) /µL were included in the sub-study. HIV RNA remained < 50 cps/mL in all patients. 9/10 pts had detectable plasma levels prior to intake (C_{trough}). Median (IQR) C_{trough} levels were 637 (483-923) ng/mL for DTG and 1245 (575-1818) ng/mL for DRV. Maximum levels measured were 3427 (2964-4048) ng/mL for DTG and 6170 (5708-8950) ng/mL for DRV (Fig_A). C_{trough} remained 4-17-fold above the protein-adjusted IC_{90} (64 ng/mL) for DTG and 1-22-fold above the protein-adjusted EC_{90} (200 ng/mL) for DRV (excluding the patient with undetectable DTG and DRV C_{trough} levels), respectively. Median (IQR) AUC_{12} DTG was 26,809 (22,441-28,459) ng·h/mL and for DRV 49920 (36,729-56,234) ng·h/mL, respectively. No drug-related adverse events (AEs) or serious AEs (SAEs) have been observed.
Conclusions: Overall drug levels showed an increase in DTG and DRV plasma levels after ART intake with C_{trough} levels for DTG and DRV above the protein-adjusted IC_{90} and EC_{90} levels, respectively, without evidence of virologic failure.
Switching to once-daily dual therapy with dolutegravir in combination with ritonavir-boosted darunavir appears to be safe and effective with regard to their pharmacokinetic profiles.

MOPEB0327

High peak plasma level of dolutegravir in patients with ABCG2 genetic variants

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Background: The ATP-binding cassette transporter B1 (ABCB1) and the ATP-binding cassette transporter G2 (ABCG2) are both expressed in the intestines, which are efflux transporters of drugs. Dolutegravir (DTG) was recently identified to be a substrate of both ABCB1 and ABCG2. In this study, we analyzed the relations between single nucleotide polymorphisms of ABCB1 and ABCG2 genes and plasma DTG concentrations.
Methods: HIV-1-infected patients treated with DTG-containing regimens (DTG 50 mg once daily with two nucleotide/nucleoside reverse transcriptase inhibitors and/or protease inhibitors) were recruited at the AIDS Clinical Center, National Center for Global Health and Medicine, Tokyo, Japan. Blood samples were withdrawn into heparinized tubes, and the plasma and peripheral blood mononuclear cells were separated and stored at -80°C. The Ethics Committee for Human Genome Studies at the National Center for Global Health and Medicine approved this study (NCGM-A-000243-01) and each patient provided a written informed consent. Plasma samples were obtained from HIV-1-infected patients treated with DTG-containing regimens 0.5-4 hours after DTG dosing. Plasma DTG concentrations were measured by the liquid chromatography-mass spectrometry (LC-MS) method. Genomic DNA was isolated from peripheral blood mononuclear cells. Genotyping of allelic variants of ABCB1 1236 C>T (rs1128503), 2677 G>T/A (rs2032582), 3435 C>T (rs1045642), 4036 A>G (rs3842) and ABCG2 421 C>A (rs2231142) were carried out using the TaqMan Drug Metabolism Assays.
Results: Plasma samples were collected from 42 patients and used for measurement of DTG concentrations. None of the genotypes in ABCB1 1236 C>T, 2677 G>T/A, 3435 C>T and 4036 A>G showed a correlation with plasma DTG concentration. On contrary, the mean peak plasma concentration of DTG was significantly higher in the genotypes of ABCG2 421 AA (5,002 ng/ml, n=3), compared to the genotypes of ABCG2 421 CC (2,569 ng/ml, n=22) and CA (2,479 ng/ml, n=17) (P=0.0005, one-way ANOVA).
Conclusions: The peak level of plasma DTG concentration was significantly higher in ABCG2 genetic variant holders which may be explained by low expression of efflux transporters in the intestines associated with these genetic variants.

MOPEB0328

Correlation between UGT1A1*6 and *28 genotypes, and plasma dolutegravir concentrations in Japanese HIV-1-infected patients

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Background: Dolutegravir (DTG) is metabolized mainly by glucuronidation via UDP-glucuronosyltransferase 1A1 (UGT1A1). Several UGT1A1 polymorphisms have been correlated with the UGT1A1 expression level and enzymatic activity. In these polymorphisms, *6 and *28 alleles are associated with reduced levels of UGT1A1. In particular, the *28 allele accounts for most of the UGT1A1 polymorphisms in the population. On the other hand, in Asian patients, the *6 alleles are more commonly found in comparison with white patients. So we compared the effects of the two polymorphic alleles, UGT1A1*6 and *28, on plasma DTG concentrations in Japanese HIV-1 infected patients.
Methods: We recruited 179 Japanese HIV-1 infected patients (male:female=171:8) in the National Hospital Organization, Japan. Next, we measured DTG plasma trough concentrations using LC-MS, and performed UGT1A1 genetic screening (*6 and *28). This study was reviewed and approved by the Institutional Review Board of the National Hospital Organization, and each subject provided written informed consent.
Results: Among 179 patients, the frequencies of UGT1A1 genotypes were 13 patients (*6/*6, 7%),
38 patients (-/*6, 21%), 4 patients (*28/*28, 2%), 24 patients (-/*28, 13%), 8 patients (*6/*28, 4%). The trough concentrations of plasma DTG were significantly higher in patients homozygous for UGT1A1*6 (n=13, 1.44 μg/ml; p< 0.001) and compound heterozygous for UGT1A1*6/*28 (n=8, 1.23μg/ml; p=0.003) than in patients carrying the normal allele (n=92, 0.73 μg/ml). The trough concentrations of DTG in patients homozygous for UGT1A1*28 (n=4, 0.92 μg/ml), heterozygous for UGT1A1*6 and *28
(n=38, 0.86 and n=24, 0.95 μg/ml, respectively) were not significantly different from those in patients homozygous for the normal allele.
Conclusions: There were significant correlations between *6 allele and the plasma DTG concentrations. Therefore, UGT1A1*6 polymorphisms are predictive of high plasma concentrations of DTG in Asian patients. To prevent side effects of DTG, it is important to analyze UGT1A1*6 genotypes for Asian each patient.

MOPEB0329

Pharmacokinetic modelling of darunavir/ritonavir dose reduction (800/100 mg to 400/100mg once daily) containing regimen in virologically suppressed HIV-infected patients as maintenance treatment: ANRS-165 DARULIGHT sub-study

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Background: Several strategies aiming at simplifying maintenance antiretroviral therapy without jeopardizing efficacy are being explored to improve long term tolerability, adherence and reduce costs.
This sub-study was conducted in the setting of the ANRS-165 Darulight trial to evaluate DRV and RTV plasma pharmacokinetic parameters in patients switching from DRV/RTV (800/100mgQD) containing regimen to DRV/RTV (400/100mg QD).
Methods: Patients enrolled in this multicenter, open-label, phase II single arm trial with plasma HIV-RNA (pVL)< 50c/mL for ≥12 months while receiving stable DRV/RTV (800/100mg QD)+2 NRTIs were offered to participate in this pharmacokinetic sub-study. Intensive 24h pharmacokinetic blood sampling was performed at D0 (before the switch) and 12 weeks after switching to DRV/RTV (400/100 mg QD) (W12). Total and unbound (DRV) and total (RTV) plasma concentrations were determined by UPLC-MS/MS. Steady-state pharmacokinetic parameters (AUC, Cmin, Cmax, $t_{1/2}$) were determined by a non-compartmental analysis. Paired Geometric Mean Ratio (GMR; IC90%) (W12/D0) was calculated (Wilcoxon test). Apparent Clearance (Cl/F) and distribution volume (Vd/F) and effect of RTV AUC were assessed by a non-linear mixed effects modelling approach, using Monolix software.
Results: Fifteen men were included and 12 full pharmacokinetic pairs (W12/D0) were available. Median age was 42 years (IQR, 41-47). Pharmacokinetic parameters are presented in Table. DRV and RTV half-lives remained unchanged. DRV and RTV Cl/F and Vd/F were determined using one-compartment model with first order absorption and linear elimination. DRV Cl/F and Vd/F were 28.4L/h (RSE (relative standard error) 22%) and 199L (RSE16%). RTV Cl/F and Vd/F were 21.3L/h (RSE7%) and 171L (RSE9%). RTV AUC did not appear to be of significant effect on Cl/F.
Conclusions: In HIV-infected patients receiving maintenance therapy with DRV/RTV (800/100mg QD)+2 NRTIs, a reduction of DRV/RTV to 400/100mg QD was associated with non-significant decreases of total DRV AUC and total/unbound DRV Cmin and a small decrease of unbound DRV AUC. Unexpectedly, RTV exposure slightly increased with the reduced DRV dosing regimen.

MOPEB0330

Exposure of darunavir (DRV), ritonavir (RTV), emtricitabine (FTC), and tenofovir (TFV) in duodenal tissue: implications for gastrointestinal (GI) immune reconstitution among HIV-infected patients undergoing antiretroviral treatment

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Background: Despite viral suppression, immune recovery in GI tissue lags behind peripheral blood, particularly in the small intestines. Whether poor antiretroviral penetration into GI tissue is a contributing factor for blunted GI immune reconstitution remains controversial.

Methods: 18 HIV+ men (pts) initiating daily DRV/RTV (800/100 mg) and FTC/tenofovir disoproxil fumarate (200/300 mg) underwent duodenal biopsy before and 1-year after starting therapy. Peripheral blood mononuclear cell (PBMC) pellets, plasma, and duodenal tissue (homogenate of snap-frozen tissue or collagenase-digested, single-cell pellets (DMC)) were analyzed by LC-MS/MS methods to quantify TFV, FTC, TFV diphosphate(-dp), and FTC triphosphate(-tp) concentrations. Published IC_{50} values were used for comparisons.
The area under the concentration time curve (AUC) was calculated in Phoenix® WinNonlin v6.4. The tissue penetration and cellular ratios (TPR/CR) were calculated as tissue/DMC AUC ÷ plasma/ PBMC AUC. Values are medians (minimum, maximum) unless stated otherwise.
Results: Median age was 40.5 (23-59) years, baseline CD4+ count and HIV RNA were 431 (93-809) cells/mm^3 and 40.5 (10-358) x10^3 copies/mL, respectively. Pts became undetectable by 3 months and CD4+ rose to 742 (124-1024) cells/mm^3 at one year. In 100% of samples, DRV and RTV tissue concentrations and TFV-dp in DMCs were >IC_{50}. In 61% of DMC samples, FTC-tp was ≥ IC_{50}. TPRs were 421 (TFV), 25.1 (RTV), 1.71 (FTC), 1.09 (DRV). CRs were 43 (TFV-dp) and 0.01 (FTC-tp). Half-lives were similar across compartments. Concentrations were higher in tissue than plasma (Table 1).
Intracellular TFV-dp and FTC-tp correlated between snap-frozen tissue and DMCs. (Spearman r=0.59 and r=0.81, respectively).
Conclusions: Active drug concentration was ≥IC_{50} in tissue for three or more agents in 100% of patients. These data provide evidence to suggest poor GI immune reconstitution may not be due to lack of local pharmacologic activity.

	Darunavir		Ritonavir		Tenofovir		Emtricitabine	
	Plasma	Tissue	Plasma	Tissue	Plasma	Tissue	Plasma	Tissue
C_{max} (ng/mL)	5,580	8,004	862	43,567	308	225,947	1,704	4,251
C_{min} (ng/mL)	1,337	570	55.1	1,275	54.1	10,244	71.4	139
$T_{1/2}$ (h)	8.16	4.66	4.57	5.13	7.76	6.65	5.86	4.61
$AUC_{0-\tau}$ (ng*h/mL)	91,358	99,486	7,842	196,933	2,695	1,135,878	11,835	20,254
TPR	-	1.09	-	25.1	-	421	-	1.71

[Pharmacokinetic Parameters]

MOPEB0331

Predator effects of nevirapine on dolutegravir pharmacokinetics after switching

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Background: Co-administration of dolutegravir (DTG) 50 mg QD and nevirapine (NVP) 400 mg QD resulted in significant changes in DTG pharmacokinetics as a consequence of the enzymatic induction by NVP. Current study aimed to evaluate the duration of NVP predator effect on DTG pharmacokinetics when patients were switched from NVP to DTG.
Methods: SWAD study evaluated the efficacy, safety and satisfaction of switching from abacavir/lamivudine (600 mg/300 mg QD) + NVP (400 mg extended-release tablets QD) (ABC/3TC+NVP) to ABC/3TC/DTG (600mg/300 mg/50 mg QD). Fifty-three patients were included in this prospective, bicentric, single-arm, open-label switch study (NCT02067767). A PK substudy was conducted in 43 patients to evaluate DTG trough concentrations (C_{min}), as well as NVP residual concentrations. DTG and/or NVP plasma concentrations were measured at switch and at W1, W2, W4 and W12. Patient receiving concomitant therapy modifying DTG pharmacokinetics were excluded.
Results: At inclusion, patients were virologically suppressed for a median duration of 9.6 years and receiving an ABC/3TC+NVP regimen for a median duration of 6 years.
Mean DTG C_{min} [Standard Deviation (SD), number of subjects (n)] were 666 ng/mL [355; 35] at W1, 947 ng/mL [585; 38] at W2, 1130 ng/mL [571, 38] at W4 and 1439 ng/mL [923, 38] at W12. All patients were maintained above DTG IC90 (64 ng/mL) at all sample times. Mean NVP concentrations [SD, n] were 3435 ng/mL [1063, 35] at switch, 43 ng/mL [107, 35] at W1, 1 ng/mL [8, 38] at W2 and were undetectable at W4 and W12. NVP terminal half-life after switch was 27 hours. All patients were maintained above NVP IC90 (40 ng/mL) at switch. At W1, 27/35 patients were measured below NVP IC90 and 38/38 at W2.
At W12, all the patients maintained plasma HIV-1 RNA below 20 copies/mL.
Conclusions: After switching from ABC/3TC+NVP to ABC/3TC/DTG, DTG reached steady-state by W4/W12 when expected by D5/D10. All patients were maintained above DTG IC90 at all sample times without virological failure. Moreover, terminal half-life of NVP after switch was comparable to expected values. These PK data support switch from a NVP-based regimen to a DTG-based regimen without DTG adjustment.

MOPEB0332

A study evaluating the pharmacokinetics, safety, and tolerability of the bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) single tablet regimen (STR) in Japanese subjects

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Background: Bictegravir (BIC) is an investigational, once-daily, unboosted HIV integrase strand transfer inhibitor (INSTI) with a high barrier to resistance and potent in vitro activity against most INSTI-resistant variants. BIC, coformulated with the NRTI backbone of emtricitabine/tenofovir alafenamide (FTC/TAF), is currently in development for treatment of HIV-1 infection. This study evaluated the pharmacokinetics (PK), safety, and tolerability of BIC/FTC/TAF (B/F/TAF) in HIV-uninfected Japanese and Caucasian subjects.
Methods: Japanese subjects (n=25) were born in Japan, had not lived outside Japan >5 years, and had traceable maternal and paternal Japanese ancestry of parents and grandparents. Caucasian subjects (n=25) were not of Japanese or Asian descent. All subjects received a single, oral dose of B/F/TAF (50/200/25 mg) under fasted conditions. Intensive PK sampling was performed and statistical comparisons of the exposures of BIC, FTC, TAF, and TAF metabolite, TFV, were conducted by geometric mean ratios (GMR), associated 90% confidence intervals (CI), and no-effect boundary of 70-143%, with Japanese subjects as the test and Caucasian subjects as the reference. Safety was monitored throughout the study and follow-up.
Results: Table 1 shows the primary BIC, FTC, TAF, and TFV PK parameters (AUC_{inf}, AUC_{last}, C_{max}) and statistical comparisons. The PK of all components of B/F/TAF was similar in Japanese and Caucasian subjects and the GMR and corresponding 90% CIs of all parameters were contained within the protocol-defined no-effect boundary of 70%-143%. B/F/TAF was well tolerated and all subjects completed the study except one Caucasian subject who discontinued due to adverse events (AEs) of Grade 2 nausea and Grade 1 vomiting. No Grade 3, 4, or serious AEs and no clinically relevant laboratory abnormalities were observed.

PK Parameter		Japanese Subjects (n=25) Mean (%CV)	Caucasian Subjects (n=25) Mean (%CV)	GMR (%) (90% CI)
BIC	AUC_{inf} (ng*h/mL)	115,000 (21)	103,000 (31)	114 (100, 130)
	AUC_{last} (ng*h/mL)	114,000 (21)	102,000 (31)	115 (101, 131)
	C_{max} (ng/mL)	6,560 (18)	5,220 (21)	126 (115, 139)
FTC	AUC_{inf} (ng*h/mL)	11,200 (18)	10,600 (14)	105 (96.6, 113)
	AUC_{last} (ng*h/mL)	11,000 (19)	10,400 (14)	105 (97.0, 114)
	C_{max} (ng/mL)	2,680 (40)	2,450 (22)	103 (88.2, 121)
TAF	AUC_{inf} (ng*h/mL)	175 (52)	171 (41)	97.4 (78.6, 121)
	AUC_{last} (ng*h/mL)	170 (52)	167 (41)	95.9 (77.3, 119)
	C_{max} (ng/mL)	301 (58)	262 (42)	106 (85.4, 113)
TFV	AUC_{inf} (ng*h/mL)	325 (24)	324 (24)	100 (89.5, 113)
	AUC_{last} (ng*h/mL)	267 (24)	267 (20	99.3 (89.2, 111)
	C_{max} (ng/mL)	12.0 (30)	11.0 (24)	107 (93.4, 123)

[Table 1. B/F/TAF PK Parameter Summary]

Conclusions: Following administration of B/F/TAF, equivalent pharmacokinetics and similar safety and tolerability were observed in Japanese and Caucasians subjects supporting the use of the 50/200/25 mg dose of B/F/TAF in HIV-infected Japanese patients.

MOPEB0333

Characteristics of dolutegravir protein binding in human and nonhuman primate: a first approach for the study of pharmacologic sanctuaries

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Background: The unbound concentration of a drug is considered the active moiety, which is available to cross cell membranes. This study aimed to characterize dolutegravir (DTG) protein binding to human serum albumin (HSA) and to plasma proteins in plasma of human and nonhuman primate (NHP, Macaca fascicularis).
Methods: DTG protein binding was measured in vitro in blank human plasma from the Blood Bank and in blank NHP plasma which were spiked with DTG to final concentrations of 800 and 1,600ng/mL. DTG HSA binding was measured using a 40g/L HSA solution prepared in pH 7.4 phosphate-buffered saline and spiked with DTG to yield 8 final concentrations from 25 to 25,000ng/mL. The influence of pH on DTG binding was studied in a 40g/L HSA solution spiked with DTG at 800 and 1,600ng/mL at pHs ranging from 7.0 to 7.8. Each experiment was run in triplicate. Bound and unbound fractions were separated by ultrafiltration (Centrifree devices). Total and unbound DTG concentrations were measured by quality controls validated assays (LC-MS/MS). A graphical Scatchard plot method was used to estimate the albumin binding characteristics.
Results: At the 800 and 1,600ng/mL DTG total concentrations, mean DTG plasma protein bindings were 99.4% (CV, 4.4%) and 99.1% (CV, 6.6%) respectively in human plasma and 98.9% (CV, 8.5%) and 98.5% (CV, 3.1%) respectively in NHP plasma. The mean binding of DTG to HSA was 89.6% (range, 83.2%-94.7%), and independent of DTG total concentration. DTG was found to bind to two classes of albumin sites: one with high affinity and one nonsaturable with low affinity. Interestingly in the pH range from 7.0 to 7.8, a 0.2U decrease in pH led to a 2% decrease in DTG albumin binding (P< 0.0001).
Conclusions: DTG binding is high mainly with HSA and is pH sensitive that could influence diffusion in some biological fluid and cells. As characterization of binding of DTG is similar in human and in NHP, the NHP model could be an adequate model for studying tissue distribution, particularly in inaccessible human tissues.

MOPEB0334

Co-administration of doravirine with an aluminum/magnesium containing antacid or pantoprazole, a proton pump inhibitor, does not have a clinically meaningful effect on doravirine pharmacokinetics

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Background: Doravirine is a novel, potent, HIV-1 non-nucleoside reverse transcriptase inhibitor currently being evaluated in Phase 3 trials for treatment of HIV-1 infection in combination with other antiretroviral therapy. As many patients with HIV-1 infection are treated with antacids or acid-reducing agents, this study was conducted to evaluate the effect of these agents on doravirine pharmacokinetics (PK).
Methods: This was an open-label, 3-period, fixed-sequence drug-interaction study in healthy adult subjects. In Period 1, a single dose (SD) of a doravirine 100mg tablet was administered. In Period 2, a SD of a doravirine 100mg tablet was co-administered with a SD of 20mL of an antacid suspension containing 1600mg of each aluminum hydroxide and magnesium hydroxide and 160mg of simethicone. In Period 3, a pantoprazole sodium 40mg delayed-release tablet was administered on Days 1-5 and a SD of a doravirine 100mg tablet was administered on Day 5. There was a washout of 10 days between each period. Blood samples to measure doravirine plasma concentrations were collected predose and through 72 hours post dose in all periods.
Results: Fourteen subjects (8 male and 6 female) were enrolled and 13 completed the study; one subject discontinued for personal reasons. Following co-administration with an aluminum/magnesium containing antacid, doravirine PK was not affected to a clinical meaningful extent. The geometric mean ratios (GMR) (90% confidence intervals) [doravirine + antacid/doravirine] for Cmax, AUC0-∞, and C24 were 0.86 (0.74,1.01), 1.01 (0.92,1.11), and 1.03 (0.94,1.12), respectively. Following co-administration with pantoprazole, there was no clinically significant effect on doravirine PK. The GMR (90% confidence intervals) [doravirine + pantoprazole/doravirine] for Cmax, AUC0-∞, and C24 were 0.88 (0.76,1.01), 0.83 (0.76,0.91), and 0.84 (0.77, 0.92), respectively. There were no serious adverse experiences (AEs) and all AEs were mild in intensity. Overall, 3 (21%) subjects reported at least one AE during the study. The most common AE was headache reported by 3 subjects.
Conclusions: Doravirine is generally well tolerated when administered alone or with an aluminum/magnesium containing antacid or with the proton pump inhibitor, pantoprazole. Coadministration of either of these agents with doravirine does not have a clinically meaningful effect on doravirine PK.

MOPEB0335

Bioequivalence of a darunavir-based single-tablet complete HIV-1 regimen compared to the separate agents

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Background: DCFTAF is the first once-daily, single-tablet complete HIV-1 regimen containing darunavir (DRV, D 800mg), cobicistat (COBI, C 150mg), emtricitabine (FTC, F 200mg) and tenofovir alafenamide (TAF, 10mg). The efficacy and safety of DCFTAF is being investigated in two large, international, randomized Phase 3 studies AMBER (NCT02431247) and EMERALD (NCT02269917). The present study (NCT02578550) evaluated if the DCFTAF tablet is bioequivalent to combined intake of the separate agents.
Methods: This was a Phase I, open-label, randomized, 2-sequence, 2-period crossover study in healthy volunteers (n=96). In two treatment sessions, participants received a single oral dose of the DCFTAF tablet (test) or combined intake of a single oral dose of DRV (one 800-mg tablet), FTC/TAF (one 200/10-mg tablet), and COBI (one 150-mg tablet) (reference), under fed conditions (standardized regular-calorie, regular-fat breakfast), with a ≥7-day washout period in between. Bioequivalence was evaluated when taken with food in line with other DRV-based treatment regimens. Pharmacokinetic profiles were determined over 72 hours after dosing (8 hours for TAF). Plasma concentrations of DRV, COBI, FTC and TAF were determined using validated LC-MS/MS assays. Pharmacokinetic parameters were determined using non-compartmental analysis, and treatments compared using geometric mean ratios (GMR) with 90% confidence intervals (CIs). Safety and tolerability were assessed throughout.

Parameter, mean (SD)[a]	D/C/F/TAF (800/150/200/10mg) (test) N=94	Separate agents DRV 800mg, FTC/TAF 200/10mg FDC, and COBI 150mg (reference) N=96	Geometric mean ratio (90.14% CI)[b], %
DRV			
C_{max}, ng/mL	7042 (1481)[c]	6620 (1429)[c]	106.73 (103.50–110.06)[c]
t_{max}, hours	4.00 (1.50–8.00)[c]	4.00 (2.00–12.00)[c]	–
AUC_{last}, ng.h/mL	87200 (27385)[c]	84406 (29481)[c]	104.84 (100.87–108.97)[c]
AUC_{inf}, ng.h/mL	87280 (28097)[d]	85210 (29561)[d]	103.74 (99.62–108.02)[d]
$t_{1/2term}$, hours	5.9 (2.1)[d]	6.2 (2.7)[d]	–
COBI			
C_{max}, ng/mL	894 (254)[c]	881 (207)[c]	100.69 (96.80–104.73)[c]
t_{max}, hours	4.00 (1.50–6.00)[c]	4.00 (1.50–5.05)[c]	–
AUC_{last}, ng.h/mL	6681 (2486)[c]	6763 (2436)[c]	98.77 (95.14–102.52)[c]
AUC_{inf}, ng.h/mL	6785 (2518)[c]	6868 (2459)[c]	98.76 (95.15–102.52)[c]
$t_{1/2term}$, hours	3.7 (0.7)[c]	3.7 (0.7)[c]	–
FTC			
C_{max}, ng/mL	2041 (481)[e]	2053 (469)[e]	99.32 (95.61–103.17)[e]
t_{max}, hours	2.00 (0.60–5.00)[e]	2.00 (0.50–5.00)[e]	–
AUC_{last}, ng.h/mL	11722 (1959)[e]	11746 (1868)[e]	100.04 (98.46–101.66)[e]
AUC_{inf}, ng.h/mL	11882 (2002)[f]	11927 (1935)[f]	100.13 (98.36–101.93)[f]
$t_{1/2term}$, hours	16.5 (3.3)[f]	17.0 (3.4)[f]	–
TAF			
C_{max}, ng/mL	110 (54.1)	120 (74.0)	96.87 (88.95–105.50)
t_{max}, hours	1.50 (0.25–3.50)	1.01 (0.25–4.00)	–
AUC_{last}, ng.h/mL	123 (42.0)	132 (58.1)	96.59 (91.72–101.73)
AUC_{inf}, ng.h/mL	127 (39.4)[g]	141 (59.7)[g]	95.42 (90.62–100.48)[g]
$t_{1/2term}$, hours	0.3 (0.1)[g]	0.3 (0.1)[g]	–

[a]Except t_{max} = median (range); [b]An adjusted CI of 90.14% was calculated (as opposed to a 90.00% CI) as a result of a blinded (for treatment) sample size re-estimation during the study (given uncertainty of the TAF pharmacokinetic variability), in order to control the nominal type I error rate; no additional participants were recruited beyond the planned number
[c]n=93 test, n=95 reference; [d]n=87 test, n=91 reference; [e]n=93 test, n=96 reference; [f]n=85 test, n=87 reference; [g]n=79 test, n=78 reference
SD = standard deviation; CI = confidence interval; C_{max} = maximum plasma concentration; t_{max} = time to C_{max}; AUC_{last} = area under the plasma concentration-time curve (AUC, calculated by linear-linear trapezoidal summation) from time of administration up to the last timepoint with a measurable concentration post-dose
AUC_{inf} = AUC from time of administration to infinity; $t_{1/2term}$ = terminal elimination half-life

[DRV, COBI, FTC and TAF pharmacokinetic parameters]

Results: No major differences were observed in the pharmacokinetic profiles for DRV, COBI, FTC and TAF between the DCFTAF complete HIV-1 regimen and the separate agents. The 90.14% CIs of the GMRs of all main pharmacokinetic parameters were within the 80.00%-125.00% bioequivalence limits for all four components (DRV, COBI, FTC and TAF) (Table). DCFTAF was generally well tolerated. No new safety issues, Grade 3/4 or serious AEs, deaths or discontinuations due to AEs occurred.
Conclusions: The DCFTAF 800/150/200/10-mg single-tablet complete HIV-1 regimen is bioequivalent to the combined administration of the separate agents DRV, FTC/TAF and COBI.

MOPEB0336

Low concentrations of darunavir once daily when coadministered with maraviroc + raltegravir, Optiprim-ANRS 147 trial

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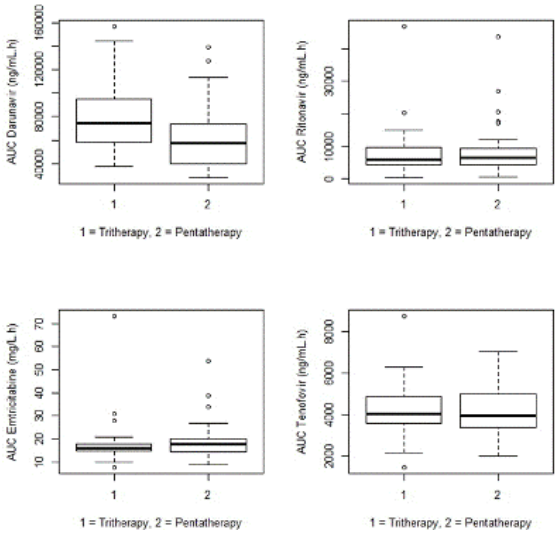
Background: The OPTIPRIM-ANRS 147 trial compared intensive combination antiretroviral therapy-darunavir/ritonavir (DRV/RTV), tenofovir disoproxilfumarate/emtricitabine (TDF/FTC), raltegravir and maraviroc - started early during primary HIV-1 infection to standard tritherapy with DRV/RTV/TDF/FTC. A poorer percentage of undetectable viral load (< 50 cp/mL) was reported in the pentatherapy versus tritherapy arm from month 6 to 18. This pharmacokinetic sub-study aimed to compare antiretroviral drug concentrations in the 2 arms.
Methods: Plasma samples were collected from 50 patients at variable times from drug administration. To compare ART level between groups, for each patient a concentration just before intake (trough concentrations C_{trough}) and an exposure (area under the concentration-time curve AUC) was predicted using a maximum a posteriori probability (Bayesian estimation) from published population pharmacokinetic models. These parameters were compared between the tritherapy and pentatherapy arms using a mixed linear regression.
Results: Published models adequately described data and could be used to predict trough concentrations and exposures. No significant difference was evidenced for tenofovir, emtricitabine and ritonavir between the tritherapy and the pentatherapy arms. However, darunavir C_{trough} and AUC were significantly lower in the pentatherapy arm than in the tritherapy arm (p=0.03 and p=0.04 respectively). Due to the small number of patients enrolled in this sub-study, no pharmacodynamics relationship between viral load and AUC or $C_{through}$ could be demonstrated.



[Figure. Exposures of darunavir, ritonavir, tenofovir and emtricitabine in combination therapy and pentatherapy arm.]

Conclusions: An interaction between maraviroc and darunavir could be involved. Indeed, there are more pharmacological arguments to attribute this interaction to maraviroc than to raltegravir. We can therefore assume that this interaction had an impact on the kinetics of viral decay in the pentatherapy arm. A combined maraviroc/darunavir regimen can be an option in particular situations at the chronic stage: it would be relevant to prospectively evaluate an increased darunavir/ritonavir dosage to 600/100 mg twice daily in such situations.

MOPEB0337

Drug concentrations and HIV-1 RNA in CSF in patients switching to ritonavir-boosted atazanavir (ATV/r) plus lamivudine (3TC) dual therapy

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Background: Simplification to ATV/r + 3TC dual therapy in virologically suppressed patients has shown non-inferior efficacy compared to triple therapy. Since the penetration of ATV/r in CSF may be suboptimal, the aim of this study was to assess HIV-1 RNA and drug concentrations in CSF in patients who switched to ATV/r + 3TC.
Methods: Cross-sectional study including HIV-1 infected adults with suppressed plasma HIV-1 RNA and no history of resistance or failure to ATV/r and 3TC who switched from ATV/r+TDF/FTC to ATV/r+3TC. Total ATV and 3TC concentrations at the end of the dosing interval (C_{24h}) and HIV-1 RNA were measured in paired CSF and plasma samples 12 weeks after switching to ATV/r+3TC. Validated LC-MS/MS methods were used to quantify drug concentrations, and HIV-1 RNA was determined by real-time PCR.
Results: Ten patients were included, 4 male, 6 female. Median (range) age was 42.5 years (33-70), time on ART 39.5 months (11-197), time with plasma HIV-1 RNA < 40 c/mL 15.5 months (6-46), nadir CD4 count 289 cells/µL (79-580) and current CD4 count 740 cells/µL (357-1380). All had HIV-1 RNA < 40 c/mL in CSF at baseline. Twelve weeks after switching to ATV/r+3TC, 9/10 patients maintained HIV-1 RNA < 40 c/mL in both plasma and CSF. One patient with suboptimal adherence to ART had HIV-1 RNA rebound in both plasma (2658 c/mL) and CSF (1233 c/mL) although she was asymptomatic. The median CSF-to-plasma concentration ratios of ATV and 3TC were 0.013 and 0.417 respectively. Median ATV C_{24h} in CSF was 10.39 (3.71-33.45) ng/mL (in vitro ATV IC_{50} range for wild type HIV-1, 1-11 ng/mL). Median 3TC C_{24h} in CSF was 43.42 (16.20-99.33) ng/mL (in vitro 3TC IC_{50} range for wild type HIV-1, 0.68-20.6 ng/mL).
Conclusions: Twelve weeks after switching to ATV/r+3TC most patients maintained HIV-1 RNA < 40 c/mL in CSF despite CSF ATV C_{24h} close to or within the IC_{50} range in a proportion of them. The good CSF penetration of 3TC may have contributed to HIV-1 RNA suppression in this compartment. Nevertheless, a rigorous patient selection and optimal adherence is advisable to assure effective CSF viral suppression with this dual ARV simplification regimen.

MOPEB0338

The effect of fostemsavir on methadone and buprenorphine pharmacokinetics

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Background: Fostemsavir is a prodrug of temsavir, a first-in-class attachment inhibitor that binds directly to HIV-1 gp120, preventing initial viral attachment and entry into host CD4+ T cells. This study assessed the impact of fostemsavir on the pharmacokinetics (PK) of the opioids methadone (R-, S-, and total) or buprenorphine/norbuprenorphine when coadministered.
Methods: AI438068 was a Phase 1, open-label study in subjects on methadone maintenance therapy (40 - 120 mg QD, Part 1, N=16) or buprenorphine/naloxone maintenance therapy (8/2 - 24/6 mg QD, Part 2, N=16). HIV- and HBV-positive subjects were excluded; a positive test for HCV antibodies with documentation of anti-HCV therapy was acceptable. In Part 1, subjects received methadone on Day 1 and methadone QD with fostemsavir 600 mg BID on Days 2-9. In Part 2, subjects received buprenorphine/naloxone on Day 1 and buprenorphine/naloxone QD with fostemsavir 600 mg BID on Days 2-9. Serial blood samples were collected up to 24 hours post-dose Day 1 and Day 9. Plasma concentrations were quantified by validated LC/MS/MS methods. Geometric mean ratios (GMRs) and 90% confidence intervals (CI) were derived for dose-normalized methadone (R-, S-, total), buprenorphine and norbuprenorphine PK using linear mixed-effects models. The

effect of fostemsavir was deemed clinically insignificant if the 90% CI fell within 0.70-1.43 for methadone and 0.50-2.00 for buprenorphine and norbuprenorphine. Adverse events were monitored throughout the study, including signs of withdrawal or toxicity.
Results: Methadone exposures (R-, S-, and total) increased 9-15% and buprenorphine/norbuprenorphine exposures increased 24-39% when coadministered with fostemsavir. In subjects on a stable regimen of methadone or buprenorphine/naloxone, coadministration of fostemsavir was safe and generally well tolerated with no reported symptoms of overdose or withdrawal.

Analyte	Cmax GMR (90% CI)	AUC(TAU) GMR (90% CI)	C24 GMR (90% CI)
R-methadone	1.15 (1.11, 1.20)	1.13 (1.07, 1.19)	1.09 (1.01, 1.17)
S-methadone	1.15 (1.10, 1.19)	1.15 (1.09, 1.21)	1.10 (1.02, 1.19)
total methadone	1.15 (1.11, 1.19)	1.14 (1.09, 1.20)	1.10 (1.02, 1.18)
buprenorphine	1.24 (1.06, 1.46)	1.30 (1.17, 1.45)	1.39 (1.18, 1.63)
norbuprenorphine	1.24 (1.03, 1.51)	1.39 (1.16, 1.67)	1.36 (1.10, 1.69)

[Cmax, AUC(TAU), and C24 GMR (90% CI)]

Conclusions: Methadone and buprenorphine may be coadministered with fostemsavir without dose adjustment. Consistent with recommendations for other antiretrovirals, monitoring for clinical signs of sedation with buprenorphine may be warranted.

MOPEB0339

The effect of fostemsavir on the pharmacokinetics of a combined oral contraceptive (OC) containing ethinyl estradiol (EE) and norethindrone (NE) in healthy female subjects

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Background: Fostemsavir is a prodrug of temsavir, a first-in-class attachment inhibitor that binds directly to HIV-1 gp120, preventing initial viral attachment and entry into host CD4+ T cells. Women of child-bearing potential represent a significant proportion of the heavily-treatment experienced HIV-infected population; effective and convenient contraception is important. This study assessed the impact of fostemsavir on the pharmacokinetics (PK) of a combined OC containing EE and NE (Loestrin 1.5/30; 1.5 mg NE, 30 µg EE).
Methods: AI438019 was a Phase 1, open-label, single-sequence, 4-cycle, 4-treatment study in 26 healthy female subjects. Serial blood samples for PK up to 24 hours post-dose and single samples for serum progesterone were collected. Plasma concentrations were quantified by validated LC/MS/MS methods. Geometric mean ratios (GMRs) and 90% confidence intervals (CI) were derived for EE and NE PK using linear mixed-effects models. Adverse events (AEs) were monitored throughout the study.

Cycle 1	Cycle 2	Cycle 3	Cycle 4
Days 1-8	Days 1-28	Days 1-28	Days 1-21
Day 1 = 21st day of existing OC once daily (QD) (Treatment A)	Existing OC QD Days 1-21 (Treatment B)	Loestrin 1.5/30 QD Days 1-21 (Treatment C)	Loestrin 1.5/30 QD Days 1-11 Loestrin 1.5/30 QD + fostemsavir 600 mg BID Days 12 - 21 (Treatment D)
serial PK collection Day 1	serial PK collection Day 21	serial PK collection Day 10 and 21	serial PK collection Day 21
serum progesterone Day 1	serum progesterone Day 21	serum progesterone Day 11, 15 and 21	serum progesterone Day 11, 15 and 21

[Study Design]

Results: Only comparisons of EE and NE PK between Treatment D and Treatment C are presented. Fostemsavir coadministration increased EE exposures ~40%. The 90% CIs for NE Cmax and AUC(TAU) GMRs were within 0.80-1.25. Serum progesterone levels suggested fostemsavir did not negatively impact suppression of ovulation. Most study drug-related AEs were mild; 1 subject (3.8%) reported a moderate AE of headache (Treatment D).

Parameter	Treatment C Day 21 Adjusted Geometric Mean	Treatment D Day 21 Adjusted Geometric Mean	GMR (90% CI) Treatment D vs. C
EE Cmax (pg/mL)	108	150	1.39 (1.28, 1.51)
EE AUC(TAU) (pg.h/mL)	1083	1514	1.40 (1.29, 1.51)
NE Cmax (pg/mL)	23629	25582	1.08 (1.01, 1.16)
NE AUC(TAU) (pg.h/mL)	170293	184302	1.08 (1.03, 1.14)

[EE/NE Cmax and AUC(TAU)]

Conclusions: Fostemsavir, in the absence of a pharmacoenhancer, may be coadministered with combined oral contraceptives containing NE and a reduced dose of EE.

MOPEB0340

Eight weeks safety results of high-dose rifampicin in HIV-tuberculosis co-infected patients in Uganda: RIFAVIRENZ-ANRS 12292 trial

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Background: Despite the reported safety of high-dose Rifampicin (R) among HIV negative tuberculosis (TB) patients, no data exists among HIV-TB co-infected patients. We report the safety results from a high-dose rifampicin (20mg/kg) and efavirenz (EFV)-based ART (600 and 800mg) drug interaction study in HIV-TB co-infected patients by week-8 of TB treatment.
Methods: In a phase-2, randomized, open-label therapeutic trial (NCT01986543), newly diagnosed, XpertMTB/RIF positive and rifampicin-susceptible active pulmonary TB, HIV positive, ART-naïve, adult patients were enrolled and randomized to 3-study regimens (SR): SR_1: 8 weeks R20mg/Kg + Isoniazid(H) + pyrazinamide(Z) + ethambutol(E) and EFV600mg/J; SR_2: 8 weeks R20mg/Kg + H+Z+E and EFV800mg/J; Control regimen (CR): 8 weeks R10mg/Kg + H+Z+E and EFV600mg/J. EFV was given with tenofovir-lamivudine for all patients 2 weeks after starting anti-TB treatment(ATT). At 8 weeks, all patients were switched to standard R and EFV doses. Treatment was observed at home by a domiciliary treatment monitor. Weekly clinical assessments and bi-weekly biochemistry and full blood count monitoring was done.
Results: We enrolled 98 patients (SR_1: 33, SR_2: 32 and CR: 33), median age 33.6 years, 26.5% were females. Baseline median BMI, CD4 count and ALT were 19.5kg/m2, 142 cells/L and 19.5IU/L respectively. One and four patients were co-infected with hepatitis B and C respectively. Six patients; 2 from each arm had grade 3 or 4 increases in ALT or AST within the first 8 weeks: 1 during ATT alone vs 1 during ATT+ART for both SR1 and CR, and 2 during ATT alone vs 0 during ATT+ART for SR2. Only 4 patients (CR: 1, SR_1: 1, SR_2: 2, p = 0.780) had grade 2 neuropsychiatric AEs. No grade 3 or 4 neuropsychiatric AEs were noted. Fifteen patients, 5 from each arm had SAEs, with 2 of which resulting in death unrelated to treatment and 2 with their treatment arm changed from 20mg/kg-10mg/kg of R dose due to increase in hepatic transaminases.
Conclusions: Co-administration of a double-dose of rifampicin with efavirenz (600 or 800mg) among HIV/TB co-infected patients was well tolerated with very few severe transaminitis and no severe neuropsychiatric disorders.

MOPEB0341

Rare emergence of resistance in treatment-naive patients receiving E/C/F/TAF for 144 weeks

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Background: Tenofovir alafenamide (TAF) is a novel tenofovir (TFV) prodrug achieving higher levels of TFV-diphosphate in lymphocytes at a lower dose compared to tenofovir disoproxil fumarate (TDF). The single-tablet regimen (STR) elvitegravir/cobicistat/emtricitabine/TAF (E/C/F/TAF) was compared to the STR of

E/C/F/TDF in clinical studies. High proportions of patients achieved HIV-1 RNA <50 copies/mL at weeks 48, 96, and 144, and the response at week 144 (84.2% vs. 80.0% for E/C/F/TAF and E/C/F/TDF groups, respectively) favored the E/C/F/TAF group in a statistically significant manner. The final Week 144 integrated resistance analysis across two completed Phase 3 clinical studies is described.
Methods: HIV-1 genotypic testing was conducted pre-treatment using commercial population sequencing (Monogram Biosciences) to assess HIV-1 PR/RT/IN sensitivity to study drugs. For patients with HIV-1 RNA ≥400 copies/mL at time of virologic failure (VF) or early discontinuation, genotypic analysis and phenotypic antiretroviral susceptibility were evaluated.
Results: HIV-1 subtypes identified in the 1733 enrolled patients included A, A1, A2, AE, AG, B, BC, BF, C, D, F, F1, and G. Pre-existing primary resistance-associated mutations (RAMs) were observed pre-treatment in 7.4% (NRTI-RAMs), 18.1% (NNRTI-RAMs), and 3.3% (PI-RAMs) of enrolled subjects. Baseline HIV-1 subtype or NRTI- or NNRTI-RAMs did not affect E/C/F/TAF treatment response at week 144. VF resistance analyses were conducted for 28/866 (3.2%) and 30/867 (3.5%) patients in the E/C/F/TAF and E/C/F/TDF arms, respectively. Over the 3-year study, the rate of resistance emergence remained low at 1.4% in each treatment group (12/866 in E/C/F/TAF, and 12/867 in E/C/F/TDF). Resistant virus emerged in a total of 24 patients who developed primary resistance to antiretrovirals in the STRs (E/C/F/TAF: INSTI-RAMs [n=8], M184V/I [n=11], K65R/N [n=2]; E/C/F/TDF: INSTI-RAMs [n=8], M184V/I [n=9], K65R/N [n=4]). Overall, similar patterns of emergent mutations were observed in both treatment groups, with M184V/I being the most prevalent RAM (1.2% overall).
Conclusions: E/C/F/TAF achieved a high level of virologic suppression in HIV-1 treatment-naïve patients through 144 weeks of treatment. Resistance development was rare with comparable genotypic changes across the E/C/F/TAF (1.4%) and E/C/F/TDF (1.4%) treatment groups.

MOPEB0342

Prevalence and transmission dynamics of HIV-1 transmitted drug resistance in central North Carolina

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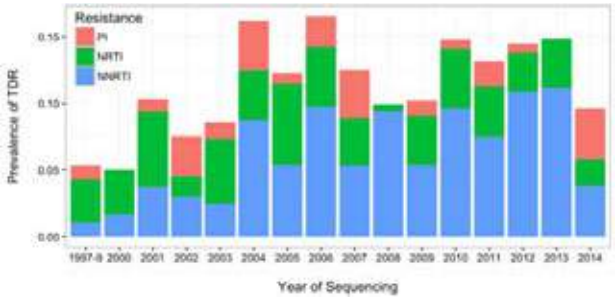
Background: Transmitted drug resistance (TDR) compromises clinical management and outcomes. TDR surveillance and identification of growing transmission clusters is needed in the Southeast, the epicenter of the US HIV epidemic. We investigated prevalence and transmission dynamics of TDR in North Carolina (NC).
Methods: We analyzed surveillance drug resistance mutations (SDRM) using partial pol sequences among antiretroviral therapy (ART)-naïve patients with available genotypes presenting to two large HIV outpatient clinics from 1997-2014. We used logistic regression to compare TDR prevalence (SDRM among ART-naïve patients) by demographic and clinical factors, sequencing year, and transmission clusters. Transmission clusters were identified using maximum-likelihood trees and Bayesian methods including background pol sequences (n=15,247).
Results: 1,658 patients had a pre-ART genotype; 73% were men, 62% black, and 47% identified as MSM. Overall, ≥1 SDRM was identified in 199 patients, with an aggregate TDR prevalence of 12% (95%CI: 10-14%), increasing over time (p=0.04, Figure). Of 229 transmitted SDRM, most were NNRTI-associated mutations (58%), followed by NRTI (31%) and PI (12%). Sequences with mutations to two (n=20) and three drug classes (n=5) were uncommon. Compared to those without TDR, patients with TDR were more likely to be MSM (OR=1.39, 95%CI: 1.04-1.88), white (OR=1.42, 95%CI: 1.03-1.96), have higher CD4 counts (median 374 vs. 306 cells/mm^3, p< 0.01), and identified in a cluster (OR=1.64, 95%CI: 1.17-2.30). In our phylogenetic analysis, TDR was identified in 106 clusters. Of these clusters with TDR (range 2-26 members, 546 total sequences), 53% had K103N. In 75% of clusters, the majority of sequences shared an identical SDRM, and in 35%, all sequences had the same SDRM.



[Increasing TDR prevalence by year and drug class (N=1,658)]

Conclusions: Moderate TDR prevalence persists in NC predominantly driven by NNRTI resistance. Most TDR cases were identified in transmission clusters, signifying multiple local transmission networks and suggesting TDR circulation among ART-naïve persons. Continued TDR surveillance may help detect transmission networks for targeted prevention.

MOPEB0343

HIV-1 acquired drug-resistance during first-line regimens does not impact virological outcome after long-term second-line protease-based therapies in resource-limited countries: genotyping is not required for the reverse-transcriptase inhibitors-selection during treatment switch

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Background: Viral load (VL) quantification is not widely available in resource-limited countries (RLCs) and diagnosis of a failing treatment may be delayed leading to the accumulation of drug resistance mutations. HIV-1 drug-resistance testing is not recommended for treatment switch and it is thus important to assess if genotyping may improve therapy optimization.
Here, we investigated the association between acquired resistance during first-line regimens and virological outcome after long-term second-line protease-based therapy in RLCs.
Methods: A total of 387 patients from the 2LADY-study (a randomized, open-label trial of three different second-line PI-based regimens in Burkina Faso, Cameroon and Senegal) were followed for 104 weeks. We model the relationship between treatment resistance data at baseline of second-line treatment initiation (genotypic susceptibility scores, resistance scores calculated for the observed mutations, number of Reverse-transcriptase inhibitors-mutations (RTIs) by drug class and duration of first-line treatment) and virological failure (three thresholds: ≥50, ≥200 or ≥1000 copies/ml) at week 104 using logistic regressions. Additional covariates included demographic (sex, age and country), biological (baseline HIV-1 VL and CD4+ count) and adherence (measured using standard questionnaires at week 4, 104, and average adherence) data.
Results: Overall, 193 (49.9%), 150 (38.8%) and 44 (11.4%) patients had respectively low/none, intermediate and high-predicted RTI-activity in their prescribed second-line regimen. The average number of mutations by RTI drug class and proportion of patients by genotypic susceptibility scores category were statistically similar irrespective of treatment outcome. No resistance, demographic or adherence data were consistently associated with successful response. VL at switch was the only consistent prognostic factor (OR>1) for virological failure after multivariate adjustment. Findings did not differ when the second-line regimens or data on the patients with incomplete adherence information were included.
Conclusions: Genotypic resistance tests are not required to guide RTIs choice for second-line PI-based regimens in RLCs and probably NRTIs may be recycled. However, VL quantification during first-line treatment is crucial to promptly detect failure and avoid a greater VL increase, which may compromise future treatment outcome. Our findings stress the need for more studies on the drug resistance mutation-selection dynamics when a drug from a new class is added to the treatment.

MOPEB0344

Correlates and outcomes of transmitted drug resistance among adults starting first-line therapy in rural Uganda

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Background: Transmitted drug resistance (TDR) is increasing globally. However, correlates of TDR in sub-Saharan Africa are not well defined and could assist with risk stratifying patients initiating antiretroviral therapy (ART) in the absence of resistance testing. We sought to identify correlates of TDR and characterize its effects on mortality and loss to follow-up in Uganda.
Methods: We analyzed data from the Uganda AIDS Rural Treatment Outcomes study, a cohort of adults initiating first-line ART (2005 to 2015). We retrospectively sequenced reverse transcriptase on pre-ART specimens. We defined TDR as any WHO 2009 surveillance mutation and classified TDR level using Stanford susceptibility scores. We fit univariable logistic regression models with clinical characteristics as correlates and TDR as outcome. We then fit Cox proportional hazards models to assess whether TDR was associated with mortality and/or loss to follow-up.
Results: 643 subjects had pre-ART sequences. Median age was 34, and 69% were female. TDR was rare (N=21; 3.3%), and frequency seemed to increase over time, though trend was not significant (2.9% in 2005-2009 versus 4.4% in 2010-2013; P=0.36). Resistance to NRTIs (2.6%) was more common than NNRTIs (1.1%). Of those with TDR, 81% (17/21) had intermediate or high-level resistance to first-prescribed regimens. Female sex, no education, and each decrease in baseline $\log_{10}$ HIV RNA were significant correlates of TDR (Table). We identified a non-significant trend that TDR to first-prescribed ART regimen increased hazard of loss to follow-up (HR 2.75, 95% CI 0.85-8.84, P=0.09) but not mortality, though power was limited by low rates of TDR.
Conclusions: Female sex, no education, lower baseline viral load, and year (though non-significant) are correlates of TDR in rural Uganda. Further studies are needed to evaluate PMTCT practices as a potential factor in higher TDR risk in women. Greater vigilance is needed in the region if increasing rates of TDR are confirmed.

Variable	OR	95% CI	P value
Female	4.37	1.01-18.95	0.049
Age at ART initiation	0.95	0.90-1.01	0.107
Log10 viral load at ART initiation	0.45	0.26-0.79	0.005
CD4 at ART initiation	1.00	1.00-1.00	0.907
Year of ART initiation			
2005-2009 (reference)			
2010-2013	1.55	0.61-3.90	0.356
No education	3.05	1.13-8.25	0.028
Distance from clinic (km)	1.00	0.99-1.01	0.615

[Univariable Regression Models for TDR Correlates]

MOPEB0345

Surveillance of HIV-1 subtype and antiretroviral resistance in Cuban individuals failing therapy during 2009-2016

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Background: In Cuba, more than 70% of patients are currently under antiretroviral (ARV) therapy. In the year 2009 ARV resistance and subtype surveillance was introduced in clinical practice. This work aims to investigate the level and profile of ARV resistance and subtype distribution among HIV-1 patients failing therapy.
Methods: The study compiled data of subtype and genotypic resistance analysis performed to 756 samples of HIV-1 patients taken between April 2009 and December 2016 in Cuba. HIV-1 subtype was determined with Rega Subtyping Tool v.3. Drug resistance interpretation was conducted using the resistance algorithm Rega v9.1.0. For statistical analysis, the package SPSS v.19 was used.
Results: The most prevalent HIV-1 genetic forms were subtype B (30.6%), BG recombinants (22.7%) and CRF19_cpx (19.3%). Subtype B was more prevalent in MSM (p<0.001). Subtypes A, C, F, G and H prevailed among individuals diagnosed with HIV between the years 1986-1990 (p<0.05), while BGs recombinants increased over the other subtypes after the 2000 (p≤0.0001). Interestingly, viral variant CRF19_cpx, associated with rapid progression to AIDS in Cuba, significantly increased after the year 2011(14.9% in 2009-2011 to 21.3% in 2012-2016, p=0.01). The average of acquired drug resistance to NRTI, NNRTI and PI was 51.8%, 55.1%, 24.1% respectively and increased in patients with ≥48 months of treatment. The highest drug resistance levels against NRTIs, were detected for 3TC/FTC (76.9%); against NNRTIs were for NVP (71.2%) and EFV (70.9%); against PI for NFV (33.2%). Full-class resistance (FCR) to NRTI, NNRTI, PI, and MDR was detected in 19.0%, 32.8%, 10.0%, and 6.9% of the patients, respectively. When compared the period 2009-2011 with 2012-2014, a significant declining trend of NRTI- FCR (27.0 vs 13.4%), PI-FCR (15.2% vs2.0%) and MDR (21.1% vs 5.3%) incidence was noticed (p<0.05) Worrisome, during 2016 the incidence of FCR and MDR was increased again (23.2%, 22.3% and 19.6% respectively).
Conclusions: The genetic diversity of HIV in Cuba is high and the circulation of some local recombinant forms is increasing. The high level of resistance emphasizes the need of a therapy change for first line and a further integral analysis of this situation.

MOPEB0346

No impact of PI minority resistant variants on the virological response of a first-line PI-containing regimen

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Background: We assessed, in a clinical cohort of HIV-1-infected patients, the impact of minority resistant variants (MRV) harboring PI-resistance mutations at baseline on the virological response to a first-line PI-based regimen.
Methods: In an observational single-center cohort, all ARV-naïve patients initiating a first-line including 2 NRTI and DRV/r or ATV/r between January 2012 and March 2015, were enrolled. A virological failure (VF) was defined as two consecutive VL >50 c/mL following VL < 50 c/mL or absence of VL < 50 c/mL after six months of ARV. Protease (PR) ultra-deep sequencing was performed at baseline using Illumina® technology (cut-off=1%). PR mutations were identified using the WHO transmitted drug resistance list and IAS-USA major PI resistance mutations list. Supervised data mining analysis was performed to identify PR mutations associated with virological outcome. PR structural modeling analysis was performed using Fold-X software.
Results: Ninety-four and 16 patients initiated a DRV/r- or an ATV/r-based regimen, respectively, were assessed. Overall, median baseline VL and CD4-cell-count were 5.61 $\log_{10}$ c/mL and 345/mm^3, respectively. Twenty-eight percent of the patients were HIV-1 subtype B, 39% CRF02_AG and 33% other "non-B" subtypes. Thirteen patients (13.8%) in the DRV/r group and three (18.8%) in the ATV/r group experienced a VF, occurring at the median time of 15.5 months. Overall, 17 (15.5%) subjects had baseline PI-MRV at the median proportion of 1.3% (IQR=1.1-1.8), mainly G73C (n=5, 4.5%), M46I
(n=3, 2.7%) and M46L (n=2, 1.8%). The proportion of patients harboring baseline PI-MRV was similar between those in virological success (14.9%) and those experiencing VF (18.8%) (p=0.71). No difference was observed in the prevalence of PI-MRV by viral subtype (p=0.56) or by PI (p=0.27). Supervised data mining analysis identified three mutations significantly more prevalent in patients experiencing VF: T4A, E21D and I72M/T (p=0.02 for all). Structural modeling analysis showed that all these mutations induced some conformational changes of some PR side-chain residues located near mutated residues.
Conclusions: These findings, including for the first time DRV, showed the limited impact of baseline PI-MRV on virological response of a first-line PI-based regimen. In addition, we identified some new positions that could be involved in HIV-1 susceptibility to PI.

MOPEB0347

Resistance profile of GSK3532795

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Background: HIV-1 maturation inhibitors (MIs) disrupt the final step in the HIV-1 protease cleavage of the Gag polyprotein between capsid (CA) and spacer peptide 1 (SP1), leading to the production of non-infectious virus. In vitro studies were conducted with the MI GSK3532795 in order to understand its resistance profile.
Methods: Selection for in vitro resistance was performed in MT-2 cells with NL_{4-3} virus or recombinants containing polymorphisms in the gag gene. Gag/pr genes from selected viruses were sequenced and recombinant viruses with the selected changes were analyzed for susceptibility to ,795 and a newer generation MI. Selected amino acids were mapped to recently described structures of the purported region of MI binding to immature Gag capsids in order to better understand the mechanism for decreased susceptibility.
In vitro results were also correlated with genotypes and phenotypes observed in the 10 day Ph2a monotherapy proof of concept study.
Results: In cell culture, GSK3532795 primarily selected for the Gag changes A364V or V362I (with additional secondary substitutions in concert with V362I). In some cases, V362I was initially selected, but later replaced by A364V. Secondary substitutions observed in vitro in the capsid C-terminal domain (CTD) included R286K, A326T, T332S/N and I333V. By themselves, these changes imparted ≤ 2-fold reductions in susceptibility; however combinations of these changes, with V362I or V370A alone, or with V362I/V370A, exhibited 1.7- to >1000-fold reduced GSK3532795 susceptibility. A next generation MI with expanded polymorphic coverage retained complete activity toward ,795 selected viruses, except for A364V. The in vitro results with GSK3532795 correlated with genotypic substitutions observed in the Ph2a proof of concept study, with certain individuals exhibiting changes at V362, A364 or V370 showing a reduced antiviral response.
Conclusions: Reduced susceptibility to GSK3532795 in vitro and in the clinic mapped to defined amino acid changes within Gag. These changes occurred in the capsid CTD region or in or nearby SP1, and potentially reduced susceptibility through destabilization of a six-helix bundle structure involved in virus maturation. With the exception of A364V, a next generation MI retained activity against the emergent changes selected by GSK3532795.

MOPEB0348

Epidemiology of HIV drug resistance in HIV patients with virologic failure in the country of Georgia

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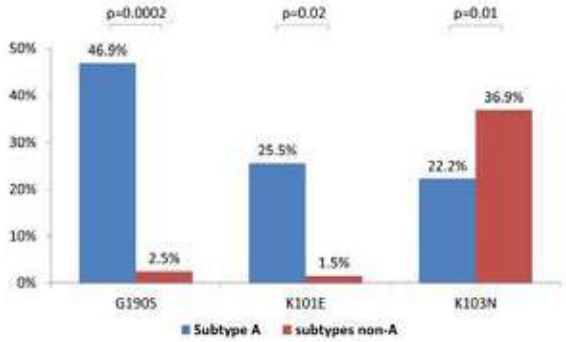
Background: HIV drug resistance is a major threat to sustained impact of antiretroviral therapy (ART). We studied epidemiology of HIV drug resistance in the Eastern European country of Georgia.
Methods: Study included all adult patients who experienced virologic failure on first line ART and received HIV drug resistance testing between 2004-2016. HIV pol gene sequences were examined for the presence of resistance-associated mutations. Stanford HIV Sequence Database was used for interpretation of resistance data. Patient-level data were extracted from the national AIDS health information system.
Results: Of 447 patients included 75.3% were men, leading routes of transmission were injection drug use (52.8%) and heterosexual contact (40.7%), 87.8% harbored Subtype A virus, 8.3% - subtype B, 3.0% - G, other subtypes were less than 1%. The most frequent first-line regimens were Tenofovir/Emtricitabine/Efavirenz (28.9%), Zidovudine/Lamivudine/Efavirenz (26.7%) and Abacavir/ Lamivudine/Efavirenz (15.9%). The majority (85.0%) of patients with treatment failure developed at least one drug resistance mutation affecting susceptibility to ART. The most commonly detected NRTI mutations were M184V (65.3%), K65R (19.7%) and L74V (17.0%). At least three thymidine analogue mutations were detected in 6.2%.
From NNRTI mutations G190S was shown to be the most prevalent (49.4%), followed by K101E (27.0%), K103N (24.4%) and Y181C (23.3%). G190S and K101E were more common in subtype A as compared to non-A viruses (G190S - 46.9% vs. 2.5%, p=0.0002; K101E - 25.5% vs. 1.5%, p=0.02).
On the other hand, K103N was more frequent in non-A subtypes (36.9%) compared with subtype A (22.2%), p=0.01.
Conclusions: Majority of persons failing on ART had HIV drug resistance. Subtype A may have distinct NNRTI drug resistance pattern with higher prevalence of G190S and K101E mutations. Prevalence of K65R mutation remains below 20% and given the high use of Tenofovir both for treatment and prevention, efforts are needed to prevent increase in resistance to this drug.



[Distribution of the mutations by subtypes]

MOPEB0349

Virologic suppression and emerging resistance on first-line antiretroviral therapy following universal test and treat: the ANRS 12249 cluster randomised trial

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Background: Poor virologic outcomes on antiretroviral therapy (ART) and HIV drug resistance pose the biggest threats to the success of ART scale-up for the individual and public health. We assessed virological response and emergence of drug resistance in a cluster randomised trial of universal test and treat strategy in South Africa comparing immediate ART initiation versus CD4-guided national guidelines.
Methods: HIV-positive individuals enrolled March 2012-June 2016 on ART ≥6 months were included and data from both trial arms were combined. Participants either transferred care from the public ART programme (Transferees; N=1389 or were new ART initiators within the ANRS 12249 trial (Initiators; N=983). A 1.3kb region of the pol gene was amplified, sequenced using the Sanger method, assembled in Geneious V9.1.5 and interpreted using the Stanford Drug Resistance algorithm. Chi-Squared or Mann-Whitney tests were used for comparisons as appropriate. Logistic regression was used to estimate odd ratios (OR) and their 95% confidence intervals (CI)
Results: 96% of Initiators were on fixed-dose combination of tenofovir+emtricitabine+efavirenz vs. 16% of Transferees. 6 months viral load (VL) was available for 908 Initiators; of whom 94% (851) achieved virologic suppression [VS] (VL<400 copies/mL). Amongst Transferees, 80% had VS at their first trial clinic visit after a median ART duration of 4.0years (IQR 2.2-6.0). For both groups, the probability of VS increased with every 100 cells/mm^3 increase in CD4 at initiation [adjusted OR=1.30 (95%CI=1.07-1.58) and 1.33 (1.14-1.55) for Initiators and Transferees respectively]
Of all 2372 individuals on ART ≥6 months, 227 (9.6%) experienced virologic failure [VF] (VL>1000 copies/mL ≥6 months on ART). Of 135 (59%) for which resistance testing was possible, 119 (88%) had ≥1 drug resistance mutation at VF: M184V/I (76%); K103N/S (56%); K65R (25%). The median plasma VL at VF was similar in individuals with and without the K65R mutation [35,504 copies/mL (IQR 4961-109,278) vs. 19,699 copies/mL (3,969-80,064); p=0.96, respectively].
Conclusions: Despite good levels of VS, we observed high levels of tenofovir resistance in individuals failing the recommended first-line ART. K65R did not confer a reduced infectivity (VL). Our data suggest that drug resistance may continue to emerge and spread during a test and treat strategy.

MOPEB0350

The application of artificial intelligence to predict response to different HIV therapies, without a genotype: new models for therapy optimisation in resource-limited settings

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Background: Optimisation of antiretroviral therapy in resource-limited settings (RLS) can be challenging without access to the newest drugs, or genotyping to help tailor therapy for the individual. Computational models have been developed to predict virological response to therapy but many require a genotype and have been developed using western data.
Here we describe the development of new models that do not require a genotype, using a large data set that includes substantial data from RLS and including, for the first time, tipranavir, maraviroc and elvitegravir.
Methods: Random forest (RF) models were trained to predict the probability of virological response (viral load < 50 copies/ml) to a new regimen following virological failure, using baseline viral load, CD4 count, treatment history, new drug regimen and time to follow-up from 52,270 treatment change episodes (TCEs), including 5,329 from RLS (4,190 from South Africa). The models were assessed during cross-validation, with an independent test set (n=3,000 including 461 from South Africa). The area under the ROC curve (AUC) was the main outcome. The predictive accuracy of the models was compared to genotyping using three rules-based interpretation systems to derive genotypic sensitivity scores (GSS).
Results: The models achieved a mean AUC of 0.83 during cross validation and 0.81 with the 3,000 TCE test set. Sensitivity was 73%, specificity 76% and overall accuracy 75%. For the South African test cases the models achieved an AUC of 0.76, sensitivity of 72%, specificity of 69% and overall accuracy of 70%. The AUC values for cases involving tipranavir, maraviroc and elvitegravir, ranged from 0.75 to 0.89. Of the 3,000 test TCEs, 634 had genotypes and the AUC for the GSS ranged between 0.55 and 0.57 - significantly inferior to the accuracy of the models ($p<0.0001$).
Conclusions: These new models, trained with our largest dataset so far, were able to predict response to HIV therapy significantly more accurately than genotyping with rules-based interpretation. They were accurate for cases from South Africa and cases involving new drugs. The models are freely available online at www.hivrdi.org/treps and have the potential to predict and avoid treatment failure by identifying potentially effective, alternative regimens.

MOPEB0351

Favorable drug-resistance background for successful use of dolutegravir in Botswana

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Background: Botswana is the first country in sub-Saharan Africa to use dolutegravir (DTG)-based cART as the first-line regimen on the national level. This study aims to survey the background prevalence of viral mutations associated with INSTI resistance before the national scale-up of DTG in Botswana starts in June 2016.
Methods: Blood samples were collected from HIV-positive participants in the Botswana Combination Prevention Project (BCPP) residing in 15 communities. A long-range HIV genotyping protocol was applied regardless of ART history. In addition to viral RNA, proviral DNA was used as an alternative template which makes HIV genotyping possible in individuals on ART.
INSTI resistance mutations were analyzed according to the IAS-USA 2015 list with the addition of H51Y and G118R mutations described recently. All viral sequences were screened for hypermutations (HM). Mutations in sequences with adjusted HM rate and HM ratio values above the 3rd quartile of the subset of viral sequences without mutations were considered to be generated by HM, and were not counted toward drug-resistant INSTI.
Results: The majority of genotyped individuals, 413 of 665 (62.1%; 95% CI 58.3-65.8%), were receiving ART and 405 (60.9%; 95% CI 57.1-64.6%) had undetectable HIV-1 RNA £400 copies/mL. After adjustment for HM, the proportion of individuals with any INSTI mutation was low, 0.75% (95% CI 0.24-1.75%). This included H51Y (0.15%), L74M (0.30%), E138A (0.15%), and Q148H (0.15%). Without adjustment for HM, the proportion of individuals with any INSTI mutation could be inflated: 5.41% (95% CI 3.82-7.42%) due to added mutations related to HM at amino acid positions G118R (0.46%) and R263K (1.20%), and an increase at position E138A (3.55%).
Conclusions: This is the first large study surveying the prevalence of INSTI resistance mutations on a population level in Botswana. A low prevalence, below 1%, of INSTI resistance mutations in Botswana provides a strong rationale for use of DTG as the first-line regimen nationally. Adjustment for HM seems to be an important step toward proper interpretation of viral mutations associated with HIV drug resistance, particularly if proviral DNA is used for amplification. The clinical significance of INSTI resistance in HM sequences needs further investigation.

MOPEB0352

Long-acting ibalizumab susceptibility in multi-drug resistant HIV patients

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Background: Ibalizumab (IBA) is a humanized monoclonal antibody that binds CD4 domain 2 and blocks HIV-1 entry. TMB-202 was a Phase IIb clinical trial investigating the safety, efficacy and tolerability of IBA administered by intravenous (IV) infusion every 2 or 4 weeks in patients with triple-class resistant HIV-1 infections. Viral resistance testing was performed to assess the activity of IBA against multi-drug resistant (MDR) HIV.
Methods: 113 patients with MDR HIV were treated with IV IBA in combination with an optimized background regimen. Baseline resistance test results for n=105 patients were evaluated to assess the IBA susceptibility of MDR HIV and of HIV with reduced susceptibility to the approved HIV entry inhibitors enfuvirtide (ENF) and maraviroc (MVC). IBA susceptibility was determined by maximum percent inhibition (MPI) and $IC_{HALFMAX}$ Fold Change (ICHMFC) in the PhenoSense HIV Entry assay (Monogram Biosciences).
Results: There was no significant difference in IBA MPI or ICHMFC between patient HIV isolates with wild-type susceptibility to nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), or protease inhibitors (PIs) (median MPI = 98%, 96%, and 97%, respectively; median ICHMFC = 1.1, 1.1, and 1.0, respectively) and isolates that were resistant to all NRTIs, NNRTIs, or PIs (median MPI = 99%, 99%, and 97%, respectively; median ICHMFC = 1.0, 1.0, and 0.9, respectively).
No difference in IBA susceptibility between patient HIV isolates with wild-type susceptibility to integrase inhibitors (INSTIs) (median MPI = 97%; median ICHMFC = 0.9) and those with resistance to INSTIs (median MPI = 95%; median ICHMFC = 0.9) was observed (n=17). IBA susceptibility was similar for patient isolates with wild-type susceptibility to ENF (median MPI = 96%, median ICHMFC = 1.0) and for those with reduced susceptibility to ENF (median MPI = 94%, median ICHMFC = 1.0). IBA susceptibility was similar for patient isolates with wild-type susceptibility to the coreceptor antagonist MVC (median MPI = 99%, median ICHMFC = 1.0) and for those with reduced susceptibility to MVC (median MPI = 98%, median ICHMFC = 0.8).
Conclusions: Ibalizumab is effective despite resistance to all other antiretrovirals. Ibalizumab is a potent new tool for treatment of MDR HIV.

MOPEB0353

Differential antiretroviral localization and drug transporter expression within gut-associated lymphoid tissue of HIV+ subjects: comparison to pre-clinical species

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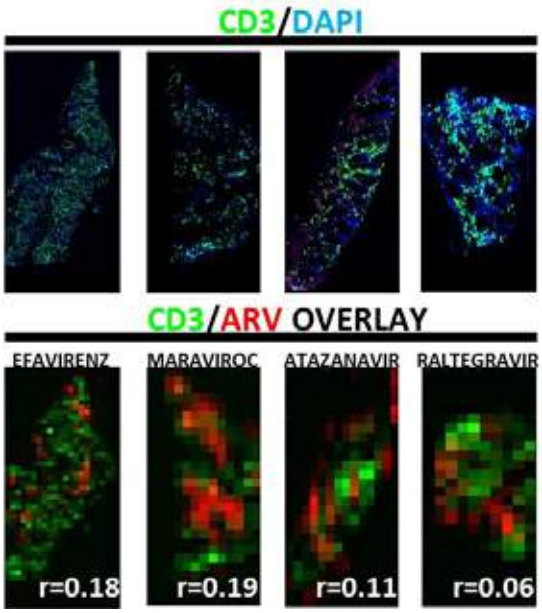
Background: Inadequate antiretroviral (ARV) exposure within gut-associated lymphoid tissue (GALT) may contribute to HIV persistence, but traditional LC-MS techniques cannot fully address this hypothesis. Mass spectrometry imaging (MSI) shows heterogeneous ARV distribution in GALT in animal models, which may be affected by drug transporters. However, application of these findings are limited without comparing these data to humans. Here, we assess ARV localization and drug transporter expression in HIV-infected subjects and make novel inter-species comparisons.
Methods: Ileum and rectum biopsies (n=10 each) were collected from five HIV-infected females receiving combination ARVs (Truvada® + raltegravir (RAL), efavirenz (EFV), atazanavir (ATV), or maraviroc (MVC)). Co-localization analysis of ARVs (measured by MSI) and T cells (measured by immunofluorescence) was performed in Matlab using Pearson correlation (r). Drug transporter protein concentration was measured from replicate biopsies by LC-MS/MS proteomics. Human data were compared to our previously generated animal data in non-human primates (n=12) and humanized mice (n=49) using ANOVA on ranks.
Results: ARV localization was heterogeneous within tissue and across therapeutic classes (Figure 1; rectum).



[Figure 1]

After correction for heme signatures, MVC and EFV showed the best ARV-T cell co-localization, which was 5-fold higher in the rectum versus ileum, and not significantly different (p>0.05) from data in primates or mice. Human drug transporter concentration was in better agreement with mice (1 to 9-fold difference) versus primates (1 to 21-fold difference), with 4-fold lower P-gp expression in primates.
Conclusions: We show that ARV distribution within biopsies is heterogeneous and may not co-localize with HIV target cells. This is consistent with animal data and may implicate ARV tissue exposure in the propagation of HIV GALT replication. Human drug transporter concentrations agreed with humanized mice better than primates, suggesting that the former may be a better animal model for developing novel ARV therapies targeted at GALT, particularly for P-gp substrates.

MOPEB0354

Can we talk about cost when choosing antiretroviral therapy? A 6 months survey with people living with HIV and prescribers in France

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Background: With more efficient and better tolerated antiretroviral therapies (ART), when various regimens with similar efficacy and adverse events profile are available national and international recommendations now discuss ART cost.
The aim of this study is to evaluate the PLHIV's (People Living with HIV) and prescribers' perception of talking about ART cost in PLHIV's management.
Methods: We proposed a community-based approach to assess the knowledge, beliefs and representations of ART cost among PLHIV followed-up in a French University Clinic and among HIV-specialists providing care.
The 2 questionnaires were built on data collected during focus groups with PLHIV and HIV-specialist prescribers of this North of Paris HIV-clinic. The pilot questionnaires were discussed in a multidisciplinary team of HIV activist organisations, social psychologists and clinical researchers.
Questionnaires were proposed to PLHIV coming in the clinic for their follow-up appointment between January-April 2016, and HIV-specialist prescribers were reached through email between March-June 2016.
Results: The 129 PLHIV and 79 prescribers who answered broadly represented our cohort of more than 4,700 PLHIV and local and national HIV-specialists respectively. Among PLHIV on ART, 80% (102/128) declared they know the cost of their ART, 65% (83/128) gave a fair estimation of the cost of their current regimen when 24% (19/79) of the prescribers thought that most of their patients precisely know it; 75% (97/129) PLHIV thought their prescribers should know ART cost.
Finally, 56% (72/129) of the PLHIV declared they could consider asking their HIV-specialist to switch to a less expensive ART regimen if effectiveness and side-effects would be the same.
Though: 67% (86/129) would not change if the number of pills or the dosing frequency would increase, 37% (48/129) if pills were bigger, while 64% expressed fear of more adverse events occurrence when switching (17% of prescribers thought PLHIV felt bad about switches).
Conclusions: PLHIV knowing ART cost seems unexpected by HIV-specialists; openly discussing the issue between them appears interesting. Our multidisciplinary research group works on guidelines for shared decision-making in ART regimen choice using these results. Their pilot implementation will be monitored in terms of medical, psycho-social and economic outcomes, with constant feedback from PLHIV and HIV-associations.

MOPEB0355

Factors associated with recruitment to antiretroviral therapy trials in a large London clinic

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Background: Some demographic groups are likely to be under-represented in antiretroviral therapy (ART) trials. We aimed to determine whether gender, ethnicity, or other factors were associated with non-participation in randomised controlled trials (RCTs) at a large HIV clinic in the UK.
Methods: Age, sex, ethnicity, country of birth, mode of transmission and home postcode were obtained from clinic databases on adult patients with >1 clinic visit at least 1 year apart in 2012-2016. Participation in ART trials running during the study period was ascertained from recruitment logs. Distance from clinic and socioeconomic indices were determined from postcodes. Associations between RCT participation and demographic variables were estimated using logistic regression.
Results: Of 5371 patients, mean age was 45.6 years (standard deviation [SD] 10.6). 947 (18%) were women. Of men, 3862 (87%) were men who have sex with men (MSM). The largest ethnic groups were white UK-born (1711, 32%), white non-UK-born (1841, 34%) and black African (950, 18%). Mean duration of clinic attendance was 11.5 (7.8) years, median distance from clinic was 6.2 km (interquartile range [IQR] 3.8-11.1), and median Index of Multiple Deprivation was in the third-lowest national decile (IQR 2nd- to 5th-lowest deciles). One hundred and fifty-four patients (2.9%) had participated in a RCT. RCT participation was positively associated with longer duration of clinic attendance (OR 1.45 per decade,

95% CI 1.20-1.76, p<0.001) and older age (OR 1.33 per decade, 95% CI 1.14-1.54, p<0.001). Associations with broad ethnicity and gender categories are shown in the table.

Ethnic category	Gender / orientation	Odds ratio (95% confidence interval)	p
White, UK-born	MSM	Reference category	
	Heterosexual men	0.74 (0.23-2.42)	0.62
	Women	0.32 (0.04-2.34)	0.26
White, non-UK-born	MSM	0.86 (0.59-1.26)	0.44
	Heterosexual men	0.93 (0.28-3.02)	0.90
	Women	0.44 (0.11-1.81)	0.25
Black or other minority ethnic group	MSM	0.52 (0.29-0.94)	0.029
	Heterosexual men	0.49 (0.22-1.07)	0.074
	Women	0.41 (0.22-0.77)	0.006

[Gender, ethnic factors and trial participation]

Conclusions: Women, those of black or minority ethnicity, younger patients and newer clinic attendees were less likely to participate in ART trials. We cannot ascertain if this is due to clinician- or patient-led factors. Ongoing qualitative work will explore research participation among HIV+ women. Meanwhile, efforts should be made to involve under-represented patient groups in trials.

Cure and Other Strategies

MOPEB0356

Use of herbal drugs by PLHAs: data from cross-sectional survey done at National AIDS Research Institute, Pune, India

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Background: Proportion of people living with HIV and AIDS (PLHAs) on antiretroviral therapy (ART) and PLHAs not on ART using Herbal drugs is not known in India. In this cross sectional survey we analyzed the frequency and reasons for use of herbal drugs,source of information about herbal drugs and reasons for not informing the use of herbal drugs to health care providers.
Methods: We screened 794 PLHAs on ART and 600 PLHAs who were not on ART attending our clinics in Pune for use of herbal drugs. PLHAs reporting use of herbal drugs were interviewed with a semi-structured questionnaire after taking written informed consent during September 2015 to November 2015.
Results: Use of Herbal drugs was reported by 11.3% (90/794) PLHAs on ART and 9.04% (56/600) PLHAs who were not on ART. Female to male ratio was 1.1:1 and median age was 43 years in both the groups. Herbal drugs were used to improve immunity and CD4 count in 45% of PLHAs on ART and 40% PLHAs not on ART. Herbal drugs were also used for co-morbid conditions like hemorrhoids, gastritis, hair fall, weight loss. Use of more than one herbal drug formulation was more common among PLHAs on ART (55.5%) rather than PLHAs not on ART (29%).
"Triphala churna "was the most common ingredient (n=45) in branded herbal drug formulations PLHAs used followed by herbal powder (n=36) and liquid (n=24) with unknown ingredients packed and dispensed in unlabeled paper envelopes and bottles.
28.8% PLHAs on ART and 25% PLHAs not on ART had not informed the use of herbal drugs to health care provider since nobody asked them about use of herbal drugs
Internet and local news papers were the source of Information for 57% of PLHA using herbal drugs rather than qualified Ayurvedic professionals (12%).
Conclusions: Herbal drugs are considered safe hence are neither taken under expert guidance nor the use is informed to health care providers. Immunomodulatory activities of herbal drugs need to be evaluated in clinical trials to generate evidence based results. There is a need to create awareness regarding use of herbal drugs among PLHAs as well as health care providers.

MOPEB0357

IPT (isoniazid preventive therapy) uptake among HIV-infected patients attending ART clinics in Southeastern Nigeria: a CQI initiative

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Background: Nigeria bears a major brunt of global HIV and TB burden with a prevalence of 4.1% and ratio of 323/100000 cases (National HIV sero prevalence survey 2010 and first National TB prevalence survey 2012). WHO recommends IPT as an effective TB prevention strategy to reduce the burden of TB among PLHIV (WHO 1998). A 12 month retrospective CCCRN ART program data revealed the rate of IPT uptake was low at 3.1%. The goal of this initiative was to increase rate of IPT uptake at CCCRN PEPFAR supported ART Clinics in SE Nigeria to reduce the burden of TB.
Methods: Capacity to implement IPT was evaluated at 49 PEPFAR supported treatment sites in three southeastern states in Nigeria. Criteria for evaluation included - Availability of clinician to evaluate for active TB; Access to TB Microscopy and Chest X-ray ;Capacity to prescribe and manage INH stock. A root cause analysis was conducted to identify reasons for low uptake. Interventions were identified and prioritized. A 3 day facility based IPT training for clinic providers was conducted; reporting tools were provided;' stick on ,reminder notes with the clinical screening algorithm were provided at strategic facility points. The primary outcome was defined as proportion of newly enrolled HIV patients who received IPT over a 12 month period from October 2014 to September 2015 and measured quarterly
Results: 40 sites (82 %) were eligible for IPT implementation. During study period, 5,045 newly diagnosed HIV positive clients were enrolled and 4,623 were found to be eligible for IPT. Patients receiving IPT increased from 3.1% in the first quarter to 24% in the last quarter. Most cited barrier to IPT uptake was isoniazid stock out and inadequate human resource at facilities to implement multiple parallel health initiatives.
Conclusions: Simple interventions can be used to scale up IPT in resource limited settings. To further strengthen IPT uptake, efforts should be dedicated towards retention of trained staff, positive reinforcement towards increased staff productivity and task shifting of non-essential duties from skilled staff to trained lay workers.

MOPEB0358

Sequential Vacc-4x/GM-CSF and romidepsin during combination antiretroviral therapy (cART): Vacc-4x/GM-CSF induced immune effects and changes in HIV reservoirs

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Background: The REDUC clinical study (NCT02092116) Part B investigated Vacc-4x/GM-CSF therapeutic vaccination prior to HIV latency reversal using romidepsin. Main findings showed statistically significant reductions from baseline in total DNA (39.7%; n=17, p=0.012) and in the inducible replication competent HIV reservoir (38%; n=6, p=0.019). Reductions in integrated DNA were not statistically significant (19%; n=15, p=0.123). Plasma HIV RNA remained undetectable throughout romidepsin treatment in 9/17 participants. Here we evaluated functional T-cell responses following Vacc-4x/GM-CSF immunotherapy in relation to virological outcomes on HIV reservoir measurements.
Methods: This single center study conducted in Aarhus, Denmark, enrolled participants (n=20) with CD4>500 cells/mm^3 on cART. Eligible participants received six Vacc-4x (1.2mg) intradermal (i.d) immunizations using rhuGM-CSF (60µg) i.d as local adjuvant at week (wk) 0,1,2,3,11,12 followed by 3 weekly intravenous infusions of romidepsin (5mg/m^2) at weeks 15,16 and 17. Immune responses were determined by IFN-γ ELISPOT and T-cell proliferation to p24 15-mer peptides at weeks 0, 15,

17 and 25. Participants showing a ≥2 fold increase in T-cell proliferation from baseline were defined as ‚responders'. Intracellular cytokine staining and viral inhibition were also determined.
Results: Participants (14/16; 87.5%) had robust ELISPOT responses at baseline. We observed the frequency of participants with positive CD8+ T-cell proliferation assay responses increased from 8/16(50%) at baseline to 11/15(73%) post-vaccination (wk15), a slight decrease during romidepsin (6/14(43%)) before recovering at wk25 (9/15(60%). These modest changes were not statistically significant. Positive CD8+ T-cell proliferation assay responses post-vaccination showed significant changes from baseline in total HIV DNA post-vaccination (wk15; p=0.00585) and after latency reversal (wk23; p=0.00506), and a change in CA-RNA post-vaccination (wk15; p=0.0152) unlike those with negative assay responses. The proportion of participants that showed increased CD8+ T-cell proliferation compared to baseline was 6/15(40%). These ‚responders' showed a statistically significant reduction in CA-RNA post vaccination from baseline (wk15; p=0.0277). There was a trend towards increased viral inhibitory capacity post-vaccination (wk15;p=0.08) and an increase in dual-functional (IFN-γ/TNF-α) CD8+ T-cells to HIV^{Gag} from baseline to post-romidepsin (p=0.039).
Conclusions: This study provides the first data supporting a relevance for including immune-based therapies in HIV ‚shock and kill' approaches to reduce HIV reservoirs during ART.

MOPEB0359

Predictors of HIV reservoir size in peripheral blood of perinatally HIV-infected children: preliminary results from EPIC4 (Early Pediatric Initiation, Canada Child Cure Cohort Study)

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Background: EPIC4 is a multicenter Canadian study investigating the impact of early initiation of combination antiretroviral therapy (cART) on HIV reservoirs and HIV-specific immune responses in perinatally infected children. Preliminary results on predictors of HIV reservoir size are described.
Methods: Cross-sectional analysis of children enrolled in EPIC4 with sustained virologic suppression (SVS) after initiation of their first cART regimen; children with intermittent virologic blips were included if SVS was subsequently achieved without cART regimen change. HIV reservoir size estimated by measuring viral load in cell culture supernatants following stimulation of CD4+ T-cells with a synthetic prostratin analog. HIV serologic responses were quantified using the Architect HIV-1/2 Ag/Ab combination screening test, expressed as signal-to-cutoff value (S/CO).
Results: Twenty-nine children with median age 10.7 years (range 4.2-18.4 years) were included; 62% were female. Median age at cART initiation was 1.3 years (range 1 day-16 yrs), age at SVS was 2.4 years (range 89 days-17.6 years), and duration of SVS was 6.5 years (91 days-14.5 years). Median reservoir size (copies/10^6 CD4 T-cells) was significantly lower for children initiated on cART prior to 6 months of age (n=10) compared to those started later (n=19) (median 3.4 copies/10^6 CD4 T-cells [IQR 0, 48.1] vs. 67.4 copies/10^6 CD4 T-cells [IQR 30.3, 287.3]; p=0.02). Five children had no detectable virus, three of whom initiated cART within 72 hours of birth. Reservoir size correlated directly with age at cART initiation (Spearman correlation, p<0.01) and age at virologic suppression (p=0.04) and inversely with proportion of life on cART (p=0.02); all correlations were more robust in analysis restricted to those without virologic blips (n=23; p<0.01). The magnitude of HIV serologic response (n=20) correlated directly with age at cART initiation and age at virologic suppression and inversely with proportion of life on cART and proportion of life with SVS (all p<0.001).
Conclusions: In perinatally HIV-infected children, earlier initiation of cART is associated with reduced HIV reservoir size in peripheral blood as estimated by the prostratin stimulation assay. Other potential predictors of reservoir size include age and duration of SVS, and magnitude of HIV-specific humoral immune response.

MOPEB0360

HIV-1 viral outgrowth during ART and rebound viremia during an analytical treatment interruption originate from genetically different proviruses

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Background: Integrated HIV-1 proviruses are a barrier to cure and cause viral rebound when antiretroviral therapy (ART) is interrupted. Most of the integrated HIV-1 DNA is known to be defective, however it remains unclear which intact HIV-1 proviruses have the capacity to produce infectious virions. Here we investigate the phylogenetic relationship between circulating proviruses, stimulated outgrowth viruses and rebound viremia.
Methods: In a clinical trial, 17 participants on suppressive ART were treated with six doses of the therapeutic HIV gag peptide vaccine Vacc-4x (Bionor Pharma) over 12 weeks, then three doses of romidepsin over three weeks followed by an analytical treatment interruption (ATI). Viral outgrowth assay (VOA) was performed at baseline, after the immunization phase and at follow-up. Four of the participants with a positive VOA were selected for sequencing analysis. CD4+ T cells were obtained from baseline, once during and after the immunization phase, twice during romidepsin therapy and at follow-up (total of six time points).
We performed single-genome/proviral sequencing of a 2.1 kb region spanning the p24-RT region on HIV-1 DNA and cell-associated (CA) RNA from peripheral CD4+ T cells, VOA supernatants and plasma HIV-1 RNA from the treatment interruption.
Results: One participant had a viral diversity of 0.1% and was excluded from phylogenetic analysis. In the remaining three participants we observed no instances of intermingling between stimulated outgrowth viruses and rebound viremia. In one participant we identified a viral outgrowth sequence from baseline that was identical to an expansion of 14 identical proviruses sampled from four time points as well as one CA RNA sequence sampled during romidepsin therapy. In another participant, we found an ATI plasma HIV-1 RNA sequence that was identical to an expansion of 36 identical proviruses sampled from all six time points. Notably this expansion was not identified in any of HIV-1 CA RNA sequences.
Conclusions: These results emphasize that expansions of identical proviruses may have the capacity to produce virions and are activated by romidepsin to produce cell-associated RNA. Furthermore, there was no overlap between the viral outgrowth and ATI sequences representing replication-competent virus, suggesting that activation of replication-competent provirus is a unique, random event.

MOPEB0361

Pharmacokinetics and pharmacodynamics of disulfiram on inducing latent HIV-1 transcription in a phase 2b trial

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Background: Disulfiram was well tolerated and activated viral transcription (cell-associated unspliced [CA-US] and plasma HIV RNA) in a phase 2 dose-escalation trial in HIV-infected individuals on suppressive antiretroviral therapy (ART). Here, we investigated whether exposure to disulfiram and its metabolites predicted these changes in HIV transcription.
Methods: The participants in a dose-escalation study of disulfiram at 500 mg (N=10), 1000 mg (N=10), and 2000 mg (N=10), given daily for 3 consecutive days were enrolled in the sub-study. Disulfiram and four metabolites were measured by ultra-performance liquid chromatography-tandem mass spectrometry on dosing days 1-3 as well as days 4, 8, and 31. Changes in CA-US HIV RNA in CD4+ T cells and plasma HIV RNA were quantified by PCR. Data were analyzed using the non-linear mixed effects approach in NONMEM. Pharmacokinetics of the metabolites were linked to the pharmacodynamics endpoints using an indirect response model.

Results: Disulfiram and four metabolites were simultaneously described using a seven-compartment PK model. The pharmacokinetics of disulfiram was not dose-proportional; its metabolites demonstrated non-linear elimination. The cumulative area under the curve (AUC_{total}) for disulfiram given at 500, 1000, and 2000 mg were 3,420, 8,942, and 23,834 mg*hr/L, respectively. Higher PK exposure was associated with greater increases in CA-US HIV RNA (Emax=134%, AUC_{50}=844 mcg*hr/L, P< 10^{-5}). There was no identifiable exposure-response for plasma HIV RNA, except for a suggestive association at day 31 (5.0-fold increase in plasma HIV RNA per fold-increase in AUC_{total}, P=0.050). We also observed that participants with higher pre-disulfiram plasma HIV RNA had higher post-disulfiram plasma HIV RNA, and that participants in the lowest dose (500 mg) cohort had higher median baseline plasma HIV RNA.
Conclusions: Despite considerable inter-individual variability in PK, there were statistically significant increases in CA-US HIV RNA with increasing exposure to disulfiram. A similar trend was seen with plasma HIV RNA at day 31, but higher observed responses in participants with greater baseline plasma HIV RNA may have confounded the overall interpretation. Given the toxicity of other latency reversing agents (LRAs) currently being tested in HIV cure trials, these results provide rationale for further development of disulfiram as a safe and potentially effective LRA.

MOPEB0362

Immunovirological evolution in HIV-infected patients treated with anti-PD1 therapy

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Background: Immune checkpoint-blocking antibodies can reverse T cell anergy, boost immune responses against tumors, and has become the new standard of care for second-line treatment of advanced non-small cell lung cancer (NSCLC). The question of whether anti-PD-1 could be a tool for HIV-cure is still pending. Here we report for the first time the clinical experience in 12 HIV-infected patients treated with the anti-PD-1 antibody nivolumab, and the detailed immunovirological evolution in one patient with lung cancer.
Methods: Twelve HIV-infected patients (10 male, 1 female, 1 transgender) received nivolumab as a second line therapy for NSCLC (n=11) or melanoma (n=1). Ultrasensitive plasma viral load (US-VL), HIV-cell associated DNA, phenotypic and functional T cell analysis, intracellular-cytokine-staining assay against 15-mer HIV peptides, and plasma IL-6 levels were quantified at all time points (D0, D14, D30, D60, D120) in one patient.
Results: In the 12 patients, best tumoral response was partial response (n=3), stability (n=5), or progression (n=4). All plasma HIV viral load were undetectable at D0, and no viral rebound was further observed. CD4 and CD8 cell counts were slightly modified upon nivolumab in only 5/12 patients (median 338 and 674/mm^3 at D0; 351 and 525/mm^3 after 3 or 4 nivolumab injections). In one patient, US-VL was undetectable and stable, but a slight 2-fold increase in HIV-cell associated DNA levels was observed (116 at D0 vs 213 copies/10^6 PBMC at D30). IL-6 plasma levels peaked at D14 (539 pg/mL) and returned to normal beyond D60. PD-1 and LAG3 expression on total CD4 and CD8 T cells decreased at D30. PD-1 expression remained low at D120 whereas LAG3 expression returned to D0 level. HIV-specific IFNg+CD8+ cells increased from 0.1% at D0 to 0.4% at D30. Finally, the total transitional-memory (CD8+CCR7-CD27+CD45RA-, TM) CD8 population increased (+64%) while the RA-re-expressing effector-memory cells decreased (-41%) at D120.
Conclusions: Our data suggest that nivolumab is well tolerated in HIV-infected patients, is successful at enhancing the capacities of HIV-specific CD8 TM cells to proliferate and to secrete cytokines, expanding the PD-1low T cell subset, with no or little impact on HIV replication or reservoirs.

MOPEB0363

Implementation of routine multivitamin supplementation decreases mortality and improves treatment outcomes for Tanzanian HIV-infected adults enrolled in care

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Background: Randomized trials indicate that multivitamin supplementation may be an effective intervention to reduce mortality and slow HIV progression. The objective of this study was to evaluate implementation of routine multivitamin supplementation on mortality and health outcomes within a large HIV care and treatment program in Tanzania.
Methods: The urban Dar es Salaam HIV care and treatment program provided adult patients with multivitamin supplements (containing vitamins B-complex, C, and E) as routine care during 2004-2012; however, stockouts and other implementation issues did not afford universal coverage. We present a prospective cohort study of the 67,707 adult program participants during this period and use multivariate Cox proportional hazard models to assess the time-varying association of multivitamin supplement provision with mortality and HIV progression outcomes.
Results: The study cohort was seen at 1,731,385 clinic visits and contributed 170,855 person-years of follow-up time. Multivitamins were provided at 86% of all ART-naïve clinic visits and at 55% of all ART clinic visits. Among 48,207 ART-naïve adults, provision of multivitamins significantly reduced the risk of mortality (adjusted hazard ratio (aHR): 0.67; 95% CI: 0.58-0.78), incident tuberculosis (TB) (aHR: 0.78; 0.72-0.85), and reaching ART eligibility criteria (aHR: 0.75; 95% CI: 0.70-0.80) after adjustment for possible confounding. Similarly among 46,977 ART-experienced patients, multivitamin provision reduced the risk of mortality (HR: 0.87; 95% CI: 0.82-0.93), incident TB (aHR: 0.86; 95% CI: 0.80-0.92), and immunologic failure (aHR: 0.76; 0.73-0.78). There was no indication multivitamin provision increased the risk of hepatotoxicity.
Conclusions: In the context of a large urban adult HIV treatment program in Tanzania, implementation of routine pre-ART and ART-adjunct multivitamin supplementation was a simple, effective, and safe intervention to improve survival, reduce incidence of TB, and improve treatment outcomes.

MOPEB0364

Impact of serum-derived bovine immunoglobulin (SBI) on vitamin D metabolite levels in subjects with HIV enteropathy measured by a novel sensitive method using mass spectrometry

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Background: The mechanism(s) for vitamin D (VitD) deficiency and the optimal metabolites that should be measured are controversial. SBI is an oral medical food the neutralizes bacterial antigen in gastrointestinal (GI) tract, improves mucosal immunity, and reduces systemic inflammation in patients with HIV enteropathy. We measured VitD metabolites by a novel methodology in patients receiving SBI to explore correlations with immune reconstitution and inflammation.
Methods: Eight virologically-suppressed patients on multiple stable regimens with HIV enteropathy received SBI 500 mg orally twice daily for eight-weeks with a 4-week washout period. We validated a novel derivatization reagent (PyrNO) to abrogate isomeric endogenous-species interferences for mass spectrometry according to FDA guidance using DEQAS reference samples. 1,25-vitaminD3 (the active metabolite), 25-vitD3, C3-epi-25 vitD3, 25 vitD2, C3-epi-25 vitD2, and 24,25 vitD3 were measured at weeks 0, 7 and 12 from plasma. GI immune reconstitution was measured from duodenal biopsies and plasma biomarkers for inflammation and microbial translocation were measured by ELISA. Values are reported as medians (range)(Wilcoxon signed-rank p-value). Correlations between parameters were calculated by dividing the timepoint in question by the baseline value and performing Pearson correlations.
Results: Resolution of GI symptoms, duodenal immune reconstitution, and improved systemic inflammation/microbial translocation have been previously published. Levels increased from baseline to week 7 and continued to rise to week 12. 25VitD3 went from 12.45 (10.8-32.5) to 23.99 (16.7-39.9) (p=0.055) and

1,25VitD3 went from 0.026 (0.012-0.052) to 0.034 (0.021-0.078) at week 12 (p=0.039). Correlations between increased duodenal CD4 density and 25VitD3 (R^2=0.54, p=0.04) and 1,25VitD3 (R^2=0.74, p=0.006) were observed at week-7. We also observed correlations between decreased MCP-1, a biomarker of monocyte activation and 25VitD3 (R^2=0.77, p=0.004) and 1,25VitD3 (R^2=0.82, p=0.002) and between decreased BPI, a biomarker of gram-negative microbial translocation, 25VitD3 (R^2=0.89, p=0.0004) and 1,25VitD3 (R^2=0.93, p=0.0001), all at the week 0-7 timepoints.
Conclusions: In this small exploratory cohort, VitD metabolites improved during treatment with SBI due either to improved absorption or the impact of SBI on inflammatory pathways that impacted improved immune reconstitution, reduced systemic inflammation and/or microbial translocation. This novel PyroNO method for measuring the most relevant metabolites of VitD in HIV patients can be used in future research into the association between VitD and immune reconstitution.

Prevention of HIV Transmission from Mother to Child and in Other Populations

MOPEC0595

High rates of mother to child HIV transmission among pregnant and breastfeeding women with delayed HAART initiation in Kenya

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Background: Despite rapid scale up of highly active antiretroviral therapy (HAART) among pregnant and breastfeeding women, mother to child HIV transmission (MTCT) remains high in Kenya at 7% at 6 weeks and 17% at 18 months. The study evaluated MTCT rates among women receiving routine prevention of mother to child HIV transmission (PMTCT) services at Eastern Deanery AIDS Relief Program (EDARP) sites in Nairobi, Kenya.
Methods: A retrospective chart review of mother-infant pairs enrolled in all 14 EDARP sites for PMTCT between January 2013 and January 2015 was done. HIV-infected women who received HAART (defined as 2NRTI +1NNRTI or PI) were included. Five percent of charts with incomplete information were excluded. Quantitative data were analyzed using STATA. Timing of HAART initiation, maternal viral suppression, and 6 week and 18 month MTCT rates were obtained using descriptive statistics. We controlled for confounding factors for MTCT and obtained odds ratios at bivariate and multivariate analyses.
Results: We reviewed 1,440 mother-infant pair charts. Median maternal age was 29 years (IQR 25-34 years). Timing of maternal HAART was: 55% pre-pregnancy, 17% at 1st and 2nd trimester, 8% in 3rd trimester and 20% postpartum. There were 395 maternal viral load (VL) results: 82% < 1000 copies/ml and 18% >1000 copies/ml. Uptake of infant ARV prophylaxis was 94%. MTCT rates were 2.7% at 6 weeks and 4.5% at 18 months. HAART initiated in third trimester or post -delivery was associated with higher MTCT rates compared to pre- pregnancy or 1st or 2nd trimester, adjusted odds ratio (AOR) 3.2 (95% CI, 1.6 -6.3), p-value=0.001. Lack of, or undocumented infant ARV prophylaxis was independently associated with higher MTCT rate, AOR 3.4 (95% CI, 1.6-7.3) p= 0.001. MTCT rates were higher among women with a VL > 1000 copies/ml, crude Odds Ratio 4.5 (95% CI, 0.6 -32.5) p= 0.135; VL sample size was underpowered to detect a statistically significant difference.
Conclusions: High MTCT rates are associated with delayed HAART initiation for PMTCT and lack of infant prophylaxis. To achieve virtual elimination of MTCT efforts should be made to improve case identification and early initiation of HAART in the pre-partum or intrapartum period

MOPEC0596

Male partner HIV testing is associated with maternal HIV retesting in pregnancy: a prospective cohort study

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Background: World Health Organization recommends maternal HIV retesting in pregnancy for timely identification of HIV-negative women who seroconvert so as to offer interventions that minimize risk of mother-to-child HIV transmission. We evaluated whether couple-based male partner HIV testing, an elimination of mother-to-child HIV transmission (EMTCT) strategy, increased maternal HIV retesting
Methods: This was a prospective cohort study nested within a randomized controlled trial comparing effectiveness of home-based versus clinic-based couple education and HIV testing on maternal and perinatal outcomes in Nyanza, Kenya. Eligible HIV negative women in stable relationships were enrolled antenatally and followed until 6 weeks postpartum from September 2013 to June 2014. Using facility records and study data, we defined association between male partner HIV testing and maternal HIV retesting and determined if the association was modified by the venue of male partner testing or the woman's awareness of male partner testing before pregnancy. Odds ratios (OR) for associations were obtained using logistic regression. Adjusted OR were estimated in a multivariable regression model adjusting for potential confounders. In stratified analyses, we assessed modification of the association between male partner HIV testing and maternal HIV retesting.
Results: Among 408 HIV negative women, 103 (25%) underwent couple-based male partner HIV testing. Baseline characteristics were similar between women who tested alone and those who tested with partners. The majority of women were young, with median age 24 years, in second trimester (median 20, IQR 17-25 weeks), and during follow-up most (81%) delivered in government institutions. Overall, 311 (76%) of women were retested for HIV. Maternal retesting was higher if women tested with their male partners (n=94 of 103, 91%) compared to testing alone (n=217 of 305, 71%). In the crude analysis, male partner testing was associated with four-fold greater odds in maternal HIV retesting OR 4.24; 95% Confidence interval (CI) [2.05-8.77]; P <0.001). This association persisted in adjusted analysis (OR 4.95; 95% CI [2.29-10.72]; p<0.001), and did not vary by either venue (p=0.734) or pre-pregnancy knowledge (p=0.483) of male partner testing
Conclusions: Couple-based male partner HIV testing during pregnancy is associated with increased maternal HIV retesting and may contribute to accelerated progress towards EMTCT

MOPEC0597

Effects of PMTCT-interventions and feeding-options on the HIV vertical transmission in Yaoundé-Cameroon: targeting areas for improved implementation

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Background: The advent of antiretrovirals has significantly contributed in eliminating mother to child transmission of HIV (eMTCT) in high-priority countries, with a rate from 12.10% in 2010 to 5.6% in 2015 MTCT in Cameroon. Though countries are transitioning to option B+, there are settings where prophylaxis is still applied, thus indicating the need to evaluate the extent to which such PMTCT-intervention might contribute in eMTCT. Our study aimed at assessing the effect of different PMTCT-interventions and feeding options on eMTCT.
Methods: A cross-sectional study was conducted among 218 HIV+ mothers and their infants at the Chantal BIYA International Reference Centre for research on HIV/AIDS prevention and management (CIRCB) in Yaoundé-Cameroon from January 2013 to September 2015. A standard questionnaire was used to collect data on the maternal PMTCT-regimen; and early infant diagnosis of HIV was performed using the roche PCR amplicor kit version 1.5. Statistical analysis were performed using Mann Whitney U test, with p< 0.05 considered significant.
Results: The overall rate of MTCT was 19.9% (42/218), with a statistically significance between the four groups (triple antiretroviral therapy [ART] (9%) vs.

biprophylaxis (11%) vs. monoprophylaxis (19%) and ARV-naïve (37% for) group (p<0.0002). Specifically, the group of mothers exposed to triple ART or monoprophylaxis exhibit significant reduction in MTCT compared to ARV-naive mothers (p<0.0001 or p=0.04 respectively). According to feeding options, infants exposed to mixed feeding had the highest rate of MTCT (43%) compared to those on exclusive breastfeeding (20.1%) or formula feeding (12.5%), p=0.005.
Conclusions: The present finding underscores the necessity of scaling-up option B+, including at primary healthcare levels in all PMTCT high-priority countries. Similarly, efforts to limit the practice of mixed feeding would be of great relevance in eMTCT. Thus, strategies supporting the wide implementation of these policies would greatly contribute to the virtual eMTCT and an AIDS-free generation in children.

MOPEC0598

Mother to child transmission of HIV and retention in care of HIV-exposed children enrolled in Malawi's national HIV program

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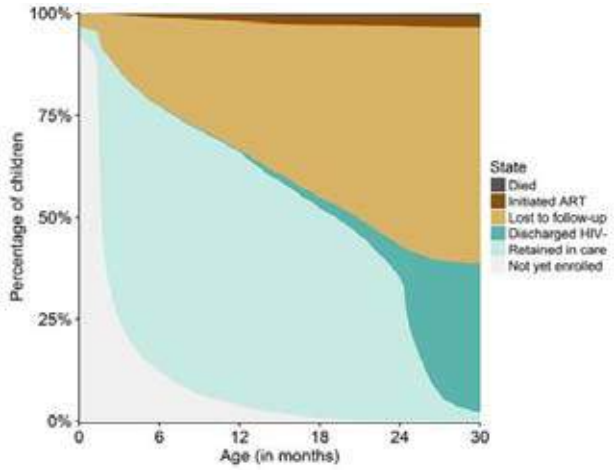
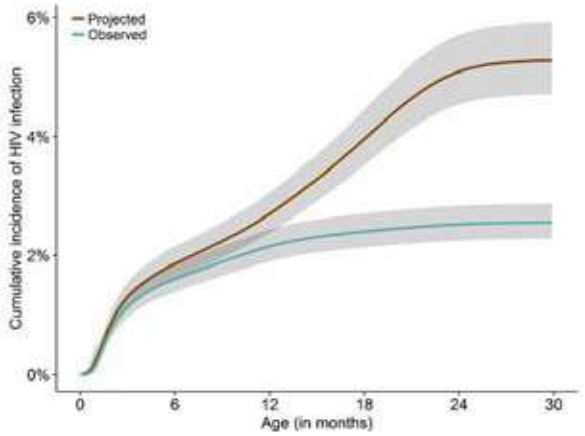
Background: In Malawi, HIV-infected pregnant and breastfeeding women receive antiretroviral therapy (ART) according to Option B+ and HIV-exposed children are enrolled in the national HIV program. We examined retention and risk of HIV mother-to-child transmission among HIV-exposed children enrolled in Malawi's HIV program.
Methods: We abstracted data from routine patient records at 21 health facilities, and included HIV-exposed children enrolled into care between September 2011 and June 2014. We used competing risks models to estimate the probability of retention, loss to follow-up, discharge, ART initiation, and death, and used pooled logistic regression and inverse probability of censoring weighting to estimate the mother-to-child transmission risk at the end of breastfeeding.
Results: More than 80% of 11,285 children were born to women who initiated ART during pregnancy. By the time children were 30 months old, 57.9% were lost to follow-up; 36.5% were discharged HIV-free (Figure 1). Loss to follow-up was highest among children who enrolled late, who did not receive nevirapine prophylaxis, or whose mothers were not on ART. We projected that 5.3% (95%-confidence interval 4.7-5.9) of the children who enrolled were HIV-infected by the age of 30 months, but only 2.6% (95%- confidence interval 2.3-2.9) were diagnosed (Figure 2).
Conclusions: Mother-to-child transmission rates were low, but due to poor retention, less than half of the projected total number of HIV-infected children were diagnosed. We recommend implementation of infant defaulter tracing and HIV testing of children in immunization centers and out-patient clinics to ensure that all HIV-positive children have access to early ART.



[Figure 1: HIV care outcomes]



[Figure 2: Cumulative incidence of HIV infection]

MOPEC0599

"Real life" use of raltegravir during pregnancy in France: the Coferal-IMEA048 retrospective study

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Background: Few "real life" data on raltegravir use during pregnancy are available.
Methods: Data on women receiving raltegravir during pregnancy between 2008 and 2014 in ten selected clinical centers across France were collected retrospectively. The primary objective was to describe the proportion of women who received raltegravir anytime during pregnancy and achieved an HIV-RNA < 50 copies/ml at delivery. Secondary objectives were to describe demographic and immune-virological characteristics, timing of raltegravir initiation during pregnancy and pregnancy outcome.
Results: Ninety-four women were included: median age was 33 years, 80/94 originated from Sub Saharan Africa, 15/94 did not have a regular health insurance coverage, 16/94 were antiretroviral treatment (ART) naïve (HIV diagnosis at a median of 30 weeks of gestation)and 78/94 were already on ART before pregnancy (40% of them had an HIV-RNA <50 copies/ml). In those with an HIV-RNA >50 copies/ml before pregnancy, median HIV-RNA was 9823 copies/ml (range 63 - 638388). 33/94 were already on a raltegravir-based ART before pregnancy, and raltegravir was initiated during the second trimester in 11/94 (2 switch for intolerance of boosted-protease inhibitor and 9 intensification because HIV-RNA was >50 copies/ml) and during the third trimester in 50/94 (34 intensification and 16 ART initiation in naïve late-comers pregnant women). Raltegravir was well tolerated during pregnancy with no discontinuation due to adverse event. Overall, at the time of delivery, HIV-RNA was <50 copies/ml in 70% and <400 copies/ml in 84% of women. Interestingly, at delivery, HIV-RNA was <50 copies/ml in 82%, 54.5% and 56% of cases when raltegravir was started before pregnancy, during the second or during the third trimester of pregnancy, respectively. Median term was 38 weeks of gestation (20% before 37 weeks), with vaginal delivery in 49% and C-section in 51% of cases. Median newborns' weight was 3.1 kg, no defect was reported and all were HIV-negative at Month 6.
Conclusions: Raltegravir appears safe and efficacious in this "real-life" study, with the achievement of an undetectable HIV-RNA at delivery in 70% of pregnant women overall: 82% when started before pregnancy and 56% when started during the third trimester. No defect was reported in newborns and all were HIV-negative.

MOPEC0600

Viral suppression at delivery among pregnant women newly initiated on antiretroviral therapy (ART) during pregnancy: PMTCT Option B+ in Malawi

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Background: Effective ART for PMTCT reduces HIV viral load in pregnant women to minimize vertical transmission during pregnancy, labor or delivery. In PMTCT Option B+ programs, HIV-infected pregnant women who are not on ART are started on ART during pregnancy and continued for life. As women may present late in their pregnancy for first antenatal care, whether women achieve viral suppression by delivery and how suppression varies with time on ART is unclear.
Methods: We conducted a prospective cohort study of HIV-infected pregnant women initiating ART for the first time under PMTCT Option B+ program at Bwaila Hospital in Lilongwe, Malawi from June 2015 to November 2016. We used multivariable Poisson models with robust variance estimators to estimate risk ratios (RR) and 95% confidence intervals (CI) of the association between duration of ART and both viral load (VL) ≥1000 copies/ml and VL ≥40 copies/ml at delivery.
Results: Among 300 women enrolled, the median gestation age at first antenatal visit was 22 weeks (Interquartile rage (IQR): 18.2 - 26). The median duration of ART prior to delivery was 17 weeks (IQR: 13 - 21). Of the 253 women (84%) who had viral load test at the time of delivery, 40 (16%) and 78 (31%) had VL ≥1000 copies/ml and VL ≥40 copies/ml respectively.
Compared to women who were on ART ≤12 weeks at the time of delivery, women who were on ART 13 - 20 weeks (RR = 0.52; 95% CI: 0.36 - 0.74) or 21 - 35 weeks (RR = 0.26; 95% CI: 0.14 - 0.48) were less likely to have VL ≥40 copies/ml.

	Viral load at delivery			
Duration of ART	≥1000 copies/ml (N=40)	<1000 copies/ml (N=213)	Unadjusted RR (95% CI)	Adjusted RR † (95% CI)
≤ 12 weeks	15 (37.5)	42 (19.7)	1.00	1.00
13 - 20 weeks	19 (47.5)	106 (49.8)	0.58 (0.32, 1.05)	0.67 (0.37, 1.22)
21 - 35 weeks	6 (15.0)	65 (30.5)	0.32 (0.13, 0.78)	0.36 (0.15, 0.90)
	≥40 copies/ml (N=78)	<40 copies/ml (N=175		
≤ 12 weeks	32 (41.0)	25 (14.3)	1.00	1.00
13 - 20 weeks	35 (44.9)	90 (51.4)	0.49 (0.35, 0.72)	0.52 (0.36, 0.74)
21 - 35 weeks	11 (14.1)	60 (34.3)	0.28 (0.15, 0.50)	0.26 (0.14, 0.48)
†Adjusted for age, BMI, baseline CD4 cell count, baseline viral load, education, marital status, parity, and HIV WHO clinical stage				

[ART duration at delivery and viral suppression]

Conclusions: Women with longer duration of ART during pregnancy had lower risk of non-suppressed viral load at delivery. Countries implementing PMTCT Option B+ should encourage early ANC attendance in pregnancy to facilitate prompt ART initiation for HIV-positive women.

MOPEC0601

Prevalence of antiretroviral therapy (ART) treatment failure among HIV-infected pregnant women at first antenatal care: PMTCT Option B+ in Malawi

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Background: ART treatment failure can lead to the development of HIV drug resistant (HDR) strain. For HIV-infected pregnant women, the HDR strain can be transmitted to the child, resulting in impaired ART efficacy in both mother and child. In Malawi´s PMTCT Option B+ program, HIV-infected pregnant women who are already on ART are continued on therapy without testing for treatment failure at the first antenatal care (ANC). As women are not tested for treatment failure, the prevalence of treatment failure among women who are already on ART at first ANC is unknown.
Methods: We conducted a cross-sectional study of HIV-infected pregnant women who were on ART at the first ANC under PMTCT Option B+ program at Bwaila Hospital in Lilongwe, Malawi from June 2015 to December 2016. We used logistic regression models to investigate predictors of ART treatment failure.
Results: A total of 434 women were tested for ART treatment failure and their median age was 30.8 years (interquartile range: 26.9 - 34.2). Of the women tested 402 (93%) were married, 343 (82%) were in HIV-WHO stage 1, and 353 (82%) attended first ANC during the 2nd trimester. The overall prevalence of ART treatment failure was 7.1% (95% confidence interval (CI): 5.1 - 10.0). Compared to women with none or primary education, women with secondary or tertiary education had an indication of reduced odds of having developed treatment failure, odds ratio (OR) = 0.67, 95% CI: 0.27 - 1.70. For women who knew their partners' HIV status, women with HIV-infected partners had an indication of reduced odds of having developed treatment failure (OR = 0.45, 95% CI: 0.10 - 2.03) compared to those with HIV-uninfected partners.
Conclusions: A notable number of pregnant women who were already on ART at first ANC had ART treatment failure. Countries implementing PMTCT Option B+ but have limited resources for HIV-RNA screening at first ANC should develop mechanisms that will identify women at risk of having developed ART treatment failure to prompt switch to an alternative and effective ART regimen during pregnancy.

MOPEC0602

Level and predictors of receiving essential mother-infant PMTCT services in Tanzania: maternal ART adherence, infant ARV prophylaxis and early diagnosis

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Background: Full PMTCT service adherence, including maternal ART, HIV-exposed infant (HEI) nevirapine (NVP) dosing, and early infant diagnosis (EID), is not routinely measured in Tanzania's PMTCT program. This secondary cohort analysis from 27 PMTCT clinics describes the level and predictors of full PMTCT adherence.
Methods: The Supporting Attendance for Facility Delivery and Infant Health study recruited HIV-positive pregnant women, administering interviews at enrollment and 12-weeks postpartum, with medical-record-abstraction of outcomes. Mother-infant PMTCT adherence--defined as maternal ARV adherence (zero self-reported missed ARV doses in past seven days and not missing two consecutive days of ARV dosing in past six months) HEI NVP birth/6-week dosing, and EID--is described among 584 women-infant pairs. Generalized-estimating-equation regression methods were used to predict PMTCT adherence, adjusting for age, education and site cluster. Hypothesized predictors included known/new HIV-positive, phone access/contact with health providers, ART/MTCT knowledge, facility delivery and clinic volume.
Results: Among HEI overall, 75% received the full NVP regimen; and 70% received both NVP and EID. Maternal ART adherence was 83%, and predicted receipt of HEI services. Eighty-one percent of ART-adherent mothers' HEI received NVP and EID compared to only 51% of non-adherent mothers (p<0.0001). Overall, 67% of mother-infant pairs were PMTCT adherent.
Factors reducing PMTCT adherence were pre-ART status compared to women on ART before pregnancy (known-positive, pre-ART: adjusted odds ratio [AOR] 0.28, p<0.0001; newly diagnosed HIV-positive, pre-ART: AOR 0.25, p<0.0001); and loss of mobile phone access (AOR 0.48, p=0.006) compared to maintaining access from baseline to follow-up. Factors positively associated with PMTCT adherence included knowing that ARVs reduce MTCT risk (AOR 3.18, p<0.0001), delivering in a facility (AOR 2.90, p<0.0001), having phone contact with a health provider (AOR 2.33, p<0.0001), and attending a low-volume ANC facility compared to a high-volume ANC (AOR 5.28, p<0.0001; <90 new patients/quarter vs. >=200).
Conclusions: Increased client-provider interaction may improve PMTCT adherence through promoting ART/PMTCT knowledge and access to facility delivery. Special attention should be focused on newly diagnosed and newly ART-initiated. Facilitating provider-client communication using mobile phones may enhance effectiveness of PMTCT service models. Further investigation is needed to understand why lower volume ANC clinics are associated with better adherence.

MOPEC0603

Risk factors for loss to follow-up before delivery: identifying those most in need of retention interventions

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Background: Cohort monitoring of prevention of mother-to-child HIV transmission (PMTCT) retention under Option B+ often begins at ART initiation, rendering vulnerable newly-diagnosed pregnant women who delay or refuse ART uncounted. Understanding factors linked to early non-retention among all HIV-positive pregnant women (PW) can improve retention interventions.
Methods: A retrospective cohort study using medical record abstraction of 917 HIV-positive pregnant women receiving any PMTCT services from January 2012 to June 2015 was conducted at 12 clinics in four regions of Tanzania. Data sources included ANC/HIV clinic registers and HIV medical charts which documented testing status, ART initiation or pre-ART status, pregnancy/delivery, and clinic attendance history. The outcome of interest was early PMTCT retention, defined as having a documented antenatal entry visit and a documented delivery.
Results: Overall, early PMTCT PW retention was 70% (95% CI: 67,73), and did not differ before or after the introduction of Option B+ in October 2013 (p=.66). PMTCT PW retention among ART-initiated was 85% (CI:82,87), compared to only 22% (CI:17,28) among PW who did not initiate ART during pregnancy. High PMTCT PW retention (93%) was observed among women who started ART before pregnancy, while only 76% of those starting ART during pregnancy were retained (p<0.0001). Among known-positive PW whose partners tested, 94% were retained to delivery compared to 78% whose partners did not test (p<0.04). After introduction of Option B+, 19% of newly-diagnosed PW were lost prior to ART initiation, which represented 48% of all non-retained PW.
Conclusions: Option B+ policies have not resulted in universal ART initiation among PW in Tanzania. One-in-five PW delay or refuse initiation of ART, contributing to sub-optimal early PMTCT-PW retention and accounting for nearly half of PW lost prior to delivery. The high proportion of PW lost during pregnancy who never started ART necessitates programs to adapt service delivery models to better prepare PW for ART initiation, and develop specific interventions that actively counsel, support and track newly-diagnosed PW who initiate ART, delay/refuse ART, or who do not report their partner has tested for HIV.

MOPEC0604

Systematic HIV-testing in delivery rooms is crucial, even when mothers are tested during pregnancy: a pilot program through 8 624 consecutive deliveries in Burundi, East Africa

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Background: Burundi associates high HIV prevalence (1,3% in 15-49 years old, 2012) and limited resources. Since april 2012, systematic HIV-testing has been proposed for all women in the delivery room of Bujumbura´s main hospital. If a woman is diagnosed HIV-positive, she is proposed immediate lamivudine/tenofovir/efavirenz intake and a free 72H hospitalization. More than 98% of women are tested.
Methods: As free HIV testing during pregnancy is recommended by national guidelines, more and more women know their status before delivery. To know if systematic HIV-testing in delivery rooms is necessary, we describe the women who have been tested and their previous tests results.
Results: From June 2014 to November 2016, 7570 women were tested for HIV during delivery : the median age was 26 years, 75% were married. It is the first pregnancy for 32%, the median number of children is 2 per woman. Only 48 women (0,6%) have never been tested for HIV, 37% have been tested one time, 56% two, 5% three, with an average of 1,7 tests. The median duration between the test in delivery room and the previous one is 75 days (IC25,75 [47;112]). 37 first tests and 34 confirmation tests were positive, and the prevalence of newly positive tested women is 0,45%. Among these 34 positive women, 19 have previously been tested HIV negative (56%), 17 during this pregnancy. The 15 other positive assert no prior HIV-test, which represents a HIV-seroprevalence of 31% within the group of women with no prior test. 55% of women know the HIV negative status of their partner, 0,5% the HIV positive one. Among the newly positive women, only 3 knew the HIV status of their partner who are all HIV-negative.
Conclusions: Systematic testing in delivery rooms is feasible and useful to decrease mother-to-child-transmission as a third of women who say having never been tested are positive. Despite a good rate of HIV testing during pregnancy, a majority of women tested newly positive in delivery room have been infected during the current pregnancy, and very few are aware of their partner HIV-status. Further efforts are needed to test men during their partner's pregnancy.

MOPEC0605

Prevention of mother to child transmission of HIV: trends in strategies and outcomes over 30 years in the French perinatal cohort

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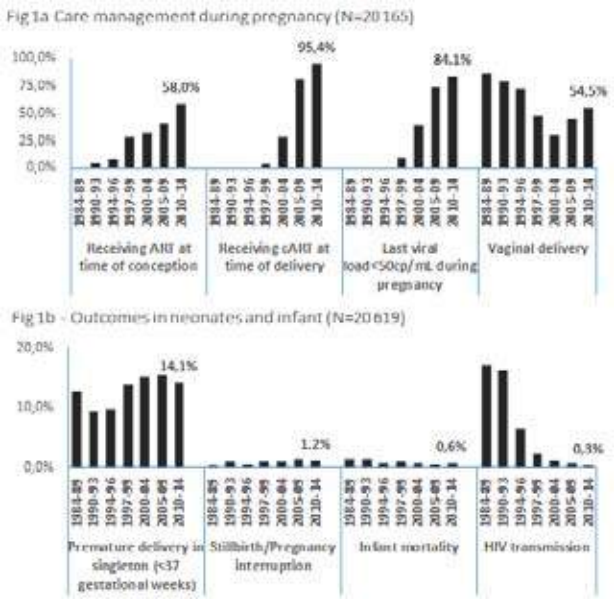
Background: We aimed to describe trends over 30 years of the strategies of prevention of perinatal HIV transmission, and of neonatal and infant outcomes in France.
Methods: The ANRS-EPF-CO1/CO11 cohort prospectively enrolls pregnant HIV-infected women in 90 centers throughout France. Children are followed until 2 years old, and more if infected.
Results: Between 1984 and 2014, 20 619 mother-infant pairs with delivery ≥ 22 gestational weeks were included. Since 1997, the proportion of undetectable viral load (VL) near delivery increased in parallel with early exposure to combined antiretroviral therapy (cART) (Fig 1a). Elective cesarean section peaked in 2000 to sharply decrease since 2013, with a majority of vaginal deliveries. Among the 4967 women who delivered in 2010-14, 58% were already treated at time of conception, 95% received cART during pregnancy, and 84% had a VL < 50 cp/mLnear delivery. Premature delivery in singletons increased from 10% before 1996 to around 15% after 2000, with a non-significant lower rate in 2010-14 (14%) (Fig 1b). Stillbirths and pregnancy terminations increased from 0.8% in 1997-2004 to 1.3% in 2005-14 (p=0.009). Infant mortality did not significantly differ over these two periods (0.8% and 0.6% p=0.24). The transmission rate continuously decreased through 0.3% [95% confidence interval: 0.2-0.5] in 2010-14.
Conclusions: The use of early and highly effective cART tends to eradicate perinatal HIV transmission in France. The short and long term monitoring must be maintained for other adverse perinatal outcomes.



[Fig. 1 Trends of PTME outcomes - ANRS EPF 1984-2014]

MOPEC0606

Sexual risk behaviors and alcohol use among HIV-infected and -uninfected pregnant and postpartum women in Cape Town, South Africa

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Background: HIV prevention efforts have focused separately on reducing HIV acquisition risk and perinatal HIV transmission among pregnant and breastfeeding women. However, there is limited knowledge of behavioral risk in HIV-infected (HIV+) and -uninfected (HIV-) pregnant and postpartum women.
Methods: We conducted a mixed method study among pregnant and postpartum women. We investigated demographic, substance use and sex behaviors through interviewer-administered questionnaires as well as in-depth interviews (n=25) to evaluate and contextualize factors associated with sexual risk behaviors and alcohol use.
Results: We surveyed 226 HIV- and 151 HIV+ women (52% pregnant; mean age, 29y). Sexual risk behaviors and alcohol use differed significantly by serostatus. Overall 46% of HIV+ women and 42% of HIV- women were married/cohabiting with the father of the index pregnancy/child (FOC). 1 HIV- woman reported having a HIV+ partner, and 35% didn't know; 21% of HIV+ women reported being in serodiscordant relationships with the FOC, and 38% didn't know. 51% of HIV- and 45% of HIV+ women who didn't know the FOC's status reported condomless sex at last sex. HIV- women reported more condomless sex (21% vs. 45% of HIV+ women at last sex), sex partners (16% vs. 14% of HIV+ women), and anal sex, but less alcohol use during pregnancy. One-third of pregnant women reported alcohol use during pregnancy (32% HIV+; 27% HIV-) of whom 66% HIV+ and 57% HIV- women reported ≥6 drinks on ≥1 occasion. Results from in-depth interviews demonstrated common themes including: lack of control over decisions in sex and condom use, high prevalence of substance use during pregnancy, beliefs around condom use during pregnancy (e.g. sex is good for baby) and fear of discussing HIV testing/disclosure with partner(s) (Table 1).

Theme	Select results from in-depth interviews (n=25)	Select ultivariate regression results
Heavy alcohol use during pregnancy	"When you are drunk, you don't think that if I have sex with this person I can get HIV."	Alcohol use during pregnancy was associated with increased odds of reporting =>1 partner (aOR=3.06;95%CI=1.10-8.49) and serodiscordant FOC (aOR=2.39; 95% CI=1.29-4.45) adjusted for age
Condomless sex during pregnancy/ postpartum period	"I once suggested we use a condom, he got angry and asked why I am saying we should use a condom....he asked if I have a disease."	Condomless sex was associated with: pregnancy vs. postpartum period (aOR=3.24; 95% CI=2.03-5.17) & serodiscordant vs. seroconcordant FOC (aOR=3.16; 95% CI=1.39-7.19) adjusted for age
Lack of knowledge of partner's serostatus	"When you go to test, they say they are also (HIV) negative because you tested negative"	HIV+ mothers (vs. HIV- mothers) had increased odds of not knowing their FOC's serostatus (aOR=3.27, 95% CI=2.09, 5.14) adjusted for education and age

[Table 1]

Conclusions: We identified significant HIV transmission and acquisition risk during pregnancy and postpartum periods including alcohol use, multiple partners, condomless sex, serodiscordance and lack of knowledge of partner's serostatus. Primary and secondary prevention of sexual HIV transmission in pregnant and postpartum women is a neglected but important area for reducing horizontal and vertical HIV transmission.

MOPEC0607

Maternal humoral immune correlates of mother to child transmission of HIV-1 in the setting of peripartum antiretrovirals

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Background: More than 150,000 annual pediatric HIV-1 infections occur due to mother to child transmission (MTCT) despite the availability of antiretrovirals (ARVs). In the pre-ARV era U.S. Women and Infants Transmission study (WITS), we previously reported that maternal HIV envelope-specific anti-V3 IgG, CD4 binding site antibodies, and tier 1 virus neutralization predicted reduced HIV-1 MTCT. As the majority of pediatric HIV infections occur in clade C HIV-infected populations with increased access to ARVs, we studied a Malawian HIV-infected pregnant women cohort from the Breastfeeding, Antiretrovirals, and Nutrition (BAN) study. We sought to determine if immune factors in the setting of ARVs predict reduced MTCT and help eliminate pediatric HIV-1.
Methods: Plasma from a subset of BAN clade C HIV-infected Malawian mothers (n=88, 45 transmitting and 43 non-transmitting) and their infants were studied. Women and infants received ARVs at delivery, and the majority of peripartum MTCT was during pregnancy (91%). Binding antibody multiplex assays, HIV-1 neutralization assays, and soluble CD4 blocking ELISAs measured plasma IgG against multiclade HIV Env antigens, neutralizing capacity, and CD4 binding site antibodies, respectively.
A multivariable logistic regression model analyzed the association of maternal and infant immune responses with peripartum MTCT risk.
Results: No significant association was detected between maternal anti-clade C V3 IgG (OR 0.57, p=0.42) or tier 1 neutralization (OR 1.37, p=0.70) and MTCT. Surprisingly, plasma blocking of the CD4 binding site (OR 1.06, p=0.03) and maternal anti-clade C V1V2 IgG (OR 1.62, p=0.04) were associated with increased MTCT independent of maternal viral load. Maternal anti-V1V2 IgG transfer efficiency to infants was not associated with transmission (OR 1.00, p=0.67).
Conclusions: This study revealed an association between high maternal CD4 binding site antibodies and anti-V1V2 IgG and transmission. Distinct humoral immune correlates of MTCT in the BAN and previous studies could be due to differences between transmission mode, virus clade, or maternal antiretroviral use. The association between specific maternal antibody responses and in utero transmission, distinct from potentially protective maternal IgG in the WITS cohort, underlines the importance of investigating additional cohorts with well-defined transmission modes to understand the role of maternal antibodies during HIV-1 MTCT.

MOPEC0608

Reducing paediatric HIV transmission in Northern Namibia

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Background: USAID's HIV Clinical Services Technical Assistance Project (UTAP), led by IntraHealth International, supports Namibia's Ministry of Health and Social Services in HIV high-burden districts in Northern Namibia by increasing capacity to provide high-quality HIV prevention, care, and treatment services. With expanded prevention of mother-to-child transmission (PMTCT) of HIV and accessibility of HIV testing for children, UTAP observed an increase in HIV-exposed children testing HIV-positive. UTAP conducted a case study of HIV-positive children to identify missed opportunities to reduce HIV-positivity in HIV-exposed children.
Methods: The study analyzed cases of HIV-exposed and HIV-positive children from July-September 2016 in eight districts. Quantitative data were derived from patient care booklets and clinic reports. Qualitative analysis was obtained through interviews with parents/guardians.
Results: UTAP traced 63 (80%) of 79 infants and children testing HIV-positive. Children ranged from five months to eight years old, and were tested using age-appropriate HIV testing algorithm. Further review revealed 22 of the 63 were later confirmed HIV-negative using the DNA/PCR test. The remaining 41 children were

confirmed HIV-positive; 33 (80%) were born to known HIV-positive women. Six were born to women who tested HIV-negative during the antenatal period but did not undergo HIV testing during the breastfeeding period. Recently expanded provider-initiated HIV testing and counseling (in clinics and hospitals) identified 26 (63%) HIV-positive children. Fourteen children (34%) received inadequate Nevirapine prophylaxis.
Noteworthy characteristics of mothers included: HIV-positive and defaulted or refused to take HIV treatment; HIV-negative during antenatal period; did not attend antenatal care; and/or had a home delivery. During this same period 6,839 pregnant, labor and delivery women were tested in these same districts; 17.5% were known or new HIV-positive.
Conclusions: Delivering a full package of PMTCT services and strengthening adherence and retention of pregnant and breastfeeding women who are on ART are needed. A concerning number of women seroconverted in breastfeeding period (15%) highlighting the importance of continued HIV prevention interventions for HIV-negative women during postnatal and breastfeeding periods. Universal treatment for pregnant and breastfeeding women works best when adherence and retention of known HIV-positive pregnant and breastfeeding women are improved and HIV-exposed children receive comprehensive, integrated HIV services.

MOPEC0609

Pregnancy and neonatal outcomes following prenatal exposure to dolutegravir

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Background: Dolutegravir (DTG) is an integrase strand inhibitor approved for the treatment of HIV in adults and adolescents since 2013. There is minimal information on use of DTG in pregnant women. Our aim was to assess maternal and fetal outcomes following DTG use during pregnancy in real-world European settings.
Methods: A retrospective analysis of individual patient data prospectively collected in observational studies of pregnant women living with HIV and their infants within the European Pregnancy and Paediatric HIV Cohort Collaboration was conducted. All women with any prenatal exposure to DTG and reported to studies by September 2016 were included.
Results: A total of 81 pregnancies in 81 women were identified. Median maternal age at conception was 33.1 years (interquartile range [IQR], 26.7-37.1 years), and 44/81 (54.3%) born in sub-Saharan Africa. Most (62/74, 83.8%, 7 unknown acquisition) women had heterosexual acquisition of HIV, 9 women were vertically infected and 3 had injecting drug use acquisition. Most women had been diagnosed with HIV before conception (70/75, 6 unknown), 48 conceived whilst on any ART and 28 conceived on a DTG-based regimen. There were two twin pregnancies (all live births). Pregnancy outcomes were known for 64 pregnancies (1 moved to another country before delivery, 16 continuing): 61 ended in live births (29 with 1st trimester DTG exposure), 1 in stillbirth (without 1st trimester DTG exposure), 1 in termination (with 1st trimester DTG exposure) and 1 in spontaneous abortion (with 1st trimester DTG exposure). Birth outcomes for the 63 delivered liveborn infants (including 2 twin pairs) and 1 stillborn infant (62 pregnancies) are in the Table. The congenital abnormalities with 1st trimester DTG exposure were: patent foramen ovale; bilateral hexadactyly of hands (familial) and hypospadias (both in 1 child); in 2nd trimester: ankyloglossia.

	1st trimester earliest DTG exposure	2nd / 3rd trimester earliest DTG exposure
First prenatal CD4 count (median, IQR)#	525 cells/mm3 (323-660)	338 cells/mm3 (218-591)
Preterm delivery (<37 weeks)*	2/27 (7.4%)	9/33 (27.3%)
Low birth weight (<2500g)*	8/25 (32.0%)	13/33 (39.4%)
Very low birth weight (<1500g)*	0/25 (0.0%)	0/33 (0.0%)
Congenital abnormality (livebirths)	2/29 (6.9%) (2 missing)	1/32 (3.1%) (0 missing)
# available for 58 of 62 pregnancies	* calculated for the 60 singleton deliveries (59 livebirths, 1 stillbirth) only	

[Characteristics by trimester of DTG exposure]

Conclusions: Although this is the largest study to date, small numbers preclude firm conclusions regarding safety of DTG in pregnancy and further prospective monitoring is required.

MOPEC0610

Prevention of mother to child transmission of HIV: postpartum adherence to Option B+ until 18 months in Western Uganda

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Background: Since 2012, the WHO has recommended Option B+ for the prevention of mother-to-child transmission of HIV. This approach entails the initiation of lifelong antiretroviral therapy in all HIV-positive pregnant women, also implying protection during breastfeeding for 12 months or longer. Research on long-term adherence to Option B+ throughout breastfeeding is scarce to date. Therefore, we conducted a prospective observational cohort study in Uganda to assess adherence to Option B+ until 18 months postpartum.
Methods: We recruited 67 HIV-positive, Option B+ enrolled women six weeks after giving birth in Fort Portal, Western Uganda and scheduled them for study follow-up after six, twelve and 18 months. Two adherence measures, self-reported drug intake of the previous month and rate of drug refill visits, were combined to define adherence, and were assessed together with feeding information and infants´ HIV status at all study visits. Risk factors for postpartum adherence were analyzed.
Results: At six months postpartum, 51% of the enrolled women were considered to be adherent, and 91% of the babies had been exclusively breastfed for 6 months. Until twelve and 18 months postpartum, adherence for the respective follow-up interval decreased to 19% and 20.5% respectively. No woman was completely adherent until 18 months. At the same time, 76.5% of the women breastfed for 12 months or beyond. Longer breastfeeding duration was not linked with higher adherence. Risk factors for postpartum adherence to Option B+ were older age of the mother ($p< 0.01$), higher travel costs ($p=0.02$), and higher number of previous deliveries ($p=0.04$). We found no case of vertical transmission in our cohort.
Conclusions: Our results imply that postpartum long-term adherence is a challenge in Option B+ implementation, while at the same time, prolonged breastfeeding until 12 months or beyond is widely applied. This needs to be taken into serious account by healthcare providers, because poor postpartum adherence might eventually cause a setback in prevention of vertical transmission during the breastfeeding period. HIV-positive mothers require intense support for postpartum adherence to Option B+. Effectiveness in terms of low transmission despite suboptimal adherence needs to be verified in further research.

MOPEC0611

Serological and nutritional outcome of infants born to HIV-positive mothers undergoing option B + therapy in Guédiawaye

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Background: As part of its Plan to eliminate mother-to-child transmission of HIV, Senegal has adopted since 2012 WHO´s B + option, which consists of systematic triple therapy for HIV-positive pregnant women associated with breastfeeding and antiretroviral (ARV) prophylaxis for their infants. Our study aims to analyze the risks of mother-to-child transmission of HIV and the nutritional outcome of infants undergoing B + option.
Methods: We conducted a descriptive, retrospective study at the Roi Baudouin hospital in Guédiawaye from 1 September 2012 to 30 April 2015. All infants whose mothers were on triple therapy, undergoing protected breastfeeding, ARV prophylaxis and serological test at 14th months were included in the study.
Results: Out of the 126 infants undergoing PMTCT program, 42 or 33.33% of infants following the B + guidelines were included in the study. The age of mothers ranged from 15 to 42 years, with an average age of 31 years. The majority of mothers (88.1%) carried type 1 virus and 11.9% carried type 2 virus; 20 couples (47.62%) were sero-concordant, 14 were serodifferent, while the serological status was unknown or not investigated in 8 fathers (19.05%). A significant difference between fathers´ serological profile and the sharing status ($p < 0.05$) was found. The majority of infants (88.1%) were born at term via vaginal delivery (95.2%), with an average birth weight of 2880 grams. In relation to prophylaxis, the majority of infants

received prophylactic monotherapy, 27 (64.28%) received Nevirapine, 4 (9.52%) received Zidovudine, while 11 (26.19%) received triple combination of Zidovudine + Lamivudine + Nevirapine. The exclusive breastfeeding was effective in 80.9% of infants and weaning began at 12 months in 80.9% of infants. In relation to nutritional status, at 6 months 12% and 7.1% of infants had moderate acute malnutrition and severe acute malnutrition respectively. At 12 months, 19.1% of infants had moderate acute malnutrition. Retroviral serology was negative in all the 42 infants at 14 months.
Conclusions: B + option is an effective strategy to reduce the MTCT rate. However, early malnutrition in children requires nutritional support for breastfeeding mothers as well as a good psychosocial Support.

MOPEC0612

Improvement in viral suppression among women up to one-year post-partum after implementation of universal ART in the SEARCH test-and-treat trial

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Background: The WHO's "Option B+" strategy calls for lifelong ART for pregnant women; however, a substantial proportion of women on ART at delivery are lost from care during the post-partum period. Post-partum women may be more likely to remain in care and on ART when universal test-and-treat is implemented at a population level. We evaluated viral suppression among HIV-infected women who were up to one-year post-partum living in communities with universal ART as part of the SEARCH (NCT01864603) test-and-treat trial.
Methods: Women age 15-49 years who were residents of 16 SEARCH intervention communities in Uganda & Kenya were tested for HIV at baseline and annually through engagement in hybrid mobile testing between 2013-2016, which reached 93%, 94%, and 87% at baseline, one year (FUY1), and two years (FUY2). Among HIV-infected women who reported a live birth within the previous 12 months at testing, the proportion with viral suppression (HIV RNA< 500 copies/ml) was calculated at baseline, FUY1, and FUY2; a missing viral load (VL) was considered non-suppressed. Predictors of non-suppression at FUY1 and FUY2 were assessed using logistic regression. Multivariate models included age, region, marital status, education, number of previous pregnancies, and years since HIV diagnosis
Results: Among HIV-infected women who reported a live birth in the previous 12 months 72% (443/609) at FUY1 and 76% (384/503) at FUY2 were virally suppressed in comparison to 35% (335/944) at baseline prior to the SEARCH intervention. Younger women (15-24 years) were more likely to have detectable VL at FUY1 than women ≥24 years (aOR 1.78; 95% CI 1.06-2.97). Women diagnosed with HIV within the previous year were more likely to have detectable VL at both FUY1 (aOR 2.45; 1.48-4.05) and FUY2 (aOR 1.89; 1.24-2.87) compared to HIV+ women with an earlier diagnosis. Among women with detectable VL, 94% had HIV RNA >1000 copies/mL.
Conclusions: Among post-partum women seen at annual hybrid mobile campaigns, the proportion virally suppressed doubled after two years of community-wide universal ART. Young women and those recently diagnosed are at highest risk for viremia that may result in poorer maternal health outcomes and ongoing transmission in the post-partum period.

MOPEC0613

Experiences and perceptions of community-based mentor mothers (cMM) supporting HIV-positive pregnant/postpartum women on lifelong antiretroviral therapy in Southwestern Kenya

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Background: Community-based mentor mothers (cMM) are HIV-positive mothers providing peer support to HIV-positive pregnant/postpartum women in the community with the aim to enhance lifelong antiretroviral therapy (ART) adherence and retention in care.
Methods: To explore the perceptions of cMMs on their role in supporting HIV-positive pregnant/postpartum women, we completed 24 in-depth interviews with cMMs from ten communities in Kenya between April-May 2016. Transcripts were coded with Dedoose software using a coding framework based on the literature, interview guides, and emerging themes from transcripts, and fine-coded using an inductive approach. Main themes were explored in longitudinal questionnaire data collected by cMMs during their home visits for 159 women and their infants at 6-weeks postpartum.
Results: cMMs expressed high acceptability of their work in the community and health facilities, and emphasized their positive impact on HIV-positive women and their infants. They described provision of health education; making linkages to HIV care, prevention of mother-to-child transmission (PMTCT) and maternal and child health (MCH) services. The cMMs reported serving as role models and confidantes, supporting acceptance of HIV status, providing encouragement about the potential of having an HIV-negative child; assisting with partner disclosure/communication, and providing tangible support (development of birth plans, picking up medications). Additionally, cMMs described personal benefit through self-empowerment and increased income. Reported challenges included possible inadvertent disclosure of clients' HIV status, transportation, and cultural barriers/myths. Positive impact of home visits described by cMMs was reflected in questionnaire data. At 6-weeks postpartum, 96% of women visited at home self-reported 100% adherence to ART as well as increase in disclosure to male partner to 96% from 84%; all infants were on preventive HIV regimen and 99% were properly adhering, 94% of infants had been tested for HIV, 89% were delivered at the hospital, and 99% were exclusively breastfed and immunized.
Conclusions: Kenya, similar to other countries, is in a need of innovative approaches to overcome challenges associated with the scale-up of lifelong ART services. This study suggests that a cMM strategy may play an important role in enhancing PMTCT as well as MCH in Kenya and may have positive effects on the cMMs themselves.

MOPEC0614

Preliminary results of prevention of mother to child transmission of hepatitis B virus through treatment of mothers and vaccination of newborns at Ouagadougou, Burkina Faso

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Background: Vaccination practices alone are not enough to control the HBV epidemic. Treatment of women in the third trimester of pregnancy with tenofovir, if the maternal DNA level of hepatitis B virus is >106 IU / ml, has also been confirmed as an effective strategy but very little evaluated in sub- Saharan Africa. The objective of this study was to assess the effectiveness of these two strategies in Ouagadougou.
Methods: The data collection took place from 01/09/2014 to 01/09/2015 during a prospective study with regular monitoring of pregnant women and their newborns. Pregnant women were infected with hepatitis B with or without HIV / HCV co-infection and were followed for their infection at Yalgado Ouedraogo University Hospital. Women at high risk of transmission (DNA >106 IU / ml) were all on treatment and vaccination in the first 24 hours of life was offered to all newborns. The effectiveness of the strategy was evaluated at 7 months of life by the assays of Ag HBs and Ac anti HBs in all newborns.

Results: A total of 266 pregnant HBs positive HBs were followed. Co-infections HBV / HIV and HBV / HCV were found in six patients (2.26%) and two patients (0.75%), respectively. During our study 190 babies were born alive including one twin pregnancy. There were 5 (2.63%) deaths born or miscarriages. The perinatal mortality rate was 1.58% or 3 cases. Ten women had a viral load greater than 10^6 IU / ml, and all were put on treatment in the third trimester of pregnancy. Among the 190 children, 96 or 50.52% had their serological status at 7 months and 92 of them, 95.84% were HBs Ag-negative compared with 4 positive (4.16%). The mothers of these infected infants had in 3 cases a viral load greater than 10^6 IU / ml and 2 of them were Ag HBe positive. In all infants the anti-HBs antibody assay was positive and protective.
Conclusions: In the prevention of mother-to-child transmission of hepatitis B virus, the combination of these two strategies gives us a success rate of 95.84% even in the absence of immunoglobulins.

MOPEC0615

Barriers and facilitators for men obtaining HIV voluntary counseling and testing during prenatal care in Brazil

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Background: Providing HIV voluntary counseling and testing (VCT) to men who attend their partner´s prenatal care is an intervention with potential to reduce HIV transmission to women and infants during the vulnerable period of pregnancy. Little is known about the acceptability of this intervention in global settings outside of Africa.
Methods: We conducted in-depth qualitative interviews to evaluate potential barriers and facilitators to male prenatal care attendance for HIV VCT with 20 men who did and 15 men who did not attend prenatal care with their partners in Porto Alegre, Brazil. Men were recruited at the labor and delivery unit via a scripted invitation while visiting their newborn infant. Interviews lasted from 35-55 minutes and were conducted by a trained local resident. All interviews were transcribed verbatim, translated, and then analyzed using thematic coding in Atlas.ti.
Results: If offered HIV testing during prenatal care, all men in both groups stated they would accept this intervention. Yet, individual, relationship and systemic factors were identified that affect these Brazilian men´s decision to attend prenatal care, informing our final conceptual model. The men interviewed had a general understanding of the value of prevention of mother to child HIV transmission. They also described open and communicative relationships with their significant others and displayed a high level of enthusiasm towards optimizing the health of their expanding family. The major barriers to attending prenatal care included perceived stigma against HIV infected individuals, men's lack of involvement in planning the pregnancy as well as inconvenient scheduling of prenatal care, due to conflicting work schedules.
Conclusions: Brazilian men displayed high levels of HIV-related knowledge as well as open communication about HIV testing; especially when compared to findings from African studies. Future efforts should reorient prenatal care towards providing care to the entire family with a clear focus on protecting the infant from preventable diseases.

MOPEC0616

Late diagnosis of HIV and shorter duration of antiretroviral drug exposure in HIV-infected mothers in PMTCT program, Mandalay, Myanmar

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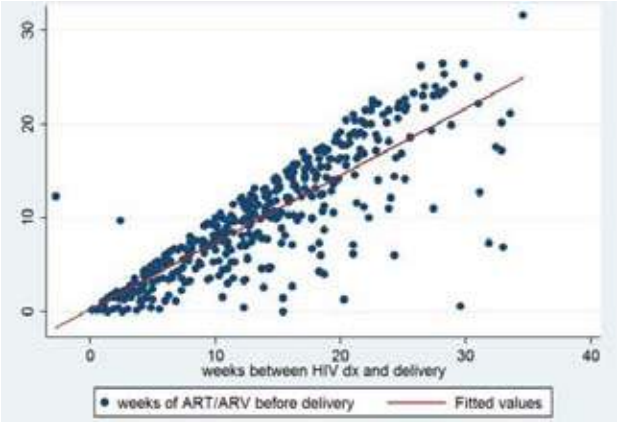
Background: Longer duration of antiretroviral treatment (ART) before delivery is critical to reduce viraemia during pregnancy, delivery and postpartum breastfeeding and reduce the chances of mother to child transmission (MTCT). We aimed to determine the duration of ART/ antiretroviral drugs (ARV) received by HIV-positive pregnant mother and factors associated with unfavourable outcomes (non-initiation or late ART; duration of ART/ARV ≤12 week) in prevention of MTCT (PMTCT) program in Mandalay, Myanmar.
Methods: This is a retrospective cohort study on routinely collected data.
Results: Of 671 ART naïve HIV-positive mothers newly enrolled in PMTCT program between March 2011 and November 2016, 570 (85%) have delivered as of November 2016. Only 80% of them (461/570) got ART/ARV before delivery in which 60% has ≤12 week duration of ART before delivery. The median (Interquartile range, IQR) duration of ART/ARV before delivery was 9 week (4-15). The median (IQR) time to initiate ART/ARV since diagnosis and since enrolment to PMTCT program were 3 week (1-6) and 1 week (0-3). Figure shows positive correlation (r 0.72, P< 0.001) between earlier diagnosis of HIV before delivery and longer duration of ART before delivery.



[Figure. Plot of weeks of ART/ARV before delivery]

HIV-infected mothers lived outside Mandalay and unknown spouse HIV status were significantly associated with late ART (duration of ART/ARV ≤12 week) and no ART/ARV before or after delivery.

Characteristics		Total	Unfavourable ART/ARV status n (%)	Unadjusted Rate Ratio (95% CI)	p value	Adjusted Rate Ratio (95% CI)	p value
Total		570	384(67)				
Age group	≤20	32	22(69)	1			
	20-30	311	201(65)	0.94(0.73-1.2)	0.627		
	>30	227	161(71)	1.03(0.8-1.32)	0.806		
Patients resident	Outside Mandalay	134	102(76)	1.18 (1.05-1.32)	0.007	1.18 (1.05-1.33	0.005
	In Mandalay	436	282(65)	1		1	
Spouse HIV status	Unknown Spouse HIV status	259	194(75)	1.23 (1.09-1.37)	<0.001	1.23 (1.1-1.38)	<0.001
	Known Spouse HIV status	311	190(61)	1		1	

[Characteristics and factors associated with Unfavo]

Conclusions: There is an urgent need to increase early uptake of antenatal care and early diagnosis of HIV in pregnant mothers to maximize the duration of ART before delivery to prevent mother to child transmission of HIV by addressing the challenges.

MOPEC0617

Retesting in pregnancy at Zambian Defense Force (ZDF) health facilities: an important strategy for preventing new infections and achieving the 90-90-90 UNAIDS targets

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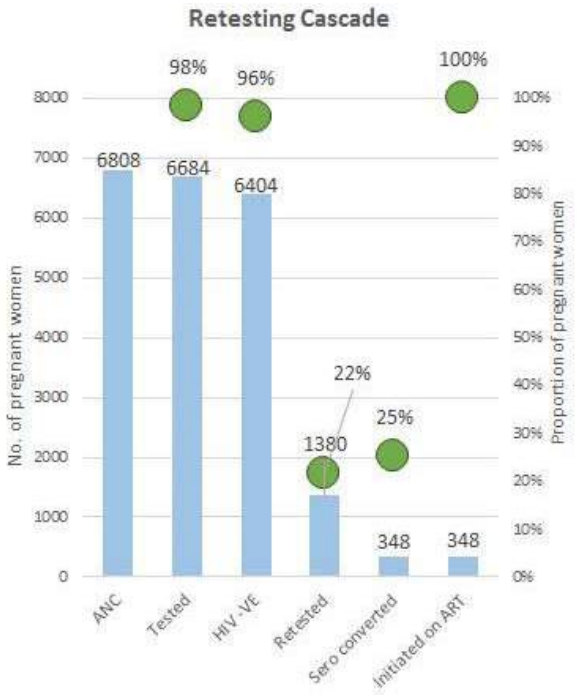
Background: In Zambia, provider-initiated HIV testing is conducted routinely for pregnant women during their first antenatal care (ANC) visit, as part of prevention of mother-to-child HIV transmission (PMTCT). Per Zambia national guidelines, HIV-positive women immediately initiate antiretroviral treatment (ART; Option B+), and HIV-negative women irrespective of risk profile, retest every 3 months, at delivery or postpartum, due to the high risk of infection during pregnancy.
Methods: We assessed the degree of adherence to national HIV testing guidelines at 14 ZDF ANC clinics supported by Jhpiego through DOD PEPFAR funding. Retesting coverage for 6,808 pregnant women from October, 2015 to September, 2016 was reviewed and health care providers were interviewed to determine retesting barriers.
Results: 6,808 pregnant women attended ANC during the review period; 6,684 (98%) tested for HIV at first ANC visit (known positives were not tested). 6,404 (96%) tested HIV-negative and 280 (4%) tested HIV-positive. 1,380 (22% of negatives) retested, leaving a high proportion (78%) failing to retest. 348 (25%) seroconverted and were initiated on ART. Barriers to retesting included women not attending all four ANC visits (4th Visit Rate: 60%); providers experiencing heavy workloads and failing to check for retest eligibility; and stock outs of test kits. The reasons for the high seroconversion among retested women could however not be determined from routine data.



[Resting Cascade 2]

Conclusions: Retesting HIV-negative pregnant women is an important strategy for identifying women who have seroconverted during pregnancy, who can benefit from ART, PMTCT, oral PREP for partner, and early infant diagnosis. The high rate of seroconversion among the re-testers (though only 22% of initial negatives) suggests a need to not just improve retesting for pregnant women but to also offer testing to male partners at subsequent ANC visits, thus preventing transmission during pregnancy and contributing to achieving the UNAIDS 90-90-90 targets.

MOPEC0618

Reasons for lost to follow-up and levels of HIV sero-status disclosure among traced patients receiving routine care in urban Uganda

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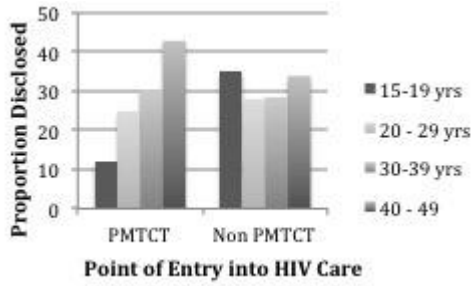
Background: Retention in HIV care remains critical in achievement of the UNAIDS 90-90-90 goals for the HIV continuum of care. Understanding the reasons for dropping out of care is crucial and HIV sero-status disclosure may be associated to low retention levels. We sought establish the reasons of LTFU and level of disclosure among patients who dropped out of HIV care.
Methods: Data was from 6 Kampala City Council HIV public clinics in Uganda. We included last seen >90 days, and traced between September 2012 and April 2016. Information collected at tracing included reasons for LTFU and HIV sero-status disclosure. Clinical data was obtained from the electronic medical records.
Results: From a total of 33850 patients registered in care, 4161 were LTFU, and 2766 were successively traced. Among traced patients, 2104(76.1%) were female, 984(35.6%) enrolled into HIV care through Option B-Plus, 1176(42.5%) through Out Patient department (OPD) and 606(21.9%) from other mechanisms.
Reasons for LTFU included structural 75.7%, psychosocial 29.5% and facility-related 11.2%. At the time of tracing, 197/662(29.8%) of the males had disclosed their HIV status compared to 542/2104(25.7%) women, (P=0.043).
Women on Option B-Plus had lower disclosure rates compared to OPD (24.6%versus 29.7%, P=0.018). HIV disclosure was low (11.1%) among women aged 15-19 years on B-Plus (see Figure).
B-Plus women spent least time in care 1.6 months (IQR:0.0, 8.9) compared to 3.3 months (IQR:0.5 - 16.9) from OPD, P<0.001. Disclosure was low among the early dropouts; with 18.7% disclosure among patients who stayed in care <6 months, 34.6% for those in care 6-12 months, and 39.8% >12 months in care.



[Disclosure among HIV positive women by age group]

Conclusions: We observed very low levels of HIV sero-status disclosure especially among young women on Option B-Plus. Strategies for disclosure during HIV care among young women on Option B-Plus are important in the global fight against HIV/AIDS.

MOPEC0619

"The co-authors of pregnancy": leveraging men's sense of responsibility and other factors to tailor male involvement interventions in antenatal and pregnancy-related services in Kinshasa

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Background: Despite efforts to improve male involvement (MI) in EGPAF-supported facilities in Kinshasa, few male partners attend antenatal care (ANC), PMTCT, and delivery services. MI has been shown to increase acceptability of and adherence to PMTCT interventions and is an entry point for partner HIV testing. The study aimed to describe barriers and facilitators to partners' attendance and identify MI interventions considered effective within a Congolese context.
Methods: This exploratory study involved two women-only and two men-only focus group discussions (FGD) conducted with 8-10 participants, in high-ANC volume facility catchment areas in Kinshasa. Pregnant women and men of reproductive age were recruited from ANC clinics and surrounding communities. Key informant interviews were conducted with purposively selected participants from health facil-

ity leadership and central government HIV and reproductive health departments. FGD and interviews took place in June 2016. Topics included factors influencing MI in ANC/PMTCT, experiences with male HIV testing and couples' ANC attendance and perspectives and recommendations on current or proposed MI interventions. Qualitative thematic analysis of barriers, facilitators and interventions was conducted using in MAXqda (V10).

Results: Thirty-five FGD participants and three key informants participated. The table lists the most promising interventions participants identified (invitation letters, service quality improvement, peer-to-peer outreach) linked to frequently reported MI facilitators and barriers. Only men identified responsibility, referring to themselves as "authors of the pregnancy," and wanting to be tested for HIV as facilitators. Receipt of clinic staff advice was the most commonly-reported facilitator. No time off work was the most commonly-reported barrier.

Most Promising Intervention Identified by Participants	Facilitating MI factors addressed by intervention	Barriers to MI addressed by intervention
Improvements to the male partner invitation letter, with content referring to men's responsibility as father, love for his family and a need to understand progression of pregnancy and expectations for delivery. HIV testing should not be specifically mentioned but addressed once at the clinic.	• Sense of male responsibility • Desire to receive counseling/ information from clinic staff • Assess partner's pregnancy or delivery • Love of wife and child • Authority conveyed by doctors	• Consider pregnancy to be the woman's domain • Men's fear of HIV testing • Men's ill-preparedness at time of delivery
Improvement to quality of ANC/ delivery services for men and couples, such as the addition of male-specific services and more inclusion of men during ANC/ delivery, expanded clinic hours, separate spaces for couples and health workers who are sensitive to couples' needs.	• Desire to receive counseling/ information from clinic staff • Assess partner's pregnancy or delivery • To be tested for HIV	• Time/work commitment • Unwelcoming facility environment for male partners • Consider pregnancy to be woman's domain • Men's ill-preparedness at time of delivery
"Expert" Peer to Peer Community Outreach, in which peers would serve as a conduit to the clinic and refer men for counseling and services, discuss importance of attending ANC and what to expect during delivery. This would provide men with opportunities to discuss pregnancy and other issues without women present.	• Sense of male responsibility • Desire to receive counseling/ information from clinic staff • Assess partner's pregnancy or delivery	• Time/work commitment • Unwelcoming facility environment for male partners • Consider pregnancy to be the woman's domain • Men's ill-preparedness at time of delivery

[MI Interventions, Facilitators and Barriers]

Conclusions: This study moved beyond an identification of MI barriers and facilitators by eliciting feedback from program recipients and planners on existing and proposed MI interventions. Men expressed responsibility for their partners' pregnancies and their unborn children. They indicated that greater information and a clinic setting more conductive to couple's needs would result in improvement in male attendance at pregnancy-related services.

MOPEC0620

Factors influencing HIV-testing practice in Zambia: a systematic review

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Background: HIV-testing is a critical entry-point of HIV treatment cascade especially for countries with high HIV prevalence including Zambia. There is no recent literature review to address its latest HIV-testing practices shaped by evolving government strategies and application of new testing approaches. This study aims to systematically review multi-level factors that influence HIV-testing in Zambia.

Methods: Literature was searched among six electronic datasets using the algorithm "(HIV OR "human immunodeficiency virus") AND Zambia* in [Title]". After screening, 35 empirical studies published in English in peer-reviewed journals prior to November 2016 with a focus on HIV-testing in Zambia were included. Two researchers independently extracted key information using structured summary table. The disagreements were discussed and resolved in coding process.

Results: Multi-level factors that influenced HIV-testing practices including socio-demographic characteristics, family structure and relationship, sociocultural context, health facility, and government policies. Generally, adults with higher perceived risk and higher education attainment were more likely to accept and take HIV-testing. The impacts of age and marital status were fixed and dependent on the sub-population. Family relationship was a significant factor influencing decision-making regarding HIV-testing for women and adolescents. Fear of partner reaction and lack of family support hindered women's uptake of HIV-testing service. Discussion with family was positively associated with HIV-testing among adolescents. Gender inequality, HIV-related stigma, and traditional health beliefs remained as barriers. The lay belief that knowing HIV-positive status led to rapid physical deterioration of death resulted in delayed HIV diagnosis. Trust of counsellor, confidentiality issues, quality of post-testing counselling and care, distance to clinics, supply of testing kits, training and supervision of lay healthcare workers shaped the acceptance and practice of HIV-testing. Integration of HIV-testing with immunization service for infants and home-based testing service suggested promising outcomes.

Conclusions: HIV-testing intervention needs individualized strategies for diverse populations. The success of task-shift strategy depends on appropriate training and supervision of lay healthcare workers and capacity building of health facilities. Novel HIV-testing approaches may promote uptake of HIV-testing but need to address challenges in sociocultural changes (family structure, gender equality, health beliefs) since modernization and introduction of new medicine technology in Zambia.

MOPEC0621

Rate and causes of mortality in the first 12 months of life among HIV-exposed infants in rural Nigeria: results of an adapted verbal autopsy

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Background: At 71.2/1,000, Nigeria has one of the highest infant mortality rates (IMR) globally. Leading causes of infant mortality in sub-Saharan Africa are preterm birth, pneumonia, birth asphyxia, diarrhea, malaria and HIV/AIDS. Little is known about HEI mortality in Nigeria, especially in rural areas. We present data on HEI mortality from a prospective PMTCT study in rural North-Central Nigeria.

Methods: Perinatal and fetal/infant mortality data was collected from mothers, relatives and healthcare workers using a 21-item mini verbal autopsy (VA) form. VA was conducted within 2-4 weeks of loss; in English or local language by trained multilingual research staff. Data on miscarriages at < 20 weeks gestational age (GA)), stillbirths (≥20 weeks GA), neonatal (1-28 days) and postneonatal (>28 days-12 months) deaths were abstracted. IMR was calculated as number of infant deaths per 1,000 live births. VA data were systematically organized into attributable cause-of-death categories based solely on data available.

Results: Data from 445 women revealed 408 (89.7%) livebirths and 455 products of conception. By 12 months post-delivery, there were 75/455 (16.5%) fetal and infant losses, of which 37/75 (49.3%) were live-born infants. Approximately 50% of fetuses/infants deceased were delivered at a health facility; 43% at home, and 7% elsewhere. IMR for the 408 live births was 90.7/1,000. Table 1 presents detailed results.

Timing/Cause of Death		n	%
Miscarriage:9.3% of losses (N=7)	Not otherwise specified	6	85.7
	Known (anencephaly)	1	14.3
Stillbirth: 41.3% of losses (N=31)	Not otherwise specified	28	90.3
	Known (maternal infection, labor complications)	3	9.7
Neonatal: 25.3% of losses (N=19)	Not otherwise specified	5	26.3
	Birth asphyxia	5	26.3
	Other known causes (hyperbilirubinemia, SIDS, infection)	9	47.4
Post-neonatal: 24.0% of losses (N=18)	Not otherwise specified	7	38.9
	Known (diarrhea, febrile illness, infection, electrolyte imbalance, poisoning)	11	61.1

[Causes of Fetal/Infant Losses among HEI (N=75)]

Conclusions: IMR among rural HEI in our study was higher than national, however our small sample size warrants cautious interpretation. Nevertheless, crude mortality among study HEI appears high, despite targeted Maternal-Child Health programming for this population. Most in utero deaths could not be assigned an attributable cause. Birth asphyxia was the single most common attributable cause of neonatal death. Neonatal death accounted for more than 50% of infant deaths. To improve HEI infant survival in rural areas, general obstetric, perinatal and neonatal care and relevant documentation has to be improved.

MOPEC0622

Empowering rural women to prevent mother to child transmission (PMTCT) of HIV through WORTH

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Background: The uptake of PMTCT and ANC services have been affected by barriers such as poor health seeking behavior, poverty and other factors at community level in Bayelsa, Nigeria (WHO, 2007) Researches have shown that women and children are the most vulnerable groups in sub Saharan Africa. For example, women and girls are less likely to receive formal education, have generally low income and at higher risk of HIV infection and death than men. Evidence has also shown that women made significant contributions to the overall wellbeing of their families. This paper reviews the role Women Empowerment Program (WORTH) plays in providing access to ANC/ PMTCT services for women in Southern Ijaw, Bayelsa, Nigeria.
Methods: The WORTH model is tied to the community based PMTCT project designed to increase PMTCT uptake, prevent new pediatric HIV infections and mobilize community and government support for prioritizing and sustaining PMTCT in Bayelsa. This intervention focuses on promoting health care seeking behaviors among women of reproductive age (15 - 49 years). WORTH aims to serve people whose fragile economic position prevents them from meeting their basic needs. 3 WORTH literacy volunteers,15 management committees and 85 WORTH members have been trained and participates the group savings and loans.
Results: Preliminary findings have shown that WORTH groups despite the prevailing harsh economic situation, have started weekly mandatory savings and have contributed for more than 10 weeks. These self-contributions assist group members with loans for small scale businesses with little interest as low as 5% per month. Women acquired shared understanding on improved income generation and developed a savings culture to pay for ANC/PMTCT services. Available records show increase in uptake of PMTCT/ ANC services by 5 pregnant women resulting from referrals in one of the communities - Anyama, Ijaw. Integrating WORTH into community based prevention of mother to child transmission (PMTCT) has a strong potential of improving uptake of PMTCT/ANC services among women of reproductive age.
Conclusions: Onsite mentoring support is required to ensure women channel and utilize a certain percentage of their savings to access PMTCT/ ANC services. Health facility records will be strengthened to showcase evidence based intervention.

MOPEC0623

Mother to child HIV transmission in adolescents and young women: findings from an 18-month prospective observational cohort of a nationally representative sample of mother-infant pairs, Zimbabwe, 2013-2014

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Background: Mother-to-child transmission (MTCT) of HIV accounts for 90% of pediatric HIV cases. Mother-to-child transmission is observed to be higher in adolescents than older mothers; however, understanding of the reasons is limited. We assessed 18-month cumulative MTCT risk and prevention service coverage among HIV-positive adolescents aged ≤19 years and young women aged 20-24 years.
Methods: We analyzed data from a prospective cohort that used multistage sampling to recruit a nationally-representative sample of 6051 mothers and their 4-12 week-old infants from 151 immunization clinics in Zimbabwe from February to August 2013. HIV-exposed infants were followed until HIV diagnosis, death, or age 18 months. Infant HIV infection was defined by positive HIV DNA polymerase chain reaction test. We analyzed data collected from maternal interviews, child-health cards, and infant HIV test results. Findings were weighted and adjusted for complex survey design and non-response. Data were analyzed with STATA version 14.1.
Results: Among mothers, 16.3% were adolescents and 29.8% were young women. HIV prevalence was 7.5% (95% confidence interval [CI]: 6.1%-9.3%) and 14.8% (95% CI: 12.8-16.9), respectively. In both age groups, 95% of mothers had ≥1 antenatal care (ANC) visit, 97% had ≥1 HIV test, and 99% knew their HIV status. No difference in gestational age at first ANC visit was found. A higher proportion of HIV-positive adolescents, compared to HIV-positive young women, reported no ARV use during pregnancy (20.6%, 95% CI: 12.6-31.7 vs. 13.5%, 95% CI: 9.9-18.1). Infant ARV prophylaxis did not differ between adolescents and young women (95%). The cumulative 18-month MTCT was 12.1% for adolescents and 7.5% for young women; however, these values were not significantly different (p=0.22). At age 4-8 weeks, the first of six timepoints measured, MTCT was 8.4% for adolescents and 3.2% for young women (p=0.056).
Conclusions: Uptake of maternal ARVs in pregnancy is lower in adolescents than young women. Although 18-month MTCT is not significantly higher among adolescents compared to young women, our findings suggest a trend towards higher early MTCT among adolescents. Targeted approaches to increase ARV use among pregnant adolescents could further reduce MTCT in this vulnerable age group.

MOPEC0624

Importance of antenatal care attendance and mother's awareness of status on early childhood HIV testing in a cohort of female sex workers living with HIV in Cameroon

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Background: Female sex workers (FSW), many of whom are mothers, are disproportionately affected by HIV and have limited access to treatment. Testing for HIV-exposed infants is crucial in monitoring for and reducing vertical transmission. This study explores associations between antenatal care attendance(ANC) and early childhood HIV testing among FSW in Cameroon.
Methods: This is a secondary analysis of a cross-sectional study of 2272 FSW in Cameroon between Dec/2015-Dec/2016. Women were included in these analyses if they were living with HIV and had ≥1 child. Characteristics of FSW by ANC attendance were compared using Fisher's exact tests. Ordered logistic regression was used to model proportional odds ratios for number of a woman's children who had been tested for HIV before age 5, categorized as none, some, or all tested.
Results: A total of 481 FSW living with HIV who had ≥1 child were included with a median age of 35(IQR 30-41). 18% of FSW did not report any form of contraception, with those attending ANC being more likely to use long-acting reversible contraceptives than those not attending(p=0.005). Nearly 70% reported none of their children had been tested for HIV before age 5(326/481), and 17(3.5%) reported one or more of their children had been diagnosed with HIV. ANC (OR 3.49[1.66, 7.38]), knowledge of HIV status (OR 3.94[2.62, 6.16]), and higher education (OR 3.94[2.62, 6.16]) were all independently associated with increased odds of women having a greater number of children tested before age 5.

	Proportional Odds Ratio [95% CI]	Adjusted Proportional Odds Ratio [95% CI]
Antenatal care attendance		
Did not attend	ref	ref
Attended during last pregnancy	**4.00 [1.93, 8.23]*** **	**3.49 [1.66, 7.38] ** **
Age		
18-24	ref	ref
25-34	1.03 [0.70, 1.53]	0.63 [0.30, 1.35]
35+	0.89 [0.61, 1.31]	0.66 [0.31, 1.41]
Education		
Primary or less	ref	ref
Some secondary	0.81 [0.55, 1.18]	0.82 [0.53, 1.26]
Secondary or more	**2.92 [1.38, 6.19]****	**2.50 [1.03, 6.05]***
Pregnancy Intentions		
No future intentions	ref	ref
Has future intentions	1.37 [0.93, 2.01]	1.49 [0.94, 2.37]
Knowledge of HIV status		
No knowledge	ref	ref
Has knowledge of HIV status	**3.73 [2.45, 5.68]*****	**3.94 [2.62, 6.16]*****

Proportional odds ratios were estimated using ordered logistic regression. aEighteen women were excluded from analysis due to missing data on proportion of children tested before age 5 (n=4) or not applicable pregnancy intentions (n=13).*Statistically significant at p <0.05; **p <0.01; ***p<0.001. Bolded results represent results that are statistically significant at least at the p<0.05 level.

[Proportion. odds ratios of children tested for HIV]

Conclusions: While exact timing of mother's diagnosis was unknown, vertical transmission of HIV was high and testing among children low. ANC and promotion of mother's health were associated with better testing outcomes. For women at high risk of HIV and for whom engagement in the health care system low, finding unique strategies to promote and ensure ANC is essential.

MOPEC0625

Early mother to child HIV transmission risk amongst young women: findings from three national surveys, South Africa, 2010, 2011-12 and 2012-13

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Background: Adolescents and young women (15-24 years) contribute to 20% of all new HIV infections globally and seroconvert 5-7 years earlier than their male peers, making them a high-risk population for mother-to-child transmission of HIV (MTCT). In the context of global goals to eliminate MTCT the differential risks of MTCT amongst adolescents, young women and adults was quantified using nationally representative data from South Africa, where HIV prevalence amongst women 15-24 years is 11.4%. We previously reported MTCT amongst adolescents versus other women, without disaggregating other women into young (≤24 years) versus older.
Methods: A secondary analysis was performed using data collected from three facility-based, nationally representative cross-sectional surveys conducted in 2010, 2011-12 and 2012-13 in South Africa. Mothers with infants aged 4-8 weeks receiving their six week immunization, were enrolled and interviewed to collect data on maternal socio-demographics, antenatal and postnatal care and uptake of prevention of MTCT services. Infant dried blood spots were collected and tested for HIV exposure and infection. Weighted analysis, accounting for sample ascertainment, South African livebirths, and survey design was conducted to determine early MTCT risk amongst adolescents (≤19 years), young women (20-24 years) and adults (≥25 years).
Results: Data from 4814 adolescents, 9190 young women and 16525 adults were analysed. Early MTCT percentage (95% confidence interval, with a p-value for comparison with adults), among adolescents, young mothers and adults, respectively, was 7.2% (4.1-12.1,p=0.040), 3.6% (2.4-5.5,p=0.538) and 3.1% (CI:2.4-3.9) in 2010; 5.8% (3.3-10.1,p=0.031), 3.5% (2.3-5.3,p=0.079) and 2.1% (1.5-2.9) in 2011-12; 6.8% (3.4-13.4,p=0.034), 4.4% (2.8-6.7,p=0.008) and 1.7% (1.1-2.5) in 2012-13. Pooled analysis using data from all three surveys revealed significant associations between early MTCT and age ≥25 years (adjusted odds ratio, AOR: 0.04 (0.01-0.21,p< 0.0001) and gestational age at first ANC booking: every one week delay in gestational age at first ANC booking increased early MTCT by 9% (AOR 1.09 (1.01-1.18,p=0.025).
Conclusions: In a high HIV prevalence setting like South Africa, mother's ≤24 years have higher early MTCT compared with mother's ≥25 years, and the MTCT difference between adult and adolescent/young mothers seemed to increase with time. Targeting women ≤24 years is critical to achieve elimination of MTCT.

MOPEC0626

Prevention of mother to child transmission of HIV in Tanzania: the case of pregnant adolescents in Morogoro region

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Background: In Tanzania youth aged 15 - 24 years account for 60 percent of new HIV infections. Adolescents age 15-19 have higher birth rate of 116 per 1000. HIV prevalence for women who attended antenatal care is 6.9%. The burden of HIV extends deeply to children having children. HIV contributes to a high portion of maternal deaths in Tanzania. Transmission rates of HIV from mother to infant is 8.6%. In Morogoro 38.5% of adolescents age 15-19 have begun child bearing and the prevalence of HIV infections is 3.8%. The objective of this study is to show the need of PMTCT amongst pregnant adolescent in rural, Morogoro.
Methods: Mixed research approach. Qualitative research approach used in order to get in-depth interview from the 5 health centre selected. The study reached 50 adolescents mothers. In quantitative research approach, the study used 2016 Tanzania Demographic and Health Survey and 2016 Tanzania National Road Map Plan II.
Results: Some participants didn't know about the PMTCT services and only got tested for HIV during the first clinic visit. Over half of the participants said they came late for the clinic because of the traditional and norms that limits early clinic attendance, no friendly services and lack of knowledge to prevention services. The TDHS shows 38.5% adolescents age 15-19 have begun childbearing; 9.9% of 15-19 adolescents are pregnant with their first child and that teenagers with no education and those in the lowest income tend to start childbearing earlier than others and this increase risk of HIV. TNRMPII suggests that male involvement in PMTCT is very low and comprehensive knowledge of HIV prevention is still low among adolescents.
Conclusions: This study revealed important unmet prevention needs for female adolescents in Morogoro. Adolescent requires access to services to prevent HIV. Adolescents need to be educated; awareness of the importance of educating girls should be priority and provided in the communities. Safe corners and mobile services is urgently needed. Engagement of boys and men in sexual health and rights initiatives is key for prevention.

MOPEC0627

Assessing the implementation status of programmes for the prevention of mother to child transmission of HIV in three sub-Saharan african countries between 2013 and 2016: findings from sequential heath facility surveys

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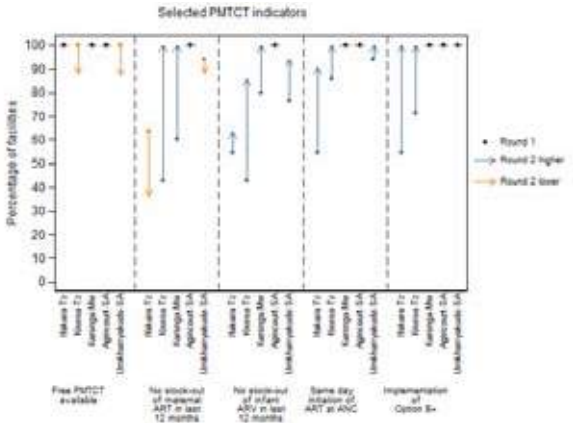
Background: In 2012, the World Health Organisation recommended the immediate initiation of anti-retroviral therapy (ART) for all HIV-positive pregnant women (Option B+). Countries adopted different roll-out approaches: Malawi, an early adopter, implemented it across the whole country in 2011; Tanzania, a mid-term adopter, chose a staggered scale-up beginning in 2013 at the tertiary level then decentralising to peripheral facilities. South Africa, a late adopter, also used a staggered approach starting in 2015, but implemented one province fully at a time. We aimed to assess the implementation status of these prevention of mother-to-child transmission (PMTCT) programmes.
Methods: Two rounds of health facility surveys took place in 43 health facilities situated within health and demographic surveillance sites in Karonga, Malawi (n=6), Ifakara and Kisesa, Tanzania (n=14) and Hlabisa and Agincourt, South Africa (n=23). A standardised questionnaire was used in 2013/2014 (round 1) and 2015/2016 (round 2). Descriptive statistics were used to compare key indicators of PMTCT implementation across the rounds.
Results: Overall, 43 (96%) of facilities offered PMTCT in round 1; by round 2, 100% offered Option B+. The proportion of facilities offering free PMTCT, reporting no ART stock-outs and offering same-day ART initiation increased or remained at 100% across the rounds and in all sites (Figure 1).



[Figure 1: Changes to selected PMTCT indicators]

However, in Tanzania and South Africa, some facilities imposed charges for PMTCT services and stock-outs still occurred. In Tanzania, same-day ART initiation at antenatal clinics was not fully implemented.
Conclusions: Regardless of the strategy chosen for Option B+ implementation, all countries demonstrated improvements in service delivery illustrated by 100% achievement of key PMTCT indicators in many settings. However sub-optimal implementation, particularly in charging for "free" services or in ensuring ART supplies jeopardizes access and availability. As countries strive for universal access, care needs to be taken to consolidate these impressive gains.

MOPEC0628

Efficacy of option B-plus in a cohort of mothers with high retention in averting paediatric transmission: low rates of transmission but high proportion of unreported outcomes

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Background: Since 2012, the WHO recommend start of lifelong ART constituted by TDF+FTC/3TC+EFV for all HIV-positive pregnant and breast feeding women (Option B-plus). There is limited information on the infants' sero-status due to poor documentation and high rates of lost to program, up to 68% in sub-Saharan Africa. In this analysis we describe proportion of early and late transmission in a cohort of mothers with high (92%) retention.
Methods: At the Infectious Diseases Institute, Kampala, Uganda, women found to be pregnant are referred to the HIV-Sexual Reproductive Health integrated clinic to receive both HIV and antenatal care. We included women enrolled from January 2012 to August 2014 with a follow-up extended to August 2016, and retained up to the end of the pregnancy. We extracted data on baseline demographics and clinical information. Infants HIV-DNA PCR tests at week 6, month 6 and 18 were traced in the clinic files.
Results: Seven hundred women were included, median age 34 years (IQR: 26-35), 36.3% in WHO stage 3 /4, median CD4 count was 447(IQR:301-651)cells/μL; 76% joined during the 1st or 2nd trimester, the parity was >2 for 36.3%, and 73.3% were already on ART for a median time of 28(IQR:10-57) months; 48% of the infants were female, median weight was 3.2 Kg (IQR:2.5-3.5).
Table 1 shows the sero-status of the babies; 22 (3.1%) infants died, all with unknown sero-status; 3 tested positive at week 6, and 1 additional at month 12 and 18. Two of the mothers of the 4 HIV-positive infants were ART-naïve at the time of the pregnancy.

Time of HIV test	Total number	N(%)Positive	N(%) Negative	N(%) Unknown
6 weeks	700	3 (0.4)	562 (80.3)	135 (19.2)
12 Months	675	4 (0.6)	469 (69.5%)	202 (29.9)
18 Months	655	4 (0.6)	437 (66.7)	216 (32.7)

[Serostatus of babies at week6, month 12, month18]

Conclusions: We report very low documented HIV transmission comparable with those reported in clinical trials settings (PROMISE study, 13 sites in sub-Saharan Africa: 0.6% at month 12); however demonstrating the efficacy of Option B-plus in terms of averted transmission in routine settings is challenging since high proportion of infants don't have a documented HIV tests due to lack of traceable documentation, or mothers attending clinic visits without their babies.

MOPEC0629

Increasing contraceptive uptake by people living with HIV through integration of family planning and HIV service delivery: the center for integrated health programs' experience in Benue and Kaduna states, Nigeria

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Background: The use of family planning services is reportedly low among HIV positive women in Nigeria. Traditionally, HIV and Family planning services function as parallel programs even in the same hospital, resulting in missed opportunities for family planning services uptake by People Living with HIV (PLHIV). In order to increase use of family planning services among PLHIV, Centre for Integrated Health Programs, Nigeria with funding from Centre for Disease Control (CDC) implemented Family Planning/HIV (FP/HIV) integration program in Benue and Kaduna States, Nigeria. The aim of this study was to assess the utilization of family planning methods amongst People Living with HIV (PLHIV) in Kaduna and Benue States, Nigeria.
Methods: Using a pre-defined criteria, a structured questionnaire was used to assess 187 health facilities where100 health facilities were selected. 349 trained HIV counsellors were trained on FP methods focusing on short term methods (pills,injectables) Long Acting Reversible Contraceptives (LARC) and integration of services. 200 PLHIVs were selected using purposive sampling to create demand for family planning. In the HIV clinics, spaces for family planning service were created and equipped with instruments and FP commodities. FP services were integrated into HIV Testing Services (HTS), the ART clinic and Prevention of Mother to Child Transmission of HIV (PMTCT) services. Tools to capture data for FP methods were developed and distributed to the health facilities. Data was collected between April and September, 2016. The collected data was collated and compared with the baseline data.
Results: Compared to 172 PLHIV accessing FP methods at baseline, a total of 17,009 (9,888%) PLHIV were reached with various FP methods in the HIV clinics within a space of 6months of data collection. Out of which 11677(68.7%) women accepted short term methods while 5332 (31.3%) women accepted long term methods.
Conclusions: This finding revealed integration of Family planning into HIV services greatly improves access and uptake of Family Planning services among PLHIV.

MOPEC0630

An economic evaluation of the integrated approach for triple elimination of mother to child transmission of HIV, hepatitis B and syphilis

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Background: The prevention and ultimate elimination of mother-to-child transmission (EMTCT) of HIV, hepatitis B and syphilis share a common platform of maternal and child health services and related interventions. An integrated framework for triple elimination of mother-to-child transmission of HIV, hepatitis B and syphilis in Asia and the Pacific is under development aiming at proposing an integrated and coordinated approach to achieve elimination in an efficient and sustainable manner. The study aims to develop an economic evaluation tool to assess the cost-effectiveness of the integrated approach.
Methods: Based on existing frameworks for the EMTCT for each individual infection, we constructed an integrated framework that combines infection prevention procedures with routine antenatal care (ANC). The integrated approach provides

the same services to pregnant women and exposed children. We then evaluated the potential reduction in the investment of the integrated approach as a result of resource pooling and improvements in service coverage and coordination, based on a decision tree analysis. We further conducted an economic evaluation to assess the cost required to avert one infection in exposed infants. The tool was constructed using Microsoft Excel and ratified on simulated epidemiological data that resemble epidemics in Asia-Pacific countries.
Results: The tool provided detail estimates on the number of pregnant women and children on each stage of continuum of care. Based on this, it demonstrated that coverage of ANC and provision of screening are crucial to the reduction of mother-to-child transmission of these infections. The integrated approach substantially reduces 30-55% personnel costs and maximizes the screening coverage by allowing pregnant women to be screened for all three infections in a single antenatal visit. The integrated approach was shown to be cost-saving in most simulated cases. Sensitivity analyses on the model parameters indicated the evaluation tool was robust and findings were reliable.
Conclusions: We developed a feasible and reliable economic evaluation tool and demonstrated the integrated approach using maternal, perinatal and postnatal care as a platform for triple elimination of HIV, hepatitis B and syphilis is highly cost-effective.

MOPEC0631

Prevention of mother to child transmission of HIV in an urban area of the USA: are we doing too much?

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Background: Special Immunology Services (SIS) at Children's National Medical Center serves the majority (>95%) of perinatally HIV-exposed infants (HEIs) in the high HIV prevalence (2%) metropolitan Washington, DC area, USA. The study aimed to analyze the current approaches to and outcomes of prevention of mother-to-child transmission (MTCT) in the DC area.
Methods: This was a retrospective cohort analysis of SIS HEIs referred for HIV testing, care and treatment. We collected maternal demographics, antiretroviral treatment (ART) during pregnancy and delivery, HIV viral load (VL) pre-delivery and delivery type; infant data included post-partum ART prophylaxis and final HIV status. Descriptive statistics were used for analysis.
Results: Data were abstracted from 262 records of 328 HEIs referred to SIS during 2013-2015. Mean maternal age was 30 years (range 15-48) and 94% (n=245) were Black. The majority (96%; n=252) received ART during pregnancy. The most frequently used backbone was fixed dose combination (FDC) of zidovudine+lamivudine (35%; n=89) and emricitabine+tenofovir (41%; n=103), with lopinvair/ritonavir (37%; n=92), and atazanavir/ritonavir (34%; n=86). A small proportion of mothers took novel ART including rilpivirine (10%; n=24), dolutegravir (0.4%; n=1) and raltegravir (4%; n=9). A majority (75%; n= 196) of mothers received intravenous zidovudine during labor and 98% (n=258) of infants received zidovudine prophylaxis postpartum. Only 15% (n=40) of mothers were considered high-risk based on high (>1000 copies/mL) or unknown pre-delivery VL; 13 HEIs (5%) received triple and 13 HEIs (5%) dual ART prophylaxis. More than half of all deliveries (58%; n=152) were conducted via C-section; 111 (73%) of which occurred in low-risk mothers with mean VL < 20 copies/mL (range 0-767). One infant (0.38%) was confirmed HIV-infected and initiated on ART.
Conclusions: Low MTCT risk was observed among the majority of HEIs; however, a majority of mothers (75%) received intravenous zidovudine and more than half (58%) had a C-section. Evaluation of indications for the C-section is ongoing to identify whether it was based on MTCT risk assessment. Despite national USA guidelines recommending intravenous zidovudine in labor for high-risk deliveries only, we observed frequent use of intrapartum zidovudine prophylaxis within our cohort of HEIs in urban settings in the USA.

MOPEC0632

Retention of mother/baby pairs along the PMTCT cascade: a systematic review and meta-analysis of current evidence of options B and B+ strategies

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Background: Since 2010, a growing number of sub-Saharan African (SSA) countries have revised their national PMTCT guidelines to include either Option B or Option B+ to phase out Option A. A comprehensive PMTCT program must guarantee follow-up, care and antiretroviral treatment (ART) / prophylaxis for HIV+ mothers and their exposed infants until 18 months post-partum.
This study aims to systematically review published literature to estimate retention and lost-to-follow up (LTFU) rates of mother/infant pairs from maternal ART initiation to Early Infant Diagnosis (EID) and to explore reasons of poor retention under B/B+ strategies.
Methods: We searched electronic databases for relevant quantitative and qualitative studies, published between January 2010 and December 2016, reporting retention and/or LTFU of mother/infant pairs as a primary outcome. To increase sensitivity, we reviewed gray literature databases and reports. The review was performed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines. Quality of evidence was assessed using the GRADE strategy. Heterogeneity was appreciated by the I_2 statistic.
Results: Of the 96 records identified, 25 articles were included (analysis in progress), the majority being from sub-Saharan Africa. For HIV+ pregnant and breastfeeding women, pooled retention estimates were 81% [95%CI: 73-87; I_2=88%] at 6 months and 70% [95%CI: 62-77; I_2=98%;] at 12 months on ART. Pooled estimates of LTFU were 20% [95%CI: 16-25; I_2=85%] at 6 months and 17% [95%CI: 3-35; I_2=98%] at 12 months on ART. Pooled proportion of HIV-exposed infants tested for HIV by PCR at 6-8 week post-partum was 66% [95%CI: 57%-75%; I_2=86%]. Frequent reported reasons for poor retention were initiation of ART on the same day as HIV diagnosis, facility resource constraints (e.g. long waiting hours, staff and drug shortages) and high-volume health facilities.
Conclusions: Retention of mother/infant pairs under Option B/B+ is affected at each step of the PMTCT care cascade, especially after birth. PMTCT national and sub-national programs should be aware of the potential negative impact of low retention rates on the effectiveness of option B/B+ in reducing HIV transmission. Enhanced patient-oriented pre-ART counseling, referral to smaller sites for ART initiation should be considered to maximize follow-up of the mother/infant pairs.

MOPEC0633

Induced abortion, migration and HIV: an analysis of migrants from sub-Saharan Africa living in Île-de-France, France

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Background: Migration can strongly affect fertility due to adaptation to new socioeconomic and cultural context. The aim of this study was to examine abortion practice in regard to migration in women living with HIV/Aids (WLHA) and women not living with HIV/Aids (WNLHA).
Methods: Data analyzed came from the ANRS Parcours study, a retrospective life event survey conducted in health facilities with two groups of migrant women born in sub-Saharan Africa and living in Île-de-France: WLHA (HIV group) and women attending primary care centers (reference group). Association between migration and induced abortion was evaluated through Generalized Estimating Equation in unadjusted and adjusted models. Adjustment considered variables linked to women (age, level of education and practice of religion at the survey) and to the pregnancy (before/after migration, age at pregnancy, contraceptive use at the beginning of pregnancy, intendedness, type of relationship and history of previous abortions). A clustered chi square was used to evaluate association between intendedness of pregnancy and migration.
Results: A total of 1,822 pregnancies at HIV and 1,377 at reference groups were analyzed. In the HIV group, 22.8% of pregnancies occurred before and 16.1% occurred after migration were ended by induced abortion, same situation for 15.6% and 11.0% of pregnancies in the reference group. These proportions differed for HIV and reference groups, both, before (p=0.010) and after (p=0.012) migration. In both groups, probability that a pregnancy was ended by abortion decreased after migration in unadjusted analysis (HIV group: OR 0.66, CI95% 0.51-0.85; reference group: OR 0.59, CI95% 0.42-0.84).

However, after the inclusion of intendedness of pregnancy, this association was undone (HIV group: OR 0.82, CI95% 0.56-1.19; reference group: OR 1.52, CI95% 0.91-2.54). For both groups, there is a statistically significant decrease of unplanned and unwanted pregnancies after migration.
Conclusions: Although the determinants of abortion are virtually the same for WLHA and WNLHA, its practice is more frequent among the firsts, and it is especially motivated by their greater social and programmatic vulnerability. After migration in France, abortion practice decreases among African sub-Saharan women, due to a decrease of unplanned and undesired pregnancies, either in WLHA or WNLHA.

MOPEC0634

Maternal health and ART use at 4-26 weeks postpartum in Option B+ in Malawi

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Background: The PMTCT Option B+ rationale proposed that lifelong ART reduces mortality and morbidity in pregnant/breastfeeding HIV-infected women. We report factors associated with maternal health of a cohort of HIV-infected women at 4-26wks postpartum at enrollment in the National Evaluation of the Malawi PMTCT Programme (NEMAPP).
Methods: In a cross-sectional study, structured interviews collected socio-demographics, ART use, and self-reported health status and function (ie.Karnofsky scale). We measured BMI, CD4 and HIV1 RNA for intensified clinical monitoring in a nested cohort.
Results: Of1307 Option B+ women, most were 6-12wks postpartum (n=879;67.3%) and on ART (n=1151;88.1%).
For self-reported health status at ART initiation, 171 (13.1%) women had minor illness and 51 (3.9%) major illness; most reported improved health status at study enrollment (155/171 (90.6%) and 47/52 (90.4%), respectively).
Of the 580 in the nested cohort, the following functional health status was measured at enrollment: 545 (94.0%) normal, 21 (3.6%) minor illness not affecting normal activities and 4 (0.7%) major illness requiring daily assistance. In the 3 months before enrollment, women reported the following conditions: malaria (n=53;9.1%), pneumonia (n=32;5.5%), diarrhea (n=40;6.9%), TB (n=11;1.9%) and hospitalizations (n=7;1.2%). Twenty-six(4.5%) women had BMI< 18.5, 326 (56.2%) had a CD4>500 and 417 (71.9%) had viral loads< 50 copies.
More women on ART reported normal functional health than women who stopped ART (95.6% vs 87.5%, p< 0.001), and more women with CD4 >500 reported normal functional health than those with CD4 < 500 (97.2% vs 92.8%, p=0.02). No associations were seen between ART status or CD4 count and recent malaria, TB, pneumonia, diarrhea or hospitalization.
In multivariable analysis, poor functional health was associated with CD4< 500 (aOR2.6,p=0.03) when controlled for ART status and duration of known HIV-status.
Conclusions: Overall, women had low mortality and morbidity at 4-26 weeks postpartum consistent with increased ART uptake in asymptomatic women via Option B+. ART use was high amongst this cohort and ART was associated with improved self-reported health status, affirming the rationale for implementing Option B+ in Malawi. Further research should explore maternal health and ART use over time to inform long-term benefits of Option B+.

MOPEC0635

Retention and viral suppression of newly diagnosed and known HIV-positive pregnant women on Option B+ in Kenya

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Background: Kenya introduced continuous antiretroviral treatment (ART) for all pregnant women living with HIV (Option B+) in 2014. We describe the uptake of viral load (VL) testing and outcomes, comparing newly diagnosed HIV positive (NP) and known positive (KP) pregnant women in western Kenya.
Methods: This is a retrospective cohort study among 164 HIV-positive pregnant women presenting for antenatal care (ANC) at five clinics September to November 2014 and followed through February 2016. Virologic testing was conducted per Kenyan National Guidelines for pregnant women six months after (ART) initiation or six months from last VL if already on ART. KPs (n=92, defined as women with HIV diagnosis prior to current pregnancy) were compared to NPs (n=72) regarding virologic suppression and retention in care.
Results: At first ANC visit, NP were younger (24.2 years (SD 4.6) vs. 28.2 years (SD 5.6), p<0.001) compared to KP (Table 1). The majority of NP (96%) were initiated on Option B+ while over half of KP (58%) started ART for clinical/immunological criteria (p<0.0001). KPs were more likely than NPs to have a VL performed following guidelines (64% vs. 33%; p< 0.001). Among those tested, virologic suppression was high in both groups (92% KP vs. 100% NP; p=0.31). More KPs (83%) vs. NPs (66%) remained active in care at end of the follow up (p=0.02). Uptake of infant testing was higher among KP (87%) vs. NP (69%) (p<0.01). Two (2%) infants were HIV infected at six weeks, both from newly diagnosed mothers (p=0.15).
Conclusions: Women newly diagnosed with HIV during pregnancy show poorer uptake of VL and worse retention in care than those diagnosed prior to pregnancy. Elimination of mother-to-child transmission targets will require a greater focus on women newly diagnosed with HIV in pregnancy.

	New Positives n (%)	Known positives N (%)	p-value
Mothers' characteristics and outcomes	N=72	N=92	
Marital status*			0.01
Married	57 (80.3)	78 (84.8)	
Widowed/divorced	1 (1.4)	8 (8.7)	
Single	13 (18.3)	6 (6.5)	
Gestational age (weeks)*, median (IQR)	26 (13-26)	18 (12-25)	0.14
WHO stage†			0.0008
I	59 (84.3)	53 (57.6)	
II	9 (12.9)	24 (26.1)	
III/IV	2 (2.9)	15 (16.3)	
Initiated on ART	69 (95.8)	91 (98.9)	0.32
Duration on ART at VL test (months), median (IQR)	6 (6-7)	23 (7-44)	<.0001
Indication for ART			<.0001
Option B+	65 (95.6)	37 (41.6)	
Clinical/Immunological Criteria	3 (4.4)	52 (58.4)	
ART regimen during pregnancy			0.13
NNRTI-based	69 (100.0)	84 (94.4)	
PI-based	0 (0.0)	4 (4.5)	
Other	0 (0.0)	1 (1.1)	
6-mo viral load			0.31
<50 cp/mL	23 (100.0)	54 (91.5)	
50-1000 cp/mL	0 (0.0)	0 (0.0)	
>1000 cp/mL	0 (0.0)	5 (8.5)	
Uptake of 6-mo VL test	23 (32.9)	59 (64.1)	<.0001
Outcome¶			0.02
Active	47 (66.2)	76 (82.6)	
Transferred/Discontinued	3 (4.2)	4 (4.4)	
Deceased	0 (0.0)	1 (1.1)	
Lost to follow-up	21 (29.6)	11 (12.0)	
Infant outcomes	N=72	N=95	
Delivery outcome			0.54
Live birth	56 (98.3)	79 (92.9)	
Stillborn/SAB/Died	1 (1.8)	7 (8.0)	
6-week PCR test result			0.15
Positive	2 (4.1)	0 (0.0)	
Negative	47 (95.9)	77 (100.0)	
6-week PCR uptake	49 (69.0)	77 (87.5)	0.004

[Table 1. Characteristics and outcomes of known and newly diagnosed HIV positive pregnant women and the infants]

MOPEC0636

Food insecurity and intimate partner violence among HIV-infected pregnant women in Western Kenya

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Background: Potential interactions between pregnancy, food insecurity (FI), intimate partner violence (IPV) and HIV have not been well characterized. The aim of this study was to explore associations between FI and IPV among a mixed cohort of HIV infected and uninfected women in pregnancy. We hypothesized that FI would be associated with IPV, probable depression, adverse birth outcomes among all women and decreased adherence among HIV-infected women.
Methods: Pregnant Kenyan women (n=368) of mixed HIV status were enrolled into the Pith Moromo observational cohort study and were surveyed on demography, FI, physical and psychosocial health and any type of violence. IPV was operationalized as any physical, sexual or psychological harm by a current or former partner within the incident pregnancy. Maternal probable depression was measured using

the Center for Epidemiological Studies Depression Scale (CES-D 20). Adverse birth outcomes comprised of miscarriage (< 22wk), stillbirth (≥22 wk), and infant death. Multivariate logistic-regression analysis was conducted to analyze factors that were independently associated with IPV.
Results: The mean age of the 368 participants was 24.8 years. Of these, 333(90.49%) were married or cohabiting. One hundred and eighty three (49.73%) were HIV-infected and on antiretroviral therapy. At baseline, the proportion of those with FI was 67.93% and did not differ by HIV status. In the index pregnancy, IPV (any type) was reported by 104 women (28.26%). Approximately 11.48% was emotional, 4.92% physical and 4.1% was sexual violence. IPV did not differ by HIV status (30.05% vs. 26.49%). In multivariate analysis, we found that among HIV-infected women reporting IPV, there were: i)high odds of moderate and severe FI (aOR 3.06, 95%CI: 1.29-7.26); ii)high odds of maternal probable depression (aOR 2.26, 95%CI: 1.06-4.81); iii)no evidence of non-adherence to HAART during pregnancy (aOR 0.86, 95%CI: 0.28- 1.40 and; iv)no evidence of adverse birth outcomes (aOR 1.86, 95%CI: 0.63-5.50).
Conclusions: Almost two in three women had FI and one in three suffered IPV in the index pregnancy. Having IPV and mental health screenings coincide with nutrition assessments during pregnancy may help identify women who would benefit from resources designed to increase physical safety, psychological well-being, and food security.

MOPEC0637

Pregnant and breastfeeding women healthcare seeking in a high HIV prevalence area, Ndhiwa sub-county, Kenya: a qualitative study

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Background: The number of newly infected children per year in Kenya is still high at 13,000 despite increased provision and uptake of prevention of mother to child (PMTCT). Better understanding of health seeking is critical to improve and design PMTCT programs. We assessed women's healthcare seeking during pregnancy and breastfeeding.
Methods: Individual in-depth interviews were conducted with 40 pregnant and breastfeeding women and 20 men. Key informant interviews were conducted with 20 healthcare workers across antenatal care facilities in Ndhiwa sub-county. This qualitative data collected between March and June 2016 was managed using Nvivo 8.0. A descriptive, exploratory and explanatory approach was used in the analysis of healthcare seeking behavior.
Results: Main sources of healthcare included both alternative (trusted traditional birth attendants (TBA), faith healers, herbalists and traditional healers) and modern (public and private hospitals, chemists, shops and market pill vendors). TBA was consulted mainly because they were trusted and allowed convenient modes of payments not necessarily monetary. Alternative sources of healthcare were preferred for conditions that were believed to be not understood by modern medicine. Hospitals was preferred for monitoring the safety of the baby, health education, availability of complications and emergency resources (e.g. blood) and to acquire the antenatal care card as proof of compliance and symbol of a being a good patient in case of future need. Barriers to seeking facility care included distance to the facility, transport costs, costs of facility care, long queues, time spent waiting, poor provider's attitude, perception of the illness, and fear of HIV test.
Conclusions: It may be useful for health providers to appreciate the full reality of medical pluralism and its implications on healthcare utilization. Involving alternative care providers through education and training programs can be used for prevention, referral and linkages to requisite skilled care.

MOPEC0638

A retrospective study on still birth rate of HIV-infected pregnancy and related contributory factors in West Bengal, India

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Background: In HIV infected pregnancies, pregnancy does not seem to alter the course of HIV infection significantly but HIV apart from vertical transmission may result in adverse obstetric outcomes. Several factors like maternal immunological status, status of Anti Retroviral treatment and adherence , Literacy status, family support, etc may also be contributory.
Methods: A retrospective cohort study was carried out through analysis of secondary data from 252 Integrated Counselling and Testing Centres across the state of West Bengal from April' 2012 to March'2016. A total number of 1729 HIV infected pregnancies were followed up and financial year wise still birth rate was calculated and it was compared with still birth rate of the state among all pregnancies as per SRS figure of 2012. Year wise trend analysis was done and test for statistical significance was undertaken to substantiate probable association between HIV infected pregnancy and still birth.
Z Tests (Two Tailed) for two means and two proportions were performed to find out the effects of other contributory factors like maternal baseline CD4 count during pregnancy, whether on Anti Retroviral treatment or not during pregnancy, age of conception, literacy status of mother, family involvement in terms of spouse testing for HIV.
Results: Still Birth Rate was found significantly higher (28 per 1000) in HIV infected pregnancies compared to all pregnancies (5 per 1000) in West Bengal. With initiation of anti retroviral treatment still birth rate was found to be reduced significantly and if the spouse of HIV positive pregnant woman was tested for HIV which was considered indirectly related to family involvement in PPTCT (Prevention of Parent to Child Transmission) / PMTCT (Prevention of Mother to Child Transmission) / program, adverse obstetric outcomes were minimized significantly.
Conclusions: Since HIV infection may cause adverse obstetric outcomes, early initiation of antiretroviral treatment and ensuring family involvement in PPTCT/ PMTCT program can decrease the still birth rate significantly.

MOPEC0639

Prevention of HIV transmission among young girls under 19 in Boulmiougou, Burkina Faso: backtracking

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Background: - Determine the prevalence of risk behaviors among girls under 19 years of age
- Evaluate residual risk factors
- Assess the prevention coverage of the target group in the area
Methods: - This is a survey that involved 1000 girls under 19 years of high schools and colleges
- A free screening counseling with specific maintenance guide was administered followed by a blood sample and delivery of the results after a post-test
- An analysis of the results was carried out which allowed to characterize the dynamics of risk behaviors
- A survey on the services offered by the health structures and the associations has been carried out
Results: - This survey involved 1000 girls aged 14-18, 67% of whom were sexually active,
- Of the 670, 85% came out with older men for economic reasons and occasionally protected themselves, 65% had multiple partners, 75% poorly defined modes of transmission and means of prevention or planning, 16% Already practiced a voluntary abortion,
- The prevalence of risk behaviors reported in the target group is much higher than among adults (2.8 vs. 1.6)
- 100% of the positive cases were referred to the medical and psychosocial care structures
- Coverage of the target group for prevention is zero
- Highlighting potential contradictions between strong political mobilization and program sustainability
- A preventive program in schools is awaiting implementation provided that it receives funding

Conclusions: Our findings highlight the current lack of prevention among young girls in the area. It is clear that the TFPs are abandoning prevention, which explains the lack of coverage and the silent rebound of the epidemic among young people. There is a need for intensive and specific strengthening of prevention programs for girls. New strategies for the involvement of partners and prevention programs should be developed.

MOPEC0640

"Key" yet marginalised: an analysis of the HIV prevention response and "Key" populations in Zambia - a case study of the Southern province

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Background: Zambia's and southern province adult HIV prevalence measured at 14.3% and 14.5% respectively. Recent data suggests that Key populations are disproportionately infected with HIV compared to the general population. The Measure Know Your Response (KYR) study took place from September 2013 to July 2014 in the Southern Province of Zambia with support from USAID. The aim was to map and characterize the HIV response and to identify gaps in the response, in particular to key populations - MSM, migrants, incarcerated, PLWHIV, transgender and sex workers.
Methods: Mixed method - survey and FGDs - were used to collected data on:
1. broad view of the policy environment for HIV prevention vis key populations and gender;
2. Interventions of Government and NGOs; strategic information to help identify high risk groups and geographical areas where HIV and associated problems are common;
3 extent district-level health facilities provided health services to a range of groups;
4. HIV-prevention interventions by the Government sectors other than health; and,
5 interventions of NGOs and their services. Data from the quantitative questionnaires was analysed using SPSS.
Results: There are no specific policies to guide program implementers on dealing with key populations. Activities of key populations - MSM, sex workers and transgenders are illegal in Zambia, hence major key populations and sexual minorities excluded from both government and NGO HIV prevention programs. Limited advocacy to amend policies and laws. No data routinely collected on key populations due to lack of policy guidance. No government health facilities in the 12 districts targeted key populations and none of the three prisons provided condoms to prisoners as a means of HIV prevention.
Fewer than three of the 93 organizations surveyed targeted key populations. Few catered for sex workers.
Conclusions: Key populations remain marginalized in HIV prevention interventions of both government and NGOs in Southern Province of Zambia. Implementers prohibited by law and policies from providing services for some key populations and no data are collected on key populations. Legal and policy environment needs to be changed to allow implementers to cater for key populations. Activities needed to reduce stigma around sexual minorities and key populations.

MOPEC0641

PMTCT program utilization and HIV transmission rates in young and adolescent mothers compared to adult mothers: a nationally representative sample of women screened at 4-26 weeks postpartum in Malawi

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Background: Evidence from limited studies indicate that prevention of mother-to-child-transmission (PMTCT) outcomes in young and adolescent women are worse than for adult women. In this study we compare utilization of PMTCT services (uptake of antenatal testing and antiretroviral treatment (ART)) and mother-to-child transmission (MTCT) rates between young (< 25yrs) or adolescent (< 20yrs) mothers, and adult mothers (≥25yrs) in a national PMTCT evaluation in Malawi.
Methods: Mothers were consecutively consented and screened in 54 under-5 clinics with their 4-26 week old infant between October 2014 and May 2016. Structured interviews with mothers confirmed uptake of antenatal testing and ART. Maternal HIV rapid-testing was conducted at site. Exposed infants underwent infant virological HIV testing. Weighted survey design analysis was conducted using SPSS.
Results: A total of 33,744 mother-infant-pairs were included; 17,928 (53.8%) were young (12-24yrs), 6,427 (20.5%) were adolescent (12-19yrs) mothers. Among all, 33,276 (97.8%) reported being tested for HIV before or during last pregnancy. Young mothers had more likely missed antenatal HIV testing than adult mothers [OR 1.8(95%CI1.2-2.7)]. Overall, 3,233 (11.3%) mothers were identified HIV-infected before or during pregnancy; this prevalence was lower in young (4.6%) and adolescent (2.8%) mothers. At time of study, 286 new infections were identified (244 previously negative; 42 previously unknown). Adolescents were less likely newly identified infected (previously negative) then young and adult mothers [OR 0.5(95%CI0.2-0.9)]. However, newly identified HIV-infected (previous unknown) young mothers may have missed earlier diagnoses than adult mothers [OR 3.5(95%CI0.9-14.4)]. Among the known HIV-infected women, 3,034 (94.7%) reported being on ART, with no difference between young or adolescent and adult mothers. Overall MTCT rate at 4-26 weeks was 4.7%, with no difference between young or adolescent and adult mothers.
Conclusions: Over half of mothers attending under-5 clinics in Malawi are under 25 years. Utilization and effectiveness of PMTCT services in Malawi is high and MTCT rates are relatively low. HIV prevalence is much lower among young and adolescent compared to older mothers, but the risk of missing antenatal HIV testing appears higher among younger and adolescent women. There appears little difference in PMTCT outcomes between younger and older mothers in Malawi.

MOPEC0642

Beliefs and practices underlying *"undetectable = uninfectious"* in a study of serodiscordant couples enrolled in the Positive Plus One study in Canada

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Background: The idea that "undetectable=uninfectious" has increasingly received endorsement from HIV experts and AIDS Service Organizations (ASOs). Yet controversy remains, with many advising continued condom use to ensure the greatest protection. We examine whether the behavior of people in serodiscordant relationships is in keeping with this message - namely whether they use condoms at a lower rate when the positive partner's viral load (VL) is undetectable.
Methods: People were recruited via 143 Canadian ASOs and clinics to participate in a survey of serodiscordant couples. Both partners were asked to complete a survey addressing sociodemographics, HIV-transmission management, health status, and more. Descriptive statistics and ordered logistic regressions (OLR) were used.
Results: A total of 244 current HIV-serodiscordant relationships were represented in the data; 115 relationships were male-female, 116 were male-male, and 13 were a mix of gender identities. Sixteen percent of couples reported no sexual activity, 8.5% reported sex but no intercourse, 27.1% reported intercourse always using condoms, 24.5% sometimes used condoms, and 23.9% never used condoms. When asked if they agreed/disagreed with the statement: "when a person's VL is undetectable VL they can safely have intercourse without a condom, 47.2% agreed. There were no significant differences in agreement by HIV status or relationship-type; those who were neutral were more likely to have abstained from sex. The positive partner's latest VL was: undetectable in 81.9%, detectable in 10.1%, and unknown in 8% of couples. In an OLR of condom use, when the HIV-positive partner was insertive, controlling for relationship-type and socio-demographics, we found condoms were less likely to be used by those with an undetectable VL (AOR=0.11, 95%CI 0.020—0.64). Condom use was also lower when the HIV-positive partner was receptive and undetectable (AOR=0.23, 95%CI 0.060—0.87).
Conclusions: Although VL suppression is high and many support the idea that "undetectable=uninfectious" Canadian serodiscordant couples are cautious in avoiding transmission. Couples with undetectable VL are less likely to use condoms; however, as many as a quarter reported no sex or no intercourse. For serodiscordant couples discussions on this issue may be most effective including both partners so they are encouraged to assess the complexity of their relationship risk factors.

MOPEC0643

Sexual behaviour among people with HIV in Brazil according to antiretroviral treatment and viral load status

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Background: Transmission of HIV in the Brazil continues to be high with average of 41,1 thousand cases of AIDS per year in the last five years being the sexual transmission the main route. Since 2013, the country has adopted the combined prevention strategy as treatment as prevention, with the early use of ART for all persons diagnosed regardless of CD4 count, with a view to reducing transmissibility of HIV and achieve the 90-90-90 treatment target. Objective : To evaluate the association between the condomless sex self-reported with HIV-serodifferent partner and viral load status and sociodemographic factors.
Methods: The cross-sectional study was conducted on HIV adults in Brazil, in 2014 to 2015. A standardized questionnaire was administered, socio-behaviour and clinical data were collected. The condomless sex in the past 12 months self-reported and the latest documented viral load were analysed using the laboratory examination control system (SISCEL). The HIV-transmission risk was defined as condomless sex with HIV-serodifferent partner with clinic-recorded viral load more than 40 copias/ml in the last 12 months.
Results: A total of 258 participants and 57.4% had a sexual partner in the last 12 months, in which 67.6% had a partner with negative or unknown serology. The condomless sex were self-reported by 41.9%, 40.6% and 31.8% among men, women and men who have sex with men, respectively and viral load were detectable (more than 40 copies/ml/detectable) betwen 39.9% of individuals. The HIV-transmission risk was 10.1 % and 66.7% were associated with age ranging from 20 to 39 years (p = 0.005).
Conclusions: The goal of ART is to reduce viral load, ideally to an undetectable level, however, optimal treatment adherence is required. Support to improve adherence to HAART are needed as well as counseling for the use of HIV transmission prevention guidelines for HIV-infected PLHIV and use of condom with HIV seronegative partner. Understanding patterns of sexual behavior accord to antiretroviral treatment use among people diagnosed with HIV has implementation for clinical care and public health.

MOPEC0644

Disclosure of HIV-serodiscordant relationships to healthcare providers is associated with viral suppression in the HIV-positive partner: preliminary findings from the Canadian Positive Plus One Study

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Background: Although disclosure of one's HIV-status to sexual partners is well studied, less is known about associations between disclosure of HIV-serodiscordant relationships by both partners to healthcare provider(s) and HIV outcomes. As many as 23% of people living with HIV in Canada may be in an HIV-serodiscordant relationship. In this investigation, we hypothesized that HIV-positive partners would be more likely than HIV-negative partners to disclose their relationship to their respective healthcare provider(s) and that relationship disclosure by either partner would be associated with HIV viral suppression.
Methods: We used data from a Canadian national sample of people currently engaged in HIV-serodiscordant relationships in online and telephone-based surveys. Analyses used generalized estimating equations with a logistic link function to address non-independence of individuals within dyads and Firth logistic regression to address small-sample bias.
Results: At the time of writing, the study has recruited N=331 participants (138 HIV-negative; 193 HIV-positive; 87 dyads), all in current relationships. Compared with HIV-negative partners, HIV-positive partners had twice the odds of disclosing their relationship to healthcare provider(s) (AOR=2.0; p=0.02). For HIV-positive partners, disclosure of the relationship was less likely for those diagnosed after their relationship began, compared to those diagnosed prior to the relationship (AOR=0.09; p<0.001). While HIV-positive partners who had disclosed their relationship to healthcare provider(s) had 3x greater odds of reporting viral suppression compared with those who had not disclosed (AOR=2.98; p=0.05), HIV-negative partners who had similarly disclosed their relationship had 7.5x greater odds of reporting that their HIV-positive partner had attained viral suppression when compared with those who had not disclosed (AOR=7.46; p=0.004).
Conclusions: Disclosure of HIV-serodiscordant status by HIV-positive and HIV-negative partners to their respective healthcare provider(s) was associated with viral suppression. Although HIV-negative partners were less likely to disclose their relationship, their disclosure was associated with more than twice the odds of viral suppression when compared with disclosure by HIV-positive partners. These results suggest that HIV-negative partners represent an important HIV-prevention opportunity within HIV-serodiscordant relationships. Future work should consider the reasons for (non)disclosure and ways to incorporate HIV-negative partners in activities that help their partners sustain viral suppression.

MOPEC0645

Psychological wellbeing of children orphaned by HIV/AIDS: a comparative study in public primary schools of Jimma town, Southwest Ethiopia

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Background: In developing countries the number of children orphaned by AIDS is growing rapidly. Consequently, the psychological well-being of these children has become a serious concern. This study explored and compared the psychological status of orphan and non-orphan children in Jimma town, Ethiopia.
Methods: A comparative cross-sectional study was employed on 270 children who were between 10-18 years of age. Eighty five orphaned children (those who lost at least one parent due to HIV/AIDS) and 185 non-orphaned children (control, who had two parents alive) were selected by systematic sampling technique from child clubs of selected schools. The psychological wellbeing of the orphans and non-orphans was measured using the psychological wellbeing scale. The scale consists of a series of statements reflecting the six areas of psychological well-being: autonomy, environmental mastery, personal growth, positive relations with others, purpose in life and self-acceptance. Higher scores on each scale indicate greater wellbeing on that dimension.
Results: A total of 270 children (85 orphaned and 185 non-orphaned children) were included in the study. About 61.2% (52/85) of orphaned and 60.5% (112/185) of non-orphaned children were females. Interims of age, 62% of orphaned and 80% of non-orphaned (controls) were found between age groups of 10-14 years. Our findings demonstrated that orphaned children (children from HIV/AIDS-affected families) showed significantly lower total psychological wellbeing (t=6.05, p=0.001), autonomy (t=3.06, p=0.002), environmental mastery (t=3.7, p=0.001), positive relation with others (t=4.32, p=0.000), and self acceptance (t=5.58, p=0.000) than those from unaffected families (non-orphaned). The main psychological problems of orphaned children included lack of confidence in their opinions, lacks sense of control over external world, frustrated in interpersonal relationships and feeling dissatisfied with self.
Conclusions: The psychological wellbeing of orphaned children was lower than those of non-orphans (controls). Our study illustrates that HIV/ AIDS has impacted negatively on the psychosocial wellbeing of children. Thus, a new type of orphan support project which provides not only material support but also psychosocial support is required to improve the quality of life of children orphaned by HIV/AIDS.

MOPEC0646

Identifying pathways between depression, substance use and sexual risk practices can inform HIV and sexually transmitted infections prevention strategies for young women in the northwest territories, Canada

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Background: There are profound sexual and mental health disparities in the Northwest Territories (NWT), with youth sexually transmitted infections (STI) rates 10-fold higher, and youth suicide rates double, the Canadian average. Despite these co-occuring epidemics, little is known about syndemics of mental health and HIV/STI vulnerabilty in the NWT. This study examined associations between depression and multiple sex partners among young women in the NWT, Canada.
Methods: We conducted a cross-sectional study with a venue-based sample of young women aged 14-17 in secondary schools in 14 NWT communities. We examined factors associated with multiple sex partners (2 or more past year sex partners). We tested a multi-step mediation analysis model with 10,000 bootstrap samples to examine the effects of depression (X) on multiple sex partners (Y), with peer support (M1) and substance use (M2) as mediators.
Results: Among 199 participants (mean age: 13.8, SD: 1.27), 77.4% (n=154) identified as Indigenous, one-fifth (20.5%; n=39) as sexual minority, one-quarter (26.6%, n= 53) were currently dating, and 16.1% (n=32) reported multiple sex partners (MSP). Depression symptoms were higher among sexual minorities than heterosexuals, and among those dating vs. not dating. Substance use was higher among Indigenous vs. non-Indigenous participants, and among those dating vs. not dating. There was a direct relationship between depression and MSP (B=0.13, p<0.001, CI 95%: 0.37-0.264). Substance use (M2) significantly mediated the effect of X on Y (X→ M2→Y). Depression was directly associated with substance use (B=0.2, p<0.05, CI 95%: 0.04-0.36), in turn substance use predicted MSP (B=0.451, p<0.001, CI 95%: 0.22-0.68). When controlling for substance use, the beta for the relationship between depression and MSP reduced from 0.29 to 0.13, suggesting partial mediation. Depression was negatively significantly associated with peer support (B= -0.25, p<0.01, CI 95%: -0.47- -0.023). However, peer support did not predict MSP (B= -0.14, p= -0.136, CI 95%: -0.31- 0.04).
Conclusions: Depression was associated with MSP, and substance use partially mediated the effect of depression on MSP. Findings highlight the need for HIV and STI prevention interventions to focus on syndemics of depression, substance use and sexual risk among young women in the NWT, Canada.

MOPEC0647

A randomized trial of brief assessment interventions to reduce HIV/STI sexual risk and drug use among young adults who use drugs

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Background: Although the intersections of drug use and sexual HIV/STI risk behaviors and infections are well documented within the social context of clubs, raves, and circuit/dance parties, efficacious interventions to reduce HIV/STI risk behaviors and drug use for club drug using populations are not apparent in the literature. We tested interviewer- (CAPI) and self-administered (ACASI) comprehensive health and social risk assessments as distinct interventions compared to waitlist control, hypothesizing that those assigned to the assessment conditions would reduce their sexual risks and drug use to a similar degree and to a significantly greater extent than waitlist control.
Methods: 750 men and women ages 18-39 with multidrug use and heterosexual behavior were recruited between September 2011 and November 2014 using respondent driven sampling, and randomized in equal proportions to the three conditions. Instrumentation included well-tested measures of condomless sex, drug use, mental distress and substance dependence. Hierarchical linear models (HLMs) examined the effects of study condition on sexual HIV/STI risk, drug use, and comorbid health outcomes, measured as effect size (Cohen's d) differences.
Results: The sample was 56% male; mean age=25; 65.7% Hispanic; 20.4% Black, 11.6% White and 2.3% other race/ethnicity. HLM analyses showed a significant main effect of assigned condition on all outcomes. CAPI participants had greater reductions in sexual HIV/STI risk, drug use, and mental distress and substance dependence symptoms, compared to ACASI intervention or control participants at 12 months, except that the CAPI and ACASI conditions had similar efficacy for reductions in drug use. Effect sizes for CAPI versus ACASI participants were d=0.2-0.3, and between CAPI and controls d=0.2-0.4. Effect sizes for improved outcomes between ACASI compared to controls were small to non-significant.
Conclusions: The study established the therapeutic benefit of interviewer interaction in reducing HIV/STI sexual risk behavior and drug use among young adults who use drugs. The study is the first to demonstrate the efficacy and acceptability of a low threshold intervention in reducing HIV/STI sexual risk, drug use, and related co-morbidities among a not-in-treatment young population that exhibits severe and complex levels of drug use, but that is also highly resistant to intervention.

MOPEC0648

Reasons for not using PrEP in a national on-line sample of U.S. men who have sex with men (MSM)

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Background: Although the CDC estimates that >400,000 U.S. MSM could benefit from oral PrEP, many have not initiated it, prompting this analysis
Methods: An on-line survey was mounted on 2 popular MSM sexual networking sites during March 2016 to assess socio-demographics, HIV risk, PrEP knowledge, attitudes and use. Factors independently associated with never using PrEP were evaluated using multivariable logistic regression with backward selection.
Results: Of 4,698 respondents, 21% were 18 to 24 y.o. and 38% were 40 or older. Almost half (47%) were White, 25% Black, 11% Hispanic/Latino, and were from all U.S. states. Almost 12% were born outside the U.S. Nearly 60% had private health insurance; 12% had none. About two-thirds reported condomless anal intercourse (CAI) at least once in the prior 3 months. Most (85%) had not used PrEP previously, with 22% unaware of PrEP. Among 2,926 PrEP-informed non-users, the most common reasons cited for non-use were: concerns about costs (40%), side effects (31%), not knowing where to access PrEP (31%), worries about effects on insurance (20%), and/or not feeling at risk (19.3%). Older MSM were more likely to cite side effects, and less likely to cite access concerns as reasons for non-use. Black MSM were also more likely to cite access concerns, but less likely to cite insurance barriers than other MSM. Less educated MSM were more likely to report access issues but less likely to cite cost, insurance or anticipated side effects, as barriers to using PrEP. MSM born outside of the U.S. were more likely to identify access as a major barrier to PrEP use. MSM who reported monogamous relationships were more likely to report low risk as a reason for PrEP non-use, whereas those who reported more than 2 CAI acts in the prior 3 months, or a history of syphilis, were less likely to cite low risk as a PrEP barrier.
Conclusions: The major barriers to PrEP uptake endorsed by U.S. MSM included structural factors (cost, access, insurance), anticipated side effects, and low perceived risk, and their importance differed between subgroups. Additional programs to educate at-risk MSM about how to address these issues are warranted.

MOPEC0649

Crystal methamphetamine initiation among HIV-positive and HIV-negative men who have sex with men in Vancouver, Canada: a longitudinal analysis

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Background: Crystal methamphetamine is associated with HIV acquisition among HIV-negative men who have sex with men (MSM) and unsuppressed viral load among HIV-positive MSM. We used prospective behavioural cohort data from MSM to measure temporal trends and initiation predictors of crystal methamphetamine use.
Methods: Sexually-active MSM aged ≥16 years were recruited using respondent-driven sampling (RDS) and from 02/2012-02/2016 they completed study visits every six months, which included a computer-assisted self-interview and nurse-

administered HIV/STI screening. We used multi-level generalized estimating equations to evaluate temporal trends in crystal methamphetamine use and univariable survival analysis to identify predictors of crystal methamphetamine initiation (hazard ratios [HR]; 95% confidence intervals [95%CI]).
Results: Over the 4-year study period, 581 participants completed at least 1 follow-up visit for a median follow-up of 2.49 years. At baseline, 20.1% of MSM reported recent crystal methamphetamine use, which was significantly higher among HIV-positive (44.3%) than HIV-negative MSM (10.3%, p< 0.001). Route of use did not differ by HIV status (all p>0.05): 79.3% smoking, 55.0% snorting, 27.9% injecting, and 26.4% hooping. Frequency of use did not differ by HIV status (p=0.237): 43.6% used less than monthly, 20.7% used monthly, and 35.7% used at least weekly. There were no statistically significant temporal trends overall (p=0.069) or for HIV-negative (p=0.179) or HIV-positive (p=0.087) MSM.
During follow-up, 32 HIV-negative MSM (8.5%) and 14 HIV-positive MSM (15.2%) initiated crystal methamphetamine use (no difference by HIV status, p=0.10). This table presents predictors of initiation:

	HIV-Negative HR (95%CI)	HIV-Positive HR (95%CI)
Number of recent male anal sex partners, per partner	1.01 (1.01-1.02)*	1.02 (1.00-1.05)*
HIV treatment optimism scale score, per point	1.07 (1.00-1.15)*	0.98 (0.89-1.09)
Self-esteem scale score, per point	1.11 (1.03-1.20)*	1.10 (0.99-1.09)
Anxiety scale score, per point	1.08 (1.00-1.17)*	0.98 (0.87-1.11)
Sought sex online at least monthly (ref: none)	4.66 (2.15-10.11)*	2.91 (0.69-12.25)
Recent escort/sex work (ref: none)	5.05 (1.53-16.68)*	2.97 (0.38-23.62)
Recent group sex participation (ref: none)	2.72 (1.31-5.65)*	3.51 (1.23-10.03)*
Recent STI diagnosis (ref: none)	3.23 (1.24-8.45)*	1.63 (0.21-12.67)
Recent anal sex behaviour (ref: none) NB: only levels of categorical variable with statistically significant associations shown	Any condomless anal sex with an HIV serodiscordant or unknown status partner: 3.45 (1.16-10.26)*	Any condomless anal sex with an HIV seroconcordant partner: 10.30 (1.24-85.74)*

*[*denotes statistical significance at p<0.05]*

Despite initiators reporting greater objective HIV risk (i.e. more anal sex partners, group sex, condomless sex), they did not self-perceive this risk: 100% of HIV-positive MSM and 78.1% of HIV-negative MSM self-assessed their risk of transmitting or acquiring HIV as "low", respectively.
Conclusions: Crystal methamphetamine use was prevalent, stable over time, and initiation was common. Renewed population-specific interventions and health promotion efforts are desperately needed.

MOPEC0650

High HIV incidence among married couples in fishing communities: implications for achieving epidemic control

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Background: Global efforts to achieve HIV epidemic control by 2030 focus on identifying and shutting down sources of new infections through targeted interventions. We sought to establish HIV incidence and associated risk factors among married people in the fishing communities on Lake Victoria.
Methods: We conducted a 3-year resurvey of 545 couples who had previously been enrolled in a cross-sectional survey conducted between September 2011 and June 2014. Although the target was to trace and re-interview all couples, we only contacted 903 individuals of whom 89.5% were couples. Among those contacted were 371 men and 356 women who had tested HIV negative during the first survey. On contact, the individuals or couples were asked to return to the study clinic to participate in a follow-up survey. Returning couples were consented and invited for concurrent face-to-face interviews in private rooms. We invited them for HIV test using Kenyan rapid HIV testing protocol. For those testing positive, we assumed infection to have occurred midpoint between first and second surveys. We calculated incidence rates and factors associated with new infections using Cox regression.
Results: Fifty three new infections occurred between the surveys; 23 in men and 30 among women; giving an overall HIV incidence of 4.5% (95% CI: 3.4%-5.9%) with no significant difference between men 3.8% (2.5-5.7) and women 5.2% (3.6-7.4) (p=0.27). The majority of the people who participated in second survey as couples were concordant negative (68%) with 15% being concordant positive and, 9% discordant women positive and 8% discordant men positive. For men, new HIV infection was associated with being recently married (aOR 0.11; 95%CI: 0.02-0.84); uncircumcised (aOR 2.93; 95%CI: 1.03-8.37), polygynous (aOR 0.18; 95%CI: 0.05-0.61) and reporting protected sex (aOR 0.26; 95%CI: 0.07-0.97). For women, new HIV infection was associated with increasing income (aOR 0.98; 95%CI: 0.95-0.99); and being separated from spouse (aOR 4.39; 95%CI: 1.47-13.10).
Conclusions: Married people in the fishing communities on Lake Victoria have high HIV incidence. This HIV hotspot need to be targeted with appropriate interventions such as PrEP rollout to shut down new infections.

MOPEC0651

High prevalence of syphilis, hepatitis B and HIV among men who have sex with men in Tanga region, Northern Tanzania

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Background: Whilst studies have shown a high prevalence of HIV and sexually transmitted infections (STIs) among men who have sex with men (MSM) globally and in Africa, few studies have been conducted in Tanzania.
Methods: A cross sectional study was conducted between April and June 2015 in four districts of Tanga region in north-east Tanzania. Interviews were conducted with 266 MSM followed by serological testing for syphilis, hepatitis B surface antigen and HIV.
Results: The mean age of the participants was 27.2 (SD 6.7) years, 48% were married or cohabiting, with median of 20 lifetime male partners and 23% reported consistent condom use. The prevalence of Hepatitis B, syphilis and HIV were 28.2%, 31.2%, and 33.8% respectively. Syphilis seropositivity was significantly higher in HIV-positive (54%) compared to HIV-negative men (24.6%), p< 0.001.
Conclusions: An effective response is needed in this setting to address the high prevalence of both sexually transmitted infections (STIs) and HIV amongst MSM. Programs that reach MSM and offer systematic screening for HIV and STIs, early entry in HIV antiretroviral treatment and effective treatment for STIs are urgently required to reduce HIV transmission among MSM themselves and in the general population.

MOPEC0652

The comparative ability of two network interventions to locate undiagnosed positives and recently infected individuals in Odessa, Ukraine: the TRIPLE (TRIP-LitE) intervention, designed for improved implementation feasibility

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Background: The TRIP study showed that a complex network intervention was effective at locating recently infected HIV+ individuals (at its Athens, Greece site) and previously undiagnosed HIV+ individuals (at Athens; Chicago; and Odessa sites). Since TRIP is labor-intensive and might be difficult to translate to large-scale public health practice, we developed the lower-cost TRIP-LitE (TRIPLE), and compared it to TRIP on its ability to locate/recruit undiagnosed positives and recent infections.
Methods: Recruitment started with recently-HIV-infected (in last six months, as determined based on Limiting Antigen Avidity (LAg) assay, testing history, and viral load) "seeds." Members of seeds' sexual and injection networks were recruited for two network "steps": seeds' direct network connections (Step 1), and the direct connections of those in Step 1 (Step 2). Network members received the same intervention (TRIP or TRIPLE) as the seeds whose networks precipitated their recruitment. TRIP seeds and Step 1 network members were asked to name all individuals they personally had sex with and/or injected drugs with, and all venues where they met people to have sex and/or inject drugs. We attempted to recruit all named individuals to the study using recruitment coupons given to the seeds or Step 1 members. TRIPLE participants received brief education from intervention staff about recent infection and its associated risks and prevention. TRIPLE seeds and Step 1 network members were asked to name anyone they knew who they thought might have been recently infected (regardless of whether they personally had direct sexual/injection ties). We asked them not to name/recruit people they thought had been infected a long time. Finally, TRIPLE participants were given five extra recruitment coupons to give to anyone they had forgotten or deliberately not named who might have been recently infected.
Results: TRIPLE was not significantly different from TRIP in its ability to recruit undiagnosed positives (see Table), and recruited a larger proportion (n.s.) of recent infections.

Intervention Type	N	Previously Undiagnosed Positives (OR = 0.94; 95% CI 0.67, 1.30)	Recently Infected (OR = 2.23; 95% CI CI 0.84, 5.87)
TRIPLE (03/2016-12/2016)	399	55 (13.8%)	7 (1.8%)
TRIP (11/2013-03/2016)	1131	165 (14.6%)	9 (0.8%)

[Comparing Network Yields from TRIPLE and TRIP]

Conclusions: TRIPLE is an appropriate choice for regular public health practice since it does as well or better at meeting its goals and is easier to implement.

MOPEC0653

The high-risk sexual practices among adolescents accessing HIV/AIDS care services in the central region of Uganda

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Background: HIV positive adolescents in Uganda are sexually active just like their uninfected peers and with the availability of Antiretrovirals, the surviving population of adolescents perinatally infected with HIV is increasing and they are becoming sexually active with most of them engaging in unprotected sex.
Objectives: This study aimed at determining whether HIV positive adolescents disclose their HIV status to sexual partners, identifying factors associated with sexual activity among them, finding out if they practice safe sex and determining age at first sex debut among them.
Methods: A descriptive cross-sectional study with an analytical component. Quantitative data was collected from a probability selected sample of 330 HIV positive adolescents aged 14- 19 years using interview schedules and qualitative data from 4 key informants. Data was analysed using both quantitative and qualitative methods.
Results: Overall, 47.7% of them have ever been in a sexual relationship with a higher likelihood among females (RR 1.51; p =0.0014). Peer pressure was the major cause of the sexual relationships (54.6%). 16.6% of them had non penetrative sexual activities only. HIV positive adolescents in urban areas had a higher likelihood of not engaging in sexual relationship than those from rural areas (OR 0.41; p =0.0032). Over 35% of the respondents were sexually active with females showing a greater likelihood (RR 1.65; p =0.0035). About 66.7% had disclosed their HIV status to sexual partners, 84.3% were of the same HIV status as their sexual partners (p =0.002). 36% of those who had not disclosed to their partners felt guilty. HIV positive males had a higher likelihood of having sexual partners of the same HIV status (RR 1.39; p =0.02). Only 41.9% used condoms during last sexual activity and 87.2% had one sexual partner. About 33.6% had first sexual debut when they were below 15years with (females 25.2%, males 8.4%, p =0.87).
Conclusions: HIV positive adolescents were sexually active especially females, more in rural areas. There was low condom use which was likely to propagate the spread of HIV and AIDS in Uganda. This calls for reproductive health needs of HIV positive adolescents to be addressed and integrated into HIV care programs.

MOPEC0654

Clinical, psychosocial and structural reasons for disengagement in routine HIV care in urban Uganda: results of a cohort study

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Background: The recent WHO test and Start guidelines recommend all newly diagnosed HIV patients initiated on ART irrespective of CD4 count. These guidelines are also a way of pushing the global effort to reach the 90-90-90 UNAIDS target. However, loss to follow up (LTFUP) still remains a big set back in the successful implementation and achievement of the goals. We sought to ascertain the clinical, psychosocial and structural reasons for LTFUP in six Kampala clinics in Uganda.
Methods: This was a prospective cohort study carried out between January 2013 and August 2016. Patients who were ≥3 months late for their visits were outreached through telephone calls and/or home visits. Reasons for disengagement, disclosure status were sought from all the patients successfully traced and interviewed. Socio-demographic and clinic variables were obtained from the clinics. Reasons for LTFUP were categorised into 3 broad groups; structural (lack of transport, moving homes), clinical (long waiting hours, drug stock out) and psychosocial (doubtful of HIV status, stigma and discrimination). Comparisons of socio-demographic and clinic variables with the categories of LTFUP and point of entry into care (PMTCT/ out patients department (OPD)) were examined.
Results: From a total of 33,850 registered patients, 4,161 were lost and 2,767 traced. 2,107 (76%) were females with a median (IQR) age in years; 27 (23, 32). The median CD4 count cells/uL at enrolment was 480 (IQR 300, 675) with 71% on ART. 986 (46%) registered into clinics through PMTCT and 1,176 (54%) via the OPD. Structural barriers were the major reason reported for stopping care (76%) followed by psychosocial barriers (29%) and clinical barriers (11%). Patients completely disengaged from care reported more psychosocial reasons compared to those self-transferred and in care elsewhere (81% vs 19%, p< 0.0001). Women on PMTCT reported more psychosocial reasons compared to those entering through OPD (54% vs 46%, p=0.015). Patients reporting psychosocial and clinical reasons for disengagement were less likely to have disclosed compared to those reporting structural reasons (p=0.021).
Conclusions: In order to achieve the 90-90-90 target, there is need to address the structural, and psychosocial barriers to engagement in HIV care, particularly among women.

MOPEC0655

Linkage to HIV care among transgender women in Lima, Peru

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Background: The prevalence of HIV infection in transgender women (TW) in Peru reaches up to 30% and their needs are not adequately addressed by current HIV care programs. Our objective is to explore if being a male-to-female TW is an obstacle to linkage to HIV care in Lima, Peru.
Methods: We evaluated cross-sectional relationships between self-definition as a TW and linkage-to-care. The data collected from two sexually transmitted infection (STI) clinics that provide specialized services for men who have sex with men (MSM) and TW. Linkage-to-care was defined as having at least one self-report visit with the national HIV care program after HIV diagnosis. Associations with linkage-to-care were analyzed using Poisson regression to estimate adjusted prevalence ratios.
Results: The study included 101 MSM and 29 TW living with HIV whose mean age was 31.4 ± 9 years. College education was reported by 30.0% of participants and 56.7% had a monthly income greater than the local minimum wage ($250/month). A recent STI was diagnosed in 55 (42.3%) participants. In the adjusted multivariable model, the probability of linkage-to-care was 23% lower among TW (aPR = 0.77; 95% CI 0.61-0.98). Among the 31 MSM/TW participants diagnosed during the study, 21 (67.7%) were linked to care and linkage took an average of 3.1 months. Among all participants, 93 (71.5%) received HAART at some period during the study.

Characteristic	Crude PR	95% CI	Adjusted PR*	95% CI	p-value
Transgender woman	0.84	0.65 - 1.09	**0.77**	0.60 - 0.99	0.040
Age (years)	1.01	1.01 - 1.02	**1.01**	1.00 - 1.01	0.002
Diagnosis of STIs, last 6 months	0.87	0.72 - 1.05	0.86	0.73 - 1.02	0.090
Time of diagnosis of HIV					
Before starting the study	Ref.		Ref.		
At baseline	0.68	0.50 - 0.93	**0.67**	0.49 - 0.90	0.010
During the study	0.75	0.58 - 0.97	0.80	0.63 - 1.01	0.062
*Adjusted for self-definition as transgender, age and STI diagnosis in the last 6 months.					

[Factors associated with linkage-to-care among MSM]

Conclusions: These findings shed light on the need for additional interventions to improve linkage-to-care among TW as a part of achieving the WHO's „90-90-90 objective".

MOPEC0656

Condom use behaviour among people living with HIV: A 7-country community-based participatory research in the Asia-Pacific region

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Background: Sexual transmission still drives HIV incidence among key populations in the Asia-Pacific region. Thus, understanding current risk factors and patterns of sexual risk behaviour among people living with HIV (PLHIV) is important for effective prevention. We examined the prevalence of inconsistent condom use and its correlates among PLHIV in the Asia-Pacific region.
Methods: Between 1 October 2012 and 31 May 2013, a total of 7 843 PLHIV aged 18 to 50 years were recruited using targeted and venue-based sampling in Bangladesh, Indonesia, Lao, Nepal, Pakistan, Philippines and Vietnam. Condom use behaviour in the past six months was assessed both at sexual intercourse with a regular partner and at sex with a casual partner ("In the past six months, how frequently did you use condoms when you had sex?"). Condom use behaviour was dichotomized into consistent use ("always") and inconsistent use ("never", "sometimes" or "most of the time"). Logistic regression was used to explore the association between condom use behaviour and demographics, social support, stigma and discrimination, HIV-related literacy and various health-related variables.
Results: Overall, 43% of 3 827 PLHIV practised inconsistent condom use at sexual intercourse with their regular partner. An even higher proportion, 46% of 2 044 PLHIV admitted that they practised unprotected sex with a casual partner. Participants from Lao reported the lowest prevalence of inconsistent condom use for both regular and casual partners, while participants from the Philippines had the highest risk behaviour. Inconsistent condom use was significantly associated with belonging to a key population (drug user, sex worker or refugee sub-population), not knowing that condoms are still needed if both partners are HIV positive, having a regular partner whose HIV status was either positive or unknown, having experienced physical assault as well as with not receiving antiretroviral treatment.
Conclusions: This large 7-country study highlights a high prevalence of inconsistent condom use among PLHIV in the Asia-Pacific region. In addition to knowledge imparting interventions, the adoption and expansion of the ‚Test and Treat' strategy (most of the countries in the Asia-Pacific region still use CD4 criteria for treatment) could help to maximise the prevention benefits of antiretroviral treatment.

MOPEC0657

The potential effect of initiating combination antiretroviral therapy with integrase Inhibitors on HIV transmission risk in British Columbia, Canada

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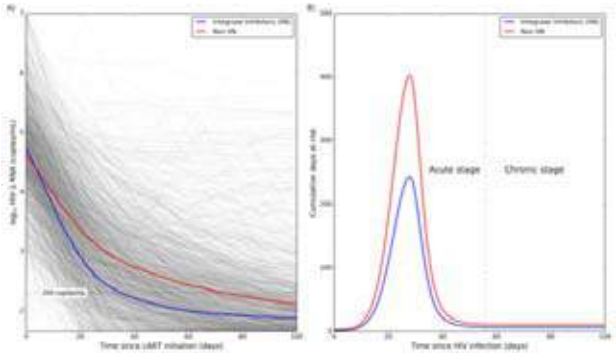
Background: Integrase Inhibitors (IIN) represent one of the most efficacious classes of antiretroviral drugs currently available to achieve virologic suppression. Our objective was to estimate possible reductions in HIV forward-transmission risk from antiretroviral-naïve individuals initiating combination antiretroviral therapy (cART) with IIN-based regimens.
Methods: The change in plasma viral load (pVL) levels from cART initiation to virologic suppression, defined as < 200 HIV-1 RNA copies/mL, was calculated from a cohort of 1426 individuals who initiated cART between 2011 and 2014 with at least one year of follow-up; of those, 191 individuals initiated IIN-based cART. Cumulative risk of HIV transmission (CRHT) between the time of cART initiation and virologic suppression was estimated from the area under the pVL curves (Figure1A), using a mathematical formula derived from the Rakai study. CRHT depended on the stage of HIV at cART initiation, and was measured as the number of days at-risk based on the chronic stage of HIV, (one acute day corresponds up to 26 days at-risk; one suppressed day corresponds to 0.04 days at-risk).
Results: Time to virologic suppression for IIN regimes was 35.4 days (95% confidence interval (CI) 30.7-40.7), compared to 73.9 days (95% CI 69.3-78.7) for non-IIN. CRHT when initiating cART in the chronic stage was estimated to be equivalent to 6.4 days at-risk for IIN regimens, compared to 10.7 days for non-IIN. If cART were initiated in the acute stage, CRHT can be up to 243.4 days at-risk for IIN, compared to 402.6 days for non-IIN (Figure1B).
Conclusions: IIN regimens achieve faster virologic suppression, but the difference in cumulative risk with respect to other regimens is small in patients initiating cART in the chronic stage of HIV. The difference in cumulative risk is much greater for patients that start cART in the acute stage.



*[Figure 1. A) Cohort pvl trajectories, in the background, were aggregated to generate population-wide pVL curves. Non IIN regimes include Boosted and Non-Boosted Protease Inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors.
B) The number of days at-risk, from cART initiation to virologic suppression, based on the stage of HIV at cART initiation.]*

MOPEC0658

Reducing sexual risk and promoting acceptance of MSM living with HIV in India: outcomes and process evaluation of a pilot randomised multi-level intervention

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Background: MSM living with HIV (MSMLH) in India require culturally-relevant interventions to promote safer sex and reduce stigma. We developed and tested a theory-based (social personal model) multi-level intervention among MSMLH: one-to-one counselling intervention using motivational interviewing techniques to promote safer sex, and a community-level intervention to promote acceptance of MSMLH among MSM communities.
Methods: In 2015/16, we conducted a 2x2 factorial randomised controlled trial (RCT) with 119 MSMLH randomised to receive either individual-level intervention (ILI), community-level intervention (CLI), a combination of ILI+CLI, or standard-of-care. MSMLH were recruited through community agencies in Tamil Nadu. In ILI, MSMLH received a 4-session tailored sexual risk reduction counselling; and in CLI, activities included community events to promote acceptance of MSMLH and speeches by MSMLH role models. Participants completed assessment at baseline (pre-intervention) and at 3rd and 6th months (endline). The primary outcome measure was sexual risk (e.g., unprotected anal/vaginal sex) in the past 1/3 month(s). Mixed ANOVA analysis was conducted with standard-of-care, ILI, CLI, ILI+CLI conditions as between-subjects factor, and time (baseline/endline) as within-subjects factor. CLI's effectiveness on community stigma was assessed by a cross-sectional pre-/post-CLI survey among 300 ‚general' MSM. Process evaluation included activities to assess intervention fidelity and post-intervention satisfaction survey.
Results: Participants´ mean age was 38.4 (SD 9.1) and monthly income was INR 7602 (~USD 126). Self-identification of participants were: kothis=57.1%; double-deckers=24.4%; panthis=7.6%; bisexuals=6.7%, and gays=4.2%. Out of the 119 MSMLH randomized, 105 (88%) completed pre- and post-intervention assessment. Intent-to-treat analysis showed a decrease in sexual risk across all four conditions (Time effect: F=32.5, p=.001), although only the three intervention groups showed a significant decrease. The ILI+CLI group showed a marginally significant decrease in sexual risk over time compared to the standard-of-care group (p=.08). Further, effect sizes are medium/large (d>.50) for the ILI+CLI group and CLI group. High intervention fidelity and high satisfaction were found among intervention participants.
Conclusions: This pilot RCT among MSMLH has demonstrated feasibility and potential effectiveness of theory-based interventions to reduce sexual risk. A combination of individual (motivational interviewing-based counselling) and community level (stigma reduction) interventions could effectively reduce sexual risk among MSMLH.

MOPEC0659

Associations between HIV-related discrimination, sexual stigma, internalised HIV stigma and depression: testing an extended minority stress model among HIV-positive MSM in India

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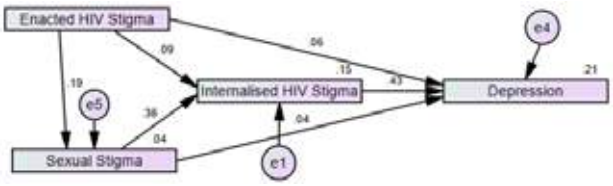
Background: Limited data is available on the associations between stigma and mental health outcomes among men who have sex with men living with HIV (MSMLH) in India. In line with Meyer's minority stress model and prior research, we tested the hypothesis that HIV-related enacted stigma and sexual stigma will predict depression, and their effects on depression will be mediated through internalised HIV stigma. Based on our qualitative formative research findings that MSMLH might blame their same-sex sexuality for having become HIV positive, we also hypothesised that HIV-related discrimination experiences could heighten sexual stigma (See Figure), thus extending the minority stress model.
Methods: In 2015/16, we conducted a baseline survey among 119 MSMLH as part of a multi-level intervention to promote safer sex and reduce community stigma. Standardised scales measured: two key predictors - HIV-related enacted stigma (discrimination due to HIV) and sexual stigma (stigma due to same-sex sexuality); a mediator - internalised HIV stigma; and an outcome variable - depression. Path analysis was conducted with SPSS Amos-22.
Results: Participants´ mean age was 38.4 (SD 9.1) and mean monthly income was INR 7602 (~USD 126). A majority identified as kothis (57.1%) or double-deckers (24.4%), with others identifying as panthis/bisexuals/gays. Internalised stigma significantly mediated the effects of HIV-related stigma (indirect effect=.24, p=.02) and sexual stigma (indirect effect=.09, p< .001) on depression. Sexual stigma significantly predicted internalised stigma (direct effect=.36, p<0.001) and depression. HIV-related stigma did not significantly predict depression. As hypothesised, HIV-related stigma significantly predicted sexual stigma (direct effect=.18, p=.03).



[Testing an extended minority stress model - MSMLH]

Conclusions: The findings offer evidence for the influence of both HIV-related stigma and sexual stigma on depression, and the influence of HIV-related stigma on sexual stigma, supporting an extended minority stress model among MSMLH. Interventions to prevent/reduce depression among MSMLH need to target internalised stigma, in addition to reduction/elimination of HIV-related discrimination and sexual stigma.

MOPEC0660

Substance use and high-risk sexual behaviour in PLWH in France: results of the EQUIPIER study

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Background: Substance use and associated risk behaviors are common in PLWH and require harm reduction interventions. We aimed to better understand how they relate to health-related quality of life, anxiety / depression, and to personality traits among French PLWH.
Methods: French PLWH were enrolled from hospitals or the community using a web-based survey. Addictive behaviors included specific psychoactive substance use and consumption modes. Health-Related quality of life (HRQL) was measured using the PROQOL-HIV four dimensions: physical, mental, social health and treatment impact (scores ranging from 0 to 100, 100 reflecting better HRQL). Anxiety/depression was measured by HADS (2 dimensions). Temperament and Character Inventory questionnaire (TCI) assessed the personality traits.
Results: 517 PLWH were recruited (mostly in hospitals: 81%). 30% were women, mean age was 48 years, 89% had undetectable viral load. 15% reported daily alcohol use and 34% binge drinking at least once per month. One third of the sample smoked. Most commonly used drugs were cannabis (16%), poppers (14%), cocaine (6%), ecstasy (4%) and GHB (4%). Injecting drug use (IDU) was associated with lower HRQL : physical (64 vs 73), mental (62 vs 70) , social (58 vs 61) and higher anxiety (8,5 vs 7,3) and depression (6,8 vs 5,4) scores. 34% of patients reported unprotected sex and 5% sex for money. Most consumed substances during sex were poppers (18%), alcohol (12%), and cocaine (7%). From the entire sample 12% reported always or often using drugs or alcohol during sex. Use of these substances was significantly associated with unprotected sex (65% vs 35%, p 0.001). Risk-seeking behaviour and personality trait was significantly associated with alcohol, tobacco smoking and drug use but not with unprotected sex.
Conclusions: In EQUIPIER study, risky sexual behaviour was seen to be predominantly associated with drug and alcohol use; while IDU was associated with lower HRQL and increased depression/anxiety. Interventions to reduce rates of substance use continue to be needed for this population.

MOPEC0661

Mass incarceration, prison release, and HIV incidence in the US South

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Background: In the United States, the prevalence of HIV among incarcerated individuals is 5 times greater than among the non-incarcerated. The southern region of the US has the highest rates of incarceration, HIV incidence, poverty and economic inequality. Individuals living with HIV frequently cycle in and out of prison with return to home communities. We sought to determine the impact of prison release on HIV incidence in the US South.
Methods: Using 5-year cumulative case counts for new HIV diagnoses (2010-2014), we calculated HIV incidence rates at the ZIP code level for nine cities in the US South: Atlanta, Houston, Miami, Orlando, Tampa, Jacksonville, Columbia, New Orleans and Baton Rouge. Regression models were estimated for HIV incidence rates. Independent variables included number of people released from prison per 1000 population (prison release rate), economic inequality (GINI index), % population living in poverty, % Black residents in the population, and a spatial variable to control for clustering of HIV.
Results: Mean incarceration rate across all 9 jurisdictions was 560 per 100,000 adult population. Mean 5-year HIV incidence across all cities in the analysis (600 ZIP codes) was 215 per 100,000 population. Across the nine cities, HIV incidence was significantly associated with prison release overall (r=0.43, p< 0.01) and for each city: Atlanta (r=0.46, p< 0.01), Houston (r=0.58, p< 0.01), Miami (r=0.59, p< 0.01), Orlando (r=0.40, p< 0.01), Tampa (r=0.41, p< 0.01), Jacksonville (r=0.67, p< 0.01), Columbia (r=0.45, p< 0.01), New Orleans (r=0.64, p< 0.01), and Baton Rouge (r=0.88, p< 0.01). In multivariate analysis including all nine cities, controlling for economic inequality, % living in poverty and % Black population, prison release rate remained significantly associated with HIV incidence. A 10 person increase in prison release rate was associated with a 4.8% increase in overall HIV incidence—approximately 10 additional cases per 100,000 population.
Conclusions: In the US South, prison release is significantly associated with HIV incidence. HIV prevention interventions should promote timely linkage to ongoing treatment for released inmates living with HIV, as well as HIV testing, condoms, pre-exposure prophylaxis and safer injection equipment for all inmates and their partners to decrease onward HIV transmission post-release.

MOPEC0662

Short message service communication between HIV patients and their health care providers in a randomized controlled trial in Nairobi, Kenya

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Background: Weekly short message service (SMS) conversation between people initiating ART and their health care providers (HCP) lead to improved ART adherence and viral load supression, and provides and opportunity for outpatient support. We conducted an analysis of weekly SMS conversation between patients newly diagnosed with HIV and thier HCPs in the intervention arm of a randomized controlled trial (Weltel Retain NIH R01 MH097558-01) on retention in HIV care.
Aims: to assess reasons for patients' non-respondence to weekly SMS and document health and psychosocial related problems reported by patients who respond to the SMS.
Methods: Trial participants were randomly allocated to intervention and control groups at a ratio of 1:1 at two HIV clinics in informal urban settlements in Nairobi. Those in the intervention arm received weekly SMS to check in on how they were doing by asking "Mambo?"and provide them the opportunity to identify whether assistance is required within 48 hours by responding "Sawa"or "Shida". A HCP experienced in HIV care followed-up all patients who responded "Shida" for appropriate advice. Those who did not respond within 48 hours were called by the HCP. The participants were followed-up for one year and all phone conversation from the SMS and voice calls recorded in the WelTel automated technology platform and clinic charts.
Results: The 352 intervention arm participants were followed-up for an average of 49 weeks. Almost all (98%, n=346) the participants failed to respond at least once to the weekly texts; 94% (n=332) ever responded "Sawa" and 43% (n=151) ever reported "Shida". Main reasons for non-responce were; lack of airtime, responce with unrecorgnized text, no phone and difficulty operating phone to send SMS. Some of the health and psychosocial issues reported include: abdominal pains, body itchines, chest pains, diarrhoea, misplacement of drugs, not able to get time off work, termination of employment because of positive HIV status and lack of bus fare to clinic.
Conclusions: SMS communication may be an effective way to engage patients newly diagnosed with HIV for timely identification of communication challenges, health and psychosocial related problems faced for appropriate medical and social engagement.

MOPEC0663

How can we improve development, implementation and evaluation of HIV prevention interventions in sub-Saharan African schools? A qualitative study with researchers

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Background: To date, trials have shown limited effectiveness of school-based sexual health interventions on prevention of sexually transmitted infections including HIV. Limitations in content, implementation or evaluation are some of the reasons for the limited effectiveness. We explore facilitators and challenges to designing, implementing and evaluating sexual health interventions in sub-Saharan African Schools from the perspectives of researchers.
Methods: We conducted 27 semi-structured interviews with researchers that have developed, implemented or evaluated a school-based sexual health intervention in sub-Saharan Africa. Researchers were purposely selected based on a published interventions and suggestions by experts. Interviews were conducted face-face or via Skype video call, lasted 30-60 minutes and audio recorded. Interview audios were transcribed verbatim and analysed thematically. Intervention Mapping framework was used to organise themes that emerged from our data.
Results: Researchers interviewed are international experts with 2 to over 30 years of experience and were involved in at least one intervention in one of the following countries- Kenya, Niger, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. We identified 33 themes that mapped onto the six steps of Intervention Mapping framework. During development, social factors such as poverty and school infrastructures including quality of teaching, in addition to sexual health needs, should be addressed. School-based HIV prevention interventions should be culturally sensitive, address inter-generational and open communications on sexual issues, and clearly state aims to avoid any misunderstanding. Curriculum should also address contemporary issues in HIV prevention (Treatment as Prevention, Pre-exposure Prophylaxis, Voluntary Medical Male Circumcision and Gender-Based Violence). During implementation, interventions should be prepared for oppositions at various levels for which we have also identified effective approaches for overcoming them. Due to limited teachers' training in sub-Saharan Africa, provisions of simple but detailed facilitators' manual together with supportive supervisions may be critical in ensuring delivery fidelity. During evaluation, computerised audio devices and qualitative interviews with participant observations may facilitate collection and improve validity of adolescents' sexual behaviours data respectively.
Conclusions: We identified specific recommendations useful for improving design, implementation and evaluation of school-based sexual health interventions in sub-Saharan Africa.

MOPEC0664

The crystal meth factor in the dynamic of HIV epidemic

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Background: We are on the way of reducing considerably the transmission of HIV in Canada since effective strategies to impede the epidemic, including TasP, PEP and PrEP are multiplying and easy to access here. However, chemsex (using new synthetic drugs, including crystal-methamphetamine in a sexual context) raises concern about reaching this goal. The objective of this study was to assess the impact of crystal use on risk factors of HIV transmission.
Methods: We conducted a single site, clinical based, anonymous survey at Clinique Médicale du Quartier Latin in Montreal, from Oct to Dec 2016. Information was self-reported through a questionnaire and all patients consulting at the clinic were eligible to the study. Data were analysed by ANOVA, Chi2-test and HIV determinants were assessed by logistical regression, using SPSS.
Results: 529 patients filled the questionnaire, 73% were male, 65% MSM, mean age was 48 (IQR 36-60). Lifetime drug experience was high: cannabis (75%), cocaine (46%), speed (37%), ecstacy (35%), ketamine (20%), GHB (25%) and crystal (15%). 45% of crystal users were HIV+ (compared to 18% of other drugs users and 19% of non drug users, p< 0.001). As shown in the table, crystal users have distinct behaviour compared to other participants.

	total (N=529)	No drug (N=112)	Drug other than Crystal (N=234)	Crystal (N=77)	p-value
HIV-positive	111	19%	18%	45%	< 0.001
Often/sometime combine Sex&drug	98	-	19%	56%	< 0.001
Use drug to have a different sexual experience	80	-	16%	59%	< 0.001
Number of sexual partners x last12months (mean,IQR)	9	4 (1 - 3)	8 (1 - 6)	51 (1 - 38)	< 0.001
Had STI x last 12months	86	9%	18%	34%	< 0.001
Use ALWAYS condom with occasional partners	196	45%	45%	14%	< 0.001
Use NEVER condom with occasional partners	83	16%	17%	38%	
MSM/Bisexual	309	53%	64%	89%	< 0.001
Found sexual Partner by apps	130	18%	38%	71%	< 0.001

[Table. Bivariate analyses for lifetime drug use]

HIV infection was 10 time more prevalent in recent crystal users (OR=9.14; 95%CI= 3.55-23.55) even after controlling for other major risk factors (IDU, number of sexual partner, anonymous sexual partner, MSM).
Conclusions: A particular attention should be given to the assessment of crystal-methamphetamine use in patients who come for STI screening, HIV prevention and also HIV care. Crystal users have high number of sexual partners; low condom use consistency; sexual intercourse with person they don't know; high rate of STIs and high rate of HIV. Crystal specific harm reductions strategies should be developed rapidly to avoid losing the control over HIV epidemic.

MOPEC0665

Barriers of HIV testing in health care facilities, knowledge, attitude and practice of health care providers in the country of Georgia

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Background: Georgia is a small country with HIV prevalence less than 0.5%. There is universal access to HIV treatment and care; however 50% of all HIV infected persons are not diagnosed until late in their infection.
In order to evaluate the knowledge, attitude and practice of health care providers and barriers to HIV testing, we surveyed health care providers to develop recommendations for improving the current strategies for HIV testing in health care facilities in Georgia.
Methods: Anonymous interviews were conducted of 330 randomly sampled physicians from June 1 to November 30, 2016. They were asked multiple questions concerning their knowledge, attitudes and practices concerning HIV and their perceived barriers to HIV screening. Data were analyzed using Epi_Info 7 survey module.
Results: Mean age of physician respondents was 43; 71% (234) were women with the mean work experience of 19 years. 44% (144) reported having received training on HIV and 87.5% (289) were aware of the national free HIV testing program. 79% (261) of providers reported that in their clinical settings HIV testing is performed. Clinical symptoms of HIV/AIDS were incorrectly identified by 65% (216) of respondents and 16% (52) did not know the means of HIV transmission. Disclosure of patients HIV status to ensure physicians safety was considered mandatory by 84% (277). Among respondents 32% (106) considered stigma, 48% (157) lack of information and 58% (190) financial resources and governmental and administrative support as barriers for HIV testing.
Conclusions: The main barriers of HIV testing in health care facilities of Georgia include: low level of knowledge on HIV testing, treatment and prophylactic strategies; poor motivation; HIV related stigma among health care workers; lack of HIV training programs, and insufficient financial or administrative support. Based on these findings, we suggest the need to improve HIV testing performance in health care facilities, in order to increase the early diagnosis and effective treatment of HIV patients, education of health care providers concerning the importance of screening for early diagnosis and treatment to preserve the health of HIV patients and prevent transmission is critically needed.
Acknowledgment: Study is supported by the International Science and Technology Center.

MOPEC0666

Reported impact of intimate partner relationships on adherence to the vaginal ring in the MTN 020/ASPIRE trial

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Background: Two recent trials have demonstrated that the dapivirine vaginal ring is a safe and effective method of female-initiated HIV prevention whose efficacy increases with adherence. A variety of factors impact product adherence, including intimate partner relationship dynamics and male partner support.
Methods: In-depth and focus group interviews were conducted with 214 participants in Malawi, South Africa, Uganda, and Zimbabwe during the nested qualitative component of the MTN-020/ASPIRE trial, a phase III placebo-controlled trial of a dapivirine vaginal ring. Women were asked about their intimate partner relationships (type and number), the impact of ring use on their relationships, disclosure, perceptions of partners' attitudes and support of ring use, partner engagement with the study, and challenges associated with ring use. Interviews were conducted in local languages, transcribed and translated into English, and coded and analyzed thematically using Nvivo.
Results: Intimate partnerships of ASPIRE participants varied in power dynamics and levels of traditionalism, trust, and commitment. The dynamics of each relationship, particularly the balance of power between participants and male partners, shaped their influence on adherence. Women whose narratives suggested higher independence from male partners, either because their relationships were casual or egalitarian, were more likely to describe using the ring without pre-emptively gaining partner acceptance. They also reported fewer partner-related barriers to adherence, often emphasizing that ring use was their decision alone. By contrast, among women who described engaging in relationships aligned with culturally-traditional, gender-imbalanced norms, there were more reports of challenges to ring use related to partners, including experiences of physical violence or forced ring removals. The majority of women described being in stable, non-casual partnerships that were neither fully equitable nor inequitable. These women commonly discussed a dual sense of obligation and interest in sharing decisions about ring use with their partners, with some facing barriers in the process of disclosing and negotiating ring within their partnership.
Conclusions: The ways in which gender equality and dynamics are experienced individually by a woman, her partner, and within each relationship are important factors influencing women's adherence. Strategies to involve men, and to address gender norms and relationship barriers more proactively could positively impact ring adherence.

MOPEC0667

Keeping HIV status secret from steady partners: gender differences among migrants from sub-Saharan Africa living in France

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Background: Gender roles induce gender differences in keeping HIV status secret from steady partners that should be considered in HIV prevention. In Europe, sub-Saharan African migrants are a key population for HIV infection. The aim of this study was to assess the prevalence and determinants of HIV status secrecy to steady partners among sub-Saharan African migrants living with HIV in France.
Methods: The ANRS-PARCOURS study is a life-event survey conducted in 2012 in health-care facilities in the Paris region among a random sample of sub-Saharan migrants living with HIV (N=926). Migrants were retrospectively asked whether they had disclosed their HIV status to all their steady partners (i.e. a partner for at least a year) since HIV diagnosis to data collection. Characteristics associated with HIV secrecy were identified using mixed-effects logistic regression models, including time and place of diagnosis (i.e. before or since migration), relationships' characteristics (their duration, whether partners were married, had a child; lived in different countries or had other partners during the relationship) and partners' characteristics (their age, educational level and nationality).
Results: Keeping HIV status secret from steady partners was more frequent among men than among women (31.3% versus 24.8%, p=0.05). Among men, keeping HIV status secret from steady partners was associated with transnational relationships (ORa=1.75[1.06-2.91]) and steady partners with no or primary educational level (ORa=2.09[1.00-4.37]). Among women, keeping HIV status secret from steady partners was associated with not being married to partners (ORa=3.77[1.73-8.20]), to the fact that partners had other partners during the relationships (ORa=1.91[1.11-3.29]) and to the fact that partners had no or a primary educational level (ORa=4.20 [1.93-9.15]).
Conclusions: Our study shows gender differences in level and determinants of HIV secrecy within the couple. Secrecy was higher among men and must be related to norms of masculinity that prevent men from seeking testing, care and talk about their HIV infection. Secrecy was linked to physical distance for men and social distance with the partner for women in contexts of polygamy, whether formal or informal.

MOPEC0668

Social oppression, sexual coercion and marital duty: the drivers of HIV among immigrant Afro-Caribbean women in Canada

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Background: Afro-Caribbean women account for the largest number of new HIV infections in women in Canada, especially those emigrating from countries with generalized HIV epidemics. The MSAFIRI Study uses mixed methods to characterize the social drivers of HIV acquisition in African, Caribbean and Black (ACB) immigrants post-migration to Ontario, Canada. We present a novel analysis of the relationship dynamics leading immigrant women to acquire HIV.
Methods: In-depth interviews were conducted with a purposive sample of ACB participants enrolled in the MSAFIRI study, who identified their source partner and were infected post arrival. Analysis based in grounded theory.
Results: Participants included 21 women (4 Canadian born) of median 41 years´ age (range, 28-63); 52% were from Africa and 42% from the Caribbean. Participants had immigrated at diverse time-points; median time to HIV diagnosis post-migration was 14.5 years (range, 2-38). Participants´ source partners were either their immigration sponsors, or men still residing in participants´ countries of origin (whereupon infection occurred post-migration during a trip „home"). Relationship dynamics - many marital - were governed by women's precarious immigration status, and financial and emotional dependence on the source partner, which disempowered them from asserting any dominance or decision-making capacity in the relationship and in their social environment. This lack of control surfaced in participants' accounts of sexual activities that led to HIV acquisition, ranging from their partner's infidelity to subtle sexual pressures, but also more overt oppressive acts such as rape and incest. Sexually coercive acts were consistently reported by study participants, regardless of socio-demographic characteristics, acts that they were seldom able to openly acknowledge or resist.
Conclusions: HIV acquisition among Afro-Caribbean immigrant women is reflected in a culture of social oppression, marital duty and silent sexual coercion. The hierarchal structure of participants' intimate relationships, coupled with fear, trust and dependence upon their partners - all tied to their immigration status - left them in a state of HIV vulnerability. There is cause to explore culturally competent HIV prevention strategies for this racialized population by addressing gender inequality, and delivering sustainable programming that builds immigrant women's capacity to resist the oppressive dynamics that drive their risk for HIV.

MOPEC0669

Trust issues: perspectives of male and female partners navigating dapivirine vaginal ring (VR) use in dyadic relationships; formative research outcomes from the CHARISMA study in Johannesburg, South Africa

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Background: Research suggests that women prefer to seek male partner agreement to use microbicides, and partners' knowledge and acceptance of microbicide use promotes product acceptability and self-reported adherence. To inform development of the CHARISMA intervention to address gender inequalities in ring/prevention use, we aimed to better understand how partners influenced disclosure and support for use.
Methods: Using semi-structured guides, we conducted 42 in-depth interviews with former participants of the MTN-020/ASPIRE trial of the dapivirine vaginal ring and their male partners in Johannesburg, South Africa, to explore how ring use and partnership dynamics interacted. We purposively sampled women who reported social harms or partner non-support (n=14; 33%) and women with supportive partners (n=14; 33%). We recruited a convenience sample of male partners (n=14; 33%). Interviews explored participants' intimate partner relationships and their partner's interaction with the trial. Thematic analysis of interview data was conducted using Dedoose software.
Results: Male and female narratives suggested that relationship trust was a key factor influencing HIV testing and partner disclosure and acceptance of study participation/ring use. Women's perception of HIV risk was influenced by the level of trust within their relationships, and several women sought sharing HIV test results (by both partners) as a method of building or maintaining trust. Women reported that partner-related mistrust motivated ring use, and some male partners worried that ring use indicated their partner's mistrust in them. ASPIRE participation also had negative and positive impacts on men's trust in their partners. Some men indicated ring use strengthened their partnership, while more commonly, men suggested women may have used the ring to safely have side partners. The risk of generating male partner mistrust made some women apprehensive about disclosing ring use to their partner. Key elements influencing trust were communication style, tracking whereabouts, perceived in/fidelity, and dynamics around socializing.
Conclusions: Results indicate trust is an important factor impacting open communication and male partner acceptance of ring use. As the dapivirine ring proceeds closer to licensure, interventions supporting women's agency to use microbicides safely and effectively are a priority, and trust issues are an important topic to address in counseling directed to ring users.

MOPEC0670

Free HIV tests on public spaces: a strategy which allows easy access to diagnose in the Autonomous City of Buenos Aires (CABA)

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Background: To reduce the negative impact caused by late HIV diagnoses in CABA (44% in men), since 2013, 25 testing centres and a new diagnose method, consisting in the use of a rapid test in the screening and viral load in the confirmation, were created. Different campaigns took place on public areas to promote the quick HIV test and increase the demand of diagnose.
Methods: In 2015, the Ministry of Health started the campaign "Rapid HIV test on your neighbourhood". This campaign consists in the use of sanitary trailers where the test is offered voluntarily, free and confidential with pre and post-test advice. For preliminary positive cases, the patient is transferred to the nearest hospital. The trailers are located in strategic points of the City of Buenos Aires.
We analysed the surveys for the people who took the test between 2015 and 2016.
Results: A total of 3847 tests were executed - 2087 men (54%) and 1760 women (46%) around 33 years of age on average. 48% of the total had never had an HIV test before (45% women and 52% men). 28% showed low level of instruction (incomplete high school education or lower), no mayor difference between men and women.
There were 49 preliminary positive results (38 men and 11 women, from which 9 and 4 were tested for the first time respectively) with a global prevalence of HIV infection of 1.27%.
The prevalence according to sexual practices in the male population was: MSM 6.75% and HTS 0.71%.
In most of the cases, people who took the test said they approached the trailer by seeing it while they were walking, by reading about it in articles on the media or in social networks.
Conclusions: The results of the campaign showed a greater influx of males than usual in the health system. Compared to the general population data (0,4%), there's a higher prevalence of HIV infection in heterosexual men (0.71%). This reaffirms the importance of continuing with the promotion of rapid tests on public areas.

MOPEC0671

HIV risks among Thai transgender women and potential technology-based HIV prevention interventions

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Background: Transgender women (TG) in Thailand with HIV prevalence ranging between 10-17%, experience unique health inequities and face multiple barriers to accessing HIV services. A paucity of research exists on their HIV vulnerability and how interventions should be designed to address TG-specific needs. We examined HIV risk characteristics and elicited strategies for HIV prevention interventions from a sample of Thai TG.
Methods: TG participants were randomly recruited from community-based organizations (CBOs), TG-focused and gender-friendly clinics, websites, and online TG networks. Self-administered survey links, containing questions on socio-demographic, stigma, risk behaviors, technology use and preferences for technology-based interventions, were distributed via e-mail, instant-messaging (IM) applications and social media networks to interested participants.
Results: Of 541 TG recruited, 212 (39.2%) responded to the survey from CBOs (45.3%), clinics (21.2%), websites (24.5%) and TG online networks (9%). Median age was 25 years (IQR: 22-30), 7.7% reported HIV-positive status, and 59.4% reported previous STIs. Mean HIV/AIDS knowledge score was 9.56 (SD = 3.4) out of 16. Mean age at first sex was 14.1 years (SD = 6.75).
In the past 6 months, 23.6% had >5 partners and 47.2% inconsistently used condoms. In the past 3 months, 35.5% had exchanged sex for money, 18.8% used recreational drugs, and 10.3% had group sex. Gender identity had caused fear among 45.8% to receive health care and 39.1% had ever been rejected from providers. More than half (54.7%) spent >8 hours using Internet per day and 43.4% had sought sex online in the past 3 months.
To optimize HIV prevention, a credible website featuring TG-friendly HIV testing sites (61.3%), TG-specific health videos (51.9%), health forums (57.6%) and eCounseling (56.2%) was desired. A TG counselor (63.2%) was the most preferred eCounselor, followed by a woman (18.4%), and a man (10.4%). Personalized HIV and health-related reminders were acceptable for 84.4% with IM applications (44.7%) and SMS (21.8%) being the most preferred platforms.
Conclusions: Among Thai TG who were mainly young, at high-risk, and felt stigmatized by health care system, technology-based interventions proved to have very high potential to deliver needed support in non-stigmatizing settings and link TG from online to offline HIV clinical services.

MOPEC0672

Factors that promote occupational substance use and related HIV risk: a qualitative assessment among female sex workers in Tijuana, Mexico

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Background: HIV prevalence among Female Sex Workers (FSW) in Tijuana, Mexico is 5-8% and as high as 14% among FSW who inject drugs. Factors related to work environment are primary in contributing to HIV risk among FSW. Occupational substance use (i.e., use of drugs/alcohol while working) is a critical work-related risk factor associated with inconsistent condom use with clients and increased HIV risk. However, more work is needed to better understand the factors promoting occupational substance use and the pathways by which such use heightens HIV risk.
Thus, the present study aimed to investigate the specific scenarios and factors in the work environment that promote occupational substance use and how such use increases HIV risk among FSW.
Methods: Qualitative data were from substance-using FSW (n=30) participating in a longitudinal study assessing HIV risk environments among a venue-based (e.g., bars, clubs) sample of FSW in Tijuana. Qualitative interviews were conducted to explore the specific scenarios of occupational substance use and how such use heightens risk for violence and HIV among FSW. Atlas Ti was used to code interviews for themes related to occupational substance use.
Results: Factors promoting occupational substance use among FSW included: a) making more money for sex trades that involve substance use with clients, b) using substances to facilitate working longer hours in sex work and c) substance use as a means to cope with stressors associated with sex work, particularly experiences of client violence. Factors identified by FSW to explain how occupational substance use increases HIV risk included: a) heightened experiences of client violence during sex trades when clients and/or FSW were using substances, and b) reports that substance use (either with clients or while working) prior to sex with clients decreased condom use negotiation power among FSW.
Conclusions: Findings highlight economic motivations and emotional coping as primary in contributing to occupational substance use among FSW, and violence was identified as a primary mechanism explaining the link between occupational substance use and HIV risk. Findings suggest that reducing economic vulnerability and violence will be critical to address occupational substance use and related HIV risk among FSW.

MOPEC0673

Masculinity and uptake of HIV testing: validity of the conformity to masculine norms inventory-22 in Malawi and Zambia

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Background: Men across sub-Saharan Africa are less likely to test for HIV or link to care than women. Qualitative research has highlighted the potential influence of masculine norms. We explored the Conformity to Masculine Norms Inventory (CMNI) scale in Malawi and Zambia, aiming for a validated scale to investigate associations between masculinity and previous HIV testing.
Methods: We reviewed psychometric scales measuring constructs related to masculine norms, behaviours or attitudes. The CMNI was selected based on previous validation in Kenya, reported association with health-seeking outcomes, and simplicity. The short version (CMNI-22) was amended for applicability, translated and back-translated into local languages, and piloted in Malawi. The scale was administered as part of a baseline household questionnaire to men in rural Malawi (n=485) and periurban Zambia (n=334). Iterated principal factor analysis was used with oblique rotations. Factor loadings below 0.3 were disregarded. Eigenvalues and variance captured were used to select retained factors.
Results: Sampling adequacy (Kaiser-Meyer-Olkin) was 0.80 and 0.65 in Zambia, respectively. Cronbach's alpha (scale reliability) was 0.75 and 0.68 in Malawi and Zambia. In Malawi, three factors were retained based on items relating to virility, violence and power over women; items associated with dominance and winning; and items pertaining to pursuit of status. In Zambia, two factors were retained. The first was associated with virility, violence and winning; the second, emotional control, dominance and power over women.
Conclusions: The interpretability of the items loading onto the retained factors was mixed and the tool performed differently in Malawi and Zambia, suggesting poor performance of the short-form scale. No masculinity-related scales have been validated in a rural or peri-urban African context. More research is needed to develop locally validated and generalizable scales for African settings: successful development would facilitate investigation of masculine norms and their effect on uptake of HIV services.

MOPEC0674

High HIV test yield among older men testing for the first time in Zimbabwe: implications for reaching 90-90-90 and preventing incident infections in young women

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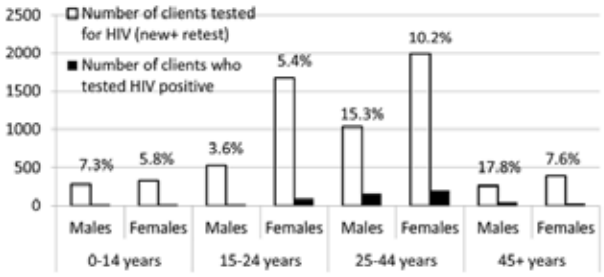
Background: Recent evidence highlights how sexual networks between young women and older men are driving HIV transmission in sub Saharan Africa. With a national HIV prevalence of 14.6%, reaching 90-90-90 in Zimbabwe will require

supporting undiagnosed individuals to know their status and initiate ART. Our objective was to explore HIV testing rates and yields by age, sex and health service entry points at 29 health facilities in Zimbabwe.
Methods: We conducted a retrospective cohort analysis of de-identified data from clients accessing HIV testing services at 29 purposively selected PEPFAR prioritised health facilities in 3 Districts of Zimbabwe (Bulilima, Mangwe, Mutare). All clients accessing HIV testing services from May-Aug 2016 were traced through multiple registers to document HIV test result and subsequent access to HIV Care and treatment services. Proportions were compared using Chi-squared tests in STATA V12.
Results: From May-Aug 2016, 7,027 HIV tests were conducted with a prevalence of 10.4% (95%CI:9.7-11.2). The majority of tests were conducted among women (67.3%; n=4,717), in antenatal care (28.3%; n=1,991). Men aged 25 and above had significantly higher HIV test yields than women of the same age (15.8% vs. 9.7%, p<0.0001).



[HIV test rate, new positives and test yield (%)]

Older men (45+yrs) HIV testing for the first time had the highest test yield (22%). Due to higher test rates, females accounted for 57.7% (n=423; 95%CI:54.0-61.3) of new positives identified. Men testing HIV positive presented at older median[IQR] age (37[30-43] vs. 31[27-39]), had significantly lower ART initiation rates (75% vs. 82%, p=0.05), and lower median CD4 cell count[IQR](186 cell/μL[101-316] vs. 334 cell/μL[186-519] than their female counterparts.
Conclusions: We observed lower HIV test rates, higher yields and lower linkages to HIV care among adult men. Reaching 90-90-90 and preventing new infections in Zimbabwe will require investment in evidence-based differentiated models of care to support timely uptake of HIV testing and treatment among adult men with unknown HIV status.

MOPEC0675

Qualitative findings of an HIV prevention intervention that empowers young women: Rise club case studies of social cohesion

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Background: Soul City Institute Social Justice introduced the RISE Young Women's Clubs to build social cohesion, self-efficacy and resilience and access to health, social and economic services. The clubs are a space for young women (15 -24 years) to support each other, work as a group to undertake projects in the community and, ultimately, prevent HIV through addressing structural drivers of HIV including discriminatory gender norms and gender based violence. Over 1000 clubs with 15000 members were established across 6 provinces.
Methods: A qualitative study was conducted with young women across 6 provinces. This was in the form of a series of case studies that utilised focus group discussion and in-depth interviews with stakeholders to measure the success of clubs in building social cohesion, resulting in young women being linked to required services to prevent HIV. Data was analysed thematically on Atlas Ti.
Results: Young women were linked to services such as social grants, access to condoms, health services including access to Sexual and Reproductive Health and HIV testing. The girls talked about having fun together. They felt empowered with life skills to protect themselves from HIV, substance abuse, violence and intimidation. Activities included, fundraising and gardening to support poverty stricken club members and families, as well as discussions about career guidance, tertiary studies and bursaries, dealing with finances and how to become leaders and role models in their communities.
The girls reported how clubs foster an environment for supporting each other, thereby building social cohesion and resilience around health, social and educational outcomes.
Conclusions: The Rise clubs play an important role in building self-esteem and social cohesion among young women, and often fill a gap in their social support structures. Together addressing gender based violence, poverty and positive peer pressure are some of the ways that the clubs function to enable young women to remain HIV free.

MOPEC0676

Changing the game for girls: encouraging results from a longitudinal study of a soccer-based HIV and SGBV prevention programme for adolescent girls in South Africa

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Background: More than a third of women in South Africa experience violence before the age of 18. Women are at a much higher risk of HIV infection than men, with young women aged 15-24 accounting for 60% of all new infections among young people. Gender inequality and intimate partner violence have been linked to increased risk of HIV. Grassroot Soccer (GRS) designed SKILLZ Street Plus (SSP), a programme that combines girls' soccer with educational activities meant to empower at-risk adolescent girls to form gender-equitable attitudes and negotiate healthy relationships; respond better to violence in their lives and gain HIV-related knowledge, thus reducing the chances of risky sexual relationships and HIV infection. A longitudinal study and external evaluation measured changes in knowledge, attitudes and experiences of violence among girls before and after SSP.
Methods: Baseline and endline questionnaires were administered to girls (n=146, average age = 13.6) in two intermediate and two secondary schools in Soweto over an 18-month period. Project monitoring data were collected, including uptake of HIV testing and disclosure of experiences requiring follow-up. An external evaluation investigated quantitative results through rapid ethnographies, focus group discussions (n=6) and interviews (n=19) with staff, coach mentors, SSP participants as well as male participants in mixed-sex GRS programmes.
Results: We observed increased percent of girls who reported intimate partner violence (IPV) as unacceptable (70% baseline; 89% endline) and reported decreases in justification and experiences of IPV. Some girls chose to leave physically and emotionally abusive relationships. HIV testing uptake (ever tested for HIV and tested for HIV in last 3 months) increased from 12.3% to 43.9% and from 4.8% to 27.4% respectively. Girls reported greater confidence, self-efficacy and improved decision making. Disclosure of violence doubled from baseline to endline.
Conclusions: The SSP intervention has the potential to empower girls to pursue healthy and gender equitable partnerships and leave violent relationships, which put them at higher risk of HIV. It highlights the important role that families, friends and other support systems play, including schools, police and clinical services. GRS will use these encouraging findings to develop a more robust programme that tackles violence at multiple levels.

MOPEC0677

Lessons learned: employing Indigenous methodologies and women-centred approaches to understand Indigenous women's experience of HIV prevention and care in Quebec, Canada

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Background: Approaches to HIV-prevention and care with Indigenous Women in Canada must integrate and address challenges, and build on this population's strengths. For Indigenous women (First Nations, Métis, Inuit), vulnerability to HIV is structured by gender inequity, colonization, racialization and social immobility (poverty, education). These structural inequities lead to disproportionate HIV rates; although Indigenous women are 4.3% of the Canadian female population, they represent 30.6% of new female diagnoses. Importantly, these vulnerabilities coexist with resilience, cultural continuity and strength. This abstract details lessons learned for prevention and care programming, drawn from our process conducting four full-day workshops with Indigenous women in Quebec, Canada.

Methods: The research is embedded within the Canadian HIV Women's Sexual and Reproductive Health Cohort Study - Prioritizing the Health Needs of Positive Aboriginal Women (CHIWOS-PAW). In Quebec, the purpose was to understand Indigenous women's perspectives regarding women-centered strategies to improve HIV prevention, care and overall health. Between December 2015 and December 2016, under the direction of an all-female team of Indigenous leaders, and drawing on Indigenous Methodologies, two research retreats, a community analysis workshop, and a celebration event were conducted with 14 Indigenous women.
Results: From our process we draw the following recommendations for the creation of accessible and acceptable prevention and care strategies for Quebec Indigenous women. Lessons learned included:
1) incorporating women-centered, culturally-adapted sharing circles, arts, and ceremony, encouraged participation, safety and comfort;
2) conducting numerous workshops with the same women was valuable to participants and facilitators to build trust and adapt subsequent workshops to participants needs;
3) confirming findings with participants was essential to ensuring that the knowledge, experience, and priorities of Indigenous women were respected.
Facilitators to our process included:
1) existing networks with Indigenous Elders, art-therapists, musicians;
2) a strength-based, neutral space to conduct the workshops (e.g. Aboriginal Art Gallery);
3) experienced Indigenous researchers with facilitation skills; and
4) sufficient funds and coordination support to carry out multiple events.
Conclusions: Adopting a women-centered, strength-based, culturally adapted, peer-lead approach is essential to ethical, effective and appropriate prevention and care for Indigenous women. Further work by and with Indigenous women is needed to address HIV in Canada.

MOPEC0678

Barriers to care and non-prescribed sex hormone use among trans women in São Paulo, Brazil

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Background: Transwomen face significant discrimination and barriers to healthcare worldwide. Lack of trans-specific care has not only been associated with HIV-related risk behaviours as gender affirming coping practices, but often results in non-prescribed sex hormone use and other medically unsupervised transition methods, leading to significant health complications. However, little is known about barriers to trans-specific care among transwomen in Brazil, where few facilities provide such services. To address this research gap, we analyzed factors associated with non-prescribed sex hormone use by transwomen in 7 municipalities of São Paulo state in Brazil.
Methods: Muriel Project was a cross-sectional consecutive snowball sampling study conducted from November 2014 to October 2015. A total of 673 transgender persons were recruited through health care and social welfare services and answered a face-to-face interviewer-administered survey. This analysis focused on transwomen (n=616 out of 673). Descriptive statistics and poisson bivariable and multivariable regression models with robust variance were employed to assess, respectively, sample characteristics and non-prescribed sex hormone use associations with sociodemographic factors, discrimination experiences, gender identity, transition procedures, sex work and health care access.
Results: Overall, 90.7% (n= 559) transwomen reported ever taking sex hormones, with mean age for starting at 17 years. Most (79.2%; n=444) of those who took sex hormones detailed non-prescribed use, which was associated with sex work (adjusted Prevalence Ratio [aPR]=1.23; CI95%=1.12-1.35) and medically unsupervised filler use (aPR=1.11; CI95%=1.01-1.21). Furthermore, use of chosen name in public health services (aPR=0.87; CI95%=0.76-0.99), and gender identity of woman (aPR=0.77; CI95%=0.65-0.91) or transsexual (aPR=0.89; CI95%=0.80-0.98) were found to be protective against medically unsupervised sex hormone use.
Conclusions: A high unsupervised sex hormone use prevalence was observed in our sample, possibly underestimated given the high proportion of participants recruited from health care services. Such findings may indicate barriers to trans-specific care and resort to medically unsupervised transition procedures, which might be exacerbated for sex workers. Ensuring social rights and providing adequate health and trans-specific care services may lessen non-prescribed sex hormone use and other unsupervised transition procedures, preventing subsequent risk behaviours and ensuing better health outcomes for transwomen.

MOPEC0679

Social Network Analysis of Women with HIV in South India

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Background: Stigma is a global challenge to the prevention and treatment of HIV. Intersectionality, or layered stigma has compounded these barriers for women. Previous literature suggests health disparity among women with HIV compared to their male counterparts, with women reporting less support and greater stigma. In order to disentangle various contributors to stigma and its impact on mental health and overall wellbeing it is necessary to first understand the support systems and social networks in the general population compared to those of people living with HIV. The objective of this study was to map ego-networks of Indian women with HIV and demonstrate differences when compared to women without HIV. It also sought to uncover alters (people) providing primary support and substitutes who replaced traditional support-givers.
Methods: This study used a mixed-method design.
Four hundred South Indian women (300 HIV-negative and 100 HIV-positive) between the ages of 18-40 (m=24) completed surveys on support, quality of life, and social networks. Sixty of these women (30 HIV-negative and 30 HIV-positive) also joined semi-structured focus group discussions (6-8 women per group) on social networks, support, and HIV-knowledge. The following statistical tools were used for analyses: Atlas.ti for qualitative analysis, EgoWeb2.0 for social network analysis, and SPSS-21 for Anovas and multiple regressions.
Results: Preliminary results demonstrate significant between group differences, with women identifying as HIV-positive reporting fewer and weaker links in the between alters (people) in their networks when compared to HIV-negative counterparts. Furthermore women with HIV reported significantly less friends, but greater support from their adult children, particularly daughters and substitute alters, such as HIV-support group members.
Conclusions: HIV-related stigma may impact social and support network structures. It is necessary to further research this topic in order to improve prevention and intervention programs to include social awareness and support, with the eventual goal of improved mental health outcomes for people living with HIV.

MOPEC0680

Psychological challenges and coping strategies among pregnant HIV-positive women aged 15-24 years in Lagos state

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Background: in Sub-saharan Africa, 76% of young people (15-24) living with HIV are female. an unplanned pregnancy can be an emotionally wrenching experience for woman and can be especially frightening for an unmarried adolescent, who may be unprepared to raise a child. Given the combination of stressors that are likely, the need for information about the psychological impact of HIV infection during pregnancy is imperative. The objective of this study is to identify the psychological challenges and coping strategies adopted among pregnant HIV positive young women aged 15-24 years.
Methods: The study design was descriptive cross-sectional. Two hundred and three young women aged 15-24 PLWHA from PMTCT centers located across the urban Lagos state in Nigeria were consecutively selected. A structured interviewer-administered questionnaire was used to collect data on socio-demographics, assessed psychological challenges using adapted WHOQOL-HIV and coping strategies using adapted Ways of Coping. Data was analyzed with SPSS version 20. Quantitative data were analyzed using inferential statistics and qualitative variables using percentage.
Results: Two hundred and three pregnant HIV positive young women were confronted with various negative experience including: shame, confusion, anxiety over non-disclosure, poverty, lack of employable skill, interrupted education, lack of access to age appropriate sexual health information and services, social isolation and stigma and depression. A significant proportion of respondents were in psychological distress (40%). Findings showed that,respondents who were married or co-habiting with a partner or in supportive relationships experienced less psychological distress. Employment status and income of respondents were significantly associated with the experience of psychological distress. In response to these challenges, majority of them 72.9% adopted problem focused coping strategy while about 27.1% used emotion focused strategy. They reported relatively high use of accepting responsibility and distancing but poor use of social support , self controlling and positive reappraisal which are positive constructs. The negative constructs used were confrontative coping and escape-avoidance coping.

Conclusions: HIV infected pregnant young adults faced many serious psychological and social challenges. These challenges elicit both positive and negative coping and survival strategies. The coping strategies selected highlights need for interventions to aid healthier coping choices among those experiencing psychological distress.

MOPEC0681

Relationship power imbalance and history of partner HIV testing among pregnant women in Uganda

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Background: In some societies, a power dynamic is shifted towards greater power and resources given to males over females, and this imbalance can have a negative impact on health, including HIV prevention. Here we investigate the association between gender power imbalance and male partner testing for HIV among pregnant women attending antenatal care (ANC) in central Uganda.
Methods: This analysis uses baseline data from a cluster-randomized HIV self-testing intervention from three ANC clinics in central Uganda. Pregnant women with HIV- male partners were recruited and randomized by day into standard of care or intervention (HIV self-testing kits for the male partner). Screening and baseline interviews were conducted using REDCap software on electronic tablets. Women were asked about history of partner testing, characteristics of their relationship, and other factors. Analyses were performed in SAS (9.4), with chi-square tests and a p-value <0.05 for significance.
Results: 1,473 women were recruited across the three sites between July and November of 2016 (698 in the standard of care arm, 767 in the intervention arm). Only 17.7% of the women's partners had ever accompanied them to ANC (17.7%) and of the women who asked, only 39.6% of male partners had ever tested for HIV. Among women under 26, women's contributions to household expenses were different by partner testing (overall p<0.001), with 36.3% of women whose partners tested making no contribution to expenses compared to 64.2% of women whose partners did not test. Relationship status also differed by partner testing (overall p=0.03), but 11.95% of women whose partners tested had a sometimes difficult relationship with their partner vs. only 5.6% of women whose partners did not test. Among women aged 26+, decision making for visiting family differed by partner testing (overall p=0.002), with 54.6% of women making joint decisions with partners who tested compared to 36.9% whose partners did not test.
Conclusions: A higher relationship power balance is significantly associated with increased HIV testing among male partners testing when measured by household expenses and decision making, but not relationship status. Interventions aiming to increase relationship power balance could increase HIV testing among males in Uganda.

MOPEC0682

Sociodemographic factors related to relationship power imbalance among pregnant women and their partners in Uganda

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Background: In relationships where the power dynamic is shifted to males, the female partner may have numerous disadvantages, including lack of self-efficacy to prevent adverse health outcomes and obtain health care. We investigated sociodemographic variables related to relationship power imbalance among pregnant women and their male partners in central Uganda.
Methods: We have completed recruitment into a cluster-randomized trial of HIV self-testing to increase partner testing in central Uganda. We recruited pregnant women from three ANC clinics. Women enrolled had a male partner aged 18+ whom she saw at least once a week, who she believed to be HIV-, and who did not test for HIV in the previous 6 months. We sought to determine at baseline, the relationship between sociodemographic factors and measures of relationship power imbalance within the couple.
Results: 1,473 women were recruited from July to November 2016 (698 standard of care, 767 intervention). Among women aged 25 and under, decision-making regarding her health care differed by her education status (overall p=0.0463), with 12.15% of women with secondary education making joint decisions versus 6.49% of women with less education. Decisions on use of the woman's income differed by partner's education (overall p<0.001), with the man alone making the decision in 11.37% of couples where the man had secondary education or higher, versus 26.64% among couples where the man had less education. Among women aged 26 and older, decisions regarding visiting family differed by the woman's education level (overall p=0.004), with 50.98% of women with secondary education making joint decisions, versus 36.62% of women with less than secondary education.
Conclusions: While higher educational attainment in the male partner was related to increased decision making by the male only, we found that higher educational attainment by the female was related to more joint decision making. Educational parity within the couple, and in particular higher educational attainment by the woman, may help improve gender equity and health outcomes among couples in Uganda.

MOPEC0683

Effect of adding TB/HIV referral coordinators on TB and HIV screening: a programme evaluation in Benue state, Nigeria

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Background: Nigeria has the fourth largest TBHIV burden in the world. Benue state, in North Central, Nigeria has a high TB burden attributable to its high HIV prevalence of 5.6%.An assessment of the implementation of ICF among PLHIV in HIV care and treatment settings in Benue state by the US Centre for Disease Control revealed significant drop offs in the cascade from TB screening to treatment of co-infected patients.
We assessed the impact of introducing TBHIV referral coordinators on the number of people screened as well as diagnosed and started on TB treatment in five Local Government Areas (LGAs) of Benue State, Nigeria supported by the Centre for Integrated Health Programs.
Methods: 59 TBHIV volunteers and 5 LGA referral coordinators were trained in cough triaging, presumptive case identification, data management and linkages to comprehensive ART sites and were provided with monthly stipend. PLHIV were symptomatically screened for TB, Presumptive TB cases were referred to the DOTS clinic for sputum sample collection and follow up. The LGA coordinators supervised the volunteers.
Data from four months (October 2015-January 2016) before implementation of the TB referral coordinators and four months after implementation (February -May 2016) were analysed using three TB indicators (PLHIVs screened for TB, Number of presumptive TB cases identified, number of TB cases diagnosed and placed on TB treatment) to evaluate the impact of the intervention.
Results: The number of clients offered TB screening increased by 91% within the period under review from 10,676 to 20,444 this was accompanied by a significant increase in number of presumptive TB cases identified (934 vs. 2567, p=0.00) However, there was no statistically significant increase in the case detection rate amongst the screened cases (5.8% vs. 7.1%, p >0.05).
Conclusions: The use of TBHIV referral coordinators improved TB screening and referrals in the LGAs.Additional measures need to be put in place to improve the case detection rate.

MOPEC0684

Tuberculosis intensified case finding among people living with HIV in Côte d'Ivoire: coverage, caveats and way forward

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Background: Intensified case finding (ICF) for tuberculosis (TB) among people living with HIV (PLHIV) is not performed routinely by health staff in Côte d´Ivoire (CI) despite being a mandatory routine practice since 2010. Implementation of TB-ICF in 39 CDC-sponsored HIV care centers (HCC) was assessed to quantify the extent of the application of national guidelines and to provide recommendations for improvement.
Methods: A retrospective cohort study extracting data from PLHIV medical records was conducted. PLHIV were selected through two-stage cluster sampling. First, HCC were selected proportional to the current number of PLHIV on treatment. Second, a fixed number of PLHIV medical records were selected among those aged 15 or older who had attended the HCC between September 2014 and March 2015. Data from selected patients' last visit during the study period were recorded.

Results: A total of 4410 patient records were used from 39 HCC spread nationwide. PLHIV had a mean age of 42.0 years and 72.6% were women. TB-ICF was performed for 79.0% of PLHIV. A multivariate logistic regression was used and odds ratios were estimated with 95% confidence intervals. Predictors of the absence of TB screening (p< 0.001) included attending facilities with more than 50 PLHIV per health care provider (HCP) (OR: 0.3583; 0.3075-0.4173) and HCC located in Abidjan (OR: 0.4353; 0.3730-0.5078), being older (>40 years; OR: 0.9824; 0.9755-0.9895), having a higher CD4 count (OR: 0.9995; 0.9992-0.9997), and attending HCC with greater numbers of PLHIV (OR: 0.9998; 0.9998-0.9999). The implementation of TB-ICF was not associated with the existence of a diagnostic and treatment center for TB in the HCC (p=0.146).
Conclusions: TB-ICF in CI is hampered by understaffing at HCCs, and elderly people are less likely to receive TB screening, possibly because they require lengthier consultation time than younger patients or because of a possible impact of survivor bias. Task shifting TB-ICF to lower level cadres at the HCC or community has the potential to improve coverage. Mentoring HCP on the need to attend to all patients, regardless of their CD4 count, and to older PLHIV are possible strategies for improving health service delivery in the short term.

MOPEC0685

Access to and utilization of health and social services for people who inject drugs (PWID) in two urban areas of Mozambique, 2013: results from a formative assessment

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Background: Prior to the 2014 Integrated Biological and Behavioral Survey (IBBS) among PWID in Mozambique, data about health seeking behaviors or service uptake for PWID did not exist. We present the results from the formative assessment component of the IBBS.
Methods: Standardized interview guides were used during key informant interviews (KII) and focus group discussions (FGD) in Maputo and Nampula/Nacala to discuss issues related to risk behaviors and access to and utilization of health and social services by PWID. The target sample size was not defined a priori, but instead KII and FGD were conducted until responses reached saturation. Data analysis was based on the principles of grounded theory related to qualitative research. Transcripts were double coded and analyzed using NVivo (QSR International Pty Ltd. v10).
Results: Eighty-four respondents, ages 15 to 60, participated in KIIs and FGDs. Participants were majority male from diverse income levels and included current and former PWID, non-injection drug users, health and social service providers, peer educators, and community health workers. Respondents reported that PWID engage in high-risk behaviors such as needle and syringe sharing, exchange of sex for drugs or money, and low condom use. According to participants, PWID would rather rent, share or borrow injection equipment at shooting galleries than purchase them due to stigma, fear of criminalization, transportation and purchase costs, restricted pharmacy hours, personal preference for needle sharing, and immediacy of drug need. Barriers to access and utilization of health and social services include distance, the limited availability of programs for PWID, lack of knowledge of the few programs that exist, concerns about the quality of care provided by health providers, lack of readiness as a result of addiction and perceived stigma related to the use of mental health services.
Conclusions: Mozambique urgently needs to establish specialized harm reduction programs for PWID and improve awareness of available resources. Services should be located in hot spot areas to address issues related to distance, transportation and the planning required for safe injection. Specific attention should go to the creation of PWID-focused health and social services outside of state-sponsored psychiatric treatment centers.

MOPEC0686

The risk of HIV transmission at each step of the HIV care continuum among people who inject drugs

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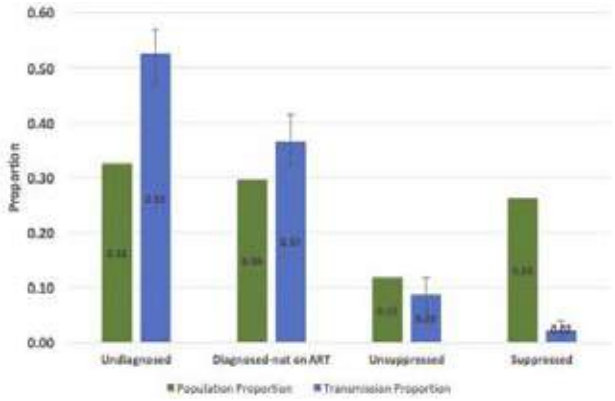
Background: People who inject drugs (PWID) are at continued risk for HIV in the US, and experience disparities across the HIV care continuum compared to other high-risk groups. Estimates of the risk of HIV transmission at each stage of the care continuum may assist in identifying public health priorities for averting incident infections among PWID, and sexual transmissions to those outside this risk group.
Methods: We created an agent-based model simulating HIV transmission and the HIV care continuum for PWID in New York City (NYC) in 2012. Using surveillance data and estimates from the National HIV Behavioral Surveillance system, we simulated a dynamic sexual and injecting network. We estimated the proportion of HIV transmission events attributable to PWID in the following categories, those: without an HIV diagnosis (‚Undiagnosed'); diagnosed but not on antiretroviral therapy (ART) (‚Diagnosed−not on ART'); those who initiated ART but were not virally suppressed (‚Unsuppressed'); and, those who achieved viral suppression (‚Suppressed').
Results: We estimated HIV incidence among PWID to be 113 per 100,000 person-years in 2012. The main results are presented in Figure 1; despite accounting for only 33% of the HIV-infected PWID population, the Undiagnosed were associated with 52.6% (95% simulation interval [95% SI]: 47.1-57.0%) of total transmission events. The Diagnosed−not on ART population contributed the second-largest proportion of HIV transmissions, with 36.6% (95% SI: 32.2-41.5%). The Unsuppressed population contributed 8.7% (95% SI: 5.6-11.8%), and Suppressed 2.1% (95% SI: 1.1-3.9%), relatively little of overall transmission.



[Figure 1. Population size and transmission attributable to HIV care continuum steps among people who inject drugs in New York City, 2012]

Conclusions: Among PWID in NYC, more than half (53%) of transmissions were from those who were unaware of their infection status and more than 36% were due to PWID who knew their status, but were not on treatment. Our results indicate the importance of early diagnosis and interventions to engage diagnosed PWID on treatment to further suppress population-level HIV transmission.

MOPEC0687

Regional differences in injection drug use behaviors: baseline results from the HPTN 074 vanguard HIV prevention trial

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Background: High-risk sharing practices among people who inject drugs (PWID) are thought to be primary sources of HIV transmission in several parts of the world, including Eastern Europe and Southeast Asia. PWID in these regions face significant barriers to HIV testing and engagement in care. Understanding regional differences among PWID is essential to developing effective intervention strategies.
Methods: The HPTN 074 trial is a two-arm, randomized, vanguard study designed to determine the feasibility of an integrated intervention combining psychosocial counseling and supported referral for antiretroviral therapy and substance use treatment for HIV-infected PWID in Vietnam, Ukraine and Indonesia. Network units consisting of an HIV-infected index with VL >= 1000 copies/ml and up to five of his/her HIV-uninfected injection partners were randomly assigned to the intervention or standard of care. Here we evaluate baseline demographic and behavioral data by country.
Results: Between April 2015 and June 2016, 504 networks (504 indexes and 656 partners) were enrolled. The majority of enrollees were men (87%), with 82% of the enrolled women coming from Ukraine. The overall mean age was 34. Drug use and injection practices varied substantially by country. In Vietnam heroin was almost exclusively used (99%), while in Indonesia participants reported using both heroin (82%) and buprenorphine (38%). In Ukraine there was little reported heroin use (9%) but significant injection of diverted methadone (84%), homemade opioids (75%), and amphetamines (36%). In Indonesia 73% reported using non-injectable stimulants, compared to 28% in Ukraine and 18% in Vietnam. Risky injection practices also varied, with 42% of HIV-negative partners in Ukraine reporting using a needle after someone else, compared to 33% in Indonesia and only 18% in Vietnam. Over 70% of partners in Vietnam reported no needle sharing in the past three months, compared to 45% in Ukraine, and 0% in Indonesia. Ukrainian indexes reported an average of seven injection partners, compared to four in Indonesia and three in Vietnam.
Conclusions: Demographics and drug-use behaviors differ dramatically across the three HPTN 074 sites. These differences highlight the heterogeneity of substance-use-related HIV epidemics and suggest the need for flexible, region-specific strategies for combating HIV among PWID.

MOPEC0688

Predictors of HIV seroconversion in people who inject drugs in Ukraine

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Background: While there were 39,664 people who inject drugs (PWID) officially registered with drug addiction clinics in 2016, WHO estimates 310,000 PWID in Ukraine. Even though harm reduction services for PWID were introduced in Ukraine in 2001, national surveillance studies show that in 2015 the prevalence of HIV in PWID was 20.1%. The objective of this analysis was to assess the level of HIV seroconversion in PWID in Ukraine and its predictors.
Methods: The data were collected in 2014-2015 within 'Access to Medication Assisted Therapy' project implemented in partnership with Yale School of Medicine. Respondent-driven sampling was used to recruit current PWIDs (n=521) and random sampling was used to recruit opioid antagonist treatment (OAT) patients (n=434) in 5 regions of Ukraine. Interviews were followed by rapid HIV testing. Seroconversion was defined as present if the respondent stated he had been tested HIV-negative before and was tested HIV-positive after the interview. The predictive model using logistic regression weas built with HIV seroconversion as the outcomes. Potential confounders included demographics, risky sexual behavior, risky injecting behavior, length and frequency of injecting, alcohol intake, and history of incarceration.
Results: Mean age of participants was 37.3 years (s.d.8.2); most of respondents were male (73.8%); lived with their partner (40.5%); mean length of injecting was 22.2 years (s.d.9.1). Prevalence of HIV in the sample was 47.7%. Prevalence of seroconversion was 4.1%(n=39). The mean interval for HIV seroconversion was 2.9 years (s.d.3.3; range: 1-20). The results of logistic regression showed that OAT had a protective effect against HIV(OR=0.45, 95%CI=0.26-0.78) seroconversion. Neither risky injecting behavior nor length/frequency of injecting were statistically significant.
Conclusions: Despite large coverage of PWID with harm reduction services countrywide, the prevalence of HIV seroconversion in this key population remains very high. As of January 2017, OAT programs cover only 22.5% of PWID officially registered with drug addiction clinics. Given the low coverage of PWID with OAT, transition to governmental funding of OAT programs as well as OAT being proved to be effective in HIV prevention, there is an urgent need in large OAT programs scaling up in Ukraine on national level.

MOPEC0689

Injecting drug use and sex work: two interconnected risky behaviors in Egypt

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Background: Injecting drugs and involvement in sex work are often interrelated and populations involved in both behaviors are at higher risk of acquiring HIV. According to the Bio BSS conducted in 2010, an estimated 13.1% in Cairo and 10.8% in Alexandria of Male Injecting Drug Users (IDUs) had sex with commercial sex workers. The Drosos and Ford Foundations, in collaboration with FHI 360, have established the Network of Associations for Harm Reduction (NAHR) in Egypt in an attempt to reduce risky behaviors among key populations.
Methods: Biological and behavioral data were collected from six NAHR Comprehensive Care Centers (CCCs) in Greater Cairo and Alexandria between March 2013 and August 2016. The population sample was selected using two main indicators; males ever injecting drugs and ever having sex in exchange for money or goods.
Results: NAHR CCCs received 934 male IDUs involved in sex work. The majority was between the ages of 25 and 35 (64.4%). About one quarter were married (24.7%), 44.0% received some university education, and 53.1% were employed. More than two thirds of the sample started injecting drugs between the ages of 16 and 24 (71.3%). Ever sharing needles or syringes was reported by 82.4% while 91.5% ever shared paraphernalia. Injection of Heroin last month was reported by 67.1% whereas 76.8% had sex last month. Exchanging sex for drugs in the last six months was reported by 37.1% of the visitors. During the last sex, only 3.1% and 3.0% used condoms with steady and non-steady partners respectively while 59.3% expressed their willingness to use condoms. The HIV prevalence was 3.3% among the studied population.
Conclusions: Given the high rate of drug injection and needle sharing, coupled with extremely low condom use, there is a need to integrate a double faceted approach in Harm Reduction projects targeting populations at risk. An interlocked method of safe sex safe injection should lead the new era of an HIV-free generation.

MOPEC0690

Large scale respondent driven sampling among persons who inject drugs in Haiphong, Vietnam: involvement of peer-support groups is key for success

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Background: Haiphong has seen a high prevalence of HIV and HCV infections among persons who inject drugs (PWID); recruitment of drug users can often be difficult due to the stigmatized nature of their behavior. In this study, we assess the efficiency and obstacles of respondent driven sampling (RDS) survey in Hai Phong, Vietnam.

Methods: Using RDS we enrolled participants into a large HIV care and prevention intervention. The PWID peer support groups acted as Community-Based Organizations (CBO). The RDS participants were recruited in 2 offices of CBOs, who were also critical in the RDS implementation, by examining sensitive topics such as the amount of the honorarium, the use of the fingerprint reader (to avoid participating multiple times in the study) and on-site urine analysis (to confirm recent drug use eligibility criterion). In addition, CBO members also were involved in adapting RDS procedures to the increased police pressure on traditional hot spots and its subsequent changes in the drug scene. Initially, a total of 20 seeds were used to launch the RDS and enroll participants from two sites, both CBO offices. An additional estimation of coupon distribution was conducted to understand locating PWID.
Results: RDS recruitment was particularly efficient, with 1385 subjects recruited in 13 weeks; the average age of participants was 39 (SD 9) years and 94% were male. The rate of recruitment was most affected by the changing drug "market" among PWID in Hai Phong. Changes in the RDS procedures included increased number of coupons given to participants, recruitment of new seeds and increased participation fees. Among the coupons distributed to participants, approximately 50% were given to other potential participants. The main reasons participants could not distribute their coupons included difficulties in locating PWID, the clearing of hot spots by the police and PWID being uncomfortable with disclosing their injection status.
Conclusions: RDS is still efficient for recruitment of PWID, but modification of RDS procedures will require adaptation of RDS network analyse. The involvement of CBO members well connected with the drug milieu is crucial for this purpose.

MOPEC0691

Increased methamphetamine use among persons injecting heroin in Vietnam: time to rethink harm reduction and addiction care for HIV control? ANRS 12299/NIDA P30DA011041 DRIVE-IN study

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Background: In Vietnam, HIV and HCV epidemics are much concentrated among persons who inject drugs (PWID). A national control program including combined interventions have decreased the rate of new HIV infections. However, recent increase in methamphetamine (Ice) use is alarming, since it has been associated with HIV/HCV risky behaviors and therefore could alter the program efficacy. The objective of this survey is to assess Ice use and associated HIV/HCV risks among intravenous heroin users.
Methods: A respondent driven sampling (RDS) survey was first conducted to identify drug use and characterize HIV risky behaviors among PWID in Haiphong, Vietnam, through a face-to-face questionnaire, urine testing for drug use and HIV/HCV testing. A sample of PWID was then included in a one-year cohort study to describe community-based organization (CBO)-supported access to care (methadone treatment) and the evolution of drug use over time. Methamphetamine and cannabis use were based on self-report or urine detection.
Results: Among the 603 PWID included in the RDS survey, all were injecting heroin with 2.6 injections per day on average, 186 (30.9%) were also using methamphetamine (Ice) including 3 injectors. In multivariable analyses, not having a medical insurance (OR=1.70, 95%CI: 1.01-2.85), having a household registration in Hai Phong (OR=2.33, 95%CI: 1.09-5.01), having methadone in urine (OR=1.70, 95%CI: 1. 12-2.59), having several sexual partners during the last 3 months (OR=2.28, 95%CI: 1.43-3.65), having their syringes used by others (OR=2.15, 95%IC: 1.06-4.37), number of injections in a typical day (OR=1.34 per 1 injection increase per day, 95%IC: 1.10-1.63) and having ever been tested for HIV (OR=1.78, 95%CI: 1.17-2.68) were associated with a higher risk of methamphetamine use (self-report+urine test). Among the 250 RDS participants enrolled in the cohort, Ice use increased dramatically from 30.4% to 49.0% at one year, and was clearly associated with not starting methadone during follow-up (OR=3.34, 95%IC: 1.92-5.79).
Conclusions: Ice use increased dramatically among PWID in Vietnam. PWID using heroin together with Ice had a higher-risk profile and a lower likelihood to enroll in the methadone program, despite CBO support. Current HIV harm reduction strategies should be tailored for this subpopulation in a comprehensive way.

MOPEC0692

New strategy to implement HIV, HCV and HBV screening and surveillance in Centers for Drug Addiction, Italy North-West

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Background: In spite of excellent results to decrease new HIV infections, as demonstrated by the national HIV surveillance system, in the last 20 years in the Italian Drug Addiction Services (DAS), due to educational and preventive programs, drug users (DU) remain a vulnerable population. Recent data shows a generally low coverage of screening testing for the major drug-use-related infections in DAS. In this context, a project aimed to increase HIV, HCV and HBV testing coverage and build up specific recommendations was conducted over two years (2014 and 2015) involving the 66 local DAS in Piemonte, Italy North-West.
Methods: Four key points were focused and developed:
1) educational and testing training of about 180 health care providers;
2) set up of an electronic database to monitor testing activity (SPEDI);
3) offering oral HIV rapid test in the so called "refractory" patients (i.e. person repeatedly not compliant to HIV testing;
4) linkage to care for new infected people.
DUs with a least one visit were included and offered HIV, HCV and HBV testing with conventional serology.
Results: The DUs population consisted of 16,931 people (20% females, median age 42.5). The global testing rate significantly increased from 2014 to 2015 (from 25.1 % to 30.7 % for HIV; 33.7% to 44.3 % for HCV and 37.6 to 44.3 % for HBV). The percentage of "never tested" people fell down by about 10% for each virus (from 50.5 % to 40.6 % for HIV, 61.7 % to 51.9 % for HCV and 50.2 % to 40.4 % for HBV). The prevalence rate of HIV, HCV and HBV infections was 4.1 %, 28.2 and 14.7 %, respectively. Regional recommendations on HIVand Hepatitis screening in DAS setting were developed considering critical issues such as testing in not compliant clients.
Conclusions: The project was successful in enhancing HIV and Hepatitis testing in DAS; HIV rapid testing on oral fluid helped to screen difficult-to test clients. The prevalence HIV, HCV and HBV infection was significantly high, thus justifying new strategies of testing coverage for disease prevention and linkage to care of patients.

MOPEC0693

Testing and linkage to care for injecting drug users (TLC-IDU) in Kenya: a baseline assessment in western region

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Background: HIV infections in sub-Saharan-Africa increasingly occur among people who inject drugs (PWID). The World-Health-Organization (WHO) recommends antiretroviral-therapy (ART) to enhance viral-suppression among persons at high-risk of transmission including PWID. We present data from an behavioral and biomedical study of a baseline-assessment in the Western region in Kenya among PWID.
Methods: We used respondent-driven-sampling (RDS) to reach PWID for HIV-1 and Hepatitis-C-virus (HCV) prevalence and viral load determination, using established procedures from the parent TLC-IDU study done in Nairobi and Coast. In western Kenya we collected study data in a six-month period in PWID service sites, including behavioral data collected using computer tablets, rapid HIV and HCV testing, point of care (POC) CD4 determination and referral to HIV clinics for HIV-positives for follow-up and early ART initiation for those with CD4 < 500/µL, before the recent change of ART guidelines.
Results: 655 have been screened with 649 found eligible (99.1%). Most eligible participants are male (97.1%). Median age is 30 years. Median age at first injection is 26 years. Median number of injections per day is 2. Use of marijuana is common (42.6%). 24.3% had vaginal or anal sex without a condom in the past 12 months. Most men are circumcised (89.3%). 4.3% (n = 28) are HIV positive. 80% of those

with HIV infection reported having been prescribed anti-HIV medication. 10.7% of those with HIV infection were newly diagnosed by our study. 0.5% (n = 3) are HCV reactive/PCR confirmed. 1 of those screened (0.2%) participated in the study in an earlier survey period in Nairobi.
Conclusions: Current Kenyan guidelines have facilitated access to ART among PWID. The combination of RDS and rapid HIV testing has been an effective strategy for finding PWID with HIV and HCV infection in the Western region of Kenya, including those not previously diagnosed. POC CD4 was helpful in terms of early ART-initiation for those who are HIV-positive; under the new guidelines everyone should initiate ART right after testing HIV-positive regardless of CD4 count. HCV-prevalence among PWID appears to be still low in the western Kenya region, presenting an important opportunity to avoid further HCV (and HIV) transmission.

MOPEC0694

Differences in characteristics by preferred point of access for sterile injection equipment among people who inject drugs (PWID) in Washington, DC

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Background: Research indicates that people who inject drugs (PWID) who use syringe service programs (SSPs) engage in fewer risky injection behaviors and have lower rates of HIV and Hepatitis C. Those who engage with SSPs receive additional wrap around services (i.e. HIV testing, referrals for PrEP, etc.) which are not available through other methods of syringe access, such as intermediaries who distribute sterile injection equipment obtained at SSPs among other PWID, also known as secondary syringe exchange (SSE). We examined the demographic and substance use characteristic differences of PWID in Washington, DC by preferred method of accessing sterile injection equipment.
Methods: Surveys were collected from 514 PWID between March and April 2014. Variables included demographic and drug use information. Of those sampled, 345 participants reported a preferred method for accessing syringes: 236 preferred SSPs, 76 preferred SSE, and 33 indicated no preference (NP). Qualitative data describing participant preference provided context for understanding preference and bivariate analyses identified characteristic differences between groups.
Results: When asked why they preferred their specified method for obtaining clean syringes, both SSP and SSE PWID reported trust and ease of access/convenience as primary reasons for their preference. Those preferring SSP also used words like safe and clean while those preferring SSE used the word privacy to describe their preference. Bivariate analysis found that compared to those preferring SSPs, SSEs were significantly ($p<0.05$) younger, preferred injecting heroin and cocaine combined, reported less preference for heroin injection alone, and reported more illicit drug use (particularly cocaine and marijuana). Compared to SSEs, those with NP were significantly ($p<0.05$) older, reported using more channels to obtain clean syringes, and more alcohol use (but less cocaine and marijuana use).
Conclusions: These data shed valuable insights into HIV prevention among PWID populations. Specifically, SSPs can use this information to devise new strategies for gaining access to marginalized segments of PWID populations and provide more intensive services (e.g., PrEP) that support their HIV prevention needs (including linkage to treatment for HIV+ PWID). SSPs should strive to understand client preferences for service delivery and the factors that characterize different preference groups.

MOPEC0695

Assessment of the risky behavior among female PWIDs at harm reduction program in Georgia

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Background: Needle sharing practice remains the main factor for spreading HIV (47.3%) among PWIDs in Georgia. In spite of 5 times increased coverage of female IDUs by Needle and Syringe program (NSP) women IDUs remain hard to reach population. The objective of this study was to analyse risky injection/sexual behavior of PWIDs/female IDUs who are the clients of NSP, if there is a difference in behavior of male and female PWIDs.
Methods: Consecutive sampling was used to recruit PWIDs during 5 months in 2015. The selection criteria was:
a) Drug injection practice during last month;
b) Being a beneficiary of NSP program for more than 6 month;
c) Age more than 17 years.
Sample size was 1032, among them females were 129 (12,5%). Structured questionnaire of Risk Assessment Battery (RAB) was used to assess Drug Risk and Sex Risk Items separately and calculate RAB Score.
Results: Female IDUs reported not using drugs in a close environment. They inject drugs with more than 2 person and mostly don't share injectable equipment (94.9%) While 38% of male PWIDs stated needle sharing practice at least once during last month, among them 43.8% shared with one person and 56.1% with more than 2 persons ($p< 0.05$). As referring to sexual practice, 15.97% female IDUs had more than 2 sexual partners during the last 6 months with whom 22.7% use condoms regularly, 21.1% sometimes and 32.3% always. It was meaningful to find that 10.08% of female study participants (2 times less than men) never had an HIV test and 34.45% of them had HIV test a year ago. Total RAB Scale Score for female PWID study participants was 0.26 (Range=0-1).
Conclusions: The study results demonstrate that female IDUs practice risky behavior but their practice is less risky than men IDUs. This refers to both sexual and injection behaviors. HIV testing rate is low among female PWIDs and reasons behind this need further investigation. The findings of this study will be used to address the risks female IDUs face, to modify program according to their needs, to develop and test new approaches for attracting, retaining and increasing safe behaviors of female IDUs.

MOPEC0696

PrEP interests among people who inject drugs in Baltimore, Maryland, USA: A missed opportunity in prevention

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Background: PrEP is indicated for those most at risk of HIV including people who inject drugs (PWID). In the U.S., there has been a lag in engaging PWID in PrEP initiation and maintenance compared to other high-risk populations. Among PWIDs (N=298) in Baltimore, Maryland, USA, we examined PrEP knowledge, interest, and uptake among HIV-uninfected participants (n=267), as well as correlates of PrEP interest.
Methods: Interviews were administered via CAPI to PWIDs who were recruited from the Baltimore Syringe Exchange Program (SEP). Demographic, drug use, and PrEP-related frequencies were explored and multivariate associations with ever having heard of PrEP.
Results: Study participants reported being a median of 45 years old, were 31% female, 55% Black, and 36% White. The sample was socioeconomically vulnerable with 82% reporting having ≤high school degree and 58% currently homeless. The majority (87%) reported daily injection, 14% reported having engaged in receptive syringe sharing, and 38% reported primarily injecting in public (e.g., street, park, stairwell, car, bathrooms, shooting gallery, abandoned house). HIV infection was reported by 11%. Among HIV-negative uninfected participants, 83% had tested for HIV in the past year, 25% had ever heard of PrEP, 62% were interested in being on PrEP, and 86% endorsed that they could easily take a pill daily. The majority of those interested in PrEP reported that they would use sterile needles (94%) or condoms (90%) while on PrEP. In a multivariate model, being interested in PrEP was associated with receptive syringe sharing (AOR 3.3: 95%CIs: 1.4-8.2) and primarily injecting in a public place in the past 30 days (AOR 1.9, 95%CIs: 1.1-3.4).
Conclusions: In an urban US city, HIV-uninfected PWIDs are largely unaware yet interested in receiving PrEP. As with ART roll-out and coverage, PWID have been largely underserved in regards to PrEP. Their PrEP interest was driven by the risky injection practices of receptive syringe sharing and public injection. Three decades into their HIV epidemic, HIV persists at high rates. Programs are needed to promote PrEP to PWID and engage them in PrEP care. Their ritual drug use potentially bodes well for taking oral PrEP daily.

MOPEC0697

A comprehensive HIV and stimulant use prevention intervention for Cambodian female entertainment and sex workers reduces psychological distress and improves economic well-being

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Background: HIV prevention services for female entertainment and sex workers (FESW) could function as a platform for targeting key risk factors for HIV infection, including amphetamine-type stimulant (ATS) use and economic distress. We examined the effectiveness of sequentially delivered interventions to decrease ATS use and improve economic well-being for addressing psychiatric as well as structural outcomes relevant to HIV prevention with FESW.
Methods: This cluster randomized stepped-wedge trial in 10 Cambodian provinces enrolled 1,198 FESW to test the effectiveness of a comprehensive HIV and ATS use prevention package leveraging SMARTGirl, an existing HIV prevention platform for Cambodian FESW. The prevention package included a conditional cash transfer with cognitive-behavioral aftercare (CCT+AC) intervention to reduce ATS use followed by a microenterprise (ME) opportunity. Outcomes assessed in 600 FESW purposively targeted for the 18-month follow-up were:
1) clinically significant distress (≥ 25 on the Kessler -10);
2) monthly income 3) housing instability; and
4) food insecurity. After baseline, FESW with problematic patterns of ATS use were allocated to receive a 4-month CCT+AC intervention. All FESW who were abstinent from ATS at six months were allocated to receive a ME opportunity, which included a 3-day financial literacy training and optional microloan application.
Results: At 12 months, relative to baseline participants had 79% lower odds of reporting clinically significant psychological distress (Adjusted Odds Ratio [AOR]=0.21; 95%CI 0.07-0.64; p=.006) and 68% lower odds of any housing instability AOR=0.32; 95%CI 0.13-0.78; p=0.01). At 18 months, FESW had 89% lower odds of any food insecurity (AOR=0.11; 95%CI 0.02-0.53; p=0.006) but significant reductions in psychological distress and housing instability were not maintained. There were no concurrent increases in monthly income over the 18-month follow-up (p's>0.14).

	Psychological Distress	Monthly Income	Any Housing Instability	Any Food Insecurity
	AOR (95% CI)	*ARR (95% CI)*	*AOR (95% CI)*	*AOR (95% CI)*
6 Months	**0.43 (0.22 - 0.83)***	1.12 (0.91 - 1.39)	0.67 (0.41 - 1.12)	0.55 (0.28 - 1.08)
12 Months	**0.21 (0.07 - 0.64)***	1.21 (0.94 - 1.56)	**0.32 (0.13 - 0.78)***	**0.18 (0.05 - 0.59)***
18 Months	0.26 (0.06 - 1.18)	1.08 (0.79 - 1.49)	0.63 (0.19 - 2.12)	**0.11 (0.02 - 0.53)***

[Table. Intent-to-treat analyses (N = 1,198 at Baseline)]

Conclusions: Integrating interventions to reduce ATS use and improve economic well-being with HIV prevention services can address psychiatric as well as structural risk factors for HIV with Cambodian FESW.

MOPEC0698

Cost-utility analysis of a national six-site retention in care program

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Background: Engaging people living with HIV (PLWH) into ongoing, high-quality HIV primary care is critical for the health of PLWH and a key strategy for United States (U.S.) HIV prevention policy.
However, little is known about the costs associated with implementing HIV retention in care programs, especially in real-world settings and with vulnerable populations. This abstract presents findings from the cost-utility analysis the six Retention in Care (RiC) intervention sites. RiC was a national multi-site program implemented from 2011-2016.
Methods: This cost-utility analysis used standard methods from the U.S. Panel on Cost-effectiveness in Health and Medicine. We modeled the cost per quality adjusted life year (QALY) saved using the formula (R=C-AT (AQ)) where R was the cost-utility ratio. The cost for implementing the program (C) was estimated from the societal perspective and thus took into consideration costs to the participant. The number of HIV infection averted (A) was estimated based on changes in viral suppression among program participants. T, the lifetime cost for HIV care, came from the HIV literature. Q included both discounted QALYs saved for improvements in individual quality of life associated with HIV viral suppression as well as QALYs saved through each averted HIV infection. The return on investment (ROI) was calculated using the formula: ROI = TA/C.
Results: The cost-utility ratio estimated the net cost per QALY. The cost-utility ratio ranged from $-42,242.34 to $126,570.23. All Retention in Care programs were cost-effective, as the cost utility ratio for all programs was less than the threshold of $163,889, or the amount society is will to pay per QALY. Four programs were cost-saving. The return on investment ranged from $0.28 to $1.80.
Conclusions: The findings from the cost-utility analysis overwhelming support the assertion that retention in care programs are a productive use of resources. Despite varying program models, RiC programs were cost-effective and the majority were cost-saving.

MOPEC0699

Addressing the ‚risk environment': changes in substance use patterns amongst people living in an HIV-specific housing facility in Vancouver, Canada

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Background: Housing stability has been shown to decrease substance use and improve health outcomes for people living with HIV (PLHIV) who use drugs. However, little is known about how HIV-specific housing impacts substance use, as well as social-structural factors in ‚risk environments'. We examined changes in drug use for PLHIV after entry into an HIV-supportive housing facility in Vancouver, Canada.
Methods: Surveys were conducted with participants at baseline (after admission to housing facility) and 12-18 month follow-up from March 2015 to October 2016. The biviariate analysis compared socio-demographic and drug use differences between those with reported decrease in drug use versus those without decrease in drug use at follow-up. Fisher's exact test was used for categorical values and Wilcoxon rank sum test for continuous variables.
Results: Among the 69 participants who completed both interviews, 27 (39.1%) reported a decrease in drug use at follow-up, 25 (36.2%) reported either an increase in drug use or no change in drug use since moving, and 16 responded not applicable. Comparatively, those reporting a decrease in drug use at follow-up (n=27) were more likely to be living at the housing facility for fewer months (median 33 vs. 35, p=0.019) and lived alone before entry into the facility (77.8% vs. 40.0%, p=0.010). Feeling emotionally supported (56.0% vs. 20.0%, p=0.034), having a better sense of community (81.5% vs. 40.0%, p=0.004), and having no depressive symptoms (66.7% vs. 24.0%, p=0.003) were also more likely among those reporting decrease in drug use at follow-up.
Conclusions: Despite nearly 40% of our sample reporting a decrease in drug use after entry into supportive housing, a large proportion reported an increase in drug use or no impact at all. This suggests that supportive housing facilities must consider social, as well as physical, aspects of housing as determinants of health, and work to address the complex and interrelated challenges faced by this population within their immediate risk environments.

MOPEC0700

Knowledge of human rights and uptake of social protection schemes: findings from a community mobilization intervention for female sex workers in Southern India

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Background: Female sex workers (FSWs) experience extreme health and gender inequities and rights violations, elevating HIV risk. Promoting knowledge of rights and saturating social protection coverage can address the multiple structural determinants of the HIV epidemic and reduce vulnerability. In India, HIV prevention

interventions for FSWs are promoting access to government-provided social protection schemes, such as pension, nutrition, livelihood and shelter, in an effort to address individual and household vulnerability; however, little is known about their effectiveness. This study examines knowledge of human rights, uptake of social protection schemes, and the association between rights knowledge and uptake of protection schemes among FSWs who are part of a community mobilization program in Andhra Pradesh, a high HIV prevalence state in India.
Methods: Data are drawn from a cross-sectional survey (2014) among 2400 FSWs who are community organization members. Human rights knowledge was determined based on knowledge of any of the following five rights: Health; Dignity/Equality; Education; Property; Freedom from Discrimination. Univariate and multivariate analyses were used.
Results: Most FSWs were 30 years or older, had no formal education, were currently married, and living with spouse /family. Overall, 22% of FSWs were not aware of any human right and 43% had not availed a social protection scheme in the past year. Awareness of human rights was significantly associated with uptake of social protection schemes. Compared to those not aware of any right (46.9%), FSWs aware of any one right (62.7%; adjusted odds ratio [AOR] 1.88; 95% CI 1.51-2.33), any two rights (59.6%; AOR 1.71; 95% CI 1.34-2.19) and three of more rights (55.5%; AOR 1.52; 95% CI 1.15-2.00) were significantly more likely to have recently availed a protection scheme.
Conclusions: Findings highlight that despite intensive program efforts, not all FSWs are aware of their basic human rights or have recently availed any social protection scheme. As rights knowledge is positively associated with access to social protection schemes, future interventions must prioritize strategies to make all FSWs aware of their rights, including their right to access multiple social protection schemes. Additionally, programs must support FSWs to access these schemes to reduce vulnerability and mitigate their HIV risk.

MOPEC0701

Measuring strength of community organizations implementing large scale HIV focused intervention using Community Organizations Preparedness Index

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Background: Measuring impact of community mobilization is always challenging as the process often driven participatory practices. Assessing strength of COs is crucial for sustained organization to delivery programs effectively. The study aims to measure the strength of COs.
Methods: Baseline data collected as part of evaluation of community mobilization of Avahan phase III program from 87 COs (COs) during May- July 2015 has been used. Community Organizations Preparedness Index (COPI) tool was adopted to measure strength of COs in seven domains; Board meetings(BM), events conducted(EV), financial security(FS), social protection(SP), Social security & justice (SSJ), resource mobilization (RM) and second line leaders (SL) domains. Each domain further classified into six categories; basic, foundation, promising1&2 and vibrant 1&2. Univariate and bivariate analysis was done. Association between strength of COs by typology, age, size and TI implementation status were examined.
Results: Higher proportion of COs, were in vibrant category in the domains of BM, board meetings (72.4%), SP (58.6%), SSJ (60.9%), in promising stage for FS(59.7%) and EV (80.3%) and in basic/foundation for domains-SL (57%), RM (52.9%). By topology, higher proportion of COs were in vibrant stage for BM (52% FSW, 92% MSM), (59% FSW, 58% MSM), and in SSJ (70% FSW, 75% MSM). Looking at the TI implementation status; non TI COs are more in vibrant in case of all COPI domains except in resource mobilization. Higher proportion of COs aged less than 5 years are in vibrant stage in most of the COPI domains except in second line leaders. With respect to CO size, it was evident that higher proportion of larger COs (>1200 members) are in vibrant categories in domains of EV, SSJ, RM and SL while younger COs in FS and SP.
Conclusions: Though majority of the COs demonstrated their strength in domains of BM and EV, they are yet to reach promising levels in other components. Given that most of the COs irrespective of their characteristics were in very initial stage (Basic/foundation) in domains of SL and RM domains which are crucial in strengthening COs. Grouping of smaller COs into cooperatives, assigning implementation of TI programs may lead to strengthen COs.

MOPEC0702

Impact of supportive housing on immunological and virological status and antiretroviral therapy adherence amongst people living with HIV and at risk of homelessness in Vancouver, Canada

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Background: Despite advances in antiretroviral therapy, people living with HIV (PLHIV) who are homeless or unstably housed continue to experience poor clinical outcomes compared to their stably housed counterparts. We sought to characterize antiretroviral therapy adherence levels, plasma viral load, and CD4 cell counts for a sample of previously homeless or housing insecure PLHIV following entry into an HIV-specific supportive housing facility in a Canadian setting offering universal access to HIV treatment and care.
Methods: The 100 residents of the HIV-specific supportive housing facility were invited to participate in baseline interviewer-administered surveys after admission to the housing facility with the objective of assessing the impact of housing on HIV outcomes. Self-reported demographic and behavioural survey data were linked with clinical data made available through a linkage with the provincial HIV treatment registry at the BC Centre for Excellence in HIV/AIDS.
Results: Between March and August 2015, 95 participants completed the baseline survey, of which 88 participants had available clinical data. The median age at baseline survey was 51 years (Q1-Q3: 48-57). Of the 88 participants, 73.9% were male, 55.1% identified as gay, and 51.5% self-reported Indigenous ancestry. History of injection drug use and homelessness were common in the cohort (72.5% and 84.1%, respectively). At baseline interview, 83% of participants were receiving antiretroviral treatment and 56.8% had achieved optimal adherence (adhering to ≥95% of prescribed treatment). Clinical data nearest to baseline interview suggest that 78.4% of participants achieved a viral load < 50 copies/ml and 68.2% had a CD4 cell count of ≥350 cells/µl. Overall, 67.2% of participants reported improved access to health services and 69.4% perceived an improvement in physical health.
Conclusions: Baseline data suggest that access to this HIV-specific housing facility may improve virological and immunological status and self-reported improved health amongst participants with a history of injection drug use and homelessness, known barriers to care. Preliminary findings suggest that supportive housing is a structural intervention that may facilitate access to care and treatment, and improve health outcomes amongst PLHIV at risk of homelessness. Follow-up data (after 12-18 months from move in) will be available for future longitudinal analyses.

MOPEC0703

Intimate partner violence, sex work-related stigma, and risk of HIV acquisition among female sex workers in Zambia

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Background: Intimate partner violence (IPV) and dimensions of stigma are thought to increase HIV risk by increasing stress and changing power dynamics that may lead to reduced self-protected behaviors. These factors may be especially important among members of groups with historically elevated HIV risk, including female sex workers (FSW). We report IPV and sex work stigma among FSW in Zambia and their association with HIV risk-related factors.
Methods: In September-October 2016, a quantitative survey was conducted with 965 HIV-uninfected FSW in Livingstone, Chirundu, and Kapiri, Zambia. IPV was measured by asking if participants had been physically or sexually abused in the previous 12 months, or if they had had sex because they were afraid not to. Sex work-related stigma was measured by a scale consisting of six questions measuring experiences of stigma related to sex work. The scale was summed and had a range of 1-24 (higher numbers indicate more stigma). Factors affecting HIV risk included HIV testing history and condom use with clients. Multivariable logistic and linear regression models were built to determine the association between 1) HIV testing and 2) condom use with clients and IPV and sex work stigma, adjusted for sociodemographic variables.
Results: Median age was 25 years (IQR 21-30 years) and 560 (59.0%) reported a monthly income of < 500 ZMK (~USD$50). Most participants (61.1%) reported at least one form of IPV in the previous 12 months. Median stigma score was 18 (IQR 14-21). Most participants reported inconsistent condom use with clients (74.6%),

and most had tested for HIV at least once (79.3%). IPV and sex work stigma were associated with decreased odds of HIV testing (IPV: aOR 0.59, 95% CI 0.41-0.85; sex work stigma: aOR 0.94, 95% CI 0.89-0.99). IPV (aOR 1.73, 95% CI 1.34-2.23) but not sex work stigma (aOR 1.04, 95% CI 0.99-1.09) were associated with non-condom use with clients.
Conclusions: Experiences of IPV and sex work-related stigma were high in this population, and may contribute substantially to HIV acquisition risk. Interventions mitigating IPV and stigma may be an important component of comprehensive HIV prevention programs for FSW in Zambia.

MOPEC0704

Prevalence and circumstances of forced sex after migration among sub-Saharan migrant women living in France and post-migration acquisition of HIV

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Background: Studies on sexual violence on migrant women in destination countries are scarce and the impact of this violence on their sexual health, especially HIV infection, is even more rarely assessed.
This study evaluates the prevalence of forced sex after migration and its association with post-migration acquisition of HIV among sub-Saharan African women living in France. It also investigates the associations between forced sex after migration and sexual partnerships, housing, economic and administrative situations after migration.
Methods: The ANRS-PARCOURS study is a retrospective life-event survey (2012-2013) conducted in health-care facilities in the Paris region, among two random samples of sub-Saharan migrant women: 570 receiving HIV care and 407 not diagnosed with HIV consulting in primary health-care facilities. The frequencies of forced sex from 15 years old onwards after migration were compared between women who acquired HIV after migration and women not diagnosed with HIV using a multivariate design-based Poisson regression model. Associations between having experienced forced sex from 15 years old onwards each year since migration and sexual partnerships, housing, economic and administrative situations each year since migration were computed using a mixed-effects generalized structural equation model.
Results: Forced sex from 15 years old onwards after migration was more frequent for HIV infected women who acquired HIV after migration than women not diagnosed with HIV (15.1% versus 3.5%, p<0.001). Women were significantly more at risk of being subjected to forced sex when hosted by family or friends [β=0.95(0.19-1.72)] and when they had no stable housing [β=1.10(0.17-2.03)]. Administrative insecurity was related to forced sex through the mediation of sexual partnerships. Having no resident permit was significantly associated with casual and concurrent relationships, (respectively: [β=0.61(0.22-1.01)]; [β=0.90(0.53-1.27)]), which both increase the likelihood of being subjected to forced sex [β=1.54(0.81-2.27)]; [β=2.17(1.31-3.03)].
Conclusions: Among sub-Saharan migrant women living in France, the prevalence of forced sex after migration is high and related to post-migration acquisition of HIV. Being hosted by family and friends and having no stable housing expose women to sexual pressures and violence. Having no resident permit exposes women to forced sexual intercourse through the engagement in casual and concurrent partnerships.

MOPEC0705

Assessment of prevalence of HIV, hepatitis C, HIV/hepatitis C co-infection and risk behaviours among female injecting drug users in Nepal

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Background: Injecting drug users (IDU) are at the greatest risk of being infected with HIV and Hepatitis C (HCV). Most of the studies on IDU have been performed on men, but evidence related to the burden of HIV, HCV and its co-infection is scarce among female IDU. One of the barriers researchers face for this hidden key population is prejudice and stigma affecting women who inject drugs, especially in low and middle-income countries. The aim of this study is to investigate the prevalence of HIV, HCV, HIV/HCV co-infection, and associated risk factors among female IDU in Nepal.
Methods: A total of 160 female IDU were recruited using modified network sampling from the capital city of Nepal from April to May 2016. The inclusion criteria was female at least 16 years old who had been injecting drugs for at least three months before the survey period. Serum samples were collected and all tested for HIV and HCV by the WHO certified rapid test kit.
Results: The prevalence of HIV and HCV was respectively 8.8% and 21.9%, with a co-infection rate of 5.6%. Almost one in every five participant (19.1%) declared to have used shared syringes in the past month, while only 31.9% declared to have used condoms during the last sexual intercourse. As many as 68.1% of female IDU reported ever getting an HIV Test, 89.0% of them did it voluntarily. Only 31.3% acknowledged receiving some treatment or help from any organization, without significant difference in condom use or needle exchange behavior between those who have received treatment or help and those who did not.
Conclusions: The prevalence of HIV and Hepatitis C was much higher among female IDU than the official national figures previously reported among male IDU. Regardless many health care centres for key populations are available in the Kathmandu Valley, a low uptake of their service and a high-risk behaviour were found among female IDU. A better understanding of the reach and performance on these help and support services must be assessed to mitigate the high prevalence of HIV and especially of Hepatitis C among this group.

MOPEC0706

Burden and determinants of violence and negative police interactions among young women who self-identify as sex workers in Mombasa, Kenya

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Background: Human rights violations (HRVs) against sex workers (SWs) are widespread, and associated with HIV risks. We determined the burden and determinants of three HRVs among young female SWs in Kenya: sexual violence (SV), physical violence (PV) and negative police interactions (NPI; including assault/arrest).
Methods: We conducted a cross-sectional survey of 408 self-identified SWs aged 14-24 years in Mombasa, Kenya. We estimated the prevalence of HRVs by time period (lifetime and since self-identifying as SWs). We used multivariate logistic regression to identify individual, interpersonal and structural determinants of lifetime SV, PV and NPI; and conducted univariate logistic regression to examine the association between HRVs experienced in the first month and most recent month of sex work.
Results: 30%, 30%, and 45% of SWs reported SV, PV, and NPI in their lifetime, respectively, with 65% reporting any HRV and 10% reporting all three. Prevalence of any HRV increased from 12% to 24% between the first and most recent month of sex work (about 2 years apart). 50% of SWs reported their first SV experience before self-identifying as SWs whereas most SWs (78%) reported PV after self-identifying as SWs. In multivariate analysis, lifetime SV was associated with being coerced/deceived into sex with your first 10 clients (AOR=2.5; 95%CI=1.4-4.6) and lifetime PV (AOR=6.9; 95%CI=4.0-12.1). Lifetime PV was associated with daily alcohol use (AOR=2.5; 95%CI=1.1-6.0), regular income (AOR=0.5; 95%CI=0.3-0.9), and lifetime SV (AOR=6.6; 95%CI=3.6-12.0). Lifetime NPI was associated with being inebriated 1-3 times (AOR=2.7; 95%CI=1.5-5.1) or 7+ times (AOR=4.1; 95%CI=1.3-12.5) per month, ≥ 3 years in sex work (AOR=1.7; 95%CI=1.0-2.7) and ≥1 non-paying partner in the past week (AOR=0.5; 95%CI=0.3-0.8). SWs who experienced HRVs in the first month of sex work had higher odds of experiencing the same HRV in the most recent month of sex work (ORs 7.5-15.9; p-values< 0.001).
Conclusions: Self-identified young SWs in Mombasa have high burdens of SV, PV and NPI. Violence prevention and response for these women is crucial and should focus on those with prior history of HRVs and heavy alcohol use. Programmes aiming to reach young SWs could use violence prevention and response as an entry point to reach them.

MOPEC0707

Use of social name in the antiretroviral treatment system as the identification of transgender people living with HIV in Brazil

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Background: Studies suggest that transgender women are a high burden population for HIV. Despite that, they are often classified as men who have sex with men in epidemiological studies, which leads to a poor understanding of HIV epidemics in this population group. However, Brazilian government has granted the use of social name by transgender people. A 2016 law recognizes every person's right to be acknowledged according to their gender identity.
We assessed data for social name available in the national antiretroviral therapy (ART) database to analyze the use of social name before and after the law enforcement, and its impact on ART data.
Methods: We analyzed records from the national ART dispensation system from 2009 to 2016. We considered as transgender people those whose registries contained a social name that differed from the birth name. For the analysis, we included individuals aged 18 and over.
Results: Between 2009 and 2016 we observed an annual average increase of 10% in the identification of transgender people on ART. In 2016 the number of transgender people on ART was 137% higher than the previous year, representing 2.3% of all people living with HIV on ART in Brazil. In the same year, the registration of transgender persons initiating ART was 860% higher than in 2015, representing 8.4% of all new antiretroviral treatments.
Conclusions: Gender identity is part of every person´s dignity and humanity, and its recognition is a human rights matter. The increasing number of data regarding transgender people in ART systems shows a gradual improvement in quality of information, very likely to be associated with the law enforcement in 2016. The more we know about transgender people within the HIV scenario, the better we can design prevention and assistance policies. The main limitation of this analysis is not being able to distinguish between transgender men and women in this population stratum.

MOPEC0708

Sexual partner violence and HIV treatment and care among female sex workers participating in a multilevel HIV intervention in Santo Domingo, Dominican Republic

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Background: Female sex workers (FSW) are 13.5-times more likely to be living with HIV than other women in low and middle income countries, and globally, up to 75% ever experience sexual partner violence (SPV). Among FSW living with HIV in Santo Domingo, Dominican Republic (DR) who participated in the Abriendo Puertas intervention, our team found that 18% had experienced SPV within the last six months. Experiencing SPV—more commonly perpetrated by non-paying partners than clients-- was associated with multiple negative HIV treatment and care outcomes, which limit treatment-as-prevention (TasP) effectiveness. Here we identify the context of SPV, pathways through which it negatively affected treatment and care, and how intervention participation influenced factors along these pathways.
Methods: Abriendo Puertas is a multi-level intervention including individual counseling, peer navigation, clinician sensitivity training, and community mobilization among FSW living with HIV in the DR. In 2013-2014, 250 women enrolled in a 10-month pilot study and scale up with 90 women in three government-sponsored HIV clinics occurred in 2015-2016. In 2016, we conducted in-depth interviews with 20 original cohort members and 20 scale up participants regarding the intervention, treatment, substance use, and violence. Textual data was coded and analyzed using thematic content analysis.
Results: Participants perceived alcohol and jealousy to cause SPV, and economic dependency to prevent women from ending abusive relationships. Some experienced stigma from partners upon HIV status disclosure; others avoided disclosure, fearing violence. Violence caused stress and depression, which decreased treatment adherence and care engagement, and produced negative immunologic effects. Participation in Abriendo Puertas - especially counseling-- intervened in this cascade of effects by greatly improving their sense of well being, self-esteem, and resilience feelings, which enabled some to leave violent relationships. Participants recommended peer support groups focused on SPV within community mobilization activities for aiding SPV survivors.
Conclusions: Multilevel interventions for FSW that address SPV's mental health impacts through counseling and peer support, and increase FSWs' economic independence hold promise for reducing undermining effects of SPV on HIV treatment, care and TasP. Intervening upon contextual factors enabling SPV perpetration against FSW, namely alcohol, gender norms, and stigma, will also be necessary for reducing these effects.

MOPEC0709

Preventing intimate partner violence in the context of the HIV response: the MAISHA study in Tanzania

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Background: There is increasing evidence linking women's experience of intimate partner violence (IPV) and enhanced risk of acquiring HIV. In a study conducted in rural communities in Uganda, the adjusted population attributable fraction of incident HIV attributable to IPV was 22.2% (95% CI 12.5-30.4). With increasing interest in addressing violence against women in the context of the HIV response, we are conducting the MAISHA study to evaluate the impact of two contrasting social and economic intervention approaches in northwest Tanzania
Methods: We are conducting trials to evaluate the incremental impact on participants' experience of IPV of a participatory gender training curriculum for women in existing microfinance groups and for women in newly-formed groups not receiving microfinance. To date, we have enrolled 1021 women in microfinance groups and 1052 women not receiving microfinance. At baseline, ever partnered women were interviewed by trained, same sex interviewers about their lifetime and past 12-month experience of IPV, economic abuse, emotional abuse and controlling behaviour.
Results: Among women enrolled into the study, 61% (95% CI: 58-64%) of women receiving microfinance and 67% (95% CI: 64-70%) not receiving microfinance reported ever experiencing physical and/or sexual IPV with 27% (95% CI: 24-29%) and 36% (95% CI 33-39%) reporting IPV in the previous 12 months. Partner controlling behaviour was the most prevalent type of abuse - 82% of women receiving microfinance and 78% not receiving microfinance reported having experienced it in their lifetime, while 63% and 64% reported experiencing it in the previous 12 months. Other abuses were also common; more than one third (34% microfinance, 39% non-microfinance) of women reported economic abuse and a high proportion of women reported emotional abuse (39% microfinance, 56% non-microfinance) during the previous 12 months. Higher prevalence rates were observed among younger women, women with young partners, and less educated women. Intervention delivery is ongoing, with the results expected in 2018.
Conclusions: Levels of violence and abuse are very high in this study population, particularly among younger women, who are also at highest risk of HIV infection in Tanzania. These findings underline the importance of developing and testing appropriate violence prevention interventions.

MOPEC0710

Sexual relationship power and periconception HIV-risk behavior among men living with HIV in serodiscordant relationships

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Background: The risk for HIV transmission within HIV-serodiscordant partnerships is high and and may be highest when couples try to conceive. Gender norms affect HIV risk and likely impact reproductive decision-making. We assessed sexual relationship power and its association with periconception HIV risk behaviors among men living with HIV (MLWH) in serodiscordant partnerships.
Methods: We conducted in-person surveys with MLWH reporting a recent partner-pregnancy with an HIV-negative or unknown-serostatus partner in a township outside of Durban, South Africa. Surveys assessed partnership characteristics, Decision-making Dominance (DMD) subscale of the Sexual Relationship Power Scale, and HIV risk behaviors including disclosure, condom use, ART use, and sexual and reproductive health communication. The DMD subscale assesses whether the participant, his partner, or both partners make decisions in the relationship (e.g. Who has more say about whether you have sex?). Higher DMD scores indicate that the participant has more leverage in making decisions. Logistic regression models evaluated associations between DMD score and HIV-risk behaviors.
Results: 82 MLWH were median age of 34 (Range 22, 44) years, and 61 (74%) were employed. Fifty-three (65%) reported their recent pregnancy partner was a casual partner, 27 (33%) reported disclosing HIV-serostatus to their partner prior to the pregnancy and 23 (28%) reported condomless sex since pregnancy. The median DMD score was 3.06 (IQR 2.88, 4), and men in casual partnerships had higher DMD scores than those in stable partnerships (p≤0.01). Higher DMD scores were independently associated with non-disclosure of HIV-serostatus to pregnancy partner, not knowing partner's HIV status, condomless sex since pregnancy, and poor reproductive health communication.

Associations Between Higher DMD Score and HIV Risk Behaviors	Adjusted OR (95% CI) per point increase on Decision-making Dominance scale, n=82	P Value
Non-disclosure of HIV status to partner*	22.96 (3.45, 152.76)	0.001
Not knowing pregnancy partner's HIV status*	4.65 (1.31, 16.49)	0.02
Condomless sex since pregnancy*	3.24 (1.06, 9.96)	0.04
Concurrent sexual partners*	4.59 (0.90, 23.37)	0.07
Rarely/ never discuss sex with partner**	13.53 (3.93, 46.60)	<0.0001
Rarely/never discuss HIV prevention with partner*	10.00 (2.18, 45.70)	0.003
Rarely/never discuss having children with partner*	6.86 (2.43, 19.38)	0.0003
Rarely/never discuss contraception with partner**	8.85 (3.02, 25.93)	<0.0001
*Adjusted for education, type of partnership: casual vs. stable (i.e. main partner), partner age **Adjusted for education, type of partnership		

[Table 1]

Conclusions: MLWH dominate sexual and reproductive health decisions within partnerships. Efforts to minimize periconception HIV risk behavior must address gender norms and power inequities to promote the health of men, their partners and families.

MOPEC0711

Addressing intimate partner violence in HIV testing services: positive results of a randomized controlled trial in Nairobi, Kenya

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Background: Intimate partner violence (IPV) undermines women's uptake of HIV services, plus violates their human rights. This intervention study piloted enhanced HIV counseling and testing (HCT) sessions in a public hospital in Nairobi, Kenya to address IPV and gender-based power disparities in relationships.
Methods: A randomized controlled trial design was used to assess the efficacy of an integrated IPV-HCT pilot compared to HCT alone. Study participants were ANC clients aged 15-49 (N=698) interviewed immediately after the IPV-HCT or standard HCT session, and again at their subsequent ANC visit (N=545). In-depth interviews with providers were conducted before and after piloting the intervention to assess feasibility and perceived utility of enhanced HCT. Quantitative data were analyzed using an intent-to-treat approach. Chi-square tests assessed cross-sectional differences between study groups; generalized linear mixed modeling measured change over time, adjusting for repeated measures.
Results: In total, 35% of women reported experiencing IPV (physical, sexual or psychological) in the past year, 33% reported low power in their relationship, and 6% were HIV+. Qualitative findings suggest integrated IPV-HCT counseling was well-accepted by providers, although it took on average 6.5 minutes longer to implement. Compared to women who received standard HCT, intervention group participants were more likely to report receiving IPV screening (86% vs. 21%) and disclose violence to the provider (32% vs. 7%) (p< 0.0001, respectively). Women in the intervention group scored higher on a 6-point IPV knowledge index (p=0.049); and were more likely to report that speaking with the provider made a positive difference to them (AOR 19.8; p< 0.0001). The study was not powered to detect statistically significant differences among subgroups, nonetheless, evidence suggests positive health outcomes such as a greater percent of HIV+ women intending to adhere to their PMTCT regimen (62% intervention vs. 48% control, ns).
Conclusions: Results demonstrate the feasibility and positive intermediate outcomes of integrated IPV-HCT counseling in an urban public ANC setting in Kenya. Given the high prevalence of IPV and its role in hindering HIV testing, treatment and retention in care, this strategy to address structural issues like IPV and power in relationships should be further tested through a larger evaluation.

MOPEC0712

Peer counselor an essential position & effective strategy to improve the uptake of HIV services: meaningful involvement of drug users in generating demand for OST and uptake of ART adherence

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Background: The Indian government currently reports the population of PWID in India to be approximately 200,000 with an estimated HIV prevalence of 9.19 (NACO, 2014-15). In the states where the Hridaya (Community Action on Harm Reduction) is being implemented, 58% (Bihar-49%; Haryana-50% and Uttarakhand-94%) of the PWID living with HIV are registered in ART centers of which 22% (59%-Bihar; Uttrakhand-26% and Haryana-11%) were initiated and on ART treatment. Among those registered with ART center, the regular follow up for CD4 testing and ART adherence is very low in comparison to other key population.
Methods: Dutch government-funded five-country Community Action on Harm Reduction (CAHR) initiative, India HIV/AIDS Alliance implements the Hridaya programme in Bihar, Haryana, Jammu, Uttarakhand and Manipur. The programme supplemented staffing for the government's HIV prevention strategy for PWID and added Peer counsellor. Capacities of peer counsellors were developed through training, refresher training, mentoring and handholding support on harm reduction and service delivery. They educated PWID and their families mainly on treatment linkages and importance for retention on OST and ART - adherence for medication in addition education on safer sex and safer injecting practices, overdose prevention and management with provision of procurement of Naloxone and HIV/STI treatment services.

Results: 12,643 PWID and their family members were educated on harm reduction services including treatment linkages (ART and OST). There is significant increase in uptake of services (P <0.05); OST linkages increased from 46% to 51% and registration for HIV care increased from 86% to 92%, de-addiction services uptake increased from 47% to 57% as per Hridaya's impact assessment study.
Conclusions: The Peer counsellor is an important position and role has been acknowledged by PWID community and the project.Community Involvement directly supports enhancing harm reduction and services uptake. It is included in Phase-II of he project to increase the number of Peer Counselor for retention in prevention, care and support services. The whole process from identification, induction, capacity building, ToR will be documented to share with national harm reduction program to sustain the position and ensure meaningful involvement PWID in direct service delivery

MOPEC0713

A randomized controlled trial of a resilience-based intervention for children affected by HIV/AIDS in central China: effects at 6- and 12-month follow-up

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Background: Global literature suggests that resilience-based interventions may yield improvements in wellbeing for vulnerable children. However, attempts to rigorously evaluate such approaches for children affected by HIV/AIDS have been limited. Thus, with the support of the National Institutes of Health, we developed a multi-level, resilience-based intervention for children affected by parental HIV/AIDS in central China. We then evaluated the efficacy of the intervention in improving psychosocial wellbeing and resilience-related outcomes at 6- and 12-months post-intervention.
Methods: Seven hundred and ninety (N=790) children, 6 to 17 years of age were recruited from Henan Province. Children were either AIDS orphans or lived with a parent infected with HIV/AIDS. Children and primary caregivers were randomly assigned by community cluster to participate in a 4-arm trial to evaluate the Child-Caregiver-Advocacy Resilience (ChildCARE) intervention. This psychosocial HIV intervention provides programming at three levels. At the child level, children affected by parental HIV receive 20 hours of intervention to build a number of skills (e.g., positive thinking, emotional regulation, coping, problem solving). At the caregiver level, caregivers receive 10 hours of programming to increase positive parenting skills and to build the capacity for self-care and social support. At the community level, trained community advocates (e.g., teachers, village nurses) conduct home visits and organize activities to strengthen the capacity of local communities to offer support for HIV-affected families.
Initial survey data were collected at baseline, 6-months, and 12-months. To assess the impact of the child-only and child+caregiver interventions, we ran a series of random effect difference score models to compare mean change over time across treatment arms from baseline to 6- and 12-month follow-ups.
Results: Intervention groups displayed improvements in several resilience-related outcomes at 6- and 12-month follow-ups, including self-reported coping skills, hopefulness, emotional regulation, and self-control. The child-only intervention arm showed some fading of intervention effects by 12-months.
Conclusions: Preliminary findings suggest that ChildCARE may be efficacious in promoting wellbeing for children affected by parental HIV/AIDS. Targeting both children and caregivers for psychosocial intervention may be effective in increasing resilience. Additional evaluation and modifications should be considered to further strengthen the program.

MOPEC0714

Measuring the levels of HIV stigma in Buenos Aires, Argentina: development of a new instrument for stigma reduction programmes

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Background: Valid and reliable instruments are required to measure HIV stigma and the efficacy of stigma reduction programmes. The expression of stigma is culturally determined and has changed through decades, assuming more subtle, but still harmful forms. Therefore, measures should be periodically reviewed and new local instruments designed to capture particularities in specific contexts. Three dimensions of stigma are recognized in most theoretical frameworks: internalized, anticipated (both internal) and enacted (external).
The objective of this study was to describe the level of stigma among people living with HIV (PLWH) from Buenos Aires and to obtain evidence of validity and reliability of a new measurement instrument.
Methods: Eighty eight items were designed based on interviews with PLWH, other valid instruments and main theories of stigma. Five experts evaluated this first set of items' clarity, relevance and content validity. A depurated version of 77 items was administered. The statistical analysis included item analysis, Cronbach´s alpha to evaluate reliability and correlations with the Spanish short version of the HIV Stigma Scale, for criterion-related validity.
Results: The final sample consisted of 46 PLWH (67% men, 31% women and 2% transgender women). Mean age was 41 years (SD=10.68). More than half (52%) were men who have sex with men, 44% heterosexual and 4% homosexual/bisexual women. Fifty items with adequate skewness, kurtosis and item-total correlation were retained in the final version. Subscales showed adequate reliability (Cronbach's Alphas: Internalized=.86; Anticipated=.85; Enacted=.86). Each subscale significantly and positively correlated with its criterion (Internalized: r=.68; Anticipated: r=.81 and .47; Enacted: r=.79). Half of the sample (50%) had experienced HIV stigma. Higher levels of anticipated stigma were observed (M=58.54, SD=13.72), followed by internalized (M=41.85; SD=13.02) and enacted stigma (M=33.76; SD=13.19).
Conclusions: PLWH showed higher levels of anticipated and internalized stigma compared to enacted stigma. The newly developed instrument, designed to measure HIV stigma considering local particularities, demonstrated adequate validity and reliability. This instrument can be useful to gather information about stigma to design more effective stigma reduction programmes for PLWH and assess their efficacy. The following step of this study will be a factor analysis with a larger sample to increase evidence of validity.

MOPEC0715

Perceptions of community empowerment approaches for HIV among female sex workers in fishing villages in Uganda: a qualitative study

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Background: Community empowerment approaches have been found to be effective in responding to HIV among female sex workers (FSWs) in South Asia and Latin America. To date, little is known about the acceptability and effectiveness of these approaches in sub-Saharan Africa. One setting where community empowerment approaches might be beneficial is fishing communities along Lake Victoria in East Africa. HIV prevalence is as high as 44% in these communities overall and 74% among sex workers.
We sought to better understand perceptions and acceptability of sex worker community empowerment programs in fishing communities to inform more effective, tailored strategies for the HIV response.
Methods: We conducted in-depth interviews with 18 FSWs in Kasensero, a Lake Victoria fishing community in south-central Uganda. Semi-structured interview guides covered personal experiences with and barriers to HIV services in addition to perspectives on community empowerment approaches among FSWs. Findings were analyzed for both inductive and deductive themes using a framework analysis approach.

Results: Sex work was viewed as a common profession in fishing communities. FSWs were identified as home-based, bar-based, or lodge-based and could either be permanent members of the community or mobile (moving to and away from the community frequently and with little advanced planning). A few participants identified existing community groups which primarily provided financial support; none of these existing groups were formally established or affiliated with academic or non-governmental institutions. Participants identified potential benefits of community empowerment groups, which included financial (savings and loan) services and health and safety support. Important barriers to community empowerment groups included mobility of FSWs across communities and perceived competition between types of FSWs. Some participants also felt that FSWs of different ages could not form groups due to generational differences.
Conclusions: Mobility, perceived competition, and other occupational factors present challenges to community empowerment approaches in Lake Victoria fishing communities, but FSWs also felt such approaches could provide benefits. Tailored community empowerment approaches should emphasize financial and health benefits and consider the unique geographic, occupational, and social characteristics of FSWs in these hotspot communities.

MOPEC0716

Synergistic impact of sexual stigma and psychosocial well-being on HIV testing among Nigerian men who have sex with men: a mixed methods study

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Background: Uptake of HIV testing is consistently low across studies of Nigerian men who have sex with men (MSM). Sexual stigma may explain low levels of HIV testing but the mechanisms by which this occurs remain poorly understood. The aim of this study was to explore how stigma and suicidal ideation impact HIV testing among MSM in Nigeria.
Methods: This study leveraged baseline data from 1,480 MSM in Abuja and Lagos recruited into the TRUST/RV368 cohort study from March/2013-February/2016. The study clinics are co-located with community-based organizations that provide non-stigmatizing services to MSM. Latent class analysis and structural equation modeling were used to develop stigma classes and assess whether suicidal ideation moderated the association between stigma and HIV testing. 24 semi-structured in-depth interviews were conducted with participants who had experienced elevated stigma in the parent cohort in order to understand barriers and facilitators to HIV testing. Interviews were transcribed and coded using thematic analysis.
Results: Participants were classified into low(n=633), medium(n=663), and high(n=184) sexual stigma classes. While there was no association between stigma and HIV testing, there was a negative association between suicidal ideation and HIV testing. There was a synergistic negative interaction between stigma and suicidal ideation, with a combined effect greater than for suicidal ideation alone (Table). The qualitative data showed that prior stigma experiences often generated psychological distress and perceptions of feeling unsafe, which could in turn decrease willingness to disclose same-sex practices or receive health services and counseling appropriate to MSM, including the avoidance of HIV testing. In contrast, MSM reported feeling safe at the study clinic but still described a need for psychosocial support services.
Conclusions: Addressing unmet mental health needs among Nigerian MSM has the potential to mitigate stigma's negative interaction with suicidal ideation and to improve feelings of safety in health settings. Such an approach may increase HIV testing and enhance existing stigma reduction approaches at MSM-friendly venues.

Main effect of association between suicidal ideation and HIV testing and interaction effects of stigma´s assocation with HIV testing moderated by suicidal ideation, in a sample of 1,480 Nigerian men who have sex with men.

Covariates of HIV Testing*	AOR	95% CI		p-value
Main Effect: HIV Testing on Suicidal Ideation	0.79	0.74	0.86	0.000
Interaction Effects: HIV Testing on Stigma, moderated by Suicidal Ideation				
High Stigma vs Low Stigma	0.65	0.20	2.11	0.543
Medium Stigma vs Low Stigma	0.46	0.39	0.55	0.000

*Class membership adjusted for age, gender, recruitment wave, and knowledge of riskiest sex position.

[Main effect of association between suicidal ideation]

MOPEC0717

Community level intervention among MSM to reduce stigma towards HIV-positive MSM in India: outcomes and process evaluation

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Background: Little attention is given to stigma/discrimination faced by MSM living with HIV (MSMLH) within MSM communities. Risk of discrimination prevents MSMLH from getting social/emotional support and accessing services. We implemented and evaluated a theory-based (social-personal model) pilot community level intervention (CLI) to reduce stigma/discrimination faced by MSMLH from other MSM. CLI included cultural events, talks by positive speakers, and messages to promote acceptance of MSMLH in outreach educational sessions with MSM.
Methods: In 2016, as part of a multi-level RCT, we implemented this CLI in two cities (Chennai and Kumbakonam) in Tamil Nadu, India. Baseline and endline surveys were conducted among a total of 300 ‚general' MSM. Based on the degree of exposure to CLI, 150 endline participants were classified into three groups: Unexposed endline group (n=21); Low-exposure endline group (n=63); and High-exposure endline group (n=66). We conducted One-way ANOVA, with planned comparisons, among four groups (baseline and three endline groups), and t-test (baseline vs. endline groups). Survey measures included: sociodemographics, symbolic stigma, and negative attitudes towards sexual behavior of MSMLH. Process evaluation included observations of CLI activities and satisfaction assessments among intervention participants.
Results: Participants' mean age was 31.8 years and mean monthly income was INR 10,054 (~USD 166). There were no differences in sociodemographics of baseline (n=150) and endline (n=150) participants. Endline participants had lower mean scores in: negative attitude towards sexual behavior of MSMLH (22.6 vs. 20.5, p< .001), and symbolic stigma (7.6 vs. 5.5, p< .001). Scores on symbolic stigma (SS) and negative attitudes towards sexual behavior of MSMLH (NASB) were significantly lower among Low-exposure and High-exposure endline groups (SS=21/20; and NASB=5.7/4.7, respectively), when compared to baseline group (SS=22.6/ NASB=7.6). Process evaluation found high intervention fidelity and high satisfaction levels among intervention-exposed participants. No other interventions to reduce stigma faced by MSMLH were implemented during the period of this CLI.
Conclusions: The findings indicate the feasibility and effectiveness of a theory-based community level intervention in reducing stigma faced by MSMLH from general MSM. As the intervention activities were conducted within the local communities by community agencies working with MSM, this community level intervention model can be easily scaled up.

MOPEC0718

Effects on HIV stigma, homophobia and HIV testing of CHHANGE: challenge HIV stigma and homophobia and gain empowerment

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Background: Reducing barriers to HIV treatment and prevention is critical to addressing the HIV epidemic in the United States (US) among gay, bisexual and other men who have sex with other men (MSM). This is particularly true for African-American or Black MSM, who are disproportionately affected by HIV/AIDS. HIV stigma and homophobia are barriers to treatment and prevention, with stigma reducing access to HIV testing, anti-retroviral treatment (ART), and uptake of biomedical HIV prevention technologies, such as pre/post-exposure HIV prophylaxis (PrEP/PEP). Homophobia, although less studied than HIV stigma, has also been identified as a barrier to prevention access. Project CHHANGE, Challenge HIV Stigma and Homophobia and Gain Empowerment, is a community-level, multi-component intervention designed to reduce HIV stigma and homophobia and increase access to HIV prevention, including testing. CHHANGE provided trainings/ workshops, space-based events and bus shelter ads in a high HIV prevalence, primarily African-American, Black and Afro-Caribbean, neighborhood in New York City (NYC).
Methods: To evaluate CHHANGE we used a quasi-experimental, matched neighborhood, pre- and post-intervention study design. Serial cross-sectional, street intercept surveys among residents of the invention neighborhood and matched con-

trol neighborhood were conducted before and after the intervention. Propensity score matching and generalized estimating equation regression models assessed the impact of CHHANGE on HIV stigma and homophobia. In addition, we analyzed post-intervention, street intercept survey data to assess relations among key intervention components and self-reported HIV testing. Finally, we assessed administrative HIV testing data before and after CHHANGE.
Results: We did not find a significant treatment effect of CHHANGE on HIV stigma and homophobia among residents of the intervention neighborhood as compared with control community residents. However, HIV testing increased by 350% at the testing site in the intervention community after the intervention implementation. Further, lower HIV stigma, attending an HIV stigma workshop and having friends or family living with HIV were independently associated with past six-month HIV testing among post-intervention respondents in both neighborhoods.
Conclusions: CHHANGE was feasible and acceptable to community residents. Our triangulated evaluation approach yielded conflicting results, which may be due study to design limitations. Further research is needed to understand whether and how CHHANGE affected HIV testing.

MOPEC0719

Victim impact: analyzing dispartiies by race, gender, and sexuality under U.S. HIV exposure and disclosure laws, 1992-2015

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Background: During the summer of 2014, an explosive arrest was splashed across Midwestern newspapers: A young gay Black man in a conservative county in Missouri and the accusations against him quickly became a flashpoint for racial and sexual politics - leading some critics to charge that HIV-specific criminal laws in the U.S. target gay Black men. This paper draws on an original dataset of convictions under HIV-specific criminal laws in 6 states to evaluate whether the enforcement of HIV exposure and disclosure laws has discriminatory effects.
Methods: Deidentified datasets describing cases in which a defendant was convicted under an HIV disclosure or exposure law were obtained from state agencies in Arkansas, Florida, Louisiana, Michigan, Missouri, and Tennessee. The defendant was subsequently identified in 431 cases between 1992 and 2015 using a variety of sources, including newspaper reports, online mugshot websites, and court records systems. Demographic data on each defendant was then collected. These data are compared against data obtained from state public health agencies describing the population of individuals diagnosed as HIV-positive during the same time period.
Results: Contrary to expectations, the analysis shows that heterosexual men and white female defendants are convicted at greater rates than expected. Heterosexual men are convicted at rates seven times that of men who have sex with men (MSM): 146 convictions per 10,000 HIV diagnoses as compared to 23 for MSM. Black and white heterosexual men are convicted at similarly high rates (234 and 211, respectively) as compared to Black and white MSM (16 and 15, respectively). White women are convicted at rates twice that of HIV-positive Black women (22 versus 11, respectively).
Conclusions: Findings suggest that victim characteristics - rather than defendant demographics - shape uneven patterns in the application of the law. MSM and Black female defendants may be less likely to have been convicted because their potential accusers are less willing to make contact with law enforcement. Further, this study observes an inverse correlation between a demographic group's HIV prevalence and the conviction rate. This study finds that communities less impacted by HIV (namely, heterosexual men and white women) are more impacted by criminalization.

MOPEC0720

Incarceration history and HIV testing among female sex workers in Zambia

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Background: Criminalization of sex work is thought to be a major structural driver of the HIV epidemic among female sex workers (FSW). Incarceration may lead to marginalization, which can reduce access to healthcare and HIV prevention services. Here, we investigated the association between incarceration history and recent HIV testing among FSW in three transit towns in Zambia.
Methods: A quantitative questionnaire was conducted among FSW without known HIV infection in Livingstone, Chirundu, and Kapiri Mposhi, Zambia. Participants were eligible if they were 18 years or older, reported exchanging sex for money or goods at least once in the past month, and were self-reported HIV uninfected or status unknown. Participants were asked if they had ever been arrested or incarcerated, if they had ever had an HIV test, and if so, months since their last test. Logistic regression models were used to determine the association between incarceration history and HIV testing, adjusting for sociodemographic characteristics.
Results: Of 965 participants enrolled, median age was 25 years (interquartile range 21-30 years), 722 (75.3%) were literate, and 560 (59.0%) reported a monthly income of < 500 ZMK (~USD$50). Most (760, 79.5%) reported ever testing for HIV and 617 (65.1%) reported testing for HIV in the previous 12 months. More than one-quarter (275, 28.5%) had a history of incarceration. Most (89.8%) of women reporting incarceration reported that it was related to their engagement in sex work. In an adjusted model, incarceration was associated with 38% reduced odds of HIV testing in the previous year (aOR=0.61, 95% CI 0.45-0.83, P=0.002).
Conclusions: FSW with a history of incarceration significantly less frequently reported recent HIV testing. In this population, incarceration may increase barriers to HIV testing, possibly through increased marginalization or fear of disclosure of sex worker status or police harassment for HIV testing. This may contribute to the disproportionate burden of HIV in this population. Decriminalization of sex work may increase accessibility of HIV testing, and could have profound effects on the HIV epidemic among FSW in Zambia.

MOPEC0721

Predictors of police behaviors that shape the drug user HIV risk environment in Tijuana, Mexico: the role of occupational safety, legal knowledge and attitudes on harm reduction programs

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Background: The HIV epidemic in Tijuana, Mexico is concentrated among people who inject drugs (PWID). Policing practices, such as syringe confiscation and arrest, are structural drivers of HIV transmission among PWID. Conversely, police referral of PWID to health/social services may protect against transmission. Little is known about drivers of police practices critical to HIV risk. Our objective was to evaluate how legal knowledge and harm reduction attitudes associate with police behaviors that shape the HIV risk environment among PWID in Tijuana, Mexico.
Methods: In a context of a department-wide police training initiative, between February 2015 - May 2016, 1751 municipal police officers self-administered a baseline survey on drug law enforcement practices, occupational safety, legal knowledge, attitudes related to harm reduction and drug user health. We used ordinal logistic regression to assess whether legal knowledge and attitudinal factors predicted syringe confiscation, arrest, and referral to health/social programs. The analysis focuses on respondents reporting any contact with syringes as part of their duties (N=1319).
Results: Respondent median age was 38 (IQR: 32-43), mostly male (88%, N=1150), and worked for a median of 11 years (IQR: 9-18). Thirty seven percent reported incorrect legal knowledge about syringe possession and 71% were unaware that small amounts of heroin were decriminalized under recent reforms. Officers who had ever been stuck by a needle were 1.39 (aOR: 1.03 - 1.88) times as likely to confiscate syringes. Those reporting favorable views of methadone maintenance were 1.26 times as likely to refer PWID to health/social programs (95% CI: 1.00 - 1.57). Additionally, police who believed that their role is to refer PWID to health/social programs were 2.52 (aOR: 2.04 - 3.12) times as likely to refer PWID to these programs. Male officers who believed that laws that treat addiction as a public health problem were 0.72 (aOR: 0.57-0.90) times less likely to arrest someone for heroin possession.
Conclusions: Police practices that shape HIV risk for PWID are independently associated with legal knowledge, needle stick injuries, and attitudes on harm reduction. These novel findings help rationalize interventions targeting police occupational safety, knowledge, and attitudinal factors as structural modalities to reduce PWID HIV risk.

MOPEC0722

Universal access? Legal and regulatory barriers to accessing HIV treatment across Europe that damage public health and hinder treatment as prevention

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Background: Universal HIV treatment access is a key tool in reducing ongoing transmission. Regulations in many countries restrict access to state-provided HIV treatment for one or more key populations, leaving people diagnosed but untreated, often with transmissible virus. GNP+ and EATG set out to map the extent and diversity of these barriers within Europe as part of the OptTEST project.
Methods: A questionnaire to assess legal and regulatory barriers across the WHO Europe region was developed. More than 160 individuals and organisations from 49 countries provided responses which were analysed and cross-checked with other data sources. The resulting website *"Barring The Way To Health"* provides an updatable, searchable, cross-comparable database of the most common barriers to testing and treatment access including key populations affected.
Results: Only 9/49 countries reported genuine, legal universal access to free HIV treatment. These included EU (6), EFTA (2) and non-EU/EFTA (1) countries. Restrictions reported related primarily to migrants, with 5/49 also excluding current PWID.
Of EU countries, 9/27 had exceptions to free access for other EU nationals, 2/27 had no legal access for non-EU migrants and 10/27 reported exceptions to access for some non-EU nationals. Refugees and asylum seekers had some restrictions in 9/27 EU countries and no access in 2/27 countries (a further 2 could not answer).
Of the 3 EFTA countries, the only one not providing universal access excluded undocumented migrants from treatment access.
Among non EU/EFTA countries, 5/19 gave no legal, free treatment access to any migrants; a further 3/19 had some exceptions. 5/19 gave no legal access to asylum seekers/refugees while a further 2/19 had exceptions to this and 5/19 could not answer. Six did not give access to undocumented migrants while a further 5 could not answer.
Conclusions: Treatment access laws and regulations across Europe are complex, sometimes contradictory and often fall short of universal access. They particularly restrict migrant access to HIV treatment, often including those legally resident. This barrier to public health and preventing onward HIV transmission deserves closer scrutiny and challenge.

MOPEC0723

Awareness of HIV non-disclosure case law among women living with HIV in Canada: a call to build women centered knowledge and support around HIV disclosure and the law

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Background: Canada has one of the strictest approaches to the use of criminal law against people living with HIV (PLWH) globally. In 2012, the Supreme Court of Canada (SCC) ruled that PLWH must disclose their HIV-serostatus to sexual partners unless they use a condom and have a low viral load (VL) (< 1500 copies/mL). Awareness and understanding of this ruling remain undefined among women living with HIV (WLWH), who experience gendered barriers to healthcare engagement.
Methods: We analysed wave 2 cross-sectional data (June 2015-January 2016) from the peer-led Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS). Participants were asked if they were aware of the 2012 SCC ruling. The law was then defined and those reporting awareness were asked how similar their understanding was to the provided definition. Existing and preferred sources of information about the law, and perceived impacts, were also assessed. Multivariable logistic regression identified correlates of ruling awareness.
Results: 584 of 1425 CHIWOS participants were included. Median age was 45 (IQR: 37-52), and 84% reported an undetectable VL (<40 copies/ml). Overall, 74% (n=431) were aware of the ruling, and of those, 47% (n=204) had accurate understanding of the legal obligation to disclose. Among the 431 aware, 36% had discussed disclosure and the law with healthcare providers. Regular HIV physicians (61%), peer workers (25%), and community workers (25%) were identified as preferred providers with whom to discuss disclosure laws. Most participants (65%) believed disclosure laws might affect the type of information WLWH would share with providers. Participation in community HIV work (Adjusted Odds Ratio [AOR]: 1.74, 95% confidence interval [CI]:1.10,2.76) was positively associated with ruling awareness, whereas experience of violence in adulthood (AOR: 0.39, 95% CI:0.21,0.70), self-reporting a detectable/unknown HIV VL (AOR: 0.52, 95% CI:0.30,0.90) and lack of awareness of HIV prevention benefits of ART (AOR: 0.59, 95% CI:0.38,0.91) were negatively associated with awareness.
Conclusions: Awareness and understanding of HIV non-disclosure law is suboptimal among WLWH. Women more socially marginalized were least likely to be aware of the law. Efforts are needed to build women centered knowledge and support around HIV disclosure and the law.

MOPEC0724

Estimating the current and potential future impact of the Mexican drug law reform on HIV incidence among people who inject drugs (PWID) in Tijuana, Mexico, using mathematical modeling

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Background: Mexico's ‚Narcomenudeo reform' depenalized possession of small amounts of drugs and instituted drug treatment instead of incarceration. Additionally, in Tijuana, the main hub for injecting drug use in Mexico, the federal government has funded non-evidence-based centers for involuntary drug treatment. We used mathematical modeling to investigate potential impacts of this reform on HIV incidence among PWID in Tijuana.
Methods: We developed a deterministic model of injecting and sexual HIV transmission among PWID disaggregated by sex, incarceration status, recent exposure to syringe confiscation, and exposure to drug treatment - either opioid agonist therapy (OAT) or involuntary drug treatment. We calibrated the model to HIV prevalence and incidence data among PWID in Tijuana, parameterized with local data on elevated syringe sharing among PWID exposed to recent (5.3 and 6.7-fold higher among men and women, respectively) and non-recent (1.4 and 1.6-fold higher among men and women, respectively) incarceration versus not, as well as recent syringe confiscation (1.9-fold higher among exposed men versus not), and involuntary drug treatment (1.7-fold higher versus never). We estimated the impact on HIV incidence of observed changes in policing since reform enactment 2012-2016 [i.e. significant decline in recent syringe confiscation, from 11% to 0%, but no change in recent incarceration] and predicted the impact of different levels of future reform enforcement (reduced incarceration by 80%, diversion to OAT, or to involuntary drug treatment) from 2017-2030.
Results: The model estimated that observed reductions in syringe confiscation averted only 3%[95%Credible Interval (CrI): 0.5-7%] of new HIV infections among PWID between 2012-2016. If appropriate reform implementation additionally reduces incarceration by 80%, then 14%[95%CrI: 4-28%] of the estimated 784[95%CrI: 557-1017] new HIV infections between 2017-2030 could be averted, with 18%[95%CrI: 7%-31%] averted if PWID were referred to OAT instead of incarcerated. However, referral to involuntary (non-evidence-based) drug treatment would avert fewer infections (10%[95%CrI: -12% to 29%]), and could even increase incidence.
Conclusions: Current implementation of drug policy reform has had limited impact on the HIV epidemic among PWID in Tijuana. Appropriate enforcement has the potential to markedly reduce HIV incidence especially if linked to OAT referral, but expansion of involuntary drug treatment could increase transmission.

Infrastructure and Delivery Models for the Scale Up of HIV Services

MOPED1060

Modifications to ART service delivery models by health facilities in Uganda to accommodate increased patient volumes: a mixed-methods study

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Background: The rapid expansion in antiretroviral treatment (ART) coverage in resource-limited settings and the continually increasing demand for treatment will require modifications to traditional ART service delivery models. We identify modifications to ART service delivery models by health facilities in Uganda to accommodate increased patient volumes over a ten-year period (2004-2014).
Methods: A mixed-methods approach involving two study phases was adopted. In the first phase,
a survey of a nationally-representative sample of health facilities (n=195) in Uganda was conducted between February and April 2015. The second phase involved semi-structured interviews (n=18) with ART clinic managers of 6 of the 195 health facilities purposively selected from the first study phase.
A thematic framework consisting of four categories of modifications (format, setting, personnel and population)was adopted. Descriptive statistics were used for expansion of these four broad themes.
Results: The majority of health facilities 185 (95%) reported making modifications to ART interventions between 2004 and 2014.Of the 195 health facilities, 157(81%) rated the modifications made to ART as ‚major'. Modifications to ART were reported under all the four themes.
Format: Reducing the frequency of Clinic appointments and pharmacy-only refill programs were identified as important strategies for decongesting ART Clinics. Setting: Home-based care programs were introduced to reduce provider ART delivery costs. Personnel: Task shifting to non-physician cadre was reported in 181(93%) of the health facilities. Population: Visits to the ART Clinic were rationalized in favor of the sub-population deemed to have more clinical need. Two health facilities focused on patients living nearer the health facilities to align with ART adherence targets set by funders.
Conclusions: Over the study period, health facilities in Uganda made several modifications ART interventions to accommodate increased patient volumes. Further research evaluating the effect of these modifications on patient outcomes and perceived reductions in ART delivery costs is recommended.

MOPED1061

Scale-up of treatment as Prevention® in British Columbia, Canada: opportunities and challenges identified by policy makers and service providers

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Background: The Canadian Province of British Columbia (BC) was among the first jurisdictions to scale up TasP to the population level, including funding and policy commitments that enhanced HIV testing efforts (e.g., expansion of routine, opt-out testing; targeted testing campaigns among high-risk groups), while also ensuring that all medically eligible persons living with HIV in BC have access to free antiretroviral therapy. As such, BC represents a critical context within which to identify the factors that influenced the scalability of TasP (e.g., acceptability, adoption, fidelity, equitable reach, sustainability), including key opportunities and challenges.
Methods: We draw on in-depth, semi-structured interviews regarding the scale up of TasP with 11 key stakeholders, including high-level policy makers, front-line service providers, and representatives from ASOs. We use thematic analysis to identify the key themes identified within the interviews.
Results: Key factors that influenced scale up included:
(i) social and political factors that created opportunities to implement new ‚systems level' approaches to HIV intervention;
(ii) organizational factors, including the capacity to adapt features of TasP programming based on ‚real-time' program data;
(iii) provider-related factors, including training and resources for frontline service providers and community stakeholders; and
(iv) innovation-related factors, including a growing body of scientific evidence supporting the effectiveness of TasP in BC and elsewhere.
Key challenges included:
(i) maintaining "nimble and evidence-informed" adaptations across a highly-decentralized service delivery system; and
(ii) integrating TasP approaches with other aspects of the care deliver system, including addictions medicine.
Conclusions: Based on our findings, we identify a set of TasP implementation trajectories that have resulted in a highly adaptive approach to systems-level scale up of TasP. We show how the program continues to adapt to the evolving HIV landscape, including new funding mechanisms to respond to newly-identified HIV outbreaks (e.g., clusters of HIV-resistant strains) as well as new and revised clinical guidelines and policies to better articulate HIV practice approaches with other related specialties (e.g., addictions medicine).

MOPED1062

Strong preference for rapid oral over blood HIV testing among patients and providers at an urban public health facility in Kampala, Uganda

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Background: The prevalence of HIV in Uganda is high at 7.3% and approximately 40% of people living with HIV (PLHIV) are unaware of their HIV sero-status. Currently Uganda's HIV testing policy is strictly blood-based. However, this method poses several challenges including demands for high level laboratory skills, stringent waste disposal needs and invasive sample collection. Introducing a rapid, non-invasive and painless alternative HIV oral-fluid test will likely increase the uptake of HIV testing. We determined the performance and preference of rapid HIV oral testing (versus blood-based testing) among clients and providers in Kisenyi Health Centre IV in Kampala, Uganda.
Methods: We conducted a cross-sectional study to assess the preference for and performance of the oral-fluid (OraQuick® Rapid HIV-1 antibody test) and blood-based national HIV serial testing algorithm (Determine® through Statpak® and Unigold®, as a tiebreaker) among 440 consecutive adults at Kisenyi Health Centre IV from January to March 2016. We also assessed for patient and provider preference of oral over blood HIV testing through three focus group discussions with the patients and seven key informant interviews with providers. The providers were also favorable since their reasons could be a little different.
Results: HIV prevalence among study participants was 14.8%. The blood and oral-fluid results were 100% concordant in all 400 patients. The majority of participants; 87% (95%CI; 83.6 - 89.9) preferred oral to finger-prick blood HIV testing because it was painless (91%, n=399), did not require blood draw (82%, n=360), had an easy sample collection process (58%, n=257), convenient (41%, n=180) and could motivate more frequent testing (28%, n=124). Similar themes for preference of oral testing also emerged from the subsequent qualitative study.
Conclusions: Our data show that the performance of the oral was as good as the blood HIV test in our high HIV prevalence population. More importantly, our findings suggest a strong preference for rapid HIV oral testing over blood among clients and providers. These attributes suggest that increased use of oral testing strategies may increase access to HIV testing services in Uganda.

MOPED1063

Gaps in care or data issues? The challenges to reaching the 90-90-90 targets in South Africa

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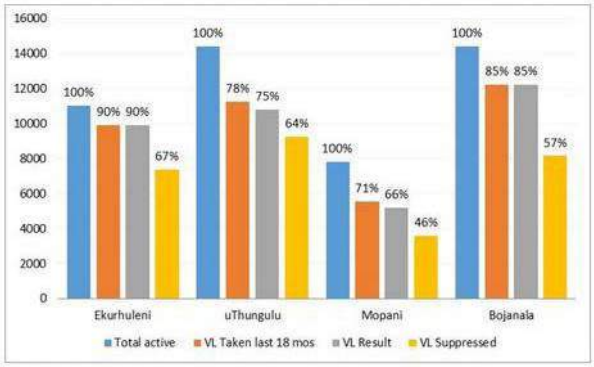
Background: To reach 90-90-90 targets requires strong healthcare systems, improved patient care and adherence and robust data systems to identify gaps. Preparations for an evaluation of South Africa's national adherence guidelines provided insights into gaps in care and data issues.
Methods: Routine patient data collection systems were reviewed at 24 clinics in 4 districts. Completion of viral load (VL) testing in the previous 18 months was assessed in TIER.Net (South Africa's electronic HIV patient record) to identify patient and provider gaps. The number of VLs captured at the National Health Laboratory System (NHLS) (which records all labs done) and in TIER.Net (which represents facility records) were compared to estimate gaps in recording VL results.
Results: The proportion of ART patients with a VL in the last 18 months in TIER.Net varied greatly by district (range 71-90% - Figure 1) and facility suggesting some patient/provider gaps in testing. 32,073 VL measures were recorded in the NHLS between April-August 2016, but only 27,598 (86%) were captured on TIER.Net with variation between districts (Table 1) and facilities, indicating that recording of results also needs improvement.



Blue = total active in care adult patients who have been on ART for > 9 months (i.e. VL test)
Orange= total no. (%) of those patients with at least 1 VL recorded on TIER
Grey= Total no. (%) of patients who had a VL done who also have a VL result on TIER
Yellow= total no. (%) of patients who had a VL done, have a VL result and are suppressed (<400 copies/ml)

[Figure 1. Viral load (VL) tests done and results at 24 facilities by province (TIER Net 2015 data)]

District	April 16	May 16	June 16	July 16	August 16	Total
Ekurhuleni	0.86 (1331/1555)	0.89 (1495/1686)	0.86 (1421/1655)	0.8 (1361/1691)	0.75 (1282/1717)	0.83 (6890/ 8304)
Mopani	0.91 (842/ 921)	0.84 (920/ 1092)	0.86 (855/ 990)	0.88 (1021/1166)	0.89 (1020/1142)	0.88 (4658/ 5311)
Bojanala	0.86 (1222/1416)	0.92 (1122/1214)	0.93 (1821/1968)	0.91 (1890/2087)	0.89 (1498/1683)	0.9 (7553/ 8368)
uThungulu	0.79 (1527/1928)	0.89 (1542/1736)	0.78 (1316/1688)	0.86 (1711/2000)	0.88 (2401/2738)	0.84 (8497/ 10090)
Total	0.85 (4922/5820)	0.89 (5079/ 5728)	0.86 (5413/ 6301)	0.86 (5983/6944)	0.85 (6201/7280)	0.86 (27598/32073)

[Table 1 - Ratio of VLs captured in TIER to NHLS]

Conclusions: Efforts to improve coverage of VL testing and recording of results is essential to achieving 90-90-90 targets as complex and diverse data systems and missing data impact our ability to measure patient status accurately. Comparison across the two data systems identifies gaps in VL recording on TIER.Net .which must be rectified to enable provision of quality care, and accurate tracking of viral suppression. Further research is needed to better understand reasons why VL coverage often falls below the government target of 100%.

MOPED1064

Implementation of interventions aimed at improving linkage, retention and adherence: lessons learned from Phase 1 of the roll out of the National Adherence Guidelines for Chronic Diseases in South Africa

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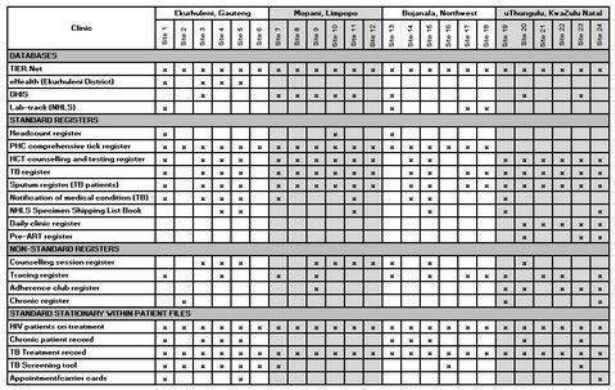
Background: South Africa, which has integrated HIV into primary health care, recently introduced National Chronic Disease Treatment Adherence Guidelines (AGL) to improve patient linkage, retention and adherence. The guidelines include ART fast-track initiation counselling, enhanced adherence counselling, early patient tracing, adherence clubs and decentralized medication delivery.
Methods: In preparation for an evaluation of AGL implementation (matched cluster-randomized study in 24 clinics, 4 provinces), we identified routine practices for tracking patients, documented current adherence strategies, described AGL training, and interviewed clinic staff about routine data collection, patient care documentation and facility resources. We report on lessons learned from the preparation phase.
Results: Numerous paper and electronic registers are used to track patient information including standardised government registers/stationery and non-standard registers developed locally each with varying degrees of completeness (Figure 1). AGL training was conducted in 2015 and supporting tools disseminated; final guidelines were disseminated early 2016. Some adherence support models were in place prior to AGL (22/24 facilities had fast-track initiation; 20/24 patient tracing; 10/24 adherence clubs; 13/24 counselling for unsuppressed patients) but implementation varied. Early implementation showed additional training needs resulting in partner-supported training for specific interventions and plans for staff mentoring. Resource issues (e.g. staff and stationery shortages) were also identified and mitigation plans developed.



[Figure 1: Databases and registers in use]

Conclusions: Early AGL implementation happened in the context of existing adherence models, diverse patient tracking systems, and other policy initiatives including universal test-and-treat. Balancing rationalisation of registers with collection of sufficient data to monitor health services in this context is challenging. The development of high-quality guidelines and supporting materials was well received by facilities although local interpretation and adaptation remains a challenge for standardisation. Optimal national-level implementation depends on sufficient staff (particularly non-clinical cadres), training, staff mentoring, and a clear communication strategy to support effective implementation of these guidelines and other strategies.

MOPED1065

Treat All: the magic bullet for the second "90"?!

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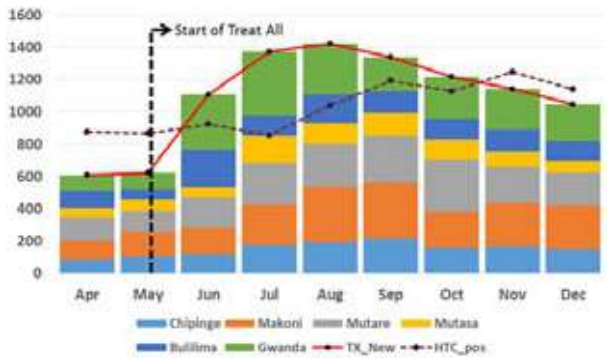
Background: Attainment of the 90-90-90 goals is a priority for Zimbabwe. With 62% of PLHIV receiving ART in 2015, the country embraces the roll-out of TREAT ALL. This presentation reviews the impact of TREAT ALL implementation on the uptake of HIV services in 90 PEPFAR-prioritized health facilities in six learning districts in Zimbabwe.
Methods: Sites were prepared for TREAT ALL in May 2016 through introduction of the concept to provincial, district and site level leadership, community sensitization, capacity building of HCWs, readying the supply chain and distribution of implementation tools. Routine program data for patients newly identified as HIV positive and ART initiations was compiled and cleaned. Program performance/district was compared pre- and post TREAT ALL implementation using paired t-tests.
Results: From April to December 2016, the learning sites initiated 9875 patients on ART.
Before TREAT ALL was implemented, the numbers of patients initiated on ART are 30 % lower than the number of patients newly identified as HIV positive representing patients either not yet being eligible or lost to follow-up.
With the introduction of TREAT ALL, the mean number of ART initiations increased by 130% (p=0.0013) from May to August 2016, exceeding the number of patients newly identified as HIV positive. This reflects the efforts of clinics to follow up on previously not eligible patients recorded in pre-ART registers.
Five months post-introduction of TREAT ALL, initiation rates had declined and stabilized at a level 78% higher than pre TREAT ALL (p=0.0051).



[HIV service uptake pre-/post TREAT ALL]

Conclusions: TREAT ALL is an important strategy. In our dataset, as TREAT ALL is implemented, ART initiation increases sharply initially to stabilize at numbers only slightly lower (<10%) than the patients newly identified as HIV positive. Continued data collection will provide evidence whether the attainment of the second "90" can be sustained, whilst upholding the quality of service provision.

MOPED1066

Mapping of health facilities is a prerequisite for saturating the coverage of positive pregnant with PMTCT services in the private sector in India

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Background: The national PMTCT program in partnership with GFATM and SAATHII, embarked on an ambitious expansion of PMTCT services in the private sector which accounts for 20% of the deliveries in India. First phase is focussed on scaling up in 14 states which accounts for 90% of the estimated HIV positive pregnant women in the private sector.
A comprehensive database of the vast and diverse private sector, which is a prerequisite for saturation of the coverage is lacking in the country. To address this gap, a rigorous mapping of private facilities was undertaken in 231 districts from the 14 intervention states.
Methods: The processes of mapping entailed compilation and assessment of the facilities. The sources of data for facility listing included; District health officials; electronic and hard copy directories of obstetricians, pediatricians, physicians, laboratories and nursing homes; and street walks. Facility assessment entailed validation of the site functioning and obtaining information on required infrastructure, human resources and service availability,.
Results: A list of 23,739 facilities spread across 1769 towns in 231 districts of 14 states was compiled; and 59% (13,987) of these were assessed. Among those assessed, majority (78%) were nursing homes and hospitals, 10% were outpatient clinics and 12% were laboratories. Fifty five percent of the facilities offer delivery services, however only 4% deliver positive pregnant women. Ninety four percent of the assessed facilities expressed their willingness to participate in the program and 54% of them were successfully enrolled in the PMTCT program. Facilities that offer delivery services were prioritized for enrollment for better yield.
Conclusions: Enlisting the universe of health facilities, prioritizing scale up at sites offering delivery services and periodic updation and validation are critical for saturating the coverage of pregnant women with PMTCT services in context of the dynamic private sector in India.

MOPED1067

Retention in care and deaths in a decentralized model for ART delivery: lessons from field

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Background: The HIV Program in India started in 2004 and currently caters to 1.2 million PLHIV under care. In state of Gujarat, there are 30 ART centers that provide ART services to > 50000 PLHIV. In 2007-08, the concept of link ART centers (LAC) was introduced in the program to decentralize sites for dispensing ART to stable PLHIV on ART as defined under the program. The primary aim was to decongest the ART centers and to provide ART closer to homes for PLHIV thereby reducing the travel time and cost that could influence regular follow-up. As the LAC caters to stable PLHIV, deaths were not expected to occur at LAC. The death rates at the LAC was assessed in the state as the intervention nears 9 years of implementation.
Methods: The monthly report of the link ART centers were reviewed along with the reports from the nodal ART center, in November 2016. The LFU and death rates were calculated for each LAC. An analysis of the possible causes of death identified by the LAC staff was done to get insight into it.
Results: The number of LAC in state have been scaled up from 1 in 2008 to 61 in 2016. Total 4788 PLHIV on ART have been linked out to LAC of which 3012 are seeking care at LACs, there were 75 lost-to-follow-up and 147 deaths reported. 52(35%) deaths had clear documentation of an associated OI with TB as commonest reported cause and 07(5%) had malignancies, which includes Hodgkin's-lymphoma, cervical-cancer, brain-tumor, oro-pharyngeal caner. 64(44%) had non-HIV related natural death, of which 08(5%) reported as Myocardial Infarction, 3(2%)as respiratory diseases, while 02(1%)were due to accidents, 9(6%) PLHIV committed suicide and other reported causes of natural death were infection of gall bladder, COPD and bronchial asthma. The reason was not well established in 24(16%).
Conclusions: Decentralized care delivery model is effective and possible. However, there is need to address non HV related health needs and mental health of PLHIV. Capacity building of staff delivering decentralized care is essential. Adherence counseling should not be undermined while decentralizing services.

MOPED1068

Is hospital care an outdated approach in HIV and TB programmes? A pre-implementation assessment of admissions to a rural district hospital in Malawi

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Background: Médecins Sans Frontières (MSF) has supported the Ministry of Health (MoH) in Nsanje District since 2011 in an effort to deliver improved HIV and TB services to the population. In 2016, a decision was made to extend support to the District Hospital (NDH) because of an observed high mortality rate among patients admitted due to advanced HIV disease and TB. In order to set priorities, we undertook a review of admissions and deaths.

Methods: All adult HIV- and TB-related admissions as well as all-cause adult deaths at NDH from May to December 2016 were reviewed.
Results: There were 1183 adult admissions altogether. HIV-related admissions amounted to 25.6% of all admissions (n = 303), among which 65 (21% of all HIV-related admissions) were due to HIV/TB co-infection. Forty-one individuals of HIV-negative (n = 35) or unknown (n = 5) status were admitted due to severe tuberculosis. Overall, there were 149 deaths (death rate, 12.5%). The pooled risk of death from HIV-related causes or TB, regardless of HIV status, was 27.3% (94/344) vs 6.6% (55/839) in patients admitted for all causes other than HIV or TB (p<0.0001). In addition, at death, HIV-infected patients were younger than their peers of negative or unknown status (median age, 40 years vs 51 years, p<0.001). Among the HIV-related admissions, 90.7% of the patients had a known positive status upon arrival and 76.9% were ART-experienced. Among the HIV-infected patients, CD4 count was done in 102 patients. Median CD4 count was 142 cells/mm^3 (IQR, 56-315) and 79.4% of these patients had a CD4 count lower than 350 cells/mm^3, whereas 18.6% presented with a CD4 count lower than 50 cells/mm^3. A targeted viral load was ordered in 47 admissions, but no results were available at the time of outcome because of exceedingly long turnaround time.
Conclusions: HIV and TB are the main drivers of in-hospital mortality in Nsanje, Malawi and affect younger patients disproportionately. Despite treatment, advanced HIV disease was a frequent presentation to hospital. Investments in hospital care are needed to reduce mortality among defaulting and failing patients and thus put them back into the 90-90-90 loop.

MOPED1069

Evaluation of a PMTCT program in a resource-constrained setting: are we near virtual elimination of mother to child transmission of HIV?

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Background: In 2011, Zimbabwe developed a five-year national strategic plan to achieve virtual elimination of mother-to-chid HIV transmission (eMTCT). Zimbabwe's AIDS Prevention Project (ZAPP), working as a sub-grantee to EGPAF, partnered with Gweru City to reach eMTCT to implement this plan. The approach focused on HIV service demand-creation and increasing retention in care. An assessment of prevention of mother-to-child HIV transmission (PMTCT) sites was performed in Gweru in 2016 to ascertain whether eMTCT plan goals had been reached.
Methods: A logic framework processes-outcomes evaluation was conducted to assess PMTCT program performance at ZAPP-supported sites in 2016. Site-based and community health workers were purposively recruited for the evaluation. Records of women and children enrolled in the PMTCT program in 2011-2015 at these sites were also pulled and reviewed. Confidentiality was assured and maintained through collection of de-identified data and secure storage of questionnaires. Data were collected from health workers using semi-structured interviewer administered questionnaires and health facility checklists. Microsoft Excel and Stata were used for data analysis. Qualitative data were manually sorted by thematic content. Verbal informed consent was obtained.
Results: Two program managers, 13 community health workers and eight nurses were interviewed. Average HIV testing in antenatal care was 98.4% versus a set target of 97% for the five program years evaluated. Average proportion of HIV-positive pregnant women receiving ARV for PMTCT was 97% (higher than a set target of 95%). Average maternal retention rate at six months was 74% (below set target of 87%). Infant six-week DNA PCR positivity rates declined from 6.9% (19/267) in 2011 to 3.3% (19/582) in 2015. Seventy five percent (6/8) of all PMTCT sites had mechanisms to identify and track defaulters through use of PMTCT appointment diaries, mHealth and physical follow-up activities. Only two sites were fully implementing defaulter tracking mechanisms.
Conclusions: The eMTCT plan has been successful in Gweru at reducing the number of children infected in-utero and through delivery. Further evaluation of PMTCT rate at breastfeeding cessation is needed, but these results should help program implementers target implementation of defaulter tracing at all supported sites.

MOPED1070

Faith-based strategy for HIV sigma reduction: a Nigerian case study

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Background: Religion has come to be recognized as a strong force that shapes the beliefs and actions of people, particularly in Nigeria where majority see life from the religious spectrum. The erroneous association of HIV with sexual immorality and the resultant stigma attached to it has been, to a larger extent, propagated by Religious teachings. This study is an assessment of a faith based strategy for fighting HIV related stigma using structured messages disseminated in religious gatherings in forms of sermons and information leaflets.
Methods: A simplified version of the Nigerian HIV anti-discrimination Act 2014 was produced with each component of the Act interpreted using relevant verses from the Bible and Quran. Twelve religious groups (7 churches and 5 mosques) were purposively selected and randomly grouped into intervention group (5 churches and 3 mosques) and control group (2 churches and 2 mosques). In the intervention group, the religious leaders (Pastors and Imams) were asked to share the information leaflets containing the simplified anti-discrimination Act to their congregations and preach briefly about the messages in their sermons once every week, while the control group received leaflets containing summary of the Nigerian HIV anti-discrimination Act 2014 with no religious interpretation. After six weeks, quantitative data were collected from 310 respondents (47% female) and qualitative data from 12 religious leaders in the two groups using a semi structured questionnaire that addressed issues around knowledge of the anti-discrimination Act and stigma related attitude.
Results: From the data analysis, knowledge of HIV anti-discrimination Act was low in both groups; however, the intervention group expressed less stigmatizing attitudinal disposition with no significant difference between the Christian and the Muslim groups. The religious leaders were of the opinion that the simplified religious version of the anti-discrimination Act appeals more to the conscience and triggers more empathy than the original National Act that sounds more punitive.
Conclusions: This study has once again supported the call to engage religious leaders and faith communities in initiatives targeted at behavioral change for social and public health importance. This is particularly true for developing countries like Nigeria where religion plays central role in the people's lives.

MOPED1071

Rapid initiation of antiretroviral treatment in newly diagnosed HIV at a London clinic

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Background: Achieving viral suppression is associated with a reduced risk of HIV transmission. In primary HIV, guidelines recommend offer of immediate antiretroviral therapy (ART). ART is also recommended in chronic HIV infection. In July 2016, we increased capacity at our clinic to enable individuals with newly diagnosed HIV to have a first medical review within 48 hours of diagnosis rather than the standard 2 weeks. We set out the results from the first 6 months of the new service.
Methods: Case-note review of individuals newly diagnosed with HIV at a London clinic between 1st July and 31st December 2016 up to 3rd January 2017. Comparison data was taken from all new HIV diagnoses at our service between 1st May 2015 and 30th September 2015, before the new service was introduced.
Results: There were 149 new HIV diagnoses. Median age was 33 y. Median baseline CD4 was 469 cells/mm3 and viral load was 71738 copies/mL. 53% (72/135) tested positive on the recent infection testing algorithm (RITA), suggesting HIV acquisition within 4 months.
Of 149 new diagnoses, 13 had no further follow-up (7 moved away, 6 lost to follow-up) and 136 attended first doctor appointment, all were offered ART. Of these, 78% (106/136) started ART at first doctor appointment. Of those starting ART at first appointment, 29% (31/106) did so within 2 days of diagnosis. To 3rd January 2017, 96% (130/136) initiated ART.
Median time from HIV diagnosis to first doctor appointment decreased from 16 days (IQR 14 -21 d) in 2015 to 6 days (IQR 2 -12 d) (p< 0.05). Median time from diagnosis to ART initiation decreased from 26 days (16 - 55 d) in 2015 to 7 days (IQR 3 -16 d) (p< 0.05).

Early data suggest excellent outcomes at 6 months; of the 26 who initiated ART in July 2016, 24 had VL< 200 by 3rd January 2017 in median time from HIV diagnosis of 59 days.
Conclusions: Our new service has resulted in significantly shorter time to medical review and ART initiation. Uptake of ART is high suggesting that rapid initiation is acceptable and feasible for patients with newly diagnosed HIV.

MOPED1072

The impact of an integrated adolescent youth centre and clinic on sexual reproductive healthcare utilization and HIV testing in the Western Cape

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Background: Despite the increasing HIV incidence among young South African women, HIV counselling and testing (HCT) rates remain unacceptably low. One in three young women has a pregnancy by age 20. Alternative strategies need to be explored in order to increase prevention and screening among high-risk adolescents.
Methods: The Desmond Tutu HIV Foundation (DTHF) Youth Centre (YC) in Masiphumelele offers integrated health, educational and recreational programs in order to increase adolescent access to comprehensive sexual and reproductive health services (SRH). Participation is incentivized and clinic statistics tracked with a biometric data system. We compared HIV testing and contraception rates with data from a public clinic in Imizamo Yethu (IY), a community of similar demographics, to ascertain the impact of the YC on SRH and HCT utilisation rates for adolescents.
Results: In 2015, adolescent females under 18 had 3.74 times more contraception visits at the YC than adolescents at IY clinic. There was no difference in the type of contraception used, with both populations favouring injectable methods. Adherence to contraception was sub-optimal, with the average YC female using contraception for 6.1 months/year. Masiphumelele youth were 1.85 times more likely to have HCT at the YC than youth in IY. This difference was greater in boys, with those aged between 15-24 3.83 times more likely to test. Masiphumelele YC attendees were a third less likely to test HIV positive than their Imizamo Yethu counterparts. Female sex, older age, Clinic attendance for Family Planning and STI treatment, high incentive participation, and high Youth Centre attendance were all independent factors associated with increased HIV testing.
Conclusions: Adolescents from Masiphumelele were significantly more likely to access SRH and HCT services at the YC in comparison to the city clinic in Imizamo Yethu that has made adolescent friendly accommodations. The differences were most dramatic in contraception coverage for females under 18 and HIV testing rates in males. Lessons from the DTHF YC may be applied to public clinics in order to increase adolescent healthcare utilisation rates.

MOPED1073

Prevalence of testing and preference for self-testing in Malawi and Zambia: baseline data from the STAR (HIV self-testing in Africa) project

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Background: Substantial barriers to accessing HIV testing services (HIVST) in Sub-Saharan Africa remain, but HIV self-testing (HIVST) is a promising new tool. The STAR (HIV Self-testing in Africa) study is assessing interventions to improve uptake of testing and linkage to care in Malawi and Zambia.
Methods: The impact of community distribution of HIV self-tests on testing and on ART initiation at local clinics is being evaluated in cluster-randomised trials. In 22 rural communities in Malawi and 12 rural and peri-urban communities in Zambia, a population-based household survey was conducted at baseline. We describe baseline prevalence of prior ever HIV testing and recent testing (past 12-months), and preference for self-testing among prior testers.
Results: Baseline data were collected from 5,682 and 5,878 respondents in Malawi and Zambia, respectively. The age and sex distribution in both samples was similar (Malawi: median 31 years, IQR: 22-44, 57.2% female; Zambia: median 32 years, IQR: 23-44, 55.7% female) Prior testing was high in both countries, but less common among young men (less than 25 years) than among older men or women (see **table 1**). Within the past 12 months, 53.1% of all respondents in Malawi had tested, both only 29.3% of young men. The pattern was similar in Zambia, with 66.1% of all respondents testing recently, and only 36.1% of young men. Before distribution of self-testing, self-testing was the preferred mode for next test for 20.9% of respondents in Malawi and 33.3% in Zambia.

	Younger men (<25 yrs)	Older men (25+ yrs)	All Men	Younger women (<25 yrs)	Older women (25+ yrs)	All Women	Total (N)	Total (%)	P-value
Malawi - Total respondents (No.)	824	1463	2428	1158	1770	3254	5529	100	-
Malawi - Ever tested (% respondents)	64.1	78.1	73.1	85.1	84.9	84.9	4420	80.1	<0.001
Malawi - tested within past 12 mos. (% respondents)	29.3	41.4	36.3	68.6	62.4	64.6	1244	53.0	<0.001
Malawi - Preferred mode of next test is self-testing (% ever tested, extended survey n=1,387)	24.5	26.1	25.9	17.0	18.6	18.1	226	20.8	0.3324
Zambia - Total respondents (No.)	736	1791	2607	1080	2180	3271	5787	100	-
Zambia - Ever tested (% respondents)	61.4	83.6	75.4	82.8	89.7	87.3	3863	82.7	<0.001
Zambia - Tested within past 12 months (% respondents)	36.1	65.6	53.1	68.7	78.4	74.6	1574	66.1	<0.001
Zambia - Preferred mode of next test is self-testing (% ever tested, extended survey n=1,043)	31.2	30.7	30.9	34.9	34.1	34.4	280	33.3	0.8791

[Table 1. Testing and self-test preference]

Conclusions: Malawi and Zambia have made major progress towards scaling up HTS, but testing gaps remain, especially among men. Even before introduction, HIVST appears highly acceptable in these rural and peri-urban communities.

MOPED1074

The impact of a universal test-and-treat policy on CD4 at ART initiation at an urban, public-sector HIV treatment facility in Johannesburg, South Africa

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Background: Prior to August 2016, antiretroviral therapy (ART) for people living with HIV (PLWH) was available in public sector facilities in South Africa for patients with CD4 < 500 cells/mm^3. In September 2016, test-and-treat was implemented, making all PLWH eligible for ART. We investigated whether this change resulted in an increase in baseline CD4 among initiating patients in an HIV treatment facility in Johannesburg.
Methods: We included all adult (≥18) patients initiating first-line ART at the Themba Lethu Clinic in Johannesburg between January-December 2016 and present the median (with interquartile range [IQR]) baseline CD4 count and the number of patients initiating with CD4 >500 cells/mm^3 over time. Patients without a baseline CD4 count recorded were excluded.
Results: 865 patients were included. 55.6% were female and the median (IQR) age at ART initiation was 38.4 (31.3-46.5). From January-August, 514 people initiated ART, 52 (10.1%) with CD4 >500 cells/mm^3, with a median (IQR) baseline

CD4 count of 176.5 (56-344) cells/mm³. The median (IQR) baseline CD4 count increased to 266 (85-482) cells/mm³ in 351 patients (22.8% >500 cells/mm³) who initiated between September-December.
We observed differences in the impact of test-and-treat by sex and age: the median baseline CD4 count increased by approximately 71 cells/mm³ for female patients compared to 46 cells/mm³ for male patients (Figure). Patients ≥45 (n=259) increased their median (IQR) baseline CD4 count from 146.5 (64-344) cells/mm³ from January-August to 259 (77-491) cells/mm³ from September-December. The median baseline CD4 count increased by approximately 81.5 cells/mm³ for patients aged 30-44 (n=417) and by 22 cells/mm³ for patients < 30 (n=189).

[Figure. Number of patients initiating ART monthly in 2016 with median baseline CD4 count, disaggregated by sex]

Conclusions: The implementation of test-and-treat has resulted in a 90 cells/mm³ increase in median baseline CD4 at this urban HIV treatment facility. Improvements were greatest in women and older patients, highlighting the need for further engagement of men and youths in HIV care in South Africa.

MOPED1075

Strategies for rapid initiation of test and start: validated tools tested in the field

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Background: The 90-90-90 UNAIDS targets are aimed at ending the AIDS epidemic by 2030. This entails bringing HIV treatment to all who need it, a major challenge in resource limited countries often faced with the greatest burden of disease. These targets are expected to significantly impact the human, financial and commodity resource needs to meet the increased programmatic demands. Determining the capacity needs of Test and Start nationally can be a daunting challenge. Due to the urgency of need, effective tools are needed that can be rapidly applied by governments and health planners to identify key bottlenecks and enablers. EQUIP, a consortium of African Partners, developed and validated an assessment tool that is easily adaptable for this purpose.
Methods: The questions for the first "90" focused on achieving maximum yield from targeted HIV testing. The second "90", addressed linkages to treatment, differentiated models of drug delivery and retention strategies. The third "90" targeted viral load scale-up and monitoring. The assessment in Lesotho was conducted on a sample of 85 facilities (public and private) across 10 districts.
Results: All facilities had at least one nurse trained in Test and Start and 39% trained in supply chain management. Pharmacy technicians and Records Officers were available in 34% and 33% of facilities, respectively. The average testing yield was 12.2%, but linkages to treatment were not consistently documented. Community ART Groups were operating effectively in 22% of facilities and viral load records were available in 54% of facilities. To strengthen service delivery recommendations included developing and implementing a structured facility-level mentorship support program in clinical care, inventory and data management.
Conclusions: The assessment provides comprehensive baseline information that facilitate the development of appropriate implementation plans. Collaboration with other implementing partners eliminated duplications, promoted synergies, ownership, efficiencies and decreased costs. The tool will support governments and stakeholders to establish the state of readiness to implement rapid roll-out of Test and Start, expediting achievement of the 90-90-90 goals.

MOPED1076

Entry point analysis of provider initiated HIV testing services: progress towards achieving the first 90 in Zimbabwe

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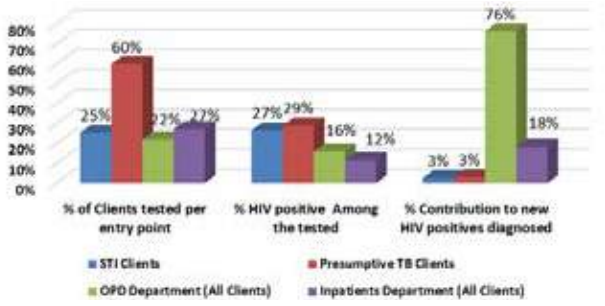
Background: An estimated 74% of adults >15 years living with HIV in Zimbabwe know their status. Although remarkable progress, there is need to scale up efforts towards reaching undiagnosed individuals considering prevalence remains disproportionately high, 14.6%. Provider initiated testing and counselling (PITC) at every health service entry points has been a key strategy for HIV diagnosis. The evaluation objective was to estimate and compare PITC coverage and yield by entry point.
Methods: Modified sampling approach for conducting enhanced monitoring was used to select eight health facilities in three Families and Communities for Elimination of HIV supported districts namely Bulawayo, Kwekwe and Makoni. Data on attendances and HTC services among adults >15 years were retrospectively abstracted for July to September 2016 from the outpatients (with TB and STI as subentry points) and inpatients (medical and surgical wards as subentry points) departments. Descriptive and inferential analyses were conducted using STATA V12.
Results: Overall, 12050 adults accessed health services through the outpatients department and 3581 adults accessed services through inpatients department. Clients presenting with TB related symptoms had the highest proportion tested for HIV. The majority of new HIV+ cases, 76% were diagnosed through the OPD. While medical inpatients were more likely to be tested than surgical inpatients, 73% vs 36% (p<0.05), a higher proportion of medical inpatients tested positive when compared with surgical inpatients, 17% vs 8% (p<0.05).



[Distribution of HIV Testing and new diagnosis]

Conclusions: High yield entry points present an opportunity for early diagnosis and treatment subsequently reducing HIV transmission, morbidity, and mortality. Findings demonstrate that to achieve UNAIDS first 90 we need to strengthen PITC in OPD, with large patient volumes substantially contributing to our epidemic. High HIV testing rates among medical inpatients demonstrate feasibility of increased testing and should be replicated in other entry points. Further investigation is required on reasons for opting out of PITC.

MOPED1077

The acceptability and feasibility of community health worker-led home-delivery of antiretroviral therapy: early findings from a health systems trial in Dar es Salaam, Tanzania

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Background: Delivering antiretroviral therapy (ART) to patients' homes using community health workers (CHWs) could reduce patient volumes at healthcare facilities, improve ART adherence and retention, and decrease patients' out-of-pocket health expenditures. This study uses baseline data from a randomized health systems trial in Dar es Salaam to ascertain the acceptability and logistical feasibility of CHW-led ART home-delivery in Dar es Salaam.
Methods: We randomized 48 healthcare facilities in Dar es Salaam to either the standard of care (facility-based ART care) or CHW-led ART home-delivery. The CHW cadre is a long-standing public sector cadre in Dar es Salaam, called home-based carers. Patients had to be clinically stable on ART to be eligible for ART home-delivery. We present data from three questionnaires administered between March 1st 2016 and January 15th 2017: i) an enrolment questionnaire (n=1,572), ii) a patient exit questionnaire administered to a random sample of patients at the end of a HIV care visit (n=718), and iii) a healthcare provider questionnaire administerd to clinical personnel at the study healthcare facilities (n=102). In addition, we conducted semi-structured qualitative interviews with eight participants who were offered ART home-delivery but refused.
Results: Regarding acceptability, 14% (46/334) of participants who were offered ART home-delivery opted for standard facility-based care instead. The main reason for opting against ART home-delivery appeared to be confidentiality concerns, as suggested by both questionnaire and qualitative data. Regarding logistical feasibility, CHWs had conducted a total of 533 ART home-delivery visits by September 30th 2016 and there had not been any reports of a CHW being unable to locate a participant. Eight participants complained to the study team that their ART had not been delivered on time.
Conclusions: The home-delivery of ART by CHWs appears to be logistically feasible in Dar es Salaam and socially acceptable to a majority of patients who are stable on ART. In general, programs that deliver ART to patients' homes while minimizing the perceived risk of unintentional HIV-status disclosure would likely achieve the highest social acceptability in urban sub-Saharan Africa.

MOPED1078

HIV testing and counselling (HTC) costs in public sector settings in Southern Africa: evidence from Malawi, Zambia and Zimbabwe

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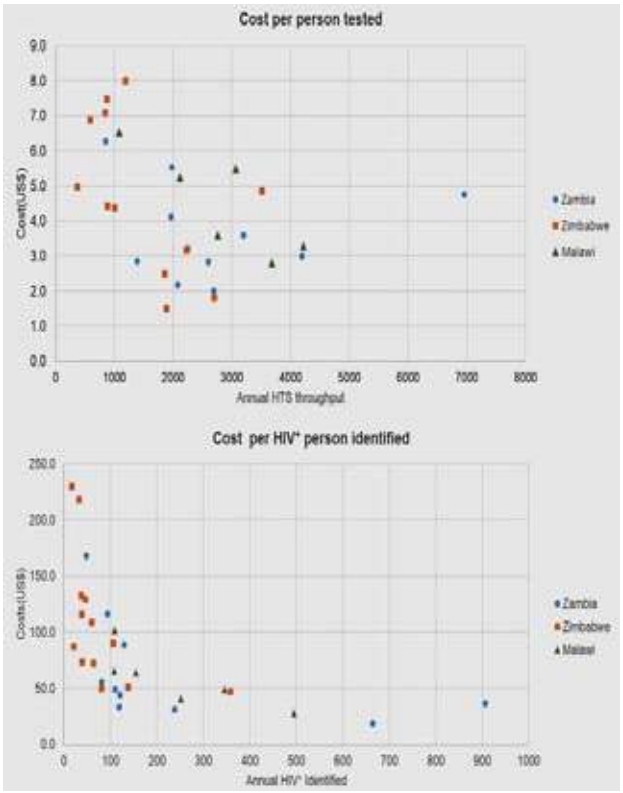
Background: Though substantial progress has been made to achieve the UN 90-90-90 targets, 27%-34% of people living with HIV (PLHIV) in Malawi, Zambia and Zimbabwe, are unaware of their status. We present the cost of HIV testing services (HTS) in 29 public facilities in these countries, and investigate throughput and HIV prevalence as potential causes of variance.
Methods: Standardised costing methods were collaboratively developed to ensure consistency across countries. Top-down and ingredient-based costing methods were applied from the provider's perspective, identifying the full annual costs for each facility reported in 2016 US$. Facilities were both rural and per-urban, clinics and hospitals. Quantities and costs of resources were collected through interviews, expenditure and outcome review. Annual costs per: facility; test; and HIV-positive individual identified were estimated.
Results: The annual economic costs of providing HTS were US$6,142, US$10,263 and US$11,521 per facility for Zimbabwe, Zambia and Malawi, respectively, with personnel being the largest category, driven by variations in staffing numbers and reimbursements. Facilities tested on average 1,552, 2,789 and 2,820 people in Zimbabwe, Zambia and Malawi, respectively. Reactivity rates ranged from 5% in Zimbabwe to 8% in Malawi and Zambia, with wide within country variation (1-14%). The cost per person tested was US$4-US$5 and US$58-US$108 per HIV-positive individual identified with wide variation across clinics (US$19-US$230). Economies of scale were evident, suggesting testing is more efficient in larger and/or high HIV prevalence facilities.



[HTS Unit costs]

Conclusions: Though HTS can be provided at relatively low cost, supply- and demand-side constraints stand in the way of achieving this more generally. Complementarity between clinic- and community-based testing, including HIV self-testing must be explored as a means to alleviating barriers to uptake and reaching untested populations.

MOPED1079

Soccer & vocational training: moving out of health care settings to engage men in HIV care

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Background: Across Africa, men are not getting tested for HIV, are underutilizing HIV care and are less adherent to ARV than women. Rather than pushing men into care, placing prevention and care at soccer practices, games, and vocational training sites have the potential to attract men, destigmatize HIV, and increase HIV services uptake. A pilot study found significant increases in the uptake of drug testing over time and decreases of substance use over 6 months. This report focuses on a large randomized controlled study.

Methods: : All men aged 18-25 years old in 18 communities (n=900) in Cape Town, South Africa were recruited and randomized by community to receive either: 1) soccer practices/games three times weekly for one year; 2) 6 months of soccer and 6 months of vocational training; 3) or no intervention. At soccer, coaches provided HIV interventions, random rapid diagnostic tests (RDT) for alcohol/drugs once a week, and access to HIV testing and care. To date, outcomes have been monitored over the first six months.
Results: Over the first six months of soccer, attendance increased 250%, until an average of 75% of the communities' young men attended regularly, three times weekly. Alcohol use rose from 62.5% on average during the first 3 months of soccer to 70% the next 3 months of play. However, other substances decreased significantly between the first three months of soccer over the subsequent three months of practices. Marijuana use declined from 52% to 44%; methamphetamine use declined from 20% to 11%. Over 6 months, about 15% of men entered jail. The uptake of HIV testing, concurrent sexual partners, and condom protected sexual risk acts will be reported at the conference.
Conclusions: Attendance increased dramatically over time, as well as negative drug tests of more serious drugs; these drugs appear to be replaced with an 8% increase in alcohol use. A negative RDT became a source of team pride and cohesion. To engage men, HIV services must go to the men, capitalizing on their interests, in order to meet the goals of eliminating HIV by 2030.

MOPED1080

Improving relationships between needle and syringe programs and police: the potential role of in-service training

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Background: Training police on the public health benefits of needle and syringe programs (NSPs) is viewed as a best practice to facilitate more collaborative relationships between police and these programs. To date, while the limited published literature contains promising cases of harm reduction in-service training for police, evaluative evidence is preliminary.
Methods: Using an online survey, we asked NSP managers across Canada about their programs and the quality of their NSP-police relationships.
Results: We analyzed data from the responses of 75 program managers among whom 69% reported that their program had a "positive" or "mostly positive" relationship with the police. In-service training about topics such as needle-stick injury prevention and NSP effectiveness was provided by less than 50% of the programs surveyed. Seventy-five percent reported no established protocols to resolve conflicts between NSP staff and police. Four variables, all related to in-service training, were significantly related to positive NSP-police relationships, including training about: NSP program goals (OR 7.7; 95% CI 2.0, 33.1); needle-stick injury prevention and basics of blood-borne virus transmission (OR 4.0; 95% CI 1.1, 15.34); the health and social concerns of people who use drugs (OR 3.9; 95% CI 1.1, 13.5); and evidence about the impact of injection equipment distribution (OR 3.9; 95% CI 1.1, 13.5).
Conclusions: Development of in-service training for police that is focused on harm reduction goals and initiatives is a new and evolving area. We highly encourage NSPs to offer and evaluate any such in-service training programs.

MOPED1081

Facility-level barriers to antiretroviral therapy experienced by men in Malawi

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Background: Men are underrepresented in antiretroviral therapy (ART) programs. In particular, facility-based services have failed to attract men. We examined the organization of ART services in Malawi to understand factors that may influence male participation and explored provider perceptions of facility-based barriers and facilitators to engaging men in ART programs.
Methods: A facility-level survey was conducted at 53 mid- and large-level health facilities across 4 districts in central and southern Malawi to assess the organization of ART programs within health facilities. Twelve focus group discussions were conducted with ART providers (n=31), HIV counselors (n=19), and community-based staff (n=29) from 6 facilities to understand provider perceptions of barriers to ART care for men and strategies to improve male participation.
Results: Forty-three percent (n=23) of 53 ART sites were located in stand-alone buildings separate from other health services. Thirty-two present (n=17) lacked privacy, with ART waiting areas easily seen by general clients or community members. Twenty-one percent (n=11) of ART sites were located in female-focused sections of the facility, such as antenatal, family planning, and/or children's clinics. Nine percent (n=5) of health facilities only offered ART on clinic days when family planning and/or antenatal services were offered. None of the sites offered male-friendly or tailored ART services.
In focus group discussions, providers believed the structure of ART programs increased men's risk of unwanted disclosure due to the location of ART sites, days of ART services that coincided with female-specific services, and health seeking behavior. Men are generally expected to attend health facilities during times of illness; therefore, men who seek regular facility-based care are assumed to be HIV+. Providers identified three strategies to address male-specific barriers to care:
(1) improve privacy in ART waiting spaces;
(2) integrate ART with other health services such as care for non-communicable diseases; and
(3) promote primary health care for men to reduce the assumption that men who regularly visit health facilities are HIV+.
Conclusions: Lack of privacy and male-friendly services are important barriers to increasing men's use of ART. Additional studies are needed to explore strategies to decrease male-specific barriers to care within health facilities.

MOPED1082

Provider perspectives on delivering HIV care in western Kenya: results of a qualitative study

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Background: Given the dramatic rise in the numbers of people being diagnosed with HIV, entering care, and starting antiretroviral therapy (ART) in sub-Saharan Africa, as well as the additional volume projected due to the shift towards test and treat approaches in many settings, the burden on inadequate health systems will continue to rapidly increase. Providers are critical to the delivery of high quality HIV care and optimal implementation of ART. The goal of this study was to examine provider perspectives on their abilities to deliver high quality care within an increasingly over burdened system.
Methods: Sixty health care providers within the Academic Model Providing Access to Healthcare (AMPATH), a large HIV treatment and care program in western Kenya, were recruited to participate in this qualitative study. Providers included clinical officers, nurses, and support staff from three sites (Moi Teaching and Referral Hospital, Webuye, and Busia) selected to reflect a broad range of professional experiences from both rural and urban settings. We conducted in-depth interviews focused on providers' perspectives on facility and health system barriers and facilitators for patients engaging in HIV care. Interview transcripts were inductively content-analyzed to derive a set of descriptive categories representing provider experiences delivering care in their respective facilities.
Results: Providers described inefficient and disorganized systems for managing patients amidst limited resources in this setting. Provider motivation and satisfaction were generally low with high levels of stress and frustration, influenced by their perceptions of lack of interest by program managers, insufficient opportunities for professional growth, and barriers to participation in problem solving. Overall, providers perceived that their high strain, low-control roles in the system negatively influenced their ability to focus on patient needs, potentially translating to lower patient engagement with care and ART.
Conclusions: Changes in system-level factors such as the organization of care and programs for improving provider satisfaction and motivation may improve provider motivation and job satisfaction in high prevalence, low-resource settings. Additional research is needed to determine if such system-level improvements increase provider satisfaction, in turn impacting patient engagement in care, adherence to ART, and clinical outcomes.

MOPED1083

HIV/AIDS patients' perception of quality of service in Manaus, Brazil and its influence on treatment initiation and adherence to antiretroviral therapy

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Background: The study aims to understand HIV/AIDS patients' perception of quality of services provided in five health centers in Manaus, Amazonas, Brazil. It also evaluates the relationship between patient satisfaction and treatment initiation as well as adherence to antiretroviral therapy (ART). The study establishes a baseline of patient opinion ahead of a decentralization project led by Brazil's Ministry of Health (MOH) and the AIDS Healthcare Foundation. The decentralization seeks to improve quality of care by relieving the city's overburden main hospital, Fundação de Medicina Tropical Doutor Heitor Vieira Dourado (FMT), by routing patients to four HIV/AIDS-specialized health units (SAEs, for their acronym in Portuguese).
Methods: Researchers interviewed 812 patients (410 at FMT and 402 at the SAEs) between September and December 2016 during routine consultations. Samples included men and women, 18 years old or older, living with HIV/AIDS. Data was collected through a structured survey. Researchers also used viral load and CD4 count results obtained from government databases. Descriptive and inferential methods were used to analyze the data.
Results: Results validate the need for decentralization, showing lower patient satisfaction, longer wait times, and worse perceptions of communication with health staff at FMT than at SAEs. The convenience of the health center location, short wait times, and respectful treatment from nurses were found to be associated with higher satisfaction. While the study found similar patient adherence to ART at FMT and SAEs, FMT had a higher proportion of patients with CD4 counts under 200/mL, indicating late diagnosis/treatment initiation.
Although overall satisfaction with health services did not have an effect on adherence to ART, specific factors associated with patient satisfaction, such as wait times, time to reschedule appointments, and respectful treatment by doctors positively influenced ART adherence. Gender did not have a statistically significant influence on satisfaction levels.
Conclusions: Findings help the MOH understand patient satisfaction levels with health services and inform the decentralization process. Results also identify characteristics of health services that can be improved to increase ART adherence. Lastly, the study establishes a reference to understand whether the decentralization will effectively increase quality of service at FMT without creating adverse effects at the SAEs.

MOPED1084

Key population risk factors associated with differentiated HIV care in Tanzania

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Background: Recognizing the need to roll out differentiated care, Sauti project provides HIV combination prevention services to key population (KP) through mobile Community-Based HIV Testing and Counselling Plus (CBHTC+) sites and Drop-in Centers (DIC), both located at hotspots.
Methods: Between January and June 2016, data was collected from female sex workers (FSW: age 18 and above who exchange sex for cash or goods) and men who have sex with men (MSM), who accessed mobile CBHTC+ sites and 24 DIC in 11 regions and 24 districts in the Sauti project. Chi square and Mantel-Haenszel tests were used for statistical analysis.
Results: The program reached 39,180 KP (35,185 FSW and 3,995 MSM), through CBHTC+ (37,112: 33,797 FSW; 3,315 MSM) and DIC (2,068: 1,388 FSW; 680 MSM). Young KP were more likely to access DIC compared to CBHTC+ (p<0.001). The overall HIV prevalence was 3.5%, and KP accessing DIC were 2.4 times more likely to be HIV-infected compared to those at CBHTC+ (p <0.001), particularly for ages 25-49 (p <0.001). KP reporting alcohol or drugs use during sex in the last month were respectively 2.5 and 3.8 times more likely to access DIC compared to CBHTC+ (p <0.001).
Among all MSM, 35% reported vaginal sex, of whom 63% accessed DIC. Overall, about half of the KP reported lack of condom use at the last vaginal sex, particularly MSM accessing DIC were more likely to never use condom compared to those at CBHTC+ (46% vs 59%; p <0.001); when asked about condom use at last anal sex, KP accessing CBHTC+ were more likely to had never used it (FSW 86% vs 79%, p <0.001; MSM, 31% vs 23%, p <0.05).
Conclusions: Drop-in centers represent the ideal venue to reach young KP (ages 15-24), who use alcohol or drugs during sex, MSM in heterosexual relationships who do not use condom, and HIV-infected KP ages 25+. Such findings suggest that more investments could be channeled to drop-in centers, thus reaching higher risk populations, whose HIV acquisition and transmission can be prevented through HIV Testing Services, alcohol and drug risk reduction services, condom promotion and provision and pre-exposure prophylaxis.

MOPED1085

The role of needle and syringe programs (NSP) in linking people who inject drugs (PWID) to the HIV clinical care continuum in Kyrgyzstan

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Background: Although Kyrgyzstan has implemented NSPs in a range of settings since 1999, their role in facilitating access to HIV testing and care and treatment services (HCTS) for PWID had not been assessed.
Methods: We conducted surveys among 1153 PWID who use NSP services; 10 focus groups with 99 PWID (both users and non-users of NSP); interviews with 24 NSP staff and a review of 7449 NSP program records from January 1, 2015 to June 30, 2015. The assessment focused on 19 NSP sites (health facility-based, fixed NGO-based, and pharmacy-based sites) across six geographical areas.
Results: HIV Testing: Program data showed that on-site HIV testing was reported by only 3/19 (16%) NSPs and only 30% of NSP clients were referred for off-site HIV testing. Despite that, overall, 1140/1153 (99%) NSP clients surveyed reported ever being tested for HIV, 1089 of them (95.5%) knew the result of their last HIV test and 945 (82%) were tested ≤6 months ago. Among the 981 (90%) willing to disclose their HIV status, 90 (9%) reported being HIV-positive and 82 of them (91%) were enrolled in HIV care.
HIV Care & treatment: Approximately half of HIV-positve respondents (40/82 (49%) rated the support they got from NSP as being a factor that improved their adherence to HCTS in a manner that was "Very effective", 35 (43%) rated the support they were getting as "Somewhat effective", while 7 people (9%) did not receive any support from the NSP to access HCTS. Information on referrals from NSP to HIV services was not routinely collected or recorded. Many NSP staff reported not feeling sufficiently empowered or trained to counsel HIV-positive clients about HIV care and treatment. There were no differences detected between different types of NSP sites in linking and referring PWID to HIV testing, care and treatment.
Conclusions: NSPs could be better utilized to facilitate access of HIV-positive PWID to HIV testing, care and treatment, given the positive perception of NSP by PWID. However, as a prerequisite, NSP staff must be empowered to counsel HIV-positive PWID about care, and treatment services. Linkages between NSP and HCTS need to be strengthened and formalized.

MOPED1086

Forecasting the adoption of new antiretrovirals (ARVs) for first-line (1L) adults in generic accessible (GA) low- and middle-income countries (LMICs) through 2025

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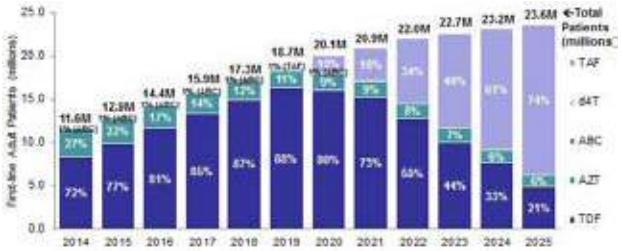
Background: Several new generic ARVs will likely launch in LMICs by 2020, representing a range of clinical and cost advantages. These include low-dose efavirenz (EFV400), and dolutegravir (DTG), and tenofovir alafenamide fumarate (TAF). Further clarity on potential adoption is needed.
Methods: CHAI's annual forecast for currently available drugs in GA LMICs was used as baseline. Uptake curves based on historical analogs were used to model competition between new and current products. Country-specific launch years and uptake curves were chosen based on market intelligence from 12 countries representing ~75% of ART patients in GA LMICs in 2015. The "rest of world" population was modeled as one group, mirroring the least aggressive focal country. Forecast scenarios in 1L include EFV400 and DTG replacing EFV600 and nevirapine (NVP), and TAF replacing TDF.

Results: Assuming launch as a triple in H2 2017, EFV400 is modeled to gain 23% share of the "third-position" drug market by 2020, but then slowly decline to 8% by 2025 in favor of DTG. With launch of singles in H1 2017 and triples in H2 2018, DTG is projected to reach 35% share of that market in 2020, growing to 84% by 2025. Provided a H2 2019 launch, TAF is projected to gain 10% share of the "first-position" drug market by 2020, growing to 74% by 2025.

[Figure 1. Patient growth and share of first-line adult NNRTI/INSTI market in GA LMICs]



[Figure 2. Patient growth and share of first-line adult NRTI market in GA LMICs]

Conclusions: TAF, EFV400, and DTG are expected to disrupt the LMIC ARV market. Coordinated work from governments, funders, and suppliers to match supply and demand is crucial to ensure patients have access to the new drugs.

MOPED1087

Improving anal cancer screening rates among HIV-positive veterans: utilization of an electronic reminder tool

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Background: Anal cancer rate among HIV infected individuals is 174/100,000 person-years versus 2/100,000 person-years for the general population. This project assesses a site-specific intervention used to evaluate anal cancer risk factors, and increase appropriate screening with anal pap smear at a Veterans Affairs Medical Center HIV clinic.
Methods: Electronic medical record data were extracted from encounters for all HIV clinic patients seen from December, 2014 to June, 2016. Baseline anal pap smear rate was below expectation. An HIV inter-professional team including infectious disease and public health physicians developed and implemented an electronic tool for anal cancer risk assessment and screening. Anal pap smear technique was reviewed with all HIV clinic providers. Anal pap smear rate was again analyzed three months post- electronic tool implementation. Electronic reminder tool usage was also evaluated with binary logistic regression.
Results: Data from 403 active HIV clinic patients (97.2% male) were included in pre-implementation analysis. Anal pap smear rate was 1.3/100-patient-years. Three months post-implementation, anal pap smear rate increased more than eight-fold to 10.6/100-patients year. 263 patients were seen during post-implementation period. Of these, 188 (71.5%) had the anal cancer risk assessment performed; 160 of whom (85%) had no anal cancer risk factors.
Risk factors for the remaining 28 included 22 reporting man who has sex with men (MSM), 15 reporting receptive anal intercourse (RAI), 9 with history of ano-genital condyloma, and 1 with a history of abnormal pap smear.
Anal cancer risk assessment varied significantly among providers in multivariate analysis. In adjusted analysis, a significant difference was seen between providers who were inter-professional team members versus those who were not (OR 3.3; 95% CI 1.3-8.3; p-vaue 0.0128). Neither patient socio-demographics nor recent CD4 count were associated with likelihood of provider electronic tool usage.
Conclusions: An electronic tool to screen improves anal cancer risk factor identification and anal pap smear rate. Adjusted analysis suggests that including providers in the development and implementation of electronic medical tools enhances appropriate tool usage.

MOPED1088

Primary Health Care (PHC) clinical placement improve services offered to people living with HIV and TB in Lesotho

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Background: Lesotho has one of the highest burdens of HIV and TB in the world, with 25% of adults living with HIV and 75% of TB patients co-infected with HIV. The country also has severe shortage of human resources for health. Nurses and midwives are the first, and often the only healthcare access point especially for more than 75% Basotho living in rural areas. It is therefore important that their pre-service education equip them with the necessary skills to manage TB and HIV/AIDS. However, nurses and midwives receive most of their clinical education at late stage, when they are assigned to work at hospital level. To bridge this clinical education gap, Jhpiego supported nursing schools to implement PHC clinical placements for students to acquire key skills including those related to TB and HIV care, treatment and support.
Methods: We conducted an assessment to determine the effect of including PHC clinical placements on student competence and confidence. HIV related tasks were identified and tracked from the clinical placements' logbooks for students that were placed in PHC settings during the academic year 2015-2016. Seventeen tasks related to TB and HIV were tracked for nursing and nine tasks for midwifery students. Analysis of data was done using Epi Info 7.
Results: A total of 226 students (179 nursing and 47 midwives) from six training institutions were placed for PHC clinical rotations throughout the country. The following HIV and TB related skills were performed at least once by 92% (N=165) of the nursing students: HIV counseling and testing, WHO HIV clinical staging, and TB screening. Tasks conducted frequently by midwives were: screening for symptoms of TB (91%, N=43) and HIV testing services (83%, N=39).
Conclusions: The evaluation concludes that PHC clinical placements significantly expose students to the range of TB and HIV skills they have to practice and master before their graduation. Pre-service education of nurses and midwives should include varied experiences to ensure students gain skills in all areas relative to deployment. In addition, students during PHC rotations assisted with service delivery in settings where there are inadequate human resources for health.

MOPED1089

Adaptation of effective models to build capacity of health workers to increase disclosure of HIV to infected children, Dar es Salaam Tanzania: a quality improvement project

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Background: Delays or not disclosing a HIV positive status to the infected child can cause depression, suicidal behavior, and refusal of ARVs, and poor school performances if a child finds out accidentally or much later in life. Evidence shows that making decisions to disclose a HIV positive status to the infected child still remains a dilemma for both health care workers and guardians/parents.
In Tanzania, the National guidelines requires child disclosure to be completed by age of 10 years, however, there are still many HIV infected children who do not know their status by the age 10 years thus increasing chances for accidental disclosures and the associated negative consequences.
We report a quality improvement project implemented from 2015-2016 in Tanzania to address this gap.
Methods: In-depth interviews with 20 health workers (HW), chart reviews for 450 HIV infected children and clinic flow observations were done. Based on this information child disclosure training curriculum for HW was modified and piloted among 52 HW for 3 months. Pre and post training tests were done, mean test scores were calculated and compared using student t-tests. Proportion of children supported for disclosure was compared before and after the intervention; chi square test was used to detect differences.

Results: The mean age was 41years (SD=8.9), 85% were females, doctors (21%), nurses (52%), and others (27%). Mean scores of disclosure knowledge among HW were 37% and 79% for pre and post-tests respectively (P <0.0001). Doctors' scored higher compared to other HW (P <0.001).
At baseline only 48 (22%) children had support for disclosure. At the end of 3 months 262 guardians/ parents were supported; 112 (43%) children were fully disclosed of their HIV positive status; 99 (38%) were partially disclosure and only 36 (14%) remained undisclosed, (P <0.0001).
Conclusions: Using simple quality improvement approach to address gaps on disclosure knowledge and practice of HW improved support and disclosure of HIV positive status to the infected children. Scaling up this approach to similar sites and expanding to address other gaps that guardians/parents and children may be facing on disclosure could improve the health of HIV infected children.

MOPED1090

State AIDS Clinical Expert Panel (SACEP): a mechanism to ensure rationale switch and clinical mentoring

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Background: India's ART programme which started in 2004, introduced second line treatment in 2008. With introduction of newer regimens in National programme, a major concern remained ensuring rationale switch as well as regular clinical mentoring of peripheral facilities. SACEP mechanism was established with aim to systemize and institutionalize early identification and treatment for failures and hence prevent emergence of drug resistance.
Methods: Selected Institutes with required capacity were identified and a panel was formed with specialist with varied expertize including program managers. This panel is trained specifically for management of treatment failure, difficult case scenarios and need based clinical mentoring. The panel regularly conducts meetings and examine patient's referred from linked center and assess them for treatment failure. The number of SACEP panels were scaled up as lessons from program implementation were learnt.
Results: SACEP mechanism has scaled from less then 10 in 2008 to 106 centers in 2016. Currently India has 106 centers with functional and trained SACEP covering 528 ART centers. Till May 2015, 27027 PLHIV have been assessed by this panel which were suspected for treatment failure at ART centers, out of which only 16159 (59%) were found eligible for second line and 15097 (93%) were initiated on ART. Though suspected as immunological or clinical failure by ART centers, 31% PLHIV did not meet the criteria for failure or had sub optimal adherence.
The SACEP mechanism prevented undue exposure to second line in significant number of patients and also ensure high uptake of second line among those who required it.
Conclusions: With comparatively limited options for treatment it is essential that judicial use of regimens be ensured. At the same time early detection and switch is crucial for treatment failure cases to improve survival and avoid emergence of drug resistance. SACEP serves an effective mechanism and should be scaled up so that the benefits are maximized and patient travels are minimized.

MOPED1091

Community perspectives on supporting the ethical scale-up HIV services among transgender women in Argentina in the context of treatment as prevention

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Background: Transgender women (TGW) are the most affected group by HIV epidemic in Argentina and continue to have limited access to HIV services. Globally, the TGW community has expressed ethics-related concerns regarding targeted HIV scale-up strategies, the potential impact of discrimination by healthcare providers, and the need to tailor HIV services based on TGWs' needs. This qualitative study aimed to understand TGW's experiences and perspectives on ethical issues related to HIV services.
Methods: This community-based study explored the following ethical issues: autonomy, informed consent, beneficence and equity across all stages of the HIV cascade, as well as knowledge and attitudes regarding the secondary prevention benefit of ART (i.e., treatment as prevention [TasP]). Interviews were conducted by a trained TGW peer research associated (PRA) and were on average 1 hour in duration. After obtaining informed consent, interviews were audio-recorded, transcribed verbatim and analyzed using participatory coding techniques.
Results: Twenty-five TGW living with HIV were interviewed. We found that TGW lacked adequate information about HIV before being tested, and some did not recall an appropriate informed consent process. Regarding treatment, TGW felt disregarded by health workers, who failed to explain even basic HIV concepts (e.g., the meaning of CD4 T cell, viral load, how ART works). Many participants suggested a peer-navigator within healthcare settings would help improving access and comfort with HIV services. None of the TGW interviewed were aware of the potential prevention benefit of ART, but after explaining the TasP concept, all agreed on the potential of this strategy.
Conclusions: Our study offers several community-driven suggestions to support patient rights and the ethical scale-up of HIV services needed to improve treatment outcomes. Given the communication barriers and lack of adequate information received by patients along each step of the HIV cascade, patient education and the use of peer navigators are recommended to help improve TGWs' access and experiences with HIV services. In line with UNAIDS guidelines towards achieving the 90-90-90 targets, specialized training for healthcare workers focused on respectful communication skills, ethics, gender-based stigma and discrimination is an essential step towards achieving comprehensive care for TGW and the 90-90-90 targets.

MOPED1092

Reducing HIV-related stigma in healthcare settings through the development of an evidence-informed guideline

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Background: HIV-related stigma has been an obstacle against the achievement of the global health priority targets by negatively impacting adherence to, and uptake of services. As an effort to improve the practice and service in HIV and related areas, this project sought to develop an evidence-informed guideline to reduce HIV-related stigma.
Methods: We used a mixture of guideline de novo and adaptation technique to develop the guideline drawing upon the Knowledge to Action Model. First, we conducted a systematic literature search for guidelines and systematic reviews. The units of evidence were then critically appraised. A content analyses of the units of evidences was then carried out to generate the list of working recommendations. Summaries of findings table were produced using Gradepro software package. Consensus was finally established through two rounds Delphi panel survey and two consensus meetings. Then, the feasibility and appropriateness of the recommendations were assessed through external panel review and seven in-depth interviews with health professionals and health managers.
Results: The literature search yielded a total of 1532 records. Based our inclusion criteria and the results of critical appraisal, we included 11 records (5 systematic reviews and 6 guidelines). Initially, 26 recommendations were drafted from the content analyses of the documents included. The recommendations were evaluated using a survey of Delphi panel and external experts. Based on these evaluations, 10 recommendations were retained in the final draft. The Delphi panel, external reviewers and the key informants suggested that the guideline be introduced through training, workshops, availing hard copies, through a multidisciplinary team meeting of experts working on care and treatment of clients living with HIV and through HIV mentorship program. It was also suggested that the indicators be integrated into the hospital performance indicators. Participants reported that the guideline would help not only to achieve HIV-related goals, but also other health facility initiatives such as compassionate and respective care (CRC) and clean and safe health facility (CASH).
Conclusions: The current project has keep rigor and applicability of the evidence into current initiatives and practices. The current guideline can be integrated into new and existing health facility initiatives such as CRC and CASH.

MOPED1093

Setting research priorities for the intersection of alcohol and HIV/AIDS in low and middle income countries

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Background: The harmful use of alcohol is a component cause for more than 200 diseases. The association between alcohol consumption, risk taking behavior and a range of infectious diseases such as HIV/AIDS is well established. The prevalence of HIV/AIDS as well as harmful alcohol use in low and middle income countries is high. Alcohol has been identified as a modifiable risk factor in the prevention and treatment of HIV/AIDS. The objective of this paper is to define research priorities for the interaction of alcohol and HIV/AIDS in low and middle income countries.
Methods: The Child Health and Nutrition Research Initiative (CHNRI) priority setting methodology was applied in order to assess research priorities of the interaction of alcohol and HIV/AIDS. A group of 171 global and local experts in the field of alcohol and or HIV/AIDS related research were identified and invited to generate research questions. This resulted in 205 research questions which have been categorized and refined by senior researchers into 48 research questions to be evaluated using five criteria: answerability, effectiveness, feasibility, applicability and impact, as well as equity.
Results: The 48 research questions will be sent out during the course of February 2017 for independent evaluation and scoring. Each competing research question will receive a score on each of the five criteria ranging from 0 to 100%. The scores will represent a shared opinion of the experts independent scoring. Results following scoring of research questions expected May 2017.
Conclusions: Recent research has shown the causal link between alcohol consumption and the incidence of HIV/AIDS including a better understanding of the pathways through which alcohol use affects ARV adherence (and other medications to treat opportunistic infections) and CD4 counts. This paper will present potential research priorities relating to HIV/AIDS prevention, treatment, care and or support. These research priorities have implications for international funding organizations and policy makers.

MOPED1094

Mapping and size estimation of key populations in Kosovo

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Background: This is the first study of this nature in Kosovo. The objective of the research was to conduct population size estimate at granular and national level, distribution, settings and typologies of Female Sex Workers (FSWs), Men who have Sex with Men (MSM) and People Who Inject Drugs (PWID) in order to provide a sound platform to improve service delivery and suggest ways to scale up the response.
Methods: Cross sectional survey in 26 municipalities of Kosovo, Feb-April 2016 through two sequential steps: systematic information-gathering from secondary key informants within each zone and validating each spot through primary key informants. In addition internet sites and mobile apps were mapped for MSM in the similar way. KP size estimates were calculated for each spot and rolled up into municipality estimates then aggregated into national estimates.
Results: Men who have sex with men is the largest key population identified with a total number of 6814 (range 6445 to 7117). MSM congregate at 141 geographical spots across six types of spots including geo and virtual mapping, with an overall national rate of 12 MSM per 1000 adult men. Fewer MSM operate at geographic spots, due to social norms MSM keep their activities hidden and mostly operate through internet and cell phones. An estimated number of FSW was 5037 (4213 to 5860) with national rate of 8.9 FSWs per 1000 adult females. The study identified 790 geographical spot with eight different spot typologies. An estimated 1/5th of the FSWs do not operate on geographical spots, while approximately 10% of FSW in Kosovo use websites to connect with clients. A total of 5819 (4777 to 6860) PWID were calculated with rates of 10.2 PWID per 1000 adult men spread over 847 geographical spots with five spot typologies. No female PWID were identified at geographic spots.
Conclusions: These are size estimates which were calculated through involvement of key populations and finalized with their agreement. The information on the operational structures and networks gathered through this study could be used to develop targeted public health interventions.

MOPED1095

Informing targeted HIV self-testing service delivery in Malawi and Zambia: a multi-country discrete choice experiment

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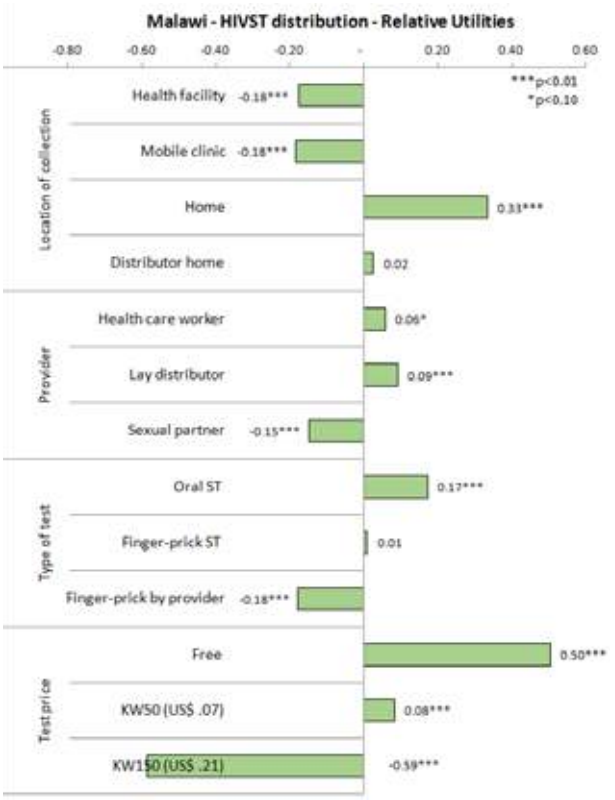
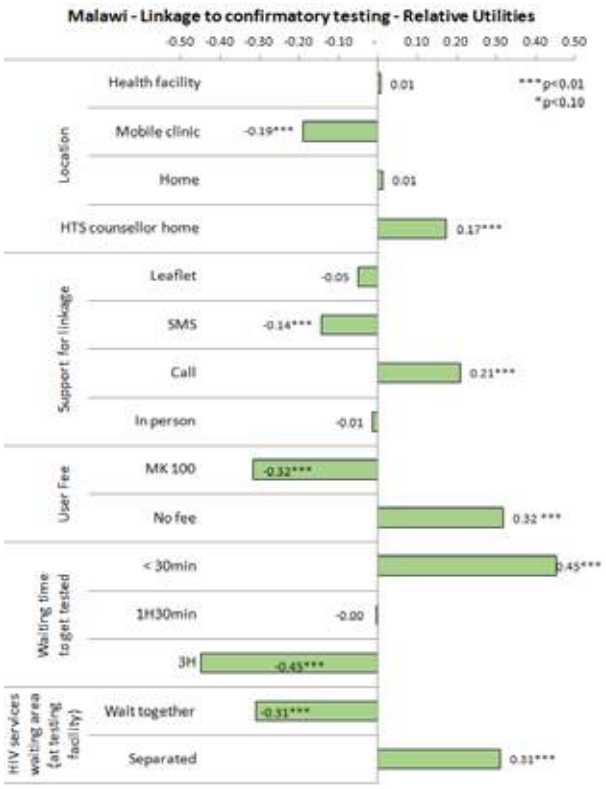
Background: Adult HIV prevalence remains high in Southern Africa. HIV self-testing (HIVST) is a new approach with potential to improve coverage. To inform HIVST implementation, we elicited user preferences to quantify the strength of preferences for alternative HIVST distribution and linkage options using discrete choice experiments (DCEs).
Methods: Four DCEs were implemented within representative household surveys in Malawi and Zambia. Adults (≥16 years) were randomly allocated to DCE on: HIVST distribution or linkage to confirmatory testing and care. We explored preference heterogeneity by country, age, gender and HIV testing experience.
Results: For distribution (n=1116), participants preferred to receive HIVST at home or at a distributor's home to mobile clinics (and drugstores in Zambia only). Oral fluid tests were preferred to provider-administered or self-administered blood-based tests. HIVST distribution via sexual partner was viewed less favourably, especially among men. HIVST price had a strong negative impact on uptake.



[Figure 1 - HIVST distribution DCE - Malawi]

For linkage to care (n=843), phone call was preferred to SMS, a personal visit or no follow-up. The home of the HIV testing services (HTS) provider was preferred for confirmatory testing after a reactive self-test in Malawi only. Facility user fee and waiting time for confirmatory testing were strong disincentives.



[Figure 2 - Linkage to care DCE - Malawi]

Conclusions: The DCE results were consistent across these countries with similar HIV context and suggest community-based distribution and linkage are critical aspects of HIVST delivery. A next step is to explore preferences of populations among whom HTS uptake and linkage to care are known to be low, such as men, youth and key populations.

MOPED1096

Building a telehealth intervention to facilitate engagement in HIV and related health services by transgender women of color in Washington, DC, U.S.A

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Background: Transgender women of color (TWC) are an underserved population who often experience HIV and barriers to healthcare including stigma, violence, and trauma. Few mobile health applications or interventions are customized to serve TWC. The purpose of this study was to conduct qualitative research to inform development of a TWC-specific telehealth intervention to increase access to care and HIV services.
Methods: TWC ≥18 years with at least one structural barrier to care, and clinicians who provide care to TWC (N=22), were recruited through peer referral and professional contacts, respectively. Two focus groups of TWC (both living with HIV and at risk for HIV) were also convened. Semi-structured interviews asked how telehealth can be implemented to serve TWC with structural barriers. Transcripts were analyzed using thematic coding and content analysis and barriers for TWC were categorized into individual, organizational, and environmental levels, sublevels. Upon completion of data collection, several day-long meetings with the study team and key TWC stakeholders were convened to discuss the findings and propose the intervention and instrumentation.
Results: Saturation was reached on barriers to be addressed by the intervention for it to be effective. These included survival and instability, temporal discounting, and prioritizing hormone therapy over health care, HIV prevention or treatment as individual level barriers to services. Type of services needed versus those provided, congruence between providers and patients, pessimism about services and provider, and lack of provider cultural competency were identified as key organizational and environmental barriers. Illustrative text is shown in Table 1.

Theme: Individual-level barriers
Summary: The telehealth intervention must not only focus on HIV-related services but must first address elements of survival which necessarily take priority over prevention. Where providers are unaware of patient prioritization of needs, the intervention can bridge a gap by supporting TWC to communicate needs to providers and/or identify priority care simultaneous with HIV-related care
Sub-Theme: Survival and general instability: "Because that's really the issue when you're homeless to the streets you're in the shelters and sometimes you just forget [to take medications]." "The HIV I'm not too much worried about it's the disease of addiction that I'm worried about that will kill me before anything else."
Sub-Theme: Temporal discounting "Some [transwomen] have a preconceived notion that they have short life spans anyway so what's the point in running to the doctor? Uh and they also fall prey to the ideology of ,I feel fine so nothing can't be wrong.' "
Sub-Theme: Prioritization of HIV care: "Their top needs were, say 1-5, and we're talking about they're homeless. You would be amazed - and we've done this before that you would be amazed to know that you would think that because a person's HIV positive, they got mental health, and they homeless that those would be the top three. But it's not. The top one is hormone therapy. And that's what they seek for, the hormone therapy and number two would be housing, and then the health care would come in there as far as primary medical and all that and then the mental health, the mental health falls to the bucket and we're talking people that's sometimes severe mental health."
Theme: Organizational and environmental-level barriers
Summary: The telehealth intervention must support TWC to identify service locations where providers are culturally-competent and available. Providers can then better address differences in priorities while ensuring all needs are being met, those both patient-identified and health-related. Referral to providers who have experience with transgender communities is needed so that stigma and insensitive practices are avoided.
Sub-Theme: Availability of services: "They [the clinics] schedule people so close to each other right I don't feel as though I get my full medical care because here I am. I'm a transgender who has um, several illness, and even past HIV it's like "you'll have to come back for that," "we'll Schedule an appointment for that." I got chronic bone disease, I got congestive heart failure and it's like everything that I need, when I have to wait 90 days to see my doctor - my appointments are like every 90 days- and when get in with her after 15 minutes it's like okay well your time is up, you know, whatever you don't get within 15 minutes we'll reschedule."
Sub-Theme: Discordance in provider / patient priorities: "Where you're worried about their cholesterol they may be worried about hormone management. Where you're worried about their blood pressure, they may be worried about um, you know um, laser hair removal." [provider]
Sub-Theme: Provider lack of cultural competency / transgender specific knowledge: "Oh, Mr. [name], this is [clinic] calling to remind you of your appointment on so and so so and so, that hurts. I mean I'm a seasoned transgender woman, if I say seasoned because I'm 55 years of age, I'm seasoned so you can imagine if I'm hurt, imagine the kid that's 16, 17, those young transgenders. They can't cope with that. But I manage to because I know how important health care is."

[Illustrative Domains and Quotes]

Conclusions: These data enabled development of a telehealth intervention customized for TWC that was piloted in another study and found to be acceptable, feasible, and associated with improvements in routine, HIV service utilization and intention to seek care. This intervention, developed through a participatory process, offers an innovative solution to improve health outcomes for TWC.

MOPED1097

Availability of antiretroviral medicines and characteristics of stock-outs in public facilities in Kinshasa, Democratic Republic of Congo

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Background: Stock-outs of antiretroviral medicines (ARVs) are early warning indicators for HIV resistance. This study aimed at analyzing the availability of ARVs in public pharmacies and characterizing the stock-outs in Kinshasa, Democratic Republic of Congo.
Methods: Data for this cross-sectional study were collected on a questionnaire during physical visits to antiretroviral treatment (ART) facilities and warehouses in Kinshasa between October and December 2016. All facilities in charge of over 200 patients on ARVs were selected, as well as one facility with 100 to 200 and one with less than 100 patients per health zone. All warehouses in the corresponding health zones were selected. Stock-outs of ARVs were determined by physical verification during the visit and through verification on stock cards for a three-month period before the visit. For those items for which a stock card was available, the stock-

out duration was collected. For four ARVs, stock cards were compared with physical stocks and considered as correct if the difference between the quantities was less than 10%. For all ARVs stock-outs, the pharmacy responsible reported coping mechanisms used.
Results: The survey included 94 facilities, covering 73% of people on ART in Kinshasa. Among facilities visited, there were 107 stock-outs of ARVs counted on day of visit and 92 reported in the preceding three-month period, of which 36% were not recorded on a stock card (33 facilities). Stock cards were correct for less than 75% of facilities and less than 50% of zonal warehouses; 50% of facilities had stock-outs of at least one ARV on visit day, with a median duration of 61 days [IQR = 23-82]. Second line and pediatric ARVs were most frequently out of stock. In 31% of stock-out cases on visit day and in 38% of stock-outs in the previous three months patients had been sent away without ART. In 44% of stock-outs on visit day and 72% of stock-outs in the previous three months, the ARVs were available in the zonal warehouse in the same period.
Conclusions: This study shows that urgent action is needed to reduce stock-outs, focusing on the last mile delivery and on specific ART regimens.

MOPED1098

Motivations of young Thai men who have sex with men to access HIV testing, 2015-2016

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Background: Young men who have sex with men (MSM) are a vulnerable population who need access to regular HIV testing. Since December 2014, Thailand has had policies supporting HIV testing for minors without parental consent. We investigated the reasons adolescents and young adults aged 15-24 years old attended HIV voluntary counseling and testing (VCT) at Silom Community Clinic (SCC), Bangkok, from January 2015- June 2016.
Methods: During the initial VCT visit, we recorded the reasons reported by clients for the visit. For this analysis, we selected 322 cases (161 clients aged 15-17 years and a random selection of 161 clients aged 18-24 years) for medical record extraction and qualitative review. We grouped the primary reason for the visit into two categories: self-motivation (to check or confirm HIV and STI status, to address symptoms of STI or need for treatment, to access post or pre-exposure prophylaxis [PEP/PrEP]) or peer-motivation (suggested or requested by provider, partner, friend, parents, community based-organization, or employer). We used Chi-Square test to evaluate the association between motivation for the visit and client characteristics.
Results: From January 2015-June 2016, 2528 new clients attended VCT; 166 (6.6%) were aged ≤18 years and 585 (23.1%) were aged 18-24 years. Among the 322 clients evaluated, 296 (89%) self-identified as MSM, 222 (67%) were students, and 191 (58%) had never been tested for HIV. Self-motivation was reported by 212 (64%); the primary reason was to check or confirm HIV and STI status (n=107, 33%). Among the 322 clients, 71 (21%) had HIV infection and 54 (16%) had an RPR titer ≥1:8. The motivation for the visit did not differ by age group. Self-motivation was higher among those who had a history of HIV testing (77% versus 54%, p< 0.001), those found with HIV infection (82% versus 59%, p< 0.001) and those found with RPR titer ≥1:8 (80% versus 61%, p=0.008).
Conclusions: Motivations for young Thai MSM attending a clinical setting for testing suggest high self-perceived risk for HIV and STIs. In order to reach more young clients for HIV and syphilis testing, evaluation of motivation for testing can enable outreach efforts.

MOPED1099

Strengthening the "last mile" distribution system of HIV-related commodities in two DRC provinces to improve product availability in support of the 90-90-90 goal

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Background: Organizing an effective supply chain in DRC, where basic infrastructure is lacking, is challenging. Regional distribution centers (CDRs) cannot deliver antiretrovirals (ARVs) and related commodities to end-user facilities/communities. CDRs deliver these products to lower health zones (HZs), which often lack the resources and logistical support to distribute ARVs to end-user facilities. This makes the "last mile" the most challenge for the supply chain in DRC. ARVs languish in HZ stores while end-user facilities/communities experience stock-outs and shortages. A lack of qualified staff to quantify orders and manage inventory and no adequate information system further aggravate the problem.
The US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program implemented an intervention package in DRC's Haut-Katanga and Lualaba provinces, and this study assessed the impact of that intervention by comparing baseline and postintervention data.
Methods: A rapid situation analysis identified factors that contribute to stock-outs. Based on the findings and in collaboration with HZ management teams, the last-mile distribution strategy was modified so that ARVs are delivered directly to end-user facilities/communities. In addition, pharmaceutical management trainings were conducted for health workers involved in ARV management, and stock-management software was updated for use in CDRs to promote efficiency. The impact of this interventional package was assessed.
Results: A total of 184 health workers were trained on stock management for ARVs and other commodities. ARVs are now delivered to the end-user facilities/communities using the modified "last-mile" distribution strategy, and under and overstocking rates have improved significantly: before the intervention, only 30% of facilities had an optimum level of ARV stock compare to 80% after the intervention—an improvement of 167% from December 2015 to September 2016. This resulted in improved patient care and health outcomes.
Conclusions: The study shows how the modified "last-mile" distribution strategy, staff capacity building, and an enhanced information system have improved the availability of and access to ARVs by patients in the Haut-Katanga and Lualaba provinces.
The replication of this intervention in similar environments has the benefit of bringing about results that can positively contribute to the Joint United Nations Programme on HIV/AIDS' 90-90-90 goal.

MOPED1100

Perceptions of introducing HIVST and peer-led delivery model amongst female sex workers in rural and urban districts in Southern Malawi

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Background: Female sex workers (FSWs) are amongst the high-risk groups for HIV in Malawi. HIV prevalence amongst FSWs is estimated at 25% which is higher than in women of the general population (12.9%). Uptake of HIV testing among FSWs remains low. HIV self-testing (HIVST) is being promoted as private and convenient in the general population but there is a gap in knowledge in relation to development of HIVST interventions that can address HIV testing needs amongst FSWs. This study aimed to explore perceived benefits and harms of introducing of HIVST, and peer-led delivery model amongst female sex workers in Malawi.
Methods: A Rapid Ethnographic Assessment (REA) was employed amongst FSWs who are based at home, street or venue, and venue owners in two rural and one urban districts in Southern Malawi for a three-month period. Participant observations were conducted in bars, rest houses and clubs where FSWs hang out or reside for a period of one month in each district. 34 FSWs and 101 venue owners were involved in-depth interviews. Data analysis was done manually using a thematic framework simultaneous with data collection.

Results: FSWs and venue owners believed HIVST could provide convenience and increase opportunity for regular testing for HIV, however, lack of immediate support after HIV positive diagnosis was identified as a potential social harm. Peer-led delivery model was perceived as an option for HIVST delivery to target the hard to reach FSWs but mistrust and storage of HIVST kits were observed as barriers to implementation of this model. FSWs and venue owners, therefore, suggested that health providers and venues owners should be incorporated in the model. FSWs also wanted the model to recognize and accommodate different types of sex work.
Conclusions: The benefits and harms of HIVST were consistent with those that have been established in the general population in Malawi. A multi-pronged approach of HIVST delivery amongst FSWs was perceived as an ideal strategy. REA was an important method of informing HIVST delivery model amongst sex workers in this setting.

MOPED1101

Building Quality Improvement (QI) capacity to achieve the 90:90:90 goals in sub-Saharan Africa: four years' experience with a multi-country QI course

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Background: The global scale-up of HIV programs has been remarkably successful, but reaching the global 90:90:90 targets is challenging for many countries. Although the use of quality improvement (QI) methods can be an effective way to bridge the "know/do gap" between the identification of effective health interventions and their successful implementation, a needs assessment conducted in 2013 indicated that Ministry of Health (MOH) and US government (USG) staff in many PEPFAR focus countries lacked robust QI capacity. In response, ICAP at Columbia University (ICAP) and the US Centers for Disease Control and Prevention (CDC) designed an Introduction to Quality and Quality Improvement course for USG staff and their MOH counterparts.
Methods: Using the "backwards design" approach to curriculum development, we developed a three-phase course emphasizing practical skills, hands-on learning, and south-to-south exchange. Phase 1 is a five-day foundational workshop, in which country teams composed of MOH and USG staff learn key elements of the Model for Improvement and begin to design a QI project aligned with national priorities and the 90:90:90 targets. These activities continue in Phase 2, via webinars and email consultation. In Phase 3, teams present their project proposals for feedback, while continuing to learn QI methods and skills.
Results: 230 participants from 18 countries took the course from 2014-2016. Using Kirkpatrick's four-level evaluation model, we assessed participant Reaction via surveys during and after the course; each year, at least 93% of participants rated the course as very good or excellent and at least 76% agreed that they had achieved all course learning objectives. Learning was assessed via pre- and post-tests, which consistently showed improvement. Behavior and Results were assessed via surveys given to alumni at 6, 19, and 27 months following the course; although response rates have been low, respondents indicate that they have continued to use the skills they learned during the course to further QI activities within PEPFAR programs.
Conclusions: The Introduction to Quality and QI course has served as PEPFAR's flagship QI course, building QI competencies and fostering a south-to-south community of practice designed to improve the coverage, quality and impact of HIV services for sustainable epidemic control.

MOPED1102

Strategies to improve Kaposi sarcoma outcomes in Zimbabwe: a community-based clinical trial of a training intervention for improved primary care of AIDS-KS (the SIKO study)

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Background: Zimbabwe is a predominantly rural country with approximately 80% of the population accessing medical care through a tiered system of local health centres. Over the past 5 years, antiretroviral therapy has been decentralized to primary care clinics staffed by generalist doctors and nurses. Little is known about how to improve Kaposi's sarcoma (KS) treatment outcomes in these settings.
Methods: A package of interventions designed to improve KS care in primary care settings by early detection and improved clinical management was evaluated in a randomized step-wedge cluster design. The package included a standardized clinical evaluation tool, palliative care integration, standardized KS treatment, and improved consultative services for rural clinicians. The interventions were implemented at 8 primary care sites (4 rural/4 urban) in Zimbabwe. All persons with suspected KS were eligible. Training modules incorporating KS recognition, particularly early KS, diagnosis and treatment, symptom control and palliative care were delivered during the intervention period at each site by a team of trained nurses and doctors experienced in KS patient care. The primary endpoint was the proportion with early stage (T0) KS pre- and post-intervention.
Results: Between February 2013 and January 2016, 1102 subjects (96% HIV+) with suspected KS were enrolled: 47%, 20% and 33% had incident, prevalent and false KS diagnoses, respectively, with 60%, 62% and 44% male; and 34%, 27% and 25% rural. For incident KS, median age (IQR) was 37 (32, 43). Incident KS One-year mortality (95% CI) was 37% (32%, 42%), over twice the previously observed rate (16%) in the university-affiliated tertiary referral KS clinic. Adjusted odds (aOR) of early diagnosis among incident cases, within clinic, before and after the SIKO intervention, were 1.48 (0.63, 3.49; P=0.37); for false diagnosis aOR was 1.83 (1.16, 2.88; P=0.0096). Adjusted hazard ratio for time to death was 1.36 (0.85, 2.20; P=0.20).
Conclusions: The SIKO package of interventions increased false positive KS diagnosis rate with no significant change in the proportion of early KS diagnosis. KS mortality in decentralized primary care clinics in Zimbabwe was higher than expected and was not affected by the SIKO intervention.

MOPED1103

Extending perinatal care for mothers living with HIV (MLH) and their children through paraprofessional home visiting: RCT results over 5 years

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Background: Uptake is high of ARV in pregnancy, but MLH do not maintain the multiple tasks required to maintain their own health and that of their children over time. Extending results from 18 months post-birth, the impact of perinatal home visiting to all community mothers and MLH was evaluated over 60 months post-birth.
Methods: In 2009-2010, a RCT was mounted in 24 neighbourhoods of Cape Town townships. Matched neighbourhoods were randomized to standard clinic care (n=596 mothers; 12 neighbourhoods) or to receiving perinatal home visiting over time (n=644 mothers, 12 neighbourhoods), with visits declining substantially at 6 months post-birth. Maternal and child outcomes, including MLH, were monitored during pregnancy, at 2 weeks post-birth, 6, 18, 36, and 60 months post birth, with follow-up rates from 83%-96%. The 354 MLH and their children (5.6% positive) were also monitored over time. Over 5 years, 9.9% of mother-child dyads had one death.
Results: All mothers, including MLH, who received home visiting, were significantly less likely to be depressed at 36 months and to use alcohol or have problematic drinking at 60 months. Children of MLH were more likely to be shorter at 36 months and underweight at 60 months than children of uninfected mothers

- however, there was no intervention difference. While less than a third of MLH had been consistently linked to care from 6 months to 36 months, 87% of MLH were linked to care by 60 months; 79% were receiving ARV and 88% were adherent to ARV - similar across conditions. Children were similar in cognitive, behavioral, and social behaviors between intervention and control. However, children of MLH and HIV uninfected mothers scored almost 3 points lower on the Kaufman assessment at 60 months.
Conclusions: Perinatal visits must be extended over time in low and middle-income countries in order to sustain substantial gains observed early. MLH do not sustain consistent HIV care over time. Yet, benefits remain both to all community mothers, MLH, and to their children.

MOPED1104

A quantitative study of workforce patterns and the PMTCT Option B cascade in Côte d'Ivoire

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Background: Côte d'Ivoire continues to face regionally high rates of mother-to-child transmission of HIV despite implementation of a national program to prevent transmission (PMTCT). The aim of this study was to assess the impact of workforce factors (density, distribution and training of physicians, midwives, nurses, pharmacists, community health workers and other staff) on PMTCT program success.
Methods: Primary and secondary data were collected from a nationally representative sample of 50 PMTCT sites between June 2015 and February 2016. Assessment of the association between workforce factors and PMTCT outcomes (testing, treatment and retention) were assessed using multivariate logistic regression with generalized estimating equations.
Results: Statistically significant positive associations were found between HIV testing and the following workforce densities (odds ratios presented are for a difference of 1 healthcare worker per 1000 new antenatal care patients): total healthcare worker density (OR = 1.01, 95% CI 1.01-1.01), physician density (OR = 1.03, 95% CI 1.01-1.05), density of trained staff (OR = 1.09, 95% CI 1.08-1.10) and midwife density (OR = 1.10, 95% CI 1.08-1.12). Negative associations were found between pharmacist density and testing and treatment (OR = 0.91 [0.86-0.96] and 0.83 [0.69-0.99] respectively) and between community health worker density and testing (OR = 0.96, 95% CI 0.95-0.97). No associations were found between workforce indicators and retention in care.
Conclusions: While this study showed some statistically significant associations between workforce patterns and PMTCT service delivery, the effect size of these associations was small. For an average site, the largest positive association (OR of 1.10) equates to increased testing for only 7.7 patients per year per additional midwife per 1000 patients. The study's complex results suggest that even in settings with a limited healthcare workforce, a greater density of healthcare workers does not necessarily correlate with better PMTCT outcomes. This highlights the need for additional research aimed at understanding more complex workforce factors, as well as non-workforce factors, impact PMTCT success.

MOPED1105

Lay provider HIV testing: a promising strategy to accelerate 90-90-90 in Vietnam

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Background: The HIV epidemic in Vietnam is concentrated among key populations (KP), including people who inject drugs (PWID), men who have sex with men (MSM), and female sex workers (FSW). Although conventional testing services are available at all levels, annual KP uptake of HIV testing is low (~30%). In 2015 Vietnam Ministry of Health (MOH) adopted the WHO recommended lay provider HIV testing strategy to accelerate the committed UN 90-90-90 targets. USAID/PATH Healthy Markets project partnered with the MOH to pilot community-based HIV testing through KP-led community-based organizations (CBO) and village health worker networks (VHW) in four provinces (Ho Chi Minh City, Hanoi, Nghe An and Dien Bien).
Methods: Operations research was designed to evaluate the acceptability, feasibility, and effectiveness of the models for increasing HIV testing, diagnosis and treatment among KP. We observed HIV testing using rapid diagnostic test kit (Determine HIV-1/2 Antibody) performed by 153 lay providers (78 CBO and 75 VHW) through two rounds (3 clients per person each), interviewed with 918 clients before and after testing, and reviewed routine monitoring data on HIV testing from December 2015 to December 2016.
Results: Lay providers identified a higher proportion of positive cases (5% overall and 6.9% in urban areas, with false positive of 0.9%) than conventional HIV testing (0.9% according to national data). Among confirmed HIV cases, 93% were enrolled in treatment. Lay providers successfully reached and tested KP and sex partners (SP) who had never been tested for HIV before (72%), or tested infrequently (>12 months): 49%. Reasons for choosing lay providers for HIV testing included confidentiality (66%), receiving a rapid result (51%), and convenience (40%). Clients were highly satisfied with HIV testing by lay providers (91%), and would recommend this testing option to others (96%).
Conclusions: This study confirms that lay providers in Vietnam are capable of providing quality and satisfactory HIV testing services. Lay provider HIV testing is an effective approach to reach KP and their sex partners who otherwise would not test, or not as frequently. The MOH is supporting for scaling up this promising approach to reach 90-90-90 in Vietnam.

MOPED1106

Innovating to improve health worker continuous professional development (CPD): challenges in evaluating utilisation of interactive online resources in Uganda

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Background: Capacity building of health workers (HW) in Africa has traditionally relied on face-to-face training which is labor intensive and takes HW away from their workplaces for extended periods. E-Learning however is gaining popularity as an alternative means of training HWs in resource limited-settings, since it reaches more HW, is cheaper and causes less disruption of work. The Infectious Diseases Institute (IDI) was accredited by the Ministry of health to provide CPD for HW. Since 2002, IDI offered short classroom courses to over 23,680 health workers across 39 countries. We are now innovating with cost effective models to increase our reach and impact.
Methods: IDI launched the Ugandan Academy for Health Innovation and Impact program in 2015 aimed at improving outcomes in HIV and TB care through design and implementation of innovative projects. Through this, we established an open access clinical training website for development of HW capacity. The website is based on Moodle; a free online learning management system. The website presents real life patient complex cases from the IDI HIV clinic. These are converted into interactive presentations. Consent is sought from the patients but no identifying features are used. IDI is using Google analytics to track the number of HW who have accessed the website since its launch in May 2016.
Results: 2,638 sessions were downloaded and 16,984 had viewed the e-Learning page from 10 countries. User feedback requested a mobile phone based platform as well as computer interface and also certification for CPD.
Conclusions: Lessons-learnt and way forward: Google analytics captures internet protocol (IP) addresses unique to each computer. However this doesn't capture individual users, and in some health centers, particularly rural, many HW use the same computer. We would also like to evaluate the impact of the training on practice of HW. We are establishing user accounts to track individual use to enable award of CPD points and e-certificates upon completion following a knowledge assessment. We aim to assess change in practice with questionnaires 6 months after completion of the online sessions. IDI aims to be the first training institute to provide online CPD to HW in Uganda.

MOPED1108

Development and assessment of a tablet-based clinical training approach for nurses providing Option B+ services in Mozambique

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Background: Introduction of Option B+, which has rapidly expanded in many sub-Saharan countries with high HIV burden and limited resources, including Mozambique, requires targeted strengthening of nurse clinical competencies to ensure adequate care and management of HIV-infected pregnant women. A tablet-based training approach building core clinical competencies of nurses introducing Option B+ in pregnancy was designed and evaluated to strengthen routine supervision by nurse managers.
Methods: A standardized assessment tool measured nurse competency at baseline, endline and post 3 months across 30 health facilities (20 intervention, 10 control) to 90 nurses by six district nursing supervisors. Focus group discussions assessing acceptability were conducted at 3 clinics following implementation.
Results: From baseline to endline, nurses who received the intervention experienced a three to four-fold greater improvement in Option B+ knowledge and skills assessment scores, compared to nurses at control facilities (10.2% vs 2.9%; p<0.014). In subgroup analyses, nurse managers at intervention facilities had on average a 14.5% improvement in assessment scores, while no change was noted in nurse managers at control facilities (p<0.025). During implementation, the tablet-based training intervention was integrated into routine supervision, and was perceived by MCH nurses to be easy to use, contextually appropriate, engaging, and with level-appropriate content.
Conclusions: Results demonstrated the feasibility and acceptability of this tablet-based training approach in resource limited settings, and significant improvements in nurses' knowledge and skills to implement Option B+. The study demonstrated that instructional videos and accompanying assessments can be built into tablet-based modules, through Open Data Kit (ODK) (https://opendatakit.org/), to capture results centrally and be rapidly used to identify low-performing facilities. Ensuring maternal and child health nurses are adequately trained and supported to provide quality care is a priority to maximize the potential impact of this approach.

MOPED1109

Perceived cost advantages and disadvantages of purchasing HIV self-testing kits (HIVST) among Tanzanian men: a qualitative analysis to inform demand generation

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Background: Impoverished men have lower rates of HIV testing and higher unknown HIV-positive status than women. Low socio-economic status can hinder demand generation of testing services. Yet, few studies have investigated men's financial views regarding the benefits or drawbacks of HIVST. Economic theory suggests that individuals will obtain an HIV test if anticipated benefits are greater than anticipated costs. Therefore, we examined how poor men's perceptions of the cost advantages and disadvantages of HIVST may influence demand.
Methods: Twenty-three interviews were conducted to qualitatively assess perceived costs saved and incurred from use of HIVST kits in infrequently- or never-tested Tanzanian men. All men were shown an HIVST kit and video. They were then asked about the costs associated with provider-led HIV testing, financial benefits and concerns of HIVST, and willingness to pay for HIVST. Data were coded and analyzed using inductive content analyses. We then grouped codes into perceived cost advantages and disadvantages and tabulated the range of prices men were willing to pay for a self-test kit.
Results: Perceived cost advantages of HIVST were avoidance of spending money to test in facilities, omission of follow-up fees, affordability relative to private clinics, and increased time for earning income and other activities. Men also discussed the imbalance of the financial benefit of accessing free, public HIV testing with the resources spent for transport, purchasing meals away from home, and long wait lines. Perceived cost disadvantages of HIVST were prohibitive kit costs, required prior savings to purchase kits, expenditures relating to death, and preferences for free provider-performed testing. Men were also concerned about the psychological costs of inaccurate results. HIVST demand was moderate with varied willingness to pay.
Conclusions: Men's decisions to self-test for HIV takes into account expected financial gains and losses. Demand generation for HIVST among men should consider use of low fees or free HIVST, while emphasizing potential savings from reduced travel, clinical costs, or time way from work. Efforts are also needed to address anticipated emotional costs of HIVST, such as anxiety from kit errors, purchasing "death", or testing alone, which for some men was a substantial barrier.

MOPED1110

Innovative, targeted, evidence-based demand creation approaches for voluntary medical male circumcision (VMMC): a 3-month pilot in Zambia

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Background: Although Zambia has seen an increase in VMMC since 2009, targets have not been achieved hence need for innovative demand creation methodologies including use of market research and human centred design (HCD). These methods should target the most impactful ages (15-29 years) and shorten the journey to circumcision. Utilizing findings from a 2014 journey mapping study conducted in Zambia, Society for Family Health (SFH) employed HCD strategies to analyse and translate findings into demand creation solutions. The process prioritized four of seven identified segments of men, created robust archetypes, and uncovered insights used to inform tailored messages and prototypes for new VMMC demand creation tools to be piloted for effectiveness, efficiency and usability.
Methods: A non-randomized implementation pilot was conducted in eight SFH supported public facilities in four districts. Twenty-three Community Health Workers (CHWs) (13 male, 10 female) and eight supervising CHWs were selected and trained on new messaging and tools. A similar number of CHWs continued to utilize standard demand creation methods in the same facilities.
CHWs conducted door-to-door mobilization activities using new tools and potential clients were classified into a specific segment, exposed to tailored messaging and tools, and recorded in the daily activity report (DAR). Clients interested in getting

circumcised were scheduled for an appointment and provided with a referral card. Clients who missed appointments were followed-up a maximum of three times by the CHW.

Results: Overall conversion rate (circumcisions/appointments) was 43% (1,461/3,421) during pilot compared to 35% (884/2,532) for standard methods. Conversion rate was higher amongst priority segments at 45% compared to 39% in non-priority segments. 68% of those circumcised were aged 15-29 years in both methods. On average, men took 42 days from first contact to circumcision. Younger CHWs were more effective whilst female CHWs' conversion rate was 47% compared to 38% for male CHWs.

Conclusions: The use of segmentation to provide tailored messages and tools is as effective as established demand creation methods and has potential to improve and revolutionize approaches to demand creation for VMMC. Emphasis should be placed on mapping the cascade to VMMC and shortening a man's journey to circumcision.

MOPED1111

Optimising uptake of HIV testing among young people: a mixed-methods study on HIV self-testing preferences in Zimbabwe and Malawi

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Background: HIV self-testing (HIVST) is a promising method for reaching young people underserved by standard HIV testing and unaware of their status. This study uses mixed methods to examine young people's preferences for HIVST distribution and inform scale-up of youth-targeted HIVST services in southern Africa.

Methods: This study is nested within large-scale distribution of oral HIVST kits in Malawi and Zimbabwe (STAR). Twelve focus groups (n=107) and 15 interviews were undertaken with purposively sampled youth (16 to 25 years) exposed to distribution. Discrete choice experiments (DCE) on HIVST delivery were administered to randomly sampled household members. Multinomial logit models were used to identify preference strength and heterogeneity among young people in Malawi (n=245) and Zimbabwe (n=96).

Results: There was strong concordance between the two methods and countries. HIVST was highly accepted by young people, particularly young men. Self-testing was seen to address youth-specific barriers around conventional HIV testing, including stigma of testing outside of marriage. Distribution of HIVST kits at home was the biggest driver of demand and valued as time and cost-saving. Alternative locations, such as mobile clinics and health facilities, were disliked. Compared to adults 26 years and older, batch distribution to the household was less preferred by young people, who reported decreased decision-making autonomy when offered in the presence of family members. Lay distributors were valued over HTC counsellors and intimate partners as HIVST providers, with qualitative participants also liking peer distribution.

Free tests were important to young people, with small fees ($0.07-$1) acting as disincentives. First-time testers expressed a desire for support before and after testing, including by helpline or in person. The qualitative findings were mixed in terms of preferred testing methods, though DCE respondents highly valued oral fluid-based HIVST. Untested young people had similar utilities for oral and blood-based HIVST, reflecting indifference for sample collection method and overall value for self-testing.

Conclusions: HIVST appealed to young people whom might not have otherwise tested. Young people are not a homogenous group and our findings supported proactive and low-cost distribution by lay providers, with more support needed for first-time testers. Concordance of results by method will also be presented.

MOPED1112

Leveraging local intelligence: use of Volunteer Community Advocates (VCAs) leads to a five-fold increase in number of VMMCs in routine services in Tanzania

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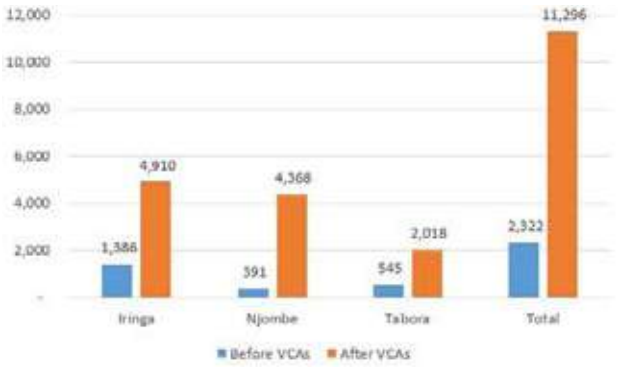
Background: Tanzania has been implementing VMMC services for HIV prevention since 2009. With PEPFAR and USAID support, AIDSFree through Jhpiego has supported the Ministry of Health to implement VMMC services in 27 routine sites providing service in the Iringa, Njombe, and Tabora regions. A variety of strategies have been employed to sensitize and recruit clients. Between October 2015 and March 2016, demand creation was led by a team of non-local Community Health Promoters (CHPs). Based on formative research findings, in April 2016 CHPs were replaced by Volunteer Community Advocates (VCAs) who are early VMMC adopters and live within the catchment area of the sites offering VMMC services. VCAs receive a 2-day training on VMMC and ongoing on-the-job support.

Methods: We conducted a retrospective review of the Jhpiego VMMC database, comparing the number of VMMCs conducted during routine services before VCAs were introduced (October 2015-March 2016) and after (April-September 2016). No new routine VMMC sites were introduced during this time period. Statistical tests were used to analyze significance of the differences observed.

Results: A total of 13,618 clients were circumcised in the 27 static sites during the review period (October 2015-September 2016). Overall, there was a five-fold increase in VMMCs conducted across all static sites compared to the previous 6 months from 2,322 to 11,296 VMMCs (Fig 1). The observed increase in the number of clients seen in the routine VMMC sites before and after VCAs were introduced was statistically significant (chi-square = 404.45, p-value <0.00001).



[Fig. 1: Impact of VCAs on Number of VMMCs]

Conclusions: The introduction of VCAs led to a significant increase of clients seen in VMMC routine sites across the three supported regions within the six month period. This demonstrates the important role that volunteers from the communities they serve play in educating and advocating for services and translating this to new VMMC clients.

MOPED1113

Spending to alleviate demand constraints lowers unit costs: a cost-effectiveness analysis of voluntary medical male circumcision to prevent HIV in Tanzania

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Background: Although voluntary medical male circumcision (VMMC) reduces HIV acquisition and is widely considered cost effective, demand side constraints result in sub-optimal efficiency in service provision: campaign-style VMMC programmes have site-specific fixed costs, and uptake among men with the highest HIV incidence (20-34 years), is low. A cluster randomised controlled trial was conducted to assess the effectiveness of a locally-adapted demand creation intervention in increasing uptake of campaign-delivered VMMC among men aged 20-34 in Tabora and Njombe regions. The intervention included messages targeting older men, use of peer promoters, age group-specific waiting areas, and information sessions for female partners.
Methods: Cost data were collected on surgical, demand-creation and supervisory activities across all clusters in both trial arms. The DMPPT 2.1 was used to estimate the number of HIV infections averted and related cost savings given the number of VMMCs per cluster. DALYs were calculated and used to estimate incremental cost-effectiveness ratios (ICERs).
Results: The intervention resulted in large increases in VMMC uptake. Client load varied across clusters and was higher in the intervention arms (480-1187 in Tabora; 218-500 in Njombe) than in the control arms (272-951 and 102-268, respectively). Despite the additional costs of tailored demand creation, demand increased more than proportionally: mean costs per VMMC in the intervention arms were $61 in Tabora and $130 in Njombe, and in the control arm $70 and $193, respectively. Sites with higher uptake had lower unit costs, suggesting economies of scale. More HIV infections were averted in Njombe (likely due to higher HIV incidence), in both control and intervention arms (102 and 164, respectively) than in Tabora (67 and 123, respectively). Once averted treatment costs were considered, greater cost-savings were observed in Njombe. Consequently, the intervention was more cost-effective in Njombe (-$427/DALY) than in Tabora (-$331/DALY).
Conclusions: The number of clients in Tabora was 2.5 times higher, leading to lower unit costs. The achievement of cost savings attributable to spending more to address local preferences successfully reduced demand constraints. However, in the case of Njombe, it was still worth spending more on increasing demand among hard-to-reach men due to their higher HIV acquisition risk.

MOPED1114

Preferences for models of HIV self-test kit distribution: results from a qualitative study and choice experiment in a rural Zimbabwean community

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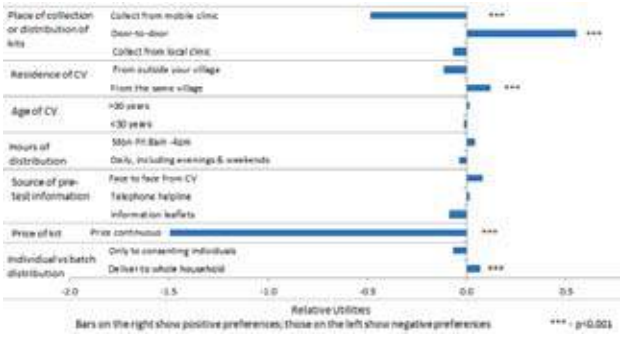
Background: New HIV testing models are needed to reach the UN's 90-90-90 testing target. HIV self-testing (HIVST) has potential to improve testing uptake, but optimal models of distribution are uncertain. We conducted a qualitative study and discrete choice experiment (DCE) to explore preferences for models of HIVST kit distribution in rural Zimbabwe.
Methods: Following door-to-door distribution of HIVST kits by community volunteers (CV) in Mazowe district, focus group discussions (FGDs) were held to explore views on distribution models. FGDs were analysed thematically and used to identify distribution attributes that might be important for HIVST scale-up. After piloting the pictorial and paper-based questionnaire, a DCE was used to estimate relative preferences for each attribute. Analysis used multinomial logit modelling.
Results: Between Apr-May 2016, we ran 8 gender-specific FGDs (n=81, 39 female). Participants favoured household HIVST distribution by CV because it reduced travel and time costs. Distribution by nurses or community health workers was viewed less favourably because they were thought to be too busy. In contrast to other testing models, CVs from the same village were preferred, being considered more likely to relate well to locals and able to support all households. Participants valued the confidentiality that is offered by HIVST. Most emphasized kits should not be sold because people would not afford them.
296 participants were surveyed in the DCE. The figure shows presented attributes and their relative preference.



[Relative Utilities for HIVST Program Characteristics]

An optimum HIVST model is one where local CVs distribute kits door-to-door to whole households. Participants were strongly against selling of kits; even a small increase in price could offset some of the highly favoured attributes.
Conclusions: Door-to-door HIVST kit distribution is acceptable in rural communities. The mixed methods study allowed us to anticipate which service-delivery attributes were important and the reasons thereof. The relative strength of preferences can also guide planning and implementation priorities.

MOPED1115

Multi-disease community health campaigns: responding to community health priorities and reducing stigma for HIV testing in the SEARCH Study

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Background: Achieving the first 90-90-90 goal of >90% HIV-infected persons tested requires innovative approaches that address known barriers to HIV testing. The SEARCH trial (NCT:1864603) reached 97% testing coverage of stable adult residents after two years with an approach that aimed to incentivize participation by offering multi-disease services with HIV testing, and reduce stigma associated with accessing HIV testing alone, at community health campaigns (CHC). We sought to assess demand for non-HIV services and evaluative community attitudes towards this approach.
Methods: We advertised and offered multi-disease services (Table), at 2-week CHCs that provided HIV testing in Uganda and Kenya annually. We used finger-prick for testing requiring blood draws. New diagnoses made were either treated on-site (e.g. malaria), or linked to care (often same-day; e.g. TB). We shared our findings with the Ministries of Health. We measured demand via service uptake by residents at three annual CHCs. We assessed attitudes via in-depth interviews and focus-group discussions with CHC participants and community leaders.
Results: Overall, 120,312 (76%) of 159,179 stable residents attended a CHC at least once over three annual campaigns. Among adults, 84% were screened for hypertension and 79% for diabetes. In eastern Uganda, 89% of adults underwent TB screening. Fever/malaria screening was performed in 84% of adults, and 92% of children, and 22% of adults accessed urgent care services. With high CHC participation, local organizations partnered with SEARCH to provide medical male circumcision, cervical cancer screening, family planning and antenatal care, when available. Qualitative data showed CHC participants were drawn in by non-HIV services, and CHCs attracted individuals who reported prior reluctance to access HIV testing, and provided concealment for those seeking HIV testing.

Service	Method	Population accessing services	Demand: population uptake (%)	Demand: Population uptake % women vs. % men
Hypertension screening	Blood pressure once; with repeated measures x 2 if elevated	≥18 year olds	56911/68118 (84%)	88% vs. 78%
Diabetes screening	Random blood glucose	≥15 year olds	61,258/77,784 (79%)	83% vs. 74%
Malaria screening	If fever present, offer rapid diagnostic testing	All residents	≥15: 65,475/77,784 (84%) <15: 74,864/81,395 (92%)	≥15: 88% vs. 79%
TB screening	If cough >2 weeks, offer sputum fluorescence microscopy x 2	≥15 year olds; Eastern Uganda region only	22,269/25,126 (89%)	90% vs. 86%
Urgent Care	On-site clinician to address urgent complaints (e.g. skin complaints, musculoskeletal pain, etc.)	All residents	17,058/77,784 (22%)	25% vs. 18%
Men's Health Tent	Group discussion & individual counseling for men's health complaints	≥15 year old men, Eastern Uganda & Kenya regions only	7,274/21,251 (34%)	N/A

[Multi-disease services & population uptake at CHCs]

Conclusions: Demand was high for integration of multi-disease services into population-wide HIV testing, and inclusion of these services may have reduced stigma associated with HIV testing. A multi-disease approach to HIV testing is one way to achieve the 90% testing goal.

MOPED1116

Knowns and unknowns: a review and mapping of existing, ongoing and planned research on adolescent girls and young women in sub-Saharan Africa as end users of HIV prevention products

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Background: Adolescent girls and young women (AGYW) 15-24 account for 20 percent of all new HIV infections globally.[1] To address the disproportionate number of new infections in this population, a variety of HIV prevention products are needed and need to be introduced to the market in a manner that supports use. Studies have shown oral pre-exposure prophylaxis (PrEP) is effective in preventing HIV; however, uptake and adherence pose potential limitations to use among AGYW. The HIV Prevention Market Manager analyzed completed, ongoing and planned work on AGYW in sub-Saharan Africa as the end users of HIV prevention products to assist prevention product introduction and marketing efforts. [1] UNAIDS, 2015
Methods: Focusing on AGYW ages 15-28 in sub-Saharan Africa three types of inquiry were used: 1) systematic review of existing literature, 2) landscape mapping of ongoing and planned research from 2010 to 2016 and 3) an analysis of the review and mapping. The review utilized key terms to screen relevant articles and the Ability-Motivation-Opportunity framework, combined with marketing's four Ps—product, price, place, promotion—as the inquiry framework. The mapping, informed by structured interviews with stakeholders and surveys, tracked research by study type, location, study size and intent. The analysis looked at stages of product adoption and mapped information against each stage.
Results: The mapping identified 34 organizations working on 53 end-user projects primarily in South Africa, Kenya and Zimbabwe, with acceptability and adherence the primary study areas and oral PrEP the primary product under study. The review of almost 80 articles identified factors which may influence AGYW's acceptance, uptake and adherence to prevention products. Among other findings, literature shows cultural norms against adolescents' sexual activity limit AGYW's ability to negotiate HIV prevention. The analysis identified key gaps in research, including understanding an AGYW's journey from awareness to the decision to use, and to adhere, to a prevention product.
Conclusions: While this is a crowded space, there are significant gaps in in research towards understanding how AGYW's think, act and are influenced along the prevention journey. The review, mapping and analysis provide a solid foundation for future research, marketing or intervention design.

MOPED1117

Rapid scale-up of PMTCT program through public-private partnerships in 14 states/ UTs in India

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Background: Twenty percent of 27 million deliveries (annual) take place in the private sector, yet the coverage of PMTCT services is limited. The National AIDS Control Organization (NACO), in partnership with GFATM and SAATHII, initiated Project Svetana to increase HIV counseling and testing of pregnant women in the private sector, and to link those diagnosed positive to care and treatment services.
Methods: The project was rolled out in 231 districts from 14 states that contribute to 90% of the estimated positive pregnant women in the private sector. The project employed a public-private partnership strategy, whereby the government, private facilities, and SAATHII shared resources and responsibilities. Private facilities were engaged through implementation (PPP) or referral site (RS) models. PPP sites entered into formal agreements, provided PMTCT services and maintained and shared data, whereas referral sites referred identified positive pregnant women for care and treatment services and shared data. District-level Interventions included: (i) compilation of lists of facilities; (ii) facility assessment of infrastructure, human resources and client load; (iii) sensitization of private providers in partnership with professional medical associations (PMAs); (iv) enrollment and sensitization of consenting sites; and (v) technical assistance for establishing PMTCT services and reporting.
Results: Between October 2015 and December 2016, 23,739 facilities were mapped, 54% of these were enrolled (2791 as PPP and 9946 as referral sites) and 63% were functional. In addition, 4389 private providers were oriented on the national guidelines. The program reached 2.16 million pregnant women with testing services, accounting for 46% of estimated deliveries in the private sector. Among these 1,481 were positive, 91% (1352) received treatment, 147 opted for medical termination of pregnancy, 891 delivered and 854 were live births. 68% (554) of the 820 eligible infants underwent early infant diagnosis (six months) and 4 found to be positive (1%).
Conclusions: Strong government ownership, Public-Private Partnership models and technical assistance by interface agency enabled rapid scale-up. Diverse models of intervention facilitated engagement of over 50% of mapped facilities. Intensified involvement of PMAs and policy changes requiring mandatory reporting from the private sector are critical for elimination of pediatric HIV.

Integration of HIV Services with Other Programmes

MOPED1118

Uptake of HIV testing and counselling (HTC) among acutely malnourished children in rural and urban Blantyre, Southern Malawi: a retrospective comparative review

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Background: Human Immunodeficiency Virus (HIV) is understood to contribute substantially to the increased burden of malnutrition-related morbidity and mortality in sub Saharan Africa. Fittingly, integration of HTC in Community Management of Acute Malnutrition (CMAM) services is envisioned to facilitate prompt identification and referral into care.
However, there is limited evidence to establish HTC uptake and location-specific variations which may exist in CMAM programmes. We aimed at assessing the uptake of HTC in CMAM programme in Blantyre and compare these findings in rural and urban settings.
Methods: We conducted a retrospective review of CMAM monthly reports for 2014 and 2015 from 6 urban and 12 rural health facilities. The population comprised acutely malnourished children aged 6 months to 12 years. A pre-tested data abstraction tool was used to extract data on location, new admissions, HTC referral, and HIV sero status. We used descriptive statistics, univariate and bivariate analysis to assess the associations between HTC referral/testing and covariables, expressed as odds ratio with 95% CI.

Results: Of the total 4527 children newly admitted/enrolled in CMAM programme, 2411 (53.5%) were referred for HTC. HIV test was done in 913 (92%) and 1346 (95%) children at urban and rural health facilities respectively. HIV prevalence was 23.7% and 17.3%, respectively, corresponding with a 49% (95%CI 21-83%) higher level in urban relative to rural Blantyre. Level of HTC referral did not differ between rural and urban facilities (OR=1.09, 95%CI 0.97-1.23). Rural facilities were 68% more likely to test referred children compared to urban facilities (OR=1.68, 95%CI 1.21-2.34).
Conclusions: While HTC referral rates were similar across settings, urban facilities were less likely to test referred children for HIV and had higher HIV prevalence, compared to rural facilities. Interventions to increase CMAM HTC uptake should contextualise location. Future research ought to target factors leading to location-specific variations in HIV testing and prevalence. Use of retrospective secondary data was a limitation in terms of level of analysis since CMAM reporting is grouped and not per child.

MOPED1119

Successful results from TB/HIV integrated pilot model leading to national TB/HIV integration initiatives in Vietnam

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Background: Tuberculosis (TB) is a leading cause of death among people living with HIV/AIDS (PLHIV), including in Vietnam where fragmented TB and HIV systems enable high attrition, mortality, and service inefficiencies. In July 2014, the USAID SMART TA project, implemented by FHI 360, and Vietnam Ministry of Health (MoH) began piloting an integrated TB/HIV service model in Nho Quan and Hung Ha District Hospitals in Thai Binh and Ninh Binh provinces. The pilot incorporated HIV services into two TB sites to deliver TB and HIV services by one healthcare team.
Methods: Two years (July 2014-June 2016) of service and staffing data for integrated sites were reviewed and compared to those of standalone facilities.
Results: The integrated model reduced the number of room and staff required to deliver HIV and TB services from seven staffs and five rooms to three staffs and two rooms. The sites integrated TB and HIV services into hospital examination procedures and secured health insurance reimbursements for services. The model reduced the number of visits required to diagnose TB in HIV patients from three to one, and waiting time for diagnostic results from seven to two days.
Integrated sites outperformed standalone facilities within the same provinces in proportion of (1) TB patients tested for HIV (Thai Binh: 100% vs. 95%; Ninh Binh: 100% vs. 94%); (2) new HIV patients on IPT (100% vs. 75% in Thai Binh); and (3) AFB-positive new TB patients cured (Thai Binh: 95% vs. 94%; Ninh Binh: 100% vs. 91%). ART quality was comparable across sites, with similar proportions of on-schedule patient re-examination, adherence assessment, and ART initiation.
Pilot sites delivered services to 216 HIV and 404 TB patients, of whom 12 (12 male, 0 female) were TB/HIV co-infected and treated for both TB and HIV. Eight of these completed treatment for and recovered from TB during the pilot. No new active TB cases were identified among HIV patients.
Conclusions: Although a modest sample size, the pilot yielded positive results. This prompted the MoH to expand the integrated model to 12 provinces, with plans for 18 others, to improve treatment outcomes and sustainability as external funding declines.

MOPED1120

Willingness to donate organs for transplants among persons living with HIV

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Background: The HIV Organ Policy Equity (HOPE) Act was recently enacted and now permits persons living with HIV to donate organs in the US. HIV+ to HIV+ organ transplantation could shorten waitlist times among both HIV-infected and uninfected individuals. However, it is unknown whether people living with HIV (PLWH) are willing to donate organs.
Methods: We conducted a survey of willingness to donate among PLWH at an HIV clinic in an urban academic research hospital. Fisher's exact and chi-squared tests were used to compare participants who were willing vs unwilling to donate.
Results: Among 114 survey participants, median age was 55 (IQR=49-58), median duration of HIV infection was 20 years (IQR=12-25), 52.2% were men, 96.4% were African American, 99.1% had government insurance, and 54.4% were hepatitis C-coinfected. Participants reported broad willingness to donate: 79.8% as deceased donors and 62.3% as living donors. Twenty one percent were registered organ donors.
Participants unwilling to be deceased donors were more likely to report concerns about trusting the medical system (47.8% vs 7.7%, p <0.001) and whether HIV infection would affect organ function in recipients (60.9% vs 20.9%, p <0.001) (Table 1). Participants unwilling to be living donors were more likely to express concerns about going through surgery (46.5% vs 23.9%, p <0.01), worsened health post-donation (55.8% vs 21.1%, p <0.001), changes in their HIV treatment (41.9% vs 18.3%, p <0.01), and poor health due to HIV (55.8% vs 21.1%, p <0.001) (Table 2).

Concerns with (%)	Willing to donate (N=92)	Not willing to donate (N=22)	P-value
Financial burden	4.4	8.7	0.6
Trusting the medical system	7.7	47.8	<0.001
Adequate organ function despite donor's medical history	20.9	60.9	<0.001
Organs taken before death	25.3	17.4	0.6
Body disfigured before funeral	9.9	21.7	0.1

[Table 1. Concerns with being a deceased donor]

Concerns with (%)	Willing to donate (N=71)	Not willing to donate (N=43)	P-value
Undergoing surgery	23.9	46.5	0.01
Worse health post-donation	21.1	55.8	<0.001
Changing HIV treatment	18.3	41.9	<0.01
Poor health post-donation because of HIV	21.1	55.8	<0.001

[Table 2. Concerns with being a living donor]

Conclusions: A majority of PLWH surveyed expressed willingness to be deceased and/or living organ donors. This supports the feasibility of implementing HIV+ to HIV+ transplants, which can have a public health benefit. However, few PLWH were registered as organ donors indicating an opportunity for further education and outreach.

MOPED1121

Therapeutic outcomes of TB-HIV co-infected patients in the Lualaba mining province in the DRC

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Background: The Democratic Republic of Congo's (DRC) limited infrastructure and weak health system help make it among the countries most deeply affected by TB-HIV co-infection globally. While the therapeutic success rate of HIV-negative TB patients is 85% in the DRC, there is little published research documenting the therapeutic success rate for TB/HIV co-infected patients. The objective of this retrospective study is to present the therapeutic outcome of TB in TB-HIV co-infected patients in a southern DRC province characterized by high HIV prevalence (3.2%).
Methods: This study was conducted in the mining town of Kolwezi, in the Lualaba province of southern DRC, under the USAID-funded Integrated Health Project Plus (IHPplus). Co-infected patients from 23 HIV care sites were included in the study, and all health care providers were trained in the management of patients co-infected with TB-HIV. IHPplus provided TB commodities and tools for data collection and transmission.
Data were collected retrospectively from routine programmatic data, patient medical records, and HIV testing registers for the period of October 2015 to September 2016.
Results: Of 1,484 tuberculosis patients, 1,379 were counseled and tested (93%) during the study period. Of these, 324 were co-infected with TB-HIV (23.5%), and 314 of them were placed on TB treatment and ART (98.7%). 125 patients completed their TB treatment and were evaluated with the following outcomes: 60 patients were declared cured of TB (48%); 44 reported treatment completed for TB (35.2%); 11 were unevaluated at the end of their treatment (8.9%); 9 were reported to have died during treatment (7.2%); 1 was reported lost to follow-up (0.8%); and there were no cases of treatment failure. The therapeutic success rate was 104 out of 125 (83.2%), and mortality was 9 out of 125 (7.2%).

Conclusions: The study results demonstrate that trained providers, regular monthly follow-up, and a steady supply of TB and HIV commodities improve therapeutic success for TB-HIV co-infected patients in underserved settings, although TB-HIV co-infection negatively affects the outcome of TB treatment.

MOPED1122

Measuring integration of HIV and other primary care services in South African clinics: the challenges of using routine data

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Background: South Africa has the world's largest HIV epidemic. The South African National Department of Health favors an integrated approach for provision of primary healthcare services. HIV and other healthcare needs must be addressed holistically. However, there is limited effort to track integration in the country. Our aim was to assess whether facility-based registers used for routine data collection could be used to track integrated service provision.
Methods: We conducted a retrospective review of patient registers and electronic aggregate records at three primary healthcare clinics (PHCs) in Johannesburg. We identified all paper registers used in the PHCs. From February-August 2016, trained study staff transcribed service data representing one month (November 2015) from the registers into an Excel workbook. Then we attempted to match patients across service registers using their name, age, gender, and national identification number. Services found to have been provided to the same individual on the same day-although noted in different registers-was a priori identified as a proxy for integration.
Results: According to publicly available electronic data a total of 13,780 patients (4,602, 4,605 and 4,573 per clinic) visited the three clinics during the month of November 2015. One register, called the "Comprehensive Tick Register" (CTR), was designed to allow for documentation of multiple services per individual patient. According to the CTR, 25.5%-37.5% of all patients obtained more than one healthcare service on a given day; 1.7%-10.0% received HIV testing plus another primary care service.
The clinics also maintained several other, individual service registers. Unfortunately, it was impossible to match patients across these registers. Patient identifiers were not consistently and adequately recorded. Where patients were required to be listed in two or more registers, there were errors and missing information. Comparing electronic statistics derived from facility reports to the paper registers, including the CTR, there was over- and underreporting.
Conclusions: Data reviewed in the CTR and other registers in the study PHCs were inconsistent and incomplete. Plans for moving to an entirely electronic record keeping system may help; however, staff likely requires support and guidance regarding the importance and usefulness of high quality service data.

MOPED1123

Increasing antiretroviral therapy initiation rates among people who inject opioids in Tanzania: the integration of methadone and antiretroviral therapy (IMAT) strategy

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Background: The prevalence of HIV among the population of people who inject opioids (PWIO) in Dar es Salaam is 42%, compared to 7% in the general population of the city. Beginning in 2011, an opioid treatment program (OTP), using methadone, was established in Tanzania to reduce the risk and transmission of HIV. Enrollment of PWIO into the OTP program surged, but linking HIV-positive, eligible OTP patients into anti-retroviral therapy faced many obstacles. To address these challenges, we engaged the community of OTP patients and providers to design an integrated methadone and anti-retroviral therapy (IMAT) program.
Methods: We conducted in-depth interviews with patients (n=20) and providers (n=12) and a cross-sectional survey (n=140) with HIV-positive OTP patients to understand perceived challenges and recommendations. Findings were presented and discussed at community engagement meetings with patients, providers and government stakeholders to further refine IMAT. In October 2015, IMAT implementation began. Using routine, programmatic data, binomial regression was used to compare the probability of ART initiation before verses after IMAT, adjusting for eligibility status.
Results: Results showed that 93% of OTP patients thought integration would improve their satisfaction with services, but 34% were concerned that ART co-dispensed with methadone would disclose their HIV status to their peers. Providers were concerned about the potential increased workload. To accommodate these concerns, the IMAT strategy allowed for a private room for consultations, 3 ART dispensing options chosen by the patient and flexible scheduling at the discretion of the HIV provider.
After IMAT implementation, all 126 HIV-positive OTP patients received HIV care. ART initiation rates increased 38% (95% CI: 2-88%; p< 0.001) from 71% pre-IMAT to 97% post IMAT, adjusting for eligibility status. ART was dispensed as follows: 4% at pharmacy window with methadone, 18% directly observed therapy in a private room and 78% monthly supply from an OTP nurse.
Conclusions: We successfully integrated HIV care and treatment into an OTP program in Dar-Es-Salaam, Tanzania with increased rates of ART initiation. IMAT's success was driven by the early consideration of perceived challenges by OTP patients and providers. Future work will address the ongoing concerns about stigma and scale-up without overburdening OTP clinics.

MOPED1124

Mistimed and unwanted pregnancy among female sex workers in India: a potential marker of reproductive and HIV risk

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Background: While a number of studies of female sex workers (FSWs) have focused on HIV and other sexually transmitted infections, there has been less emphasis on reproductive health issues. Research from India shows a large proportion of FSWs getting pregnant with limited use of family planning methods. However, it is not known whether these births were planned on unintended and to what degree unintended pregnancies are evidence of risky sex. In this context, the current study examines the level of mistimed/unwanted pregnancy and explores the factors linked to wanted, mistimed and unwanted pregnancy among FSWs.
Methods: Data was collected using a two-stage sampling design from 4098 FSWs across five Indian states (Andhra Pradesh, Telangana, Karnataka, Maharashtra and Tamil Nadu) in 2015. FSWs were asked a series of questions related to pregnancy and their intent for last pregnancy. FSWs who indicated that they did not want their last pregnancy were classified as "unwanted"; those who wanted but not at that time were categorized as "mistimed" and rest were considered as "wanted". We fitted a multinomial logistic regression to estimate predictors of mistimed and unwanted pregnancy among FSWs.
Results: About 62% of FSWs surveyed were ever pregnant; 8% of these identified their last pregnancy as mistimed, 40% as unwanted and 52% wanted. The relative risk ratio (RR) of mistimed pregnancy as compared FSWs who wanted pregnancy was higher among those who were literate (RR:1.46, P=0.019), mobile for sex work (RR:1.81, P< 0.001), currently married (RR:2.08, P< 0.001) and those having poor negotiation skills on condom use (RR:1.97, P=0.029). Similarly, RR of unwanted pregnancy was higher among FSWs who were 30 years or older, not-formerly married, having occupation other than sex work, street based, mobile for sex work, and diagnosed as HIV positive.
Conclusions: Unwanted and mistimed pregnancy is prevalent among FSWs and can be an indicator of HIV risk, MTCT as well as the risk of bringing an unwanted child into a precarious living situation. These results indicate that reproductive health and HIV risk reduction program should not be looked in isolation; an integrated and comprehensive curriculum for FSWs is necessary to comprehensively reduce reproductive risks.

MOPED1125

Cervical cancer screening outcomes among safer conception service clients, Johannesburg, South Africa

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Background: Cervical cancer is a leading cause of mortality amongst reproductive-aged women. Despite effective antiretroviral therapy (ART), cervical cancer incidence remains significantly higher amongst HIV-infected women. Integrating cervical cancer screening into HIV prevention and treatment programmes may address unmet prevention and diagnostic needs. We report cervical cancer screening outcomes for safer conception clients in Johannesburg, South Africa.

Methods: HIV-affected couples desiring pregnancy accessed an integrated safer conception service including HIV testing, ART and STI management, pre-conception risk reduction counselling, PrEP for HIV-uninfected partners and cervical cancer screening. Females were eligible for a Papanikolaou smear if HIV-infected and last pap was >1 year ago, had unknown results or had never been done or if HIV-uninfected, >30 years old and no pap smear in the last ten years. Clinical records and laboratory results were reviewed for smears done between June 2015-January 2017.
Results: 361 females enrolled (median age 33yrs, IQR 30-37yrs). Pap smear coverage was 82% with 221 of 271 eligible clients accessing a pap smear. Twenty-four eligible women were not offered, 18 declined the offer whilst eight conceived before a pap was performed.
Of 221 smears performed, 15% of women required colposcopy, including 22 with high grade squamous intraepithelial lesions (HGSIL), eight atypia where HGSIL could not be excluded and four persistent atypia. Follow-up for abnormalities was indicated for a further 42% of women including 19 with atypical squamous cells of unknown significance and 71 low grade squamous intraepithelial lesions; 41% (90) were reported negative for intraepithelial lesions or malignancy, 2% had inadequate samples. Shift in flora suggestive of bacterial vaginosis was reported in 79 (36%) cases and seven had trichomonas vaginalis infection. Both infections may increase HIV transmission and miscarriage risks.
Conclusions: Women accessing cervical cancer screening via a safer conception service had high rates of cervical pathology requiring further management. This highlights the importance of improved sexual and reproductive health and HIV service integration to ensure WLH, including those already on ART, are routinely offered cervical cancer screening to reduce cervical cancer incidence. Women presenting for preconception care require screening to ensure timely management of cervical pathology and infections before pregnancy is achieved.

MOPED1126

Perceptions of living organ donation among people living with HIV

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Background: The HIV Organ Policy Equity (HOPE) Act, passed with broad HIV community support, lifted the United States prohibition on transplanting HIV+ organs into HIV+ recipients. However, using organs from HIV+ living donors remains controversial as the risks of living donation (LD) among people living with HIV (PLWH) is unknown. Although the HOPE Act requires protecting donors' rights and interests, doing so requires information about the motivations and concerns of potential HIV+ donors.
Methods: We conducted semi-structured interviews with PLWH to assess their motivations for donating and perceived risks and benefits of LD. Ten participants who reported they would "definitely" be willing to be an LD in a quantitative survey were interviewed. Interviews were recorded, transcribed, coded, and reconciled by two coders using NVivo.

Theme	Representative Quote
HIV-specific Motivations for Donation	
Solidarity with other PLWH	"Those of us who are long term survivors, like my buddy, we help each other out... I think that's a little more unique to the whole HIV thing"
Stigma of HIV	"Cause the stigma with HIV still, and a lot of people don't wanna help people with HIV so it's an important way to raise awareness about HIV and raise awareness about [people] who need an organ transplant"
HIV-specific Benefits of Living Donation	
Feeling "normal"	"Even though you sick yourself you can help somebody else, sure that's a major benefit, it'd make your feel normal"
HIV-specific Concerns about Living Donation	
Concerns about self (donor):	
Risks of compromised immune system	"Just the recovery period, our immune system is a little bit weaker, and it may take longer to recover... You know what I mean, just to have to worry about infections and stuff"
Other health problems (related to HIV)	"... they probably have other health problems to deal with"
Concerns about recipient:	
Superinfection	"I think the biggest thing for some people might be, what's the different strains... what's your strain, what's the strain of the other person that you're givin' it to"

[Table 1. HIV-specific motivations for as well as perceived benefits and risks of HIV+ Living Organ Donation]

Results: Several themes emerged, including general and HIV-specific motivations and concerns about LD (Table 1). Most participants were motivated by a desire to save someone's life. HIV-specific motivations for LD included solidarity with other PLWH and the stigma of HIV. Most participants described helping someone as a general benefit of LD; some participants identified "feeling normal" as an HIV-specific benefit. Participants identified general and HIV-specific concerns about the risks of LD both for themselves and for the recipients, including the donor's compromised immune system, the donor's HIV-related health problems, and risk of HIV donor-to-recipient super-infection.
Conclusions: Some motivations, benefits and concerns raised by PLWH interested in LD were consistent with attitudes of HIV-uninfected LD in other studies. However, unique HIV-specific motivations and benefits included demonstrating solidarity among PLWH and overcoming stigma to confer a sense of normalcy. Participants were concerned about potential risks for both donor and recipient. HIV+ LD education should address these HIV-specific issues. The actualization of these expectations should be monitored as HIV+ LD is performed.

MOPED1127

A comparative analysis between a community-based and a hospital-based model of HIV care for men who have sex with men in the city of Chicago

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Background: Men who have sex with men (MSM) are disproportionately affected by HIV in Chicago. MSM who use drugs or are homeless are harder to retain in medical care. The University of Illinois Health Community Clinic Network (UCCN) operates 6 HIV storefront clinics throughout Chicago. These clinics are co-located with a University of Illinois (UIC) program that provides street outreach and harm reduction interventions to drug users.
The purpose of this study was to compare the effectiveness of this community based model to the traditional hospital based model (HBM) for providing HIV care to MSM in Chicago.
Methods: This was a retrospective cohort study of HIV infected MSM treated at storefront clinics and at the UIC hospital in Chicago, Illinois, USA, from January 1, 2010 to December 31, 2014. Data were extracted from electronic medical records. We generated descriptive statistics and calculated Chi squares and t tests to compare variables. Main outcomes of interest were: aggregate time during which the HIV viral load was undetectable and proportion of AIDS related illnesses during the study period.
Results: A total of 290 men were included in the study. Half received care at UCCN (49%). Most of the clinics were staffed by nurses. Mean age was 39 (±12) years. UCCN served a higher proportion of uninsured or publicly insured (75% vs. 54%, p< 0.01), active drug users (38% vs. 24%, p=0.01) and homeless patients (16% vs. 0%, p=< 0.01). UCCN patients missed more clinic visits (Median= 7 vs. 2.5, p=< 0.01) and were more likely to interrupt antiretroviral therapy (39% vs. 19%, p=< 0.01); however, there was no difference in the aggregate time in which the viral load was undetectable (1.3 yrs. vs. 1.3 yrs., p=0.88) or in the proportion of AIDS related illnesses (UCCN: 7% vs. HBM: 12%, p=0.15) during the study period.
Conclusions: Despite serving a more marginalized population and being staffed by mid-level providers our community clinic model is as effective as a hospital based clinic in providing care to HIV infected MSM. Sexual orientation- and drug abuse-affirming services, intensive street outreach and targeted case management likely contributed to the success of this model.

MOPED1128

Community-based integrated cervical cancer screening and HIV testing: experience from demand creation and community mobilization in rural Tanzania

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Background: In Tanzania, cervical cancer is the leading cause of cancer-related deaths in women, representing 38.4% of new cancer cases. Evidence show links between cervical cancer, Human Papilloma Virus (HPV) and HIV infections. T-MARC Tanzania conducted integrated community mobilization and demand creation to increase HIV and cervical cancer testing and screening respectively. We aim to describe VIA positivity rate in relation to HIV and age.

Methods: A prospective cross section approach was used. Project activities were implemented in Iringa region through a network of trained team of 61 community volunteers and 33 village health workers. Mass screening was conducted across seven health facilities in three predominantly rural districts. Data on HIV testing, cervical cancer screening status by Visual Inspection with Acetic acid (VIA) and treatment offered were collected by trained personnel. Descriptive statistics and 95% CI were calculated.
Results: A total of 2,869 women responded to sensitization across seven facilities. All of them (100%) were screened for cervical cancer and 85% were tested for HIV. Overall HIV prevalence and VIA positivity rate were 17.27% (95%; 95% CI: 15.8%-18.8%) and 7.3% (95% CI: 6.1%-8.3%) respectively. VIA positivity rate was significantly higher among HIV positive women (11.2%; 95% CI: 9.1%-15.3%) than HIV negative (6.2%; 95% CI: 5.2%-7.3%) and unknown status (8.1%; 95% CI: 5.9-11.1%). By age groups, the VIA positivity rate was higher among 20-29 years (10.7%; 95% CI: 8.5%-15.5%) compared to the rest of the groups i.e. < 20 years at 6.4%; (95% CI: 2.5%-15.4%), 30-39 years at 8.7% (95% CI: 7.2%-10.6%), 40-49 years at 5.3% (95% CI: 3.9%-7.2%) and 50 years and above at 2.1% (95% CI: 1.2%-3.8%).
Conclusions: VIA positivity rate was higher amongst HIV positive women irrespective of age. VIA positivity rate was higher amongst 20-29 years old women irrespective of their HIV status. The integration of cervical cancer screening services within existing PMTCT, HIV care and treatment, and other reproductive health programs will ensure that those most vulnerable to the disease are accessed cost effectively with a more comprehensive continuum of health care package.

MOPED1129

Rapid scale-up of reflexed cryptococcal antigen (CrAg) screening across a CD4 laboratory network in South Africa

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Background: Cryptococcal meningitis (CM) is a major cause of HIV-related morbidity and mortality preventable by early detection of cryptococcal antigenaemia (CrAg) using the lateral flow assay (LFA) followed by fluconazole treatment. In South Africa, a pilot study for reflexed CrAg detection against confirmed CD4 samples with a count < 100 cells/µl was initiated in 2013 to include selected clinics from eight CD4 testing laboratories. A national reflexed CrAg screening program was introduced across the remainder of the CD4 laboratory network of the National Health Laboratory Service (NHLS) from July 2016. This study reports the implementation scale up of reflexed CrAg testing and its impact on test volumes.
Methods: Retrospective data analysis was performed on CD4 and CrAg data from January to October 2016 to assess monthly CrAg test volumes, coverage and positivity rates. Data collected from January to June 2016 represents the pilot laboratories (n=8) serving pre-selected health facilities only. July to October data reflects implementation scale up across an additional 41 CD4 testing facilities to include all referring health facilities.Coverage is reported as the percentage of CrAg tests done divided by the total number of CD4 samples < 100 cells/µl. Statistical analyses were done using Excel and Stata software. Percentage CrAg positivity is also reported.
Results: Monthly CrAg volumes for the pilot period ranged from 4.5k-6.5k, representing coverage of 15.6 to 23.6% (Jan to June 2016). After implementation of national CrAg screening between July and October 2016, monthly CrAg test volumes increased from 11.5k to 29.6k respectively. This represents a 6-fold increase in CrAg test volumes by October.Coverage increased from 39.5 (July) to 98.2% in October. Positivity rates did not change significantly between pilot and implementation periods, at 5-6% of CD4< 100cells/µl.
Conclusions: This study demonstrates the rapid scale up of reflexed CrAg screening across the national CD4 laboratory network in South Africa over a four month implementation period made possible through the existing CD4 central support system. It is anticipated that reflexed CrAg screening would save lives base on published cost-effectiveness study results.

MOPED1130

Piloting the integration of routine maternal HIV screening in Malawi's immunisation programme

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Background: There is a high risk of HIV seroconversion during pregnancy and postpartum in the sub-Saharan African setting. While most pregnant women in Malawi are screened for HIV during antenatal care, there is no current requirement for maternal retesting postpartum. Given the risk of mother-to-child transmission via breastfeeding, it is critical to evaluate additional HIV screening points for mothers postpartum. Additionally, a persistently low uptake of follow up HIV testing for known HIV exposed infants (HEIs) throughout breastfeeding has led to delays in initiation of antiretroviral therapy. To evaluate the viability of integrating maternal postpartum and HEI HIV screening at an existing highly-utilized health service, a pilot was conducted to screen mothers and infants attending clinics for routine infant immunisations.
Methods: A cross-sectional, non-experimental implementation pilot was conducted in 15 randomly selected health centres in two districts between June and November 2016. Mothers with an unknown HIV status, a previous HIV-negative result greater than 3 months prior to their visit, or a known HEI that had missed a scheduled HIV test were eligible for enrolment. Following routine immunisation services, eligible and consenting mothers were offered on-site referral for HIV testing and counselling for themselves and/or their infants.
Results: 3675 mothers were screened during immunisation visits at 15 health centres. Of these women, 1977 were eligible and 1400 enrolled in the pilot. Most mothers reported having a previous HIV test (94%), with a median time from last test of 6 months and median time since delivery of 3.3 months. Of those enrolled, 96% received HIV testing and counselling, yielding 0.30% positive, 99% negative, and 0.37% indeterminate results. 54 eligible HEIs were identified and referred for testing, yielding 5.5% positive, 76% negative, and 18.5% unknown results.
Conclusions: While the testing yield for mothers with a previous HIV-negative or unknown status was less than expected, the high uptake of HIV testing among eligible women suggests that routine postpartum HIV screening at immunisation visits is both acceptable to mothers and feasible for health centres. Additionally, screening at this entry point for HEIs missing a testing milestone could be a viable supplement to existing PMTCT programs.

MOPED1131

WHO clinical care recommendations to respond to children and adolescents who have been sexually abused including for preventing HIV and sexually transmitted infections (STIs)

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Background: Globally, 20% of girls and 8% of boys are estimated to have experienced child sexual abuse (CSA). Such violence can lead to adverse mental health outcomes, STI and HIV acquisition, unwanted pregnancies and injuries. It is also associated with increased HIV risk-behaviours such as substance and alcohol use, engagement in sex work, and having multiple concurrent sexual partners later in life. Therefore, integrating interventions to address CSA including PEP and STI prophylaxis in primary or emergency care, sexual and reproductive health, HIV, child and adolescent health services is critical. We present evidence-based recommendations to provide clinical care to children and adolescents who have been sexually abused including for STI and HIV prevention.
Methods: The recommendations are based on the methods laid out for developing WHO guidelines and include evidence retrieval through systematic reviews and qualitative reviews, synthesis and quality appraisal for the following topics: provision of first-line support; PEP adherence support; STI prophylaxis; mental health support; and addressing police reporting obligations. Five reviews were conducted to address these topics, which were discussed by an international expert group to formulate recommendations. Other topics are addressed through existing guidelines.

Results: A review of barriers to PEP adherence highlighted common factors to be: fear of HIV, forgetfulness, traumatic associations and stigma linked with the assault and mental health problems. The review on STI treatment highlighted that few sexual assault survivors come back for treatment. Reviews of mental health interventions highlighted the need to address post-traumatic stress disorder. Qualitative studies indicated that children and adolescents want care that is non-judgmental, respects their preferences, assures them confidentiality and is timely. Requirements to report child sexual abuse to the police deterred care seeking and obtaining timely care.
Conclusions: Clinical care for sexual abuse of children and adolescents needs to be provided in a manner that supports their psychosocial wellbeing, respects their rights and addresses their physical health care needs, including for HIV, STI and pregnancy prevention. Barriers to PEP adherence and STI treatment follow up need to be addressed. Psychological interventions should ideally be part of the package of care.

MOPED1132

Successful decentralisation and integration of cervical cancer screening and treatment in rural Swaziland

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Background: Cervical cancer is one of the leading causes of cancer deaths in women in resource limited settings. Cervical cancer screening aimed at detecting and treating precancerous lesions is now recommended by the World Health Organisation (WHO) in both HIV negative and positive women to limit the burden of invasive cervical cancer.
However, access to cervical cancer screening is limited in low to middle income countries due to programmatic constrains such as logistics and human resources for health. We aimed to introduce and decentralise cervical cancer screening in the public health sector in order to decrease morbidity and mortality from cervical cancer.
Methods: Medecins Sans Frontieres in collaboration with the Ministry of Health established a mobile screen and treat programme using visual inspection with acetic acid (VIA).Trainings were conducted for the mobile screening teams between July and August 2016. Since September 2016 the mobile teams visited 26 predominantly rural primary and secondary health care facilities to perform cervical cancer screening to sexually active women. If found positive, clients received onsite treatment for cervical pre-cancerous lesions using cryotherapy. Those with advanced or extended lesion and suspicion of invasive cervical cancer were referred to the gynaecologist at the regional hospital.
We used frequencies and proportions to describe the women who were screened and reported their outcomes.
Results: A total of 647 clients were screened using VIA method with a median age of 33 (IQR: 27- 42) and a median parity of 3 (IQR: 1-4). Of those screened 317 (49%) were HIV positive. One hundred and twenty (18.5%) had positive VIA and of these 55 (45.8%) were HIV positive. The prevalence of pre-cancerous lesions among the HIV positive was 17.4% compared to 19.7% in HIV negative women (p=0.33). Among those VIA positive, 84 (70.0%) received onsite cryotherapy and 10 (8.3%) were suspicious of invasive cervical cancer and were referred to gynaecologist for further treatment with 1 (10.0%) undergoing the loop electrosurgical excision procedure (LEEP) therapy.
Conclusions: Decentralisation of cancer screening is feasible in resource limited countries and offers the opportunity to detect and treat precancerous cervical lesions thereby reducing the burden of cervical cancer in these settings.

MOPED1133

Prevalence of diabetes and hyper- cholesterolemia among adults on ART for more than 10 years in Malawi

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Background: Data on cardio-vascular disease (CVD) risk among patients receiving long term ART are critically needed in sub-Saharan Africa. We assessed prevalence of diabetes, hypercholesterolemia and evaluated Framingham Risk Score (FRS) among those on ART for more than 10 years in Chiradzulu, Malawi.
Methods: HIV positive patients receiving ART for more than 10 years (patients) and HIV-negative people living around the selected health centers (controls) were invited to participate. Following informed consent, a standardized questionnaire, clinical, and laboratory exams (HbA1c, and LDL Cholesterol) were performed and the Framingham Risk Score (FRS) calculated for each participant. Two multivariate logistic regressions were used to assess the association between high HBA1C level (≥6%) or hyperlipidemia and ART status.
Results: A total of 379 ART patients and 356 controls were included in the study. Median age was 48 years [IQR 42-57] and 73.2% (95%CI 69.9-76.3) were female. The median time on ART for patients was 11.6 years [IQR 10.6-12.4].
The prevalence of HbA1c ≥6.0% in the 30-44, 45-59, and ≥60 year's age groups was 5.0%, 6.4%, and 13.2% among patients, and 3.4%, 4.2%, and 1.7% among controls respectively. Using the multivariate model with variables; HIV status, age group, gender, education, and BMI; patients were more likely than controls to have an HbA1c ≥6.0% (aOR 1.9; 95%CI 1.1-3.2, p=0.02). Prevalence of LDL Cholesterol >130mg/dl in the 30-44, 45-59, and ≥60 year's age groups was 8.0%, 15.4% and 23.7% among patients and 1.8%, 12.5% and 11.8% among controls respectively. Using the multivariate model with same variables as above, difference of having LDL >130mg/dl between patients and controls was only marginally significant (aOR 1.6; 95%CI 0.9-2.7; p=0.1).
FRS increased with age and male gender, up to 41.2% and 53.9% of male patients and controls age≥60 years having a FRS≥20%, respectively. However, no significant differences in FRS were identified between patients and controls.
Conclusions: The prevalence of diabetes and hypercholesterolemia were significantly higher for patients on ART >10 years compared to controls. However, FRS was high for elder HIV-negative controls, suggesting that an approach focusing on decreasing CVD risk should target both HIV-positive and HIV negative at high risk.

MOPED1134

High magnitude of under nutrition among HIV-infected adults who have not started ART in Tanzania: a call to include nutrition care and treatment in the test and treat model

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Background: Undernutrition among people living with HIV (PLHIV) can be ameliorated if nutrition specific and sensitive interventions are integrated into their HIV care and treatment centers (CTC). Integrated care is lacking despite expansion of antiretroviral therapy (ART) coverage, representing a substantial missed opportunity. This research aims to examine nutrition status and associated risk factors among HIV-positive adults prior to ART initiation in Tanzania in order to characterize existing gaps and inform early integration of nutrition care into CTC.
Methods: We analyzed data from 3,993 pre-ART adult PLHIV enrolled in CTCs within the Trial of Vitamin (TOV3) and progress of HIV study in Dar es salaam, Tanzania.. Baseline data included demographics, feeding characteristics, clinical, psychological, and biological variables. The primary outcome for this analysis was nutrition status, measured as body mass index (BMI) below 18.5 kg/m^2. We conducted descriptive analyses of baseline characteristics and utilized multiple logistic regression to determine independent factors associated with pre-ART undernutrition.

Results: Undernutrition was prevalent in about 27.7% of pre-ART adults, with a significantly higher magnitude among males compared to females (30% vs. 26.6%, p <0.025). Severe undernutrition (BMI <16.0kg/m^2) was prevalent in one in four persons, with a trend toward higher magnitudes among females (26.2% vs. 21.1% p=0.123). Undernutrition was also more prevalent among younger adults (p <0.001), those with lower wealth quintiles (p=0.003), and those with advanced HIV clinical stage (p <0.001) compared to their respective counterparts. Pre-ART adults presented with poor feeding practices, hallmarked by low dietary diversity scores and infrequent consumption of proteins, vegetables, and fruits. After adjusting for confounders and important co-variates, pre-ART undernutrition was associated with younger age, low wealth indices, advanced clinical stage, and low dietary diversity.
Conclusions: One in every four pre-ART PLHIV presented with undernutrition in Dar es salaam, Tanzania. Risk factors for undernourishment included younger age, lower household income, advanced HIV clinical stage, and lower dietary diversity score. Knowledge of the prevalence and prevailing risk factors for undernutrition among pre-ART PLHIV should guide targeted, early integration of nutrition interventions into routine HIV care and treatment in high-prevalence, low-income settings such as Tanzania.

MOPED1135

Key lessons from a low threshold, results-oriented medically assisted programme along Kenya´s coastline

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Background: HIV prevalence among people who inject drugs (PWID) in Kenya is 18.3% versus 5.6% for general adult population. Since 2014 Kenya's Ministry of health and its partners has strived to scale up Medically Assisted Therapy (MAT- alias Opioid Substitution Therapy) to achieve national strategic goal of universal access to HIV prevention, treatment and care for all by 2030. UNODC with USAID/ PEPFAR, supported national and county health authorities and CSOs partners to establish 3 MAT clinics in Kilifi and Mombasa Counties.
Methods: Retrospective records review performed to assess implementation process and results of GOK-UNODC-USAID Coast MAT Programme. Findings appraised against national guidelines and best practices.
Results: Total 1,020 opioid dependent persons enrolled for MAT from February 2015, females 12.5%, median age of females 30 (IQR 26.5-34) versus males 37(IQR 32-42) years. 75% not in union, 70% primary level education, 55% unemployed, 40% lived alone. Average duration heroin use 12.2 years from median age 20 years (IQR 18 to 25). 63% ever injected heroin average 7.3 years from heroin initiation. 14% HIV infected (females 35% versus males 11%), 8% HCV infected. 50% ever incarcerated, 20% previous 30 days.
After 22 months, 85% MAT clients retained, 9% lost to follow up, 1% died (half in hospitals) from HIV/TB, meningitis, jaundice/liver failure; Dengue, Immunosuppressant Syndrome, overdose. Urine drug toxicology confirms decline in heroin use (12%) compared to cannabis (>40%) at 12 months. 5 MAT clients successfully weaned off due to economic migration, feel recovered, treatment fatigue. Another 8% voluntarily tapering down, primarily males without co-morbidities. Improved behavior of MAT Clients and decline in community criminality increasing community demand.
Conclusions: Within 2 years Kenya's MAT program revealed notable impact at individual, family and community levels. MAT providers acquiring expertise with individualized results-oriented treatment approach, with optimal dosage, concurrent management of co-morbidities, and structured psychosocial support. Decentralization and integration of MAT services within primary health care vital for scale up. However, MAT coverage remains low - 10% PWID reached due to: scarcity of MAT sites, health worker shortages, distance/transport costs, misconceptions, limited family support and livelihood assistance.

MOPED1136

High prevalence of postpartum suicidal ideation among women living with HIV in rural Zimbabwe

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Background: Available research indicates postpartum depression is widespread in low- and middle-income countries (LMICs), and suicide accounts for approximately 20% of postpartum deaths worldwide. Psychosocial stressors of initial HIV+ diagnosis and living with HIV, together with shared social determinants of HIV+ status and depression, indicate postpartum mental morbidity is likely an important health concern for women living with HIV. Mental morbidities can constrain capacity to adhere to HIV treatment, yet mental health is rarely addressed in routine service delivery in LMICs. Prevalence data from rural Zimbabwe is used to assess the importance of this gap in service delivery.
Methods: A cross-sectional baseline survey was conducted June-August 2016 for a community-based health program in rural Mutasa District, Zimbabwe. Trained non-clinical female enumerators administered the survey in eight health facility catchment areas with women who had given birth in the previous six months. The questionnaire included a Shona-language version of the Edinburgh Postnatal Depression Scale (EPDS), previously validated in Zimbabwe. Survey data was analysed with Stata 13.0, adjusted for clustering effects.
Results: A sample of 452 women was achieved, 12.4% of whom identified as HIV+. Mean age was 25.5 years, mean number of children 2.4, and mean age at first marriage 19.1 years. Using the validated EPDS cutoff of 11, symptoms of clinically significant depression and anxiety were common across all women, with no significant difference between HIV+ and HIV- women. Suicidal ideation as captured by EPDS was high in the total sample, but significantly more common among women living with HIV.

Scale	Prevalence, 95% CI(%) N=452	Prevalence among HIV+ women, 95% CI (%) N=56	OR HIV+ vs HIV-, 95% CI
EPDS ≥ 11	31.86, 28.08-35.90	35.71, 27.05-45.43	1.24, 0.74-2.08
Suicidal ideation	18.58, 14.42-23.62	32.14, 23.67-41.97	2.37, 1.25-4.48

[Mental health outcomes]

Conclusions: These findings affirm growing evidence of the high burden of postpartum mental morbidity in LMICs, and indicate substantially increased suicidal ideation among postpartum women living with HIV. Low-cost community and clinic-based interventions for women with postpartum mental morbidity have been proved effective and feasible. For the safety and care of HIV+ women and their newborns, including improved adherence to HIV treatment, the integration of mental health screening and referral with maternal-child health and HIV services across the continuum of care is a priority, particularly in high prevalence settings.

MOPED1137

Managing HIV TB co-infection at HIV treatment centers: six months experience

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Background: HIV-TB Co-infection ranks high among the major public health challenges. Addressing dual burden has been a key priority for the National AIDS Control Organisation (NACO) and Central TB division (CTD). The joint aim of NACO and CTD is to reduce the HIV-TB burden as well as to reduce the morbidity and mortality associated with the dual infection. All PLHIV under care are routinely screened for TB at each visit as part of program guidelines.
Methods: Program records and reports between April-Nov 2016 were reviewed on the reported HIV TB co-infection. Data reported in monthly report as well as specifically collected from all states was compiled and analysed for the same period. Analysis of referrals from HIV to TB program as well as initiation on ART was undertaken for the year 2016-17(April 2016-November 2016).
Results: 12,28,295 PLHIV were in active care and were getting HIV care services at 528 Centers across India and were screened for TB. 54,489 (4% of visits to ARTCs) PLHIVs were TB suspects and were referred for confirmation of diagnosis.

22,261 PLHIV were found to be confirmed HIV-TB positive. Amongst these, 34% were sputum positive, 34% sputum negative and 32% had extra pulmonary TB. Of the PLHIVs diagnosed with HIV-TB co infections 9819(44%) were already taking ART. Of the remaining 12471(56%) in Pre-ART Care, 8144(65%) were initiated on ART within one month of diagnosis and further 3457(28%) between one to two months of diagnosis while 1295(10%) did not start ART. Overall, 19187(91%) of the PLHIV with co-infection were started on ATT and 20607(93%) were initiated on CPT.
Conclusions: HIV-TB programmatic coordination at ART centers has yielded very good results with improved and timely initiation of treatment for both diseases and prophylaxis with co-trimoxazole. However, further efforts are needed to cover the last leg of co-infected individuals. Same cohort should be followed for treatment outcomes.

MOPED1138

Integration of WASH service into HIV/AIDS care and treatment package for PLWHA: an effective way to improve HIV treatment outcomes

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Background: Globally, efforts to scale-up HIV care and treatment services doubled. However, access to improved water and sanitation is still suboptimal. Many life threatening opportunistic infections are caused by inadequate access to safe drinking water, sanitation and hygiene (WASH). This paper presents strategies and key lessons from an integrated WASH and HIV/ADS service package to improve ART response in resource limited settings.
Methods: Mityana Uganda Charity (MUC) started implementing WASH project in 2015 to improve access to reliable sources of clean water and adequate sanitation facilities in Mityana district. Priority was given to areas or households infected and affected by HIV. Individuals trained and given information on HIV prevention and treatment, safer behavioral practices, water purification and simple technology water filtering systems. Water springs were protected and boreholes drilled in the project area. Model homes which comprised of HIV positive children were established which also acted as community reference points and water management committees were established and trained for project sustainability and each committee had representation of PHA
Results:
· A total of 538 Households with 4,476 individuals benefited from the project to access clean and safe water, of which 32% were HIV infected persons.
· 20 Water management committees with 190 members (70% women) were established and trained on safe water management of water purification systems
· 10 model homes with specific focus to families with children living with HIV were established with adherence levels monitored to have increased to 90% from 60% at project inception.
· 20 water sites (10 springs, 10 boreholes) were developed and protected to provide safe water the community
· Increasing access to safe water can result into improved nutritional status infected and affected people and reduce susceptibility to HIV.
· Development partners can contribute to a comprehensive response to HIV prevention and care through by increasing access to safe water and adequate sanitation facilities as a human right. A community participatory approach is important for ownership and sustainability.
Conclusions: HIV and poverty eradication programs need to design integrated interventions that account for social-economic and equity aspects to achieve better HIV treatment outcomes in resource limited settings.

MOPED1139

Integrating pediatric HIV diagnosis with relevant health programs for optimal pediatric HIV uptake

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Background: In Malawi, in 2015 an estimated 150,000 new pediatric infections occurred and 110,000 children living with HIV aged 0-14 years died from HIV-related causes. In 2016, 65% of children were on ART as compared to 68% of the adult population. Identifying optimal HIV integration points with other child health service points may demonstrate the benefits of targeted case finding.
Methods: An analysis of HIV data from studies and program was conducted. The analysis included 2016 HIV Early Infant Diagnosis (EID) data generated using Point of Care (POC) devices placed in pediatric wards (Inpatient and outpatient) and ART/PMTCT/Mother Infant Pair (MIP) clinics in 8 health facilities over the period of 8 months, an analysis of 2016 Nutrition Rehabilitation Unit (NRU) data, and an analysis of the 2015 national laboratory management system (LMIS) data for HIV EID. Chi square and Fisher's exact tests were used to determine if there were significant differences in HIV positivity at various service points of health centers.
Results: 76% of 6,570 children admitted in NRU were tested for HIV and 14% of total tested were found to be infected with HIV. When, 857 HIV exposed children, aged 6 weeks to 11.9 months, were tested using EID POC devices at various service delivery points, HIV positivity rates were 46% for the inpatient pediatric ward and 2% for ART/PMTCT clinics. Analysis of the LMIS data for HIV EID revealed that 45% of children tested in the pediatric ward were infected with HIV compared to 30% of children tested through NRUs and 4% in ART/PMTCT/MIP clinics. A Chi-square test of significance showed that HIV positivity varies between entry points at 5% level of significance.
Conclusions: Integrating HIV testing at Pediatric wards and NRU yielded the highest HIV positivity in children as compared to HIV testing at ART, PMTCT or MIP service delivery points. Integrating HIV EID and rapid HIV testing in these settings is strategic and optimum for identifying HIV-infected children and initiating life-saving treatment at the earliest.

MOPED1140

Expanding access to early infant diagnosis through integration of services at immunization service points in Rwenzori region, Uganda

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Background: Coverage for early infant diagnosis (EID) remains low in Uganda with many HIV exposed infants receiving their first DNA PCR test beyond the second month of life. The EID coverage at 2 months i.e. percentage of the expected HIV exposed infants accessing a first DNA PCR test at 2 months is low(35%) and yet the immunization coverage for DPT_1 is high (99%). Infants receive DPT_1 vaccine at six weeks of age, coinciding with the time for the first DNA PCR test.
Therefore, the high DPT_1 coverage presents an opportunity to improve EID coverage at 2 months.
Against this background, Baylor-Uganda implemented interventions to integrate EID into existing immunization services in four districts of Rwenzori region in an effort to improve EID coverage at 2 months.
Methods: The following interventions were implemented:
1) Training of immunization workers and HIV testing services(HTS) providers at immunization service points on pro-active identification of HIV exposed infants (started July 2016)
2) Rolling out of the ,appointment' stickers (started October 2016). The stickers were placed on the child health cards at immunization service points to alert health workers of infants' HIV exposure status.
They also prompted health workers to determine HIV exposure status of the infants in the event that it had not been determined earlier. We abstracted consolidated data from the District Health Information system and summarized the EID coverage at 2 months in proportions for the period before and through the intervention.
Results: EID coverage at 2 months has steadily increased from the time of the interventions from 33% to 48% (see figure 1).

[Figure 1]

Conclusions: Training of immunization workers and HTS providers at immunization service points and use of stickers enhanced EID coverage by 2 months in Rwenzori region. These interventions are recommended in low EID coverage areas with good DPT1 coverage.

MOPED1141

Cost of integrating non-communicable disease (NCD) care into Ugandan HIV/medical clinics in the SEARCH study

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Background: Changes in body weight, nutrition, exercise, smoking and aging in Sub-Saharan Africa have led to rising rates of non-communicable diseases (NCDs), including diabetes (DM) and hypertension (HTN). The SEARCH Study (NCT:01864603)—an HIV test-and-treat community-randomized trial—includes community censuses, community health campaigns (CHCs), and immediate linkage to care. NCD screening (for DM/HTN) was included in CHCs to reduce stigma associated with HIV testing, and to improve NCD outcomes. We previously estimated costs of HIV care in SEARCH communities at $275/patient/year. Here, we sought to estimate the incremental cost of adding NCD care for both HIV-positive and HIV-negative community members.
Methods: DM/HTN care was integrated into 10 Ugandan medical clinics serving SEARCH intervention communities from 08/2015-05/2016. Clinics provided NCD care for HIV-positive patients during HIV-related visits and for HIV-negative patients on one focus day/week. Quarterly visits included blood glucose/BP management and medication dispensation. We estimated the incremental cost/year/patient with DM/HTN. We calculated costs using standard micro-costing techniques, time-and-motion studies, interviews with management staff, and review of administrative/clinical records. Cost categories included staff salaries, fixed costs (e.g., facilities and equipment), recurring goods (e.g., medications) and services (e.g., laboratory tests).
Results: Overall, 107 HIV-positive patients and 2324 HIV-negative patients received NCD care an average of 3.4 and 2.9 times, respectively, during the first year of implementation. Average incremental cost of NCD care was $11.34 per HIV-positive patient/year (a 4% marginal increase over HIV care), and $14.74 per HIV-negative patient/year (5% of the cost of HIV care). Key incremental costs for HIV-positive patients included medications ($9.66/patient/year; 85%) and laboratory testing ($1.68/patient/year; 15%). Key costs for HIV-negative patients included medications ($8.24/patient/year; 56%) and clinic staff salaries ($3.09/patient/year; 21%), while minor costs included laboratory testing ($1.43/patient/year; 10%), fixed ($1.55/patient/year; 11%) and other recurring costs ($0.43/patient/year; 3%).
Conclusions: For only 4-5% in additional costs, NCD care was added to HIV care, and also expanded to all HIV-negative patients in prototypic Sub-Saharan African clinics, demonstrating substantial cost synergy. These results should encourage accelerated scale-up of NCD care in existing clinics to inexpensively improve management of DM/HTN, reduce stigma from HIV testing and care, and improve community health.

MOPED1142

An example of integration with health system in India: screening for HIV at primary health centre

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Background: In India, the adult HIV prevalence is 0.27 and estimated number of people living with HIV (PLHIV) is around 2.1 Million. For early detection of HIV positive individuals, it is essential to s prioritize the population who need to be screened viz. High Risk Group, Pregnant Women, patients with TB, STI/RTI infection etc. To screen the majority of these population for HIV, the Facility Integrated Counselling & Testing Centres (FICTC) have been established in Government as well as Private Health Institutions. In facility Integrated Counselling centers, the existing health staff identified is trained to conduct HIV counselling and HIV screening through point of care testing kit. Individuals who found reactive to HIV through Point of care Test Kits are linked to Stand Alone ICTC for confirmation of HIV with three test strategy.
Methods: In year 2015, a total of 13,698 FICTCs have been established, which increased to 16,458 in year 2016. Out of these, 13,092 (80%) are located at Government health facilities at Primary Health Centers & Community Health Centers and 3,366 (20%) in private institutions. In year 2015, 2.17 & 3.98 Million Individuals & pregnant women respectively have been tested at FICTC, which is 14 & 34% of total tested. This increased to 2.54 individuals & & 5.65 million pregnant women in the year 2016, which is 14.3 & 39% of total tested. The Individuals who found reactive to HIV are linked to SA ICTC with triplicate referral form.
Results: In year 2016, there is 20% increase in establishment of FICTC, which in turn increase in the HIV screening at FICTC, which is 17 & 42 % higher in general individuals & pregnant women respectively as compare to year 2015.
Conclusions: To screen the priority population for HIV in concentrated epidemic, it is essential to establish FICTC as screening centre at all Public Health service delivery points in the country. It will contribute towards achieving the target of elimination of Mother to Child Transmission of HIV and 90% (PLHIV who know their HIV status) of 90:90:90.

MOPED1143

Can STI screening be suitably integrated into community-based HIV testing services for men in Cape Town, South Africa?

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Background: In sub-Saharan Africa, a 59% increase in new cases of curable STIs has been reported. Having an STI increases the chances of acquiring HIV infection. Men do not typically get screened for STIs because they do not access health services.
Community-based HIV testing (CBHTS) services for HIV and other integrated services (STI; Condom promotion) offer early case detection and linkage to care for populations who do not typically access health services.
This study describes the proportion of clients (HIV infected & uninfected) with STI symptoms dis-aggregated by males and females.
Methods: Five CBHTS centres were established in HIV prevalent communities around Cape Town. Clients self-referred for HTS at either fixed sites/on a mobile basis; services were provided from a mobile van and tents set up at main thoroughfares in the community. HIV rapid testing was conducted according to national guidelines. All clients were screened for STI symptoms, presentation of 1 or more symptoms would result in referral to a STI health facility. Data was collected between August 2013-August 2016 and entered into a Microsoft Access database & validated.
Results: Overall, 68 877 clients tested for HIV, 34 688(50.3%) were male.2 662 (4%) were HIV+. Median CD4 POC test result was lower for males versus females (268-499vs 301-634). 6% of HIV+ females reported STI symptoms, 4% of HIV+ male clients reported STI symptoms. A higher proportion of HIV negative men reported STI symptoms compared to HIV negative females (91%vs84%). HIV negative clients were more likely to link to a health facility for STI services compared to HIV+ clients (50%;47%vs 19%;10%).HIV+ men were more likely to link to a health facility for STI services compared to females (p< 0.001; 19%vs10%).
Conclusions: An integrated HIV and STI service within the community can identify men with STI symptoms and refer them to diagnostic services. Screening HIV negative male clients for STIs can identify those clients who still practice high-risk sexual behaviour. This data identifies the urgent need for the re-prioritisation of condom promotion and programs.

MOPED1144

"We need incentives!" Health care professionals' reluctance to propose systematically HIV testing during general consultation in Cote d'Ivoire

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Background: To increase access to HIV testing, WHO recommended in 2007 provider-initiated HIV testing using a simplified but still exceptional approach in terms of pre-test counseling and consent. Cote d'Ivoire implemented in 2009 systematic HIV testing proposal in all medical consultations, irrespective of reasons. What are health care professionals (HCPs) perceptions and experiences related to testing proposal?
Methods: An ethnographic multi-site study was conducted in 3 general medical services (urban, semi-urban, rural) in 2 Ivorian health districts: 37 in-depth interviews with HCPs and 200 observed medical consultations (general medicine). A thematic analysis was performed on HCPs' practices and discourses.
Results: The proportion of patients offered an HIV test was low (around 20%), due to HCPs' reluctance to propose an HIV test in the absence of clinical suspicion. When offered, HIV test was more often prescribed than proposed. The analysis revealed 4 types of explanations in HCPs discourses.
(1) Due to stigma associated to HIV, HCPs feared a negative reaction from their patients: refusal, offence, distrust, loss of patients.
(2) Time-consuming specificity of HIV testing in terms of counseling, consent and administrative procedure (separate record and dedicated prescription) is perceived by HCPs as not useful and inducing a work overload that should be financially compensated or realized by dedicated providers, as it was before 2009.
(3) In the absence of clinical suspicion, they considered that proposing an HIV test during a general consultation is not medically justified and not their priority.
(4) Finally, HCPs felt that they are not sufficiently trained.
Conclusions: HCPs experiences and perceptions are negatively affected by the legacy of the successive HIV policies implemented since the beginning of the epidemy. Some complex procedures, historically implemented due to confidentiality and stigma issues, could maybe be simplified today. Integrating HIV testing in routine is a challenge considering that these activities were previously implemented with dedicated incentives, training and human resources. In a context of limited resources and mixed epidemic, how to prioritize and reorganize HIV testing in general consultations while motivating HCPs and being efficient in terms of public health?

MOPED1145

Low immunization coverage of the expanded immunization program in HIV-infected children initiated on ART and its determinants in Abidjan and Ouagadougou, Project MONOD ANRS 12206, 2011-2013

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Background: Thank to the access to antiretroviral treatment (ART), HIV-infected children survive, but their vulnerability to residual infectious diseases remains, justifying the National Expanded Program on Immunization (EPI) recommendations in this population. We assessed the vaccine coverage and its associated factors in HIV-infected children included in a research project in Abidjan, Côte d'Ivoire and Ouagadougou, Burkina Faso.
Methods: All confirmed HIV-infected children, less than two years of age, and whose parents have given their written consent were included from 2011 to 2013 in the ANRS 12206 MONOD therapeutic cohort to receive a lopinavir-based ART for 12 months. At inclusion, all EPI immunizations planned at birth for BCG, at 6, 10, and 14 weeks for diphtheria-tetanus-pertussis -polio-Hib-HBV, and at 9 months for yellow fever measles, and its relative dates were recorded. Those, with incomplete vaccine program had catching-up doses. At baseline, the EPI immunization coverage was measured, and its associated factors studied using a logistic regression.
Results: Between 05/2011 and 01/2013, 161 children were initiated on ART at median age of 13.7 months. At inclusion, vaccination coverages were: BCG: 85% (95% Confidence Interval [CI]: 78% -90%); Oral polio vaccine coverage was 52% (CI: 41% -61%) in Abidjan and 81% (CI: 69% -90%) in Ouagadougou; 3-dose diphtheria-tetanus-pertussis-polio: 70% (95%CI: 63% -77%), 3-dose Hepatitis B: 58% (95%CI: 50% -66%); 3-dose Haemophilus influenzae b: 56% (95CI: 48% -64%); yellow fever: 62% (95%CI: 52% -71%) and measles: 61% (95%CI: 51% -70%). Mother in charge of the child, living in a single dwelling rather than a common living-place, living in Abidjan rather than Ouagadougou and child´s mother having no mobile phone, were variables independently associated with the absence of immunization.
Conclusions: This study showed insufficient immunization coverage among HIV infected children compared to the national recommendations. Strengthening both the EPI coverage and early initiation of antiretroviral therapy among HIV-infected children remains a priority to improve their survival in West-Africa.

MOPED1146

Increasing efficiency in sample logistics: integrated sample transportation and results delivery of HIV and TB samples in the Federal Capital Territory (FCT), Nigeria

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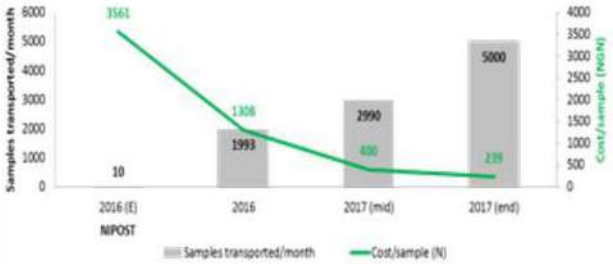
Background: Transportation of HIV and TB diagnostic samples to testing facilities is a major challenge across Nigeria and has proven to be uncoordinated, inefficient, and costly, leading to long turn-around-times (TAT) for results delivery and delays in initiation of treatment for clients.
Methods: Poor sample collection and storage practices have been major barriers particularly in scaling up the number of diagnosed clients and initiating them on treatment in the HIV and TB space as the cold chain logistics of sputum and plasma samples are specific and the associated costs, prohibitive. In 2015, the Clinton Health Access Initiative (CHAI) Nigeria in collaboration with the Federal Ministry of Health, designed an integrated sample transportation and results delivery (iST) model to mitigate sample transportation challenges and reduce TAT to patients receiving test results. Key objective was to pilot an efficient and cost-effective iST system at 278 health facilities across 6 area councils in Abuja, Nigeria.
Results: As of 2016 December, 15,000 samples had been transported. 100% of facilities recorded a reduced TAT, with 65% of these facilities recording TAT within 30 days. In addition, 88% of CD4 and TB sputum sample results were returned within 14 days. Cost projections comparisons achieved 63% cost savings when compared to baseline.
Conclusions: Overall, the pilot has increased efficiencies in terms of frequency, reliability and TAT of sample collection and results reporting; however, addressing pre-existing fragmentation of systems, funding and incentives structures may be necessary to ensure continued success.



[Figue 1 - Cost Projections]

MOPED1147

Implementation effectiveness: qualitative analysis of the integrated methadone and antiretroviral therapy (IMAT) strategy

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Background: HIV prevalence in Dar es Salaam, Tanzania is approximately 7%, research indicates prevalence is higher among people who inject drugs (PWID) with approximately 42% of PWID being HIV-positive. Given high HIV prevalence among PWID, integrating ART with opioid treatment programs can capitalize on treatment and prevention benefits. In 2015, an integrated methadone and antiretroviral therapy (IMAT) program was established at Muhimbili National Hospital in Dar es Salaam. Understanding how implementation of care integration is carried out is critical for future implementation efforts. We explore the connection between implementation context, intervention characteristics and implementation using the Consolidated Framework for Implementation Research (CFIR).
Methods: In-depth interviews were conducted with HIV-positive OTP patients (n=35) and their providers (n=8), 6-months after IMAT implementation. Provider interviews were assessed using CFIR's implementation constructs to assess implementation effectiveness. Patient interviews were analyzed using thematic content analysis, to understand experiences with the implementation process and perceptions of care integration.
Results: Providers felt the ability of the intervention to incorporate patient needs, fit into clinic procedures, and evidence for the effectiveness of the intervention had a positive influence on implementation effectiveness. Strong positive influences included adaptability, and perceptions of the advantage of implementing IMAT compared to alternative solutions. Resources dedicated to intervention such as physical space and time presented a challenge to implementation effectiveness.
OTP patients felt the ability to receive ARVs in the clinic made it easier for them to receive care. Patients identified challenges to implementation, such as clinic resources, consistent access to nutrition, and concerns about stigma from their fellow OTP patients. OTP patients enrolled in IMAT felt positively about the program overall, indicating that IMAT improved care receipt, and streamlined the care process.
Conclusions: This research uses qualitative data and CFIR constructs to assess the effectiveness of an implementation strategy that integrates HIV care into an OTP program in Dar es Salaam Tanzania. This work allows us to understand the key contributors to the success of the project; while at the same time recognizing the challenges that are being faced. These are important considerations when looking to expand the strategy to other OTP programs in the region.

MOPED1148

The prevalence of HIV, hepatitis B & C in a South African emergency department

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Background: Emergency departments (ED) are recognized as a high yield venue for HIV testing worldwide. In many resource-rich countries routine HIV and hepatitis screening has allowed for the early recognition and treatment of asymptomatic, previously undiagnosed infection. In this study we sought to define the scope of HIV and hepatitis infection in a South African emergency care context where screening is not routinely implemented.
Methods: This study utilized an identity-unlinked methodology to determine the point-prevalence of HIV, Hepatitis B, and Hepatitis C infection in the Frere Hospital ED, in the Eastern Cape from September 1st to November 30, 2016. All patients who had blood drawn in the Adult ED during the study period were enrolled. After clinically collected samples had been stored for one week in the onsite laboratory, excess sera was de-identified (except age and sex) and tested for HIV Ag/Ab, Hepatitis B surface Ag, Hepatitis B core IgM, and Hepatitis C antibody. Data were compared using T-test and chi-square tests for statistical analysis.
Results: Over the 3-month period 1246 patients had routine laboratory testing with sufficient excess sera for further analysis. In this unbiased sample, the HIV prevalence was 27.6%. HIV positive individuals were significantly younger (mean age 37.9 years versus 42.4 years, p<0.0001) and more likely to be female (59.3%, p<0.0001) compared to their HIV negative counterparts. The HIV positive patients had a significantly higher proportion of Hepatitis B and/or Hepatitis C co-infection (Table 1).

	All Participants (n-1246)	HIV positive (n=344)	HIV negative (n=902)	p-value
Age, mean in years (95% CI)	41.2 (40.7-41.8)	37.9 (36.6-39.2)	42.4 (41.0 - 43.9)	p<0.0001
Male Sex	635 (50.9)	140 (40.7)	495 (54.9)	p<0.0001
Female Sex	611 (49.1)	204 (59.3)	407 (45.1)	p<0.0001
Hep B Surface Ag positive	65	27	38	p<0.0001
Hep B Core IgM positive	12	4	8	p<0.0001
Hep C Total Ab positive	14	8	6	p<0.0001

[Charecteristics of Participants by HIV status]

Conclusions: The HIV prevalence in this ED setting is more than double the nationally estimated prevalence of 12.2%. This likely reflects the burden of HIV related disease presenting to the ED, and is evidence for the ED being a high yield setting for routine HIV testing. Of interest, the prevalence of Hepatitis B (5.6%) and Hepatitis C (1.1%) viral infections were lower than anticipated, but higher in the HIV positive population compared to HIV negatives.

MOPED1149

Uncovering the burden of HIV infection in South African emergency departments

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Background: South Africa has the highest HIV burden in the world (6.8 million people), but almost half of these are undiagnosed or not engaged in care. Extending HIV testing strategies to unreached population groups is essential. Routine HIV testing is mandated in all government health facilities, but seldom offered in emergency departments (ED)'s. ED's provide transient care to large numbers of patients, with a generally younger patient profile, making it a potentially useful HIV testing setting. In this exploratory study we sought to implement and evaluate the 2015 National South African counselor initiated HIV Counseling and Testing (HCT) strategy within one large ED in the Eastern Cape of South Africa.
Methods: We performed a point prevalence survey and implemented a HCT strategy with 24-hour coverage at Frere Hospital ED (volume approximately 3,000 patients per month) in the Eastern Cape from September 1st to November 30, 2016. All adult patients (≥ 18 years) that presented for care in the ED during the study period, were clinically stable (i.e., South African Triage level 2-5), and fully conscious (i.e., able to provide informed consent) were offered rapid point-of-care HCT and clinical data collection by trained HIV counselors.
Results: Our study enrolled 2181 patients, of which 66.9% (n=1461) consented to a rapid POC HIV test. The prevalence of HIV infection in these patients was 17.3% (n=377). This is significantly higher than the national estimate for adults of 12.2% (p <0.001). Furthermore 72.1% (n=272) of patients with a positive HIV test were previously unaware of their HIV positive status. The majority of new diagnoses (over 74.3%) were made between 7pm and 7am, in young males presenting with traumatic injuries.
Conclusions: This study provides evidence that EDs should be utilized as a testing venue to combat the HIV epidemic in SA and to reach an under-tested population. Unfortunately, the HCT strategy implemented was only able to enroll a fraction of the patients that presented for care. Further research is required on how best to optimize testing in this setting and the provision of linkage to care from the emergency department.

MOPED1150

Chronic hepatitis C among intravenous drug users in Tanzania: assessment of the liver disease and utility of HCV core antigen detection and quantification

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Background: The World Health Organisation (WHO) has recently called for hepatitis C virus (HCV) elimination and has identified injecting drug users (IDUs) as a key population. This study aimed to assess 1) the prevalence and severity of chronic hepatitis C among IDUs in Dar-es-Salaam, Tanzania, and 2) the validity of a HCVcAg detection and quantification using serum and dry blood spots (DBS) for identification of viraemic subjects in the sub-Saharan Africa resource-constrained setting as compared to the standard HCV quantitative PCR.
Methods: Between May and July 2015, consecutive HCV-seropositive patients enrolled in the local opioid substitution treatment (OST) centre were invited to participate in the study. All completed an epidemiological questionnaire and were offered comprehensive liver evaluation including liver stiffness measurement (LSM). HCV RNA detection (CAP/CTM HCV version 2.0, Roche Molecular Systems, Pleasanton, CA), genotyping (NS5B gene phylogenetic analysis) and HCVcAg on blood samples and DBS (Architect assay; Abbott Diagnostics) were also performed.
Results: Of the 1,011 IDUs registered in the OST clinic, 731 (72%) underwent anti-HCV antibody testing and 388 (53%) had a positive result. 153 patients from the positive group were enrolled: 141 (92%) were male, median age was 38 years (IQR 34-41), and 65 (42%) were co-infected with HIV. The median LSM was 5.3 kPa (IQR 4.4-6.5): 21 (17%) had clinically significant fibrosis (≥F2) and 6 (5%) had cirrhosis (F4). 116 patients (76%) had a detectable and quantifiable HCV RNA (median value: 5.3 Log IU/mL (IQR 4.0-6.3)). Only genotypes 1a (68%) and 4a (32%) were identified. Sensitivity of HCVcAg to identify patients with positive HCV RNA was 99% using sera and 77% using DBS. HCVcAg levels were linearly correlated with HCV RNA levels both in sera (r=0.80 p< 0.0001) and DBS r=0.75 p< 0.001).
Conclusions: In order to comply with the HCV global elimination goal, an increased focus on chronic hepatitis C screening and treatment in IDUs in East Africa is critical. The HCVcAg offers an interesting practical alternative to overcoming the diagnostic barrier in Africa. However its utility in DBS remains sub-optimal.

MOPED1151

Predictors of HCV seroconversion in people who inject drugs in 5 regions of Ukraine

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Background: While there were 39,664 PWID officially registered with drug addiction clinics in 2016, WHO estimates 310,000 PWID in Ukraine. Even though the harm reduction services for PWID were introduced in Ukraine in 2001, national 2015 surveillance showed 55.9% prevalence of Hepatitis C Virus (HCV) in PWID reaching 90% in some areas. The objective of this analysis was to assess HCV seroconversion in PWID in Ukraine and its predictors.
Methods: The data were collected in 2014-2015 within the research project implemented in partnership with Yale School of Medicine on access to opioid antagonist treatment (OAT). Respondent-driven sampling was used to recruit current PWID (n=521) and random sampling was used to recruit OAT patients (n=434) in 5 regions of Ukraine. Interviews were followed by rapid HCV testing. Seroconversion was defined as present if respondent stated he had been tested HCV-negative before and was tested HCV-positive after the interview. Predictive model using logistic regression was built with HCV seroconversion as the outcome. Potential confounders included demographics, risky sexual behavior, risky injecting behavior, length and frequency of injecting, alcohol intake, HIV status, and history of incarceration.
Results: Mean age of participants was 37.3 years (s.d.8.2); most of respondents were male (73.8%); mean length of injecting was 22.2 years (s.d.9.1). HCV prevalence in the sample was 64.1%. The prevalence of HCV seroconversion was 11.6% (n=111). The mean interval for HCV seroconversion 2.8 years (s.d.3.2; range:1-19). The logistic regression showed that OAT had a protective effect against HCV (OR=0.52; 95%CI=0.37-0.88) seroconversion. Surprisingly, neither risky injecting behavior nor length/frequency of injecting were statistically significant.
Conclusions: Despite large coverage of PWID with harm reduction services countrywide, the prevalence of HCV seroconversion in this key population remains very high. The results of our study show that OAT programs are an effective means of HCV prevention in PWID that is why there is an urgent need in the country for scaling up OAT programs as well as expanding access to HCV treatment on a national level.

MOPED1152

Eliminating HCV/HIV coinfection through enhanced treatment: HCV treatment in primary care is feasible and highly effective

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Background: Gay and bisexual men (GBM) are the key population affected by HIV and hepatitis C (HCV) coinfection in Australia. Access to HCV direct-acting antivirals (DAA) for all in Australia provides an opportunity to dramatically increase treatment access. The co-EC Study supports general practitioners to initiate treatment in primary care settings, aiming to provide proof-of-concept that treatment scale-up can eliminate HCV in coinfected GBM. We report on the feasibility of this model-of-care based on preliminary treatment outcomes.
Methods: The co-EC Study is an ongoing (March 2016-) clinician-directed, non-randomised trial of DAA among people with HIV/chronic HCV coinfection. HCV testing and treatment are delivered by specialists or general practitioners with nursing support at tertiary (n=2) and primary care (n=4) sites in Melbourne, Australia. Nurses deliver education, treatment support and coordinate visits.
Enrolment involves routine clinical data (haematological, biochemical, fibrosis assessment), which may prompt a specialist to be consulted for advice or referral prior to treatment initiation, and participants complete a self-reported behavioural survey. The primary outcomes of this preliminary analysis are treatment uptake and sustained virological response (SVR12).
Results: To date, 160 participants have enrolled (99% male; median age 48), including 106(66%) seen in primary care. Of these, based on clinic data 40(38%) could commence treatment immediately, 25(24%) required specialist advice, 17(16%) required specialist referral, and 22(21%) had incomplete data. Overall, 136(85%) participants have commenced treatment (sofosbuvir/daclatasvir-50%; sofosbuvir/ledipasvir-47%) with no difference in uptake between primary and tertiary sites. The majority have been treated for HCV genotype 1 (70%) or 3 (24%).
High-risk behaviours were commonly reported at enrolment, including: ever injecting drugs (62%) and of those, ever injecting with a used needle/syringe (33%); past month recreational drug use (50%); and in the previous six months, group sex (27%) and inconsistent condom use among those with casual male sex partners (79%).
Fifty-six participants have been assessed 12-weeks post-treatment. Where HCV RNA was available (n=50), 100% achieved SVR12.
Conclusions: This model-of-care has successfully reached HIV/HCV coinfected men with high-risk sexual and drug-use behaviour. Treatment in primary care settings is feasible, highly effective and may lead to sustained increases in treatment uptake and HCV elimination in HIV-coinfected GBM.

MOPED1153

Role of PLHIV networks in facilitating hepatitis C cascade of care in South and South East Asia

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Background: Greater access to ART significantly improved PLHIV health. However, HCV co-infection remains major cause of morbidity and mortality. A study from WHO estimated 285,600 (221,100 - 406,500) co-infected individuals in South and South East, which contributes 13% in global estimation of HIV - HCV co-infection[1]. Absence of HCV services threat PLHIV life quality despite successful anti retroviral therapy.
[1] Prevalence and burden of HCV co-infection in people living with HIV: a global systematic review and meta-analysis Lucy Platt, Philippa Easterbrook, Erin Gower, Bethan McDonald, Keith Sabin, Catherine McGowan, Irini Yanny, Homie Razavi, Peter Vickerman WHO 2015. Published by Elsevier Ltd/Inc/BV
Methods: In 2014, APN+ started HCV treatment literacy for PLHIV and advocacy program towards availability of integrated HIV - HCV program in 7 south and south east Asia countries, include India, Indonesia, Myanmar, Nepal, Pakistan, Thailand and Vietnam. Treatment literacy materials developed and trainings conducted with local PLHIV groups. At regional level APN+ established regional advocacy platform to address patent and other intellectual property barriers to access for medicines. New website www.hepcasia.com developed to reach broader community.
Results: Significant price reduction of DAA drugs resulted from advocacy led by community in India, brought down the price as low as 500 USD per treatment course, followed with approval of generic version DAAs to be marketed in Indonesia and Myanmar and leads to insertion of hepatitis C program in National AIDS strategic plan in those two countries. In December 2016 Indonesian MoH announced procurement bid for DAA drugs to treat 6,000 co-infected patients in the following years. While at the same time Myanmar started preparation of HIV-HCV integrated pilot program for PWID community. In addition APN+ helps IAC, local partner in Indonesia to set up buyers club, which by December 2016 has allowed 120 patients accessed treatment with DAAs drugs under trained physicians.
Conclusions: Providing HCV treatment literacy to PLHIV groups enabled them to self organized and creates pressure towards government to improve its AIDS program and address HCV co-infection. Community initiated buyers club can get patients treated, but presence of integrated HIV-HCV program is instrumental to reach desired impact.

MOPED1154

Evaluation of implementing integrated HIV services with other development programs: the case of Ethiopian Electric Utility and Power Companies

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Background: HIV&AIDS is a global development problem. Its drastic effects are much higher among productive work forces in large scale hydropower construction projects and electric service workplaces. These workplaces are located in hotspots with commercial sex workers and internally displaced youth driving them to HIV risks hence this calls for execution of integrated HIV services with development programs. This study aims to evaluate the integration of HIV services with development programs and workplaces of Ethiopian Electric Utility (EEU) and Ethiopian Electric Power (EEP).
Methods: This is a cross sectional study conducted between February 12 and July 30 20016.Both quantitative and qualitative methods were employed. Multi-stage sampling techniques were used to select the study settings (5 regions & 2 project sites) and sample respondents. Primary data was gathered through questionnaire survey from 600 respondents, key informants, focus groups, in-depth interviews. Project documents, strategic and operational plans, annual reports of the two companies were reviewed. Triangulation was made to ensure validity and reliability of data.
Results: Almost all respondents declared that HIV services were implemented in the companies while the majority (68%) of them reported inadequate level of integration of the services with the development programs. 79.5% of them reported that HIV service was adequately integrated with clinical care and treatment. 62.9% respondents declared that HIV services in hotspot project areas were integrated with commercial sex worker targeted projects with whom the young displaced migrant workers have a high client relationships. However, less than 20% of the respondents utilized VCT within a year with significant variations ($p < 0.05$) among regions and project sites.. ¾ of PLHIV participants reported that the level of integration is not adequate hence they confront stigma and discrimination. 73.4% of respondents reported accessibility of condom is high. Data from document review and qualitative methods also confirmed the findings.
Conclusions: The majority of respondents knows and appreciates the integration of HIV services with development programs of the companies. However, the findings show that there are needs for improving adequacy and comprehensiveness of integrating HIV services to all the development projects and strengthening the efforts in all work places of the companies.

MOPED1155

Integration of HIV services: the case of the Kenya Police Service recruits training

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Background: HIV prevalence in Kenya is 5.9%. 51% of the 77,647 adult new infections in 2015 were adolescents and young people aged 15-24 years. Out of the 1.5 million people living with HIV, 268,586 are adolescents and young people aged 15-24 years. The Kenya Police Service recruits new staff aged 18-30 years from among the general population. Some of these young people do not know their HIV status and their knowledge level is below 70% with HIV stigma level estimated at 45%. It is therefore critical for the newly recruited police officer to acquire HIV and AIDS competency inorder to prevent new infections, reduce mortality and morbidity and reduce stigma and discrimination among themselves and their clients.
Methods: The Kenya Police intergrates HIV services into the newly recruited police officers training every year using the Evidence-based Combination HIV and AIDS Prevention interventions. The AIDS Control Unit works together with partners to provide HIV, AIDS and human rights information, HIV services, co-morbidities screening and referrals provided in line with the existing government guidelines with meaningful participation of young PLHIV as mobilisers, peer educators, facilitators and service providers.A total of 6000 recruits were targeted for this intervention.
Results: The integration of HIV services into recruits training yielded the following results:
1. 5981 young people were reached with comprehensive HIV information
2. 5858 young people were tested for HIV
3. 11 young people receiving positive HIV results referred for further care
3. 5858 young people were screened for TB and STIs
4. 659 of clients with signs of TB were tested for TB and tested negative
5. 6 of young people with signs of STI were tested for STI and none tested positive
6. 10 young men were referred for VMMC and received VMMC services
7. 5981 of the recruits demonstrated a clear understanding of the HIV prevention, treatment, care and support needs themselves, clients and key populations
Conclusions: 97.4% demand for services and 100% demand for information was catalysed through MIPA and high level support. Integration of HIV services, therefore, is cost effective, sustainable, complements facility based service provision and contributes to "Getting to Zero".

MOPED1156

Integration of economic empowerment into combination prevention for out-of-school adolescent girls and female sex workers in Tanzania

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Background: In the USAID-funded Sauti program, out-of-school adolescent girls and young women (AGYW) aged 15-24 and female sex workers (FSW) are offered an economic strengthening savings and loans (WORTH) platform that provides a unique combination of curriculum-based financial literacy, community banking, microbusiness development and behavioral change communication, "WORTH+ includes biomedical services such as HIV testing and linkage to care and family planning (FP).
Methods: Data were collected from a representative sample of 9,034 AGYW and 1,452 FSW in 28 wards of five regions in Tanzania selected through multi-stage random sampling in April 2016 using mobile data collection. Univariate analyses were conducted using Chi-square test.

Results: While 56% considered FP their responsibility with no significant difference between AGYW and FSW, condom use was low (45%), and 36% of participants considered anal sex to be an acceptable FP method. Compared to AGYW, FSW were less literate (77% vs. 65%, p=0.001), but more likely to own a micro-enterprise prior to joining WORTH+ (68% vs. 47%, p<0.001). FSW were also committed to higher mandatory and voluntary savings, with 40% of FSW saving >2 USD against 54% of AGYW saving < 1 USD per week (p<0.001).
Irrespective of the beneficiary groups, savings amounts differed significantly by region of the country and marital status (p<0.001), but not by micro-enterprise ownership.
Conclusions: The high proportion of microenterprises already owned by the target populations suggest great potential for interventions that develop feasible economic alternatives to commercial or transactional sex for populations at elevated risk of HIV. However, AGYW and FSW differ by their baseline financial literacy, economic status, and ability to save, therefore economic empowerment interventions need to be tailored to their group-specific dynamics.

MOPED1157

Harm reduction through Medically Assisted Therapy (MAT): a new paradigm to curb human immunodeficiency virus (HIV) transmission among people who use drugs in Malindi, Kenya

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Background: The Kenya Modes of Transmission (KMoT) 2008 study attributed 3.8% of new adult HIV infections to injecting drug use. The positive impact of MAT on opioid-dependent individuals with respect to harm reduction is well documented. Various studies confirm longer retention in MAT (≥ 1 year) yields better treatment outcomes. As Kenya strives to curb the dual HIV and drug use epidemic through MAT, there is urgent need to evaluate treatment retention and establish risks for attrition.
Methods: A retrospective MAT record review of clients enrolled by April 2015 using longitudinal Excel-based attendance, clinical and pharmacy registers. Variables analyzed co-morbidities, socio-demographic characteristics, daily methadone pick-up and monthly treatment status. Time-points for 6, 12 and 18 months were September 2015, April and September 2016. All data disaggregated by age and gender at baseline. Treatment retention defined as being active on MAT each month of selected time frame, without treatment interruptions.
Results: A total 271, 145 and 138 clients regularly accessed MAT for 6, 12 and 18 months respectively. About 95% of them injected drugs; males comprised 85%. 91 clients (80% males) had communicable co-morbidities; with 57, 17, 13 and 23 clients positive for HIV, Tuberculosis, Hepatitis B and Hepatitis C viruses respectively (males comprising 79%, 94%, 85% and 87% respectively). The modal age cohort with co-morbidities was between 35 to 45 years. Median duration on MAT for 6, 12 and 18 months cohorts was 4.8, 9.6 and 14.2 respectively. By end of 18 months, MAT retention rate of 37% was recorded, compared to 89% (81/91 clients, 64 males) for co-morbid population.
Conclusions: MAT program in Malindi achieved an average of 63% retention after 12 months, surpassing the 50% average retention for developing countries (PubMed: 23859638). Drug use is a predisposing factor to contracting HIV and other sexually transmitted infections that require multidisciplinary intervention. Regular psychosocial support for males is paramount to improve treatment outcomes.

MOPED1158

Tit integration of HIV testing and prevention services among men who have sex with men (MSM) in the government owned health facilities in Western Kenya

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Background: HIV prevalence (18.2%) and incidence (35%) among men who have sex with men (MSM) in Kenya are disproportionately high, compared to the rest of the population. Risky sexual behavior and poor health seeking among MSM (especially in government facilities) exacerbate their HIV epidemiological burden. There is little evidence on the feasibility of integrating MSM focused HIV prevention services in government health facilities. To generate this evidence, LVCT Health partnered with government health facilities and a regional MSM health organization to mobilize MSM for HIV prevention, care and treatment services.
Methods: In this implementation research, we analyzed service delivery data in 11 government facilities in Western Kenya between November 2015 and September 2016. We collected quantitative data to assess the integration of MSM focused services (testing, Sexually Transmitted Infections (STI) screening, linkage to care and treatment in routine health services, uptake, viral suppression and retention). Qualitative data on perception of services by MSM were collected through 11 informal interviews. Data on HIV Testing Services, STI Screening and Care and Treatment was abstracted from service delivery records. Quantitative data was analyzed using descriptive methods and qualitative data was analyzed using content analysis method.
Results: In total, 5,290 MSM were reached with HIV prevention messages, and 85% (n=4497) screened for STI. STI prevalence was recorded at 3% and uptake of STI treatment services at 100%. 5,132 were tested for HIV with a HIV positivity rate of 4% (n=188) recorded. 78% (n=146) were linked to care and treatment and 94% (n=146) were initiated on ART. Retention in care was 84%; viral load uptake (87%) and viral suppression was achieved in 78% of MSM clients.
The consistency in the services from the static site has been a motivating factor for the clients to seek service for instance "...walking to a MOH facility and getting a friendly provider motivates you to go to the clinic..."
Conclusions: This partnership between civil society and government facilities improved the HIV cascade of care - towards the 90:90:90 targets. This study provides a benchmark for the integration of MSM services in government facilities.

MOPED1159

Exploring the psychosocial well-being of HIV-positive children and youths orphaned by HIV

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Background: One major challenge in the successful implementation of retention and adherence intervention programmes in sub-Saharan Africa is limited interventions that address the psychosocial needs of HIV positive children orphaned by AIDS. Few available studies have shown that children orphaned by AIDS reported higher depression, peer problems, PTSD, conduct problems and delinquency than the non-orphans or orphans due to other causes. Therefore, this study seeks to assess the psychosocial changes that take place amongst adolescents living with HIV. The Regional Psychosocial Support Initiative (REPSSI) is an NGO that specialises in the provision of psychosocial support services to infants, children, and youths through her partners including government, and other NGOs and CBOs in 13 Southern and Eastern African countries.
Methods: An intervention involving twenty support groups operating in Harare was developed using a concept of supporting grief in children and adolescents. HIV+ adolescents and their caregivers played an active role in the development of the curriculum intervention. This approach assures contextualization and is both innovative and sustainable. Baseline, and follow-up in a randomised control trial approach was conducted in which qualitative and quantitative data was collected from adolescents exposed to the curriculum and those who are not exposed. Ethical approval was obtained from the Zimbabwe Research Ethics Committee.
Results: Overall, 242 children and youth in the age group 10-24 years participated in the baseline survey. Of which 55% of the participants are girls. Furthermore, 76% of participants have lost both parents, (61%) father only, and 54% mother only. Of those who lost father 67% reported that their father was the bread winner. More than half of the participants who lost either one or both parents reported that life was too tough, failed to sleep, and felt run down. There was no significant difference between type of orphan hood and the key psychosocial indicators measured, as well as, gender, and age.
Conclusions: Interventions addressing the psychosocial needs of HIV positive children and youth orphaned by HIV is crucial in programming as this will improve their psychosocial well-being which in turn improves their adherence and retention to treatment, care and support.

Diagnostics

MOPED1160

Viral load and treatment adherence among pediatric patients in Bouaké, Côte d'Ivoire

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Background: Elimination of pediatric AIDS requires not only the elimination of mother-to-child transmission of HIV, but also better treatment adherence for HIV+ children. The WHO recommends viral load testing every six months to monitor health and assess treatment adherence for children 6 months to 13 years old. In Côte d'Ivoire, no study has yet been conducted to describe the HIV+ pediatric population with relation to their viral loads, nor assessed whether viral load levels are correlated with reported treatment adherence. This study seeks to measure adherence levels of pediatric patients with high viral loads compared to low viral loads in a university teaching hospital of Bouaké, Côte d'Ivoire.
Methods: This is a retrospective, descriptive study among all children (0-14 years) on ARV treatment for at least 6 months who received viral load analyses at the study site from July 2015 - December 2016. Viral load, ARV treatment, and pharmacy registries were cross referenced to determine viral load, reported adherence (as described by parents and caregivers), and other demographic indicators. Descriptive and statistical analyses were done to assess correlation between reported observance and viral load level, both in the aggregate and disaggregated by age.
Results: Preliminary descriptive results show that, among the 101 patient charts analyzed, 59% had viral loads of less than 1000 copies/ml ("low") while 42% had greater than 1000 copies/ml ("high"). More younger children (0-8 years) had lower viral loads (62%), while older children were almost evenly split between low (51%) and high (49%) viral loads. Among reported adherent patients, 71% had low viral loads, while only 32% of non-adherent patients had low viral loads. Further statistical analyses are being undertaken to determine whether factors such as sex, further disaggregated age, or other health conditions are associated with viral load levels or reported adherence.
Conclusions: Though monitoring of pediatric viral loads is essential to ensuring the management of HIV in children, especially in resource-poor settings, challenges remain in adherence to and suppression of viral load. Further research should measure associated factors to adherence as well as to understand to what level viral load is a result of non-adherence or treatment failure.

MOPED1161

Implementation of a health information system to improve uptake of early infant diagnosis in HIV-exposed infants and birth immunization coverage in HBV-exposed infants in Abidjan, Cote d'Ivoire: the DEPISTNEO project

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Background: Early infant diagnosis (EID) coverage is insufficient in Abidjan, estimated 33% in 2015, partially due to poor linkage between birth and 6-week EID. We implemented a novel routine screening strategy that combines rapid diagnostic testing for both maternal HIV and HBV exposure in newborns at time of birth linked to a computer-based health information system (HIS) that tracks from birth HIV/HBV-exposed mother-infant pairs through the continuum of postnatal care in Abidjan, Côte d'Ivoire.
Methods: All mother-infant pairs who give maternal consent in the five participating maternity clinics are included. At birth, all mothers are tested and those infected who are unaware of their status are offered a second opportunity to be enrolled in care. All those HIV-infected receive PMTCT. Additionally, rapid HBV-testing is offered; HBs-Ag-exposed children receive immunization at birth. All livebirths are recorded in the HIS; HIV and/or HBV-exposed children are tracked through the continuum of care. Each step of the EID and immunization cascades (6-10-14W) is recorded in the HIS. Weekly reports alert social workers in case of a missed visit, who then contact families to re-schedule. Children are followed-up until definite diagnosis after breastfeeding cessation.
Results: Between August-December 2016, 3209 births were recorded. HIV testing coverage at time of birth was 99%: maternal prevalence of HIV was 3.7% (95%Confidence Interval (95%CI): 3.1-4.4). Of those HIV-infected, 56% were already on combined ART. Among the 111 HIV-exposed live-born infants, 63 had reached follow-up >6 weeks: 44% (95%CI:32-56) had a DBS for virological testing. After HIS alerts, 6-week virological testing coverage reached 56% (95%CI:43-68); overall 6-week immunization coverage in HIV-exposed infants was estimated 48% (95%CI:36-61). Acceptability of maternal HBV testing reached 95%: prevalence of HBV was 7.0% (95%CI: 6.1-7.9). Among the 219 HBV-exposed children, 99% were immunized at birth. Of these children, 128 had reached a follow-up>6 weeks: their 6-week immunization coverage was 65% (95%CI:57-73).
Conclusions: Maternal HIV and HBV rapid diagnostic testing at birth is both feasible and acceptable. While immunization at 6 weeks and EID coverage remain low, HBV immunization coverage at birth is high. Compared to Ivorian national reports, the HIS improved EID uptake.

MOPED1162

Early infant diagnosis: review of antibody test results and linkage loss

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Background: Indian Early infant Diagnosis (EID) for HIV program began in 2010. Under Indias' EID algorithm infants are called for testing at 6 weeks, 6 months, 12 months and 18 months of age, unless found positive and linked to care. Any infant arriving at age greater than 6 months is administered an antibody test at the sample collection centre, and a Dried Blood spot (DBS) sample is sent for PCR testing at laboratory only if antibody test is found positive. This paper seeks to quantify antibody negativity at different ages and linkage losses between stages of testing.
Methods: A retrospective analysis was conducted on program data comprised of 4,294 infants presenting for testing from May 2013-October 2016 in Maharashtra. The following metrics were evaluated - (a) Antibody negativity at different ages and (b) Loss to follow up (LFU) between 1) antibody positivity and collection of DBS sample, 2) DBS detected and collection of confirmatory sample and 3) between confirmatory diagnosis and treatment linkage. Analysis was done for Financial Years (FY), starting with April and ending with March.
Results: Median age at first, second, third and fourth visit were 2.2, 6.9, 13 and 18.5 months. The proportion of patients registering within ages 0-2 months increased from 26% in FY 14-15 to 56% in FY 15-16. 85% of antibody tests were unreactive for infants within ages 6-9 months. DBS sample weren't collected for 27% of those detected on antibody test. 34% of those detected on DBS screening test didn't return for a confirmatory test. 54% of those found detected on confirmatory test weren't linked to treatment.
Conclusions: The decreasing median age at first visit indicates that the programme has been successful in reaching infants earlier but LFU at various stages necessitates focused strategies to reduce linkage loss. Infants found negative on antibody are not administered a PCR test, making high antibody test negativity a concerning finding due to possibility of false negativity and missing out infected infants. Further research in this area is required.

MOPED1163

Analysis of HIV testing trends among HIV-exposed infants in Malawi using an electronic laboratory system, 2012-2016

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Background: In 2016, 5.5% of HIV-exposed infants (HEI) aged 1-6 months were diagnosed with HIV infection in Malawi. Since 2011, Malawi has expanded testing to align with WHO guidance on testing of HEI between the ages of 4-6 weeks. We describe the impact of infant virologic testing (IVT) scale-up activities on the number of infants tested, diagnosed, and on treatment using clinical, laboratory, and M&E data sources.

Methods: An analysis was performed utilizing nationally representative IVT data collected from 2012-2016 from 9 reference laboratories and entered into a centralized laboratory management system (LIMS) with nationally reported aggregated statistics of HEIs from Malawi Ministry of Health (MOH) Integrated HIV Program Quarterly Reports, 2012-2016. Using these two data sources, we reported change in HEI care and IVT overt time.
Results: In 2012-2016, 170,543 IVT results were entered into LIMS, including 12,344 (7%) positive IVT from 636 health facilities in the Northern (8%), Central (28%), and Southern (64%) regions. The distribution of IVT by district was consistent with population distribution, with most tests reported in Lilongwe (12%) and Blantyre (10%) Districts. According to MOH data, of the total number of infants born, 160,236 (7%) infants discharged alive from maternity were known to be HIV-exposed; 148,398 (92%) of these infants received anti-retroviral (ARV) prophylaxis; and 114,162 (70%) were enrolled in HEI follow-up before 2 months of age. The data also showed an increase in total testing volume by 55% and a 53% increase in the number of facilities utilizing LIMS laboratories. Most notably, the number of HEI linked to care following a positive HIV test increased progressively from 47% to 96%.
Conclusions: By synthesizing LIMS data on IVT with routine program monitoring clinical and laboratory data for HEIs, we were able to demonstrate an increase in number of IVT performed on HEIs, an improvement in the number of HEIs enrolled in follow-up care, and a sustained percentage of HEIs receiving ARVs after a positive EID test. The study also demonstrates electronic LIMS data as an important source of information that complements routine sources for monitoring HIV programmatic activities in Malawi.

MOPED1164

An assessment of the effectiveness of reaching untested HIV-exposed infants through community-based mobile outreach clinics in Lesotho

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Background: In 2014, only 56% of HIV-exposed infants (HEIs) in Lesotho received an Early Infant Diagnosis (EID) test within two months of birth. Mortality rates for HIV+ infants peaks between 6-8 weeks of life, and before the age of two, half of all untreated babies will die. Thus, detection and initiation on treatment at the earliest possible stage is crucial in saving these lives. An evaluation was conducted in Lesotho to measure the effectiveness of reaching previously untested HEIs through community-based mobile outreach clinics (MOCs).
Methods: From December 2015-December 2016, seven public-private MOCs operated four days a week, visiting a different site once per month. The MOCs were located in remote areas and offered a range of clinical services with a focus on HIV testing for children, including collection of dried blood spots. A mobile application was designed for real-time data collection at point-of-care for healthcare workers to capture data on HEIs; including residence, gender, age, and testing history.
Results: Out of 1,336 MOCs, 164 HEIs were identified, averaging 0.12 identifications per MOC, with near equal male-to-female distribution. Overall, only 34.1% were known to have been previously tested (EID or rapid). There was a negative correlation between age and volume identified, with 32.9% of infants between 0-1 months old, 31.7% 2-4 months old, 25% 5-11 months old, and 10.4% 12-24 months old. Previous testing had been conducted on infants aged 0-1 month (3.7%), 2-4 months (42.3%), 5-11 months (58.5%) and 12-24 months (47.1%).
Conclusions: While the number of identifications per MOC was low, they were effective at finding young HEIs (< 6 weeks) and those with no known previous testing. The MOCs also found a surprisingly high proportion of untested HEIs between 12-24 months old. This suggests that in addition to the geographical barriers faced in remote communities, caregiver reluctance to receive facility-based testing was a factor in preventing HEIs from being tested until a community option was available. It is therefore recommended to increase community EID as a supplement to facility-based EID, with prioritization in regions with underserved communities in remote locations, as well as places where HIV stigma remains prevalent.

MOPED1165

Uptake of birth testing for early infant diagnosis of HIV among HIV exposed infants at Livingstone Central Hospital: 2008 to 2016

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Background: In 2014, only 37% of HIV exposed infants in Zambia had an HIV DNA-PCR test for HIV diagnosis within the first two months of life. Limited laboratory services led to poor uptake of Early Infant Diagnosis (EID) among other things. The aim of our study is to evaluate the effectiveness of HIV testing at birth or within the first 6 weeks of life under programmatic conditions in a setting with a high prevalence of HIV.
Methods: Using a retrospective cohort study design, we abstracted data from inpatient and outpatient records in the department of pediatrics. We performed descriptive analysis and estimated HIV testing and positivity rates at different time intervals. We evaluated the proportion of infants who tested positive for HIV within the first 6 weeks of life. We include only the first test for each child in this analysis.
Results: We enrolled 2,452 children who tested for HIV with DNA-PCR below 2 years of age. Of these, 850 (37%) tested within the first 2 months of life. Of those that tested within 2 months, 197 (23%) tested within the first 6 days of life. At least 5% of all the tests done within the first 6 days of life confirmed HIV infection while 5% of all tests done from 1 week to 4 weeks of age and 6% of all tests done from 5 to 8 weeks of age confirmed HIV infection.
Overall, 51% of those tested were female. Although infant HIV testing numbers did not increase substantially during this period, the proportion of mothers who knew their HIV status during pregnancy increased (5% in 2008 to 72% in 2015). Sixty five percent (65%) of infants tested within the first 6 weeks of life completed follow-up to at least 2 years.
Conclusions: In this cohort of HIV exposed babies, HIV testing within the first 6 days of life had similar results with testing from 1 to 4 weeks and 5 to 8 weeks of age. This finding supports HIV testing for HIV-exposed infants using nucleic acid tests at birth and during the first 6 days of life in resource limited settings.

MOPED1166

Viral load monitoring with SAMBA-1, a semi-quantitative nearly point-of-care method in Arua, a rural district in Uganda

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Background: Point-of-care (POC) systems for viral load (VL) monitoring have considerable potential but evidence from ‚real-life' use is limited. In September 2013, Médecins sans frontières, with UNITAID funding implemented SAMBA-1, a semi-quantitative (1000 copies threshold) nearly point-of-care VL test system in the Regional Referral Hospital of Arua, a rural district, Uganda. The objective was to provide access to routine VL testing to approximately 7000 ART patients followed by Ministry of Health (MOH). We describe the VL cascade to highlight successes and challenges in the first 3 years of implementation.
Methods: We performed a retrospective observational cohort analysis using routine patient monitoring data. We describe the sequence of VL tests performed between September 2013 and November 2016 for patients followed with at least 6 months on ART (eligible for VL), and outcomes up-to 1 year after an initial VL≥1000 copies/ml.
Results: Over the study period, 9,305 patients were eligible for VL and coverage was 78.1%. Of the patients tested, 1748 (24.1%) had a VL ≥1000 copies/ml, and of these, 1221 (69.9%) received a repeat VL test. Median time to repeat VL was 6 months (following MOH protocol), at which 457 (37.5%) suppressed, 763 (62.5%) remained with a VL≥1000 copies/ml. Of the 763 patients with two consecutive VLs ≥1000 copies/ml, 59 (7.7%) were switched to the next ARV line. Clinical review was same day for 92% of tests. National VL testing protocol was incomplete for 3265 (35.1%) eligible patients, of whom 45.3% were lost-to-follow-up, 1.5% died and 13.2% transferred-out by date analysis censorship.
Conclusions: POC VL testing achieved good VL-testing coverage, permitted same-day clinical review of results and timely follow-up. However, ensuring every patient gets their VL test remains a challenge in a dynamic cohort. Close program monitoring and support to staff is essential to identify and address gaps in the VL monitoring cascade. Very few treatment failures switched regimen. Key constraint is reluctance, by clinicians to switch patients based on semi-quantitative results and

by some patients even after failure confirmation. The issue could be overcome by improving clinicians' knowledge on the validity of the 1000-threshold, patients' education and psychosocial support.

MOPED1167

HIV self-testing in Zambia: User ability to follow the manufacturer's instructions for use

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Background: HIV self-testing (HIVST) is a new approach to increase testing uptake. Although evidence demonstrates that supervised users can accurately perform HIVST, the ability of unsupervised users to do so, using manufacturer's instruction for use (IFU) requires further investigation. The Clinical Performance study (CPS) within the PSI/ UNITAID STAR Project provided participants with the OraQuick® HIV rapid self-test (OFT) and IFU, and asked them to perform the test. In the pilot phase of the CPS (June 2016), participants were provided IFU only. Video recording showed low levels of comprehension and poor sensitivity and specificity were obtained. Hence, additional step-by-step demonstrations by health workers were provided before the participant initiated the HIVST. This study investigated intended user ability to understand and follow the IFU.

Methods: Cognitive interviews were conducted with 17 purposely selected adults and adolescents to assess understanding of the IFU. Video recordings of 17 participants conducting unsupervised HIVST (76.5% males, 88% rural) were analysed descriptively and scored using a predetermined standardised checklist.

Results: Cognitive interviewing revealed that participants struggled to open the test kit easily. The most difficult instructions to understand were those related to the collection of oral fluid by swabbing the gums. Adolescents were more likely to swab accurately and to rely on both images and written instruction compared to adults. Understanding and interpreting images and particular terms (pouch, press firmly e.g.) was perceived challenging.

Video analysis showed that only 8/17 participants read the IFU before the test, despite explicit instructions to do so. There was a significant association ($p< 0.05$) between participants who read the instructions and their ability to correctly collect oral fluid sample. Only 4/17 participants were able to conduct all steps correctly. Women were 2.5 times more likely to perform all steps of the test correctly.

Conclusions: The OraQuick® HIV rapid test, though validated under ideal conditions, is shown to be challenging to use under real life conditions even after step-by-step demonstrations. Further improvements of pictorial/written IFU and the way the HIVST kits are designed is required to decrease user errors and to enable people to follow the IFU reliably.

MOPED1169

Clinical evaluation of a smartphone-based electronic reader of two dual rapid diagnostic tests for HIV and syphilis

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Background: Combination assays for HIV and syphilis are becoming increasingly available. Handheld automated readers that read and quantify lateral flow-based rapid tests provide a novel approach to diagnostics and a centralized data system for epidemiologic research.

Methods: We enrolled MSM and transgender women ≥18 years of age seeking medical services at an STD clinic in Lima between October 2016 and January 2017. Venous blood was tested using two rapid dual HIV and syphilis tests (SD BIOLINE HIV/Syphilis Duo, Hagal-dong, Republic of Korea and First Response HIV 1+2/ Syphilis Combo, Nani Daman, India). HIV infection was confirmed with 4th generation EIA tests, while syphilis infection was confirmed with RPR, TPPA, and TPHA titers. Clinic staff visually inspected dual-test results, after which, the dual-tests results were read by the Cellmic HRDR-200 automated reader (Cellmic, LLC. Los Angeles, USA), an opto-mechanical smartphone attachment. Automated reader results were compared with visual inspection results. To assess how well the automated reader results correlate with visual inspection results, we calculated negative and positive percent agreement, concordance, and kappa statistic.

Results: On confirmatory testing of the 172 participants, 29% were HIV-infected, and 50% had treponemal antibodies (71% of whom had reactive RPR titers). The comparison of reader results with the results of visual inspection for both rapid assays can be found in Table 1.

Syphilis Antibody		No. Positive Tests	No. Negative Tests	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	Concordance	Kappa Statistic
First Response	Reader	57	100	98.3 (90.6 - 100)	98.0 (93.0 - 100)	0.98 (0.95 - 1.00)	0.96 (0.91 - 1.00)
	Operator	58	99	96.6 (88.1 - 99.6)	99.0 (94.5 - 100)		
SD BIOLINE	Reader	56	101	98.2 (90.5 - 100)	98.0 (93.02 - 99.8)	0.98 (0.95 - 1.00)	0.96 (0.91 - 1.00)
	Operator	57	100	96.5 (87.9 - 99.6)	99.0 (94.6 - 100)		
HIV Antibody		No. Positive Tests	No. Negative Tests	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	Concordance	Kappa Statistic
First Response	Reader	47	110	97.9 (88.7 - 100)	97.3 (92.2 - 99.4)	0.98 (0.94 - 0.99)	0.94 (0.88 - 1.00)
	Operator	49	108	93.9 (83.1 - 98.7)	99.1 (95.0 - 100)		
SD BIOLINE	Reader	50	107	98.0 (89.4 - 100)	100 (96.6 - 100)	0.99 (0.97 - 1.00)	0.99 (0.96 - 1.00)
	Operator	49	108	100 (92.8 - 100)	99.1 (95.0 - 100)		

[Table 1]

Conclusions: Our results show that the performance of the automated reader correlated well with visual inspection. Given that high correlation, further implementation of the automated reader is warranted to investigate its utility in areas without technicians trained in visual inspection of rapid tests, as well as for the purposes of epidemiologic monitoring and surveillance.

MOPED1170

Performance of the point of care Cepheid GeneXpert HIV qual for early infant diagnosis: field experience in Kenya

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Background: Access to testing services at the patient clinic can reduce loss to follow-up and result turn-around times hence minimizing barriers to early linkage to care and treatment among HIV infected children. Currently samples for HIV diagnosis are sent to centralized testing facilities which are located only at specific regions in Kenya. However, there are Point of Care (POC) early infant diagnosis (EID) technologies elsewhere, but none has been evaluated in Kenya despite the urgent need for data to inform policy formulation regarding EID. The Cepheid Xpert technology for POC EID, offers a great opportunity to minimize the HIV associated high morbidity and mortality rates through decentralization of early HIV testing. This technology also allows for same-day results thus facilitating prompt linkage to care. We evaluated the GeneXpert HIV Qual EID POC in Homabay County, Kenya against the standard of care platform, Roche CAP/CTM HIV-1 qualitative PCR, using dried blood spots (DBS).
Methods: Between January - July 2016, DBS samples were collected from HIV exposed children < 18 months of age enrolled in a cross-sectional study. Samples were collected by qualified nurse counselors, and were tested by trained technicians using field based GeneXpert and conventional laboratory based Roche CAP/CTM HIV-1 qualitative PCR. Sensitivity and specificity were determined.
Results: 3814 mother/baby pairs were included in the study, out of which 968 babies were HIV exposed as per the mothers' HIV status. A total of 34 (3.5%) children were concordantly positive using both platforms. GeneXpert yielded a sensitivity of 97.1% and specificity of 100% with an overall error rate of 0.9%. The PPV and NPV were 100% and 99.9% respectively.
Conclusions: Our findings show that the POC GeneXpert performs comparable to the conventional CAP/CTM using DBS, suggesting that this technology may be adopted in the laboratory near POC and used in quick diagnosis of HIV and its result used to inform linkage to care of children who are found to be HIV exposed at the same time supplementing the progress of EID in the region.

MOPED1171

Early infant diagnosis at integrated HIV program in Myanmar: is it early enough?

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Background: World Health Organization recommended Early Infant Diagnosis (EID) using polymerase chain reaction (PCR) technology since 2010. Integrated HIV care program in Myanmar implemented EID of HIV exposed babies in March 2012 across its 10 antiretroviral therapy (ART) centers. Blood samples from the ART centers were sent using public transport to a centralized PCR facility at public health laboratory (PHL), Mandalay. We aimed to determine the uptake of EID services, turnaround time (TAT) to result receipt by mother from sample collection and factors associated with delayed (≥8 weeks of age)/no EID uptake and long TAT (≥7 weeks)/non-receipt of result by mother among HIV exposed babies < 9 months at enrollment between 2013 and 2015.
Methods: Retrospective cohort study involving record review.
Results: Of 1349 babies, uptake of EID (< 8 weeks) was 47% (633/1349), sample collection was delayed (≥8 weeks) in 27% (367/1349) and not done in 26% (349/1349) babies. Among 1000 babies' sample collected, long TAT or non-receipt of results by mother was seen in 680 (68%). After adjusting for confounders, mothers neither on ART or PMTCT before pregnancy when compared to mothers on ART before pregnancy [aRR (0.95 CI): 1.8 (1.5, 2.2)] and distance of ART center from PCR facility ≥128 km when compared to < 128 km [RR (0.95 CI): 2.2 (1.8, 2.7)] were risk factors for delayed or no sample collection. Babies with mother's CD4 count of 100-350 cells/mm^3 at enrollment [aRR (0.95 CI): 0.8 (0.7, 0.9)] had 20% lower risk of long TAT or non-receipt of results when compared to ≥350 cells/mm^3. Distance between ART centers and PHL ≥105 km [aRR (0.95 CI): 1.2 (1.1, 1.4)], when compared to < 105 km, had 20% higher risk of long TAT or non-receipt of results, respectively.
Conclusions: Uptake of EID was low and turnaround times were prolonged. This study supports the implementation of universal ,test and treat' recommendation among people living with HIV at field level in Myanmar which has the potential to improve the uptake of EID. Innovative interventions like point of care EID testing and/or systematic use of mobile technology to communicate results are urgently needed.

MOPED1172

Point-of-care HIV viral load testing: suitable performance with Alere™q 50µl plasma cartridge

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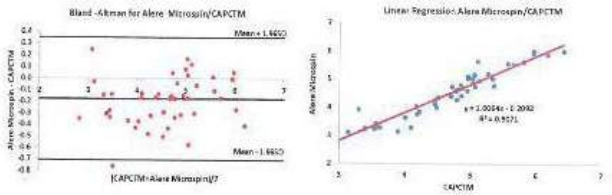
Background: Universal HIV viral load (HIVVL) scale-up is urgently needed if the 90-90-90 target of 90% viral load suppression is to be reached by 2020. HIVVL testing in Southern Africa is provided by central laboratories, with some areas still recurring improved coverage. Point-of-care (POC) assays can assist in increasing access to HIVVL in remote locations. Plasma remains the gold standard sample type for HIVVL, but centrifugation for sample separation remains a challenge in facilities. We evaluated the performance of the new Alere q 50ul plasma cartridge against the Roche (CAPCTM) HIV-1 V.2 assay using standard and alternative methods of plasma separation.
Methods: Parallel testing of routine 147 samples was performed between Alere™q and Roche assay (1000µL input volume). Viral load >1000 cp was considered virological failure. The lower limit of detection (LLOD) of the assay was determined by probit analysis of 30 repeats at 5 concentrations. Fifty samples were tested using three methods of plasma separation viz.: standard centrifugation, 1 hour of standing (leucodepletion) and 1 minute of microspinning.
Results: The Alere™q assay had a sensitivity of 98.1% and specificity of 96.8%. The LLOD was 734 copies/mL. 95% confidence intervals (CI) at mean ± 1.96SD were set for the Bland-Altman graph and linear regressions were performed (Figure 1); 6 of the 147 sample values (4,8%) lay outside the CIs. Regression model fit is as follows: CAPCTM / Alere standard centrifugation (R^2= 0.95), CAPCTM / Alere leucodepletion (R^2=0.83) and CAPCTM / Alere microspin (R^2=0.91), Alere leucodepletion / Alere centrifugation (R^2 =0.83) and Alere microspin / Alere centrifugation (R^2=0.91).



[Figure 1. The Bland-Altman and linear regression graphs for Alere™q assay using one minute of microspinning for plasma separation.]

Conclusions: The 50µL Alere cartridge with its adequate LLOD and comparable performance to the reference, with no compromise in sensitivity or sensitivity favours POC testing. Plasma separation can be simplified to suit POC HIVVL as a short microspin appears sufficient to remove leucocytes.

MOPED1173

HIV rapid test external quality assessment: Brazil´s experience

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Background: Policies promoting access to HIV diagnosis have led to the widespread use of rapid tests (RT) in health facilities of different complexities throughout Brazil. To monitor the quality of the testing procedures, the Ministry of Health introduced the National Program of External Quality Assessment for RT (EQA-RT). This involves healthcare professionals registering on an online platform to receive a panel with four dried tube specimens with unknown reactivity for HIV. The respondents should test the samples as if it they were from their own patients and follow the algorithms recommended by Ministerial Directive of HIV diagnoses. The results are then submitted online for subsequent analysis.
Methods: We analyzed reports from eight EQA-RT rounds conducted in 2014-2016. The quality of the professionals´ performance was assessed by examining the degree of concordance between the results from the panel samples that were expected and those actually reported, and the agreement of their conduct with the Brazilian guidelines. Certificate of approval is issued in the event of 70% accuracy. Any professional receiving less than 70% approval rating is sent a report suggesting possible causes and solutions for issues that might have been responsible to prevent the quality of testing.
Results: The average number of participants per round was 843 (545 in 2014, 909 in 2015 and 1,075 in 2016) distributed in 347 mainly primary healthcare units. It was interesting to note that many higher complexity services, despite registering in the program, failed to report the results (e.g. a 55% abstention rate in one of the rounds). Regarding the performance on EQA-RT, an average of 94% of respondents was approved per round, with 61% achieving 100% accuracy. The most common failures identified so far have been the lack of knowledge of Brazilian guideline with erroneous algorithms executionfor HIV diagnosis.
Conclusions: The majority of healthcare professionals currently participating in Brazil´s EQA-RT program are maintaining a high level of RT quality. While the number of participants doubled in 2014-2016, there is still a need for education work to encourage more adherence to the Program aimed at ensuring the reliability and credibility of the TR results.

MOPED1174

Dried blood spots for viral load: evaluating the use of DBS in order to increase access to viral load monitoring

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Background: Access to viral load based on HIV RNA level quantification in plasma remains limited in resource-constrained settings. Measurement of HIV viral load using DBS could facilitate the expansion of treatment monitoring to support viral load suppression in these settings. We assessed the performance of a newly modified RNA elution protocol (FVE) for DBS compared to the predicate testing with plasma on the COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 v2.0 Test.
Methods: 435 parallel EDTA plasma and whole blood (DBS) samples were collected from adult patients referred for routine viral load monitoring at the Charlotte Maxeke Johannesburg Academic Hospital (n=281) and KEMRI/CDC Kisumu, Kenya (n=154). DBS were processed using the modified FVE protocol that required elusion of DBS in 1X phosphate buffered saline; both plasma and DBS were tested on the COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 v2.0 Test and the results.
Results: Plasma VL ranged from < 20 copies/mL to >100,000 copies/mL. Of the 155 plasma >= 1000 copies/mL, 128 DBS were also >= 1000 copies/mL for a sensitivity of 82.6%. Of the 228 plasma < 1000 copies/mL, 224 DBS were also < 1000 copies/mL for a specificity of 98.2%. There was strong correlation between DBS and plasma across all stratifications (concordance = 0.92). There were no statistical differences between DBS and plasma VL up through 42 days after collection when using a 1000 copy/mL threshold.
Conclusions: DBS can be used for monitoring viral load up to 42 days after collection and should be considered for increasing access of viral load monitoring resource limited settings.

MOPED1175

Marker-assisted HIV-1 viral load pooling deconvolution improves monitoring capacity

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Background: The World Health Organization (WHO) recommends global routine viral load (VL) testing for antiretroviral therapy monitoring. VL testing in many resource-limited settings (RLS) is constrained by cost and technology. To increase VL monitoring capacity, we hypothesized that VL pooling, which reduces VL assays needed, can be further improved by incorporating in its deconvolution process information from low-cost, routinely-collected clinical markers (RCMs; e.g. CD4 count).
Methods: We developed mMPA (marker-assisted mini-pooling with algorithm), a new VL pooling deconvolution strategy that utilizes available RCMs to determine an efficient order of sequential individual VL testing in positive pools, and dictates when the sequential testing can be stopped. Using data from 918 study participants at the Academic Model Providing Access to Healthcare (AMPATH) in Eldoret, Kenya, we simulated our method's implementation; evaluated the impact of pool size, prevalence of virological failure, VL measurement error and assay detection cutoffs; and compared our method with individual VL testing and existing pooling deconvolution algorithms.
Results: Using a pool size of 5 and incorporating CD4 count as a RCM to assist deconvolution, mMPA can significantly reduce the number of VL assays by 52% (Confidence Interval (CI)=48-57%) compared with individual testing, and by 19% (CI=14-22%) compared with existing VL pooling algorithms. Incorporating additional RCMs in addition to or instead of CD4 (e.g. time on therapy, WHO staging) in mMPA can further reduce the number of assays needed. mMPA also improves sensitivity (82% vs 74%), negative predictive value (97% vs 95%), and positive predictive value (98% vs 96%) over an existing pooling algorithm, with a comparable high specificity (>99%). mMPA depends on the pool size, virological failure prevalence, and RCMs used for deconvolution, but is relatively insensitive to the impact of assay detection cutoffs and assay measurement errors.
Conclusions: mMPA can substantially increase the capacity of VL monitoring. By using information from RCMs, mMPA can deconvolute pools more rapidly and with higher diagnostic accuracy than existing methods, resulting in less VL tests needed. Particularly relevant for RLS, mMPA has potential to provide comprehensive VL monitoring to more HIV-infected people receiving treatment.

MOPED1176

Effect of routine viral load testing on turnaround time and availability of results among target patients receiving antiretroviral therapy in Kenya

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Background: The Kenya national guidelines on viral load (VL) monitoring changed from targeted to routine testing in June 2014. While scaling-up VL testing may improve the standard of monitoring for all patients on antiretroviral therapy, these new guidelines may shift focus away from target populations. This study aimed to determine the effect of the new guidelines before and after implementation on turn-around time and availability of results.
Methods: We conducted a retrospective cohort study of routine program data from 42 health facilities under the Christian Health Association of Kenya HIV program and the National AIDS and STI Control Program (NASCOP) website database. Target patient populations comprised of pregnant women, children, confirmatory and drug-switch patients.
We compared the time period prior to (January to June 2014) and after (January to June 2015) implementation of the new Kenya national guidelines. Median turnaround time (TAT) from the time of sample collection to dispatch of results periods was calculated.
Results: VL results were available for 5115 patients over the routine period, compared to 971 during the targeted period. Approximately half of the confirmatory VL results (154/286) were available during the targeted period compared to 47/505 (9.3%), p< 0.001 during the routine period. Single drug substitutions in the targeted period had 101/971 (10.4%) VL results and pregnant women 64/672(9.5%) results available versus 294/5115 (5.7%) and 158/3532 (4.8%), p<0.0001 in the routine period respectively.

Overall, median TAT was 13 days in the targeted period, increasing to 32 days (p<0.001) for the routine period. TAT for venous dry blood spot samples increased by 3 days compared to 31 days for frozen plasma.
Conclusions: Introduction of routine viral loads increased available VL results for patients on ART but reduced the proportion available to priority patients and prolonged their TAT. The effect of the new guidelines on TAT was more pronounced for frozen plasma than venous dry blood spot samples. Careful planning is essential prior to VL scale-up to minimize negative effects on target patient populations.

MOPED1177

Evaluation of routine viral load monitoring during pregnancy at antenatal clinics in South Africa

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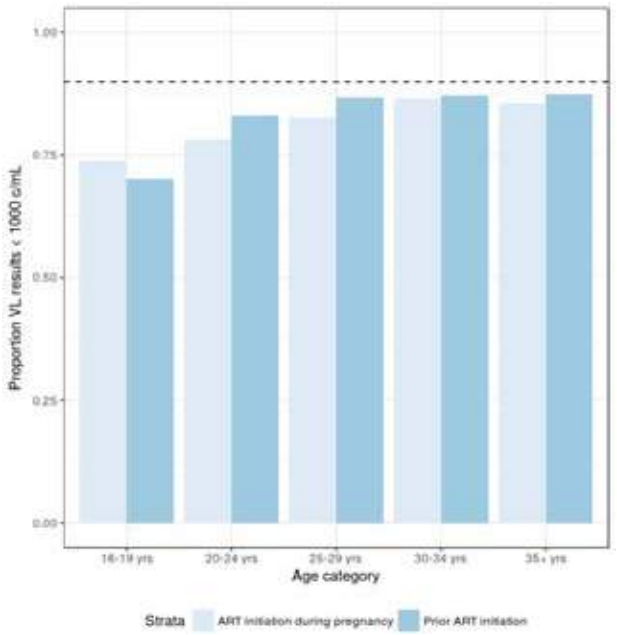
Background: Global targets for antiretroviral therapy (ART) programmes call for ≥ 90% of patients on ART with VL < 1000cps/mL. However there are few insights into progress towards this goal among pregnant women despite the importance of viral control for PMTCT and maternal health. We examined levels of VL < 1000cps/mL among pregnant women on ART attending public sector antenatal clinics (ANC) in the Western Cape province of South Africa.
Methods: Routinely collected public sector VL monitoring data from the South African National Health Laboratory Service were examined from 8 primary care ANC clinics from 2009-2015. In this setting VL monitoring is routinely conducted in women at their first ANC visit (for women on ART prior to pregnancy) or 12-16 weeks after ART initiation (for women initiating during pregnancy). Analyses examined time trends in the proportion of women with VL< 1000cps/mL by patient age and ART status (initiation prior to versus during pregnancy).
Results: Among 6017 women (7529 VL tests) the median (IQR) age was 30 (26-34) years. The proportion of women initiating ART prior to pregnancy increased from 11% in 2009-2010 to 42% in 2014-2015. The number of VL tests/month increased from < 100 in 2009 to >300 in 2015. After excluding repeat tests, the aggregate rate of VL< 1000cps/mL was 84.7%, and was slightly lower in women initiating ART in pregnancy (83.3%) versus women initiating prior to pregnancy (86.2%). For both ART status groups, younger women had significantly lower levels of VL < 1000cps/mL (Figure; p< 0.001).
Conclusions: Against a background of rapid scale-up of VL monitoring during pregnancy in this setting, levels of viral control in pregnant women appear below global targets, raising concerns for MTCT and maternal health. In particular, young women initiating ART in pregnancy are at persistently increased risk for elevated VL and may require special programmatic consideration.



[Figure 1]

MOPED1178

Progress towards achievement of the UNAIDS 3rd 90 in Zimbabwe: capacity and functionality of viral load monitoring in 22 districts

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Background: Zimbabwe is one of the 22 high burden countries that adopted the UNAIDS targets, and launched a viral laod (VL) scale up plan in 2015. The plan provides a road map to scale up VL monitoring from 3% in 2015 to 70% by the end of 2017 and 90% by 2018. To aid the Ministry of Health and Child Care in its efforts, the Organization of Public Health Interventions and Development (OPHID) conducted an assessment establishing existing capacity and functionality of VL monitoring in Zimbabwe.
Methods: In May 2016 data on the current availability of VL monitoring, functionality of equipment human resource capacity and existing bottlenecks was collected in 22 purposively sampled districts. Stata V12 was used to conduct the descriptive analysis.
Results: At time of survey, 50% (11/22) of districts were not collecting samples for VL monitoring. High variability across districts was observed in VL sample transportation and result notification systems, mostly being partner dependent. None of the districts implementing VL had standard operating procedures on who can interpret VL results and initiate switch to second line regimens. Less than 5% of the health workers in post were trained in VL sample collection and result interpretation. No district indicated health care workers are "confident at interpretation of VL results". Only 18% (4/22) districts and 33% (1/3) of the labs surveyed were aware of their annual viral load target.
Conclusions: Our assessment revealed limited availability and capacity to conduct VL monitoring in 22 districts serving 367,399 people on ART. There is an urgent need to support MOHCC to make VL testing available, accessible and affordable for PLHIV on ART to reach the 3rd 90 in Zimbabwe. Standardization of VL sample transportation must be prioritized. We recommend viral load machine capacity utilization analysis be conducted to improve optimization. Improved communication of national policies and targets to provincial, district and site level is needed to achieve VL scale up. Expansion of VL monitoring and capacity building health workers should be simultaneously.

MOPED1179

Performance characteristics of a new commercial assay for HCV RNA viral load quantification in plasma: preliminary results in Cambodia

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Background: Since 2016, direct-acting antivirals (DAA)-based treatments for hepatitis C are available in Cambodia. Therefore, there is an urgent need for low-cost hepatitis C virus (HCV) RNA viral load (VL) assays for identifying subjects with active HCV infection and for monitoring of treatment efficacy. Here we report the performance in Cambodia of the OMUNIS PUMA HCV kit (Omunis, Clapiers, France), a new commercial HCV RNA VL test using an open real-time PCR machine, on plasma harboring mainly HCV genotype 6.
Methods: The evaluation was conducted on 101 plasma specimens collected and stored at -80°C between 2015 and 2016 at Pasteur Institute in Cambodia. After a manual Qiagen extraction (QIAamp Viral RNA Mini kit) with 140 ml of plasma, the real-time OMUNIS HCV RNA PCR amplification was done by targeting the 5' UTR region of the HCV genome. The lower limit of quantification of the test was 70 IU/mL. Results of the OMUNIS test were compared with those obtained using the fully automated closed Roche platform (Roche Cobas AmpliPrep/Cobas TaqMan HCV Test, v2.0) used as gold standard. HCV genotyping was performed from the same Qiagen extracts in the NS5B region for samples with detectable HCV RNA VL.
Results: All 76 (100%) plasma samples that had detectable HCV RNA VL with the Roche TaqMan HCV kit showed detectable VL results with the Omunis PUMA HCV assay. Results were highly correlated (correlation coefficient R = 0.87) between the two techniques, with a median difference of -0.4 log IU/mL. HCV genotype distribution was as follows: genotype 6 (55%, mostly subtype 6e), genotype 1b (31%), genotype 2a (12%), and genotype 1a (2%). Of 25 plasma samples that were undetectable with the Roche test, 25 (100%) were also undetectable with the OMUNIS assay.

Conclusions: This new low-cost (around 25-30 USD per test) HCV RNA assay should be further evaluated/used in resource-limited countries where the prohibitive cost for HCV RNA VL measurement is currently a barrier for monitoring viremic HCV-infected patients treated with DAA.

MOPED1180

Plasma IP-10 levels as a surrogate of virological failure in treated HIV-patients

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Background: As anti-retroviral treatment (ART) coverage continues to increase, achieving effective first-line ART monitoring is a key determinant to optimize HIV management, reduce further transmissions and achieve the global target of 90% viral suppression. The gold standard for detecting virological failure is plasma viral load (VL) determination; however its availability is very limited in low-income countries. We hypothesized that because of its association with VL, IP-10 levels could be a surrogate marker of potential virological failure in ART-treated individuals, representing an affordable tool in low-income countries.
Methods: HIV-1-infected adults on first-line ART for at least 1 year attending routine visits in the Manhiça District Hospital, Mozambique, were evaluated for virological failure in a cross-sectional study conducted in 2013. Plasma levels of IP-10 were quantified by ELISA. From the total sample, 80% was used for model construction and 20% for validation. Logistic regression with penalized likelihood was used to build a prediction model able to identify the cases, defined as individuals with VL>150 copies/mL. Receiver operating curves (ROC) from univariate and adjusted-multivariate models were compared for the best prediction.
Results: From the 319 ART-treated individuals analysed, 106 had detectable VL (33%) of which 81 (76%) had VL>1000copies/mL. Mean age was 41 years, 70% were females, median CD4 T-cell count was 441 (IQR 273-614) and median time on ART was 3.2 years (IQR 2.0-5.2). IP-10 levels were significantly different among patients with detectable (104.4pg/mL) and undetectable VL (39.2pg/mL) [d2] (U-test p< 0.0001). IP-10 levels demonstrated high accuracy for discrimination of cases in both the univariate and the multivariate model adjusted by CD4 T-cell count and days on ART (AUC>0.80). Both models showed substantial agreement of classification (kappa=0.68) so for practical use the univariate IP-10 model was considered. A cut-off value of IP-10≥43.6pg/mL provided the best classification performance, showing a sensitivity of 91.0% (95%CI 83.1-96.0) and specificity of 56.0% (95%CI 48.1-63.7) for detection of virological failure, which was confirmed in the validation set.
Conclusions: IP-10 is an affordable and easily quantifiable biomarker that can be used to pre-screen individuals on ART for treatment failure, reducing the number of VL determinations required to monitor ART in low-income countries.

MOPED1181

HIV viral load monitoring in four West and Central African countries: how is virological failure managed by caregivers in the OPP-ERA project ?

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Background: Since 2013, WHO recommends HIV viral load testing (VLT) as the preferred marker to monitor efficacy of antiretroviral therapy (ART). WHO recommendations include that patients with VL above 1000 copies/mL should be counselled to reinforce ART adherence and VL be retested after 3/6 months. Patients with a second VL remaining above 1000 copies/mL need a switch to a second line of ART. The OPP-ERA project supported the increased access of VLT in four West and Central African countries (Burundi, Cameroun, Guinea, Ivory Coast) with the aim to implement VLT and apply WHO VL guidelines for patient follow up, including for those with virological failure.
Methods: Patients data from 6 OPP-ERA laboratories, from August 2014 to March 2016 were analyzed using Stata 11.1. Chi square test were used for group comparison.
Results: A total of 31,286 patients have benefited from at least one VLT after a median ART duration time of 4 years (2-7). Most of them (89.7%) were on first line ART. For 6687 patients (21%), the first VL was >1000 cp/mL (that means virological success at 79%). Among them, 695 (10,4%) benefited from a second VLT; 1.1%, 2.9% and 6.4% had a second VLT < 3 months, 3 to 6 months and >6 months respectively. Among 620 (9.3%) patients (range 0 to 49% between health facilities, p<0,001) who have benefited from a second VLT more than 3 months after the initial VLT, virological failure was confirmed in 45% of cases (range 22% to 67% between health facilities, p< 0,001).
Conclusions: Despite good results of 79% virological success within the OPP-ERA project, management of patients with virological failure by caregivers remains challenging. Despite disparity between facilities., less than 1/10 of patients with virological failure has benefited from a VL control according to WHO recommendation. Furthermore, our data suggest that with the implementation of VLT and proper appropriation by caregivers, a high number of patients requiring a second line ART is likely to be identified. Therefore strengthening of caregivers skills is recommended for VL scale up, better HIV care management and adequate planning of second line ART needs.

MOPED1182

Time to achieve viral load undetectability in ART patients living in four West and Central African countries (the OPP-ERA project)

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Background: Shortening the time to viral load (VL) undetectable threshold at 1000 copies/ml has positive implications in decreasing the risk of HIV morbidity, mortality and transmission. The aim of this study is to estimate the probability to achieve VL undetectability among ART patients who had first detectable VL at enrollment, within the OPP-ERA project.
Methods: Data of antiretroviral treatment (ART) patients collected during the first 20 months in six OPP (open polyvalent platforms) laboratories located in Guinea, Cameroon, Burundi and Ivory Coast were examined. The analysis were restricted to patients with first VL measurement detectable at enrollment in OPP-ERA and having benefited from at least two VL. Kaplan Meir method was used to estimate the duration and probability to achieve VL undetectability and to compare these indicators between groups.
Results: About 35,000 VLT were performed for 31,300 patients with a median duration of 4 years on ART. Among them, 695 were included in the study for a total of 1538 VL. At enrollment, median age was 36 years (IQR: 27-45), 66% were women, median VL was 43,815 copies/ml (IQR: 7,155-276,093), 90% were on ART. Median time between two consecutives VL was shorter among patients initiating ART during OPP-ERA than before (5 versus 7 months, p< 0.001). The proportion of patients achieving VL undetectability within 6, 12 and 18 months after enrollment was, respectively, 14, 41 and 83%. The median time to achieving undetectable VL was 13 months. This median was shorter among patients initiating ART during OPP-ERA than before (8 versus 14 months, p< 0.0001). Probability to achieve VL undetectability was lower among patients with a VL >50,000 copies/ml at enrollment, compared to patient with < 50,000 copies/ml (p< 0.0001).
Conclusions: Time to achieve VL undetectability is longer than expected among these patients who are on ART since several years. However, patients who initiated ART during OPP-ERA achieve VL undetectability more rapidly, suggesting that earlier access to VL allows a closer virological monitoring that helps reinforcing adherence to ART and reduce risk of ART resistance.

MOPED1183

Improving access to quality-assured HIV-related in vitro diagnostic medical devices through the transparency and strategic partnership of the Global Diagnostics Working Group

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Background: In the wake of a large product failure for a widely used HIV rapid diagnostic test (RDT) in 2012, the lack of communication between implementing partners and procurers severely limited the response required by national testing programmes. When such uncoordinated actions are taken in response to product complaints, and when delays occur in quality assessments of IVDs, the impact on public health is immense. The GDWG consists of ASLM, US CDC, CHAI, Global Fund, MSF, UNICEF, UNITAID, USAID and WHO.
Methods: In order to respond swiftly to quality and regulatory issues, several members of the GDWG responsible for procurement or quality assurance of HIV-related IVDs are supporting a joint quality strategy with the aim of improving access to affordable, quality-assured HIV-related IVDs, while also creating a forum to cultivate transparency around the conditions and quality concerns of these products. WHO and USAID, along with the US CDC agreed to establish a joint quality assessment mechanism for HIV-related IVDs. Furthermore, GDWG members have agreed to establish a taskforce on post-market surveillance for IVDs. Lastly, GDWG members meet face-to-face twice per year, and by teleconference if matters of urgency permit.
Results: From January 2015 through to December 2016, three joint assessments have been successfully conducted (Aquios CL flow cytometer, Alere™ q HIV-1/2 Detect, Xpert® HIV-1 Qual Assay). These assessments were completed in half the time compared to the average time for WHO prequalification assessment in 2016. This method of joint assessment will ultimately lead to a common list of product approved for use by GDWG members. The GDWG has also been successful in identifying discrepancies in quality assurance policies among agencies, suggesting there is room for further collaboration in this area
Conclusions: The formation of the GDWG for HIV-related IVDs has enhanced collaborating, collective knowledge and transparency on changes to products already approved for procurement, as well as acted as a platform to exchange information and coordinate when product concerns arise. As new diagnostics come to market and the trend towards decentralization continues, transparency and strategic partnership will be critical to ensure quality IVDs reach the people who need them most.

MOPED1184

Cost-effectiveness of external quality assurance to prevent early infant *mis*-diagnosis of HIV in 4 African countries

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Background: Decentralised early infant diagnosis (EID) of HIV using point-of-care testing (POCT) has the potential to narrow current testing gaps, which ranges from 13% to 58% across Kenya, South Africa, Uganda and Zimbabwe. However, without external quality assurance (EQA) systems, POCT can lead to potentially high mis-diagnosis rates. EQA programmes aim to assess the provider proficiency in performing POCT and identify critical gaps in the laboratory systems. Problems identified are addressed through corrective actions. We are the first to model the cost-effectiveness of EQA programmes, with application to POCT EID in these countries, representing varying HIV epidemics and health systems.
Methods: Countries were brought together to develop a national EQA programme and estimated costs related to implementing these programmes using a bottom-up costing approach, including start-up and recurrent costs. Optimal POCT performance was estimated using published data on sensitivity (98.5%) and specificity (99.9%), while a suboptimal programme without EQA was conservatively modelled using lower confidence bounds (sensitivity 91.7% and specificity 99.3%). Assuming EQA improves programmes to optimal performance, $/DALY averted was modelled. Potential for a 1-year EQA programme to avert missed HIV infections, false positive diagnoses and unnecessary treatment costs over 20-years was modelled from observed clinical EID POCT performance from published studies.
Results: The national annual incremental cost of EQA, including corrective action ranged from US$100,000 in Kenya to $365,000 in Zimbabwe. Even in optimal testing scenarios, misdiagnosis rates are estimated around 0.3%. Without EQA, the misdiagnosis in the deteriorated programme ranged from 1.4% in Uganda to 1.7% in Zimbabwe, or 179 to 555 infants misdiagnosed annually in Kenya and South Africa, respectively. Adding EQA to POCT EID is cost-saving across all countries, i.e. the costs saved by averting unnecessary treatment exceeds the EQA programme costs.
Conclusions: Though EQA would initially require increased funding, it rapidly provides a positive return on investment by averting the costs of treating HIV-negative infants (potentially for life), and save lives by correctly identifying HIV-positive infants needing treatment. This study is the first to demonstrate the value of funding EQA programmes.

Tuesday 25 July

Oral Abstract Sessions

TUAA01 The Wrestling Match: Virus Versus Immune Cells

TUAA0101

Evaluation of memory CD8+ T cell responses in individuals initiating cART during hyperacute HIV-1 infection

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Background: Previous studies have shown that the emergence and proliferation of antigen-specific CD8+ T cells during early stages of HIV infection is associated with persistent antigenemia. Early initiation of combination antiretroviral therapy (cART) confers clinical benefit to HIV infected persons but the impact of cART on HIV-specific immune responses and the potential for recall or boosting of these responses is unknown. In this study, we evaluated the maintenance of CD8+ T cell responses longitudinally in early treated individuals with hyperacute HIV-1 subtype C infection.
Methods: Samples of young females identified with acute HIV-1 infection (HIV PCR positive, antibody negative) who initiated cART very early and untreated patients were used. The magnitude, breadth and maintenance of HIV-1 specific CD8+ T cell responses were defined using IFN-gamma ex vivo ELISPOT and cultured ELISPOT. Also, the phenotype (HLA-DR, CD38, CD127) and functional (IFN-gamma) characteristics of tetramer specific CD8+ T cells were investigated using MHC class I tetramers and intracellular cytokine staining (ICS).
Results: Early treated patients with hyperacute infection induced initial CD8+ T cell responses that coincided with a sharp drop in viremia and an increase in CD4 counts. These early induced CD8+ T cell responses were however low in magnitude (144.3 SFC/million PBMC) when compared to untreated patients [316.6 SFC/million PBMC (p=0. 009)]. Interestingly, compared to untreated patients, CD8+ T cells in early treated patients were less activated and had a high expression of CD127; thus suggesting a potential for long term survival of these responses. Additionally, memory responses specific to HIV-1 measured at later stages (six months onwards) of infection were maintained in these treated patients as indicated by cultured ELISPOT assays.
Conclusions: Summarily, our results demonstrate that early initiation of cART led to an induction of CD8+ T cell responses that were less activated and had higher potential for long term survival. These responses were also maintained as memory responses which may be recalled rapidly upon re-stimulation with HIV-1 antigens. This data may offer insight in implementing novel therapeutic strategies in order to enhance protective immunity and promote control of viral replication post treatment interruption.

TUAA0102

Early anti-SIV CD8+ T cell antiviral activity is associated with durable elite control of SIV infection in macaques carrying or not protective MHC alleles: the ANRS SIC study

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Background: Natural control of infection has been associated with efficient HIV/SIV-specific CD8+T-cell responses. However, the determinants leading to the development of such responses and the role of protective HLA alleles are still unclear.
Methods: We monitored for 18 months 16 Mauritius Cynomolgus macaques (CM) after infection with SIVmac251 and studied immunological and virological events leading to durable control of infection. CM receiving a low viral dose (nonH6 $5AID_{50}$, n=4) or carrying the protective H6 MHC haplotype (H6 50AID50, n=6), both conditions leading frequently to control of viremia, were compared to H6-negative CM exposed to the higher dose of the virus (nonH6 50AID50, n=6).
Results: Twelve CM spontaneously controlled plasma viremia (VL) below 400 SIV-RNA copies at 6 months p.i. No differences were found in VL or SIV-DNA in blood at the VL peak (day 15 p.i.) between SIV controllers (SIC) and non-controllers, but these levels correlated with levels during the chronic phase, and controllers had a faster viral decline to set point. SIC had lower levels of SIV-DNA in lymph nodes at day 15 and in all tissues analyzed at the end of the study. SIC and non-controllers had a different cytokine profile during the follow up. All animals developed SIV-specific CD8 T-cell responses (measured by ICS) coinciding with the start of VL decline at primary infection, however no differences could be found between SIC and non-controllers. In contrast, an efficient capacity of CD8 T-cells to eliminate infected CD4 T-cells was developed preferentially in SIC (both H6 and nonH6) and its magnitude increased overtime coinciding with the establishment of elite control. Moreover, SIV-suppressive capacity of CD8+ T-cells at day 15 and 70 p.i. negatively correlated with VL at day 15 (in the first case) and at the end of the study (in both cases). This activity was stronger in SIC at the end of the study in all tissues.
Conclusions: We provide here unprecedented insight into the dynamic development of effective CD8 T-cell responses against SIV. Initial enhanced capacities of CD8 T-cells to suppress SIV infection shaped viral levels during primary infection and increased over time until reaching levels allowing viral control.

TUAA0103

CD8+ T cell depletion leads to a different profile of SIV viral decay under integrase inhibitor monotherapy

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Background: How CD8+ T-cells control virus during HIV infection is not understood. We hypothesized that the main effect of CD8+ T-cells occurs before viral integration, due to minimal direct viral cytopathic effects. We developed a model of viral dynamics with pre- and post-integration stages to study the effect of CD8+ T-cell depletion. Model predictions were tested in SIV-infected rhesus macaques (RMs) receiving integrase inhibitor raltegravir (RAL) monotherapy with or without CD8+ T cells.
Methods: Sixteen SIVmac251-infected RMs were treated with both RAL and CD8-depleting antibody M-T807R1 (RD), or just RAL (R) and followed, with RAL treatment interrupted after 23 days. Plasma viral loads (VLs) were measured by qRT-PCR. T-cell counts and immune activation were monitored flow-cytometrically. We analyzed the VLs during the first ~12 days following RAL initiation using a viral dynamics model including infected cells pre- and post-viral DNA integration. We fitted the model to the data using a nonlinear mixed effect model to estimate the death rate of infected cells pre- and post-virus integration and the efficacy of RAL.
Results: CD8+ T-cell depletion was profound and lasted throughout RAL therapy. Depletion of CD8+ T-cells led to an increase in VL prior to the start of therapy. Macaques receiving just RAL treatment had much greater decays in VL than those treated with RAL and the CD8-depleting antibody. The latter group had small decays or rebounded early during RAL therapy. From the fits of the model, we estimated the efficacy of RAL in blocking integration at 96.3%, the half-life of virus-producing cells at ~13h, and a different loss rate of infected cells pre-integration in the two groups (0.0016/day vs. 0.19/day, for DR and R groups respectively). A model allowing for these different loss rates was better than a model with a common loss rate for both groups (p=0.0001).
Conclusions: Use of RAL monotherapy revealed that the turnover of infected cells pre-integration has a half-life of about 3.6 days. However, in the absence of CD8+ T-cells, this half-life reaches >100 days. These results suggest that CD8+ T-cells have a strong cytolytic effect on infected cells before viral integration.

TUAA0104

Memory-like NK cells exploit innate priming and alternative signaling mechanisms to enhance function and mobilize at HIV/SIV mucosal portals of entry

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Background: Burgeoning evidence indicates a broader functional repertoire for NK cells beyond innate immunity including memory and other memory-like functions. One recent example is memory-like NK cells identified by lack of the FcR intracellular γ-signaling chain (FcRΔg-NK cells) which still require antibody to grant antigen-specificity, but are pre-sensitized and capable of rapid mobilization and more robust responses against viral antigens. Interestingly, FcRΔg-NK cells are initially expanded by huCMV infection as part of innate-priming, but can execute memory-like killing against other pathogens through incompletely understood mechanisms.
Methods: Sixty rhesus macaques were used in this study: twenty-one specific pathogen-free, rhCMV-; 10 rhCMV+ but otherwise experimentally naïve; and 22 chronically SIVmac-infected macaques. Samples were analyzed from 10 naïve and 10 untreated HIV-infected human subjects. NK cell analyses were performed using polychromatic and phospho- flow cytometric phenotypic and functional assays.
Results: FcRΔg-NK cells were systemically distributed in mucosal and secondary lymphoid organs, but, correlating with viral load, increased two- and four-fold in CMV+ and HIV/SIV-infected individuals, including the GI tract. CD16 and α4β7 were concomitantly upregulated in infection suggesting innate memory-like priming is required for both antibody-dependent functional potency and mucosal homing. FcRΔg-NK cells displayed little difference in binding affinity to virus-antibody immunocomplexes compared to traditional NK cells, but exhibit two-fold more robust IFN-γ secretion and cytotoxicity, suggesting disparate signaling or activation could account for improved function. To that end, FcRΔg-NK cells showed significantly reduced expression of Helios and Eomes — indicative of a broader functional repertoire and/or epigenetic modification, and clustered independently from traditional NK cells in 20-parameter analyses via multidimensional t-SNE. The γ-chain adaptor, Syk, was reduced or inactively dephosphorylated in FcRΔg-NK cells, but expression of ζ-chain, which is phosphorylated by adaptor Zap70, was significantly upregulated, suggesting these cells may exploit the ζ-chain/Zap70 pathway in the absence of γ-chain/Syk to achieve greater functional potency.
Conclusions: Collectively, our work presents the first description of a combinatorial mechanism of innate-priming and alternative signaling cascade to explain the functional potency of memory-like phenomena of NK cells mobilizing in the mucosae against HIV/ SIV. Future studies harnessing memory-like NK cells could create exciting modalities for both vaccine and curative therapies.

TUAA0105

The human penis is an immunologically active tissue: a preliminary study on the development of an HIV vaccine

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Background: HIV-1 is primarily sexually transmitted. We have shown that the human penis, including the foreskin but also the urethra, fossa navicularis and glans, is one of the main portal of entry for the virus. Unlike other mucosa, the penile immune system and mechanisms that induce a penile immune response remain unclear, most likely due to the difficulty to access human tissues. Our previous studies demonstrated that the male urethra contains macrophages, the main targets of HIV-1, as well as memory T cells. These studies relied on morphologic analyses, and thus failed to provide a comprehensive phenotype. To asses the role of these mucosal immune cells, that are a prerequisite to the elaboration of efficient preventive strategies against HIV-1, we therefore characterize extensively the immune profile of immune cells of the different penile regions.
Methods: Single cell suspensions were prepared for each region of 32 penile tissues collected from individuals undergoing transgender surgery and analyzed by multi-parametric flow cytometry. The expression patterns of memory, activating and homing receptors of B and T lymphocytes were evaluated as well as that of NK cells. In complement, the tissue distribution of each of these immune populations in the different penile compartments was also studied morphologically.
Results: In all penile compartments, CD3-/CD19+ B cells represent around 2% of CD45+ cells and >50% B cells display CD27 and FcRL4 receptors thus harbor a memory phenotype. However, < 5 % are IgG+ or IgA+ and thus able to secrete antibodies in the lamina propria. TCD4+ and TCD8+ lymphocytes represent the major populations of CD45+ cells, with 90% with a CD38-/HLADR-/CCR7-/CD45RA- resting effector memory phenotype (T_{EM}). These resting T_{EM} cells reside in all penile region epithelium and lamina propria but lack CD103+ resident phenotype. Furthermore, all penile compartments contain low numbers of CD3-/ CD56+ NK cells capable of antibody-dependent cell-cytotoxicity and surface-expressing the NKp44 receptor indicative of activation.
Conclusions: Altogether, the human penis is an immunologically active tissue including the cellular machinery required to induce/produce a specific and effective immune response against mucosal pathogen. This must be taken considered when elaborating efficient vaccine strategies against HIV-1.

TUAB01 Antiretroviral Therapy - ART: Season Two

TUAB0101

Efficacy and safety of switching from boosted-protease inhibitor plus emtricitabine/tenofovir disoproxil fumarate regimens to the single-tablet regimen of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) in virologically-suppressed, HIV-1-infected adults through 24 weeks: EMERALD study

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Background: D/C/F/TAF, a once-daily, single-tablet regimen containing darunavir (D 800mg), cobicistat (C 150mg), emtricitabine (F 200mg) and tenofovir alafenamide (TAF 10mg), is undergoing investigation in two Phase 3 studies, EMERALD (NCT02269917) and AMBER (NCT02431247).
Methods: EMERALD, a randomized (2:1), open-label, international, multicenter, parallel-group, non-inferiority, 48-week study, is evaluating the efficacy and safety of switching to D/C/F/TAF vs continuing a boosted protease inhibitor plus emtricitabine/TDF (control) in patients who are virologically suppressed [viral load (VL)< 50c/mL] for ≥2 months. FDA-stipulated primary endpoint is proportion with cumulative virologic rebound (confirmed VL≥50c/mL or premature discontinuations, with last VL≥50c/mL) through Week 48 (non-inferiority margin=4%). Pre-planned Week 24 interim results are presented.
Results: 1141 patients were randomized and treated (N=763 D/C/F/TAF vs N=378 control). Baseline characteristics: median age 46; 18% women; 25% non-white (21% black); 10% CD4+< 350 cells/mm^3; 71%, 22%, and 8% on darunavir, atazanavir and lopinavir, respectively (15% on cobicistat). Cumulative virologic rebound was 1.8% (n=14 D/C/F/TAF) vs 2.1% (n=8 control), of which 10/14 and 5/8 respectively, resuppressed (< 50c/mL) by Week 24; there were no confirmed rebounds ≥200c/mL. At Week 24, FDA snapshot analysis showed virologic suppression (VL< 50c/mL) was 96.3% (D/C/F/TAF) and 95.5% (control), and virologic failure occurred in 0.5% and 0.8%, respectively, with no discontinuations for virologic failure and no detected resistance to any study drug.
Safety was similar between arms through 24 weeks, with low incidences of Grade 3-4 adverse events (AEs) (D/C/F/TAF 4.5% vs control 4.5%), serious AEs (2.6% vs 3.2%), and treatment discontinuations (overall, 2.9% vs 2.9%; due to AEs, 1.4% vs 1.1%). The most common AEs (≥5% both arms) were: nasopharyngitis (7.6% vs 6.6%), URI (6.3% vs 6.3%), vitamin D deficiency (5.5% vs 5%). There were no deaths. Total cholesterol/HDL-cholesterol ratios were similar between arms, with minimal changes from baseline. Changes from baseline in renal safety parameters were consistent with known profiles of the individual D/C/F/TAF components; Mean ΔeGFR (cystatin-C clearance by CKD-EPI): +0.3mL/min/1.73m^2 (D/C/F/TAF) vs. -1.0mL/min/1.73m^2 (control).
Conclusions: In virologically suppressed adults, switching to once-daily D/C/F/TAF was well tolerated, resulted in a low cumulative virologic rebound rate, and a high virologic suppression rate through 24 weeks.

TUAB0102

Switching from a boosted protease inhibitor (PI/r) based regimen to a dolutegravir regimen in virologically suppressed patients with high cardiovascular risk or age ≥50 years is non-inferior and decreases lipids

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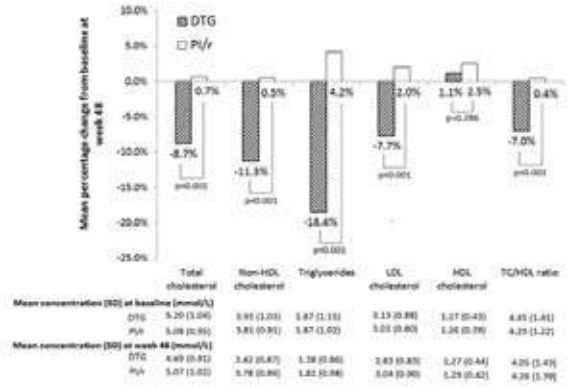
Background: Switching from a PI/r to dolutegravir (DTG) may improve convenience and lipid profile.
Methods: NEAT022-NCT02098837 is a European, open label, randomized, non-inferiority trial. HIV-infected adults ≥ 50 years or with a Framingham score ≥10% were eligible if HIV RNA <50 copies/mL for at least 24 weeks while on a PI/r regimen. Patients were randomized (1:1) to switch to DTG or to remain on PI/r. Primary end-points were: proportion of patients with HIV RNA <50 copies/ml at week 48 and a non-inferiority margin of -10% and percentage change of total plasma cholesterol. Secondary end-points included changes in other plasma lipid fractions, and adverse events.
Results: 415 patients were randomized: 205 to DTG and 210 to continue PI/r. 89% were men, 87 % were ≥50 years, 74 % had a Framingham score >10%, and suppressed viremia for a median of 5 years. At week 48, in the ITT analysis, treatment success rate was 93% in DTG arm and 95% in PI/r arm (difference -2.0%, 95%CI -6.5 to 2.6, non-inferiority demonstrated). There were 4 virological failures with DTG (from 58 to 130 copies) and 1 with PI/r (3,373 copies) without selection of resistance. There was no significant difference in terms of grade 3 or 4 AE´s or treatment modifying AE´s (7 in DTG arm -of whom 6 due to mood disturbances or insomnia- and 3 PI/r arm). Total cholesterol and other lipid fractions (except HDL) significantly (p<0.001) improved in the DTG arm overall



[Fig 1. Changes in lipid fractions at 48 weeks]

and in all baseline PI/r strata. About 30 % were on lipid lowering agents at weeks 0 and 48 in each arm.
Conclusions: Switching from a PI/r based regimen to a DTG regimen in virologically suppressed HIV patients ≥ 50 years old or with a Framingham score ≥10% was non-inferior, well tolerated and improved the lipid profile.

TUAB0103

Efficacy of dual therapy with protease inhibitors plus lamivudine as maintenance treatment in HIV-positive patients on second-line in Africa: the ANRS 12286/MOBIDIP trial 96 weeks results

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Background: In the MOBIDIP trial, dual therapy with boosted protease inhibitors (bPI) plus lamivudine showed superiority to bPI monotherapy in maintenance of virologically controlled HIV positive patients on second line antiretroviral treatment (ART) at 48 weeks. At week 48, the monotherapy arm was interrupted on DSMB advice and patients on dual therapy continued their follow up until week 96. Here we present the results of the dual therapy arm at 96 weeks.
Methods: This open label trial, conducted in Cameroon, Senegal and Burkina Faso, randomized 265 patients on stable PI plus NRTIs second line ART with HIV1 RNA (VL) < 200 copies/ml, CD4>100 cell/mm3 and adherence >90%, to receive ongoing ritonavir-boosted PI (darunavir or lopinavir) or on going bPI plus lamivudine. The main outcome was failure rate at 96 weeks in the intention to treat (ITT) population. Failure was defined as 1) a confirmed VL above 500 copies/ml (VF), 2) reintroduction of the NRTI backbone or 3) interruption of bPI.
Results: At inclusion, the 132 patients in the dual arm were mainly women (70%), median CD4 was 472 (IQR 360-621) cell/mm3, 83% had VL <50 copies/ml, median time on second line was 38 (IQR 30-47) months, PI was darunavir (one third) or lopinavir (two third). At first line failure, 97% had the M184V mutation.
At 96 weeks, in ITT analysis, 8.3% (IC95% 4.2-14.4%) patients failed in the dual arm (8 VF, 1 death, 2 lost to follow-up). Median delay to failure was 60 weeks. Three/4 patients who reintroduced tenofovir had VL <200 copies/ml in a median time of 13 weeks.
At 96 weeks, 79% and 91% of patients had VL below 50 and 200 copies/ml respectively.
Median increase in CD4 was 62 cell/mm3. We registered 28 severe adverse events, 1 in relation with study drugs. No significant changes in metabolic parameters were observed.
Conclusions: After viral suppression with bPI plus NRTIs in second line therapy, maintenance with bPI plus lamivudine is associated with a high rate of long-term success despite the presence of M184V mutation.

TUAC01 Updates from PrEP Clinical Trials

TUAC0101

Long-term follow-up of PROUD: evidence for high continued HIV exposure and durable effectiveness of PrEP

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Background: The PROUD trial clearly demonstrated the clinical effectiveness of TDF/FTC in the first year of use. The continued follow-up of participants on PrEP (range 2-4 years), which included regular testing for HIV and other STIS, allows assessment on whether effectiveness is maintained in the longer term and the extent of potential exposure to HIV.
Methods: PROUD was a pragmatic trial in which MSM were randomised to receive daily TDF/FTC either immediately (IMM) or after a deferral (DEF) period of 12 months. Main efficacy findings were based on follow-up during the deferred phase when IMM had access to PrEP and DEF did not. Since Nov 14, when all participants were offered PrEP, the trial has entered a post-deferred phase. We compare incidence rates of HIV and selective STIs during the deferred and post-deferred phases.
Results: 524(269 IMM, 255 DEF) and 449(244 IMM, 205 DEF) participants contributed to the deferred and post-deferred phases. Of 368 who attended a clinic in the last 6 months of follow-up, 327(89%) had at least one PrEP prescription. HIV and rectal gonorrhoea(rGC)/chlamydia(rCT) incidence in each phase is shown by group in the table.

	Deferred Phase		Post-deferred Phase	
Infection	**IMM**	**DEF**	**IMM**	**DEF**
HIV	1.6 (4/254)	9.4 (21/223)	1.2 (5/423)	0.3 (1/353)
Rectal GC	35.3 (81/229)	33.1 (67/203)	31.4 (129/411)	32.7 (116/355)
Rectal CT	33.6 (77/229)	21.2 (43/203)	33.1 (136/411)	29.9 (106/355)

[HIV and STI incidence (per 100 PY)]

There was no difference in HIV incidence between the groups in the post-deferred phase (p=0.18), but a significant decrease in the DEF group once they had access to PrEP (p< 0.0001). The rate in the IMM group remained similar in the two phases (p=0.66). The incidence of rectal infections was high in both groups and phases. rCT was lowest in the DEF group during the deferred phase, and this was driven by those who did not report rCT in the year before enrolment.
Conclusions: The reduction in HIV incidence in the DEF group confirms the remarkable effectiveness of TDF/FTC. The relatively stable incidence in the IMM group indicates this effect is durable. High ongoing incidence of rCT/rGC shows that participants remained at high risk of HIV and this needs to be taken into account when planning PrEP provision in public health programmes.

TUAC0102

On-demand PrEP with TDF/FTC remains highly effective among MSM with infrequent sexual intercourse: a sub-study of the ANRS IPERGAY trial

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Background: The ANRS IPERGAY trial demonstrated among MSM a 86% relative reduction of HIV-1 incidence with on demand PrEP in the TDF/FTC arm (2 infections, 219 person-years (py) of follow-up (FU), incidence: 0.91/100 py) as compared to the placebo arm (14 infections, 212 py of FU, incidence: 6.60/100 py). Participants in this trial used a median of 15 pills /month and had a median of 10 sexual intercourse /month. We wished to investigate whether on demand PrEP remained effective among participants having less frequent sexual intercourse and using fewer pills.
Methods: Assuming that participants with less frequent sexual intercourse would use fewer pills, and because individual patterns of pill use showed large intra-participant variability over time, we focused our analysis on person-time between 2 consecutive visits when participants used ≤15 pills /month and PrEP was used "systematically or often" during sexual intercourse, and not "from time to time or never". We then cumulated in each arm FU time spent with this pattern of pill use. A 4th generation HIV-1/2 ELISA assay was performed at each visit allowing to date the time of HIV-infection. Incidence rates of HIV-infection/100 py in both arms were then compared using mid-p exact test.
Results: Six HIV-1 infections occurred during FU among participants using ≤15 pills/month taken "systematically or often" during sexual intercourse: 6 in the placebo arm (incidence: 9.3/100 py, total FU time: 64.8 py) and 0 in the TDF/FTC arm (incidence: 0/100 py, total FU time: 68.9 py, p=0.013). The relative reduction of HIV incidence was 100% (95% CI: 20-100). During these follow-up periods, a median of 5 (IQR: 2-10) sexual intercourse/month were reported and a median of 9.5 (IQR: 6-13) pills/month were used. Restricting the analysis to periods when participants reported at least one condomless sexual act yielded similar results with HIV incidence of 12.3/100 py in the placebo arm (6 infections, 48.8 py of FU) and 0/100 py in the TDF/FTC arm (0 infection, 54.3 py of FU, p=0.011).
Conclusions: On-demand PrEP with TDF/FTC remains highly effective in MSM having infrequent sexual intercourse.

TUAC0103

An open-label multiple dose phase 1 assessment of long-acting rilpivirine

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Background: Long-acting (LA) injectable formulations of antiretroviral agents are being developed for HIV-1 prevention. The MWRI-01 Phase 1 study was undertaken to characterize the safety, acceptability, pharmacokinetic (PK), and pharmacodynamic (PD) profile of LA rilpivirine (RPV). Single dose (SD) data have previously been reported (McGowan I et al. Lancet HIV 2016). We now present data on the multiple dose (MD) phase of the study.
Methods: HIV-1 uninfected participants received three intramuscular doses of 1200 mg LA RPV at 2 month intervals. We collected plasma, genital/rectal fluids, and tissue (rectal (RT), cervical (CT), and vaginal (VT)) before and after exposure to LA RPV for assessment of PK and PD (ex vivo biopsy challenge with HIV-1). Clade B (HIV-1_{BaL}) and Clade C (G147-1) viruses were used separately in the explant

challenge model. The primary study objective was to characterize product safety and the analysis included all enrolled participants.
Results: We enrolled 8 women and 4 men. There were 195 adverse events reported, of which 193 (99%) were Grade 1 (71%) or Grade 2 (28%) and the majority were related to injection site discomfort. Table 1 provides the PK values (geometric mean; 90% CI) for each compartment 56 days after dosing.

	Plasma		RT		VT	CT
	Women	Men	Women	Men	Women	Women
Dose 1	39 (33-45)	29 (17-40)	46 (34-53)	29 (17-40)	22 (14-29)	28 (23-33)
Dose 3	59 (45-73)	40 (30-51)	61(52-70)	40 (30-51)	40 (28-52)	44 (22-66)

[Table 1: PK Data 56 Days After Injection (ng/mL)]

We found significant suppression of viral replication in RT for both Clade B ($p<0.05$) and Clade C ($p<0{\cdot}0001$) viruses at all time points in RT. In contrast, viral suppression was only seen in CT at Day 56 after the first dose of LA-RPV and at no time point for VT.
Conclusions: : MD administration of LA RPV was safe and well tolerated. As with our previous SD data, we saw prolonged suppression of viral replication in RT following exposure to LA RPV. Interestingly, despite modest accumulation of plasma RPV over time, there was minimal evidence of viral suppression in CT or VT.

TUAC0104

Impact of microbiota on female genital tissue and plasma concentrations of dapivirine

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Background: Women having a non-Lactobacillus dominant vaginal microbiota enrolled in CAPRISA 004 had lower detection of tenofovir (TFV) in cervicovaginal lavage (CVL) fluid than women having a Lactobacillus dominant microbiota. In FAME-04, decreased concentrations of TFV diphosphate in genital tissues and TFV in the plasma were highly correlated to higher Nugent score and increased vaginal concentrations of Gardnerella vaginalis and Atopobium vaginae. Vaginal rings containing dapivirine, a nonnucleoside reverse transcriptase inhibitor, have been shown to reduce incident HIV. The objective of this secondary analysis was to evaluate whether vaginal microbiota associated with bacterial vaginosis similarly impacted dapivirine concentrations in genital tract tissues and plasma following vaginal application.
Methods: 24 healthy HIV negative women (mean age 27, 58% white) used either dapivirine 0.05% gel (1.25 mg) or films (1.25 mg) for 6 days at home. On the 7th day, women inserted the final dose in the clinic with confirmation of correct product placement. Two hours later, cervical and vaginal biopsies along with CVL and plasma were obtained for dapivirine quantification using a validated liquid chromatography tandem mass spectrometry assay. Vaginal samples for diagnosis of bacterial vaginosis using the Nugent criteria and quantitative polymerase chain reaction (qPCR) detection of G. vaginalis and A. vaginae were collected prior to product use. The relationship between vaginal microbiota and dapivirine levels was assessed using linear regression models.
Results: There was no association between increasing concentrations of G. vaginalis in the vagina detected by qPCR and dapivirine concentrations in vaginal tissue, cervical tissue, CVL, or plasma ($p=0.45, 0.93, 0.51, 0.99$ respectively). Similarly, vaginal concentrations of A. vaginae were not associated with dapivirine concentrations in CVL, vaginal and cervical tissues or plasma ($p\geq0.31$). Nugent criteria associated with bacterial vaginosis were not associated with lower CVL, tissue or plasma concentrations of dapivirine ($p\geq0.19$).
Conclusions: In contrast to tenofovir, genital and plasma concentrations of dapivirine, were not impacted by increasing concentrations of vaginal bacteria associated with bacterial vaginosis. While replication of these results is needed, these data suggest that the levels of dapivirine following vaginal application should not be impacted by the microbiota associated with bacterial vaginosis.

TUAC0105

Experiences and perceptions of PrEP among gay and other men who sex with men (MSM) using PrEP in the PROUD study in England

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Background: There are concerns that PrEP could increase risk compensation, especially reducing condom use. The PROUD study (Nov12-Nov16) reported an 86% reduction in HIV and no increase in STIs. We explore PROUD participants' experiences and perceptions of PrEP in relation to other risk reduction strategies.
Methods: We conducted semi-structured in-depth-interviews with 41 HIV-negative MSM, purposively selected based on self-reported high/low PrEP adherence and increased/same risk behaviour. Interviews were digitally recorded, transcribed and analysed using framework analysis.
Results: The majority of participants reported risk reduction strategies including occasional condom use, strategic positioning, or sero-sorting. Participants applied rules to their sexual behaviour, such as using condoms "if it was a one night stand", or not being receptive "outside of a relationship". Typically, PrEP was added to the existing set of ‚rules'. For some participants, PrEP allowed a relaxing of the rules, for example about strategic positioning: "I have definitely experienced more as a bottom", or about condomless sex: "I have had more unprotected sex than before… it doesn't mean that I only have unprotected sex". Other participants insisted PrEP had not changed their rules: "I haven't changed the way I think because I am taking this pill". Participants described PrEP as a "security blanket", an added "defence mechanism" and used analogies such as wearing a "crash helmet… on my bicycle". PrEP was described as affording "more intimacy", "reassurance", and giving "added control". By using PrEP, many participants with HIV-positive partners sought to reduce their partner's anxiety about the risk of transmission. The benefits of PrEP were described within the social context of risk environments in cities like London, the chemsex scene, and the digitization of sexual contact. PrEP use was viewed as time-limited: "clearly it is a period, a moment… it is not going to be a lifetime".
Conclusions: These data suggest that PrEP was added to a range of ‚rules' already used to mitigate risk, rather than replacing them. PrEP impacted on the boundaries of the rules for some people but not all. In social contexts of high-risk behaviour, PrEP offers added protection and psycho-social benefits that increase individual choice in the mitigation of risk.

TUAC02 Prevention and Adolescents

TUAC0201

High uptake of community-based HIV testing by adolescent girls and young women aged 15-24: implications and synergies for PrEP roll out?

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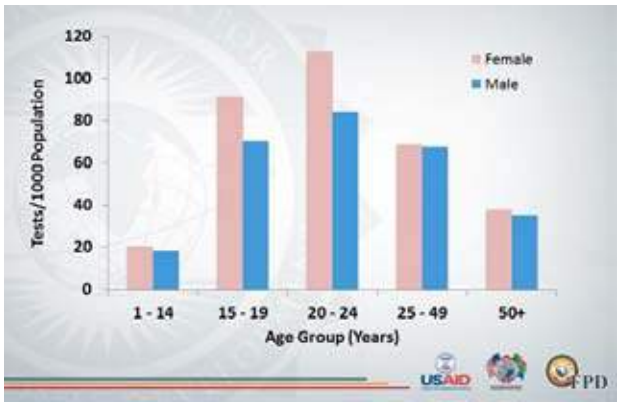
Background: HIV incidence among female youth aged 15-24 in South Africa is four times higher than their male counterparts. Recent HIV prevention trials in South Africa documented incidence of 5-6% per year in 15-24 year old adolescent girls and young women (AGYW). HIV counselling and testing is the entry point for treatment and prevention services, and is key to implementing effective HIV prevention strategies. Community-based HIV counselling and testing (CBCT) has the potential to increase testing among key populations. We present interim findings of our at-scale CBCT program targeting high transmission areas in 13 high HIV burden districts in South Africa.
Methods: Routine programmatic data from October 2015 - September 2016 were used. Descriptive statistics were performed. HIV positivity and testing uptakes rates were calculated and stratified by age group, gender, and district.

Results: A total of 660,351 individuals were tested (positivity= 6.6%; uptake= 54.9/1000 population). The largest number of testers were individuals age 25-49 (n= 309,323; uptake= 68.2/1000 population). The highest testing uptake was by individuals age 15-24 (uptake= 90.6/1000 population).
Further disaggregation into 15-19 and 20-24 year old age groups reveal that adolescent girls age 15-19 (uptake= 91.6/1000 population) and young women age 20-24 (uptake= 112.8/1000 population) had the highest testing uptake of any age groups of either gender (Figure 1). These finding persist when uptake was disaggregated by district.
Conclusions: Implementation of our CBCT program has been extremely successful. Though the largest number of tests were performed on those aged 25-49 years, AGYW had the highest testing uptake. If access to PrEP by AGYW is to be scaled up, innovative supply-side interventions and service delivery platforms must be identified. Stakeholders involved in PrEP implementation should consider the synergies that CBCT programs may provide for identifying and delivering PrEP services to AGYW.



[Testing Uptake by Age Group and Gender]

TUAC0202

Finding the right target population for PrEP: the cost-effectiveness of pre-exposure prophylaxis provision to female and male adolescents and young women in South Africa

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Background: The South African government is in the process of identifying a suitable roll-out strategy for providing oral PrEP to young people at risk of acquiring HIV. We were tasked to evaluate the cost-effectiveness of providing PrEP to young women (20-24 years) vs male or female adolescents (15-19 years), both when covering everyone in these groups or only those self-identifying as being at high risk.
Methods: We used Thembisa, an existing HIV transmission model, and cost input from the first PrEP demonstration projects to model the impact of PrEP provision on new HIV infections and cost per HIV infection averted over 20 years, over a baseline of the current HIV programme, including potential cost savings due to reduced treatment need.
We compared provision to all young people in a sub-population to targeting via self-selection by high-risk individuals. Target coverage was set to 18% of either population and varied in sensitivity analysis.
Results: PrEP provision to adolescents of both genders is the most cost-effective option, being more effective and less costly than provision to young women (see Table). Provision to female adolescents is slightly more effective and cost effective than provision to male adolescents. At 18% coverage of either all young people in the target population or only those at high risk, the impact on HIV infections averted is similar, but self-selection by high-risk individuals results in much smaller populations on PrEP.
As a result, targeted provision is much more cost effective. PrEP is however not cost saving at any of the coverage rates tested (1-99%) for any of the populations, with or without successful targetting to high-risk sub-populations.

	Base-line	Young women (20-24)		Adolescents; both genders (15-19)		Adolescents; females (15-19)		Adolescents; males (15-19)	
Risk group		All	High risk	All	High risk	All	High risk	All	High risk
Number of person years on PrEP [millions]	-	8.7	1.4	10.7	3.7	5.9	1.6	4.7	2.1
Total cost [billions USD]	43.86	45.43	44.10	45.67	44.38	44.86	44.06	44.69	44.21
Incremental cost [billions USD] (% change)	-	1.53 (3.5%)	0.20 (0.5%)	1.76 (4.0%)	0.48 (1.1%)	0.96 (2.2%)	0.16 (0.4%)	0.79 (1.8%)	0.31 (0.7%)
Total new HIV infections [millions]	4.63	4.54	4.56	4.38	4.39	4.47	4.49	4.52	4.53
HIV infections averted [thousands] (% change)	-	82.4 (1.8%)	65.61 (1.5%)	250.0 (6.1%)	230.3 (5.5%)	153.4 (3.6%)	140.1 (3.2%)	106.4 (2.4%)	98.7 (2.2%)
Incremental cost-effectiveness ratio [USD/HIV infection averted]	-	$18,511	$3,013	$7,058	$2,099	$6,264	$1,164	$7,438	$3,144

[Results by sub-population]

Conclusions: Provision of PrEP to female adolescents is more cost effective than to male adolescents or young women. PrEP, although expensive, can be made more cost effective if high-risk sub-populations successfully self-select for PrEP.

TUAC0203

State-level school-based sex education policies on sexual orientation are associated with changes in teaching about HIV prevention

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Background: The Sexuality Information and Education Council of the United States (SIECUS) reported in 2015 that 11 states had state-level laws or policies regarding school-based sex education that were discriminatory toward lesbian, gay, bisexual, and/or transgender (LGBT) individuals or stated that homosexuality must not be promoted or addressed as a socially acceptable alternative. This was an 83% increase from the number of states in 2014. The implementation of these policies may limit the HIV education available to LGBT students and their heterosexual peers.
Methods: We constructed a panel dataset for even numbered years from 2006-2014. The independent variable was an indicator from SIECUS State Profiles about whether states´ sex education laws were LGBT-stigmatizing. The three dependent variables were from the Centers for Disease Control and Prevention (CDC) School Health Profiles system. Based on self-administered questionnaires from the principal and the lead health education teacher in a sample of high schools, the CDC reported for each state the percentage of schools that tried to increase students' knowledge about HIV prevention, human sexuality, and sexually transmitted disease (STD) prevention. We conducted ordinary least squares regression analysis in Stata/SE 14 with state and year fixed effects to control for unobserved time-invariant state-level confounders and state-invariant time-varying confounders.
Results: In the regression models, having a state sex education policy that was anti-LGBT was associated with a 17.4%, 21.7%, and 16.3% decrease in the percentage of schools that tried to increase student knowledge about HIV prevention, human sexuality, and STD prevention, respectively ($p<0.05$).

Year →	2006	2008	2010	2012	2014	State sex education law is negatively LGBT-biased (combined states and years) ↓	
% (n/N) of states with negatively LGBT-biased sex education laws →	21.6% (11/51)	13.7% (7/51)	13.7% (7/51)	11.8% (6/51)	11.8% (6/51)	No	Yes
% of schools that tried to increase student knowledge about HIV prevention	81.4%	88.9%	88.4%	86.9%	85.9%	87.4%	81.4%
% of schools that tried to increase student knowledge about human sexuality	73.7%	84.6%	84.2%	82.4%	80.5%	82.4%	75.6%
% of schools that tried to increase student knowledge about STD prevention	77.5%	86.4%	86.7%	85.7%	84.9%	85.4%	79.4%

[Sex education implementation by LGBT policy]

Conclusions: State sex education laws that are negatively biased toward LGBT people may increase reluctance of teachers to try to increase student knowledge about sex education topics in general, including those that are not related to sexual orientation or gender identity. Given the increase in these laws in the past year, we expect that additional teens will be denied instruction on these topics. Further research is necessary to assess how this may affect youth risk behaviors and sexual health outcomes.

TUAC0204

Potential for HIV transmission among adolescents and young adults receiving antiretroviral therapy

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Background: Adolescents and young adults (AYA) living with HIV have lower rates of virologic suppression and higher rates of sexually transmitted infections (STIs) than older adults, which increases HIV transmission potential. We aimed to identify the proportion of participants with, and risk factors for, high HIV transmission potential within a cohort of HIV-positive AYA.
Methods: Retrospective cohort study of HIV-positive, antiretroviral therapy (ART)-treated, AYA, ages 13-24, at a U.S. adolescent HIV clinic from 2002-2015. We included all visits with viral load (VL) measurement after ART initiation. High transmission potential was defined as incident STI (Neisseria gonorrhea, Chlamydia trachomatis or Treponema palladium) with concurrent VL >1500 copies/ml. Generalized estimating equations (GEE) were used to calculate odds ratios (ORs) and 95% confidence intervals (CI) for hypothesized risk factors for high transmission potential, including age, gender, insurance status, sexual orientation, race and history of STI at entry to care.
Results: Participants (n=251) were followed for a median of 3.2 years (IQR 1.5-5.3), contributing 2,860 visits. Participants were 87% African-American (n=218), and 73% men and transgender women who have sex with men (n=182) and 48% (n=120) had a history of STI at entry to care. The median visit age was 21 years (IQR 19-23). Incident STI was detected in 68% (n=166) of participants comprising 15% (n=299) of visits. Participants were viremic (VL >1500 copies/ml) at 27% (n=640) of visits. High transmission potential occurred at least once in 16% (n=39) of participants and 3% of visits. In the final GEE model, history of STI at or before entry to HIV care conferred a nearly four-fold increased odds of high transmission potential (OR 3.8, 95% CI: 2.0-7.1, p< 0.001). There was no significant association between age, gender, sexual orientation, race, or insurance status and high HIV transmission potential.
Conclusions: In this conservative model of transmission potential, 16% of ART-treated AYA in care were episodically at high risk of HIV transmission, demonstrating the limits of treatment as prevention in this setting. A baseline history of STI conferred higher risk of transmitting HIV, emphasizing the need for secondary prevention interventions targeting both ART adherence and sexual risk reduction for HIV-positive youth.

TUAC0205

HIV and HSV-2 risk among young women in age-disparate partnerships: evidence from KwaZulu-Natal, South Africa

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Background: Young women in sub-Saharan Africa continue to exhibit high HIV prevalence and incidence rates. We explored the role age-disparate partnerships play in HIV-infection risk among 15-24 year old women in an endemic setting in South Africa.
Methods: During June 2014-June 2015, a cross-sectional household survey was conducted in KwaZulu-Natal Province, South Africa comprising 9812 individuals aged 15 to 49 years. Venous blood samples were collected for HIV antibody and viral load tests, and herpes simplex virus type 2 (HSV-2) antibody tests. A partnership was defined as age-disparate if the age-difference between partners was five years or more. Multiple logistic regression analyses were first used to assess the associations between age-disparate partnerships and both HIV and HSV-2 status - HSV-2 may increase a young women's risk of HIV-infection - among 15-24 year old women who reported at least one sexual partner (n=1557).
The second set of analyses used partnership data reported by men - restricted to on-going partnerships with 15-24 year old women (n=1078) - to assess whether age-disparate partners of young women were more likely to be HIV-positive with a detectable viral load (≥20 copies/ml), and therefore pose a greater level of risk, than age-similar partners.
Results: Women who reported any age-disparate partnerships were more likely to test positive for HIV (37% vs 22%, p<0.01) and HSV-2 (65% vs 46%, p<0.01). After controlling for, inter alia, age and number of lifetime sexual partners the odds of young women having HIV (aOR:1.56, p<0.01,95%CI:1.13-2.17) and HSV-2 (aOR:1.85, p<0.01,95%CI:1.41-2.44) were greater for those who reported age-disparate partnerships. Men in age-disparate partnerships with young women were also more likely to be HIV-positive (5-9 year age-difference: aOR 2.12, p<0.01,95%CI:1.26-3.57; 10+ year age-difference: aOR 4.93, p<0.01,95%CI:2.67-9.12) and be HIV-positive with a detectable viral load (5-9 year age-difference: aOR 2.30, p<0.01,95%CI:1.36-3.87; 10+ year age-difference: aOR:2.57, p<0.01,95%CI:1.34-4.92) compared to men in age-similar partnerships with young women.
Conclusions: Results suggest a positive association between age-disparate partnerships and young women's HIV risk. Expanding treatment and combination prevention, including targeted interventions addressing risk from age-disparate sexual partnering, is vital to reducing HIV incidence amongst young women.

TUAC03 Hitting the First 90 Target: Lessons from Population-Based Surveys

TUAC0301

Findings from the 2016 Zambia Population-based HIV Impact Assessment (ZAMPHIA): HIV prevalence, incidence and progress towards the 90-90-90 goals

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Background: Based on modeled estimates, 13% of people in Zambia were living with HIV in 2014. The 2016 Zambia Population-based HIV Impact Assessment (ZAMPHIA) is the first national survey to directly assess the status of Zambia's HIV epidemic by measuring HIV incidence. Findings from ZAMPHIA and progress toward meeting the UNAIDS 90-90-90 targets, including viral load suppression (VLS), are presented.
Methods: A nationally representative household-based sample of 12,310 eligible households was selected in 511 enumeration areas; analyses account for study design. Consenting participants provided demographic and clinical information and blood samples for household HIV testing per national guidelines. HIV-seropositive results were confirmed using the Geenius supplemental assay; viral load and limiting antigen (LAg) avidity EIA testing were performed at a central lab on all HIV-seropositive samples. HIV incidence estimates were based on World Health Organization criteria for recent infection (LAg <1.5 OD units and HIV RNA >1000 c/ml). VLS was defined as HIV RNA <1000 c/ml.
Results: In total, 19,029 adults and 7,959 children provided interviews and blood samples (response rate: 68%). Participation by eligible adults was higher for women than men (71% vs 63%, P< 0.0001). HIV prevalence estimates among adults aged 15-59 and children aged 0-14 were 12.3% and 1.3%, respectively. Adult HIV incidence was 0.66% (female 1.00%, male 0.33%); mean VLS prevalence among all HIV-seropositive adults was 59.8%. An estimated 67.3% of persons living with HIV (PLHIV) knew their HIV status (1st 90), 85.4% of PLHIV who reported knowing their status also reported receiving ART (2nd 90), and 89.2% of these PLHIV who reported receiving ART were virally suppressed (3rd 90).

Conclusions: Zambia has achieved progress towards meeting the UNAIDS 90-90-90 goals. HIV prevalence is stabilizing; HIV incidence is low; and prevalence of VLS is high. Identification of gaps in testing, ART, and viral load suppression is needed to better target expansion of HIV treatment services in Zambia.

Indicator	Males	Females	Total
HIV prevalence among adults, % [95% CI]	9.5 [8.8, 10.3]	14.9 [14.0, 15.8]	12.3 [11.6, 12.9]
HIV prevalence among children, % [95% CI]	--	--	1.3 [1.0, 1.6]
HIV incidence among adults % [95% CI]	0.33 [0.11, 0.56]	1.00 [0.65, 1.36]	0.66 [0.45, 0.88]
Viral load suppression (VLS) prevalence among HIV+ adults, % [95% CI]	57.4 [53.4, 61.5]	61.3 [58.7, 63.8]	59.8 [57.4, 62.2]
Prevalence of HIV+ adults who report knowing their HIV status, % [95% CI]	62.8 [58.7, 66.8]	70.0 [67.5, 72.5]	67.3 [64.8, 69.7]
Self-reported ART prevalence among HIV+ adults who report knowing their HIV status, % [95% CI]	86.2 [83.1, 89.4]	84.9 [82.5,87.4]	85.4 [83.4, 87.4]
VLS prevalence among HIV+ adults who report ART and knowing their HIV status, % [95% CI]	88.2 [85.1, 91.4]	89.7 [87.7, 91.8]	89.2 [87.4, 91.0]

[Selected Findings from 2016 ZAMPHIA]

TUAC0302

Correlates of being outside the 90-90-90 cascade among adults ages 15-64 years in Zimbabwe

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Background: Zimbabwe has made great strides in combatting HIV, partially through increasing testing and treatment. To reach the UNAIDS 90-90-90 targets it is necessary to know who is unaware of their HIV infection, who is not on treatment, and who is not virally suppressed in order to engage or re-engage them in HIV services. We identify correlates of being outside this cascade.

Methods: The 2015-2016 Zimbabwe Population-based HIV Impact Assessment was a cluster-based nationally-representative household survey. Face-to-face interviews were conducted with 22,496 adults aged 15-64 years, and blood specimens collected from 20,572 of them for HIV testing following the national serial rapid testing algorithm of Determine, First Response and Stat-Pak. Treatment status was self-reported and viral load testing was conducted using Roche Taqman 96. Weighted analysis was conducted in SAS. Variables associated with being outside the 90-90-90 cascade at p<0.1 in bivariate analysis were included in the multivariate model.

Results: HIV prevalence was 14.6% among 15-64 year olds. Among HIV-infected participants, 25.8% were unaware of their infection. Among those aware of their infection, 13.2% were not on treatment. Of those on treatment, 13.5% were not virally suppressed. In multivariate analysis, males were more likely than females to be unware of their HIV infection (AOR: 1.74, 95% CI: 1.43-2.10) as were those aged 15-24 years (AOR: 4.59, 95% CI: 3.13-6.72) and aged 25-34 (AOR: 2.43, 95% CI: 1.73-3.41) compared to those aged 55-64 years. Compared to those ages 55-64 years, those aged 15-24 and 25-34 years were least likely to be on treatment (AOR: 3.88, 95% CI: 1.93-7.80 and AOR: 5.03, 95% CI: 2.85-8.89, respectively). Being on treatment and virally unsuppressed was associated with being male (AOR: 1.57, 95% CI: 1.17-2.09) and being aged 15-24 and 25-34 years compared to 55-64 years (AOR: 2.99, 95% CI: 1.50-6.11, and AOR: 3.82, 95% CI: 2.09-7.01, respectively). Neither province nor urban residence were associated with being outside any step of the cascade. Sex was not associated with being aware and not on treatment.

Conclusions: People < 35 years and men should be further targeted for HIV testing and additional support for linkage to and retention on treatment.

TUAC0303

90-90-90 targets in HIV-positive women using results from MPHIA: a Malawi success story

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Background: While women in Malawi continue to experience a high burden of HIV infection, implementation of Option B+ since 2011 has led to substantial improvement in increasing access to antiretroviral therapy (ART) for HIV-positive women. This study aimed at describing the progress in women towards achieving the UNAIDS 90-90-90 targets in Malawi.

Methods: The Malawi Population-Based HIV Impact Assessment (MPHIA) was a two-stage cluster survey of randomly selected households in Malawi. Data collection occurred from November 2015 to August 2016. Participants answered a questionnaire involving reproductive history, PMTCT/option B+, and HIV testing and care. The survey involved collection of blood samples, home-based counseling and testing (HBCT) using the national rapid HIV test algorithm followed by laboratory-based confirmation using Geenius™. Incidence was measured using the Lag-Avidity EIA. Viral load suppression (VLS) was defined as <1,000 HIV RNA copies/mL. Descriptive analyses were conducted to examine progress towards 90-90-90 parameters in women and accounted for the study design.

Results: Of 12,231 eligible women ages 15 to 64 years, 9,956 (81.4%), women were interviewed and tested. Seventy-six percent (76.3%, 95% Confidence Interval (CI):74.2-78.9) of women reported knowledge of their HIV+ status. Of the women who knew their HIV+ status, 90.0% (95%CI:87.1-92.9) reported being on ART. Of the women who reported ART use, 92.3% (95%CI:90.4-94.2) had achieved VLS. Progress towards 90-90-90 targets also varied by age, see Table. At population level (irrespective of knowledge of HIV and ART status), prevalence of VLS among HIV+ women 15-64 years was 72.9% (95%CI:69.9-75.9); highest among older women but much lower in young women. HIV incidence among women was 0.48% (95%CI:0.20-0.76), which was about 50% greater in women than men (0.25%, 95%CI:0.05-0.46).

Age Group	Diagnosed	On Treatment	Virally Suppressed
	% (95% CI)	% (95% CI)	% (95% CI)
15-24 years	58.7 (48.4-69.0)	76.9 (59.0-94.7)	79.3 (68.4-90.2)
25-34 years	72.6 (67.5-77.8)	88.0 (82.0-94.1)	94.5 (92.0-97.0)
35-44 years	84.8 (81.0-88.5)	91.7 (88.5-94.9)	91.7 (88.3-95.1)
45-54 years	76.4 (68.8-84.0)	95.3 (92.3-98.2)	93.6 (89.4-97.7)
55-64 years	85.1 (76.7-93.5)	94.7 (89.3-100.0)	95.3 (88.7-100.0)

[90-90-90 Targets by Age Group among Women]

Conclusions: Although women are at greater risk of HIV infection in the reproductive age group, they seem to get into treatment, stay on treatment, and achieve VLS. However, the first 90 was not reached, suggesting that a reasonable number of women are not accessing Malawi's PMTCT program and further efforts are needed to diagnose and treat these cases; and prevent new infections.

TUAC0304

Children living with HIV in Malawi: first survey-based measurement of national pediatric HIV prevalence and viral suppression

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Background: To date, national pediatric HIV burden estimates in Malawi were derived from modeling using clinic-based data. In 2015, an estimated 84,000 children 0-14 years old were living with HIV in Malawi. The Malawi Population-based

HIV Impact Assessment (MPHIA), a national household survey conducted from 2015 - 2016, provides the first direct measurement of national HIV prevalence and viral suppression (VS) prevalence among children 0-14 years.
Methods: MPHIA tested children in every other surveyed household (n=13,234) using the national HIV rapid test (RT) algorithm consisting of Determine™ (screening RT) and UniGold™ (confirmatory RT). Children >18 months who tested positive by both RTs were confirmed by laboratory-based testing using Geenius™ HIV 1/2 Confirmatory Assay (Bio-Rad). Children ≤18 months screening reactive on Determine underwent DNA PCR testing for HIV diagnosis. HIV RNA viral load suppression was defined as < 1,000 copies/mL. Weighted national pediatric HIV prevalence and VS prevalence were measured using SI-CHAID weights. Jackknife Replication method was used to calculate 95% confidence interval (CI). Number of children living with HIV was estimated using population projections from the Malawi National Statistics Office (NSO).
Results: Of 9,952 eligible children, 6,143 (61.7%) provided blood for HIV testing. Of those tested, 99 children were HIV positive; 2 were DNA PCR positive. Overall prevalence was 1.6% (95% CI: 1.2% - 2.0%), equivalent to 122,721 children living with HIV (95% CI: 90,868 - 154,573). Among those infected, VS prevalence was 42.9% (95% CI: 30.5% - 55.4%). HIV prevalence was greater in urban compared to rural areas; VS was considerably low among children< 5 years, and those residing in urban areas.

Variable	Unweighted number of children who tested HIV positive/ Number tested	prevalence (%)	95% CI	Weighted number of children living with HIV	95% CI	Number of children (NSO projection)	Viral suppression (%)	95% CI
0-4 years	20/1,854	1.2	0.6 - 1.8	30,541	14,492 - 46,591	2,583,791	21.9	3.6 - 40.4
5-9 years	37/2,197	1.6	0.9 - 2.3	49,271	27,076 - 71,466	3,063,666	49.1	31.2 - 67.0
10-14 years	42/2,092	2.0	1.3 - 2.7	42,909	27,069 - 58,749	2,143,287	50.3	29.7 - 70.9
Urban residence	37/1,911	2.3	1.4 - 3.1	26,826	13,621 - 40,032	1,181,940	28.9	12.2 - 45.5
Rural residence	62/6,143	1.5	1.0 - 1.9	95,894	65,917 - 125,872	6,608,804	47.0	32.2 - 61.9

[HIV prevalence and viral suppression in children]

Conclusions: The MPHIA estimate of the number of children living with HIV is 46% greater than the current estimate which is currently being used for planning of pediatric HIV interventions. Low rates of viral suppression seen in children indicate the need for uptake of effective HIV treatment and adherence interventions to achieve the UNAIDS target of 73% viral suppression among children.

TUAC0305

Estimating HIV incidence and the undiagnosed HIV population in the European Union / European economic area

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Background: Each year, about 30,000 people are newly diagnosed with HIV in the 31 countries of the European Union/European Economic Area (EU/EEA). We aimed to estimate the number of people living with undiagnosed HIV in the entire EU/EEA and in four sub-regions.
Methods: Annual data on HIV diagnoses in 2003-2015 were retrieved from a database for HIV/AIDS within The European Surveillance System (TESSy). HIV diagnoses were adjusted for reporting delay and stratified by the presence of an AIDS-defining event within 3 months of HIV diagnosis, and, for individuals without AIDS, by CD4 cell count (≥500, 350-499, 200-349, < 200 cells/mm^3) at the time of diagnosis. Countries were grouped in sub-regions as defined by United Nations. A back-calculation method based on the ECDC HIV Modelling Tool was used to estimate annual numbers of newly acquired HIV infections, the distribution of time between infection and diagnosis by calendar year, and the number of people still undiagnosed by the end of 2015.
Results: In 2003-2015, there were 403,169 HIV diagnoses: 142,010 (35%) in Western, 121,624 (30%) in Northern, 27,662 (7%) in Eastern, and 111,873 (28%) in Southern Europe. In the entire EU/EEA, 120,100 (95% CI:113,000-127,800) people were estimated to be living with undiagnosed HIV by the end to 2015, of whom 47% had a CD4 count ≥500 cells/mm^3 and 31% <350 cells/mm^3, with 28,000 (95% CI: 24,700-31,700) new infections in 2015. The estimated number of undiagnosed HIV infections was highest in Southern Europe, while infection rates were highest and time to diagnosis shortest in Northern and Western Europe (Table).

Sub-region	Undiagnosed, total	Undiagnosed, CD4 ≥500		Undiagnosed, CD4 <350		Infection rate [/100,000 population]	Time to diagnosis (years)
Western	36,000 32,500-39,600	18,700 16,700-20,800	52%	9,800 9,200-10,700	27%	5.8 5.0-6.8	2.5 [1.2-4.6]
Northern	27,800 25,700-30,700	14,200 12,900-15,900	51%	7,800 7,300-8,400	28%	9.4 8.5-10.8	2.3 [1.1-4.3]
Eastern	12,700 10,900-14,900	5,800 4,800-7,100	46%	4,100 3,600-4,700	32%	3.3 2.4-4.2	3.3 [1.6-6.0]
Southern	42,900 39,800-46,400	17,800 16,000-19,900	41%	15,600 14,900-16,500	36%	3.4 2.1-4.6	3.9 [1.9-7.0]
Total	120,100 113,300-127,800	56,600 52,400-61,000	47%	37,600 35,900-39,300	31%	5.4 4.8-6.2	2.9 [1.4-5.4]

Undiagnosed population and infection rate with 95% confidence intervals, and median time to diagnosis [interquartile range] in 2015.

[Undiagnosed population and infection rates]

Conclusions: A substantial number of people in the EU/EEA are living with undiagnosed HIV. Although the estimated CD4 distribution suggests that approximately half of them are in an early stage of infection, a significant proportion are estimated to have late stage infection, suggesting more efforts are needed to test and diagnose these people.

TUAC04 Prevention: It's Not Just about PrEP

TUAC0401

The effect of a conditional cash transfer for HIV prevention on the experience of partner violence for young women: evidence from a randomized experiment in South Africa HPTN 068

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Background: Evidence has shown that the experience of violence by a partner has important influences on women's risk of HIV acquisition. Conditional cash transfers (CCTs) targeted to young women in sub-Saharan Africa have been advocated as an intervention to reduce the risk of HIV-infection, but the success of such interventions may be conditional upon changes in gendered power inequalities. Using a randomized experiment in northeast South Africa, we find that a CCT targeted to poor girls in high school reduced the risk of intimate partner violence (IPV) by 34%. The purpose of this study is to understand the pathways through which the CCT affects IPV.
Methods: Our study is a phase 3, randomized controlled trial (HPTN 068) in a rural area in Mpumalanga province, South Africa. Eligible young women (aged 13-20) and their parents or guardians were randomly assigned (1:1) to receive a monthly cash transfer conditional on school attendance versus no cash transfer. Participants (N=2,448) were interviewed at baseline, then at annual follow-up visits at 12, 24, and 36 months. We estimate the primary outcome, physical IPV in the past 12 months, using a GEE log-binomial regression model. We examined mediation of direct effects through intermediate pathways using methods designed for nonlinear models under the counterfactual framework. Mediators include sexual behaviors, empowerment, and economic well-being measures.
Results: We find evidence that the CCT works through delaying sexual debut or reducing the likelihood of having a sexual partner. The intervention interacts with these mediators leading to a larger reduction in IPV risk. Compared to the direct effect of the CCT on any physical IPV [RR 0.66, CI(95%):0.59-0.74], the risk of IPV is further reduced when we set the controlled direct effect to either no sexual debut [RR 0.53, CI(95%):0.45-0.63] or to no sexual partners [RR 0.56, CI(95%):0.48-0.63].
Conclusions: Results indicate that a CCT for adolescent school girls has protective effects on girls' experience of violence in part because the intervention reduces the likelihood of debut or having a sexual partner, thereby reducing the opportunity for IPV. Since these behaviors also protect against HIV acquisition, this evidence strengthens the case for CCTs for HIV prevention.

TUAC0402

The effect of school attendance and school drop out on incident HIV and HSV-2 among young women in rural South Africa enrolled in HPTN 068

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Background: Education may protect against sexual transmitted infections but has primarily been studied as educational attainment in adults or using measures of prevalent rather than incident infection. Few studies have explored schooling as a measure of time spent in a structured school environment. We hypothesize that low versus high attendance in school and school drop out versus staying in school are associated with a higher risk of incident HIV and HSV-2 infection among young women
Methods: We used longitudinal data from the HPTN 068 randomized trial in Agincourt, South Africa to determine if percentage of school days attended between annual surveys and school dropout affect incident HIV and HSV-2 in young women aged 13-23. We examined inverse probability of exposure weighted survival curves and used them to calculate 1, 2 and 3-year risk differences and risk ratios for the effect of school attendance on incident HIV and HSV-2, accounting for confounding. A marginal structural cox model was then used to estimate the hazard ratios for the effect of school attendance and school drop out on incident HIV and HSV-2.
Results: Over the study period, 107 incident HIV cases occurred among the 2328 women without HIV at baseline, and 208 HSV-2 incident cases occurred among the 2238 women without prevalent HSV-2 at baseline. Risk of HIV and HSV-2 increased over time and was lower for young women who had high attendance (>=80% school days) versus low attendance (< 80%) at all time points. After accounting for relevant confounders, young women with low attendance were more likely to develop HIV (HR: 2.97; 95% CI: 1.62, 5.45) and HSV-2 (HR: 2.47; 95% CI: 1.46,4.17) over the follow up period than young women with high attendance. Similarly, young women who dropped out of school had a higher weighted hazard of both HIV (HR 3.25 95% CI: 1.67,6.32) and HSV-2 (HR 2.70; 95% CI 1.59,4.59).
Conclusions: Young women who attend more school and stay in school have a lower risk of incident HIV and HSV-2 infection. Interventions to prevent infections should continue to encourage young women to attend school more frequently and to avoid drop outs.

TUAC0403

Increasing HIV test uptake and case finding through assisted HIV partner notification services: a systematic review and meta-analysis

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Background: Despite the expansion of HIV testing services (HTS), an estimated 40% of people with HIV infection remain undiagnosed. New approaches are needed enhance HTS efficiency in order to reach the first UN 90-90-90 goal to diagnose 90% of people with HIV infection by 2020. We conducted a systematic review on the effectiveness of assisted partner notification in improving HIV test uptake and diagnosis, and the occurrence of adverse events, to inform the development of WHO normative guidelines.
Methods: We systematically searched five electronic databases through June 2016. We also contacted experts in the field and authors for additional information where needed. Eligible studies compared assisted HIV partner notification services to passive or no notification, and measured one of the following outcomes: HIV test uptake, proportion of partners tested and diagnosed HIV-positive, CD4 or viral load, linkage to clinical assessment or antiretroviral therapy, linkage to prevention for HIV-negative partners, and any social harm among HIV-positive patients or their partners. We used the Cochrane Collaboration's tool to assess risk of bias and GRADE to evaluate the quality of the evidence. Where appropriate, random-effects meta-analysis was conducted.
Results: Of 1742 citations identified, four randomized controlled trials (RCT) and six observational studies totalling 5150 index patients from eight countries were included. Meta-analysis of three individually-randomised trials provided moderate quality evidence that assisted partner notification services increased HTS uptake among partners 1.5 times compared to passive referral (Relative Risk [RR]=1.46; 95% CI: 1.22-1.75; I^2=0%). Overall, studies reported 13-72% of partners were HIV positive, and between 12-66% of partners were newly diagnosed. The proportion of HIV-positive partners was 1.5 times higher with assisted partner notification than with passive referral (RR=1.47; 95% CI: 1.12-1.92; I^2=0%; moderate quality evidence). Few instances of violence or harm were reported.
Conclusions: Assisted partner notification improved partner testing and increased diagnosis of people with HIV infection, with few reports of harm. WHO strongly recommends offering voluntary assisted HIV partner notification services as part of a comprehensive package of testing to all newly diagnosed persons, and periodically to all HIV positive persons throughout their care and treatment.

TUAC0404

Association between HIV and sexually transmitted infections and partner circumcision among women in uMgungundlovu District, South Africa: a cross-sectional analysis of HIPSS baseline data

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Background: Randomized controlled trials and observational data have demonstrated that circumcision partially protects men from acquiring HIV and some sexually transmitted infections (STIs) through heterosexual sex. They also suggest that female partners receive some protection, possibly indirectly through lower infection prevalences among men. However, population-level data outside experimental settings is lacking. The HIV Incidence Provincial Surveillance System (HIPSS) is a longitudinal study in Vulindlela and Greater Edendale sub-districts, South Africa, which collected population-level baseline data in 2014 and 2015.
Methods: Female HIPPS participants were aged 15-49 years. Those with at least one past or current male sexual partner who were able to report his circumcision status were analyzed. Participants were assessed for HIV status via double 4th-generation ELISA testing with confirmatory Western Blot; N. gonorrhoeae, C. trachomatis, T vaginalis, and HPV infection with standard testing of self-collected vulvovaginal swabs; T. pallidum, HSV-2 and Hepatitis B with serology; and STI diagnosis history and current STI symptoms with self-report. They were grouped by circumcision status of their most recent partner, stratified into age below or at least equal to 25 years, and compared on presence of STI outcomes by chi-square testing, weighted for selection probability and nonresponse.
Results: 4766 women were included. Women with circumcised partners had similar numbers of lifetime partners (mean 2.45) to those with uncircumcised partners (mean 2.71). In the younger stratum, partner circumcision was negatively associated with HIV (24% vs. 35%, p<0.01) and HSV-2 (49% vs. 62%, p<0.01). In the older stratum, partner circumcision was negatively associated with syphilis (1.5% vs. 3.4%, p=0.04) and HSV-2 (83% vs. 86%, p=0.04), but was associated with ever having had an STI (11% vs. 7%, p<0.01).
Conclusions: Partner circumcision was associated with decreased prevalence of HSV-2 in all female HIPSS participants, decreased prevalence of HIV in younger women, and decreased prevalence of syphilis in older women. Its positive association with self-reported STI history in older participants may derive from differential ascertainment; circumcision typically involves STI screening in men, potentially leading to partner notification. Findings support community-level protection against HIV and some other STIs among women from male circumcision.

TUAC0405

Effects of syringe distribution policy change at a syringe services program in Baltimore, MD: a forecast analysis

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Background: Syringe services programs (SSPs) are associated with decreases in prevalence and incidence rates of blood-borne diseases (e.g., HIV and hepatitis C [HCV]), soft tissue infections, and other morbidities among people who inject drugs (PWID). The core goal of SSPs is to decrease the circulation time of contaminated syringes and to increase the volume of new syringes, effectively increasing the "coverage" of sterile needles and syringes for every injection. In 2014, the Baltimore City SSP shifted from a strict one-to-one syringe exchange policy to a needs-based distribution policy whereby PWID could receive as many syringes as they require. The purpose of this research is to examine the impact of this policy change on syringe distribution among PWID.
Methods: Syringe distribution data from April 2012 to November 2016 were abstracted from the Baltimore City SSP and divided into monthly observations. These data were used to build an ARIMA model that forecast the estimated number of syringes that would have been distributed had the syringe distribution policy not changed in the 26-month period following the policy change.
Results: There were significant (p< .05) differences in the mean number of syringes distributed per month in the pre- and post-policy change periods (44,410 and 96,187, respectively). During the post-policy change period, we forecast that 1,786,174 syringes would be distributed. In actuality, 2,500,857 syringes were distributed during this period. Changing to a needs-based syringe distribution policy resulted in the distribution of an additional 714,683 syringes.
Conclusions: Needs-based syringe distribution leads to greater circulation of sterile syringes and may prevent new HIV/HCV infections.

TUAC05 The Key to Key Populations

TUAC0501

Are migrants acquiring HIV before or after migration to Spain? Results from the aMASE study

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Background: To know if HIV acquisition among migrants living in Spain takes place before or after migration to the country.
Methods: Cross-sectional study in 18 centers/hospitals following patients with HIV. We selected patients diagnosed with HIV in the last 5 years, aged 18 and more, born outside Spain and able to complete the survey in one of the 15 available languages. Two questionnaires were used: one self-completed by participants in a computer/tablet and another about patients' clinical data. We collected epidemiological, socioeconomic, clinical, behavioral, migratory trajectory, previous HIV serology, CD4 determinations, viral load and viral subtype data. To estimate timing of HIV acquisition, Bayesian methods with longitudinal measurements of CD4 and viral load were used and estimates were made applying mixed linear models based on HIV natural history (data from the European collaboration of seroconverters CASCADE).
Results: 685 in 710 participants (97%) had data to estimate time of HIV acquisition (TA). Participants with information on TA had a median of 9 years [RI: 6-13] of residence in Spain, were mainly male (77%) and from Latin America and the Caribbean (LAC) (64%), Other European Countries (OEC) (17%) and Sub-Saharan Africa (SSA) (13%). Most common route of transmission was the relationship between men who have sex with men (MSM) (60%), followed by heterosexual transmission (34%); Injecting drug users (IDUs) were minority (3%) and in 3% were unknown. 76% of patients acquired HIV after migrating to Spain. HIV post-migration acquisition was higher among MSM (85%) than in heterosexuals (67%), and in people from LAC (77%) and OEC (75%) compared to those from SSA (62%). HIV was acquired after migrating in greater proportions among those aged more than 50 years (82%), with secondary or university studies (77%) and with legal residency status (79%).
Conclusions: A significant proportion of migrants living with HIV in Spain acquired HIV after migration. The proportion of post-migration HIV acquisition is higher among MSM and in people from LAC and OEC. These results show a failure in preventive interventions in specific migrants' groups and emphasize the need to design interventions taking into account migrants heterogeneity.

TUAC0502

Prevalence, trends and risk factors of transactional sex among men who have sex with men in metro Vancouver, Canada: a longitudinal event-level analysis

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Background: Debate continues with respect to whether transactional sex among men who have sex with men (MSM) constitutes increased risk of HIV transmission. We sought to identify factors associated with transactional sex using event-level data from a population-based longitudinal behavioural cohort of MSM in Metro Vancouver, Canada.
Methods: Sexually-active MSM aged ≥16 years were recruited using respondent-driven sampling (RDS), and from 02/2012-02/2016 participants completed study visits every six months, which included a computer-assisted self-interview. At each visit, participants provided event-level data by reporting on their last sexual encounter with their five most recent partners (e.g. participant and partner substance use, partner's relative age). We used a four-level mixed effects model (RDS recruitment chain; participant; visit; event) to evaluate temporal trends and factors associated with transactional sex. We built a multivariable model to compare events where money, drugs or goods were received for sex to events with no transaction reported using backward selection with minimization of QIC and type III p-values.
Results: Of 690 participants, 8990 sexual events were reported across 2792 study visits (median follow-up time of 3.62 years). Although 11.7% of participants reported any transactional sex, event-level reports were rare: 2.4% of events included receiving money/drugs/goods, 1.5% of events included providing money/drugs/goods, and 96.0% of events did not include transactional sex. Transactional sex decreased over time (3.8% to 1.0% from first to eighth visit: odds ratio [OR]=0.82, 95% confidence interval [CI]:0.73-0.92). After controlling for significant individual-level factors, the following event-level factors were associated with greater odds of transactional sex: having met online (adjusted OR [aOR]=3.32, 95%CI:1.32-8.37), having a shorter relationship (aOR=0.99 per month, 95%CI:0.99-1.00), having an older partner (aOR=2.42, 95%CI:1.02-5.75), and having a partner who used crystal methamphetamine (aOR=3.85, 95%CI:1.12-13.17) or used gamma-hydroxybutyrate (aOR=6.79, 95%CI:2.19-21.01). Across all events, sexual HIV risk was not associated with transactional versus non-transactional sex: 23% versus 24% reported condomless anal sex with a sero-concordant partner (p=0.212) and 17% versus 12% reported event-level condomless anal sex with a sero-discordant/unknown status partner (p=0.946).
Conclusions: Transactional sex events were rarely reported. Partner substance use was strongly associated with transactional sex, but we found no significant associations with HIV risk behaviour.

TUAC0503

Is on-demand HIV pre-exposure prophylaxis (PrEP) a suitable tool for men who have sex with men (MSM) who participate in chemsex? Results from a sub-study of the ANRS-IPERGAY trial

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Background: Chemsex - the use of psychoactive substances during sexual encounters - is a growing concern among men who have sex with men (MSM). It includes the even riskier practice of "slamming", which consists in injecting a substance before having sex. On-demand HIV pre-exposure prophylaxis (PrEP) may be a suitable tool to prevent HIV transmission in "chemsexers" (i.e., those practicing chemsex). We used a sub-study of the ANRS-IPERGAY trial to describe chemsexers and their PrEP use.
Methods: Among the 361 MSM (3051 visits) enrolled in ANRS-IPERGAY's open-label extension study, we selected the 331 (1657 visits) who reported drug use during at least one sexual encounter. A two-monthly web questionnaire over 12 months collected socio-behavioral data including the use of PrEP and practicing chemsex. We compared sexual behaviors between visits where chemsex was reported and those where it was not. A GEE logistic regression was used to study whether practicing chemsex was associated with PrEP use.
Results: Among the 331 participants, during follow-up, 29% reported chemsex while 8% reported slamming at least once. Chemsex was reported in 16% of all visits (12 and 4%, respectively, with one and multiple partners) mainly involving the use of GHB/GBL (51%) and synthetic cathinones (46%). Chemsexers were not significantly different from non-chemsexers regarding sociodemographic characteristics, although they reported higher use of anxiolytics during the previous 12 months ($p< 10^{-2}$). When MSM reported chemsex during their most recent sexual encounter, it was associated with a greater likelihood of receptive anal sex ($p< 10^{-3}$), hardcore sexual practices ($p< 10^{-3}$), casual partner(s) ($p< 10^{-3}$), and a higher perception of risk ($p< 10^{-3}$). Those who reported chemsex at their most recent encounter were more likely to use PrEP than those who did not ($p< 10^{-3}$), and less likely to use condoms ($p< 10^{-3}$). After adjustment for other potential correlates, chemsex remained associated with PrEP use (OR[95%CI=2.18[1.04;4.59]).
Conclusions: Our findings show that chemsexers are more likely to report high-risk sexual practices but also have a higher perception of risk. Consequently, they are also more likely to use PrEP when practicing chemsex; PrEP may be a suitable tool to reduce HIV risk transmission among chemsexers.

TUAC0504

Assessing HIV prevalence and health outcomes of children of female sex workers in Port Elizabeth, South Africa to guide PMTCT programming for vulnerable populations

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Background: Female sex workers (FSW) are disproportionately affected by HIV. Although the majority of FSW are mothers, little is known about the health outcomes, including HIV prevalence and programmatic needs, among their children.
Methods: FSW in Port Elizabeth, South Africa were recruited at mobile clinics and within the community to bring their children ≤12 years to the study site. A cross-sectional interview with the mother, followed by health assessments for the mother and her children were completed. HIV testing was completed for mothers and children; children were tested using rapid antibody tests (≥18 months) or polymerase chain reaction (< 18 months). HIV outcomes and health status of mothers and children are characterized. Stunting and wasting were estimated using WHO 2006 Child Growth Standards.
Results: From July 2015-February 2016, 114 mothers and 200 children were enrolled. Overall, 77/114 (68%) mothers were living with HIV, of which 53% (41/77) were on antiretroviral therapy. On average, FSW continued sex work for a median of 5 months during their last pregnancy [IQR 4-7]. The median age of children attending was 6 years [IQR 3-9]. The majority (73%, n=145/200) of children were breastfed; the median and mean duration of breastfeeding were 6 (IQR 3-24) and 12 months (sd 12) respectively. Just over half (108/200) of children had ever been tested for HIV, including 95/133 (71%) of children with HIV-positive mothers. HIV prevalence among children was 3% (5% among those with HIV-positive mothers n=6/133). Seventy-three percent of children were reported as up-to-date on their vaccinations. Among the 79 children under 5, 29% were stunted according to height-for-age and 13% wasted per weight-for-age.
Conclusions: The majority of FSW mothers were HIV-positive and many were not on treatment. HIV prevalence among children was higher than the national average among children and nearly one-third of children with HIV-positive mothers had never received HIV testing. Aside from children's HIV risks, substantial chronic nutritional deficiencies were identified through height-for-age, alongside acute nutritional deficiencies (weight-for-age) and immunization gaps. Programs for FSW should address vertical transmission risks including treatment support during pregnancy and breastfeeding, and consider catch-up HIV testing and vaccination campaigns to promote children's health.

TUAC0505

Low HIV incidence but high HCV incidence among people who inject drugs in Haiphong, Vietnam: results of the ANRS 12299/NIDA P30DA011041 DRIVE-IN study

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Background: In Vietnam, HIV control programs targeting persons who inject drugs (PWID), including harm reduction and scaled up ART have been implemented for about 10 years. Although HIV prevalence is declining in this group, the impact of this program on the rate of HIV new infections, but also on HCV transmission, remains unknown.
Methods: We carried out a community-based respondent driven sampling (RDS) survey among ‚active PWID' (i.e. with positive urine test for heroin and presence of injection marks) in Haiphong, with HIV and HCV testing. Then, HIV-negative participants and HCV-negative participants not on methadone maintenance therapy (MMT) were eligible for 1 year follow-up. HIV/HCV was tested at 6 months and 1 year along with routine harm reduction activities from community-based organizations (CBO) and support to access MMT. We estimated HIV and HCV incidence and risk factors associated with HCV seroconversion.
Results: Among 603 RDS participants, 90% were males, and their median age was 36.5 years. HIV prevalence was 25% (95%CI: 22-29) and HCV prevalence was 66% (95%CI: 63-70). 204 RDS participants were enrolled in the cohort, including 94 HIV-/HCV-, 5 HIV+/HCV-, 105 HIV-/HCV+. The cohort participants were mainly males (90%) with a median age of 37 years [IQR 30-44] and a median number of injections over the last month of 90 [IQR 60-90]. The retention rate at 63 weeks was 78%. No participant seroconverted for HIV during the 206.0 person-years of follow-up (HIV incidence unilateral CI: 0-1.8/100 persons-year). Eighteen participants seroconverted for HCV, mainly during the first six months (13/18), for a HCV incidence of 18.8/100 person-years [95%CI; 11.2-29.8]. In multivariable analyses, only injecting more than 75 times per month vs injecting less than 75 times per month (OR: 8.7 [95%CI; 2.1-41.4]) was associated with HCV seroconversion.
Conclusions: In Haiphong, harm reduction activities and high levels of antiretroviral treatment likely contributed to the reduction of HIV epidemic among PWID. However, HCV incidence is still unacceptably high. Current harm reduction activities cannot control the HCV epidemic, additional strategies such as universal ART and large-scale HCV treatment should be urgently evaluated to end the HIV epidemic and tackle HCV transmission among PWID in Vietnam.

TUAD01 Treat All: How to Make It Happen and Can We Afford It?

TUAD0101

Wide-ranging real-world impacts of a policy change on treatment eligibility on ART initiation and retention in care in Zambia

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Background: Incomplete uptake as well as unforeseen consequences often accompany changes in public health guidance. In April 2014, Zambia increased the CD4 threshold for HIV treatment from 350 to 500 cells/μL. We evaluated the effect of this guideline change on ART uptake and retention in patients both targeted and not targeted by this change to evaluate for unintended consequences using a regression discontinuity design.
Methods: We analyzed non-pregnant ART-naïve patients in Zambia who newly enrolled within 6 months of the guideline change (September 1, 2013 to November 1, 2014), excluding patients enrolled within 30 days of the implementation date to account for imprecise rollout. We utilized a quasi-experimental regression discontinuity design with local linear regression to estimate the effects of this policy change on ART initiation within 3 months of enrollment and retention in care at 6 months (defined as clinic attendance between 3 and 9 months after enrollment) in all new enrollees, stratifying by enrollment treatment eligibility.
Results: 20,513 patients (53.1% female, median age 34 years [IQR 28 - 41]) were eligible for our analysis. Newly-eligible patients (CD4 350-500, 15.5% of patients) saw a significant increase in ART initiation within 3 months (risk difference [RD] +35.3%, 95% CI 28.1-42.4%, p< 0.001) and retention at 6 months (RD +7.4%, 95% CI 0.5-14.3%, p=0.034) with the policy change. Additionally, never-eligible patients (CD4>500, 17.0% of patients) also saw an increase in ART initiation with the guideline change (RD +16.3%, 95% CI 9.8-22.7%, p< 0.001), though retention was unaffected (p=0.203). Among always-eligible patients (CD4≤350 or WHO Stage≥3, 67.6% of patients), ART initiation at 3 months (p=0.955) and retention at 6 months (p=0.600) were unaffected.
Conclusions: Policy increasing CD4 threshold for treatment eligibility led to rapid changes in ART initiation practices as well as enhanced retention in the group targeted by the guidelines. ART initiation also improved amongst treatment-ineligible patients with the policy change, a positive spillover effect perhaps due to expansion of ART supply, while initiation and retention among those always-eligible was not compromised. Real-world implementation of evidence-based practice often has broader impacts than those directly targeted that should be routinely evaluated to guide policy interventions.

TUAD0102

Pre-ART peak and plateau: early lessons from Zimbabwe on operational impact of "pre-ART mop-up" on ART initiation rates under Treat All

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Background: WHO 2015 test and treat guidelines recommend ART initiation for all people living with HIV regardless of CD4 count or WHO clinical staging. Implementation of Treat All will require identification and return of pre-ART patients previously clinically ineligible for ART into care for timely initiation. Little is known about the feasibility and timelines required to conduct pre-ART mop-up in resource-limited settings. Our objective was to establish the proportion of clients initiated on ART from pre-ART mop-up following start of Treat All in 92 public health facilities in 7 districts of Zimbabwe.
Methods: We purposively selected 92 health facilities implementing Treat All learning phase. We analyzed routinely reported data from Apr-Dec-2016, comparing proportion of new ART initiations to patients newly diagnosed as HIV positive using Chi-square. A facility-based survey of pre-ART register data and health care worker (HCW) perceptions and experiences of pre-ART mop-up during initial stages of Treat All was conducted to identify key operational themes.
Results: Over the period of interest, 9,875 clients newly initiated on ART. The proportion of new ART initiations vs. newly-diagnosed peaked at 160% after start of Treat All, and plateaued back to below 100% of new diagnoses after 6 months, rates significantly higher than before Treat All (69.4% vs 91.9%, p< 0.0001).

[Proportion ART initiation from new HIV diagnosed]

Additional cell phones, air time and staff for identifying and contacting pre-ART patients were crucial for tracing large numbers of pre-ART clients at start of Treat All.
Conclusions: We demonstrate success of Treat All at returning previously ineligible HIV positive clients for ART initiation in a resource-limited, high-burden setting. Provision of additional resources to support pre-ART mop-up phase were required and recommended for replication as Treat All scales up. Following return to care of traceable pre-ART clients, ART initiations stabilise to rates above 90%, indicating the value of Treat All for progress towards the 2nd 90.

TUAD0103

Evaluating the feasibility of implementing UNAIDS' 90 90 90 strategy, achieving universal access to treatment and eliminating HIV in Malawi

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Background: Malawi has a severe HIV epidemic: prevalence in the general population is ~11%. The majority of the population of ~16 million live in rural communities. We estimate the total number of HIV-infected individuals (both diagnosed and undiagnosed) in Malawi, and determine their geographic location. We use these results to evaluate the feasibility of implementing UNAIDS'90-90-90 strategy and of achieving universal access to treatment.
Methods: We constructed an epidemic surface prevalence (ESP) map using georeferenced HIV-testing data from ~14,000 individuals (15-49 years old) who participated in a nationally representative population-level survey: the 2010 Malawi Demographic and Health Survey. We constructed a density of infection (DoI) map by combining the ESP map with gridded demographic data from the WorldPop database and a census-based age-structure map. The DoI map shows the estimated number of HIV-infected individuals (15- 49 years old) in each square kilometer in Malawi, diagnosed and undiagnosed individuals. We calculated the total number of HIV-infected individuals by aggregating the mapped estimates.
Results: The ESP map shows prevalence (in 15-49 year olds) varies from ~1% to ~25%, there is a strong North-South trend in increasing prevalence, and a substantial urban-rural difference. Prevalence is highest in cities in the South (Blantyre and Zomba), Lilongwe in the Central region, Mzuzu in the North, and villages along Lake Malawi. The DoI map reveals the geographic dispersion pattern of all infected individuals. DoI ranges from one infected individual/ km^2 in rural areas to more than 1,000 infected individuals/km^2 in the four major urban centers. The map shows substantial regional differences in the DoI; our results show that these reflect differences in settlement patterns, population density, and prevalence. We estimate there were ~692,000 HIV-infected individuals (15-49 years old) in 2010 in Malawi, and only ~25% were living in urban areas.
Conclusions: Our results show the vast majority of HIV-infected individuals in Malawi live in rural areas in small communities where the DoI is low. This indicates that implementing the 90 90 90 strategy and achieving universal access to treatment may not be feasible. We recommend that HIV elimination strategies for resource-constrained countries are designed based on DoI, and not prevalence.

TUAD0104

Generic treatments for HIV, HBV, HCV, TB could be mass produced for <$90 per patient

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Background: High prices to treat HIV, viral hepatitis and TB can limit treatment access. This analysis aimed to determine prices currently feasible for HIV, HBV, HCV, and first-line (1L) DS-TB treatment, assuming competitive generic manufacture.
Methods: Data on API exported from India were collected from an online database (www.infodriveindia.com) for July 2014-July 2016. Linear regression was used to plot API cost/kg versus export date, weighted by export volumes: the generated model was used to calculate current average cost/kg of API. Target prices were calculated based on the per-pill cost of API, plus costs of manufacture ($0.01/pill), 10% profit margin, and assumed 27% tax on profit. Current lowest global prices are from public reports and the Global Drugs Fund (TB), US prices from the Centers for Medicare & Medicaid Services. Patent protection expiry dates are from FDA Orange Book and Medicines Patent Pool Patent Status Database.
Results: The Table shows current prices of antiretrovirals for HIV, entecavir (ETV) for HBV (per person-year), HCV treatments (per 12-week course) and 1L DS-TB treatment (RHZE, per 6-month course). API costs/kg were $1189 for ATV, $182 for TDF, $241 for 3TC, $109 for EFV, $380,965 for ETV, $1224 for SOF, $4448 for LDV and $852 for DCV. EFV, 3TC, ETV, and RHZE are already generic in USA. The US substance patents on atazanavir expire in 2017, TDF 2018, sofosbuvir 2030, daclatasvir 2031. Sofosbuvir+ledipasvir combination patents expire in 2032.

DRUG	USA	GLOBAL LOWEST	TARGET	PATENT EXPIRY
ATV	$16,093	$170	$151	2017
TDF/3TC/EFV	$23,965	$107	$83	2018
ETV	$5,915	$409	$82	GENERIC
SOF/LDV	$91,207	$408	$85	2032
SOF/DCV	$142,710	$66	$52	2031
TB: RHZE	$945	$27	$28	GENERIC
PRICES: HIV&HBV - PER YEAR, HCV - PER 12 WEEK COURSE, TB - PER STANDARD 6 MONTH FIRST-LINE REGIMEN. USD.				

[Prices and year of patent expiry]

Conclusions: Treatment of HIV, HBV, HCV, and TB could be achieved for < $90 per person globally, if robust generic competition is enabled. In most countries, generic TDF/3TC/EFV, TDF/3TC, ETV or 1L DS-TB treatment could be available for < $90 by early 2018, after patent expiry. Most HCV DAAs will remain on patent for ≥12 more years. Voluntary licensing or other mechanisms will be required to enable access to HCV DAAs at low prices.

TUAD0105

Comparative analysis of ARV costs before and after the Clinical Protocol and Therapeutic Guidelines for the management of adult HIV infection (PCDT) was adopted in 2013 in Brazil

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Background: The PCDT of 2013 established standardization of treatment, practice of early treatment and treatment for all. These initiatives have diverse and opposing consequences on the costs of antiretrovirals (ARVs). Objectives were to know and ponder these consequences by comparing costs between the antiretroviral treatment structure used until 2013 and the PCDT changes applied since 2014. The problem evaluated was if the number of patients and the resulting increase in total costs would be counterbalanced by a significant reduction in average costs as consequence of recommendations for standardization and simplification of treatment, considering the 2020 timeline.
Methods: The study covered 2009-2013 and 2014-2015, scenarios before and after the adoption of the PCDT, in Brazil by the Institute of Economics of the Federal University of Rio de Janeiro with the Ministry of Health. The study design estimated the total and average costs for the total adult patients treated in December 2009 and 2015, comparing them to estimate the observed cost difference between the two strategies adopted; followed by a simulation of results for 2020. Scenarios of the evolution of costs of HAART took into account treatment targets of the analysed population and changes of schemes. The study population involves all adult patients under treatment 207.014 and 444.093 respectively. Data collection used Systems for Control of Laboratory Tests (CD4 and viral load), for ARV Dispensation, and price records of ARV.
Results: Findings indicate decrease in the average costs due to a higher concentration of patients in first-line regimens in 2015. The difference is even more important in the incoming population. The significance is that the total cost of patients in 2015, with an average cost of 41.46% lower, allowed savings of more than 250 million US$. With the average cost of 2009, the total annual cost of patients in 2015 would be 70.83% higher if the PCDT had not been adopted. This is enough to cover 675.000 new patients, and more than compensate for the adoption of treatment as prevention.
Conclusions: Results become even more relevant since cost savings were accompanied by a better clinical outcome of patients with simplification of treatments.

TUAD02 Decisions, Decisions, Decisions: Behavioural Economics

TUAD0201

Association between user fees and dropout from methadone maintenance therapy: results of a cohort study in Vietnam

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Background: Starting in 2015 with the devolution of fiscal responsibility for methadone maintenance therapy (MMT) to provinces in Vietnam, some provinces started to collect user fees at MMT clinics to cover the costs of incidentals. A pilot study in Hai Phong province suggested that user fee collection is feasible and affordable to MMT clients. How user fees might affect clients' ability to maintain MMT attendance in other provinces has not been assessed. The primary objective of this study is to assess the association between user fees and client dropout from MMT exploiting the fact that some provinces had implemented user fees in 2015 while other had not. The secondary objective was to estimate the catastrophic payments associated with MMT.
Methods: An observational cohort study of 1,021 MMT clients in seven provinces from May/June 2015 to May/June 2016. Three provinces implemented user fees, while four provinces did not. Provinces and facilities were randomly selected, while all MMT clinics in the selected provinces were included. Box Cox proportional hazard models were used to assess the association between user fees and (i) dropout and (ii) being inactive.
Results: About 85% of the cohort was actively on MMT at the end of the observation period, including 10% of clients had transferred facilities and 1% of clients quit with facility staff permission. About 14% of the cohort had stopped MMT care, about 8% dropped out, 3.5% were incarcerated, 1.5% died, and 2% stopping for other reasons. The hazard ratio for paying user fees compared to not paying user fees ranged from 0.70 (unadjusted, p=0.26) to 0.29 (adjusted, p=0.33) for dropout and from 0.75 (unadjusted, p=0.24) to 0.50 (adjusted, p=0.48) for being inactive. However, 29% of clients at facilities paid more than 40% of non-subsistence expenditures for MMT associated user fees and transportation.
Conclusions: Over the course of one year, we do not find evidence that user fees increased dropout or reduced retention in MMT. Overall, dropout rates in Vietnam are very low compared to other countries. However, catastrophic payment rates remain a concern, and longer term follow-up is needed.

TUAD0202

A combination intervention strategy to enhance outcomes across the HIV care continuum and support epidemic control: data from a cluster-randomized trial in Mozambique

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Background: Identifying practical interventions that can be implemented at scale to enhance outcomes across the HIV care continuum is essential to maximizing individual and population benefits of ART.
Methods: Engage4Health, an implementation science study using a cluster-randomized design, was conducted at 10 health facilities in Mozambique and evaluated the effectiveness of a combination intervention strategy (CIS) vs the standard of care (SOC) on important HIV care continuum outcomes. CIS included: (1) point-of-care CD4+ count at HIV testing sites; (2) accelerated ART initiation for eligible patients; and (3) SMS appointment reminders. A subset of CIS participants additionally received non-cash financial incentives (CIS+FI). Adults ≥18 years newly diagnosed with HIV and willing to receive HIV care at the diagnosing health facility were enrolled from 4/13-6/15 and followed for 12 months. Clinic-based outcomes were assessed using electronic medical records, while death was determined by triangulating data from medical records, patient tracing, and mortality registries.
Results:
A total of 2004 participants (767 SOC, 744 CIS, 493 CIS+FI) were enrolled; the majority (64%) were female and the mean age was 34 years. In intent-to-treat analyses, participants at CIS vs SOC sites were more likely to link to care on the day they were diagnosed (89% vs 16%, RR=5.60, 95%CI 4.79-6.69); have their ART eligibility assessed (100% vs 77%, RR=1.30, 95%CI 1.25-1.35), be identified as ART eligible (75% vs. 60%, RR=1.24, 95% CI 1.15-1.33), initiate ART (65% vs. 54%, RR=1.20, 95% CI 1.10-1.30), and be retained at 12 months (58% vs 44%, RR=1.32, 95%CI 1.19-1.45). No additional benefits on these outcomes were observed when FI were added to the CIS. Neither CIS nor CIS+FI had a significant effect on mortality within 12 months of diagnosis or after ART initiation, but mortality prior to ART initiation was lower at CIS+FI vs SOC sites (1% vs. 4%, RR=0.27, 95% CI 0.10-0.69).
Conclusions: The CIS offers a promising, pragmatic approach for enhancing critical outcomes necessary for epidemic control. Further efforts are needed to identify interventions to reduce mortality, particularly among patients on ART.

TUAD0203

Economic evaluation of non-financial incentives to increase couples HIV testing and counselling uptake in Zimbabwe

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Background: Uptake of couples HIV testing and counselling (CHTC) in southern Africa remains low despite multiple HIV prevention and health benefits. Small incentives can increase CHTC uptake by offsetting real and perceived costs to couples. We estimate cost-effectiveness of providing non-financial incentives for CHTC in a cluster randomized controlled trial (RCT).
Methods: 34 communities in rural Zimbabwe received standard community mobilization for HIV testing at mobile clinics while in 34 randomly selected communities individuals seeking CHTC were offered in-kind incentives (choice between a laundry bar, petroleum jelly, or cooking oil) worth $10,859.22. Costs for community mobilization, CHTC, and incentives were calculated from the program perspective (2015 US$). Incremental cost-effectiveness ratios (ICERs) were estimated for the number tested, number tested with a partner, and number of HIV-positive individuals tested.
Results: In control communities, 1,062/10,580 (10.0%) individuals tested as couples compared to 7,852/14,099 (55.7%) in intervention communities. 530 additional HIV-positive persons were identified in intervention communities. Total incremental intervention cost was $25,687.50, translating to an ICER of $7.98 per couple tested ($3.99 per individual client tested) and $48.47 per HIV positive diagnosis. Mean costs per person tested in control and intervention communities were $8.18 and $7.96 respectively, with costs per HIV-positive person identified $93.10 and $128.10, respectively.
Conclusions: This RCT provides evidence that in addition to increasing HTC access, policymakers, implementers, and external donors should consider providing in-kind incentives as they are cost-effective at increasing CHTC uptake and identifying HIV-positive persons.

Capital costs	Intervention Cost ($)	% contribution	Control Cost ($)	% contribution
Incentives	$10,859.22	10%	$0.00	0%
Human resources	$78,705.00	70%	$69,423.75	80%
Equipment	$1,154.95	1%	$1,154.95	1%
Medical supplies	$2,541.42	2%	$1,919.76	2%
HIV test kits	$2,266.16	2%	$1,537.96	2%
Stationary and other supplies	$16,753.95	15%	$12,556.78	15%
Total cost ($)	$112,280.70	100%	$86,593.20	100%
Mean cost/client	$7.96		$8.18	
Cost per HIV + client	$93.10		$128.10	

[Economic cost ($) calculation]

Intervention incremental cost (Incentive arm - standard mobilization arm)	$25,687.50
Intervention effect (incentive effects - non-incentive effects)	46%
Additional clients tested as a couple (14,099*46%)	6437
Additional clients tested individually	3519
Additional clients tested HIV positive	530
ICER per individual client tested HIV positive	$48.47
ICER per individual client tested ($25,687.50/6437)	$3.99
ICER per couple tested ($3.99x2)	$7.98

[Cost-effectiveness analyses]

TUAD0204

The effects of short-term cash and food incentives on food insecurity and labor force participation among HIV-infected adults initiating antiretroviral therapy in rural Tanzania

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Background: We previously demonstrated that short-term cash and food incentives increased antiretroviral therapy (ART) possession and retention in HIV services in Tanzania. To elucidate potential pathways that led to these achievements, we examined whether these incentives also improved food security and labor force participation.
Methods: At three clinics, 805 food-insecure adults who recently initiated ART (≤90 days prior) were randomized to receive cash or food transfers (~$11/month for ≤6 months, conditional on visit attendance) or standard-of-care (SOC) ART. After 6 months, we re-assessed food security (Household Hunger Scale), body-mass index (BMI), employment, and functional limitation (illness prevented work or housework) among patients returning for ART. The incentives' effectiveness at increasing retention contributed to differential loss-to-followup (13% overall; 20% SOC; 8% cash; 15% food; p< 0.01), which we accounted for in the current analysis using inverse probability weighting.
Results: After 6 months, food security improved from 0% to 37% (p< 0.01) and did not differ comparing the SOC (33%) to cash (36%, p=0.64) or food (39%, p=0.37) groups. Mean BMI increased from 21.5 to 22.7 kg/m^2 (p< 0.01), with no differences comparing SOC (22.5 kg/m^2) to cash (22.6 kg/m^2, p=0.76) or food (22.9 kg/m^2, p=0.15). Employment rose from 58% to 76% (p< 0.01), with no differences between SOC (80%) and cash (75%, p=0.47) or food (75%, p=0.43). Functional limitation decreased from 55% in the year before enrollment to 12% in the following 6 months (p=0.02) and was significantly lower in the food group (9% vs. 18% SOC, adjusted OR=0.41, 95% CI: 0.18, 0.96, p=0.04); cash was non-significantly lower (13% vs. 18% SOC, adjusted OR=0.64, 95% CI: 0.27, 1.5, p=0.32).
Conclusions: Food security and employment substantially improved across all study groups after 6 months of ART. Short-term cash and food incentives did not augment these gains relative to standard-of-care ART, with the exception of significantly less functional limitation among the food group. This suggests that cash and

food transfers acted primarily via the price incentive (increasing ART adherence), rather than mitigating socioeconomic barriers through income effects. Future studies are needed to better understand the mechanisms through which incentives may increase and sustain retention in HIV services.

TUAD0205

Using conjoint analysis to model hospital directors' decision making in adoption of an evidence-based stigma-reduction intervention

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Background: Behavioral interventions that have demonstrated efficacy in randomized trial conditions have been underutilized in healthcare delivery. This study used conjoint analysis, a marketing research technique, to quantify the impact of different aspects of intervention in hospital stakeholders' decision making in adoption of evidence-based interventions (EBI).
Methods: The used a real-life intervention with efficacious outcome to reduce HIV-related stigma in healthcare settings as a "product" to study adoption of EBI. Conjoint analysis was conducted among 60 hospital directors recruited from 30 hospitals of different levels and types in Fujian Province, China. The directors evaluated their willingness to adopt the evidence-based stigma reduction intervention in their hospitals by rating across eight hypothetical scenarios with preferred and non-preferred levels of seven attributes, including 1) administrative support, 2) cost, 3) personnel involvement, 4) format, 5) duration, 6) technical support, and 7) priority alignment with the hospital. A mixed effect model was fit to the likelihood of intervention adoption for the eight scenarios, and the seven attributes (categorized as preferred=1 or not preferred=0) served as independent variables in the model.
Results: Monetary cost of intervention implementation (impact score=24.8) had the greatest impact on the directors' willingness to adopt a certain EBI, followed by duration of the intervention (impact score=10.0), availability of technical support (impact score=7.5), and flexibility of format (impact score=4.6). The majority (88.3%) of the hospital directors perceived the conjoint administration process as clear and easy to understand. The data collection time was relatively short, which was approximately 30 minutes.
Conclusions: Conjoint analysis was proven to be feasible in modeling hospital directors' decision making in adoption of EBI. There were several issues that one should consider when operationalizing conjoint analysis in dissemination and implementation research, including selection of EBI example, assigning the component level of the attributes, generating scenarios, and interviewer training. The findings have implications for design and dissemination of existing EBI in healthcare settings to optimize the public health impact.

Tuesday 25 July

Poster Discussions

TUPDA01 Immunotherapy: Outsmarting the Virus

TUPDA0101

Combined IL-21 and IFNα treatment limits residual inflammation and delays viral rebound in SIV-infected macaques

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Background: Although antiretroviral therapy (ART) suppresses HIV replication, immune dysfunctions and chronic inflammation critically contribute to non-AIDS-related morbidity and mortality in infected subjects. Furthermore, inflammation facilitates HIV persistence during ART. We previously demonstrated that addition of Interleukin (IL)-21, an immunomodulatory cytokine, reduces chronic inflammation and HIV persistence in ART-treated, SIV-infected rhesus macaques (RMs). In this study, sought to combine the anti-inflammatory functions of IL-21 with the antiviral properties of IFNa to reinvigorate antiviral responses. We hypothesize an impact on viral rebound following ART treatment interruption (ATI).
Methods: 15 RMs were infected with SIV_{mac239} IV. RMs started a triple-formulation of TDF, FTC, and Dolutegravir (DTG) day 35 post-infection and continued for at least 12 months. Eight RMs received Macaquized (M)-IL-21-IgFc (100 mg/kg, SC, once weekly for four weeks) at initiation and mid-way thru ART. Additionally, this group received M-IFNa-IgFc (500,000 IU, SC, once weekly for five weeks) prior to ART-interruption. Upon ART-discontinuation, the eight IL-21-treated RMs received PEGylated-IFNa-2a (PEGASYS), 7 mg/kg, SC, once weekly for seven weeks; while the remaining seven RMs were ART-treated controls. Blood (PB), lymph nodes (LN), and colorectal (RB) biopsies were longitudinally collected to assess the effects of IL-21 and IFNa on inflammation, T cell subsets, and viral persistence.
Results: ART fully suppressed plasma viremia (pVL) (< 30 RNA copies/mL) in all RMs. During ART, IL-21 reduced levels of activated ($HLA\text{-}DR^+CD38^+$) and proliferating ($Ki\text{-}67^+$) T cells in PB, RB, and LN in comparison to ART-only controls ($P< 0.01$). Levels of inflammation remained significantly lower also during and after addition of IFNa ($P< 0.01$). Upon ART-interruption, IL-21/IFNa-treated RMs exhibited delayed viral rebound with a median of 21 days as compared to 9 days in the controls ($P=0.0009$). Moreover, IL-21/IFNa-treated RMs maintained reduced viremia in comparison to controls up to 45 days after ATI ($P=0.0004$).
Conclusions: These data support the safety of a combined IL-21 and IFNa treatment for HIV infection. While IL-21-treatment effectively reduces inflammation, addition of IFNa prior- and after- ART-discontinuation resulted in a prolonged and more effective control of viral rebound. The synergy of such therapeutics may promote reinvigoration of host responses toward reduction of latent HIV reservoirs.

TUPDA0102

Interleukin (IL)-27 induces HIV-resistance in T cells and dendritic cells via different mechanisms: identification of YB-1 and ANKRD22 as novel host dependency factors

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Background: We have reported that IL-27 inhibits HIV replication in macrophages, T-cells and dendritic cells (DC), and proposed that IL-27 is a potent novel antiviral cytokine. We have also demonstrated that IL-27 induces HIV-resistance in macrophages via downregulating SPTBN1 (Spectrin-beta chain brain 1) expression, however, the mechanism whereby IL-27 induces HIV-resistance in T-cells or DC has not been described
Methods: T-cells and monocytes were isolated from healthy donor PBMCs. T-cells were stimulated with PHA. Monocytes were differentiated to DC in the presence of IL-4 and granulocyte macrophage colony-stimulating factor (GM-CSF) with or without IL-27. HIV replication was monitored using a commercial p24 ELISA kit. CD4 and chemokine receptor expression were analyzed by FACS. Post-translational modification (PTM) of proteins were analyzed using 2-Dimentional Difference in Gel analysis (2D-DIGE) and Western blotting. Genes of interest were knocked down using siRNA.
Results: IL-27-treated PHA-stimulated T cells (27-T) and IL-27-induced DC (27-DC) resisted HIV infection by 70% and > 90%, respectively, without significant change in the expression of CD4, CCR5 or CXCR4. To define the mechanism of these anti-HIV effects, microarray and western blotting were performed. In 27-T cells, 4 genes were up-regulated by >3-fold and no genes were significantly down-regulated by > 2-fold in microarray analysis of ~20,000 genes. 2D-DIGE revealed that the amounts of PTM Y box binding protein 1 (YB1: a Y-box transcription factor) was diminished in 27-T by 60%. Knockdown of YB-1 in control T-cells led to 70% resistance to HIV infection. In 27-DC, over 100 genes were upregulated or down-regulated by >2-fold. A series of qPCR and Western blot analyses confirmed that the expression of ANKRD22 (ankyrin repeat domain 22) was consistently induced in 27-DC. Knock down of ANKRD22 reversed resistance to HIV infection in 27-DC. These results indicated that IL-27 induced HIV resistance in T cells and DCs by a decrease in PTM-YB1 and an increase in ANKRD22, respectively.
Conclusions: PTM-YB-1 and ANKRD22 were identified as novel host dependency factors in T-cells and DC, respectively. Taken together with our previous report, these data demonstrate that IL-27 induces HIV resistance in macrophages, T-cells and DC in cell type dependent manners.

TUPDA0103

Increased effector cytotoxic lymphocytes in lymph nodes of hetIL-15 treated macaques suggest potential to disrupt SIV/HIV reservoirs

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Background: Heterodimeric interleukin-15 (hetIL-15) activates and expands cytotoxic T and NK cells, which suggests that the cytokine could be useful for the treatment of malignancies and HIV infection. Based in these properties, hetIL-15 is currently evaluated in humans for the treatment of cancer. We also study the effects of hetIL-15 in infected macaques to evaluate its use in HIV infection.
Methods: Twelve rhesus macaques received six subcutaneous injections of hetIL-15 over 2 weeks using increasing doses of cytokine (step-dosing). At the end of the treatment, the animals were sacrificed and the hetIL-15 effects on different lymphocyte populations isolated from tissues collected at necropsy were monitored by multi-parametric flow cytometry and quantitative multiplexed confocal microscopy (Histo-cytometry).
Results: This protocol was safe in rhesus macaques and resulted in systemic expansion (Ki67+) of CD8+ T lymphocytes and NK cells with higher granzyme B content. These expanded cell populations were found in both effector sites, such as liver, vagina and rectum, and secondary lymphoid tissues. Among the gut-resident CD8+ T lymphocytes, we found a gradient, based on anatomical location, of the IL-15-induced T cell proliferation, which follows the proliferation pattern found in untreated animals. Importantly, a significant increase in cytotoxic effector memory CD8+ T cells was found in lymph nodes (LN) from all hetIL-15-treated macaques, and this increase was bigger than that in SIV-infected animals. CM9 tetramer staining demonstrated that the increase of CD8+ effector T cells in lymphoid organs included actively proliferating SIV-specific T cells with higher granzyme content. Imaging analysis by Histo-cytometry revealed that these effector CD8+ T cells infiltrated the B cell follicles where chronically infected follicular helper CD4+ T cells are located.
Conclusions: Step-dose administration of hetIL-15 is a well-tolerated regimen that results in systemic activation and expansion of cytotoxic leukocytes that infiltrate areas where chronic HIV-infected cells reside. These results suggest that hetIL-15 could be useful in disrupting or eliminating long-term viral reservoirs in HIV-1 infected individuals, thus contributing to a functional cure of the infection. Work assessing the long-term impact of hetIL-15 on the size of the viral reservoir is currently ongoing.

TUPDA0104

The human IL-15 superagonist ALT-803 activates NK and memory T cells, reactivates latent SIV and drives SIV-specific CD8+ T cells into B cell follicles

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Background: There is an urgent need to develop alternate approaches to activate and clear the latent HIV reservoir that do not negatively impact immune function and are independent of viral sequence. IL-15 is a key cytokine for homeostatic maintenance, proliferation, and expansion of memory CD4+ T cells, the primary HIV cellular reservoir. Here, we explored the human IL-15 superagonist, ALT-803, as an immunostimulatory molecule and potential latency reversing agent (LRA) in cART-suppressed SIV-infected macaques.
Methods: SIV-naïve and SIV-infected macaques were administered ALT-803 IV and subsequently monitored for NK and T cell proliferation. SIV-infected macaques treated with ALT-803 were assessed for intrafollicular migration via in situ staining of lymph nodes with MHC class I tetramers. ALT-803 was tested as an LRA in vitro with primary CD4+ T cells from cART-suppressed macaques, and in vivo in SIV-infected, cART-suppressed macaques.
Results: ALT-803 activated and induced robust proliferation in NK cells, and in both effector and central memory T cells. ALT-803 redirected activated cells to secondary lymphoid tissues, a known anatomical location of the viral reservoir, and in situ with MHC class I tetramer staining showed increased migration into B cell follicular sanctuaries. ALT-803 did not affect viral loads in macaques with uncontrolled SIV infection; instead, ALT-803 potentiated low-level viral replication in elite controllers. In experiments using CD4+ T cell from cART-suppressed macaques, ALT-803 induced robust viral replication in vitro. When administered to macaques with cART-suppression of plasma viremia, ALT-803 treatment resulted in plasma viral "blips" and unlike previous reports of other common g-chain cytokines like IL-7, ALT-803 did not cause an increase in the size of the latent viral reservoir.
Conclusions: ALT-803, an IL-15 superagonist, is well tolerated in SIV-infected, cART-suppressed macaques and induces virus reactivation both in vitro and in vivo. In addition to reactivating quiescent virus, ALT-803 potently activates NK and memory CD8+ T cells, which traffic to lymph nodes, specifically entering B cell follicles where latently-infected CD4+ T follicular helper cells reside. The ability of ALT-803 to potentially mediate both the "shock" and "kill" make it an appealing candidate for further studies aimed at durable cART-free HIV remission.

TUPDA0105

Tissue factor pathway inhibitor Ixolaris improves disease outcome in progressive SIVsab-infected pigtail macaques

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Background: Despite viral suppression with antiretroviral therapy, HIV-infected subjects face high risk of non-AIDS comorbidities, which is often associated with elevated immune activation and inflammation (IA/INFL) and hypercoagulability. Tissue factor (TF) may bridge IA/INFL and hypercoagulation via protease-activated receptor (PAR) signaling. We hypothesized that a TF pathway inhibitor can reduce the hypercoagulation and IA/INFL associated with HIV/SIV infection, and thus improve the disease outcome.
Methods: We compared the dynamics of TF expression on monocyte isolated from progressive (pigtail macaques, PTMs) vs. non-progressive (African green monkeys, AGMs) models of SIVsab infection to establish its role in SIV pathogenesis. We tested the specificity and potency of a new TF inhibitor, Ixolaris, ex vivo on nonhuman primate (NHP) plasma and monocytes stimulated with LPS. Ixolaris was administered to five SIVsab-infected PTMs, with three SIV-infected, untreated PTMs as controls. IA/INFL markers (CD38/HLA-DR and proinflammatory cytokines) and hypercoagulation markers (D-dimer) were monitored throughout Ixolaris administration in treated and control PTMs.
Results: Monocyte TF expression increased postinfection in PTMs while it remained at baseline levels in chronically infected AGMs, confirming the role of TF in exacerbating SIV pathogenesis. Ixolaris specifically inhibited the extrinsic coagulation pathway and strongly inhibited TF activity by monocytes stimulated with LPS. In vivo administration of Ixolaris resulted in significantly lower inflammation (IL-17) and immune activation ($HLA\text{-}DR^+$- and $CD38^+$-expressing $CD4^+$ and $CD8^+$ T cells) during early chronic infection in treated SIVsab-infected PTMs compared to controls. Ixolaris also reduced hypercoagulation levels (D-dimer) in acutely SIVsab-infected PTMs. While viral loads and CD4 counts were minimally impacted by treatment, Ixolaris improved PTM survival, with no PTMs developing disease during the first 100 days postinfection, which is rarely seen in untreated SIVsab-infected PTMs.
Conclusions: Our results support a role of TF pathway in promoting disease progression and cardiovascular comorbidities in SIV-infected NHPs. In vivo TF inhibition by Ixolaris resulted in reduced IA/INFL and hypercoagulation in SIVsab-infected PTMs independent of CD4 counts and plasma viremia, and improved the outcome of the SIVsab infection. Therefore, targeting TF pathway in HIV-infected subjects may represent an effective approach to prevent the deleterious consequences of HIV infection.

TUPDA0106

Engineering HIV immunity with a chimeric antigen receptor in the non-human primate model

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Background: HIV-1 specific cytotoxic T lymphocytes are crucial for the elimination of HIV infected cells. We have previously demonstrated using humanized mice that hematopoietic stem cells (HSCs) modified with a protective CD4 chimeric antigen receptor (CD4CAR) successfully differentiated into CD4CAR expressing T cells that significantly suppressed HIV replication. These results demonstrated the feasibility of engineering HIV-specific T cell immunity with a HSC based approach.
Methods: We tested the safety and feasibility of engineering T cell immunity via HSC in a non-human primate (NHP) model of SHIV infection. We utilized CD4CAR vectors that also carry an anti-HIV protective gene (C46) that would inhibit infection. 2 pigtailed macaques (Macaca nemestrina) were transplanted with C46CD4CAR modified autologous HSC and 2 were transplanted with HSC modified with control vector C46CD4CARdeltaZeta that lacks the signaling Zeta chain. After hematopoietic recovery, the animals were challenged with SHIV and went through combined anti-retroviral drug (cART) treatment and withdrawal. Animals were monitored for viral load, CAR cell detection, and immune function for over a year.
Results: We determined that engraftment of pigtailed macaques with C46CD4CAR-modified HSCs was safe and the animals had normal transplant recovery. We observed long-term engraftment and stable production of C46CD4CAR expressing cells without any significant toxicities and found that C46CD4CAR modified HSCs could differentiate into multiple hematopoietic lineages. Following challenge of the animals with SHIV, we observed significant expansion of C46CD4CAR expressing cells after infection and wide distribution of CAR expressing cells in multiple lymphoid tissues. Importantly, we found lower viral loads in lymphoid tissues in C46CD4CAR containing animals than in control animals, suggesting viral suppression by C46CD4CAR expressing cells.
Conclusions: This study in NHPs demonstrates the safety and feasibility of a HSC based therapy utilizing a HIV-specific chimeric antigen receptor for treating chronic HIV infection. These results set the stage for future investigational new drug (IND) development to eradicate viral infection and provide more effective immune surveillance of HIV.

TUPDB01 HIV Reservoirs: Ups and Downs

TUPDB0101

Dynamics of HIV-1 DNA in children over long-term sustained viral suppression: impact of the time of infection at viral control on reservoir size

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Background: The dynamics of HIV-1 DNA reservoir in perinatally infected children throughout long-term sustained viral suppression (VS) -and how they are affected by the time of infection at VS- have not been defined. Improved understanding of HIV-1 dynamics is necessary for therapeutic interventions that aim to achieve sustained antiretroviral therapy-free HIV-1 remission.
Methods: This study included 37 perinatally HIV-1 infected children on suppressive antiretroviral therapy. Children were grouped according to the timing of antiretroviral therapy (ART) initiation (≤0.5 or >0.5 yrs) and the time to achieve VS (≤1.5, between >1.5 and 4, and >4 years). Decay of cell-associated HIV-1 DNA (CA-HIV-1 DNA) level -quantified by semi-nested real time PCR- and 2-long terminal repeats (2-LTR) circles frequency -detected by hemi-nested real time PCR- were analyzed over 4 years of viral suppression using piecewise linear mixed-effects model with two splines and logistic regression, respectively.
Results: CA-HIV-1 DNA in peripheral blood mononuclear cells (PBMC) had a high decay during the first two years of VS [-0.26 (95% CI: -0.43 to -0.09) log_{10} copies per one million (cpm) PBMC/year], followed by a slow decay and reaching a plateau between 2 and 4 years of VS [-0.06 (95% CI: -0.15 to 0.55) log_{10} cpm PBMC/year]. The level of CA-HIV-1 DNA in PBMCs highly correlated with those estimated in $CD4^+$ T cells (r=0.97, P< .0001) and whole blood (r=0.98, P< .0001). The initial decay according to time of infection at VS was -0.51 (95% CI: -0.94 to -0.07), -0.35 (95% CI: -0.83 to 0.14) and -0.21 (95% CI: -0.39 to -0.02) log_{10} cpm PBMC/year for children who achieved VS by 1.5, >1.5-4 and >4 years of infection, respectively. The frequency of 2-LTR circles decayed significantly, from 82.9% at pre-VS to 37.5% and 28.1% at 2 and 4 years of viral suppression, respectively (P=.0009).
Conclusions: A marked decay of HIV-1 DNA occurs during the first two years of viral suppression -where the earlier the time of infection at viral suppression, the higher the rate of decay- and seems to set HIV-1 reservoir size. After 2 years, HIV-1 DNA decreases slowly and independently of the time to achieve effective viral control.

TUPDB0102

Impact of T cell homeostasis and thymic output on the seeding of the HIV reservoir in infants

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Background: Early antiretroviral therapy (ART) limits the size of the HIV reservoir and immune activation levels in adults; however pediatric data are limited. We evaluated the impact of immune parameters on the size of the HIV reservoir in early-treated vertically infected infants.
Methods: Virologically non-suppressed HIV-infected Thai infants (n=12, < 2 months old) and fully suppressed children (for >1 year) who started ART within the first 6 months of life (n=57, median 4 years old) were included. We quantified total HIV DNA in CD4 T-cells by RT-PCR. Immune activation and proliferation markers in CD4 and CD8 naïve, stem cell (SCM), central (CM), transitional (TM) and effector memory (EM) T cells as well as frequencies of effector (EMRA), recent thymic emigrants (RTE) and T-regulatory (Treg) cells were assessed by flow cytometry.
Results: High frequencies of naïve $CD4^+$ T-cells were observed in non-suppressed and ART-treated children (median 78 and 64, respectively). Interestingly, the frequency of RTE was significantly increased in ART-treated children despite their older age (median 81 vs 89, p=0.009), suggesting that HIV replication in non-suppressed infants may limit thymic production. Frequencies of T-cells undergoing proliferation ($Ki67^+$) were significantly lower in $CD4^+$ (median 4.8 vs 3.6, p=0.04) and $CD8^+$ (median 29 vs 4.6, p< 0.0001) T-cells from ART-treated children. Similarly, frequencies of activated $CD8^+$ T-cells ($HLA\text{-}DR^+CD38^+$) were significantly lower in ART-treated children (median 29 vs 4.6, p< 0.0001). High frequencies of Treg were observed in both groups (>5.1% of $CD4^+$ T cells) with no significant differences. In non-suppressed infants, the frequency of cells harboring HIV DNA was negatively correlated with the frequency of RTE (r=-0.9, p=0.01) and positively correlated with the frequency of memory Treg cells ($CD45RA^-CD27^-CD25^{bright}FOXP3^+$, r=0.7, p=0.04). Similarly, HIV DNA levels in ART-treated children negatively correlated with RTE (r=-0.3, p=0.02) and positively correlated with Treg (r=0.3, p=0.04).
Conclusions: The high frequencies of RTE resulting from enhanced thymic production in pediatric population may limit the establishment and persistence of the HIV reservoir. In contrast, the positive association between the frequency of HIV-infected cells and Treg, suggests that this subset may play a prominent role in the establishment of the HIV latent reservoir during infancy.

TUPDB0103

Prolonged HIV-1 remission and viral rebound in an individual treated during hyperacute infection

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Background: It is unknown if extremely early initiation of ART may be curative. We describe an individual who started ART an estimated 10 days after infection with plasma HIV RNA of 220 copies/ml. After extensive blood and tissue sampling, he underwent an analytical treatment interruption (ATI) following 34 months of ART.
Methods: Colorectal and lymph node tissues, bone marrow, cerebral spinal fluid (CSF), plasma and large numbers of PBMC obtained longitudinally were studied for HIV persistence in several laboratories using molecular and culture-based detection methods including a humanized mouse outgrowth assay.
Results: The individual initiated PrEP (TDF/FTC) during very early Fiebig stage I (HIV-1 RNA+ EIA-) followed by ART intensification (TDF/FTC/r/DRV/RAL) 8 days later. HIV RNA levels were 120 and < 40 copies/mL, 7 and 22 days after PrEP initiation, respectively, followed by no detectable level. Low-level cell-associated HIV RNA (3.2 copies/million CD4+ T cells) was detected 32 days after infection. Over the following 2 years, no further HIV could be detected, despite massive sampling from ileum, rectum, lymph nodes, bone marrow, CSF, CD4+ T cell subsets and plasma. 530 million CD4+ T cells were also assayed in a humanized mouse outgrowth assay. One mouse (53 million input cells) experienced very low level viremia (201 copies/mL) after 5.5 weeks, but sequence confirmation was unsuccessful. The participant stopped ART and remained aviremic for 7.4 months, rebounding with HIV RNA of 36 copies/mL that rose to 59,805 copies/mL 6 days later. ART was restarted promptly. Rebound plasma HIV sequences were identical to those obtained during acute infection by single-genome sequencing. Mathematical modeling predicted that the latent reservoir size was approximately 200 cells prior to ATI, and that only around 1% of individuals with a similar HIV burden may achieve lifelong ART-free remission.
Conclusions: We report HIV relapse despite initiation of ART at one of the earliest stages of acute HIV infection possible. Near complete or complete loss of detectable HIV in blood and tissues did not lead to indefinite ART-free HIV remission. However, the small numbers of latently infected cells in individuals treated during hyperacute infection may be associated with prolonged ART-free remission.

TUPDB0104

HIV RNA persists in rectal tissue despite rapid virologic suppression in blood plasma with dolutegravir-based combination antiretroviral therapy in treatment-naïve patients

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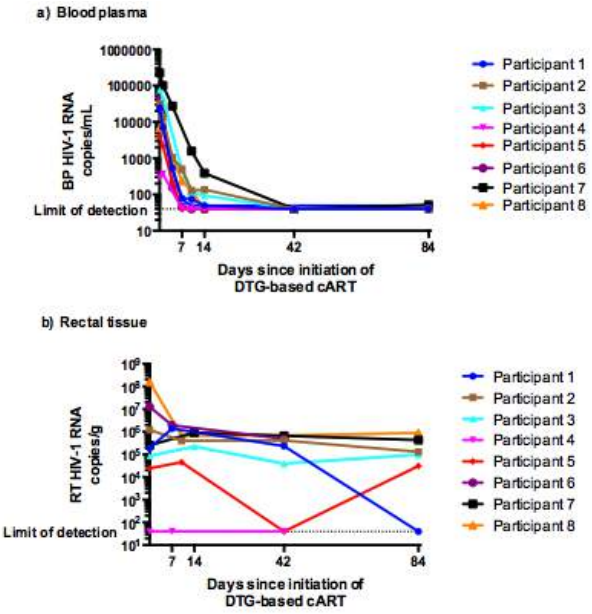
Background: Despite virologic suppression in blood plasma (BP) with combination antiretroviral therapy (cART), HIV eradication remains elusive, largely due to incomplete suppression in reservoir sites including gut-associated lymphoid tissue. We compared HIV RNA dynamics within BP and rectal tissue (RT) following initiation of cART with integrase strand transfer inhibitor dolutegravir (DTG).
Methods: Treatment naïve HIV+ volunteers began DTG-based (50 mg daily) cART and serial sampling of BP and RT through 84 days as per Figure 1. HIV RNA and DTG concentrations were quantified using Abbott Real-Time HIV-1 assays and tandem mass spectroscopy, respectively, in both compartments. Median DTG concentrations were compared between undetectable and detectable RT HIV RNA groups using Mann-Witney nonparametric tests.
Results: Eight participants were enrolled: 4 (50%) females, 6 (75%) black, median age 39.2 years (IQR 32.9-52.7). Median baseline CD4 and HIV RNA were 208 cells/mm^3 (IQR 104-320) and 24,847 copies/mL (IQR 6237-50,269), respectively. All participants (100%) had undetectable BP HIV RNA (< 40 cop/mL) by Day 42; only 3 achieved RT viral suppression at any time (Figure 1). DTG quantitation was performed on 22 paired BP and RT steady-state samples collected Days 7 through 84. The undetectable RT RNA group had higher median DTG RT concentrations than those with detectable RNA: 1340 ng/g (IQR 683-2100) vs 624 ng/g (IQR 377-939), p=0.03. There were no significant differences in BP DTG or RT:BP DTG ratios between undetectable and detectable groups: median 2810 ng/mL (IQR 1720-4140) vs 1400 ng/mL (IQR 687-3250) and median 0.45 (IQR 0.30-0.55) vs 0.40 (IQR 0.28-0.69), respectively.



[Figure 1. HIV RNA over time following initiation of DTG-based cART]

Conclusions: Despite rapid virologic suppression in BP, HIV RNA persisted in RT for the majority of participants. Along with larger studies examining DTG compartmental pharmacokinetic/pharmacodynamic relationships, assessment of the infective potential of HIV RNA recovered from RT are warranted, as this may have implications for ongoing rectal transmission notwithstanding plasma virologic suppression.

TUPDB0105

Viral rebound in semen after treatment interruption in a HIV therapeutic vaccine double-blind trial (VRI02/ANRS149-LIGHT)

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Background: Antiretroviral treatment interruption (ATI) leads to HIV replication rebound in both blood and semen, however dynamic of HIV-RNA rebound in semen is poorly known. We compared HIV-RNA timing of and level of rebound in blood and seminal plasmas (BP-SP) and characterized the HIV rebounding populations in both compartments after ATI in HIV-1 infected patients enrolled in the therapeutic vaccine trial VRI02/ANRS149-LIGHT.
Methods: Ten male from the VRI02/ANRS149-LIGHT trial with CD4 cells ≥600/mm^3 and HIV-RNA < 50cp/ml under treatment for at least 18 months were studied. ATI occurred from week (W)36 to W48. Paired blood and semen samples were collected at W32 (before ATI), W36, W38, W40, W42, W44 and W48 following ATI, for HIV-RNA and DNA quantification. Ultradeep sequencing (UDS, 454/Roche) of partial env (C2/V3) HIV-DNA and -RNA was performed in 5 out of 10 participants in PBMC before ATI and in plasma/semen during ATI. Sequenced reads were quality filtered and assembled using an in-house data processing pipeline.
Results: Patients had sustained suppressed blood viral load for a median of 44 months (range: 28-152) before ATI. HIV-RNA rebounded in blood and semen in all patients after ATI (median 5.12 $\log_{10}$ cp/ml (range: 4.61-6.35) and 4.26 $\log_{10}$ cp/ml (range: 3.20-4.67), respectively). BP HIV-RNA rebounded as soon as W38 in 8/10 patients, and SP HIV-RNA between W38 and W40 in 8/10 patients. HIV-DNA median level was 2.97 $\log_{10}$ cp/10^6 PBMC (range: 1.61-3.26) at W32 and 3.30 $\log_{10}$ cp/10^6 PBMC (range: 2.50-3.67) at W44. Non-sperm cells HIV-DNA was detected in at least one sample in 6/10 patients. Phylogenetic analysis of UDS revealed that 1) rebounding HIV-RNA population in BP and in SP originated from PBMC HIV-DNA at the time of ATI and 2) intermingled HIV-RNA populations in BP and in SP with no evidence of compartmentalization.
Conclusions: The rapid and intense HIV RNA rebound observed very early both in blood and semen after ATI emphasizes the need for targeted prevention strategies to reduce the risk of sexual transmission during ATI. PBMC HIV-DNA is the major contributor for HIV-RNA rebound in both compartments, even after several years of sustained suppressed viral replication.

TUPDC01 TRANScending Barriers for Prevention

TUPDC0101

Transgender women willingness to use PrEP in northeastern Brazil

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Background: PrEP can dramatically reduce HIV acquisition risks, particularly for transgender women and other sexual and gender minorities. However, access to PrEP in developing countries remains very limited. Brazil has one of the largest and oldest HIV treatment programs in the world and will soon integrate PrEP in the national public health system. We explored PrEP willingness among transgender women.

Methods: We recruited 127 transgender women using Respondent Driven Sampling (RDS) in Salvador, Brazil's third largest - and one of its lowest-income and highest afro-descendants- cities. Participants were interviewed about PrEP. Latent class analyses were used to identify those willing to take PrEP from the following list of variables: 1-disposition to use PrEP; 2 - willingness to use PrEP if available in the public health system; 3- willingness to use PrEP even if had to pay; 4- interest in using PrEP even if it is not 100% effective; 5-being less afraid of contracting HIV if using PrEP; 6- willingness to take one pill a day; 7- knowledge about PrEP. Entropy was 0.992 indicating good distinction of classes.
Results: Only 18.4% of women knew about PrEP. However, upon becoming aware, willingness to use PrEP was reassuring. Two latent classes were identified: Class 1-willingness to use PrEP (91.3%); Class 2- non willingness to use PrEP (8.6%). Most participants noted that PrEP was an important HIV prevention tool for transgender women. Correlates of Latent Class 2 were: Socio-behavioral factors including not being black, having a monthly income greater than R$900.00 and regular use of condoms in sexual intercourse. When asked about implementation strategies, participants suggested integrating conversations about PrEP into a suite of HIV prevention services, addressing health system services that address the broader social and structural factors influencing transgender health risks.
Conclusions: PrEP willingness was very high as 91% of transgender women wanted it in Northeast Brazil. While access to PrEP is still limited, uptake among transgender women will likely be high when Brazil releases PrEP. However, it is important to take into account socio-behavioral factors and combination prevention as those regular users of condom may not see and additional benefit of PrEP.

TUPDC0102

How are transwomen acquiring HIV? Insights from phylogenetic transmission clusters

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Background: Worldwide, HIV prevalence among transwomen is 50 times higher than in the general adult population. In many surveillance systems and surveys, transwomen and their male sexual partners are classified as "men who have sex with men" (MSM), irrespective of gender identity and sexual orientation. Little is known about how transwomen acquire HIV, which may be due in part to this misclassification as "MSM". We sought insights on sexual and needle-sharing networks as potential sources of HIV among transwomen by examining phylogenetic transmission clusters. We also assessed a new transmission risk paradigm that re-classifies males closely linked to transwomen as non-MSM.
Methods: San Francisco residents diagnosed with HIV (2000-2015), in care at public facilities and with available viral pol sequences were included in the analysis. Transmission clusters with ≥2 cases were identified by bootstrap values ≥90% and mean pairwise genetic distances ≤0.025%.
Results: Transwomen were 275 of 5,200 cases with viral sequences; 86 transwomen were in 70 clusters; 44 (51%) had injection risk. Many clusters with transwomen contained MSM-persons who inject drugs (MSM-PWID) (47% of clusters) and non-MSM PWID (26%); whereas MSM were in 54% of clusters and heterosexual men in 1%. After re-classification, the profile of clusters shifted: 16% of clusters contained MSM-PWID, 57% had non-MSM PWID, 16% had MSM and 47% had heterosexual men. Similarly, among 130 clusters containing cis women, 27% had MSM-PWID, 41% had non-MSM PWID, 28% had MSM and 58% had heterosexual men.
Conclusions: Applying the new paradigm for classifying the transmission risk of transwomen and their partners suggests that transwomen may stand apart from the MSM epidemic. The risk profile of transwomen's transmission clusters is highly sensitive to whether or not male partners are classified as MSM. Under the new paradigm, transmission clusters containing transwomen closely resemble clusters containing cis women, with a strong presence of PWID and heterosexual men. There is increasing recognition that transwomen should be considered by their gender identity for health services and research. The same consideration perhaps should apply to male sexual partners of transwomen. Examining transmission clusters may bring new insights to the applicability of MSM-focused research to transwomen and their partners.

TUPDC0103

Discrepancy between risky sexual behavior and perceived HIV risk among transgender women in community-based test and treat cohorts in Thailand

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Background: Transgender women (TG) are a high-burden population for HIV. Globally, their risk of HIV is 49 times higher compared to the general population, indicating that HIV-prevention and care services for TG are critical and urgent. To understand the facilitators and barriers for TG to access HIV-testing and antiretroviral therapy (ART) at community-based clinics, we studied socio-demographic characteristics, behavioral risk and knowledge and attitudes towards HIV and ART.
Methods: Thai TG aged ≥18 years were recruited from 6 community-based clinics in Thailand. Demographic characteristics, behavioral risk, HIV-knowledge and attitudes towards ART were assessed using questionnaires. Trained community health-workers provided same-day result HIV testing and sexually transmitted infection (STI) screening, as well as CD4 testing and linkage to care for HIV-infected participants.
Results: Of 734 TG participants enrolled, 56.1% were between 18 and 25 years old. Only 15.7% had a college degree or higher, and 36.8% earned less than 280 USD monthly. Prevalence of any STI was 32% (syphilis 3.5%, chlamydia 23.3%, gonorrhea 14.6%). Nobody (0.0%) reported a negative attitude towards people with HIV, 42.0% of participants knew that ART can reduce HIV transmission, and 65.4% thought all people with HIV should use ART. Almost 90% said they would start ART immediately if they were diagnosed with HIV. Multiple sexual partners in the last six months was reported by 53.5%. While 77.4% of TG reported unprotected sex in the last 6 months and 91.1% identified proper condom use as a manner of decreasing HIV-risk, only 17% perceived their HIV-risk as high. Almost half (45.0%) had never tested for HIV. HIV prevalence was 9.0%, and among 66 HIV-infected participants, median (IQR) CD4 count was 406 (306-562), 84% initiated ART within 2 weeks of diagnosis.
Conclusions: Among these young Thai TG presenting for HIV-testing at community-based clinics, the prevalence of HIV and STIs was high. Attitudes towards HIV and ART were positive, and ART uptake was high. However, there was a remarkable discrepancy between risky sexual behavior and perceived HIV risk. Our findings are crucial to informing HIV education and prevention programs targeting TG in Thailand.

TUPDC0104

Engaging transgender women of color in HIV prevention: findings from mixed methods community-based research

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Background: Transgender women (TW) across the globe are highly vulnerable to HIV. TW of color (TWOC) in the US are particularly burdened, with an estimated HIV prevalence over 50% in some studies. Effective HIV interventions are needed to prevent HIV acquisition and onward transmission, and to improve health outcomes. We used mixed-methods approaches to understand how to develop and implement accessible, acceptable, and effective HIV interventions for TWOC.
Methods: Qualitative, in-depth key informant (KI) interviews (n=20) were conducted with TW and health and social service providers. Interviewer-administered surveys and rapid HIV tests were implemented among TWOC (n=46) in Baltimore, USA.
Results: Among TWOC, HIV prevalence was 48%, with 18% unaware of their HIV status and 33% who had not been tested for HIV in the last 12 months. History of sex work (78%) and condomless anal intercourse (47%) were high. Most participants had heard of PrEP (89%); of those, 78% knew where to get it and 23% had ever taken it. Of those who had ever taken PrEP (n=9), 67% had done so in the prior 12 months.

Despite low uptake, 81% of HIV-negative TWOC stated they would take PrEP if it was made available to them. Interviews elicited diverse reflections on how to better engage TWOC in HIV programs. KIs emphasized the importance of embedding HIV services within social service programs that are responsive to community needs (e.g., job readiness, mental health support, housing), to improve access and acceptability of HIV programs for TWOC. KIs also recommended regular staff training in transgender competent care (e.g., using correct gender pronouns), recognizing that experiencing discrimination in health venues deters TWOC from future care seeking. Other suggestions included: offering services where TWOC regularly visit, hiring TWOC to lead programs, and doing tailored outreach and advertising.
Conclusions: Acceptable high-impact HIV prevention and care interventions for TWOC are urgently needed as evidenced by an elevated HIV prevalence and low PrEP uptake. Noting the disconnect between willingness and uptake of PrEP among TWOC, HIV prevention programs could better bridge this gap by incorporating strategies voiced by TW and responding to identified access barriers.

TUPDC0105

Factors associated with HIV infection among transgender women in Cambodia: results from a national integrated biological and behavioral survey

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Background: Transgender women are at high risk for HIV infection, and little is known about the burden of HIV infection and its related factors in this population worldwide. This study was conducted to examine factors associated with HIV infection among transgender women in Cambodia.
Methods: This cross-sectional study was conducted between December 2015 and February 2016 in the capital city of Phnom Penh and 12 HIV high-burden provinces. Respondent driven sampling was used to recruit sexually active transgender women aged 18 and over. A structured questionnaire was used for a behavioral survey, and rapid finger-prick HIV testing was performed using Determine™ antibody test. Multivariate logistic regression analysis was conducted to identify factors associated with HIV infection using STATA.
Results: A total of 1,375 transgender women participated in the study with a mean age of 25.9 years (SD= 7.1). The overall HIV prevalence among this population was 5.9%. In multivariate logistic regression, participants living in urban areas were twice as likely to be HIV infected as those living in rural areas. Participants with primary education were 1.7 times as likely to be infected compared to those with high school education. HIV infection increased with age; compared to those aged 18-24, the odds of being HIV infected were twice among transgender women aged 25-34 and 2.8 times higher among those aged ≥35. Self-injection of gender affirming hormones was associated with a fourfold increase in the odds of HIV infection. A history of genital sores over the previous 12 months increased the odds of HIV infection by threefold. Transgender women with stronger feminine identity dressing up as a woman all the time were twice as likely to be HIV infected compared to those who did not dress up as a woman all the time. Having never used online services developed for transgender women was also associated with higher odds of being HIV infected.
Conclusions: Transgender women in Cambodia are at high risk of HIV. To achieve the goal of eliminating HIV in the country, effective combination prevention strategies focusing on the above risk factors among transgender women are urgently needed.

TUPDC0106

Prevalence and correlates of police harassment among transgender women in Jamaica: implications for HIV prevention and care

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Background: Criminalization of homosexuality limits access to HIV prevention and care. Little is known about police harassment targeting transgender women in contexts where homosexuality is criminalized, such as Jamaica. We examined prevalence of police harassment and its association with HIV infection and risk factors among transgender women in Jamaica.
Methods: We implemented a cross-sectional survey with transgender women in Kingston, Ocho Rios, and surrounding areas in Jamaica using chain referral sampling. Unadjusted and adjusted logistic regression analyses were conducted to identify health (e.g., HIV status), intrapersonal (e.g., sex work), interpersonal (e.g., social support), and structural (e.g., transphobic violence) factors associated with ever experiencing police harassment perceived to be due to transgender identity.
Results: Participant (n=137) mean age was 24.0 years (SD: 4.5; range 18-44); two-thirds (n=92; 67.2%) lived in Kingston, and half (n=71; 51.8%) reported sex work involvement. Three-quarters (n=103; 75.7%) had received an HIV test; of these, one-quarter (n=26; 25.2%) were HIV-positive. Almost half (43.8%; n=60) reported experiencing police harassment due to their transgender identity. Of participants with complete data (n=127), 16.5% (n=21) reported a history of incarceration due to transgender identity. Of those, 71.4% (n=15) reported being incarcerated 1 to 3 times and 28.6% (n=6) were incarcerated 4 to 6 times. In unadjusted analyses, police harassment was associated with: sociodemographic (< high school education vs. ≥ high school [OR: 3.04, 95% CI: 1.1-8.4]), health (HIV positive serostatus [OR: 2.44, 95% CI: 1.01-5.86], depression [OR: 1.23, 95% CI: 1.01- 1.50]), intrapersonal (sex work [OR: 2.61, 95% CI: 1.30-5.25]), interpersonal (higher need for social support [OR: 1.09, 95% CI: 1.03-1.15]) and structural (transphobic physical violence [OR: 6.97, 95% CI: 3.14-15.51]). In adjusted multivariable analyses, HIV positive serostatus (AOR: 2.96, 95% CI: 1.04, 8.43) and transphobic physical violence (OR: 6.06, 95% CI: 2.53, 14.55) maintained strong associations with experiences of police harassment.
Conclusions: Nearly half of transgender women in this Jamaican study reported police harassment, and this was associated with HIV positive serostatus and physical violence. Criminalization and violence are structural drivers of HIV, constraining access to the HIV care continuum. Human rights for transgender women are central to HIV prevention and care in Jamaica.

TUPDD01 The Missing Men

TUPDD0101

Poor retention and care-related sex disparities among youth living with HIV in rural Mozambique

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Background: Despite a 30% decline in HIV-related deaths over the past decade, HIV remains still the leading cause of death among African adolescents. Our objective was to summarize performance along the continuum of HIV care, and identify predictors of loss to follow-up (LTFU) among youth enrolled in HIV care in rural Mozambique.
Methods: We analyzed a retrospective cohort of youth (15-24 years) accessing care at one of 89 PEPFAR-supported clinics in Mozambique between 2012-2015. We determined the proportion of patients pre-antiretroviral therapy (ART) LTFU at 6 months, cumulative incidence of post-ART LTFU and mortality 1 year post-initiation. We defined LTFU as being > 60 days late for the last scheduled visit (pre-ART), or ART pick-up (post-ART). We used logistic and multivariable Cox regression models to identify predictors of pre- and post-ART LTFU, respectively, in the year after enrollment.
Results: Of 23,322 patients in the cohort, 19,287 (83%) were female. Primary referral source was prevention of mother-to-child transmission clinics for females (49%, n=8,639), and voluntary counseling and testing sites for males (65%, n=2,314). Females enrolled in care at earlier HIV disease stage (median CD4 469 vs. 363 cells/mm^3, p< 0.001) and initiated ART more expeditiously than males (median 6 [IQR 0-129] vs. 35 [IQR 2-180] days, p<0.001). Pre-ART LTFU at 1 year was 36% overall, and lower for females vs. males (33% vs. 56%, OR=0.28; 95%CI:0.24-0.33). The cumulative incidence of post-ART LTFU was 36% overall (95%CI:35-36%), with small differences by sex (F:M 35% vs. 37%, aHR 0.66 95%CI:0.58-0.75). Adjusted one-year mortality rate for ART patients retained in care was 12.6% (95%CI:6-22%).
Conclusions: In the cohort of youth enrolled in care four-fifths were female. Females were enrolled in care earlier in their disease course, initiated on ART more quickly, and less likely to experience pre-ART LTFU than young males. After ART initiation, 1/3rd of all patients were LTFU, and mortality rates were high. While outcomes were poor overall in this setting, young women may require enhanced prevention efforts, while young men need targeted testing and treatment interventions.

TUPDD0102

Gender age considerations and likelihood of viral load suppression at sub-national level in five counties, Kenya

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Background: Sub-Saharan Africa accounts for 66% of new HIV infections globally. Program responses need to focus on sub-national contexts if epidemic control is to be achieved. The objective of this paper is to describe the likelihood of viral suppression at sub-national level, considering age and gender in five counties in Kenya.
Methods: This retrospective correlational survey reviewed the significance of age and gender on the likelihood of viral load suppression among clients on antiretroviral therapy (ART) who had accessed at least one viral load test in the period October 2015 to September 2016. ART was initiated as per the national guidelines in Kenya. Raw viral load data was assessed from the national viral load database for 139 facilities in five counties (Baringo, Kajiado, Laikipia, Nakuru and Narok) and 38,113 records were analyzed. The survey used logistic regression to assess relationships between gender, age and viral load suppression (< 1000 copies ml), with P <0.05.
Results: Overall, females were 16% more like to be virally suppressed compared to males. Females aged 1-9 years,10-14 years, 20-24 years were (62%, p=0.00), (26%, p=0.024), (79%, p=0.001) respectively more likely to be virally suppressed than males. There was no significant difference in the likelihood of viral suppression between females and males for clients under one-year-old, (p=0.230), 15-19 years (p=0.254), and in 25 years or older (p=0.079).
In Laikipia, males aged 10-14 years were 25% less likely to be virally suppressed. In Nakuru and Narok, males aged between 1-9 years were 53% less likely to be virally suppressed. Further, in Nakuru those aged 20-24 years were 48% less likely to virally suppressed compared to female counterparts.
In Kajiado, Baringo and Laikipia counties, the likelihood of clients being virally suppressed increased with age. While in Narok and Nakuru counties, it was not dependent on increase in age.
Conclusions: The likelihood of achieving viral suppression seemed to agree with literature that female clients are likely to be suppressed. However, there are sub-national differences in the suppression rates. There are also differences in suppression rates through age groups in the counties. This information can be used for further research and effective programming.

TUPDD0103

An exploratory study to determine the survival period to switching for adult ART patients (15+ years) in Swaziland using routinely collected data

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Background: It has been observed over the past five years that there is limited use of data stored in electronic data systems for making targeted programmatic decisions and conducting operational research. To demonstrate how routine data stored in these electronic systems can be used to inform HIV programming, SIAPS worked with the Ministry of Health (MoH) to conduct a study to determine the survival period to switching for adult patients (15+ years) on antiretroviral therapy (ART).
Methods: This was a retrospective cohort design study. The study population consisted of 117,586 adult (≥15 years) ART patient records identified as active between years 2010 to 2015 in the national ART database. The survival rates from time of ART initiation to time of regimen switch were evaluated according to gender and age using Kaplan-Meier models i.e. outcome variable was switching (binary event) and explanatory variables were: WHO staging I; II; III; IV, Age categories: 15-24; 25-34; 35-44; and 45 years and above, and Sex: Male; Female.
Results: 3.6% (n = 4266) of the studied ART patients were found to have switched at some point during the course of treatment. Median survival time for all ART patients switching from first to second line regimen was found to be 607 days (95%CI: 601 - 613) days or 19 months. Patients aged 45 years and older at ART initiation remained on the first line regimen for longer periods than other age groups at 93.5%. Survival times for males were less than those of females. Only 83% of patients initiated at WHO stage IV remained on first line regimen by end of a 5 year follow up period.
Conclusions: There were significant differences in survival periods with men exhibiting a poorer survival period. Also, for the 18-25-year age group, we found that women actively switch regimen more often than men. Further studies would be required to understand the factors contributing to these findings. This can inform policies in HIV programming that target the unique needs of males and female clients.

TUPDD0104

Tanzanian men more successful than women in referring sexual partners to HIV testing via partner notification

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Background: Partner notification (PN) is effective at increasing uptake of HIV testing services (HTS) and identifying previously undiagnosed individuals. 2016 Guidance from WHO recommends inclusion of PN into HTS programs. PN and referral to HTS can be conducted by the index client (passive notification) or with provider-assisted strategies. Passive PN involves HIV status disclosure and is impacted by socio-cultural dynamics surrounding sex and gender. This abstract describes the success of male vs. female index clients in listing and referring sexual partners for testing in Tanzania.
Methods: A cross-sectional observational study was conducted in three hospitals in Njombe region, Tanzania, from June - September 2015. Individuals newly diagnosed with HIV in VCT or PITC were offered their choice of passive or provider-assisted referral for partner HIV testing. Odds ratios were calculated for likelihood of male and female index clients to successfully refer partner(s) to HTS or list multiple partners, and in-depth interviews were conducted with 40 index clients and partners.
Results: Almost all (91.6%) of the 390 (183 males and 207 females) index clients chose passive rather than provider-assisted referral. Of the 439 listed partners, 249 (56.7%) were successfully referred to HTS (63.4% of female partners; 49.8% of male partners). Male index clients were 2.2 (1.4 - 3.5) (p<0.001) times more likely than female index clients to successfully refer at least one partner, and 6.2 (2.7 - 14.1) (p<0.001) times more likely to list more than one partner. In qualitative analysis, both gender-specific (feeling undervalued if the relationship had not produced children; lacking contact info for commercial sex partners) and non-gender specific (difficulty communicating with past partners) challenges were described.
Conclusions: PN has been shown to be effective and is being scaled up in multiple African countries, but little discussion has addressed gender and PN. In this study, men were more likely to list multiple partners and to successfully refer at least one partner to HTS. This strength could be built upon in programmatic approaches which target men for PNS. Women's more limited ability to successfully refer their partner(s) could signal a need for different approaches to support women in the PN process.

TUPDD0105

Male engagement strategies effective in improving Option B+ retention in rural Mozambique

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Background: Retention in antiretroviral therapy services initiated during antenatal care (ANC) in Mozambique is less than 30% at one year. To nurture supportive prevention of mother-to-child transmission (PMTCT) services we introduced a Male Engagement Strategy (MES) that involved partnering with Traditional Birth Attendants and training a new cadre of male-to-male community health agents, "Male Champions." Together they counseled expectant couples to change community norms around male engagement in spousal/partner pregnancies and uptake of HIV services.
Methods: We conducted a retrospective analysis of women (>15 years) enrolled in HIV care and treatment through PMTCT services at 112 sites in rural Zambézia province, Mozambique. We compared clinical retention rates among sites receiving MES vs. those receiving standard of care (SOC) using chi-squared tests, Wilcoxon rank sum tests, and Cox regression models. In addition, we assessed the effect of MES on retention by implementation time using a Cox regression model.

Results: Six thousand five hundred women were enrolled in PMTCT care at MoH-run clinics receiving Friends in Global Health technical support from January 2015 - November 2016. Median age was 24 years (IQR: 20-29), 84% were married or living with a partner, median CD4 cell count was 463 cells/mm^3, and 51% were enrolled in sites supported by MES. Cumulative incidence of ART loss to follow-up (LTFU) at six months was 38.1% (36.4%, 39.8%) among those enrolled at MES sites vs. 43.3% among those who received SOC (p=0.001). Controlling for clinical (e.g. CD4 cell count) and social (e.g. education, marital status) characteristics, those who attended MES clinics had a 33% lower risk of being LTFU at 6 months vs. those receiving SOC (p <0.001). Longer duration of MES exposure at a clinic was associated with increased retention: covariate-adjusted hazard ratios for late ART pick-up decreased from 0.75 (0.65, 0.86) at 12 months to 0.47 (0.38, 0.58) at 36 months.
Conclusions: Programs designed to encourage PMTCT services should include community and clinic-based interventions targeting male involvement in ANC and HIV services to improve maternal retention. Successful programs should see continuous improvement in clinical outcomes as activities become more socially acceptable and better integrated into clinical services.

TUPDD0106

Using traditional techniques to increase uptake of male circumcision and HIV testing and counselling services of males ages 15-29 through Lihawu Male Mentoring Camp

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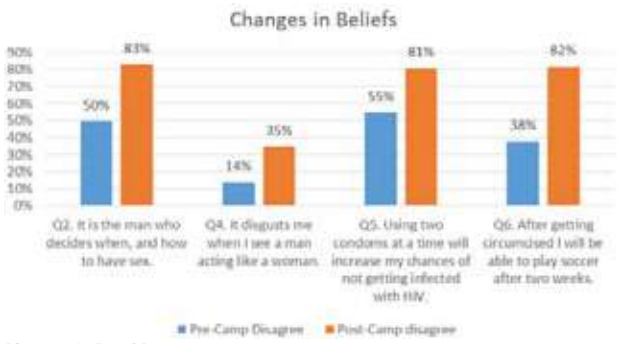
Background: Swaziland's HIV prevalence remains the world's highest at 26%. However, Swazi men often report fear and suspicion towards VMMC, mostly caused by solely biomedical approaches. In response, KI's innovative project, Lihawu Male Mentoring Camp (LMMC), offers 15-29 year old men a comprehensive package of adolescent male mentoring and health services, sensitization and interventions, with the following objectives:

- To increase number of circumcisions in the pivot age.
- To create a conducive space for VMMC clients to engage with mentors and peers in a fun way, clarifying myths and misconceptions about male health issues, masculinity and MC.
- To increase adherence to post-operative MC complementary care, conduct and lifestyle choices.

Methods: LMMC is a three-day residential camp of activities aimed at age pivot adolescents, combining behaviour change tenants of traditional Bantu initiation rites of passage with clinical best practice in VMMC.
Activities include challenges, games and cultural observances as well as sensitization on masculinity and gender awareness, goal setting, HIV and male health issues and services.
At the end of the camp, participants are offered a comprehensive package of male health services including HTC and VMMC.
Results: Increased VMMC (86%) and HTC (87%) uptake amongst pivot-age clients (national av. 19%) exposing them to a package of interventions and life skills marking a transition from childhood to adulthood. Pre and post camp surveys show a dramatic increase in gender equitable beliefs and acceptance of gender deviance, as well as increases in post-circumcision care and conduct, and in condom usage and efficacy knowledge.

Health service	HIV status knowledge on entry	HIV status knowledge on exit
HTC	93/352 (26%)	307/352 (87%)
	# of clinically eligible clients	# of Circumcisions performed
VMMC	318/352	275/318 (86%)

[Increases of VMMC and HTC]



[Changes In Beliefs]

Conclusions: Contrary to common beliefs, traditional approaches may be utilized as effective methods to sensitize men on positive masculinity, SRH issues, and the benefits of VMMC, as well as dramatically increase uptake in prevention services.

Tuesday 25 July

Poster Exhibition

HIV Pathogenesis

TUPEA0095

Negative checkpoint regulatory molecule 2B4 (CD244) contributes to iNKT cell dysfunction during HIV infection

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Background: Invariant natural killer T (iNKT) cells are unique subset of T-lymphocytes that expresses a highly restricted T cell receptor (TCR) to recognize glycolipid and phospholipid antigens presented in context to CD1d molecules. iNKT cell involvement is implicated in human chronic viral infections. However, the determinants of cellular dysfunction across the iNKT cell subsets are seldom defined during HIV infection. Herein, we explore the contribution of negative check point regulatory molecule 2B4 on iNKT cells phenotype and function, and their relevance to clinical parameters associated with HIV disease progression.
Methods: We analyzed peripheral blood mononuclear cells (PBMCs) obtained from antiretroviral therapy (ART) naïve (n=23), ART-treated (n=19), elite controllers (ECs, n=6) and healthy controls (n=15). We employed flow cytometry to asses the phenotypic and functional alterations in iNKT cells. Briefly, PBMC were labeled with PBS-57 loaded/ CD1d tetramer along with panel of antibodies. For IFN-γ detection, intracellular staining was performed on α-galactosylceramide (aGalCer) stimulated cells.
Results: We report an exaggerate 2B4 expression on peripheral blood iNKT cells in naïve subjects compared to healthy controls. Further, there was a severe $CD4^+$iNKT cell subset depletion in naïve subjects. In sharp contrast to $CD4^-$iNKT cells, 2B4 was predominantly expressed by $CD4^+$iNKT cell subset in naïve subjects. Given the suppressive role of 2B4 in HIV-specific $CD8^+$ T cells, we examined the levels of 2B4 expression on T-cell subsets. There was a marked increased on bulk of $CD3^+$ T cells. In contrast to $CD4^+$ T cells, $CD8^+$ T cells displayed significantly higher levels of 2B4 in naïve individuals. Notably, the increased level of 2B4 on iNKT cells strongly correlated with parameters of HIV disease progression. Functionally, iNKT cells from naïve individuals were defective in IFN-γ production and HIV disease severity.
Conclusions: Our results suggest that the levels of 2B4 expression and the downstream co-inhibitory signaling events potentially contribute to impaired iNKT cell responses. Hence, the 2B4 pathway could be a key target for prospective immunotherapeutic interventions against HIV infection.

TUPEA0096

NK cell subset frequency and developmental markers are altered in HIV-1^+ pregnancies

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Background: HIV-1^+ pregnancies are associated with increased incidence of preterm labour, thought to be due to the disruption of normal alterations of the immune cell function and phenotype induced by pregnancy. An association has been seen between preterm HIV-1^+ women and increased $CD56^+$ cell count, implying natural killer (NK) cells may be involved in this disorder. This study aims to investigate NK cell phenotype in HIV-1^+ pregnant women.
Methods: HIV-1^- pregnant women (n = 11) and HIV-1^+ pregnant women on antiretroviral therapy (ART) (n = 12) were recruited, their peripheral blood mononuclear cells isolated, and flow cytometric analysis of NK cells performed to determine the expression of differentiation and activation markers on NK cells. Statistical analysis was carried out using Prism version 7.0. Intergroup variation was assessed by Mann-Whitney tests and statistical significance defined as $p \leq 0.05$.
Results: There was no difference seen in total NK ($CD56^{bright}$, cytolytic and anergic) frequency between groups, though total HIV-1^+ NK cells with phenotype $CD11b^+CD27^-$ were significantly decreased ($p = 0.0036$), and $NKG2D^+$ cells had higher median fluorescence intensity (MFI) of NKG2D marker ($p = 0.0052$). $CD56^{bright}$ NK ($CD56^+CD16^-$) frequencies did not differ, however HIV-1^+ women had decreased cytolytic NK ($CD56^+CD16^+$) and increased anergic NK ($CD56^-CD16^+$) frequencies ($p = 0.0053$ and $p = 0.0164$ respectively). HIV-1^+ $CD56^{bright}$ NK populations demonstrated a lower frequency of $CD11b^+CD27^+$ cells ($p = 0.0317$), whereas cytolytic NK populations showed decreased $CD11b^+CD27^-$ profile and higher $NKG2D^+$ marker MFI ($p = 0.0086$, $p = 0.0283$). Anergic NK cells exhibited decreased $CD11b^+CD27^-$ profile, $NKG2A^+$, $NKp30^+$, and $NKp46^+$ cells, and higher $NKG2D^+$ marker MFI ($p = 0.0036$, $p = 0.0473$, $p = 0.0036$, $p = 0.0037$, and $p = 0.0230$).
Conclusions: Despite ART NK cell subsets in HIV-1^+ pregnant women demonstrate both disrupted frequency and altered phenotype from HIV-1^- pregnant women. Differences in CD11b and CD27 expression indicate potential dysregulation of NK cell maturation, and altered expression of inhibition and activation markers in both cytolytic and anergic cell subsets supports this. These findings contribute to understanding the modifications of NK cell function by pregnancy and HIV-1 infection.

TUPEA0097

Differential distribution of M1 and M2 macrophages in the decidua and chorionic villi of placentas from HIV-1-infected mothers on combination antiretroviral therapy

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Background: A balance of M1 and M2macrophages plays a critical role in regulating maternal tolerance to a developing fetus. ART provision to HIV-infected pregnant women is known to reduce mother-to-child HIV transmission, but also results in poor birth outcomes, such as premature and small-for-gestational age infants. We hypothesize that prolonged exposure to ART in utero results in disruption of the balance between M1 and M2 macrophages at the feto-maternal interface.
Methods: Using immunohistochemistry, we enumerated the density of $CD68^+$ (M1), $CD163^+$ (M2) and $CD206^+$ (M2) macrophages within tissue sections of decidua parietalis (DP), decidua basalis (DB) and chorionic villus tissue (CVT) taken from placentas at delivery from HIV-1-infected mothers. Placentas were collected from women who were stable on ART (commenced ART before pregnancy) (n=9) and women initiating ART at ±20 weeks gestation (n=11). DAB-stained cells were enumerated using an automated software from 5 separate random images after sections were counterstained with Mayer's hematoxylin. Cell density was expressed as a ratio of DAB stain (numerator) by nuclei stain (denominator).
Results: The duration of ART exposure had no effect on the distribution of $CD68^+$, $CD163^+$ and $CD206^+$ cells within DP and DB membranes of placentas from mothers who were either stable or initiating ART. However, there was a higher density of CD163/nuclei (median of 2.47) in the decidua parietalis (DP) of mothers initiating ($p=0.0037$) or on stable ART ($p=0.0085$) compared to CVT (median of 0.45). $CD206^+$/nuclei in the DP was significantly higher when compared to the DB (median of 1542.9 to 1.57; $p=0.0005$) and CVT (median of 1542.9 to 1.60; $p=0.0021$) from mothers initiating or on stable ART. There was no difference in the CD68/nuclei ratio in any of the placental tissue compartments for mothers in either of the ART groups.
Conclusions: Overall, the duration of ART exposure appeared to have no effect on the distribution of M1 (CD68) and M2 (CD163/CD206) macrophages in the decidua. The higher density of M2 macrophages within the maternal decidua compared to the chorionic villi, suggests that ART exposure may not disrupt these regulatory macrophages at the feto-maternal interface.

TUPEA0098

Influence of the genetic LILRA3-deletion on HIV and Hepatitis C

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Background: Members of the the leukocyte immunoglobulin-like receptor family (LILRs) exert various immunmodulatory functions. A naturally occuring 6.7 kbp deletion in the gene locus of LILRA3 results in a null allele and an absence of the

protein. The genetic LILRA3 deletion has been associated with autoimmune and malignant disorders. The influence of LILRA3 and of the genetic LILRA3 deletion on the transmission and the clinical course of HIV and Hepatitis C was assessed in this study.
Methods: LILRA3 genotypes of patients and controls were determined by polymerase chain reaction. Studies of LILRA3 gene regulation and protein concentrations were performed using real-time PCR, intracellular flow cytometry and ELISA. An infectivity assay was performed for HCV after addition of recombinant LILRA3 protein.
Results: The prevalence of homozygous LILRA3 deletion was significantly higher in HIV positive individuals (n= 439) than in controls (n= 651) (p= 0.02). In contrast, in the hepatitis C positive population (n=314) the prevalence of the homozygous LILRA3 deletion was reduced compared to controls (p<0.02).
The disease progression of HIV was faster in patients with homozygous LILRA3 deletion with a higher proportion of short-term progressors among homozygously deleted patients than in heterozygous
(p= 0.03) and in homozygously positive (p=0.002) individuals. Functional analysis revealed an upregulation of the LILRA3 gene in real-time PCR in treated HIV patients when compared to untreated patients (p= 0.007) and controls (p= 0.02) resulting in a higher LILRA3 expression in $CD4^+$ (p= 0.008) and $CD14^+$ (p= 0.02) cells of untreated patients than in controls in intracellular flow cytometry. No up-regulation could be found in the Hepatitis C infected individuals.
LILRA 3 concentrations in the sera were similar between the groups, in untreated HIV patients a correlation between viral load and LILRA3 concentration was found. An infectivity assay showed a reduced infectivity of HCV when recombinant LILRA3 protein was added.
Conclusions: The homozygous LILRA3 deletion is associated with a higher susceptibility for HIV infection and with a faster disease progression.
In Hepatitis C the LILRA3 leads to a reduced infecivity of HCV, thus the deletion is risk factor for the transmission of Hepatitis C.

TUPEA0099

Sensing of HIV-1 entry triggers a type I interferon response in human primary macrophages

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Background: Along with CD4+ T lymphocytes, macrophages are a major cellular source of HIV-1 replication, and a potential viral reservoir. Following entry and reverse transcription in macrophages, cloaking of the viral cDNA by the HIV-1 capsid limits its cytosolic detection, enabling efficient replication. However, whether incoming HIV-1 particles are sensed by macrophages, prior to replication, remains unclear.
Methods: Macrophages were diferentiated from monocytes of healthy human blood donors. Viruses and viral-like particles were produced by transfection of the corresponding pro-viral DNA in HEK 293 T cells.
Results: Here, we show that HIV-1 triggers a broad expression of interferon-stimulated genes (ISG) in monocyte-derived macrophages within a few hours after infection. This response does not require viral reverse transcription or the presence of HIV-1 RNA within particles, but viral fusion is essential. This response is elicited by viruses carrying different envelope proteins and thus different receptors to proceed for viral entry. Expression of ISG in response to viral entry requires TBK1 activity and type I IFNs signaling. Remarkably, the ISG response is transient but impacts on subsequent viral spread.
Conclusions: Together, our results shed light on an early step of HIV-1 sensing by macrophages at the level of entry, which confers an early protection through type I IFN signaling and has potential implications in controlling the infection.

TUPEA0100

In vivo analysis of LILRB2 on dendritic cells reveals specific up-regulation in early phase of SIV / HIV infection: implication in anti-viral immune responses

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Background: Dendritic cells (cDC) play a major role in the early immune responses that tip the balance toward viral control or persistence. Previous in vitro studies suggest that HIV increases the binding capacity of LILRB2 inhibitory receptor for MHC class I leading to cDC dysregulations and thus inefficient immune responses. However the dynamic of LILRB2 during the course of HIV infection in vivo and its relationship with cDC dysregulations is still unknown.
Methods: Here we use a cynomolgus macaque model of infection by SIV to monitor LILRB2 expression on cDC throughout time.
Results: Our data show that LILRB2 expression is enhanced on cDC from blood and lymph nodes in the early phase of infection and reach a peak 10 days after infection. Moreover, up-regulation of MHC class I, the ligand of LILRB2, is also induced in the early phase of SIV infection. By contrast, infection of cynomolgus macaque by chikungunya virus, that elicit efficient anti-viral immune responses, revealed a decrease of LILRB2 on cDC during acute phase of infection despite similar plasmatic cytokine profiles in both models. Ex-vivo analysis of cDC in blood from early HIV infected patients confirmed that LILRB2 expression is up-regulated during acute phase of infection. Moreover, ex vivo infection of human DC by HIV enhances the expression of LILRB2 in productively infected cells.
Conclusions: Altogether our data reveal a specific up-regulation of LILRB2 and MHC class I in the early phase of SIV / HIV infection that may account for the dysregulations of cDC at a critical stage of the anti-viral immune response.

TUPEA0101

Allogeneic NK-CD4 co-cultures reveal potential protective KIR/HLA mechanisms against HIV

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Background: KIR/HLA incompatibility between HIV-exposed seronegatives (ESN) and their partners has been identified as a potential HIV-protective mechanism, whereas HIV-transmission was linked to the presence of an allogeneic KIR/HLA match. This protective effect has been ascribed to the missing-self mechanism, where activated NK cells eliminate the influx of allogeneic HIV-infected cells. We aim to provide evidence for the existence of these alloreactive Natural killer (NK) cell responses against HIV patient derived CD4 T cells.
Methods: NK cells were isolated from 62 healthy individuals and co-cultured with CD4 T cells derived from 62 HIV patients. After 4 hours, co-cultures were analyzed for 7-AAD, CD107a and inhibitory KIR (iKIR) expression using an 8-color flow cytometer. KIR and HLA genes were genotyped using PCR KIR/KIR-ligand kits.
Results: We observed higher percentages of CD4 T cell death in co-cultures with a KIR/HLA mismatch between NK cells and CD4 T cells, compared to KIR/HLA matched co-cultures (p>0.0001). NK cell degranulation by single iKIR expressing NK cells was also increased in the presence of their respective KIR/HLA mismatch as compared to KIR/HLA matches (KIR3DL1:p=0.0005; KIR2DL1:p≤0.0001 and KIR2DL2/3:p≤0.0369). Extrapolation of these results to the total NK cell population showed a strong relation between the total degranulating NK cell population induced by a KIR/HLA mismatch and CD4 T cell death (p>0.0001; R=0.8109), while no clear relation was found in context of a KIR/HLA match (p=0.0008; R=0.3498). Independent of KIR/HLA mismatches, CD4 T cell killing and NK cell degranulation were elevated in the presence of a telomeric activating KIR profile (p=0.0203, p=0.0115 respectively) compared to donors with a telomeric inhibiting KIR profile.
Conclusions: Our results suggest that the presence of a KIR/HLA mismatch is the driving force behind the killing of allogeneic CD4 T cells. Additionally, the presence of activating KIRs increases the cytotoxic capacity of NK cells. These results illustrate a potential contribution of alloreactive NK cells to HIV restrictive mechanisms in ESN.

TUPEA0102

HIV-1 Vif adaptation to host immune pressure impact of cytidine deaminases and host HLA

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Background: Members of the APOBEC3 cellular cytidine deaminase family inhibit HIV-1 replication in the absence of the HIV-1 Vif protein. However, HIV-1 Vif is able to counteract the inhibitory action of all key APOBEC3 proteins by targeting them for premature proteasomal degradation. The ability of transmitted/founder virus Vif to adapt to immune pressure mediated by diverse cytidine deaminases and other host proteins such as human leukocyte antigen (HLA), and the subsequent impact on disease pathogenesis has not been fully characterized. We hypothesized that the transmitted/founder virus Vif adapts in vivo to specific APOBEC protein mediating most immune pressure as well as to host HLA class I mediated host immune pressure.
Methods: 17 HIV-1 acutely infected individuals from Durban, South Africa were studied. HIV-1 vif was amplified and cloned into the pCRV1 expression vector. For each patient sample, 2-4 clones were generated at both 1-month post-infection and 1-year post-infection. Putative sequence changes mediated by APOBEC or HLA-I immune pressure were analysed.
Results: In total, 64 clonal sequences were generated. All HIV-1 vif clones were subtype C. Sequence analysis showed that most APOBEC-3G, -3F and -3H binding sites in HIV-1 vif were conserved. However, at Vif amino acid position 17, located within the APOBEC3F binding site ^{14}DRMK^{17}, 64% of 1-month post infection (transmitted/founder) viruses had a non-consensus subtype C Arginine (R) which increased to 71% at 1-year post-infection.
Although there was sequence variability at APOBEC3G binding domains between individuals, there were no predictable changes noted over the course of infection. Analysis of Vif HLA epitopes within transmitter/founder viruses showed that 43% had cytotoxic T cell mutations associated with the host HLA, whereas 26% possessed known CTL escape mutations not associated with the infected person's HLA genotype.
Conclusions: This data suggests a high rate of transmission of Vif HLA-associated immune escape variants and adaptation to pressure exerted by the host HLA over 1 year. There was also evidence of Vif adaptation to APOBEC3F but not to the other APOBEC proteins. The impact on Vif adaptation to host pressure on its ability to bind and counteract APOBEC proteins requires further investigation.

TUPEA0103

Blood precursor DCs are the most efficient transmitters of HIV-1 to T cells

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Background: Blood dendritic cell precursors (preDCs) can give rise to conventional cDC1 and cDC2. As DCs represent critical targets for the establishment of HIV-1 infection and for efficient anti-viral immunity, the present study aims to evaluate the impact of HIV-1 exposure on preDCs as compared to other blood DC subsets.
Methods: DC populations (plasmacytoid pDC, conventional cDC1 and cDC2, and preDC) were sorted from PBMCs of healthy donors. Cells were then infected using HIV-$1_{NL4.3}$ or HIV-1_{AD8} virus expressing GFP in the presence or not of Vpx for 48h. For transmission experiments, 24h p.i. DCs were co-cultured with activated CD4$^+$ T cells and cells were harvested 48h later. Transcription profile of HIV-1 infected preDCs were analysed using the Human Gene 2.1 ST array.
Results: We found that among the DC subsets freshly purified from seronegative blood donors, preDCs are slightly more susceptible to HIV-1 infection than cDC2; 4.3±2.5% vs 3.2±2.6% infected cells at 48h, while cDC1 and pDCs were hardly infected (0.2±0.4% and 0.6±0.5%, respectively). However, when SAMHD1 restriction was counteracted by the addition of Vpx, preDCs became much more susceptible to HIV-1 than any other DC subset including cDC2 (48.0±8.4% for preDCs vs 6.2±4.0% for cDC2). In contrast to terminally differentiated DC populations, preDCs were susceptible to both CXCR4 and CCR5-tropic HIV-1.
Moreover, HIV-1-infected preDCs efficiently transmitted the infection to activated primary CD4$^+$ T lymphocytes. HIV-1 infection of preDCs induced an up-regulation of genes involved in T cell activation as seen by transcriptomic analyses. Investigations are underway to assess the impact of preDC exposure to HIV-1 on their capacity to activate T lymphocytes and on their differentiation into conventional cDC1 and cDC2.
Conclusions: We showed that preDCs, a novel blood DC population preferentially transmits HIV-1 infection to T cells as compared to known DC subsets, owing to its higher infectability. Thus, in addition to their role in the ontogeny of DCs, preDCs appear as a subset endowed with specific properties and functions that HIV-1 may exploit. Unravelling the impact of HIV-1 infection on preDC biology should provide insights in key steps of viral spreading and open new venues on therapeutic strategies.

TUPEA0104

SUMOylation influences the sensitivity of SAMHD1 to Vpx-mediated degradation

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Background: SAMHD1 inhibits the HIV-1 replication in non-cycling myeloid cells and resting T cells. Some related viruses of the HIV-2/SIVs lineage counteract this restriction by expressing Vpx, an accessory protein which promotes the proteasomal degradation of SAMHD1. Numerous lines of evidence indicate that SAMHD1-mediated restriction relies on its ability to degrade dNTPs, keeping their concertation below a threshold required for reverse transcription of the viral genome. Phosphorylation of T592 is proposed to inactivate SAMHD1 antiviral activity in cycling cells. Consistently, SAMHD1 harboring T592D mutation to mimic phosphorylation does not restrict HIV-1. However, reports that this mutation does not affect dNTPs hydrolysis question whether SAMHD1-mediated restriction relies exclusively on its dNTPase activity or might require additional post-translational modifications or cell-type specific cofactors.
Methods: Cells expressing HA-SAMHD1 and His-SUMO proteins were lysed in denaturing conditions and SUMOylated SAMHD1 was enriched on Ni-NTA beads and analyzed by Western blotting. SUMOylation sites were confirmed by site-directed mutagenesis. The localization of endogenous SUMOylated SAMHD1 was studied by Proximity Ligation Assay and fluorescence microscopy. The antiviral activity of SUMOylation-deficient SAMHD1 variants was tested in differentiated U937 cells. After challenge with VSVg-pseudotyped HIV-1 or HIV-2 harboring a GFP reporter gene, infected cells were quantified by flow cytometry. To assess the sensitivity SUMOylation-deficient SAMHD1 mutants to Vpx-dependent degradation, U937 cell lines were incubated with Virus-like particles carrying or not Vpx.
Results: .We found that SAMHD1 is modified by SUMO proteinsand that endogenous SUMOylated SAMHD1 accumulates in the nucleus. Residues K469 and K622 are major SUMO-conjugation sites. SAMHD1 variants where these sites are mutated restrict the infection of Vpx-deficient viruses. Strikingly, infection of Vpx-positive viruses is also inhibited, likely because SUMOylation-deficient SAMHD1 mutants are resistant degradation by Vpx.
Conclusions: Our results suggest that SUMOylation is required for Vpx-mediated degradation of SAMHD1 and, as a consequence, influences its antiviral activity.

TUPEA0105

Interplay between infection and innate sensing mechanisms of the HIV vaccine vector MVA in human dendritic cells

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Background: Modified vaccinia virus Ankara (MVA) a promising candidate live attenuated vaccine vector for HIV, induces antigen-specific T cell responses. MVA replicates in human cells but does not produce viral progeny. Multiple innate sensors including TLRs, cytosolic DNA and RNA sensors as well as the inflammasome have been implicated in MVA sensing by myeloid cells. Among myeloid cells, dendritic cells (DCs) are critical for the induction of protective immune responses. In DCs, MVA infection leads to vaccine antigen expression, but paradoxically also to cell death. How DCs sense and respond to MVA infection remains incompletely understood. We have studied the immune response of human monocyte-derived DCs (MDDCs) to MVA and compared it to HIV-1 with Vpx a well-establish model of cGAS-dependent sensing in MDDCs.
Methods: Monocyte-derived DCs (MDDCs) were generated from healthy donors. We overexpressed a dominant-negative IRF3 (IRF3DN) and silenced cGAS using shRNA containing lentivectors. MDDCs were infected with MVAGFP or HIVGFP. CD86, Siglec-1, GFP and cytokine expression were analyzed by FACS.
Results: We found that CD86 was induced on uninfected bystander DCs, while it was downregulated on MVA-infected DCs. IRF3DN inhibited DC activation by MVA and HIV. In contrast, cGAS depletion only modestly decreased DC re-

sponse to MVA, while it abrogated the DC response to HIV. Cross-talk between MVA-infected and bystander DCs was mediated by soluble factors. Using blocking antibody cocktails, we showed that transactivation partially required type I IFN, and also additional JAK/STAT pathways. Unexpectedly, we found that MVA did not replicate in DCs, while it did in control HeLa cells. We identified a restriction factor responsible for blocking MVA replication in DCs. Alleviating this restriction increased MVA antigen expression in DCs.
Conclusions: Our results highlight the interplay between infected and bystander human DCs in response to MVA. Interestingly, our results show that MVA antigen production in DCs is largely compromised by the activity of a restriction factor. Altogether, these insights may help to improve MVA as a HIV vaccine vector.

TUPEA0106

Plasmacytoid dendritic cells (pDC) produce Interferon-λ intrinsically, whereas BDCA3⁺ DC rely on cellular cross-talk, in response to HIV-1 and HIV-2

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Background: Interferons (IFN)-lambda1, 2 and 3, also called IL-28A, IL-28B, and IL-29, constitute the Type III IFN family. They display antiviral properties similar to those of type I IFN, but use a different receptor. Polymorphisms in the IFN-λ2 gene were correlated with responsiveness to HCV infection treatment and with spontaneous clearance and IFN-λ was tested for HCV therapy. Despite this important role in a major chronic viral infection, IFN-λ responses to HIV have not been studied. We studied these responses to HIV-1, which induces AIDS in most infected patients in the absence of antiretroviral treatment, and to HIV-2, which is less pathogenic because of a different host-virus interaction which needs better understanding.
Methods: We isolated PBMC from cytapheresis residues obtained from healthy donors by the Etablissement Français du Sang. We sorted them by flow cytometry into pDC, BDCA1⁺ DC and BDCA3⁺ DC. We stimulated them, either unseparated or as sorted populations, for 18 h with replicative HIV-1 (NL4.3) or HIV-2 (GLAN), compared to a RNA-virus, Influenza-A/PR8, a DNA-virus, HSV-1, both well-known to induce IFN-α and -λ, or to Toll-like receptor (TLR)-3 (polyI:C) or -7/8 (R848) ligands. We assessed IFN mRNA transcription by RT-qPCR, measured IFN secretion by ELISA, and intracellular production using flow cytometry.
Results: After stimulation of PBMC with HIV-1 or HIV-2, we detected IFN-α and to a lesser extent IFN-λ in the supernatants. Large amounts of IFN-α and -λ were detected after polyI:C, influenza or HSV stimulation, and weak amounts after R848 stimulation. Flow cytometric analysis demonstrated that among PBMC, HIV1 and HIV2 induced the production of IFN-λ by pDC and BDCA3⁺ DC. However, when using sorted cells, HIV-1 and -2 induced the production of IFN-λ only by pDC. Despite some variability, transcription of IFN-α, -λ1 or -λ2/3 mRNA followed similar patterns as protein production.
Conclusions: This is the first study evidencing IFN-λ production by human pDC and BDCA3⁺ DC after in vitro stimulation by HIV. HIV-1 and HIV-2 induced IFN-λ expression and secretion in PBMC. The ability to produce IFN-λ in response to HIV-1 or -2 is cell-intrinsic for pDC but relies on cellular cross-talk for BDCA3⁺ DC.
Support: ANRS, IBEID

TUPEA0107

Comparison of genital tract immune mediators between HIV-infected and HIV-uninfected Malawian women randomized to the depot medroxyprogesterone acetate injectable or levonorgestrel implant

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Background: Studies suggest that the depot medroxyprogesterone acetate (DMPA) injectable, but not other progestin-only contraceptives, may increase the risk of HIV acquisition and transmission. The biological mechanisms may include local immune alterations in the genital tract. We therefore compared changes in soluble immune mediators between HIV-infected and HIV-uninfected Malawian women randomized to DMPA or the levonorgestrel (LNG) implant.
Methods: Between May 2014-April 2015, we randomized 97 women (73 HIV-infected, 24 HIV-uninfected) to DMPA or LNG implant. We obtained samples at 6 time points: 2 prior (follicular/luteal phase) and 4 after contraceptive initiation (day 3; months 1, 3, 6). ELISA and Luminex were performed on cervicovaginal lavage (CVL) samples to measure 19 immune mediators. Baseline values were calculated as the mean of the follicular and luteal phase samples. The following comparisons were performed using the nonparametric Wilcoxon-Mann Whitney test:
1) Baseline levels between HIV-infected and HIV-uninfected women,
2) Immune marker levels at day 3 and 6 months after contraceptive initiation between HIV-infected and HIV-uninfected women, and;
3) Differences at each time point from baseline between DMPA and LNG implant users.
Results: At baseline, HIV-infected had higher CVL levels of CXCL-10 (p=0.036), BD-3 (p=0.002), and IL-1a (p=0.009) when compared with HIV-uninfected women. LNG implant initiation did not result in significant differences in any mediators between HIV-infected and HIV-uninfected women at day 3 or month 6. However, DMPA initiation led to reduced CVL levels of CXCL-10 (p=0.043), IL-6 (p=0.024), TNF-a (0.002), and GM-CSF (p=0.029) in HIV-infected women at day 3 (but not month 6), which was not seen among HIV-uninfected women. Among HIV-infected women (but not HIV-uninfected women), DMPA compared with LNG implant was associated with a decrease in 8 different immune mediators after contraceptive initiation. None of the comparisons remained significant after Bonferroni correction (p>0.0006).
Conclusions: Among HIV-infected women, changes in some CVL immune mediators were observed after contraceptive initiation in the DMPA, but not the LNG implant arm. The decreases were mostly of inflammatory cytokines. While our sample size is small, these results are generally reassuring regarding the genital effects of DMPA over 6 months of use, particularly among HIV-uninfected women.

TUPEA0108

Seminal plasma exposures strengthen vaccine responses in the female reproductive tract mucosae

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Background: HIV-1 sexual transmission occurs mainly via semen exposures. Seminal plasma (SP) induces physiological modifications, including inflammation, in the female reproductive tract (FRT) mucosae. An effective HIV vaccine should elicit mucosal immunity. However, modifications of vaccine responses by local environment remain to be characterized. The aim of this study was to determine whether HIV-1⁺ SP has an impact on the local immune responses in a vaccination context.
Methods: Twelve female cynomolgus macaques were vaccinated by two subcutaneous inoculations of the ANRS-MVA-HIV B, used as a vaccine model. Two weeks after the second vaccine inoculation, animals received four intravaginal inoculations of PBS (n=6) or SP pool from HIV-1⁺ individuals (n=6). Immune composition and vaccine responses were analysed in the blood, lymph nodes and FRT compartments, by flow cytometry, ELISA and transcriptomic analyses.
Results: Tissue characterisation by cytometry and transcriptomic approaches highlighted the compartmentalisation of the immune cell distribution in the FRT. Specific anti-MVA CD8⁺ T cells were characterized in all the FRT compartments. Anti-MVA IgG/IgA were detected in vaginal fluids after the second vaccine inoculation.
Multiple HIV-1⁺ SP exposure did not impact the anti-MVA antibody responses. Interestingly, SP exposures induced local cell recruitment of antigen presenting cell (APC), especially CD11c⁺ cells; and CD8⁺ T cells recruitment in the FRT draining lymph nodes. Analyses of differentially expressed genes confirmed the impact of SP exposures on cell recruitment in the cervix and the draining lymph nodes. The frequency of specific anti-MVA CD8⁺ T cells increased, especially in the cervix. Furthermore, anti-MVA response quality enhanced in the FRT exposed to SP since percentage of polyfunctional CD8⁺ T cells (IFNγ, MIP1β, TNFα and IL-2 production) increased. Interestingly, SP exposures revealed an anti-MVA response mediated by CD4+ T cells, which was not observed in the control group.
Conclusions: Our results clearly show a local recruitment of APCs and an increase of the frequency and quality of the specific immune responses within the FRT after HIV-1⁺ SP exposures. These data highlight the fact that physiological conditions, such as SP exposures, should be taken into consideration to test and to improve vaccine efficacy against HIV-1 and other sexually transmitted infections.

TUPEA0109

Mucosal neutrophil activation is associated with gastrointestinal and systemic T-cell activation

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Background: HIV disease progression, comorbidities, and mortality are associated with mucosal dysfunction and systemic inflammation. However, the mechanisms underlying these dysfunctions are not resolved. Neutrophils infiltrate the gastrointestinal (GI) tract during HIV infection, yet their contribution to inflammation is unknown. In inflammatory bowel disease, activated neutrophils contribute to tissue damage and disease pathogenesis. In HIV, blood neutrophils expressing high levels of PD-L1 suppress T-cell function and correlate with T-cell exhaustion. However, neutrophil phenotypes in the GI have yet to be examined during HIV . Our study assessed neutrophil activation and whether suppressive neutrophils are present in the GI in HIV infection. Additionally, we determined how these neutrophil states associate with markers of GI and systemic T-cell dysfunction known to contribute to HIV disease progression.
Methods: Isolated leukocytes from colon biopsies taken from treated, HIV-infected (n=14) and uninfected (n=11) individuals were phenotyped by flow cytometry to examine the expression of CD11b (activation) and PD-L1 (suppression) on neutrophils, and CD38 (activation) and PD-1 (exhaustion) on colon and blood T-cells.
Results: We found increased CD11b expression on GI neutrophils from HIV-infected indviduals compared to uninfected controls (p=0.0128). Importantly, GI neutrophil activation levels positively correlated with the percentage of CD8 and CD4 T-cells expressing CD38 in both the GI and blood (p< 0.01). Furthermore, we found a decrease in suppressive (PD-L1+) neutrophils in the GI tract (p= 0.0457), which may contribute to aberrant T-cell activation during HIV infection, as these myeloid-derived suppressor cells (MDSC) are known to regulate T-cell activation.
Conclusions: Overall, these are the first quantitative data demonstrating neutrophil infiltration in the GI tract of HIV-infected individuals, and that GI neutrophil activation may play an important role in contributing to GI tissue damage and T-cell activation in HIV infection. These data also increase our understanding of the relationship between neutrophils in the blood and GI mucosa and importantly, how neutrophils in these compartments differ in their phenotypes and their likely functional interactions with the immune system. It will be important to better understand whether these neutrophils contribute to local tissue damage and systemic biomarkers of disease progression, and studies are currently underway to assess this.

TUPEA0110

T cell immune exhaustion in gut-associated lymphoid tissue during treated primary HIV infection: implications for HIV persistence

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Background: Early ART in primary HIV infection (PHI) limits both HIV reservoir size and immune dysfunction in blood. Gut-associated lymphoid tissue (GALT) harbours the largest anatomical HIV-1 reservoir and supports viral persistence. Exhausted CD4+T-cells are enriched for HIV-1 DNA in peripheral blood. Furthermore, CD4+ and CD8+ T-cell exhaustion predict disease progression and viral rebound on treatment cessation. The significance of exhausted T-cells in tissue is less clear.
This study investigates the expression of immune exhaustion markers in GALT and the relationship with their expression in peripheral blood (PBMC).
Methods: Gut biopsy samples from terminal ileum (TI) and rectum were collected from HIV+ virally suppressed individuals enrolled in HEATHER, an observational study of treated PHI. Biopsy tissue was processed by collagenase digestion. Lineage (CD3, CD4, CD8) and exhaustion (PD-1, Tim-3, TIGIT) marker expression were assessed on mucosal mononuclear cells and PBMCs by flow cytometry. Comparisons were made with healthy control GALT.
Results: 26 individuals were included in this analysis; 13 HIV+ individuals and 13 controls. Significantly lower CD4/CD8 ratio was noted in HIV+ TI GALT compared to controls (p=0.03), but not in rectal GALT.
Overall, exhaustion marker expression (PD-1, TIGIT & Tim-3 on CD4+T-cells and Tim-3 & PD-1 on CD8+T-cells) was significantly higher in GALT compared to PBMC (all p<0.01) HIV+ GALT had significantly higher CD4+PD-1+ (p=0.02) and CD4+TIGIT+ (p<0.01) expression compared to controls. Among HIV+ individuals CD4+PD-1+ (p=0.01), CD4+TIGIT+ (p=0.03) and CD4+Tim-3+ (p=0.02) was significantly higher in rectum compared to TI.
CD8+TIGIT+ was higher in HIV+ GALT than HIV- GALT (p=0.01), with this difference most marked in the TI (p=0.04).
Expression of exhaustion markers PD-1, TIGIT and Tim-3 on CD4+ and CD8+ T-cells in rectal GALT correlated with TI GALT, but no significant correlation was observed between markers of exhaustion measured in either GALT site compared to PBMC.
Conclusions: Differential expression of T-cell exhaustion markers by anatomical compartment may reflect and support varying levels of HIV persistence in GALT despite early ART initiation in PHI. Measurement of immune exhaustion markers in blood does not reflect expression in GALT and highlights the importance of tissue sampling in HIV cure studies.

TUPEA0111

Impaired genital wound-healing pathways in women experiencing chronic sexual abuse: implications for HIV acquisition

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Background: Sexual violence is associated with increased risk for HIV acquisition/transmission in women. Chronic exposure to sexual abuse can result in genital tract trauma and psychosocial stress subsequently affecting immune functions. Specifically, HIV susceptibility can be enhanced if genital epithelium is wounded as a consequence of sexual assault and wound-healing pathways are impaired. We hypothesized that levels of specific immune mediators that play a role in wound healing will be dysregulated in women experiencing chronic sexual abuse.
Methods: Using the Women's Interagency HIV Study (WIHS) repository, we identified 4 groups of HIV+ and HIV- women (8-10/group) representing chronic sexual abuse exposure and depression (CES-D score > 16): 1) no history of sexual abuse at baseline or depression (Control); 2) no history of sexual abuse at baseline but current depression (Depression); 3) chronic sexual abuse but no depression (Abuse); 4) chronic sexual abuse with current depression (Abuse+Depression). Endogenous growth factors (PDGF, VEGF, EGF, FGF, IGF) and cytokines (TGF-beta, Gro-alpha) that are critical for wound healing functions, were analyzed in cervical-vaginal lavage (CVL) by ELISA assay. Linear regression was used to model levels of biomarkers with both depression and abuse as predictors. Models were run separately for HIV+ and HIV- women, with CD4 counts and viral load as covariates for HIV+ group.
Results: In HIV- women reporting chronic sexual abuse and depression, we found significantly lower levels of platelet-derived growth factor (PDGF) (p< 0.01) and transforming growth factor beta (TGF-beta) (p< 0.01), compared to Control. The associations were maintained after adjusting for total protein content of CVL. There were no significant changes in these growth factors and cytokines within the HIV+ groups. However, Control HIV+ women had significantly lower levels of PDGF compared to Control HIV- women indicating an effect of HIV status.
Conclusions: PDGF and TGF-beta are critical initiators of wound healing response and exogenous PDGF is FDA approved to treat non-healing ulcerative wounds. Our data indicate genital wound healing might be impaired in women who experience chronic sexual abuse. As wounds in genital epithelium can allow easier access to HIV and other pathogens, specific interventions might be explored in these women to promote healing.

TUPEA0112

Distribution and phenotype characterization of HIV-specific CD8 T cells *in situ* in the rectal mucosa of HIV+ elite controllers

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Background: Mucosal tissues including the gastrointestinal tract are important reservoirs for HIV replication. HIV-specific CD8 T cells are essential in controlling HIV infection. Elite controllers (EC) can suppress the viral replication without treatment and represent less than 1 % of the HIV-infected population. In order to gain insights into HIV-specific CD8 T cells in EC, we characterized this important cell population in rectal mucosa of HIV+ EC.
Methods: Rectal biopsies from EC were collected and stained using in situ tetramer staining combined with immunohistochemistry. Distribution and phenotypes of tetramer+ HIV-specific CD8 T cells were characterized by confocal microscopy and quantitative analysis.
Results: Results showed that tetramer+ HIV-specific CD8 T cells distributed unevenly throughout the rectal mucosa including within lymphoid aggregates. Frequencies of tetramer+ HIV-specific CD8 T cells ranged from 2 to 25 cells/mm^2. A mean of 45% tetramer+ HIV-specific CD8 T cells did not express the effector protein perforin. Of the 55 % tetramer+ HIV-specific CD8 T cells were positive for perforin, the majority expressed low to medium levels of perforin and relatively few expressed high levels.
In addition, we also observed a subset of perforin+ HIV-specific CD8 T cells in which perforin was located exclusively within the cell membrane, possibly representing a novel subset of armed resident or effector memory cells. Almost all tetramer+ HIV-specific CD8 T cells in the rectal mucosa were negative for Ki67, a marker for activation and proliferation (mean of 96%); a mean of 59% of tetramer+ HIV specific CD8 T cells in rectal mucosa were PD-1+, a marker for recent T cell stimulation or exhaustion (mean of 59%), and some expressed CD103, a marker for a subset of resident memory T cells (mean of 6%).
Conclusions: Taken together, these findings suggest that EC maintain diverse populations of memory HIV-specific CD8 T cells distributed throughout the rectal mucosa including within lymphoid aggregates and suggests that these cells are likely continually being exposed to antigen, but not dividing.

TUPEA0113

Sexually transmitted infections (STIs) increase levels of cytokine and cellular biomarkers of HIV risk

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Background: Recent studies of women at high risk of HIV infection have demonstrated that increased concentrations of inflammatory cytokines in the female reproductive tract can increase the risk of HIV acquisition. Here, we investigated an association between STI and genital inflammation; and whether genital inflammation is characterised by high levels of HIV target cell recruitment and immune cell activation.
Methods: The concentrations of 48 cytokines were measured by multiplex ELISA in cervicovaginal lavage samples (CVLs) collected from 166 high risk HIV-uninfected women participating in the CAPRISA 008 trial. In addition, genital T cell immune activation status [CD38+/HLA-DR+] and HIV target cell frequency (CD4+CCR5+) were investigated in cervical cytobrushes by flow cytometry. Genital swabs were screened for Neisseria gonorrhoeae, Chlamydia trachomatis, Trichomonas vaginalis and Mycoplasma genitalium by PCR.
Results: No correlations were observed between immune cell activation and either individual cytokines or genital inflammation in the 166 participants. However, women with high levels of immune activation had elevated frequencies of CD4+CCR5+ T cells compared to women with low levels of immune activation (p< 0.0001). Women infected with C. trachomatis had significantly higher frequencies of CD4+CCR5+ cells compared to women without any STIs (p=0.0040). Higher prevalence of C. trachomatis (p=0.0034) or T. vaginalis (p=0.0024) was observed in women with genital inflammation compared to those without inflammation.
Conclusions: Our findings suggest that STIs play a crucial role in cellular recruitment of target cells and are potential drivers of inflammation and immune activation in the genital tract and may foster an environment conductive to HIV acquisition.

TUPEA0114

Potential immune mechanism for the relationship between HIV risk and multiple concurrent HPV infections

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Background: In Sub-Saharan Africa women are disproportionately affected by both human papillomavirus (HPV) and HIV. Concurrent infection with multiple HPV strains has commonly been implicated as a risk factor for HIV acquisition, but the biological mechanism for this remains unclear. Here we investigated whether pro-inflammatory immune responses associated with multiple HPV infections contribute to a genital immune environment conducive to an increased risk of HIV infection.
Methods: This study included a baseline assessment of 133 women of the CAPRISA 008 trial, aged between 18-40 years, and all without PCR evidence of common STI (Trichomonas vaginalis, Chlamydia trachomatis, Neisseria gonorrhoeae, and Mycoplasma genitalium). The Roche Linear Array was used to detect the presence of HPV genotypes. The frequency of highly activated (CD38+ and/or HLA-DR+) T cells were assessed on cervical cytobrush-derived specimens by multiparametric flow cytometry. Multiplex ELISA was conducted at baseline to detect the concentrations of 48 different cytokines in the CVL supernatant.
Results: The prevalence of HPV in the population was 50.9% (95% CI 43.2-58.5), with 44% of women presenting with multiple HPV strains at the genital tract. HPV infected women had a greater frequency of lymphocytes compared to uninfected women, even after adjustment for multiple comparisons (p=0.0132). Infection with multiple HPV types predicted significant increases in lymphocyte (β=3.3%; p=0.021) and HLA-DR+ CD3+ T cell frequencies (β=3.0%; p=0.04). In addition, infection with multiple HPV types was associated with increased concentrations of the chemokine RANTES (β=14.1pg/ml; p=0.041).
Conclusions: Concurrent infection with multiple HPV strains is associated with increased frequencies of activated immune cells, and with increased concentrations of the chemokine responsible for HIV target cell recruitment. These data suggest a potential biological mechanism for the relationship between HIV risk and infection with multiple HPV types.

TUPEA0115

Degranulating immune cells are associated with higher viral load at cervico-vaginal surface of HIV-infected women in India

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Background: Heterosexual contact is the most predominant mode of HIV transmission in women, accounting a global annual estimate of 30-40%. It is important to understand the local factor(s) contributing towards HIV immunopathogenesis at female genital mucosa. Hence we characterized the cellular immune components at the cervicovaginal mucosa and determined their association with cervical viral load (VL) and CD4 count.
Methods: HIV seropositive women (n=37) including 29 progressors & 8 LTNPs, and seronegative women (n=24) in their premenopausal phase were enrolled. Cervico-vaginal lavage (CVL) and cytobrush samples were collected. CVL from HIV infected women was used to determine the viral load. From the cytobrush, mucosal mononuclear cells were separated and stained for various markers to identify the effector cells (natural killer [NK], DCs, CD4+ and CD8+T cells) and their degranulation using flowcytometry. Samples were acquired on FACSAria and analyzed. Their association with cervical VL and CD4 count was determined using Spearman-Correlation test.
Results: Higher frequencies of CD8+T cells and lower frequencies of CD4+T cells were found in HIV-infected women than HIV-ve women (p<0.05), while the frequencies of DCs, mDCs and pDCs remain unchanged at the cervicovaginal mucosa. Among NK cell subsets, frequency of only defective NK cells (NK_{def}) was

higher in both progressors and LTNPs than HIV-ve women. Though total NK, cytotoxic NK (NK_{cyt}) and regulatory NK (NK_{reg}) cell frequencies were similar in all study groups, the expression of CD107a on all NK subsets was higher in HIV-infected progressors than both LTNPs and HIV-ve women (p<0.05).
Further the frequency of CD107a expressing CD4+T cells was higher in HIV-infected progressors than the HIV-ve women. CD107a expressing CD4 and NK_{def} cells were inversely associated with CD4 count (r=-0.46; p<0.02 & r=-0.55; p<0.004 respectively). CD107a expressing T cells were significantly associated with cervical VL (r=0.62; p<0.003 & r=-0.59; p<0.005 respectively), while CD107a expressing NK_{reg} and NK_{cyt} were found to be associated with cervical VL close to significance level (r=0.43; p<0.057 & r=-0.43; p<0.056 respectively).
Conclusions: Degranulating NK and T cells at the mucosal surface of female genital mucosa are associated with higher cervical viral load and lower CD4 count and may contribute towards increased HIV transmission.

TUPEA0116

Early antiretroviral therapy (ART) initiation improves gut mucosal immunity in SIV-infected Chinese rhesus macaques

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Background: Both HIV and SIV infections result in higher immunosuppressive regulatory T-cells (Tregs) frequency, rapid CD4 T-cells depletion and increased immune activation in gut mucosal tissues, beginning in early infection. Here, we assessed the dynamic of gut mucosal CD4 T-cells following early ART initiation in SIV-infected monkeys.
Methods: Nine outbred, Chinese-origin, female rhesus macaques were infected with SIVmac251 virus (20 AID_{50}) intravenously. The ART cocktail contained reverse transcriptase inhibitors Tenofovir (20 mg/kg) and Emtricitabine (20 mg/kg), protease inhibitors Indinavir (2 mg/kg) and Ritonavir (20 mg/kg), and integrase inhibitor Raltegravir (20 mg/kg). ART was initiated at day 3 post-infection and administered once daily via the subcutaneous route. Four ART-treated monkeys were sacrificed at days 11, 14, 27 and 35 post-infection. In three monkeys, ART was interrupted after 53 days of treatment and animals were sacrificed at days 10, 15 and 18 post ART-interruption. Two monkeys remained untreated and were sacrificed at days 33 and 60 post-infection. Mucosal cells were freshly isolated via mechanical purification from ileum, jejunum, colon as well as mesenteric lymph nodes. Mucosal CD4 T-cells were characterized by multi-parameter flow cytometry in comparison with matched peripheral blood samples.
Results: As expected, CD4 depletion was observed in untreated animals. Early ART initiation resulted in a decreased frequency of total Tregs (FoxP3+) and Tregs expressing immunosuppressive ectonucleotidase CD39 - also known as a marker of immune activation - compared to untreated animals in both blood and gut mucosal tissues. Early ART also reduced the frequency of CCR6+ memory CD4 T-cells, suggesting a lower CD4 recruitment in gut mucosal tissue. Furthermore, early ART diminished CD8+CD39+ T-cells as a cellular marker of immune activation linked to the local viremia within the gut. ART-interruption resulted in an increase in frequencies of total and CD39+ Tregs, CCR6+ memory CD4 T-cells and CD8+CD39+ cells in gut mucosal tissues.
Conclusions: Initiation of ART within the first few days of SIV-infection of Chinese rhesus macaques improved gut mucosal immunity by decreasing immunosuppressive Tregs, immune activation and CD4 T-cells recruitment, which in turn could reduce the fuel of local viral reservoirs.

TUPEA0117

PD-1, KLRG1, and Eomesodermin^{High} as potential markers of CD8$^+$ T-cell exhaustion in rectal mucosa during chronic HIV infection

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Background: T-cell exhaustion (T_{EXH}) is a hallmark of chronic HIV-1 infection. As the rectal mucosa is an important site of HIV pathogenesis and rectal CD8$^+$ T-cells differ functionally and phenotypically from blood, understanding T_{EXH} in this compartment may inform the development of therapeutics aimed at blocking exhaustion pathways to boost the immune response. Co-expression of PD-1 and Eomesodermin (Eomes^{High}) has been associated with terminally exhausted T-cells that retain some cytotoxic potential. We previously observed increased Eomes expression in rectal CD8$^+$ T-cells from HIV$^+$ individuals not on antiretroviral therapy (ART) compared to those on ART (Kiniry et al., 2016), and hypothesized this might indicate greater T-cell exhaustion.
Methods: To elucidate the co-expression of Eomes with inhibitory receptors on mucosal Gag-specific CD8$^+$ T-cells, flow cytometry was used to assess KLRG1, PD-1, Tim-3, and 2B4, along with transcription factors T-bet and Eomes on rectal CD8$^+$ T-cells from HIV+ and HIV- adults. Functionality was assessed in a 6h ex vivo assay, stimulating with DMSO, HIV Gag peptides, or Staphylococcal Enterotoxin B, and staining for CD107a, IFNγ, TNFα, perforin and Granzyme B.
Results: Expression of PD-1 and KLRG1, but not Tim-3 or 2B4, was significantly greater in HIV$^+$ Non-Controllers and Controllers compared to ART-treated and HIV- adults. Furthermore, HIV$^+$ Controllers undergoing ART had reduced expression of exhaustion markers compared to Controllers not on treatment. KLRG1 and PD-1 expression were positively correlated with an Eomes^{High} phenotype and CD8$^+$ T-cells co-expressing these molecules were elevated in Non-Controllers and Controllers compared to all other groups. Expression of Perforin and GrzB, although significantly lower in gut compared to blood, were positively correlated with PD-1 expression, and Gag-specific degranulating CD8$^+$ T-cells tended to be Eomes^{High}PD-1$^+$.
Conclusions: Through co-expression of PD-1, KLRG1, and Eomes^{High}, Gag-specific rectal CD8 T-cells displayed an ‚exhausted' phenotype. Nevertheless, they appeared to retain some functionality, suggesting a spectrum of T-cell activation and dysfunction that remains to be fully elucidated. As the mucosa houses a large fraction of tissue-resident CD8$^+$ T-cells with characteristically low KLRG1 expression, KLRG1 may be an especially valuable marker of mucosal T-cell dysfunction. Further exploration of factors that differentiate T-cell dysfunction from activation is warranted.

TUPEA0118

Enhancement of HIV-1 spreading and persistence by MIF/CD74 interaction in primary monocyte-derived macrophages (MDM) and CD4$^+$ T-lymphocytes (CD4TL) in vitro

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Background: Understanding the mechanisms involved in HIV-1 infection would facilitate the identification of new therapeutic targets to control the infection in the face of HAART limitations. CD74 membrane expression is up-regulated in infected cells during HIV-1 infection and correlates with immune hyperactivation in HIV-infected individuals. Additionally, plasma level of CD74 activating ligand MIF (Macrophage Migration Inhibitory Factor) is increased in infected subjects. However, the role played by MIF/CD74 interaction in HIV pathogenesis remains unexplored.
Aim: to study the effect of MIF/CD74 interaction in primary HIV-infected monocyte-derived macrophages (MDMs) and CD4$^+$ T-lymphocytes (CD4TLs).
Methods: CD4TL and MDMs were obtained from healthy donors. MDMs were infected, with a R5-tropic HIV-1 virus, and stimulated with MIF concentrations ranging from 1 to 200 ng/ml. Cytokine production and Toll-like receptor 4 (TLR4) expression were measured. Resting CD4TLs were treated with MDM supernatants or exogenous cytokines to evaluate stimulation of permissiveness to X4-tropic HIV-1 infection by p24 quantitation. Cell death was measured by flow cytometry in infected and MIF-treated CD4TLs. Data analysis was performed by parametric methods.
Results: Treatment of infected MDMs with MIF resulted in a dose-dependent increase in IL-6, IL-8, TNFα, sCD23 and sICAM production (p=0.006; p=0.013, p=0.0003, p<0.0001, p=0.022, respectively) compared to untreated cells. Similarly, there was a MIF-driven 2-fold increase in TLR4 expression. By using an anti-CD74 antibody, MIF/CD74 interaction was blocked and these effects were reverted. Treatment of quiescent CD4TL with MIF-treated MDM-derived culture supernatants led to an enhanced permissiveness to HIV-1 infection manifested as 2-fold increase in viral production. MIF itself induced enhanced permissiveness to HIV infection in a dose-dependent manner. This effect was recapitulated by exogenous addition of IL-6, IL-8, or IL1β. Moreover, MIF stimulation reduced the percentage of necrotic cells within the HIV$^+$ population by 50% compared to unstimulated infected cells (p=0.0006).
Conclusions: These findings indicate that MIF/CD74 interaction in infected MDMs contributes to the generation of an inflammatory microenvironment. This effect enhances resting CD4TL permissiveness to HIV infection, viral replication and spreading. Moreover, MIF also increases HIV-infected CD4TL survival, contributing to viral persistence. Overall, these results support a novel role for the MIF/CD74 axis in HIV pathogenesis.

TUPEA0119

Expression and role of chemokine fractalkine in HIV neuro-pathogenesis: a new approach to understand and treat HAND

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Background: HIV infection of microglia and astrocytes causes release of neurotoxic viral proteins with a neuro-inflammatory environment. Clinically, this results in HIV-associated neurocognitive disorders (HAND) with an uncontrolled prevalence in treated individuals. The objective is to shed light on HAND pathogenesis by studying the interactions of HIV with neuroprotective factors. We focus on fractalkine, an anti-inflammatory chemokine highly produced by neurons that controls microglia neurophysiologic functions and reduces neuronal apoptosis. We hypothesize a potential modulation by HIV affecting HAND severity.
Methods: Human astrocytes were infected and/or stimulated with pro-inflammatory cytokines (IL-1β, IL-6, TNF, IL-8) and fractalkine measured by qPCR (RNA), bioluminescence (transfecting a luciferase-conjugated fractalkine promoter), ELISA (soluble form) and flow cytometry (membrane-anchored form). The enzymatic activity of ADAM-10, the metalloprotease responsible for fractalkine shedding, was evaluated with a fluorimetric assay. Infected macrophages were co-cultured with astrocytes to analyse fractalkine secretion upon cell contact. Microglia were infected and evaluated for fractalkine receptor expression and their responses to fractalkine (MAPK phosphorylation by Western blot and production of neurotoxic products by ELISA).
Results: First, we did not see any differences in terms of fractalkine expression/secretion upon infection. Nonetheless, we saw a concentration dependant increase in TNF or IL-1β treated astrocytes. Surprisingly, we obtained a potent impact of HIV on TNF and IL-1β stimulating potential; a decrease in fractalkine secretion and an increase in the membrane-anchored form in infected and stimulated cells (compared to non-infected and stimulated cells).
We used ADAM-10 inhibitor GI-254023X to demonstrate the role of this enzyme in fractalkine shedding in astrocytes, and observed a reduced ADAM-10 activity in infected astrocytes. MTS assays confirmed cell viability. Establishment of infected macrophages/astrocytes co-cultures enhanced fractalkine secretion by astrocytes, possibly by cell contact. At last, HIV reduced fractalkine receptor expression in microglia/macrophages.
Conclusions: In conclusion, our results indicate a new and clear impact of HIV on fractalkine secretion in astrocytes (by ADAM-10) and receptor expression in microglia. Considering anti-inflammatory functions of fractalkine, reducing its shedding and functional responses in microglia could have important outcomes/implications in chronic inflammation and immune activation for HAND. Overall, intervention with fractalkine-based treatment could offer neuroprotection and reduce HAND severity.

TUPEA0120

Fatty acid profiles altered by HIV infection persist despite suppressive antiretroviral therapy (ART) and are associated with immune activation in the ACTG 5248 study

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Background: HIV infection and ART alter lipid profiles. Among HIV-infected (HIV+) populations the concentrations of various lipid classes (i.e. ceramides, lysophosphatidylcholine, LPC) and their saturated (SaFA), monounsaturated (MUFA), and polyunsaturated fatty acid (PUFA) composition are related to inflammation and cardiovascular disease risk. Associations among changes in the lipidome and immune activation in persons initiating ART have not been described.
Methods: Plasma concentrations (μM) of lipid species (N=1,300) and FA composition (mol%) were measured by differential mobility spectroscopy (TrueMass Complex Lipid Panel, Metabolon), and markers of inflammation were measured by ELISA in plasma samples from HIV+ participants initiating raltegravir (RAL) based ART (N=35, baseline and week 48), and from HIV-individuals (N=13) of similar demographics. All analyses (paired t-tests, 2-sample t-tests, and Pearson correlations) were exploratory.
Results: Compared to levels in HIV- donors, the plasma concentrations of multiple lipid species are altered in HIV+ persons pre-ART (32.2% increased, 4.9% decreased, p<0.05) and at 48 weeks of ART (29.6% increased, 2.2% decreased, p<0.05). Levels of PUFAs (including 18:3, 20:4, and 20:5) are enriched in HIV- donors compared to HIV+ donors pre-ART (p<0.01); levels of these PUFA species increased by 48 weeks of ART. Levels of SaFAs (including 16:0 and 18:0) tend to be enriched in HIV+ participants (pre-and post-ART). Levels of palmitic acid (16:0) were positively correlated with levels of IL-6, sCD14, and TNFR1 at baseline and week 48 (p<0.02 for all). LPC levels are increased in HIV+ participants, both pre- and post-ART vs HIV- participants (204 μM, 216 μM, and 184 μM, p=0.003, p<0.001), and the composition of LPC is enriched for SaFAs (16:0 and 18:0) among HIV+ individuals. Also at baseline and week 48, several LPC molecules containing SaFAs were positively correlated with sCD14, D-dimer, and TNFR1 (p<0.01, for all) and levels of PUFA containing LPC (18:3, 20:5, 22:5, 22:6) were positively correlated with CD4 counts and inversely correlated with sCD14 and IL-6 (all p<0.01).
Conclusions: The composition of the lipidome is altered in HIV-infection and changes with ART. Alterations in SaFAs were generally associated with inflammatory markers and may contribute to immune activation and comorbid disease pathogenesis.

TUPEA0121

IP-10 and IL-18 are good markers of persistent inflammation in HIV-1 elite controllers

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Background: Elite controllers are rare individuals able to natural control of HIV replication below the detection limit of commercial assays. Some studies have pointed a higher immune activation and/or inflammation in elite controllers when compared to HIV negative individuals, whereas others have found no significant differences between both groups. Answer this question is essential to help in the decision to start or not cART or other non-specific HIV therapy in elite controllers.
Methods: We used ELISA assays to evaluate the plasmatic levels of IP-10, IL-18, sCD163, sCD14, CRP and IL-6. The frequency of CD8+CD38+HLA-DR+ T cells was evaluated by flow cytometry. The analyses were performed in 16 elite controllers (eight with persistent undetectable viremia [EC] and eight with occasional viral blips [EEC]), 12 viremic controllers (VC - plasma viral load between 80-2000 RNA copies/ml), 15 cART-treated patients (cART- with >5 years of viral load suppression) and 15 HIV-negative individuals (HIVneg) from Rio de Janeiro/Brazil. All EC, EEC and VC have at least four years of follow-up. The Mann-Whitney test and Spearman correlation were used for statistical analyses.
Results: Among the plasmatic markers evaluated, the levels of IP-10 and IL-18 in VC and EEC were higher than in HIVneg (P <0.005) and in EC (P <0.005), but not significantly different between EC and HIVneg. The cART group showed higher IP-10 and sCD163 levels than HIVneg and EC (P < 0.05). We found a positive correlation between CD8+ T cell activation and the IP-10 (P = 0.0009; R = 0.4252) and IL-18 (P = 0.0019; R = 0.3987) levels. The sCD14, CRP and IL-6 levels were similar among all groups.
Conclusions: Our results showed that IP-10, IL-18 and sCD163 are important markers for evaluating persistent inflammation in the setting of undetectable viremia in both HIV controllers and cART-treated patients. The high IP-10 levels observed in cART-treated individuals indicate that therapies, other than cART, should be considered to reduce chronic inflammation in elite controllers.

TUPEA0122

Combination antiretroviral therapy has minimal effect on the HIV-associated expansion of adaptive, memory-like NK cells and NK cell activation

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Background: Innate immune dysfunction persists in HIV+ individuals despite effective combination antiretroviral therapy (cART) and is thought to contribute to the increased risk of chronic non-AIDS disease. We recently demonstrated that an

adaptive CD56dim NK cell population lacking the signal transducing protein FcRγ is expanded in HIV+ individuals. Here we used a longitudinal study to investigate the effect of suppressive cART on adaptive NK cells and on HIV-related NK and T cell activation.
Methods: We analyzed a cohort of HIV+ men who have sex with men (MSM, n=20) at baseline and following 6, 12 and 24 months of cART, and compared them with uninfected MSM (n=15) to investigate the impact of cART on NK cell dysfunction using immunophenotyping and mixed effects modelling.
Results: Proportions of HLA-DR+/CD38+ and CD69+ activated NK cells were elevated in cART-naïve HIV+ MSM (p=0.015 and 0.004, respectively), as were adaptive FcRγ- NK cells (p=0.003). Using latent growth curve modelling, we show that cART did not reduce levels of adaptive FcRγ- NK cells (p=0.115) or activated HLA-DR+/CD38+ NK cells (p=0.129) but did reduce T cell and monocyte activation (p< 0.001 for all). Proportions of adaptive FcRγ- NK cells were not associated with NK cell, T cell or monocyte activation, suggesting different factors drive adaptive NK cell expansion and immune activation in HIV+ individuals.
Whilst proportions of activated CD69+ NK cells declined significantly on cART (p=0.003), the rate of decline was significantly slower than that of T cell and monocyte activation, with 12 months of suppressive cART reducing 40% and 70% of CD4+ and CD8+ T cell activation respectively, but only 20% of CD69+ NK cell activation.
Conclusions: Levels of activated NK cells and adaptive, memory-like FcRγ- NK cells remain elevated in virologically suppressed HIV+ individuals for a minimum of 24 months after cART initiation with no evidence of decay over time. The persistence of NK cell activation and adaptive NK cell expansion after normalisation of other immune parameters indicates a reduced potency of cART against NK cell activation, and may have implications for the development of malignancies and chronic inflammatory disease in cART-treated HIV+ individuals.

TUPEA0123

Platelets of HIV-infected patients release a large amount of Growth-regulated Oncogence Alpha (GRO-a): a chemokine stimulating HIV replication

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Background: Platelets are not only cells involved in hemostasis, they are able to produce pro and anti-inflammatory cytokines, and may contribute to immune activation in HIV-infected patients. Our aim was to assess whether the ability of platelets to produce inflammatory cytokines was altered in HIV-infected patients compared to healthy blood donors.
Methods: We enrolled 94 HIV-infected patients, and 108 healthy blood donors. Plasma was collected and platelet-rich plasma samples were prepared by centrifugating peripheral blood at 150 × g for 10 min. Platelets were stimulated, or not, with thrombin receptor-activating peptide (TRAP-6, 50 µg/ml for 30 min). Soluble (s) CD40L, GRO-α, RANTES, and sCD62P were quantitated in platelet supernatants by Luminex® technology and concentrations of factors released by platelets were normalized for 3×10^8 platelets to enable comparisons. For each individual, the reactivity of platelets to thrombin stimulation was evaluated by calculating the ratio of cytokine concentration released after stimulation to the respective concentration observed without stimulation.
Results: Mean age was comparable between blood donors (49±12.7 years old) and HIV-infected patients (48.2 ±11 years old, p=0.599). Seventy-four patients (85.1%) were receiving antiretrovirals, 69 of them had an HIV-viral load under 40 copies/mL. No difference was observed for plasma concentrations of sCD62P, sCD40, GRO-a, and RANTES between HIV-infected patients and blood donors. In the same way, we did not evidence any statistical difference between platelets from HIV-infected patients compared to blood donors with regard to their ability to release sCD62P or sCD40L upon stimulation. However, TRAP-6 stimulation of platelets from HIV infected patients induced a 28.5-fold (±107) increase of GRO-a while only a modest 5.6-fold increase in blood donors (p=0.028). In addition, we also observed a higher, although not significant, increase of released RANTES level after platelet stimulation in HIV-infected patients compared to healthy blood donors, 407-fold (±1037) vs 185.5 fold (± 668) increase, respectively (p=0.068).
Conclusions: Platelets of HIV-infected patients display an increased ability to release inflammatory cytokines, particularly GRO-a, which may support residual viral replication in cells, and contribute to the maintenance of immune activation and systemic inflammation.

TUPEA0124

Altered macrophage phenotype in HIV-infection may contribute to vascular inflammation

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Background: HIV-infected individuals are at increased risk of vascular thrombosis, likely driven by interactions between activated leukocytes and the endothelium. Proportions of inflammatory (CD14+CD16+) and patrolling ($CD14^{Dim}CD16+$) monocytes are expanded in HIV-infection, and these cells express altered levels of vascular homing molecules. Monocytes differentiate into macrophages in the vessel wall and produce factors that contribute to subendothelial inflammation and atherosclerotic plaque formation. The mechanisms by which macrophages contribute to increased cardiovascular disease (CVD) risk in ART-treated HIV+ individuals are incompletely understood.
Methods: PBMCs were isolated from HIV- (n=16) and ART-treated HIV+ participants (n=22) and cultured in Teflon wells for 5 days in medium containing 20% autologous serum to generate monocyte derived macrophages (MDMs). Immune activation was assessed by flow cytometry and by ELISA. MDM transcriptomes were analyzed using ribo-depleted RNA-Seq. Reactive oxygen species (ROS) production was assessed by flow cytometry following CellRox Deep Red incubation. MMP activity was evaluated using AnaSpec matrix metalloproteinase (MMP) assay kits. Mean values were compared by parametric t test.
Results: Mean age of study participants was 33 years for HIV- (88% male) and 48 years for HIV+ subjects (90% male). All HIV+ participants had suppressed viremia (< 40 copies/mL), and a mean CD4+ T cell count of 573 cells/mL. Serum levels of myeloid and endothelial cell activation (sCD14, sCD163, ICAM-1, VCAM-1, TNFR-I/II, IL-6, and Lp-PLA2) were increased in samples from HIV+ participants (p<0.05). We identified 54 differentially expressed genes in MDMs from HIV+ subjects (p<0.05), including MMP-14 and CD300E, which are related to plaque instability and innate immune activation. Surface protein expression of CD300E was also increased, and the costimulatory molecules CD80 and CD40, and the scavenger receptor SR-A, were decreased on MDMs from HIV+ donors (all p<0.005). Increased MMP activity was detected in supernatants collected from HIV+ MDMs, and these cells produced more TNFα, IL-6, and ROS spontaneously (p=0.01), and in response to LPS (p=0.007), compared to cells from HIV- donors.
Conclusions: MDMs obtained from ART-treated HIV+ participants produce increased levels of several mediators that contribute to vascular inflammation, including MMPs and ROS, potentially leading to increased CVD risk.

TUPEA0125

High cannabis levels associated with decreased T cell activation in HIV-infected individuals

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Background: Despite advancement of antiretroviral therapies (ART) that provide stable and sustained viral suppression, ART-treated HIV-infected individuals have elevated risk of morbidities and mortality compared to uninfected individuals. Even with long-term consistent ART, HIV-infected individuals experience more inflammation, T-cell activation, and altered CD4+ T-cell frequencies. Cannabis is a widely used drug in the United States. However, how cannabis may affect HIV pathogenesis is unknown.
Methods: Plasma and PBMCs from 185 HIV-1-infected, ART-suppressed individuals recruited through the SCOPE cohort (San Francisco, CA) who self-reported either no or daily cannabis, and all reported no use of other drugs of abuse, were sampled. Positive cannabis levels were confirmed in plasma by mass spectrometry. The interquartile range of the cannabis metabolite, 11-nor-carboxy-THC, was used to stratify the cannabis-using group into low (below 38.5nM), medium (38.55-251.8nM) and high (above 251.8nM) cannabis levels. Inflammatory biomarkers were quantified in plasma by Luminex. Flow cytometry was used to determine

expression of PD-1 (exhaustion) and HLA-DR+CD38+ (activation) on CD4+ and CD8+ T-cells. Differences between groups were assessed using a Mann-Whitney test.
Results: No differences in clinical characteristics (Table1) or inflammatory biomarkers were found between the non-cannabis users and any cannabis-using groups. Significantly lower frequencies of PD-1 and HLA-DR+CD38+ expressing CD4+ (p=0.01; p=0.03) and CD8+ (p=0.03; 0.045) T-cells were detected in the high cannabis level group compared to non-cannabis users (Table1). Differences remained significant after adjusting for age, gender, CD4 count, tobacco and alcohol use (p<0.05 for all).
Conclusions: High-level cannabis use is associated with lower levels of T-cell activation and exhaustion in ART-suppressed HIV-infected individuals, highlighting a potential immunologic benefit of cannabinoids that could be assessed in future studies. Further research is also underway to determine the mechanisms of this reduced activation, impact on reservoir, and whether non-psychoactive cannabinoids may exert similar effects.

	Never Cannabis Median (IQR) (n=128)	Low Cannabis Median (IQR) (n=14)	Medium Cannabis Median (IQR) (n=29)	High Cannabis Median (IQR) (n=14)
Male, No. (%)	111 (86%)	14 (100%)	26 (90%)	10 (71%)
Age	53 (46-59)	47 (48-60)	51 (45-54)	51 (45-54)
CD4+ Count	533 (434-755)	568 (274-615)	531 (477-747)	530 (364-893)
HIV Viral Load	<75	<75	<75	<75
Current Tobacco	16 (13%)	4 (31%)	6 (22%)	4 (29%)
%HLA-DR+CD38+ of CD4+	2.4 (0.5-6.7)%	2.6 (1.1-9.7)%	2.4 (0.6-8.4)%	1.9 (0.9-3.7)%
%PD-1 of CD4+	6.0 (1.1-18.8)%	7.4 (1.6-15.9)%	7.4 (0.9-12.0)%	4.4 (1.5-17.1)%
%HLA-DR+CD38+ of CD8+	3.8 (0.6-13.5)%	3.2 (1.8-9.7%)	3.6 (1.1-10.7)%	3.3 (0.9-5.6)%
%PD-1 of CD8+	7.0 (0.5-23.1)%	8.4 (1.3-20.7)%	5.7 (1.0-14.4)%	4.5 (2.1-10.0)%

[Table 1]

TUPEA0126

Upregulation of chronic inflammatory cytokines despite early treatment and virological suppression in children: a role in HIV persistence?

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Background: There is limited knowledge of the immunological mechanisms contributing to HIV subtype C persistence in infected children. Observations in adult cohorts have implicated proinflammatory cytokines in viral reservoir establishment and long-term persistence through low-level viral replication despite long-term therapy. This study therefore aimed to longitudinally compare inflammatory cytokine levels in virologically suppressed children soon after therapy initiation and at 7-8 years.
Methods: Baseline (within 6 months of age) and follow-up (7-8 years) plasma samples originating from the Children with HIV Early Antiretroviral Therapy (CHER) trial were evaluated. The trial included three study arms (Arm 1: delayed therapy; Arms 2 and 3: early therapy until interruption at 40 and 96 weeks). Children evaluated began ART at < 1 year of age and sustained viral suppression at follow-up. Twenty-six cytokines were measured using validated Luminex® Multiplex assays. Statistical analysis employed a Wilcoxon matched paired test for nonparametric data. A subset of participants was also tested for total HIV-1 DNA using qPCR targeting a conserved region in HIV integrase.
Results: Thirty-eight samples were evaluated. The median baseline viral load at ART initiation was 738,500.5 copies/ml (range: 399-750001 copies/ml). Six participants had detectable viral loads from <40 to 19,549 copies/ml at follow-up. The median CD4 counts at baseline and follow-up were 1,853.5 (range: 823-3450) and 933.5 (range: 20-2063) respectively.
In Arm 1, significantly higher levels of INF-γ (P = 0.0117), IL-17A, TNF-α, RANTES (all P = 0.0039) and G-CSF (P = 0.0078) were observed at baseline. A significant increase in cytokine expression was observed for IL-13, IL-4 (P = 0.0156), VEGF, MCP-1, and PDGF-BB (all P = 0.0039) at follow-up. Cytokine expression in Arm 2 showed highly significant elevations at follow-up for IL-13 (P = 0.0005), VEGF (P<0.0001), FGF-basic (P<0.0001), MCP-1 (P<0.001), and PDGF-BB (P<0.0001). Similar trends of significant markers were noted for Arm 3.
In 23 children assessed for HIV-1 DNA at follow-up, a median of 32.5 copies/million cells (range: 0-247.6) was observed.
Conclusions: Children initiated on ART early showed an increase in chronic inflammatory disease-cytokine expression following 7-8 years on suppressive therapy. Despite the low level of cell-associated DNA detected, the persistence of HIV appears associated with upregulation of chronic inflammatory cytokines.

TUPEA0127

CD49d expression in T-lymphocytes subsets and cardiovascular risk in HIV-positive subjects

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Background: The integrin-α4 (CD49d) is a transmembrane co-stimulatory molecule, involved in lymphocyte homing from peripheral blood to the gut (α4β7) and to the central nervous system (α4β1). In this study CD49d expression on T-lymphocyte subsets and its relationship with cardiovascular damage was evaluated in the context of HIV infection.
Methods: Thirty HIV+ subjects (6 females/24 males) with a mean age ± standard deviation (SD) of 52±10.1 years, on effective antiretroviral treatment (ART) and 15 age- and sex-matched healthy donors (HD), were enrolled. T-lymphocyte immunophenotype and CD49d median fluorescence intensity (MFI), were detected by flow cytometry. Carotid-Intima Media Thickness (c-IMT) was assessed by ultrasound. Pathological c-IMT was defined as a measured value greater than 0.9 mm.
Results: HIV+ subjects showed lower CD4+ T-lymphocyte absolute counts (p=0.04) and increased levels of CD4 and CD8 immune activation (p<0.001 and p<0.001, respectively) and immune senescence (p=0.02 and p<0.001, respectively) compared to HD. CD4 and CD8 naïve [N] cells were decreased (p=0.02 and p=0.01) while CD8 effector memory [EM] cells were increased (p=0.007) in HIV+ subjects compared to HD. CD49d expression was increased on CD4 (N: p=0.01, central memory [CM]: p<0.001, EM: p<0.001, effector [E]: p=0.05) and CD8 (N: p=0.0006, CM: p<0.001, EM: p<0.001, E: p=0.003 and intermediate [I]: p<0.001) of HIV+ subjects compared to HD. In HIV+ subjects, a positive correlation between CD49d MFI on CD4 and CD4 immune activation was found (p=0.0012). c-IMT values were increased in the HIV+ group than in HD (mean±SD: 0.85±0.17 vs 0.28±0.24 mm, p<0.001). Among HIV-infected patients, 15 (50%) had a normal c-IMT and 15 (50%) a pathological c-IMT. c-IMT was positively correlated with CD49d MFI on CD4 and CD4 immune activation (p=0.04, p=0.085, respectively). Moreover, HIV+ subjects with pathological c-IMT showed higher levels of CD49d MFI in the CD4 CM subset than HIV+ subjects with normal c-IMT (p=0.02).
Conclusions: During chronic HIV infection, CD49d increased expression on T-lymphocytes could be considered an alternative marker of immune activation related to cardiovascular comorbidities. The integrin-α4 could represent a therapeutic target to reduce cardiovascular comorbidities in chronic HIV patients.

TUPEA0128

Host determinants associated to immunological non-response in patients on cART

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Background: Host determinants of CD4 T-cell restoration in HIV patients with cART and suppression of viral replication are not well understood. A subset of HIV patients, termed immunological nonresponders (INR), achieve only modest increases of CD4 counts that is more frequent in patients starting cART with low CD4 counts. Herein, we have analyzed the association of several host genetic variants with the phenomenon of immunological discordance.
Methods: A case-control study was conducted in 412 HIV infected patients on cART. Inclusion criteria were: naïve patients starting cART with CD4 counts< 200 cels/μL and maintaining complete viral suppression for two years. INR patients (cases) were defined as those patients with CD4 counts ≤250 cells/μL after two years on cART, and immunological responder patients (controls) as those with CD4 counts >250 cells/ μL. An array of 51 single nucleotide polymorphisms (SNPs) previously involved in HIV pathogenesis were selected and genotyped using Sequenom's MassARRAY platform. Association studies were performed using SNPStats software.

Results: Ninety-three patients were classified as cases and 319 as controls. CD4 counts at two years after cART were (median[IQR]) 180 [132-210] and 422[337-554] cels/μL in cases and controls respectively (p<0.0001). After adjusting by gender, age, years of infection from diagnosis, baseline CD4 counts and cART regimen (PI-containing vs. NNRTI-containing), three SNPs were significantly associated with INR: rs1493013 in IL15 gene (p=0.021), rs1799864 in CCR2 gene (p=0.042) and rs2280789 in CCL5 gene (p=0.028). Mechanisms underlying this association could include: modulation of IL15 production, a cytokine with a pivotal role in T-cell proliferation and survival; variation of the CCR2 transmembrane region, an alternative HIV coreceptor; and CCL5 downregulation, a chemokine that blocks HIV infection. Otherwise, 2 SNPs were significantly associated to IR: rs2430561 in IFNg gene (p=0.016), and rs724710 in BIM gene (p=0.012). Variation in rs2430561 has been shown to increase IFNg production, a cytokine with a pivotal role in cell-mediated antiviral immunity; and variation at rs724710 diminish BIM-mediated signaling of the intrinsic apoptosis pathway.
Conclusions: Our results suggest that mechanisms underlying the phenomenon of immunological discordance are multifactorial, and involve disturbance of T cell homeostasis and of host viral defense.

TUPEA0129

Chronic immune activation as a cause of poor T-helper cell migration in successfully ART-treated HIV-1-infected individuals

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Background: CD4+ T-cell depletion, and in particular Th17 cell loss in the mucosal compartment, is a hallmark of HIV-1 infection in humans. Alterations in the integrity of the mucosal barrier have been indicated as cause for chronic immune activation and disease progression, which occur despite successful anti-retroviral therapy (ART). In this study we have investigated the effect of chronic immune activation, or selective Toll-like receptors (TLRs) triggering on the homing capacity of lymphocytes, with the aim of understanding the mechanisms at the basis of a poor repopulation of T-helper cells in the gut during successful treatment with ART.
Methods: Blood samples were collected from a total of 58 HIV-1-infected individuals, either ART-naïve (n=15) or on long-term ART (n=43), and from healthy donors (HD). T-helper cell dynamics, their migration capacity, and levels of soluble CD14 (sCD14) were assessed. A mouse model, mimicking the alterations observed in HIV-1 infection was also used to assess the impact of chronic immune activation on T-helper cell migration. In vitro triggering of selective TLRs, was performed on HD samples to dissect the involvement of the different TLRs in modulating cell migration capacity.
Results: CCR6+ and CXCR3+ T-helper cells accumulate in the blood of ART-treated HIV-1-infected individuals, and their frequency positively correlates with the levels of sCD14. In HIV-1-infected individuals, migration of T-helper cells in response to chemotactic stimuli is impaired, regardless therapy. Chronic immune activation induced by TLR signaling is sufficient to dampen T-helper cell migration, which can be restored by pharmacological modulation of cytoskeleton activity.
Conclusions: In patients under long-term ART, chronic immune activation contributes, by altering T-helper cell migration, to the poor gut repopulation observed. This study calls for novel pharmacological approaches targeting the cytoskeleton machinery to achieve a better reconstitution of the mucosal compartments.

TUPEA0130

Reduced naïve CD8+ T-cell priming efficacy in HIV-infected patients

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Background: Priming of de novo immune responses from the naïve CD8+ T-cell repertoire in order to recruit cells with new antigenic specificities or to replenish waning lymphocyte populations is a prerequisite for the long-term control of persistent viruses, and responsiveness to vaccination. However, our knowledge of individual capacity to prime new T-cell responses is limited, in particular due to the lack of practical approaches to examine such capacity in humans. In this study we set out to examine the potential of HIV-infected patients to mount de novo antigen specific CD8+ T-cell responses. In addition, as HIV-positive individuals experience premature immunosenescence, their priming capacity was compared to that of elderly subjects.
Methods: To this end, we have developed and used a simple and original in vitro assay to assess CD8+ T-cell priming efficacy from antigen specific precursors. This approach is based on the in vitro stimulation of naïve CD8+ T-cells that are specific for a model antigen, chosen for the high frequency of specific precursors in individuals.
Results: Using this approach, we found that HIV-infected patients consistently mounted quantitatively and qualitatively impaired de novo CD8+ T-cell responses. Interestingly, priming capacity of HIV-positive subjects was comparable to that of elderly individuals. This immune deficit was directly associated with the number of antigen-specific precursors and the size of the naïve CD8+ T-cell pool. Based on our recent finding that the combination of TLR8 ligand with FLT3 ligand improves effector capacity of in vitro primed naïve T cells, we tested whether this combination of adjuvants could restore priming capacity in HIV-infected patients. However, the addition of TLR8L/FLT3L did not improve, either quantitatively or qualitatively, de novo CD8+ T-cell responses in HIV-positive individuals.
Conclusions: These findings provide experimental evidence of reduced capacity to mount de novo CD8+ T-cell responses in HIV infected patients, and further expose the functional insufficiencies that accompany HIV disease progression and immune aging.

TUPEA0131

Pre-senescent state of hematopoietic progenitors from HIV-1-infected treated patients with immunological failure

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Background: Chronic immune activation (IA) is predictive of disease progression in HIV-1 infection. However, the consequences of IA and its links to the failure to reconstitute and maintain the CD4+ T cell pool with antiretroviral therapy (ART) in HIV-1 infection remain a matter of debate. The capacity to regenerate the immune system, including CD4+ T cells, depends on the ability of CD34+ hematopoietic progenitor cells (HPCs) to initiate adequate lymphopoiesis. We hypothesized that high systemic IA and recurrent inflammation drive an exhaustion of the primary immune resources, which is an important determinant of immunological failure with ART. The objective of the study is therefore to characterize further the HPC compartment resources in HIV-1 infected patients.
Methods: We studied circulating HPCs from HIV-1 infected patients (aged 25-55 years) with successful immune reconstitution or not under ART, compared to healthy adults stratified by age (18-95 years). We performed ex vivo phenotypic analyses as well as telomere length and telomerase activity measurements by q-PCR on circulating CD34+ cells, in vitro T-lymphocyte differentiation assays using OP9hDL1 culture system line, and measured plasmatic inflammation markers.
Results: HIV-1 infected patients exhibited quantitatively and qualitatively altered lymphopoietic capacity. Our in vitro approach revealed biases in the capacity of

HPCs from HIV-1 infected patients to produce and differentiate into lymphocytes, compared to HPCs from aged matched healthy individuals. The presence of proinflammatory factors like IL-6, IP-10 or LPS in the culture of control HPCs, restricted the differentiation pattern towards T lymphocytes in a similar way. Interestingly, HPCs from patients failing to reconstitute their CD4+ T cell pool under ART presented an obvious loss of common lymphoid progenitors, together with marked telomere attrition and lack of telomerase activity, reminiscent of HPCs uninfected elderly people.
Conclusions: Our study provides direct evidence for the defective capacity of CD34+ HPCs from HIV-1 infected patients to differentiate along the T lineage due to intrinsic (senescence) and extrinsic (inflammation) factors. This work brings new lights into the potential cause of immune failure with ART, due to exhausted lymphopoiesis with HIV infection.

TUPEA0132

Microbial dysbiosis does not alter immune activation or disease progression in SIV-infected Asian macaques

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Background: Progressive HIV infection is associated with systemic immune activation that is not fully ameliorated with effective antiretroviral therapy. Measures of immune activation - including elevated concentrations of circulating pro-inflammatory cytokines, low frequencies of intestinal T_H17 cells, and exacerbated T-cell activation - have been shown to correlate with the enrichment of disease-associated intestinal microflora, namely an expansion of bacteria within the phylum Proteobacteria at the expense of the Firmicutes and Bacteroidetes. Although several studies have indicated that the therapeutic administration of probiotic, or commensal species may significantly improve disease progression in non-human primate models of HIV infection, an empirical assessment of the contribution of microbial dysbiosis to disease progression has not yet been executed.
Methods: To assess the contribution of microbial dysbiosis to untreated lentiviral disease progression, we administered vancomycin (10 mg/kg p.o.; 5 doses/month) to 7 rhesus macaques prior to and throughout SIV infection. Prior to infection, vancomycin treatment resulted in a significant increase in the frequency of fecal Proteobacteria and Fusobacteria and a concordant decrease in Bacteroidetes and Firmicutes, as compared to 6 control animals. We infected all animals with SIVmac239 and routinely measured lymphocyte frequency and function by polychromatic flow cytometry, viral loads by SIV-Gag qRT-PCR, and fecal microbial frequencies by 16S sequencing by Illumina.
Results: Fecal microbial instability was evident throughout SIV infection, with increased frequencies of Deltaproteobacteria and Gammaproteobacteria, and decreased frequencies of Bacteroidales and Clostridia. Surprisingly, despite evidence for progressive and high levels of dysbiosis, no significant differences in viremia, immune activation, or systemic microbial translocation were noted between the experimental groups throughout SIV infection. Furthermore, clinical indices of disease progression including survival curves did not reveal any evidence for enhanced disease progression in the dysbiotic animals.
Conclusions: Our results demonstrate that microbial dysbiosis does not significantly influence host/viral dynamics during untreated SIV infection and may suggest that observed dysbioses in untreated HIV infection may be ancillary to disease progression.

TUPEA0133

Nadir CD4+ T-cell count strongly predicts gut disbyosis in HIV infection

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Background: HIV-1 infection exerts rapid, severe and continuous damage to the intestinal lining and gut-associated lymphoid tissues, followed by chronic inflammation and severe immune deregulation, which are only partially restored with antiretroviral treatment. However, the nature, extent, constrains and mechanisms by which HIV infection may alter the composition and function of the gut microbiome remain controversial. Whole metagenome shotgun sequencing (WMGS) analyses could advance our understanding on HIV disbyosis by providing higher taxonomic and functional resolution over 16S rDNA sequencing.
Methods: Fecal WMGS (Illumina HiSeq, 10 million sequences/sample) was used to characterize the taxonomic (Metaphlan.v2), genetic (Integrated Gene Catalogue) and functional (KEGG) composition of the intestinal microbiome of HIV-1-negative (N=27) and HIV-1-infected (N=129) individuals with different immune profiles. The relative abundance of microbial species and functions were correlated with gene richness, soluble inflammation and bacterial translocation markers and CD4+ counts, using Wilcoxon and Kruskal-Wallis tests with Benjamini-Hochberg correction and Spearman rank tests, as needed. Multivariate linear regression was used to identify independent predictors of low microbial gene richness.
Results: Microbial gene richness showed a bimodal distribution, enabling the classification of subjects into Low (LGC) and High Gene Count (HGC) categories. Most (89.3%) HIV-1-infected subjects but only 40.7% HIV-negatives clustered in the LGC group ($p<0.001$). Lower nadir CD4+ count was a strong independent predictor of LGCs [OR for <100 c/mm3 vs HIV negative: 14.0 (95%CI: 2.0, 288.7), $p=0.023$]. HGCs were significantly enriched in Reactive Oxygen Species (ROS)-sensitive methanogenic archaea and butyrate-producing and cellulose-consuming bacteria, and showed increased methane and butanoate metabolism, as well as pathways linked to DNA replication. Conversely, subjects in the LGC group were enriched in gram-negative ROS-resistant bacteria, including Proteobacteria, and had increased LPS biosynthesis, complex carbohydrate metabolism and microbial antioxidant enzymes able to counterbalance ROS accumulation. Microbial species associated with higher gene richness were negatively correlated with soluble markers of systemic inflammation and bacterial translocation.
Conclusions: HIV-induced immune deficiency is linked to significant shifts in the composition and function of the gut microbiome, which suggest adaptation to oxidative stress. Loss of methane and butyrate-producing anti-inflammatory microbes and increase in LPS biosynthesis and Proteobacteria might contribute to self-perpetuate HIV disbyosis.

TUPEA0134

Gut dysbiosis during acute HIV infection

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Background: Gut dysbiosis contributes to HIV disease progression. However, little is known about the critical changes that occur to the gut microbiome during the course of HIV infection and how they may affect the establishment and maintenance of the HIV reservoir. A clear understanding of how the gut microbiome is altered during the course of acute HIV infection and its role in disease is essential to inform the development of novel interventions that could interfere with the establishment of the HIV reservoir and curtail disease progression. Direct experimentation in humans to establish gut microbiota's role in HIV disease and persistence is not possible. Therefore, we used a new in vivo model consisting of bone marrow/liver/thymus (BLT) humanized mice that have been colonized with human gut microbiota (HuM-BLT mice).
Methods: HuM-BLT mice were generated from germ-free NOD/SCID/IL2Rγc-/- (NSG) mice maintained in germ-free isolators. Germ-free NSG mice were colonized with human gut microbiota by oral fecal transplantation of a well-characterized human fecal sample. HuM-BLT mice were exposed vaginally to HIV. Fecal pellets collected longitudinally from HuM-BLT mice before and after HIV exposure (6 weeks) were analyzed with 16S amplicon sequencing. Infection was monitored longitudinally by measuring peripheral blood levels of HIV-RNA, CD4+ T cells, and CD8+ T cell activation.
Results: Consistent with HIV infection in humans, we observed significantly decreased CD4+ T cell levels ($p=0.0101$) and increased CD8+ T cell activation ($p=0.0241$) in the peripheral blood of HIV-infected HuM-BLT mice. Consistent with the composition of the human inoculum, the gut microbiome of HuM-BLT mice was dominated by Bacteroidetes, Firmicutes, and Verrucomicrobia. Our analysis demonstrated significant alterations in the frequency of genera Coprococcus and Dorea ($p=0.0163$ and $p=0.0167$ respectively) in the gut microbiome of HuM-BLT mice during acute HIV infection.
Conclusions: Our results show that alterations in gut microbiome composition begin during acute HIV-infection and suggest that gut dysbiosis likely develops overtime. This is in agreement with data collected from a limited number of recently infected patients. Administration of novel interventions that promote maintenance of healthy gut microbiota during acute HIV infection are needed to inhibit the development of gut dysbiosis during chronic infection and disease progression.

TUPEA0135

High levels of polymicrobial vaginal communities and genital inflammation in HIV-infected women

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Background: Studies on the vaginal microbiome (VM) in HIV infection have been primarily focused on HIV transmission and acquisition. Data on the VM after HIV infection is limited. Understanding how HIV infection and antiretroviral therapy (ART) shapes the VM and the local host inflammation may inform on women's reproductive health and contribute towards developing therapies aimed at manipulating the VM of HIV-infected women.
Methods: We conducted a cross-sectional study by enrolling HIV+ (n=28) and HIV- (n=26) women. Metagenomic shotgun sequencing was performed on total DNA extracted from vaginal swabs and analysed using MetaPhlAn2 package. Bacterial communities were clustered into Lactobacillus- and polymicrobial-dominant VM. Microbial diversity was calculated by computing the Shannon index. Principal coordinate analysis (PCoA) was performed based on UNIFRAC distances using QIIME. Cytokines were measured in supernatants obtained from the cervical cytobrushes using a 30-plex Luminex assay. Comparisons between groups were performed using non-parametric Mann-Whitney test. Correlations were performed using Spearman rank correlation coefficient.
Results: Demographic and clinical characteristics are presented in Table 1.

	HIV-	HIV+	p
N	26	28	
Age	40 [25.50-44.50]	41 [34.50-49]	0.1764
Vaginal pH	5.5 [5-6.0]	5.5 [5-6.5]	0.8109
CD4 T cell count (cells/mm3)	NA	491 [329-728]	
Plasma Viral Load (HIV-1 copies/mL)			
Undetectable (n=23)	NA	<40	
Detectable (n=5)	NA	82 [52-8324]	
N ART-Naïve; N on ART	NA	5/28; 23/28	
Values are given as median and 25%-75% percentiles. NA: not applicable			

[Table 1]

We found a trend for a higher percentage of Lactobacillus-dominant VM in HIV- compared to HIV+ women (61.8% versus 39.2%; p=0.17). Mucosal microbial diversity (Shannon index) was similar between HIV- and HIV+ women (p=0.61). PCoA analysis revealed no clustering of bacterial communities according to HIV status (PERMANOVA p=0.56). Overall, low abundance of Lactobacillus spp. inversely correlated with higher pH (r=-0.3148, p=0.021). Several cytokines including IL-1β, TNF-α, IL-17 and IL-10 were significantly increased in women with polymicrobial VM compared with Lactobacillus-dominant VM (p= 0.043, p=0.0138, p=0.0368 and p=0.0308 respectively).
Conclusions: Profiling of the VM revealed that the majority of HIV+ women had polymicrobial VM and high levels of pro-inflammatory cytokines indicative of local host inflammation. Our work suggests that intervention studies targeting the VM would benefit women´s reproductive health in addition to ART.

TUPEA0136

High abundance of *Prevotella* in gut microbiota of perinatally HIV-infected children despite suppressive antiretroviral therapy is indirectly associated with CD4 T cells

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Background: Perinatal HIV infection is characterized by rapid HIV disease progression with high initial HIV replication rate compared to adults. Although antiretroviral therapy (ART) has greatly reduced HIV replication to undetectable levels, there is persistent HIV-associated inflammation. While gut microbiota changes have correlated with increased levels of inflammation in HIV-infected adults, little is known about microbiota composition and inflammation in perinatally HIV-infected children.
We hypothesized that compared to uninfected children, perinatally HIV-infected children will have distinct microbiota composition, that will be associated with persistent inflammation and disease progression despite ART.
Methods: We performed bacterial 16s ribosomal DNA sequencing on fecal samples collected from 26 HIV-infected children; treatment-naïve (n=14), ART-experienced, virologically suppressed (n=12); and age-matched HIV-negative controls (n=6) as described in Table 1. Multi-analyte bead-based assays were used to analyze soluble cytokines, TNF-α and IP-10.

Parameters	Treatment-naive	ART-experienced	HIV negative controls
Number of subjects	14	12	6
Age (years)	10 (8-12)	11 (7-12)	9 (7-15)
Male/Female ratio	11/3	8/4	3/3
CD4 count (cells per µl)	644 (330-1334)	1141.5 (523-2406)	1343 (863-1884)
Plasma viral load (HIV RNA copies per ml)	33,779 (1,461-4,31,237)	Not detectable	Not applicable

[Table 1: Subject characteristics]

Results: HIV-infected children had, compared to HIV negative controls, significantly higher levels of Prevotella (median 70.8% vs 7.33%; p=0.02), and decreased Bacteroides (median 0.27% vs 15.25%; p=0.01). The ART therapy had no effect on the relative abundance of Prevotella between treatment-naïve and ART-experienced HIV-infected children. Compared to controls, Prevotella levels remain elevated in HIV-infected children despite ART therapy (p=0.03, median 77.9% vs 7.33%). Prevotella levels negatively correlated with the absolute CD4 counts in treatment-naïve (p=0.03, r=-0.69) or ART-experienced HIV-infected children (p=0.03, r= -0.75). Untreated HIV-infected children had higher levels of soluble TNF-α (median 5.91 vs 0; p=0.0001) and IP-10 (median 1692 vs 394; p=0.001) compared to controls. The levels of soluble IP-10 and TNF-α decreased during ART-therapy (p<0.05). However, IP-10 remains elevated in ART-experienced group compared to controls (median 523 vs 394; p=0.03). The levels of IP-10 positively correlated with Prevotella in treatment-naïve HIV-infected children (p=0.03, r=0.66), however this correlation was lost during ART therapy.
Conclusions: Compared to controls, HIV-infected children present unique gut-microbiota with higher abundance of Prevotella and decreased Bacteroides, and elevated levels of IP-10 that persists despite ART.

TUPEA0137

The study of gorilla enteric virome dynamics: association with SIV infection

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Background: The pathogenicity of Simian Immunodeficiency Virus (SIV) in great apes is unclear, but infection in chimpanzees has already been associated with progression to an AIDS-like disease. The expansion of the enteric virome associated with disease progression in an AIDS-like context has also been described in the rhesus macaques model. The aim of this study was to identify and compare enteric viromes of SIV-infected and uninfected gorillas, and to assess their relationship with SIVgor pathogenesis in their natural host.
Methods: We have used Next-Generation Sequencing (NGS) to analyze non-invasive samples (faeces) of 22 wild gorillas from Cameroon, 11 SIV-infected and 11 uninfected individuals. NGS was carried out in a HiSeq 2500 Illumina platform and analyses were conducted with an in-house pipeline using the programs FastQC, Sickle-Master, BlastX - Viral Database from GenBank/NCBI, MEGAN5 and RStudio.
Results: The viral families Bromoviridae, Myoviridae, Podoviridae, Rhabdoviridae and Tymoviridae were statistically (p< 0.01) more abundant in the uninfected group, whereas Alloherpesviridae, Herpesviridae, Reoviridae and Siphoviridae families were more abundant (p< 0.01) in the SIV-infected group. Also, two distinct clusters were recognizable when a 1,000 cp/mL cutoff of SIVgor viral load in faeces (ranged in 655 to 31,497 cp/mL) was used to assess within-group diversity. Finally, we are able to detect adenovirus-assigned reads (virus associated with intestinal disease in rhesus monkeys with advanced AIDS) only in the SIV-infected samples that belong to the smaller viral load group with known infection status for at least 3 years. In general, we clearly notice that few families can serve as proxies for SIV infection, such as Reoviridae and Alloherpesviridae associated with SIV-infected samples.
Conclusions: This is the first evidence for the association of some mammalian viral families (like Adenoviridae, Herpesviridae and Reoviridae) with the presence of the SIVgor in a putative dysbiosis context, linking this phenomenon to disease progression. Virome stability studies clearly provide better markers of pathogenic infection progression than bacteriomes. However, further studies are still needed to better understand the influence of SIV pathogenesis on infected gorilla populations in the wild, and to associate deeper taxa (virus genera and species) to SIV status in these animals.

TUPEA0138

Changes in the gut and blood microbiome after starting antiretroviral therapy in HIV-1-infected patients

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Background: HIV infection is characterized by intestinal damage, gut microbiome dysbiosis, immune activation and systemic inflammation.
We aim to examine whether starting ART altered the GI and serum bacterial microbiota of HIV-1-infected-subjects and whether immune activation markers correlated with microbiome changes
Methods: 23 HIV-1 infected subjects were enrolled. Six patients were elite controllers (EC) or viremic controllers (VC) who did not receive ART. Blood and stool samples were collected at baseline and 4 weeks after starting ART. Microbiota-community composition was profiled by 16S-rRNA sequencing in stool and serum. sCD14 was measured by EIA
Results: There was no significant difference in the GI-microbiome alpha-diversity between HIV-infected and historical non-infected subjects.
The main dominant phyla in HIV-infected patients based on relative abundance were Firmicutes and Bacteroidetes, followed by Proteobacteria and Actinobacteria. At the genus level, demonstrated that the most abundance taxa were Faecolobacterium, followed by Prevotella, Lachnospiraceae, Blautia and Bacteroides.
At week 4, median HIV RNA was 41copies/mL. ART did not significant increase alpha-diversity in the GI-microbiome. There was decrease of Bacteroidetes and increase of Firmicutes. At the genus level, there was an increase in the abundance of Prevotella, Lachnospiraceae, Blautia and decrease of Bacteroides. Median sCD14 level was 2500 +/-926 ug/mL pre-ART and 2175 +/-803 ug/mL post-ART (p=0.6)
EC and VC patients have reduced alpha diversity of the GI microbiome compared to HIV non-controllers. Moreover, they have different microbiota composition at the genus level. EC patients have more Bacteroides and less Prevotella compared to the other groups. Both EC and VC cases have more Clostridiales and Pseudobutyrivibrio compared to the HIV non-controllers. EC and VC had higher sCD14 compared to HIV-naïve-subjects (2812+/-1206 ug/mL vs 2500+/-926 ug/mL p=0.07) and treated subjects (2812+/-1206 ug/mL vs 2175+/-803ug/ml, p=0.07).
Bacterial microbiome was not identified in serum samples of any of the patients.
Conclusions: HIV-1-infected-patients microbiome has increased abundance of pathobionts such as Prevotella. There was a trend of ART to improve markers of immune-activation and alter the microbial communities. HIV-controlers have a more favorable GI-microbiome. Further HIV studies are needed to better understand the GI-microbiome in this population.

TUPEA0139

Effect of HIV on the rectal microbiome in the Chicago site of the Women's Interagency HIV Study (WIHS)

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Background: Individuals with HIV have increased gut microbial translocation and distinct gut microbiota compared to uninfected controls. Prior studies were small and included few women or matched controls, it remains unclear whether this difference is caused by behavior in men who have sex with men (MSM) or HIV. To determine if differences in gut microbiota are due to HIV versus behavioral factors, we evaluated rectal swab derived microbiota of HIV-infected and well-matched uninfected women from similar neighborhoods in the Chicago cohort of the Women's Interagency HIV Study (WIHS).
Methods: Rectal swabs were collected with a Dacron swab at two time points one year apart. Samples were snap frozen in liquid nitrogen. DNA was extracted using PowerSoil® DNA Isolation Kit (MO BIO Laboratories, Carlsbad, CA) and amplified for sequencing of fragments of bacterial small subunit (SSU or 16S) ribosomal RNA (rRNA) genes. Sequence data were processed using a QIIME pipeline. Shannon and Bray-Curtis indices were calculated with default parameters in R using the vegan library. The rarefied genera data, taxonomic level 6, were used to calculate both indices. For Bray-Curtis indices, the rarefied data were filtered to remove any taxon with an abundance of less than 1% of the total abundance in the dataset.
Results: Rectal microbiota of HIV infected (n=136) and uninfected women (n=55) did not differ by Shannon diversity index (p=0.14), Bray-Curtis dissimilarity indices (ANOSIM, R=0.0027, p=0.488) or copy number of individual taxa. Bray-Curtis analysis of samples from the same individuals collected one year apart demonstrated similar rectal microbiome stability over time in both HIV infected and HIV uninfected women (p=0.889).
Conclusions: This large study of rectal microbiota in WIHS women suggests that HIV infection alone does not alter the diversity, composition or stability of the rectal microbiome. Differences in prior serostatus findings may be driven by sex/gender differences in sexual practices rather than HIV specifically. Additionally rectal swab samples were highly acceptable, feasible, and efficient to collect. The microbiome was relatively stable over time suggesting that this method of microbiome investigation does not suffer disproportionately from artifact. Further studies should assess whether differences exist in the microbiome of the proximal bowel.

TUPEA0140

Alterations in dendritic cells status and B cell subsets in HIV-1-infected children at different stages of disease

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Background: Multiple B cell defects have been reported in HIV-1 infected individuals including alterations in distribution of B cell subsets and excessive B cell activation. Dendritic cells (DCs) regulate B-cell activation through B lymphocyte stimulator (BLyS). Disease progression is faster in children than adults. Less than 5% children maintain stable CD4 counts beyond 7 years of infection without ART and are termed as Long Term Non Progressors (LTNPs). Hence understanding the effect of HIV-1 on DC mediated B cells dysfunction in HIV-1 infected children at different stages of the disease is important to develop strategies for intervention and restoration of B cell function.
Methods: A total of 19 asymptomatic, perinatally HIV-1 infected, ART naïve children, and 14 seronegative children (controls) were recruited. Based on the CD4 counts and years post infection, they were categorized as LTNPs (n=11), and progressors (n=8). Median Fluorescent Intensity (MFI) of BLyS on dendritic cells surface, percentages of myeloid dendritic cells (mDCs), plasmacytoid dendritic cells (pDCs), naïve B cells, mature activated B cells and memory B cells were determined by flow cytometry.
Results: Progressors demonstrated significantly lower CD4 counts and higher viral load as compared to LTNPs ($p < 0.05$). Lower percentages of mDCs and pDCs were observed in progressors vs. LTNPs and controls. The expression of BLyS on mDCs and pDCs was significantly higher in progressors vs. controls ($p<0.05$), whereas in LTNPs it comparable to that in the controls ($p>0.05$). We observed higher percentages of mature activated B cells and significantly lower percentages of memory B cells in Progressors compared to LTNPs ($p<0.05$).
Conclusions: Our study suggests that lower percentages of DCs subsets is associated with faster disease progression in HIV-1 infected children. Higher expression of BLyS on the surface of DCs is associated with lower percentages of memory B cells and higher percentages of mature activated B cells in progressors vs. LTNPs, thereby promoting disease progression

TUPEA0141

Epigenetic dysregulation of the major histocompatibility complex region in HIV-infected children on antiretroviral therapy

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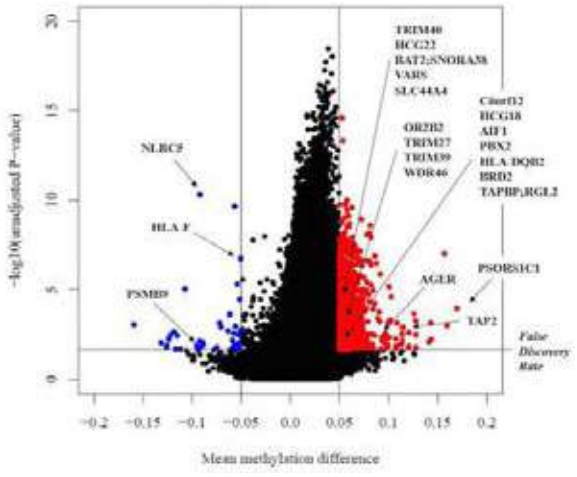
Background: Recent data in adults suggest HIV infection and antiretroviral therapy (ART) affect the host epigenome. However, epigenetic dysregulation in children with HIV has not been reported. We performed an epigenome-wide association study (EWAS) to identify differential DNA methylation patterns between treated HIV-infected and HIV-uninfected South African children.
Methods: Genome-wide DNA methylation was profiled using the Illumina Infinium HumanMethylation450 BeadChip array in whole blood from 120 HIV-infected children (46% male) and 60 age-matched HIV-uninfected children (50% male) aged 4-9 years (mean 6.4 years) in Johannesburg, South Africa. HIV-infected children were initiated on ART <2 years of age and were all suppressed <400 copies/mL on a lopinavir/ritonavir-based regimen when methylation was assessed. Pre-processing was performed with the R/Bioconductor RnBeads package. Differentially methylated CpG sites (DMCs) were selected (limma) if they had a False Discovery Rate q-value <0.05 and $|\Delta\beta|>0.05$, where $\Delta\beta$ is the mean methylation difference between groups. Differentially methylated regions (DMRs) were selected (DMRcate) if they had a Stouffer p-value <0.05, maximum $|\Delta\beta|>0.05$, and contained ≥2 CpG sites. Analyses were adjusted for age, sex, and estimated cell type proportions (minfi).
Results: 370,683 CpG sites and 179 samples were suitable for analysis after pre-processing. 1,309 DMCs were selected (Figure 1), including 1,271 hyper-methylated and 38 hypo-methylated in HIV-infected children. The top hypo-methylated DMC was located in the promoter region of the NLRC5 gene on chromosome 16 which regulates major histocompatibility complex (MHC) class I molecule expression. Many additional sites were associated with genes on the extended MHC region on chromosome 6. The selection of 315 DMRs also identified 23 genes located in this region.
Conclusions: We found extensive DNA methylation dysregulation in treated HIV-infected children compared to age-matched uninfected children. Many of these methylation changes were on genes involved in adaptive immunity. These results provide novel insights into immunology pathways affected by HIV.



[Figure 1. Volcano plot displays mean DNA methylation difference between HIV-infected and HIV-uninfected children at genome-wide CpG sites vs. -$\log_{10}$ (unadjusted P-value), after adjustment for age, sex, and cell type proportion; selected sites on genes related to major histocompatibility complex region are labeled]

TUPEA0142

Biomarkers of progression after HIV acute/early infection: nothing compares to CD4⁺ T-cell count?

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Background: Progression of HIV infection is variable among individuals. Despite implementation of effective ART, definition of disease progression biomarkers is still fundamental. Apart from CD4⁺ T-cell count (CD4TC) and viral load (VL), several parameters have been individually proposed as biomarkers by our group and others. Here, we aimed to categorize their predictive potential using decision trees and analyze their possible implementation in the clinical setting.
Methods: A total of seventy-five subjects were enrolled during acute/early HIV infection (< 6 months postinfection). CD4TC and VL determinations were performed at enrollment (baseline sample) and during 1 year. This study only included samples and data from subjects while off-treatment. Immune activation (HLA-DR and CD38 expression), HIV-specific immune response (ELISPOT) and HLA haplotype were determined in a subset of 41 individuals at baseline sample. Within this group, plasma levels of 39 cytokines were determined by Luminex in 27 individuals. Progression was defined as CD4TC decreasing below 350 cells/µl or experiencing AIDS-related B/C events within 12 months post-infection. Data was analyzed by machine learning and non-parametric methods and adjusted for multiple comparisons. Variable hierarchization was performed by Weka correlation based feature selection and J48 decision tree
Results: Plasma IL-10, IP-10, sIL-2Rα and TNF-α directly correlated with baseline VL while IL-2, TNF-α, FGF-2 and Mip-1β inversely correlated with CD4+ T-cell activation ($p<0.05$). However, none of these cytokines had good predictive value to distinguish progressors from non-progressors. Similarly, immune activation, HIV-specific immune responses and HLA haplotypes had lower discrimination power when compared to clinical parameters (CD4TC and VL). Baseline CD4TC was the most potent variable to distinguish progressors from non-progressors with a cut-off of 436 cells/µl (accuracy=0.93, k-Cohen=0.85)
Conclusions: In our cohort, baseline CD4TC was the strongest predictor of disease progression early after infection. Limited discerning power of the other factors might be related to frequency, variability and/or sampling time. Surprisingly, high baseline CD4TCs were observed even in subjects that progressed rapidly, reinforcing the importance of early ART initiation. Also, efforts should be made to develop and make available CD4TC determination techniques to all possible settings. Future studies based on decision trees to identify biomarkers of posttreatment control are warrantied.

TUPEA0143

Illicit drug use alters the composition and HIV inhibitory function of semen exosomes

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Background: Sexual contact is one of the most common modes of HIV transmission. Although semen is the primary vector, the likelihood of transmission per act of heterosexual coitus with an infected individual is less than 1%. These facts suggest that in addition to the protection provided by the mucosa, semen contains factors that may render HIV non-infectious. Previously, we showed that the nanovesicles called exosomes that were isolated from semen of HIV-uninfected men who do not use illicit drugs robustly inhibit infectivity of HIV-1. Exosomes have emerged as efficient vesicles of intercellular communication, whose composition and function depends on their originating cell. Because the cellular response to HIV infection is impaired by illicit drug use and has been associated with worsening disease progression, it is critical to evaluate the effect of illicit drug use on the characteristics of semen exosomes and their protective property against HIV infection.
Methods: Exosomes were isolated from semen of illicit drug users (n=3) and non-users (n=4). Transmission electron microscopy, NanoSight NTA, and dynamic light scattering were used to examine the physical properties of exosomes. SDS-PAGE gel silver staining, acetylcholine esterase assay, flow cytometry, and qRT-PCR were used to evaluate exosomal composition. TZM-bl HIV-1 infectivity reporter assay was used to assess exosomal function.

Results: Illicit drug use does not alter the physical properties or overall protein footprint of semen exosomes. However, assessment of exosome-specific markers revealed reduced proteinaceous and RNA content from donors that used illicit drugs. Functionally, semen exosomes from donors that used illicit drugs did not inhibit HIV infection, while exosomes from non-users potently inhibit HIV infection. Correlative comparisons suggest that reduced expression of the exosome markers CD63 and CD9 may be linked to the diminished HIV-inhibitory phenotype of semen exosomes from illicit drug users.
Conclusions: These findings suggest that illicit drugs may alter the composition and function of semen exosomes during biogenesis. Further comprehensive analyses are required to identify the mechanistic action of illicit drugs on semen exosome cargo composition and function. These studies will provide the knowledge necessary to disentangle the complex nature of illicit drugs and increased susceptibility to HIV infection from a biological perspective.

TUPEA0144

Multiple effects of nef on host by-stander cells: from cholesterol metabolism to epigenetic changes

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Background: The Nef protein of HIV-1 is the main factor of viral pathogenesis. The mechanisms of Nef-mediated impairment of cholesterol metabolism in HIV-infected cells involve downregulation and inactivation of the main cellular cholesterol transporter, ABCA1, via Nef binding to ER chaperone calnexin and disrupting the interaction between calnexin and ABCA1. Recent studies demonstrated that Nef is included into exosomes produced by HIV-infected cells, and exosomal Nef has pathogenic activity against by-stander cells. However, mechanisms of this activity remain unknown.
Here, we present analysis of the effects of exogenously added Nef on cholesterol metabolism and inflammatory responses of uninfected monocyte-derived macrophages.
Methods: For cholesterol metabolism studies, MDM were incubated overnight with recombinant myristoylated Nef (100 ng/ml) or exosomes harvested from supernatant of Nef-transfected HEK293T cells (1 ng/ml of Nef measured by ELISA). ABCA1 was measured by Western blot and ABCA1-calnexin interaction - by co-immunoprecipitation. For innate memory analysis, undifferentiated monocytes were incubated with rNef during the first 24 h of differentiation, Nef was removed, and cells were allowed to differentiate for additional 6 days. MDM were stimulated with 25 ng/ml LPS (TLR4 ligand), 25 ng/ml PAM (TLR 2/3 ligand), or 500 ng/ml R848 (TLR 7 ligand), and IL-6 and TNFα release was measured by ELISA. Inflammatory gene expression was analyzed by QIASeq RNA panel.
Results: Nef-treated cells expressed reduced levels of ABCA1 and cholesterol efflux. Nef also disrupted interaction between ABCA1 and ER chaperone calnexin. Similar levels of inhibition were observed with recombinant and exosomal Nef, despite the fact that exosomes contained 100-fold less Nef. Stimulation of Nef-exposed macrophages with TLR7 ligand resulted in a significant (3 fold) increase in IL-6 and TNFα release. The increase after TLR4 stimulation was smaller (about 50%), but significant, whereas no increase was observed after TLR2/3 stimulation. Expression analysis revealed overexpression of a number of genes, including IL6, IFITM1, MIF, IFI27.
Conclusions: This study reveals a potent effect of exosomal Nef on cholesterol metabolism of MDM. It also shows that Nef induces pro-inflammatory memory in MDM. Given that Nef is produced in ART-treated subjects, these results may explain sustained inflammation and metabolic co-morbidities in this population.

TUPEA0145

Comorbidities in people living with HIV (PLWHIV) compared to general population: an epidemiological analysis using a claims database in France

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Background: Improvements in diagnosis and care, including the development of antiretroviral therapies (ART), has increased the life expectancy of PLWHIV. Several studies have assessed the epidemiology of comorbidities in HIV patients; however a gap remains to see the prevalence of these comorbidities when compared to a control group (non-HIV infected). Despite the treatment improvements, comorbidities continue to complicate patient outcomes. We aimed to assess the current prevalence of comorbidities of the HIV infected population and compare to a matched control group from the general population in France.
Methods: This study is a retrospective health insurance claims database analysis using Echantillon Généraliste de Bénéficiaires (EGB), comprising of 1% representative sample of subjects covered by the general health insurance scheme. A cohort of patients diagnosed with HIV in 2011 was extracted from the database and followed to 2014. Comorbidity prevalence, assessed using ICD-10 codes, were estimated and compared with a non HIV infected control group (1 HIV infected to 2 controls) matched based on an age, gender, area of residence and socioeconomic status.
Results: 1,092 subjects were HIV infected and 2,183 were identified in the control group: in both populations 68.9% were male, mean age was 46.6 years. Results for comorbidities are shown in Table 1. More prevalent in the HIV than the control group were hypertension (27.8% versus 23.6% (p=0.003), (21.9% versus 14.7% (p< 0.0001)) and chronic renal disease (1.0% versus 0.1% p = 0.0007). Prevalence of diabetes and bone fractures were similar between the two groups.
Conclusions: In this HIV population with a mean age approaching 50, the prevalence of important non-AIDS-related comorbidities is higher that matched HIV negative controls. In this analysis, cardiovascular diseases and risk factors are more frequent in HIV patients, highlighting the need for changes in HIV management including regular monitoring and specific therapy to reduce long term risk.

	HIV infected (%)	General Population (%)	p Value
Cardiovascular diseases*	7.5	4.1	<0.0001
Hepatitis B or C Coinfection	15.0	0.4	<0.0001
Chronic Renal Disease	1.0	0.1	0.0007

*Cardiovascular diseases include any of the five comorbidities: Chronic Ischaemic heart disease; Cardiac failure; Chronic Rheumatic Heart disease; Stroke or TIA or Peripheral artery disease.

[Table 1: Prevalence of comorbidities amongst HIV + and control group]

TUPEA0146

Class-modeling analysis reveals T-cell homeostasis disturbances involved in loss of immune control in elite controller patients

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Background: Although elite controller (EC) patients are able to maintain undetectable HIV-viral load, not all of them achieve immunological control (stable CD4 T-cell counts), which can lead them to relevant clinical implications. Therefore, it is important to elucidate mechanisms involved in the CD4 T-cells loss in these subjects. In this study, a deep approach of the immunological factors related to the CD4 T-cells loss was explored.
Methods: A total of 36 EC patients, 22 with stable CD4 counts („control group") and 14 with CD4 decline („case group") were included, plus 20 healthy controls (HC). Different aspects of HIV immunopathogenesis (activation, maturation, exhaustion, thymic production, senescence, Treg-cells) were evaluated using a comprehensive flow cytometry analysis. Statistical analysis was approached by means of Partial Least Squares (PLS)-class modeling methodology in order to detect subtle differences associated with loss of immunological control.
Results: Both groups of patients were comparable in terms of age, sex or CD4 counts at the moment of the analysis. Two PLS models were developed: one to discriminate between EC patients and HC (PLS1), and another to discriminate between case and control groups of patients (PLS2). Both PLS models showed very high levels of sensitivity (98% and 97% for PLS1 and PLS2 respectively) and specificity (98% and 97% respectively). Thus, PLS-class modeling enabled us to decide whether a sample belonged to one of the three categories: control group, case group, or HC. Using this approach we were able to detect subtle, but determinant, alterations in T-cell homeostasis parameters associated to loss of immunological control in EC. Among them, high-levels of exhaustion of CD4 (p=0,01) and CD8 (p=0,04) T-cells, high levels of effector CD8 T-cells (p=0,008), high levels of senescence of CD8 T-cells (p=0,02), and low levels of naïve CD8 T-cells (p=0,02).
Conclusions: Our results demonstrate the existence of a state of T-cell homeostasis disturbance associated to immunological progression in EC patients, suggesting the existence of active pathogenic mechanisms operating even in the face of undetectable viral replication. Knowledge of mechanisms underlying T-cell homeostasis disturbance will be of pivotal.

TUPEA0147

Older age at infection is associated with long-term non-progression in women infected with non-subtype B HIV-1

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Background: A number of studies of people infected with HIV-1 have reported on antiretroviral (ART)-naïve individuals who show little disease progression despite prolonged infection (long-term non-progressors [LTNPs]). Few have assessed the prevalence and correlates of LTNPs in populations predominantly infected with non-subtype-B HIV-1.
Methods: We analyzed data from the Mombasa Cohort, a prospective study of female HIV-1 seroconverters in Kenya with estimated dates of infection. We defined two LTNP groups: LTNP-7 had ART-naïve duration of infection ≥7 years with the majority of CD4+ counts ≥600 cells/mL; LTNP-10 had a duration ≥10 years with the majority of CD4+ counts ≥500 cells/mL. We conducted a nested case-control study comparing correlates among LTNPs (7 and/or 10) versus non-LTNPs who accrued similar, ART-naïve follow-up using logistic regression.
Results: Between February 1993 and March 2014, there were 332 HIV-1 seroconverters with estimated dates of infection. Of 77 women with sufficient follow-up to be evaluated for LTNP status, 13 (16.9%) were categorized as LTNPs based on one or both definitions (8 LTNP-7 and 2 LTNP-10 and 3 both). The predominant infecting HIV-1 subtype was A (75.0%). Significant correlates of LTNP status in multivariable analyses included age >30 years versus ≤30 years at infection (adjusted odds ratio [aOR]=29.02, 95% confidence interval [CI]: 2.72-309.83, P=0.005) and history of prior pregnancy at enrollment compared to nulliparity (aOR=0.02, 95% CI: 0.00-0.47, P=0.02). Each log10 increase in plasma viral load set point was associated with a significantly lower likelihood of LTNP status (aOR=0.23, 95% CI: 0.08-0.68, P=0.008).
Conclusions: Long-term non-progression was strongly associated with older age at time of infection and parity. The association between older age and LTNP status was not attenuated by adjustment for viral set point, suggesting an alternative mechanism for long-term non-progression.

TUPEA0148

Decrease of blood HIV reservoirs over years in HIV-controllers

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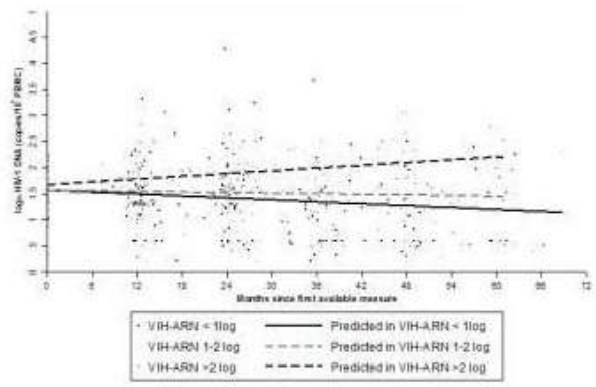
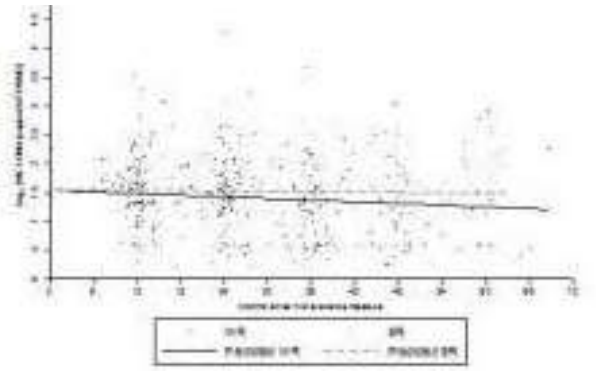
Background: Total HIV-DNA is a convenient marker to monitor the reservoir size in HIV-infected patients. This study aimed to describe the HIV-DNA dynamics in blood of HIV-1 infected individuals showing natural long-term virological and/or immunological control (ANRS CODEX cohort).
Methods: HIV-DNA was quantified prospectively by ultrasensitive real-time PCR in frozen PBMC during follow-up of 36.4 months [24.2-48.2]. 192 subjects (95 men) with at least two measurements (median 3 measurements, [2-7]) were analyzed. Marker dynamics were modeled by mixed-effect linear models.
Results: At the time of the first HIV-DNA quantification in the cohort, CD4 count was 760 (196-2063) cells/mm3 (median (range)), HIV-RNA load was 0.71 (0.01-2.87) log cp/mL andHIV-DNA was 1.45 (0.00-3.36) log cp/Million PBMC. Individuals with HIV-RNA>2log at inclusion in the cohort (n=9) increased their total HIV-DNA over time (slope: +0.108 log/year, p=0.02), whereas HIV-DNA decreased in HIV controllers with 1 log< HIV-RNA< 2log (slope: -0.024log/year, p=0.38)(n=31) or HIV-RNA< 1log (slope: -0.072log/year, p< 0.001)(n=54).



[Fig 1. HIV-DNA kinetics according to HIV-RNA levels]

HIV-DNA decreased overtime in subjects with weak anti-HIV CD8 T cell responses (slope: -0.060log/year)(n=130) whereas the slope was not significantly different from 0 in individuals with strong anti-HIV CD8 T cell responses (n=62).



[Fig 2. HIV-DNA kinetics according to weak responder or strong responder status]

Conclusions: In this large long-term study, we report that HIV blood reservoirs significantly decrease over years in some HIV controllers, similarly to post-treatment controllers. We hypothesize that this decrease contribute to the maintenance of high control. This is in contrast with the HIV-DNA increase observed in HIV-infected progressors. Weak CD8 T cell responses among controllers might be the result of a tighter control of infection.

TUPEA0149

Post treatment control in an adult with perinatally acquired HIV following cessation of antiretroviral therapy

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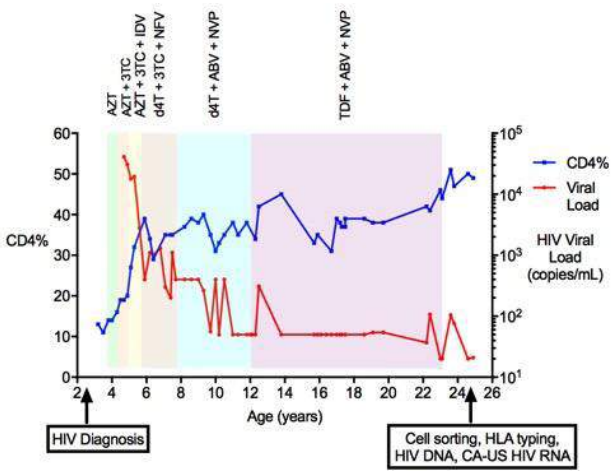
Background: Virological remission is reported after antiretroviral therapy (ART) cessation in adults and one infant treated very early after infection. However post-treatment control [PTC] has never been described in chronic infection after perinatal acquisition and rarely in adults.
Methods: Clinical review and laboratory analysis of a perinatally HIV infected adult with PTC. We quantified HIV persistence by PCR including HIV DNA and cell-associated unspliced (CA-US) HIV RNA in total and sorted CD4+ T-cell subpopulations (naïve, central, transitional, effector memory and terminally differentiated, [N/CM/TM/EM/TD]). Four-digit HLA typing was performed.
Results: A 25-year-old woman diagnosed at age 2.2 years and no prior opportunistic infection, commenced ART at 3.5 years with one and then two antivirals. She achieved virological suppression after combination ART from age 7.5-23 years with 26/33 plasma HIV RNA measurements below limit of detection. When detected, HIV RNA ranged 37-309 copies/mL. At age 25, two years before enrolment, ART was ceased, HIV RNA ranged from < 20-104 copies/ml off ART, with stable CD4+ T-cell counts (704-869 cells/μL) and percentage (47-51%).



[ART history HIV viral load and CD4%]

The participant had subtype B virus, was homozygous for wild-type CCR5 and demonstrated one HLA-allele associated with viral control (B14:02/C08:02) and two alleles seen in the previously reported perinatally infected PTC (A23:01, C08:02). CA-US HIV RNA was 2.4 log_{10}copies/million copies. 18S and HIV DNA was 0.9 log_{10}/million cell equivalents. Flow cytometry sorting of naive (0.8%), central (0.6%), transitional (23.1%), effector memory (0.7%) and terminally differentiated (71.9%) CD4+ subpopulations revealed all cells were infected with highest to lowest levels of CA-US HIV RNA in CM>EM>N>TM>TD and HIV DNA was CM>N>TM>EM>TD.
Conclusions: We describe PTC in an adult with perinatally acquired HIV and prolonged viremia before ART. Virus was enriched in long lived T-cell subsets and one protective HLA allele was detected. Understanding PTC in different clinical settings may identify new strategies to achieve HIV remission.

TUPEA0150

Follicular helper t cell function sustains high-level specific memory B cell responses in sponstaneously controlled HIV infection

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Background: Follicular helper T cells (Tfh) play an essential role in the maturation of the antibody response by providing help to B cells. To determine whether this CD4+ T cell subset may contribute to the spontaneous control of HIV replication, we analyzed the phenotype and function of circulating Tfh (cTfh) in HIV Controllers from the ANRS CO21 CODEX cohort.
Methods: HIV Controllers (HIC, n=13) with a viral load < 50 copies/mL were compared to treated patients with a similarly low viral load (HAART, n=16). HIV-specific cTfh were detected ex vivo by MHC-II tetramer labelling of CD4+CD45RA-CXCR5+ T-cells. The transcriptional profile of tetramer-positive cells was determined by single-cell multiplexed qPCR analysis (Biomark). To evaluate cTfh function, cocultures of cTfh with autologous CD20+ CD27+ memory B lymphocytes (BL) were tested for plasmablast differentiation (CD38hi BL) and total or gp140-specific IgG secretion.
Results: The total cTfh population was predominantly central memory (CCR7+) and showed comparable PD-1 expression levels in both groups (medians: HIC: 29%; HAART: 26%). The study of HIV-specific CD4+ T cells revealed a marked increase in PD-1 expression (medians: HIC: 76%; HAART: 77%) in the cTfh compartment of both groups, suggesting that specific cTfh received chronic antigenic stimulation in spite of low viremia. At the transcriptional level, HIV-specific cTfh expressed low Blimp-1 levels, as expected, but did not upregulate Bcl-6. While cTfh from healthy donors proved highly functional, cTfh from both the HIC and the HAART groups showed a degree of dysfunction as measured by the number of plasmablasts and by total IgG secretion. This defect appeared reversible, as it was abrogated by the addition of IL-6 in the cTfh/BL cocultures. Of note, the HIV-specific memory B cell response differed in the HIC and HAART groups, with higher Env-specific IgG production in cTfh/BL cocultures from Controllers (P=0.02). Supplementation with IL-6 increased the difference, resulting in 60x higher Env-specific IgG concentrations in cocultures from the HIC group (P=0.004).
Conclusions: These findings suggest that key Tfh/BL interactions are preserved in naturally controlled HIV infection, resulting in potent memory B cell responses that may play an underappreciated role in HIV control.

TUPEA0151

Exome-wide association study in HIV-infected individuals identifies a functional variant related to long-term non progression in *UBXN6*

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Background: Long-term non-progressors (LTNP) are a heterogeneous group of HIV-1 infected individuals characterized by their ability to maintain high $CD4^+$ T cell counts and control viral replication for years in the absence of antiretroviral therapy. Nevertheless, LTNP phenotype is far to be fully understood. The present study aims to identify host functional determinants of non-progression in a Spanish cohort of LTNPs.
Methods: An exome genotyping microarray interrogated 247,722 single nucleotide polymorphisms (SNPs) of 85 LTNP. The allelic frequencies of this group were compared with a healthy population of 267 individuals through Fisher´s test. Different populations were used to confirm an aberrant frequency of rs1127888 in LTNP, including a group of HIV-1 infected individuals with a typical pattern of disease progression (TP; n=58) and two reference populations, 1000 Genomes Project (EUR; n=503) and Exome Sequencing Project (EA; n=4300). UBXN6-knockdown mediated by siRNAs were conducted to assay the role of this gene in HeLa and mature dendritic cells (MDC) infected with different HIV-1 luciferase-expressing recombinant viruses, including NL4.3-Luc (CXCR4-tropic), JR-Ren (CCR5-tropic) and VSV-NL4.3Luc-R−E− (CD4/coreceptor-independent entry). Cell infection was assessed through measurement of Relative Luciferase Units (RLU). The expression of UBXN6 and UBXN6-interacting protein CAV1 was measured by Western-blot and immunofluorescence assays.
Results: The SNP rs1127888 located in 19p13.3 and associated with UBXN6 reached genome-wide significance ($p=7.34x10^{-11}$; $q=2.11 \times 10^{-6}$, after Bonferroni correction) in the LTNP/control association study. The anomalous allelic and genotypic frequencies of rs1127888 observed in LTNP were confirmed with reference populations (EUR and EA) and by sequencing in TP population. The predicted effect of rs1127888 causes A31T missense variant in UBXN6 protein. UBXN6-knockdown in HeLa cells increases CAV1 expression by 33% and its accumulation in the plasma membrane. UBXN6-knockdown increased infection with VSV-NL4.3Luc-R−E− by 29.5% compared with controls whereas no differences were found after the infection with NL4.3-Luc. Preliminary results in MDC showed an increase in RLU by more than 3 times after the infection with JR-Ren in cells where UBXN6 were silenced.
Conclusions: The SNP rs1127888 causing A31T variant of UBXN6 was associated with LTNP phenotype. UBXN6-silencing resulted in altered CAV1 availability and increased HIV-1 infection through enhancement of CD4/coreceptor-independent endocytosis.

TUPEA0152

Compromised macrophage-mediated HIV *trans* infection of CD4 T cells is linked to lipid raft dissociation

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Background: A small percent of persons control HIV infection without antiretroviral therapy. We previously showed that this non-progressor (NP) phenotype is linked to dysfunctional cholesterol-dependent trans infection of HIV from profes-

sional antigen-presenting cells (APC; dendritic cells [DC] and B cells) to CD4 T cells. Macrophages (MΦ) have enhanced cholesterol sensing abilities and are involved in HIV dissemination. We sought to determine if MΦ cholesterol is altered in NP, and what effects cholesterol content and distribution have on trans infection and surface protein expression.
Methods: MΦ were generated in vitro from monocytes. Trans infections were performed by co-culture of R5 HIV Bal-exposed APC with autologous CD4 T cells followed by p24 ELISA. Total cell cholesterol was measured with the Amplex Red assay. Cell membrane cholesterol was visualized by flow cytometry.
Results: MΦ trans infection was undetectable in NP compared to progressors (PR). NP MΦ displayed less total cholesterol, but similar cell membrane cholesterol concentrations compared to PR. DC-SIGN expression on MΦ was significantly lower in NP, suggesting NP and PR may have differential plasma membrane lipid rafting that is required for functional surface expression of DC-SIGN. Within seronegatives (SN), MΦ trans infection efficiency positively correlated with the percentage of DC-SIGN$^+$ MΦ. Deficient trans infection in SN was associated with dissociated lipid rafting in APC. Interestingly, lowering cholesterol synthesis in SN MΦ decreased trans infection efficiency and cis infection, as well as lipid rafting.
Conclusions: We linked MΦ-mediated trans infection with HIV progression. Differential MΦ cholesterol concentrations and DC-SIGN expression in NP and PR, and the ability of statins to impede lipid rafting and decrease trans infection, suggest that a cholesterol-associated, virus-cell interaction is paramount for HIV trans infection and disease progression. We are currently comparing NP and PR by RNA Seq to elucidate mechanistic components of cholesterol mediated trans infection. Based on APC-T cell proximity and interactions in lymphoid organs, our data support APC-mediated trans infection as an important mechanism of virus dissemination and reservoir maintenance.

TUPEA0153

Functional characterization of a public TCR clonotype identified against the HIV-1 Gag A2-FK10 epitope

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Background: T cell receptor (TCR) repertoire diversity determines the breadth and specificity of an individual's cytotoxic T lymphocyte response against HIV infection. A better understanding of features associated with highly active antiviral TCR may inform strategies to reduce or eliminate latent HIV-1 infection, particularly in the context of diverse or "escaped" epitopes.
Methods: Tetramer+ CD8 T cells against Gag FS8 (FLGKIWPS) were isolated by FACS from HLA-A*02+ HIV non-progressors. Paired TCR alpha and beta CDR3 sequences were determined using single-cell RT-PCR. Full-length TCR genes were reconstructed and transfected into Jurkat cells along with CD8 alpha and NFAT-driven luciferase reporter. TCR+ Jurkat "effector" cells were co-cultured with A*02+ "target" cells pulsed with FK10 peptide or variants and TCR-mediated signaling was quantified by luminescence.
Results: A dominant TCR clonotype reactive against A2-FK10 was observed in two unrelated individuals. In one case, clone 1A9 was observed at ~60% frequency in tetramer-sorted cells. In the second case, clone 4A4 was observed at 100% frequency. 1A9 and 4A4 encoded identical alpha and beta Variable genes (TRAV12-1, TRBV7-2). Furthermore, their alpha CDR3 sequences differed by 1 amino acid, and their beta CDR3 sequence differed by 4 amino acids. 1A9 and 4A4 showed similar antigen sensitivity to FS8 (EC50: 0.29 ng/μL and 0.23 ng/μL, respectively) and FK10 (EC50: 2.1 ng/μL and 0.97 ng/μL) in a TCR signaling assay. Analysis of FS8 variants indicated that positions 4, 6 and 7 were critical for signaling by both TCR, and a natural polymorphism at peptide position 4 (Gag K436R) similarly abrogated their activity.
Conclusions: We have identified a novel "type 2" public TCR clonotype against A2-FK10 with nearly identical sequences, signaling capacities and peptide cross-reactivity profiles. Our results indicate that the T cell response elicited towards this HIV epitope may be highly restricted, but nevertheless effective once generated.

TUPEA0154

Evaluation of combined protective effect of five variant genotypes on susceptibility to HIV infection in discordant couples

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Background: HIV-negative partners in discordant couples provide a fair opportunity to study highly exposed seronegative individuals (HESN). Having analyzed epidemiological information about 500 HESN from discordant couples, we selected a subgroup to analyze a number of allele variants contributing to HIV resistance.
Methods: The study was performed in 2016 and included HESN from heterosexual discordant couples with history of sexual relationship ranging 1 to 12 years. These couples are being followed-up in Moscow Regional AIDS Center. DNA was extracted from venous blood. Allelic variants were determined by PCR/RFLP in five polymorphic loci related to HIV susceptibility (CCR5-Δ32, CCR5-T303A, CCR2-V64I, DC-SIGN-VNTR, and SDF-1 3'A). Combined contribution of the genotypes to presumable protective effect was evaluated using the total genotype score (TGS) approach. In statistical comparisons, exact Fisher test was used.
Results: For genotype analysis, we selected HESN who
(i) had lived together for 6-12 years,
(ii) had partners with confirmed viral load,
(iii) self-reported regular unprotected sexual contacts, and
(iv) had been passing regular medical examination in the AIDS Center.
This HESN subgroup consisted of 9 men and 25 women, though in the total HESN sample the proportions of men and women were almost equal (247 and 253). Having stratified our HESN sample by years of sexual relationship, we found that proportion of women increased with time: from 43.5% after 1-5 years to 69.1% after 6-12 years ($p<0.001$). A control group (matched by age and gender) was composed of 34 HIV patients who had been infected through heterosexual contacts. Genotypes in the selected loci were determined in both groups. Allele and genotype frequencies evaluated separately for each locus did not show significant difference between the groups. To analyze a possible combined effect, TGS values were ascribed to each individual, based on published data. TGS distributions in the HESN and control groups were significantly different ($p=0.030$).
Conclusions: Our results, indicating protective role of the combined variation in five genes affecting HIV entrance into cells, contribute to understanding the genetic background of HIV susceptibility. The TGS method proved to be a useful tool for evaluation of genotype interplay in samples of limited size.

TUPEA0155

Interleukin-21/microRNA-29 axis in natural resistance to HIV-1 infection

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Background: Interleukin-21 (IL-21) controls HIV-1 infection through the elicitation of different antiviral mechanisms, including Th17 lineage commitment and the induction of microRNA(miR)29, a miRNA endowed with anti-HIV activity whose expression is significantly increased in HIV-exposed seronegative individuals (HESN). We investigated possible interactions between IL-21 and the overall immunological outcome responsible for natural control of HIV-1 infection.
Methods: CD4+ T lymphocytes isolated from 15 Italian HESN exposed to HIV through unprotected sexual intercourses and from 15 HIV-unexposed healthy controls (HC) were in vitro infected with an R5 tropic HIV-1_{Ba-L} strain .
Seven days post infection we evaluated:
1) p24 production (ELISA);
2) CD4+/IL21+ and CD4+/IL17+ T lymphocytes (FACS);
3) IL-21 and IL-17 concentration in supernatants (ELISA); and
4) IL-21, IL-17 as well as mir29a, b, c expression by CD4+ T lymphocytes (qPCR).
The same analyses were performed at baseline on 15 HIV+ partners.
Results: At baseline, IL-6 and IL-21 expression was significantly higher in HESN and HIV+ patients compared to HC. Seven days after in vitro HIV-1 infection, CD4+/IL21+ and CD4+/IL17+ T lymphocytes, as well as IL-6, IL-17 and IL-21 expression and

production were significantly augmented in HESN compared to HC. Interestingly, IL-21 upregulation correlated with a significantly increased expression of miR29a, b, c and reduced susceptibility to in vitro HIV-1 infection in HESN alone.
Conclusions: The IL-21-miR-29 axis is upregulated by HIV infection in HESN; this axis could play an important role in the natural resistance to HIV-infection seen in HESN. Approaches that exogenously increase IL-21 production or prompt pre-existing cellular IL-21 reservoir could confine the magnitude of the early HIV-1 infection.

TUPEA0156

Immune signatures linked with HIV-1 neutralization breadth

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Background: The factors that drive broadly neutralizing antibodies (bnAbs) development in natural infection are still poorly understood. In the Swiss 4.5K Screen, a systematic survey of bnAb activity in 4,484 HIV-1 infected individuals (Rusert, Kouyos Nat Med 2016), we identified 239 bnAb inducers, and showed that viral load, infection length, viral diversity, and black ethnicity were positively and independently associated with bnAb development. We recently found several HIV-1 antibody binding profiles predictive of neutralization breadth (Kadelka CROI 2017). Here, we compare the parameters associated with binding activity with those associated with bnAb activity, and report on improved predictors of neutralization breadth.
Methods: Using an in-house established Luminex bead assay, we probed 4,283 plasma samples included in the Swiss 4.5K Screen for binding antibodies of IgG subclasses 1, 2 and 3 against 13 HIV-1 proteins and peptides encompassing Gag (p17, p24) and Env. Multivariable regression models were used to detect associations. Predictive power was measured using the area under the ROC-curve (AUC).
Results: Viral load differentially steered responses to HIV-1 antigens affecting both the magnitude of the response and the IgG subclass diversification; high viral load was linked with low binding titers of IgG1 p17&p24, and IgG3 gp41 (each $p< 10^{-9}$), but also with high binding titers of IgG1 gp41 ($p< 10^{-7}$) and IgG2 gp120 ($p=0.01$-10^{-10}). Viral diversity was positively associated with gp120 responses, particularly strongly with IgG1 BG505 trimer ($p< 10^{-9}$). Interestingly, diversity had no influence on Gag and gp41, both of which have lower genetic variability than gp120. Infection length was in contrast linked with high IgG1 binding titers across diverse antigens highlighting that breadth development requires time. Independent from viral subtype, black ethnicity was associated with high IgG1 BG505 trimer responses ($p<10^{-24}$) and IgG1 BG505 trimer responses were most predictive of neutralization breadth (AUC=0.85). Advanced prediction models based on multiple binding responses and patient characteristics provided even better bnAb prediction.
Conclusions: Previously identified independent drivers of bnAb activity proved to be associated with distinctive HIV-1 binding antibody immune signatures. Importantly, binding antibody responses to the BG505 trimer reliably predict neutralization breadth, providing a valuable assessment tool of forthcoming vaccine efficacy trials.

TUPEA0157

Preservation of lymphopoietic potential and virus suppressive capacity by CD8+ T cells in HIV-2-infected controllers

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Background: Compared with HIV-1, HIV-2 infection is characterized by a larger proportion of slow or non-progressors. A better understanding of HIV-2 pathogenesis should open new therapeutic avenues to establish control of HIV-1 replication in infected patients.
Methods: In this study, we performed a fine characterization of HIV-2-specific CD8+ T cells in HIV-2 infected controllers from the French ANRS CO5 HIV-2 cohort, taking in consideration CD8+ T-cell production capacity, the phenotype of HIV-2 tetramer positive cells and HIV-2 suppressive capacity.
Results: HIV-2 controllers display a robust capacity to support long-term renewal of the CD8+ T-cell compartment by preserving immune resources, including hematopoietic progenitors and thymic activity, which could contribute to the long-term maintenance of the CD8+ T cell response and the avoidance of premature immune aging. Our data support the presence of HIV-2 Gag-specific CD8+ T cells that display an early memory differentiation phenotype and robust effector potential in HIV-2 controllers. We show for the first time to our knowledge that HIV-2 controllers possess also CD8+ T cells that show an unusually strong capacity to suppress HIV-2 infection in autologous CD4+ T cells ex vivo. The HIV-2 suppressive capacity of CD8+ T cells correlated with patient CD4+ T cell counts, supporting a role of these cells to limit disease progression.
Conclusions: Our data suggest that the effective and durable control in HIV-2-infected individuals probably participates in a virtuous circle, during which controlled viral replication permits the preservation of immune functions, including potent HIV-2-specific CD8+ T cells, thus preventing HIV-2 disease progression.

TUPEA0158

HLA-C expression levels and binding stability to β_2m modulate HIV-1 infectivity

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Background: HLA-C expression levels lead to different HIV-1 infection outcomes. A higher expression is associated with a better activation of cytotoxic T lymphocytes (CTLs) and thus a better HIV-1 infection control. Vice versa, a lower HLA-C expression leads to a rapid progression toward AIDS. Thus, HLA-C highly and lowly expressed alleles are defined as protective and non-protective, respectively. Furthermore, different HLA-C alleles have different binding stabilities to $\beta_2$microglobulin (β_2m). Interestingly, HLA-C protective alleles are also those that bind β_2m more efficiently, while the non-protective variants present more free chains (not bound to β_2m) on the cell surface. It is also known that virions lacking HLA-C have reduced infectivity and increased susceptibility to neutralizing antibodies.
Methods: The A3.01 cell line and its HIV-1-infected counterpart ACH-2 were used as an in vitro infection model. 293T β_2m negative cells, generated using CRISPR/Cas9 system, were utilized to produce HIV-1 pseudoviruses. PBMC from healthy blood donors, harboring both protective or non-protective alleles, were exploited to

characterize the proportion between HLA-C associated to β_2m and HLA-C presents as free chains on the cell surface. In addition, PBMC from the same donors were tested for their ability to support HIV-1 infection in vitro.
Results: HLA-C free chains, specifically more represented on the surface of infected cells, are responsible for the increase of virions' infectivity. We observed that HIV-1 Env-pseudotyped viruses produced in β_2m negative cells, thus lacking HLA-C on their envelope, are less infectious than those produced in the presence of β_2m.
In PBMC we found that protective HLA-C variants are more stably bound to β_2m than non-protective ones and that HIV-1, in vitro, infects more efficiently PBMC harboring non-protective, weakly bound to β_2m, HLA-C alleles.
Conclusions: We propose that the outcome of HIV-1 infection might be driven both by the HLA-C surface expression levels and by the HLA-C/β_2m binding stability. According to this model, the expression of non-protective HLA-C alleles, which bind weakly β_2m, leads to a reduction of immunocompetent complexes expressed on the cell surface and to an increase of HLA-C free chains that raises viral infectivity, both leading to a rapid progression toward AIDS.

TUPEA0159

HIV-specific CD8+ T cells from natural HIV-1 controllers have a distinct signature associated with enhanced metabolic plasticity and antiviral function. ANRS CO21 CODEX

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Background: HIV-controllers (HIC) are a rare group of infected patients who can control the virus below the limit of detection without antiretroviral therapy. This control is usually associated with a strong capacity of HIV-specific CD8 T cells to eliminate infected autologous CD4 T cells ex vivo. This capacity seems to be related to inherent characteristics of CD8 T cells but the mechanisms are still not well understood. We made the hypothesis that such enhanced antiviral capacity could be engraved in the transcription profile of HIV-specific memory CD8 T cells from controllers.
Methods: To define a transcriptional signature associated with control of infection, and take into account cellular heterogeneity, single HIV-specific central memory CD8 T cells from HIC and antiretroviral treated individuals were flow-sorted. Single cell gene expression was then measured by real time PCR. Statistical analyses were performed to identify markers that are differentially expressed between the two groups and to identify clusters of cells sharing common characteristics. Intracellular cytokine staining was used to assess HIV-specific CD8 T cells responses under metabolic stress conditions.
Results: Single cell profiling showed that HIV-specific memory CD8 T cells from HIC and non-controllers have distinct transcriptional signatures. When compared with non-controllers, HIC upregulated genes linked to effector function and survival. In contrast non-controllers upregulated genes associated with proliferation and exhaustion. These profiles were associated with higher expression of genes promoting glycolysis in non-controllers and a different balance of the mTORC1/mTORC2 pathways in HIC and non-controllers. Functional analyses showed that HIV-specific CD8 T cells from HIC were partially dependent on glucose and mitochondrial activity, while cells from non-controllers were exclusively dependent on glucose.
Conclusions: Overall our results suggest that poor functionality of HIV-specific CD8 T cells from non-controllers could be related to their dependence on glycolysis as primary energy source. In contrast cells from HIC appear to diversify their metabolic resources. Our data highlight the inherent singularity of HIV-specific CD8 T cells from HIC and hint to a metabolic profile compatible with better cell survival and potential to develop anti-HIV effector function under metabolic stress conditions. HIV-specific CD8 T cells metabolism appears to be paramount for control of infection.

TUPEA0160

Functionality of tissue-resident SIV-specific CD8+ T cells

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Background: Simian immunodeficiency virus (SIV)-specific CD8+ T lymphocytes can reduce SIV replication, slowing disease progression. However, SIV-specific CD8+ T cells are incapable of reducing viral replication to low levels for the lifespan of most SIV-infected rhesus macaques (RM) and the majority of animals progress to simian AIDS. Recent studies demonstrated that SIV persists in lymphoid follicles. In a small group of elite controller Asian macaques, SIV replication is spontaneously controlled.
This phenomenon is suggested to be attributed to the unique ability of some CD8+ T cells to penetrate into lymphoid follicles and reduce SIV infection of CD4+ follicular helper T (T_{FH}) cells.
Methods: To determine whether there are signatures of tissue-resident SIV-specific CD8+ T cells associated with increased virologic control, we analyzed molecular and immunological characteristics of SIV-epitope specific CD8+ T cells in lymphoid and gastrointestinal tract tissues of 12 SIVmac239, SIVsmE543, or SIVsmE660 infected RM. Seven macaques with viral load less than 10,000 copies/mL were considered to be controllers while the remaining 5 were noncontrollers. MHC-I tetramers loaded with SIV epitopes were used to identify SIV-specific CD8+ T cells and flow cytometric and gene chip analyses were used to unravel phenotypic and functional qualities.
Results: While we found no differences in the magnitude of SIV-specific T cell responses based upon their ability to control viral replication, RM who controlled viral replication to low levels exhibited increased CXCR5 expression in lymphoid tissues compared to RM with higher viral loads and frequencies of CXCR5+ SIV-specific CD8+ T cells negatively correlated with plasma RNA viral load and viral DNA within T_{FH} cells. Additionally, frequencies and phenotypes of SIV-specific CD8+ T cells were closely associated with those found in the gastrointestinal tract.
Conclusions: Our data suggest that inherent functionality and particular trafficking of SIV-specific CD8+ T cells are important for virologic control. Additionally, these results demonstrate that analysis of lymphoid tissues may be reflective of T cell responses within the gastrointestinal tract. These results will help to better understand the mechanisms that underlie SIV disease progression and the role of SIV-specific CD8+ T cells in SIV pathogenesis, which may lead to rational vaccine development.

TUPEA0161

NK cell capacity to accumulate in lymph node follicles is associated with SIV control

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Background: During cART, HIV persists in lymph nodes (LN), in particular in B-cell follicles. LN follicles also represent a niche for HIV to hide from most CD8+ T cells in HIV/SIV controllers. In this study, we explored mechanisms that allow control of viral replication within follicles using a natural host of SIV model, the African Green monkey (AGM), which has an uncommon capacity to efficiently control SIV replication in LN.
Methods: Six AGM and six cynomolgus macaques were infected respectively with SIVagm.sab$_{92018}$ and SIVmac$_{251}$ and followed for 6 months. Blood, peripheral LN and rectal biopsies were collected at regular intervals before, during acute and during chronic infection. Viremia as well as cell-associated viral RNA and DNA were quantified. Confocal microscopy was used to determine viral RNA distribution, changes in NK cell localization and cytokine expression. NK cell phenotypes and IL-15+cells were analysed by flow cytometry. Functional assays for evaluating NK cell suppressive activity were performed.
Results: We confirmed that AGM show a strong control of viral replication in LNs, in particular in follicles. Surprisingly, SIVagm infection induced the accumulation of high numbers of NK cells within follicles, associated with a high frequency (25%) of CXCR5+ NK cells in secondary lymphoid organs not observed in gut. Follicles during SIVagm infection were a large source of IL-15 suggesting a contribution in NK cell survival and/or differentiation. We observed an increase of differentiated NK cells in AGM LNs at the end of the acute phase when the virus starts to be controlled. CXCR5+NK cells from LN displayed a cytotoxic phenotype. We also observed a strong capacity of LN AGM NK cells to degranulate. In contrast, intestinal NK cells were rare in AGM in contrast to MAC and did not show an increased degranulation during infection.

Conclusions: We present the first evidence for a distinct anatomical location of NK cells between pathogenic and nonpathogenic SIV infection. The discovery of NK cell accumulation in follicles reveals a new feature of NK cells in primates. Their cytotoxic phenotype brings us to consider NK cells as one possible player in the control of HIV/SIV infections in LN.

TUPEA0162

Dolutegravir-based simplification of antiretroviral therapy (mono- and dual therapy) in humanized mice with chronic HIV infection

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Background: The integrase inhibitor Dolutegravir (DTG) has a high genetic barrier to drug resistance. To date, clinical resistance to DTG has not been reported in first-line therapy of ART-naïve patients. Proof-of-concept studies suggest that DTG might simplify current ART regimens from 3 to 2, or even to 1, drug. Yet, it is unclear whether DTG-based mono- or dual-drug therapy will durably sustain HIV suppression, without the emergence of resistance.
Methods: In a first study, we evaluated the efficacy of 20-week monotherapy with DTG or raltegravir (RAL) in humanized mice (HSC-NSG) infected with HIV_{BaL}. In a second study, using the same animal model, we evaluated dual therapy with DTG plus lamivudine (3TC). Plasma HIV RNA was measured by qRT-PCR every 2-3 weeks, lymphocyte subsets by flow cytometry, and drug levels by LC/MS/MS. Escape viruses were genotyped and analyzed for replication capacity and drug susceptibility in tissue culture.
Results: In the monotherapy study (DTG vs RAL), mice in the RAL group had decreases in HIV viremia, which became undetectable in 3/4 mice within 6 weeks of treatment. However, such suppression by RAL lasted for 2-3 weeks only, rebounding in all animals afterwards. In contrast, DTG suppressed viremia to undetectable levels in 5/5 mice within 6 weeks, and suppression was durable in all but one mouse that rebounded. Levels of RAL and DTG in plasma were within ranges in humans. Viruses from mice failing RAL monotherapy had developed mutations G140S and Q148H/K in IN, and were resistant to both RAL (EC_{50} values of > 100 nM) and DTG (EC_{50} values ranging 8.8-13.3 nM). The only mouse with viremia during DTG monotherapy had mutations E138K, G140S, Q148H, N155H and S230R. The virus from this mouse was highly resistant to both RAL (EC_{50} > 1000 nM) and DTG (EC_{50} of 550 nM), and replicated to high levels in primary PBMCs. In contrast, viruses from untreated mice were sensitive to RAL (EC_{50} < 8 nM) and DTG (EC_{50} < 1 nM). In a follow-up, ongoing study, mice treated with dual therapy (DTG+3TC) maintain durable suppression.
Conclusions: DTG monotherapy does not maintain HIV suppression, suggesting therapy simplification may require dual therapy.

TUPEA0163

Modeling viral kinetics predicts a rapid establishment of the cytotoxic immune response targeting distinct infected cell compartments in SIV controller macaques (ANRS SIC study)

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Background: Our group recently demonstrated that long term control of SIV can be obtained in cynomolgus macaques presenting a H6 MHC allele or in non-H6 animals infected with a low dose inoculum of SIVmac251 by mucosal route (see abstract by Passaes et al.).
Methods: Here we applied mathematical modeling to viral kinetics in this model to help unraveling the determinants of viral control. The kinetics of SIV-RNA and SIV-DNA was obtained for 18 months in 16 macaques in 3 groups:
i) H6 macaques infected with 50 AID50 (n=6) ;
ii) non-H6 macaques infected with 5 AID50 (n=4) ;
iii) non-H6 macaques infected with 50 AID50 (n=6, controls).
SIV-RNA and SIV-DNA data were jointly fitted with a mechanistic model of viral infection, using population approach (Monolix software).
Results: The rapid viral decline after the peak in controllers could be best reproduced assuming a cytotoxic immune response with a saturable infected cells-dependent growth rate. Interestingly in our model viral control did not correlate with the strength of the immune response per se, but rather with an early effective response after peak viremia, as corroborated independently by longitudinal ex-vivo assessment of CD8 T cells cytotoxic activity (Passaes et al.). Further, SIV-DNA after the peak declined slowly in a biphasic manner, suggesting that SIV-DNA after the peak largely originates from not or low actively productive cells. In fact, best fit to SIV-RNA and SIV-DNA kinetics was obtained assuming 3 compartments of infected cells: highly productive cells with a short half-life decreasing from 5.5 days (early infection) to 0.3 days after peak viremia, and two populations of weakly or nonproductive cells, with half-life of 5.1 and 118 days. Thus one predicts that these compartments respectively account for about 1, 5 and 96% of circulating infected cells, respectively, in typical controllers at the setpoint viremia.
Conclusions: In conclusion modeling predicts that an early establishment of an effective CD8 response is key to achieve viral control. Discrepancy between SIV-RNA and SIV-DNA kinetics reveals that more than 90% of SIV-DNA containing cells are not highly producing and not highly targeted by the immune response in these controllers.

TUPEA0164

RNA-Seq reveals lymph node resident pDCs as the primary cellular producer of type I IFN in SIV infection

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Background: Type I IFN has been long implicated as driver of pathogenesis in untreated HIV infection, and recently has been demonstrated to be a barrier to eradicating latent virus. Despite its importance, and although elevated expression of Interferon Stimulated Genes has long been reported in pathogenic HIV and SIV infection, the source of Type I IFN (IFNA and IFNB) has remained elusive.The goal of this study was to investigate the transcriptional profiles of pDCs in the blood and tissue of pathogenic and non-pathogenic NHPs and test if tissue resident pDCs produce Type I IFN in pathogenic SIV infection (Rhesus macaques) and in NHP species that do not develop AIDS (Sooty mangabeys).
Methods: Approximately 5,000 pDCs from blood were harvested from 4 SIV- Rhesus macaques, and 8 SIV+ Rhesus, 4 SIV+ Sooty mangabeys, and 4 SIV- Sooty mangabeys. We also tested pDCs from 10 SIV+ RMs from lymph node, blood and gut at necropsy. We profiled gene expression in each subset using Illumina RNA-Seq. Samples were sequenced to depths of 15 M reads in 100-base single read reactions. The reads were aligned to the Macaca mulatta reference genome MacaM 7.0 using the STAR algorithm, and gene expression assessed using DESeq2 software.
Results: Strikingly, we found that although IFN-A and IFN-B transcripts were absent from pDCs isolated from blood and mucosa, but high levels of transcripts were detectable in in pDCs isolated from LNs of SIV-infected rhesus macaques. IFNA transcripts were not detectable CD4 T cells from either LN or blood. A contrast of transcriptional signatures in pDCs between rhesus (AIDS susceptible) and sooty mangabeys (AIDS resistant) demonstrated that pDCs in rhesus had significant upregulation of Interferon Stimulated Genes in SIV-infected RM, but not in SMs. Expression of lentiviral restriction factors and inhibitory genes was consistent across species and infection status of pDCs from the blood.
Conclusions: In this study, we demonstrate that Type I IFN is robustly detectable in pDCs isolated from LN, but not blood or gut in SIV-infected rhesus macaques. The identification of LN pDCs as the main source IFNA production provides a cellular target for depletion-based therapies.

Co-infections

TUPEB0365

JC virus progressive multifocal leucoencephalopathy clinical presentation and prognosis in HIV and non-HIV patients: a case series

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Background: Human polyomavirus JC (JCV) is responsible for progressive multifocal leucoencephalopathy (PML). Introduction of combined antiretroviral therapy (cART) and increased use of immunosuppressive and oncologic therapies have modified the epidemiology and prognosis of PML. This study objective was to evaluate and compare the prognosis, diagnostic delays and clinical and radiological presentation of PML in HIV and non-HIV patients.
Methods: This retrospective observational multicentre study was performed in 4 university-affiliated hospitals of Montreal (Quebec). Patients were recruited through laboratory information systems and clinical archives interrogation. Patients with positive JCV polymerase chain reaction on cerebrospinal fluid and/or with a clinical diagnosis of PML during a hospitalization episode between January 2009 and December 2016 were included. Clinical data were collected through medical chart review following institutional review board approval. Fisher´s exact test and Mann-Whitney tests were used for comparative analysis of categorical and continuous variables.
Results: The study includes 13 HIV-infected-patients and 8 non HIV-infected-patients. One-year survival and time to diagnosis delay data were respectively available for 13 and 10 patients in the HIV positive group and for 6 and 8 patients in the HIV negative group. One-year survival was 91.7 and 16.7 percent in the HIV positive and negative groups respectively (p=0.0039). Median time between initial symptoms and PML diagnostic was 70.5 (IQR: 32-147) and 31.5 (IQR 20-133.5) days in the HIV positive and negative groups respectively (p=0.45). No differences between groups were noted in clinical and radiological presentations.
Conclusions: Preliminary data suggest that PML prognosis is significantly better among HIV positive patients. Modern cART and immune status restoration could explain this finding. Whether PML or the underlying neoplastic or immunosuppressive condition is responsible for high mortality rates in the non-HIV population needs further exploring. Diagnostic delays, clinical and radiological presentations between HIV positive and negative patients showed no significant differences.

TUPEB0366

No effect of adjunctive corticosteroids on CD4 cell count recovery in HIV patients with *Pneumocystis jirovecii* pneumonia

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Background: Pneumocystis jirovecii pneumonia (PJP) remains an important cause of morbidity and mortality in HIV-infected patients. In case of severe hypoxemia, corticosteroids are added to the antibiotic therapy. As corticosteroids are known to cause lymphocytopenia, there are concerns that corticosteroid use will cause slower CD4 cell count increase after commencement of combined antiretroviral therapy (cART). The aim of this study was to evaluate CD4 cell count recovery after adjunctive corticosteroid treatment in ART-naïve HIV-infected patients with PJP starting cART.
Methods: HIV-infected patients who presented with PJP in the University Medical Center Utrecht (Utrecht, The Netherlands) between 1996 and 2015 were included in this retrospective study. Demographic and laboratory data, details on ART and corticosteroid treatment were retrieved from the hospital charts. The primary outcome was the difference in mean CD4 count increase between the corticosteroid-treated (CS) group and the non-corticosteroid (non-CS) group after 1-year follow-up. The association between corticosteroids and CD4 cell count increase was evaluated with linear mixed model adjusted for baseline CD4 counts, age and gender. Secondary outcomes were the time needed to achieve plasma HIV-RNA <400 copies/mL, and 1-year mortality and recurrence of or new opportunistic infections (OIs).
Results: Sixty-two patients (n=36 in the CS- and n=26 in the non-CS group) were included. The groups were matched at baseline except the more profound hypoxemia in the CS-group. There was no significant difference in the mean increase of CD4 cell counts at 1-year follow-up between the CS and non-CS group (243 versus 222; p=0.60). There was no significant association between the corticosteroid use and the increase in the CD4 count (p=0.41). Furthermore, there was no significant difference in the time to achieve HIV RNA < 400 copies/mL and occurrence of OIs between both groups in the first year after PJP diagnosis. All patients were alive at the end of follow-up.
Conclusions: No deleterious effect of adjunctive corticosteroids on CD4-cell count was seen in our cohort of HIV patients with PJP. It is reassuring for the treating physicians to know that this short course of corticosteroid therapy does not put these vulnerable patients at risk for future OIs.

TUPEB0367

Prevalence and determinants of rifampicin resistance among patients screened for tuberculosis by gene xpert assay in a military hospital, Lagos State, Nigeria January to June, 2016

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Background: Tuberculosis (TB) is an infectious disease which develops under conditions of deficient immunologic response. Antibiotic resistance is a growing problem with increasing rate of multi-drug resistant tuberculosis (MDR-TB). MDR-TB is a serious public health issue in many developing countries in that its treatment is longer and requires more expensive drugs. GeneXpert assay is a molecular technique that simultaneously detects Mycobacterium tuberculosis (MTB) and Rifampicin resistance (RR) in approximately 2 hours. This study was done to determine the prevalence of RR among MTB patients and associated risk factors.
Methods: A retrospective cross sectional review of patients screened for TB with GeneXpert assay at Nigerian Navy Reference Hospital, Ojo, Lagos State, Nigeria from January to June, 2016 was performed (n=257). Data analysis was done using Epi-Info Software, version 7.2 and Microsoft Office Excel 2007.
Results: Mean age of subjects was 35.1 ± 17.2 years and 132(51.4%) were females. 51(19.8%) were confirmed TB positive and age group 20-29 years were mostly affected 15(29.4%). Majority of the cases were students, 14(27.5%) and predominantly males 31(60.8%). Six (11.8%) of the MTB positive subjects were HIV positive and the prevalence of RR-TB was 11.8%. Age, (OR=0.3; CI=0.10-0.92), HIV status, (OR=0.3; CI=0.11-0.67) and Tribe, (OR=3.46; CI=1.75-6.81) were all significantly associated with TB while occupation, marital status and gender were not statistically significant. Of all tribes in the data, even though there were more Igbo/Urhobos, Yoruba accounts for the most affected ethnic category, accounting for 29(56.9%) TB confirmed cases as well as having 5(83.3%) out of the RR-TB cases (OR=10.1; CI 1.16-88.0). Other factors such as age, gender and HIV status were not significantly associated with the development of RR-TB.
Conclusions: There was high prevalence of Rifampicin resistant tuberculosis among the population studied and HIV/TB co-infection was present. Tribe was a determinant of RR-TB. We recommend that active surveillance should be intensified for early detection of cases and embarking on all-year mass public health sensitizations targeted at students and young adults on the knowledge and prevention of tuberculosis.

TUPEB0368

Increasing TB case detection through the active case findings (ACF) in selected slums project in Ajeromi local government area of Lagos state

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Background: Issues: Nigeria TB burden higher than previously estimated by WHO as revealed by the national TB Prevalence survey - 610,688 TB cases estimated out of which only 91,354 cases were notified (NTBLCP, 2014) Case detection for all forms now 17%-lowest in the world. Where resources is dwindling specific community targeted intervention must be carried out in TB prone slums using the vi-

sion 90;90;90 model. The Global Fund supported new funding model Active case findings (ACF) is designed to reach every household within a specific slum through door to door case search, while slum cost effective Advocacy Communication Social Mobilization (ACSM) interventions must be adopted to provide seamless support and referral linkages.
Methods: Appropriate Advocacy visit to key stakeholders facilitated the selection of 10 community TB workers (CTWs) 2 per slums to carry out daily door to door active search within specific slum. Community level mobilization, sensitization and demand creation for TB/HIV services through Behaviour Change Communication strategies were conducted in each slums. Quarterly stakeholders launch meeting was held in each of the 5 slums to provide feedback mechanism to address community related issues and provide action points. The trained CTWs carried out daily door to door search within the slums for presumptive TB clients while the program team fast track sputum collection and transport to Laboratory for diagnosis and referrals to DOTs for enrollment and treatment A total of 7,660 households were reached, 598 presumptive TB Clients were identified made up of Male,345 Female 253 and refer for AFB diagnosis. HIV Testing services (HTS) were routinely provided for all PTB clients.
Results: The ACF project in selected slums in Ajeromi Local Government Area in Lagos recorded huge increase in numbers of cases detected within the first eight months (March - December 2016). A total of 90 Active positive Cases referred by CTWs were diagnosed and place on treatment out of which 4 were co-infected (Male 60 Female 30) The quarterly stakeholder meeting provided feedback mechanism and needed impetus for community ownership
Conclusions: The active TB case finding in selected slums is yielding the expected result and can be scaled-up and replicated.

TUPEB0369

Performance of the interferon gamma release assay Quantiferon® TB gold in-tube for the diagnostic of tuberculosis in HIV-infected children

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Background: Diagnosing tuberculosis is challenging in children, especially in those HIV-infected. There is a need for additional diagnostic tools. We assessed the performance of the Interferon Gamma Release Assay QuantiFERON Gold In-Tube (QFT) for tuberculosis diagnosis in HIV-infected children.
Methods: From April 2010 to May 2014, HIV-infected children ≤13 years with a suspicion of tuberculosis were included in the ANRS 12229 PAANTHER 01 study in Burkina Faso, Cambodia, Cameroon, and Vietnam after parental consent. In addition to clinical and microbiological assessment, QFT assays were performed. We evaluated sensitivity, specificity, positive and negative predictive (PPV, NPV) value of the QFT both in intention-to-diagnose (ITD) and per protocol approaches, using tuberculosis microbiologically-confirmed by culture or Xpert MTB/RIF as reference standard. We assessed the area under the-receiver operating characteristic curve (AUROC) for quantitative results of QFT. We identified factors associated with indeterminate QFT as compared with interpretable results using logistic regression models.
Results: Of 438 children enrolled in the study, 420 had QFT performed and were included in this evaluation. Their median age was 7.3 (IQR: 3.4-9.7) years and CD4 14% (IQR 3.2-24). 172 (39.5%) children were on ART. 54 (12.9%) children had microbiologically-confirmed tuberculosis. Overall, QFT was positive in 52 (12.4%) children, negative in 270 (64.3%), and indeterminate in 98 (23.3%). In those with microbiologically-confirmed tuberculosis, it was positive in 27 (50%), negative in 13 (24%), and indeterminate in 14 (26%). In intention-to-diagnose, QFT sensitivity was 50% (95%CI 45.2-54.8), specificity was 70% (95%CI 65.8-74.6), NPV was 90.5% (95%CI 87.7-93.3), and PPV 19.9% (95%CI 16.0-23.7). Per protocol, QFT sensitivity was 66.5% (95%CI 62.4-72.6) and specificity was 91% (95%CI 62.4-72.6). NPV and PPV were 95% (95%CI 92.8-97.5) and 52% (46.5-57.4), respectively. AUROC of QFT quantitative results for tuberculosis diagnosis was of 0.76. Factors independently associated with indeterminate QTF were: age <4yo (OR 2.6; IC95% 1.5-4.5), moderate and severe anemia [(OR 2.4; IC95% 1.3-4.7) and (OR 6.7 IC95% 3-14.9)], and CD4%< 10% (OR 2.4; IC95% 1.5-4.1).
Conclusions: QFT performed poorly due to a high proportion of indeterminate tests and sub-optimal sensitivity in microbiologically-confirmed tuberculosis, as reported previously.

TUPEB0370

TB diagnosis in HIV+ patients in Mozambique. A field study of combined point-of-care evaluation with GeneXpert, LAM and symptom screening

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Background: Tuberculosis (TB) is a major public health concern in many African countries, especially in HIV+ patients, with important economic impact. Systematic screening and early diagnosis are keystones of the WHO End-TB strategy, and effective diagnostic algorithms and prevalence data are urgently needed.
Methods: All HIV+ patients >15 years eligible for antiretroviral therapy (ART) in the NGO DREAM health centres of Maputo, Machava and Beira (Mozambique) between September 2014 and October 2016 were screened for TB before starting ART, with a combined approach: the WHO 4-symptom screening (fever, cough, night sweats, weight loss) (4SS), a rapid test for detection of mycobacterial lipoarabinomannan in urine (LAM), and a molecular TB assay on sputum (GeneXpert, repeated if first result was negative). Patients positive to either GeneXpert or LAM were considered TB-infected, with TB treatment prescribed. All patients were prescribed ART.
Results: At closure of enrolment, 1004 patients (58.2% women) had WHO symptom screening, together with GeneXpert (n:999), LAM (n:1003), or both (n:998). Population characteristics at entry were the following (interquartile ranges): age 30-43; body mass index 19.4-25.4kg/m^2; CD4 count 142-396 cells/mm^3 (< 50/mm^3: 9.4%), plasma HIV-RNA 3.2-5.1 $\log_{10}$copies/ml, haemoglobin 10.3-13.1 g/dl. Most of the patients (66.2%) were clinically asymptomatic (HIV-WHO stage I). Rates of positivity were: 35.0% (352/1004) for 4SS (at least one symptom) and 10.2% (102/1004) for either GeneXpert or LAM, with significant territorial differences. Among 90 GeneXpert-positive patients, 16 had a first negative GeneXpert result. Among 38 LAM-positive patients, 26 were GeneXpert-positive, 10 GeneXpert-negative and 2 had no GeneXpert done. Among patients positive for either GeneXpert or LAM, 22 (21.6%) had negative WHO 4SS, corresponding to a prevalence in symptom-negative patients of 3.4%. Among GeneXpert-positive patients, LAM-positive patients had significantly lower median CD4 counts than LAM-negative patients (78 vs. 149/mm^3, p=0.005). Three of the GeneXpert-positive cases had rifampicin resistance (3.3%).
Conclusions: Based on point-of-care diagnostic tests, we found a 10.2% TB prevalence among HIV-positive patients eligible for ART in Mozambique, with limited occurrence of rifampicin resistance. Data underline the need of combined diagnostic approaches, possibly based on test repetition, in order to reduce the late-stage disease prevalence and its economic effects.

TUPEB0371

Isoniazid preventive therapy uptake and completion in the era of differentiated HIV care

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Background: HIV care is moving towards a differentiated care delivery model with less frequent ART visits. We measured the success of isoniazid preventive therapy (IPT) delivery, requiring 6 monthly visits for completion, when initiated in the context of a streamlined HIV care model with 3-month visits.
Methods: We screened a convenience sample of 137 HIV-infected adults receiving universal ART with streamlined HIV care for IPT eligibility at five government-sponsored clinics in rural Uganda as part of the SEARCH test and treat trial (NCT01864603). Streamlined care included patient-centered care with annual viral load measurements and clinic visits every 3 months for stable patients. During IPT, visit frequency was increased to monthly, per country guidelines. We measured: (1) IPT uptake: proportion who initiated IPT; (2) IPT completion: proportion

who picked up 6 refills of isoniazid; and (3) IPT/ART success: proportion achieving IPT completion and HIV viral load <500 copies/ml. We used multivariable logistic regression to examine factors associated with IPT completion.
Results: Of the 137 HIV-infected adults screened for IPT, 134 (98%) were eligible for IPT, 133 (97%) started IPT, and 97 (71%) completed IPT. Viral suppression was 93%, and 68% achieved both viral suppression and IPT completion. Mean age was 41.6. 75% were female. Median CD4 count was 513 (IQR:395-665). Median time since ART initiation was 2.3 years. 15% of patients reported a side effect within 2 weeks from IPT, with dizziness reported most frequently (10%). IPT completion was associated with age tertile (>45 years: aOR 5.8, 95%CI: 1.1-31.3, ref <36 years), wealth tertile (highest: aOR 3.9, 95%CI: 1.3-12.0, ref lowest), any education (aOR 2.8, 95%CI: 1.1-7.0), and experiencing a side effect in the first two weeks of treatment (aOR: 0.20, 95%CI: 0.11-0.39). Gender, marital status, and CD4 count were not associated with IPT completion.
Conclusions: Over 90% of screened patients receiving streamlined HIV care achieved viral suppression, but despite high IPT uptake, only 68% achieved both IPT completion and viral suppression. Harmonizing visit frequency for IPT and ART delivery while preserving safety in an era of differentiated HIV care may be necessary to achieve higher IPT completion rates.

TUPEB0372

Prevalence of darunavir resistance in the United States (2010-2015)

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Background: Emergence and transmission of antiretroviral drug resistance is a concern among HIV-1-infected patients. Darunavir (DRV), approved for once-daily dosing in the US in 2010, has shown a high genetic barrier to resistance and its use in protease inhibitor (PI)-containing regimens has increased.
Methods: DRV and primary PI resistance were assessed in US clinical samples submitted to Monogram Biosciences for PhenoSenseGT® testing from January 2010-December 2015. 11 DRV and 23 primary PI resistance-associated mutations (RAMs) were evaluated. Annual frequency of individual RAMs and DRV RAMs were assessed among all samples and a subset with phenotypic resistance to ≥1 PI (fold-change >2x lower clinical/biological cut-off). Phenotypic resistance to DRV, atazanavir (ATV), and lopinavir (LPV) was evaluated.
Results: Among all samples (n=48,786), the proportion with 0 DRV RAMs was 92% in 2010 and 95% in 2015 (Table). During this period, the median number of DRV and primary PI RAMs was 0. The proportions of samples with phenotypic resistance to DRV, ATV, and LPV were respectively 3%, 6%, and 5% in 2010, and 2%, 4%, and 3% in 2015. Among the subset with phenotypic resistance to ≥1 PI (n=4,259; 9% of samples), the proportion with 0 DRV RAMs was 36% in 2010 and 2015. The median number of DRV RAMs was 1 in 2010 and 2015; correspondingly, the median numbers of primary PI RAMs were 3 and 2. The proportions with phenotypic resistance to DRV, ATV, and LPV were respectively 26%, 59%, and 54% in 2010, and 29%, 57%, and 48% in 2015.
Conclusions: The prevalence of DRV RAMs among commercially-tested isolates remained low and generally stable from 2010-2015. In 2015, 98% of samples demonstrated phenotypic sensitivity to DRV. Among the subset with phenotypic PI resistance, DRV sensitivity was maintained in 71% of samples, which was numerically greater than ATV (43%) and LPV (52%) in 2015.

	All samples (N=48,786)		Samples with phenotypic PI resistance (n=4,259)	
	2010	2015	2010	2015
Proportion of samples with 0 DRV RAMs[a]	92%	95%	36%	36%
Proportion of samples with ≥3 DRV RAMs[a]	3%	2%	28%	30%
Median number of DRV RAMs[a]	0	0	1	1
Median number of primary PI RAMs[b]	0	0	3	2
Frequency of individual DRV RAMs[a]	<1-4%[c]	<1-3%[c]	4-38%[c]	2-44%[c]
Frequency of individual primary PI RAMs[b]	<1-7%[d]	<1-5%[d]	1-50%[d]	<1-45%[d]
Proportion of samples with phenotypic resistance to DRV	3%	2%	26%	29%
Proportion of samples with phenotypic resistance to ATV	6%	4%	59%	57%
Proportion of samples with phenotypic resistance to LPV	5%	3%	54%	48%

PI, protease inhibitor; DRV, darunavir; RAM, resistance-associated mutation; ATV, atazanavir; LPV, lopinavir.
[a]DRV RAMs: V11I, V32I, L33F, I47V, I50V, I54L/M, T74P, L76V, I84V, L89V.
[b]Primary PI RAMs: D30N, V32I, M46I/L, I47A/V, G48V, I50L/V, I54L/M, Q58E, T74P, L76V, V82A/F/L/S/T, N83C, I84V, N88S, L90M.
[c]Least common RAM: L76V (2010 and 2015); most common RAM: L33F (2010 and 2015).
[d]Least common RAM: I47A and V82S (2010), and V82F (2015); most common RAM: L90M (2010 and 2015).

[Table. Summary of resistance results]

TUPEB0373

Feasibility of TB screening of unselected HIV-positive hospital admissions in sub-Saharan Africa: the STAMP trial

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Background: HIV-associated tuberculosis (TB) remains a significant cause of mortality in patients admitted to hospital in sub-Saharan Africa, much of which is left undiagnosed. The rapid urine-based Screening for TB to reduce AIDS-related Mortality in hospitalised Patients in Africa (STAMP) trial aims to determine the impact of a sensitive TB screening strategy on mortality, measured at 2-months, in Malawi and South Africa.
Methods: The study recruited unselected HIV-positive adult admissions to medical wards, irrespective of presenting complaint or presence of TB symptoms. 50mls of urine and a single sputum sample were requested at enrolment for TB screening. We report early enrolment data from the STAMP trial describing the feasibility and acceptability of this TB screening approach.
Results: 1,875 eligible patients were screened to date, with only 25 (1.3%) citing additional samples for TB screening as the reason for non-participation. Of the 1,629 patients enrolled across both sites, 56.1% were female. TB symptoms were common; current cough was reported by 52.7%, fever 62.2%, weight loss 70.2% and night sweats 42.2%. Overall, 91.5% were positive using the WHO four-symptom TB screen. In contrast, only 39.2% were suspected of having TB by the admitting clinical team. 248 (15.3%) of participants were newly diagnosed with HIV. Of those with an existing HIV diagnosis, 83.3% were currently taking antiretroviral therapy (ART). The median CD4 cell count was 212 cells/mm^3 (interquartile range 69-421). 99.1% of participants were able to produce a urine sample for TB screening but only 54.8% produced a sputum sample. 97.6% of sputum samples and 98.8% of urine samples tested with Xpert MTB/RIF produced valid results. 47.4% of participants had a chest x-ray done during their admission.
Conclusions: TB screening of unselected HIV-positive hospital admissions in sub-Saharan Africa is both feasible and acceptable to patients. Twice as many patients reported TB symptoms compared to those suspected of having TB by their clinicians, although both were common despite high ART coverage and median CD4 cell count >200cells/mm^3. Urine specimens could be produced by almost all patients, in contrast to sputum, and were tested using Xpert MTB/RIF with a very low error rate.

TUPEB0374

Distinct patterns of clinical characteristics in adult tuberculosis patients from urban compared to rural settings in Tanzania

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Background: Rural-urban settings could account for some of the differences in the epidemiology of tuberculosis (TB) in Tanzania. We aimed to study the epidemiology of TB and co-infections in adult patients from two distinct settings in Tanzania.
Methods: We included adult patients (>18 years) with smear-positive pulmonary TB consecutively enrolled in two ongoing cohort studies in the largest city of Tanzania, Dar es Salaam with ~4.3 million inhabitants (urban), and Ifakara in the sparsely populated Kilombero district with ~400,000 inhabitants (rural). Clinical and laboratory data were collected electronically from all participants at recruitment. Stool and urine were examined for intestinal helminths using Kato-Katz, Baermann, urine filtration and Circulating Cathodic Antigen tests. Differences between groups were assessed by Chi-square or Wilcoxon rank sum test as appropriate.
Results: We analyzed 602 participants enrolled between August/2015 and November/2016, 412 (68.4%) at the urban and 190 (31.6%) at the rural site. The median age was 34 (interquartile range [IQR] 27-41), 408 (67.8%) were men, and 152 (25.3%) were HIV-positive with a median CD4 cell count of 161 (IQR 117-295 cells/μL). Patients from the rural site were significantly older (median age 38 vs. 33 years, p=0.001), had a lower median body mass index (17.5 vs. 18.5 kg/m2, p=0.001), a lower median hemoglobin concentration (10.6 vs. 11.3, p=0.001), borderline lower median CD4 count (147 vs. 220, p=0.06) and a higher proportion of relapse cases (9.5% vs 1.2%, p< 0.001) compared to those from urban. There was no significant difference in the prevalence of HIV (23.5% vs. 29%, p=0.16) and diabetes mellitus (7.1% vs. 2.8%, p=0.07) between urban and rural settings. The overall prevalence of intestinal helminth co-infection was 22.1% (n=133) with no significant

difference across sites, with a higher prevalence of Schistosoma mansoni (15.9% vs. 3.5%, p< 0.001) at the rural site and lower prevalence of Strongyloides stercoralis at the urban site (5.5% vs. 15.9%, p=0.001).
Conclusions: Clinical and sociodemographic characteristics differ in TB patients from urban and rural Tanzania. The observed differences underline the need for public health interventions tailored to urban as well as rural settings to improve clinical outcomes of TB and co-infections.

TUPEB0375

Mycobacterium tuberculosis lateral flow urine lipoarabinomannan assay (TB-LAM) and cryptococcal antigen lateral flow assay (CRAG LFA) as screening among patients with advanced HIV-disease in Conakry, Guinea

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Background: Guinea is a low HIV prevalence country (1.7%) with a high number of documented AIDS-related deaths in 2015[4600 (3700 - 5600), http://aidsinfo.unaids.org/] . Routine hospital morbidity and mortality data from tertiary hospitals consistently highlight tuberculosis and cryptococcal meningitis to be commonly leading causes of mortality and frequently diagnosed among advanced HIV-infected patients. Médecins sans Frontières (MSF) started systematically screening for tuberculosis and cryptococcus infection advanced HIV- infected patients using point-of-care technologies to foster early detection and treatment. The aim of this study was to document this screening strategy at an MSF HIV-clinic in Conakry, Guinea.
Methods: Retrospective analysis of routine data collected in laboratory registers. TB-LAM tests and CrAg LFA were used to screen HIV-infected patients >15 years presented to care with CD4 count <100 cells/ul, irrespective of antiretroviral treatment (ART) status, between 1st January 2015 to 30th June 2016. We estimated screening up-take and the yield of TB and cryptococcal antigenemia among patients screened.
Results: Among 616 HIV- infected patients with CD4 count < 100 cells/ml, mean age was 37 years [Inter Quartile Range (IQR): 15-86], median CD4-count was 28 cells/ml (IQR: 1-100), female were 66%, and 15 (2%), 47(7%), 388 (62%), 74 (12%) were on stage I, II, III & IV respectively. Up-take of screening was: 174/616 (28 %) for TB-LAM. and 366/616 (59%) for CRAG test. Respectively, 32 % of patients were TB-LAM Positive and 4% of patients screened using lateral flow assay for CrAg were positive. According to the ART status, the prevalence of TB-LAM positive tests was 37% in post ART, 26% in pre-ART patients and 4% , the same in pre ART and post ART patients, for CRAG test.
Conclusions: Up-take of a screening strategy using point-of-care tests for TB and cryptococcal infection among patients with advanced HIV disease in Guinea was low, especially for TB. The yield was high for TB and relatively low for cryptococcal disease. The implementation of a systematic screening strategy in settings with high advanced HIV disease burden is challenging but remains essential.

TUPEB0376

Use and effects of pediatric isoniazid preventative therapy (IPT) in HIV-positive patients at the Baylor Clinical Center of Excellence (COE) in Mbabane, Swaziland

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Background: People living with HIV (PLHIV) are especially susceptible to tuberculosis (TB), with >70% of TB cases in Swaziland occurring in PLHIV. Isoniazid preventative therapy (IPT) has been recommended for PLHIV ≥1 year of age regardless of TB exposure since 2009 and all PLHIV including infants <1 year of age following close exposure to infectious TB. To enhance IPT program strategies, we assessed IPT prescribing practice and effectiveness in pediatric HIV patients (ages 1-17 years) at the Swaziland-Baylor Children's Foundation Center of Excellence (COE).
Methods: Retrospective analysis was conducted using patient data from the COE electronic medical records (EMR), from February 2006 through November 2016, focusing on which patients were prescribed IPT, effect of IPT on antiretroviral therapy (ART) adherence, and risk factors for developing TB after IPT. Crude odds ratios were obtained and adjusted odds ratios calculated using logistic regression. A paired t-test was used to evaluate ART adherence before and after IPT.
Results: Of 1664 eligible pediatric patients identified with over 10 visits to the COE and at least one visit after 2009, 922 (55.4%) have been prescribed IPT. Of 305 patients who initiated IPT over four years ago, 64 (20.1%) later developed TB. Past TB, age >14 years, <40 clinic visits, and ART adherence <95% were negatively associated with being prescribed IPT, while CD4 < 500 and age <5 years were positively associated with IPT prescription. Children with CD4 counts <500 and ART naïveté at IPT initiation were more likely to develop TB following IPT. Average ART adherence (measured via pill count) decreased by 0.5% (p=0.001) during IPT as compared to the preceding year in the cohort as a whole; however, those with <95% ART adherence before IPT initiation (n=23) increased ART adherence by 4.4% (p<0.001) during IPT.
Conclusions: We have identified patients at increased risk for IPT failure and missed opportunities for IPT prescription. Although clinicians were wary of prescribing IPT to children with low ART adherence, this population experienced an increase in ART adherence during IPT. Children at higher risk of developing TB after IPT may benefit from additional courses of IPT.

TUPEB0377

WHO four-symptom screening for tuberculosis in people living with HIV receiving antiretroviral therapy: a systematic review

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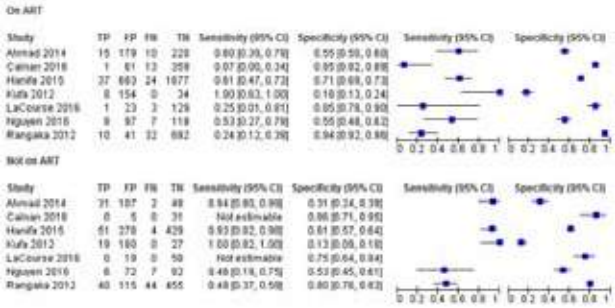
Background: WHO currently recommends the use of four-symptom screening (defined as positive by the presence of any one of cough of any duration, loss of weight, night sweats and fever) to exclude active tuberculosis (TB) prior to initiation of TB preventive treatment in people living with HIV (PLHIV). We systematically reviewed the published evidence supporting the diagnostic accuracy of WHO symptom screening.
Methods: We searched studies published between 2011 and 2016 using Pubmed and Embase as well as abstracts from TB and HIV international conferences. We included primary studies reporting data on the four-symptom screening in PLHIV. The gold standard of the diagnosis of active TB was at least one positive culture or Xpert MTB/RIF. Randomized trials, cross-sectional studies, and cohort studies were included. We assessed the potential influence of ART status and pregnancy in subgroup analysis. We also assessed the additive effect of chest x-ray.
Results: From an initial screen of 3683 records we included 17 studies; additionally 3 conference abstracts were included from 16 countries. Of these 20 studies, data disaggregated by HIV status were available from 7 studies (Figure). The pooled sensitivity and specificity of the four-symptom screening for PLHIV on ART was 51.0% (95% confidence interval [CI] 28.4%-73.2%) and 70.7% (47.7%-86.4%), respectively compared to 88.5% (55.0%-98.0%) and 46.5% (24.5%-70.0%) for those not receiving ART. For studies that also included chest x-ray pooled sensitivity was higher (77.8%, 63.4%-87.6%) but specificity was lower (30.3%, 27.0%-33.8%).
Conclusions: The available data suggest the four-symptom screening can still be used for excluding active TB before preventive treatment. Consideration should be given to adding chest x-ray to the four-symptom screening in PLHIV on ART to improve sensitivity for detecting and ruling out active TB prior to initiation of TB preventive treatment.



[Forest plot of the sensitivity and specificity]

TUPEB0378

Could GeneXpert MTB/RIF be useful in detecting NTM infections in HIV patients?

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Background: Tuberculosis (TB) continues to be a leading cause of morbidity and mortality in developing countries. Rapid diagnosis is essential for controlling and preventing spread of TB infection. The Real-Time PCR based GeneXpert MTB/RIF assay is a promising diagnostic tool, owing to its rapid and accurate results in detecting Mycobacterium tuberculosis (MTB) and rifampicin (RIF) resistance.
We propose an additional utility of GeneXpert MTB/RIF to detect non-tuberculous mycobacteria (NTM) among cases tested negative for MTB, following an algorithm.
Methods: The performance characteristics of GeneXpert MTB/RIF assay was evaluated with stored sputum specimens and EQAS strains (n=140) with known AFB culture results based on BACTEC-MGIT. Seventy two of them were negative for MTB and NTM, 39 were MTB positive and 29 were culture positive for NTMs. The detailed results of GeneXpert MTB/RIF assay were investigated for the presence of any significant markers to detect NTM positivity.
Results: It was observed that in 13 of the 29 NTM specimens tested, the molecular beacons (either probe A or probe C) were amplified and all these cases were smear positive as well. Thus, when evaluated based on the C_t values of the molecular beacons, the sensitivity and specificity of GeneXpert MTB/RIF assay in detection of NTMs were found to be 44.8% and 100%, respectively.
Conclusions: The results show potential utility for detection of NTMs using GeneXpert MTB/RIF assay. The lower sensitivity observed for detection of NTMs could possibly be related to the mycobacterial species tested. Therefore, GeneXpert negative sputum specimens, but smear positive and positive Ct values in probe A or C should be suspected for possible presence of NTMs and these specimens should be subjected to either culture or other available assays for the detection of NTM infection. This algorithm could be particularly more useful in HIV care settings, where the NTMs are common.

TUPEB0379

High mortality among HIV-positive patients with MDR-TB and second-line drug resistance reflects the urgent need for new drug regimens

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Background: Treatment success rates for MDR-TB patients with resistance to second-line (SL) injectable agents and/or fluoroquinolones are approximately 15-40%, with high rates of mortality.
Methods: Mortality and patient outcomes from a treatment programme in Khayelitsha, South Africa were assessed 24-months after MDR-TB diagnosis, among patients with SL-resistance detected at diagnosis or during SL-treatment.
Results: From 2008-2013, 167 patients, 71% HIV-positive, were diagnosed with MDR-TB with resistance to either ofloxacin (n=52,31%) or amikacin (n=59,35%) or both (XDR-TB, n=56,34%). Fifteen percent (25/167) of patients never started treatment; 88% were HIV-positive. Another 39 (n=28, 72% HIV-positive) MDR-TB patients, had SL-resistance detected during treatment.
Overall, 24-month mortality was 47% (97/206); 54%(79/146) among HIV-positive and 30%(18/60) among HIV-negative patients(p<0.01). Of those that died, 22%(21/97) died before treatment initiation within a median of 21-days (IQR 13-35); 84%(21/25) that never started treatment died. Mortality was 37% compared to 46% for MDR-TB with ofloxacin resistance only or amikacin resistance only at diagnosis, respectively (p=0.32).
Patients diagnosed with XDR-TB had high mortality at 64% (36/53) (p<0.01 compared to resistance to only one SL-drug). Mortality among MDR-TB patients with SL- resistance detected during SL-treatment was 39% (15/39). Mortality was 70% (30/43) among HIV-positive patients with XDR-TB. Overall, 12% (25/206) were successfully treated.
Conclusions: Mortality was extremely high 24-months following diagnosis of MDR-TB with SL-resistance detected at diagnosis or during treatment. The presence of resistance to ofloxacin or amikacin had similar impacts on mortality. HIV-infection contributed substantially to mortality, but mortality remains high among HIV-negative patients, particularly those with XDR-TB. There is a pressing need for urgent treatment initiation and more effective regimens at initial diagnosis of SL-resistance.

TUPEB0380

Usefulness of screening latent tuberculosis infection (LTBI) using interferon-gamma releasing assay and treating LTBI to prevent developing active tuberculosis in Korean HIV-infected patients

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Background: HIV-infected patients are high risk group of developing active tuberculosis. Howere, there is few study concerning usefulness of interferon-gamma releasing assay (IGRA) for developing active tuberculosis among HIV infected patients in country with intermediate tuberculosis burden.
Methods: To identify the usefulness of IGRA test to diagnose latent tuberculosis and predict active tuberculosis, retrospective cohort study was conducted at a large tertiary care hospital in Korea. HIV-infected patients who had ≥ 1 IGRA test results from Jan 2006 to Dec 2015 were enrolled excluding patients with active tuberculosis or previous tuberculosis history. We evaluated the effectiveness of isoniazid prophylaxis to prevent developing active tuberculosis.
Results: Among 603 HIV-infected patients with IGRA tests, 35 active tuberculosis patients and 94 patients with previous tuberculosis history were excluded. Sixty four patients (13.5%) were positive for IGRA test, 400 (84.4%) negative and 10 (2.1%) equivocal.
Sixty three IGRA positive patients and 345 IGRA negative patients were retained in care for more than 1 year. Incidence rate of active tuberculosis of IGRA positive versus negative patients were 12.05 (95% CI 3.06-32.79)/1000 person-years versus 0.72 (95%CI 0.03-3.55)/1000 person-years (p=0.001). Sensitivity, specificity, positive predicative value and negative predictive value of IGRA test was 75% (19.4-99.4%), 85.2% (81.3-88.5%), 4.8% (1.0-13.3%), and 99.7% (98.4%-99.9%), respectively. Among 63 patients with positive IGRA test, 26 were treated for latent tuberculosis infection (LTBI) and 37 were not. There was no active tuberculosis development among patient with LTBI treatment while 3 active tuberculosis developed among patients without LTBI treatment.
Among 345 patients with negative IGRA test, 264 patients received follow-up IGRA test and 34 (12.9%) patients converted to positive. There was a tendency to conversion of IGRA test in patients with low initial CD4 + T cell counts although there was no statistical significance (CD4 ≤100, 19.6% vs. > 100, 11.5%, p = 0.136). No active tuberculosis developed in patients with IGRA conversion.
Conclusions: Screening of LTBI using IGRA test and treatment of LTBI can be useful to protect developing active tuberculosis in intermediate tuberculosis burden country such as Korea. Clinical significance of conversion of IGRA test is not clear and further study is warranted.

TUPEB0381

Gemycircularviruses in HIV-positive patients, France

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Background: Gemycircularviruses (family Genomoviridae) are a group of highly diverse single-stranded DNA viruses (genome length ~2,100 nt), initially found in fungi and plants. Their identification in animal and human biologic samples, including blood, was described recently, as exemplified by our characterization of a full-length viral genome from a HIV-positive plasma sample (Uch et al, Emerg Infect Dis 2015).
In order to add clue to potential co-infections occurring in HIV-infected persons, we tentatively investigated both distribution and diversity of gemycircularviruses DNA in a French cohort of patients.
Methods: Five hundred HIV-positive patients entered the study; initial investigation focused on the PCR screening of 10 plasma pools (10 microliters of 50 plasma samples). In a way to optimise the detection of viral DNA, pools were pre-treated by nucleases, followed by particle-protected nucleic acids extraction (NucliSENS easyMag, bioMérieux) and 2-hour Phi-29 DNA polymerase treatment.

Gemycircularviruses DNA was investigated using in-house PCR systems based on updated data (Krupovic et al., Arch Virol 2016): 6 hemi-nested amplifications systems were designed (<200 bp), following alignment of Rep gene sequences and subsequent selection of clusters harbouring at least one gemycircularvirus sequence identified in humans. Resulting amplification products were cloned, sequenced, and analysed phylogenetically.
Results: Of the 10 plasma pools tested, 3 exhibited positive signals for 1 PCR system; sequence analysis confirmed the gemycircularvirus origin of corresponding amplification products. Nucleotide divergence in the range 1-9% (140 nt tested) were identified with the closest genomic sequences characterized previously in human blood or pericardial fluid. Observed genetic diversity between amplified sequences reached 8%.
Conclusions: These first data confirm the presence of gemycircularviruses in circulating blood of HIV-infected patients. They also suggest significant genetic diversity with gemycircularvirus sequences previously detected in humans based on short sequences analysed.

TUPEB0382

CMV disease and CMV specific IFN-gamma/IL-2 response impairment despite CD4+ lymphocyte recovery

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Background: CMV end organ disease in HIV after CD4+ recovery is poorly understood. In a case of active de novo CMV retinitis (CMV-R) in a patient with CD4+ count of 405 with prior history of CMV proctocolitis, we investigated the immunologic responses to CMV at 8, 44 and 80 wks after presentation, induction and ongoing suppression of CMV-R.
Methods: PBMCs from JM and HIV+/CMV+ asymptomatic controls and CSF from JM were assayed at each time point. Immune function assays following 24 hrs or 6 days of culture with CMV and HIV antigens, intracellular cytokine expression and T-cell proliferation at 6 days, intracellular staining for CD4+ and CD8+ cell populations and flow cytometry were performed.
Results: At 8 wks, JM exhibited high levels of TNFa by PBMCs and CSF, with no PBMC TNFa responses to CMV at 24 hrs, but detectable TNFa responses to CMV by both CD4+ and CD8+ in CSF; there were no IFNg and IL-2 responses to CMV at 24 hrs and 6 days, compared to control. JM displayed strong CD4+ and CD8+ CMV proliferative responses at 6 days by PBMC and CSF cells. At 44 wks, there was borderline IFNg and IL-2 response by CD8+ to CMV in CSF and PBMCs. At 80 wks, there was detectable low IFNg response by CD4+ and CD8+ to CMV in PBMCs and CSF.
Conclusions: CMV-R can occur in failure of CMV proliferation responses reconstitution; but high IFNg, IL-2 and TNFa cytokine expression are maintained. JM's robust proliferative response suggests recovery of CMV central memory CD4+ and CD8+ responses both locally (in CSF) and in blood, but there were no IFNg and IL-2 responses at 24 hours and 6 days. The high lymphocyte count in CSF, strong CMV proliferative response, elevated proliferation at 6 days and TNFa at 24 hours, indicate continued activation and inflammation in CSF. Absence of IFNg and IL-2 responses partially restored at 80 weeks. Predominant proliferating cells in response to CMV at 8 weeks were CD4+CD8+ and at 80 weeks CD3-CD4-CD8-CD56+ NK-like cells. The impairment in IFNg and IL-2 responses and immune signaling might explain CMV-R in this subset of patients.

TUPEB0383

Effect of sex and hepatitis C co-infection on HIV treatment and mortality: a 15-year follow-up

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Background: We aimed to investigate if hepatitis C (HCV) co-infection is modified by biologic sex on time to virologic suppression (VS)(two consecutive viral loads < 50 copies ≥3 months apart), rebound (VR)(two consecutive viral loads ≥50 copies/mL ≥3 months apart), and all-cause mortality in HIV disease.
Methods: Using data from the Canadian Observational Cohort Collaboration, a multi-site cohort of HIV+ adults (≥18 years) initiating antiretroviral therapy (ART) 2000-14, Fine and Gray models adjusted for competing risk of death estimated the hazard ratio (HR) and 95% confidence intervals (CI) of sex and HCV on time to VS following ART initiation and to VR following VS. A Cox proportional hazard model estimated time to death following ART initiation. Multiple imputation methods estimated missing HCV status (5% missing), race (37%), IDU (13%), and MSM (20%).
Results: Of 10,400 participants (median follow-up 5.0 years), 1865 were women (38% HIV-HCV) and 3583 men (21% HIV-HCV). Cumulative incidence differed significantly ($p < 0.001$) for
(i) VS at 48 weeks between men (HIV: 88.8%; HIV-HCV: 85.8%) and women (HIV: 93.5%; HIV-HCV: 80.0%)
(ii) VR (1134 events) 12 weeks following VS for men (HIV: 4.8%; HIV-HCV: 13.5 %) and women (HIV: 11.8%; HIV-HCV: 21.1%) and
(iii) for all-cause mortality at one year between men (HIV: 2.2%; HIV-HCV: 6.5%) and women (HIV: 0.1%; HIV-HCV: 7.0%).
Compared to HIV+ men, co-infected participants were less likely to achieve VS and at higher risk for mortality. Risk of VR was higher for HIV+ women and co-infected participants relative to HIV+ men. We failed to detect significant interaction effects.

		HIV	HIV-HCV	HCV within sex	p value
Outcomes	**Sex**	**aHR* (95% CI)**	**aHR* (95% CI)**	**aHR* (95% CI)**	**(HCV*sex)**
(i) Virologic Suppression	**Male**	1.00	0.86 (0.79, 0.93)	0.86 (0.79, 0.93)	0.48
	Female	1.04 (0.90, 1.13)	0.82 (0.79, 0.98)	0.96 (0.86, 1.07)	
(ii) Virologic Rebound	**Male**	1.00	1.57 (1.32, 1.89)	1.57 (1.32, 1.89)	0.42
	Female	1.35 (1.07, 1.73)	1.96 (1.54, 2.49)	1.44 (1.08, 1.94)	
(iii) All-Cause Mortality	**Male**	1.00	1.83 (1.44, 2.33)	1.83 (1.44, 2.33)	0.59
	Female	0.79 (0.52, 1.20)	1.81 (1.33, 2.47)	2.30 (1.46, 3.64)	
*Adjusted for variables shown plus age, race, injection drug use, men having sex with men status, province, baseline viral load, CD4 cell count, AIDS defining illness, ART class, and year of ART initiation.					

[Adjusted models with marginal effect of infection]*

Conclusions: HIV-HCV co-infected have poorer responses to ART with greater risk of mortality. Although women were more likely to rebound, sex did not moderate outcomes. Further work is necessary in other observational settings and in response to modern HCV therapies.

TUPEB0384

Glecaprevir/pibrentasvir fixed dose combination for 8 or 12 weeks in patients co-infected with HCV and HIV-1: a sub-analysis of the phase 3 ENDURANCE-1 study

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Background: The once-daily direct-acting antivirals (DAAs) glecaprevir (identified by AbbVie and Enanta)/pibrentasvir (G/P) have demonstrated high efficacy in patients with hepatitis C virus (HCV) infection. The Phase 3 ENDURANCE-1 study evaluated G/P (300 mg/120 mg) for 8 versus 12 weeks in HCV genotype (GT) 1-infected, non-cirrhotic patients with or without HIV-1 co-infection. Rates of sustained virologic response 12 weeks post-treatment (SVR12) were >99% in mono-infected, DAA-naïve patients, demonstrating non-inferiority of 8-week to 12-week treatment. Herein we report the efficacy and safety of G/P in HCV/HIV-1 co-infected patients.
Methods: ENDURANCE-1 was an open label, randomized study evaluating 8- versus 12-week G/P in treatment-naïve and -experienced HCV GT1-infected non-cirrhotic patients. HIV-1 co-infected patients with suppressed HIV RNA on stable antiretroviral regimens including the backbone agents of emtricitabine/tenofovir disoproxil fumarate or abacavir/lamivudine with an anchor agent of raltegravir, dolutegravir or rilpivirine, or antiretroviral-naïve patients with stable CD4 counts (≥500 cells/mm^3) were allowed. Safety, CD4 count and HIV-1 RNA levels were monitored. The primary endpoint was SVR12 (HCV RNA < 15 IU/mL).
Results: In total, 33 HCV/HIV co-infected patients were enrolled. Demographics and safety are shown in Tables 1 and 2, respectively.

Characteristic	8-Week G/P	12-Week G/P
Male, n/N (%)	14/15 (93)	15/18 (83)
Age, median (range) years	47 (31-69)	47 (26-60)
HCV treatment-experienced	5/15 (33)	6/18 (33)
HCV RNA, median (range), log10 IU/milliliter	6.26 (5.27-7.14)	6.30 (5.36-6.90)
Raltegravir-containing ART, n/N (%)	7/15 (47)	3/18 (17)
Dolutegravir-containing ART, n/N (%)	5/15 (33)	12/18 (67)
Rilpivirine-containing ART, n/N (%)	3/15 (20)	3/18 (17)
CD4+ cell count, median (range), cells/mm3	644 (211-1098)	801 (362-1208)

[Table 1. Baseline Demographics and Disease Charact]

SVR12 rates were 100% in both 8- and 12-week arms. No adverse events (AEs) occurred in more than 10% of overall patients; no patient experienced confirmed HIV virologic failure (HIV RNA ≥200 copies/mL). Prevalence of baseline polymorphisms in NS3 and NS5A will be presented.

Event, n/N (%)	8-Week G/P	12-Week G/P
Any AE	6/15 (40)	11/18 (61)
AEs leading to study drug discontinuation	0	0
Serious AEs	0	1/18 (6)
ALT Grade ≥2 (>5 × ULN), post nadir	0	0
AST Grade ≥2 (>5 × ULN)	0	0
Total Bilirubin Grade 3 (>3-10 × ULN)	1/15 (7)	0

[Table 2. Safety and Laboratory Abnormalities]

Conclusions: The once-daily, interferon- and ribavirin- free regimen of G/P administered for 8 or 12 weeks in HCV GT1/HIV-1 co-infected patients without cirrhosis was well-tolerated and achieved a 100% SVR12 rate, suggesting that co-infection with HIV has no impact on the efficacy of G/P.

TUPEB0385

Association of uncontrolled HIV-RNA with failure to direct acting antiviral (DAA) combinations in HIV/HCV co-infected patients on antiretroviral therapy (ART): ANRS CO13 HEPAVIH cohort

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Background: In HIV/HCV co-infection, DAA treatment regimens achieve virological cure in ≥90%. Factors associated with failure and frequency of resistance-associated substitutions (RASs) are not well documented.
Methods: This sub-study, performed in the French ANRS CO13 HEPAVIH cohort, included HIV/HCV co-infected patients starting a first all-oral DAA regimen before January 2016 (3 months treatment) or October 2015 (6 months treatment). Failure was defined as:
i) a non-response if HCV-RNA remained detectable at any time during treatment, at end of treatment (EOT) or still detectable after EOT,
ii) a breakthrough if HCV-RNA became undetectable at least once during treatment and was again detectable at EOT and thereafter,
iii) a relapse in case of a detectable HCV-RNA after EOT after suppression at EOT,
iv) a death during treatment with last HCV-RNA positive.
Exact logistic regression was used to identify factors associated with failure.
Results: Of 516 patients fulfilling inclusion criteria, 33 patients (6.4% [95%CI: 4.4-8.9]) failed DAA therapy with 24 relapses, 4 non-responses, 1 breakthrough, 1 death under treatment and 3 non evaluable failures (viral load at EOT not known) on the following regimen: sofosbuvir (SOF) + daclatasvir (DCV) ± ribavirin (RBV) in 11 patients (33%), SOF + RBV in 11 (33%), SOF/ledipasvir ± RBV in 8 (25%) and SOF + simeprevir in 3 (9%). Mean treatment duration was 16 weeks [1-50]; 70% were HCV treatment-experienced; HCV genotype was 1/3/4 in 45%/15%/27%, respectively. All failing patients were on ART with suppressed HIV-RNA (< 50 copies/mL at DAA treatment initiation in 72%); 48% were cirrhotic. Post-treatment NS3 or NS5A RAVs were detected in 8/14 (57%) of patients with samples available for sequencing analysis. In patients receiving at least 2 DAA +/-RBV, after adjustment for age, sex, ribavirin use, cirrhosis stage and treatment duration, a detectable HIV-RNA was the only factor associated with a higher risk of failure (OR: 2.8; 95%CI: 1.02-7.6).
Conclusions: In this prospective real-life cohort, failure to all-oral DAA regimens occurred in 6.4% of the patients. The low rate of HIV control despite ART in patients failing HCV treatment might indicate poor adherence to both ART and anti-HCV treatment.

TUPEB0386

HBV co-infection is associated with high one-year mortality in HIV-infected Tanzanians on ART

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Background: There is limited data on the effect of HBV-active antiviral therapies on liver fibrosis progression and other clinical outcomes in HIV- and HBV-infected individuals in sub-Saharan Africa.
Methods: We conducted a prospective analysis of 267 HIV-monoinfected, 165 HBV-monoinfected and 63 HIV/HBV-coinfected adults (≥18), enrolled between April 2014- Dec 2015 and followed for 12 +/- 2 months on HBV-active therapy, at Management and Development for Health (MDH) supported HIV Care and Treatment clinics in Dar es Salaam, Tanzania. All HIV-monoinfected and HIV/HBV-coinfected patients received tenofovir, lamivudine plus efavirenz; all HBV-monoinfected patients received lamivudine. Multivariate (MV) regression models were constructed to identify factors associated with mortality in HIV- and HIV/HBV-coinfected patients.
Results: At baseline, HBV-monoinfected patients were younger and had higher BMI´s than HIV-monoinfected and HIV/HBV-coinfected patients. Median APRI was higher in HIV/HBV-coinfected compared to HIV- and HBV-monoinfected patients [0.36 (IQR 0.40) vs. 0.23 (0.17) vs. 0.29 (0.16); p<0.01]. HIV RNA levels were higher in HIV-monoinfected compared to HIV/HBV-coinfected patients, whereas CD4+ T cell counts were similar. After a median of 370 (IQR 57) days on HBV-active therapy, 61% HIV-infected vs. 74% HIV/HBV-coinfected patients achieved HIV RNA <20 copies/mL (p=0.09). Similar rates of HBV virologic suppression (<20 IU/mL) were observed in HBV-monoinfected and HIV/HBV-coinfected patients (80% vs. 79%; p=0.6). A greater decline in APRI was observed in HIV/HBV-coinfected patients. Mortality at 1 year was higher among HIV/HBV-coinfected patients compared to HIV and HBV-monoinfected patients [10/63 (16%) vs. 26/267 (10%) vs. 2/165 (1%); p<0.01]. In univariate analyses of all HIV-infected patients, HIV/HBV co-infection, lower CD4+ T cell counts, higher HIV RNA levels and APRI at baseline were all significantly associated with higher mortality (p's <0.01), however, only CD4+ T cell counts [OR 0.99, (95%CI 0.98, 0.99); p=0.01] and HIV RNA [OR 3.53, (1.66, 7.51); p<0.01] predicted mortality in adjusted MV models.
Conclusions: Mortality at one year was high among HIV/HBV-coinfected individuals compared to patients with HIV or HBV alone, despite similar rates of virologic suppression and greater APRI declines on HBV active ART. HIV-related factors rather than liver disease severity may explain the excess risk of mortality in HIV/HBV-coinfected individuals.

TUPEB0387

Low frequency of NS5A relevant resistance-associated substitutions to Elbasvir among hepatitis C virus genotype 1a in Spain: a cross-sectional study

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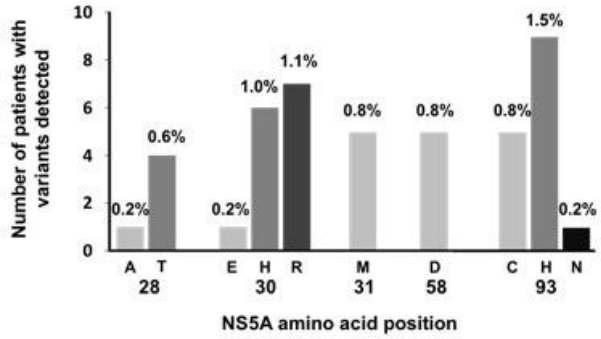
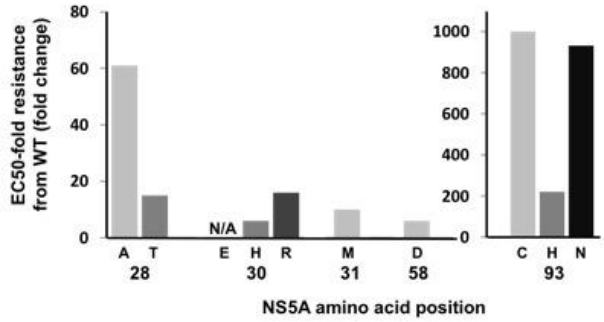
Background: Naturally resistance associated variants (RAVs) to the new HCV NS5A inhibitor elbasvir (EBR) may limit its efficacy and lead to no cure in HCV-GT1a-infected. To assess the prevalence and impact of clinically relevant natural NS5A RAVs to EBR in HCV-GT1a infected patients from Spain and predict the proportion of patients who could benefit from treatment with zepatier®.
Methods: A multicenter cross-sectional study of 617 treatment-naïve HCV-G1a-infected individuals attended in 84 Spanish hospitals. The samples were collected between 2014-2015. Sanger sequencing (HCV population sequencing) was used to identify natural NS5A RAVs. NS5A mutational pattern and drug sensitivity were confirmed by geno2pheno[HCV].
Results: Viruses bearing natural NS5A RAVs to EBR were present in 38 samples (6.2%) of HCV-G1a infected patients, six of those having viruses with double RAVs. The most common natural RAVs were the Y93C/H/N (2.4%; n=15) and Q30E/H/R (2.3%; n=14), while M28A/T, L31M and H58D being less represented (0.8%, n=5, each). The double mutations Q30H+Y93H and Q30R+Y93H had a low frequency (0.6%, n=4, and 0.3%, n=2). Only 3.4% (n=21) of the identified RAVs to EBR conferred reduced susceptibility to EBR by geno2pheno[HCV]. This algorithm identified exclusively the positions Q30H/R (n=7) and Y93C/H/N (n=8) as single mutations and Q30H+Y93H (n=4) and Q30R+Y93H (n=2) as double mutations considered as major NS5A RAVs to EBR.



[Fig1A. Types and prevalence of NS5A variants]



[Fig1B. Fold change of NS5A variants]

Conclusions: Naïve HCV-G1a-infected patients had a low prevalence of NS5A RAVs to EBR in Spain. This information may be essential to guide the implementation of zepatier® in Spain and the management of G1a-infected patients.

TUPEB0388

Chronic hepatitis C in human immunodeficiency virus infected patients: real-life treatment with new generation direct-acting antivirals in a Portuguese centre

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Background: The Direct-Acting Antivirals (DAA) revolutionized the Hepatitis C virus (HCV) infection treatment. Since 2015, DAA became available in Portugal due to a universal access policy. Its use in Human Immunodeficiency Virus (HIV) infected patients has some peculiarities, specially due to drug interactions. Our aim is to assess the DAA efficacy in real life and to monitor fibrosis and alpha-fetoprotein (AFP) changes with treatment.
Methods: We performed a retrospective study of HCV-HIV patients treated with DAA between 02/2015 and 12/2016. The primary outcome was "sustained virologic response" (SVR) at week 12 after treatment and the secondary outcomes were changes in fibrosis, transaminases and AFP. We used the most appropriate measures of central tendency/distribution and statistical test.
Results: We included 291 patients that completed 12 weeks after treatment evaluation (from 402 patients with chronic HCV-HIV). Eighty-night percent (n=260) were men and the mean age was 47,96 (SD 9). The majority acquired the infection through drug abuse (90%) and 64% were HCV treatment naïve.
The most frequent HCV genotype was 1 (74,3%), followed by 3 (13,4%). The cirrhotic rate was 30%.
Concerning the HIV treatment, 99% of patients were on treatment. In 68 patients (23,4%) the HIV treatment had to be changed due to drug interactions: efavirenz (38,3%), boosted atazanavir (27,9%), boosted lopinavir (23,5%), nevirapine (8,8%) and boosted elvitegravir (1,5%). The patients changed the HIV treatment to raltegravir, rilpivirine, boosted darunavir or dolutegravir.
Regarding HCV treatment, the majority did sofosbuvir/ledipasvir (81,8%), followed by sofosbuvir/ribavirin (11,3%), sofosbuvir/ledipasvir/ribavirin (5,5%) and sofosbuvir/daclatasvir/ribavirin (1,4%). The duration of treatment was 12 weeks in 49,8% and 24 weeks in 50,2%.

Our SVR rate was 96,9% (282 patients cured the infection): six patients did not cure the infection owing to lack of adherence, in two patients the treatment was stopped (acute renal failure and alveolar haemorrhage, respectively) and one patient had a relapse.
The elastography stiffness, AFP and transaminases decreased in a statistically significant manner comparing before and after treatment (Wilcoxon test).
Conclusions: Our results confirm in real life the efficacy of these DAA with improvement of fibrosis, hepatic cytolysis and AFP.

TUPEB0389

Daily cannabis use and reduced risk of severe steatosis in a population of patients co-infected with HIV and hepatitis C virus (HCV) (ANRS CO13-HEPAVIH)

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Background: Liver steatosis is common in HIV-HCV co-infected patients. Some recent studies have found that cannabis use is negatively associated with insulin resistance in the general population and in HIV-HCV co-infected patients. Given the causal link between insulin resistance and steatosis, we hypothesized that cannabis use is a protective factor for steatosis. Therefore, we aimed to study whether cannabis use in this population was associated with a reduced risk of severe steatosis, as measured by ultrasound examination.
Methods: The ANRS CO13-HEPAVIH cohort is a French nationwide multicenter of HIV-HCV co-infected patients. Medical and socio-behavioral data from clinical follow-up visits and annual self-administered questionnaires are prospectively collected. A cross-sectional analysis was conducted using data from the first visit where both the ultrasound examination data for severe steatosis (positive or negative diagnosis) and data on cannabis use (every day, regularly, never/sometimes) were available. A multivariable logistic regression model was used to evaluate the association between cannabis use and severe steatosis.
Results: Among study sample patients (n=838), 69.8% were men, 40.1% had severe steatosis and 14.0% reported daily cannabis use, 11.7% regular use and 74.7% never or sometimes. The percentage of patients with genotypes 1, 2, 3, 4, and 5 was 55.6%, 3.2%, 18.5%, 22.4%, and 0.3%, respectively. The percentage of patients with a BMI > 27 kg/m^2 was 17.4%. With regards to HIV transmission route, 64.7% of the patients had contracted the disease via intravenous drug use. Overall, 8.8% had hazardous alcohol consumption (AUDIT>8). Daily cannabis use was independently associated with a reduced risk of severe steatosis (adjusted odds ratio [95%]=0.60 [0.39;0.93]; p=0.02), after adjusting for hazardous alcohol consumption (adjusted odds ratio [95%]=1.82 [1.10;3.00] ; p=0.02), current or ever use of lamivudine/zidovudine (adjusted odds ratio [95%]=1.53 [1.14;2.06]; p=0.004) and elevated levels of alanine transaminase (adjusted odds ratio [95%]=1.46 [1.01;2.13]; p=0.05).
Conclusions: Daily cannabis use may be a protective factor against steatosis in HIV-HCV co-infected patients. As cannabis use was also shown to lower the risk of insulin resistance in a previous study in the same population, these findings confirm the need for a clinical evaluation of cannabis-based pharmacotherapies in co-infected patients.

TUPEB0390

Assessment of liver fibrosis in former injection drug users with HIV/HCV co-infection and alcohol use disorder

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Background: High rates of Hepatitis C Virus (HCV) infection occur in individuals with substance use disorder. When HIV infection or HIV/HCV co-infection occur patients with alcohol use disorder (AUD) are at increased risk of liver disease. We aimed to assess Advanced Liver Fibrosis (ALF) in former injection drug users (IDUs) seeking treatment of AUD.
Methods: Cross-sectional study in patients admitted for hospital detoxification between 2000 and 2014 in metropolitan Barcelona, Spain. Substance use characteristics, blood samples for viral infections and liver function tests were collected at admission. Fibrosis of the liver was assessed by APRI, FIB-4 and Forns indexes. ALF was defined by APRI >1.5, FIB-4>3.25 and Forns>6.9.
Results: Among 1.313 patients admitted, 208 (80.3% M) were former IDU. Age at admission was 40 years (IQR: 36-44 years), age at starting alcohol use 19 years (IQR: 17-24 years) and the amount of alcohol consumption 210 g/day (IQR: 147-350 g/day). Prevalence of HCV infection was 83% (173/208) and 9% (15/173) had antecedent of HCV treatment. Forty percent (70/173) of patients were HIV/HCV-coinfected and median CD4 cell count at admission was 336 cell/µL (IQR: 175-579 cell/µL)
Table 1 shows prevalence of ALF according to indexes and viral infections:

	HIV-/ HCV- N=35 n (%)	HIV+/ HCV- N=101 n (%)	HIV+ / HCV+ N=70 n (%)	p value
APRI >1.5	7 (20.0)	36 (37.9)	30 (46.9)	0.031
FIB-4 >3.25	4 (11.4)	22 (23.2)	27 (42.2)	0.002
Forns>6.9	4 (11.8)	33 (35.1)	34 (55.7)	<0.001

[Table 1]

Table 2 shows the ORs for ALF in patients with HCV-infection and HIV/HCV co-infection with respect to those without viral infections:

	APRI OR (95%CI)	FIB-4 OR (95%CI)	Forns OR (95%CI)
HIV-/HCV- (n=35)	1	1	1
HIV-/HCV+ (n=101)	2.4 (1.0-6.2)	2.3 (0.7-7.3)	4.1 (1.3-12.5)
HIV+/HCV(+) (n=70)	3.5 (1.3-9.2)	5.6 (1.8-17.9)	9.4 (3.0-30.1)

[Table 2]

Conclusions: Risk of symptomatic, advanced fibrosis of the liver is high in AUD patients with HIV/HCV co-infection. Treatment of alcoholism and HCV infection with direct-acting antivirals should be prioritized in this population.

TUPEB0391

Validation and scale-up of Hepatitis B viral load on polyvalent open PCR platforms in West African and South East Asian countries. A study of the AC12 working group (ANRS 12327)

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Background: Quantification of HBV DNA is critical for therapeutic decision, however access to affordable HBV DNA testing remains limited in resource-constrained countries. The ANRS AC12 Virology group is an international working group of clinical virologists promoting validation and scale up of molecular tests. In this multi-laboratory study we evaluated the performance of a new generic HBV PCR assay performed with automated open polyvalent platforms (OPP) and compared with proprietary classical assays.
Methods: The generic HBV viral load assay was based on an in-house PCR assay previously evaluated with different HBV genotypes. This assay uses the same thermocycling protocol as the ANRS generic HIV-1 assay, thus enabling HIV-1 RNA and HBV DNA testing during the same PCR run. Optimization, standardization and production of the PCR assay were done in collaboration with two private companies Omunis (Clapiers, France) and Biocentric (Bandol, France) that

pursue regulatory approval of the "Generic HBV Charge Virale" assay. The PCR was evaluated in nine West/Central African and South East Asian countries. HBV DNA results were compared to Roche COBAS® HBV test version 2.0 and Abbott RealTime HBV PCR assays.
Results: Laboratories in France, Côte d'Ivoire, Burkina Faso and Cambodia provided intermediary results of HBV viral load using the generic HBV PCR versus Roche and Abbott PCR assays. Of 186 clinical samples with HBV DNA level over 1,000 IU/ml, 184 (99%) tested positive for HBV DNA with the generic PCR. High correlation (r >0.90, p >0.001) and good agreement between the Biocentric assay and the Roche and Abbott tests were obtained. The generic assay presents also a good specificity (100%) among 99 HBs Ag negative samples.
Conclusions: The use of this nucleic acid test with OPP could contribute to better implement HBV DNA testing and therapeutic decision-making in low- and middle income countries. Good agreement between the generic HBV PCR and Roche/Abbott assays was observed for samples collected from patients with chronic active hepatitis B. A higher input volume for DNA extraction would be useful to lower the limit of detection below 100 IU/ml and improve the quantification of HBV DNA in inactive carriers.

TUPEB0392

Factors associated with liver fibrosis progression from minimal (F0F1) to advanced liver fibrosis (F3F4) in HIV-infected patients with or without chronic hepatits coinfection: a prospective study

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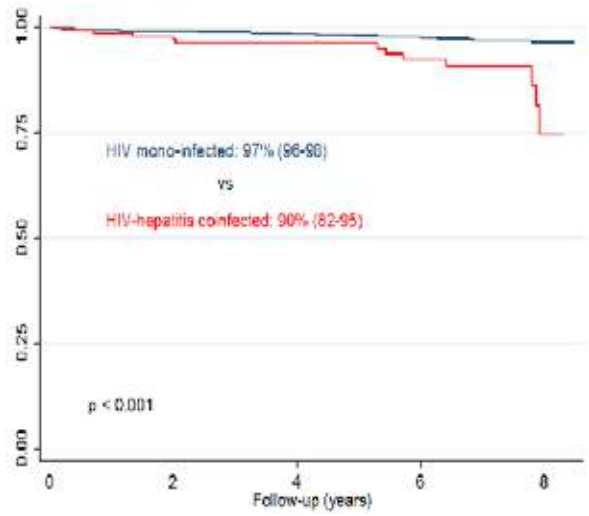
Background: Liver fibrosis progression might lead to cirrhosis and end-stage liver disease. This longitudinal study aimed to evaluate the risk factors for development of advanced fibrosis in HIV infected patients with no/minimal fibrosis at baseline.
Methods: 4,071 HIV patients were prospectively followed from 2007 to 2015. Liver fibrosis was estimated at baseline and at the last blood analysis by FIB-4 biomarker [FIB-4=(age*AST)/(platelet count*[sqrt(ALT)])].
Minimal (METAVIR=F0F1) and advanced fibrosis (METAVIR=F3F4) were defined by FIB-4 <1.45 and FIB-4 >3.25, respectively. The exclusion criteria were missing transaminases or platelet count (n=795); missing hepatitis serology (n=211); absence of follow-up (n=120) and FIB-4 > 1.45 at baseline (n=427).
Hepatitis coinfection was defined by positive HBsAg or anti-HCV. Age-gender-adjusted multivariate Cox proportional-hazards regression models were performed. Baseline and nadir CD4 cell counts and baseline HIV viral load were considered as confounders.
Results: 2,518 HIV patients [64% male, median age=37(IQR,29-44) years, 7% (N=158) with hepatitis coinfection)] were included. During a median of 5.1 years (IQR,2.7-6.9) of follow-up, 63 patients developed advanced fibrosis. The incidence rates (95%CI) of advanced fibrosis in HIV mono-infected and coinfected patients were 4.1 (3.1-5.4) and 16.0 (9.1-28.2) per 1000 person-year, respectively. The 7-year survival without advanced fibrosis [Kaplan Meier (95%CI)] was higher in HIV mono-infected compared to those with coinfection [97% (96-98) vs 90% (82-95; p<0.001] [Figure]



[Survival without progression to advanced fibrosis]

In multivariate Cox model [HR (95%CI)], age >45 years [1.86 (1.05-3.24), p=0.033]; CD4 count <200 cells [2.96 (1.51-5.77), p=0.002]; nadir CD4 <200 cells [4.48 (1.72-11.67), p=0.002] and hepatitis coinfection [2.62 (1.62-5.41), p=0.010] were independently associated with progression to advanced fibrosis. Considering HIV mono-infected patients (n=2,616), CD4 count <200 cells [2.51 (1.23-5.10), p=0.011]; detectable HIV viral load [2.43 (1.06-5.59), p=0.036] and nadir CD4 <200 cells [6.80 (2.20-21.05), p=0.001] were independently associated with fibrosis progression.
Conclusions: Hepatitis coinfection, low nadir CD4 and baseline CD4 count were independently associated with progression from minimal to advanced fibrosis in HIV-infected patients.

TUPEB0393

Usual APRI score thresholds lack sensitivity to prioritize for hepatitis C treatment in a HCV/HIV coinfected cohort in Cambodia

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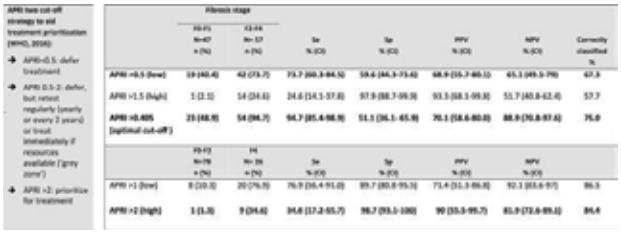
Background: The vast demand and limited resources justify in some contexts stepwise scale-up of hepatitis C treatment. We evaluated the Aspartate-to-platelet ratio index (APRI) threshold strategy for treatment prioritization, as proposed in the WHO guidelines, in the HCV/HIV coinfected cohort of Sihanouk Hospital Center of Hope in Cambodia.
Methods: Liver fibrosis was evaluated by Fibroscan (stageF0-F1: < 7.2 kPa, F2: 7.2-9.5, F3: 9.5-14.5, F4: ≥14.5). ROC curves for APRI to diagnose significant fibrosis (≥F2) and cirrhosis (F4) were established with area-under-curve (AUC) and 95% confidence interval. Performance of APRI low (>0.5, for ≥F2) and high (>2.0, for cirrhosis) cut-off was evaluated. The optimal cut-off was determined by weighing false negatives (FN) twice as harmful as false positives (FP).
Results: Hundred-seven coinfected were identified among 3046 HIV patients. Median age was 48.7 years. All, but three, were on ART (median duration 6.5 years); 97.7% had undetectable viral load. FibroScan was done for 104 coinfected; 47 staged F0-F1, 31 F2-F3 and 26 cirrhosis.
The AUC of APRI was 0.79 (95% CI 0.71-0.88) for ≥F2. At cut-off >0.5, sensitivity was 73.7% (60.3-84.5) and specificity 59.6% (44.3-73.6). For cirrhosis, AUC was 0.93 (0.88-0.98), with for cut-off >2.0 sensitivity 34.6% (17.2-55.7) and specificity 98.7% (93.1-100).
Applying the cut-off strategy, treatment would be prioritized for 10 patients and deferred in 43. Fifty-one would be in the grey zone. Thirty-one patients with advanced fibrosis, including 17 cirrhotics, would not be prioritized. A unique APRI cut-point for >F2 (=minimizing number FP + 2* number FN), 0.405 in our cohort, would identify 77 patients to treat, including 54 with significant fibrosis.



[APRI threshold strategy and performance]

Conclusions: The APRI two cut-off strategy lacked sensitivity in our coinfected cohort. A unique lower APRI cut-point (0.405) allowed more balanced and inclusive prioritization, and seems more adapted given the improving affordability of HCV treatment. Further validation in other cohorts is needed.

TUPEB0394

Comparative steatosis rates by liver biopsy and transient elastography controlled attenuated parameter (CAP) in hepatitis C (HCV) and HIV/HCV coinfection in a large U.S. hepatitis clinic: time to take notice

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Background: Steatosis contributes to liver fibrosis in both HCV and HIV/HCV coinfection. Liver biopsy (LB) is the gold standard for grading steatosis and staging fibrosis, yet recent non-invasive staging modalities have largely supplanted LB in HCV, which may limit recognition of underlying steatosis. We compare steatosis rates in LB to transient elastography (TE) CAP among HCV and HIV/HCV patients in a U.S. hepatitis clinic.
Methods: Demographic information, fibrosis stage, and steatosis grade using standardized cutoffs were recorded among unique patients with chronic HCV during pre-treatment evaluation by LB (N=319, December 2001-December 2010) and TE CAP (N=822, May 2016-January 2017) at The CORE Center. Univariate analysis was performed, and p-values with α< 0.05 were calculated for comparisons of fibrosis and steatosis rates by LB and TE with CAP stratified by HCV versus HIV/HCV coinfection status.
Results: Steatosis was not reported in 26% of LBs (Table 1). Significant steatosis rates (≥S2) were greater by CAP compared to LB (26% versus 10%), and median CAP scores were significantly higher in HCV versus HIV/HCV coinfection (231 versus 216; p<0.0001)(Tables 1 and 2). Steatosis ≥S2 was significantly associated with greater fibrosis severity overall and in HCV monoinfection by CAP (Table 2).

		Total Patients	P-Value	HIV/HCV Coinfection (%)	HCV Monoinfection (%)	P-Value
Liver Biopsy Pathology Reports December 2001-December 2010		N=319		N=183 (57.4)	N=136 (42.6)	
Median age (years)		49		49	49.5	
Male		245 (76.8)		156 (85.2)	89 (65.4)	
Female		74 (23.2)		27 (14.8)	47 (34.6)	
Fibrosis Stage						
F0		29 (9.1)		17 (9.3)	12 (8.8)	
F1		106 (33.2)		61 (33.3)	45 (33.1)	
F2		90 (28.2)		50 (27.3)	40 (29.4)	
F3		64 (20.1)		37 (20.2)	27 (19.9)	
F4		30 (9.4)		18 (9.8)	12 (8.8)	
Steatosis grade						
S0		1 (0.3)		0 (0)	1 (.7)	
S1 (<10%)		204 (63.9)		130 (71.0)	74 (54.4)	
S2 (11-30%)		21 (6.5)		10 (5.4)	11 (8)	
S3 (>30%)		11 (3.4)		3 (1.6)	8 (5.8)	
Not reported		82 (25.7)		45 (24.6)	37 (27.2)	
S2-S3		32 (10)		12 (6.6)	20 (14.7)	P=0.0157
F0-1	N=100					
	S0-1	94 (69.6)	P=0.0087	60 (88.2)	34 (87.2)	P=0.1790
	S2-3	6 (4.4)		1 (1.6)	5 (12.8)	P=0.0848
F2-4	N=137					
	S0-1	111 (60.3)		71 (85.5)	50 (78.1)	P=0.8960
	S2-3	26 (14.1)	P=0.0027	12 (14.5)	14 (21.9)	P=0.0507
F3-4	N=62					
	S0-1	52 (55.3)		36 (94.7)	16 (66.7)	P=0.0806
	S2-3	10 (10.6)	P=0.3182	2 (5.3)	8 (33.3)	P=0.0186

[Table 1. Association between significant steatosis with severity of fibrosis by liver biopsy]

		Total Patients	P-Value	HIV/HCV Coinfection (%)	HCV Monoinfection (%)	P-Value
TE Fibrosis (kPa) and CAP Scores May 2016-January 2017		N=822 (%)		N=168 (%)	N=654 (%)	
Median age (years)		57		58	56	
Male		530 (64.5)		128 (24.2)	402 (76.8)	
Female		292 (35.5)		40 (13.7)	252 (86.3)	
Medium Probe		702 (85.4)		159 (94.6)	543 (83.0)	
XL Probe (Body Mass Index ≥30)		99 (12.0)		9 (5.4)	90 (13.8)	P=0.0014
Fibrosis Stage						
F0-1 (<7.1 kPa)		333 (40.5)		71 (42.3)	262 (40.1)	P=0.4597
F2 (7.1-9.4 kPa)		200 (24.3)		49 (29.2)	151 (23.1)	P=0.1073
F3 (9.5-12.4 kPa)		101 (12.3)		22 (13.1)	79 (12.1)	P=0.6944
F4 (>12.5 kPa)		188 (22.9)		26 (15.5)	162 (24.8)	P=0.0100
Median CAP Score		227		216	231	P<0.0001
CAP S0 (0-237)		455 (55.4)		115 (68.5)	340 (52)	P=0.0001
CAP S1 (238-259)		136 (16.3)		23 (13.7)	113 (17.3)	P=0.2955
CAP S2 (260-292)		117 (14.0)		22 (13.1)	95 (14.5)	P=0.7110
CAP S3 (≥293)		97 (11.6)		8 (4.8)	89 (13.6)	P=0.0011
F0-1	N=333					
	CAP S0-1	268 (80.4)	P=0.0059	61 (85.9)	207 (79.0)	P=0.2685
	CAP S2-3	65 (19.5)		10 (14.1)	55 (14.1)	P=0.3389
F2-4	N=489					
	CAP S0-1	341 (69.7)		77 (81.1)	264 (67.7)	P=0.2934
	CAP S2-3	148 (30.3)	P=0.0006	18 (18.9)	126 (32.3)	P=0.0087
F3-4	N=289					
	CAP S0-1	185 (64.0)		34 (65.4)	151 (54.5)	P=0.4104
	CAP S2-3	104 (36.0)	P=0.0003	18 (34.6)	126 (45.5)	P=0.0087

[Table 2. Association between significant steatosis with severity of fibrosis by transient elastography (TE) with controlled attenuated parameter (CAP)]

Conclusions: Steatosis was underreported by LB, and severity may be increasing in the modern HCV treatment era, particularly in HCV monoinfection. Without LB steatosis quantification requires advanced technology and may go unrecognized if soluble biomarkers are used exclusively for fibrosis staging. Improved biomarkers are needed to serially assess HCV patients with significant steatosis undergoing curative HCV therapy.

TUPEB0395

Circulating mucosal associated invariant T cells (MAITs) fail to be recovered by successful direct-acting antiviral therapy (DAA) in HIV/HCV co-infected patients

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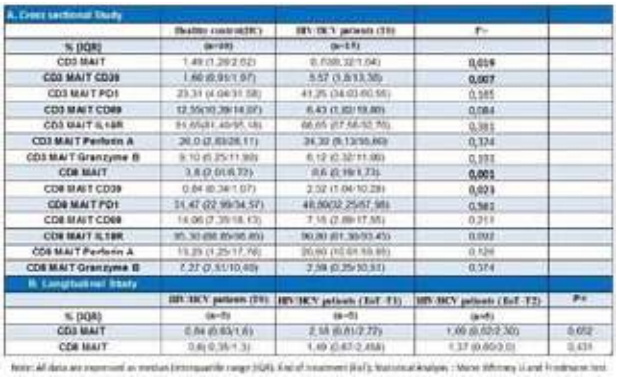
Background: MAITs play a crucial role in innate immunity. A substantial reduction in MAITs has been described in untreated HIV, which is not restored by cART. Little is known about MAITs frequency/function in HIV/HCV co-infected patients and their fate after HCV elimination by DAA. We assessed MAITs in cART-treated HIV/HCV co-infected patients (pts) and the impact of anti-HCV therapy (both interferon and DAA-based).
Methods: We enrolled 15 HIV/HCV+ cART-treated pts [HIV-RNA< 40cp/ml; median CD4 527/mmc (IQR 409-780)] and 10 age-matched healthy controls (HC). All pts were treated with pegIFN-based anti-HCV treatment: 9/15 patients (60%) achieved a sustained virologic response (SVR), 6/15 patients (40%) failed to clear HCV infection (non responders-NR), 5/6 NR pts started DAA-based therapy (3 PI-based vs 2 with NS5A inhibitors)
We measured MAITs frequency (CD161++Va7.2+ CD3 or CD8), activation (CD69), exhaustion (CD39/PD-1), IL18R expression, cytolytic activity (granzyme B/perforin A) (flow cytometry) at baseline (T0), Interferon end-of-treatment (T1) and DAA end-of-treatment (T2). Statistical analyses: Mann-Whitney, Friedman.
Results: As compared to HC, HIV/HCV pts displayed substantially contracted total and CD8 MAITs (Table 1A). All MAIT subsets of HIV/HCV pts showed a trend towards higher CD39 expression, especially within the CD8 subset, but no differences in PD-1, IL-18R, granzyme B and perforin A expression were detected between HIV/HCV pts and HC (Table 1A). Following IFN-based therapy (T1), we found a non-significant increase in total and CD8 MAITs (Table 1B). Likewise, no significant recovery of total and CD8 MAITs frequency was shown following DAA treatment (T2) (Table 1B).
Conclusions: In HIV/HCV co-infected patients we show a profound depletion of the circulating MAITs compartment that is not recovered by anti-HCV treatment and HCV virus eradication, indicating a profound and irreversible virus-mediated depletion in MAIT cell subsets. Future research is needed to dissect molecular mechanisms governing the homeostasis of circulating and tissue MAIT cells upon viral clearance.



[Table 1. Phenotypes of circulating mucosal-associated invariant T cells (MAIT) in cross-sectional and longitudinal study]

TUPEB0396

Efficacy of ledipasvir/sofosbuvir (LDV/SOF) for 8 weeks in real life setting for patients with HCV/ HIV-1 co-infection

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Background: The AASLD/IDSA/IAS-USA Guidance and EASL Recommendations on Treatment of Hepatitis C state that HIV/HCV coinfection should be treated the same as HCV monoinfection. Real world cohorts (RWC) have demonstrated excellent efficacy of LDV/SOF for 8 weeks in HCV monoinfected patients. The aim of this study was to describe the effectiveness of the single tablet regimen of LDV/SOF for 8 weeks in HCV genotype (GT) 1 patients with HIV/HCV coinfection in RWC.
Methods: Real world effectiveness data of LDV/SOF for 8 weeks in HIV/HCV coinfection is emerging from several prospective and retrospective cohorts. In this analysis, data from two prospective studies, one investigator sponsored (Ain et al.) and 1 registration trial (Isakov et al.), and three retrospective RWC (Deutsches Hepatitis C-Register, Madrid Coinfection Registry (Madrid-CoRe), and Veterans Affairs HCV Registry) of LDV/SOF for 8 weeks in HIV/HCV co-infected patients were compared. RWC were selected based on willingness to participate with at least 15 HIV/HCV co-infected patients. Baseline characteristics and efficacy were analyzed.
Results: The majority of the 279 patients included in analysis were GT 1, treatment naïve (TN), noncirrhotic (NC), and had HCV viral load < 6 million. The prospective cohorts enrolled 79 patients with the following baseline characteristics: mean age (43 years), male (74%), white (78%), and GT 1a (55%). The RWC studies assessed enrolled 200 patients with the following overall baseline characteristics: mean age (53 years) male (79%), white (98%), and GT 1a (82%) in those that reported demographics. The overall SVR12 from five diverse real world and post-marketing cohorts was 94% (263/279). The individual study results are presented in Table 1.

Clinical trials and RWC with LDV/SOF for 8 weeks in HIV/HCV coinfection				
Study	**Study Design**	**Treated (n)**	**SVR12 (n)**	**SVR 12%**
Ain et al.	Prospective LDV/SOF x 8 weeks	20	18	90
Russian cohort (Isakov et al)	Prospective LDV/SOF x 8 weeks	59	57	97
VA (Backus et al)	Retrospective LDV/SOF x 8 weeks	31	30	97
DHC-R (Buggish et al)	Retrospective LDV/SOF x 8 weeks	76	73	96
Madrid-CoRe	Retrospective LDV/SOF x 8 weeks	93	85	91

[Table 1]

Conclusions: This analysis of diverse cohorts from the EU and US yielded high SVR rates similar to SVR rates seen in multiple RW moninfected cohorts and supports the use of 8 weeks of LDV/SOF in TN, NC GT 1 HIV/HCV coinfected patients with a baseline HCV viral load <6 million.

TUPEB0397

Chronic hepatitis C and HIV co-infection among people who inject drugs along the Kenyan Coast

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Background: People who inject drugs (PWID) are a major driver of HCV spread worldwide. The use of injecting drugs is an emerging but neglected problem in Africa, particularly in East Africa. This study aimed to determine the prevalence and severity of chronic hepatitis C and HIV co-infection among a group of PWID in Mombasa, Kenya.
Methods: Participants were recruited at local drop-in centres supported by Kenya AIDS NGOs Consortium (KANCO). Epidemiological data and blood samples were systematically collected for liver function tests and virological analysis (HIV/HCV serology, RNA and genotyping). PathCare Kenya Limited as well as Kenya Medical Research Institute (KEMRI) provided support for processing and storage of blood samples. In the absence of a Fibroscan, liver fibrosis was assessed using the Aspartate Transaminase to Platelet Ratio Index (APRI) score according to the WHO guidelines.
Results: 400 PWID (85% Male) were recruited in Mombasa and Kilifi Counties. The mean (± SD) age was 34 years (± 7.5), 33% (130/400) admitted to sharing needles while injecting heroin. 95% (378/400) had spent time in or prison. 34% (137/400) were heavy drinkers. Only 1% of participants had completed secondary level education.
Only 8% (31/400) had previously been tested for HCV whereas all participants had been tested for HIV previously, with the majority receiving regular HIV care. The prevalence of positive HCV and HIV serologies were 36% and 17%, respectively. 72% (50/69) were HIV-HCV co-infected. More than 40% had a positive HCV RNA and the vast majority were infected with HCV genotype 1 or 4. Of the 143 infected with HCV, 14% (20/143) had an APRI score >1 and 6% (9/143) >2 suggesting the presence of cirrhosis.
Conclusions: PWID along the Kenyan Coast are at high risk of HCV infection and HCV-HIV co-infection but are not systematically screened for HCV although 14% might need urgent antiviral therapy. High rate of incarceration and low level of education might be potential barriers to implement screen-and-treat interventions in this key population.

TUPEB0398

Virtual elimination of hepatitis C in an Australian regional area: what a difference access to the new medications makes!

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Background: Australia has been estimated to have about 230,000 people living with hepatitis C virus (HCV). Approximately 10% of people living with HIV are coinfected with HCV. On 1 March, 2016, the Australian Government made new direct acting HCV medications (DAAs) available to all Australians with HCV, regardless of liver fibrosis, HIV status, or injecting drug use status. Cairns is a city in Far North Queensland and has a population of 160,000, though it services a vast area containing about 250,000 people.
Methods: A "Make Cairns Hep C Free by 2020" program was instituted with the input of the Cairns Sexual Health Service, the Liver Clinic at the Cairns Hospital, local General Practitioners (GPs), the Alcohol and Drug Service, and the 800-bed male prison in the region. Initial focus was on reducing the hospital waiting list for those awaiting the new DAAs, upskilling GPs, involving users of the Alcohol and Drug services, and rapidly clearing the prison of HCV. In addition, all HIV/HCV coinfected individuals were treated as a priority.
Results: After 9 months of access to new hepatitis C DAAs the majority of individuals already identified with HCV in Cairns and surrounding areas have been treated and cured of HCV. The hospital clinic waiting list has been reduced to zero, the prison is virtually free of HCV infection, and efforts to find a smaller number of individuals who have not yet been diagnosed or treated have been increased.
Conclusions: Easy and widespread access to new hepatitis C DAAs at a variety of sites throughout Cairns and the broader region has led to the virtual elimination of hepatitis C in this part of Australia. Involvement of local clinicians with the ability to prescribe these agents, along with the communities of those such as people living

with HIV, injecting drug users, and prisoners appears to have been successful and has allowed these results to occur within a matter of months. Cairns is on track to be "Hep C Free by 2020".

TUPEB0399

HCV cure for HIV-infected patients: not so easy to achieve in routine practice

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Background: High efficacy of Direct Antiviral Agents (DAAs) lead us to consider that HCV cure is now the main challenge for HIV-HCV coinfected people. We report the results of a care program aimed to reduce prevalence of hepatitis C in a cohort of HIV-infected patients.
Methods: This program was initiated in February 2016 in an outdoor-HIV-clinical unit. According to French guidelines, the program included (i) HCV serology for patients with unknown or negative HCV antibodies evaluated for most than 12 months or whatever the date in case of risk factor (ii) HCV-RNA viral load for patients with positive HCV antibodies and for those with a negative HCV-RNA (spontaneous or post treatment) evaluated for more than 12 months. DAAs regimen was defined during multidisciplinary staff and nurse' intervention for compliance and education was planned during treatment. Tolerance was evaluated through questionnaires.
Results: At program initiation, the cohort included 622 HIV-monoinfected and 276 HCV-HIV co-infected patients. Among these last one, 116 had positive HCV-RNA (83 never treated), 140 were negative (36.6% after treatment) and 20 patients were under HCV-treatment. Up to now, HCV serology was controlled in 481 patients (89%) and two cases of acute hepatitis C were diagnosed. HCV-RNA was measured in 122 patients (58%) without reinfection diagnosis and 25 patients are still lost of follow-up. DAAs regimen (mostly: 59% with sofosbuvir /ledipasvir for 12 weeks) was started in 54 patients (70% males, HCV genotype 1/3/4 in 34/13/7; F0-F1/F2/F3-F4 in 35/7/12), recused in 18 cases for medical reason and refused by 7 patients. Among the 30 patients reaching 12 weeks post-end of treatment, 2 failed therapy: 1 breakthrough and 1 relapse (SVR rate=96%). Tolerance questionnaires were fulfilled by 37 patients. At 2 weeks (W2) of treatment, 64% declared at least one adverse events. They were 76% at W4, 81% at W8, 68% at W12 and 50% at W16. Detail of adverse events are presented in Graphic 1.
Conclusions: Despite a specific care program, HCV treatment uptake in our cohort was of 46%, highlighting that HCV cure in HIV-infected people will be not so easy to achieve in routine practice.

TUPEB0400

Untreated HCV-coinfection in HIV-infected patients induces additional CD4+ T-lymphocyte deficiency due to mobilization of naive cells into immune response resulting in their regeneration failure

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Background: One of the major immune discrepancies differing HIV/HCV-coinfection from HIV-monoinfection is the development of a deeper CD4+ T-cell deficiency that is mainly due to the naive cell loss. In HIV-infected subjects, the reasons for the naive CD4+ T-cell decline are well known: thymus productive function failure, and lymph nodes sclerosis that blocks lymphocyte access to IL-7 and disrupts their ability to regenerate. However, the role of HCV-coinfection in deepening the CD4+ T-cell deficiency induced by HIV-infection remains unknown.
Methods: Twenty ART-treated HIV/HCV-coinfected patients without interferon or anti-HCV drugs prescription were examined. ART-treated HIV-monoinfected subjects (n=21) and uninfected volunteers (n=20) served as controls. HCV viral load in the first group exceeded 1000000 copies/ml, HIV viral load in infected groups was < 50 copies/ml. On the basis of CD31 naive CD4+ T-cells were divided into recent thymic emigrants (CD4+ RTE: naive CD4+CD31+ T-cells) and mature naive T-lymphocytes (naive CD4+CD31- T-cells). IL-7R (CD127) expression by naive T-cells was determined. Cell proliferation was assessed by Ki-67 expression. Blood IL-2 and IL-7 concentrations were measured.
Results: Naive CD4+ T-lymphocyte content was reduced in the HIV+HCV+ group as compared to the HIV+HCV- group. In HIV-monoinfected subjects, naive CD4+ T-lymphocyte regeneration was characterized by two principles:
1) the less cells were presented, the more intensive their proliferation was;
2) mature naive CD4+ T-cell numbers were directly associated with the CD4+ RTE counts. In HIV/HCV-coinfected patients, both principles were disregarded. However, in that group the number of mature naive CD4+ T-lymphocytes was directly related both to blood HCV concentration and to hepatitis activity indices. IL-7 levels in two HIV-positive groups did not differ from each other but were significantly higher than in uninfected volunteers. CD127 expression on naive CD4+ T-cells in HIV/HCV-coinfected patients was reduced but corresponded to the level in HIV-monoinfected subjects. IL-2 concentration in HIV/HCV-coinfected individuals significantly exceeded the ones in people without infections and in HIV-monoinfected subjects.
Conclusions: Presented results demonstrate that active immune response to HCV antigens takes place in HIV/HCV-coinfection. It leads to the naive CD4+ T-cells' recruitment and, consequently, to their regeneration process failure.

TUPEB0401

Prevalence and molecular characterization of hepatitis B virus in blood donors in Botswana

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Background: Blood transfusions remain a major challenge in resource-limited settings like Sub-Saharan Africa where sexually transmitted diseases mainly hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis and HIV are hyper-endemic. HBV is ranks as the 7th leading cause of annual global deaths. There are 10 genotypes (A to J) that differ in >8% in genetic diversity and all show unique geographic distribution, response to treatment and prognosis. Genotype A, D and E are circulating in different African HBV-cohorts. There is limited data on this in Botswana. We aimed to determine the HBV prevalence and to molecularly characterize the HBV circulating genotypes among blood donors in Botswana.
Methods: This was a cross-sectional study of hepatitis B surface antigen positive (HBsAg+) allogeneic blood donations at National Blood Transfusions Services in Botswana (NBTS) confirmed using ELISA conducted in a 10 month period between 2014 and 2015. Nucleic acid extraction was done using UltraSense DNA/RNA Kit followed by polymerase chain reaction (PCR) reaction using SuperScript Platinum III Taq-polymerase covering 2.1kb surface antigen .Genotyping was done using Sanger sequencing.
Results: In the 10798 allogeneic donations done during study period, the prevalence of $HBsAg^+$ was 0.92% (75). Co-infections confirmed were of Syphilis 1.72%, 1.54% for HIV and 0.43% for Hepatitis C. The total population had normally distributed age with mean of 29 ±1.7 years and a range of 44 years. PCR was successful on 41 (82%) of which 87.8% were successfully sequenced and genotyped. Sub-genotype A1 (48%) serotype adw2 and D (52%) serotype ayw2 were found in the study population. Secondary escape mutations with high impact associated with failure to Immunoglobulin G therapy, vaccine and failure to HBsAg detection were noted on positions **A120L** and **130R** in genotype A with a frequency of 1 and 2 respectively. In sub-genotype D3, escape mutations were observed on positions **134H** and **144A.** The impacts of D3 mutations were similar to A1.
Conclusions: Predominant genotype amongst Botswana blood donors is D3 There are some escape mutations which are present in Botswana blood donors.HBV complications and its HIV co-infection is high in Africa and more analysis should be done in larger cohorts.

TUPEB0402

Prevalence of polymorphism within HCV NS5A gene in HCV-GT1A patients in Spain

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Background: Hepatitis C virus (HCV) resistance-associated substitutions (RASs) in the NS5A gene may limit the sustained viral response during antiviral therapy and lead to no cure. The objective was to evaluate the prevalence of RASs in the NS5A gene in HCV-GT1a infected patients from Spain.
Methods: A nationwide cross-sectional study of 617 treatment-naïve chronic HCV-GT1a infected patients (292 HIV/HCV-coinfected and 325 HCV-monoinfected) from 84 Spanish hospitals between October/2014-June/2016. Direct sequencing of the NS5A gene was performed. The prevalence of clinically-relevant RASs and degree of resistance to approved NS5A inhibitors was evaluated.
Results: Overall, 80.1% (n=494) of subjects were men and had a median of age of 50 years (IQR=47-53). A higher frequency of GT1a clade II [82.5% (n=509)] than clade I [17.5% (n=108)] was observed (p=0.0001). Clade I was more represented in HIV/HCV-group (22.9%) than HCV-group (12.6%) whereas clade II was less represented in HIV/HCV-group than HCV-group (77.1 vs 87.4%, respectively; p=0.001). Overall, the presence of RASs that confer a reduced susceptibility to NS5A inhibitors was observed in 7.9% (n=49) patients. Of them, 2.1% (n=13/617) had RASs that conferred resistance to all approved NS5A inhibitors (daclatasvir, ledipasvir, ombitasvir, elbasvir and velpatasvir) while 2.6% (n=16/617) harbored viruses that were possibly resistant to these drugs. The frequency of clinically relevant RASs was: 3.7% (n=23) M28A/T/V; 2.3% (n=14) Q30E/H/R; 0.6% (n=4) L31M; 0.3% (n=2) H58D and 2.3% (n=14) Y93C/H/N. RASs that conferred resistance to all NS5A inhibitors in 7 HIV/HCV-coinfected patients were: Y93C (n=4), Y93H (n=1) and double (Q30H or Q30R and Y93H) in two patients; in 6 HCV-monoinfected patients were: Y93C (n=1), Y93H (n=1) and double (Q30H or Q30R and Y93H) in four patients. The frequency of RASs was not uniform in Spain. Eight autonomous communities (CCAAs) had a prevalence ≥10% (e.g. Madrid: 16.1%. Murcia: 14.3%, Cantabria: 13.3%); four CCAAs had a prevalence of 5%-< 10%, and in three CCAAs was < 5%. Three CCAA did not show RASs isolates in the samples analyzed.
Conclusions: In Spain, the overall prevalence of NS5A RASs was low in HCV-GT1a infected patients, did not differ in HIV/HCV-coinfected or HCV-monoinfected subjects but showed a marked geographical variability.

TUPEB0403

Evolution of glomerular filtration rate in patients concomitantly treated with ledipasvir and tenofovir

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Background: Since ledispavir can increase tenofovir plasma levels, there is concern about renal safety of these two drugs co-administered in HIV-infected patients. However, few data are available on the evolution of glomerular filtration rate(eGFR) in patients treated with ledipasvir and tenofovir in clinical practice.
Methods: We performed a retrospective study including patients treated for HCV with directly acting antivirals(DAA) at two reference centers in Northern and Central Italy. eGFR was estimated through CK-EPI at baseline(time of DAA start), at week 12 during DAA treatment(T1) and 12 weeks after DAA discontinuation(T2). Evolution of eGFR during follow-up was compared in patients concomitantly treated with ledipasvir-tenofovir or not.
Results: 302 patients (73% males, median age 55 years, 50% HIV-HCV co-infected) were enrolled. Sofosbuvir/ledipasvir was prescribed in 139(46.0%) patients; other DAA regimens were sofosbuvir+ribavirin(n=65,21.5%), sofosbuvir +daclatasvir(n=57,18.9%), sofosbuvir+simeprevir(n=41,13.6%). Among 151 HIV-infected patients, 104(68.9%) were treated with a tenofovir-containing regimen and 19(18.5%) also received a boosting agent (ritonavir or cobicistat). Overall, patients were classified in the following groups: 91 treated with ledipasvir only(group 1), 48 concomitantly treated with ledipasvir-tenofovir (group 2), 108 treated with tenofovir only(group 3) and 55 treated with none of the two drugs (group 4). At baseline, median eGFR was 95 mL/min/1.73m^2(IQR 78-103). No significant modification of eGFR was observed in group 1, whilst patients in group 2 showed a significant decrease of eGFR at all time points during DAA treatment, with a mean eGFR loss at week 12 of -6 mL/min/1.73m^2 (p<0.001). Only partial eGFR recovery was observed 12 weeks after DAA discontinuation (-4.6 mL/min/1.73m^2, p=0.002). In group 3, eGFR decreased during DAA treatment (week-12 change -6 mL/min/1.73m^2, p<0.001) but, after DAA discontinuation, a recovery to values similar that observed at baseline occurred (T2 versus baseline mean change -2 mL/min/1.73m^2, p=0.126).

	Week 4	Week 8	Week 12	12 weeks post-treatment
Ledipasvir (group 1)	-0.5 (9.4) 0.468	-0.1 (8.1) 0.981	+0.3 (7.8) 0.584	-1.4 (8.5) 0.1845
Ledipasvir+Tenofovir (group 2)	-6.2 (8.7) <0.001	-7.1 (7.7) <0.001	-6.0 (6.9) <0.001	-4.6 (7.1) 0.001
Tenofovir (group 3)	-1.6 (10.5) 0.452	-5.1 (12.1) 0.009	-6.2 (7.6) <0.001	-2 (9.2) 0.128
No tenofovir nor ledipasvir (group 4)	-1.8 (7) 0.013	-2.4 (6.9) 0.004	-1.4 (7) 0.024	-2.8 (6.2) <0.001

[Mean eGFR change in the 4 groups (SD)]

Conclusions: Patients concomitantly treated with ledipasvir and tenofovir showed a slight decrease in eGFR, which persisted also after DAA discontinuation. The clinical relevance of this finding should be verified over a long-term follow-up.

TUPEB0404

HCV genotype profile in Brazil among HIV-infected and uninfected individuals: a survey truly representative of an entire country

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Background: In order to receive antiviral treatment, HCV infected patients need a genotype determination provided by the Brazilian government after initial diagnosis. We assessed the HCV genotype profile vis a vis Brazilian geographic region, gender, age and HIV co-infection.
Methods: We assessed 6,338 samples from HCV infected patients subjected to HCV genotype (Abbott RealTime HCV Genotype) collected from January 2016 to July 2016. 620 randomly selected samples were tested for HIV co-infection using the kit TR DPP HIV 1/2 Bio-Manguinhos. Descriptive statistical analyses were performed using the R statistical system and language.
Results: Overall median age was 53 years old (1 to 93); 57.4% being males. Overall HCV genotype distribution was 41.9% G1A, 28.5% G1B, 24.5% G3, 3.1% G2, 0.5% G4, and 1.5% mixed genotypes. Prevalence of G1A was 64.9% among males and 35.1 among females, and G1B, G2 and G3 were more prevalent in older ages than other genotypes. G3 was more prevalent in the far South (Rio Grande do Sul, 29.4%) than in other Brazilian States.
Among 620 samples tested for HIV co-infection, 18.4% were HIV+, with a median age of 46.5 among co-infected patients as compared to 54.0 among mono-infected individuals. 71.1% of co-infected patients were male as compared to 57.1% of mono infected individuals. G1B was less prevalent among HIV+ individuals as compared to mono-infected individuals (8.5% and 32.8% respectively). HIV co-infection was more prevalent Rio Grande do Sul State (23.4%), as compared to the next highest state, São Paulo (19.6%).
Conclusions: This is a report of the genotype HCV that is truly representative of the entire Brazil, which show a relatively high HIV overall co-infection prevalence. High prevalence of G3 in the south of Brazil poses an extra challenge related to HCV disease progression and treatment response, as well as the higher prevalence of G1A especially among males, a genotype with lower genetic barrier to resistance to protease inhibitors.

TUPEB0405

Outcomes after direct-acting antiviral therapy initiation in patients with cirrhosis

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Background: Virological responses are excellent with direct-acting antivirals (DAAs) in HIV/HCV cirrhotic patients but the longer term outcomes are unclear.
Methods: Prospective study of coinfected HIV/HCV patients with cirrhosis (N=181) who received oral direct-acting antivirals in a tertiary center in Madrid, Spain from April 2013 with overall follow-up data after DAAs initiation. Endpoints were sustained virological response, deaths, hepatocellular carcinoma (HCC), decompensation events or hospitalisations. All statistical analyses were conducted with IBM SPSS Statistics 15.0.
Results: Among 181 cirrhotic patients 82% men, GT1 (61%), peg-IFN/RBV pretreated (58%); median age 52 yo (IQR: 49-54), CD4 431 cs/mm^3 (IQR: 249-611), CHILD 6 (IQR: 5-7), MELD 9 (IQR: 7-11), there were 21% patients with prior decompensation events. Median DAAs duration was 3 months (IQR: 3-6) and median follow up from DAAs initiation was 21.3 months (IQR: 19.6-23.4). 30% (n=54) were admitted in the hospital for any reason. Twenty five (14%) had at least one admission for liver related disease (7 during therapy and 18 after DAAs) with a median time of 9.5 months (IQR: 5.1-14.7). Overall mortality was 5.5% (n=10), 3% liver-related deaths (n=6): 3 hepatocarcinoma, two with multicentric HCC „de novo" with rapid progression, 2 hydropic decompensation and 1 upper gastrointestinal bleeding. Median time to death was 2.8 months (IQR: 0-12.7). There were 5 HCC (2.8%), 2 of them in palliative care (multicentric HCC). Median time from DAAs initiation to HCC diagnosis was 8,1 months (IQR: 3,4-14,5). 154/181 (85%) patients achieved sustained virological response at 12 weeks post-treatment. On univariate analysis, the absence of SVR was associated with prior decompensations (69% vs 20% p=0,007), decompensations during follow-up (33% vs 8% p=0,001) and mortality (26% vs 2% p=0,0001).
Conclusions: Over 21 months of follow-up, 3% of liver-related deaths were found in patients with cirrhosis treated with DAAs. Four of 5 HCC were multicentric, early presentation and had poor prognosis.

TUPEB0406

Sustained virologic response (SVR) after hepatitis C virus (HCV) treatment does not lead to improved renal function in HIV/HCV coinfected patients

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Background: Direct-acting antivirals for chronic HCV infection have improved cure rates and may have extrahepatic benefits for specific comorbidities linked to HCV infection. We assessed the effect of SVR on renal function in HIV/HCV co-infected patients.
Methods: We obtained data from the Canadian Coinfection Cohort, a prospective study which has recruited co-infected patients from 19 clinical centres since 2003. All patients with SVR after either interferon or interferon-free HCV treatment were matched using a 1:2 ratio, without replacement, to individuals chronically infected with HCV on calendar time (study visit +/- 30 days of the SVR index date) and the propensity score for receiving treatment using variables shown in the Table with a nearest-neighbor algorithm. We modeled differences in the annual rate of eGFR decline from the index date between SVR and comparable chronically infected patients using repeated-measures linear generalized estimating equations.
Results: Of 1,695 recruited patients, 424 were treated for HCV, of whom 332 developed SVR (78%). Interferon-free regimens were used in 45%. Baseline characteristics between SVR and chronically infected patients are shown in the Table. Patients were followed for a total of 1,491 person-years; median, 1.4 years (IQR 0.6, 3.6). The annual rate of eGFR decline (mL/min/1.73 m^2/year) did not differ between patients with SVR and those chronically infected: -1.2 (95% confidence interval [CI]: -1.7, -0.7) and -1.0 (95% CI: -1.5, -0.4), respectively. The principal factor associated with eGFR decline was injection cocaine use (adjusted eGFR decline: -2.3, 95% CI: -3.8, -0.8 and -1.9, 95% CI: -3.1, -0.7 in cocaine users with SVR and chronically infected, respectively).

Characteristic	Sustained Virologic Response (n=332)	Chronically Infected (n=664)
Median age (IQR), years	50 (45, 55)	50 (44, 55)
Female, n(%)	64 (19%)	128 (19%)
Black , n(%)	13 (4%)	25 (4%)
Aboriginal, n(%)	25 (8%)	51 (8%)
Median CD4$^+$ count (IQR), cells/μL	520 (360, 730)	510 (340, 720)
Detectable HIV RNA (> 50 copies/mL), n(%)	38 (11%)	69 (10%)
Previous AIDS diagnosis, n(%)	82 (25%)	146 (22%)
Current or past tenofovir exposure, n(%)	227 (68%)	433 (65%)
Current or past ATZ or LPV/r exposure, n(%)	158 (48%)	303 (46%)
Recent injection cocaine use, n(%)	35 (10%)	68 (10%)
Recent other injection drug use, n(%)	16 (5%)	25 (4%)
Current or past hypertension, n(%)	50 (15%)	112 (17%)
Current or past diabetes, n(%)	36 (11%)	71 (11%)
Past end-stage liver disease, n(%)	81 (24%)	167 (25%)
Median HCV viral load (IQR) prior to index date, IU/mL	2,430,000 (359,000, 7,520,000)	2,350,000 (315,000, 7,790,000)
Median eGFR (IQR), mL/min/1.73m^2	92 (75, 104)	93 (77, 106)

[Table 1. Baseline characteristics between SVR and chronically infected patients in the matched sample]

Conclusions: In HCV/HIV co-infected patients, SVR was not associated with improved eGFR over the short term suggesting HCV replication has a minimal impact on kidney function. Other modifiable factors such as cocaine use may be responsible for eGFR decline in this population.

TUPEB0407

Alanine aminotransferase level monitoring to detection hepatitis B virus reactivation in 170 HIV/hepatitis C virus-infected patients on direct-acting agent-based therapies

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Background: Hepatitis B virus (HBV) reactivation during therapy of chronic hepatitis C by direct-acting agents (DAA) has been recently reported. Such issue could be particularly relevant among HIV-infected patients because real-life HIV cohorts[PC1] are associated with high prevalence of positivity for HBV serological markers indicating either HBsAg-positivity or past resolved infection. In addition, immunosuppression is associated with a greater risk of HBV reactivation. We aimed to analyze retrospectively liver transaminases in HIV/HCV-co-infected patients under DAA-based therapies followed-up in Marseille university hospitals.
Methods: Alanine aminotransferase levels (ALT) and HBV serological patterns analyzed were those available in the Nadis database. ALT were analyzed retrospectively at baseline (or at the most recent assessment within the 12-month period prior treatment), at weeks 4, 8, and at end (week 12 or 24) of DAA therapies administered between May-2014 and September-2016 to HIV/HCV-co-infected patients followed-up in Marseille university hospitals, southeastern France.
Results: 170 HIV/HCV-co-infected patients were treated by DAA-based therapies during the 29-month study period. 76% were male. Mean age (±standard deviation) was 51±5 years. 5% and 69% had serological markers of on-going or past resolved HBV infection, respectively. HCV treatments included sofosbuvir+daclatasvir or ledipasvir in 91% of the cases. At baseline of DAA regimens, mean ALT was 65±49 IU/L (range, 9-352). These values were 31±21 IU/L (10-143) (n=148), 29±20 IU/L (10-126) (n=150), and 28±22 IU/L (9-189) (n=157) at weeks 4, 8, and 12/24 of treatment, respectively. Maximum ALT on HCV therapy was 189 IU/L. Mean reduction of ALT between baseline and maximal on-therapy values was 35±25 IU/L. Maximal increase was 35 IU/L. ALT >2x the upper normal value (90 IU/L) were only observed in 7 patients (4%; ALT=94-189 IU/L), and were greater than at baseline (of 16-23 IU/L) in only 3 of these cases. Overall, no HBV reactivation was identified based on liver cytolysis detection.
Conclusions: HBV reactivation appears to be a rare event in HCV/HIV-positive patients on DAA-based regimen, which may be due in part to administration of anti-HBV compounds as part of their combined antiretroviral therapy. Notwithstanding, previous observations warrant for HBV assessment at baseline of DAA-based treatment initiation and in case of ALT elevation.

TUPEB0408

Hepatitis E virus serological and molecular testing in 1979 patients followed-up in 2014-2016 in HIV reference centers of University Hospitals of Marseille, southeastern France

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Background: Hepatitis E virus (HEV) is an emerging cause of autochthnous hepatitis in developed countries. These infections can become chronic in severely immunocompromised patients, including those transplanted and HIV-infected. We studied results of HEV serological and molecular testing performed for patients followed-up in HIV reference centers of university hospitals of Marseille, southeastern France.
Methods: Serum or plasma samples analyzed were collected between December 2013 and November 2016 from patients followed-up in HIV reference centers of university hospitals of Marseille, the second largest French city, southeastern France. Anti-HEV IgG and IgM testing were performed using ELISA microplate assays (Wantai). HEV RNA detection, quantification was performed using in-house real-time PCR assays targeting ORF2 and 3 regions of the HEV genome. HEV genotype was determined based on sequences of ORF2 and ORF1 genes obtained by Sanger population sequencing by in-house protocols.
Results: Over the three-year period of the study, 2299 serum or plasma samples collected from 1979 HIV-positive patients were tested for the presence of IgG and IgM anti-HEV antibodies. These samples represented 20% of all those serologically-tested for HEV infection (N=11687). 1535 IgG/IgM testing (67%) were negative. 703 serum/plasma (31%) indicated past HEV exposure (IgG-positivity/IgM-negativity). 56 serum/plasma (2.4%) from 45 patients (2.3%) were IgM-positive, suggesting possible on-going or recent HEV infection; of these 56, 9 (16%) were IgG-negative/IgM-positive. Serum/plasma from 7 patients were HEV RNA-positive, which involved 0.3% of the patients tested serologically for HEV infection. Mean(+/-standard deviation) HEV RNA load was 5.5+/-5.7 log_{10}copies/mL (range, 2.3-6.1 log10). HEV genotype was 3, which is the one involved in autochthonous HEV infections, in six cases, and could not be determined due to a low viral load (2.3 log10) in the 7th case.
Conclusions: Almost one third of patients followed-up in 2014-2016 in Marseille HIV reference centers had serological evidence of past HEV exposure, and 0.3% were HEV infected with autochthonous viruses at time of testing.

TUPEB0409

Usefulness of high-risk Human Papillomavirus (hrHPV) detection despite non-pathologic cervical cytology in women living with HIV

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Background: Women living with HIV (WLwH) are at increased risk of persistent hrHPV infection, cervical dysplasia and cervical cancer. Detection of cervical hrHPV is recommended only in case of abnormal cytology. This study aimed to describe the prevalence of abnormal cervical cytologies and hrHPV infection, and associated factors with hrHPV infection in WLwH in France.
Methods: Monocentric, observational, prospective cohort study of adults WLwH followed in an HIV reference center in Nantes. At each cervical cancer screening, WLwH were examined for cervical hrHPV (HPV16, HPV18 and others hrHPV) and cytologic abnormalities (classified as non-pathologic, atypical squamous cells (ASC) and low-grade or high-grade squamous intraepithelial lesions (L/HSIL). Socio-demographic characteristics, HIV history and immuno-virological data were prospectively collected.
Results: From September 2012 to October 2016, 323 WLwH with at least one cervical cancer screening were included in the study (median age 38 years; IQR 31-44). At first screening, 95 WLwH were found with hrHPV+ (29%). Cervical cytology was non-pathologic in 82% (hrHPV + in 21%), ASC in 6% (hrHPV + in 28%), L/HSIL in 12% (hrHPV + in 90%). WLwH hrHPV + were younger (35 vs 38 years), had a lower median CD4 nadir (190 vs 248 cells/mm^3) and current CD4 ≤350 cells/mm^3 (36% vs 11%), no antiretroviral therapy (ART) (18% vs 9%) or a shorter median duration of ART (2.5 vs 5.9 years), and a detectable HIV viral load (28% vs 10%) than WLwH with no hrHPV (all p<0.05). Among the 55 WLwH with non-pathologic cytology hrHPV+, 32 had at least a second screening: viral clearance was observed in 8/32 cases (25%) within a median time of 14.5 months, cervical cytology progressed to ASC or L/HSIL in 8 cases (25%) within a median time of 12 months and no change in 16 cases (50%) with the same hrHPV genotypes detected within a median time of 10.5 months.
Conclusions: A quarter of WLwH with non-pathologic cytology but presence of hrHPV progress to a pathologic cytology within 14 months. High risk HPV screening seems more informative than annual cervical cytology to prevent cervical dysplasia in this French cohort of WLwH.

TUPEB0410

High-risk genital HPV infection , dysplasia and cancer of the cervix in a cohort of women infected with HIV in Senegal

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Background: Screening programs to prevent development of cervical cancer in sub-Saharan African women with HIV infection are lacking. We have undertaken the study to determine the burden of HPV infection and dysplasia of the cervix in a cohort of HIV-positive women
Methods: atThis is an analysis of prevalence data from a the baseline visit of a prospective cohort study conducted from October 2005 to September 2011. Inclusion criteria included no pregnant woman aged 18 years and more, infected with HIV, who consented to participate in the study. Exclusion criteria included pregnancy and an abnormal cervical finding by cytology at baseline. Study visits visits were scheduled every four months with cervical Pap smear, HPV detection by PCR at all visits,and biopsy at the initial and final exit visit, as well as with abnormal cytologic findings.
Results: 209 women infected with HIV (HIV-1: 79% (n = 167); HIV-2: 14% (n = 29); HIV-1 and HIV-2: 7% (n = 13)) were enrolled. Median age was 41 years (range 20-66), 54% were married, and 84% reported no contraception during study follow-up. The median CD4 count was 375 cells/mm^3, 58% were on ART, and average length of follow-up was 2.45 years.
At baseline, HPV DNA was detected in 75% of HIV-1, 62% of HIV-2, and 77% of dually HIV-1 and HIV-2 infected subjects, respectively; p = 0.3), among them 118 (78%) were positive for multiple HPV types. High risk genital HPV types most commonly detected were HPV-52 (17%), HPV-58 (16%), HPV-35 (15%), HPV-16 (14%), HPV-51 (11%), HPV-18 (10%), and HPV-33 (10%).
At baseline, 30% (n = 62) had prevalent cytological abnormalities (HIV-1 (33%), HIV-2 (25%), dual HIV-1/HIV-2 (23%); p = 0.7), including 6% with ASCUS, 12% with low grade lesions, 4% with high grade lesions, 4% with carcinoma in situ (CIS), and 4% with invasive cancer (ICC).
Conclusions: In a cohort of HIV infected women in Senegal, there was a high burden of prevalent HPV infection and prevalent cervical abnormalities identified at baseline. Early detection of cervical abnormalities through cervical screening, or their prevention by HPV vaccination, is critical to prevent cervical disease among the HIV-positive women.

TUPEB0411

Prevalence of asymptomatic STI in HIV-positive MSM in Germany

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Background: Sexually transmitted infections (STI) occur frequently in high-risk populations such as HIV-positive men having sex with men (MSM). Rapid diagnosis is important for accurate treatment and reduction of onward transmission. However, the role of screening programs of asymptomatic STI carriers remains controversial as data on prevalence are conflicting to date.

Methods: We enrolled asymptomatic, sexually active, HIV-positive MSM (pts) in a prospective cross-sectional sentinel study from 23.02.2016 until 30.08.2016 at 7 German HIV care centers. All subjects (pts) were screened for Treponema pallidum infection, HIV RNA, HBV- and HCV-serology, as well as oral, rectal, and urethral colonization by Chlamydia trachomatis (CT) and/or Neisseria gonorrhea (NG), using a cartridge based nucleic acid amplification system (GeneXpert CT/NG®; Cepheid, Frankfurt,Germany). In addition, all patients completed a sexual risk questionnaire.
Results: In total, 296 pts with a median age of 43.5 (36,5-50) years were enrolled. 294 patients were on antiretroviral treatment for a median of 5.5 (2.5-11) years. HIV RNA was < 50 cps/ml in 94% of all pts. The majority of sexual contacts were unprotected (79% of oral, 61% of anal contacts and 68% of fisting). While 22% had unprotected intercourse with 1 partner, unprotected sex with 2-5, 6-10, 11-20, and >20 partners were reported by 23%, 10%, 9%, and 9% within the last 6 months, respectively. Active syphilis infection was found in 5% of all patients, while 55% had a history of syphilis infection. While only 2% had HBsAg-positive chronic Hepatitis-B infection, an unexpectedly high number of 29% had no detectable anti-HBs-antibodies in absence of anti-HBc-antibodies. 9% had active hepatitis C infection. 13% had positive CT/NG swabs (NG: 4% anal, 4% urethral and 2% pharyngeal; CT: 7% anal, 1% urethral, 2% pharyngeal). Statistically significant more STIs were found in pts with more than 1 sexual partner and a history of recreational drug abuse (14% vs. 2%, p=0.046).
Conclusions: We found a high number of asymptomatic syphilis-, HCV- and CT/NG-infections in HIV-positive MSM, especially in those reporting recreational drug use and a history of multiple sexual partners. Intensified screening and treatment strategies should be addressed especially to high-risk populations to curtail ongoing high numbers of STIs.

TUPEB0412

High prevalence and incidence of sexually transmitted infections and poor test-of-cure outcomes among HIV-infected pregnant women in Soshanguve Township, South Africa: what are the next steps?

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Background: During pregnancy, Chlamydia trachomatis (CT), Neisseria gonorrhoea (NG) and Trichomonas vaginalis (TV) may lead to intrauterine death, preterm delivery, and may facilitate mother-to-child-transmission of HIV. Treatment of those infections is sub-optimal due to the syndromic approach to diagnosis and management. We determined the prevalence of those sexually transmitted infections (STI) among HIV-infected pregnant women, test-of-cure (ToC) outcomes and identified new infections post-delivery.
Methods: Participating HIV-infected pregnant women attending their first antenatal care (ANC) visit at two clinics in Soshanguve, a historically disadvantaged township, were interviewed and asked to self-collect two vaginal swab specimens for CT, NG and TV testing. STI-infected women were treated, provided a partner treatment pack, and asked to return in three weeks for ToC. All women were re-tested for CT, NG and TV at their first post-delivery visit. STI tests were performed by nurses in the clinic using Xpert® CT/NG and Xpert® TV assays [Cepheid, Sunnyvale, California].
Results: To date 214 women were tested for CT, NG and TV at first ANC, of which 106 (49%) had at least one infection (CT=39%, TV=25%, NG=7%). Of those, 57% were asymptomatic infections. Of those with ToC, 36/83 (43%) had a positive result (CT=39%, TV=26%, NG=0%). Overall, 67% of women reported sexual activity following treatment for their infection. ToC+ was associated with >1 partner at enrollment (+ToC=29% vs -ToC=7%; p=0.007) and less condom use at last sex (+ToC=17% vs -ToC=30%; p< 0.05). ToC+ women reported that 59% of partners accepted a take-home pill packet provided by study staff, 38% did not seek care and 3% sought care after disclosure. Currently, 48 of 214 enrolled women have returned for post-delivery services, of whom 35% (n=17) had at least one STI infection (new and re-infections; CT=31%, TV=6%, NG=6%).
Conclusions: HIV-infected pregnant women attending ANC in our study clinics have a high burden and infection rate of curable STIs. Given the high rate of asymptomatic infections, routine STI testing with ToC must be considered. Poor ToC outcomes may be associated with poor uptake of treatment by sex partners. Optimal impact of STI screening and treatment during pregnancy might require interventions to increase treatment uptake by partners.

TUPEB0413

Behavioral risk factors among HIV-infected pregnant women with a sexually transmitted infection in South Africa

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Background: Sexually transmitted infections (STI) may increase the risk of vertical and horizontal HIV transmission. However, more knowledge is needed about risk factors associated with STIs among HIV-infected pregnant women to develop targeted diagnostic, treatment and STI and HIV transmission prevention interventions.
Methods: We conducted a study of HIV-infected pregnant women in antenatal care at two primary care facilities in Pretoria, South Africa to evaluate prevalence and risk factors for STIs. Participants were interviewed and self-collected vulvovaginal swabs which were tested for Chlamydia trachomatis (CT), Neisseria gonorrhoea (NG) and Trichomonas vaginalis (TV), Xpert® (Cepheid, Sunnyvale, USA). We report descriptive and multivariate logistic regression results of risk factors associated with any STI.
Results: To date we enrolled 214 HIV-infected pregnant women (median age=29y; median gestational age=20-weeks). Prevalence of any STI was 50%. Overall, 90% of pregnant women reported having sex during pregnancy (of whom 9% reported oral sex and 4% anal sex). Most (62%) had sex 7-days prior to study enrollment. Over 70% of women were not virally suppressed (>200 copies/mL). At last sex 75% reported condomless sex and 15% reported having >1 sex partner in the past 12 months. Of women 14% reported any alcohol use during pregnancy of whom 25% reported ≥5 drinks on a typical day. Twenty-two percent reported being in a serodiscordant relationship with father of the child; 27% seroconcordant relationship; and 51% didn't know their partner's serostatus. Odds of having any STI decreased as age increased (OR/year=0.93; 95%CI=0.88-0.98). Odds of having any STI increased with increased gestational age at time of testing (aOR=1.07; 95% CI=1.02-1.12) and recent sex (past 30 days vs. longer) (aOR=1.42; 95% CI=1.04-1.93). Trends toward increased odds of any STI included: >1 recent sex partner (aOR=2.36; 95% CI=0.96-5.84; p=0.06) and reporting ≥5 drinks on more than one occasion (aOR=3.61; 95% CI=0.77-35.7; p=0.09), adjusted for age.
Conclusions: Preliminary results demonstrate risk behaviors for HIV vertical and horizontal transmission including: high prevalence of STIs, frequent condomless sex, anal sex, heavy alcohol use and multiple sex partners. Interventions to diagnose, treat and prevent STIs and further HIV transmission among HIV-infected pregnant women are urgently needed.

Cancer

TUPEB0414

Cancer mortality among HIV-positive adults in British Columbia, Canada: a retrospective analysis

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Background: Since the advent of modern combination antiretroviral therapy (cART), life expectancy for people living with HIV/AIDS (PLWH) has significantly improved, making way for a rise in comorbid conditions, including cancer. There is little known about how PLWH may be differentially impacted by cancer-related mortality in the modern cART era.
Methods: The Comparison of Outcomes and Service Utilization Trends (COAST) study is a population-based retrospective study that is inclusive of all PLWH in the province of BC, including those on and off cART, between April 1996 and March 2013. It utilizes demographic and clinical data from the BC Centre for Excellence in HIV/AIDS provincial Drug Treatment Program and administrative health data from Population Data BC.
We calculated crude and direct age-adjusted mortality rates for all-type cancers, by AIDS-defining malignancies (ADM) and Non-AIDS defining malignancies (NADM), and system-specific cancers among our sample of PLWH and a general

population sample using the age distribution for the 2011 Canadian standard population to adjust.
Results: Between 1996 and 2013, there were 1121 PLWH in BC diagnosed with cancer, of which, 155 (13.8%) were women, 384 (34.3%) had a Hepatitis C diagnosis, and the median age at cancer diagnosis was 47 years. Of the 1121 PLWH with a cancer diagnosis, 555 (49.5%) died during the follow-up period, inclusive of 11 (2.0%) deaths attributed to ADM and 222 (40.0%) attributed to NADM. The age-adjusted cancer-related mortality rate for PLWH was 63.1 (95% CI: 51.6, 74.6) per 1000 PY compared to 48.3 (95%CI: 46.7, 49.8) per 1000 PY in the general population sample. Mortality rates were higher among PLWH with NADM diagnosis (Rate Ratio: 1.3 (95% CI: 1.0, 1.5)), as well as for those with a lymphatic system cancer diagnosis (Rate Radio: 13.2, 95% CI: 8.4, 17.9), compared to the general population.
Conclusions: Age-adjusted cancer-related mortality rates are elevated among PLWH compared to the general population. It is important to consider confounding factors such as smoking status that could not be accounted for in this analysis. These findings suggest that the majority of cancer-related deaths are attributed to NADM in the modern cART era, highlighting future priorities for HIV-care.

TUPEB0415

Impact of cART and chemotherapy on lung function of HIV-infected individuals with pulmonary Kaposi sarcoma in Harare, Zimbabwe

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Background: Pulmonary Kaposi sarcoma (pKS) in HIV positive patients is associated with impaired lung function and high mortality. While the combination of chemotherapy and combined antiretroviral therapy (cART) for pKS substantially improves survival, there is no evidence that there is concomitant improvement in lung function in HIV positive patients with pKS in response to cART and chemotherapy.
Methods: This was an observational longitudinal study of HIV positive patients with a diagnosis of pKS at Parirenyatwa hospital in Harare Zimbabwe. Chemotherapy naïve patients were enrolled after bronchoscopy confirmed pKS, which was classified as extensive (affected ≥2 lobes) or localised (affected only 1 lobe) and excluded if they had active tuberculosis. Spirometry, pulse oximetry (SpO_2), six minute walk test (SMWT) and Karnofsky performance status score were performed on patients every 3 weeks for 9 weeks. Chemotherapy was given according to the local standard of care. Chest X-rays were performed at baseline and at 9 weeks. Statistical analysis was performed using chi-square test, t-test and analysis of variance (ANOVA).
Results: Forty patients (mean age 37 years, 85% male) with a diagnosis of pKS on bronchoscopy were enrolled. 57% had extensive disease; baseline lung function tests (mean ± standard deviation): FVC 61.7±18.0, FEV_1% 59.9±18.5, SpO_2%91.3±3.7, SMWT 294.5±158.5. Treatment of pKS was associated with a statistically significant improvement in resting SpO_2 from baseline to 9 weeks (93%versus 96%; p=0.005), SMWT (347 m versus 449 m; p= 0.038) and Karnofsky score (70 versus 80; p= 0.013) but not FVC (73.3±25.0 versus 78.5±18.1; p=0.737) or FEV_1 (70.4±23.7 versus 79.0±15.9; p= 0.303). 71.4% of patients had significant radiological improvement. Mortality was 22.5% over 9 weeks of follow-up.
Conclusions: Extensive pKS is associated with impaired lung function. Current therapy for pKS is associated with significant improvement in the resting SpO_2, SMWT, radiological changes and Karnofsky score but no significant short term improvement in spirometry measures (FVC and FEV_1) was detected.

TUPEB0416

Real-world use of chemotherapy for Kaposi's sarcoma in a large community-based HIV health care network in Kenya

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Background: Kaposi's sarcoma (KS) is one of the commonest HIV-associated malignancies in sub-Saharan Africa. In the current era, KS survival has improved largely due to antiretroviral therapy (ART). In resource-rich settings, survival has also benefited from chemotherapy. Little is known, however, about the epidemiology of chemotherapy for KS in resource-limited regions. We sought to determine the prevalence of indications for chemotherapy amongst patients with new HIV-associated KS, penetration of chemotherapy, and regimens used in a large community-based health care network in East Africa.
Methods: We identified all patients newly diagnosed with HIV-related KS from 2009-2012 in the 26-clinic AMPATH network in Kenya, a member of East Africa IeDEA. Through chart review, we ascertained disease severity at diagnosis and KS-specific treatment. Indications for chemotherapy were considered AIDS Clinical Trial Group (ACTG) T1 stage and/or "severe" disease defined by WHO KS treatment guidelines.
Results: Of 674 patients diagnosed with KS, charts were available for 599 (89%); 61% were men, median age was 35 years, and median CD4 at KS diagnosis was 184 cells/μl. At diagnosis, of 476 patients with evaluable ACTG T stage, 72% were T1 stage. Of 354 patients with evaluable WHO KS treatment guideline staging, at least 27% had documented "severe" disease. Among all patients, 49% received chemotherapy of any kind within 2 years of KS diagnosis. Of those receiving chemotherapy, median time to first chemotherapy was 28 days (IQR 4-57 days). Restricting to patients with a chemotherapy indication, for T1 disease, 57% received chemotherapy; for patients with WHO "severe" disease, 59% received chemotherapy. Initial regimens were bleomycin-vincristine (78%), adriamycin-bleomycin-vincristine (10%), etoposide (7%), gemcitabine (3%), and vincristine (1%).
Conclusions: A substantial fraction of patients with KS in East Africa are diagnosed at advanced disease stage. For patients with apparent chemotherapy indications, nearly half did not receive chemotherapy; prospective work is needed to understand why (e.g., poor access, inability to tolerate, sufficient response to ART alone, or patient preference). Liposomal anthracyclines, which are often first-line in resource-rich settings, are very expensive in this setting, and were not used as first line. These findings highlight challenges in East Africa in cancer care.

TUPEB0417

Epstein-Barr viral load predicts prognosis of AIDS-related Non-Hodgkin Lymphoma

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Background: Non-Hodgkin lymphoma (NHL) is still one of the important comorbidities among HIV-infected individuals and Epstein-Barr virus (EBV) reactivation is thought to be a risk factor for developing NHL. However, the role of EBV-DNA load in peripheral blood has yet to be established in the management of AIDS-related NHL. We aimed to evaluate the prognostic value of plasma EBV-DNA loads in AIDS-related NHL.
Methods: Data was retrospectively reviewed on HIV-infected individuals diagnosed as systemic NHL who received chemotherapy at National Center for Global Medicine in Tokyo, Japan since 2000 through 2015. Overall survival was defined as time from NHL diagnosis to death from any cause.
Results: Sixty-one AIDS-related NHLs were involved to the analysis, including 25 diffuse large B cell lymphomas (DLBCL), 21 Burkitt lymphomas (BL), 7 plasmablastic lymphomas and 8 primary effusion lymphomas. All were male and their median age was 42 years old (range 25-75). Thirty-five (57%) had detectable plasma EBV-DNA load (>198 IU/ml) at baseline. The proportion of patients in the international prognostic index (IPI) category of either low and low-intermediate or high-intermediate and high was not different by plasma ENV-DNA detection (31% vs 27%, p=0.97) and CD4 count at NHL diagnosis was higher in the detectable EBV-DNA group but not statistically significant (90 cells/μl vs. 186 cells/μl, p=0.06) During median 1.03 years of follow up (range 0.02-12.7), 33 patients died after median 0.54 years (range 0.02-11.8) and progression of NHL was attributable for 85% (28/33) of the deaths. Overall survival rate at 2 years were 48% in total [95% confidential interval (CI) 34-60], 36% (95% CI 21-58) in the detectable EBV-DNA group and 64% (95% CI 49-79) in the undetectable EBV-DNA group (p=0.04). Cox proportional hazard models revealed EBV-DNA detection was significantly predictive in mortality after adjustment for IPI category and baseline CD4 counts, which presented hazard ratios of 2.83 (95% CI 1.16-6.89), 2.59 (95% CI 1.05-6.38), and 3.15 (95% CI 1.28-7.77) with EBV-DNA load cut-off values of 198, 496, and 991 IU/ml respectively.
Conclusions: Our findings demonstrate the detection of plasma EBV-DNA is an independent indicator of poor prognosis of AIDS-related NHL.

TUPEB0418

Human herpes virus 8 (HHV8) in HIV-1-infected individuals receiving cancer chemotherapy and stem cell transplantation

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Background: Little is known about the association between cancer chemotherapy or hematopoietic stem cell transplantation (HSCT), circulating HHV8 DNA levels, and clinical Kaposi Sarcoma (KS) in HIV-1-infected individuals with various malignancies. However, some targeted therapies (e.g. rituximab) are known to trigger HHV8 reactivation and the development of KS. Therefore, we examined the associations between chemotherapy, T-cell phenotypes, and circulating HHV8 DNA in 29 HIV-1-infected participants with KS or other malignancies.
Methods: We quantified HHV8 plasma and cell-associated DNA and determined the relationship between HHV8 DNA, T-cell counts, and markers of early and late T-cell activation, proliferation and exhaustion (CD69, CD38, HLA-DR, Ki67 and CD57, respectively) inHIV-1 infected individuals with KS (N=6), non-Hodgkin lymphoma (N=15), Hodgkin lymphoma (N=6), and other tumors (N=2).
Results: Twelve (41%) participants, including all individuals with clinical KS, had detectable anti-HHV8 antibodies; 83% of these participants with KS and 17% of participants with other malignancies had detectable circulating HHV8 DNA. Four additional participants were HHV8 DNA+ but antibody negative. Twenty three participants were on ART throughout the study, and no significant correlations were observed between circulating HHV8 DNA and plasma HIV-1 RNA.
Overall, there were no significant differences between baseline and post-chemotherapy HHV8 DNA levels, but two participants experienced increased circulating HHV8 DNA following treatment for KS or allogeneic stem cell transplantation for lymphoma. We also observed an approximately 2-$\log^{10}$ reduction in plasma HHV8 DNA in an individual with KS and multicentric Castleman disease following rituximab monotherapy.
Although, individuals with clinical KS had lower mean $CD4^+$ lymphocyte counts and percentages, there were no significant associations between $CD4^+$ T-cell counts and plasma HHV8 levels.
However, increased frequencies of $CD8^+$ and $CD4^+$ T-cells expressing CD69 and $CD4^+$ T-cells expressing CD57 were observed in participants with detectable HHV8 (P=0.01, P=0.04, and P=0.003, respectively).
Conclusions: Cancer chemotherapy and HSCT exhibit variable effects on HHV-8 reactivation. While CD4+ T-cell counts were not associated with circulating HHV-8, plasma HHV8 is positively correlated with early markers of T-cell activation and exhaustion. Overall, these results suggest that there is a complex relationship between circulating HHV8 DNA and tissue-based disease in HIV-1-infected individuals with malignancy.

TUPEB0419

AIDS related Kaposi Sarcoma in a cohort in Rio de Janeiro, Brazil: KSHV viral dynamics, immune response and clinical outcome

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Background: HIV-associated Kaposi Sarcoma (AIDS-KS) remains an important cause of morbidity and mortality in Brazil. It remains crucial to understand Kaposi Sarcoma herpes virus (KSHV) infection viral dynamics and immune response in our setting to develop serological and virological assays for monitoring clinical treatment response and as prognostic markers. We conducted a prospective study of individuals with AIDS-KS at INI/FIOCRUZ, a major referral center for HIV care in Rio de Janeiro, Brazil. We measured KSHV immune response and plasma KSHV DNA in individuals with AIDS- KS initiating treatment and assessed relationships to clinical outcomes.
Methods: We enrolled all patients diagnosed with HIV-KS at INI/FIOCRUZ. Blood samples collected at enrolment and the last visit during follow up, were used in the analysis. Plasma KSHV DNA was determined using real-time PCR; immune response to KSHV latent (ORF73) and lytic (K8.1) antigens were evaluated using ELISA; immune response to a panel of KSHV antigens was assessed by multiplex assay. Logistic regression was used to determine risk factors for death.
Results: From 2011-2013, 50 patients were enrolled; 2 were lost to follow-up and excluded from analysis. One patient also fulfilled criteria for KICS and another for MCD. Mean age at KS diagnosis was 32.7 (SD9.2) years. 47.9% were white, 10.4% were female. Plasma KSHV DNA was detected in 77.8% and seroreactivity to ORF73 and K8.1 were 75% and 90.9% respectively. 8 (16.7%) died, and 6 (75%) deaths were KS related. Women had significantly higher odds of dying (OR=11.4; 95%CI=1.516-85.72; p=0.018). Plasma KSHV DNA and seroreactivity to K8.1 and ORF73 were not associated with clinical outcome. Seroreactivity to ORF19 and ORF59 significantly correlated with death (OR=14.4; 95%CI=1.095-189; p=0.026 and OR=7.778; 95%CI=1.281-47.2; p=0.034, respectively), as well as the number of antigens for which the patient was seroreactive at the time of diagnosis, (OR=1.279; 95%CI=1.018-1.605; p=0.034).
Conclusions: Our study does not support the routine use of plasma KSHV DNA nor ELISA for ORF73 or K8.1 as monitoring or prognostic markers, but we know our study has a small number of patients. Further studies are necessary to better understand the role of the multiplex assay in clinical practice.

TUPEB0420

HIV-associated Kaposi sarcoma in the post-HAART era

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Background: After the introduction of High-Activity AntiRetroviral Therapy (HAART), incidence of AIDS-related events decreased significantly. Despite this fact, HIV-associated Kaposi Sarcoma (HIV-KS) remains as the most frequent neoplasm in this group.
Methods: An descriptive, retrospective, unicentric study of patients with HIV-KS diagnosis in a tertiary hospital in Madrid was performed from January 2001 to December 2016. Epidemiological, clinical and therapeutical characteristics, as well as evolution criteria, were analysed with SPPS 20.0.
Results: 124 patients with HIV-KS were studied, being most of them (98%) men who have sex with men (MSM), with a mean age of 39 years (21-70). 75% were caucasic (64% Spanish) and 22% Latin-American. 37% smoked or had smoked before, and 9% had hepatotropic viruses coinfection. In 82% (90 patients) KS was the reason to start HAART, being HIV diagnosis simultaneous in 58% (52p). Mean CD4 lymphocyte count at diagnosis was 294 ± 255 c/μ, being 43% < 200, and in 75% a CD4/CD8 ratio ≤ 0,4. In 5 patients, KS appeared in the context of an immune reconstitution syndrome (IRS) and in 15 patients (14%) it was diagnosed after virological control (mean 2,3 years after HAART; mean CD4 339± 140 cel/μ; 66% CD4/CD8 ≤ 0,4). In 88% HHV-8 was detected in the hystopathological exam. 66% had a cutaneous form exclusively, while 12,5% it was mucocutaneous, 9% in lymph nodes and 11% had visceral affection. 27% associated an oportunistic infection. Treatment depending on the type of affection was started, being 60% the HAART, while 32% required adjuvant chemotherapy with 11% of toxicity; two patients required radiotherapy and 5% surgery.
20% ha one or several relapses, requiring a second-line treatment. 5 patients died during treatment, 6 had Castleman disease, and two developed cavity lymphoma.
Conclusions: HIV-KS is a prevalent disease in MSM, with a high morbi-mortality in spite of HAART implementation. HIV control does not avoid its development nor its control in some cases. Abscense of immune recovery and immunoactivation persistence could be related factors.

Paediatrics

TUPEB0421

Piloting very early infant diagnosis (VEID) of HIV in Lesotho: acceptability and feasibility among mothers, health workers and laboratory personnel

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Background: Mortality associated with in-utero HIV infection rises rapidly within weeks after birth. Current guidelines recommend HIV testing at age six weeks, but very early infant diagnosis (VEID) - testing at birth-two weeks - followed by immediate initiation of antiretroviral therapy (ART) has potential to avert mortality associated with in-utero transmission. However, our understanding of acceptability and feasibility of VEID among mothers, health workers (HW) and laboratory staff is limited.
Methods: VEID was piloted in an observational prospective cohort of HIV-positive pregnant women and their infants in 13 Lesotho health facilities from July 2014 to October 2016. Semi-structured interviews were conducted March-July 2016 with 20 HIV-positive women attending 6-week or 14-week postnatal visits in eight study facilities in three districts. Counselors/study nurses (n=18) and district/central laboratory staff (n=9) involved in VEID were also interviewed. Interview themes included acceptability of birth and subsequent HIV testing and early treatment, perceived VEID challenges and HIV birth testing procedures and how well they were performed. Thematic analysis was conducted using MAXqda (V10).
Results: Nearly all mothers interviewed were happy to know their child's HIV status at birth. Mothers and HW did not indicate that birth testing affected subsequent acceptance of infant HIV testing or clinic attendance. No respondents expressed a challenge with early ART initiation (though only the perspective of HW was captured, as all mothers interviewed had HIV-negative children). Some women expressed concern about obtaining blood from newborns and stated they received limited counseling about HIV testing. HW and laboratory staff reported weak follow-up systems for mothers with home delivery, and concern regarding limited number of diagnostic machines, reagent stock-outs and increased workload associated with additional testing requirements. All groups reported turnaround time delays for all EID, and that sometimes results were never received, which would be exacerbated by adding a test to the algorithm.
Conclusions: While respondents found VEID acceptable and feasible, the study also highlighted challenges within the existing EID system that must be addressed for birth testing to be effective. These include strategies to strengthen counseling on infant HIV testing, improve turnaround time, increase the number of facility-based deliveries and improve client tracing procedures.

TUPEB0422

Evaluation of a pilot chain peer referral approach for HIV testing among adolescents in Kisumu County, Kenya

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Background: In Kenya, it is estimated that 18,000 adolescents become infected with HIV annually. Yet they are among the least likely to access HIV testing. We sought to evaluate the feasibility of a chain peer referral approach to mobilize adolescents for HIV counseling and testing.
Methods: Index participants (IPs) were identified among adolescents ages 15 to 19 years seeking any health services from September through December 2016 (intervention period) at Rabuor Sub-County Hospital in Kisumu County, Kenya. IPs were offered testing and those willing to recruit age-group peers for HIV testing received 3 to 5 referral coupons, with a cash incentive of 100 Kenyan shillings (approximately US$1) for each referral tested.
Data were analyzed using Chi-square, Fisher's exact and Wilcoxon Rank-Sum tests. We compared the monthly rates of adolescent testing and HIV-positivity per number tested (yield) between the intervention and baseline (January-August 2016) periods.
Results: Of the 1,076 coupons issued to 293 IPs, 242 (22.5%) referrals were tested, which accounted for 28.5% of the total 850 adolescents tested at Rabuor during the intervention period. 113 (38.6%) IPs recruited one or more referrals for testing, with a mean of 0.8 [standard deviation 1.26] referrals per IP. Tested referrals were predominately male (63.5%) and friends (66.4%) or classmates (14%) of the IP. No referrals tested HIV-positive. IPs with ≥1 tested referrals were more likely to be older, male, single, in school, seeking HIV testing services, without children, and themselves referred by a peer for testing (all p<0.05). Overall, adolescent testing rates did not differ significantly during the intervention [median 182 per month; IQR 147-278] compared to before the intervention [median 154 per month; IQR 117-179; p=0.31). Yield was consistently low during and before the intervention (0.7% vs. 1.5%, respectively, p=0.11).
Conclusions: The chain peer referral approach to increase HIV testing among adolescents did not lead to an increased number of positive HIV test results. Males, adolescents in school, and those seeking testing were more likely to refer others successfully for HIV testing. This approach requires further evaluation, with efforts to specifically target girls and those with undiagnosed HIV infection.

TUPEB0423

Shifting dynamics of HIV transmission timing among infants in the era of option B+ and implications for infant testing

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Background: Universal antiretroviral treatment(ART) for HIV-positive pregnant women is anticipated to significantly reduce mother-to-child HIV transmission (MTCT). The World Health Organization recommends infant HIV testing at 4-6 weeks to capture in-utero/intrapartum/early breastfeeding transmission. In-utero infection is associated with high mortality of 20-30% by age 8-12 weeks. We conducted an implementation research study to determine the relative yield of HIV birth testing.
Methods: HIV-positive and negative pregnant women were enrolled in an observational cohort to evaluate effectiveness of universal maternal ART within 13 health facilities in Lesotho following introduction of Option B+. HIV birth testing (DNA PCR within two weeks of birth) was introduced at study sites in addition to routine six-week infant testing, per national guidelines. Dried blood spots were collected at birth for PCR testing (Roche CAP/CTM HIV v2) followed by routine six-week testing. Data were analyzed to identify HIV transmission rates at birth and six weeks.
Results: Among 602 women (median age, 29 years; median gestational age at first ANC visit, 24 weeks), 427/602 (70%) of their infants were tested at birth, 497/602 (83%) were tested at 6 weeks, and 363/422 (86%) of infants uninfected at birth were retested at 6 weeks. In utero HIV infection with positive birth PCR occurred in 5/427 (1.2%) infants. An additional 2 infants, one with a prior negative birth test and a second without a prior birth test tested positive at 6 weeks, for a cumulative MTCT incidence of 1.25% (95%CI: 0.5%-2.6%). The 6-week MTCT rate was 1/211 (0.5%) among women who initiated ART before pregnancy compared to 6/331 (1.8%) among women who started ART during pregnancy. Maternal HIV RNA levels were associated with transmission: median HIV RNA was 1.27 log10 copies/mL among non-transmitting women versus 5.03 log10 copies/mL among transmitting women.
Conclusions: Universal antenatal maternal ART resulted in very low 6-week MTCT (<1.5%); MTCT rates were lowest with pre-pregnancy ART initiation. Among infants, in contrast to pre-ART era, where ~30% of infections occurred in utero, most infections (5/7, 71%) were identified at birth, suggesting that introduction of birth testing, if accompanied by rapid infant ART initiation, could significantly impact the health of infected infants.

TUPEB0424

Rapid diagnostic tests ineffectively identify infants in need of definitive PCR testing

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Background: HIV programs operationalize WHO recommendations for the use of Rapid Diagnostic Tests in infants by offering testing as a screening tool at sick-care visits or for wider screening of healthy infants, as well as within PMTCT programs for known HIV-exposed infants returning at 9 months of age. In all cases, the result of the RDT is used as a screening test to reflex to definitive PCR testing, but has not been formally evaluated for effectiveness in HIV diagnosis.
Methods: A cross-sectional prospective study of children younger than two years presenting at primary health facility entry points was conducted at four Ugandan hospitals. Infants were systematically sampled from five entry points at each facility: Immunization/EPI/well-child, pediatric outpatient, pediatric inpatient, nutrition ward, and outreach. All participants, regardless of HIV exposure status, received an RDT to determine exposure status and a PCR test to determine infection status. The samples were collected in parallel and PCR samples were run irrespective of the RDT outcome.
Results: The sensitivity of the RDT to accurately identify HIV-positive children in need of PCR testing was 61.7% (95% confidence interval: 51.1 - 71.5), while the specificity was 97.3% (95% CI: 96.6 - 97.8). The positive predictive value in this population was 42.3% (95% CI: 34.0 - 51.1), while the negative predictive value was 98.7% (95% CI: 98.3 - 99.1). We also examined performance of the RDT in different age groups in four-month intervals and found that for each age category under one year, the estimated sensitivity was less than 50%, including 8 - 12 months of age (47%). The median age of HIV-positive infants with a negative RDT was 8.5 months, while the median age of HIV-positive infants with a positive RDT was 14 months. Additionally, approximately 40% of HIV-positive infants identified were negative by RDT.
Conclusions: These data suggest that the use of RDTs to screen HIV-exposed infants or those in need of a definitive PCR test could result in a large proportion of vulnerable HIV-positive infants being sent home without receiving care and treatment. In order to improve identification and linkage of HIV-positive infants, PCR testing could instead be considered.

TUPEB0425

Status of early infant diagnosis and bottlenecks to paediatric ART services in heavy HIV burden districts in Malawi

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Background: Paediatric ART in Malawi is sub-optimal with coverage in 2016 of only 65%. A major problem is delayed HIV testing (HT) of infants and loss to follow up (LTFU). Interventions to improve paediatric ART initiation, coverage and retention include early infant diagnosis (EID), training and client follow-up models. Current management information systems aggregate service delivery data for 0-14 year olds. An assessment of the current status of HIV testing, ART initiation and retention among children aged 0-9 years was conducted to identify gaps that are critical to early diagnosis and enrolment in care and treatment.
Methods: Stratified random sampling was used to select 61 out of 276 health facilities in 8 high HIV burden districts. The sample included peripheral, district and tertiary level health facilities. Age-disaggregated data on EID and ART were abstracted from HIV service delivery registers and data analysis conducted using Excel.
Results: Of 11,401 children aged 0-9 years tested for HIV during July-September 2016, 10% were aged 0-11 months. Four percent of infants 0-2 months and fourteen percent of infants 3-11 months tested positive. Sixty-five percent of children aged 0-11 months who tested HIV-positive were started on ART. ART retention was lowest in the age group 0-11 months, at 76% and 74% at 3 and 6 months, respectively.
Conclusions: Reporting HTC and ART data for children aged 0-14 years masks inadequate HIV testing and ART retention in children 0-11 months. The increase in HIV positivity yield in infants 3-11 months suggests the need to aggressively promote HIV prevention among HIV negative mothers to prevent sero-conversion of mothers and infants during the breastfeeding period. Disaggregating paediatric data is critical to delivering appropriate HIV services to mothers and their children.

TUPEB0426

Intensified vertical HIV-1 transmission prevention influences the rate and eventual outcome of indeterminate HIV-1 PCR results

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Background: Indeterminate HIV-1 PCR results obtained from testing HIV-exposed infants may represent very early HIV-1 infections, established infections with viral suppression by antiretroviral drugs, or non-specific amplification. Indeterminate PCR results are defined by laboratory criteria currently used across all public health laboratories in South Africa. We investigated rates of indeterminate PCR results and outcomes of subsequently obtained samples from the Western Cape province of South Africa, and hypothesised that the predictive value of an indeterminate PCR for a subsequent positive result has increased in the setting of intensified vertical HIV transmission prevention regimens.
Methods: Routine diagnostic PCR data of a public health laboratory from June 2009 to October 2014 was analysed and categorised by South African vertical HIV transmission prevention regimen. All included PCRs were performed with the Roche CAP/CTM HIV-1 Qualitative Version 1 test. First indeterminate HIV-1 PCRs in patients younger than 12 months were linked with follow-up HIV-1 PCRs (any age) and serological tests (when >18 months of age). Linked results sets were analysed for CAP/CTM amplification characteristics and subsequent sample outcome.
Results: The dataset comprised 38,043 infants tested at a median age of 45 days of life. Over intensified vertical transmission prevention regimens, the rate of indeterminate and positive PCRs decreased significantly (5.6% to 3.2%, 2.4% to 0.4%, respectively; both p<0.001). Most notably, significantly more patients with indeterminate PCRs had positive PCRs on subsequent samples during WHO Option B+ use compared to previously used vertical transmission prevention regimens (64.1% vs 14.7%, p<0.001) at a median 28 of days later.

VTP regimen	Numbers (%)			Indeterminate PCRs as % of non-negative results	% indeterminate PCRs positive on follow-up
	Negative	Positive	Indeterminate		
ART initiated at CD4<200 cells/mm3	5936 (92.0)	359 (5.6)	152 (2.4)	29.8%	7.4%
WHO Option A	19927 (95.5)	687 (3.3)	257 (1.2)	27.2%	18.9%
WHO Option B+	10343 (96.4)	338 (3.2)	44 (0.4)	11.5%	64.1%

[Frequency and outcome of indeterminate PCRs]

Conclusions: Indeterminate HIV PCRs, although decreasing in frequency with Option B+ use, should be regarded with a high index of suspicion for being representative of true HIV-1 infections. Intensified vertical HIV transmission prevention regimens as well as diagnostic assay software improvements may account for this finding. Infants with indeterminate PCR results should receive close follow up and additional virological tests to arrive at a definitive diagnosis.

TUPEB0427

Adolescents enrolling in HIV care in East Africa from 2000-2014

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Background: The objective of this study is to understand the characteristics and outcomes, over time, of adolescents enrolling in HIV care in Kenya, Tanzania, and Uganda.
Methods: This retrospective cohort study utilizes patient-level data from six HIV care programs affiliated with the East African International epidemiologic Databases to Evaluate AIDS (EA-IeDEA) Consortium. The study population con-

sists of all individuals enrolling in HIV care at study facilities during adolescence (10-19 years) between 2000 and 2014. Adolescents were stratified into two groups based on age at time of enrollment: younger adolescents (YA [10-14 years]) and older adolescents (OA [15-19 years]). Descriptive analyses were used to compare groups at enrollment and antiretroviral therapy (ART) initiation across four time periods 2000-2004, 2005-2009, 2010-2012, and 2013-2014. The proportion of enrolling adolescents was compared to the total number of individuals ≥10 years enrolling during each period. Competing risk analysis was used to estimate 12-month retention, defined as the inverse of death/loss to follow-up (LTFU), after enrollment/pre-ART initiation; standard survival analysis was used to estimate 12-month retention after ART initiation.

Results: A total of 6,342 adolescents enrolled between 2000-2014, 56.4% were OA, and 54.3% of YA and 77.1% of OA were female (Table). Median CD4 at enrollment in 2000-2004 compared to 2012-2014 increased for YA (208 vs. 359 cells/mm^3, p<0.0001) and OA (155 vs. 431 cells/mm^3, p=0.0002). The proportions of YA and OA enrolling with WHO stage 1-2 disease, compared to stage 3-4 disease, increased over time (p<0.0001). Retention rates were: 89% (95% CI 88-90%) for YA and 78% (95% CI 77-80%) for OA at 12 months after enrollment; 83% (95% CI 81-84%) for YA and 72% (95% CI 70-74%) for OA at 12 months after ART initiation.

Period of Enrollment	2000-2004		2005-2009		2010-2012		2012-2014		
	Younger adolescent n (%)	Older adolescent n (%)	Younger adolescent n (%)	Older adolescent n (%)	Younger adolescent n (%)	Older adolescent n (%)	Younger adolescent n (%)	Older adolescent n (%)	P values For comparison across periods
Proportion of adolescents enrolled among all individuals ≥10 years of age enrolled	135 (1.4)	100 (1.1)	1451 (1.3)	1456 (1.3)	904 (1.4)	1224 (2.0)	274 (1.0)	798 (2.9)	YA< 0.0001 OA< 0.0001
Female sex	63 (46.7)	67 (67.0)	781 (53.8)	1086 (74.6)	503 (55.6)	949 (77.5)	155 (56.6)	656 (82.2)	YA< 0.0001 OA< 0.0001
WHO stage 1-2 at enrollment	41 (50.0)	33 (62.3)	636 (53.2)	717 (62.9)	420 (64.6)	717 (77.7)	35 (76.1)	571 (85.5)	YA< 0.0001 OA< 0.0001
WHO stage 3-4 at enrollment	41 (50.0)	20 (37.7)	559 (46.8)	407 (37.1)	230 (35.4)	206 (22.3)	11 (23.9)	97 (14.5)	YA< 0.0001 OA< 0.0001
WHO stage 1-2 at ART initiation	7 (8.6)	13 (20.0)	138 (13.7)	261 (36.3)	185 (23.0)	423 (51.8)	85 (28.0)	524 (72.7)	YA< 0.0001 OA< 0.0001
WHO stage 3-4 at ART initiation	15 (18.5)	14 (21.5)	196 (19.4)	314 (43.7)	132 (16.4)	206 (16.8)	43 (14.1)	97 (12.2)	YA< 0.0001 OA< 0.0001
CD4 at enrollment, median	208	155	268	304	313	379	359	431	YA< 0.0001 OA= 0.0002
CD4 at ART initiation, median	81	60	164	128	234	209	260	323	YA< 0.0001 OA< 0.0001

[Adolescent characteristics from 2000 to 2014]

Conclusions: Program retention is suboptimal for adolescents, particularly OA, in East Africa. Strategies to understand LTFU and promote retention are needed.

TUPEB0428

Progress towards 90-90-90 for children in Kenya: results from the Accelerating Children's HIV Treatment (ACT) initiative

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Background: The ACT Initiative aimed to double the number of children on ART. We describe outcomes within the ICAP Columbia University program at 442 health facilities in five counties in Kenya.
Methods: Trained lay counselors were deployed to provide HIV testing at multiple facility entry points, linkage officers facilitated enrollment from testing to HIV care, and clinicians were trained on prompt ART initiation, and adherence support. Peer counselors were trained to provide SMS reminders for clinic appointments, call and trace clients' who missed visits, and provide adherence/psychosocial support. Routinely collected aggregate data was analyzed to describe progress towards 90-90-90 for younger (<10 yrs) and older children (10-14 yrs).
Results: Overall, 292,213 younger children and 178,551 older children received HIV testing between October 2015 and September 2016, a two-fold increase compared to the prior 12 months. Of these, 1,814 (0.6%) younger children and 735 (0.4%) older children tested HIV-positive, compared to 1,926 (1%) younger and 682 (0.8%) older children in the previous 12 months. Of those testing HIV-positive, 93% of younger and 81% of older children enrolled in HIV care. Between the first and last quarter, there was a 22% increase in ART initiation among younger children (341 to 415), and 195% increase among older children (110 to 325). By September 2016, the proportion of children on ART reached 99% of younger and 94% of older children and retention at 12 months after ART initiation for children <10 yrs was 81% and 79% for 10-14years. The proportion of children who received a viral load (VL) test 6 months after ART initiation increased from 67% to 89% for children <10yrs, and from 60% to 85% for 10-14 yrs. Among those with documented VL results at 6 months (<10 yrs: 63%; 10-14 yrs: 66%), the proportion with VL< 1000 copies/ml was 80% and 84% in younger and older respectively.
Conclusions: Intensified testing strategies resulted in a substantial increase in the number of children tested, however the yield was low. Although ART initiation, 12-month retention, and viral suppression were high, additional strategies are needed to identify, engage and successfully treat all children with HIV.

TUPEB0429

Population level assessment of HIV+ Ugandan/Kenyan children who remained viremic in the SEARCH test-and-treat study, which achieved 90-90-90 coverage of adults

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Background: The SEARCH HIV test-and-treat study (NCT01864603) achieved the 90-90-90 target of 80% population-level virologic suppression among adults in rural Kenyan and Ugandan communities. The HIV-status of 89% of children was ascertained, but the probability of suppression at 2 years was only 62%. We sought to describe the characteristics of viremic children and identify population-level predictors of risk.
Methods: All HIV+ children in 16 intervention communities were offered ART in a streamlined-care model. Viral loads (VLs) were measured during annual community heath campaigns and at clinic visits. We assessed children aged 2-14 years with ≥1 VL measured (May 2013-November 2016). Using multivariable logistic regression, we evaluated potential predictors of viremia (most recent VL>500 copies/ml), including demographic characteristics, HIV care-status (never linked, linked but lost to follow-up [no visit in prior ≥9 months], or active), household wealth index, and presence of HIV+ mother with suppressed VL in the household.
Results: Overall, 700/739 (95%) HIV+ children living in SEARCH communities had ≥ one VL. They were 55% female, with 42% aged 2-6, 32% aged 7-10, and 26% aged 11-14 years. Among 262/700 (37%) viremic children, care-status varied: 43(16%) never linked to care, 54(21%) linked but were lost to follow-up and 165 (63%) were known to be in active care. Children aged 11-14 and 2-6 years had greater likelihood of viremia than those 7-10 years. Greater household wealth predicted viremia, while presence of an HIV+ mother with suppressed VL lowered risk.

Variable	Univariate OR (95% CI)	Adjusted OR (95%CI)
Female gender	1.29 (0.94-1.75)	1.21 (0.87-1.67)
Age (years), 11-14 vs. 7-10	2.63 (1.73-3.98)	2.45 (1.58-3.78)
2-6 vs. 7-10	1.71 (1.17-2.50)	1.90 (1.28-2.82)
Care status, never linked vs. active	2.35 (1.46-3.81)	2.00 (1.21-3.30)
LTFU vs. active	1.38 (0.93-2.05)	1.32 (0.88-2.00)
HIV+ mother with suppressed VL present in home	0.63 (0.46-0.87)	0.69 (0.49-0.98)
Kenya vs. Uganda	1.53 (1.08-2.17)	1.50 (1.04-2.18)
High household wealth*	1.73 (1.01-2.97)	1.78 (1.00-3.15)
Household wealth ranked in quintiles; Odds ratio (OR) for highest vs. lowest shown.		

[Predictors of viremia in children]

Conclusions: To address the gap in community-level HIV suppression in children, improved linkage and retention will be important, but the highest proportion of viremic children are already in care, underscoring problems of adherence and/or drug resistance. Multiple interventions, tailored to different regions, age groups and higher wealth households will likely be required to achieve 90-90-90 in children living in rural East Africa.

TUPEB0430

Risk and warning signs for loss to follow-up in a cohort of HIV-infected children on antiretroviral therapy in Thailand

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Background: Detecting signs associated with an increased risk of loss to follow-up (LTFU) may help maximize the effectiveness of antiretroviral therapy (ART) programs. Adolescence is a well-known factor contributing to the risk of LTFU but other information collected during follow-up may help clinicians focus on children at higher risk.
Methods: We used demographics and clinical data collected at ART initiation (baseline), 2 weeks, 1 month, 3 and 6 months, and every 6 months thereafter in children participating in the PHPT multicenter pediatric cohort in Thailand between January 1, 1999 and December 31, 2014. Children who did not come for follow-up >9 months after their last appointment were considered as LTFU. Discontinuation of ART was considered if >7 days. Baseline and time-updated variables associated with LTFU were identified using Fine and Gray competing risk regression models accounting for deaths and referrals to other clinics as competing events. We adjusted for characteristics of the Thai program: calendar years of enrollment (quartiles: before 2003, 2003-2004, 2005-2006 and after) and regions in Thailand (northern and others). Missing values of time-updated variables were imputed using linear interpolation within 1 year before and after the missing visit.
Results: 832 children (445 female, 53%) were included in the analysis. Baseline median age was 7.2 years (IQR 3.1-10.0); 67 (9%) were living in orphanage and 508 (61%) in northern Thailand. 255 (34%) had HIV-RNA load >400 copies/mL at 5 years after initiation and 99 (12%) discontinued ART at least once. Median follow-up was 8.2 years (4.1-10.3): 184 (22%) were LTFU (observed cumulative risk of LTFU: 7.6% at 5 years and 29.5% at 10 years). The estimated cumulative incidence of LTFU (considering 184 children referred elsewhere and 72 deaths as competing) was 6.9% (95%CI 5.3-8.7%) at 5 years and 22.8% (19.8-26.0%) at 10 years. In the multivariable analysis, factors associated with a higher risk of LTFU were: not living in orphanage (p=0.006); and, as time-updated, age ≥13 years (p<0.001), HIV-RNA load >400 copies/mL (p=0.001), and previous ART transient discontinuation (p=0.001).
Conclusions: Transient discontinuation of ART at any time during the follow-up should draw clinicians' attention to prevent definitive LTFU.

TUPEB0431

"*Not all Mogen Clamps are created equal*": standardising Mogen Clamp specifications for EIMC

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Background: According to the "WHO Manual for Early Infant Male Circumcision under Local Anaesthesia" there are 3 devices that have been pre-qualified to be used on infants; namely, the Gomco Clamp, Plastibell and Mogen Clamp. An EIMC pilot study in South Africa, which used the Mogen Clamp found that there are currently no standard specifications for Mogen Clamps for EIMC - except that the WHO guidelines state that there must be an aperture of 2 mm, but does not indicate where this aperture of 2 mm refers to on the Mogen Clamp. During the start-up phase of the pilot study on EIMC in South Africa, and after several AEs due to low quality Mogen Clamps, it was found that standard specifications are required to ensure the safety of infants circumcised using the Mogen Clamp.
Methods: CHAPS, together with the supplier, measured the dimensions of the Mogen Clamps from three different suppliers to compare. The 3 different products are "Product A" (the Mogen Clamp found to be of the best quality and with the most appropriate specifications for EIMC), "Product B" and "Product C". Dimensions were taken from 7 different points on the Mogen Clamp.
Results: After several qualitative discussions with the clinicians, and the supplier in South Africa, it was determined that the best point of reference for determining a "good" quality Mogen Clamp was on dimension A (maximum opening width) given that it is at this point that the foreskin is pulled through before the crushing action (table 1).

Clamp Dimensions (mm)	Product A	Product B	Product C
A -Maximum opening width	2.35	3.39	3.10
B- Middle opening width	1.40	2.01	1.70
C- Inner hinge opening width	0.43	0.53	0.45
D- Clasp diameter	10.88	12.70	12.79
E- Back hinge width	0.40	0.45	0.45
F- Working surface length	< 0.04 (Length = 43.71)	< 0.04 (Length = 44.40)	< 0.04 (Length = 44.00

[Table 1: Mogen Clamp Dimensions]

Conclusions: This research will assist in establishing the parameters for the Mogen clamp in order for them to comply to WHO guidelines.

TUPEB0432

Pharmacokinetic (PK) modelling and simulation to support weight-based dosing of maraviroc (MVC) in paediatric subjects when co-administered with potent CYP3A inhibitors

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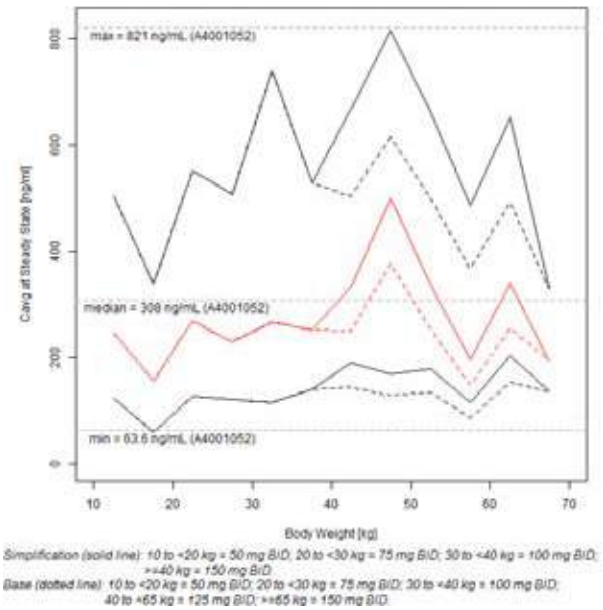
Background: A4001031 is a PK and safety study of MVC in treatment-experienced HIV-1-infected paediatric subjects. Initial MVC dose was adjusted on body surface area (BSA) and co-administered potent CYP3A inhibitors or inducers. Most subjects (90/103) took MVC with CYP3A inhibitors (i.e. protease inhibitors) in optimized background therapy. The objectives were to describe the PK of MVC with potent CYP3A inhibitors and determine weight-based dosing by simulation for paediatric subjects.
Methods: MVC PK data from 85 paediatric subjects were combined with adult data from Phase1-4 studies. Nonlinear mixed effects modelling was used to fit a 2-compartment model with first-order absorption; covariates (See Table) were assessed in stepwise modelling.

	Paediatric Study (A4001031)	Adult Phase 2b/3/4	Adult Phase 1
Number of subjects (males/females)	85 (43/42)	125 (112/13)	56 (45/11)
Weight (kg) : Median (Range)	28.9 (10.2-69.8)	76.7 (50.2-120.0)	71.0 (46.0-92.2)
BSA (m2) : Median (Range)	1.05 (0.48-1.83)	1.93 (1.50-2.44)	1.87 (1.39-2.19)
Age (years) : Median (Range)	11 (2-17)	45 (28-69)	29.5 (20-55)
Race: White/Black/Asian/Other (N)	13/58/11/3	96/20/4/5	24/5/26/1
Subjects/PK Sampling Occasions/Samples (N)	Intense: 38/67/468 Sparse: 84/0/648	Intense: 0/0/0 Sparse: 125/0/861	Intense: 56/74/628 Sparse: 0/0/0
Protease Inhibitors: ATV/ATV/r /FPV/r /LPV/r /DRV/r (N)	0/2/1/68/14	5/33/0/79/8	0/12/0/19/25
Food Status for Samples: Fasted/Fed/Not Known (N)	Profiles: 0/460/8 Sparse: 0/491/157	Profiles: 0/0/0 Sparse: 152/539/170	Profiles: 628/0/0 Sparse: 0/0/0
Baseline Estimated Creatinine CL (mL/min): Median (Range)	Under 12 years: 111 (57-180) 12 years and over: 135 (42-189)	107 (53-240)	108 (68-172)

[Covariates and Populations]

The paediatric covariate dataset was bootstrapped with replacement to produce a simulation dataset (N=1000) to determine concentrations for various dosing scenarios, using the PK model.

Results: The 2-compartment model was satisfactory. Statistically significant covariates were: weight (Central and Peripheral CL and Volumes); dose nonlinearity (Relative Bioavailability); CYP3A inhibitor groups, CYP3A inducer & creatinine CL (all on CL); Race (central Volume).
The Figure shows 5th, 50th and 95th percentiles of MVC average concentration (Cavg) simulations for two dosing scenarios (Base=5 weight bands for BSA-to-weight translation and Simplification=4 weight bands with flat adult dose for subjects >40 kg) compared with median and range MVC Cavg for 150 mg BID with DRV/r in adult Study A4001052.



[Simulations for Paediatrics vs Adult Data]

Conclusions: Using modelling and simulation, MVC dosing in paediatric subjects with the simplified, 4 weight bands across 10-70 kg achieves comparable exposures (Cavg) to adults on MVC 150 mg BID with potent CYP3A inhibitors.

TUPEB0433

Maraviroc pharmacokinetics and dosing recommendations in CCR5-tropic HIV-1-infected children aged 2 to < 18 years

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Background: Maraviroc (MVC) is a CCR5-antagonist approved to treat adults, and recently children/adolescents, infected with CCR5-tropic HIV-1.
Methods: A4001031 is an open-label, two-stage (stage-1: dose-finding, stage-2: safety/efficacy), non-comparative, multicenter study of MVC plus optimized background therapy in treatment-experienced children aged 2 to < 18 years. Participants were dosed twice-daily according to body surface area and concomitant medications (i.e., presence of CYP3A inhibitors and/or inducers). Intensive and sparse MVC pharmacokinetics (PK) up to Week 48 were determined in subjects to assess dose or modify dose in stage-1, if required, to achieve average concentration (C_{avg}) ≥100ng/mL.
Results: A total of 97 subjects were treated with MVC tablet or oral solution with/without food in stage-2 including the 50 subjects who also participated in stage-1 (MVC dosed with food).

Concomitant Medications	MVC dosed with potent CYP3A inhibitors (with or without a CYP3A inducer)	MVC dosed with non-interacting drugs	MVC dosed with a potent CYP3A inducer (without a potent CYP3A inhibitor)
Number of subjects (males/females)	85 (43/42)	10 (4/6)	2 (0/2)
Weight (kg) : median (range)	28.9 (10.2-69.8)	32.1 (16.2-40.3)	32.8 (17.0-48.5)
BSA (m2) : median (range)	1.05 (0.48-1.83)	1.1 (0.67-1.30)	1.0 (0.69-1.41)
Age (years) : median (range)	11 (2-17)	11.5 (3-17)	9 (4-14)
Race (White/Black/Asian/Other)	13 / 58 / 11 / 3	2 / 6 / 0 / 2	0 / 2 / 0 / 0

[Table 1]

MVC PK in children/adolescents based on body weight (kg)-bands and concomitant medication fell within the ranges observed in adults on approved doses.
Children receiving non-interacting drugs required greater mg/kg MVC dose compared to adults in order to achieve target exposures. Regulatory approval in US was achieved for children ≥30kg receiving non-interacting concomitant medications and for children 10kg to ≥40kg receiving concomitant CYP3A inhibitors (with/without CYP3A inducers). EU approval is pending and submissions in other regions are planned. Insufficient PK data are available to make dose recommendations for children receiving MVC in combination with potent CYP3A inducers (without CYP3A inhibitor).

Observed MVC Geometric Mean PK Parameters in TE Children and Adolescents Receiving MVC with Other Concomitant Medications (not Potent CYP3A Inhibitors and/or CYP3A Inducers)						
Weight (kg)	***MVC Dose***	***AUC12 (ng.h/mL)***	***Cavg (ng/mL)***	***Cmax (ng/mL)***	***Cmin (ng/mL)***	
10 to <20 kg (n=2)	No recommendation*	1941	162	746	16.0#	***# arithmetic mean (geometric mean could not be calculated as one value was zero)***
20 to <30 kg (n=1) α	No recommendation*	2498	208	751	44.1	***α - Two observations from 1 subject***
≥30 kg (n=5)β	300 mg twice daily	1998	167	413	50.6	***β - Nine observations from 5 subjects***
Simulated MVC Geometric Mean PK Parameters in TE Children and Adolescents Receiving MVC with Potent CYP3A Inhibitors (with or without a Potent CYP3A Inducer)^						
10 to <20 kg	50 mg twice daily	2349	196	324	78	***^model-predicted steady-state PK parameters***
20 to <30 kg	75 mg twice daily	3020	252	394	118	
30 to <40 kg	100 mg twice daily	3229	269	430	126	
≥40 kg	150 mg twice daily	4044	337	563	152	

[Table 2]

CYP3A=Cytochrome P450 3A; kg=kilogram; mg=milligram; TE=treatment-experienced
[a]Two observations from 1 subject;
[b] Nine observations from 5 subjects;
*PK following MVC 200mg (10kg to < 20kg) and 300mg twice daily (20 to <30kg), respectively;
arithmetic mean (geometric mean could not be calculated as one value was zero);
^model-predicted steady-state PK parameters
Conclusions: MVC exposures in pediatric subjects, with MVC dosing based on body weight and concomitant medication, were similar to those observed in adults at approved doses and serve as the basis for MVC dose recommendations in children 2 to <18 years of age weighing ≥10kg.

TUPEB0434

Factors associated with seronegativation in early treated HIV-infected children in Cameroon

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Background: Negative serological test in early treated HIV-infected children is no more a rare phenomenon. However, the host factors determining the absence of HIV antibodies are not completely understood. Here, we explored characteristics associated with the absence of HIV-antibodies in early treated children followed-up during five years in the ANRS-Pediacam cohort.
Methods: From November 2007 to December 2011, HIV-infected children <7 months were included in the ANRS-PEDIACAM cohort in Cameroon after parental consent, treated and followed-up during five years. HIV serology was carried out

with a fourth-generation ELISA as from fifteen months of age, and was repeated during follow-up. Retrospectively, we defined using serological test and viral load result and compared two groups of children: seronegative group (children with at least one negative serological test during follow-up) and control group (children with positive serological test who maintained HIV viral load under 1000 copies/ml during follow-up).
Results: Of 210 children enrolled in the study, 144 performed at least one HIV serology and were considered in the analysis. Median age at cART initiation was 4.1 months [IQR: 3.2-5.6] and the median duration of cART was 4.7 years (IQR: 4.5-4.8). Median age at first HIV serology was 20.3 months [Interquartile range (IQR): 18.3-22.8]. Of the 144 children, 28 (19%) children were seronegative and 26 (18 %) fulfilled the control group criteria. Age at cART initiation, duration from cART initiation to first HIV suppression, and pre-term birth were significantly associated with absence of HIV-antibodies (Table 1).
No difference was observed between the two groups concerning gender, PMTCT prophylaxis, mode of delivery, cART regimen at initiation, and other social and economic characteristics of the mothers.

Characteristics	Seronegative group N=28	Control group N=26	p
Age at treatment initiation less than 3 months	11 (39 %)	3 (12 %)	0.04
Duration from cART initiation and first viral load <1000 copies/ml	3.31 [2.97 - 6.46]	5.27 [3.17 - 6.06]	<0.001
Duration from cART initiation and first CD4 lymphocytes >35%	3.13 [2.95 - 13.98]	6.03 [5.14 - 12.69]	<0.001
Preterm birth (gestational age <38 weeks)	11 (39 %)	4 (15 %)	0.04

[Table 1: Significant characteristics between the 2 groups]

Conclusions: These results underscore the interest of early cART, and highlight the fact that lack of children maturation could influence the production of HIV-antibodies. There is a need to continue this exploration in order to gather convincing data for families to maintain adherence in case of seronegativity

TUPEB0435

Longer-term safety of maraviroc in paediatric patients with R5 HIV: follow-up data from study A4001031

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Background: Study A4001031 evaluated the pharmacokinetics (PK), safety and efficacy of maraviroc (MVC) in treatment-experienced (TE) paediatric patients with R5 HIV. Week 48 data demonstrated that MVC exposures achieved were in the same ranges as those seen in adults. MVC was safe and well-tolerated with a similar safety profile and efficacy compared to adults. Based on this data MVC was recently approved in the USA (with doses based on body weight and concomitant medication) for the treatment of children (2-18 years) with R5 HIV. Safety and efficacy data from the longer-term post Week 48 follow-up of patients remaining in study are described.
Methods: This open-label, age-stratified, non-comparative, multicenter study of MVC plus optimized background therapy (OBT) had a primary endpoint analysis conducted at Week 48, but is continuing to 5 years to assess long-term safety. Patients were enrolled into one of four age/formulation cohorts and received twice daily doses of MVC, selected based on body surface area and adjusted for potential interactions with OBT.
Results: One-hundred and three patients were enrolled, of whom 52% were female. The majority (68.9%) were black, with 15.5% White and 10.7% Asian. As of 19 February 2016, all patients remaining in study (n=65) have reached 96 weeks, and 18 have reached the 5 year endpoint. Fifty patients discontinued from treatment, with insufficient clinical response (n=32) being the main reason for discontinuation. Of patients remaining in study, 52/65 (80%) and 47/55 (85%) had HIV-1 RNA <48 copies/mL at Weeks 96 and 144, respectively, compared to 49/72 (68%) at Week 48. CD4 cell count increases (absolute and percentage) were maintained after Week 48. Three patients discontinued due to adverse events (AEs). AEs occurring in >10% (diarrhoea, vomiting, pyrexia, bronchitis, upper respiratory tract infection and cough) are common in this population. The frequency and nature of AEs remained similar to what was seen at Week 48, and consistent with MVC's safety profile in adults.
Conclusions: Long-term follow-up data from study A4001031 confirmed the safety and tolerability of MVC in paediatric patients with no new safety concerns observed. Virologic responses were maintained in the majority of patients remaining in study.

TUPEB0436

Pediatric long-term outcomes following enrollment in an HIV perinatal clinical trial

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Background: Early diagnosis of HIV infection followed by ART initiation among infants who participate in perinatal trials for prevention/identification of infection are often associated with improved outcomes. We evaluated the clinical/laboratory status of HIV- infected children identified in an early trial 5 to 11 years later.
Methods: We offered study participation to HIV-infected children previously enrolled in the NICHD/HPTN 040 neonatal study between 2004-2011 from Brazil. Medical history, timing of infection (in utero/ intrapartum), time of ART initiation and number of regimens were evaluated along with anthropometric measures, plasma virus load, T- cells, and viral reservoir studies.
Results: 77 of 140 HIV-infected infants (55%) from the original trial came from 3 sites; 37/77 (48%) were available for study follow-up. The median age was 8 years (range: 5.3-11.8 years). Twelve children (16%) died in the first 6 months of age; 4 (5%) died subsequently; 20 (26%) were lost to follow-up and 4 (5%) could not be enrolled. Of 37 children, 19 (51%) were infected in utero (IU) and 18 (49%) intrapartum (IP). The median age of ART initiation was 11 months, range: 9 days to 6 years [IQR: 5-19.5]. Twenty-three children (62%) had undetectable plasma virus load (53% IU vs. 72% IP, p =0.37); 5 (14%) had sustained virologic suppression since the first ART regimen [0/19 IU vs. 5/18 (28%) IP, p=0.02]. The median number of ART cycles was 2 (range: 1-8). Thirty-one children (83%) had normal CD4 cell counts. Eight children (22%) had past or present findings of HIV disease, 7/19 (37%) IU vs. 1/18 (5.6%) IP. Two children had abnormal weight/height Z-scores for age. Presence of symptomatic HIV disease was associated with IU infection (p=0.04). No children had negative HIV-1 EIAs or Western Blots secondary to early treatment initiation. Early ART for prophylaxis in the first month of life (single, double, triple ART) was not associated with viremia at present.
Conclusions: Despite early HIV recognition and careful follow-up in perinatal trials, adverse outcomes (mortality, loss in retention) are frequent. Among children retained in care, virologic suppression was achievable in 2/3. Symptomatic HIV disease and initial ART failure was more frequent in IU infection.

TUPEB0437

Virologic failure and drug resistance mutations patterns after 25 months on LPV/r-based antiretroviral therapy in children early treated before the age of two in West Africa

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Background: Effectiveness of early antiretroviral therapy (ART) in young children needs to be evaluated. We assessed the virological suppression (VS) in West-African children on a LPV/r based-ART over 25 months and the impact of drug resistance mutations.

Methods: From 05/2011 to 01/2013, 156 HIV-infected children < 2 years of age were initiated in an initial LPV/r based-ART cohort for 12 months before being enrolled at 13-month for those in VS in a randomized simplification trial, assessing LPV/r vs EFV-based ART, in Ouagadougou, Burkina Faso, and Abidjan, Côte d'Ivoire. Viral load (VL, Biocentric) were measured three-monthly. VS (HIV RNA < 500 copies/mL) was determined after 12 months and 25 months of LPV/r-ART. HIV-1 genotypic resistance testing was performed before ART initiation and when VL was ≥1000 copies/mL.
Results: At 12-month of LPV/r-based ART, 13/156 children have died (8%), 5 were lost-to-follow-up/withdrew (3%) and 106/138 of children alive/followed (77%) achieved VS. Following randomisation, 86 children were further maintained on LPV/r therapy (54 in VS and 32 in virological failure, VF). At 25 months of therapy, 3 additional children were lost-to-follow-up: 57/83 children (69%) were virologically supressed (46/54 of children in VS at 12 month and 11/29 of children in VF at 12 month). HIV genotyping at 12-month showed that 21/28 viruses (75%) with a VL≥1000cp/mL had ≥1 drug resistance mutation (DRM) (61% to lamuvidine; 29% to efavirenz, 4% to zidovudine and lopinavir/ritonavir): 11 (52%) were transmitted drug resistance (TDR) with 5 viruses exposed to a maternal PMTCT intervention. 5/19 viruses genotyped from children in VF at 12-month showed the emergence of DRM to lamivudine between 12 and 25 months and 3/19 viruses pursued to accumulate other DRM after 12 months of LPV/r-based therapy (one to LPV/r). For children in VS at 12-month, 5/7 viruses with a VL≥1000cp/mL harboured ≥1 DRM to lamivudine or EFV, 3/5 were TDR from exposure to a maternal/PMTCT intervention.
Conclusions: These data highlighted the high prevalence of DRM in LPV/r-based treated HIV-1 children compromising long-term VS. A high frequency of HIV-TDR (54%) was detected in children in VF. The majority of DRM emerged before 12 months of LPV/r-based therapy.

TUPEB0438

HIV+ve adolescents differ depending on infection mode. Implications for service from the Mzantsi Wakho cohort in South Africa

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Background: HIV+ve adolescents are the fastest growing group, with little insight into their different needs and service requirements. They include adolescents infected at birth (vertical infection) and those infected during adolescents - most commonly from sexual exposure (horizontal infection).
Methods: This study examines the world's largest community based study of HIV+ve adolescents (n=1060) drawn from the Eastern Cape, South Africa. From detailed records at all 53 health district clinics 1060 ever-ART initiated adolescents were tracked and interviewed (representing an inclusion rate of 90.1%. Ethical approval, informed consent and data collector training preceded data gathering on a detailed inventory providing validated measures of mental health, adherence , drug and alcohol use, cognitive abilities and disability, opportunistic infections, overall health, and clinic attendance.
Results: Vertically infected adolescents (n=713, 67% of the sample) were significantly (p=.001, OR .59 CI .43-,81) less likely to be non-adherent to cART, yet they were significantly more likely to miss clinic appointments (p<0.05, OR 1.6 CI 1.0-2.5). In terms of mental health horizontally infected adolescents were more likely to be depressed (p<0.001, B -.10) and express suicidal ideation (p<0.001, B -.11) - linked to the fact that they were older and greater likelihood of girls in the group. Vertically infected adolescents were half as likely to record drug and alcohol use in the past few months (p<0.012, OR.49, CI .29-.86). They performed significantly lower on cognitive tasks (p<0.008, OR 1.5 CI 1.1-2.1), and were more likely to have a disability on the WHO physical index (p=.001, OR 1.6, CI 1.2-2.1). The vertically infected group, despite better adherence than the horizontally infected, had 1.5 times higher risk of TB (p<0.03, OR 1.6, CI 1.1-2.1).
Conclusions: There are notable differences between these two groups of adolescents. Studies that conflate the groups may blur the findings. Clinic provision, if it is to be effective, needs to adapt and adjust to the different groups, take their needs into account and tailor services to them to ensure optimal adherence, development and wellbeing.

TUPEB0439

Lopinavir hair concentrations predict viremic episodes in HIV-infected Asian children and adolescents on second-line ART

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Background: Children and adolescents have suboptimal antiretroviral therapy (ART) adherence and virologic outcomes compared to adults. For children who require second-line ART, objective measures of adherence could help explain virologic outcomes and guide subsequent treatment decisions. Hair concentrations of antiretrovirals reflect drug exposure and adherence, and predict viral suppression in adults. However, hair measures (collected noninvasively) have not been examined longitudinally in pediatric populations or in the context of second-line ART.
Methods: We examined predictors of viremia (HIV-1 RNA >400 copies/ml) at least 24 weeks after switch to lopinavir-based second-line ART in a cohort of HIV-infected Asian children and adolescents. Participants were followed between 2011 and 2013. Small hair samples, HIV-1 RNA, and self-reported adherence by 30-day visual analogue scale (reported by parent/guardian when appropriate) were collected every 6 months. Hair concentrations of lopinavir were measured via liquid chromatography-tandem mass spectrometry using validated methods in the UCSF Hair Analytical Laboratory. Time to first viremic episode was examined using discrete-time Cox models.
Results: Among 244 participants, 44.7% were female; 11.1% were from Indonesia, 34.4% Thailand, 54.5% Vietnam. At switch to second-line, median CD4 percentage was 12.6% (IQR 7.0-19.0%); median HIV RNA was 103,000 copies/ml (IQR 22,300-357,000). At enrollment in the cohort, median age was 10.0 years (range 1.7-18.0); median time on lopinavir-based ART was 1.9 years (IQR 0.7-3.9). Median time of study follow-up was 48 weeks and a median of 3 (range 1-5) hair samples was collected from each participant. In a model including age, self-reported adherence, country, and CD4 percentage and HIV-1 RNA at switch, hair concentrations of lopinavir were the strongest independent predictor of a lower risk of viremia (odds ratio 0.44 for every doubling in hair level, 95% CI 0.32-0.62, p< 0.001).
Conclusions: In this longitudinal cohort of children and adolescents on second-line ART, we show for the first time that higher lopinavir hair concentrations more strongly predicted a lower risk of viremia than self-reported adherence, age or CD4. Monitoring hair antiretroviral concentrations may be useful for this vulnerable population at risk of virologic failure with limited future treatment options.

TUPEB0440

Viral resuppression and persistent failure after viremia on second-line antiretroviral treatment among Asian children and adolescents

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Background: There are limited data on the long-term durability of protease inhibitor (PI)-based second-line antiretroviral therapy (2nd-ART) regimens after virologic failure (VF). We aimed to identify factors associated with repeated VF in a cohort of perinatally HIV-infected Asian children and adolescents on 2nd-ART.
Methods: HIV-infected children who switched to PI-based 2nd-ART after first-line failure and had a history of ≥1 episode of VF (HIV-RNA ≥1000 copies/mL) after prior suppression on 2nd-ART were followed every six months over two years (2014-2015). Adherence was measured by self/guardian-report (visual analogue scale;

VAS), pill counts, and hair concentrations; therapeutic drug monitoring (TDM) via plasma levels and genotypic resistance testing were performed upon repeat VF. Generalized estimating equation approach was used to assess factors associated with VF.
Results: A total of 56 perinatally HIV-infected children were followed at sites in Thailand (N=12) and Vietnam (N=34); 65% male, 51 (91%) taking lopinavir-based regimens. At enrollment, 43% (24/56) had ≥2 prior episodes of VF while on 2nd-ART. At the first 6-monthly follow-up visit, median age was 12.3 (IQR 10.2-14.5) years, and median CD4 count was 689 (IQR 386-1,096) cells/mm3. Although 54% (30/56) remained resuppressed, 46% (26/56) had at least one subsequent occurrence of VF during study follow-up, and 34% (19/56) had persistent VF at their next 6-monthly visit with a median 2nd-ART duration of 2.7 (2.0-3.7) years. In a multivariate model, additional episodes of VF were associated with lower lopinavir hair concentrations, CD4 count < 350 cells/mm3 and adherence < 95% by VAS. Two (2/26, 8%) developed high-level resistance to both lopinavir and atazanavir, and 3 (3/26, 11.5%) exhibited major PI mutations (M46I, I54V, V82A, N88NS). At the first occurrence of VF after enrollment, 43% (10/26) of children had random lopinavir plasma levels by TDM that were lower than the lower limit of quantification.
Conclusions: Half of children with a single episode of viremia while on PI-based second-line ART resuppressed their virus, but the other half had repeated episodes related to poor adherence (by report and objective measures) and immunologic status. While few developed high-level PI resistance, mutation accumulation will increase without more effective interventions to improve adherence in this population.

TUPEB0441

Profiling adolescents and youth in HIV care in Tanzania by age, sex, pregnancy status, ART initiation and retention

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Background: Adolescents and young adults with HIV (AYHIV) have unique needs and circumstances. This retrospective analysis aims to describe age, sex, ART initiation and pregnancy status among current-in-care AYHIV, and factors associated with one-year retention in care among a recently enrolled cohort.
Methods: Electronic medical records (national HIV care/treatment database) from 135 HIV clinics across three regions were analyzed using descriptive and logistic regression methods. AYHIV (n=7538) who were enrolled from 2005-2015, received care and were ages 10-24 years at their last visit (in 2015) contributed to the current-in-care profile. One-year retention in care (i.e. enrollment) was explored in the AYHIV cohort enrolled from January 2013 to December 2014 (n=4379), with observed visits through March 2015.
Results: The proportion of female AYHIV increases from 52%, 62% to 83% in the age groups 10-14Y, 15-19Y and 20-24Y, respectively (p<0.0001). One-third of all female AYHIV were either pregnant at enrollment (23%) or became pregnant in care (10%), but even non-pregnant female AYHIV aged 15-24Y out-numbered males more than 3-fold. AYHIV starting ART did not differ by sex (73% male [M]; 72% female [F], p=0.13), but ART initiation was higher among pregnant (81%) compared to non-pregnant females (66%, p<0.0001). One-year-retention in care was higher for males, overall (49% M; 42% F, p=0.002), and among males starting ART (63% M; 55% F, p=0.002). In multivariable analysis, one-year retention in care was positively associated with being under 15Y at enrollment (AOR:1.90, 95%CI:1.44,2.49) and ART initiation (AOR:14.8, CI:11.5,19.1). Retention was lower among those enrolled who were pregnant (AOR:0.73, CI:0.63,0.86).
Conclusions: Gender imbalances among AYHIV in HIV care, and the high prevalence (one-third) of pregnancy among young women are important considerations when designing clinical and psychosocial support models of HIV care for adolescents/youth. While Option B+ has increased ART access for female AYHIV, those enrolled during pregnancy are at significant risk of non-retention. Differentiated and gender-sensitive service models should offer targeted services, depending on need and circumstances, that incorporate sexual and reproductive health education, family planning services, partner HIV testing, and efforts to support newly-diagnosed and newly ART-initiated pregnant women.

TUPEB0442

Cumulative viremia, treatment history, and immune status in youths with perinatal HIV infection: the ANRS EP38 IMMIP study

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Background: Cumulative exposure to viral replication has been consistently associated with morbidity and mortality in HIV-infected patients under successful combined antiretroviral treatment (cART) over several years. Long-term maintenance of adherence and viral control can be challenging, particularly in children and adolescents.
We previously described associations between cumulative viremia, cell-associated HIV-DNA, and naïve CD4 T-cell levels in perinatally infected youths over the age of 15 years. Here, we assessed whether cumulative viremia was associated with treatment history and biomarkers of inflammation and T-cell function.
Methods: The ANRS-EP38-IMMIP study included youths who acquired HIV during the perinatal period. Cumulative viremia was defined as the area under the curve of HIV RNA load over the last 10 years before the study. Plasma inflammatory markers were quantified using ELISA or Luminex technology. SEB-specific cytokine production by CD4 T cells was assessed by flow cytometry. Linear regression was used for univariate and multivariate analysis of cumulative viremia.
Results: The present analysis focused on the 57 patients with undetectable plasma HIV RNA at the time of the study. Their median (interquartile range) age was 18 (16-19) years and their CD4 T-cell count was 642 (522-949) cells/µl. Cumulative viremia was negatively associated with the duration of the last period of uninterrupted cART (estimate [95% confidence interval]: -315.6 [-569.1;-62.1], P=0.01) and positively with the number of cART interruptions (708.26 [34.2;1382.3], P=0.04), but not total duration of cART (-327.0 [-728.3;74.3], P=0.11).
It was positively associated with current CD8 T-cell count (2.5 [0.1;4.9], P=0.04), neopterin (511.7 [70.6; 952.8], P=0.02), and soluble tumor necrosis receptor 2 (3424.9 [741.5;6108.3], P=0.01) levels.
It was negatively associated with the percentage of polyfunctional CD4 T cells (-3281.3 [-4820.5;-1742.1], P<0.0001). These associations were significant in multivariate analysis including age, sex, and CD4 T-cell count.
Conclusions: Lower cumulative viremia was associated with reduced immune activation and improved T-cell function in youths with long-term HIV infection and suppressed viral replication. However, cART interruptions were associated with higher cumulative viremia. Our data support the importance of adherence to treatment in HIV-infected youths.

TUPEB0443

Decreasing risk of short-term virological failure with the more recent period of early cART initiation in HIV-infected infants in France

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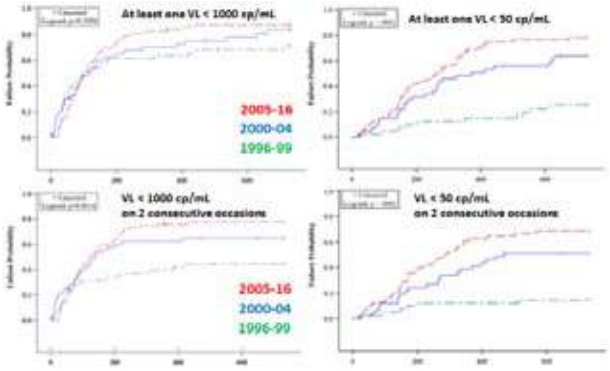
Background: Several studies have reported virological responses to be weakest in children under the age of two years. Since 2008, WHO guidelines have recommended systematic early cART initiation in infants, due to its demonstrated clinical benefits. Early ART started to be administered in France since the end of the 1990s. We estimated the probability of achieving viral suppression within two years of early cART initiation and studied trends associated with the period of initiation.
Methods: All neonates included in the national ANRS-EPF CO10 cohort from 1996 to 2016, followed since birth, and with cART initiation before one year of age were included in this analysis. The primary outcome was viral suppression (50 and

1000 cp/mL thresholds) on at least one occasion. The secondary outcome was viral suppression on two consecutive occasions. Probabilities were estimated with the Kaplan-Meier method.
Results: Overall, 148 children initiated cART at a median age of three months (IQR: 1- 5). The proportion of cART regimens including a PI increased from 65% in 1996-99 to 72% in 2000-04 and 83% in 2005-16. Three infants died during the first 24 months of cART, all beginning treatment before 2005. The probability of viral suppression increased significantly over time. For children born after 2005, the probability of having at least one viral load below 1000 or 50 copies/mL was 87% [79-95] and 78% [67-89], respectively (Fig 1). The probability of virological suppression on two consecutive occasions was 77% [67-88] and 68% [56-80], respectively.
Conclusions: The virological failure of early cART decreased over time, but the probability of not achieving sustained viral suppression below 50 cp/mL remained around 30% two years after initiation of treatment.



[Figure 1. Probabilities of achieving viral load suppression at two years of cART initiated during first year of life (Kaplan-Meier method) - The ANRS-EPF CO10 / 1996-2016]

TUPEB0444

Retention in ART care amongst adolescents attending an urban clinic in Durban, South Africa

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Background: Adherence and retention in care are critical in attaining the UNAIDS 90-90-90 goals. Adolescents are particularly challenging and a recent systematic review reported a retention rate of 83% (95%CI 68%-93%) amongst adolescents on ART. It is imperative to identify good practices which aid retention in care in an African context.
The adolescent clinic at King Edward VIII Hospital functions within a combined Paediatric and Adult HIV clinic, with dedicated adolescent-friendly days. Each adolescent is managed by a multidisciplinary team, including a doctor, lay counsellor, social worker and nurses and is seen by the same staff at each visit to allow continuation of care and bonding. Facilitated group counselling is also provided.
Methods: A retrospective chart review of all adolescents (10 years-19 years) attending the clinic between January 1996 - December 2015 was conducted. Analysis was conducted using STATA12.O; Mantel-Haenszel estimates were calculated and multivariate logistic regressions performed.
Results: Amongst the 357 eligible patients were identified, 343 files were available for analysis and the remaining 14 files were incomplete. All patients were black African of Zulu ethnicity and 43.7% are female. Most were WHO stage 3 at ART initiation (67.4%). Median age at diagnosis and ART initiation were 97 months and 102.4 months respectively. Most adolescents (62.6%) had lost one or both parents. Almost 87% of the adolescents were still being actively followed-up at the time of this analysis; with 28 (8.2%) being transferred; 16 (4.7%) lost to follow-up and 1 (0.3%) death.
Predominantly, 256 (74.6%) were still on their 1st line ART regimens (EFV based ART); 86 (25.1%) on 2nd line (Protease-inhibitor based ART); and 1 (0.3%) on 3rd line. Current or past history of TB was present in 228 (66.5%) of the adolescents. On multivariate analysis, controlling for current age, being on a once daily combination pill was almost 80 times protective for retention in care (OR 0.05; 95%CI 0.01-0.39; P=0.004).
Conclusions: Provision of adolescent-friendly days with dedicated staff results in a 90% retention in-care of adolescents, even in a busy urban clinic in South Africa. Once daily fixed dose preparations can further improve retention in adolescents.

TUPEB0445

Longitudinal cluster analysis of viral suppression during 25 months on antiretroviral therapy, adherence and factors associated in young West-African children, in the MONOD ANRS 12206 cohort

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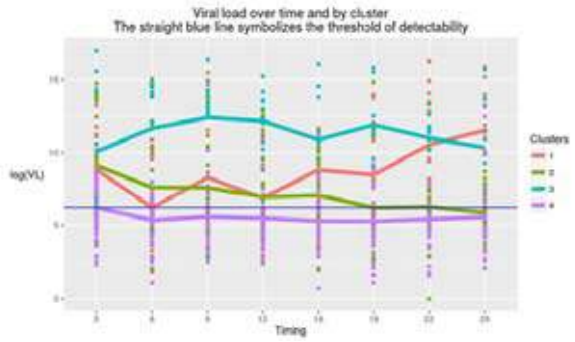
Background: Long-term viral load (VL) suppression on antiretroviral therapy (ART) in children is challenging. We described the dynamic of the virological response among children ART-treated before the age of two over 25 months in West-Africa, and investigated its association with adherence.
Methods: Between 5/2011 and 2/2013, HIV-1-infected children < 2 years were initiated on ART and followed-up over 25 months in Ouagadougou, Burkina Faso and Abidjan Côte d'Ivoire. Adherence to ART was assessed at each scheduled monthly visit, using a 4-day recall of missed doses questionnaire and adherence to medical appointments. VL was measured quarterly (success < 500copies/mL). We used a clusterwise linear regression (R package kmlcov) to adjust the logarithm of VL on the visit timing, 4-day recall of missed ART and delay between the theoretical visit and the effective visit to cluster our study population.
Results: Among the 156 children enrolled, 63% were from Abidjan; 53% were females, 67% have had access to tap water at home, and mother was the main caregiver (81%). We identified four different longitudinal profiles of VL response over 25 months (Figure 1): 66% had a good profile, with consistent VL success (purple); 9% had a longitudinal VL failure profile (blue); 16% had an initial VL failure profile, then were suppressed beyond 19 months (green); 9% had a "boom and bust" profile ending with virological failure (red). The good profile was characterized in children having more often access to tap water, females, and in those with the smallest number of missed ART doses, and days of delay. In the VL failure profile, caregiver was less often the mother, and the average number of missed doses and visit' delays were significantly highest.
Conclusions: Different virological profiles can be identified in HIV-infected children. Interventions targeting children at risk for treatment failure will be helpful in optimizing virological success.



[Viral load trajectories in four clusters in MONOD]

TUPEB0446

Premature vascular stiffness in children slowly resolves following early ART: data from post-CHER trial cohort

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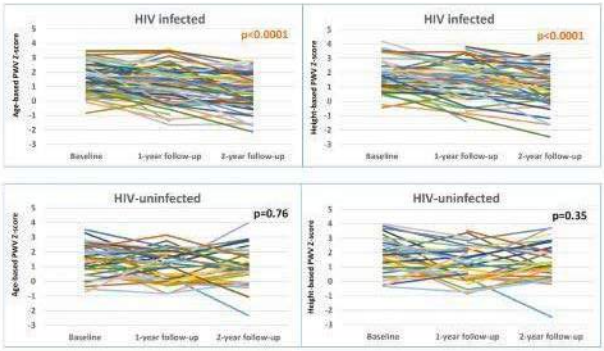
Background:
• Cross-sectional data suggests increased vascular disease in HIV+ children on antiretroviral therapy (ART) adjusting for traditional risk factors
• Thus far, pediatric studies have focused on children initiating ART after 3 months of age
• Whether very early ART will prevent HIV-related premature vascular disease is unknown
• Aorto-femoral pulse wave velocity (PWV) is a sophisticated and sensitive measure of elevated arterial wall stiffness, typically due to atherosclerosis or subclinical arteritis
• Reduced arterial wall elasticity leads to faster propagation of the arterial pulse wave
• PWV elevations strongly predict subsequent cardiovascular events in asymptomatic adults.
Methods:
• Baseline, 1-year and 2-year follow-up PWV measurements in perinatally-HIV-infected primary-school-age children who initiated lopinavir/ritonavir, zidovudine and lamivudine very early in infancy with minimal HIV disease and normal CD4 counts; and in HIV-uninfected controls (HIV-exposed uninfected, HEU, and HIV-unexposed, HU) from the same communities and socio-economic background
• Raw PWV, height-based PWV Z-scores (PWVZ-ht) and age-based PWV Z-scores (PWVZ-age) compared by ANOVA followed by pairwise T-test, and adjusted using multivariable regression for body mass index, fasted glucose, total and low density lipoprotein cholesterol, triglycerides and serum cotinine.
Results:
• 87 HIV+ (median age 7.7 [IQR: 7.6-8.5] years) who initiated ART at median 9 (7-12) weeks of age, with cumulative time on ART of median 7.1 (6.7-7.5) years and normal CD4 counts
• 53 uninfected (31 HEU; 22 HU), median age 8.5(IQR:7.8-8.7) years, with similar anthropometric Z-scores (p>0.10)
• Baseline PWV metrics in HIV+ and HEU were higher than HU and this difference persisted in HIV+ after adjustment (p≤0.04). (HEU not adjusted due to limited n)
• PWVZ-ht and PWVZ-age improved substantially over two years in HIV+ (p≤0.0001) and moderately in HEU (p≤0.05), whereas HU remained unchanged.



[Figure 1. Prospective changes in pulse wave velocity (PWV), a sophisticated measure of arterial wall softness]

Conclusions: In children initiating ART soon after birth, early PWV abnormalities gradually improve with accumulating time on ART.

TUPEB0447

Longitudinal changes in lipids after switch to boosted atazanavir or darunavir in children/adolescents with perinatally acquired HIV on older line protease inhibitors: results from the PHACS Adolescent Master Protocol Study

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Background: Dyslipidemia is common in perinatally HIV-infected (PHIV) youth receiving Protease Inhibitors (PIs). Few studies have evaluated longitudinal lipid changes in PHIV youth after switch to newer PIs.
Methods: We compared longitudinal changes in fasting lipids [Total Cholesterol (TC), Triglycerides (TG), Low Density Lipoprotein-C (LDL), High Density Lipoprotein-C (HDL), and TC/HDL] between PHIV youth enrolled in the U.S.-based PHACS AMP cohort who switched to either atazanavir/ritonavir (ATV/r) or darunavir/ritonavir (DRV/r) - based antiretroviral therapy (ART) from an older PI-based ART vs. those remaining on an older PI. Lipids were measured prior to switch or at first lipid measure, in the comparison group, and annually thereafter for three years. We excluded youth without lipid measurements, with ATV or DRV use prior to baseline, or who switched to ATV/r or DRV/r-based ART comprised of ≥ 3 classes of antiretrovirals. Generalized estimating equation models were fit to assess the association of switch to ATV/r or DRV/r-based ART with the rate of change in lipids, adjusted for potential confounders.
Results: From 2007-2014, 47 PHIV youth switched to ATV/r (n=27) or DRV/r (n=20) while 120 remained on an older PI. Of the latter, 72% received lopinavir/r and 24% nelfinavir. Baseline age ranged from 7-21 years with 73% non-Hispanic black. Compared to youth remaining on an older PI, those who switched were older (median age 14 vs. 11 years, p< 0.001) and reported receiving ART for longer at baseline (median 11.9 vs. 8.3 years, p< 0.001). At baseline, median TC was lower in the switch group (158 vs. 177 mg/dL, p=0.042). Overall, lipid profiles improved in both groups during follow-up. After adjusting for age, Tanner Stage, race/ethnicity, and HIV RNA level, switch to ATV/r or DRV/r was associated with a more pronounced rate of decline in the ratio of TC/HDL (ß= -0.12, p=0.039) over time. On average, TC declined 4.57 mg/dL/year (p=0.057) more in the switch group. There was no association between a switch to ATV/r or DRV/r and the rate of increase in HDL or decline in LDL and TG.
Conclusions: Switch to newer-line PIs may result in more rapid improvement in TC and TC/HDL in PHIV youth.

TUPEB0448

Long-term metabolic implications of initiating lopinavir/ritonavir-based regimens for infants and children: a follow-up study of IMPAACT P1060

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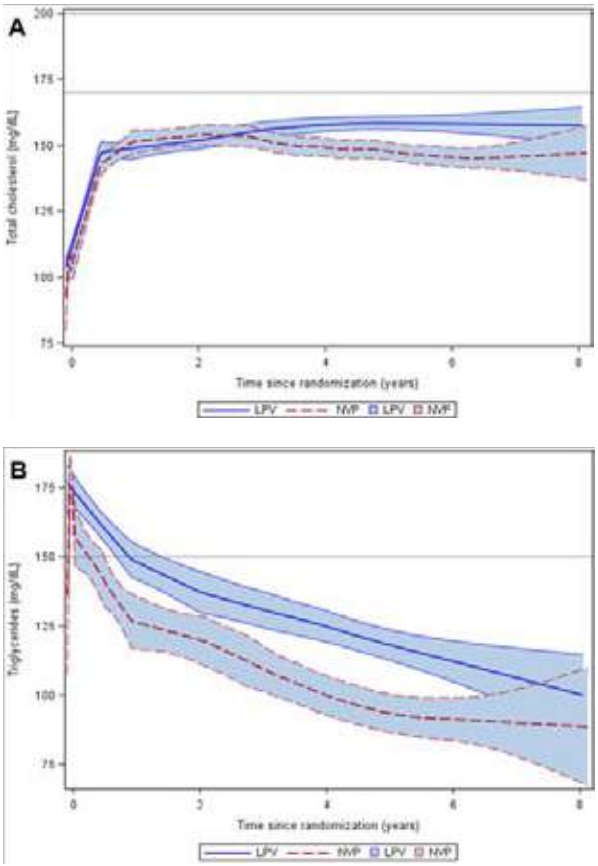
Background: A lopinavir/ritonavir (LPV/r)-based regimen is recommended as first-line therapy for HIV-infected children <3 years of age. The long-term implications of using LPV/r-based regimens among young children on lipid parameters are unknown.
Methods: 451 HIV-infected children, enrolled at 2-36 months of age from six African countries and India and randomized to initiate zidovudine, lamivudine, and either nevirapine (NVP) or LPV/r in the P1060 trial were included. Linear and

log-binomial regression models estimated differences by randomized arm in mean cholesterol and proportions of participants with high/borderline cholesterol (≥170 mg/dL) and high triglyceride (>150 mg/dL) measures, respectively. An intention to treat approach was used.
Results: Median duration of follow-up was 5.7 and 5.6 years for LPV/r and NVP, respectively. After treatment initiation, total cholesterol increased dramatically for up to 6 months, followed by more gradual trends over the rest of follow-up, while triglycerides continually decreased over follow-up (Figure). No difference was observed between LPV/r and NVP in total cholesterol during the first year, but total cholesterol was significantly higher with LPV/r between 4 and 6 years of follow-up (relative difference (95% confidence interval (CI)): Year 4: 13.5 (5.8, 21.2), Year 5: 8.4 (1.4, 15.3), Year 6: 16.6 (8.2, 25.0)). There were significantly higher risks for high/borderline cholesterol with LPV/r compared to NVP between 4 to 6 years of follow-up (relative risk (95% CI): Year 4: 1.8 (1.2, 2.7), Year 5: 1.7 (1.2, 2.4), Year 6: 2.4 (1.5, 3.9)). Significantly higher risk of high triglycerides with LPV/r compared to NVP was only observed during years 1 and 4 of follow-up.
Conclusions: Initiating LPV/r was associated with higher total cholesterol after prolonged follow-up compared to initiation of NVP. Our results are consistent with known effects of protease-inhibitors on hyperlipidemia and suggest monitoring for lipid parameters over time among children who initiate LPV/r globally.



[Figure. LOESS fit plots with 90% confidence bands for total cholesterol (A) and triglycerides (B) over follow-up randomized treatment]

TUPEB0449

Growth among HIV-infected adolescents followed-up in the paediatric IeDEA West African collaboration: evolution and association with adverse outcomes (death or loss-to-follow-up)

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Background: We assessed growth evolution and its associated factors among adolescents enrolled in the paediatric IeDEA West African cohort (pWADA), and explored the association between growth and adverse outcomes using a joint modeling approach.
Methods: We included all HIV-infected children aged 10-15 years, with at least one available measure of weight and height, and initiated on ART before 10 years. Growth was described using Body-Mass-Index (BMI)-for-age Z-score (BAZ), according to the WHO Child Growth Standards. Correlates of growth evolution were studied using a linear mixed model (1) and a survival model (2) described time to death or lost-to-follow-up (LTFU, last contact>6 months) since age 10 (baseline time). We assessed the effect of BAZ value and slope over time on the risk of death and LTFU among HIV-infected adolescents using a joint model combining models 1 and 2.
Results: Between 2005 and 2015, 1860 children were included. Median age at last visit was 12.3 years (InterQuartile Range [IQR] = 10.9-14.3). At baseline, 54% were boys, 18% were wasted (BAZ< -2 SD), 26% stunted, 16% had severe immunodeficiency (CD4 cell count< 350 cells/mL), and 62% initiated ART between ages 5 and 10. Between 10 and 15 years, 4% died and 11% were LTFU. BAZ decreased significantly, of -0.06 SD by month, with a more important decrease for males, non-wasted and stunted children at baseline (model 1). Probability of death was higher for severely immunodeficient and malnourished children at baseline (model 2). In the joint model, probability of death was higher when BAZ value decreased by one unit (associated Hazard Ratio [aHR] = 2.2, Confidence Interval [CI] 95% = 1.7-2.9) and when BAZ slope decreased (p=0.011). However, probability of LTFU was not associated with growth evolution.
Conclusions: Malnutrition was associated with a higher risk of death among ART-treated adolescents, independently of their HIV-disease progression. A joint modelling approach could investigate association between growth and other adverse events (CD4 drop or viral rebound). Growth needs to be monitored in the absence of viral load, and a decrease of growth could be a marker for guiding pediatric HIV care in resource-limited settings.

TUPEB0450

High-risk of liver fibrosis among HIV-infected youth with chronic viral hepatitis B coinfection despite receiving tenofovir-containing antiretroviral regimen

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Background: HIV and Hepatitis B (HBV) coinfection is associated with risk of progression to chronic liver disease. This study aims to determine the risk of liver fibrosis and long-term treatment outcomes of tenofovir (TDF)-containing antiretroviral therapy (ART) regimens in HBV/HIV coinfected youth.
Methods: A cross-sectional study was conducted among HIV-infected youth between 15-25 years. Inclusion criteria were
1) chronic HBV-HIV infection, and
2) received a TDF-containing ART regimen for ≥96 weeks.
Measurements included HBV DNA by Abbott® real-time PCR assay, HBV serolo-

gy profiles, liver function tests, and transient elastography (TE). The cut-off for TE results included ≥5.9 Kpa for F2-moderate fibrosis, ≥7.4 KPa for F3-severe fibrosis, and ≥ 9.6 KPa for F4-cirrhosis. AST-to-platelet ratio index (APRI) and FIB-4 index were calculated as markers of liver fibrosis.
Results: From March-December 2016, 15 HBV-HIV-infected adolescents with median (interquartile range, IQR) age of 23.0 (19.8-24.4) years were enrolled. At a median (IQR) duration on TDF of 172 (136-200) weeks, 14 (93%) achieve HBV DNA levels <200 IU/mL. Five of the 6 (40%) patients who hadd HBV DNA <10 IU/ml became HBsAg and HBeAg seronegative; all five had normal ALT; none had liver fibrosis. There were 5 patients (33%) had significant liver fibrosis: 3 (20%) had F2-moderate fibrosis, 1(6%) had F3-advanced fibrosis, and 1(6%) had cirrhosis. Only the one with cirrhosis had high ALT (110 IU/L), and abnormal APRI and FIB-4. Characteristics of study participants are shown in Table1.

[Table 1. Comparison of characteristics between groups of patient with HBsAg seroconversion, HBsAg serpositive without liver fibrosis, and presence of liver fibrosis]

Conclusions: One-third of Thai HIV/HBV-infected youth on TDF-containing ART for ≥96 weeks had significant liver fibrosis. TE to evaluate risk of liver fibrosis/cirrhosis should be advised for youth with co-infection, in particular, for those who did not achieve HBV <10 IU/ml on TDF-containing ART, or had abnormal liver biomarkers. More intensive monitoring and consultation with hepatologist might be warranted.

TUPEB0451

Insulin resistance in South African perinatally HIV-infected adolescents on antiretroviral therapy: a cross-sectional study

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Background: Access to antiretroviral therapy (ART) has reduced morbidity and mortality in perinatally HIV-infected (PHIV) children, but metabolic complications of ART including insulin resistance (IR) in adolescents are poorly understood.
Methods: We evaluated IR in a cross-sectional analysis of PHIV and HIV-uninfected adolescents enrolled in the Cape Town Adolescent Antiretroviral cohort (CTAAC). Adolescents 9-14 years old and on ART for >6 months were eligible. The Homeostatic Model Assessment (HOMA) was used to assess IR calculated from fasting insulin and glucose measurements at enrollment. IR was defined as HOMA >2.5 for pre-pubertal and >4.0 for pubertal adolescents. Multiple linear regression was used to examine adjusted associations between HOMA and both HIV-related and traditional cardiovascular risk factors.
Results: Of 403 adolescents, 356 were PHIV. Median age was 12.1 (IQR:10.7-13.3) years for PHIV and 11.5 (IQR:9.9-13.1) for uninfected adolescents. 49% of PHIV and 60% of uninfected adolescents were female. Median duration on ART was 7.5 (IQR:4.7-9.2) years with 123 (35%) of PHIV adolescents starting ART between 0 -2 years of age, 97 (27.6%) between 3-5 years and 131 (37.3%) between 6-14 years of age. The most common regimens included Abacavir (72%) and Lopinavir/ritonavir (59%). Median triglycerides were 79.7 mg/dl (IQR: 62.0-106.3) in PHIV and 62.0 mg/dL (IQR:44.3-70.9) in uninfected controls (p< 0.0001). Median waist circumferences were 61cm (IQR:58-66) and 62.5cm (IQR: 57-70) for PHIV and uninfected adolescents. Overall, 20.1% had IR, but rates of IR did not differ between groups or by duration of ART exposure. Among PHIV adolescents, waist circumference (ß=0.007, p=0.035), hypertriglyceridaemia (ß=0.074, p=0.013), and ever use of Abacavir (ß=0.071,p=0.022), were associated with increased HOMA, while viral load >1000 copies/mL (ß= -0.062, p=0.013) was associated with decreased HOMA after adjusting for age, gender, body mass index and Tanner stage.
Conclusions: : In a South African cohort of PHIV adolescents, IR did not appear significantly different from uninfected adolescents.In addition to traditional risk factors such as waist circumference and hypertriglyceridaemia, Abacavir exposure may be associated with increased HOMA, and this finding needs further exploration.

TUPEB0452

Malnutrition, growth response and metabolic disorders within the first 24 months of ART initiation in HIV-infected children treated before the age of two years in West Africa

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Background: Healthcare of HIV-infected children in resource-limited settings faces several challenges, which one of them is malnutrition. We described baseline malnutrition, growth evolution and metabolic disorders within the first 24 months of antiretroviral therapy among children initiated on ART < 2 years in Burkina Faso (BF) and Côte d'Ivoire (CI).
Methods: HIV-1-infected children < 2 years were initiated on a LPV/r based-ART for 12 months, before randomization in a simplification trial. Weight-for-age, Height-for-age and Weight-for-height Z-scores (WAZ, HAZ, WHZ) defined malnutrition (Z-score < -2 Standard Deviations [SD]), using WHO growth references. Malnutrition at baseline was studied using a multivariate logistic regression and growth evolution within the first 24 months of ART using linear mixed models. Biological data were collected every 6 months and MacNemar and students tests for paired samples were used to compare rates between ART initiation (baseline) and 6, 12 and 24 months of ART.
Results: Between 2011 and 2013, 161 children were enrolled: 64% were from Abidjan, 54% were girls. At baseline, median age was 13.6 months [IQR 7.7; 18.4], 53% were underweight (WAZ), 51% stunted (HAZ), and 36% wasted (WHZ). Overall, malnutrition at baseline was more likely for children living in BF vs CI, those never breastfed, the oldest (12-24 months), and with a low birth weight. Growth improvement occurred mainly within the first 6 months on ART and was greater for the most severely malnourished children at baseline, but 8% (wasting) to 32% (stunting) remained malnourished after 24 months. ART initiation was associated with an increase of hypercholesterolemia (38% at 24 months vs 8% at baseline, p< 0.001) and a decrease of anemia (21% at 24 months vs 74% at baseline, p< 0.001) and hypoalbuminemia (0% at 24 months vs 50% at baseline), with no difference according to the initial nutritional status.
Conclusions: Prevalence of malnutrition was high at ART initiation. Even if growth improved, a part of children remained malnourished after 2 years on ART, highlighting the need of nutritional supplementation. Lipid disorders were observed, which is concerning and need to be monitored carefully to reduce the long-term cardiovascular risk, especially among children in a lifelong therapy process.

TUPEB0453

Case report: disseminated histoplasmosis in an HIV-infected child in the southern highlands zone of Tanzania

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Background: Histoplasmosis is an uncommon opportunistic infection in HIV positive children. The most common form is primary disseminated histoplasmosis, characterized by persistent fever and failure to thrive. We present a case of disseminated histoplasmosis with a unique presentation of ulcerated skin lesions and a violaceous facial rash.
Methods: Retrospective chart review of patient´s medical file.
Results: A 10 year old HIV positive girl presented to the inpatient malnutrition ward at Mbeya Zonal Referral Hospital in Mbeya, Tanzania with ulcerated scalp lesions, facial rash and subcutaneous nodule (Figure 1). She had persistent fevers, severe acute malnutrition and severe anemia. At diagnosis, the patient was failing first line antiretroviral therapy (ART) with a CD4 of 24 cells/μL and VL of 196,658 cp/mL. The patient was changed to a second line ART regimen (ABC-3TC-LPV/r), received nutritional support, blood transfusions, multiple antibiotics and meticulous wound care.
Biopsy of a lesion showed intracytoplasmic organisms consistent with histoplasmosis. The patient was treated with conventional amphotericin B and received a total of 20mg/kg. Amphotericin B infusions. Following amphotericin, a repeat biopsy showed clearance of organisms and the patient was transitioned to oral itraconazole. However, after 3 weeks of oral itraconazole, the patient had clinical and histological relapse. She resumed amphotericin B and received an additional 30mg/kg with clinical improvement of the scalp wounds at which point she was again transitioned to itraconzole with ongoing slow improvement. After 3 months of second line ART, her CD4 was 160 cells/μL and VL of 35 cp/mL.

[Figure 1]

Conclusions: We describe a case of disseminated histoplasmosis presenting with large scalp wounds which was treated with amphotericin B and itraconazole. Diagnosis of histoplasmosis is difficult in the resource limited setting and histopathology support is essential. Histoplamosis should be considered in the differential diagnosis of the immunocompromised host with unusual skin manifestations and persistent fever.

TUPEB0454

Maternal perinatal HIV infection is associated with increased risk for hospitalizations due to infectious causes in HIV-exposed uninfected infants in a New York City tertiary center

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Background: Infectious morbidity in HIV-exposed uninfected (HEU) infants has been described. Few studies have evaluated this in HEU infants born to perinatally HIV-infected (PHIV) women.
Methods: HIV-infected and -uninfected pregnant women were enrolled in a prospective cohort in the U.S. between September 2009-2015. We evaluated the prevalence of hospitalization due to an infectious cause during the first year of life (HDIC) in HEU and HIV-unexposed uninfected (HUU) infants of these women. Maternal HIV status was categorized as PHIV vs. non-perinatally HIV-infected (NPHIV) vs. HIV-uninfected. Data on socio-demographics, maternal HIV clinical markers, antiretroviral therapy during pregnancy, mode of HIV acquisition, infant birth outcomes, and HDIC were collected. Generalized Estimating Equation modeling was used to evaluate the effect of maternal HIV status on infant HDIC.
Results: Of 205 evaluable infants, 28 were HEU born to PHIV women (HEU-P), 112 HEU born to NPHIV women (HEU-N), and 65 HUU. PHIV women were younger compared to NPHIV and HIV-uninfected women (median age 22 years vs. 29 and 23 respectively, p< 0.01). Amongst HIV-infected women, PHIV women were more likely to have a CD4 nadir < 50 cells/mm^3 during pregnancy (25% vs. 1%, p< 0.01). HEU-N infants were more likely to be in the custody of someone other than the biological mother in the first year of life compared to HEU-P and HUU infants (17% vs. 14% and 2%, p< 0.01). Overall, 18% of HEU-P, 4% of HEU-N and 12% of HUU infants had HDIC (p< 0.01). After adjusting for maternal age, education, black race, substance use during pregnancy, infant small-for-gestational age, prematurity, infant custody by someone other than biological mother, and infant outpatient visits during the first year of life, HEU-P infants were at increased risk for HDIC compared to HEU-N infants [adjusted odds ratio (aOR)=3.97, 95% Confidence Interval (CI):1.02-16.39]. In sub-group multivariable analysis of HEU infants, this relationship persisted after additional adjustment for maternal CD4 and HIV RNA level (aOR=7.73, 95% CI:1.67-63.30).
Conclusions: In our small cohort, HEU-P infants were at increased risk for HDIC. Differences in intrauterine environments, social factors, or access to care may be important factors to assess in future larger studies.

TUPEB0455

Long-term developmental outcomes and *in utero* antiretroviral exposure in HIV-exposed uninfected (HEU) children born to mothers living with HIV in British Columbia (BC), Canada

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Background: Over 1.4 million children worldwide and more than 200 children in Canada are born annually to mothers living with HIV, with an increasing proportion exposed to ARVs in utero during early development. Concerns exist on potentially adverse immunological, neurodevelopmental and mitochondrial effects from long-term ARV treatment; sociodemographic factors and adverse childhood experiences may also be involved. We previously reported a concerning prevalence of autism spectrum disorder in HEUs within the CARMA cohort. Here, we aimed to compare frequencies of neurodevelopmental disorders among HEU children born in BC and examine possible associations with exposure to maternal ARVs.
Methods: Data on 446 HEU children and 1323 HIV-unexposed uninfected (HUU) children (matched ~1:3 for age, sex and geocode) born between 1990 and 2012 were collected by Population Data BC from several data holdings including the BC Ministry of Health's Medical Services Plan (ICD9/ICD9-CM), Perinatal Services BC, and ARV treatment information housed at Oak Tree Clinic.
Results: One or more of the following developmental disorders: autism spectrum disorder, disturbance of emotions, hyperkinetic syndrome, developmental delay, intellectual disability, and/or epilepsy were diagnosed in 30% of our HEU cohort compared to 13% in the matched HUU cohort ($p< 0.0001$). Of 369 HEUs with any ARV exposure in utero, 101 (27.4%) had a disorder: a lower proportion ($p< 0.01$) than expected assuming no association between in utero ARV exposure and developmental disorders. Compared to HUUs, HEU children had higher relative risks of autism spectrum disorder (RR=2.97, p=0.02), disturbance of emotions (RR=2.76, $p< 0.0001$), hyperkinetic syndrome (RR=2.97, $p< 0.0001$), and developmental delay (RR=3.08, $p< 0.0001$), but no increased risk of medical conditions such as asthma (RR=1.01, p=0.89) or neoplasms (RR=0.68, p=0.06). The HEU cohort showed higher proportions of exposure to maternal smoking ($p< 0.0001$) and alcohol consumption ($p< 0.0001$) during pregnancy.
Conclusions: Our data suggest a possible reassuring association between ARV exposure in utero and neurodevelopmental disorders within our HEU cohort. HEU children in BC may be at a nearly three-fold higher risk for several neurodevelopmental disorders compared to matched HUUs. Our results highlight the need for careful developmental monitoring and access to early interventions to optimize neurodevelopment for at-risk HEUs.

TUPEB0456

The population effect of HIV exposure without HIV-infection on infant hospitalizations and mortality in Botswana and South Africa

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Background: With successful prevention of maternal-child HIV transmission but stagnant antenatal HIV prevalence, the population of HIV-exposed uninfected (HEU) infants accounts for >20% of the infant population in Botswana and South Africa. HEU infants are at greater risk of mortality and morbidity than HIV-unexposed (HU) infants, with these trends persisting despite maternal antiretroviral therapy and uptake of safer breastfeeding. We aimed to quantify the contribution of excess HEU infant morbidity and mortality at a population-level in Botswana and South Africa.
Methods: The attributable fraction (AF), population attributable fraction (PAF) and annual excess hospitalizations and mortality due to HIV-exposure without infection were estimated using published estimates of relative risk (RR) for infant hospitalization and meta-analysis estimates of RR for mortality in HEU compared to HU infants. 2013 UNICEF infant mortality rate (IMR) estimates for Botswana and South Africa were used to calculate excess infant mortality.
Results: At a RR of 1.5 for hospitalization in HEU relative to HU infants, AF in HEU infants was 33.3% and PAF at an HIV exposure prevalence of 23% in South Africa and 26% in Botswana were 10.3% and 11.5% respectively. In South Africa, an excess 13,660 of 132,000 hospitalizations in HIV-uninfected South African infants annually could be due to HIV-exposure after removing baseline risk for hospitalizations in all HIV-uninfected infants. Similarly, in Botswana 683/5,935 hospitalizations annually could be excess hospitalizations in HEU infants. At a RR of 1.70 for mortality in HEU compared to HU infants, AF of mortality in HEU infants was 41.2% and PAF was 13.9% in South Africa and 15.4% in Botswana. At an IMR of 33/1000 in South Africa and 36/1000 in Botswana, assuming 8% of infant mortality is associated with infant HIV-infection, HIV-exposure without HIV-infection could increase the IMR by 4.2/1000 in South Africa and 5.1/1000 in Botswana.
Conclusions: With the high prevalence of infant HIV-exposure in Southern Africa, at a population level the contribution of HIV exposure without infection to mortality is possibly exceeding that of infant HIV-infection. This threatens achievement of optimal health and well-being of Southern African infants despite tremendous efforts to avoid HIV-infection in this population.

TUPEB0457

Moving beyond PMTCT: HIV, ART and adverse birth outcomes in a Zambian pregnancy cohort

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Background: HIV and its treatment have been associated with adverse birth outcomes (ABOs), however, many studies lack ultrasound dating and do not account for important obstetrical risk factors, including cervical length. We present data from an ongoing prospective cohort study of preterm birth in Lusaka, Zambia.
Methods: We used logistic regression to assess the association between HIV and several ABOs: preterm birth <37 weeks (PTB); low birthweight <2500g (LBW); small-for-gestational age (SGA; <10th percentile); *composite* of PTB, LBW, stillbirth (SB) and SGA; very PTB <34 weeks (VPTB); very LBW <1500 g (VLBW); very SGA (VSGA; <3rd percentile) and *severe composite* of VPTB, VLBW, SB, and VSGA. All women had early ultrasound for dating and an evaluation of cervical length in the mid-trimester. HIV+ women received ART (predominately TDF/FTC/EFV). We treated timing of ART commencement (before/after conception) as a covariate.
Results: Between August 2015 and December 2016, we enrolled 962 women, of whom 410 have delivered. Characteristics are as follows: median age 27 yrs (IQR: 23, 32); median BMI 24.4 kg/m2 (IQR: 21.6, 27.9); 134 (34%) were nulliparous; 225 (24%) were HIV+; 29 (2.9%) had twins gestation; 11 (2.8%) had cervical length <20mm ("short cervix"). The following were associated with the **composite outcome** in multivariable analysis: prior PTB (AOR:1.9; 95%CI: 1.0, 3.8), twin gestation (AOR: 6.0; 95%CI: 1.5, 24), and short cervix (AOR: 7.4; 95%CI 1.7, 32). HIV infection trended toward association (AOR: 1.7; 95%CI: 0.73, 4.1). The factors were associated with the *severe composite outcome* in multivariable analysis: twin gestation (AOR: 7.2; 95%CI: 1.7, 31), vaginal bleeding at enrollment (AOR: 3.2; 95%CI: 1.2, 8.1), and short cervix (AOR: 9.2; 95%CI 2.1, 33). HIV infection trended toward association (AOR: 2.5; 95%CI: 0.86, 7.4). Among the HIV+ women, timing of ART commencement was not associated with any individual outcome or either composite outcome.
Conclusions: The known risk factors of prior PTB, short cervix, and twin gestation are associated with ABOs in this population. There is also a worrying trend between HIV and ABOs. Timing of ART commencement does not appear to affect PTB or other ABOs in this cohort.

TUPEB0458

Risk of mortality and hospitalization among HIV-exposed uninfected Ugandan infants in the setting of Option B+

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Background: V-exposed uninfected children (HEU) have an increased risk of mortality compared to HIV-unexposed uninfected children (HUU). It remains unclear whether this risk persists in the setting of the Option B+. In parallel birth cohorts of HEU and HUU from Uganda, we assessed the association between HIV-exposure and mortality and hospitalizations.
Methods: We evaluated children enrolled in the PROMOTE II birth cohorts from 0-12 months who were participating in a trial on dihydroartemisinin-piperaquine (DP) for malaria chemoprevention. Outcomes assessed were: mortality, hospitalization, and a composite of hospitalization and death. We excluded death and hospitalizations within 48 hours of life, and outcomes attributed to malaria. All HIV-infected mothers received combination antiretroviral therapy (cART) per Option B+, and were advised to breastfeed for at least 1 year. Generalized estimating equation regression models were used to assess risk. Models were adjusted by preterm birth (<37 weeks) age and wealth tertiles, unless specified. Models were not adjusted for breastfeeding, due to insufficient non-breastfeeding person time.
Results: 196 HEU (181 person-years) and 287 HUU (278 person-years) were included, and accrued from October 2014-December 2016. 9.1% of the HEU and 7.7 % of HUU children were preterm, p=0.60. By 1 year of age 99.6% of HEU and 98.5% HUU were breastfeeding. Among HIV-infected mothers, at delivery the median CD4 count was 571 (IQR 403-776) and 96% were virally suppressed (HIV RNA <500 copies/ml). There were 4 (2%) deaths among HEU and 2 (1%) among HUU (RR 2.9, 95% CI: 0.6-16.3, p=0.21, adj. for age). Death and hospitalization was associated with preterm birth (RR 4.4, 95% CI: 1.7-11.3, p<0.01) and there was a trend towards a decreased risk of the composite outcome among HEU (RR 0.4, 95% CI:0.2-1.2, p=0.1) compared to HUU. Hospitalization was associated with HIV exposure (RR 0.2, 95%CI:0.05-0.7, p<0.01), preterm birth (RR 4.6, 95% CI:1.6-12.9, p<0.01).
Conclusions: Contrary to findings from studies conducted prior to Option B+, in this cohort, the risk of mortality and hospitalization was not worse in HEU compared to HUU. Maternal cART, extended breastfeeding, and infant cotrimoxazole prophylaxis may narrow gaps between the health outcomes of HEU and HUU.

TUPEB0459

Neonatal outcomes of pregnancies complicated by HIV: preliminary results of a retrospective matched cohort study from 2004 to 2014

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Background: Pregnancy in HIV-positive women is complicated by medical and psychosocial comorbidities. Despite the breadth of the HIV crisis in the developed world, relatively little is known about these pregnancies in resource rich settings. There is an urgent need to identify the adverse outcomes for which HIV-exposed neonates are at risk.
To test the hypothesis that there would be higher neonatal morbidity associated with HIV-positive pregnancies, we conducted a retrospective matched cohort study of neonatal outcomes of HIV-positive pregnancies at MedStar Washington Hospital Center (MWHC).
Methods: We included all pregnancies complicated by HIV and delivered at MWHC from 2004-2014. We excluded multiple gestations and abortions. For each HIV-exposed neonate, we identified two HIV-unexposed neonates, propensity score matched on gestational age at delivery, maternal race, parity, zip-code, and insurance status within a calendar year of delivery.
Data collection is still ongoing. We used chi-squared and fisher's exact tests for categorical variables and t-tests for continuous variables.
Results: We identified 433 HIV-exposed neonates and 866 controls. 433 HIV-exposed neonates and 514 HIV-unexposed neonates were included in this preliminary analysis. Mean maternal age was 27 years; mean gestational age was 38 weeks. The majority were African-American (88%). Mother-to-child transmission of HIV was 2.5% (80.1% in-utero).
In HIV-exposed neonates, we found more intra-uterine growth restriction on prenatal sonogram (7.4 vs. 1.5%, p<0.001) and low birth weight (12.1 vs. 6.4%, p=0.005) compared to controls. There were increased neonatal intensive care unit (NICU) admissions (27.8 vs. 14.7%, p<0.001) among HIV-exposed neonates. We observed increased neonatal respiratory distress syndrome (9.2 vs. 5.2%, p=0.027), need for continuous positive airway pressure (8.4 vs. 4.6%, p=0.027), and intubation (7.1 vs. 3.1%, p=0.009) in HIV-exposed neonates. Although proportions of jaundice were similar, HIV-exposed neonates were more likely to require phototherapy (11.6 vs. 8.5%, p=0.037). We also observed increased hypoglycemia (15 vs. 6.7%, p<0.001).
Conclusions: This is the largest single-site cohort of HIV-exposed neonates in the United States. Our study found that HIV-exposed neonates had increased NICU admission, low birth weight, respiratory morbidity, hypoglycemia, and jaundice requiring phototherapy. Further analysis is needed to explore associations with maternal comorbidities, such as substance abuse and HIV disease status, and prenatal maternal antiretroviral therapy.

TUPEB0460

Readiness of youth living with HIV for long-acting antiretrovirals

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Background: Youth 13 to 24 years old comprise 26% of all incident US HIV infections, and are a high-risk group for non-adherence to antiretrovirals (ARV). Long-acting parenteral nanoformulated ARV (LA-ARV), now in phase-3 studies, may improve clinical outcomes in this group. However, little is known about the readiness of youth living with HIV (YLHIV) to adopt and adhere to LA-ARV technologies. We examined attitudes to LA-ARV in a mixed cohort of youth with perinatally- and non-perinatally-acquired HIV (PHIV and NPHIV, respectively).
Methods: A cross-sectional survey study of a purposive sample of 256 YLHIV followed at 4 HIV clinics in Baltimore, MD, Atlanta, GA, and Memphis, TN, to determine interest level in LA-ARV. A modified survey instrument previously used in adults was employed. Interest level across groups was compared using Mantel-Haenszel c^2 tests. Multivariable logistic regression was used to determine the impact of various characteristics on interest and enthusiasm level for LA-ARVs.
Results: Respondents were 67% male, 3% male to female transgender; 87% African-American, 8% Hispanic, and 5% Caucasian. The median age and number of years living with HIV was 22 (range 13-24) and 3 years (range 1 month to 24 years), respectively. The most common modes of HIV acquisition were male-to-male sexual contact (148/252 (58.7%) and PHIV (64/252 (25.4%). The proportion of YLHIV that probably/definitely would try LA-ARV regularly injected intramuscularly was 87% [219/252 overall; 56/64 (87.5%) PHIV vs. 148/172 (86%) NPHIV]. Willingness to use increased with lower frequency of injections. The proportion of YLHIV who would probably/definitely try a surgically-placed subdermal implant of slow-release LA-ARV was 77.1% [192/249 overall; 50/64 (78.1%) PHIV vs. 128/169 (75.7%) NPHIV]. There were no significant differences in probable or definite willingness to use by route of infection, age, or gender.
Conclusions: YLHIV at 4 urban US pediatric/adolescent HIV clinics had a high level of enthusiasm for LA-ARV. These observations may be important given the high rates of attrition in care and nonadherence of this vulnerable group. LA-ARV should be given high priority as a potentially viable treatment option to improve clinical outcomes in HIV-infected youth.

TUPEB0461

What should we do when HIV-positive children fail first-line combination antiretroviral therapy (cART)? A comparison of 4 ART management strategies

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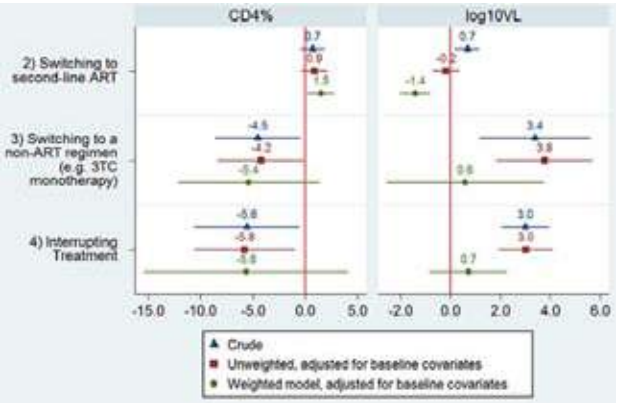
Background: Virologic failure (VF) in HIV-infected children is difficult to manage in resource-limited settings, given limited availability of alternative drugs and concerns around adherence and the development of viral resistance. We aimed to evaluate four management strategies for children following their first episode of VF by comparing their immunologic and virologic outcomes.
Methods: Children (age < 16 years at cART start) with VF, defined as having ≥2 consecutive unsuppressed viral loads (>1000 copies/ml) ≥1 month apart after ≥6 months on cART (at least 3 anti-retroviral drugs from at least 2 drug classes), were followed from their first episode of VF, starting from their second unsuppressed viral load (VL). Children from 8 IeDEA-SA cohorts initiating ART between 2004-2010, with recorded CD4% at VF, and with ≥1 subsequent CD4% were included. Children with VF followed one of four management strategies: 1) Continuing on their failing regimen with at most 1 same-class drug substitution; 2) Switching to a new cART regimen based on guidelines or resistance testing; 3) Switching to a holding regimen, either lamivudine monotherapy or other non-cART regimen; 4) Discontinuing all anti-retrovirals. We compared the effect of management strategy choice, relative to strategy 1, on both the 52-week change in CD4% and $\log_{10}$VL from VF, using the inverse probability weighting of a marginal structural linear model.
Results: We followed 982 patients over 54168 patient-weeks, during which 73%, 24%, 1% and 2% was spent on strategies 1, 2, 3 and 4 respectively. All patients started on strategy 1, 557 remained on strategy 1, 335 switched to strategy 2, 25 to strategy 3 and 65 to strategy 4.



[Figure 1. Estimating change in CD4% and log viral load at 12 months after virologic failure compared with continuing on a failing regimen, from crude, unweighted and weighted generalised linear models]

Conclusions: Consideration should be given to switching children failing first-line ART to a new regimen early, given the improved virologic and immune responses when compared with all other strategies. These results should guide clinicians when managing VF in children.

TUPEB0462

Prevalence, factors and preferred HIV-diagnosis disclosure methods among adolescents living with HIV: a mixed methods study

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Background: To date, low-resource settings have no substantive method of disclosure of HIV-diagnosis for adolescents. The study objective was: to measure, characterize and use adolescents' living with HIV (ALHIV) perspectives to derive a preferred method of disclosure of HIV-diagnosis among adolescents attending St Francis Hospital Nsambya Home Care, Kampala, Uganda.
Methods: A mixed method research design was used: a cross-sectional study was conducted among 341 randomly selected ALHIV using interviewer-administered questionnaires on sociodemographic and HIV-related characteristics. The relationship between sociodemographic and HIV-related characteristics, and dependent variable ALHIV disclosure status was analyzed in univariate and logistic regression using odds ratios: 95 % confidence interval and p-value at 0.05. To explain the important quantitative results, we conducted six focus groups each of five purposively selected ALHIV, caregivers and health care providers, total 30 participants. The interview guide had questions on "how disclosure of HIV-diagnosis ALHIV should be carried out?" We used line-by-line coding, labelled concepts from content, defined and developed categories based on their properties and dimensions to interpret the disclosure methods.
Results: Overall 341 ALHIV were enrolled: 51.2% females, mean age 15 years (SD+/-3yrs), 73.4% (248 of 338) who responded to disclosure questions, knew their HIV-diagnosis. Adolescents who knew their own HIV-diagnosis were: older (aOR 7.20, 95% CI: 3.58-14.51) p =0.000), orphans (aOR 2.5, 95% CI: 2.21 (1.15-4.24)p =0.016), self-medicating (aOR 0.39, 95% CI: 0.16-0.92, p=0.03), and had attended adherence-related workshop (aOR 4.30, 95% CI: 2.17-8.53, p =0.000). The emerging themes on method of disclosure were: adolescent's psychological age, address caregiver's emotional readiness and a supportive by health care system.
Conclusions: The prevalence of ALHIV who knew their own HIV-diagnosis was high compared to the figures in other low-income countries. Factors favouring disclosure were adolescent's individual and facility level characteristics. Our findings support the following method of disclosing HIV-diagnosis to adolescents: the healthcare provider should screen the ALHIV for disclosure using: age, orphan-hood, self-medication, and attendance of adherence-related workshop. Then identify and address caregiver's fears and communication skills, and the healthcare provider should be ready to support the disclosure process.

TUPEB0463

First line antiretroviral treatment outcomes and durability in HIV-infected children treated through the universal coverage health program in Thailand

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Background: The universal coverage health care program (UC), managed by the National Health Security Office (NHSO) since the end of 2007, has been providing HIV treatment and care for more than 70% of the Thai HIV-infected population. In 2014, 4,502 HIV children were receiving antiretroviral therapy (ART) through UC. We assessed the treatment outcomes on first-line antiretroviral therapy (ART), and factors associated with switching regimen in HIV-infected children treated through the UC in Thailand.

Methods: Children aged <15 years at ART initiation who had been receiving ART for at least 6 months between 2008 and 2014 through UC were included in the analysis. The Kaplan-Meier method was used to estimate immunological recovery (IMR), immunologic failure (IMF) and virologic failure (VF). Cox models were used to assess predictors of IMR and VF. Competing risk models were used to assess factors associated with switching to a second-line regimen, with death considered as a competing risk.
Results: A total of 4,120 children initiated ART at a median (IQR) age of 9.3 (5.8-12.0) years. The median duration of ART was 3.7 years with 17,950 person-years of follow up. 2,805 children achieved IMR and the probability of IMR increased to76% by 3 years after ART initiation. Among 1,054 children switched to second-line regimens; 84% had VF and 19% had IMF. The cumulative rate of switching regimen increased from 4% to 20% from 1 to 3 years after treatment. Children aged ≥12 years at ART initiation (≥ 12 vs 5-<9 years, aSHR 1.33, 95%CI 1.12-1.57), starting with NNRTIs (NNRTIs vs PI years, aSHR 1.61, 95%CI 1.23-2.12), and baseline CD4% <10% (<10% vs ≥16%, aSHR 1.48, 95%CI 1.22-1.79) had an increased risk of switching to second-line regimens.
Conclusions: Children receiving ART through UC had good treatment outcomes, although a fifth required switching regimen by 3 years. Earlier treatment initiation and avoiding NNRTIs first-line regimens in high risk children may prevent treatment failure.

TUPEB0464

High proportion of virological failure and drug resistance among adolescents on first-line ART in Chiradzulu district, Malawi

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Background: Adolescent are a growing proportion of the HIV-infected population in sub-Saharan Africa, mostly comprised of perinatally infected children who survived on ART. Nonadherence and drug resistance development are considered a particular challenge to this patient-group. We assessed virological response to first-line ART and drug resistance among adolescents receiving treatment in a decentralized HIV-programme supported by Médecins Sans Frontières in rural Chiradzulu District, Malawi. Routine VL monitoring was implemented in this programme by end of 2013.
Methods: Between May-November 2016 a cross-sectional assessment was conducted among HIV+ patients (10-19 years) receiving standard first-line ART for ≥ 6 months. Participants were recruited from five decentralized health centers and the district hospital outpatient-clinic. Plasma viral load (VL) was assessed with SAMBA-VL test (semi-quantitative, 1000 HIV RNA copies/ml) and by quantitative VL-method (Biocentric). Resistance-genotyping was performed if VL ≥500 copies/ml, and sequences interpreted by Stanford algorithms for drug resistance mutations.
Results: 409 adolescents (median age 13 years, 57% females) were included after a median time of 6.7 years (IQR: 3, 14.3) on ART (85% AZT/3TC/NVP, 10% TDF/3TC/EFV). One-hundred-and-twenty-nine (31.5%) had SAMBA VL detectable (≥ 1000 copies/ml), with a median CD4 of 552 cells/ml (IQR: 350, 785) among virological failures and 776 (IQR: 636, 1029) among non-failures (p< 0.001), and 98% current clinical stage 1. Currently available resistance results (46/129) revealed 87% (40/46) dual drug-class resistance, 87% 3TC, 96% NVP and 76% EFV resistance (all major). Seventy-six percent remained susceptible to TDF, and 63% to AZT. Complete VL and resistance data will be presented.
Conclusions: Nearly one-third of adolescents on first-line ART had virological failure. Overall clinical condition was good, though CD4 counts were significantly lower among failures. Currently available resistance data indicate that most were on a failing regimen equivalent to a mono-therapy, requiring prompt switch to second-line. Early and regular VL-monitoring and a robust once-per-day first-line should be considered to prevent major resistance accumulation in children and adolescents.

TUPEB0465

Reproductive health, social life and future plans of adolescents born with HIV: a case-control study in Thailand

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Background: Thanks to antiretroviral treatment (ART), perinatally HIV-infected children now survive into adolescence. This is a period when young people experience puberty, shape their sexual identity, initiate their own social life, and may experiment with sex. Several studies indicate pubertal delay in HIV-infected children. However, few have compared the broad experience of adolescence among HIV-positive and HIV-negative youth. The aim of our analysis was to compare the reproductive health, social life and plans for the future of adolescents born with HIV with a matched control group from the general population.
Methods: We used data from the Teens Living with Antiretrovirals (TEEWA) survey carried out from March 2010 to July 2012 in Thailand among perinatally HIV-infected adolescents aged from 12 to 19, living in family settings. Adolescents completed a self-administered questionnaire focusing on family, schooling, reproductive health and social life. Each adolescent born with HIV (Case) was matched on sex, age and place of residence with a randomly selected adolescent from the general population (Control). Descriptive analysis was stratified by age (above or below 15 years) and performed separately for boys and girls, using McNemar's test for paired comparison.
Results: A total of 1,142 adolescents (571 pairs) were included in the analysis: 666 (58.3%) girls and 476 (41.7%) boys. Compared to the controls, significantly fewer cases had experienced puberty before age 15 (p<0.001). At the time of the survey, they did not differ in terms of sex education, sexual intercourse, romantic relationships or friendships. However, at all ages, cases were less likely to have plans for higher education (p=0.016), marriage (p=0.011) or parenthood (p<0.001).

	Boys				Girls			
	Cases <15 yrs	Controls <15 yrs	Cases ≥15 yrs	Controls ≥15 yrs	Cases <15 yrs	Controls <15 yrs	Cases ≥15 yrs	Controls ≥15 yrs
Experienced puberty	41.2%	64.0% (p<0.001)	79.2%	74.5% (p=0.411)	55.2%	82.6% (p<0.001)	93.1%	98.8% (p=0.013)
Had sex education	78.7%	82.3% (p=0.446)	89.2%	85.3% (p=0.433)	87.8%	87.8% (p=1.000)	95.7%	93.8% (p=0.467)
Had sexual intercourse	0.8%	0.8% (p=1.000)	15.7%	18.5% (p=0.439)	0.6%	0.6% (p=1.000)	7.5%	9.8% (p=0.317)
Had a boy/ girl friend	11.8%	15.4% (p=0.369)	30.4%	39.2% (p=0.149)	9.9%	16.3% (p=0.101)	38.8%	38.5% (p=0.908)
Hang out with friends	53.8%	50.7% (p=0.541)	78.0%	82.2% (p=0.433)	47.1%	51.7% (p=0.352)	70.0%	77.0% (p=0.172)
Plan for high education	31.6%	53.7% (p<0.001)	50.0%	67.7% (p=0.016)	49.4%	75.6% (p<0.001)	65.8%	86.3% (p<0.001)
Plan to marry	26.5%	41.2% (p=0.011)	17.7%	59.8% (p<0.001)	8.1%	22.1% (p<0.001)	17.4%	39.1% (p<0.001)
Plan to have children	15.4%	40.4% (p<0.001)	13.7%	57.8% (p<0.001)	5.2%	17.4% (p<0.001)	12.4%	34.8% (p<0.001)

[Characteristics: cases vs. controls differences]

Conclusions: As WHO is now recommending ART to all HIV-infected children, pubertal delay should be reassessed. For the current generation, additional counselling and psychological support is needed to allow them envision a future with more options.

TUPEB0466

A clinical and neuroradiological study of apathy in HIV-infected South African children

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Background: Apathy is a well-recognised neuropsychiatric symptom in adults with HIV, but there is no research on the phenomenology, neuropsychology and neuroimaging of this symptom in HIV-infected children. The aim of this study was to

examine apathy in HIV-infected children in South Africa and the association with HIV disease progression, cognition and white matter microstructure.
Methods: We investigated apathy in 76 perinatally HIV-infected children in South Africa aged 6 to 16 years, including 63 on antiretroviral therapy (ART) and 13 ART-naïve slow progressors within a cross-sectional study design. We used the Children's Motivation Scale (CMS) to assess apathy severity, a battery of validated neuropsychological tests to assess cognition and diffusion tensor imaging (DTI) to examine white matter microstructure in specific frontostriatal regions-of-interest.
Results: CMS scores were associated with DTI metrics in specific brain regions using bivariate analyses including the anterior limb of the internal capsule, superior corona radiata and the cingulum. Fractional anisotropy, a measure of white matter microstructural integrity, in the anterior limb of the internal capsule remained a significant predictor of apathy when controlling for age, gender and ART use in multiple linear regression analyses (right side beta = -0.32, p=0.02; left side beta = -0.29, p=0.04). Children on ART exhibited less motivation than ART-naïve slow progressors (p=0.02), but CMS scores were not associated with laboratory markers of disease progression or cognition.
Conclusions: Apathy may be an important neurobehavioural symptom in perinatally HIV-infected children, and may reflect changes in white matter microstructure in specific frontostriatal brain regions. As growing numbers of perinatally HIV-infected children progress into adolescence and adulthood, long-term neuropsychological sequelae are becoming increasingly important and apathy may have implications in planning appropriate care.

TUPEB0467

A study of non-disclosure and associated factors among perinatal HIV-infected children and adolescents in Bangkok, Thailand

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Background: Disclosure of HIV status to children is essential for disease management but is not well characterized in resource-limited setting. This study aimed to describe the prevalence of disclosure/non-disclosure and associated factors of non-disclosure in a cohort of perinatal HIV-infected children and adolescents.
Methods: We conducted a cross-sectional study of HIV disclosure status in all perinatal HIV-infected children age ≥ 6 years at HIV-NAT, the Thai Red Cross AIDS Research Centre, Bangkok, Thailand. HIV disclosure status of each child and caregiver were collected by pediatricians by interview children and their caregivers in each scheduled clinic visits during January-December 2016. Descriptive statistics and disclosure prevalence were calculated. Univariate analysis and multivariate logistic regression were performed to assess the association of non-disclosure.
Results: Two hundred thirty six children were enrolled, current median (IQR) age was 18.5 (15.8-20.6) years, 51.6% were female, median CD4 was 663 (491-917) cells/mm^3. Two hundred thirty four (99%) children were using antiretroviral therapy and 78% had plasma HIV RNA <50 copies/ml. One hundred fifty four (65%) children had at least 1 of parents alive and 33 (14%) live in orphanage house.
Prevalence of HIV disclosure was 91% (214/236). Median age at disclosure was 12.1 (10.7-13.7) years. Twenty two (9%) children were HIV non-disclosure. The reasons of non-disclosure were caregiver felt that the child is too young 10 (45%), child had delayed cognitive development (i.e. from HIV encephalopathy) 9 (41%), caregiver is not ready to disclose i.e. not know how to do 2 (9%), and caregiver fear of HIV stigma 1 (5%).
In multivariate regression, factors associated with non-disclosure were age ≤15 years (aOR 22, 95%CI 6.8-70.9, p<0.001), and living in orphanage vs. community (aOR 6.5, 95%CI 1.6-25.7, p=0.01). Other variables such as parent alive and current CD4 were not significantly associated with non-disclosure.
Conclusions: One-tenth of perinatal HIV-infected children and adolescents were non-disclosure in our pediatric cohort. Younger age and living in orphanage were significantly associated with non-disclosure. Health care provider should give more psychosocial support to these children and caregiver in disclosing process.

TUPEB0468

Behavioral and mental health outcomes in the Cape Town Adolescent Antiretroviral Cohort

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Background: The impact of HIV together with antiretroviral therapy (ART) on long term mental health in perinatally infected children has not been well studied.
Methods: The aim of this study was to comprehensively investigate a wide range of mental health outcomes including depression, anxiety, attention deficeit hyperactivity disorder, apathy, disruptive behaviour and functional competence in perinatally infected adolescents stable on ART as part of a prospective cohort study, the Cape Town Adolescent Antiretroviral Cohort. 204 perinatally HIV-infected adolescents (mean age 10.38 years; mean duration of ART 9.11 years; mean CD4 952 cells/mm$^{3;}$ mean viral load of 5205 cells/mL) and a convenience sample of 44 uninfected matched controls aged 9 to11 years were studied. The Beck Youth Inventories, Children's Motivation Scale, Conner's Parent's Rating Scale, Child Behaviour Checklist and Columbia Impairment scale were administered by trained mental health study staff.
Results: The HIV infected group of adolescents were more likely to have had repeated grades at school, caregiver depression, the loss of both biological parents and shorter stature. HIV infected adolescents had poorer functional competence (p=.006), self concept (p=.009), motivation (p=.000), and higher levels of depressive (p=.003) and ADHD symptoms (p=.018), compared to uninfected controls. HIV infected adolescents also had higher rates of clinically significant anger and disruptive behaviour (p=.047 and p=.00) Within the HIV infected group the loss of both biological parents was associated with higher levels of disruptive behaviour (p=.08).
Conclusions: HIV-infected adolescents well controlled on ART have poorer mental health and functional competence with potential impact on learning, school performance and adult health.

TUPEB0469

Psychiatric disorders among HIV-infected adolescents in Montreal, Canada

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Background: The incidence of psychiatric disorders among perinatally HIV infected children who are on effective antiretroviral therapy (ART) is not well known, despite the neurotropic effects of the virus, and concerns about the potential ART associated neurotoxicity. The objective of this study was to document the incidence of psychiatric disorders among perinatally HIV infected children in Montreal.
Methods: Clinical records and the database of the Centre Maternel et Infantile sur le SIDA (CMIS) (Montreal) cohort (1988-2015) were reviewed to identify all children who were diagnosed with a psychiatric disorder according to DSM IV criteria. Patients were excluded if they were followed at CMIS less than 5 years, were non-perinatally infected, were less than 13 years of age at the time of study, or died before the age of 18.
Results: Out of a total of 184 HIV infected children followed at CMIS, 93 met the inclusion criteria. Of these, 8.6% were diagnosed with a psychiatric disorder (psychoses with hallucinations=2, psychosis without hallucinations=1, major depression with suicide attempt=2, major depression without suicide attempt, n=3). Mean age at psychiatric diagnosis was 14 (range 10-17 years). The majority (62.5%) were on effective ART at the time of their diagnosis, with sustained viral suppression. There was a higher proportion of psychiatric diagnosis among children born during the era of cART availability (2000-2014), vs. those for whom only sequential ART was available (1980-2000) (14% vs. 8.2%), though not statistically significant. The overall incidence of psychosis (4.3%) and suicide (2.1%) was higher that reported in the general Canadian population of adolescents (0.5% and 0.001% respectively).
Conclusions: In this cohort of perinatally infected children, the incidence of psychiatric disorders was 8.6% in adolescence, and appears significantly higher than among the general population of Canadian adolescents. These findings and specific causative factors need to be confirmed in larger studies.

TUPEB0470

Children and HIV in Nigeria: prevalence, patterns and correlates of emotional and behavioral comorbidity

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Background: With effective treatment, children with perinatally acquired HIV are reaching adolescence and adulthood in increasing numbers. Emotional and behavioural problems (EBPs) are observed among children and adolescents with perinatally-acquired HIV infection (paHIV youth) across cultures. We characterized EBPs and their correlates in a cohort of paHIV youth in South-West Nigeria, in comparison to a non-infected, unexposed (HUU) group.
Methods: Data were collected from 102 paHIV and 101 HUU at entry into the Ibadan Cohort Study on NEUROAIDS in Children (ICONIC), a longitudinal cohort (aged 8 to 15 years) at the University College Hospital, Ibadan. The paHIV and HUU groups had similar age and socioeconomic status, and resided in two communities within Ibadan. EBPs, defined as borderline and/or clinically significant problems on the caregiver-reported Child Behavior Checklist (CBCL) were assessed using age-and gender-standardized norms from the CBCL multicultural supplement. Clinical and sociodemographic variables were obtained using a structured parent interview and patient records and caregiver depression was assessed using the Centre for Epidemiological Studies Depression Scale Revised (CESD-R). CBCL problem and syndrome scale mean scores were compared using independent t tests, and univariate and multivariate analyses of EBP correlates were conducted with logistic regression.
Results: Among paHIV youth, 10.8% had EBPs in the borderline or clinical range, compared to 3.9% of comparison youth (p=0.014). Significant differences were detected in the Attention problems and Aggressive Behaviour subscales (7.8% vs 1.0%, p=0.001) and (12.7% vs 2.0%, p<0.001) for paHIV and HUU respectively. Compared to paHIV youth between 8 and 11 years (N=76/102), more of those above 11 years (N=26/102) had Social Problems (19.2% vs 3.9%; p=0.024) and Thought Problems (15.4% vs 2.6%; p=0.036). Among biomedical and psychosocial variables, caregiver depression only was associated with CBCL Total Problem Scores in the borderline and clinical range for paHIV youth (OR 1.1, 95% CI 1.02-1.14; p=0.013).
Conclusions: EBPs, especially externalizing problems, are more prevalent among paHIV than HUU children in Nigeria and are associated with caregiver depression. With ongoing access to cART, paHIV children in Nigeria require comprehensive health care, early diagnosis of existing EBPs, and family focused, evidence-informed mental health treatment and prevention programmes.

TUPEB0471

A diagnostic prediction model for tuberculosis treatment decision in smear and Xpert-negative HIV-infected children

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Background: WHO recommends assessing for tuberculosis HIV-infected children presenting with fever, cough, weight loss, or contact history. Tuberculosis diagnosis is very challenging in this population where microbiological confirmation is seldom reached. We aimed to develop a diagnostic model for tuberculosis treatment decision in smear and Xpert MTB/RIF (Xpert)-negative HIV-infected children.
Methods: HIV-infected children aged ≤13 years with a suspicion of tuberculosis were enrolled in the ANRS 12229 PAANTHER 01 study in Burkina Faso, Cambodia, Cameroon, and Vietnam. Children underwent full medical history and clinical assessment, bacteriological samples for smear microscopy, Xpert, and culture, chest radiograph (CXR), and abdominal ultrasound (AUS). The NIH classification was used as reference standard considering both confirmed and unconfirmed tuberculosis. We developed a multivariable prediction model for tuberculosis diagnosis in Xpert and smear-negative children, using logistic regression with a 0.15 significance threshold. We assessed area under the receiver operating characteristics curve (AUROC) of the model.
Results: Of 438 children enrolled, 53 were Xpert or smear-positive and 385 were considered in this analysis. Of these, 310 had full data available for all predictors, including 170 classified as tuberculosis. Hemoptysis (OR 5.39; 95%CI 0.95 - 30.76), sleep disorder >2 weeks (OR 2.84; 95%CI 1.02 - 7.93), fever >2 weeks (OR 3.45; 95%CI 1.95 - 6.09), contact with smear-positive tuberculosis (OR 10.61; 95%CI 2.10 - 53.70), tachycardia (OR 2.99; 95%CI 1.05 - 8.53), abdominal distension (OR 1.91; 95%CI 0.87 - 4.21), alveolar opacities (OR 2.84; 95%CI 1.60 - 5.05), miliary or macronodules (OR 2.30; 95%CI 0.88 - 6.03), and lymphadenopathies on CXR (OR 2.30; 95%CI 1.28 - 4.13), and abdominal lymphadenopathy on AUS (OR 5.67; 95%CI 2.85 - 11.27) remained in the model (AUROC 0.842). Selecting an individual probability threshold of 0.460, sensitivity of the model was 75.7% and specificity 66.9%.
Conclusions: A model integrating easily collectable signs and symptoms, CXR and AUS findings has good predictive performance for tuberculosis diagnosis in children without immediate microbiological confirmation by smear microscopy and Xpert. It could be used as manual or automated diagnostic score to help prompt tuberculosis treatment decision in these children. Internal and external validation is needed to refine the model.

TUPEB0472

Human genomic DNA concentration is significantly reduced among children and adolescents on antiretroviral therapy

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Background: Documented adverse effect of antiretroviral therapy (ART) include incorporation into chromosomal DNA, loss of heterozygosity, altered cell cycles, centrosomal amplification and aneuploidy, these increases genomic instability. Genomic instability has been implicated in several cancers and among HIV-positives, cancer indices are higher than in the general population. Can increased genomic instability induced by ART exposure be implicated? We thus determined human genomic DNA concentration and damage among children/adolescents exposed to ART to ascertain if genomic instability is increased.
Methods: We obtained ethical approval and informed consent. Study groups include HIV-negative children presenting for other illness (control group), children born to HIV-positive women exposed to ART possibly in utero and/or via PMTCT (exposed group), and HIV-positive children/adolescents on ART (therapy group). Human genomic DNA was extracted from venous blood. DNA concentration and damage (fragmentation and nicks) was quantified using fluorometric methods. Glutathione S-transferase (GST) T1 and M1 genotypes, crucial for xenobiotics detoxification, were determined by PCR. Kruskal-Wallis statistical test was used.

Variables	Options	Control (n=26)	Exposed (n=71)	Therapy (n=46)
Time on ART	Median (Months)	-	8.0 (IQR: 7.0 - 9.0)	74.0 (IQR: 26.0 - 90.0)
T1 Genotype&	Homozygote/ Heterozygote	10 (38.5%)	30 (42.3%)	25 (54.3%)
	Null	15 (57.7%)	37 (52.1%)	20 (43.5%)
M1 Genotype&	Homozygote/ Heterozygote	16 (61.5%)	58 (81.7%)	29 (63.0%)
	Null	9 (34.6%)	9 (12.7%)	16 (34.8%)
#DNA Content	Median (µg/mL)	10.0 (IQR: 6.9 - 23.4)	10.3 (IQR: 7.7 - 13.7)	3.7 (IQR: 2.6 - 6.3)
#Intact DNA	%	74.2 (IQR: 40.4 - 100.0)	100.0 (IQR: 100.0 - 100.0)	100.0 (IQR: 100.0 - 100.0)
Un-nicked DNA	%	88.3 (IQR: 38.0 - 98.9)	79.7 (IQR: 36.8 - 91.4)	82.8 (IQR: 67.5 - 90.0)
#Statistically Significant; &One, four and one participants' PCR failed and thus not determined for control, exposed and therapy groups respectively				

[Table 1: Group values for different variables]

Results: Proportions of T1 and M1 null genotypes was varied (Table 1). DNA concentration analyzed by time on ART was significant (p=0.0001), becoming greatly reduced after >24 months on ART. Without correction, T1 null genotype had significantly lower DNA concentration (p=0.043) among the therapy group. Thereafter, we compared DNA concentration by GST genotypes, weighting for time on ART. Among the exposed group, M1 null genotypes (3.7µg/mL; p<0.0000) had lower DNA concentration while the T1 null genotypes had higher DNA concentration (10.3µg/mL; p=0.013). Conversely among the therapy group, the T1 null genotype (3.5µg/mL; p<0.0000) had lower DNA concentration.
Conclusions: Human genomic DNA concentration was significantly reduced among HIV-positive children/adolescents on ART compared to HIV-negative ART-naïve children and those children with minimal ART exposure. The possible effect of GST-T1 and M1 genotypes on DNA concentration needs to be clarified.

TUPEB0473

Describing the continuum of care in young adults who transition from adolescent to adult care

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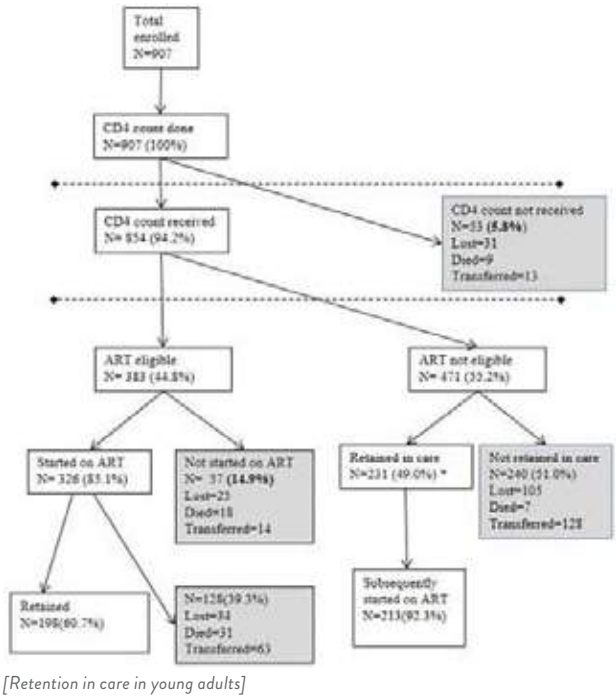
Background: In sub-Saharan Africa there is an increasing number of adolescents and young adults entering care due to reduction of mortality in HIV positive infants, and high incidence of new infections in this age group. We aimed to investigate the continuum of care in young adults (18-25 years).
Methods: We included all patients 18-23 years (to allow 2-years follow-up) at enrolment at the Infectious Diseases Institute, Kampala, Uganda, from 2010 to 2014. We describe the number of patients who were lost along the steps of the cascade 1) enrolment 2) CD4-count measurement 3) ART assessment (reception of CD4 count) 4) Follow up stratified by ART eligibility. We carried out survival analysis for time to being lost to program (LTP) at any stage by gender, WHO stage and ART eligibility. We performed Cox regression analysis to identify patients at the highest risk to be LTP defined as being dead or not have returned to the clinic for >90 days.
Results: . 907 young adults were enrolled in care, 784 (82.47%) female, median age 21 years (IQR: 20-22), 26.9% were in WHO stage 3&4, median CD4 count at enrolment was 400 cells/µL (IQR 170-612). A total of 260 were LTP (see figure).



[Retention in care in young adults]

In survival analysis we did not find any difference in LTP by gender and ART eligibility; the probability was higher in patients in WHO stage 3&4 as compared to 1&2 (0.52, CI:0.14-0.64 versus 0.31, CI:0.26-0.36, P< 0.001). Similarly in the multivariate analysis we found that the only risk factor associated with LTP was WHO stage 3&4 (adjusted HR: 1.72 (CI: 1.32-2.26, P< 0.001).
Conclusions: One quarter of young adults, especially those presenting in advance stage of disease were LTP; there is need for tracking studies to evaluate the true viral status of LTP in this group since it is likely that deaths were underestimated.

TUPEB0474

Transition of perinatally HIV-infected adolescents into adult care: lessons learned and new challenges

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Background: With improvements in antiretroviral (ART) access, a growing population of perinatally HIV-infected adolescents go through adulthood. Adolescents should start the transition into adult care around 15 years of age. This transition raises concerns of retention in care and long-term adherence to ART. From 2011 to 2016, a transition support process (TSP) was implemented in a pediatric HIV hospital in Dakar. We described retention in care and changes in virologic suppression (VS) in patients who received TSP or a standard transition process (STP).
Methods: Perinatally HIV-infected adolescents ≥15 year-old, on ART, and autonomous in their care were identified for transition into adult care. Patients were referred to TSP or STP according to their own preference. STP consisted of preparation sessions in the pediatric hospital followed by direct transfer to the adult care facility. For patients receiving TSP, transfer to adult care was preceded by a 2 year-period of joint visits with a physician and the attending pediatrician, as well as community support groups.
Results: Of 47 adolescents eligible for transition, 32 consented to enter the TSP. For those opting for the STP, 4 were pregnant, 3 about to start university and 8 were at an advanced age who had previously refused to enter transition (Table 1). Patients in both groups remained in care during the study. The percentage of VS patients at the end of transition increased following TSP (p=0.01) and those with VS at enrollment maintained it at the end of the process. By contrast, the rate of VS decreased in patients receiving the STP.

Characteristics	TSP n=32	STP n=15
Female, %	39	80
Age in years, (median IQR)	18.3 (17.1-19.7)	20.4 (18.4-22.1)
Age at HIV disclosure in years, (median IQR)	15.9 (14.5-17.5)	16.3 (15.3-18.0)
VS patients at enrollment, %	61	73
VS patients at exit, %	81	60
Transition duration in months, (median IQR)	27.1 (17.3-39.7)	6.5 (5.7-7.6)

[Table 1: Characteristics of HIV-infected Senegalese adolescents enrolled in a transition process.]

Conclusions: We report encouraging results suggesting TSP helps maintain and possibly improves VS in adolescents transitioning into adult care. However, late HIV disclosure, and reluctance to leave their pediatrician, dramatically delayed transition in many adolescents. Transition should be tailored to fit the adolescents' specific needs, including early pregnancy prevention and monitoring.

TUPEB0475

Sexual satisfaction: determining unique clinical needs of the first generation of young women living with HIV since childhood through the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS)

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Background: The profiles of young women living with HIV are becoming more diverse, now including those with HIV since childhood (YWLHC) and those who acquired HIV in late adolescence/early adulthood (YWLH). Clinicians are tasked with identifying the unique needs of YWLHC compared to YWLH, including their sexual and reproductive health (SRH) needs. We aimed to identify if YWLHC differed from YWLH regarding sexual satisfaction and pleasure.
Methods: Baseline data from CHIWOS were used (n=1425). Women between 18 and 29 who responded yes (YWLHC, n=38) or no (YWLH, n=94) to an item inquiring if they had received pediatric HIV care were included in the analysis (total

n=132). Sexual satisfaction was measured amongst all participants using 6 items from the Sexual Satisfaction Analysis scale (scores ranged from 6-30, higher=more satisfaction). Additional items measured the importance of sexual activity, pleasure from sexual activity in the past month, and sexual relationship satisfaction (SRS) in the past month (exclusive to participants who reported sexual activity in past 6 months). Bivariate analyses and linear regression were used to compare the sexual outcomes between groups.
Results: YWLHC were younger (median=22.5 years, IQR 21-25) than YWLH (median=26, IQR 23-28, p< .001). Most YWLHC (92%) and YWLH (95%) had experienced consensual sex. Ratings of sexual satisfaction were similar in both groups, and low (median=18.5 for YWLHC; median=20 for YWLH, p=0.15). No statistically significant differences were found regarding the importance of sexual activity, pleasure from sexual activity, or SRS. 69% of YWLHC and 63% of YWLH felt sexual activity was somewhat/very important, 53% of YWLHC and 50% of YWLH usually/always felt pleasure, and 94% of YWLHC and 85% of YWLH were very/somewhat satisfied in their sexual relationship.
Conclusions: While previous literature has captured the unique clinical needs of YWLHC, our findings suggest YWLHC may mirror YWLH in terms of sexual satisfaction and sexual pleasure. Although overall sexual satisfaction appears to be low, this may be related to lower levels of recent sex given particpants' reports of high SRS in the past month. This is an important clinical consideration as we support the SRH of all women living with HIV.

Epidemiology and Modeling of the HIV Epidemic

TUPEC0725

Late presentation of HIV infection in the country of Georgia: 2012-2015

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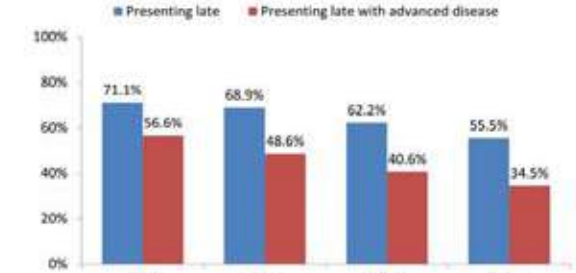
Background: Late presentation for HIV care has important individual and population implications. The objective of this study was to explore the problem of late presentation in the country of Georgia.
Methods: Data on adult persons newly diagnosed with HIV in Georgia between 2012 and 2015, where extracted from the national AIDS Health Information System. Late presentation was defined as a person diagnosed with HIV with a CD4 count <350 cells/mm^3 or an AIDS defining illness regardless of the CD4 count. Late presentation with advanced disease was defined as a person diagnosed with HIV with a CD4 count <200 cells/mm^3 or an AIDS defining illness, regardless of CD4 cell count. Mortality rates were calculated as number of events divided by the number of total person-years of follow-up.
Results: A total of 1987 persons were included in the analysis, among them 509 (25.6%) were women, 1260 (63.4%) were classified as late presenters and 870 (43.8%) as late presenters with advanced disease. Women and men had similar prevalence of late presentation (64.2% and 63.1% respectively, p=0.65). The proportion of late presenters declined from 71.1% in 2012 to 55.5% in 2015 (p<0.0001); presentation late with advanced disease decreased from 56.6% in 2012 to 34.5% in 2015 (p<0.0001). Late presentation was most common among people who inject drugs (77.7%). Overall 186 patients died over the studied period. Mortality was higher both among late presenters (6.74 per 100 person-years vs. 1.08 per 100 person-years, p<0.0001) and late presenters with advanced disease (8.93 per 100 person-years vs. 1.34 per 100 person-years, p<0.0001).



[Late presentation in Georgia: 2012-2015]

Conclusions: High prevalence of late presentation in Georgia reflects insufficiencies in HIV testing services. Better testing strategies are needed to improve earlier diagnosis and disease outcomes.

TUPEC0726

HIV-1 viral control in a large cohort of African adults with incident HIV infection

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Background: Few HIV-infected persons are able to maintain viral replication at low levels without therapeutic intervention. We report on a large cohort of African adults with incident HIV infection, describing viral control, subsequent loss of control, and evaluating predictors of control.
Methods: Volunteers from well-defined HIV-incidence cohorts in Kenya, Rwanda, South Africa, Uganda, and Zambia joined an HIV+ cohort within one year of their estimated date of infection (EDI). Plasma viral load (VL) was measured and antiretroviral treatment (ART) history was taken monthly for 3 months post EDI, quarterly for 2 years, and every 6 months thereafter. Viral subtyping was based on pol sequencing. Viral control was defined as ≥2 consecutive VL ≤2,000 copies/mL beyond 74 days post-EDI with no subsequent, consecutive visits with VL >2,000 in the absence of ART. Plasma from volunteers was tested for ART if their VL dropped to ≤2,000 copies/mL but they self-reported no ART use. Multivariable logistic regression characterized predictors of viral control.
Results: Of 590 volunteers, 44 (7%) experienced viral control and 68 (12%) controlled but later lost control. Median ART free follow-up time since EDI was 3·7 years (range: 31·0 days to 9·7 years). Factors associated with control were HIV-1 subtype A versus C infection (adjusted odds ratio [aOR]: 3·1 [95%CI: 1·4-7·0]) and having the human leukocyte antigen (HLA) class I variant B*57 (aOR: 3·7 [1·6-8·1]). Women (aOR: 2·6 [1·2-5·9]) and men who have sex with men (aOR: 2·8 [1·1-7·1]) were also more likely to control versus heterosexual men. These associations persisted when excluding controllers who later lost control.
Conclusions: We confirm associations with HLA type and viremic control, and demonstrate novel, strong associations between control and infecting viral subtype and sex/HIV risk group, even after controlling for demographics and host genetics. Our work builds on increasing evidence that HIV-1 infecting subtype has an impact on transmission and disease course, and this may be relevant for the development of vaccines, therapeutics, and other new prevention technologies.

TUPEC0727

Late Presentation Among Patients with Human Immundeficiency Virus Infection in Turkey

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Background: Turkey is among low-prevalance countries in Europe in HIV infection. The characteristics of late presentation among HIV-positives have not been previously studied. We aimed to analyze the status of late presentation among HIV-positive patients in Turkey.
Methods: The HIV-positive patients were enrolled in this study by ACTHIV-IST (Action against HIV in Istanbul) Study Group, which consists of five centers to follow up HIV-positive patients in Istanbul. Demographic data including age, sex, transmission routes, education level, marital status, and history of imprisonment, CD4+ counts, and HIV RNA were collected from medical records. Late presentation was defined as presentation for care with a CD4 count below 350 cells/ml

or presentation with an AIDS-defining event, regardless of the CD4 cell count. Advanced HIV disease was defined as presentation for care with a CD4 count below 200 cells/mm^3 or presentation with an AIDS-defining event, regardless of the CD4 cell count

Results: The cohort included 1,673 patients (1440 male, median age was 35 years). The characteristics of the patients were given in Table 1. Among them, 847 (50.6%) had an early diagnosis, with a CD4 count of more than 350 cells/mm^3. The remaining 826 were late-presenters (Table 2). Among late presenters, 427 (25.5% of all, 51.7% of late presenters) presented with advanced HIV disease.

The characteristics of late and non-late, "early" presenters are given in Table 2. Late presenters were more elderly and less educated. The gender seemed comparable between groups. Late presenters were more likely among married patients. Early presenters were more likely among homosexuals, those diagnosed on screening studies, and in lower HIV-RNA viral load category. There has been a trend in decreasing late presenters in 2011-2016 when compared to 2003-2011 period.

Conclusions: In our cohort, those presented late were more elderly, less educated, married and had heterosexual intercourse.

Efforts to reduce the proportion of late presentation are essential for almost every country. The countries should identify the risk factors of their late presenters and should use targeted public health interventions to improve early diagnosis and presentation for HIV care. Improvements in HIV testing policies, emphasizing vulnerable groups are crucial.

TUPEC0728

Determination of AIDS- and non-AIDS-related causes of death reported in death certificates as compared to physicians' reviews in a tertiary referral hospital in Vancouver, British Columbia

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Background: Reliability of death certificates in Vancouver, British Columbia (BC) for assessing causes of death (CoD) for HIV-infected individuals remains uncertain. We examine the reliability of underlying CoD as reported in death certificates for individuals enrolled in a hospital-based immunodeficiency clinic (IDC) in Vancouver, BC.

Methods: All deaths occurring between 01-Jan-2004 and 31-Dec-2015 for HIV-infected individuals aged ≥19 years enrolled in the IDC were included in the study. Patients' medical histories were obtained from the clinic's database and individual medical records. Underlying CoD were obtained from BC's Vital Statistics Agency, which registers all deaths in the province. Two physicians, using patients' medical histories, independently reviewed CoD; these were then adjudicated and recorded utilizing a previously validated algorithm. Agreement rate was assessed for AIDS-, non-AIDS-related and unknown CoD between physicians' reviews and death certificates. Cohen's kappa coefficient was used to measure the magnitude of agreement.

Results: There were 271 deaths included in the analyses. Agreement rate was 77% between physicians' reviews and death certificates (Table 1). Kappa coefficient was 0.56, indicating moderate agreement. Deaths were classified as AIDS-related (27.31% vs. 35.42%), non-AIDS-related (70.11% vs. 55.35%) and unclassifiable/unknown (2.58% vs. 9.23%) by physicians and death certificates respectively. Using more detailed categories, the most common CoD ascertained by physicians were AIDS-related (n=74, 27.31%), non-AIDS-related malignancies (n=44, 16.24%), substance abuse (n=44, 16.24%) and chronic viral hepatitis (n=16, 5.90%). As per death certificates, these were AIDS-related (n=96, 35.42%), non-AIDS-related malignancies (n=44, 16.24%), substance abuse (n=32, 11.81%) and unknown causes (n=25, 9.23%).

Vital Statistics	Physicians´ Reviews	Frequency	Percent
AIDS-related	**AIDS-related**	**65**	**23.99**
AIDS-related	Non-AIDS-related	30	11.07
AIDS-related	Unclassifiable/Unknown	1	0.37
Non-AIDS-related	AIDS-related	5	1.85
Non-AIDS-related	**Non-AIDS-related**	**142**	**52.4**
Non-AIDS-related	Unclassifiable/Unknown	3	1.11
Unclassifiable/Unknown	AIDS-related	4	1.48
Unclassifiable/Unknown	Non-AIDS-related	18	6.64
Unclassifiable/Unknown	**Unclassifiable/Unknown**	**3**	**1.11**

[Table1: Cross-Tabulation: CoD in the IDC 2004-2015]

Conclusions: While providing moderate reliability when compared to physicians' reviews, death certificates overestimated AIDS-related and unknown/ill-defined causes of deaths in this sample of patients from a hospital-based immunodeficiency clinic. As trends in cause-specific mortality continue to shift from AIDS- to non-AIDS-related CoD, it is critical to be able to more reliably capture mortality statistics.

TUPEC0729

Examining differences in cause-specific mortality among patients enrolled in a hospital-based HIV care clinic in a Canadian setting

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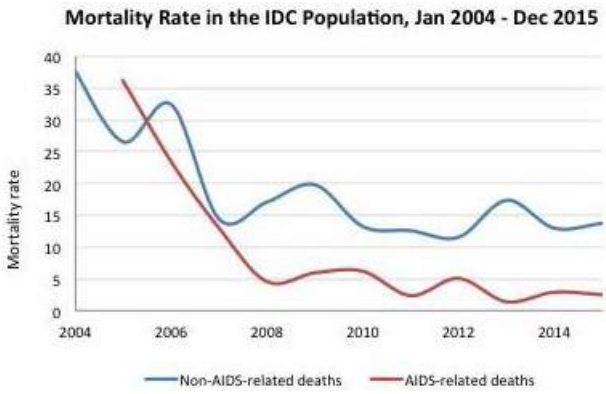
Background: Engagement in care and access to highly active antiretroviral therapy (HAART) have significantly decreased morbidity and mortality among people living with HIV/AIDS. Here we examine differences in cause-specific mortality for individuals enrolled in a comprehensive, hospital-based immunodeficiency clinic (IDC) in Vancouver, British Columbia.

Methods: A retrospective study was conducted on HIV-infected individuals aged ≥19 years enrolled in the IDC between 01-Jan-2004 and 31-Dec-2015. Patients' medical histories and laboratory data were obtained from the clinic's database, individual medical records and death certificates. Causes of death were independently reviewed by two physicians and recorded utilizing a previously validated algorithm. A Poisson regression model was used to examine trends for AIDS- and non-AIDS-related mortality and a Chi-squared test was used to compare differences between the two groups.

Results: Out of 2244 patients enrolled in the IDC, there were 271 deaths (12%), 264 of them with known causes of death, during the study period. AIDS-related mortality rate decreased from 36.18 per 1000 person-years (PY) in 2005, to 2.49 per 1000 PY in 2015 (p< 0.001). Non-AIDS-related mortality rate decreased from 37.38 per 1000 PY in 2004, to 13.72 per 1000 PY in 2015 (p=0.01) (See Figure 1). The most frequent underlying causes of death were AIDS-related events (n=74, 27%), causes related to substance abuse (n=44, 16%), and non-AIDS-related malignancies (n=44, 16%). Significant differences were observed between patients who died of AIDS-related and non-AIDS-related causes of death for age at first visit, baseline CD4, baseline VL, CD4 before death, VL before death, depression status (ever), IDC utilization and medication adherence after first clinic visit (p≤0.017).



[Figure 1: Mortality Rate in the IDC, 2004 - 2015]

Conclusions: We observed a significant decreasing trend for AIDS- and non-AIDS-related mortality over the study period. Advances in treatment are showing significant benefits for people living with HIV/AIDS; Differences between AIDS- and non-AIDS-related deaths assert the need for better management of non-AIDS-related morbidities.

TUPEC0730

Characterizing HIV antiretroviral therapy interruption and the following disease progression using population-level data in British Columbia, Canada: 1996-2015

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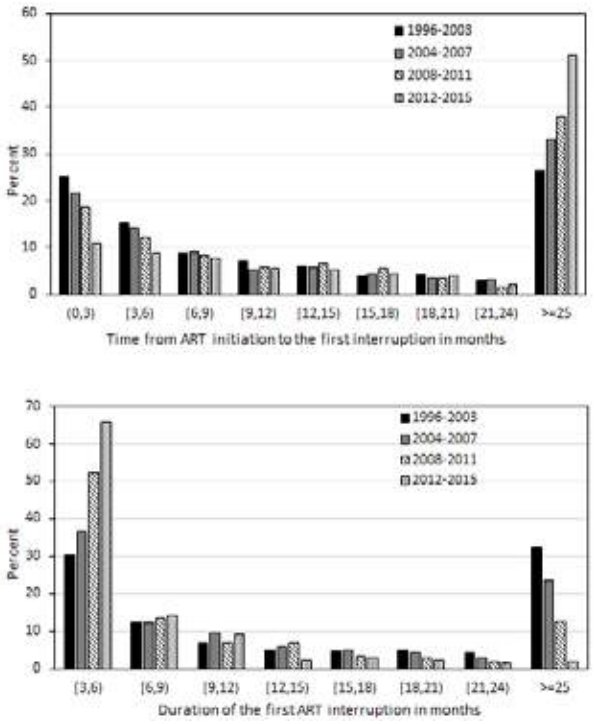
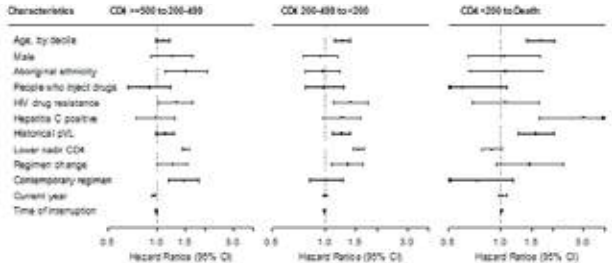
Background: Sub-optimal retention is among the biggest challenges to realize benefits of antiretroviral therapy (ART). We aim to describe ART interruption patterns and identify determinants of disease progression while off-ART in British Columbia (BC).
Methods: With population-level data on ART utilization and laboratory testing in BC, Canada (1996-2015), we described the time, frequency and duration of ART interruptions (a gap of ≥90 days in ART dispensation records). A four-state continuous-time Markov model was implemented to estimate disease progression and identify its associated determinants during individuals' first ART interruption episode. Disease progression was measured according to CD4-based state transitions (≥500 cells/mm^3 to 200-499; 200-499 to < 200; ≥500 to death; 200-499 to death; and <200 to death).



[Figure 1. Distributions of the time and duration of the first ART interruption by year of interruption (N=3129)]



[Figure 2. Adjusted hazard ratios associated with disease state transition intensities during the first ART interruption episode among 2212 individuals]

Results: Over a median eight-year follow-up [(IQR):4.3, 13.5], 3129 (38.1%) interrupted ART. The study population had a median of one interruption [1.0, 3.0], with the first interruption occurring 12.8 months [4.0, 36.1] after ART initiation, lasting for 7.5 months [4.1, 20.3]. The time from ART initiation to first interruption increased over time, while the duration of the first ART interruption decreased (Figure1). Model-estimated average probabilities of all-cause mortality after one-year ART interruption was 2%, 4% and 19% for individuals with a CD4 count of ≥500, 200-499, and < 200 cells/mm^3 respectively at ART dropout. In the multivariable analysis, age, historical plasma viral load, and ART regimen changes prior to interruption were associated with increased hazard of CD4 decline and death during interruption (Figure2).
Conclusions: Despite observed improvement over time, further efforts to develop ART re-engagement interventions are warranted.

TUPEC0732

HIV mediated immunosenescence in young adults infected at birth

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Background: Young adults infected with HIV since birth represent a small yet very important group of the HIV infected population. Immunological evolution studies in these young adults compared to patients infected with HIV later during adulthood is needed to understand the consequences of the infection at this early stage of life onwards. In particular, HIV-infected patients usually develop a premature immunosenescence profile, linked to chronic immune activation. In the context of young HIV-infected adults, these anomalies could be balanced by their robust immune resources and capacities for lymphocyte regeneration. We thus assessed the impact of HIV infection on the immune system of young adults infected by HIV at birth.
Methods: We performed a comprehensive immunomonitoring on PBMCs of patients from the ANRS Co19 COVERTE Cohort, including young adults aged between 18 and 25 years, infected by HIV either since birth or during childhood. We assessed the frequency and phenotype of circulating CD34$^+$ hematopoietic progenitor cells, as well as lymphocyte subpopulations (NK, B and T cells), in comparison to patients infected with HIV in adulthood.
Results: Young HIV-infected patients displayed a general lymphopenia with a decrease of CD4$^+$ T cells, B-lymphocytes and NK cells. They also presented altered resources, with decreased numbers of progenitor cells and naïve T cells, reminiscent on the whole of immune alterations found in patients infected in adulthood. This highlights the strong impact of HIV on the immune system despite patient young age. However, alterations were particularly obvious in a high proportion of patients (nearly 1/3) presenting high viral loads together with increased frequency of memory senescent CD8$^+$ T cells and chronic activation markers.
Conclusions: In virally controlled COVERTE patients, there was a trend towards less affected primary immune resources, supporting robust lymphopoiesis of a young immune system in the face of HIV infection. However, a significant number of HIV-infected young adults had increased markers of immune activation and senescence, related to uncontrolled viral replication. This highlights the issue of non-observance to antiretroviral therapy of young patients, resulting in loss of viral control, premature immunosenescence, and potentially irreversible damage of their lymphopoietic system.

TUPEC0733

Cascading the HIV epidemic in Kenya from national to county level for county programme planning and evaluation: a modelling study

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Background: To ascertain areas of remaining high HIV transmission (‚epidemic strongholds'), UNAIDS recommends that countries progressively utilize available data and focus on programs tailored to the local needs. Kenya has redefined its HIV epidemic by cascading the HIV estimates from national to county level for county programme planning and evaluation.
Methods: Two approaches to model the Kenyan HIV epidemic for the 2015 HIV estimates were used. First, data collected from sentinel surveillance, routine program, surveys and census from 1970 to 2015 were entered into the Spectrum software for each of the former eight provinces. Smooth prevalence curves were fitted to surveillance and survey data for each province using AIM model in Spectrum. Incidence implied by prevalence curves were combined with information on age structure of incidence and program coverage to estimate indicators of interest. Second, county estimates were produced by disaggregating the provincial totals per indicator, generated from AIM model, to the counties within each former province based on county prevalence. The county prevalence were obtained by examining surveillance and survey cluster data from 2003 to 2015. The estimates of each indicator were adjusted so that the total across all counties in a province would equal the provincial total. Estimates were validated for reliability by comparing mortality estimates with vital statistics and estimated prevalence with survey estimates.
Results: The county models showed heterogeneity in HIV epidemic in the 47 counties (see Table). For instance, whereas Nyanza province had a prevalence of 16.1%, cascading to counties within the province showed a prevalence as low as 4.7% in Kisii County (11.5% lower than the province estimate) to a high prevalence of 26.0% in Homabay County (9.9% higher than the province estimate).

Indicator	Province Estimate	County Estimates (Lowest/Highest)	
Prevalence	Nyanza; 16.1%	Kisii; 4.7% (11.5% lower)	Homa Bay; 26.0% (9.9% higher)
Adult ART coverage	Central; 51.3%	Kiambu; 39.8% (11.4% lower)	Nyeri; 87.8% (36.5% higher)
Children ART coverage	Rift Valley; 68.8%	Turkana; 33.6% (35.2% lower)	Kericho; 99.8% (31.0% higher)
PMTCT coverage	North Eastern; 22.7%	Wajir; 2.8% (19.9% lower)	Garisa; 54.7% (32.0% higher)
MTCT coverage	Eastern; 9.0%	Meru; 5.9% (3.1% lower)	Makueni; 22.4% (13.4% higher)

[Table 1: HIV Estimates 2015]

Conclusions: The county-level estimates better reflect differences in HIV epidemic in Kenya and thereby provide valuable information for county programme planning, evaluation and decision making. Nonetheless, validity and reliability of such estimates depends on the amount and quality of data available at the sub-national level.

TUPEC0734

How does the distribution of new HIV infections by age and sex vary by location and time in sub-Saharan Africa?

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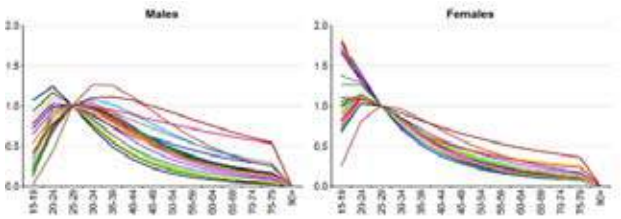
Background: National AIDS programs in Sub-Saharan Africa (SSA) produce annual estimates of key epidemic indicators, including the need for ART and PMTCT services, using the Spectrum/EPP model. Trends in HIV incidence among all adults aged 15-49 are estimated from antenatal clinic surveillance and survey data. These trends are disaggregated by sex and age according to standard patterns derived from cohort studies. These patterns are assumed to be the same in all countries in SSA and constant over time. The resulting projections generally match age and sex patterns of prevalence as measured by national surveys but often underestimate prevalence among 15-34 year-old women. This may cause Spectrum to underestimate the number of women needing PMTCT services and consequently overestimate PMTCT coverage.
Methods: We estimated age and sex patterns of incidence by country and time period by fitting the Spectrum model projections to prevalence data from national surveys in 26 countries. We modeled age-specific incidence rate ratios (IRRs) as shifted log-normal densities, calibrated using a Bayesian framework informed by incidence patterns from cohort studies. We quantified goodness-of-fit to prevalence data using a binomial likelihood. For countries with more than one survey we compared the performance of static and dynamic IRR patterns using the Akaike Information Criteria (AIC).
Results: Fitted static IRRs matched prevalence data more closely, compared to default patterns in Spectrum, for 25 of 26 countries. Fitted dynamic IRRs improved on static IRRs in 11 of 20 countries with more than one survey, but were preferred by AIC in only three: South Africa, Swaziland, and Zimbabwe. In 22 countries the estimated need for PMTCT was higher with the fitted patterns.
Conclusions: National surveys provide information that can be used to fit HIV incidence patterns by age and sex, leading to improved estimates of prevalence by age and need for PMTCT services.



[Figure 1. Fitted static incidence rate ratios (IRR)]

TUPEC0735

From HIV infection to HIV suppression: improvements in the time to reach successive stages in the HIV care continuum in the Netherlands

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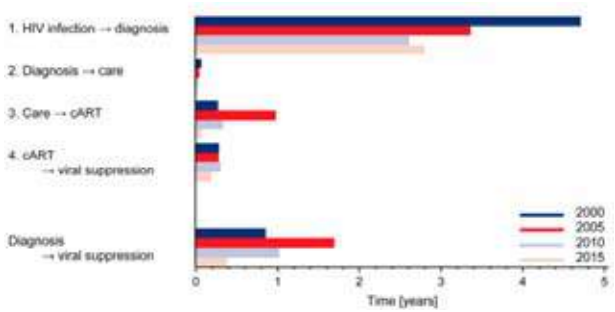
Background: The HIV care continuum summarises engagement in various stages of HIV care but does not provide information on the time to reach these stages. Here we aimed to estimate changes in the time to reach successive stages of the HIV care continuum in the Netherlands since 2000.
Methods: Data from all HIV-1-positive individuals in care aged ≥18 years at the time of diagnosis were selected from the Dutch ATHENA national observational HIV cohort. Time between HIV infection and diagnosis was estimated with the European Centre for Disease Prevention and Control HIV Modelling Tool. Survival methods were used to estimate time between HIV diagnosis, entry into care, start of combination antiretroviral treatment (cART), and viral suppression, i.e. the first HIV RNA measurement <100 copies/ml. Patients who did not start cART or reach viral suppression were censored at their last follow-up visit.

Results: Of the 23,376 HIV-1-positive individuals in ATHENA, 17,053 (73%) were diagnosed in 2000 or later. Between 2000 and 2015, the estimated median time from infection to diagnosis decreased from 4.7 (interquartile range [IQR], 2.3-8.4) to 2.8 (1.3-5.1) years reflecting an increase in CD4 counts at the time of diagnosis from 260 (IQR, 78-460) to 370 (150-560) cells/mm^3. Meanwhile, the median time from diagnosis to viral suppression decreased from 0.85 (IQR, 0.41-3.66) to 0.38 (0.22-0.75) years (see Figure). This decrease was mainly a consequence of shorter time to start of cART, being 0.07 (0.04-0.13) years in 2015, and, to a lesser extent, shorter time to viral suppression after starting cART, 0.18 (0.08-0.32) years in 2015.



[Time to reach successive stages]

Conclusions: Time from acquiring HIV to reaching viral suppression has declined, but continues to be dominated by the duration of undiagnosed HIV infection. To further improve access to care and treatment ensuring earlier diagnosis by expanding testing for HIV will be key.

TUPEC0736

Potential impact of implementing pre-exposure prophylaxis (PrEP) among young women in combination with scaling-up antiretroviral therapy and male circumcision on HIV incidence in Shiselweni region, Swaziland: a modelling study

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Background: Swaziland is one of the countries most affected by HIV. The HIV prevalence and incidence in Shiselweni region (south of Swaziland) were estimated respectively at 31% and 2.8 per 100 person-years among adults in 2011. Young women continue to be at high risk of HIV infection, with incidence levels estimated at 3.7 per 100 person-years among 18-24 years.
Our aim was to assess the potential impact of pre-exposure prophylaxis (PrEP) use among young HIV-uninfected women, in combination with antiretroviral therapy (ART) and voluntary medical male circumcision (VMMC), on HIV spreading over four years in this region.
Methods: A mathematical model was used to compare the impacts on the HIV incidence rate of extending ART eligibility to all HIV-infected individuals, increasing VMMC, and implementing PrEP use among HIV-uninfected women. This model used sex- and age-specific data on adults (18-49 years) from the 2011 Swaziland HIV Incidence Measurement Survey. Baseline ART coverage among all HIV-infected individuals was 36%. Baseline VMMC coverage among HIV-uninfected men was 12%. Circumcision was assumed to reduce female-male transmission by 60% and PrEP to reduce male-female transmission by 65%.
Results: With no additional interventions (i.e. ART at CD4 <350 and baseline VMMC), incidence would decrease by 24% over 4 years compared to the baseline level. Reaching 65% ART coverage, the decrease in incidence would be 38% over 4 years. The decrease under PrEP among 18-29-year-old HIV-uninfected women at 60% coverage or VMMC at 35% coverage would be close to this level. However, increasing ART coverage in accordance with the 90-90-90 UNAIDS target would be the most effective intervention in reducing overall and sex-specific incidence rates. Combining ART at 65% coverage with the VMMC and PrEP interventions would be even more impactful: the incidence rate would be halved after 4 years compared to the baseline rate.
Conclusions: Extending ART eligibility to all HIV-infected individuals was adopted in Swaziland in 2016; achieving high levels of ART coverage could lead to high decrease in HIV incidence. However, in this hyper-endemic setting, combining these guidelines and PrEP among young women (and VMMC) could be an effective strategy in reducing the incidence to low levels.

TUPEC0737

Mortality trends in HIV-infected hispanic during the cART era

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Background: The introduction of multiple spectrum antiretroviral therapy (ART) and the availability of combination ART (cART) have led to a dramatic improvement in the immunological function and to mortality profile changes among HIV infected patients. Our study evaluates and describes changes of the mortality rates and cause of death in a Hispanic HIV cohort during the cART era in Puerto Rico.
Methods: The database of 3,194 HIV infected adults followed in the Retrovirus Research Center at Bayamon, Puerto Rico was matched with the Puerto Rico Mortality Registry to establish the date of death and the cause of death as describe in the death certificates between 2000 and 2015. We have analyzed and compared the time periods of: 2000-2004, 2005-2009, and 2010-2015.
Results: A total of 997 cases died, with a significant mortality rate reduction throughout the study periods (19.3%, 15.0% and 9.7% respectively). Of them 71.6% were men, 52.3% injecting drug users, 19.5% men reported sex with another man, and the overall mean age at death was 47 ± 10 years. The most prevalent causes of death were: HIV (66.0%), pulmonary conditions (36.8%), septicemia (25.3%), cardiovascular conditions (21.2%), liver conditions (11.6%), renal conditions (8.8%), cancer (8.7%), viral hepatitis (7.1%), injury-poisoning (6.6%), hematological conditions (6.3), and psychoactive substance use (5.3%). When analyzed by time periods the distribution was: HIV (72.4%, 61.9%, 61.0%), pulmonary (40.1%, 37.5%, 30.1%), septicemia (24.4%, 27.6%, 23.3%), cardiovascular (17.8%, 19.9%, 28.8%), liver (11.5%, 10.2%, 14.0%), renal conditions (8.6%, 9.7%, 8.1%), cancer (7.1%, 8.5%, 11.9%), viral hepatitis (7.6%, 5.1%, 9.3%), injury-poisoning (6.8%, 4.8%, 8.9%), and psychoactive substance use (2.0%, 4.8%, 11.9%). Increment in injury-poisoning was seen only in men, while the increments of the other causes were observed simultaneously in women and in men. Contrary, HIV and pulmonary mortality decreased specially in men.
Conclusions: Availability of cART in this Hispanic HIV cohort is associated to an incremental higher mortality related to potentially preventable conditions, including cardiovascular, liver, cancer, and accidents. Aggressive prevention strategies targeting environmental agents and risky lifestyle behaviors are required, especially in young HIV infected population. Supported by NIH grants # U54MD007587, G12MD007583, and U01AI069918.

TUPEC0738

Understanding epidemic contexts within the cluster-randomized SEARCH trial: a clustering approach to grouping rural communities in East Africa according to epidemic characteristics

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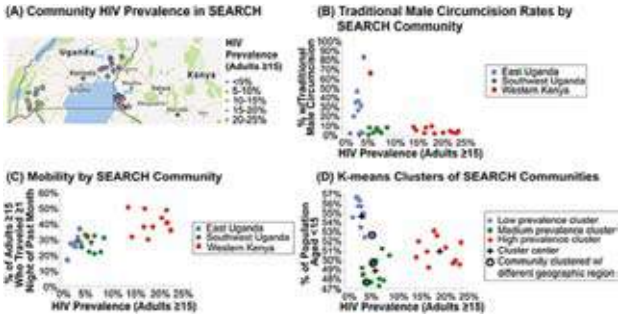
Background: SEARCH is a community-randomized trial of the "test-and-treat" strategy for HIV prevention (NCT01864603) spanning three geographic regions - Southwest Uganda, East Uganda, and Western Kenya. Using baseline HIV prevalence and household census data (N=146,874 adults ≥15), we investigated the geospatial distribution of factors potentially driving community-level HIV prevalence.
Methods: We explored community-level adult HIV prevalence and factors including demographic structure, mobility (proportion of adults spending ≥1 night away from home in the past month), and traditional male circumcision (TMC). K-means clustering was used to categorize communities (N=32) according to epidemic context and identify which communities differed from others in their region.
Results: High HIV prevalence in Western Kenya occurred in the context of low TMC and high population mobility. The only Kenyan SEARCH community with a majority of men circumcised had one-third the HIV prevalence of other regional communities. In contrast, TMC rates were low in Southwest Uganda despite far lower HIV prevalence, and there was no relationship between TMC and community HIV prevalence in East Uganda despite wide variation in TMC. East and Southwest Uganda had similar mobility, but East Uganda had a younger population and lower prevalence than Southwest Uganda. Demographic structure and HIV prevalence clustered the communities into three distinct groups, mostly corresponding to geographic region. Three communities clustered with different regions, including the lower prevalence community in Western Kenya, which clustered with Southwest Uganda.



[Figure 1]

Conclusions: Consistent with findings from DHS and AIS surveys, HIV prevalence in Western Kenya was substantially lower in a community where a majority of men are traditionally circumcised. This inverse relationship between TMC and prevalence was not observed in Uganda. Western Kenya was also distinct in its high mobility; in contrast, East and Southwest Uganda had similar mobility but different demographic structures. These factors make it possible to cluster SEARCH communities into distinct epidemic patterns.

TUPEC0739

Health-related quality-of-life of people living with HIV in Zambia and South Africa: a comparison with HIV-negative people in the baseline survey of the HPTN 071 (PopART) trial

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Background: Life expectancy of HIV-positive individuals receiving antiretroviral therapy (ART) is approaching that of HIV-negative persons. However, little is known about the health-related quality-of-life (HRQoL) of HIV-positive individuals at different stages of disease and treatment, and how it compares to HIV-negative individuals in resource-constrained settings.
Methods: Data on 38,691 adults aged 18-44 years were gathered between October 2013 and March 2015 in cross-sectional surveys of random samples of the general population in 21 communities in Zambia and South Africa as part of the HPTN 071 (PopART) study. In Zambia 21% and in South Africa 22% were HIV-positive. HRQoL information was gathered with an instrument similar to the EuroQol Group's EQ-5D-5L that measures health in five domains. Responses were scaled into scores taking values between 0 (representing death) and 1 (representing perfect health). Beta-distributed multivariable models were used to analyse differences in HRQoL scores between HIV-positive and HIV-negative individuals unaware of their status, aware but not in care, in care but not on ART, and on ART for less or more than 5 years, adjusted for treatment status, sociodemographic and lifestyle variables.
Results: 19,637 (99%) of 19,750 participants in Zambia and 18,429 (97%) of 18,941 participants in South Africa had complete EQ-5D-5L information. Multivariable regression models show in both countries individuals on ART for at least 5 years reported similar levels of quality-of-life as those HIV-negative. In Zambia, individuals on ART for less than 5 years had a small reduction in score (-0.006, 95% CI -0.009 to -0.003) compared to HIV-negative individuals. In both countries, a large proportion of the sample (44% in Zambia and 53% in South Africa) were unaware of being HIV-positive, but reported good health, showing no significant difference in HRQoL compared to HIV-negatives.
Conclusions: ART is successful in restoring HRQoL of HIV-positive individuals to that of HIV-negative individuals in this general population sample. Individuals in this study who were unaware of being HIV-positive also report good health-related-quality-of-life. The direct health benefits of early diagnosis and ART in preventing losses in health-related-quality-of-life provide support to international advocacy efforts for scale-up of testing and expansion of treatment to all HIV-positive individuals.

TUPEC0740

Unraveling the geographic and population heterogeneity of the HIV epidemic in Belgium

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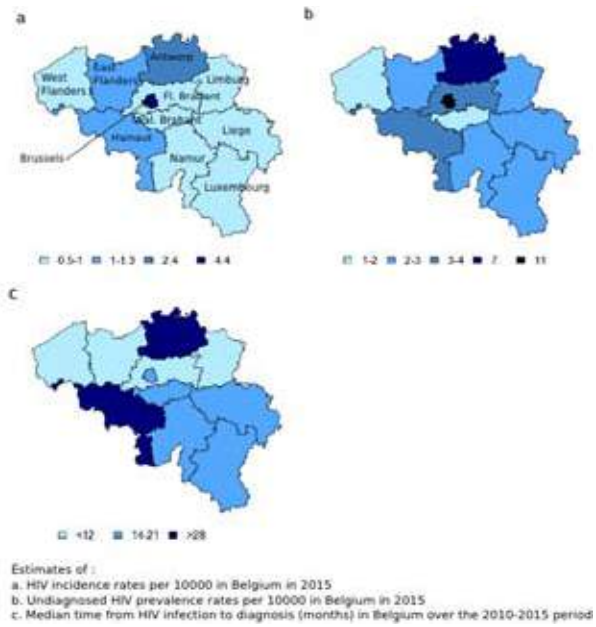
Background: Increasing our knowledge about the geographic areas and key populations the most affected by HIV is essential to improve HIV prevention and care and to ensure a more focused HIV response. However, in most settings, our understanding of the HIV epidemics, and thus HIV programs, have relied on epidemiological estimates produced at the national level.
Methods: We used Belgian surveillance data on newly diagnosed HIV cases from 2006 to 2015 and a previously developed back-calculation model to estimate three key epidemiological indicators: HIV incidence, distribution of times from HIV infection to diagnosis, and the number of undiagnosed HIV infections in 2015. Estimates were obtained at national and subnational levels and by HIV exposure group.
Results: We estimated that, in Belgium, in 2015, around 1000 (95% confidence interval: 800-1200) new HIV infections occurred and 2800 (95% CI: 2200-3500) individuals were living with undiagnosed HIV. Median time from infection to diagnosis was 22 months (inter-quartile range: 2-33) in the 2010-2015 period. More than 50% of the new infections and undiagnosed infections occurred among individuals living in two areas: the Brussels-Capital Region and the province of Antwerp. These areas had also the highest HIV incidence and undiagnosed HIV prevalence rates (Figure 1a and b). Median time from infection to diagnosis were longest in the provinces of Antwerp and Hainaut (Figure 1c). In the province of Antwerp, undiagnosed prevalence rates were highest among heterosexual women from sub-Saharan African countries (SSA), followed by MSM and heterosexual men from SSA, while in the Brussels-Capital Region, it was MSM, followed by heterosexuals from SSA (first women, then men).
Conclusions: Our findings show that, in Belgium, heterogeneity exists in how geographic areas and exposure groups are affected by HIV and thus emphasizes the need for subnational surveillance to tailor prevention programs and develop a comprehensive HIV testing strategy.



[Figure 1.]

TUPEC0741

Is MPHIA survey a validation method for HIV spectrum estimates in Malawi?

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Background: Malawi has been monitoring their HIV epidemic by combining antenatal clinic surveys among pregnant women with population demographic and HIV program data in a Spectrum mathematical model to produce population level estimates, with national household surveys incorporated into the model since 2006. This abstract seeks to determine whether indicators from Spectrum modelling are reproducible by another population-based survey, the 2015-2016 Malawi Population-Based HIV Impact Assessment (MPHIA).
Methods: MPHIA, a cross sectional household survey, was conducted for the first time between November 2015 and August 2016 in all districts in Malawi. The survey assessed HIV incidence, prevalence and viral load suppression and targeted both adults and children. Home-based HIV testing using the national rapid test algorithm with Geenius confirmation at satellite labs was conducted. HIV positive samples were centrally tested for viral load suppression and recency of infection using Lag_Avidity EIA. In 2015, antenatal clinic sentinel surveillance, MDHS, and national program data were entered into Spectrum software, which incorporated evidence-based assumptions about HIV program effectiveness and patterns of HIV transmission and disease progression to estimate HIV prevalence, incidence, and mortality in 2015, as well as future projections (unpublished).
Results: Spectrum estimated HIV incidence in 2015 to be 0.38% (95%CI:0.27-0.52%) among adults aged 15-49 years. This same model projected HIV incidence for 2016 at 0.34% (0.40% in females, 0.29% in males). The MPHIA survey estimate for HIV incidence was 0.32% (95%CI:0.16-0.48%). MPHIA found that HIV incidence was higher in females (0.39%, 95%CI:0.15-0.63%) than men (0.24%, 95%CI:0.03-0.46%).
Spectrum projected 2016 HIV prevalence for adults aged 15-49 as 9.2% (11.3% females, 7.2% males). The MPHIA estimate for HIV prevalence was 10.0% (95%CI:9.4-10.7%), with higher prevalence among women (12.4%, 95%CI:11.4-13.4%) than men (7.5%, 95%CI:6.8-8.3%)). In children aged 0-14 years, Spectrum projected 2016 HIV prevalence at 1.03%. MPHIA survey results were 1.6% (95%CI:1.2-2.0).
Conclusions: The HIV incidence and prevalence results from the 2015/2016 population-based survey in Malawi are consistent with the 2015/2016 estimates generated by Spectrum modelling, except for children. This supports the reliability of Spectrum model in estimating adult indicators and its use to inform HIV programming in Malawi.

TUPEC0742

Measuring the first 90: comparing estimation methods for "Known HIV Status"

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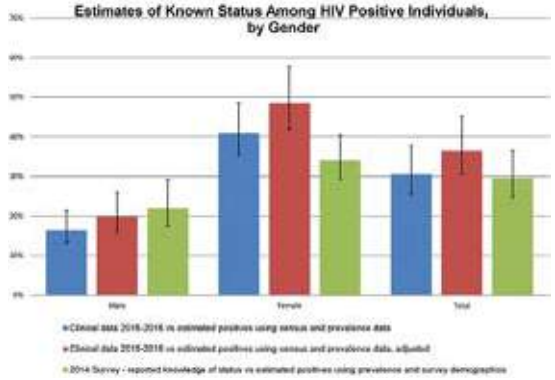
Background: UN goals propose that 90% of HIV positives know their status, 90% of known positives be on treatment and 90% of those treated achieve viral suppression. The second two goals can be monitored using clinical and laboratory records. However, measuring the first "90" is less straightforward. Given underreporting of status and expanding test options, both the number of positives and known status can be challenging to estimate.
Methods: Data were collected in rural northeast South Africa. Three estimates of the first "90" were generated using multiple data sources: two used an estimate of HIV positive individuals calculated using age and gender stratified 2014 census data and previous seroprevalence survey data compared to individuals with a record of either HIV testing or HIV care in a clinical data capture system covering all clinics in the community. The first estimate was unadjusted, the second used clinic register data to adjust for HIV testing potentially missed by the data capture system. The third estimate compared population based survey self report to estimated HIV positives applying seroprevalence data to survey demographics.
Results: The study area includes 34,009 individuals ages 18 to 49. Estimates of HIV+ with known status are shown in Table 1. In all methods, estimates for women (41%, 49% and 34%) were much higher than those for men (16%, 20% and 22%). Estimates for men were highest in self report, and estimates for women were highest using clinical data capture.



[Known Status Among HIV Positives Individuals]

Conclusions: Although none of the estimation methods are ideal, all methods showed levels of known status far from the UN goal of 90%, particularly for men who are half as likely to know their status compared to women. Comparison of self report and clinical data based estimates differed by gender, suggesting gendered differences in either reporting bias, clinic utilization or both.

TUPEC0743

Evidence from the Zimbabwe population HIV impact assessment on 90-90-90: a national and provincial call to action for the first 90

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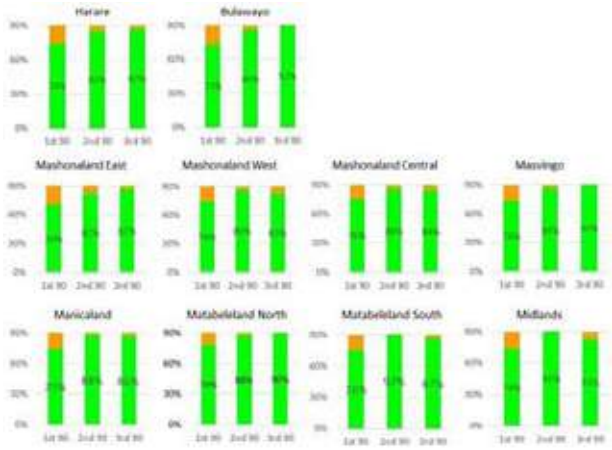
Background: The UNAIDS 90-90-90 objectives have gained a lot of momentum globally and are considered the key measures against which countries gauge their progress towards HIV epidemic control. The Zimbabwe population HIV impact assessment (ZIMPHIA), implemented in 2015/16, included population estimates for each of the 90-90-90 objectives. Here we explore progress towards 90-90-90 at national and provincial levels, and relevance to programmatic decision-making.
Methods: Consenting participants provided demographic, behavioral and clinical information and blood samples for household HIV testing using the national serial rapid test algorithm. HIV+ results were confirmed in a central laboratory and viral load was performed on all HIV+ samples. Viral load suppression (VLS) was defined as HIV RNA < 1000 c/ml.
Results: 22,496 adults (>15 years) consented to participate and 3,503 (15.6%) were confirmed HIV-positive. Of all HIV-infected adults, 73.9% (95% CI 72.0-75.8) knew their HIV status; of those who knew their status, 86.5% (95% CI 85.0-88.0) reported being on ART, and 86.2% (95% CI 84.5-87.9) of those reporting to be on ART were virally suppressed (Figure 1). At provincial level, known-positive HIV status ranged from 70.4% to 78.9% (95% CI 64.5-76.3 and 74.5-83.4 respectively); HIV-positives self-reported on ART ranged from 82.2-92.3% (95% CI 76.4-87.9 and 88.3-96.3 respectively), and VLS ranged from 82.6-91.6% (95%CI 77.1-88.1% and 87.3-96.0% respectively).
Conclusions: Zimbabwe has made remarkable progress towards 90-90-90. Notably however, the first of the three 90's is under 80% in every province. The Zimbabwe Ministry of Health reported 19-59% of patients receiving care had an HIV test at the point of service. In order to ensure the three 90's are achieved in this widely

generalized epidemic, it is critical that Zimbabwe ensure that routine opt-out HIV testing is aggressively rolled out beyond antenatal care and tuberculosis clinics to include all patients at all points of service.



[ZIMPHIA Provincial 90-90-90]

TUPEC0744

Could clinic-based antenatal HIV prevalence data be used for geographical targeting of resource allocation? Insights from an HIV hyper-endemic rural community in South Africa

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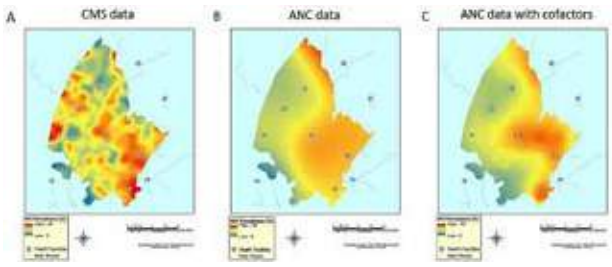
Background: Large geographical variation of the HIV epidemic in sub-Saharan Africa calls for geographically targeted resource allocation where burden is greatest. However, data available for mapping the geographic variability of HIV prevalence is scarce, and community surveillance (CMS) data are not always available. Here, we evaluated the accuracy of using clinic-based antenatal HIV prevalence data (ANC), which are routinely collected and commonly available, for capturing the desired resolution of the spatial variation of HIV.
Methods: CMS individual-level HIV data from more than 7,000 households, as well as routinely ANC data from ten health facilities located in a rural community in KwaZulu-Natal, South Africa were mapped using Kernel interpolation techniques. To assess the use of cofactors to improve spatial HIV prevalence accuracy using ANC data, cofactors such as population density and distance to main roads were included using cokriging methods. Maps were compared using Local Indicators of Spatial Autocorrelation (LISA), and Pearson Correlation Coefficient (PCC).
Results: ANC data (Figure 1A) captured large scale geographic heterogeneity described by CMS data (Figure 1B), but failed to detect some pockets of high prevalence. LISA analysis indicated that ANC data could accurately predict the spatial distribution of HIV prevalence in ~50% of the study area. ANC data with cofactors (Figure 1C) improved the resolution and accuracy of the prevalence map (PCC= 0.50; 95% CI 0.44 - 0.55), compared to the map without the inclusion of cofactors (PCC= 0.27; 95% CI 0.20 - 0.34).
Conclusions: ANC data are able to capture the spatial structure of HIV prevalence in an acceptable manner, particularly in areas where the burden of the infection is concentrated. The inclusion of cofactors may improve model estimates of HIV prevalence based on ANC data. HIV data collected from health facilities may provide valid spatial prevalence estimates for geographical targeting where resources are needed the most.



[Figure 1. Spatial distribution of HIV prevalence]

TUPEC0745

The HIV care continuum in Brazil, from 2009 to 2015

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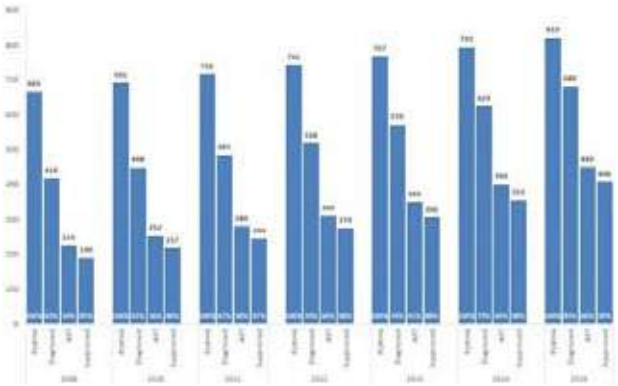
Background: The care continuum became a key tool for quantitative monitoring and evaluation of the HIV care and treatment. We aimed to characterize the cascade of HIV care in Brazil from 2009 to 2015.
Methods: We used surveillance data and programmatic individual-level information on HIV viral load(VL), CD4 and antiretroviral therapy (ART) for people living with HIV (PLWH) aged 18+, between 2009 and 2015. Four stages of the cascade were defined: PLWH; diagnosed; on ART; and virologically suppressed. Individuals who had at least one CD4, VL or ART dispensation between 2009 and 2015 were included in the analysis. We modelled trends of the cascade of care indicators by fitting generalized additive models.
Results: In 2009, HIV prevalence was 665K (0·50% of the adult population), and 418K individuals were diagnosed, (63% of the infected). 224K individuals were receiving ART (34% of the HIV infected). 190K individuals had VL < 1000 copies/mL, (29% of the infected and 85% of those on ART).
In 2015, the HIV prevalence was 0·58%(819K). 680K individuals were diagnosed (83% of the infected). 449K individuals were on ART (55% of the HIV infected). 406K individuals had VL< 1000 copies/mL (50% of the infected and 91% of those on ART).
Between 2009 and 2015, the estimated absolute HIV prevalence increased 23%, the diagnosis increased by 63%, the number of PLWH on ART was two times higher, and the number of virally suppressed increased by 114% (all p-values< 0·0001).
Conclusions: The results demonstrated significant changes in the Brazilian care continuum between 2009 and 2015. These results may be related to the important decrease in late diagnosis and the maintenance of the high percentage of viral suppression among PLWH on ART. However, innovative strategies are still required to diminish the largest leakage in the cascade of care, between diagnosis and ART.



[Care continuum. Brazil, 2009-2015]

TUPEC0746

Partner age and risk of HIV acquisition in rural Kwazulu Natal, South Africa

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Background: Recent empirical evidence from South Africa has challenged the notion that older male sexual partners increase the risk of HIV transmission to young women. Whether specific partner-age pairings are associated with increased risk of HIV acquisition in men and women is unknown. We test for non-linear effects of self-reported partner age on HIV incidence and report on high risk partner age pairings in both men and women.
Methods: We conducted a population-based cohort study among women 15-49 and men 15-55 years of age using data collected between 2004-2015 from the Africa Health Research Institute (AHRI) surveillance system in Kwazulu-Natal,

South Africa. Smoothed HIV incidence rates were estimated by age pairings with most recent sexual partner using generalized additive models (GAM). Cox proportional hazards regression was used to estimate the relative risk of HIV by age pairings.
Results: A total of 882 new HIV infections were observed in 15,935 person-years for women, IR = 5.7 (95% CI, 5.3 - 6.1) and 270 new HIV infections were observed in 9,372 person-years for men, IR = 2.9 per 100 person-years (95% CI, 2.6 - 3.2). Age-adjusted risk of HIV was elevated in women who reported male partners aged 25-29 (aHR = 1.44, 95% CI, 1.02 - 2.04) and 30-34 (aHR = 1.50, 95% CI, 1.08 - 2.09) relative to those reporting male partners aged 35+. HIV risk was elevated among men who reported female partners aged 25-29 (aHR 1.72, 95% CI, 1.02-2.90) and 30-34 (aHR 2.12, 95% CI, 1.03-4.39) compared to men who reported partnerships with women aged 15-19.
Conclusions: Partner age pairings play an important role in driving the cycle of HIV transmission. Interventions targeted at vulnerabilities in the age-specific HIV transmission cycle have the potential to greatly reduce HIV incidence in high burden areas.

TUPEC0747

Is condom use different across three sexual identities of men who have sex with men from Myanmar?

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Background: The most recent prevalence estimates clearly demonstrate HIV prevalence in the men who have sex with men (MSM) population is higher than in the general population in Myanmar; 11.6% in MSM compared to 0.59% in general population in 2015. Due to the challenges of early diagnosis and treatment of HIV, consistent condom use is still crucial for HIV prevention.
As has been demonstrated elsewhere in South East Asia, variations in self-identified sexuality among MSM in Myanmar can pose challenges for the uptake of condom use. In Myanmar, there are three MSM sexual identities:
1) Apone (hidden MSM)
2) Apwint (open MSM) and
3) Thange (heterosexual identified MSM).
Since sexual behaviours are diverse among them, it is valuable to understand their variation of consistent condom use.
Methods: The current study is a cross sectional study conducted in two cities: Yangon and Mandalay of Myanmar, surveying 520 MSM. The participants were recruited by time-location-based recruitment of a convenience sample alongside snowballing. In the current data analysis, the association of MSM sexual identity and inconsistent condom use with regular male partners versus casual male partners were explored by multivariable logistic regression method controlling for potential confounders.
Results: The research found that the reported inconsistent condom use was not significantly different across three sexual identities regardless of partner type. The adjusted odds ratio of inconsistent condom use with regular or casual male partners was 1.30 (0.71- 2.40) in Apwint and 1.10 (0.52- 2.18) in Thange compared to Apone. Those who were confident to negotiate with regular male partners for condom use were less likely to use condom inconsistently (adjusted odds ratio: 0.20, 95% CI: 0.06- 0.72).
Conclusions: Condom promotion should extend to the Apone and Thange in addition to the Apwint who usually focused on. The condom promotion should be tailored message relevant to each sexual identity of MSM, especially for MSM who live in heterosexual life. Condom promotion message should highlight the importance of consistence condom use with not only casual male partners but also with regular male partners. Condom negotiation skills training should be included as a part of condom promotion for MSM.

TUPEC0748

Factors associated with condom use at first sexual intercourse among high school students and apprentices in Benin

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Background: In January 2013, the Benin Social Marketing Association (ABMS) launched a youth project to increase condom use among sexually active high school students and apprentices. In December 2014, a study was conducted to identify factors associated with condom use at first sex in project areas.
Methods: A representative sample of 2516 students and 1923 apprentices aged 15-24 was drawn and interviewed in project areas located north and south of Benin. Univariate analysis and logistic regression were used to describe and to identify factors associated with condom use at first sexual intercourse among these young people.
Results: The proportion of unmarried youth aged 15-24 who are sexually active is 53.2% (CI : 51.7-54.7).
• The age at first intercourse is 15.7 years among students and 16.1 years for apprentices. It is 16.2 years for girls and 15.6 years for boys.
• At first sexual intercourse, only 39.8% of respondents (33.1% of boys and 43.7% girls) used condoms with their sexual partners.
• Key factors associated with condom use at first intercourse are: knowledge of condom effectiveness against STIs/HIV/AIDS (OR = 1.45), knowledge of correct condom use (OR = 1.50), being a girl (OR = 1.79), and having an older sexual partner (OR = 1.37).
Conclusions: The study shows that in the survey areas, entry into sexual life is earlier for boys than girls and that girls seem more demanding of condom use at first intercourse. In addition, knowing the benefits of condoms against HIV contributes to its use at first sex.

TUPEC0749

HIV acquisition risks among sex working men who have sex with men in Jamaica

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Background: There are global reports of widespread rights violations and violence toward sex workers. Sex working men who have sex with men (MSM) are a uniquely marginalized population, experiencing exacerbated violence and social exclusion through the intersection of multiple marginalities. In Jamaica, there is a paucity of research investigating sex work among MSM, including its association with HIV risks. The study objective was to understand social ecological and HIV risk factors associated with sex work among MSM in Jamaica.
Methods: We implemented a cross-sectional survey using respondent-driven sampling with 556 MSM in Kingston, Ocho Rios, and Montego Bay, Jamaica. Sex work included sex exchanged for money, shelter, food, transportation, or drugs/alcohol in the past 12 months. We estimated associations of correlates selected based on their a priori hypothesized relationship with sex work. Bivariable regression assessed the strength of associations between potential factors with sex work. Logit-link models were used to estimate a final multivariable model.
Results: Among 556 MSM, 67 (13.5%) were HIV-positive and 182 (32.7%) reported sex work involvement in the past 12 months. In the final multivariable model, sex work was associated with social ecological and HIV risk factors, including: higher odds of forced sex (odds ratio [OR] 2.60, 95% confidence interval [CI]: 1.55-4.38); unstable housing (OR 1.94, 95% CI: 1.14-3.29); food insecurity (OR 2.18, 95% CI: 1.30-3.68); social support (OR 1.07, 95% CI: 1.02-1.11); perceived sexual stigma (OR 1.12, 95% CI: 1.04-1.21); no regular health care provider (OR 2.59, 95% CI: 1.50-4.47) and higher number of lifetime sexual partners (OR 1.04, 95% CI: 1.01-1.07). Sex work was associated with lower odds of safer sex self-efficacy (OR 0.82, 95% CI: 0.74-0.91), lower income (OR 0.87, 95% CI: 0.77-0.98) and residing in Ocho Rios or Montego Bay (versus Kingston) (OR 0.19, 95% CI: 0.06-0.63).
Conclusions: Findings highlight associations between sex work and structural (food and housing insecurity, lower income, reduced health care access), social (sexual stigma, forced sex) and sexual risk (lower safer sex self-efficacy, higher sex partners) factors among MSM in Jamaica. HIV prevention strategies should address social and economic marginalization to reduce HIV vulnerabilities among sex working MSM in Jamaica.

TUPEC0750

Financial hardship, condomless anal intercourse and HIV risk among men who have sex with men in Paris, France

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Background: Few studies have examined financial hardship among sexual and gender minorities, who may experience financial hardship (when one has insufficient financial resources to adequately meet household's needs) due to social discrimination. The objective of this exploratory study was to examine the association between financial hardship, condomless anal intercourse, engagement in transactional sex and sexually transmitted infectious (STIs), including HIV, among a sample of gay, bisexual and other men who have sex with men (MSM) in Paris France because MSM continue to be the group most at risk of HIV infection in Western Europe.
Methods: Users of a popular geosocial networking application in Paris France (n=580) were shown an advertisement with text encouraging them to complete an anonymous web-based survey, including financial hardship, condomless anal intercourse, engagement in transactional sex, HIV status as well as other STIs and socio-demographics. The log-binomial model was used to assess association between financial hardship, condomless anal intercourse, engagement in transactional sex, and HIV infection as well as infection with other STIs, with adjustment for socio-demographics. The adjusted risk ratio (aRR) with 95% confidence intervals (CIs) were calculated.
Results: Approximately half (45.5%) of the sample reported high financial hardship. In multivariate models controlling for socio-demographic variables, high financial hardship (compared to low financial hardship) was associated with any comdomless anal intercourse (aRR: 1.28; 95% CI: 1.08, 1.52), condomless receptive anal intercourse (aRR: 1.34; 95% CI: 1.07, 1.67), condomless insertive anal intercourse (aRR: 1.30; 95% CI: 1.01, 1.67), engagement in transactional sex (aRR: 2.36; 95% CI: 1.47, 3.79) and infection with STIs other than HIV (aRR: 1.50; 95% CI: 1.07, 2.10).
Conclusions: Financial hardship was associated with condomless anal intercourse, engagement in transactional sex, and STIs among MSM in Paris. Our study therefore confirms the results in the literature, and is the first to examine a sample of European MSM, as previous research regarding financial hardship has largely focused on US-based populations and MSM other from geographic locations. This study suggests that interventions to reduce financial hardships (e.g., income-based strategies for ensuring that people have basic necessities) could promote sexual health in this high-risk population.

TUPEC0751

Injection of prescription opioids: a significant threat to HIV and hepatitis C virus (HCV) prevention among people who inject drugs (PWID)

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Background: Non-medical use of prescription opioids (PO) has reached epidemic levels in North America. This phenomenon has been observed among PWID in the province of Québec, Canada. Our ethnographic work has shown that PWID who inject PO tend to inject frequently which might impact the capacity of harm reduction programs to insure full coverage of PWID needs in terms of clean injection material.
This study aimed to quantitatively examine the association between PO injection and high injection frequency in a sample of PWID.
Methods: PWIDs are participants of an ongoing surveillance system of HIV and HCV infections. PWID (past 6 months) are recruited in 2 urban and 6 semi-urban/rural sites, mainly in harm reduction programs. Each visit includes a structured interview addressing drug use behaviors. Analyses were carried out using GEE methods. Frequent injection (FI) was defined as ≥120 injections, previous month. Five categories of injected drugs (previous month) were created: 1) PO only, 2) PO + crack/cocaine, heroin or other drugs, 3) heroin ± crack/cocaine or other drugs, 4) crack/cocaine ± other drugs and 5) other drugs only.
Results: Overall 1,651 participants (77.5% male; median age 37.0 years) made 2,829 visits between 2011-2015. FI was reported in 30.1% of visits. Category 1 of injected drugs was observed in 14.9% of visits, category 2 in 41.6%, category 3 in 7.3%, category 4 in 35.6%, and category 5 in 0.6%. Compared to category 4, proportion of FI was higher in category 2 [adjusted PR 3.73; 95%CI: 2.94-4.73], 1 [aPR 2.84; 95%CI: 2.14-3.77] and 3 [aPR 1.73; 95%CI: 1.20-2.50] controlling for age, gender, homelessness, income and crack smoking.
Conclusions: Frequency of injection was the highest among PWID who injected PO. Injection of PO has become a significant threat to HIV and HCV prevention among PWID. This poses a major challenge for public health authorities in the endeavor to fully cover needs in safe injection equipment.

TUPEC0752

Which sexual behavioural profiles are more associated with seronegative MSM becoming HIV-infected in West Africa? (CohMSM ANRS 12324 - Expertise France)

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Background: High HIV incidence in men who have sex with men (MSM) has been reported in sub-Saharan Africa. However, the heterogeneity of this group may hide specific high-risk sexual behaviours. We aimed to evaluate how sexual behavioural profiles are predictive of HIV infection among MSM in a prospective cohort.
Methods: HIV-negative participants have been recruited from a community-based cohort in four West-African countries since 2015 (Mali, Cote d'Ivoire, Burkina Faso, Togo). MSM are followed quarterly for HIV-testing and counselling. Socio-behavioural data are collected every 6 months using standardised face-to-face questionnaires. For the present intermediate analysis, HIV-seroconversions were observed over a 12-month period after enrolment. A cluster analysis helped determine specific sexual behavioural profiles at enrolment using data on sexual practices over the previous 6 months: condomless oral sex (COS); condomless anal sex (CAS); position during anal intercourse (exclusively insertive vs. receptive or both); multiple partnerships. Factors associated with sexual behavioural profiles were estimated using logistic regression.
Results: 418 MSM were recruited (median age: 24 years [Interquartile Range = 22-28]), 49% of them were employed. Three sexual behavioural profiles were identified: very high-risk (P1) (52%), high-risk (P2) (18%) and moderate-risk (P3) (30%). P1 MSM reported a high proportion of CAS (60%), multiple partners (65%), and all were receptive. Similar results were found among P2 MSM although all were exclusively insertive. All P3 MSM reported systematic condom use for oral sex, 32% were receptive, 45% practiced CAS, and 53% had multiple partners. P1 MSM showed the highest level of HIV-incidence in the first 12 months (11.5 cases/100 person-years vs. 4 in P2 and 1.6 in P3). They were more likely to define themselves as homosexual/gay (P1/P2: adjusted Odds Ratio (aOR):0.35, 95% Confidence Interval (CI)=0.17-0.70; P1/P3: aOR:0.43, 95%CI=0.24-0.76), to report multiple gender identities (P1/P2: aOR:0.10, 95%CI=0.05-0.22; P1/P3: aOR:0.17, 95%CI=0.09-0.31), and to search for partners on the internet (P1/P3: aOR: 0.55, 95%CI=0.31-0.96). P2 and P3 MSM were more likely than P1 to be bisexuals and identify themselves exclusively as men.
Conclusions: Sexual behavioural profiles may influence HIV-incidence. These findings can help prevention programs to better tailor risk-reduction interventions to reduce the dynamic of HIV-infection in MSM in West-Africa.

TUPEC0753

Potential racial/ethnic differences in the impact of institutional racism on sexual network assortativity among people who inject drugs recruited from 19 US cities

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Background: Racial/ethnic assortative sexual partnerships may partly explain racial/ethnic disparities in HIV infection among people who inject drugs (PWID). The potential impacts of racial and ethnic housing discrimination and residential segregation on racial/ethnic assortative sexual partnerships remains underexplored.
Methods: Multilevel modeling was used to assess cross-sectional associations of county-level racial and ethnic housing discrimination and ZIP code-level racial and ethnic residential segregation with self-reported racial/ethnic assortative sexual partnerships among 7,934 PWID recruited from 19 U.S. cities for CDC's 2012 National HIV Behavioral Surveillance. Racial/ethnic assortative sexual partner was last sexual partner in past year who was the same race/ethnicity. Housing discrimination and residential segregation variables were created using administrative data (e.g., U.S. Census). Racial housing discrimination and ethnic housing discrimination were separate exposures denoting the odds that black (or Hispanic/Latino) applicants were denied mortgage loans as compared to white applicants with similar characteristics in a given county. Racial residential segregation and ethnic residential segregation were separate exposures comparing concentrations of white residents to black (or Hispanic/Latino) residents in a given zip code.
Results: There were racial/ethnic differences in associations of racial and ethnic housing discrimination and racial and ethnic residential segregation with racial/ethnic assortative sexual partnerships. For example, racial housing discrimination was associated with more racial/ethnic assortativity among white and black PWID, but less assortativity among Latinos. Tables present standardized adjusted odds ratios.

Housing discrimination by race and ethnicity	Adjusted odds ratio (95% confidence interval)	p-value
Racial housing discrimination (White)	1.31 (1.07, 1.61)	0.009
Racial housing discrimination (Black)	1.25 (1.00, 1.58)	0.052
Racial housing discrimination (Latino)	0.82 (0.67, 1.00)	0.047
Ethnic housing discrimination (White)	0.93 (0.81, 1.08)	0.352
Ethnic housing discrimination (Black)	0.79 (0.67, 0.94)	0.008
Ethnic housing discrimination (Latino)	1.19 (1.02, 1.38)	0.024

[Housing discrimination and assortative partners]

Residential segregation by race and ethnicity	Adjusted odds ratio (95% confidence interval)	p-value
Racial residential segregation (White)	0.61 (0.51, 0.73)	<0.001
Racial residential segregation (Black)	1.91 (1.63, 2.24)	<0.001
Racial residential segregation (Latino)	1.10 (0.90, 1.32)	0.367
Ethnic residential segregation (White)	0.81 (0.69, 0.96)	0.016
Ethnic residential segregation (Black)	0.81 (0.68, 0.98)	0.032
Ethnic residential segregation (Latino)	1.77 (1.50, 2.09)	<0.001

[Residential segregation and assortative partners]

Conclusions: Institutional racism may differentially impact HIV transmission among racial/ethnic groups of PWID by differentially impacting sexual network assortativity. Extending this research to other key populations and identifying mechanisms behind these associations can inform housing-based HIV prevention strategies.

TUPEC0754

Characteristics associated with risky sexual behaviors reported by internet recruited MSM in the United States, eSTAMP 2015

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Background: Men who have sex with men (MSM) account for >60% of new HIV infections each year in the US. The internet has become a mechanism for meeting sex partners. We report baseline characteristics associated with "risky sex" from the 12-month internet-based Evaluation of HIV Self-Testing among MSM Project (eSTAMP).
Methods: In 2015, we recruited MSM through online banner advertisements. Eligibility included: HIV-negative or unknown status, ≥18 years old, had a male sex partner in the past year, and not taking HIV antiretroviral medications. Participants provided information on demographic characteristics, HIV testing, and sexual behaviors in the past 3 months. For this analysis "risky sex" is defined as anal sex without condoms with an HIV-positive or unknown-status male partner. Odds ratios (ORs) for associations with risky sex were computed.
Results: The 2665 MSM were 58%-white, 23%-Hispanic, 10%-black; 17%-never tested for HIV, 41%-untested in past year; 43%-college degree; 85%-employed part or full-time; 57%-recruited from internet dating sites; 63%-reported ≥2 male sex partners, and 32%-reported engaging in "risky sex". "Risky sex" was associated with being black or Hispanic, ≤high school education, never tested for HIV, recruited from dating site, unemployed, and reporting ≥2 male sex partners.

Characteristic	Proportion	Odds Ratio	95% CI	P-value
NH** Black vs. NH** White	0.38 vs. 0.30	1.46	1.11-1.92	<0.01
Hispanic vs. NHb White	0.37 vs. 0.30	1.36	1.12-1.66	<0.01
≤ High School vs. Post HS education	0.37 vs. 0.31	1.31	1.06-1.62	<0.01
Never tested HIV vs. Tested	0.39 vs. 0.31	1.43	1.16-1.77	<0.01
Dating site vs. Not Dating site	0.35 vs. 0.29	1.34	1.14-1.59	<0.01
Not employed vs. employed	0.42 vs. 0.31	1.67	1.34-2.07	<0.01
***≥2 male partners: Yes vs. No	0.43 vs 0.15	4.20	3.44-5.13	<0.01
Risky sex*: anal sex without a condom with an HIV positive or unknown HIV status male partner in the past 3 months, **NH : non-Hispanic, ***≥2 male partners: 2 or more male sex partners in the past 3 months				

[Characteristics associated with risky sex]*

Conclusions: The internet may be useful in recruiting MSM who have never or not recently been tested for HIV. Contrary to previous research, "risky sex" was more prevalent among black and Hispanic MSM than white MSM. Online studies of MSM who engage in higher-risk sexual behaviors may consider recruiting more men of lower socio-economic status, minority populations, and from dating sites.

TUPEC0755

Association between internalized stigma and depressive symptoms: a cohort study in rural Uganda

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Background: Depression affects>40% of people living with HIV (PLHIV) in low- and middle-income countries, and, >50% of all PLHIV report HIV-related stigma, a principal driver of depression. However, few longitudinal studies have examined the relationship between HIV stigma-related depression and antiretroviral therapy (ART). We sought to estimate the association between HIV, stigma, and depression among individuals initiating ART.
Methods: Data were obtained from the Uganda AIDS Rural Treatment Outcomes (UARTO) cohort of treatment-naïve PLHIV starting ART between 2007-2013 in rural Mbarara district. Eligible patients were ART-naïve, ≥18 years, and lived within 60km of clinic. Our primary outcome was depression, measured usingHopkins Symptom (HSS) checklist;our primary exposure was stigma score, measured using Internalized AIDS-Related Stigma Scale (IASS). Both scores weremeasured at en-

rollment and follow-up visits. We fit a linear generalized estimating equations (GEE) regression model to estimate the association between stigma and depression as continuous variables.We also fit a logistic regression model, dichotomizing stigma as any stigma (IASS score >0) and probable depression(HSS score ≥1.75). Estimates were adjusted for age, sex, education, marital status, household asset wealth, CD4 count, cohort entry date to account for secular trends in HIV stigma over time.
Results: The analysis included 454 participants (68% female) with mean age of 34 (SD 9.6) years; 54% were married. Mean baseline CD4 count increased from 169 for participants enrolled 2007-2009 to 310 for those enrolled 2010-2013 (P<0.001). Our GEE model demonstrated that both lower stigma (coefficient 0.032, P<0.001) and increased duration of ART (coefficient -0.0090, P<0.001) were associated with lower depression scores. Logistic regression models indicated that any stigma was associated with increased odds of probable depression (OR 2.6, 95% CI 2.0-3.5, P<0.001). The relationship between stigma and depression was similar after controlling for potential confounders (OR 2.6, 95% CI 2.0-3.3, P<0.001).
Conclusions: Higher degree of internalized stigma was longitudinally associated with higher depression scores in this large cohort of PLHIV initiating ART. Consistent with previous findings, longer duration of ART therapy was independently associated with lower depression scores. Our findings underscore the need for stigma-reduction interventions early in treatment for PLHIV.

TUPEC0756

Sexually transmitted bedfellows: exquisite association between HIV and HSV2 in 21 communities in Southern Africa in the HPTN 071 (PopART) study

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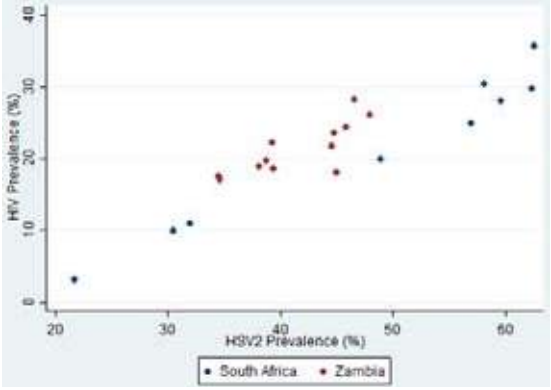
Background: Many studies have identified associations between HIV and Herpes simplex virus type-2 (HSV2), the commonest viral sexually transmitted infection, although the exact role of HSV2 as a cofactor in HIV transmission is unknown. A large community-randomised trial of an HIV preventive intervention afforded an opportunity to re-examine this association at individual and community levels.
Methods: The HPTN071(PopART) trial is measuring the impact of a combination prevention intervention on HIV incidence at population-level in 21 urban communities in Zambia and South Africa. To measure impact, a population-cohort of approximately 2,000 adults aged 18-44 was selected randomly from each community. Baseline data were collected on socio-demographic characteristics and sexual behaviour, and serological tests performed for HIV and HSV2 infection. Logistic regression was used to examine the association between HIV and HSV2 after adjustment for confounders. At community-level, HIV prevalence was plotted against HSV2 prevalence.

	HIV+ve/Total			
	HSV2-ve	HSV2+ve	OR (adj for age, community)	OR (adj for age, cty, partners, other)
Males	372/7,657 (4.9%)	834/2,401 (34.7%)	6.28 (p<0.001)	5.76 (p<0.001)
Females	790/11,380 (6.9%)	5652/13,305 (42.5%)	7.40 (p<0.001)	6.38 (p<0.001)

[Association between HIV and HSV2 in 21 communities]



[HIV and HSV2 prevalence in 21 communities]

Results: 38,691 adults were enrolled in the cohort. Overall HSV2 prevalence in men and women was 22% and 50% in Zambia, and 26% and 59% in South Africa. At individual level (Table) a six-fold higher odds of HIV was seen in HSV2-infected individuals in both sexes, even after adjustment for other risk factors including lifetime number of sex partners. At community-level there was a strong linear relationship between HIV prevalence and HSV2 infection (Figure).
Conclusions: These data show the exquisite association between these two infections, seen at both individual and community levels. While both viruses are sexually transmitted, the associations remained strong after adjustment for measures of sexual behaviour. This association is likely due at least partly to a powerful biological cofactor effect of HSV2 on HIV acquisition. Effective control tools for HSV2 could make an important contribution to HIV prevention.

TUPEC0757

Adolescent girls and young women's knowledge of sex partners' HIV status in Tanzania

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Background: Because 80% of HIV infections occur sexually in Tanzania, knowledge of sex partner's HIV status is vital to inform appropriate prevention strategies for individuals and couples, for example condom use or treatment as prevention. This analysis examines factors associated with unawareness of sex partner's HIV status among adolescent girls and young women (AGYW) in Tanzania.
Methods: We analyzed routine program data from the PEPFAR/USAID-funded Sauti Project that provides comprehensive, community-based biomedical, behavioral and structural prevention services to AGYW and key populations in Tanzania. Between November 2015 and March 2016, a vulnerability index tool was administered to out-of-school AGYW aged 15-24 years. Data analysis involved cross-tabulations with a Chi-square test for associations. Multivariate analysis was performed using mixed-effects logistic regression to identify factors associated with lack of awareness of sex partner's HIV status.
Results: Of 2,832 sexually active AGYW analyzed, 73% were not aware of the HIV status of their current sexual partners. Among the AGYW unaware of their partner's HIV status, 44% did not use condoms in all of their last three sex acts and 47% reported three or more sexual partners in the last 12 months. Multivariate analysis showed that lack of awareness of partners' HIV status was positively associated with food insecurity (OR=1.55%, 95% CI 1.23-1.94), increasing age difference between AGYW and her oldest sex partner (e.g. 10+yrs: OR=1.57, 95% CI 1.07- 2.29), having only some primary education or lack of formal education (OR=1.59, 95% CI 1.28-1.97), concurrency of sexual partners (OR=1.61, 95% CI 1.27-2.06), lack of an adult in the community that the AGYW could go to for emotional/financial support (OR=1.29, 95% CI 1.04-1.60) and being single/unmarried (OR=2.40, 95% CI 1.90-3.02).
Conclusions: Lack of awareness of sexual partner´s HIV status and inconsistent condom use are pervasive and constitute a significant risk for HIV acquisition among AGYW in Tanzania. Structural factors such as food insecurity, lack of adult support and limited education were associated with lack of awareness of partner's HIV status in our analysis, and highlight the potential role of structural interventions in reducing HIV acquisition risk.

TUPEC0758

Child sexual abuse, adolescent pregnancy and early substance use associated with underage entry to sex trade and HIV/STI infection in the Mexico - U. S. Border region

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Background: Forced or underage entry to sex trade has been linked to serious health and social impacts including enhanced risk of HIV infection, sexually transmitted infections (STIs), substance use and mental health disorders among youth. However, there is limited data about the risk factors that create vulnerability for underage entry, especially in Latin America, a region that is believed to be one of the largest sources of persons moved across international borders for the purposes of sexual exploitation.
Methods: This mixed methods study surveyed 603 female sex workers (FSWs) selected through modified time-location sampling within both indoor and street venues in two cities located on the Mexico-U.S. border region. Additionally, 30 in-depth interviews (15 in each city) were conducted with FSWs screening positive for underage entry to sex trade.
Results: One fourth of participants reported entering sex trade prior to age 18, among whom HIV and any STI (e.g., chlamydia, syphilis, gonorrhea, hepatitis B and/or C, HPV) prevalence were 5.9% and 49.6%. One in 8 participants (12.4%) reported child sexual abuse (forced sex prior to age 13), 54.5% reported an adolescent pregnancy (prior to age 18), 14.1% reported substance use prior to age 13 and 7.1% injected drugs prior to age 18. In multivariate analyses, child sexual abuse (adjusted odds ratio [AOR]= 1.9; 95% confidence interval [CI] 1.2-2.9), adolescent pregnancy (AOR=2.3; 95%CI 1.4-3.6), and substance use prior to age 13 (AOR=4.6; 95%CI 2.7-8.1) remained significant predictors for underage entry to sex trade. Qualitative data illustrates how sexual violence as a child can make girls vulnerable to adolescent pregnancy, early substance use and subsequent underage entry to sex trade.
Conclusions: Experiences of child sexual abuse, adolescent pregnancy and early substance use were associated with underage entry to sex trade. Further, FSWs who entered underage had a higher prevalence of HIV/STIs than those who did not. These results underscore the importance of targeting abused and otherwise vulnerable youth for prevention of sex trafficking in Mexico.

TUPEC0759

How changes in substance use affect psychological wellbeing and quality of life among people living with HIV/AIDS in South China?

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Background: Reductions in tobacco, alcohol, and other substance use may improve wellness of people living with HIV/AIDS (PLWH), but more empirical evidence is needed to inform interventions in diverse settings. This study aims to describe changes in substance use since HIV diagnosis, and explore whether and how the changes are associated with psychological wellbeing and quality of life among PLWH in China.
Methods: A cross-sectional survey was conducted among 2987 PLWH from 12 cities/counties in Guangxi, China to assess their health behaviors and outcomes. Data on substance use behaviors were collected from those who had ever engaged in tobacco, alcohol or other drug use. We conducted descriptive analysis and a series of multivariate regressions. Data analysis was stratified by gender.
Results: Men who were married, older, with higher education attainment and shorter period since HIV diagnosis were more likely to reduce or abstain from tobacco use. No demographic variables were related to the changes in either alcohol use or drug use among men. Similarly we did not identify any demographic variables were associated with changes of substance use among women.
For male participants, change in smoking was positively associated with perceived social support (αβ=.074, 95%PI= [.036, .210], p=.025) and self-efficacy (αβ=.055, 95%PI= [.003, .160], p=.04); reducing or abstaining from alcohol was associated with lower quality of life (αβ=-.076, 95%PI=[-.159, -.019], p=.013); reducing or quitting drug use was significantly decreased depression (αβ=-.163, 95%PI= [-.435, -.137], p<0.0001) and improved perceived social support (αβ=.160, 95%PI= [.166, .536], p<0.0001), self-efficacy(αβ=.120, 95%PI= [.072, .421], p=.006), resilience (αβ=.117, 95%PI= [.075, .474], p=0.007), and quality of life(αβ=.101, 95%PI= [.023, .289], p=0.022).
Among female participants, those reduced or quitted tobacco use reported lower self-efficacy (3. 22 vs. 3.50); those reduced or stopped drinking were more likely to show lower quality of life(αβ=-.146, 95%PI=[-.311, -.009], p=.038), self-efficacy (αβ=-.163, 95%PI=[-.477, -.040], p=.021) and resilience (αβ=-.176, 95%PI=[-.514, -.063], p=.012).
Conclusions: Abstaining from smoking, alcohol and drug may not always improve psychological wellbeing or enhance quality of life among PLWH. Psychological counseling services that assist PLWH in adaptation during post-abstaining period should be integrated into HIV care and management practice.

TUPEC0760

Prevalence and correlates of receptive anal intercourse among out of school adolescent girls and young women in Tanzania

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Background: The risk of contracting HIV through receptive anal intercourse (RAI) is up to 18 times higher than through vaginal intercourse. Qualitative research suggests an increased acceptability of condomless anal sex (AS) among young women and their sexual partners in Tanzania. This abstracts investigates prevalence and correlates of RAI in out-of-school adolescent girls and young women (AGYW) aged 15-24 reached by the USAID-funded Sauti program in Tanzania.
Methods: Data were collected August 2015 to June 2016 in 5 regions of Tanzania. Univariate and multivariate comparisons used Chi square and multivariate logistic regression respectively.
Results: Of 6,678 AGYW who had ever been sexually active, 37% were 15-19, and 63% were 20-24 years of age. Twelve percent (n=900) reported AS. Multivariate analysis showed that having no adult support (OR 1.4, p <0.01), food insecurity (OR 2.8, p <0.001), exchanging sex for cash (OR 1.8, p <0.001), having multiple sexual partners (OR 2.1, p <0.001), partners with age difference >10 years (OR 1.8, p <0.001), lifetime experience of sexual violence (SV) ≥2 (OR 2.5, p <0.001), belonging to AGYW social groups (OR 1.8, p <0.01), and first pregnancy younger than 17 or older than 20 years (OR 1.6, 2.6 p <0.001) were positively associated with the likelihood of practicing AS.
On the other hand, AGYW with primary education or more were less likely to practice AS (OR 0.4 p <0.001). Though significant on univariate model, knowledge of partner HIV status, use of contraceptives, and age of sexual debut and exchange of sex for gifts were not associated with AS.
Conclusions: RAS is a relevant risk factor for HIV acquisition in out of school AGYW in Tanzania. Programs should invest in combination prevention services that offer condom promotion, GBV screening, and support along with cash transfer, gender transformative behavior change education and caregivers mentoring to protect from HIV acquisition through AS. Furthermore, use of mapping tools to better understand the communities where the AGYW live would play a crucial role to assess safety of existing social groups and institutions and therefore to design programmatic responses to that.

TUPEC0761

Latent substance use profiles and associations with condomless anal intercourse among a sample of young black men who have sex with men and transgender women in the United States

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Background: Substance use has been associated with engagement in sexual risk behaviors among young black men who have sex with men and transgender women (YBMSM/TW), however additional research is needed to understand how patterns of substance use are associated with risk. We identified profiles of substance use among a sample of YBMSM/TW and examined associations with condomless anal intercourse (CAI).
Methods: Baseline data from 474 participants in the randomized controlled trial of healthMpowerment, a mobile-phone-optimized, Internet-based intervention to reduce sexual risk behaviors among HIV-positive and negative YBMSM/TW, ages 18-30, were examined. Latent profile analysis was used to approximate substance use profiles based on last 90 days use of alcohol, marijuana, crack, cocaine, heroin, methamphetamine, club drugs, opiates and inhalants. A zero-inflated Poisson model was used to predict mean episodes of CAI in the last 30 days based on substance use profiles and to compare CAI across profiles.
Results: Three distinct profiles of substance use were identified: low users (73% of sample; mean 11.98 days of alcohol use, 4.31 of marijuana use; low to no use of other substances); heavy marijuana users (25% of sample; mean 73.60 days of marijuana use, 20.34 of alcohol, 2.05 of cocaine; minimal use of other substances) and poly-substance users (2% of sample; mean 24.50 days of methamphetamine use, 36.40 of marijuana, 22.20 of alcohol, 9.10 of inhalants, 8.30 of club drugs, 3.90 of crack, 2.60 of cocaine and low use of other substances). Mean CAI was highest among poly-substance users (8.96, 95% CI: 7.03, 10.90), followed by heavy marijuana users (6.31: 95% CI: 5.64, 6.98) and low users (5.94: 95% CI 5.40, 6.48). CAI was significantly higher among poly-substance users compared to low users (IRR: 1.51; 95% CI: 1.20, 1.82) and heavy marijuana users (IRR: 1.42 95% 1.12, 1.72). There was no significant difference between heavy marijuana users and low users (IRR: 1.06; 95% CI 0.98, 1.15).
Conclusions: Patterns of substance use among this population were differentially associated with CAI. Although the proportion of poly-substance users was low, higher CAI in this group warrants targeted substance abuse interventions to reduce the likelihood of HIV acquisition or onward transmission.

TUPEC0762

Using exploratory factor analysis to guide the development of an HIV risk index for adolescent girls and young women in Tanzania

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Background: Improved strategies to address the disproportionate burden of HIV and sustained HIV acquisition risks remains as a crucial component of an effective HIV response. To better tailor HIV prevention interventions, the USAID-funded Sauti program aims to develop and evaluate a risk stratification tool and determinants of HIV acquisition risk among adolescent girls and young women (AGYW) in Tanzania.
Methods: A 20-item index was developed and administered by trained peers to 6,526 out-of-school AGYW aged 15-24 in five regions of Tanzania August 2015 to June 2016. Based on the composite score received on the index, AGYW were categorized into four different risk groups (Low, Middle, High, and Very High). Principal factor analysis with polychoric correlation and promax oblique rotation was used to describe an underlying latent variable for the vulnerability of HIV acquisition. Factors included in the final scale were selected based on Kaiser's criterion, eigenvalues, scree plots, Horn's test, and interpretability with items selected based on factor loading estimates greater than 0.3.
Results: Thirteen items were selected in the final scale. Inter-item correlation identified four factors: sexual behavior, psychosocial vulnerability, transactional sex, and reproductive health. A Cronbach's alpha of 0.74 suggested high reliability of the tool. Although stratification by region and age (15-19 vs. 20-24) showed slightly different item combinations, the 13 items in the final scale are measuring the same risk construct. Risk groups were significantly associated with increased odds of multiple concurrent partners and compensated sex across all risk levels compared to the low-risk group (Table 1).

Risk Group	Have had three or more concurrent partners in the past 12 months		Have had sex in exchange for cash in the past 12 months	
	Odds ratio	95% CI	Odds ratio	95% CI
Low	-	-	-	-
Medium	1.6*	(1.5, 1.8)	1.7*	(1.6, 1.9)
High	2.4*	(2.2, 2.6)	2.6*	(2.4, 2.8)
Very High	3.0*	(2.8, 3.2)	3.0*	(2.8, 3.2)

* p-value significant at 0.01 level

HIV Risk Assessment Tool Domains and Questions

Domain	Question	
Sexual Behavior	Ever had Sex (Vaginal/Anal)	
	Age at Coital Debut	More than one sexual partner in the same month
	Sex in the last 12 Months	Compensated Sex
Transactional Sex	Condom Use during last three Vaginal Sexual Acts	
	Intergenerational Sex	
	Serodiscordant Partnerships	
Reproductive Health	Pregnancy	
	Relationship Status	
Psychosocial Vulnerability	Sexual Violence	
	Food Security	
	Emotional and/or Financial Support	

[Table 1. Logistic regression assessing the relationship between HIV-related risk groups assigned by the HIV risk assessment tool and surrogate parameters of HIV acquisition risk]

Conclusions: The Sauti AGYW HIV Risk Index reliably stratifies out-of-school AGYW in Tanzania based on individual and structural HIV risks. Scaling implementation of this risk stratification tool may support better HIV prevention specification for AGYW in Tanzania ranging from enhanced counseling and education, addressing structural risk determinants, and HIV pre-exposure prophylaxis.

TUPEC0763

Relationship between sexually transmitted infections (STIs) and HIV transmission among female sex workers (FSWs) in Nigeria

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Background: STIs is a known predisposing factor to acquiring HIV. The Integrated Biological and Behavioural Surveillance Survey conducted in Nigeria in 2014 reported a high prevalence of HIV (19.4%) among brothel based female sex workers (BBFSW); with 21% and 7.2% of the BBFSW reporting unusual vaginal discharge and genital ulcers/sore respectively in the past 12 months prior to the survey.
Methods: Through the PEPFAR and USAID Integrated MARPs HIV Prevention Program (IMHIPP) in Nigeria, Heartland Alliance International works with female sex workers led community based organizations (CBOs) in 8 states of Nigeria (Akwa Ibom, Benue, Cross Rivers, Federal Capital Territory, Lagos, Kaduna, Nasarawa and Rivers) to mitigate the impact of HIV among sex workers of ages 15-49 through the provision of comprehensive HIV services. A total of 112,355 BBFSWs were reached with comprehensive HIV services across eight states in cohorts over a period of twenty months (April 2015-Novemebr 2016).
Each cohort of ten FSWs held cohort sessions weekly for six weeks. A total of 81,519 FSWs were provided HIV Testing Services (HTS) and also screened for STIs by trained providers. HTS and STI data were collected using client intake forms with each BBFSW given a unique ID. IBM SPSS statistical software 23 was used to analyze data and to ascertain the proportion of BBFSW with dual STIs and HIV infection.

Results: 3847 out of 81, 519 FSWs tested positive for HIV (4.7%). 1171 out of the 3847 FSWs (30.44%) that tested positive for HIV also had STIs. The most common STI were vaginitis (47.61%), lower abdominal pain (30.98%) and cervicitis (21.41%). There was statistical significance with a P value of 0.01. In addition, the Pearson's r was 0.947 which also indicates a very strong positive relationship.
Conclusions: The presence of STIs such as vaginitis and cervicitis increases the risk of HIV infection among BBFSWs in Nigeria. It is therefore essential that HIV prevention strategies targeting BBFSWs includes a full range of STI screening and treatment.

TUPEC0764

Comparison of HIV risks and HIV prevalence between poppers, amphetamine-type substance (ATS) and polydrug using Thai men who have sex with men and transgender women

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Background: Substance use has emerged as a part of the HIV syndemic among Thai men who have sex with men (MSM) and transgender women (TG). We compared HIV risks and prevalence between poppers, amphetamine-type substance (ATS) and polydrug users.
Methods: As part of community-based Test and Treat and Adam's Love study, MSM and TG received HIV testing and completed socio-demographic and risk behavior questionnaires. Participants were categorized on the basis of their substance use (regardless of alcohol use) into three groups: (1) 'only poppers users'; (2) 'only ATS users'; and (3) 'polydrug users'. Logistic regression analyses examined the association of each group with sexual behaviors and HIV infection.
Results: From May 2015 to December 2016, a total of 2,855 participants (75.4% MSM and 24.6% TG) were enrolled, and mean age was 26.5 (SD=7.1). There were 4.7% poppers, 3.6% ATS and 9.7% polydrug users. When compared with ATS and polydrug users, popper users were more likely to be MSM (98.5% vs. 65.1% vs. 83.8%, p<0.001), to have obtained a bachelor's degree or higher (51.9% vs. 20.4% vs. 34.9%, p<0.001), and were least likely to be bisexual (22.2% vs. 33% vs. 42.5%, p<0.001) or have only one sexual partner in the past 6 months (5.2% vs. 6.8% vs. 6.5%, p<0.001). ATS users included higher number of TG (35% vs. 16.2% vs. 1.5%, p<0.001), had less than high school education (43.7% vs. 27.7% vs. 7.4%, p<0.001), had monthly income ≤ 500 USD (63.1% vs. 49.6% vs. 42.2%, p=0.001) and had never previously tested for HIV (45.6% vs. 36.7% vs. 29.6%, p=0.001) as compared with polydrug and popper users. In multivariate regression model, using ATS was associated with unprotected anal sex (AOR 3.11, 95% CI 1.49 - 6.49, p=0.002) and testing HIV-positive (AOR 1.92, 95% CI 1.08 - 3.39, p=0.02).
Conclusions: Our study identified unique HIV vulnerabilities of distinct substance-using MSM and TG groups, ATS-users being at higher risk. Putting prevention tools such as pre-exposure prophylaxis (PrEP) and condoms into the hands of substance-users seeking clinical services, and implementing innovative models to identify those ‚unreached' for early interventions remains a critical priority.

TUPEC0765

Cluster of HIV infections associated with unsafe injection practices in a rural village in Cambodia

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Background: In late 2014 in a rural village in Cambodia, a surge in HIV infections was reported and a rapid investigation identified 114 among 915 Roka commune residents being HIV infected (12.4%).
Methods: A case-control study was performed in December 2014 to identify risk factors associated with recently diagnosed HIV positive cases in Roka commune.
Results: The results provide strong evidence that unsafe medical injection practices were associated with HIV cases. Recent exposure to medical injections (AOR=4.9 [2.2 - 10.8]), intravenous infusion (AOR=4.3 [2.1 - 8.9]) or blood draw (AOR=5.6 [2.5 - 12.2]) within the past six months were found independently associated with HIV infection. No other factors examined were significantly associated with recent HIV infection, including other invasive procedures, injection drug use and sex-related risk behaviour usually associated with HIV transmission.
Conclusions: In countries with low HIV prevalence like Cambodia, healthcare-associated HIV transmission may continue to represent substantial HIV risk and compromise HIV control. Such a risk should be closely monitored with appropriate tools and alert systems, actively prevented by improving healthcare providers' injection practices, both in the public and private sectors, and reducing the demand for unnecessary medical injections by raising awareness of both the public and medical practitioners.

TUPEC0766

Alcohol use, substance use, and risk of HIV transmission among female sex workers in Kampala, Uganda

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Background: Alcohol and substance use decrease inhibition and are thought to be associated with risk behaviors for HIV transmission. Key populations, including female sex workers (FSW), have historically high risk of HIV acquisition as well as alcohol and substance use. We investigate the association between alcohol use, substance use, and HIV-related risk behaviors among FSW in Kampala, Uganda.
Methods: HIV-naïve or perceived uninfected (no testing < 3 months) Kampala-based FSWs (n= 963) completed quantitative questionnaires in October - November 2016. Participants were asked how often they drank alcohol just before or during sex work (5-point scale, past month) and if they had used any intoxicating substances or drugs (past 12 months). HIV-related behavioral outcomes included 1) condom use with clients and 2) HIV testing (past 6 months). Multivariable logistic regression models adjusting for sociodemographic variables assessed associations between alcohol and substance use and the two behavioral outcomes.
Results: Participants had a median age of 28 years (IQR: 24-32 years) and the majority were literate (822, 85.7%) and reported monthly income < 250,000 UGX/~USD $70 (527, 55.1%). Almost half reported alcohol use before or during sex work "most times" or "every time" (435, 45.2%) and 374 participants (38.8%) reported past 12-month substance use. Inconsistent condom use was reported by 388 participants (40.4%) and 353 participants (33.7%) reported past 6-month HIV testing. Alcohol use (most or every time) before/during work and past 12-month substance use were both associated with increased odds of inconsistent condom use with clients (alcohol: aOR 1.98, 95% CI: 1.51-2.58; substance use: 1.89, 95% CI: 1.44-2.47) and decreased odds of past 6-month HIV testing (alcohol: aOR 0.85, 95% CI: 0.65-1.11; substance use: aOR 0.51, 95% CI: 0.38-0.67); the association between alcohol use and HIV testing, however, was not significant.
Conclusions: Alcohol and substance use are prevalent in this key population of Kampala-based FSWs and strongly associated with inconsistent condom use with clients and reduced HIV testing, behaviors that increase risk of HIV transmission and delay linkage to treatment and care. Interventions that reduce alcohol and substance use in the sex work environment should be developed for FSW in Kampala, Uganda.

TUPEC0767

Recent incarceration and risk of hepatitis C and HIV transmission amongst people who inject drugs: a systematic review and meta-analysis

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Background: Recent modelling has suggested that incarceration could be a significant driver of HIV and hepatitis C virus (HCV) transmission amongst people who inject drugs (PWID), primarily due to an elevated risk of HIV and HCV acquisition following recent release. We conducted a systematic review to assess the degree to which recent incarceration elevates the risk of HCV or HIV transmission amongst PWID.
Methods: MEDLINE, EMBASE and PSYCHINFO databases were searched for epidemiological studies assessing HCV (both primary infection and reinfection) or HIV incidence amongst community PWID. Studies published since January 2000 were retrieved for review without language restriction. Studies were included if they reported the association between recent incarceration and HCV or HIV incidence. Authors of incidence studies which did not report on this outcome, but may have collected data regarding recent incarceration were contacted to obtain additional data. Data were extracted and pooled in meta-analyses using a random effects model.
Results: Sixteen published studies that examined the impact of recent incarceration on HIV or HCV transmission met criteria for inclusion; 11 studies of HCV transmission (10 primary infection and 1 reinfection) and 5 of HIV transmission. Recent incarceration was associated with a 56% increase in the risk of HCV infection (rate ratio 1.56, 95% confidence interval (95%CI) 1.15-1.98; P< 0.001) and a doubling in the risk of HIV infection (rate ratio 1.99, 95%CI 1.21-2.77; P< 0.001) among PWID. There was evidence of heterogeneity between studies in the HIV analysis (I-squared = 72.3%, chi(2)=14.46, P=0.006) but not in the HCV analysis (I-squared = 32.9%, chi(2)=14.70, P=0.144).
Conclusions: Recent incarceration is associated with an increased risk of both HCV and HIV transmission amongst PWID. Because of the high rates of incarceration experienced by PWID in most settings, incarceration is likely to be a significant driver for HCV and HIV epidemics amongst PWID. To help develop future interventions, research is needed to determine the precise mechanism by which incarceration elevates HCV and HIV transmission risk amongst PWID, and so whether prison-based harm reduction and structural interventions could reduce this elevated risk and the burden of HCV and HIV.

TUPEC0768

Evaluating the HIV prevention and treatment needs among male clients of female sex workers in Senegal

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Background: Consistent data support the concentration of HIV risks in Senegal. Specifically, burden of HIV in Senegal, is highly concentrated among specific key populations with specific HIV acquisition and transmission risks. Characterizing the HIV transmission dynamics in Senegal can support continued implementation of increasingly specific HIV prevention and treatment programs. While the prevalence of HIV among female sex workers (FSW) appears to have fallen in recent years, there has been limited study of the HIV prevention and treatment needs of the clients of FSW.
Methods: Using time location sampling we visited 56 sites in Dakar, sampled 602 clients of FSW defined as men who pay money to have sex with FSW between 11/2015 and 05/2016. The survey included a structured instrument combined with biological testing for HIV and syphilis.
Results: 602 clients participated in the study, the median age of included men is 34 (IQR: 27-42) 23.0%(140/602) went to koranic school, 19.6%(118/602) did not finish high school, and 7.1% (43/602) are university students. 49.3%(297/602) are single, 40.5 %(244/602) are married , 8.4%(51/602) are widowers, with 68.1%(169/602) of participants reporting not living with their partners. The median income per week (CFA) was 75000 (IQR: 36000-150000), 31.9%(192/602) were skilled workers, and 4.5%(27/602) were unemployed. 37.4%(225/602) reported always using condoms with sex workers though 96.8%(583/602) reported using health services designed for FSW and their clients within the past year. HIV-1 prevalence was 1.2 % (7/602) with 2.3% found to have active syphilis (14/602). While 33.4%(201/602) reported having tested for HIV, none of the participants that tested positive to HIV declared knowing their status before the study.
Conclusions: These data highlight male client engagement in sex work-oriented services, but limited history of HIV testing and consequently limited awareness of HIV status among those living with HIV. Given the significant risk of onward transmission among those unaware of their HIV status to other female partners, these unmet needs are significant. Moreover, understanding the HIV acquisition and transmission risks among all people including non-FSW partners of male clients provides further insight into the distributions of HIV risks and ultimately national investments needed to address these risks.

TUPEC0769

"I've finally deleted Jack'd (for good)": in-group HIV, sexuality and racial stigma within geospatial networking apps and sexual networking websites

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Background: Geospatial networking apps (e.g., Grindr, Jack'd) and sexual networking sites (e.g., Adam4Adam, Manhunt) are often used by young black men who have sex with men (YBMSM) in the USA to identify sexual partners. Use of these online tools has been associated with increased sexual risk behavior. Experiences of HIV, sexuality and racial stigma within these sites may negatively impact sexual risk, mental health outcomes and uptake of HIV prevention and care services.
Methods: 232 YBMSM completed the intervention arm of a 12-month randomized controlled trial of healthMpowerment (HMP), an Internet-based intervention to reduce condomless anal intercourse. Intervention components included a discussion forum (The Forum) where participants could post about a variety of new and predefined topics such as coming out, HIV disclosure, and relationships. We used qualitative software to assist in systematically coding and thematically analyzing participant contributions about experiencing, anticipating, perpetuating and challenging in-group HIV, sexuality and racial stigma within geospatial networking apps and sexual networking site contexts.
Results: At baseline, 68.9% of participants reported searching for sexual partners on sexual networking sites in the last 3 months; 26.2% indicated at least daily use. The Forum participants discussed the strong emphasis on sex seeking in sexual networking apps and websites, sharing numerous examples of stigmatizing language describing HIV status, race, and sexuality. Participants debated the acceptability of expressing "preferences" regarding femininity vs. masculinity, sexual position, and body image and connected these preferences to an online culture that condoned stigmatization within the gay community. YBMSM recognized the stigma they experienced or anticipated in these virtual environments and articulated links to decisions about sex, condom use, and HIV status disclosure. Nevertheless, several participants felt unable to delete their app/website profiles because they served as a primary connection to the gay community.
Conclusions: YBMSM experience multiple layers of externally imposed stigma, impeding connection with other MSM for sexual or nonsexual relationships. Geospatial networking apps and sexual networking sites facilitate these connections, but in-group stigma within these virtual environments may contribute to increased risky sexual behaviors. Stigma reduction interventions that address in-group stigmas within sexual networking apps and websites may reduce sexual risk and HIV transmission.

TUPEC0770

Longitudinal analysis of sexual risk behavior, alcohol misuse and mental health disorders associated with STIs among U.S. military personnel across a shipboard deployment

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Background: Longitudinal sexually transmitted infection (STI) risk behavior data in mobile populations is difficult to obtain. Rates of sexual risk, alcohol misuse, mental health disorders, and other factors influencing STI acquisition may change significantly during a military deployment cycle; more accurate data on these factors may improve STI prevention. We examine factors associated with STIs before, during and after a U.S. military shipboard deployment.
Methods: Data were collected from 2012 through 2014 among active-duty U.S. Navy and Marine Corps personnel assigned to 11 deploying ships. Consenting participants completed an anonymous, paper-based survey assessing three months before deployment (T1), during the deployment (T2), and three months after deployment (T3). Questions included demographics, military history, sexual risk behavior, alcohol (AUDIT-C) and drug use, and mental health screening tools (CES-D and PCL-C). STI diagnosis was defined as a healthcare provider-diagnosed STI (chlamydia, gonorrhea, trichomoniasis, and/or syphilis). Descriptive and bivariate associations with STIs are reported for T1-T3 using t-tests and chi-square tests with statistical significance defined as p-value <0.05. Data were analyzed using SAS version 9.4. (SAS Institute, Cary, North Carolina, USA).
Results: Among participants, n=2,421(T1), n= 1,930 (T2), and n=1,444 (T3) completed the survey and reported age and sex. After excluding individuals who were not sexually active, the sample size for analysis was n=2,232 (T1), n= 649 (T2) and n=1,200 (T3). The STI prevalence was 1.5%, 6.8% and 2.3% for T1, T2 and T3 respectively among sexually active participants. Among participants reporting 2 or more sexual partners, 3% (T1), 7.7% (T2) and 5.8%(T3) of individuals also reported an STI. Among participants reporting engaging in transactional sex, 12.6% (T1), 19.9% (T2) and 22.2% (T3) also reported an STI in those respective time periods.
Conclusions: The proportion of sexually active individuals dropped to approximately 33% of all participants during T2, although those still engaging in sex during T2 had significantly higher STI rates compared to before or after deployment. Individuals who choose to remain sexually active during deployment face much higher risk of acquiring STIs and could be targeted for enhanced STI prevention and screening during this time period.

TUPEC0771

HIV risk factors and associated health outcomes among sexual minority women in the United States

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Background: Female-to-female sexual contact is an inefficient route of HIV transmission; and as such, sexual minority women have not been prioritized for HIV prevention programs. However, previous research has found high rates of sexual violence victimization, injection drug use, and lower healthcare access among sexual minority women, suggesting underlying vulnerabilities. This analysis examines sexual health outcomes and HIV risk factors among a population-based sample of sexual minority women in the United States.
Methods: 2013-2015 National Survey of Family Growth data from female respondents aged 15-44 (weighted n = 61,021,314) were analyzed. Multivariate logistic regression modeled associations between:
1) women reporting sex with women (WSW) and;
2) women identifying as lesbian, bisexual or gay (LBG), with a set of HIV and sexual health risk factors.
Results: 17.6% of U.S women (n = 10,757,319) report a same-sex experience. In adjusted analysis, WSW had increased odds of forced sex by a male, involuntary first sex, induced abortion, use of emergency contraception, and injection drug use, compared to other women.
Similar results were found among LBG women (8.5% of survey sample). WSW are more likely to have had a recent STD test, but no more likely to have HIV tests, pelvic exams, or pap smears compared to other women.

	WSW	WSW vs. non-WSW	
	%	cOR (95% CI)	aOR (95% CI)*
Ever forced sex by male	28.9	3.29 (2.59 - 4.19)	2.60 (2.03 - 3.32)
Involuntary first sex	9.7	1.82 (1.28 - 2.56)	1.67 (1.15 - 2.42)
Ever had an HIV test	80.9	1.63 (1.20 - 2.21)	1.04 (0.71 - 1.52)
STD test in past 12 months	44.5	2.11 (1.69 - 2.63)	1.51 (1.18 - 1.94)
Ever had induced abortion	32.1	2.54 (1.87 - 3.47)	2.12 (1.50 - 2.98)
Ever used emergency contraception	31.3	1.87 (1.48 - 2.37)	1.50 (1.17 - 1.92)
Pelvic exam or Pap test in past 12 months	64.0	1.24 (1.00 - 1.53)	1.02 (0.81 - 1.27)
Ever injected drugs that were not prescribed	4.6	9.61 (5.38 - 17.16)	6.33 (3.43 - 11.70)

*[*adjusted: demographic vars., # of sexual partners]*

Conclusions: Although WSW have a low risk of HIV transmission from sexual contact with women, elevated risk of sexual violence victimization, injection drug use, and proxies for unprotected sex with men including abortion and use of emergency contraception, suggest risk for STIs including HIV. Healthcare providers should understand that sexual identity does not always predict behavior, or risk, and that women who identify as LGB may still be at risk for HIV. WSW would benefit from trauma-informed medical care as well as culturally sensitive interventions that address HIV risk from injection drug use and unprotected sex with men.

TUPEC0772

Experience of sexual violence and association with HIV risk among adolescent girls and young women engaged in the DREAMS initiative in Kenya

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Background: Research shows sexual violence is associated with HIV acquisition, yet there is insufficient evidence about adolescent girl and young women's (AGYW) experiences of sexual violence and related HIV risk.
We examined the experience of sexual violence by intimate and non-intimate partners (IP vs. non-IP) among 15-24 year old women and its influence on their HIV risk perceptions and STI symptoms.
Methods: We conducted a cross-sectional survey with 914 AGYW enrolled in the DREAMS Initiative in two locations in Kenya between October and December 2016. Survey participants were randomly selected from rosters of DREAMS program beneficiaries. The survey assessed experience of sexual violence with non-IP (i.e. not boyfriend or husband) among all AGYW and sexual violence among partnered AGYW (N=574) in the last 12 months. Participants also reported on perceived risk of HIV (very /somewhat likely versus unlikely/not at all likely) and experiencing any of four STI symptoms (e.g., genital ulcer) in the last 12 months. Multivariable logistic regression analyses examined associations between experience of sexual violence (IP and non-IP) and HIV risk perception and STI symptoms. Informed consent was obtained for each respondent.
Results: Approximately 24% of all AGYW reported experience of sexual violence from non-IP and 19% reported experience of sexual violence from IP in the last 12 months. Among all AGYW, 20.4% perceived that they were at high risk of HIV. Among sexually experienced AGYW, 23.7% had experienced at least one STI symptom in the last 12 months.
Adjusted analyses show that experiencing IP or non-IP sexual violence was significantly associated with high HIV risk perception (OR_{adj}: 2.44 [1.54-3.84] and 2.68 [1.87-3.85], respectively), after controlling for age and other sociodemographic factors. Similarly, AGYW who experienced IP or non-IP sexual violence had increased odds of experiencing an STI symptom in the last 12 months (OR_{adj}: 2.23 [1.34-3.69] and 1.74 [1.13-2.66], respectively).
Conclusions: AGYW experience sexual violence from both intimate and non-intimate partners, and both experiences are associated with STI symptoms. Primary prevention programs for sexual violence are urgently needed. Further, screening for sexual violence history and provision of post-violence care is critical within HIV prevention programs for young women.

TUPEC0773

HIV risk, risk perception and uptake of HIV testing and counseling among youth men who have sex with men attending a gay sauna

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Background: Men who have sex with men (MSM) are amongst populations at-risk for HIV acquisition in Thailand. In youth MSM (aged 13-24 years), the incidence of HIV infection has substantially increased. However, data on HIV risk, risk perception and HIV testing and counseling (HTC) uptake among youth MSM in hotspots are limited.
Methods: A 3-year prospective study was conducted among MSM attending a gay sauna in Pathumthani, Thailand during 2013-2016. HIV risk and risk perception were assessed by an anonymous survey. HTC was provided on-site with result notification within 1 hour. HIV care establishment appointment was arranged by the counselors for HIV-infected participants. Care engagement within 1 year of diagnosis was subsequently assessed.
Results: There were 358 MSM participants; 87 (24%) were youth MSM. Of these 87 youth MSM, 48% were college or university students. Comparing to other MSM, youth MSM had significantly higher median number of different sexual partner (2 vs. 1; P <0.001), were more-likely to exchange sex for money (44% vs. 9%; P <0.001) and have sexual partner who exchanged sex for money (8% vs. 1%; P <0.001). Rates of consistent condom use for anal, oral and vaginal sexes were low and not significantly different between youth and other MSM (51% vs. 61%, 26% vs. 35% and 72% vs. 61%, respectively). By using the study risk categorization tool, there were 68 youth MSM with moderate or high-risk for HIV acquisition, of which 43 (63%) had false perception of low HIV risk. Youth MSM were more-likely than other MSM to accept HTC (68% vs. 33%) and to be first-time testers (42% vs. 28%). By HTC, the rates of HIV infection were higher among youth MSM comparing to other MSM [14/59 (24%) vs. 11/89 (12%); P=0.07]. Among the 14 youth MSM newly-diagnosed with HIV infection, only 6 (43%) showed-up for continuity care.
Conclusions: Youth MSM had substantial high HIV risk, false perception of low HIV risk and low rate of care engagement but demonstrated considerable rate of HTC uptake. Strategies to improve access to HTC, risk perception and linkage to care are needed for HIV prevention and management among the youth MSM.

TUPEC0774

Epidemiology of HIV and cascade of care in 2016 in injecting drug users from 1983 to 2016 in Luxembourg

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Background: HIV prevention, treatment and care for injecting drug users (IDUs), as a key population, is a priority for WHO. The National Service of Infectious Diseases (NSID) follows a cohort of all HIV infected persons in Luxembourg. In this context the epidemiology of all IDUs infected by HIV from the beginning of the epidemic could be analyzed.
Methods: Our retrospective cohort study included all HIV infected injecting drug users from 1983 to 2016. Detailed informations were reviewed from patient files to characterize the IVDU cohort, the proportion of IDUs among newly HIV infected persons, and the cascade of care in this population.
Results: Since 1983, 202/1184 (17%) new HIV infections were due to injecting drugs. 152/202 (75.2%) were coinfected with HCV, 13/202 (6.4%) with HBV and 11/202 (5.5%) with HCV/HBV. 147 (72.9%) are still alive and 49 (24.5%) died. IDUs prevalence rate was estimated in 2009 at 3.9 per 1000 persons (95% CI : 3.7 - 4.0), giving an estimated number of 2224 IDUs in 2016. Based on this estimation the overall HIV prevalence rate in IDUs was 9%. Among the 147 HIV IVDUs alive, 111 (75.5%) were under ARV treatment and 96 (86.5% of the treated persons) had an undetectable viral load.
The proportion of IDUs among new HIV infections decreased from 20% in the 80's-90's to a very low rate around 2% in 2009. However, from 2011 on, this proportion increased regularly to reach 30% in 2016 and phylogenetic analyses showed that this increase was mainly due to an active cluster of 30 IDUs infected by the same virus emerging in 2013.
Conclusions: In Luxembourg 17% of all new HIV infections since 1983 were due to injecting drugs but this rate reached 30% in 2016, showing an alarming recrudescence of HIV in this population. When looking at the cascade of care, improvement could be made in the number of treated IDUs since "only" 75.5% of them were under ARV treatment. A recent and rapid increase in the proportion of IDUs among the new HIV infections was mainly due to an active cluster of IDUs infected by the same virus.

TUPEC0775

Mixed synthetic drugs and heroin use practices, drug effects, and potential risks for HIV, syphilis, and hepatitis C infections among Chinese drug users

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Background: Mixed synthetic drugs (SDs) and heroin users have become increasingly prevalent among Chinese drug users in the past decade as the combined effects of polydrug consumption could maximise anticipated satisfaction. This study aims to identify the socio-demographic characteristics, drug-related practices, and blood-borne viruses and sexually transmitted infections among SDs users mixed use with heroin and compare differences to those sole SD and heroin users.
Methods: A total of 1,291 drug users were recruited from the national surveillance settings during 2016 in the Southwest Chinese province, which is near the "Golden Triangle" (the major drug planting and trafficking region in the world). The comparison was conducted in participants according to their drug-use categories by multivariate logistic regression.
Results: Of 1,291 participants, 447 mix-used SDs with heroin, while 526 used SDs only and 318 used heroin only. Mixed users appear to be an older population with worse socioeconomic status, longer drug use history, and consumed drugs more frequently than sole users. Individuals with monthly income below 2000 RMB (≈300 USD) almost doubled the odds of mixed drug-use (ARR=1.86, 95% CI 1.24-3.67) compared with sole-SDs users. People who initiated drug use for pleasure seeking were more likely to mix use than those occasionally use for the recreational purpose (ARR=1.89, 1.09-3.73). Long drug use history and using drug for subsequent sexual excitement were associating factors of mixed drug use (ARR=1.21, 1.12-1.32; 1.59, 1.02-2.47, respectively). Hallucination (37.1%) in sole-SDs users, hyperactivity (32.2%) in sole-heroin users, and sexual arousal (36.8%) in mixed users is the primary concern for the drug effects. Among all the drug users, mixed drug users have highest HIV (7.4%) and syphilis prevalence (2.9%), but highest HCV prevalence (49.7%) was observed in sole-heroin users. Mixed drug use was a risk factor for HIV and syphilis infections (ARR= 2.99, 1.42-8.97; 3.95, 1.43-7.04).
Conclusions: Mixed use of heroin and SDs is more frequent in older drug users and contribute to higher risk of HIV and syphilis infections. Effective interventions and drug-policy for harm and infections reduction are necessary to target an enlarging population of mixed drug users.

TUPEC0776

Potential bridging group for HIV transmission: sexual behaviors and HIV prevalence among motorcycle-taxi drivers in Cameroon (MOVIHCAM study - ANRS 12350)

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Background: Ending the AIDS epidemic is now discussed, which was unthinkable a few years ago. However, such objective can be achieved only if all affected populations are identified, reached and have access to immediate antiretroviral therapy. While motorcycle-taxi drivers have been identified as a potential bridging group in the late 90s, little is known on their characteristics and sexual behaviors. This work aims to fill this gap by adding to the recently emerging body of information on HIV risk among motorcycle-taxi drivers.
Methods: A cross-sectional survey was conducted with 1411 motorcycle-taxi drivers recruited using a time-location sampling in Yaoundé, Douala, Kribi and Bertoua (Cameroon). Face-to-face interviews were realized with all participants and HIV tests administrated to a subset of them (n = 1003).

Participants characteristics were described using weighted estimators and compared to historical data (DHS and ANRS12302 study conducted respectively in 2011 and 2015). Factors associated with HIV infection were assessed using mixed-effects logistic regression.
Results: Compared to other men, motorcycle-taxi drivers reported a higher number of sexual partners and sexual relationships with commercial and casual partners.

	DHS 2011	ANRS 12302 study	Movihcam
≥2 partners in the past year	38.4% (36.0 - 40.8)	46.4% (40.9 - 51.9)	52.2% (49.2 - 55.2)
Most recent sex partner casual	5.3% (4.1 - 6.6)	2.2% (0.5 - 3.8)	8.9% (7.2 - 10.6)
Commercial sex in the past year	5.9% (4.7 - 7.0)	26.0% (21.2 - 30.7)	35.1% (31.5 - 38.7)

[Table 1.]

During their most recent relationships, 55% of them had multiple partners. Moreover, 32% reported sexual relationships with female clients in exchange of a ride. Consistent condoms use was frequent with casual partners (69.1%) or sex workers (91.9%) but less common with clients (58.9%). HIV prevalence was 2.4% (1.6 - 3.2), slightly higher than the HIV prevalence observed among men in 2015 in the ANRS12302 study (1.5%). The prevalence of HIV infection was significantly higher among participants living with their family (OR 3.8, p=0.01) and among those not owning their motorcycle (OR 3.0, p=0.01). A high proportion of the motorcycle-taxi drivers (82%) get tested for HIV at least once (DHS2011: 65%, ANRS12302: 74%).
Conclusions: Our results show that motorcycle-taxi drivers are often engaged in risky sexual behaviors and suggest they may be at increased risk of HIV infection. As the use of motorcycle-taxi is increasing in many African settings, interventions tailored to this group are urgently needed.

TUPEC0777

Joint effects of alcohol and amphetamine type stimulant (ATS) use disorders on STI acquisition in a cohort of women engaged in sex work in Phnom Penh, Cambodia

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Background: Female entertainment and sex workers (FESW) have high rates of alcohol consumption and ATS use, which can lead to increased sexual risk, HIV, and other negative health outcomes. We estimated the joint effects of alcohol and ATS use disorders on sexually transmitted infections (STIs) acquisition accounting for time-varying confounding.
Methods: Prospective cohort of 1,198 FESW enrolled in a HIV and stimulant use prevention intervention conducted in 10 provinces in Cambodia. Alcohol and ATS use disorders (AUD and SUD) were assessed using the Alcohol and Substance Use Involvement (ASSIST) scale. STI acquisition was defined as self-reported STI diagnosis by a medical provider in the past 3 months. Marginal structural models were used to estimate the joint effects of AUD and SUD on STI acquisition.
Results: At baseline, 25% scored >27 on the ASSIST for alcohol and 7% for ATS, screening positive for AUD and SUD respectively. Twenty-six percent reported one or more recent STIs during the 18-month follow-up. After accounting for several known confounders including sexual risk behaviors, the adjusted odds ratio (AOR) for STI acquisition associated with screening positive for AUD alone was 3.19 (95% CI: 1.84, 5.54). The AOR ratio for SUD alone was 3.79 (95% CI: 1.40, 10.23). The AOR for the joint effect of AUD and SUD was not significant (AOR = 3.24; 95% CI: 0.95, 11.11; p = 0.22).
Conclusions: Even after accounting for sexual risk taking behavior, AUD and SUD are independently associated with greater odds of STI acquisition among Cambodian FESW. Those who screened positive for SUD alone had the greatest odds of acquiring a STI over follow-up. Further research is needed to understand how AUD and SUD potentiate biological as well as behavioral pathways that influence STI acquisition in FESW. Clinical research is needed to examine if interventions to address AUD and SUD among FESW can boost the effectiveness of existing HIV prevention activities.

TUPEC0778

I am venal out of necessity, but I do not risk my life for money: factors associated with men having sex with other men in exchange for monetary/non-monetary advantages

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Background: Men who have sex with men (MSM) are at much greater risk of HIV infection in Sub-Saharan Africa. Little is known about MSM transactional sex in Africa. We aimed to characterize MSM who had sex with other men in exchange for monetary/non-monetary advantages (MSM-SEMA).
Methods: CohMSM is an interventional cohort study of MSM in four West-African countries, including Mali. This analysis focused on Malian MSM enrolled between June 2015 and May 2016 with/without a 6-month follow-up visit. Data on socio-economic dimensions, psychosocial outcomes and sexual behaviours were collected through standardized face-to-face interviews. Three HIV risk-reduction strategy sub-scores were constructed using principal component analysis: avoidance score: avoidance of at-risk situations as a protection strategy; knowledge score: knowledge of ART-related strategies including informal PrEP, treatment as prevention (TasP) and condomless sex only with treated/undetectable viral load HIV-positive men; sero-adaptation score: avoidance of condomless sex with men known to be HIV-positive status or with unknown status. An experienced stigmatization score was also constructed.
Data analysis used a generalized estimating equation model to estimate the population-averaged effects on the probability of being an MSM-SEMA.
Results: Among the 200 participants enrolled in Mali, 149 completed the follow-up visit 6 months later. Of the total 349 visits analysed, 25.5% corresponded to participants reporting to be MSM-SEMA.
Overall, 49.6% were under 24 years old (median[IQR]=24[22-27]), and 79.1% qualified their financial situation as difficult. Declaring oneself to be MSM-SEMA was more frequently associated with younger age (OR[95%CI]: 0.6[0.4-0.9]), alcohol consumption during sex (OR[95%CI]: 6.4[1.5-27.7]), simultaneous multi-partner male sex (OR[95%CI]: 5.7[2.6-12.9]), satisfaction with current sexual life (OR[95%CI]: 4.7[1.5-15.2]), knowledge (OR[95%CI]: 5.6[1.1-29.7]) and sero-adaptation scores (OR[95%CI]: 11.9[1.2-120.3]), and an experienced stigmatization score >2 (OR[95%CI]: 2.3[1.2-4.4]). Having had one's most recent sexual encounter with one's girlfriend (OR[95%CI]: 0.4[0.2-0.9]), having had insertive anal intercourse with one's boyfriend in the previous 6 months (OR[95%CI]: 0.4[0.2-0.8]), and having an avoidance score (OR[95%CI]: 0.1[0.02-0.6]) were all associated with less frequent declaration of being MSM-SEMA.
Conclusions: Malian MSM-SEMA may not be the subpopulation most vulnerable to HIV infection as they seem better informed about risk-reduction strategies, especially informal PrEP, TasP. Tailored HIV prevention health promotion interventions for this group are needed to reduce sexual risks.

TUPEC0779

Does pre-exposure prophylaxis use lead to a higher incidence of sexually transmitted infections? A case-crossover study of men who have sex with men in Los Angeles, California

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Background: Pre-exposure prophylaxis (PrEP) is an effective method for reducing HIV incidence among at-risk populations. However, concerns exist over the potential for an increase in sexually transmitted infections (STIs) following PrEP initiation. This study compares STI incidence before and after PrEP initiation, within subjects among a cohort of men who have sex with men (MSM) in Los Angeles, California.
Methods: This study used data from patients who received PrEP services at the Los Angeles LGBT Center between November 2015 and October 2016 (n = 211). A generalized linear mixed model was used in a case-crossover design to determine if there was a significant difference in STIs within subjects for up to 365 days before PrEP initiation as compared to up to 365 days after. We jointly analyzed syphilis, urethral gonorrhea, rectal gonorrhea, pharyngeal gonorrhea, urethral chlamydia, and rectal chlamydia.

Results: Between the Before PrEP and After PrEP periods, there was a statistically significant within-subject decrease in STIs overall (p = 0.04) that differed by site/disease. Analyzing individual bodily site-STI combinations, there was a statistically significant increase between periods in syphilis (p = 0.01) as well as rectal chlamydia (p = 0.02), but no significant difference between periods in rectal gonorrhea (p = 0.63), pharyngeal gonorrhea (p = 0.48), urethral gonorrhea (p = 0.77), and/or urethral chlamydia (p = 0.62).
Conclusions: There was a statistically significant increase in syphilis and rectal chlamydia, but the remainder of STIs remained unchanged between periods. Future studies should determine whether this increase is an artifact of detection bias or represents a true increase in sexual risk behavior following PrEP uptake for this segment of users.

TUPEC0780

Syndemic psychosocial health problems associated with recent client-perpetrated sexual violence among female entertainment sex workers in Cambodia

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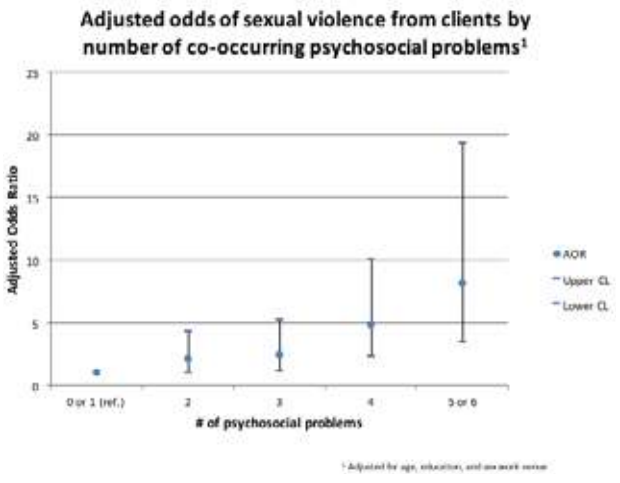
Background: Female entertainment and sex workers (FESW) are vulnerable to sexual violence, which impedes safe sex behaviors and increases the risk of HIV infection. FESW are also disproportionately affected by multiple co-occurring psychosocial health problems including substance use, depression and economic insecurity, all associated with an increased risk of exposure to violence. We used a syndemic framework to examine the additive effects of co-occurring problems on the risk of recent exposure to sexual violence among FESW in Cambodia.
Methods: Data were obtained from a sample of 1198 FESW participating in an HIV prevention program in 10 provinces in Cambodia. Women were surveyed at baseline regarding recent exposure to client-perpetrated sexual violence (prior 3 months) as well as syndemic psychological health problems (depression, alcohol use, amphetamine-type stimulant (ATS) use, housing insecurity, food insecurity and having a debt). Bivariate and multivariate logistic regression analyses were conducted.
Results: Prevalence of recent exposure to sexual violence from clients was 6.9%. Bivariate analyses showed high correlations between co-occurring psychosocial problems, and all, except ATS use, were associated with exposure to sexual violence. In multivariable models, risk of recent sexual violence increased with the number of psychosocial problems, showing an additive effect (Figure 1). Compared to those with ≤1 problem, FESW with two psychosocial problems had twice the odds (AOR=2.08; 95%CI: 1.00-4.31) and women with 5-6 psychosocial problems had eight-fold higher odds (AOR=8.10; 95%CI: 3.4-19.31) of reporting recent sexual violence from clients.



[Adjusted odds of sexual violence from clients]

Conclusions: Our findings support a syndemic model of co-occurring psychosocial problems among FESW that are associated with increased risk of recent sexual violence from clients. Effective HIV prevention interventions targeting FESW should use a comprehensive approach that takes into consideration the interconnections between these multiple co-occurring psychosocial health problems.

TUPEC0781

Social epidemiology of HIV acquisition among Afro-Caribbean immigrants post-migration: the MSAFIRI study, Canada

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Background: In high-income countries, HIV prevalence is disproportionately high among immigrants originating from HIV-endemic countries. Yet, the extent and drivers of infection after migration are unknown. The MSAFIRI Study uses mixed-methods to characterize the social epidemiology of HIV acquisition among African, Caribbean and Black (ACB) immigrants in Canada.
Methods: Socio-demographic data from a province-wide clinical cohort of 825 ACB adults attending HIV care in Ontario were analyzed to identify those who were born abroad and infected post-arrival. Interviews with a purposive sub-sample were qualitatively analyzed to understand the circumstances of sexually acquired infections post-arrival.
Results: The time of HIV acquisition could be established in 349 ACB adults born abroad (mean age 38y, 57% female); 80% were infected pre-arrival and 20% post-arrival. Persons born abroad and infected post-arrival were significantly more likely to be from the Caribbean (61.4 vs. 16.9%), male (62.9 vs. 38%), identify as gay/bisexual (37.1 vs. 10.4%), and report MSM transmission (32.9 vs. 10.8%), compared to persons infected pre-arrival; age was not a factor. Post-arrival MSM transmission was akin to the general Canadian population, but heterosexual transmission was significantly higher. Interviews with 32 participants (50% female, 34.4% gay/bisexual, 43.8% born in Africa, 56.2% born in the Caribbean) helped to contextualize the determinants of HIV acquisition in Canada: 1) Difficulties assimilating under a racialized, migrant identity post-arrival left most participants detached from traditional social networks. 2) HIV was perceived to affect people of colour in participants' countries of origin but not "white" people. 3) Men's sexual activities were governed by a desire to explore multiple, novel (often, biracial) partnerships, where they felt immune to HIV. 4) Women's sexual encounters were governed by a dependency on their partners, leaving them unable to assert agency. 5) Heterosexual encounters stemmed from long-term monogamous partnerships, whereas MSM encounters were casual.
Conclusions: Risk misperceptions and inequities of race, gender and social capital - emergent in interviews and supported by epidemiological analyses - suggest a reconstructed vulnerability to HIV among Afro-Caribbean immigrants in Canada. Prevention strategies must address the unique, intersecting drivers of HIV acquisition post-migration in persons moving from HIV-endemic countries to countries of perceivably lower risk.

TUPEC0782

High prevalence of HIV and sexually transmitted infections, along with high rate of unprotected sex, among Thai MSM and TG who reported no or low self-perceived risk level for HIV

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Background: Self-perceived risk is a significant factor associated with health-seeking behaviors, including the pursuit of HIV testing and counselling. However, discrepancies between self-perceived risk and actual risk can result in less-than optimal coverage of HIV services and allocative inefficiency. We investigated correlations between self-perceived risk and HIV and STI among MSM and TG in Thailand.
Methods: Baseline data was collected from May 2015 to September 2016 using self-administered questionnaires and HIV/STI (syphilis/gonorrhea/chlamydia) testing from MSM and TG enrolled in a cohort study in six community sites in Thailand. Based on their responses, participants were stratified into four categories of perceived HIV risk (no risk, low risk, moderate risk, and high risk). Participant characteristics and prevalence of STI/HIV infection were compared with self-perceived risk levels using Chi-square test. The associations between self-perceived risk and other factors were analyzed by logistic regression.
Results: Of 2468 individuals (70.6% MSM and 29.4% TG) with a mean (±SD) age of 26.8 (7.2) years, 17.9% reported high self-perceived HIV risk, 32.0% moderate, 37.7% low and 11.2% none. Logistic regression identified age >25 years (OR 1.32, 95%CI 1.07-1.64, p=0.009), knowing someone with HIV infection (OR 1.55, 95%CI 1.27-1.89, p< 0.001), having multiple partners in the past six months (OR 2.24, 95%CI 1.76-2.84, p< 0.001), unprotected sex (OR 2.29, 95%CI 1.83-2.87, p< 0.001),
STI (OR 1.80, 95%CI 1.23-2.66, p< 0.001) and group sex (OR 2.22, 95%CI1.68-2.93, p< 0.001) to be associated with increasing level of self-perceived risk.
In high, moderate, low and no risk groups, HIV prevalence was 23.9%, 17.4%, 11.7% and 8.9%
(p< 0.001), while STI prevalence was 39.5%, 35.2%, 30.8% and 26.8% (p=0.001), respectively. Of those who reported no/low risk, their actual risk behaviors were: multiple partners (33.2% and 50.3%), unprotected sex (61.1% and 74.2%), group sex (3.2% and 8.4%), and STI symptoms/diagnosis
(11.4% and 27.4%) in the past six months.
Conclusions: Self-perceived HIV risk positively correlated with the likelihood of having HIV/STI infections. However, self-perceived no/low risk groups exhibited high-risk sexual behaviors. Improved self-assessment skills and more strategic behavior change communication interventions to MSM and TG need to be strengthened to improve uptake of HIV/STI testing in these populations.

TUPEC0783

The portrait of HIV prevalence, risk behavior and HIV prevention response on population men who have sex with men (MSM) in Indonesia 2007-2013

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Background: The prevalence of HIV in Men who have sex with Men (MSM) populations in Indonesia continued to increase, while access to HIV treatment services in this group is low. The HIV burden in most provinces in Indonesia is concentrated in "most at risk" populations and is generalized in Papua and West Papua provinces. Estimates of the prevalence of HIV in 2012 in the general population in Indonesia is 0.4%, while in Papua 2.3%. Men sex with men is one of the key populations at higher risk of contracting HIV than men in the general population. Estimates MSM population in Indonesia by 2012 of 81.338 people.
Methods: The method is a descriptive study using the Integrated Biological and behavioral surveillance (IBBS) by Ministry of Health (MOH) Indonesia (2007,2009,2011,2013), Sero-Surveillance and Behavioral Quick Surveillance by MOH and National AIDS Commission(NAC) (2013), MSM and Transgender Program Studies in Indonesia by MOH and NAC (2013) and Impact Analysis Studies by NAC (2015).
Results: Based on the results of IBBS in 2007-2013 and the Sero Surveillance results of 2013, the prevalence of HIV in the MSM population in Indonesia is increasing. The prevalence on 2007: 5.3%, 2008 : 5.48%, 2009 :7%, 2013:13.6% and 2013:17.3%. For MSM Risk Behavior (the consistency of condom usage) on 2007 :27%, 2011 :33%, 2013 : 31%. Indonesia response for HIV prevention on MSM: Presidential Decree No.75/2006, National Strategy and Action Plan 2010 - 2014 for MSM, MSM community strengthening, Fund for HIV prevention in MSM community is USD17.379.143 in 2011 and USD23.692.860 in 2012.
Conclusions: HIV prevalence in MSM increased between the years 2007-2013 at 5% in 2007 to 17.3% in 2013. On the other survey locations in 2009 by 7% to 12.8% in 2013. Risk behaviors in MSM that may increase the risk of HIV is low proportion of MSM use condoms consistently. Strengthening policies and programs have been conducted, but the effectiveness of the program to achieve the impact of the epidemic is not yet fully meet the expectations where the HIV prevalence among MSM increased by more than 100%. More than 50% of the funding is still sourced from abroad.

TUPEC0784

Statistical adjustment of network degree in respondent-driven sampling estimator venue attendance as a proxy for personal network size among young MSM

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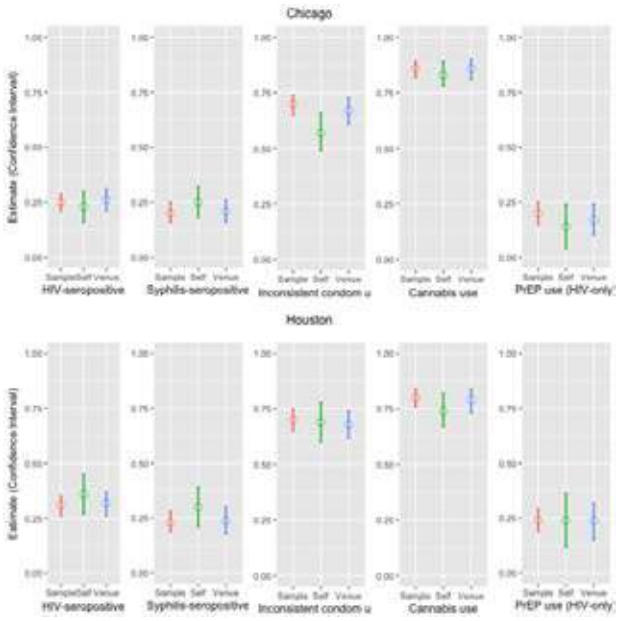
Background: Respondent-driven sampling (RDS) is widely used to sample hard-to-reach populations, such as men who have sex with men (MSM), and to estimate the prevalence of disease and risk/protective behaviors. Use of RDS among young MSM (YMSM), however, poses challenges that make RDS estimates using the standard degree measure suspect.
The objective of the current study is to introduce a statistical approach to adjust the standard degree measure of self- reported network size, which is then applied to respondent-driven sampling (RDS) estimators.
We propose a new network degree measure based on approximated frequencies of venue attendance.
Methods: We recruited 729 Young men who have sex with men (YMSM) aged 16-29 in 2014-2016 in Chicago, IL, and Houston, TX, and estimated the population seroprevalence of HIV and syphilis, risk behavior, and protective behavior by computing and comparing RDS estimates adjusted by the standard degree measure, a venue-informed degree measure, and the unadjusted sample estimates.
Results: The results indicate that RDS estimates adjusted by a venue-predicted degree tend to be more efficient (smaller variance) than adjustment by the standard self-reported network size for RDS population estimates in both cities sampled.
Conclusions: Venue attendance may provide a more reliable degree measure for RDS estimates of outcomes of interest, which can then be used to better design HIV-prevention interventions that target hard to reach populations such as YMSM.

Characteristic	Percentage (n) or Mean (SD; Min, Max) Chicago (N = 373)	Percentage (n) or Mean (SD; Min, Max) Houston (N = 356)
Age	24.3 (2.8; 17, 30)	24.8 (2.9; 17, 30)
Race/Ethnicity White	20.1% (75)	15.2% (54)
Black	63.8% (238)	59.0% (210)
Hispanic	10.7% (40)	19.4% (69)
Other race/ethnicity	5.1% (19)	6.5% (23)
Housing instability	29.5% (110)	17.4% (62)
Education High school or less	37.0% (138)	34.6% (96)
College or more	61.0% (227)	62.9% (224)
Degree measures Self-reported peer network size	51.8 (226.3; 0, 4000)	54.6 (142.5; 0, 1300)

[Characteristics of young men who have sex with men]



[Figure]

TUPEC0785

VCT data to estimate HIV incidence among key populations, Ho Chi Minh City, Vietnam

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Background: Accurate estimates of HIV incidence are crucial to evaluate program impact. VCT program cohort data can help produce incidence estimates and determine program priorities among key populations (KP) including men who have sex with men (MSM), people who inject drugs (PWID), and female sex workers (FSW).
Methods: We reviewed data from a retrospective cohort of clients at 25 VCT sites in Ho Chi Minh City during 2006-2015. Routine program data were analyzed from clients who reported ≥2 HIV tests ≥3 months apart whose first test result was negative. To calculate person-years of exposure, non-seroconverters contributed the time between the first and last tests; seroconverters contributed the time between the first test and the estimated date of seroconversion (midpoint between the last negative and first positive test). HIV incidence rate (IR) and 95% Confidence Intervals (CI) were calculated.
Results: Among 273,313 tests performed, 33,782 repeat testers with a documented initial HIV negative test contributed 27,509 person-years (py). Median time between tests was 218 days; 13,007 (39%) repeat testers self-identified as KP.
Of 769 seroconverters, 272 (35%) were PWID; 111 (26%), MSM; and 45 (6%), FSW. Overall HIV IR was 2.8 seroconversions per 100 py (95% CI: 2.6 to 3.0) and was highest in 2006 at 9.7 per 100 py, fell annually to 2.5 per 100 py in 2010 and then stabilized.
Among KP subgroups, IR was 5.0 per 100 py (95% CI: 4.2-6.1) among MSM, 4.3 per 100 py (95% CI: 3.8-4.8) in PWID, and 1.7 per 100 py (95% CI: 1.2-2.3) among FSW. IR patterns over time varied among subgroups.

Year	No of tested	No of sero-conversions	Person-years	Incidence rate (95% CI)			
				All clients	PWID	MSM	FSW
2006	795	61	627	9.7 (7.4 - 12.5)	27.6 (17.5 - 41.5)	8.9 (0.2 - 49.7)	2.4 (0.1 - 13.1)
2007	1,585	79	1,199	6.6 (5.2 - 8.2)	25.2 (18.3 - 33.9)	6.3 (1.7 - 16.1)	5.6 (1.5 - 14.3)
2008	2,568	73	2,024	3.6 (2.8 - 4.5)	7.0 (4.5 - 10.4)	0.0 (0.0 - 8.2)	2.2 (0.5 - 6.4)
2009	4,435	133	3,513	3.8 (3.2 - 4.5)	7.8 (5.9 - 10.0)	3.0 (0.6 - 8.8)	1.6 (0.5 - 3.7)
2010	5,354	104	4,211	2.5 (2.0 - 3.0)	5.2 (3.7 - 7.0)	2.2 (0.8 - 4.9)	2.0 (1.0 - 3.7)
2011	4,231	76	3,410	2.2 (1.8 - 2.8)	3.7 (2.4 - 5.6)	4.7 (2.2 - 8.6)	4.5 (2.3 - 7.8)
2012	3,303	43	2,726	1.6 (1.1 - 2.1)	2.6 (1.4 - 4.5)	2.4 (0.9 - 5.1)	0.9 (0.1 - 3.2)
2013	3,972	81	3,422	2.4 (1.9 - 2.9)	1.9 (1.2 - 3.0)	7.2 (4.7 - 10.6)	1.0 (0.2 - 2.8)
2014	3,718	56	3,246	1.7 (1.3 - 2.2)	1.3 (0.7 - 2.3)	4.5 (2.8 - 6.7)	0.6 (0.1 - 2.0)
2015	3,821	63	3,130	2.0 (1.5 - 2.6)	1.1 (0.5 - 1.9)	8.6 (5.9 - 12.1)	0.7 (0.1 - 2.1)
Total	33,782	769	27,509	2.8 (2.6 - 3.0)	4.3 (3.8 - 4.8)	5.0 (4.2 - 6.1)	1.7 (1.2 - 2.3)

[Table: HIV incidence rate among repeat testers by KP group, HCMC, 2006-2015]

Conclusions: From 2006-2015, PWID and FSW demonstrated substantial drops in IR. After initially declining, IR among MSM may be increasing in recent years. Targeted prevention efforts, like PrEP, will be required to reduce incidence further, especially among MSM.

TUPEC0786

Outsider or farmer? Deconstructing the role of migration in the HIV risk of Chinese men who have sex with men

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Background: Migration of men who have sex with men (MSM) from rural to urban areas is common across low- and middle-income countries, and is widely believed to explain elevated HIV risk among migrant MSM. Little consensus exists on whether their risk is due to their transplantation or their being from economically disadvantage rural areas. This study examined HIV risk associated with each of these two migration characteristics - transplantation and being of an economically disadvantaged rural background - to compare the association of each strategy with measures of HIV risk.
Methods: In July 2016, MSM ≥ 16 years old currently residing in one of eight urban cities in China were recruited for an online cross-sectional survey, which collected information on socio-demographics, sexual behaviors, HIV care seeking behaviors, and health services utilization. Based on several questions about residency status, each participant was classified as being either a local or a non-local, and as an urban or a rural person. Multivariable logistic regression was used to examine the associations between risky behaviors and health care utilization and the two migration characteristics.
Results: 2,007 eligible MSM participated, about two thirds (67%, n=1,359) of whom were non-local and half (44%, n=881) of whom were from rural areas. Non-locals differed from locals only in their likelihood of having ever HIV tested (adjusted odds ratio [aOR]=0.72, 95% confidence interval [CI]: 0.55-0.93), rural MSM were less likely to have ever purchased sex (aOR=0.51, 95%CI: 0.34-0.77), to have ever disclosed same-sex behaviors to a healthcare provider (aOR=0.65, 95%CI: 0.51-0.82), to have ever been HIV tested (aOR=0.65, 95%CI: 0.51-0.82), and among those who were HIV positive, to have ever initiated antiretroviral therapy (aOR=0.22, 95%CI: 0.07-0.66), as compared to their urban counterparts.
Conclusions: Migrant status as defined by urban/rural status was a far more salient predictor of HIV associated risk behaviors as compared to transplantation status. Elevated risk of HIV infection in migrants most likely stems more from their lack of social and economic resources rather than from individual behaviors. Health policy efforts to address service gaps faced by these MSM must focus on structural as well as individual level barriers.

TUPEC0787

Studying the most marginalized hijra/transgender population for burden of HIV related risk behavior, HIV prevalence and utilization of related HIV services in India

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Background: Hijra/Transgender (H/TG) people are one of the most vulnerable group to HIV epidemic. We aimed to characterize the socio-demographic status, high-risk behaviors, HIV prevalence and the related care continuum among H/TG people in India.
Methods: A cross-sectional probability-based survey enrolled 4,966 self-identified H/TG in 14 districts selected districts from eleven states in India. The H/TG population was reached with the active involvement of Gurus and Nayak. The sociodemographic status, sexual behavior, and utilization of HIV/AIDS related services were assessed using a structured questionnaire. Blood samples were tested for HIV and the prevalence was estimated by the presence of anti-HIV antibodies.
Results: The mean age of respondents was 29 years (IQR 23-32); most were literate and never married (89% and 79% respectively). More than half (55%) were engaged in selling sex and had a variety of sex (penetrative: 91%, oral: 66%, manual: 45%) with clients. Consistent condom use with paying client was 52%. Alcohol consumption during the 12 months preceding the survey was reported by 57% of respondents; 55% of them reported doing so before or during last sex act. 4% reported drug injection for non-medical purposes. Four fifth (81%) of them were at

least once tested for HIV while 40% received comprehensive package of prevention services. Weighted HIV prevalence was 7·5%; correlates of HIV infection included higher age group, being sex worker and exposure to HIV/AIDS programme. Of the 359 H/TG people that were HIV antibody positive, 281 (78%) were ever aware of their status while 255 (71%) were aware of ART. Awareness of HIV positive status was significantly associated with exposure to HIV/AIDS programme.
Conclusions: The high burden of HIV related risk behavior and HIV infection among H/TG people is an area of concern. The programme need to scale up its coverage through the comprehensive package of services in the population. Failure to do so may lead to rising prevalence not only in the population itself but also to general population through the clients as significant proportion of them are also engaged in sex work.

TUPEC0788

Lower HIV prevalence and incidence despite greater demographic and behavioral risks among transgender women when compared to MSM in community-based test and treat cohorts in Thailand

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Background: Globally, HIV acquisition risk is 49 times higher in transgender women (TG) and is 24 times higher in men who have sex with men (MSM) than in the general population. More than half of all new HIV infections annually in Thailand occur among MSM and TG women. Better understanding of the gender-specific risks and epidemiologic profiles of Thai MSM and TG is needed to inform programming.
Methods: Baseline data were collected from May 2015 to September 2016 using self-administered questionnaires and HIV/STI (syphilis/gonorrhea/chlamydia) testing from MSM and TG aged ≥18 years enrolled in a cohort study in six community sites in Thailand. HIV testing was performed at least every six months for 18 months. Factors associated with gender-specific HIV prevalence and HIV incidence were determined by logistic regression and Cox proportional hazard analyses, respectively.
Results: Of 1,763 MSM and 734 TG enrolled, mean (SD) ages were 26.4 (7.2) and 25.9 (6.6) years, respectively. TG had lower education (15.7%vs.31.7% with college degree or higher, p<0.001) and lower income (41.7%vs.49.5% >288 USD/month, p<0.001) than MSM.
In the past six months, high proportions of TG and MSM had unprotected sex (66.1%vs.70%, p=0.17) and multiple partners (74.7%vs.72.8%, p=0.71), but more TG practiced anal receptive sex (91.2%vs.61.3%, p<0.001).
HIV prevalence among MSM was 18.15% (95%CI:16.38-20.03) and was associated with: previous HIV testing (OR:0.39; 95%CI:0.28-0.54; p<0.001), self-perceived HIV risks (OR:4.20; 95%CI:1.79-9.85; p<0.001); and having STI (OR:3.09; 95%CI:2.26-4.22; p<0.001).
HIV prevalence among TG was lower at 8.99% (95%CI:7.02-11.30, p<0.001) and associated with: not attending college (OR:3.87; 95%CI:1.14-13.15; p=0.01), previous HIV testing (OR:0.42; 95%CI:0.23-0.75; p<0.01), and having STI (OR:2.71; 95%CI:1.53-4.79; p<0.001).
HIV incidence in MSM was 3.16 per 100 person-years (95%CI:2.00-4.74) and associated with previous STI (HR: 2.86; 95%CI:1.72-4.76; p<0.001). TG had lower HIV incidence (1.13 per 100 person-years, 95%CI:0.31-2.89, p=0.02) than MSM.
Conclusions: TG in Thailand had lower HIV prevalence and incidence than MSM despite having higher demographic and behavioral risks. This finding is contradictory to previous studies, suggesting that sexual networks of MSM and TG in Thailand need to be urgently analyzed to better strategize HIV prevention programs.

TUPEC0789

Unmet stigma mitigation needs among female sex workers in six countries across sub-Saharan Africa

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Background: Even in the context of more generalized HIV epidemics across Sub-Saharan Africa (SSA), female sex workers (FSW) bear a disproportionate burden of HIV. While stigma measurement and programming has traditionally focused on HIV-related stigma and stigma affecting gay men and other men who have sex with men, understanding the burden of sex-work-related stigma has direct implications for the implementation of both HIV prevention and treatment programs. Consequently, this study aims to estimate the prevalence of stigma among FSW in 6 countries in SSA, and the association between HIV infection and stigma.
Methods: Biological HIV testing and socio-behavioral questionnaires were conducted with 5253 FSW in Burkina Faso (N=699), Cameroon (N=2272), Cote d'Ivoire (N=466), Senegal (N=758), South Africa (N=410), and Togo (N=648). Participants were recruited via respondent driven sampling between 2013-2016. Consistent stigma metrics were used in each setting measuring social stigma, healthcare-related stigma, and enacted community stigma. Logistic regression was used to assess associations between HIV and stigma.
Results: Pooled HIV prevalence is 22.3% (1174/5253), with prevalence reported by country in Table 1. HIV infection was significantly associated (Table 2) with exclusion from family activities (Odds Ratio [OR]:1.4;95% Confidence Interval [CI]:1.2-1.7; p<0.001); rejection from friends (OR:1.5;95% CI:1.2-1.8 ; p<0.001); healthcare services avoidance (OR: 0.7;95% CI:0.6-0.9; p=0.003); police refusal of protection (OR:1.5;95% CI:1.3-1.8; p<0.001); verbal harassment (OR:1.4;95% CI:1.2-1.6; p<0.001); blackmail (OR:1.2;95% CI:1.1-1.4; p=0.004); physical violence (OR:1.4;95% CI:1.2-1.6; p<0.001); and forced sex (OR:1.2;95% CI:1.0-1.4; p=0.014).
Conclusions: Prevalence of social stigma, healthcare-related stigma, and enacted community stigma is high among FSW in SSA. Given the association between stigma and HIV, upstream determinants of HIV must be identified and targeted through stigma mitigation interventions adapted to the specific needs of FSW to effectively address HIV risk and HIV-related outcomes.

	Burkina Faso (N=699)	Cameroon (N=2272)	Cote d'Ivoire (N=466)	Senegal (N=758)	South Africa (N=410)	Togo (N=648)
Living with HIV	20.9%	24.4%	11.0%	5.3%	63.7%	18.9%
Felt excluded from family activities*	21.1%	7.4%	8.6%	11.6%	22.8%	11.3%
Felt rejected by your friends*	18.1%	8.3%	18.9%	7.0%	18.1%	12.1%
Avoided going to health care services*	12.3%	4.7%	23.2%	22.1%	10.2%	7.0%
Felt that the police refused to protect you*	17.4%	10.7%	24.1%	12.4%	29.5%	5.6%
Verbally harassed*	59.5%	55.7%	49.5%	44.8%	60.0%	36.6%
Blackmailed*	31.0%	44.7%	20.8%	30.1%	22.5%	28.1%
Physical violence	61.7%	24.8%	53.7%	17.5%	61.7%	32.9%
Forced to have sex	40.8%	32.7%	43.2%	29.9%	38.3%	25.0%

*attributable to selling sex

[Table 1. Prevalence of HIV, and stigma among female sex workers in Burkina Faso, Cameroon, Cote d'Ivoire, Senegal, South Africa and Togo]

Stigma	Not living with HIV (N=4079) n/N	%	Living with HIV (N=1174) n/N	%	p value	OR	95% CI
Felt excluded from family activities*	427/4018	10.6	168/1156	14.5	<0.001	1.4	1.2,1.7
Felt rejected by your friends*	421/3961	10.6	176/1163	15.1	<0.001	1.5	1.2,1.8
Avoided going to health care services*	454/4067	11.2	96/1172	8.2	0.003	0.7	0.6,0.9
Felt that the police refused to protect you*	489/3918	12.5	208/1168	17.8	<0.001	1.5	1.3,1.8
Verbally harassed*	2040/4070	50.1	683/1173	58.2	<0.001	1.4	1.2,1.6
Blackmailed*	1370/4067	33.7	448/1172	38.2	0.004	1.2	1.1,1.4
Physical violence	1350/4061	33.2	479/1171	40.9	<0.001	1.4	1.2,1.6
Forced to have sex	1335/4071	32.8	429/1171	36.6	0.014	1.2	1.0,1.4

*attributable to selling sex

[Table 2. Pooled prevalence of stigma by HIV status among female sex workers in Burkina Faso, Cameroon, Cote d'Ivoire, Senegal, South Africa and Togo]

TUPEC0790

Trends in HIV infection diagnoses among men who have sex with men, overall and by state, United States, 2008-2014

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Background: The U.S. National HIV/AIDS Strategy recommends intensification of prevention efforts in communities where HIV is most highly concentrated and establishes targets for reducing diagnoses among key populations, including men who have sex with men (MSM). Although trends in diagnoses among subgroups of MSM have been examined nationally, HIV risk, testing, and prevention behaviors vary geographically, and HIV prevention is typically delivered at a state or local level. We analyzed trends in HIV diagnoses among subgroups of MSM in the United States by state.
Methods: Using National HIV Surveillance System data submitted through June 2016 and adjusted for missing risk information, we determined the annual number of diagnoses among MSM during 2008-2014, overall and by race/ethnicity and age group. To examine trends, we calculated estimated annual percent change (EAPC) for each subgroup, nationally and for each state and the District of Columbia. We present significant increases or decreases ($p < 0.05$), given ≥12 diagnoses per year.
Results: The number of diagnoses among MSM decreased slightly during 2008-2014 (Table). Diagnoses increased among Hispanic/Latino MSM and MSM aged 13-24 y or 25-34 y and decreased among white MSM and MSM aged 35-44 y or 45-54 y. Findings were heterogeneous by state, with 7 states experiencing increases in diagnoses among MSM and 12 experiencing decreases. Notably, diagnoses among Hispanic/Latino MSM increased in 7 states and did not decrease in any states. Diagnoses among MSM aged 13-24 y and 25-34 y increased in 16 and 18 states, respectively.

	2008 diagnoses	2014 diagnoses	EAPC	P-value	No. areas* with increase	No. areas* with decrease	No. areas* with no significant change	No. areas with small cells†
All MSM	27,026	26,637	-0.4	<.01	7	12	26	6
Black MSM	10,018	10,173	-0.1	0.7	8	6	20	17
Hispanic/Latino MSM	6,071	6,907	2.0	<.0001	7	0	24	20
White MSM	9,280	7,950	-2.6	<.0001	1	14	30	6
MSM aged 13–24 y	6,097	7,300	2.6	<.0001	16	3	16	16
MSM aged 25–34 y	7,703	9,182	2.8	<.0001	18	1	20	12
MSM aged 35–44 y	7,138	4,804	-6.9	<.0001	0	23	13	15
MSM aged 45–54 y	4,433	3,690	-3.0	<.0001	0	7	28	16
MSM aged 55–64 y	1,330	1,305	0.3	0.7	0	0	21	30
MSM aged ≥65 y	326	361	2.7	0.3	0	0	4	47

[Table.]

Conclusions: Sub-national trends indicate that achieving national goals to reduce diagnoses will require intervention in a large number of states, with a focus on young, Hispanic/Latino, and black MSM. This analysis also identified states with successes in reducing HIV transmission, which may offer lessons learned.

TUPEC0791

Population size estimates of key populations at risk for HIV infection: men who have sex with men, female sex workers and people who inject drugs in multiple districts of Zambia

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Background: Size estimates of populations at higher risk for HIV infection are needed to help policy makers understand the scope of the epidemic and tailor appropriate interventions. Population size estimates of men who have sex with men (MSM), female sex workers (FSW) and people who inject drugs (PWID) are few or non-existent Zambia.
Methods: In conjunction with a formative assessment of HIV risk factors among key populations, we conducted population size estimation of MSM, FSW and PWID in multiple districts of Zambia using two integrated methods: enumeration and desk review. Enumeration occurred in two steps: first a collection of potential venues where population members are known to congregate and then a direct count of these population members at a number of sites. Desk review consisted of a literature review of previously published data on the prevalence of key populations in regions similar to Zambia, which was applied to recent census figures to obtain age-adjusted estimates. Population size estimates were made for FSW in 9 municipalities, while MSM and PWID estimates were formed for 5 and 3 municipalities, respectively.
Results: For enumeration, a total of 410 FSW, 143 MSM and 73 PWID venues were identified from KIIs; direct counts of these venues yielded an estimated 13,199 FSW, 4,211 MSM and 2,909 PWID. For desk review estimates, we used the lower quartile value of the range of each population occurrence in Africa as described in the literature (2.8% FSW, 1.2% MSM and 0.3% PWID) with national census data to obtain an estimated 23,015 FSW, 8,857 MSM and 1,652 PWID living in the selected sites. Enumeration and desk review estimates form our lower and upper range values respectively, with an overall median estimate of 18,107 FSW, 6,534 MSM and 2,281 PWID in the selected municipalities.
Conclusions: These estimates may be useful to advocate for and to plan, implement and evaluate HIV prevention and care programmes for MSM, FSW and PWID. Given potential biases, these estimates should be triangulated with additional size estimation methods, including multiplier methods, capture-recapture and wisdom of the crowds.

TUPEC0792

HIV prevalence and characteristics of men who have sex with men in the metropolitan region of Chile

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Background: In Chile, the rate of people living with HIV in 2014 reached 9.6 x 100,000 inhabitants, in the Metropolitan Region (MR) is more than 50 x 100,000 inhabitants. Chile currently has an epidemic concentrated in men who have sex with men (MSM). Second-generation HIV surveillance is not established in the country and the preventive social policies are limited. The objective of this study was to determine the prevalence of HIV in MSM in the Metropolitan Region and describe their behavioral, sociodemographic and clinical-epidemiological characteristics.
Methods: Cross-sectional study. The population was MSM living in the MR. The Responding Driven Sampling (RDS) sampling method was used. The HIV prevalence was performed through the ABON ™ HIV 1/2 / O Tri-Line Human Immunodeficiency Virus Rapid Test (Biopharm Hangzhou Co., Ltd.), all positive cases were confirmed with the Enzyme test -Linked ImmunoSorbent Assay (ELISA). A questionnaire adapted and validated for the Chilean population was applied. Data analysis included descriptive analysis, quantitative characteristics will be described using the median and interquartile range (IR), and qualitative characteristics by percentages. All ethical aspects were considered during the study.
Results: 375 men were recruited. The median age was 24 years (minimum 18, maximum 69). There were 52 HIV positive cases, which correspond to a prevalence of 17.6%; between 25-34 years the prevalence was 25.1%. Most cases of low-middle socioeconomic level. 41.7% of the participants did not use the condom with their casual partners in the last 6 months. 28.0% had not had an HIV test in the past 12 months. The majority of subjects (60.0%) had no access to HIV / STI preventive information or received condoms (42.0%) in the last 12 months, which are higher in HIV-positive men.
Conclusions: The prevalence of HIV found in MSM shows a reemergence of HIV in Chile. Cases are concentrated in young men younger than 35 years. Low access to condoms and testing is observed. Sexual education is necessary, including gender and cultural relevance. Prevention programs are insufficient and are not reaching the populations that most need it. Focused preventive interventions such as peer education and access to community testing are required.

TUPEC0793

HIV, serostatus knowledge, and viral load suppression among female sex workers in Kampala, Uganda, 2012: a respondent-driven sampling survey

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Background: The Joint United Nations Programme on HIV and AIDS (UNAIDS) set global targets for 2020, aiming for 90% of people living with HIV to know their serostatus and for 73% to have viral load suppression (VLS). We investigated progress towards these targets among female sex workers (FSW) in Kampala, Uganda, who bear a disproportionate burden of HIV.

Methods: Between April and December 2012, FSW, defined as women, 15-49 years, residing in greater Kampala, and selling sex for money in the last 6 months, were recruited using respondent-driven sampling (RDS). Venous blood was collected for HIV testing according to Uganda's national serial rapid test algorithm and for VL testing (VLS defined as <50 copies/mL). We collected data using audio computer-assisted self-interviews. Weighted population estimates were calculated using RDS Analyst software.
Results: Sampling was initiated with 4 respondents; 1,487 FSW were enrolled over 25 recruitment waves; median age was 27 years (interquartile range: 23 to 32). HIV seroprevalence was 31.4% (95% confidence interval [CI]: 28.7-34.0%). Among HIV-positive FSW, serostatus knowledge was 26.5% (95% CI: 21.7-31.4%) and VLS was 21.6% (95% CI: 16.2-27.0%). Assuming that all FSW with VLS know their serostatus yielded a corrected serostatus knowledge estimate of 37.5% (95% CI: 32.4-42.6%).
Conclusions: HIV prevalence among Kampala FSW is high, whereas serostatus knowledge and VLS are far below UNAIDS population-level targets. The high population prevalence of unsuppressed VL suggests substantial risk of transmission to partners and clients. FSW in Kampala are in need of intensified and targeted control efforts, including pre-exposure prophylaxis, frequent HIV screening, and improved linkage to treatment services.

TUPEC0794

Forced sex and physical violence affecting men who have sex with men in Senegal: associations with HIV and HIV related outcomes and perceived and enacted stigma

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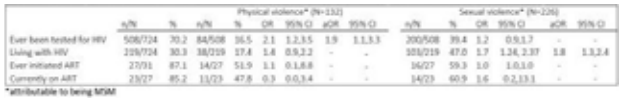
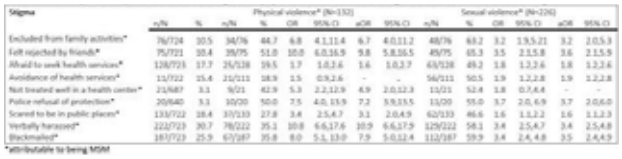
Background: Men who have sex with men(MSM) are disproportionately affected by HIV globally. In Senegal, the estimated HIV prevalence is 23.5% among MSM compared to the 0.5% national prevalence estimate. Social and structural determinants such as limited access to primary HIV prevention, stigma, and violence affecting MSM may further enhance HIV risk. This study aims to measure violence and its intersection with stigma and HIV.
Methods: In 2015, 724 MSM were recruited through respondent driven sampling in Dakar (N=462), Mbour (N=159) and Theis (N=103), Senegal. Participants completed a socio-behavioral questionnaire and biological HIV testing. Bivariate and multivariate logistic regression was used to examine relationships between violence and HIV outcomes, and between violence and stigma.
Results: Overall, 38.0%(275/724) had been forced to have sex, and 14.2%(103/724) have experienced physical violence due to being MSM. Sexual violence was associated with HIV infection (adjusted Odds Ratio [aOR]:1.8;95% Confidence Interval[CI]:1.3-2.4), and physical violence was associated with HIV testing (AOR:1.9;95% CI:1.1-3.3)(Table 1). Sexual violence was associated with stigma from family and friends; fear (AOR:1.8;95% CI:1.2-2.6) and avoidance of seeking healthcare (AOR:1.9;95%CI:1.2-2.8); verbal harassment (AOR:3.4;95%CI:2.5-4.8) and blackmail (AOR:3.5;95%CI:2.4-4.9). Physical violence was associated with fear (AOR:1.6;95%CI:1.0-2.7) and mistreatment in the healthcare setting (AOR:4.9;95%CI:2.0-12.3)(Table 2).



[Table 1. Relationship between HIV treatment cascade with physical and sexual violence among men who have sex with men in Senegal]



[Table 2. Relationship between perceived and enacted stigma with physical and sexual violence among men who have sex with men in Senegal]

Conclusions: Forced sex and physical violence are prevalent among MSM in Senegal, and associated with HIV related outcomes. Family- and social-stigma, stigma related to accessing healthcare, and community enacted stigma was prevalent among this sample. As an antecedent to both HIV and violence, stigma should be targeted through mitigation interventions to effectively reduce these outcomes; and violence reduction interventions should be integrated into HIV programming.

TUPEC0795

Health behaviors and outcomes in a U.S. cohort of transgender women in HIV care

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Background: HIV disproportionately affects transgender women (TW), with 28% testing positive for HIV in the U.S., a 34-fold increased odds of infection relative to the general U.S. adult population. We compared the prevalence of mental health symptoms, risk behaviors, and treatment outcomes between TW and cisgender (non-transgender) male patients in HIV care.
Methods: We analyzed cross-sectional data from TW and male patients in HIV care across seven geographically diverse U.S. clinics within the CFAR Network of Integrated Clinical Systems (CNICS) from 2000-2016. We identified TW in the cohort using a combined algorithm that integrated clinical data and identity-based measures. Patient-reported data included antiretroviral medication adherence (VAS), depression (PHQ-9), anxiety (PHQ-5), sexual risk behavior, substance/alcohol/tobacco use (ASSIST, AUDIT-C), and quality of life (EQ-5D). Clinical data included viral load and CD4 count. Analyses compared TW and males for each outcome in log-binomial regression models adjusted for propensity scores based on age, race/ethnicity, year of entry into CNICS cohort, and site of care.
Results: Among 12,235 HIV-infected individuals, 118 TW were identified (mean age=43.9, SD=9.9), of whom 42% were Latino, 29% African-American, 23% White, and 7% other. TW were significantly more likely to report meeting clinical thresholds for moderate-to-severe depression (29.8% vs. 22.2%, p=0.01), anxiety (43.4% vs. 25.8%, p=0.01), and worse quality of life (62.4% vs. 46.7%, p=0.01) compared to males. No statistically significant differences were observed between TW and male patients in terms of viral suppression, CD4 counts, antiretroviral medication adherence, prior and current substance use, binge drinking, or tobacco use. A significantly lower proportion of TW reported hazardous drinking, defined as a score >4 on the AUDIT-C, than in males (21.3% vs 26.7%, p=0.04). The lower rate of condom-less sex in TW relative to male patients only approached statistical significance (42.4% vs 53.1%, p=0.07).
Conclusions: TW living with HIV indicated higher rates of moderate-to-severe depression and anxiety, as well as lower quality of life, when compared to HIV-infected males. These findings suggest a need for improved mental health screening and support for TW in HIV care.

TUPEC0796

Most HIV-positive African MSM screened for HPTN 075 are unaware of their infection

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Background: Scant research has examined HIV testing and diagnosis among men who have sex with men (MSM) in sub-Saharan Africa. Through screening procedures for HPTN 075—a study to evaluate the feasibility of HIV prevention research among this population in four sites in Kenya; Malawi; and South Africa - we
(1) Explored the proportion of MSM who were previously unaware of their positive HIV status, and;
(2) Identified characteristics of these men among those who had ever tested before for HIV.

Methods: A total of 599 MSM (18 to 44 years old) recruited from community locations were screened through HIV testing and a brief questionnaire. Using multivariate logistic regression, we compared MSM who reported to be unaware of their positive HIV status with those who were aware, among men with a prior HIV test.
Results: Of 599 MSM screened, 183 (30.6%) tested HIV positive. One hundred and sixteen of these men (63.4%) reported to be unaware of their infection. Seventeen of these 116 men (14.7%) had never previously tested for HIV, whereas 99 (85.3%) reported prior HIV negative test results. Among men who had tested before, unawareness of one's positive HIV status was not associated with migrant status, behavioral factors, or study site. Multivariate logistic regression, controlling for age and gender identification, showed that not being aware of one's positive HIV status was associated with recency of the last HIV test. Men who tested between 6 to 12 months ago were more likely to be unaware of their positive status than those who had tested in the preceding 6 months (AOR=3.07, 95%CI: 1.24, 7.65); they did not differ significantly from men who had tested over a year ago. There was a marginally significant (p=.09) negative association between number of times ever tested (three or more versus two or less) and not being aware of one's positive status.
Conclusions: Given the UNAIDS 90-90-90 goals, our findings indicate suboptimal awareness of HIV positive status among this population of MSM in sub-Saharan Africa with a high HIV prevalence. Promoting repeat and frequent HIV testing seems an effective first step in addressing the HIV treatment cascade in this population.

TUPEC0797

Incidence and predictors of the initiation of crystal methamphetamine use among gay and bisexual men

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Background: Crystal methamphetamine (MA) use among gay and bisexual men (GBM) is higher than in other populations. MA has also been implicated in HIV risk behaviours and transmission among GBM. We identify incident rates and predictive factors at baseline that are associated with the initiation of MA use at follow-up.
Methods: In 2014-2015, 1710 men enrolled in the Flux cohort study of drug use among GBM; by 2016, 1328 men completed at least one follow-up interview. Using multivariate analysis, we identified factors predicting MA initiation at follow-up.
Results: Mean age was 34.9 years. Between baseline and 1-year follow-up: 81.8% had never used MA, 9.6% reported continuous use, 4.0% had ceased use at follow-up, and 4.6% had initiated use at follow-up. At baseline, 34.9% reported having gay friends who used MA.
At baseline, men who reported condomless anal intercourse with casual partners (CLAIC) (HR 1.08; 95%CI 0.62-1.88), had more gay friends who used MA (HR 3.19; 95%CI 1.88-5.43), and scored higher on sexual sensation-seeking (HR 1.08; 95%CI 1.03-1.12) were more likely to subsequently initiate MA at follow-up. In multivariate analysis, compared with men who had never used MA, men who initiated MA scored higher on the sexual sensation seeking scale (HR 1.06; 95%CI 1.02-1.11) and were more socially engaged at baseline with other GBM who used MA (HR 1.32; 95%CI 1.11-1.57).
The most common reasons men cited for using MA among those who initiated were 'fun' (44.3%), for a 'buzz' (39.3%), and 'party-n-play' (chemsex) sessions (37.7%).
Conclusions: Men who had gay friends who used MA and who enjoyed 'risky' sex were more likely to commence MA use themselves. Exposure to, and feeling comfortable around MA use within friendship networks increases the likelihood of MA use. Many men commenced using MA to increase pleasure, specifically during sexual experiences. Their MA use may be viewed as 'functional' for the purposes of enhancing sex and initiation. Initiating MA often appears to occur in the context of CLAIC. Intensive sex partying networks have been previously associated with sexual risk behaviour and HIV transmission, but may also offer opportunities for harm reduction.

TUPEC0798

Incidence and predictors of the initiation of HIV pre-exposure prophylaxis use among gay and bisexual men

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Background: HIV pre-exposure prophylaxis (PrEP) is becoming increasingly available in Australia. Australian guidelines for access to PrEP for gay and bisexual men (GBM) include condomless anal intercourse with casual partners (CLAIC) and use of crystalline methamphetamine. We estimate incidence and baseline factors associated with initiation of PrEP.
Methods: Between 2014 and 2015, 1133 GBM who reported testing HIV-negative (either at baseline or follow-up) had enrolled in the Flux cohort study of drug use among GBM. They reported their PrEP use at each six-monthly interview. We conducted a multivariate analysis to identify factors independently associated with PrEP initiation at follow-up.
Results: Thirteen men reported PrEP use at baseline. At 12-month follow-up, of 1120 men who were not using PrEP at baseline, 65 men had initiated PrEP. The cumulative12-month incidence for PrEP initiation was 0.6%.
53.6% of those who initiated PrEP at follow-up imported it online, 17.9% were participants in a clinical trial, and 10.7% used prescribed HIV post-exposure prophylaxis (PEP) as PrEP.
Among men who initiated PrEP, 55.4% reported CLAIC at baseline compared to only 26.9% of men who never used PrEP (p< 0.001). One quarter (23.1%) of those who initiated PrEP reported crystal methamphetamine use during the six months before baseline.
In multivariate analysis, factors associated with PrEP initiation included greater social engagment with other gay men (HR 1.25; 95%CI 1.07-1.46) reporting CLAIC (HR 2.29; 95%CI 1.40-3.72), group sex (HR 2.61; 95%CI 1.55-4.39), and recent amyl nitrite use (HR 2.12; 95%CI 1.29-3.50).
Conclusions: Most men who initiated PrEP had engaged in HIV risk behaviours prior to commencing use. This is consistent with the Australian guidelines for access. Men who initiated PrEP tended to be more sexually active and more socially connected to other GBM. Men with stronger connections to gay community may have greater knowledge about PrEP and how to access it.

TUPEC0799

Mapping and size estimation of key populations in Somalia and Somaliland

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Background: Somalia is characterised by a concentrated HIV epidemic among key populations. Based on two Integrated Biological and Behavioural Surveillance (IBBS) Surveys among sampled female sex workers in Hargeisa, Somaliland HIV prevalence was revealed at 5.2% in 2008 and 4.8% in 2014. Outside Hargeisa, however, the lack of data on where and how key populations exist is limiting the HIV response. Key populations are hidden partially due to cultural norms limiting sexual relations outside marriage and also force those who engage in these behaviours to remain hidden.
This study aimed at establishing the locations and size estimates of key populations to inform HIV policy and programming.
Methods: A cross sectional study was conducted in January 2016 in Mogadishu, Hargeisa and Bossaso using geographical mapping, unique service multiplier, and the Wisdom of Crowds). The study populations comprised female sex workers (FSWs) and their clients including truckers, port workers, fishermen, seafarers, policemen, military personnel, and khat and tea clients. A mobile application was used to collect field data. Descriptive analysis was computed to establish plausible bounds of the key populations.
Results: A total of 2,877 respondents participated in this study. The estimated number of FSWs and their clients were 963 and 2,599 in Mogadishu, 1,126 and 1,827 in Hargeisa and 911 and 3,530 in Bossaso respectively. Over half of the FSWs

57.3%, in Mogadishu and 61.2% in Hargeisa meet their clients at homes whereas 49.1% in Bossaso meet at khat and tea selling joints. In all three locations, commercial sex work mostly occurs on Thursdays and Fridays between 1700 hours and 2000 hours. Only 2.2% of FSWs had received free condoms within the last twelve months prior to this study. The majority of FSWs, 64.1%, are willing to attend a center dedicated to serving FSWs with HIV counselings and testing, and sexually transmitted infections screening and treatment, cervical cancer screening, and condom provision.
Conclusions: This study provided the evidence of the sex work presence and HIV risk in Somalia. Preliminary and critical data from this study showed an alarming HIV vulnerability among sex workers and their clients which need to be timely addressed.

TUPEC0800

Estimating age-specific proportion of new HIV infections among males who have sex with males and transgender women: application of the 2016 Philippine AIDS epidemic model

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Background: The national bio-behavioral surveillance (IHBSS) revealed an increasing HIV prevalence among 15 to 24 year old males and transgender women who have sex with males (M/TSM) from 2.3% in 2011 to 6.0% in 2015. Existing case registry data do not support this trend; only 30% of newly diagnosed infections among M/TSM were from 15 to 24 years old. Development of the 2016 Philippine AIDS Epidemic Model (AEM) opened a platform to generate age-specific estimates to inform the national HIV program on the age group where the highest number of new infections are occurring.
Methods: To determine incidence by age among M/TSM, change in prevalence was compared in 21 cities of the 2013 and 2015 IHBSS. This was used as input in the age distribution for incidence of the Philippine AEM to produce age-specific proportion of new HIV infections. Supporting factors on sexual debut, age at first condom use, and age at first HIV test were further analysed in the IHBSS.
Results: Estimates from AEM showed that 62% of new infections in 2016 occur among 15 to 24 years old. Majority (89%) of these new infections occur among M/TSM. Average onset of sexual activity is at 16 years old among M/TSM but first condom use starts two years later. Probability of acquiring HIV infection at this age is high due to the gap between first sex and first condom use.
However, laws requiring parental consent for HIV testing delay timely detection of HIV among minors. Among M/TSM, HIV testing uptake is low and generally starts at 22 years old.
Conclusions: Findings raised the need to prioritize young M/TSM in the national HIV plan with the goal of reducing new HIV infections by 2022. Through multisectoral collaboration, bolder strategies are taken to ensure provision of prevention, testing and treatment services to young M/TSM. These include creating partnerships with schools to increase HIV knowledge, making provisions for proxy consent, and revising existing laws so that minors will have access to HIV services.

TUPEC0801

Unmet mental health needs in HIV prevention and treatment interventions for men who have sex with men (MSM) and transgender women in Senegal

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Background: According to syndemic theory, psychosocial factors such as depression, substance abuse, and violence combine with behavioral and biological factors to increase HIV infection and transmission risk. Evidence from high-income countries estimate the prevalence of depression among MSM to be 3-5 times that of other men. However, little data exist on the prevalence and correlates of depression among MSM and transgender women in low- and middle-income countries where existing HIV prevention and treatment programs rarely include mental health components.
Methods: 521 MSM and 184 transgender women were recruited in Dakar, Mbour, and Thies, Senegal using Respondent-Driven Sampling. Participants completed a questionnaire based on the modified socio-ecological model and HIV and viral load testing. Poisson regression with robust variance estimation was used to model prevalence ratios of depression (PHQ-9 score ≥10) and known HIV risk factors.
Results: The estimated prevalence of depression was 19.4%(101/521) among MSM and 23.9%(44/184) among transgender women. 20.4%(106/521) of MSM and 20.1%(37/183) of transgender women reported recent suicidal ideation. Depression was significantly higher among MSM with experiences of exclusion (aPR:2.3, 95%CI:1.6-3.4) and gossip from family (aPR:2.0, 95%CI:1.4-3.0), verbal (aPR:1.8, 95%CI:1.3-2.5) and physical harassment (aPR:2.0, 95%CI:1.3-2.9), rape (aPR:1.6, 95%CI:1.1-2.2), and arrest on charges related to homosexuality (aPR:1.9, 95%CI:1.2-3.1). Among transgender women, depression was significantly higher among those with experiences of exclusion (aPR:2.6, 95%CI:1.6-4.2) or gossip from family (aPR:2.2, 95%CI:1.3-3.6), verbal (aPR:1.8, 95%CI:1.1-3.0) and physical harassment (aPR:2.2, 95%CI:1.3-3.6), rape (aPR:2.6, 95%CI:1.5-4.5), fear of seeking healthcare (aPR:2.0, 95%CI1.2-3.6), and rejection by friends (aPR:3.5, 95%CI2.2-5.5). (Table 1)

	MSM median age: 23 (IQR: 20-27)				Transgender women median age: 22 (IQR: 20-25)				Footnotes
	Crude PR	Crude PR 95%CI	aPR‡	aPR 95%CI	Crude PR	Crude PR 95%CI	aPR‡	aPR 95%CI	†Because they have sex with men
Felt excluded from family activities†	2.5***	1.7, 3.7	2.3***	1.6, 3.4	2.8***	1.8, 4.6	2.6***	1.6, 4.2	‡Controlling for age, level of education, and employment status
Felt family members made discriminatory remarks or gossiped about them†	2.2***	1.5, 3.1	2.0***	1.4, 3.0	2.4***	1.4, 3.9	2.2***	1.3, 3.6	*p≤0.10 ** p≤0.05 *** p≤0.01
Felt rejected by friends who are not MSM†	1.7**	1.1, 2.7	1.6*	1.0, 2.6	3.6***	2.3, 5.7	3.5***	2.2, 5.5	
Felt afraid to seek healthcare†	1.2	0.7, 1.8	1.2	0.8, 1.8	1.9**	1.1, 3.2	2.0**	1.2, 3.6	
Arrested on charges of homosexuality	2.4***	1.5, 3.6	1.9***	1.2, 3.1	1.6	0.7, 3.8	1.1	0.5, 2.4	
Verbally harassed†	1.8***	1.3, 2.6	1.8***	1.3, 2.5	1.8**	1.1, 3.1	1.8**	1.1, 3.0	
Physically harassed†	2.1***	1.4, 3.1	2.0***	1.3, 2.9	2.4***	1.4, 3.9	2.2***	1.3, 3.6	
Raped	1.6**	1.1, 2.2	1.6**	1.1, 2.2	2.4***	1.5, 4.1	2.6***	1.5, 4.5	

[Crude & adjusted PR of depression and risk factors]

Conclusions: In Senegal, the prevalence of depression is high among MSM and transgender women. However, mental health remains largely under-addressed in existing HIV prevention and treatment programs for these high-risk populations. Including mental health as well as stigma mitigation in future programs has the potential to alleviate the burden of depression and contribute to ending the HIV epidemic.

TUPEC0802

More frequent experience of homo/transphobia is associated with higher sexual risk among transgender women compared to men who have sex with men in Lima, Peru

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Background: Transgender women (TW) report exposure to homo/transphobia and sexual risk profiles distinct from those of men who have sex with men (MSM), though these two populations are often grouped. Assessing whether or not exposure to homo/transphobia is associated with differences in sexual risk between TW and MSM will help respond to TW needs.
Methods: We analyzed data from an 18-month clinical trial completed in 2011 that included 166 TW and 404 MSM from 24 low-income neighborhoods of Metropolitan Lima. Surveys collected data on gender identity, experience of homo/transphobia, sexual risk and alcohol abuse. Incidence of any STI (HIV, Syphilis, HSV-2, anal chlamydia and anal gonorrhea) was analyzed based on biological testing at the 9- and 18-month study visits. Experience of homo/transphobia was assessed as a potential mediator by calculating confidence intervals of indirect effect

standardized coefficient (SC) on the pathways between gender identity, sexual risk (number of sex partners, compensated sex and alcohol abuse).
Results: TW had higher scores of homo/transphobic experiences (17.5 vs 14, p <0.001), more sex partners (10 vs 4, p <0.001), more reported compensated sex at least weekly (45% vs 15%, p <0.001) and more alcohol abuse than MSM (68% vs 53%, p <0.001). There was no difference in STI/HIV incidence (39% vs 39%) or unprotected anal sex (60% vs 57%), all p-values >0.05. Experience of homo/transphobia had significant mediation (indirect) effect between gender identity and number of sex partners (IC 0.01 - 0.04), compensated sex (IC 0.01 - 0.06) and alcohol abuse (IC 0.01 - 0.05).
Conclusions: TW report riskier sexual behavior, more alcohol abuse an experiences of homo/transphobia than MSM. Experience of Homo/transphobia appears to contribute to risky sexual behavior and alcohol abuse among TW. The increased experience of homo/transphobia captures the increased stigma and discrimination affecting TW that can also predispose them to negative social and health outcomes. The HIV programmatic response to TW must address the structural underpinnings of social stress to reduce social inequity and subsequent risk behaviors.

Effect	Number of sex partners		Compensated sex		Alcohol Abuse	
	SC	CI	SC	CI	SC	CI
Indirect	0.02	0.01 - 0.04	0.03	0.01 - 0.06	0.03	0.01 - 0.05
Indirect/Total	0.08		0.09		0.21	
SC: Standardized Coefficient CI: Confidence Interval						

[Table 1. Homo/transphobia mediation effect]

TUPEC0803

Burden of infectious diseases and substance abuse among incarcerated women in Kuala Lumpur, Malaysia

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Background: The prevalence of infectious diseases, including HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis, are higher in prisons than in the general population. As a consequence, prisons have become venues where disease transmission is common and often continues after release to the community. While there has been increasing focus on the public health challenges of prisons, limited research has focused on the unique challenges facing incarcerated women. This study reports on the first-ever systematic study of HIV, HBV, HCV, and syphilis burden in incarcerated women in Kuala Lumpur, Malaysia.
Methods: A biobehavioral health assessment was conducted among women incarcerated at Malaysia's largest women's prison. Inclusion criteria were: 18 years of age or older, female sex, able to speak English or Bahasa Malaysia, and have been incarcerated for at least 1 month. After consent, participants underwent a standardized health assessment and serological testing for HIV, HBV, HCV, and syphilis.
Results: A total of 365 female prisoners enrolled in the study. Mean age was 35.9 years (Range 18-60), most were Malaysian nationality (76.8%), and half (49.3) were incarcerated for drug-related offenses. Most (69.8%) participants had at least one prior incarceration. Prevalence of HIV, HBV, HCV, and syphilis were 4.1% (95%CI 2.4-7.1), 2.1% (95%CI 1.0-4.4), 10.7% (95%CI 7.6-14.8), and 3.5% (95%CI 1.9-6.2), respectively. The majority of HCV was previously undiagnosed (71.0%), while only 20.0% of HIV was previously diagnosed. Amphetamine-type substances (36.0%), heroin (19.1%), and alcohol (18.1%) were the most commonly used substances 30 days prior to the current incarceration and 13.1% reported prior injection drug use. Over half (58.8%) met screening criteria for moderate to severe depression.
Conclusions: This study found a high burden of previously undiagnosed HCV among incarcerated women in Kuala Lumpur. Likewise, HIV prevalence in this sample is more than 25 times higher compared to females in the general population in Malaysia. Because there is a high degree of recidivism among this population, treatment prior to release is an important step in preventing onward transmission. Interventions to improve public health in prisons is a necessary step for curbing co-occurring epidemics of HIV, HCV, and injection drug use.

TUPEC0804

Violence and HIV vulnerability among female sex workers recruited by respondent-driven sampling in 10 Brazilian cities: base-line data for future preventive program evaluation

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Background: Violence and HIV vulnerability among female sex workers (FSW) remains marginalized in most studies on the topic. This study aims to characterize violence against Brazilian FSW and verify possible association with factors of vulnerability to HIV.
Methods: We conducted a cross-sectional study based on data from 2,523 adult FSW in ten cities, recruited by Respondent-Driven Sampling (RDS) in 2009. Weighted prevalence estimates were calculated for different types of violence and perpetrators in the last 12 months. Adjusted Odds Ratios (AOR) were calculated by logistic regression to study the associations between violence (dependent variable) and several social-demographic and behavioral variables, and inconsistent condom use (dependent variable) and violence. Multivariate models took into account the dependency structure of observations.
Results: Prevalence of verbal violence was 59.5%; and of physical violence (PhV), 38.1%. Prevalence of PhV perpetrated by intimate partner was 25.2%, and by clients: 11.7%. Factors associated to PhV were: age < 30 years old (AOR 2.27, 95%CI = 1.56 - 3.29); drug use (AOR 2.02, 95%CI = 1.54-2.65); price of sex work < ~US$ 13.20 (AOR 1.51, 95%CI = 1.07 - 2.13). Factors associated to PhV by an intimate partner were: inconsistent condom use (AOR = 1.99, 95% CI = 1.27-3.11) and age < 30 years old (AOR = 1.92, 95% CI = 1.23 - 2.99). Age under 30 years old was also associated to PhV perpetrated by clients (AOR = 2.24, 95% CI = 1.24-3.75) as well as sex work price less than ~US$ 13.20 (AOR = 2.09, 95% CI 129 - 3.38). Drug consumption was associated significantly with all types of violence and to PhV perpetrated by policemen (AOR = 2.54, 95% CI = 1.61-3.39). Intimate partner- PhV was associated with inconsistent condom use (AOR = 1.98, 95% CI = 1.12-3.51).
Conclusions: Young and underprivileged Brazilian FSW are frequently victimized by violence perpetrated by different social actors. Preventable factors such as substance consumption and inconsistent condom use constitute relevant potential barriers to safe sex practices rendering them more vulnerable to HIV. These results are useful to compare with data from a new RDS study conducted in late 2016.

TUPEC0805

HIV knowledge, perceived HIV risk, and condom use among female sex workers in Kampala, Uganda

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Background: HIV educational programs are associated with decreased HIV risk-taking behaviors including condomless sex. Female sex workers (FSW) in Kampala, Uganda have been the target of many HIV prevention campaigns. We want to understand if HIV knowledge and perceived risk among members of this high-risk population is associated with decreased HIV risk-taking behaviors, specifically condom use with clients.
Methods: In 2016, 963 HIV uninfected FSW participated in a quantitative questionnaire. HIV knowledge was measured using a 9-item scale that included true/false statements related to HIV transmission (adapted from HIV-KQ-18). The scale had a range of 0-9, points were given for correct responses. Perceived risk of HIV transmission was measured by asking participants how likely (1-10 ladder scale) a HIV negative women was to contract HIV if she had condomless vaginal sex with a HIV positive man once. Inconsistent condom use with clients was identified if the self-reported average number of clients did not match the self-reported average number of clients with whom participants used condoms. Multivariable logistic models, adjusted for sociodemographic variables, were used to measure the association between HIV knowledge, perceived risk, and condom use.
Results: Of the 963 participants, median age was 28 years (IQR: 24-32 years), literacy was 85.7% (N=822), and 55.1% of participants (N=527) reported a monthly income < 250,000 UGX (~USD $70). Median HIV knowledge score was 7 (IQR: 6-8) and median perceived risk of HIV transmission per condomless sex act was 5 (IQR: 5-8), a probability of 0.55 (IQR: 0.55-0.89). Inconsistent condom use among FSW was high (N=388, 40.3%). A higher HIV knowledge score was not

associated with inconsistent condom use with clients (aOR 0.97, 95% CI: 0.88-1.07), nor was a higher perceived risk of HIV per condomless sex act (aOR 0.96, 95% CI: 0.91-1.01).
Conclusions: High HIV knowledge and high perceptions of risk per condomless sex act are not associated with behaviors that decrease HIV transmission, namely condom use, among FSW in Kampala, Uganda. While HIV knowledge remains an important component of HIV prevention campaigns, more research should be done on the drivers of condomless vaginal sex in this FSW community.

TUPEC0806

Factors associated with previously undiagnosed HIV infection in transgender women sex workers in Greater Kuala Lumpur, Malaysia

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Background: Transgender women and transgender women sex workers (TWSW) are among the most at-risk populations for HIV. The estimated worldwide HIV prevalence for transgender women is 19.1% (95% CI 17.4-20.7). For TWSW, the global HIV burden is even higher at 27.3%. Early identification of HIV infection is critical in order to engage individuals in treatment and prevent onward transmission of the virus. This study examined factors associated with previously undiagnosed HIV infection among TWSW in Greater Kuala Lumpur, Malaysia.
Methods: From April to December 2014, respondent-driven sampling was used to recruit 193 TWSW in Greater Kuala Lumpur, Malaysia. Inclusion criteria were: ≥18 years of age, identify as a transgender woman, report involvement in sex work in the last 6 months, and ability to speak Bahasa Malaysia, English, or Tamil. After consent, all participants underwent a comprehensive bio-behavioral survey and serology for HIV, chlamydia, gonorrhea, and syphilis.
Results: HIV prevalence was 12.4% (24/193) for the sample, of which 29.2% (7/24) had been diagnosed with HIV prior to study participation, indicating 70.8% of HIV detected was previously undiagnosed. Multivariate logistic regression was conducted to identify correlates of newly diagnosed HIV (N=186). Results indicated current chlamydia infection (aOR=6.13, p=0.02), current syphilis infection (aOR=2.91, p=0.05), being in a committed interpersonal relationship (aOR=0.21, p=0.01), and any previous incarceration (aOR=3.64, p=0.02) were associated with undiagnosed HIV infection.
Most participants (74.6%) had been HIV tested at least once in their lifetime, however, only 21.2% were tested in the last 12 months. Moreover, the mean time since last HIV test was 2.5 years.
Conclusions: This is the first-ever study to explore factors associated with previously undiagnosed HIV infection among TWSW in Malaysia. Active sexually transmitted infections (STI), including syphilis and chlamydia, were robust correlates of undiagnosed HIV in this sample. Given that primary syphilis facilitates HIV transmission and acquisition, interventions that integrate HIV and STI screening may improve early identification of TWSW at high risk for HIV through early detection and treatment of STIs. Furthermore, the suboptimal frequency of HIV testing suggests a need to develop novel interventions to ensure HIV screening at least once every 12 months.

TUPEC0807

Sub-Saharan African (sSA) migrant women living with HIV lack highly effective contraception: migrant effect or HIV consequence? Results from the ANRS-Parcours study

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Background: Despite consistent evidence that hormonal contraception and IUD are at no risk for women on ART, preliminary study demonstrated that condom remained the predominant contraception among sSA migrant women living with HIV in France. Whether it is due to HIV status or it is related to their migration characteristics is still uncertain.
Objective: Compare prevalence of medical contraception among sSA migrant women in France according to their HIV status.
Methods: PARCOURS is a life-event survey conducted in 2012-2013 in 74 healthcare facilities in the Paris region, among a representative sample of sSA migrants constituted as follows: 926 receiving HIV care and 763 with neither HIV nor hepatitis B (reference group). Women concerned by contraception were in fecund age, sexually active in the past 12 months, not pregnant or seeking to get pregnant, not sterile or menopausal. Contraception was grouped in three categories: condom, medical (oral pill, IUD, implant, sterilization and injection) and no method.
Results: Among women in fecund age (18-49), 441 were HIV positive and 270 were not. Median age at migration was 28 years, 10.2% had once use medical contraception before migration.
Among women concerned by contraception (N=354), 63.3% of HIV positive women use condom, 72.3% use medical contraception in the reference group and one on ten declare no method in both groups. After adjustment on age, children, partnership, level of education, employment, time living in France and access to health insurance, HIV positive women remain less likely to use medical contraception than non HIV infected women (PRR 0.39 (0.29-0.52) p<0.000).
Conclusions: Migration to France provides contraceptive choices for sSA migrants women. However, HIV infection produces a break into access to the highly effective contraception that could not be explained by a single migrant effect. Our finding suggest that message of dual contraception, condom and medical contraception must be strongly promoted, as unintended pregnancies are still frequent.

TUPEC0808

Measures of recent migration predict STI (GC/CT) among adults in East African communities participating in the SEARCH study

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Background: Geographic mobility represents a widespread challenge to HIV prevention and treatment goals: it can break bonds between individuals and care systems, link geographically separate epidemics, and intensify transmission. This study (1R01MH104132), embedded within an ongoing HIV test and treat study (SEARCH, NCT01864603), sought to examine how mobility affects sexual behavior, STI and HIV risk in East African communities.
Methods: Survey data were collected February-November 2016 from 2,750 adults aged 16 and older in 12 communities in Uganda and Kenya, to measure mobility and sexual behavior; STI (Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) were detected using Xpert® assays. Mixed-effects logistic regression models were fitted to test associations of four measures of recent migration with STI infection, controlling for key covariates (gender, age, marital status and household wealth).
Results: 7.3% of adults undertook ≥1 migration in past year; 20.8% in past five years, most of which were internal migrations over county/district boundaries. A greater proportion of men (8.9%) than women migrated in past year (5.9%)(p=.003), and past 5 years (23.7% men vs. 18.1% women)(p=< .001).

	Model 3				Model 4			
STI (GC/CT)	OR	*p*	95% CI		OR	*p*	95% CI	
Female (ref.: Male)	1.39	0.159	0.88	2.19	1.39	0.158	0.88	2.19
Age ≥25 (ref.: <25)	0.54	0.049	0.29	1.00	0.56	0.058	0.30	1.02
Single (ref.: all other marital status)	2.15	0.026	1.10	4.20	2.37	0.011	1.22	4.61
Poorest (ref: greater household wealth)	2.10	0.005	1.24	3.53	2.03	0.007	1.21	3.40
≥1 Migrations in past year	2.22	0.014	1.17	4.20	--	--	--	--
model constant	0.02	0.000	0.01	0.06	--	--	--	--
≥1 Migrations in past 5 year	--	--	--	--	1.89	0.009	1.17	3.05
model constant	--	--	--	--	0.02	0.000	0.01	0.05

[Measures of migration predicting STI]

STI prevalence was 3.14% overall (1.6% CT, 1.5% NG, 0.1 both); 7.1% in past year migrants vs. 2.8% in non-migrants (p= 0.001). In multivariate mixed-effects models, numbers of past year (OR 1.79, 1.23-2.61 [95%CI]) and 5 year migrations (OR 1.36, 1.09-1.70 [95%CI]), and measures of ≥1 migration in past 1 year (OR 2.22, 1.17-4.20 [95%CI]) and 5 years (OR 1.89, 1.17-3.05 [95%CI]) were predictive of STI prevalence, controlling for important covariates.

Conclusions: Greater proportions of men than women participate in migration in Kenya and Uganda. Despite overall low prevalence of STI (GC/CT) among adults in the study in Kenya and Uganda, past year and also past five year migrations were predictive of STI, warranting focused prevention efforts among mobile populations.

TUPEC0809

Prevalence and predictors of human immunodeficiency virus and selected sexually transmitted infections among people who inject drugs in Dar es Salaam, Tanzania: a new focus to get to zero

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Background: : Previous studies in Tanzania indicated that human immunodeficiency virus (HIV) prevalence among people who inject drugs (PWIDs) could be as high as 40%. We aim to provide data on the prevalence of HIV and sexually transmitted infection among PWIDs to inform national plans to get to zero.
Methods: Respondent-driven sampling was used to collect drug use, and sexual practices data among PWIDs aged 15 years and older. Blood samples were examined for HIV, herpes simplex virus type 2, syphilis, and hepatitis B.
Results: A total of 620 PWIDs with a median age of 32 (interquartile range, 17-52) participated in the study. Their use of drugs had typically started during adolescence. The prevalence of HIV was found to be 15.5%, whereas that of herpes simplex type 2 was 43.3%.
Associated with an increased likelihood of HIV infection was being a female (adjusted odds ratio [aOR], 2.3; 95% confidence interval [CI], 1.0-3.6), sharing of syringes (aOR, 2.4; 95% CI, 1.1-6.1), used syringes hidden in public places (aOR, 5.1; 95% CI, 1.3-10.2), and having had a genital ulcer during the last 12 months before this survey.
On the other hand, being educated, use of non-injectable drugs, access (aOR, 0.5; 95% CI, 0.2-0.8), and use of clean syringes (aOR, 0.3; 95% CI, 0.1-0.6) were associated with decreased likelihood of HIV infection.
Conclusions: The prevalence of HIV infection among PWIDs in Dar es Salaam is 3 times higher than that in the general population. Behavioral and biological risk factors contribute to HIV transmission and needs to be addressed to be able to get to zero.

TUPEC0810

HIV care and treatment cascade among key populations living with HIV in Mozambique: results from the integrated biological and behavioral surveillance (IBBS) surveys 2011-2014

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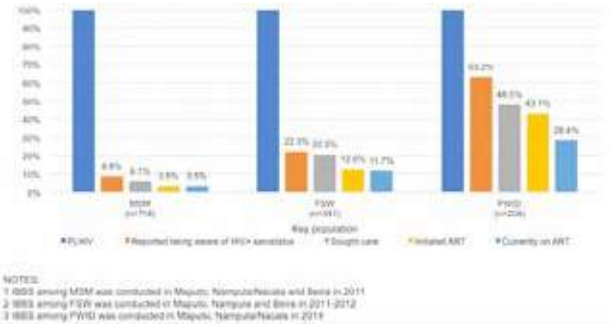
Background: Although Mozambique has a generalized HIV epidemic, key populations (KP) are disproportionately affected. Our analysis estimates HIV care and treatment cascade indicators among participants in the IBBS surveys among Men Who Have Sex With Men (MSM), Female Sex Workers (FSW), and People Who Inject Drugs (PWID) in three cities in Mozambique to track progression of People Living with HIV (PLHIV) from one service to the next and highlight attrition of coverage.
Methods: We conducted a secondary data analysis of results from respondent-driven sampling surveys conducted in Maputo, Beira and Nampula/Nacala from 2011 to 2014. Results from respondents' HIV testing results and self-reported responses to the survey questionnaire were pooled across survey cities and then used to produce unweighted proxy cascade indicators.
Results: HIV prevalence among survey participants was 8.0% (n=114), 27.5% (n=341), 45.8% (n=204) for MSM, FSW and PWID, respectively, where the number of PLHIV served as the denominators. Figure 1 illustrates the percentage of KPs that progressed through the HIV care cascade. Losses occurred throughout the continuum for the three populations, with the largest breakpoint occurring at knowledge of HIV status, which varied from 8.8% among MSM to 63.2% among PWID. Use of services appears higher among PWID, when compared to the other KPs; however, there is a high dropout rate among PWID who initiated antiretroviral therapy (ART) and those currently on ARTs.



[Figure 1: HIV Care and Treatment Cascade among KPs]

Conclusions: Special attention should be given to interventions that increase service uptake of HIV testing and retention in care among all KPs, but particularly among MSM and FSW. It is possible that some respondents may have been aware of their HIV positive status but refused to disclose, thus representing a bias that may potentially impact results. Future IBBS surveys should include viral load testing to guarantee a more complete picture of the cascade.

TUPEC0811

Trans identity and HIV risk- findings from a large study of young transwomen

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Background: Globally, transwomen bear a larger burden of HIV than any other population, and research points to discrimination and stigma as a primary cause. Transwomen exposed to more discrimination because they are out as trans at a younger age may experience higher risk for HIV. This analysis uses the first large dataset of young transwomen to examine the impact of realizing trans identity and living as trans on HIV risk.
Methods: Data for this analysis are from 243 participants in the SHINE study- a social epidemiological study of HIV risk and resilience among of young transwomen aged 16-24 years in the San Francisco Bay Area, California, USA. We conducted an exploratory analysis to identify age of transgender identity realization and outness associations with increased sexual risk behavior at baseline. Logistic regression analysis examined increased engagement in condomless anal intercourse (CAI).
Results: The sample consisted of 39.9% white youth, 31.6% Latinas, 12.2% Black/African Americans, and 16.3% youth of other racial/ethnic identities. HIV prevalence was 3% (n=8) at baseline.The mean age at which participants thought they were trans or something other than a man was 8.9 years and 17.5 years for the mean age they began living as trans. Young transwomen had significantly lower odds of engaging in CAI with increasing age at which youth felt they were trans (OR 0.93; 95% CI 0.88-0.98) and began living as trans (OR 0.78; 95% CI 0.70-0.88). African American young transwomen had significantly higher odds of engaging in CAI as age at which they began living as trans increased (OR 1.06; 95% CI 1.00-1.77).
Conclusions: We found overall that the later the age at which young transwomen realized and began living as trans, the lower their odds were for engaging in sexual risk behavior; however, later age of beginning to live as trans may be detrimental to the health of transwomen of color who already face multiple forms of stigma. Though interventions like PrEP and access to HIV testing are important, policy and human rights approaches to reducing stigma and discrimination towards transgender people may have a more sustained impact on reducing HIV and other health risks among transwomen.

TUPEC0812

Prevalence and mapping of hepatitis C infections among men who have sex with men in New York city

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Background: Emerging sexually transmitted hepatitis C (HCV) infection epidemics among men who have sex with men (MSM) have been reported worldwide, with higher HCV infection rates among HIV-infected than HIV-negative MSM. This study aims to determine prevalence of recent and chronic HCV infections among community-recruited MSM in New York City (NYC), map HCV infections by home, social, and sexual neighborhoods, and determine clusters of genetically linked HCV variants using phylogenetic analysis.
Methods: The NYC M2M study recruited MSM via modified time-space, venue-based sampling and internet/mobile app-based recruitment during 2011-12. Participants completed a Google Earth map on neighborhoods of where they lived, socialized, and had sex in the last 3 months, an ACASI questionnaire, and a sexual network inventory about their sex partners. The men received HIV testing and provided serum samples.
Testing on stored serum samples included HCV antibody and RNA viral load, HCV antibody avidity assay (avidity index <40% with positive viral load is considered recently infected), and HCV RNA extraction and amplification to generate a 432 base-pair region of Core/E1 for sequencing and phylogenetic analysis. Historic local controls were included in the phylogenetic analysis.
Results: Of 1,028 MSM, 77.2% were HIV-negative and 22.6% HIV-positive. Twenty nine MSM (2.8%) were HCV antibody-positive. MSM who were HCV antibody-positive reported a median of 2 male sex partners in last 3 months, with 6.9% aged 18-24, 17.2% 25-29, 13.8% 30-39, and 62.1% 40 and over. Over half (58.6%) of HIV-positive MSM were HCV antibody-positive vs. 21.5% of HIV-negative men (p<0.001). Of 29 HCV-antibody positive MSM, 12 (41.4%) were HCV RNA-positive (11 subtype 1a and 1 subtype 1b). Two of 12 HCV RNA-positive participants had low antibody avidity values, suggesting recent infection. Mapping of HCV infections differed slightly by home, social, and sexual neighborhoods. Based on phylogenetic analysis from 12 HCV RNA-positive samples, no evidence of a clustered HCV epidemic was found.
Conclusions: Overall HCV seroprevalence was 2.8% among community-recruited MSM in NYC, with higher prevalence among HIV-positive MSM compared to HIV-negative MSM. Only two participants were found to have recent HCV infection, with no evidence of a clustered HCV epidemic based on phylogenetic analysis.

TUPEC0813

Identification of high-incidence 'hotspots' of HIV-associated extensively drug-resistant (XDR) TB in KwaZulu-Natal, South Africa

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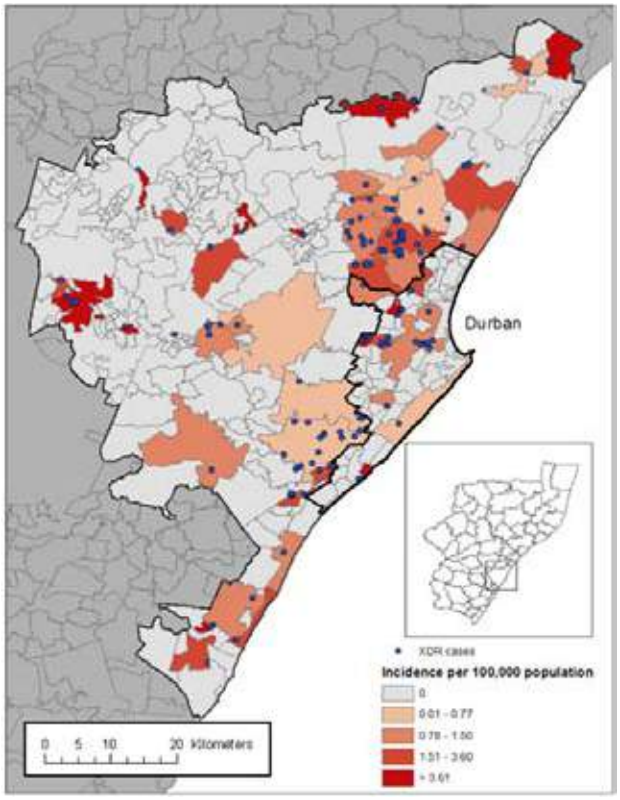
Background: Drug resistance represents a major threat to global tuberculosis (TB) control, particularly for people with HIV. In KwaZulu-Natal Province, South Africa, we determined that the majority of extensively drug-resistant (XDR) TB is due to transmission of resistant organisms rather than inadequate treatment. We hypothesize that XDR TB cases are concentrated in 'hotspots,' or areas of high incidence, which account for the majority of transmission events. We aimed to characterize the geographic distribution of notified XDR TB cases in a high HIV prevalence setting to identify hotspots for targeted prevention efforts.
Methods: We enrolled newly-diagnosed, culture-confirmed cases of XDR TB from 2011-2014 in KwaZulu-Natal. We collected participants' clinical and demographic information and GPS coordinates of their home residence. We mapped cases by home residence and calculated annual XDR TB incidence by main place (eThekwini) and sub-place (Durban), South African census units. We used Bayesian methods to stabilize rates and defined a hotspot as a unit with annual incidence above 1.5 per 100,000.
Results: We enrolled 404 participants from all 11 districts and 42 of 51 sub-districts in KwaZulu-Natal, 311 (77%) of whom were HIV-positive. eThekwini and Msinga sub-districts had the highest absolute number of cases with 132 (33%) and 42 (10%) cases, respectively. In eThekwini, which includes the provincial population center of Durban, 13 of 168 census units were identified as hotspots and 51% (67/132) of cases in eThekwini were located within a hotspot (Figure, inset shows eThekwini on a map of KwaZulu-Natal province). There was no substantial difference in case distribution by HIV status.



[XDR TB incidence in KwaZulu-Natal, South Africa.]

Conclusions: The urban district of eThekwini has the highest burden of XDR cases in KZN, with distinct hotspots within eThekwini. Bacterial genomics studies focused on these hotspots can clarify local transmission dynamics and inform the design of more effective local interventions.

TUPEC0814

Higher positivity of whole blood Epstein-Barr virus DNA among HIV-infected versus HIV-uninfected men who have sex with men in Shanghai, China

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Background: Approximately 5-10% of men who have sex with men (MSM) in China are infected with HIV. HIV-infected patients are at high risk of developing malignancies including those associated with Epstein-Barr virus (EBV). This study aimed to compare whole blood EBV DNA positivity between HIV-positive and HIV-negative MSM in Shanghai, China.
Methods: HIV-positive MSM and an equal number of age-matched (±5 years) HIV-negative MSM were recruited from an HIV counseling and testing clinic in Shanghai from Nov. 2014 to Nov.2015 and were administered with a cross-sectional questionnaire interview. Whole blood EBV DNA was tested by nested polymerase chain reaction assays on EBNA-1, EBNA-2 and LMP-1 genes.

Results: Among 1008 participants including 504 HIV-positive and 504 HIV-negative MSM, 81.8% aged at 21-40 years, 62.4% were non-local Shanghai residents, 96% were ethnic Han, 66.8% received college or higher education, 76.5% were never married, and 40.5% had depression when measured with CES-D. The two groups were comparable in distributions of residency, ethnicity and marital status, but were significantly different in age and education distributions. Compared with HIV-negative controls, HIV-positive MSM reported significantly higher proportion of lifetime experience of homosexual activities including having ≥5 partners (83.9% vs. 71.2%), unprotected anal sex (76.4% vs. 63.1%), unprotected casual sex (94.6% vs. 77.6%), receptive anal sex (86.9% vs. 76.0%), unprotected sex after drinking (27.4% vs. 21.8%), and unprotected sex after drug use (25.6% vs. 16.9%). The EBV DNA positivity was 56.0% for HIV-positive MSM and 26.0% for HIV-negative controls. Three separate multiple logistic regression analyses were performed and showed that after appropriately adjusted for potential confounding variables, the EBV DNA positivity was significantly associated with HIV infection status (aOR=3.30; 95%CI: 2.53-4.40; P< 0.001) in the whole sample, and with < 200 cells/ul CD4+ cell counts (aOR=1.64; 95%CI: 1.02-2.63; P=0.042) in the HIV-positive group, but with no any factors in the HIV-negative group.
Conclusions: The higher positivity of whole blood EBV DNA and its association with low CD4+ T cell counts among HIV-infected MSM discovered the population at higher risk for active EBV replication and underscore needs of further surveillance and research on EBV-related carcinogenesis in this population.

TUPEC0815

Predictors and incidence of sexually transmitted hepatitis C virus infection in HIV-positive men who have sex with men

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Background: Sexual transmission of Hepatitis C virus (HCV) in men who have sex with men (MSM) and its interaction with HIV status, sexually transmitted infections and sexual behaviour is poorly understood. We assessed the incidence and predictors of HCV infection in HIV positive MSM.
Methods: The electronic medical record and laboratory results from HIV positive MSM in care at a large urban public specialist HIV clinic embedded in a sexual health centre in Melbourne Australia were collected. Patients with two or more HCV antibody tests between January 2008 and March 2016 and with no record of injecting drug use were included. The HCV exposure intervals were the periods between a negative HCV test and the next HCV test. We compared HCV exposure intervals temporally associated with and without newly acquired syphilis or anorectal chlamydia. HCV exposure intervals were also categorised as being before or after HIV virological suppression and by most recent and nadir CD4 cell count.
Results: 37 new HCV infections were diagnosed in 822 HIV positive MSM with no history of injecting drug use over 3114 person years (PY) of follow-up. Mean age was 43.1 years (±12.5) and mean CD4 cell count nadir was 362 cells/uL (± 186). The incidence of HCV infection in the study population was 1.19/100PY (0.99-1.38). The incidence in exposure periods temporally close to new syphilis infection was 4.72/100PY (3.35-6.08) and to new anorectal chlamydia infection was 1.37/100PY (0.81-1.93). The incidence in men without supressed viral load was 3.19/100PY (1.89-4.49). In the multivariate Cox regression analysis only younger age (aHR 0.67 (0.48-0.92)), exposure periods temporally associated to new syphilis infection (aHR 4.96 (2.46-9.99)) and higher CD4 cell count nadir (aHR 1.26 per 100 cells/uL (1.01-1.58)) were associated with increased risk of HCV infection. During the study period the incidence of syphilis increased dramatically but the incidence of HCV infection remained the same.
Conclusions: Incidence of HCV infection is associated with syphilis but not anorectal chlamydia which suggests a biological rather than behavioural risk modification. Rising syphilis incidence may offset declines in HCV transmission through HCV treatment as prevention.

TUPEC0816

Prevalence and predictors of eye disorders among ART patients in Limpopo, South Africa, 2012-2015

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Background: Opportunistic infections are common among HIV positive individuals. Approximately 80% of HIV infected patients will develop HIV associated eye disorders during the course of their illness. Up to 40% of patients with advanced HIV develop cytomegalovirus retinitis which can lead to total blindness. Eye disorders have received minimal attention; hence there is limited data to identify the burden in South Africa (SA).
We determined the prevalence and identified risk factors of eye disorders among HIV positive patients in one South African province.
Methods: A cross sectional study among 535 HIV-infected patients was conducted in Vhembe District, Limpopo province, SA from 2012-2015. Clinical data were collected from the patients using a structured questionnaire and patient files were followed up from 2012-2015. Data were analysed using STATA13. Multivariable logistic regression analysis was used to determine risk factors. Manual backward stepwise procedure was used to select variables and a cut-off p-value of less than 0.05 was used to retain variables in the final multivariate model. We adjusted for confounders of age and gender.
Results: The overall prevalence of eye disorders among HIV positive patients was 33% (177/535, including Scotoma 13% (22/ 177) (95% CI: 8.4 - 18.6); Retinal detachment 13% (22/177) (95% CI: 8.4 - 18.6); Keratoconjunctivitis28% (48/177) (95% CI: 21.4 - 34.7) and Uveitis 54% (93/177) (95% CI: 46.2 - 61.1).
HIV positive patients with diabetes co-morbidity were four times more likely to report eye problems as compared to those without diabetes (OR=4.14, 95%CI=1.22-14.00, p=0.017).
Having a history of TB treatment (OR=1.57, 95%CI=1.04-2.37, p=0.004) and CD4 count less than 200 (OR=2.05, 95%CI=1.92-2.16, p=0.002) were significant predictors of eye disorders among HIV positive patients.
Conclusions: This study demonstrates that eye disorders are common among HIV positive patients in Limpopo. TB diagnosis and treatment, Diabetes and low CD4 count were associated with eye disorders. This highlights that eye disorders are further exacerbated by HIV and having a weakened immune system. Heightened awareness for better management of ocular disorders is recommended among health care personnel and HIV positive people. Policy makers need to integrate ophthalmic examinations in public health facilities when HIV patients receive their treatment.

TUPEC0817

PrEP usage is related to increased STD rates

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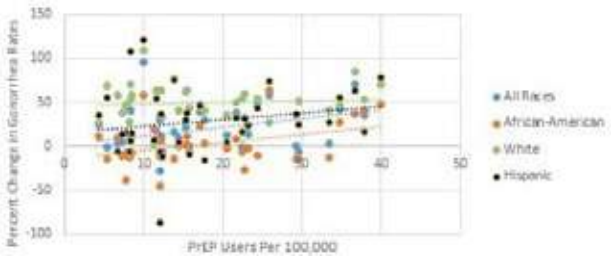
Background: Truvada has proven to be very effective for use as pre-exposure prophylaxis (PrEP). However, a possible concern is that increased Truvada use will lead to reduced condom usage and increase in STDs that were previously under control.
Methods: We obtained data on rates of Truvada usage for PrEP in the United States. We then ran correlations between Truvada usage and the percent change in STD rates across states between the two-year period from 2011-2012 and the two-year period from 2013-2014. The three STDs examined were gonorrhea, chlamydia, and primary/secondary syphilis. The hypothesis was that a higher rate of PrEP usage would correlate with greater increases in STDs.



[Percent change in gonorrhea among men as a function of PrEP usage across states]

Results: There was a significant positive correlation between PrEP usage and increase in gonorrhea rates (r=0.389, p <0.01) for men across states as well as for women (r=0.438, p <0.005). Correlations were not significant for chlamydia or syphilis. The change in gonorrhea rates were broken down further by racial group and gender. A significant correlation was found for African-American men (r=0.374, p <0.01), but there was no significant correlation for white (p >0.1) or Hispanic (p >0.1) men. For women, a significant correlation was found for whites (r=0.346, p <0.05) and Hispanics (r=0.282, p <0.05) but not African-Americans (r=0.202, p >0.1).
Conclusions: Higher usage of Truvada for PrEP is linked to greater increases in gonorrhea rates among men. Public health officials should ensure that individuals taking PrEP have access to adequate safe sex counseling, particularly if they are either African-American men or white or Hispanic women.

TUPEC0819

Better survival outcomes among HIV-infected women with cervical cancer at a national referral hospital, Kenya

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Background: Cervical cancer screening has been integrated into many HIV programs in Sub-Saharan Africa. Most women who screen positive are often referred out for further evaluation with minimal follow-up on their outcomes. We compared survival outcomes among HIV-infected to uninfected women in a cancer registry at a national referral hospital in Kenya.
Methods: Cervical cancer patients whose diagnosis was confirmed by histology/cytology and enrolled for cancer care at Kenyatta National Hospital between April 2014 and July 2015 were included. Patient demographics, HIV testing history, stage of disease at enrolment into cancer care and outcome status (dead or alive) as at Aug 2015 were collected from medical files, laboratory and autopsy records. Logistic regression with recycled predictions was used to obtain the risk ratio of death.
Results: Of 1069 cervical cancer patients, only 435 (41%) had a HIV status indicated. Of these, 211(49%) were HIV-infected. HIV-infected women were younger (median=43 years (IQR 38, 57)) compared to HIV-uninfected women (median=47 years (IQR 40, 54)).Average follow-up duration at the oncology clinic was 9.5 months (8.2, 10.7) and did not vary with HIV status. HIV-infected women had lower stage disease at enrolment compared to HIV-uninfected women (Trend test p=0.042).

Cervical Cancer Stage (FIGO)	HIV-Infected (n)	HIV-Uninfected (n)	Prevalence Ratio	95% CI
I	28	13	1.00	Reference
II	43	48	0.42	0.19, 0.90
III	50	68	0.34	0.16, 0.72
IV	17	19	0.42	0.16, 1.05

[Table 1: Cervical Cancer Stage by HIV status]

Of the 211 HIV-infected women, 17(8.1%) had died while 34(15.2%) of the 224 uninfected women had died. Adjusting for age and stage of disease ,HIV-infected women with cervical cancer were 1.1 times more likely to be alive compared to HIV-uninfected women (risk ratio 1.11 (95%CI: 1.01 - 1.2) p= 0.0174.
Conclusions: HIV-infected women with cervical cancer had lower stage disease at diagnosis and better outcome compared to uninfected women. This could be a result of systematic cervical cancer screening and referral offered in HIV care clinics. This approach could be of benefit if integrated into other programs that routinely offer services to women.

TUPEC0820

Inflammation is an important predictor of diabetes in veterans with HIV infection: a veterans aging cohort study

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Background: HIV-infected (HIV+) persons on long-term antiretroviral therapy (ART) are at risk of diabetes mellitus (DM), which has been linked to persistent inflammation. Further, an increasing proportion of HIV+ persons are overweight and obese, which is both a risk factor for DM and a pro-inflammatory condition. We used the Veterans Aging Cohort Study biospecimen cohort (VACS-BC) to assess whether the relationship between BMI or inflammatory biomarkers and DM incidence differs by HIV status.
Methods: VACS-BC is a longitudinal cohort study of HIV+ and uninfected (2:1) veterans from 8 Veterans Affairs Healthcare Centers enrolled between 2005 and 2007. DM diagnoses and onset date were determined using an algorithm incorporating glucose, HbA1c, ICD-9 codes, and medications. Cox proportional hazards models were used to model the incidence of DM as a function of baseline interleukin-6 (IL-6), d-dimer, soluble CD14 (sCD14), HIV status and BMI. HIV+ participants were stratified as suppressed (plasma HIV RNA < 500 copies/ml at enrollment) or unsuppressed (≥500 copies/ml). Models were adjusted for age, race, sex, education level, hepatitis C status, smoking status, alcohol use, and interaction terms.
Results: Excluding prevalent cases (n=556), our algorithm identified 231 incident DM cases among 1833 participants. IL-6, HIV status and BMI but not sCD14 or D-dimer were associated with incident DM. After exclusion of underweight (BMI ≤ 18.5) and stratification by HIV status, overweight and obesity as compared with normal weight were significantly associated with risk of DM in uninfected and HIV+ with suppressed virus, but not significantly in unsuppressed HIV+. High serum IL-6 (Q4) was significantly associated with higher DM risk (Q4 versus Q1) in all groups.

	Uninfected Veterans	HIV-infected Veterans	
	Uninfected (n=562)	RNA<500 (n=756)	RNA≥500 (n=454)
Normal weight (BMI 18.5-24.9)	HR 1.00	HR 1.00	HR 1.00
Overweight (BMI 25-29.9)	HR 2.90; 95%CI 1.35-6.22	HR 1.73; 95%CI 1.02-2.96	HR 0.87; 95%CI 0.43-1.77
Obese (BMI ≥30)	HR 4.39; 95%CI 2.10-9.21	HR 2.69; 95%CI 1.38-5.25	HR 1.52; 95%CI 0.67-3.46
Low IL6 (Quartile 1)	HR 1.00	HR 1.00	HR 1.00
High IL6 (Quartile 4)	HR 2.50; 95%CI 1.44-4.33	HR 2.44; 95%CI 1.06-5.63	HR 4.08; 95%CI 1.16-14.43

[Hazard of DM by BMI and IL-6.]

Conclusions: In HIV+ persons with suppressed viremia, being overweight/obese and having elevated IL-6 are independently associated with increased DM risk. BMI has less prognostic value for DM risk in HIV+ persons with unsuppressed viremia.

TUPEC0821

Phylogeographic analysis of HIV-2 ANRS CO5 cohort reveals new trends in HIV-2 epidemic patterns in West Africa

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Background: The early spread of HIV-2 in Western Africa is imperfectly described for group B and the recently identified subtype A2. Recent HIV-2 epidemiological data are also scarce outside of Guinea-Bissau. The sequence database of the HIV-2 ANRS CO5-cohort, one of the largest to date, was used to explore the early migration patterns of these strains by phylodynamics means.
Methods: All publicly available (49 and 8 for A and B, respectively) and ANRS CO5-cohort (125 and 68 for A and B, respectively) pol sequences with available time of sampling and patient's country of birth were included. Bayesian phylogeographic reconstructions and effective population size estimations were performed

under the best fitting combination of evolutionary, demographic and molecular clock models using BEAST 1.8. The tree topology was assessed with maximum likelihood trees using RAxML 8.0.0.
Results: The estimated introduction of group A in human was 1945 [95% HPD: 1935-53], as previously reported. Subtype A1, present in Senegal, Gambia, Guinea-Bissau and Guinea, experienced an early diversification around 1946 [1936-54] with two distinct early epidemics in Guinea-Bissau and Senegal. Subtype A2, present in Ivory Coast and Mali, experienced a latter diversification (1956 [1947-63]) in Ivory Coast with two introduction events in Mali (1963 [1957-69] and 1967 [1960-74]). Group B was originally introduced in Ivory Coast in 1962 [1953-13]. Changes in effective population size over time revealed an initial exponential growth followed by a population decline starting in the 2000's for the three HIV-2 strains. The rate of this decline was slower for A2 and B subtypes (Ivory Coast, Mali) than for A1 (Guinea-Bissau, Senegal).
Conclusions: This phylogeographic study is the first to reconstruct the early dispersal of A2 and B HIV-2 clades in Western Africa. Our results suggest that subtype A1 was circulating in Guinea-Bissau and Senegal before the independence war of the former, believed to have contributed to the dispersal of HIV-2. Both A2 and B clades emerged in Ivory Coast and experienced latter diversification and population expansion (starting in 1980 and 1990, respectively) than A1. There is indication of slow decreasing incidence rates of HIV-2 in Ivory Coast or Mali where recent data are scarce.

TUPEC0822

Expansion of HIV BF recombinants among men who have sex with men (MSM) in Buenos Aires, Argentina

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Background: Several HIV epidemiological studies performed among MSM from Buenos Aires, Argentina revealed high HIV prevalence (11-17%) and incidence (4.5 per 100 persons-year). First studies on molecular epidemiology established that subtype B dominated the epidemic among MSM while BF recombinants were more frequent among heterosexual men and women.
The objective of the study was to describe the subtype diversity of HIV among MSM along 10 years of epidemiological studies in Buenos Aires, Argentina (2000-2009).
Methods: Four different studies were performed from 2000 to 2009 (Study 1, 2, 3 and 4). All the studies included self-reported MSM, including those who have other partners (women and/or transgender) and those who exclusively have male partners. HIV DNA/RNA was isolated from cells/plasma samples using commercial kits and pol gene was amplified from positions 2143 to 3798 (HXB2 numbering) and sequenced in an automatic sequencer. The phylogenetic analysis was performed by Neighbor-joining and bootscanning.
Results: A total of 293 pol gene sequences were obtained and phylogenetic analysis revealed that 221 (75.4%) were subtype B and 72 were BF recombinants (24.6%). Temporal analysis demonstrated that frequency of subtype B significantly decreased over time: 89.6% in Study 1, 83.3% in Study 2, 71.2% in Study 3 and 58.5% in Study 4 (p<0.001). In the last study, the frequency of subtype B was significantly higher among men who exclusively have sex with men as compared with those also having sex with women and/or trans (74.1% vs. 42.3%, p=0.027).
Conclusions: Subtype B continues being predominant among MSM, however, in comparison to previous studies, the frequency of BF recombinants is increasing over time. Our results suggest that even subtype B might have been the subtype that originated the HIV epidemic among MSM, the interconnection with other groups where BF recombinants predominate, has produced a change in the molecular epidemiology of MSM. This fact needs to be considered for any preventive clinical trial to be conducted among MSM, where HIV subtype could be influencing the result.

TUPEC0823

Prevalence of HIV-2 and HIV-1 group O infections among new HIV diagnoses in France, 2003-2015

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Background: Both HIV-2 and HIV-1 group O (HIV-1_O) are considered as restricted geographically, either to west Africa vs Cameroon, respectively. Cases have been described outside Africa, particularly in Europe, but no extensive epidemiological surveys have determined the extent or dynamics of spread of these rare viruses in western countries on a long period.
Methods: The French reporting system for new HIV diagnoses is linked to a virological surveillance using dried serum spots (DSS) on which a serotyping assay that discriminates between HIV-1 group M (HIV-1_M), HIV-1_O and HIV-2 is performed. Clinical and epidemiological variables are collected and entered into the national database, among which: sex, age, country of birth, mode of transmission, clinical stage at HIV diagnosis.
Results: Of 47,097 new HIV diagnoses reported during the 13-year period for which DSS was available, 779 concerned patients infected by HIV-2 (1.65%) and 40 patients infected by HIV-1_O (0.09 %). In addition 46 cases of dual HIV-1/HIV-2 infections and 3 cases of dual HIV-1/HIV-1_O infections were observed. Patients infected by HIV-2 were mostly born in a west African country (83.4%), mainly Ivory Cost, Mali, Senegal, Guinea and Guinea-Bissau. Patients infected by HIV-1_O were mostly born in Cameroon (71.4%). However 34 patients infected by HIV-2 were born in Europe (31 in France and 3 in Portugal) and 6 patients infected by HIV-1_O were born in France. When compared to HIV-1_M, patients infected by HIV-2 or HIV-1_O were older and were more frequently women. Among 12,737 new HIV diagnoses in men who have sex with men, only 5 were infected by HIV-2 and none by HIV-1_O. HIV-2 prevalence decreased since the 2006-08 period: 1.58% (2003-05), 2.24% (2006-08), 1.56% (2009-11) and 1.29% (2012-15) ($p< 10^{-4}$). For HIV-1_O, the decrease was not significant: 0.12%, 0.11%, 0.09% and 0.05% (p=0.054).
Conclusions: The study shows that most of the cases diagnosed during this 13-year period still occurred in patients originating from the endemic areas, west Africa and Cameroon, for HIV-2 and HIV-1_O, respectively. There is no increasing spread of these rare variants in France.

TUPEC0824

Identification of rapid and emerging transmission clusters from genetic network

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Background: Transmission network could be inferred from HIV sequences. This study aimed at applying social network analysis to identify clusters with accelerating transmission for informing targeted intervention.
Methods: HIV sequences of gag-pol region with demographics and longitudinal viral load data were collected over a 20-year period from all three HIV clinics in Hong Kong. Individual seroconversion year was estimated by back-calculation. Transmission networks were formed by pairs with TN93 distance ≤1.5%. Network clusters were identified and decomposed by modularity if one contained more than half of the nodes. Clusters were then analysed by the following metrics: density, clustering coefficient, and transmission speed in persons per year (ppy). Emergence of new nodes was evaluated by the average number of nodes added to clusters in the foregone 2 years (2-year cluster incidence).
Results: Between 1994 and 2013, 2352 genetic sequences were available for analysis, accounting for 40% of Hong Kong's reported incident cases. Density of the entire network was 1.65%. Among 131 connected components, 68 were dyads. The largest component consisted of 72% of the connected nodes, from which 20 clusters were decomposed.
A total of 82 clusters were further analysed. Most clusters were of subtype B (62%), while subtypes CRF01_AE and CRF07_BC/CRF08_BC accounted for 22% and 10%, respectively. The largest cluster, with the highest speed (12.31 ppy), was composed of CRF01_AE heterosexuals, men who have sex with men (MSM) and some injection drug users. The second fastest (9.00 ppy) was a subtype B cluster com-

posing of largely MSM. Emerging transmission was identified from MSM clusters of subtype CRF01_AE and CRF07_BC (2-year cluster incidence: 7.00, 6.50). Some 76% of the clusters had not grown further after 2010.
Demographically, clusters with younger individuals had a higher 2-year cluster incidence and clustering coefficient. Percentage of viral suppression in clusters was negatively associated with clustering coefficient.
Conclusions: The new metrics have enabled us to uncover multiple ongoing HIV transmission networks in Hong Kong. Clusters of younger individuals emerged and grew rapidly, which are of public health concern. Viral suppression achieved from antiretroviral therapy had reduced onward viral transmission, resulting in a low clustering coefficient.

TUPEC0825

Near Full-length genomic sequencing and molecular analysis of HIV-infected individuals in a network-based intervention (TRIP) in Athens: phylogenetic clusters correlate with individuals with social links

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Background: The Transmission Reduction Intervention Project (TRIP) was a social network-based contact tracing study to detect individuals with recent HIV infection within 6 months. Most of the participants were people who inject drugs (PWID). We herein explore factors associated with transmission clustering based on full-length HIV genomic phylogenetic analysis and on well characterized social networks.
Methods: TRIP participants were grouped into clusters following a social network-based contact tracing. HIV whole genomes were generated using methods developed under the Infection Response through Virus Genomics (ICONIC) project. Full-length genomic alignments were performed with MAFFT program available online on HIV sequence database. Phylogenetic trees were inferred by an approximate maximum likelihood method derived from whole genome alignments of samples of 104 HIV+ participants using the FastTree program. Highly supported phylogenetic clusters (subnetworks) were those receiving >0.95 SH-support.
Results: All sequences belonged to previously identified local transmission networks of PWID (CRF14_BG, CRF35_AD, subtypes A and B) (LTNs) in the Athenian outbreak (n=76) and of unique recombinants (n=28). After excluding unique recombinants, phylogenetic analysis of 76 near full-length HIV genomic sequences suggested the existence of 14 subnetworks with 2-4 sequences each and 38 sequences in total (50% of all sequences). Eleven subnetworks (11/14, 78.6%) included sequences of twenty two individuals (22/38, 57.9%) with first degree social links with at least another member of their subnetwork.
Conclusions: Additional HIV whole genome sequencing data helped to better define phylogenetic subnetworks. Interestingly, all sequences falling within phylogenetic clusters (n=7) by Sanger sequencing before did so also by full-length sequence analysis. The percentage of individuals within phylogenetic subnetworks having also social links with other subnetwork members was higher with full-length genome analysis (57.9%) than with Sanger sequencing (43.8%), suggesting that the former describes subnetworks in more detail. Molecular methods can identify infected people with social connections in more than half of the phylogenetic clusters. To our knowledge, this is one of the first studies showing the added value of molecular epidemiology, which uses full-length phylogenetic analysis of HIV sequence data to identify phylogenetic clusters of individuals who also have social ties.

TUPEC0826

The geography of HIV/AIDS among marginalized highland ethnic minorities in Chiang Rai province, Thailand

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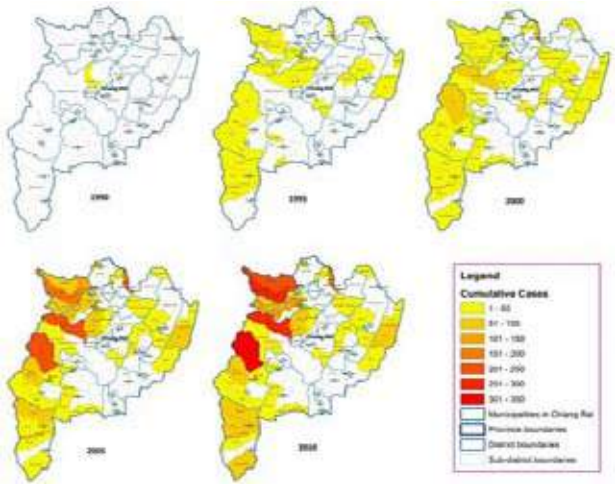
Background: Subsequent to Thailand's first HIV/AIDS epidemic wave in its urban center in recent decades, a new epidemic wave emerged among highland ethnic minorities in Northern Thailand. It is a major challenge to combat the burdens imposed by the epidemic on ethnic minorities because of barriers in social cultural-language, political, and health systems.
Methods: The Study describes and determines the spatial and temporal dynamics of the HIV epidemic by HIV cumulative incidences among six highland Hill Tribes in the province of Chiang Rai. Secondary data of 16 hospitals in the province was compiled for ethnic minority HIV reported cases during 1990 to 2011. Quantum GIS Desktop (Version 1.8.0) was used to create maps of HIV incidences of different Hill tribe village locations across districts and sub-districts in Chiang Rai.
Results: A total of 3130 HIV incidences were reported in 294 villages out of 651 with spatial density non-randomly distributed: 1420 (45.4%) female; 2738 (87%) age of 15 - 49, 229 under 15 (7.3 %) and 163 cases (5.2%) 50 or above; 1403 (45%) agriculture workers, 1003 (32%) labor worker and others (23.2%); Sexual transmission 91.6%, Mother to child transmission at 5.7% and injecting drug use <1%. The Akha tribe contributes to the highest no. of cases 1441 (46%) followed by Lahu 617 (19.7%), Yao 298 (9.5%), Lisu 282 (9%) Karen 271 (8.7%) and Hmong 221 (7.1%). The districts with dense population in highlands and those with close proximity to major municipalities are most affected.
Conclusions: Hill tribes living in Chiang Rai are among the most disadvantaged and vulnerable societies who are at risk of HIV infection due to poverty, lack of access to education, increased drug use, increase sex work and social marginalization. Education programs to promote behavioral change and priority focused interventions should be implemented.



[Cumulative HIV Incidence among Hill Tribes]

TUPEC0827

Updated estimates of HIV incidence in France, 2003-2014

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Background: A surveillance system combining case reporting and biomarker-based identification of recently acquired infection is implemented in France to monitor HIV incidence at the country level. First estimates indicated an overall downward trend in new infections but a stable number in men who have sex with men (MSM), representing half of new cases in 2008 (Le Vu et al, Lancet Inf Dis 2010). Here, we provide revised national estimates for the period 2003 to 2014, accounting for updates in data and methodology.
Methods: We used the stratified extrapolation approach described in Prejean et al. (PloS ONE 2011) that infers yearly number of new infections by weighting reported diagnoses detected as recent infections (EIA-RI assay). The weights reflect

HIV testing behaviors specific to each stratum of transmission category and demographics. Diagnosis data were adjusted for reporting delays and under-reporting. Missing data for key variables was imputed by multiple imputation. Temporal trends in incidence based upon 52 375 diagnoses were compared using variance-weighted least-square regression.
Results: We estimate that 5659 [95%CI: 5129-6189] persons were newly infected with HIV in France in 2014. This led to an overall incidence rate of 13 per 100,000 persons/year (aged from 18 to 69 years). With 2912 (51%) new infections in 2014, MSM still contributed dramatically to the overall number of cases. Among the 2680 (48%) new infections attributed to heterosexual transmission, foreign-born individuals (56%) exceeded French-born (44%). Intravenous drug users accounted for 1% of new infections. The HIV incidence globally decreased from 2003 (with 10 651 [95%CI: 9348-11955] new infections) to 2014. The decrease was significant throughout the whole period in heterosexuals, but only over the 2008-2014 period in MSM.
Conclusions: These updated results confirm the overall decrease of HIV incidence in France since 2003. MSM are still disproportionately contributing to current HIV transmission but after having kept a stable level up to 2008, new infections are now decreasing in this group. An analysis with more intricate breakdown by demographics (world region of birth, age and geographical area) is underway to fully appreciate the progress made in the country to drive down new HIV infections.

TUPEC0828

Development of a multiplex assay for HIV diagnosis, serotyping and detection of recent HIV-1 infection

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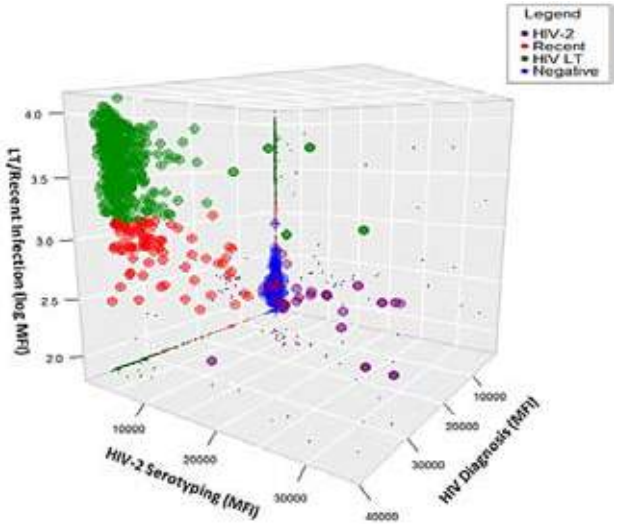
Background: Currently LAg-Avidity EIA, developed in our laboratory, is the best tool to detect recent HIV-1 infection. However, efforts to use laboratory-based assays in cross-sectional surveys are often challenged by inaccurate HIV diagnosis and presence of HIV-2 infection, requiring multiple additional steps. We developed a multiplex assay that combines HIV diagnosis, HIV serotyping and detection of recent HIV-1 infection, all in a single test.
Methods: Magpix Luminex technology which uses colored magnetic beads was used for multiplex assay development. HIV diagnosis and HIV-2 serotyping were accomplished by coupling beads with a recombinant HIV-1 p24-gp41 fusion protein and HIV-2 peptide from gp36 immunodominant region, respectively. HIV-1 recent infection detection was accomplished by using limiting amounts of multi-subtype gp41 recombinant protein, rIDR-M.
Assay conditions, including coupling, were optimized using well-characterized specimens in a stepwise manner. Beads were subsequently combined in a multiplex assay to evaluate its performance using a previously characterized world-wide panel of specimens (n=1500) from HIV-1 positive (n=570, recent = 78, long-term= 492), HIV-2 positive (n= 31) and seronegative persons (n=899) from 10 countries, representing subtypes A, B, C, D, and AE.
Reference results were generated using EIA/WB algorithm for HIV status, Multispot assay for HIV-1 and 2 serotyping and LAg-Avidity EIA for recent or long-term classification. Assay cutoffs and algorithms were determined by using 3-parameters comparing it to the results of reference standard.



[Development of a multiplex assay]

Results: The diagnostic component of the assay performed with high sensitivity (99.8%) and specificity (99.7%), while the HIV-2 serotyping sensitivity was 96.7% and specificity was 100%. There was a high level of correlation between the detection of recent infections using the LAg-Avidity EIA and that from the multiplex assay with the possibility of extending the mean duration of recent infection. The assay showed high reproducibility with coefficient of variation of <10%.
Conclusions: The new multiplex assay has the ability to accurately diagnose HIV infection, perform HIV-1 and 2 serotyping and detect and distinguish recent from long-term HIV-1 infections, all in a single test. This novel assay has the potential to simplify HIV surveillance by combining critical biomarkers on a single platform.

TUPEC0829

HIV prevalence in Argentina: a large scale study

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Background: According to the UNAIDS report of 2015, HIV prevalence in Argentina is 0.4%. This information comes from the estimation of HIV cases of the Ministry of Health in relation to the total country population in 2015. Therefore a study on the HIV prevalence in general population was carried out.
Methods: Between January 2, 2016 and December 30, 2016, HIV antibody determinations were performed in individuals from 10 provinces of Argentina, which together represent more than 60% of the total country population, through a previously validated rapid test (Alere Determine ™ HIV-1/2). Counselling was given to all people and for positive cases established the appropriate referral. The information was collected in an Ad Hoc database. Chi2, Fisher exact or Mid P tests and maximum likelihood odds ratios were used as appropriate.
Results: Determinations were made in 30013 people. Age range: 18 months to over 49 years. Gender distribution: women 53.6%, men 45.4%, transgender 1%. It was the first HIV test for 56%. There were 272 HIV positive results. Prevalence: 0.9% (95%CI: 0.8-1). Although the prevalence was significantly higher in men than in women (1.2% versus 0.5%, $p < 0.001$), the highest level was observed in transgender (4.6%). There was a greater probability of having a positive test in people who had unprotected sex (OR: 1.49 - 95%CI: 1.16-1.91; p = 0.001) and people between 25 and 49 years-old (OR: 1.46 - 95%CI: 1.15-1.86; p = 0.002). No significant differences were found in relation to sexual preferences (p = 0.69) or intravenous drug use (p = 0.40). Consistent condom use was reported in 14.5% of the people with negative results and in 22.3% of those with positive results. 80% of the population tested had at least high school education.
Conclusions: HIV prevalence observed in this population was twice as high as that reported for the general population of Argentina by UNAIDS. Multiple factors such as cultural issues, vulnerability or information on HIV transmission could explain this finding. Large scale testing is necessary to adjust estimates of the total population living with HIV and to establish better strategies for reducing the risk of transmission.

TUPEC0830

Risk factors and HIV care continuum outcomes for diagnosis during recent HIV infection in North Carolina

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Background: Distinguishing between recent and chronic HIV infection has important implications for HIV transmission dynamics and prevention programs. We examined associations with recent infection among new HIV diagnoses in North Carolina in 2014.
Methods: We used a novel Binding Antibody Multiplex Assay that has performed well compared with existing assays to distinguish recent (< 9 months) from chronic infection among individuals with newly diagnosed, antibody-positive HIV infection using remnant diagnostic specimen at the North Carolina State Laboratory of Public Health. Associations between recent infection and demographics were examined using unadjusted and adjusted logistic regression. HIV care continuum outcomes were measured with surveillance data, examining associations of recent

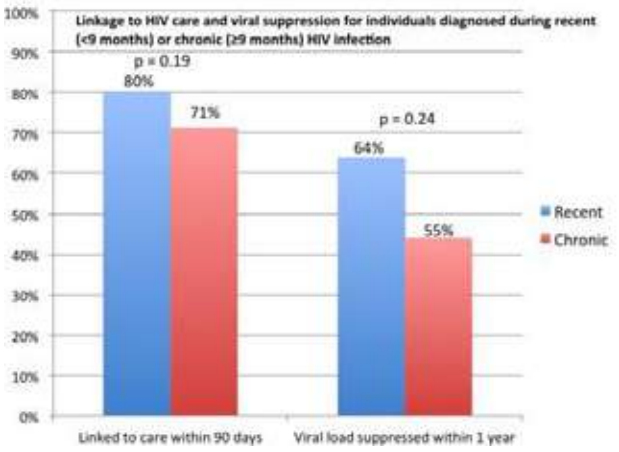
infection with linkage to care (CD4 or viral load [VL] within 90 days of diagnosis) and viral suppression at 1 year (VL < 200 copies/mL).

Results: 32% (61/190) of subjects were classified as recently infected. Median baseline CD4 and VL were 473 (quartiles: 351, 618) and 54,000 (11,560, 143,040) copies/ml for recent versus 350 (212, 609) and 28,893 (7620, 66,665) copies/ml for chronic. Younger age and traditional high-risk groups had significant associations with recent infection. More individuals with recent infection were linked and had viral suppression.

	N	% Recent	Unadjusted prevalence ratio (PR) for recent vs. chronic (95% CI)	Adjusted PR (95% CI), if retained in final model
Male (vs female)	148 (vs 42)	34% (vs 26%)	1.12 (0.51, 2.43)	-
<30 years old vs >30	106 (vs 84)	40% (vs 23%)	1.58 (1.01, 2.49)	1.65 (1.04, 2.61)
African-American (vs Hispanic)	134 (vs 18)	33% (vs 17%)	1.72 (0.61, 4.12)	-
White (vs Hispanic)	35 (vs 18)	40% (vs 17%)	2.06 (0.70, 6.09)	-
MSM (vs denied high risk transmission exposure)	112 (vs 32)	38% (vs 3%)	9.90 (1.36, 72.14)	11.61 (1.66, 81.34)
IDU (vs denied high risk transmission exposure)	10 (vs 32)	40% (vs 3%)	14.67 (1.90, 113.31)	15.09 (1.92, 118.76)
High-risk non-MSM sex* (vs denied high risk transmission exposure)	34 (vs 32)	38% (vs 3%)	11.93 (1.64, 86.70)	13.12 (1.82, 94.34)
Tested by county health department (HD) (vs non-HD testing site)	150 (vs 40)	35% (vs 20%)	1.15 (0.62, 2.13)	-

High-risk non-MSM sex defined as: not MSM and 1 or more of: female partner of MSM, sexual partner of IDU, transactional sex, sex while intoxicated, multiple sexual partners in past year

[Associations with recent HIV at time of diagnosis]



[Figure. Linkage to HIV care and viral suppression]

Conclusions: There was a strong association between diagnosis during recent infection and history of MSM, IDU and high-risk non-MSM sex, possibly reflecting high ongoing local HIV transmission in these groups and poor uptake of HIV testing in those without these risk factors. Our results also suggest that diagnosis during recent infection is not a barrier to linkage or viral suppression.

TUPEC0831

Leveraging individual and ego-network predictors of HIV incidence among Nigerian Men who have sex with men to guide network-level interventions

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Background: In Nigeria, the rate of new HIV infections in the population are declining but appears to be increasing among men who have sex with men (MSM). To guide the development of comprehensive HIV prevention and treatment interventions needed to reverse these trends, this study characterizes the individual and network-level determinants of new HIV infections among MSM in Nigeria.

Methods: TRUST/RV368 recruited MSM into HIV care and treatment in Abuja and Lagos, Nigeria. At baseline and every quarterly visit, participants (ego) completed a structured instrument studying characteristics of the individual and five most recent sexual partners (alters) along with biological specimens for HIV and sexually transmitted infections (STIs). From March/2013-Oct/2016, 365 MSM who tested negative for HIV at baseline and returned for at least one additional HIV test were included in the analysis. Crude hazard ratios (HR) were estimated for predictors of HIV incidence using Cox proportional hazard models.

Results: Fifty-one individuals seroconverted during follow-up and the overall incidence was 18.8 infections per 100 person-years [PY] (95% confidence interval [CI], 14.1-24.5/100 PY. Those who were younger, unemployed, engaged in receptive intercourse, engaged in recent condomless sex, diagnosed with rectal gonorrhea at the preceding visit were significantly correlated with incident HIV infections. Significant network-level level determinants of incident HIV infections included having older sexual partners by five years, more educated partners, and partners with a higher socio-economic status. (Table 1).

Conclusions: The high HIV incidence rate observed in our study confirms that evidence-based and appropriately scaled HIV prevention and treatment interventions are a public health priority for MSM in Nigeria. While the focus of most of these interventions to date has been addressing individual-level risks, these data reinforce the importance of addressing network-level risks when considering the implementation of interventions especially for young MSM in Nigeria.

Predictor	Category vs. Reference	Unadjusted HR (95% CI)
Age (years)	16-23 vs. 24+	3.5 (1.8-6.7)
Employment status	Unemployed vs. Employed	3.4 (1.9-6.4)
Sexual Positioning	Receptive vs. Insertive	16.0 (4.7-54.5)
Condomless sex at last anal sex	Yes vs. No	1.8 (1.0-3.3)
Rectal gonorrhea preceding visit	Pos vs. Neg	4.2 (2.3-7.4)
Any % of alters 5+ years older than ego	>1% vs. 0%	6.9 (2.8-17.5)
Any % of alters with higher education	>1% vs. 0%	2.5 (1.4-4.6)
Percent of alters with higher socio-economic status	68-100% vs. 0-33%	4.4 (2.2-8.9)
Abbreviations: vs., versus; HR, hazard ratio; CI, confidence intervals		

[Predictors of HIV Incidence among MSM in Nigeria]

TUPEC0832

Estimation of HIV incidence and the profile of incident cases in Zimbabwe Population-Based Impact Assessment (ZIMPHIA) 2015-2016

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Background: Zimbabwe estimated a decline in HIV incidence from 4.6% (1993) to 0.88% (2015) using Spectrum model. The country has made significant investments in HIV prevention, care and treatment in the last decade. Zimbabwe conducted a Population-Based HIV Impact Assessment (PHIA) that measured HIV incidence in 2015/16.
Methods: A total 22,496 adults (15-645 years) consented to both a face-face questionnaire and biomarker testing in the nationally-representative household survey which had 83.9% response. Home-based HIV testing was performed using the national serial rapid test algorithm of Determineä, First Responseä and Stat-Pak (tie-breaker). HIV positives were confirmed in a satellite laboratory using Geenius HIV-1/2ä, viral load using Roche Taqman and Biomerieux nuclisens and recency using Limiting Antigen Avidityä (LAg). Recent was confirmed by an algorithm of LAg normalized optical density < 1.5 + viral load >1000 copies. We calculated weighted annual HIV incidence.
Results: Overall, 36 of 3,503-(1.03%) HIV positive cases were confirmed as recent infection. Among these, 11 were male and 25 female. The weighted annual incidence was 0.45% (95% CI 0.28 -0.62) and 0.48% (0.29-0.66) for adults 15-64years and 15-49years respectively. The observed incidence (0.48%) is nearly half that reported by Spectrum (0.88%) The point-estimate for incidence was more than twice as high among women (0.67% [0.37-0.97]) compared to men (0.28% [0.06-0.50]) in the 15-49 year age-group. Young men (15-24 years) had lowest incidence, 0.13% (0.00-0.34), while it was three-times high (0.54% [0.14 - 0.94]) in women of similar age-group. By residence, overall incidence for adults (15-49 years) was higher in urban, 0.63% (0.25-1.01) compared to 0.38% (0.18-0.59) in rural setting. The majority of respondents (15-49 years) with incident infections (26/31, 83.9%) had previously been tested. The point-estimate among those ever tested was 0.56% (0.32 -0.80) compared to 0.25% (0.00 -0.52) for participants without prior HIV testing.
Conclusions: HIV incidence remains high among women especially in young women. The high incidence in urban setting may be a signal for increase in high risk behaviours and emergence of sub-epidemics. High incidence among previously tested cases suggest the need to strengthen prevention messaging. Additional exploration, focused interventions should be prioritized.

TUPEC0833

Estimated cumulative HIV incidence rate among men who have sex with men (MSM) in Georgia: study results from repeated bio-behavioral surveys between 2010-2015

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Background: Georgia is among the countries with rapidly increasing HIV epidemics among men who have sex with men (MSM). While preventive interventions for this key population are in place, HIV transmission from homosexual contacts is increasing among all new cases and HIV prevalence among MSM reached 25.1% in 2015. This study evaluates incidence trend among MSM in Tbilisi, Georgia.
Methods: To estimate the cumulative incidence rate we used the three rounds of Bio-behavioural surveillance surveys (BBSS) data with respondent driven sampling, conducted in 2010 (N=278), 2012 (N=218) and 2015 (N=300) among MSM in Tbilisi, Georgia. Estimates of annual cumulative incidence rate were derived as follows: the prevalence of HIV infection/person-year at risk for HIV (summing the number of days since the first anal intercourse (as the proxy of HIV negativity and start of exposure risk) and the first HIV test result). The earliest age of anal intercourse was assumed 15 years old. HIV cumulative incidence rates (per 100 persons) along with their 95% confidence intervals (CI) were calculated using Kaplan Meier method and compared among the three respective BBSS rounds by log-rank test.
Results: Cumulative incidence rate per 100 persons increased significantly from 0.59 (0.38-0.93) to 1.26 (0.87-1.83), and 2.06 (1.67-2.55) in 2010, 2012 and 2015, respectively. As for the incidence rate ratio (IRR), analyses showed that the cumulative incidence rate was 2.12 (1.18-3.79) times higher in 2012 and 3.46 (2.10-5.69) times higher in 2015 compared to 2010.

	Estimated incidence rate per 100 persons	95% CI for IR	Estimated Incidence rate ratio	95% CI for IRR	P-value for comparing the IRR
Survey 2010	0.59	0.38-0.93	1	-	-
Survey 2012	1.26	0.87-1.83	2.12	1.18-3.79	0.011
Survey 20105	2.06	1.67-2.55	3.46	2.10-5.69	<0.001
Overall	-	-	1.25	1.16-1.36	<0.001

[Incidence rates and rate ratios of HIV among MSM]

Conclusions: Given rapidly increasing HIV infection among MSM, having estimated HIV incidence along with HIV prevalence data is more useful as it reveals latest and more specific picture of HIV epidemics for effective planning of preventive interventions.

TUPEC0834

A clinical utility risk-benefit analysis for HIV self-testing

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Background: Interest in HIV self-testing (HIVST) is increasing as countries pursue the UN "90-90-90" targets and consider adopting WHO's recommendation to offer HIVST. While many self-testers can achieve results similar to trained testers, performance can vary based on context and approach. Among other important considerations is the minimum performance by self-testers at which public health benefit is achieved; defined here as "clinical utility".
Methods: To assess HIVST's clinical utility and weigh performance-related risks and benefits: sensitivity (65-99.8%), specificity (65-100%), HIV prevalence (0.01-15%), linkage to care (50-85%) and linkage to prevention (0-35%) were considered. Different scenarios characterized by varying levels of the factors listed above were simulated. A net benefit score was derived from Total Benefit (true reactive linked to care; true nonreactive linked to prevention) minus Total Risk (false reactive; false nonreactive). False nonreactives and true reactives linked to care were weighted based on expert consultation. The proportion of scenarios with positive net benefit was calculated. Sub-analysis of high (5-10%) and low (0.1-1%) prevalence scenarios, high (20-30%) and low (0-10%) linkage to prevention; and high (70-80%) and low (50-60%) linkage to care was conducted.
Results: 61% of scenarios with ≥70% sensitivity and ≥90% specificity yielded greater benefit than risk. In high prevalence scenarios, positive net benefit was observed at ≥80% specificity and ≥70% sensitivity. For low prevalence scenarios, net benefit marginally increased when sensitivity increased from 70% to 90%. Linkage to prevention drove net benefit; when high, benefit was achieved at ≥80% specificity but when low ≥90% specificity was needed. Linkage to care had modest impact except in very high prevalence settings, e.g. net benefit in all scenarios was not observed among female sex workers in Johannesburg until linkage to care was ≥50%.
Conclusions: In all scenarios, there were some false non-reactive and false reactive results; but in most, risks were exceeded by the benefits of diagnosis and linkage to prevention and treatment. While HIVST's clinical utility is greatest when performance is greatest, this analysis suggests ≥90% specificity and ≥70% sensitivity is needed to achieve a net benefit. For very high prevalence settings with very low linkage, ≥90% sensitivity and specificity would be needed.

TUPEC0835

Cost-effectiveness of nurse-driven HIV screening targeting key populations in metropolitan Paris emergency departments in the ANRS DICI-VIH cluster-randomized two-period crossover trial

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Background: In the ANRS DICI-VIH trial, nurse-driven targeted HIV screening combined with physician-directed diagnostic testing (NTS strategy) substantially increased new HIV diagnoses compared to diagnostic testing alone (DT strategy) in Emergency Departments (ED) of metropolitan Paris, one of the most affected regions in France. A cost-effectiveness evaluation of the NTS strategy was conducted and is reported here.
Methods: A prospective economic evaluation, adopting the hospital perspective, estimated the additional costs of the NTS strategy per additional HIV diagnosis among participants (18-64 year old patients presenting to the ED for reasons other than HIV exposure) compared to the DT strategy. The costs of nurse-driven targeted screening by rapid test (RT) were estimated using a bottom-up micro-costing approach and included testing equipment, procedure duration and staff involved. The total costs of both strategies were estimated for all participants. The cost difference was directly calculated. A scenario analysis explored the impact of various costs, including RT price and staff time required for positive RT result disclosure (physician vs. nurse).
Results: During the DICI-VIH trial, a total of 74,161 (NTS strategy) and 74,166 participants (DT strategy) were included in 8 EDs of metropolitan Paris. The proportion of new HIV diagnoses was higher in the NTS strategy than in the DT strategy (3.0 per 10,000 vs. 0.8 per 10,000, relative risk 3.7, 95%CI 1.4-9.8). The total costs were estimated as 23,011€ with the NTS strategy vs. 1,954€ with the DT strategy, corresponding to €0.31 and €0.03 per participant, respectively. The nurse time costs represented 60% of the costs in the NTS strategy. The Incremental Cost-Effectiveness Ratio (ICER) for the NTS strategy was €1,298 per additional new HIV diagnosis.
The scenario analysis yielded an ICER ranging from €1,251 to €1,947, which compares favorably to the 20,400€ average cost per new diagnosis estimated in 2015 in voluntary testing centers in the region.
Conclusions: Our results support the cost-effectiveness of a targeted screening strategy for HIV in areas with concentrated epidemics.

TUPEC0836

Migration and HIV: a double penalty? Assessing the respective impacts of migration and HIV diagnosis on sub-Saharan immigrants' lives in Paris greater area. Results from the ANRS parcours survey

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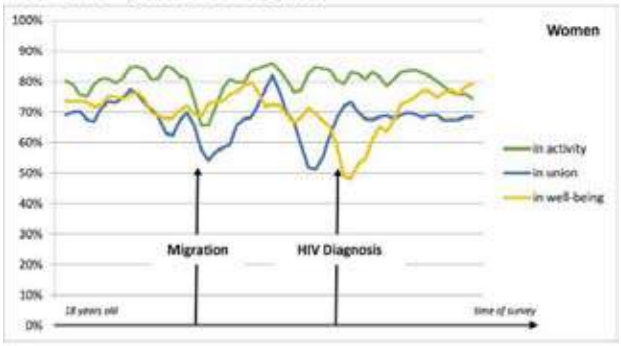
Background: Immigrants account for 35% of HIV diagnoses in the European Union (ECDC 2014). Yet little is known about the impact of such a lifelong infection diagnosis on live-courses that are already marked by migration. In this study, we assess the respective impact of migration and HIV diagnosis on the loss of activity, conjugal break up, degradation of perceived well-being among Sub-Saharan migrants living in Ile-de-France.
Methods: We use the ANRS PARCOURS retrospective life-event survey (2012-2013) which collected 926 life histories of randomly-sampled Sub-Saharan immigrants living with HIV in 24 health structures in in Ile-de-France. We use relative-time graphs to describe the levels of activity, union and perceived well-being across time. We model year by year since 18 years of age until data collection the probabilities to lose one's activity, to experience a conjugal break up and the probability of degradation of perceived well-being. We estimate the impact of migration and of HIV diagnosis on these probabilities, thanks to discrete-time logistic regressions.
Results: Our results show that the probability to lose one's activity is higher at the moment of migration than before (aOR= 8.0 [3.6-18.1] for men and 8.7 [5.1-15.0] for women), as well as the probability to experience a conjugal break up (aOR=3.7 [1.8-7.5] for men and 3.0 [1.7-5.4] for women). These probabilities do not vary at time of HIV diagnosis. However, the probability of experiencing a degradation of perceived well-being increases both at time of migration and at time of HIV diagnosis (aOR=11.3 [4.6-27.6] for men and 5.8 [2.8-11.9] for women).

Proportion of Sub-Saharan women in activity, union and perceived well-being in relation to migration and HIV diagnosis



Note: The time spent in each period (between 18 years old and migration, migration to diagnosis and diagnosis until time of survey) was scaled up for all individuals.

[Graph 1]

Conclusions: When HIV diagnosis occurs, it reinforces the negative impact of migration. Migrants living with HIV in France then face a double penalty. These results plead for better social support for recently diagnosed Sub-Saharan immigrants in France.

TUPEC0837

Advanced HIV disease and severe immunosuppression at diagnosis as Mozambique and Swaziland prepare for test and start

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Background: Early diagnosis of HIV is critical to preventing disease progression and reducing onward transmission of HIV.
Methods: We used data from two implementation science studies conducted in Mozambique and Swaziland to examine the magnitude and predictors of advanced HIV disease and severe immunosuppression at HIV diagnosis. Adults ≥18 years of age were enrolled following diagnosis in HIV testing and counseling clinics at 10 health facilities from 4/2013-6/2015 in Mozambique and 8/2013-11/2014 in Swaziland, and received same day point-of-care CD4 testing. Advanced disease was defined as CD4 count ≤350 cells/µl. Severe immunosuppression was defined as CD4 count ≤100 cells/µl. We estimated the relative risk (RR) of advanced HIV disease and severe immunosuppression in adjusted multilevel regression models.
Results: 2335 adults newly diagnosed with HIV (62.7% female) were included in the analysis. The median CD4 count at diagnosis was 314 cells/µl (IQR: 165-485) with significant differences by sex but not country (Table 1). More than half (56.4%) of the participants had CD4 ≤350 cells/µl, and 13.9% had CD4 ≤100 cells/µl, with differences observed by sex but not country. The adjusted risk of both outcomes was higher in men compared to women (advanced disease aRR=1.31, 95% CI: 1.10-1.56; severe immunosuppression aRR=1.53, 95% CI: 1.16-2.0), and those HIV tested because they felt ill (advanced disease aRR=1.31, 95% CI: 1.10-1.56; severe immunosuppression aRR=2.11, 95% CI: 1.36-2.29). Age 18-24 (vs. age 24-39) was associated with a significantly lower risk of both outcomes (advanced disease

aRR=0.71, 95% CI: 0.59-0.84; severe immunosuppression aRR=0.62, 95% CI: 0.40-0.95). No significant differences emerged when the analysis was stratified by country or sex.

Conclusions: More than 10 years into the global scale-up of HIV services, the majority of adults diagnosed with HIV in two high prevalence countries have advanced disease. Innovative strategies to identify people living with HIV earlier are urgently needed for individual and societal benefits.

	Total sample (N=2335)	Males (N=871)	Females (N=1464)	p-value	Mozambique (N=1235)	Swaziland (N=1100)	p-value
	N(%)	N(%)	N(%)		N(%)	N(%)	
CD4 count (Median, IQR)	314 (165-485)	253 (129-407)	354 (197-515)	<0.0001	318 (176-498)	311 (159-473)	0.10
CD4 count:							
CD4 ≤100	325 (13.92)	158 (18.14)	167 (11.40)	<0.0001	164 (13.28)	161 (14.64)	0.31
CD4 101-350	992 (42.48)	434 (49.83)	558 (39.28)		519 (42.02)	473 (43.00)	
CD4 351-500	476 (20.39)	136 (15.61)	340 (23.22)		247 (20.00)	229 (20.82)	
CD4>500	542 (23.21)	143 (16.41)	399 (27.26)		305 (24.70)	237 (21.55)	

[CD4 count distribution at HIV diagnosis]

TUPEC0838

Performance of 9 rapid diagnostic HIV tests on a wide panel of whole blood samples

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Background: Rapid diagnostic HIV tests (RDTs) are now used in and outside laboratories or as self-tests, to improve HIV diagnosis coverage. RDTs performances are classically tested on serum, and more rarely on whole blood, limiting interpretation on a "real life" use. Moreover, most of the RDTs tested only detect antibodies (3rd generation). We tested the performance of 9 RDTs, including two detecting p24 and antibodies (4th generation) on a large panel of fresh and reconstituted whole blood samples, corresponding to diverse clinical status and representative of the wide genetic diversity of HIV.

Methods: Seven 3rd generation RDTs - STAT-VIEW HIV 1/2 (Chembio diagnostic systems), EXACTO PRO TEST HIV (Biosynex), EZ-TRUST HIV 1 & 2 Rapid Screen Test (CS Innovation Ltd), Genie Fast HIV1/2 (Bio-Rad), HIVTOP (Biosynex), INSTI (bioLytical), VIKIA HIV 1/2 (bioMérieux) - and two 4th generation RDTs - BioTechMed HIV1/2 Rapid-4 (BioTechMed) and HIV Combo (Alere) - were tested. The specificity and sensitivity were evaluated on 200 negative and 300 positive samples. Among these latter, 100 corresponded to ART-naïve patients; 150 were representative of HIV diversity, including HIV-1/O and HIV-2; and 50 were collected during the primary HIV infection phase.

Results: HIV-1/M and HIV-2 samples were positive with all the RDTs, except for 6/13 HIV-2 samples not detected with BioTechMed assay. Only the HIV Combo and VIKIA HIV 1/2 detected all HIV-1/O samples. Among the 50 PHI samples, 27 to 37 were found positive using the 3rd generation tests; the two 4th generation tests, HIV BioTechMed HIV1/2 Rapid-4 and HIV Combo, detected 30 and 43 of the 50 samples, respectively. The specificity ranged from 98 to 100%.

Conclusions: Our method of reconstituted whole blood allowed us to evaluate RDTs close to real-life conditions, on a large panel of samples in terms of genetic diversity and clinical status. No difference was observed for diagnosis of HIV-1/M infections; nonetheless, divergent HIV-1/O samples remains of concern, with only 2 tests detecting them all. Use of 4th generation RDT can significantly increase the diagnosis of primary infection, but results are largely depending on the test used, the HIV BioTechMed Rapid-4 being worse than some 3rd generation RDTs.

TUPEC0839

Characteristics associated with HIV self-testing reported by internet-recruited MSM in the United States, eSTAMP baseline data, 2015

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Background: The introduction of OraQuick® In-home HIV Test (OQ) into the US market in 2012 renewed questions about the use, reach, and public health implications of HIV self-testing (HIVST) for men who have sex with men (MSM). Using baseline data from the Evaluation of HIV Self-testing among MSM Project (eSTAMP), we report on HIV home test (HHT) use and associated factors among MSM.

Methods: Between March 25 and August 4, 2015, MSM reporting HIV-negative or HIV-unknown status were recruited online into a 12-month randomized controlled trial of HIVST. Before randomization all participants completed an online survey. Using these data, we examined participant characteristics and calculated frequency and associations of past 12 months HIVST with selected sociodemographic characteristics. We present unadjusted relative risks (RR) and 95% confidence intervals (95% CI).

Results: Among 2,665 participants [32% 18-24 years; 58% white; 43% ≥college degree; 84% employed; 23% < $20K household income; 63% had anal sex with ≥2 male partners, past 3 months; 6% had condomless anal sex (CAS) with an HIV infected male partner, past 3 months] 59% tested for HIV in the past year, 17% tested ≥3 times in the past year, and 70% had heard of HHTs. Among 10% (259) who reported HIVST in the past year, 92% used OQ and 61% acquired HHTs from a pharmacy. Convenience and privacy were the most common reasons for HIVST, 61% and 52%, respectively. Significant associations with HIVST shown below.

Characteristics (referent is on the right side)	Proportion	RR (95% CI)	p-value
Age (years): 25-39 vs 18-24	0.10 vs 0.08	1.34 (1.01-1.78)	<0.05
Age (years): 40+ vs 18-24	0.12 vs 0.08	1.63 (1.16-2.28)	<0.01
Race/Ethnicity: Hispanic vs Non-Hispanic White	0.06 vs 0.11	0.58 (0.41-0.81)	<0.01
Education (College Graduate): Yes vs No	0.13 vs 0.07	1.79 (1.41-2.26)	<0.001
Employment: Employed vs Unemployed	0.11 vs 0.05	2.09 (1.34-3.27)	<0.01
Household income (US $): 40,000 - 74,999 vs <20,000	0.13 vs 0.06	2.21 (1.51-3.25)	<0.001
Household income (US $): ≥75,000 vs <20,000	0.16 vs 0.06	2.79 (1.90-4.11)	<0.001
Anal sex with ≥2 male sex partners, past 3 months: Yes vs No	0.11 vs 0.08	1.40 (1.09-1.81)	<0.01
CAS with HIV infected male partner, past 3 months: Yes vs No	0.15 vs 0.09	1.53 (1.02-2.30)	<0.05

[Table 1]

Conclusions: Awareness of HHTs was high, but few MSM reported HIVST in the past year. MSM who engage in HIV sexual risk behaviors may have been earlier HIVST adopters. HIVST was positively associated with higher socioeconomic status possibly due to test cost in the US (approximately $40). Providing free or subsidized tests may be necessary to increase HIVST among MSM in the US, especially among lower income populations.

TUPEC0840

Factors associated with late HIV diagnosis, based on data from 7 years of national surveillance

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Background: Late HIV diagnosis is a major concern, as it compromises both early treatment of infected persons and prevention of HIV transmission. The aim of this analysis was to identify factors associated with late diagnosis among all HIV infections diagnosed in France between 2009 and 2015.

Methods: We used data from the mandatory HIV surveillance system in France, adjusted for under-reporting, reporting delays and missing values. Late HIV diagnoses were defined as diagnoses with a CD4 count below 350 cells/mm^3 excluding HIV acute illness, or with an AIDS defining disease regardless of the CD4 count. Correlates of late diagnosis were assessed through Poisson regression.

Results: Among 43,416 new HIV diagnoses in France from 2009 to 2015, 45.2% were lately diagnosed. This proportion seemed to decrease from 46.6% in 2009, to 42.5% in 2015.

In multivariate analysis, year of diagnosis was not associated to late diagnosis. Male gender, age, transmission through heterosexual sex or through sharing of drug injection equipment, residence outside the Paris area or in the French overseas, being born abroad, occupational category as business owners or merchants, circumstances of HIV test (tested because of HIV related signs, on the occasion of another illness or because of belonging to an exposed group, test performed at physician's request), and having never been tested for HIV before the diagnosis, were positively and significantly associated to late diagnosis.
Conclusions: Late HIV diagnosis was related both to the circumstances of the test and to some epidemiological characteristics, and has not decreased between 2009 and 2015 once those factors are taken into account.
These results highlight the importance of encouraging people to ask for a test rapidly after having been exposed to HIV, and health professionals to offer a test to people exposed or never tested, especially in groups identified as more likely to be lately diagnosed.

TUPEC0841

Undiagnosed HIV is higher among urban residents, young adults and men: first findings from Malawi Population-based HIV Impact Assessment (MPHIA)

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Background: Malawi has made substantial progress towards the 90/90/90 goals. However, further progress in diagnosing people living with HIV (PLHIV), the first 90, is needed to control the HIV epidemic. Providing testing to undiagnosed PLHIV, particularly in areas with high HIV prevalence, will be critical. Here we identify which PLHIV are at greatest risk of being undiagnosed.
Methods: From November 2015-August 2016, MPHIA recruited a nationally representative sample of 17,127 adults age 15-64. Participants completed an interview and received home-based HIV testing and counseling per national guidelines. We defined participants that tested HIV positive as previously undiagnosed if they reported 1) never previously having an HIV test; or 2) testing negative on their most recent test. We estimated the relative risk of previously undiagnosed HIV by area of residence, age and sex using a multivariate log-binomial regression. All analyses accounted for complex survey design.
Results: MPHIA identified 2,214 HIV-positive adults among whom 578 (26%) were undiagnosed, 1,054 (48%) live in urban areas, 709 (32%) were male, and median age was 37 [Interquartile Range: 30-45]. HIV prevalence was significantly higher in urban areas (14.3%, 95% CI: 13.2-15.4%) vs rural areas (9.7%, 95% CI: 8.9-10.4%).
Previously undiagnosed HIV was higher in urban (30.6%, 95% CI: 27.6-33.6%) vs rural areas (25.9%, 95% CI: 22.9%-28.9%), and significantly higher in men (33.3%, 95% CI: 28.8-37.7%) vs women (23.6%, 95% CI: 21.2-25.9%) and younger (15-24 years: 46.7%, 95% CI: 38.0-55.3%) (25-34 years: 32.1, 95% CI: 27.4-36.9%) vs older age groups (35-64: 21.7, 95% CI: 18.9-24.6%). In multivariate analysis, living in an urban area (RR_{urban}=1.18, 95% CI: 1.01-1.37), being male (RR_{male}=1.56, 95% CI: 1.34-1.82) and being 15-24 or 25-34 vs 35-64 years old (RR_{15-24}=2.30, 95% CI: 1.86-2.85; RR_{25-34} =1.58, 95% CI: 1.29-1.94, respectively) were all associated with having previously undiagnosed HIV.
Conclusions: Young, male and urban PLHIV were at increased risk of having undiagnosed HIV in Malawi. These disparities threaten HIV epidemic control as urban areas have higher HIV prevalence and increasing population due to urbanization. To achieve epidemic control, Malawi's HIV programs should focus on diagnosing HIV in urban areas, particularly among young adults and men.

TUPEC0842

Is OraQuick® HIV-self-testing valid among intended users? Analysis from a clinical performance study in Lusaka, Zambia

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Background: HIVST has been proposed to increase the uptake of HIV testing and enable more linkage to treatment and prevention services thereby preventing HIV transmission. The aim of this study was to assess the clinical performance of OraQuick® self-testing (OFT-ST) among intended users in Zambia.
Methods: Consenting participants ≥16 years were randomly selected from urban and rural communities in Lusaka, Zambia. Consecutive attendees for HIV counselling and testing in the urban health facility were invited to participate. Researchers demonstrated use of OFT and provided manufacturer's instructions for use. Participants conducted the test and recorded their results by themselves. Researchers repeated the OFT and re-read the participant's test strip. Following the Zambian national algorithm a nurse blinded to OFT results performed a series of rapid HIV diagnostic tests (RDTs). A blood sample was tested for HIV following a reference standard algorithm consisting of fourth generation EIA tests. Demographic data and information of prior HIV testing was collected. The study is ongoing and we report data from 22/06/16-10/11/16.
Results: A total of 1,104 participants were recruited (Table 1).

	Rural Community	Urban Community	Urban Health Facility	Total
Overall total	460	291	353	1104
Female	216 (47%)	222 (76.3%)	189 (53.5%)	627 (56.8%)
Median Age (IQR)	31 (22,43)	26 (21,33)	25 (22,32)	27 (22,37)
Previously tested for HIV	369 (80.2%)	243 (83.5%)	316 (89.5%)	928 (84.1%)
Self-reported HIV+ (% of previously tested)	10 (2.8%)	4 (1.7%)	9 (2.5%)	22 (2.4%)

[Table 1. Participant sociodemographic characterist]

There was good agreement (kappa=0.96) between participant and researcher conducted OFT. The sensitivity of OFT-ST was 95.5% (95%CI 89.7, 98.5) when compared to RDT, and fell to 87.5% (95%CI 80.2, 92.8) when compared to laboratory testing. Specificity was 99.3% (95%CI 98.5, 99.7) compared with laboratory reference. Self-testers from the rural community achieved a lower sensitivity (74.3%, 95%CI 56.7, 87.5) compared to the urban community (92.3%, 95%CI 74.9, 99.1).
Conclusions: OFT-ST with prior demonstration provides reasonable specificity and sensitivity when compared to the Zambian rapid test algorithm. When compared to the laboratory reference standard the sensitivity decreases, though the specificity remains constant. Although HIVST is a screening test, its ability to increase HIV testing must be weighed against the lower sensitivity of test results.

TUPEC0843

Reducing the HIV undiagnosed fraction: systematic review on testing for HIV in prison settings

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Background: UNAIDS and the WHO have set the ambitious target of 90% of people living with HIV diagnosed. This depends primarily on effectiveness of HIV-testing interventions in targeting high-risk groups and boosting early diagnosis. Across the EU/EEA HIV prevalence in prison populations is much higher than in the community, therefore prison settings offer a key opportunity for active case finding (ACF). The objective was to systematically review data on HIV-ACF in EU/EEA correctional facilities.
Methods: A systematic review of literature on Pubmed and Embase (from 1990 onwards) and Cochrane Library (from 1980 onwards) was performed. This search was complemented with conference abstracts and unpublished research reports, and discussed during expert meetings.

Results: Sixteen primary studies and one systematic review (including eleven relevant studies) were included in the review. Three primary studies were from the EU/EEA and the others from the USA. Within-study comparisons were hardly performed. When comparing results across studies, no trends were seen regarding uptake, positivity rates, effectiveness or treatment initiation. Overall, opt-in testing at entry was most frequently investigated in the peer-reviewed literature, resulting in an uptake rate ranging from 6%-97%, HIV positivity rate of 0%-5.4%, and identification of 0%-1.8% new HIV cases.
For opt-out testing at entry these ranges were 22%-98%, 0%-2% and 0.1%-0.8%, respectively. However, due to heterogeneity of the studies regarding timing, offer, promoting and testing methods,
no conclusions can be drawn based on comparisons across studies. In conference abstracts, using different ACF methods, the uptake and positivity rates were 56.3-91.5% and 1.0-26.6%, respectively, and 35.2%-78.0% initiated treatment after diagnosis.
Conclusions: The evidence on HIV-testing in correctional facilities is limited and variable. Positivity rates among tested inmates indicate cases are continuously being identified. ACF for HIV in prison settings could contribute to prevent onward transmission and lower the undiagnosed fraction in the EU/EEA. Our study suggests to actively offer provider-initiated HIV-testing at entrance to all people in prison. Furthermore, it is advisable to consider offering provider-initiated HIV-testing at regular intervals during prison stay for high-risk subgroups and in case of an exposure incident and to promote client-initiated HIV-testing throughout prison stay.

TUPEC0844

How acceptable and feasible is HIV self-testing among key populations in Vietnam? Preliminary results from an intervention evaluation study

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Background: Annual HIV testing uptake among key populations is low (~30%) in Vietnam. Barriers include concerns regarding confidentiality of test result, wait time, and travel/opportunity costs. MoH leaders recognized the potential of HIV self-testing (HIVST) to accelerate 90-90-90 case detection goals, and endorsed a pilot to assess HIVST acceptability, feasibility and service linkages to inform HIV testing guidelines and scale-up.
Methods: Fourteen KP-led community-based organizations (CBOs) in Saigon and Hanoi that serve men who have sex with men (MSM), transgender women (TGW), people who inject drugs (PWID), their sex partners (PWID-SP), and/or female sex workers (FSW) were trained to offer assisted and unassisted HIVST. Clients were offered a choice of a blood-based (Determine_HIV-1/2_Antibody) or oral fluid (OraQuick_ADVANCE_Rapid_**HIV**-1/2_Antibody) assay. Vietnamese language test inserts, pamphlets and tutorial videos were provided to clients. A post-test intervention evaluation included 552 individuals out of 1,994 that HIV self-tested from June-December, 2016. Participants were recruited at randomly chosen service days and completed a computer-assisted/self-administered survey.
Results: MSM represented the majority of HIV self-testers (76.6%), then PWID (12.3%), PWID-SP (8.2%) and FSW (2.9%). The most common reasons for selecting HIVST were: being the first person to know result (59.1%), confidentiality (55.4%), and rapid result (54.2%). 41.5% of HIV self-testers had tested for HIV before. MSM were more likely to have tested previously (46.8%), compared to PWID (25%), PWID-SP (22.7%) and FSW (12.5%), representing a statistically significant difference ($p < 0.05$). 92.8% of those using Determine (n=296), and 85.4% using OraQuick (n=199) shared their test results with the CBO provider. HIV test result concordance between an observer and self-tester were high (99%) for both tests. However, 63.6% reported difficulty using Determine and 8.1% OraQuick. 8.1% of those that revealed their test results tested reactive (compared to 0.9% in public testing sites), 91% received confirmation testing, and 97.7% of those confirmed were enrolled in ART.
Conclusions: HIVST reached a majority of new HIV testers, with a high HIV yield compared to conventional HIV testing sites (0.9%), and a strong HIV-testing-to-ART-enrollment cascade. HIV self-testers generated accurate results despite challenges. Recommend integrating HIVST into national HIV testing guidelines, and increasing targeted access to HIVST.

TUPEC0845

Perceptions of HIV self-testing among a population of self-testing naïve female sex workers in Kampala, Uganda

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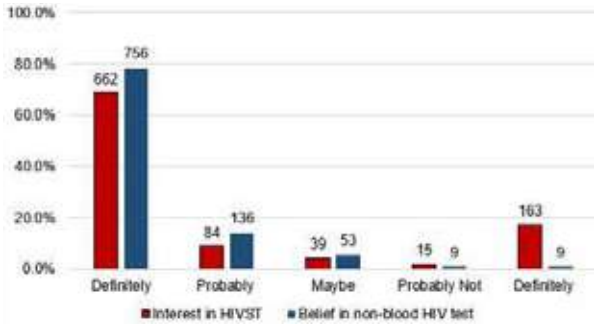
Background: Oral HIV self-testing (HIVST) has the potential to complement traditional HIV testing and counseling programs and reach individuals who are not currently accessing health services. Female sex workers (FSW) often have difficulty accessing health services as a result of stigma and working hours. Majority of sub-Saharan African countries have no policies related to HIVST; a few even have policies specifying it as illegal (i.e. Uganda). Here we measure interest in oral HIVST and belief in non-blood based testing among FSW in Kampala, Uganda.
Methods: In 2016, 963 FSW participated in a quantitative questionnaire. Eligible participants were 18 years or older, reported the exchange of sex for money or goods in the past month, and were perceived to be HIV uninfected. All participants were asked if they had ever heard of HIVST, if they would ever consider using a self-test kit to test for HIV, and if they would believe the results of a self-test kits that was not blood based. The percentage of participants that reported the various response categories was calculated and reported.
Results: Among 963 study participants, median age was 28 years (IQR: 24-32 years) and literacy was 85.7% (N=882). Only 15.4% of all participants (N=148) had ever heard of HIVST and reported interest in HIVST was high; 662 participants (68.7%) reported a definite interest, while only 163 participants (16.9%) reported that they would definitely not be interested. Majority of study participants (N=756, 78.5%) said they would definitely believe the results of a HIV test kit that did not draw blood, only 9 participants (0.9%) said they definitely would not, Figure 1.



[Figure 1. Reported interest in HIV self-testing (red) and belief in a non-blood based HIV test (blue) among 963 FSW study participants]

Conclusions: Interest in HIVST among a self-testing naïve population was high, as was reported belief in a non-blood based self-testing kit. This indicates a potential demand for self-testing and need for government HIVST policies.

TUPEC0846

An assessment of oral HIV self-testing process accuracy and results interpretation among female sex worker peer educators in Kampala, Uganda

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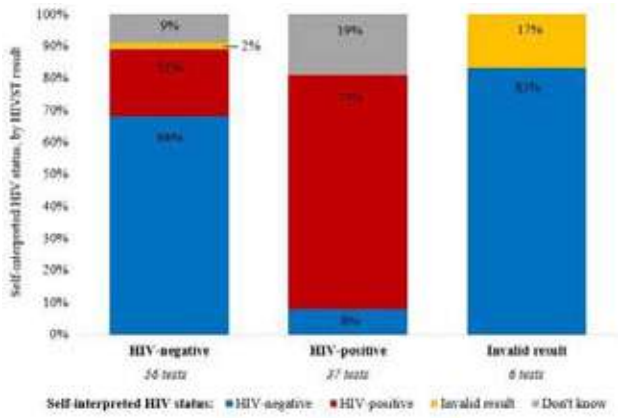
Background: Oral HIV self-testing (HIVST) may be an attractive alternative to clinic-based testing, particularly for stigmatized and inaccessible populations. Available oral HIV self-test kits (OraQuick ADVANCE Rapid HIV-1/2 Antibody Test) have high sensitivity and specificity when used precisely as intended (93.6% and 99.9% respectively), but test performance may be worse if the sequence of testing steps are not correctly executed or results are misinterpreted. We evaluate whether female sex workers (FSW) in Kampala, Uganda can correctly use HIVST

kits and interpret test results under potential real-world conditions where no pre-test training is available.
Methods: 104 FSW performed an oral HIVST without supervision under observation by a trained research assistant. Participants were given no pre-test training on kit use and had only the kit's standard pictorial and written instructions to guide them. Study participants were asked to interpret a randomly drawn, anonymous, used oral HIV self-test kit. Self-read sensitivity and specificity were calculated in reference to the trained research assistants' interpretation of the randomly drawn tests and adjusted for the kit's sensitivity and specificity when used and interpreted as intended.
Results: The majority of participants (61%) completed the necessary steps for an interpretable test result, but most (96%) struggled with the testing process in some way. Incorrect interpretation of test results was common: 23% of HIV-negative tests were interpreted as HIV-positive while 8% of HIV-positive tests were interpreted as HIV-negative, Figure 1. The self-interpreted real-world sensitivity and specificity were 67.9% (95% CI: 54.5-81.4%) and 67.7% (95% CI: 56.1-79.6%) respectively.



[Figure 1. Self-interpretation of the oral HIV self-test kit results by "true" result, determined from pictorial research assistant drawings of the used oral HIV self-test kits]

Conclusions: In the absence of pre-test training, participants struggle with the oral HIV self-testing process and self-interpreted sensitivity and specificity is lower than expected. Training on HIVST kit use or improved self-test kit instructions may be necessary to avoid false positive and false negative test results.

TUPEC0847

Closing the HIV testing gap: facility-based integration of HIV self-testing, a way to improve testing coverage, yield and efficiency of client-initiated HIV testing services in Zimbabwe

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Background: HIV self-testing (HIVST) is a new approach to HIV testing that could help identify HIV-positive individuals reluctant to test with a provider. HIVST used as a triage test with provider initiated (PITC) and client initiated HIV testing services (CITC) could relieve human resource challenges with HIV testing services, increase efficiency, reduce costs and increase HIV testing coverage.
Methods: HIVST was introduced at 4 CITC centres in 4 urban areas in Zimbabwe as an alternative option to provider delivered testing (PDT). Participants opting for HIVST were shown a short instructional video and provided the option to conduct the self-test in a private space or to conduct the self-test off site. One counselor was available to assist and facilitate linkage for self-testers needing on-site confirmative testing and anti-retroviral-therapy (ART). Demographics were captured electronically. Self-testers were asked to return used kits to locked drop-boxes and complete a short questionnaire on testing history and interpretation of HIVST results. Used kits were read by a professional and reactive results were used to estimate positivity rates. Costing, cost-effectiveness, and qualitative research to assess provider/client perceptions are underway.
Results: Between September-December 2016 a total of 6636 HIVST kits were distributed in 4 CITC clinics. HIVST was chosen over parallel PDT services by 31.2% of clients presenting at the site (6636/21260, 27.1% of females, 31.4% of men). 98.4% of self-test accepters opted to test on-site; all of whom returned their used test. 4.3% of self-testers had reactive tests (5.8% of women, 3.1% of men) as compared to 12.8% (14.2% of women, 7.2% of men) with PDT. 23% were first-time-testers. Among those who had tested before, 3% tested positive previously, none reported being on ART. All self-testers with reactive result linked to confirmative testing, 95.5% tested HIV-positive and initiated ART.
Conclusions: Uptake of HIVST as alternative testing option to PDT is high at CITC clinics. Used as triage test, HIVST might increase efficiency, freeing counsellor time previously spent on testing HIV-negative individuals to focus on those with reactive results in need of further testing and ART. HIVST will be expanded to improve PITC at public sector health facilities.

TUPEC0848

Prevalence and correlates of HIV diagnosis in domiciliary testing of transgender women in Argentina

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Background: Transgender women (TGW) are at the highest risk of HIV and often suffer discrimination in healthcare settings. The objective of this study was to explore if a proactive provider-initiated testing strategy, visiting TGW at home and other sites could improve testing rates in this population. Correlation between two different rapid tests (HIV Determine™ and HIV combo Determine™) and 4th generation ELISA (HIV DUO, BioMérieux) was also explored.
Methods: From November 2015 to December 2016, a team of infectious diseases physicians, psychologists, peer counselors and laboratory technicians performed testing in rooming-houses and other venues were TGW congregate in 4 cities in Argentina. Self-identified TGW, ≥14 years old, with unknown HIV status or previous negative test (>3 months), were included. After obtaining informed consent, participants completed social and behavioral questionnaires. Two rapid tests were used and compared with 4th generation ELISA. Using bivariable and multivariate logistic regression, we assessed factors associated with positive results.
Results: A total of 180 TGW were tested with a median age of 29 (IQR: 24-38). HIV prevalence was 24%. Most of them had a history of sex-work (86.2%) and 10.2% were foreign born. No acute infections were detected and both rapid tests and ELISA showed a correlation of 100%. A bivariable logistic regression showed that factors associated with HIV positive results were: being foreign born (OR=0.99, 95% CI:0.96-1.03), current sex-work (OR=2.16, 95% CI:1.05-4.45), previous STIs (OR=2.16, 95% CI:1.05-4.41) and not being tested before (OR=4.58, 95% CI:1.98-10.55). In multivariate analysis (Table), all factors remain with a positive correlate except foreign born. Among positive cases median CD4 was 432 (IQR:222-662).

Multivariable logistic regression of factors associated with HIV positive result in TGW

Variable	Adjusted Odds Ratio (AOR)	95% Confidence Interval (CI)	p - value
Foreign born (yes vs. no)	2.41	(0.62- 9.37)	0.202
Current sex-work (yes vs. no)	3.02	(1.16- 7.89)	0.024
Not tested before (yes vs. no)	4.79	(1.77- 12.94)	0.002
Previous STIs (yes vs. no)	3.71	(1.43- 9.59)	0.007

[Table]

Conclusions: TGW had a high prevalence of HIV. Current sex-work, previous STIs and lacking previous HIV test correlated with positive results, indicating efforts should focused on TGW sex workers. Domiciliary testing is a successful approach for this hard-to reach population and, as the quite low CD4 counts shows, a timely linkage to healthcare.

TUPEC0849

Performance evaluation of Asante™ Rapid Recency Assay for HIV diagnosis and detection of recent infection: potential for surveillance and prevention

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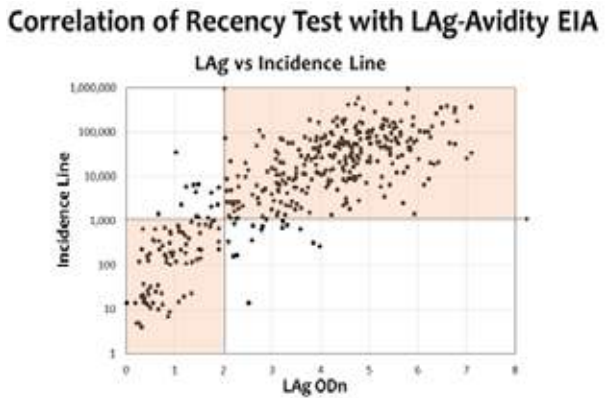
Background: Detection of recent infection is critical for incidence estimates from surveys and can also help in targeted prevention. We previously described development of a rapid test that can diagnose HIV infection and detect recency of infection in one device. This technology was successfully transferred to a commercial partner as Asante™ Rapid Recency Assay developed by Sedia BioSciences (Portland, OR). We evaluated performance of this assay in laboratory using a well-characterized panel of specimens.
Methods: Specimen panel consisted of 1500 sera or plasma from 580 HIV positive (570 HIV-1, 10 HIV-2), and 920 seronegative individuals representing subtypes A, B, C, D, and AE from multiple geographic areas. Reference data were generated using Bio-Rad HIV-1-2-O EIA + Western blot algorithm with further serotyping done using Multispot HIV-1/2 assay. LAg-Avidity EIA was used to generate recency information. Asante™ assay was performed as recommended by the manufacturer and line intensities for diagnostic and incidence lines were read using a hand-held reader. Ability to diagnose HIV and detect recent infections were determined using a recommended reader cut-off values of 1000 for each and results were compared to reference results. Reproducibility of the assay was measured with multiple measurements.
Results: Asante™ rapid recency assay detected 575/580 HIV positive specimens correctly resulting in a sensitivity of 99.1% (95% CI 98.0-99.6) while specificity of Asante assay was 98.7% (908/920) (95% CI 97.7-99.3). There was high correlation (Spearman rank correlation r=0.785) between ODn of LAg-Avidity EIA and incidence line intensity of the Asante test for 570 HIV-1 specimens with cutoff of 1000 matching with LAg ODn of 2.0 (See Figure) corresponding to mean duration of recent infection of about 180 days. Recency assay classified 98 specimens as recent infections compared to 103 by LAg-Avidity EIA. The assay had high reproducibility with %CV of < 10% in the dynamic range.



[Performance evaluation of Asante]

Conclusions: Asante™ assay meets requirements of a diagnostic assay with sensitivity and specificity close to 99%, while identifying recent infections with a mean window period of about 6 months post-seroconversion. This point-of-care assay has implications for enhancing surveillance and targeted prevention in high incidence population.

TUPEC0850

Leveraging HIV-1 resistance patterns to guide the implementation of treatment programs for MSM living with HIV in Senegal: the HIV prevention 2.0 project

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Background: Senegal represents a country with significant successes in HIV response given early implementation of routine HIV testing and access to antiretroviral therapy(ART) for those living with HIV. However, HIV prevalence among men who have sex with men(MSM) remains elevated with estimates consistently over 20%. While universal access to ART is a core component of an effective HIV response for MSM, increasing drug resistance may compromise ART effectiveness. Here we describe the prevalence of primary HIV drug resistance among MSM living with HIV in Senegal.
Methods: MSM were enrolled in 3 sites using respondent-driven-sampling including a structured survey instrument and viral load(VL) testing with an Abbott m2000 or NucliSens EasyQ. Drug resistance was evaluated for all with HIV-1 VL≥1000 copies/ml and phylogenetic analyses were completed with Seaview 4.0 and recombination by Simplot version 3.5. Interpretation of drug resistance mutations (DRMs) was performed using HIVDB algorithms with statistical analyses performed using STATA 13.
Results: Of 730 MSMs included in this analysis, HIV prevalence was 30.4%(N=222/730), with a median age of 24 years(n=217). Among the 151 MSM living with HIV who had never taken ART, 107 had VL≥1000 copies/ml. Among them, 46 sequences were obtained on RT+PROT gene, 18 on RT, 11 on PROT only. The 64 RT sequences showed that 10/64 had at least 1 DRMs, with 12.5%(8/64) no-nuc and 4.7%(3/64) nuc. No DRMs were found on the 57 proteases sequences. DRMs were T215Y/A(n=2) and M184V(n=1) for NRTI and K103N(n=4), V108I(n=3), V106M(n=3) for NNRTI. Phylogenetic analyses on the 75 RT and or PROT sequences showed 50.7%(n=38) of subtype C, 44%(n=33) of CRF02_AG, 2.7%(n=2) of B and 1.3%(n=1) of each of CRF06_cpx and URFs.
Conclusions: The data highlight that one in eight MSM living with HIV show evidence of non-nucleoside drug resistance in Senegal, which is particularly challenging given the current first line treatment regimens in Senegal. These data reinforce the importance of ART retention programs, the implementation of HIV drug surveillance as recommended by WHO including the pre-treatment HIV drug resistance and leveraging all data such as this to guide the implementation of ART choice including the potential integration of integrase inhibitors in Senegal.

TUPEC0851

Stable prevalence of transmitted drug resistance mutations and increase circulation of non-B subtype in antiretroviral-naive chronically HIV-infected patients in 2015/2016 in France: the ANRS Odyssee study

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Background: As recommended by French ANRS program for HIV-1 resistance surveillance, we estimated prevalence of transmitted drug resistance associated mutations (TDRAMs) in antiretroviral-naive chronically HIV-1-infected patients.
Methods: TDRAMs were sought in samples from 674 newly diagnosed HIV-1-infected patients in 2015/16 in 33 HIV clinical cares. Protease and reverse-transcriptase TDRAMs were identified from the 2009 Stanford Resistance Surveillance list. Etravirine, rilpivirine and integrase (IN) mutations were identified from IAS and ANRS lists. Weighted analyses, taking into account the number of patients followed in each center, were used to derive representative estimates of the percentage of patients with TDRAMs.
Results: At inclusion, median CD4 cell counts and plasma HIV-1 RNA were 357/mm^3 (IQR: 186-524) and 4.6 $\log_{10}$ cps/ml (IQR: 4.0-5.1), respectively. Median duration of known seropositivity was 0.39 months (IQR: 0.07-2.83) and below 6 months in 81.5 % of patients. Non-B subtypes were observed in 58.8% of patients. Using Stanford list, prevalence of virus with PR or RT RAMs was 10.2% (CI95%: 7.9-12.5). Prevalence of PIs, NRTIs, NNRTIs and INI RAMs was not different according to duration of HIV diagnosis and was 3.1% (CI95%: 1.8-4.5), 5.8% (4.0-7.6), 5.4% (3.7-7.1) (15.7% (12.9-18.4) including etravirine and rilpivirine RAMs) and 8.7% (6.4-11), respectively. IN RAMs observed were: L74M n=13, T97A n=11, E138K n=1, G140A n=1, Q148K/R n=2, E157Q n=30, R263K n=6. The double mutant G140A+Q148R was observed in 1 patient. Resistance to 1, 2, 3 and 4 classes of ARV was evidenced in 14.2%, 2.2%, 1.1% and 0.2% of patients, respectively. Baseline characteristics such as gender, age, transmission routes, country of transmission, CD4, viral load and subtypes were not associated with prevalence of TDRAMs, except CRF_02 strains which exhibited lower frequency of TDRAMs compared with B subtype (6.6% versus 12.4%, P=0.04, respectively). When comparing 2010/11 survey, prevalence of non-B subtype viruses increased from 43.5% to 58.8% (p< 0.001).
Conclusions: In France in 2015/2016, overall prevalence of TDRAMs was 10.2% and stable compared to 2010/2011 previous survey as well as for PI and NRTI whereas NNRTI RAMs increased. High prevalence of INI RAMs was observed. Non-B subtypes dramatically increased since 2010.

TUPEC0852

High levels of pre-treatment transmitted and acquired HIV-1 drug resistance in newborns from Argentina

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Background: Transmitted HIV drug resistance (TDR) is on the rise in Argentina, mostly associated to Non-nucleoside reverse transcriptase inhibitors (NNRTIs). Of concern, antiretroviral (ARV)-naive pregnant women already show high levels of TDR (20%), which may jeopardize the efficacy of NNRTI-based regimens used for prevention of mother-to-child transmission (pMTCT). However, TDR rate in newborns is unknown in our country. We sought to investigate HIV drug resistance (HIVDR) in ARV-naive and pMTCT-exposed newborns before starting 1st line antiretroviral therapy.
Methods: HIV-1 genotypic resistance test was performed in 115 newborns born between 2007 and 2014. Median age was 2.3 months (IQR 1.5-5.5). Characteristics and ARV exposure for pMTCT were collected in all mother-child pairs. Surveillance drug resistance mutations (SDRMs) were considered to determine TDR rates in ARV-naive infants, and acquired drug resistance mutations (DRMs) listed by IAS were identified among pMTCT-exposed infants.
Results: According to ARV exposure of the mother-child pairs, 50 of 115 infants were considered ARV-naive (no maternal cART during pregnancy and no pMTCT or AZT alone according to PACTG 076 at birth). At least one SDRM was found in 12 cases (TDR= 24%, 16% to NNRTIs, 8% to NRTIs and 8% to protease inhibitors (PIs)). In 9 of them, the mother was also ARV naïve and unaware of her HIV-1 positive status. Among 65 pMTCT-exposed infants, DRMs were found in: 75% of 28 cases exposed to a maternal NNRTI-based cART (67% to NNRTIs, 42% to NRTIs, 0% to PIs), 18% of 12 cases exposed to a maternal PI-based cART (14% to NNRTIs, 7% to NRTIs, 0% to PIs), and 40% of 25 cases who received a nevirapine-based extended prophylaxis at birth with 2 doses of nevirapine at first and third day of life according to NICHD HPTN 040/PACTG 1043 (36% to NNRTIs, 8% to NRTIs, 0% to PIs).
Conclusions: High TDR levels were found in newborns from Argentina (24%), mostly fueled by onward transmission from ARV-naive mothers. Repeated HIV-1 testing during pregnancy and rational use of NNRTI-based prophylaxis based on maternal HIV-1 drug susceptibility profiles should be implemented not only to reduce the rates of mother-to-child transmission but also prevent HIVDR from spreading.

TUPEC0853

HIV pre-treatment drug resistance in West Africa and South-East Asia

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Background: The ongoing scale-up of antiretroviral treatment (ART) in the developing world has now moved to a new era with the recent WHO recommendations to test and immediately treat HIV-positive individuals. High frequency of Pre-treatment drug resistance (PDR) can compromise ART efficacy and the 90-90-90 objectives. Our study presents updated estimates of PDR in six countries from West Africa (Cameroon-CM, Cote d'Ivoire-CI, Mali-ML, Togo-TG) and South-east Asia (Thailand-TH, Vietnam-VN).
Methods: The study was a pilot approach based on the 2014 WHO PDR protocol (www.who.int/hiv/pub/drugresistance/pretreatment_drugresistance). Eligible participants were HIV-1 positive adults, initiating the first-line ART as per national recommendations. Recruitments were conducted from December 2015 to November

2016 and enrolment sites included 1 to 5 major ART clinics in each country. HIV drug resistance (HIVDR) testings were conducted for all specimens and interpretation was done using the Stanford algorithm.
Results: Overall, 1,093 participants were recruited from the six countries, CM (n=202), CI (n=203), ML (n=175), TG (n=158), TH (n=180), and VN (n=175). Genotyping assays were successful for 944 samples. Overall, 880 pol sequences were successfully analyzed and interpreted. PDR frequency among all initiators was 10.1% (95% CI: 8.1-12.1%) overall, ranging from 4.5% and 5% in TH and ML respectively; 12% in CM, CI, and VN; to 16.8% in TG.
Among all participants with available sequences, the frequency of NNRTI resistance mutations was 7.5%, the frequency of NRTI resistance mutations was 4.2%, and PI resistance mutations represented 1.9%. Both NRTI and NNRTI mutations were observed in 2.5% of participants. K103N and M184V mutations predominated, at frequency of 50.6% and 21.3% respectively, but complex resistance profiles including TAMs profiles were found also.
Conclusions: Access to ART in the developing world relies on the used of standard first-line regimens. A low frequency of PDR is important to maintain the success of this public health approach. Our study indicates that PDR is increasing critically in many countries, exceeding 15% in some sites. Nationally representative studies are needed in countries to confirm our findings, but actions to prevent drug resistance should be implemented or improved.

TUPEC0854

International trends in new HIV diagnoses among men who have sex with men in North America, Western Europe and Australia 2000-2014

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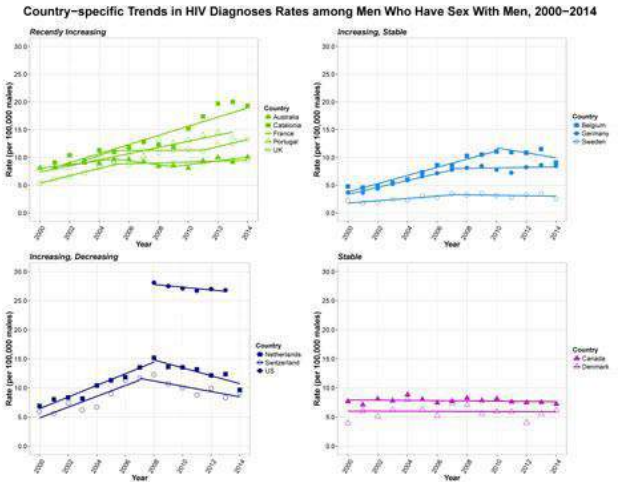
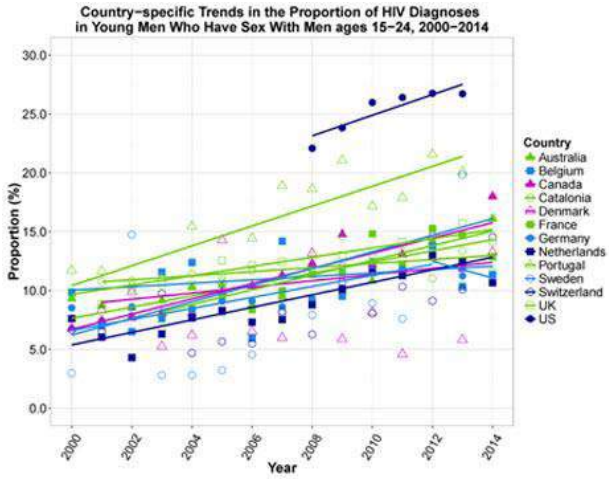
Background: An increase in HIV diagnoses in men who have sex with men (MSM) in high-income countries was identified from 2000-2005. We sought to investigate recent trends through 2014 to better inform treatment and prevention strategies.
Methods: Data on annual rates of HIV diagnoses among MSM ages 15-65 from 2000-2014 were collected from 13 high-income countries. Joinpoint regression software was used to empirically determine country-specific trend periods. Trends in the annual HIV diagnoses rates and in the proportion of diagnoses occurring in young MSM ages 15-24 were analyzed using Poisson regression and log-binomial regression respectively.
Results: Four trend typologies were identified. Six countries experienced an increasing trend from 2000 to 2007-08 followed by either a stable or declining trend through 2014. Five countries had recently increasing trends and two countries had one stable trend from 2000-2014. Trends in unprotected anal intercourse and syphilis rates increased in most countries.
All 13 countries experienced increasing trends in the proportion of HIV diagnoses in young MSM during this period.
Conclusions: High-income countries differed in HIV trend typologies. Half of the countries experienced a stable or decreasing trend in recent years despite increasing UAI and STIs, suggesting that recent treatment advances and improved ART coverage and adherence may be contributing to declines in HIV rates among MSM. Still, young MSM do not appear to be benefitting equally from such treatment-as-prevention initiatives.
Global efforts to support early sexual health promotion, reduce barriers to PrEP, and improve care engagement for YMSM are critical to addressing current international HIV trends.



[Figure 1]



[Figure 2]

TUPEC0855

HIV pretreatment and acquired drug resistance: results from the first nationally representative survey conducted in Guatemala, 2016

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Background: Guatemala has the largest cohort of adults on antiretroviral treatment (ART) in Central America. HIV drug resistance (HIVDR) emergence might compromise Guatemalan efforts to achieve 90-90-90 targets by 2020. In 2016, we conducted the first nationally representative survey to estimate the prevalence of pretreatment drug resistance (PDR) and acquired drug resistance among persons living with HIV (PLHIV) on ART for 12±3 months (ADR12) and ≥48 months (ADR48) following World Health Organization (WHO) guidelines.
Methods: We included 10 out of 14 ART clinics in the survey (excluding clinics that represented < 10% of the national cohort of PLHIV on ART). Clinic sample size was estimated using the WHO standardized calculator. Eligible participants (according to WHO survey guidelines criteria) were recruited consecutively for 6 months. All patients provided written informed consent to participate in the study. HIV Viral Load (VL) was measured using a RT-qPCR assay. HIVDR was assessed using Sanger sequencing and the Stanford HIVdb algorithm at a WHO designated regional genotyping laboratory. All analysis accounted for the survey design.
Results: We enrolled 869 participants: 269 for PDR, 222 for ADR12, and 378 for ADR48. Overall PDR prevalence was 13.6% (95%CI 9.6-18.5%), mostly related to non-nucleoside reverse transcriptase inhibitors (NNRTI) resistance (11.6%), followed by nucleoside reverse transcriptase inhibitors (NRTI, 3.6%) and protease

inhibitors (PI, 0.8%). Approximately 13% of ART initiators had prior exposure to antiretrovirals; however, PDR prevalence in this group did not differ from individuals with no previous exposure to ART. Viral suppression rate was 88.7% (95%CI 83.8-92.6%) and 86.8% (95%CI 83.0-89.8%) among PLHIV on ART for 12±3 and ≥48 months, respectively. ADR12 prevalence among patients with VL≥1000 copies/ml was 78.9% (95%CI 54.4-93.9%) with 73.7% and 57.9% NNRTI and NRTI resistance, respectively. ADR48 prevalence among patients with VL≥1000 copies/ml, was 75.6% (95%CI 59.7-87.6%), with 73.2%, 63.4%, and 2.4% of NNRTI, NRTI and PI resistance, respectively.
Conclusions: Guatemala reached a moderate PDR level (5-15%). Viral suppression rates were >85% and ADR levels >75% in those with a VL>1000 copies/ml. Our findings underscore the importance of targeted efforts to improve ART adherence strategies and review current programmatic actions to prevent HIVDR transmission to uninfected individuals.

TUPEC0856

Brazilian network for HIV drug resistance surveillance (HIV-BresNet) of naive-treatment individuals: a cross sectional study

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Background: In Brazil, more than 487,450 individuals are currently undergoing antiretroviral treatment. In order to monitor the transmission of drug-resistant strains and HIV subtype distribution in Brazil, the present work aimed to estimate the prevalence and to characterize the nationwide pre-treatment drug resistance in individuals recently diagnosed with HIV
Methods: The HIV Threshold Survey methodology (HIV-THS, WHO) targeting antiretroviral-naïve individuals with recent HIV diagnosis was utilized, and subjects were selected from 51 highly populated cities present in all five Brazilian macro-regions. HIV pol genotypic test was performed by genomic sequencing.TDR analyses based on the CPR algorithm were conducted for each geographic region separately
Results: We analyzed samples from 1,568 antiretroviral naïve individuals with recent HIV infection, and the overall transmitted drug resistance (TDR) prevalence 9·5% (150 sequences). The mean viral load was 54,827 copies/mL. The regional prevalence of resistance was 9·4% in the Northeast, 11·2% in the Southeast, 6·8% in the Central region, 10·2% in the North, and 8·8% in the South. The inhibitor-specific TDR prevalence was 3·6% for nucleoside reverse transcriptase inhibitors (NRTIs), 5·8% for non-nucleoside reverse transcriptase inhibitors (NNRTIs), and 1·6% for protease inhibitors (PIs); 1·0% of individuals presented resistance to more than one class of inhibitors. Overall, subtype B was more prevalent in all regions besides the South region where C prevails. prevalence of the NNRTI mutation K103N in recently diagnosed individuals in all Brazilian regions, ranging from 3·4 to 5·5%, which reconciles with the world trends for
Conclusions: In conclusion, we believe that the sampling technique used herein provides for the first time results on TDR that are truly representative of Brazil, revealing a moderate rate of primary prevalence of TDR in the five Brazilian macro regions, although some cities such as the city of Sao Paulo in the Southeast region and the city of Salvador in the Northeast region presents higher prevalence. These results further illustrate the important contribution of studies of surveillance in designing future strategies to mitigate TDR or initial treatment related strategies, as well as help in predicting future trends in other regions of the Globe where massive ARV treatment was implemented

TUPEC0857

Correlates of recent HIV testing among female sex workers in South Sudan

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Background: Behavioral and HIV prevalence data have not yet been described for female sex workers (FSW) in South Sudan, a key population in the HIV epidemic. Using a biobehavioral survey, we aimed to describe demographic, biological, and behavioral characteristics of FSW in South Sudan, and identify correlates of recent HIV testing to detect and target women not testing every six months.
Methods: Respondent-driven sampling (RDS) was used to recruit 846 FSW in Juba, South Sudan from November 2015-March 2016. Participants completed a risk behavior questionnaire, pre- and post-test counseling, and rapid HIV testing. We collected geospatial data on participant activity, HIV clinics, and outreach testing sites in Juba, and conducted bivariate and multivariate analyses of factors associated with HIV testing in the past 6 months. Data were analyzed in SAS, ArcGIS, and RDS-A, with RDS-adjusted results presented.
Results: Among FSW who reported being HIV-negative at last test, 27.8% had been tested in the last 6 months and 14.6% were currently infected with HIV. Nearly two-thirds (63.3%) had last tested at a clinic, and 30.2% had ever had a peer educator or outreach worker talk to them about HIV. Over half (57.1%) of FSW were from outside South Sudan, and 56.8% had been in Juba for 1-4 years. 76.7% felt FSW peers supported them in condom use, and, respectively, 35.8% and 80.3% of FSW sold sex within half a kilometer and one kilometer of a clinic or outreach testing site. Based on multivariate logistic regression, non-South Sudanese nationals (Odds Ratio (OR) = 3.38, 95% CI: 1.69-6.77) and those who had a counselor or outreach worker talk to them about HIV (OR=2.22, 95% CI: 1.29-3.83) had significantly increased odds of testing in the past 6 months, while residency longer than 1-4 years was significantly associated with decreased odds (5-9 years OR=0.34, 95% CI: 0.19-0.63, 10+ years OR=0.25, 95% CI: 0.09-0.70).
Conclusions: HIV testing in the past six months among FSW in Juba is low despite proximity to clinics or outreach sites. Greater outreach, specifically targeting South Sudanese FSW and including discussion of HIV, is needed to increase testing among FSW in Juba every six months.

TUPEC0858

Early warning indicators of HIV drug resistance among antiretroviral therapy sites in Namibia: a geospatial approach to population-based surveillance

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Background: HIV drug resistance (HIVDR) poses a significant threat to successful antiretroviral therapy (ART). The World Health Organization's Early Warning Indicators (EWIs) of HIVDR monitor site-level performance of factors associated with the emergence of HIVDR. Geographic information systems (GIS) offer a unique opportunity for Namibia and other resource-limited countries to better understand the geospatial distribution of the HIV epidemic and EWI measures to inform appropriate public health interventions.
Methods: We conducted geospatial analysis of the following EWIs at ART site level: 1. On-Time Pill Pick-Up, 2. Retention on ART at 12 months, 3. Pharmacy Stock-Outs, 4. Antiretroviral Dispensing Practices, 5. Viral Load Suppression at 12 months, and 5a. Viral Load Completion at 12 months. We assessed the geolocation and EWI indicators among 249 adult and 216 pediatric ART sites with 2015 and 2016 data. We developed thematic maps to assess geospatial patterns for HIV prevalence, EWI status, and ART delivery performance throughout Namibia.
Results: We identified regions with high HIV prevalence (>25%) and inconsistent EWI performance along Namibia's northern border with Angola. While on-time pill pick up was excellent in the northeastern region (>90%) in 2015, it was fair (80-90%) to poor (< 80%) in most other regions of the country. Retention in care was inconsistent across all regions during 2015 and 2016. Pharmacy stock-outs were widespread across all regions, with the exception of a few sites in the northern border in 2015 and one district in the northeast in 2016. ARV dispensing practices were excellent (0% mono-dual therapy) through all regions in both years. Viral load completion was poor (< 70%) across all regions in both years. Viral load suppression was unavailable in any regions in 2015, but in 2016 in regions with data available viral load suppression rates were excellent (≥90%).
Conclusions: We provided the first geospatial assessment of EWIs for HIVDR, and identified regions with EWI successes and challenges in Namibia. Integration of GIS into routine EWI analysis offers valuable insight for evidence-based decision-making at site-specific and programmatic levels and can inform targeted interventions to minimize the emergence of HIVDR and optimize patient care.

TUPEC0859

Population HIV viral load metrics: findings from household surveys in KwaZulu-Natal, South Africa

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Background: To assess the impact of combination HIV prevention strategies on achieving epidemic control, quantifiable population HIV viral load (VL) metrics are important and useful. We report on the VL metrics in HIV positive individuals irrespective of ART use.
Methods: Two sequential cross-sectional household surveys were undertaken across two sub-districts of uMgungundlovu, KwaZulu-Natal. Surveys one and two were undertaken one year apart from June 2014 to June 2015 and from July 2015 to June 2016 respectively. A randomly selected individual
(15-49 years) per household was enrolled and provided clinical samples for laboratory measurements and had a questionnaire administered.
Results: In survey one 3969/9812 tested antibody positive for HIV (weighted prevalence 36.3%, 95% CI 34.8-37.8) with 42.3% of HIV positive participants reported being on ART (36.7% males and 45.6% females). The population mean and median VL were 45913 (range 0-5400000) and 402 (IQR 0-23656) copies/ml respectively. Whilst 50% of individuals had VL < 400 copies/ml, 15.4%, 18.7% and 15.9% had VL of 400-10000, 10001-50000 and >50000 copies/ml respectively. In survey two 3870/10236 tested antibody positive for HIV (weighted prevalence 35.2%, 95% CI 33.9-36.4), despite 55.3% of HIV positive participants reporting to be on ART (48.6% males and 58.8% females). The population mean and median VL were 91896 (range 0-18000000) and 6.9 (IQR 0-14440) copies /ml respectively. The proportion of individuals with VL <400 copies/ml increased to 58.0%, however, 14.5%, 11.3% and 16.2% had VL of 400-10000, 10001-50000 and >50000 copies/ml respectively. Across both surveys men were more likely to have VL >50000 copies/ml (p<0.001). After controlling for gender, individuals <30 years of age (p<0.001), never having had an HIV test (p< 0.001) and not knowing their HIV status (p<0.0001) were more likely to have VL >50000 copies/ml.
Conclusions: Our findings show that the proportion of potential transmitters with VL >50000 copies/ml remains high. To achieve epidemic control, HIV combination prevention efforts including universal test and treat programmes must identify potential transmitters with VL >50000 copies/ml, specifically men, those <30 years of age, those not having had an HIV test and unaware of HIV status.

TUPEC0860

Estimation of mother to child transmission of HIV in the Brazilian public health system based on programmatic data on viral load, 2009-2015

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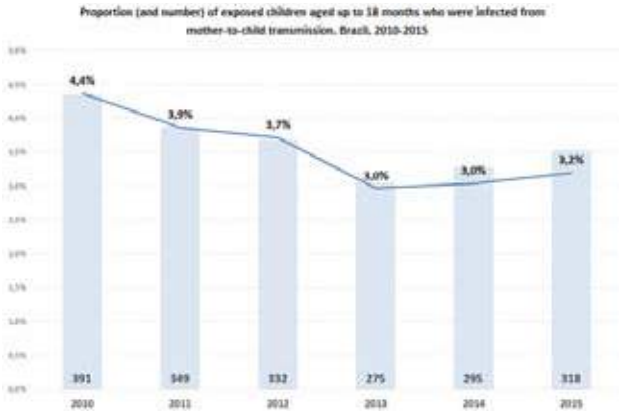
Background: The elimination of mother-to-child transmission (MTCT) is a worldwide priority for HIV programmes. For HIV MTCT elimination, transmission rates must be below 2%. This study estimates MTCT of HIV among newborns from HIV-infected mothers followed in the public health system in Brazil from 2010 to 2015 and its trends.
Methods:)We used individual-level programmatic information on HIV viral load (VL) results performed in the Brazilian public health system. We analyzed data for 55,822 children aged up to 18 months exposed to HIV from 2010 to 2015. All treatment-naïve exposed children were classified into three categories: infected (those who presented at least two VL≥5,000 copies/mL); not infected (those with at least two VL< 5,000); and undefined (those who performed only one VL in the first 18mo of life or present two discordant VL, below and above 5,000). The MTCT rate was calculated as the percentage of infected over the total analyzed.
Results: In the period of 2010-2015, the number of infected children was 1,960 and the overall MTCT rate 3.5%. Trend analysis showed a decrease in the rates from 4.4% to 3.2% (p-value< 0.001) and in the numbers of infected children from 391 to 318 (p-value< 0.001) in the period. Nevertheless, we observed an increase in both number and rate in the last three years of observation (p-value=0.030).
Conclusions: Despite the decrease trends from 2010 to 2015, the increase in the last 3 years has drawn the Ministry of Health´s (MoH) attention, who has intensified actions to prevent MTCT. This national increase conceals regional disparities, and several municipalities that have already implemented successful MTCT programs have shown relevant declines or even elimination. Among the MoH's initiatives is the certification process of municipalities that eliminated MTCT. These municipalities may serve as models for others to implement similar programs and contribute to MTCT elimination in Brazil.



[Figure 1]

TUPEC0861

Patterns and correlates of displacement of sex workers and implications for HIV programmes: findings of a community-based project in Vancouver, Canada

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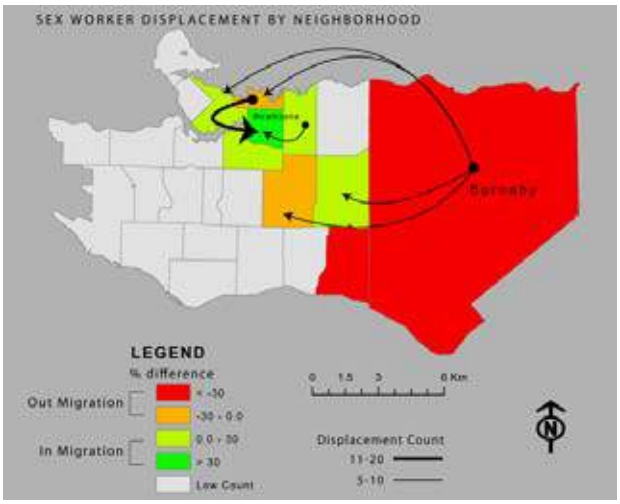
Background: Urban gentrification, criminalization and policing have increasingly displaced sex workers outside of neighbourhoods or workspaces. This displacement has been associated with increased HIV risk and reduced access to HIV services. Drawing on a community-based cohort, community mapping and spatial epidemiological analyses were used to identify:
1. spatial patterns of workplace displacement and;
2. contextual (policing, violence, and safety) and individual correlates of displacement (defined as changing the primary working neighbourhood) among sex workers in an urban Canadian setting, over time.
Methods: This analysis utilized data from a longitudinal community-based cohort of women sex workers in Metro Vancouver (AESHA, 2010-2016), including interviewer-administered questionnaires and voluntary HIV/STI/HCV testing by experiential/community interviewers. Multivariable logistic regression with generalized estimating equations was used to examine correlates of displacement. Mapping was used to examine patterns of displacement by neighbourhood (Figure1).
Results: Analyses were restricted to 543 sex workers who reported their neighbourhood of solicitation and/or service in at least two separate study visits (2010-2016).Displacement was associated with being of a younger age (adjusted odds ratio (AOR) 0.99, 95 % confidence interval (CI) 0.97- 1.00), whereas homelessness (AOR 1.41, 95 % CI 1.11-1.79), identifying as a gender/sexual minority (AOR 1.31, 95 % CI 1.02-1.67), being harassed by police(AOR 1.19, 95 % CI 0.96-1.48), changing work environments due to safety (AOR 1.37, 95 % CI 0.94-2.00) and servicing outdoors (AOR 1.48, 95 % CI 1.21-1.81) were correlated with increased odds of displacement.



[Figure 1]

Conclusions: This study indicates that the marginalized populations of sex workers (e.g., youth, sexual/gender minorities, street-based) were most likely to experience displacement. In light of prior research suggesting that displacement may exacerbate HIV risks and reduce access to critical HIV and sexual health services, structural interventions to reduce criminalization and displacement and support sex workers' access to safer work and housing environments and HIV services remain critically needed.

TUPEC0862

Trends of racial and ethnic disparities in virologic suppression among women in the HIV Outpatient Study, 2010-2015

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Background: In the United States (US), women accounted for 19% of HIV diagnoses in 2015. Black/African American (black) and Hispanic women/Latinas (Latinas) were disproportionately affected; they comprised 76.7% of all women diagnosed with HIV infection. Antiretroviral therapy (ART)-induced viral suppression (VS) results in decreased morbidity and mortality; a goal of the National HIV/AIDS Strategy (NHAS) is to have 80% of HIV-infected persons reach VS by 2020. However, factors influencing VS have been understudied among women. We sought to examine VS among women to inform gender-specific HIV management interventions.
Methods: We used medical records data from the HIV Outpatient Study (HOPS), a cohort study of HIV-infected adults receiving care at several US clinical sites. We limited analyses to women aged ≥ 18 years with ≥ 1 HOPS visit, on ART, and at least one viral load (VL) test performed between 2010 and 2015. We defined VS as VL < 50 copies/mL and calculated prevalence ratios (PR) with 95% confidence intervals (CI) for VS among women by race/ethnicity and by year of measure. Generalized estimating equations were used for multivariable analyses to assess factors associated with VS among women.
Results: Among 809 women (entering observation at median age = 44 years), 482 (59.6%) were black, 177 (21.9%) were white, 150 (18.5%) were Latina. VS was less prevalent among black women (73.0%) compared with Latinas (82.7%) and whites (90.7%) even when limited to women for whom ART was prescribed. In multivariable analyses, adjusting for age and time-updated ART use, VS was less likely among women who were black (aPR=0.45; CI=0.33-0.63) or Latina (aPR=0.61; CI=0.41-0.92) compared with white women, and who attended a public clinic (aPR=0.71; CI=0.54-0.93) compared with a private one. Among all women, VS increased from 62.5% to 77.4% between 2010 and 2015, but racial/ethnic disparities persisted in each year.
Conclusions: Despite improvements in VS over time toward the NHAS goal of 80%, racial/ethnic disparities persist among HIV-infected women, with black women and Latinas achieving significantly lower rates of VS than white women. Interventions targeting VS improvement among black women and Latinas, especially those who attend public clinics, are warranted.

TUPEC0863

Clinical, health and social outcomes associated with food and housing insecurity among a national cohort of women living with HIV in Canada

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Background: Women living with HIV (WLWH) in Canada experience disproportionate rates of food and housing insecurity. The study objective was to examine factors associated with experiencing food and housing insecurity among a Canadian cohort of WLWH.
Methods: We analyzed baseline survey data for WLWH (≥16 years) enrolled in a community-based cohort study in British Columbia, Ontario, and Québec. We assessed self-reported housing insecurity (unstable housing [transitional/shelter, living outdoors, couch surfing], difficulty paying rent) and food insecurity (concerns and/or experiences with running out of food) in the past 12 months. Multinomial logistic regression analyses were conducted to identify socio-demographic, social, health and clinical factors associated with experiencing: food insecurity, housing insecurity, or both food and housing insecurity.
Results: Of 1425 participants, the median age was 43 (IQR=36-51) years. Of 1404 participants included in analyses: one-fifth (n=300; 21%) reported no food/housing insecurity, 27% (n=381) reported food insecurity alone, 14% (n=200) housing insecurity alone, and 37% (n=523) both food and housing insecurity. In unadjusted analyses, socio-demographic factors associated with food and housing insecurity included: <high school education, <$20,000 annual income, and Indigenous or African Caribbean Black vs. Caucasian ethno-racial identity. In adjusted multinomial analyses controlling for socio-demographics, food insecurity alone was

associated with health outcomes (depression, lower health-related quality of life [HrQOL], reduced resilience, lower odds of ever received a Pap test), clinical outcomes (detectable viral load, HIV medical care barriers), and social factors (HIV-related stigma, racial discrimination, gender discrimination). In multivariable analyses housing insecurity alone was associated with social (lower social support) and clinical (CD4 count of <200 cells/mm3 vs. >500 cells/mm3) outcomes. Experiencing food and housing insecurity concurrently was associated with: health (current injection drug use, depression symptoms, lower HrQOL, lower resilience), social (lower social support, HIV-related stigma, racial discrimination, gender discrimination) and clinical (CD4 count of < 200 cells/mm3 vs. >500 cells/mm3, <80% antiretroviral adherence vs. 100% adherence) outcomes.
Conclusions: Food and housing insecurity are widespread among WLWH and associated with poorer social, health and clinical outcomes, including lower adherence and CD4 count. Findings highlight an urgent need to address housing and food insecurity to promote WLWH's health and wellbeing.

TUPEC0864

Gender and age disparities in achieving each of the 90-90-90 UNAIDS goals in three sub-Saharan countries

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Background: Understanding gender and age disparities in the HIV cascade of care can help to focus HIV strategies to achieve the 90-90-90 UNAIDS goals. We aimed to assess the effect of gender and age at each step of the HIV cascade of care in 3 sub-Saharan African countries.
Methods: Three population-based cross-sectional surveys were conducted in Ndhiwa (Kenya), KwaZulu-Natal (South Africa) and Chiradzulu (Malawi) between September 2012 and November 2013. Persons aged 15-59 years were eligible. Individuals were interviewed and tested for HIV at home. Those positive had a viral load (VL). Multivariable logistic regression models were used to assess factors associated with being diagnosed among all HIV-positive, untreated among those diagnosed, and virally unsuppressed (VL≥1000cp/mL) among those on ART.
Results: In total 9,802 houses were visited, 21,782 individuals were eligible and 19,006 (87.5%) included. In total, 1457 (24.1%) individuals were HIV positive in Kenya, 1423 (25.2%) in South Africa and 1234 (17.0%) in Malawi. Overall 90-90-90 UNAIDS goals were achieved at 59.6%-68.2%-82.5% in Kenya, 75.2%-66.9%-89.8% in South Africa, and 76.8%-82.9%-90.8% in Malawi with viral suppression among HIV-positive being 39.9%, 57.1% and 61.7% respectively. HIV diagnosis was lower in men (62.2%, 95%CI: 59.0-65.2) than in women (73.4%, 95%CI: 71.5-75.2). This difference persisted in the multivariable model (aOR: 2.1, 95%CI: 1.8-2.5). Viral suppression among HIV-positive was lower in men (46.9%, 95%CI: 43.6-50.2) than in women (54.8%, 95%CI: 52.9-56.6). However, diagnosed men did not have a higher risk of being untreated or, when on ART, being virally unsuppressed. Individuals aged 15-24 years had a 4 to 7 times increased risk of attrition all along the cascade compared to those aged 45-59 years (diagnosed aOR: 4.9, 95%CI:3.7-6.4; untreated aOR: 5.1, 95%CI:3.7-7.3; unsuppressed aOR: 6.9, 95%CI:3.9-12.0).
Conclusions: In these 3 settings, men had higher viral loads compared to women due to their lower HIV diagnosis. However, men did not have a higher risk of being untreated once they were diagnosed or of being virally unsuppressed once on ART. The effect of age persisted along the HIV cascade of care. Individuals aged 15-24 years had a higher risk of not achieving the UNAIDS 90-90-90 goals.

TUPEC0865

Elevated levels of HIV-1 RNA among newly diagnosed individuals in Botswana

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Background: High HIV-1 RNA load is associated with higher risk of virus transmission, and it is believed that virologically suppressed individuals do not transmit the virus. Identification of subpopulations with elevated levels of HIV-1 RNA is relevant to public health strategies aimed to reduce HIV transmission and control the HIV epidemic.
Methods: HIV-infected individuals (n=3,596) were identified during a household survey performed in 30 communities across Botswana. We focused on the most likely subpopulation of HIV-infected individuals able to transmit virus - ART-naïve HIV-infected people with HIV-1 RNA above 400 copies/mL (considered as a threshold of virus transmission). Within this group, we compared levels of HIV-1 RNA between newly diagnosed people and individuals who knew that they were infected at the time of household visit. We analyzed levels of HIV-1 RNA among newly and previously diagnosed people, overall and by age and gender. Individuals with recent HIV-1C infection were identified by using combined Limiting-Antigen Avidity Assay data, ART status and HIV-1 RNA load, as described in Rehle et al. (PLoS One 2015; 10(7):e0133255).
Results: Among 815 HIV-infected ART-naïve persons with detectable virus (HIV-1 RNA >400 copies/mL), newly diagnosed individuals had higher levels of HIV-1 RNA (n=490, median HIV-1 RNA 4.35, IQR 3.79-4.91 $\log_{10}$ copies/mL) than those aware of their HIV-positive status at the time of household visit (n=325, median HIV-1 RNA 4.10, IQR 3.55-4.68 $\log_{10}$ copies/mL; p-value <0.001, but p-value =0.011 after adjusting for age and gender). A non-significant trend for higher HIV-1 RNA was evident among newly diagnosed men aged 30 years or older (median HIV-1 RNA 4.58, IQR 4.07-5.02 $\log_{10}$ copies/mL vs. 4.17, 3.61-4.71 $\log_{10}$ copies/mL). Only 5% (95% CI 3-7%) of newly diagnosed people were tested as recently infected.
Conclusions: Among HIV-infected individuals with detectable viral load, newly diagnosed individuals had elevated levels of HIV-1 RNA, as compared with people who were previously aware of their HIV-positive status. Interventions targeting undiagnosed middle-aged men could enhance the value of Treatment-as-Prevention and Universal Treatment campaigns.

TUPEC0866

HIV testing preferences among men who have sex with men in China: a discrete choice experiment from a nationwide sample

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Background: Discrete choice experiments (DCE) present study participants with hypothetical choice scenarios in order to quantitatively determine the relative influence of specific factors underpinning individual choice decisions. We used DCEs to identify the most important considerations and preferences driving MSM HIV testing decisions, stratified by income and sexual orientation.
Methods: In January 2017, men over 16 years old and reported ever having sex with another man were recruited via social media throughout China to complete an online DCE. Participants were given six choice sets, each asking the participant to choose from two hypothetical HIV testing scenarios or a "do not test" selection. Each testing scenario had a combination of attributes including: test location, venipuncture or finger prick test type, whether true names were collected, whether test administrator was a health professional or person with on-the-job training, whether disclosure of MSM status was required, and cost/incentive ($7.25 USD incentive; free; pay $7.25 USD; pay $14.50 USD). Design of the DCE attributes and levels

were based on results from five focus groups and a pilot study with 95 participants. Parameter estimates and attribute influence were calculated using mixed multinomial logit modeling.
Results: 717 individuals completed 3663 choice tasks. Median age was 24 years, 51% had monthly income below $435 USD, and 20% did not identify as gay.
Overall, cost/incentive was the most important consideration for HIV testing decisions, influencing 39% of testing choices. Free HIV testing was the most preferred option, followed by $7.25 USD testing incentives and fee-based testing. Test administrator considerations influenced 20% of testing choices, with health professionals being preferred over individuals with on-the-job training. Considerations about disclosure of identifying information influenced 17% of testing choices, with anonymous testing being preferred over disclosure of true names.
Test administrator was a more important consideration for gay-identifying participants than non-gay identifying participants, influencing 21.8% and 11.7% of testing choices, respectively. Compared to higher income participants, those with lower income were more averse to any fee-based testing.
Conclusions: Increasing anonymous and free HIV-testing services administered by health professionals may increase HIV test uptake among MSM, especially for those with lower monthly income.

TUPEC0867

90-90-90 and the HIV continuum of care: how well is Papua New Guinea doing amongst key populations?

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Background: With the largest HIV epidemic in the Pacific, and limited availability of HIV Viral load testing, describing Papua New Guinea's (PNG) HIV cascade has been impossible until now. We conducted an integrated bio-behavioral survey (IBBS) of female sex workers (FSW) and men who have sex with men (MSM) and transgender women (TG) in Port Moresby, PNG to obtain these important data and inform the National HIV Strategy.
Methods: Using Respondent-Driven Sampling (RDS) we conducted a cross-sectional IBBS from June to October 2016 for FSW and MSM/TG. Eligibility criteria for FSW were: born female, ≥12 years or older, could speak English or Tok Pisin (Melanesian Pidgin) and had sold or exchanged sex with a man in the past 6 months. The Eligibility for MSM/TG were: born male, ≥12 years or older, could speak English or Tok Pisin and had oral or anal sex with another person born male in the past 6 months. Consenting eligible participants (FSW N=676; MSM/TG=400) were interviewed face-to-face and offered an HIV test, and HIV viral load, as appropriate. All tests were provided at point-of-care and results provided the same day to participants. Weighted data analysis was conducted using RDS-Analyst, except where the sample counts were too small.
Results: HIV prevalence was 14.9% among FSW and 8.5% among MSM/TG. Among FSW, only 39.3% were aware they had HIV. Of those with known HIV, 84.4% self-reported being on treatment, among whom, 54.6% had suppressed viral load (HIV RNA < 1000 copies per millilitre). Awareness of HIV status was lower among MSM/TG, (24.4%; n=6). Among this group, only three participants self-reported being on treatment, of whom, two were virally suppressed.
Conclusions: While PNG appears to be achieving high treatment access and HIV viral suppression among those who are aware of their HIV positive status, urgent intervention is needed to increase HIV testing uptake among key population groups in order to reach the first continuum of care coverage target.

TUPEC0868

Rising HIV prevalence among men who have sex with men in Nigeria: a trend analysis (2007 - 2014)

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Background: Men who have sex with men (MSM) constitute less than 1% of the Nigerian population yet nationally account for about 20% of new HIV infection. We estimated the trend in HIV prevalence and determined correlates of HIV transmission among MSM.
Methods: Data from three rounds of integrated biological and behavioral surveillance survey (2007, 2010 and 2014) were evaluated in a cross-sectional analysis. Each round used similar methodology and thus allows for comparison. Behavioral data were obtained using a structured pre-coded questionnaire. Differences in categorical variables were assessed with Chi Square. Logistic regression was used to identify factors associated with risk behaviors.
Results: A total of 879, 1,545 and 3,611 MSM were recruited in 2007, 2010 and 2014 respectively. Median age was 22 years for 2007 and 2014 while it was 24 years in 2010. Majority of the respondents had achieved secondary level education in 2007 (68%), 2010 (50%) and 2014 (55%). Over one-third of MSM in 2007 and 2014 and about two-fifths in 2010 had engaged in transactional sex. HIV prevalence increased from 14% in 2007 to 17% in 2010 to 23% in 2014 (p<0.0001). HIV prevalence was higher among those aged >= 25 years in 2007 (25% vs. 11%; p< 0.0001), 2010 (20% vs. 16%; p=0.031) and 2014 (34% vs. 19%; p< 0.0001). HIV prevalence was higher among those who engaged in receptive anal sex in 2007 (14% vs. 8%; p=0.025), 2010 (19% vs. 14%; p=0.016) and 2014 (25%vs.18%; p< 0.0001). When controlled for age [(reference) < 25 years vs. >= 25 years], educational status, engaging in transactional sex, consistent use of condom during transactional age and receptive sex [(reference) yes vs. no], only age [AOR:1.78; 95% CI:1.32-2.39, p<0.00001] and engaging in receptive sex [AOR:1.61; 95% CI:1.14 - 2.27, p=0.006] were associated with HIV.
Conclusions: There's been a consistent and significant increase in HIV prevalence among MSM with a 64% increase over seven years. Older MSM were more likely to be HIV positive and this may reflect their prolonged exposure to high risk sexual activities. Evidence based interventions are urgently needed to mitigate a vicious intra-group HIV transmission.

TUPEC0869

Religious affiliation and uptake of HIV testing, treatment and viral suppression in Botswana

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Background: Religious beliefs and practices can influence HIV-related health-seeking behaviours including HIV testing, treatment initiation and adherence. Using data from a large ongoing community-based randomized trial in Botswana, we examined the relationship between religious affiliation, HIV prevalence and uptake of HIV testing and treatment as defined by the UNAIDS 90-90-90 targets for 2020.
Methods: As part of the Botswana Combination Prevention Project, baseline household surveys were administered to 30 communities from Oct 2013 to Nov 2015. The survey was administered to all consenting Botswana citizens or spouses of citizens aged 16-64 years, in 20% of households per community, and obtained information on religious affiliation and HIV status; among HIV-infected subjects, documentation of prior diagnosis and treatment status was collected. Blood was taken for HIV testing (in the absence of prior documentation of a positive HIV status) and viral load measurement. Achievement of the combined UNAIDS 90-90-90 targets was defined as the proportion of HIV-infected participants diagnosed, on treatment and virally suppressed. Modified Poisson generalized estimating equations were used to obtain univariable and multivariable-adjusted prevalence ratios (PR) and 95% confidence intervals (CI) for the associations between religious affiliation and
(a) HIV status and;
(b) binary outcome indicating achievement of the combined UNAIDS 90-90-90 target.
Results: Among the 12,601 participants with religious affiliation data, 3,968 (32%) reported no affiliation; these participants were significantly more likely to be male and younger compared to affiliated subjects. After adjustment for age and gender, HIV prevalence was significantly lower (PR: 0.88; 95%CI: 0.83-0.95) among affiliated participants compared to unaffiliated. In univariable analyses, any religious affiliation was positively associated with achievement of the combined UNAIDS 90-90-90 target (P=0.001); the association remained significant after adjustment for age and gender (PR: 1.08; 95%CI: 1.02-1.14). Similarly, in adjusted analyses, self-reported affiliation with Apostolic, Pentecostal and Zion Christian Church religious groups (as compared to no affiliation) was significantly associated with a 7%, 9% and 13% higher probability of meeting the combined UNAIDS 90-90-90 target, respectively (P=0.02).
Conclusions: Religious affiliation was significantly associated with increased uptake of HIV testing, treatment and viral suppression in Botswana.

TUPEC0870

HIV infection among men who have sex with men attending gay venues in France: results from a time-location sampling bio-behavioural survey conducted in 5 cities PREVAGAY2015 survey

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Background: In France, Men who have Sex with Men (MSM) remain the only population for whom new HIV diagnoses have not decreased overtime. In 2015, to update data, a survey was set up to estimate the prevalence of HIV infections among MSM, including the prevalence of both undiagnosed and recent infections.
Methods: An anonymous cross-sectional survey, using a time-location sampling method and the generalized method of sampling weights, was conducted among MSM attending gay venues in five cities. Behavioral questionnaires and finger-prick blood samples on blotting paper (DBS) were collected. Samples were screened using the Genscreen ultra HIV Ag-Ab® (Biorad) assay and confirmed by western Blot and serotyping. Positive specimens were tested using an enzyme immunoassay for recent HIV-1 infection (EIA-RI). Antiretrovirals (ART) among positive specimens were detected on DBS using UPLC-MS/MS and taken into account to determine recency of infection. Viral load (VL) was estimated using the Abbott Realtime HIV-1-RNA assay for DBS (high VL ≥ $3.5\log_{10}$ copies/mL). Inclusion probabilities, frequency of venue attendance and multi-stage survey design were taken into account for all statistical analyses.
Results: Of 2,646 participants tested and analyzed, 433 were HIV-positive. The HIV weighted prevalence was estimated to 14.3% [95% CI: 12.0-16.9], ranging from 7.6% [5.1-11.1] to 17.1% [11.8-24.1] according to cities.
Among HIV-positive MSM, 90.5% [95%CI: 84.5- 94.4] were diagnosed for their HIV-infection, 94.9% [95%CI: 91.9-96.8] were on ART and among them 1.5% [95% CI: 0.6- 3.9] had high VL.
Undiagnosed HIV-positive MSM were estimated to 9.4% [95% CI: 5.6- 15.5%]. Among them, 24.7% [95% CI: 10.1-48.9] had recent infection and 33.4% [95% CI: 13.9-61.1] had a high VL.
Conclusions: The implementation of innovative statistical methodologies and biological analyses enabled us to evaluate, the current burden of HIV among MSM attending gay venues in France. Despite a high HIV prevalence, diagnosed HIV-positive MSM were mostly treated with succeed reducing VL and sexual HIV transmission risk. The proportion of undiagnosed HIV-positive MSM was low, but in regards to their high VL, they may contribute disproportionately to new HIV infections.

TUPEC0871

Only 36% of adults living with HIV aware of their HIV+ status but progress in ART coverage and viral suppression in a subnational survey in Uganda: progress towards UNAIDS 90-90-90

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Background: Recent data suggests that Uganda is making gains towards meeting the second and third UNAIDS 90-90-90 targets, however, less is known about progress on the first—90% of those living with HIV being aware of their status as well as the target of 73% population-level viral suppression.
Methods: As part of a randomized trial (NCT02545673) evaluating the effectiveness of a linkage to care intervention at achieving HIV viral suppression we conducted a population-based survey of individuals aged 15-59 residing in two rural districts in Uganda between December 2015 and December 2016. Teams visited households and offered individuals participation in a survey and HIV testing. The questionnaire captured previous HIV testing, and linkage to HIV care and treatment for those aware they were positive. Venous blood was collected for HIV viral load testing.
Results: There were 5,401 individuals eligible for participation (aged 15-59, residing in household); 201 (3.7%) declined participation. We tested 5,200 individuals (56% female) for HIV, of which 242 (4.7%) tested HIV positive. 35.5% of those who tested HIV positive knew they were positive, 86.0% of those who knew they were positive were taking ARVs, 88.9% of those taking ARVs were virally suppressed (VL < 500) and 62.8% had an undetectable viral load (VL < 20). Population-level viral suppression (VL< 500) was 46.6%. Of those unaware of their HIV positive status: 21.8% had never tested, 17.3% tested more than 2 years ago, 16.7% tested 1-2 years ago, 18.6% tested 6 months-1 year ago, 12.2% tested 3-6 months ago, and 13.5% had tested within the prior 3 months.
Conclusions: These data from rural Uganda suggest that challenges remain in reaching the first of the UNAIDS 90-90-90 targets—90% of people living with HIV aware of their status. Consequently, achieving population-level viral suppression was well below the target of 73%. These gaps may reflect disparities in access/uptake of testing. Performance was better for the second and third 90-90-90 targets (90% ART coverage for individuals with known HIV positive status, and 90% viral suppression for individuals on ART). In rural areas of Uganda, increased efforts to reach HIV positive individuals unaware of their HIV status are needed.

TUPEC0872

Fishermen and Fishing communities in East Africa: most-at-risk population of acquiring HIV infection. Results from a population-based survey

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Background: In East-Africa, fishermen and fishing communities are considered most-at-risk population of acquiring HIV but knowledge about the epidemic in these contexts is scarce.
Objective: To estimate the HIV-prevalence rate among adults and children in 12 fishing communities surrounding Lake George and Edward, Uganda and; to assess the HIV cascade of care in these settings.
Methods: We conducted a cross-sectional household-based survey. Following an exhaustive household enumeration using GPS, trained-nurses visited 890 randomly-selected households during two months, interviewing 15-69 years' old men and women. All HIV-positive individuals were asked to provide a blood sample for viral load measures. Children < 15 years old were eligible for testing only if their parents were HIV-positive. Logistic regression models, adjusted on sociodemographic-behavioral variables were used to identify factors associated with HIV testing and being HIV-positive and, factors associated with HIV-status unawareness and viral suppression among HIV-positive adults.
Results: Overall, 1738 adults and 148 children were included. The HIV-prevalence rate among adults was of 17.5%(95%CI:15.8-19.4) and among HIV-exposed children 6.1%(95%CI:3.1-11.4). HIV-Prevalence rate was higher among women (20.9%;95%CI:18.4-23.5) than among men (13.5%;95%CI:11.3-16.1). According to occupation and sex, farmers had the highest HIV-prevalence rate among women (27.6%) and fishermen among men (18.7%). After adjustment, only fishermen remained with a 4-times higher risk of being HIV-positive (aOR: 3.9; 95%CI [1.6-9.4]), compared to men of other occupations. Among HIV-negatives, 81.0% declared had a test < =12 months ago. Among HIV-positives, 86.0% declared HIV-status awareness, 78.0% on ART and 56.0% had a viral load < 20cp/ml (On ART: 67.6%) (Figure1). Men had a higher risk of being untested (aOR: 2.2;95%CI:1.4-3.7) and virally detectable (aOR:6.6; 95%CI:1.9-22.0) than women. Fishermen did not have a higher risk of being untested or virally unsuppressed.
Conclusions: In Uganda, HIV-prevalence rate in fishing communities is high, particularly among women and fishermen. Although HIV testing and ART initiation rates are high, viral suppression rate remains poor, especially among men. Nevertheless, fishermen do not seem to have a lower access to care than other men. More HIV preventive interventions are needed in these settings, particularly targeting women and fishermen. Strengthen ART-retention, particularly among men, should be a priority in these settings.

TUPEC0873

Time trends in RNA HIV-1 population viral load: results from a hyper-endemic South African setting 2011-2014

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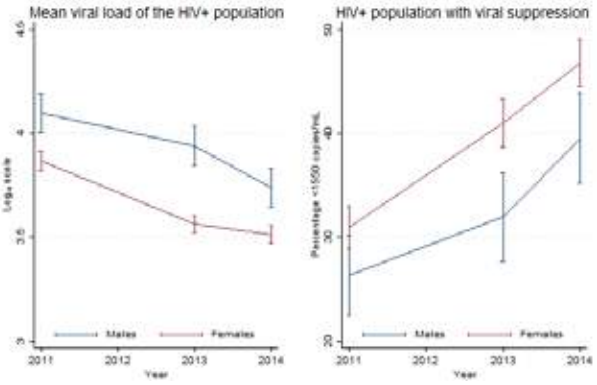
Background: HIV population viral load (PVL) has been widely advocated as a sensitive biological index of the transmission potential and the treatment program effectiveness of a particular geography. In this study, we aimed to quantify the change in the PVL over time for a South African community with a high HIV burden and a well-established ART program.
Methods: The data comes from a large population-based surveillance program, situated in the northern KwaZulu-Natal province, that has tested approximately 60% (~40,000) of all adults for HIV since 2004. We performed viral load measurements on 6959 dried blood spot samples with a HIV-positive test result in 2011 (n=2420), 2013 (n=2203), and 2014 (n=2336). For the HIV-positive population, we calculated the $\log_{10}$ viral load level and the proportion with virologic suppression, as indicated by a detection limit of <1550 copies/mL.
Results: Overall, the $\log_{10}$ viral load decreased from 3.91 copies/mL in 2011 to 3.64 copies/mL and 3.55 copies/mL in 2013 and 2014 respectively (p-value <0.001). The percentage of HIV-positive participants with viral suppression increased from 30% in 2011 to 39.1% and then 45.2% in 2013 and 2014 (p-value <0.001). Men and participants <30 years had higher $\log_{10}$ viral loads and lower rates of viral suppression (p-value <0.001).
Conclusions: Our study has evaluated the change in HIV viral load patterns in a full population (irrespective of knowledge of HIV status or linkage to care) over time in a sub-Saharan African setting. We have observed a substantial increase in the rate of viral suppression, by approximately 50%, during a four year period. Although this result is encouraging, we acknowledge that only 45% of our sample had a suppressed viral load in 2014. This result is currently well below the UNAIDS benchmark to ensure 73% of all HIV infected patients have virologic suppression by 2020.



[Figure 1]

TUPEC0874

Residual populations at risk for HIV transmission in a generalized epidemic at the UNAIDS 90-90-90 target: a cross-sectional analysis from Botswana

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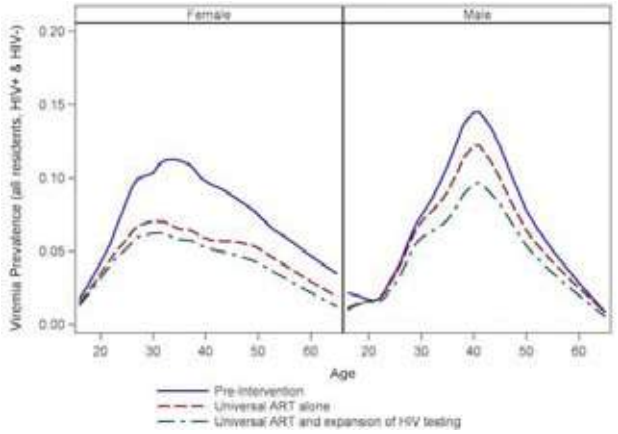
Background: Prior to universal ART, Botswana had nearly achieved the UNAIDS 90-90-90 target (83%, 87%, and 97%, respectively) in 30 surveyed communities, but annual HIV incidence remained >1%. We sought to describe residual populations at risk for transmitting HIV to guide prevention efforts.
Methods: During a baseline survey for an HIV prevention trial, we performed HIV testing (CD4 and HIV viral load, if positive) among residents (age 16-64) in a 20% random household sample in 30 small Botswana communities. Among persons with HIV viremia (>400 copies/mL), we describe knowledge of HIV status, ART history, and CD4 cell count (eligibility for ART ≤350 cells/μL at time). We modeled the effects of expanded HIV testing and/or universal ART on community viremia prevalence by age.
Results: A total of 12,610 residents participated, including 3,596 (29%) with HIV infection, 932 (26%) of whom had HIV viremia. Community prevalence of HIV viremia (including all residents, both HIV+ and HIV-) was 7.4% (women 7.9%, men 6.5%, Figure 1). Lack of knowledge of HIV+ status was the leading contributor to viremia (Table 1). Modeling projected that transition to universal ART alone would reduce viremia prevalence to 5.2% (-2.7%) in women and 5.6% (-0.9%) in men. Concurrent expansion of HIV testing (reduction in unknown HIV+ status by 50%) with universal ART lead to projected viremia prevalence of 4.5% in women (-3.4%) and 4.6% men (-1.9%).



[Figure 1. Measured community prevalence of viremia (all residents, including HIV+ and HIV-) prior to intervention and projected prevalence with universal ART with/without expansion of HIV testing]

Cause		Female	Male	Total
Unaware HIV+		233 (37%)	167 (56%)	400 (44%)
Aware HIV+, ART-naive				
	CD4 Eligible but not yet on ART	110 (17%)	45 (15%)	155 (17%)
	CD4 Ineligible and not on ART	219 (34%)	43 (15%)	262 (28%)
Aware HIV+, history of ART				
	Default from ART	12 (2%)	11 (4%)	23 (2%)
	Virologic failure	62 (10%)	30 (10%)	92 (10%)

[Table 1: Leading contributing cause for viremia]

Conclusions: Nearing the UNAIDS 90-90-90 targets, community prevalence of HIV viremia is high in Botswana. Women previously ineligible for ART by CD4 count and men unaware of their HIV status account for a disproportionate burden of viremia.

TUPEC0875

Closing the 90-90-90 Gap: ZAMPHIA, 2016

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Background: Findings from the 2016 Zambia Population-based HIV Impact Assessment (ZAMPHIA) indicate that Zambia has achieved significant progress towards meeting UNAIDS 90-90-90 goals. To better target expansion of HIV treatment services, ZAMPHIA data can be used to identify gaps in uptake of HIV testing counseling, initiation of antiretroviral therapy (ART), and adherence leading to viral load suppression (VLS).
Methods: A nationally representative, household-based sample of adults and children was recruited in all 10 Zambian provinces. Consenting participants provided demographic and clinical information and blood samples for household HIV testing per national guidelines. HIV-seropositive results were confirmed via a supplemental assay; viral load and limiting antigen (LAg) avidity testing were performed on all HIV-seropositive samples. VLS was defined as HIV RNA < 1000 c/ml.
Results: In 2016, 19,029 adults (15-59 y) from 10,959 selected households provided interviews and blood samples. One-third (32.7% [95% CI 30.2-35.3]) of persons living with HIV (PLHIV) reported being unaware of their HIV status; this was highest among adults ages 15-24 y (58.2% [52.0-64.3]).
HIV-seropositive males ages 25-34 y (58.2% [49.5-66.9]) and 35-44 y (32.2% [25.9-38.4]) had higher prevalence of unknown HIV status relative to females of the same age (25-34 y: 29.0% [24.5-33.4]; 35-44 y: 20.8%[16.9-24.7]).
Among PLHIV who reported being aware of their status, 14.6% (95% 12.5-16.7) reported they were not receiving ART; this was highest among adults ages 15-24 y (21.5% [13.2-29.7]) and 25-34 y (22.1% [17.2-27.0]).
VLS among PLHIV who reported receiving ART was 89.2% [87.4-91.0].
VLS was lowest among 15-24 y males; 48.5% (23.0-73.9) were not virally suppressed. Gender differences did not reach statistical significance for reported receipt of ART and VLS.
Conclusions: Young adults (15-34 y) living with HIV in Zambia had the lowest prevalence for each of the 90's: awareness of their HIV status, receipt of ART, and VLS. Results from ZAMPHIA confirm the need to increase HIV testing, treatment, retention and adherence for both young men and young women, in an effort to make further progress in controlling Zambia's HIV epidemic.

TUPEC0876

Unmet 90-90-90 targets among adolescent girls and young women living with HIV in Malawi

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Background: In 2015, adolescent girls and young women (AGYW), aged 15-24 years in Sub-Saharan Africa, accounted for 25% of new HIV infections among adults despite being 17% of the adult population. Nationally representative data on HIV for AGYW in Malawi are limited in scope. This analysis describes the burden of HIV among AGYW in Malawi and their progress towards achieving the UNAIDS 90-90-90 targets.
Methods: The Malawi Population-based HIV Impact Assessment (MPHIA), a national household survey, was conducted from November 2015 to August 2016 to measure national HIV incidence and sub-national viral load suppression (VLS). Participants answered questionnaires and provided blood for home-based HIV testing using the national rapid HIV testing algorithm, followed by laboratory-based confirmation using Geenius HIV 1/2 Confirmatory Assay (Bio-Rad). Viral load measurements <1,000 copies/mL were considered suppressed. Weighted point estimates and survey-adjusted 95% confidence intervals (CIs), calculated using the Jackknife replication method, are presented for the number of young women living with HIV (using population projections from the Malawi National Statistical Office), prevalence, awareness of HIV status, self-reported antiretroviral therapy (ART) status and VLS.
Results: Of 4,592 eligible women, 3,571 (78%) responded to the questionnaire and provided blood. Of those tested, 169 were HIV positive, resulting in a 3.7% prevalence (95% CI: 2.9-4.5); 1.9% (95% CI: 1.2-2.8) in 15-19 year olds (n=38) and 5.2% (95% CI: 3.9-6.6) in 20-24 year olds (n=131). HIV prevalence was significantly greater in urban (6.3%; 95% CI: 4.4-8.2) compared to rural areas (3.0%; 95% CI: 2.1-3.9). Of the 61,855 (95% CI: 48,119-75,593) AGYW estimated to be HIV infected, 58.6% (95% CI: 49.2-68.3) were aware of their HIV positive status; 76.9% (95% CI: 57.6-96.1) of those aware of their status were on ART, and 79.3% (95% CI: 67.6-91.1) of those on ART were virally suppressed. Overall VLS among all HIV positive AGYW was 52.0% (95% CI: 41.0-62.8%).
Conclusions: These results indicate a gap among AGYW in awareness of their HIV positive status, receiving ART and achieving viral suppression compared to the UNAIDS 90-90-90 targets. Concerted efforts are needed to improve prevention, diagnosis, treatment initiation and adherence among AGYW.

TUPEC0877

Geographical distribution of HIV burden in Malawi: where is the gap in achieving the 3rd 90?

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Background: Although Malawi has a generalized epidemic, previous studies have shown that the prevalence varies widely by geography, gender and other socio-economic indicators. We recently conducted a survey to measure national and sub-national prevalence and viral load suppression in Malawi to understand the progress in controlling the epidemic.
Methods: Malawi conducted a Population-based HIV Impact Assessment survey between November 2015 and August 2016, stratified by seven geographical zones (Central East, Central West, and Lilongwe City in the Centre, Blantyre City, South East, and South West in the South and North). This household level survey assessed HIV prevalence in 0-64 year olds and viral load suppression in 15-64 year olds. The estimates and confidence intervals accounted for the survey design. Home-based HIV rapid testing using the national algorithm and Geenius supplemental test for confirmation at satellite labs were conducted. HIV positive samples were centrally tested for viral load suppression and recency of infection using LAg-Avidity EIA. Viral load suppression was defined as <1,000 HIV RNA copies/mL.
Results: The weighted national HIV prevalence among 15-64 year olds was 10.6% [females (12.8%) and males (8.2%)]. By region, HIV prevalence was highest in the South particularly Blantyre City (18.2%) and lowest in Central East (5.3%) and Central West (5.8%). HIV prevalence in the Lilongwe City (11.8%) was higher than the other two zones in the Centre. Blantyre City had both the highest prevalence and the lowest viral load suppression among adults living with HIV, as seen in table.

Zone	HIV Prevalence % (95% C.I.)	% HIV Population Virally suppressed
North	7.3 (5.8-8.7)	66.9 (60.7-73.1)
Central-East	5.3 (4.0-6.6)	63.7 (51.1-76.3)
Central-West	5.8 (4.9-6.8)	70.4 (63.0-77.9)
Lilongwe City	11.8 (10.4-13.1)	65.5 (60.3-70.7)
South East	15.6 (13.4-17.8)	68.8 (62.3-75.3)
South West	15.9 (14.0-17.8)	70.3 (65.4-75)
Blantyre City	18.2 (16.4-19.9)	59.5 (53.6-65.5)
Total	10.6 (9.9-11.2)	67.6 (65.0-70.2)

[Geographical distribution of HIV indicators in Mal]

Conclusions: The HIV epidemic in Malawi continues to show geographical variation and gender disparities with the Southern Region being the most affected and with some of the largest gaps in achieving the viral load suppression target. This suggests that the HIV program in Malawi needs strengthening in the Southern Region particularly Blantyre City.

TUPEC0878

Critical situation concerning HIV exposure among people who inject drugs in France: results from ANRS-Coquelicot surveys and HIV monitoring system

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Background: Harm reduction policies has had a marked impact on HIV transmission in PWID (People Who Inject Drugs) but a much more limited impact on HCV. Therefore, harm reduction strategies are currently more focused on HCV prevention. However, some recent indicators presented here show that the French situation concerning HIV dynamic in PWID remains critical.
Methods: We used data from the mandatory HIV surveillance system in France, adjusted for under-reporting, reporting delays and missing values. Diagnoses at an advanced stage of HIV infection were defined as diagnoses with a CD4 count below 200 cells/mm3 excluding HIV acute illness, or with an AIDS defining disease regardless of the CD4 count.
We also used data from the ANRS-Coquelicot cross-sectional surveys that included a sampling plan (Time Location Sampling combined with the Generalized Weight Sampling Method) and were conducted in 2004 and in 2013 among 1,718 PWID who had injected drugs at least once in their life. Socio-behavioral data were collected from face-to-face interviews. Self-finger prick blood samples were collected on dried blood spots.
Results: PWID are more likely to be diagnosed at an advanced stage of infection (38% of new diagnoses in 2015) than MSM (18%) and heterosexually-infected people (34% among men, 27% among women). In 2012, incidence in PWID - who constituted the second most exposed group to HIV - was estimated at 86 per 100 000 person-years and has not decrease since 2003. This incidence was much higher than that in heterosexuals born in France (5/100,000) or abroad (44/100,000). The ANRS-Coquelicot surveys highlight that 26% of PWID declared they shared their syringes at least once during the previous month compared with 13% in 2004. Furthermore, in 2013, 30% of PWID declared difficulties in obtaining syringes, even in big cities as Paris.
Conclusions: All these indicators show that conditions favouring exposure to infectious diseases including HIV in PWID are still present. Our data indicate that France should remain vigilant with respect to the HIV epidemic in PWID. HIV screening is still insufficient and new harm reduction policies, focusing more on socio-structural interventions, are urgently needed.

TUPEC0879

Factors associated with longer engagement in methadone maintenance therapy among HIV-positive people who use illicit opioids

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Background: Compared to non-drug using peers, HIV-positive individuals who use illicit drugs exhibit higher rates of suboptimal HIV treatment outcomes. For many with opioid dependence, methadone maintenance therapy (MMT), is required to lower risks of negative health outcomes. Thus far, factors associated with longer engagement in MMT among HIV-positive individuals has not been described. Hence, we set out to describe behavioral, social and clinical factors associated with engagement in MMT among a cohort of HIV positive illicit opioid users in Vancouver, British Columbia.
Methods: Data was obtained from the AIDS Care Cohort to evaluate Exposure to Survival Services (ACCESS), an outgoing prospective cohort of HIV-positive illicit drug users linked to clinical records in universal no-cost HIV treatment and care. The primary outcome of interest was reporting being on MMT at the time of study interview. Baseline characteristics of HIV-positive individuals were obtained and a generalized estimating equation (GEE) with Poisson regression was used to longitudinally estimate relationships between the primary outcome and explanatory variables. In the final multivariate model, all variables with p <0.05 were included
Results: From December 1 2005 to June 1 2015, 586 HIV-positive, antiretroviral therapy (ART) exposed individuals with a history of illicit opioid use or MMT use were recruited. At baseline, there was a positive association between those on MMT and use of ART (OR 2.38, 95% CI:1.44-3.93). Over the study period, a positive association was found between longer engagement in MMT and achieving an undetectable viral load (VL) (ARR 1.30, 95% CI: 1.22-1.38) as well as having at least a high school diploma (ARR 1.14, 95% CI: 1.08-1.21). Engagement in MMT was negatively associated with daily heroin injection (ARR 0.62, 95% CI: 0.56-0.69) and daily methamphetamine use (ARR 0.40, 95% CI: 0.28-0.56).
Conclusions: In this community-recruited cohort of illicit-opioid using HIV-positive individuals, engagement in MMT was associated with positive health and social factors including maintenance of an undetectable viral load, obtaining at least a high school education, and decreased participation in the use of heroin and methamphetamines. These findings strongly reaffirm the use of opioid substitution therapy in the management of HIV-positive individuals with opioid use disorder.

TUPEC0880

Impact of HIV/AIDS on the psychological behavior of children from HIV affected families in Myanmar

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Background: Information on the impact of HIV/AIDS on the psychological behavior of children on a national scale is lacking in Myanmar. Therefore, a nationwide survey was conducted to identify and compare the psychological behaviors of children from HIV affected families with children from neighborhood.
Methods: A community-based, cross-sectional comparative study was done in 30 townships of Myanmar in 2014. Study children were children under 18 years who have/had HIV infected parents regardless of their own HIV status. Age group matched children were recruited from neighborhood. Parents/guardians of 1,511 study children and 1,511 controls were interviewed by using a pre-tested, structured questionnaire. In-depth interviews were conducted with providers and parents/guardians.
Results: Mean age of the children was 8.7±4.1 years and 46.8% of study children were orphans. Higher proportion of study children stayed in extended families (36% vs. 29%). Among 10 to 14 years old children, 8.6% of study children was working for their living compared to 4.4% of the control group (p<0.05). Over 24% of study children were HIV infective and 75% have initiated ART. Psychological behavior was measured by the Strengths and Difficulties Questionnaire (SDQ) which included 22 items organized into emotional, conduct problems, hyperactivity, peer relationship and pro-social behavior. Regarding the total difficulties score, higher proportion of study children were seen in abnormal category than their neighborhood children (13.4% vs. 9.1%, p<0.01). Similarly, higher percentage of study children were in the abnormal emotional behavior (24% vs. 18%, p< 0.01) and abnormal conduct behavior categories (15% vs. 11%, p<0.05). These findings pointed out the higher risk of developing behavioral problems among the study children in comparing to neighborhood children. Many key informants highlighted the issues of vertically HIV infected adolescents including emotional and behavioral problems, ART non-compliance and unmet need of reproductive health information. Many health care providers indicated psychological support as a priority especially for the HIV infected adolescents.
Conclusions: The needs of HIV positive adolescents should be addressed through the provision of psychological support and reproductive health information. In conclusion, long term strategic plans should be drawn up for psychological support for the children from HIV affected families.

TUPEC0881

HIV serostatus disclosure from partners before sex: results from an online survey of Chinese men who have sex with men

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Background: HIV serostatus disclosure before sex can facilitate serosorting, condom use and potentially decrease the risk of HIV acquisition. However, few studies have evaluated HIV serostatus disclosure from different partners before sex. We examined the rates and correlates of HIV serostatus disclosure from different types of partners before sex among an online sample of men who have sex with men (MSM) in China.
Methods: An online cross-sectional study was conducted among MSM in eight Chinese cities in July 2016. Participants completed questions covering sociodemographic information, sexual behaviors, HIV testing (including HIV self-testing)

history, self-reported HIV status, post-test violence, and whether or not HIV test results were disclosed between them and their different kinds of most recent partners before sex. Participants or their partners who never tested for HIV were defined as undisclosed.
Results: Overall, 2105 men completed the survey. Among them, 85.9% were never married, and 35.4% had high school or less education. 346/1678 (20.6%) of men received HIV serostatus disclosure from their regular male partners, which was significantly lower than the disclosure rate of the participants to their regular partners (704/1678 42.0%, P<0.001). HIV serostatus disclosure rates from other types of partners were: 17.8% (287/1608) from casual male partners, 16.2% (62/383) from regular female partners, and 16.8% (48/286) from casual female partners. Multivariable analysis indicated that disclosure from regular male partners was associated with a higher likelihood of post-test violence (adjusted OR (aOR) =5.18, 95% CI: 1.53-17.58). Compared to never self-tested participants, participants ever self-tested for HIV were also more likely to receive HIV status disclosure from regular male partners (aOR=1.92, 95% CI: 1.50-2.44).
Conclusions: This study showed that HIV serostatus disclosure from partners was uncommon among Chinese MSM. Interventions and further implementation research to facilitate safe disclosure are urgently needed for MSM.

TUPEC0882

HIV-related stigma, racial discrimination and gender discrimination are associated with reduced antiretroviral adherence and lower health-related quality of life among a national cohort of women living with HIV in Canada

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Background: HIV-related stigma has well-known deleterious health impacts among women living with HIV (WLWH). Less is known, however, about the effects of multiple, intersectional forms of stigma. The study objective was to examine associations between HIV-related stigma, racial and gender discrimination and WLWH's health outcomes.
Methods: We used baseline data from a national cohort study with WLWH to test a conceptual model of pathways between intersectional stigma (HIV-related stigma, racial discrimination, gender discrimination) and antiretroviral adherence and health-related quality of life (HrQOL) (mental and physical dimensions). We hypothesized that stigma would be associated with reduced antiretroviral (ART) adherence (< 90% adherence vs. ≥90%) and lower HrQOL, and that social support and HIV disclosure concerns would mediate these relationships. We conducted structural equation modeling using maximum likelihood estimation to test the model.
Results: Participant (n=1425) mean age was 42.8 (SD=10.62); 41% of participants were Caucasian, 22% Aboriginal, and 29% African/Caribbean/Black. The confirmatory factor analysis of the intersectional stigma construct demonstrated good model fit with three factors (HIV-related stigma, racial discrimination, gender discrimination) (CFI=0.91, TLI=0.90, RMSEA=0.05). In independent models, HIV-related stigma, racial discrimination and gender discrimination were each associated with: lower social support, reduced mental and physical HrQOL, increased HIV disclosure concerns, and reduced ART adherence. In the simultaneous model, HIV-related stigma had a significant indirect effect on reduced ART adherence, fully mediated by HIV disclosure concerns. HIV-related stigma had significant direct and indirect effects on mental HrQOL, partially mediated by social support and HIV disclosure concerns. HIV-related stigma had a significant indirect effect on physical HrQOL, fully mediated by social support. Racial discrimination had a significant direct effect on ART adherence, partially mediated by social support and HIV disclosure concerns. Gender discrimination had significant direct and indirect effects on mental and physical HrQOL, partially mediated by social support. The model fit the data well (CFI=0.96, RMSEA=0.062).
Conclusions: Associations between intersectional stigma—HIV-related stigma, gender and racial discrimination—and ART adherence and HrQOL are multi-faceted and associated with HIV disclosure concerns and social support. Interventions to increase ART adherence and HrQOL among WLWH must address multiple forms of stigma, HIV disclosure strategies, and build social support.

TUPEC0883

A pilot study comparing sexual risk data collected via smartphone application diaries and online survey questionnaire among at-risk HIV-negative men who have sex with men

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Background: Men who have sex with men (MSM) are disproportionately affected by HIV in the US. Self-reports of sexual risk behaviors among MSM may be biased and unreliable. The study objectives were to test the feasibility and acceptability of using smartphone app-based diaries for collection of sensitive sexual behavioral risk data among MSM in New York City.
Methods: Participants were recruited via online platforms and referral letters. Inclusion criteria were male at birth, anal sex with a man or transwoman in the last month, age 18-50 years, and self-report being HIV negative or unknown status. After informed consent, participants were randomized into 3 study arms with smartphone sex diary entries daily, weekly, or after sex. Participants completed a self-administered online survey at enrollment and at 30 days. Data collected from the surveys were compared with data from the smartphone diaries using kappa statistics.
Results: 30 MSM enrolled in the study; median age was 32 years. Mean number of anal sex partners in the last 30 days was 4. Smartphone diary completion was higher among the weekly arm (97.5%) than the daily (70.6%) (p=.025). When compared to online survey data collected at day 30, agreement in reported number of anal sex partners in the 3 sex app arms was low (kappa range: 0-0.23). The number of protected insertive and receptive anal sex acts reported by the daily study arm showed moderate agreement with the survey (kappa= 0.58 and 0.53, respectively). In the weekly study arm for the same categories, the kappa statistics were 0.231 and 0.318 respectively. Participant feedback was largely positive with 89.3% finding it to be "very easy" or "easy" to complete their sex diaries.
Conclusions: It is feasible to collect sexual risk behavior data using a smartphone app-based diary among MSM. Completion of diaries once weekly is more desirable as participants had a high completion rate. There was low to moderate agreement of data between the diary app and online survey across behaviors. This pilot study supports the use of mobile devices to obtain sensitive behavioral information that may otherwise not effectively be obtained via surveys with longer recall periods.

TUPEC0884

HIV testing patterns in MSM attending community-based voluntary counselling and testing services in Europe: preliminary results from COBA-Cohort (The Euro HIV EDAT Project)

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Background: The COmmunity-BAsed Cohort (COBA-Cohort), implemented in the framework of the Euro HIV EDAT project, aims to collect common data among HIV-negative MSM attending community-based voluntary counselling and testing (CBVCT) services in 6 European countries. The objective of the present analysis was to identify patterns in HIV-testing in the preliminary baseline data of COBA-Cohort.
Methods: All HIV-negative MSM >18 attending one of the 17 participating CBVCT services are invited to participate in COBA-Cohort. The first site started enrolling in January 2015, the last one in October 2016. We performed a Latent Class Analysis (LCA) using 5 categorical variables: time since last HIV test, main reason for the present test, steady relationship type, condomless anal intercourse (CAI)

with the last casual partner, and willingness to use PrEP. The LCA was adjusted for the country of participants (cluster option), and the number of classes relied on information criteria and interpretability of the item-response probabilities.
Results: Among the 3071 HIV-negative MSM enrolled in COBA-Cohort from commencement to 06/30/2016, 21% reported an HIV test < 6 months prior to enrolment, and 15.8% were never tested. Regular control was the main reason for the baseline HIV test (71.4%). 49.2% reported only casual partners in the last 12 months, 12.9% only steady partners and 31.6% both. CAI with the last casual partner was reported by 19.5% of participants and willingness to use PrEP by 40.7%. The first class (58% of all participants) described regular testers reporting condom use at last casual encounter; the second class (18%) grouped regular testers in steady/exclusive relationship; the third class (18%) was composed of regular testers having both CAI and non-CAI with casual partners, but no steady partner; and the last class (6%) grouped men recently tested but not coming on a regular basis, reporting CAI and willingness to use PrEP.
Conclusions: This LCA brings a first insight of HIV testing patterns in relation to several basic risk indicators, and suggests that the most regular testers are not necessarily the most at-risk individuals. Further explorations of the COBA-Cohort's data will allow to better characterise these profiles and identify possible changes over time.

TUPEC0885

Association between self-report measures of treatment adherence and viral suppression among people living with HIV/AIDS in China: optimal recall period and item content

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Background: Strong correlations between self-report treatment adherence measures and HIV viral load have been reported in several studies. Few studies, however, have assessed the ability of treatment adherence measures differing in recall time frames and item contents in predicting viral suppression. This study aims to compare the performance of four self-report treatment adherence measures in predicting viral suppression.
Methods: A cross-sectional study among 2,987 HIV patients recruited from 12 cities/counties in Guangxi, China were used in this study. Medication adherence behaviors were collected by self-administered questionnaires and most recent viral load was obtained from patients' medical records. Adherence was dichotomized at the cut-off of 90%. Viral suppression was defined as having an HIV viral load below 400 copies/ml. Tetrachoric correlation was used to assess the correlation between adherence and viral suppression. The ability to predict viral suppression was evaluated by calculating the area under the receiver-operating characteristic (AUROC) curve. Multivariate logistic regression was used to assess the association between adherence measures and viral suppression controlling for demographics, depression, and HIV risk-related behaviors.
Results: The correlation ranged from 0.49 to 0.73 between the four adherence measures, and from 0.11 to 0.24 between adherence measures and viral suppression. The difference between AUROC curves was not statistically significant. Viral suppression was positively associated with one-month adherence measured by missed doses (aOR = 2.12, 95% CI 1.08, 4.17), but not by missed days (aOR = 1.63, 95% CI 0.80, 3.31). Both 3-day (aOR = 2.12, 95% CI 1.08, 4.17) and weekend (aOR = 2.51, 95% CI 1.14, 5.54) adherence were positively associated with viral suppression. Time on treatment (aOR ranging from 1.02 to 1.03) and injection drug use (aOR ranging from 0.52 to 0.55) were associated with viral suppression.
Conclusions: One-month recall periods can be of similar accuracy in predicting viral suppression compared with shorter periods. Questions asking about number of missed doses may be more accurate than those asking about missed days, which might be due to differences in levels of dosing schedules. Therefore, adherence measurement items may need tailoring to specific dosing regimens.

TUPEC0886

Can regular HIV testing and counselling modify sexual behaviour in HIV-negative Malian MSM? (CohMSM ANRS 12324 - Expertise France)

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Background: The promotion of safe sex practices is necessary in HIV-negative men who have sex with men (MSM), especially for those who regularly attend sexual health centres. We aimed to assess possible changes in sexual behaviours of MSM in West-Africa, in the context of regular, comprehensive follow-up in healthcare facilities according to international recommendations.
Methods: Data were obtained from an interventional cohort of HIV-negative MSM implemented in Western Africa (CohMSM). Among participants enrolled in Mali, we focused on the first 90 MSM who completed 12 months of follow-up comprising quarterly HIV-testing and counselling. Socio-behavioural data were collected at baseline, 6 and 12 months, using a standardised face-to-face questionnaire. Outcomes of condom use during anal or oral sex, and number of sexual partners in the previous 6 months were used as indicators of sexual risk behaviours. A multistate Markov model was used to predict the evolution of these outcomes over time using estimated transition probabilities between baseline and M12.
Results: 174 MSM were recruited with a median age of 24 years (Interquartile Range=22-27), 90% of them were single and 78% reported financial difficulties. No significant differences were found regarding socio-demographic characteristics between the 90 MSM sub-group and the other Malian participants. Markov modelling highlighted that the probability of participants who practiced condomless anal sex at baseline changing to systematic condom use at M12 was 0.11. In contrast, the probability of participants with systematic condom use during anal sex at baseline stopping condom use was 0.04. With respect to oral sex, the probability of participants adopting systematic condom use was higher than that of stopping condom use (0.07 versus 0.05). MSM with multiple partners at enrolment were more likely to still have multiple partnerships at M12 (i.e., 0.86).
Conclusions: Predictions of risky sexual behaviours at one year of follow-up showed a modest impact of regular HIV-testing and counselling on the sexual practices of HIV-negative MSM. In a context where HIV incidence remains high among MSM, comprehensive biomedical interventions including both early ART and PrEP are needed to have a stronger impact on HIV incidence.

TUPEC0887

90-90-90 HIV targets will not be enough to achieve global incidence reduction targets

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Background: The UNAIDS 90-90-90 target aims to have 90% of people living with HIV knowing their status, 90% of people diagnosed on treatment, and 90% of people on treatment with suppressed viral loads by 2020. We estimated the HIV incidence reduction in Australia corresponding to:
(1) achieving the UNAIDS 90-90-90 targets by 2020 and;
(2) achieving extended targets of 95-95-95 by 2030, in combination with various scale-ups of HIV testing, primary prevention and pre-exposure prophylaxis (PrEP) among high-risk men who have sex with men (MSM).
These projections were evaluated against the ending AIDS target of achieving a 90% reduction in HIV incidence by 2030 compared to 2010 levels.
Methods: A mathematical model was used to project annual HIV incidence in Australia between 2016 and 2030 for all combinations of HIV care cascade targets, testing frequencies, primary prevention coverages and levels of PrEP scale-up.
Results: Achieving 90-90-90 by 2020 was estimated to reduce incidence by 8% from 2010 levels; however beyond this continued improvements were required to prevent incidence from increasing. Achieving 95-95-95 by 2030 was estimated to reduce incidence by 14% from 2010 levels. This was improved to 29% by testing low- / high-risk MSM two / three times per year respectively; to 39% by including a 5-year scale-up to 30% PrEP coverage among high-risk MSM; and to 55% by increasing condom use with casual partners from an estimated 42% to 60%. However, it was only with 95-95-95, two / three test per year for low- / high-risk MSM, 100% high-risk MSM PrEP coverage and 100% condom use that an 89% reduction in incidence was possible by 2030.

Conclusions: Even if the UNAIDS care cascade targets are met or exceeded, additional coverage of prevention programs will be required to achieve a 90% reduction in HIV incidence by 2030.

TUPEC0888

The impact of antiretroviral treatment on adult mortality trends in South Africa

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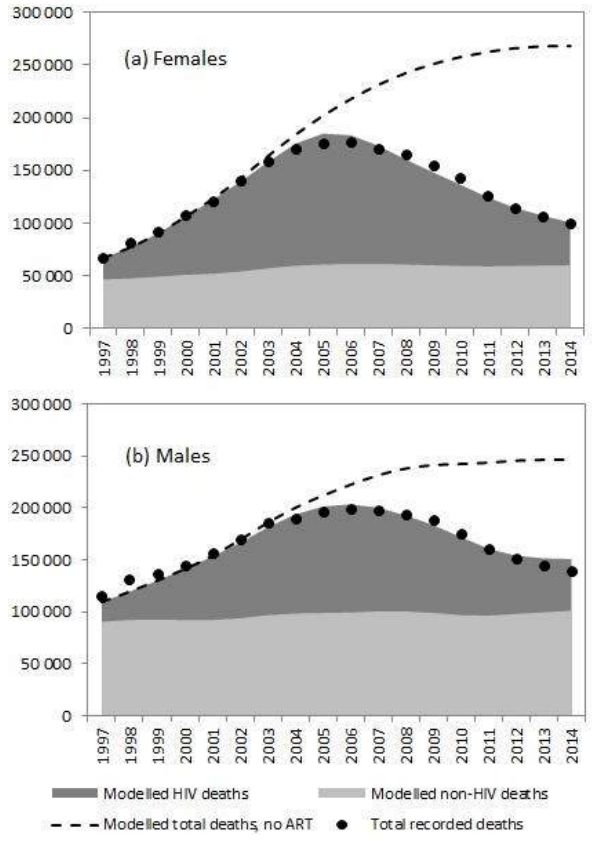
Background: Substantial reductions in adult mortality have been observed in South Africa since the mid-2000s, but there has been no formal evaluation of how much of this decline is attributable to the impact of antiretroviral treatment (ART).
Methods: A combined demographic and HIV model was developed for South Africa. Estimates of mortality rates in ART patients were obtained from the International Epidemiology Databases for the Evaluation of AIDS Southern Africa (IeDEA-SA) collaboration. The model was calibrated to HIV prevalence data and death data from the South African vital registration system, which records 94% of adult deaths, using a Bayesian approach. To evaluate the impact of ART, the model was used to simulate the mortality trend that would have been expected in the absence of ART.
Results: The model matched the recorded death data closely (Figure). In the period up to the end of 2014, 2.73 million adult HIV-related deaths occurred in South Africa. Adult HIV deaths peaked at 232 000 per annum in 2006 and declined to 97 000 in 2014, a reduction of 75% when compared to the scenario without ART (Figure). In the period up to the end of 2014, the South African ART programme is estimated to have saved 6.36 million life years in adults (95% CI: 5.55-6.92 million). This compares with a potential saving of 9.12 million (95% CI: 8.01-9.91 million) life years that might have been achieved had South Africa moved swiftly to implement WHO guidelines and achieved high levels of ART uptake in HIV-diagnosed individuals from 2004.



[Figure: Trends in adult deaths (ages 20-59)]

Conclusions: ART has had a dramatic impact on adult mortality in South Africa, but delays in the rollout of ART, especially in the early stages of the ART programme, have contributed to the loss of 2.8 million life years.

TUPEC0889

Acceptability of male circumcision by women partners in a clinical trial in the Dominican Republic

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Background: Voluntary Medical Male Circumcision (VMMC) serves as an effective HIV prevention strategy in high prevalence areas. A recent single arm clinical trial of VMMC in the Dominican Republic (DR) reported high acceptability and low complication rates in circumcised men. Little is known about the acceptability of VMMC in sex partners of circumcised Dominican men. The aim of this study was to assess satisfaction, acceptability, and sexual health in women before and after their partner's circumcision.
Methods: We recruited regular sex partners of men circumcised in a clinical trial of VMMC in the DR. Willing participants either joined focus group discussions or completed a survey on acceptability, sexual practices, and health. Focus groups were audio-recorded, transcribed verbatim, and coded using Atlas.ti software. We analyzed survey data with SAS (v9.3) to generate descriptive statistics bivariate results.
Results: Median age of women surveyed (n=55) was 28 years (IQR 24-34) and 80% had children. Almost universally (98%) women were satisfied with their partner's circumcision and would consider circumcising their sons (98%). The majority of women (89%) were more attracted to their partner after circumcision and 98% were more satisfied with sex after circumcision. Women who reported vaginal and urinary symptoms (dysuria, bleeding, abnormal vaginal discharge, ulcers) prior to their partner's circumcision reported a substantial decrease of these symptoms after circumcision. All women were very satisfied with their partner's hygiene and the majority (>70%) felt more protected against HIV/STI. Almost all (98%) had recommended the procedure to other couples. Focus group data confirmed high levels of acceptability and satisfaction, primarily due to perceived improvements in their sex life and health.
Conclusions: Regular sex partners of circumcised men perceived VMMC to improve sexual health and satisfaction. These findings suggest that VMMC may have a positive impact on women and that they could be engaged to promote VMMC.

TUPEC0890

Impact of TasP, PrEP and condoms on the HIV epidemic among MSM in British Columbia

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Background: Gay, bisexual and other men who have sex with men (MSM) are disproportionally affected by the HIV epidemic. In British Columbia (BC), the HIV epidemic has decreased among people who inject drugs. However, the same trend has not been observed among MSM. Today, condoms, Treatment as Prevention (TasP), and Pre-Exposure Prophylaxis (PrEP) are highly efficacious HIV prevention strategies that can prevent HIV transmission in MSM. We conducted this study to assess how condoms, TasP and PrEP can be used in combination to prevent further HIV infections among the MSM population in BC.
Methods: We designed a mathematical model that combines individual-based knowledge of clinical, behavioral and epidemiological aspects of the HIV epidemic among MSM in BC. The MSM population was divided into low- and high-risk of acquiring/transmitting HIV, based on the US CDC HIV Incidence Risk Index for MSM. We assessed the effect of increasing condom use and PrEP access. For PrEP, we evaluated universal (all MSM are eligible) and targeted (only high-risk MSM are eligible) scenarios. We studied the effect of increased TasP by decreasing the time to HIV diagnosis, to antiretroviral treatment (ART) initiation, and increasing the time retained on ART. The effect of the interventions at five and ten years was evaluated on HIV incidence, all-cause mortality, HIV prevalence, and the Control Reproduction Number Rc.
Results: Optimizing all aspects of TasP and increased provision of PrEP to high-risk MSM was the most effective strategy (74% reduction in incidence, Rc as low as 0.63). Increasing condom use maintained the effectiveness of the strategy while limiting the extent of targeted PrEP coverage. TasP was the only intervention that significantly decreased mortality. The most influential aspect of TasP was the time individuals were retained into treatment.
Conclusions: The results provided by this model showed that the optimization of TasP, by promoting timely HIV diagnosis, treatment initiation and higher retention,

combined with the distribution of PrEP to MSM at high risk of HIV infection was the most successful strategy to control the HIV epidemic among MSM. Consistent use of condoms should continue to be actively promoted to reduce HIV transmission by all MSM.

TUPEC0891

Using the AIDS epidemic model to guide programs of a rapidly increasing epidemic

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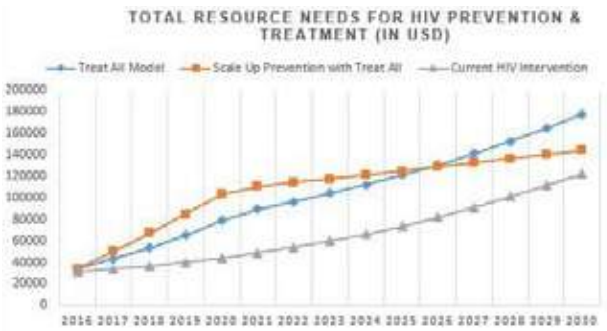
Background: Current treatment guidelines in the Philippines are not aligned with WHO treat all recommendation. The 2016 Philippine AIDS Epidemic Model (AEM) provides a means to determine the potential impact and relevance of a treat all strategy for the country's HIV program. Given the diverse distribution of the HIV epidemic in the country, the Philippine AEM was constructed using sub-national models.
Methods: Five sub-national models were developed and combined to construct the Philippine AEM using key inputs population size estimates, HIV prevalence, risk and protective behaviors, and anti-retroviral (ART) coverage. Unit cost of prevention and treatment interventions were derived from the 2014 Philippine AEM. Adjustments to treatment parameters were done for the treat all scenario, while prevention parameters were sustained. A combined scale up prevention and treat all strategy was modeled by increasing prevention coverage along with treatment adjustments.
Results: The 2016 Philippine AEM estimates 55,005 people living with HIV (PLHIV); only 30% are currently on ART. New infections are estimated to occur at 29 cases daily, and are expected to increase by 607% in 2030 if current efforts are maintained. Meanwhile, a treat all strategy averts 68% of new HIV infections, and prevents 74% of HIV-related deaths. A combination strategy not only averts significantly more new HIV infections (90%) and prevents 10% more HIV-related deaths than a lone treat all approach, it also offers a lower resource need from the program in the long run.



[Figure 1. Total resource needs for HIV prevention & treatment (in USD)]

Conclusions: A combined prevention scale up and treat all strategy is highly recommended given the potential it offers for halting and reversing the Philippine HIV epidemic coupled with a more economical resource requirement in the long-term. Current prevention coverage is at 30%, increasing this to 60% will already make a dent in the epidemic, however a 90% coverage was found to be most effective.

TUPEC0892

Valuing the synergistic benefits of multipurpose HIV and pregnancy protection: an economic evaluation of multipurpose prevention products in South Africa

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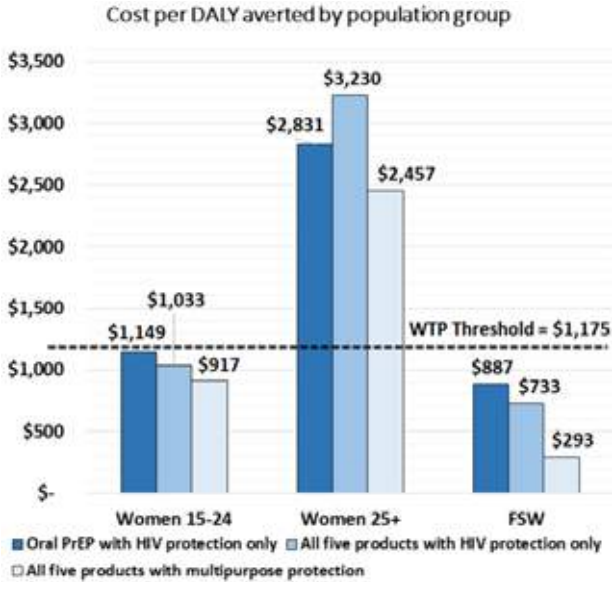
Background: The development of antiretroviral-based HIV prevention products has substantially changed the prevention landscape. A promising area of research is the development of candidate multipurpose prevention technologies (MPTs), products which could offer users protection from HIV, other STIs, or unintended pregnancy. We estimate the cost-effectiveness of a range of potential single- and multi-purpose prevention products.
Methods: We combine a cost model with a simple, static model of product impact to estimate the cost-effectiveness of five MPTs - oral PrEP, intravaginal rings, injectable ARVs, microbicide gels, and SILCS diaphragms used in concert with gel. We account for the preferences of end-users by predicting uptake using a discrete choice experiment (DCE) among 362 general population women (HIV negative, aged 16-45) and 122 female sex workers (FSW) (HIV negative, aged 18-45) in South Africa. DCE results were also used to predict additional uptake for products offering contraceptive properties. Disability-adjusted life years (DALYs) averted per HIV infection were estimated for each group under scenarios of low, median and high HIV incidence as observed in recent trials. The model incorporated costs relating to local and national implementation and MPT development, whilst averted costs included those related to treatment and the avoidance of unintended pregnancies. A sensitivity analysis explores the robustness of estimates to parameter uncertainty.
Results: On average, the cost-effectiveness of MPTs was around 35% better than single-purpose products. All rollout scenarios were cost-effective using a 1xGDP threshold, but only interventions among young women (< 25 years) and FSWs were cost-effective when lower, more methodologically robust thresholds were applied.



[Figure]

Conclusions: Candidate MPTs are attractive to both women in the general population, and female sex workers. Incorporating contraceptive indications into HIV prevention products could increase product uptake, impact, and improve cost-effectiveness. This study provides further impetus for the development of effective and attractive MPTs.

TUPEC0893

National evaluation of option B+ in Malawi: high maternal ART coverage and low early infant transmission in all areas of the country

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Background: Option B+ was conceptualized and implemented in Malawi in 2011. Routine program data suggest relatively high ART uptake among pregnant women and challenges with retention. HIV testing for exposed children is affected by delays and loss to follow-up. The Ministry of Health has led the implementation of a National Evaluation of Malawi's PMTCT Program (NEMAPP) to provide unbiased nationally representative data on maternal ART coverage and on early and late vertical transmission rates.
Methods: NEMAPP is a 2 year longitudinal cohort study implemented at 54 health facilities in November 2014 using a two-stage cluster sampling design to identify a representative sample of 4-12 week old infants. Mothers were consecutively consented and screened for HIV while attending an under-5 clinic; HIV-exposed infants receive HIV-1 DNA testing at enrolment, 12 and 24 months. Complex weighted survey design analysis was conducted using STATA.
Results: Among 2,125 HIV-positive mothers, 2,082 (96.1%) reported knowing their HIV status before or during pregnancy, and 1,865 (88.5%, 59.4-100% across sites %) were on ART in pregnancy. Overall MTCT was 4.2% (95% CI 2.9-6.1); for women on ART in pregnancy, MTCT was 2.5% (95% CI 1.6-3.9). MTCT was 17.9% (95% CI 13.0-24.2) among women not on ART during pregnancy. MTCT varied from 1.4% (95% CI 0.5-3.9) among women who initiated ART before pregnancy, to 20.2% (95% CI 5.8-50.7) in those starting ART post-partum. Early infant transmission was similar across geographic strata, ranging from 3.2% (95% CI 1.7 - 5.8) to 5.1% (95% CI 3.5-6.3) between strata (Table 1).
Conclusions: Malawi's early MTCT rates are close to those of developed nations. Decentralization of ART services to all ANC clinics and strong program leadership through quarterly supportive site supervision and active supply chain management have resulted in high levels of ART coverage and low early transmission rates in all areas of the country. The number of new pediatric infections are disproportionately contributed to by the small percentage of HIV-positive women not on ART in pregnancy.

TUPEC0894

Using the QALY to evaluate interventions for HIV treatment and prevention: value and ethics

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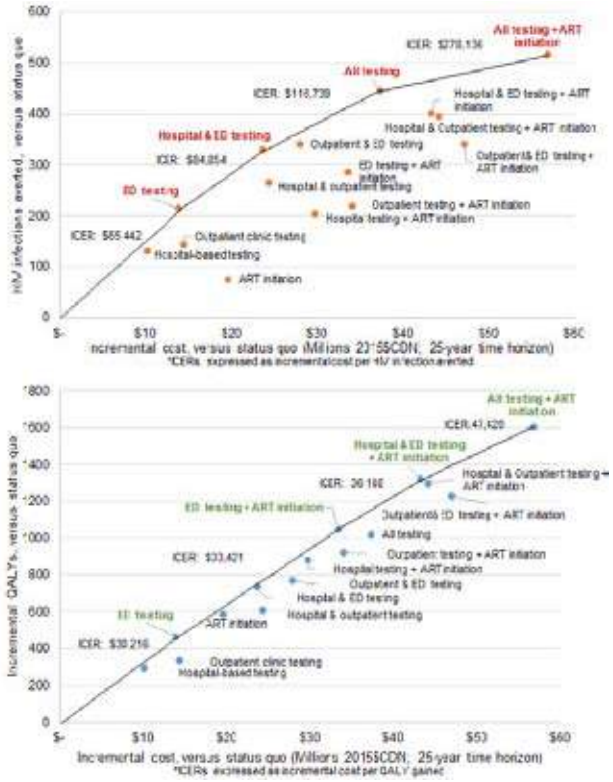
Background: Motivated by the principle of maximizing population health, the use of quality-adjusted life years (QALYs) is ubiquitous in health economic evaluation. An explicit focus on reducing new HIV infections by the US National HIV/AIDS strategy among others has prompted some to consider HIV infections averted in the denominator of the incremental cost-effectiveness ratio (ICER), used to judge incremental value of an intervention.
Our objective is to demonstrate the health and ethical implications of using HIV infections averted, as opposed to QALYs gained, in judging the relative value of HIV treatment and prevention interventions.
Methods: Building off a prior model-based evaluation of HIV care interventions (primary care testing (hospital, emergency department, outpatient) and ART initiation) in British Columbia (BC), we plotted health production functions, showing the highest-valued combinations of strategies for the range of investment levels, with QALYs and HIV infections averted in the y-axes to illustrate differences in valuation. Strategies were compared to the next-most resource intensive, with ICERs <3xGDP per capita considered for funding (BC GDP per capita:$55,405).
Results: With HIV infections averted in the y-axis (top panel), ED testing, ED+ hospital-based testing, all primary care testing and the combined intervention lie on the health production function, with all primary care testing likely to be implemented (ICER:$116,739/HIV infection averted). With QALYs in the y-axis (bottom panel) ED testing, ED testing+ART initiation, ED+hospital testing+ART initiation and the combination intervention lie on the health production function, with the combination intervention likely to be implemented (ICER:$47,420/QALY). This strategy results in an additional 584 QALYs at a cost of $19.5M compared to the strategy selected by focusing on HIV infections averted, with an ICER ($33,421/QALY) well-within international standards.
Conclusions: Using HIV infections averted in the ICER undervalues strategies providing immediate health benefits to PLHIV, resulting in sub-optimal and potentially unethical funding decisions.



[Figure 1. Health production functions]

TUPEC0895

Estimating the potential impact of providing HIV treatment and opioid agonist therapy (OAT) in prison and upon release on HIV incidence among people who inject drugs (PWID) in Tijuana, Mexico

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Background: Tijuana is a nexus for drug use on the Mexico-US border, with an estimated 10,000 PWID, among whom HIV prevalence is 3.5% and incidence 1 per 100 person-years (although much higher among women than men). Among PWID in Tijuana, access to HIV and harm reduction services is very low (< 3% receiving ART or OAT) and incarceration is frequent. We estimate the potential impact of providing ART and OAT in prisons and upon release on HIV incidence among PWID in Tijuana, using mathematical modeling.
Methods: We developed a deterministic model of injecting and sexual HIV transmission among PWID disaggregated by HIV status (including ART), sex, incarceration status and OAT. We calibrated the model to HIV prevalence and incidence data among PWID in Tijuana, parameterized with local data on incarceration patterns and elevated risk of syringe sharing among recently and non-recently incarcerated. For simplicity, we assumed no coverage of ART or OAT at baseline either in prison or the community. In the counterfactual scenarios, we varied the efficacy of ART in preventing parenteral transmission (relative risk 0.4-0.96) and assumed a drop out rate of 0.1/year in the community. We assumed an efficacy of OAT in reducing HIV acquisition of 0.53 (95%CI: 0.33-0.68) based on a meta-analysis and mean duration of 1 year. We estimated the impact on HIV incidence of providing ART to HIV-infected PWID in prison and on release, OAT to all PWID in prison and on release, or both (OAT+ART) from 2017-2030.

Results: Modeling estimated that between 2017-2030, ART provision in prison and on release could avert 16% (95% Credible Interval (CrI): 8%-28%) of new HIV infections. OAT provision to all PWID in prison and on release could avert 12% (95%CrI: 5%-22%) of HIV infections, and OAT+ART provision could avert 21% (95%CrI: 11%-34%) of HIV infections.
Conclusions: Prisons could provide a valuable opportunity for initiating PWID onto HIV prevention in Tijuana, a population in much need of HIV and harm reduction services. Indeed, a fifth of new HIV infections could be averted between 2017-2030 through the provision of ART and OAT in prison and upon release.

Strategies to Increase Uptake of and Retention in HIV Services

TUPED1185

Minors access to HCT and proxy consent: standing up for their right to highest quality of care

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Background: The Philippines is one of the seven countries with increasing HIV cases in the world, with 19 of 29 estimated new HIV infections per day occur among 15 to 24 years old. Restrictive laws remain as significant barriers especially with the recent decision of the Supreme Court on the constitutionality of the Responsible Parenthood Reproductive Health Law that requires below 18 y/o adolescents to obtain written consent from their parents; the same requirement of AIDS Law for HIV testing. With the very low comprehensive knowledge on HIV among the key populations (IHBSS 2015) and the general youth (YAFS 2013), delayed access to services and low condom use among those who engaged in risky behaviors at an early age, and unwillingness to disclose sexual activities to parents, the YOUTH will continue being drivers of the HIV epidemic in the country.
Methods: UNICEF worked with Philippine government to start reverting 62% of HIV cases among youth, thus implemented the Integrated SRH/HIV Service Delivery Model for Adolescents. Capacity of national and local government agencies, civil society organizations (CSO), PLHIV community and youth networks were strengthened on HCT provision, determining "conditions to provide proxy consent", training health providers/social workers providing adolescent friendly health services, review of ethical medical practice and use of case management tools and forms, and establishing a wide network of service delivery referrals on adolescent using standardized operational guidelines.
Results: Improved life skills education and other demand generation activities that is linked to adolescent friendly health services increased service uptake. Frontline service providers are less afraid to provide services through the partnership model. To date, 2 HIV high burden cities have amended HIV ordinance lowering age to consent for HIV testing from 18 to 15 y/o while other cities have ongoing leveraging with mayors to provide HCT services to minors through MOU. Most important is that more than a thousand of adolescent minors as young as 13 years old have accessed HCT; those positive linked to services.
Conclusions: Use of evidence-based data, documentation of experiences, and strong government/CSO/youth partnerships guarantee actions to overcoming legal barriers and other challenges to minors access to services.

TUPED1186

Engagement in care and viral suppression (VS) are not associated with *same-day* versus *delayed* antiretroviral therapy (ART) initiation during pregnancy in Cape Town, South Africa

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Background: Immediate initiation of ART on the same day as eligibility is determined ("same-day initiation") is common in PMTCT services to help maximise time on ART and VS before delivery. However there are concerns that same-day initiation may restrict patient preparation before ART start and contribute to subsequent non-adherence, disengagement from care and raised viral load (VL). We examined whether same-day initiation is associated with engagement and VS in a cohort of women initiating ART during pregnancy.
Methods: At a large primary care clinic, consecutive ART-eligible women were enrolled into an implementation science study at their first antenatal visit, 4/2013-6/2014. During the study, ART eligibility/initiation changed from delayed initiation following CD4-driven eligibility criteria ("Option A", 4-6/2013) to universal same-day initiation ("Option B+" after 6/2013). All women were followed with VL testing for the study, separate from routine care, through 12m postpartum. Postpartum engagement in ART services was measured using routinely-collected clinic, pharmacy and laboratory records.
Results: Of 628 ART-eligible women enrolled (median age=28y; median gestation=21w; 55% newly diagnosed HIV+), 73% started ART same-day; 81% and 19% under "Option B+" and "Option A", respectively; there were no significant demographic differences between same-day and delayed initiators. There were no differences in engagement through 12m postpartum (same-day=76%, delayed=75%, p=0.512). Levels of VS<1000cps/mL at delivery (92%vs90%) and 12m postpartum (75%vs71%) were the same under same-day vs delayed initiation, respectively; similar findings were observed when VS was defined at < 50cps/mL (p>0.200 throughout). Results did not vary after adjustment for demographic/clinical measures, and were consistent across subgroups of age, CD4 and timing of HIV diagnosis (Table).
Conclusions: These data suggest that same-day ART initiation is not associated with lower levels of engagement in care or VS through 12m post-delivery, reassuring findings for PMTCT/ART programmes offering immediate ART initiation.

Subgroup	At delivery [OR (95% CI)]		At 12 months Postpartum [OR (95% CI)]		
	VS<50	VS<1000	VS<50	VS<1000	Engaged in care
All women	0.97 (0.48-1.97)	1.72 (0.69-4.25)	1.33 (0.71-2.53)	1.38 (0.71-2.71)	1.54 (0.82-2.90)
Age: <28 years	1.49 (0.61-3.68)	3.64 (1.16-11.5)	1.20 (0.49-2.95)	1.32 (0.54-3.26)	1.90 (0.83-4.33
Age: ≥28 years	0.80 (0.24-2.60	0.62 (0.12-3.20)	1.56 (0.59-4.14)	1.63 (0.56-4.71)	1.39 (0.49-4.00)
Pre-ART CD4: ≤350	1.05 (0.43-2.60)	1.47 (0.44-4.92)	0.88 (0.35-2.20)	1.12 (0.43-2.88)	1.62 (0.64-4.11)
Pre-ART CD4: >350	0.81 (0.24-2.75)	2.83 (0.69-11.6)	1.70 (0.65-4.47)	1.54 (0.56-4.26)	1.35 (0.53-3.42)
HIV diagnosis: new in pregnancy	0.99 (0.36-2.70)	1.79 (0.53-6.08)	1.52 (0.57-4.02)	1.42 (0.53-3.79)	1.20 (0.53-2.75)
HIV diagnosis: before pregnancy	0.77 (0.26-2.30)	1.47 (0.37-5.87)	1.07 (0.45-2.58)	1.25 (0.48-3.24)	2.09 (0.75-5.86)
All models adjusted for pre-ART VL, time on ART, gestation at ART initiation, marital status and PMTCT Option (A/B+); models with all women also adjusted for CD4, age and timing of HIV diagnosis					

[Adjusted association same-day vs delayed]

TUPED1187

Will HIV test and start be the end of baseline CD4 monitoring? CD4 functionality and impact of transition in a resource-limited setting, Zimbabwe

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Background: In 2015, World Health Organization (WHO) released new HIV treatment and care guidelines recommending starting antiretroviral therapy (ART) in all people living with HIV (PLHIV) regardless of CD4 count or clinical stage. In June 2016, Zimbabwe started implementing the new HIV treatment guidelines which still recommend baseline CD4 monitoring. The objectives of the assessment were to describe the availability of CD4 monitoring and identify existing bottlenecks to effective and efficient use of CD4 monitoring equipment.
Methods: Qualitative and quantitative data was collected in 22 purposively sampled districts (5 provinces). Health care staff was interviewed in March 2016 using a structured questionnaire. After Treat All roll out; CD4 utilization pattern was recorded pre- and post-TREAT ALL implementation in June and July 2016 respectively. Stata V12 was used to conduct the data analysis.
Results: At the time of the assessment; 50% (15/30) of conventional and 34% (42/124) CD4 POC machines were not functioning. Average length of break down was 118 days, with most frequently cited reasons for breakdown being error messages, no cartridges or reagents, and results printer down. In the previous 6 months, 81% of all CD4 machines had experienced a reagent stock out, breakdown or both.

The proportion of patients initiated on ART that received baseline CD4 monitoring significantly reduced the month after Treat All began (47% vs. 26%, p <0.001). The table below shows the reported status of the CD4 machines per province.

Province	Total CD4 machines	Number of Point of care CD4 machines	Number of conventional CD4 machines	Number of machines CURRENTLY non-functional (May 2016)	Machines reporting cartridge or reagent stock out	Number of machines reported broken down	Machines reporting breakdown &/or stock out
Bulawayo	13	11	2	3 (23%)	10 (91%)	3 (23%)	11 (85%)
Manicaland	31	26	5	4 (13%)	18 (58%)	8 (26%)	23 (74%)
Masvingo	34	27	7	12 (35%)	17 (50%)	15 (44%)	25 (74%)
Mat. South	31	23	8	20 (65%)	26 (84%)	11 (35%)	29 (94%)
Midlands	45	37	8	18 (40%)	26 (58%)	29 (64%)	36 (80%)
Total	154	124	30	57 (37%)	97 (63%)	66 (43%)	124 (81%)

[Reported CD4 machine status per province]

Conclusions: We report frequent breakdown of both POC and conventional CD4 machines and a significant decline in documented baseline CD4 in newly initiated patients following the start of Treat All in Zimbabwe. As national scale up of VL monitoring continues, we recommend cost-effectiveness analyses to determine optimal investment for improving functionality of existing CD4 equipment to support baseline monitoring of patients on ART as recommended in Zimbabwean national guidelines.

TUPED1188

"PrEP in the Wild": results from a global survey of medical providers' PrEP practices in settings where it is approved and where it is not

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Background: Some medical providers prescribe PrEP drugs off label ("in the wild") and/or provide related medical monitoring to individuals who procure PrEP drugs on their own. Little is known about the practices of these medical providers.
Methods: During February-December, 2016, an internet survey of PrEP providers was deployed globally in English, French and Spanish. A descriptive analysis of PrEP provider practices was conducted.
Results: 70 surveys were completed by medical providers from 27 countries. Their reported patients included: people who inject drugs (76%); transgender persons (63%); men who have sex with men (91%); and, heterosexual women (84%) and men (86%). 89% of providers reported following established PrEP guidelines including: US CDC (62%); WHO (62%); South African (14%). HIV infection was ruled-out prior to prescribing PrEP by: rapid HIV antibody (70%) or HIV antibody with P24 antigen (53%) tests; ELISA with P24 antigen (54%); PCR/viral load (30%); CD4+ (11%). ARVs prescribed included: Truvada® (80%) or generic TDF/FTC (55%); 3TC+TDF (13%); TDF (5%); Stribild (5%); Atripla (7%); other (10%). Primary ARV dosing schedules prescribed: daily (92%); 1 dose the day before sex, then 1 dose every day of sex, and 1 dose the day after sex (12%); and 1 dose 4x/week (8%). HIV was testing most frequently recommended monthly (7%); quarterly (75%); or bi-annually (7%). Other testing included: gonorrhea (73%); chlamydia (77%); HPV (36%); mycoplasma (23%); syphilis (94%); hepatitis A, B, C (56%, 92% and 76%, respectively); serum creatinine clearance (92%); liver function (74%); bone mineral density (10%); and urine dipsticks (62%). Social services referrals were common (67%). Reasons for refusing to prescribe/support PrEP included: low HIV risk (52%); concerns about reduced condom use (19%); recreational drug use (13%); mental health problems (21%); < 18 years of age (20%); female (17%); transgender (13%); sex worker (11%); current condomless sex (19%); no condomless sex (35%); only heterosexual sex (17%); medication affecting kidneys (57%).
Conclusions: Most "in the wild" PrEP providers followed established guidelines; however, non-recommended PrEP regimens and tests were common. Of concern was refusal to prescribe PrEP to potentially very vulnerable individuals. PrEP approval in countries is critical to the consistent, correct provision of PrEP.

TUPED1189

Facilitators and barriers for providing HIV, sexual and reproductive health (SRH) services to adolescent key populations in Kenya: a situational analysis

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Background: AIDS related deaths among adolescents continues to rise in Africa. Key populations contribute to 30% of new infections annually and include adolescent key populations (KPs). However, limited data exists on adolescent key populations in Kenya, limiting sexual and reproductive health (SRH) and HIV policy formulation and service delivery.
In this study, adolescent KPs were defined as adolescents aged 10-19 years who engage in either sex work, same sex relationships or intravenous drug use. The study aimed to identify enablers and barriers to inform provision of HIV/SRH services to adolescent KPs in Kenya.
Methods: A cross sectional study using qualitative methods was conducted between October 2015 and April 2016. A total of 9 focus group discussions and 18 in-depth interviews were conducted with 108 adolescent KPs. Fifteen key informant interviews were conducted with national and county policy makers, 18 with health service providers (clinicians and counsellors) and 18 with key populations' program implementers (program officers and managers) in Nairobi, Mombasa and Kisumu counties of Kenya. The interviews explored perceptions of facilitators and barriers to provision of HIV/SRH services to adolescent key populations by the different groups. Data were recorded digitally, translated, transcribed and coded in NVivo10 prior to a thematic analysis.
Results: Adolescent KPs, health service providers, program implementers and policy makers identified several facilitators in the provision of services namely: a friendly and easily accessible location or environment for provision of HIV/SRH services and integrated health services that minimize referrals ("one-stop-shop"). Barriers to provision of services reported were; limited involvement of adolescent KPs in the design of HIV/SRH programs, negative health care providers' attitudes towards key populations, limited age appropriate information education materials, absence of disaggregated data that helps in decision making on programming, and lack of adolescent key population's policies & guidelines on HIV and sexual reproductive health.
Conclusions: The study has demonstrated existing facilitators and significant barriers to provision of HIV/SRH services for an at risk group for which limited data exist. These results provide a basis for policy review and program redesign involving the adolescent KPs to minimize barriers and facilitate HIV/SRH service access and uptake.

TUPED1190

Interpersonal Communications (IPC) linked with a mobile-based feedback mechanism for voluntary medical male circumcision (VMMC) demand creation: lessons from a 6-month implementation pilot in Zambia

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Background: IPC approaches are the backbone of VMMC demand, facilitating discussions and allowing men to address their unique concerns. Despite relative effectiveness of IPC, most men showing willingness to get circumcised do not get circumcised. Internal programmatic data shows one third of men reached with circumcision messages get circumcised. Most VMMC programs lack structured follow-up strategies for clients missing appointments.
A door-to-door mobilization model, which utilized Community Health Workers (CHWs) equipped with tablets to maximize follow-up, efficiency and effectiveness of contact with potential VMMC clients was implemented over six months in Lusaka.
Methods: Ten CHWs and one supervisor were trained and equipped with pre-configured tablets, given unique identifier codes and assigned to one geographical area. At each household, CHWs electronically submitted client information and booked VMMC appointments through a custom-built application, which generated unique client numbers. These were used to track clients and ultimately for reconciling appointments. Automated reminder messages were sent to appropriate CHW a maximum three times for clients missing appointments.

Results: 70% (121/171) of booked clients were circumcised, 91% of these on first booking, and 9% after follow-up visits. 37% of clients booked through a CHW were circumcised the following day, while 15% were circumcised between 2 to 5 days later, and 19% took 6 to 75 days.
Most of circumcised clients were males between 15-29 years; unmarried (84%); attained a minimum of primary school level education (96%); and unemployed (70%). Clients most likely to go for circumcision after a day were those with tertiary education (50%); heads of households (45%); unmarried (48%); employed (43%); and aged 15-29 years (41%). Conversely, clients requiring more time to get circumcised were those with up to secondary level education only (26%), and aged less than 15 years (23%).
Of the 30% clients missing appointments, most never attended school (71%) and were below 15 years (40%).
Conclusions: An innovative IPC demand creation model using CHWs coupled with a mobile-based feedback mechanism is an effective approach for identifying characteristics of clients who access VMMC services in low resource settings; monitoring client referral success rates; and promoting timely and systematic follow-ups.

TUPED1191

Evaluation of lost to follow-up tracing system in integrated HIV care (IHC) program in Myanmar: call for strengthening of current tracing activity

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Background: Access to the antiretroviral therapy (ART) has been rapidly increased during the past ten years in Myanmar as well as in Integrated HIV Care (IHC) Program. Loss-to-follow-up (LTFU) rate 7% was reported in the IHC program in 2012 although the target set by National Program is < 5%. Hence, LTFU, defined as "disengagement from clinic at least 12 weeks from last appointed date" in the program, became one of the critical area to emphasize to improve the treatment outcome in this setting. The systematic tracing of LTFU was implemented in 2015 and 2016 by contacting via phone or by visiting home with monthly interval of at least three times by peer network.
Methods: Retrospective analysis of the tracing outcomes of LTFU patients from three ART Centers of Mandalay General Hospital and one of 300 Bedded Mandalay Teaching Hospital between June 2005 and December 2016.
Results: Of 1,368 LTFU patients from four ART Centers, 733 (54%) were traced with 648 (88%) patients on ART and 85 (12%) on stopped ART at the time of LTFU. The median (interquartile range -IQR) age at time of enrolment was 35 years (30 - 40), while the median duration on ART at the time of LTFU was 7 months (IQR 2 - 19). After tracing, 185 (25.2%) were reported to be alive, 118 (16.1%) were dead, 245 (33.5%) could not reached because of wrong recording or changing of addresses and phone numbers; and 185 (25.2%) patients were reported as family lost connection with patients, loss of record booklet, etc. LTFU patients with CD4≤200 cells/mm^3 were more likely to report dead compared with those who had CD4>200 cells/mm^3 [Odd ratio 3 (95% confidence interval 1.84 - 4.88)].
Conclusions: The current LTFU tracing system is needed to strengthen to cover more LTFU patients, moreover, the recording system of the program is also required to improve to get correct contact details of patients with regular updating of the changes. In addition, it is needed to implement a new innovative strategy for patients with low CD4 count to prevent disengagement from care.

TUPED1192

Impact of household visit schedule of field teams on retention of community-recruited participants in HIV prevention research: perspectives from the HPTN 071 (PopART) study

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Background: Successful follow-up of community-recruited participants in HIV prevention research could be influenced by the household visit schedule of field teams. The aim of this study is to investigate the impact of different field work shifts on successful follow-up of participants.
Methods: HPTN 071 (PopART) is a community-randomised trial of a household-based HIV-prevention intervention package in South Africa and Zambia. The primary outcome, HIV incidence, is measured in a randomly selected Population Cohort (PC). We used data from the 12 month follow-up survey (July 2015 - June 2016) of the PC in 9 South African communities. Follow-up household visits among individuals consented to participate at baseline were scheduled in three shifts: Midweek (Monday-Friday) shifts (8 hour duration) categorized as early shift if it ended before 4pm; as late shift if it ended after 4pm; and a Saturday shift (5 hours). During each shift, 4 teams (two individuals per team) were active per community. A participant was considered successfully followed-up if the survey was completed during the household visit. The number of successful follow-up visits were calculated for each shift type and standardized to account for variation in shift duration. Poisson regression analysis was used to calculate incidence rate ratio's (IRRs) and 95% confidence intervals (CIs) of number of successful visits. Month of visit was included in the model to account for confounding with calendar time.
Results: 11,720 participants, including 8,251 females (70%), were successfully followed-up during 223 days. The rate of successful visits per hour was 5.1 for early shifts (CI=4.1-6.0), 6.8 for late shifts (CI=5.9-7.6) and 15.7 for Saturday shifts (CI=12.1-19.3). Follow-up visits during Saturday shifts were more successful as compared to visits during early or late midweek shifts (IRR=3.1, CI=2.5-3.9; IRR=2.4, CI=1.9-2.9, respectively). Among males, Saturday shifts resulted in 3.6 times as many successful visits compared to early midweek shifts (CI=2.8-4.5) and 2.9 times as many compared to late shifts (CI=2.4-3.5). Among females, these IRRs were 2.9 (CI=2.3-3.7) and 2.2 (CI=1.7-2.7).
Conclusions: To efficiently follow-up participants, in particular males, more household visits should be scheduled during Saturday shifts instead of midweek shifts. These findings can be used for implementation of community-based research.

TUPED1193

Improving documentation of antiretroviral therapy (ART) medication pick-up via electronic pharmacy barcode system in rural Mozambique

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Background: In 2011 the Mozambican Ministry of Health (MoH) modified the existing paper-based system to register individual medication pick-up for antiretroviral therapy (ART). However, use of the form (known locally as a FILA - Ficha Individual de Levantamentos de ARV) was time consuming and inconsistent, threatening accuracy of ART retention data. Therefore, in 2015 the MoH included electronic FILA systems in its national strategy for quality improvement. In March 2016, the international non-governmental organization Friends in Global Health (FGH) established a user-friendly electronic barcode FILA system (eFILA) with interoperability between its Electronic Patient Tracking System (EPTS) at the rural Alto Molocue Hospital pharmacy in Zambezia province, Mozambique; which averages 48 ART patients a day. We assessed the effect of this innovation on timely registration of patient ART medication pick-up into the EPTS and FILA processing time.
Methods: Analysis of timely registration for patients who picked up ART at the pharmacy throughout 5 consecutive business days during the following periods: March 10-16, 2016 (pre-implementation) and September 14-20, 2016 (during implementation). We triangulated data for patient pick-up date, ART regimen and dosage between the prescription, paper-based FILA, eFILA and EPTS, with timely registration in EPTS defined as no more than two days beyond the inclusion period. We also assessed, from the time a patient was attended by pharmacy staff: a) time of paper-based FILA completion, and b) time of registration into the eFILA system, to calculate mean FILA processing time.
Results: Before implementation, timely registration of ART pick-up in EPTS was noted for 173 (71%) of 243 patients. During implementation, timely registration was noted for 299 (98%) of 305 patients. Prior to eFILA implementation, the mean processing time for paper-based FILAs was 162 minutes, compared to 47 minutes (71% reduction) for paper-based FILAs and 2 minutes for eFILA following implementation.
Conclusions: The electronic barcode system, with its user-friendly scanning device and EPTS interoperability, shows great potential to improve timely registration of ART pickup in Mozambique. Future analyses are planned to explore the system's impact on retention data.

TUPED1194

Challenges in managing cryptococcal meningitis in resource-limited settings

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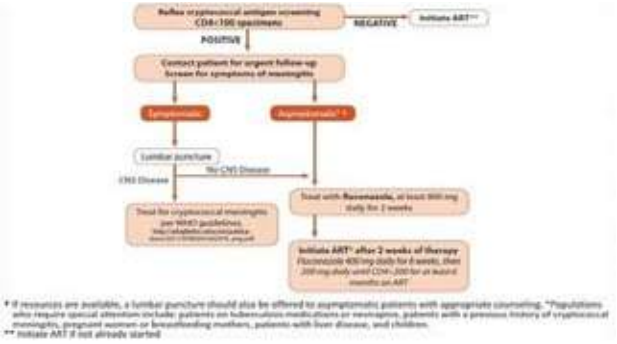
Background: Cryptococcal meningitis remains a major cause of mortality and morbidity among HIV-infected individuals. The Zimbabwe national HIV guidelines recommend screening all HIV positive clients for cryptococcal infection. I-TECH Zimbabwe, with funding from the U.S. Centers for Disease Control and Prevention, supports the Ministry of Health and Child Care's roll-out of cryptococcal antigen (CrAg) screening as standard HIV care. Prior to implementation, a baseline assessment was conducted, and we report our findings.
Methods: The baseline assessment was performed in September 2016 at seven hospitals, purposively sampled in Zimbabwe. The assessment tool contained questions assessing the capacity of sites to perform CrAg screening, other laboratory services used in the diagnosis and management of meningitis cases, and the availability of commodities. Key informants at each facility were interviewed, and the assessment took approximately a half day to complete.
Results: Five district hospitals and two provincial hospitals participated in the assessment. Two facilities assessed were currently offering CrAg screening. At facilities not performing CrAg screening, lack of test kits, reagents, and trained staff were reported as barriers to service provision. Both of the facilities offering CrAg screening reported insufficient quantities of reagents. All facilities had functional lumbar puncture packs and four facilities had the necessary reagents to perform CSF microscopy, culture, and sensitivity. Six facilities had Fluconazole available; Amphotericin B was unavailable at all sites. All sites offered haematology, six had functional CD4 services, and three offered urea and electrolytes chemistry.



[CrAG Screening Algorithm (Adopted from WHO)]

Conclusions: The majority of hospitals lacked capacity to offer CrAg screening and manage cryptococcal meningitis cases. The baseline assessment identified ways in which hospitals would need to be supported to implement CrAg screening and manage cryptococcal meningitis cases within acceptable standards. Additional support to hospitals through staff training and increased availability of commodities has the potential to reduce the morbidity and mortality caused by cryptococcal meningitis.

TUPED1195

Trends in tetanus immunization and VMMC uptake in 12 districts in Rwanda

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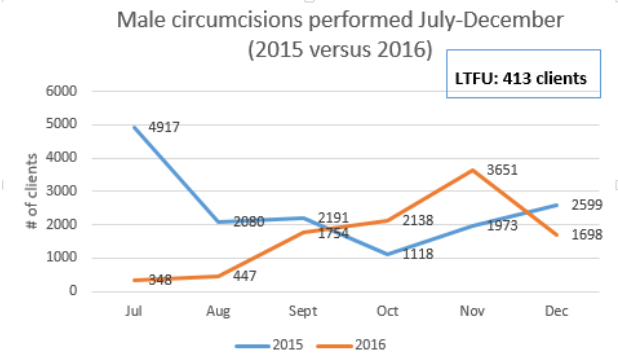
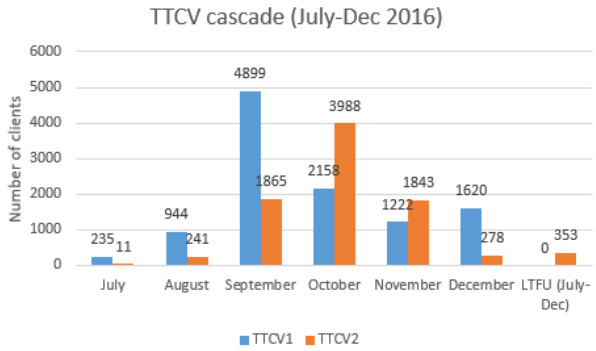
Background: By 2014, thirteen tetanus cases were reported across Sub-Saharan Africa VMMC programs. Consequently, WHO advised administering two tetanus toxoid containing vaccine (TTCV) doses prior to VMMC procedure. The impact of this new guidance on VMMC programs is unknown. This documentation assesses the trend of VMMC uptake before and after implementation of the new WHO TTCV advice issued in June 2016.
Methods: Vaccines were provided by the Ministry of Health and providers were oriented on new WHO advice. The population was sensitized on TTCV through public media and counseling. Data were included from the same months (July-December) in 2015 (before the WHO advice) and 2016 (after). All males screened for VMMC in 7 RDF sites and 13 sites in priority districts were included. Data were collected from registers, client forms, and monthly reports. There were no reported stock outs of vaccine or VMMC commodities during the assessment. Data will be collected through December 2017.
Results: Fewer VMMC procedures were performed during July-Sept 2016 vs. July-Sept 2015. 353 clients were lost to followup (LTFU) after TTCV1 and an additional 60 lost after TTCV2. Immunization rates decrease 3 months after the initial swell of clients are immunized and the program enters holidays.



[VMMC uptake]



[TTCV uptake]

Conclusions: Programs should expect a decline in VMMC procedures immediately following initiation of the pre-VMMC tetanus immunization. Clients receiving TTCV2 and VMMC were lower than initially screened, implying a need for close monitoring to minimize LTFU. There were more VMMC procedures done compared to clients completing TTCV2, indicating potential contribution from partners.

TUPED1196

HIV and tuberculosis in Malawian prisons: a comprehensive prevention, screening and management programme

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Background: Maula and Chichiri maximum security prisons in Malawi currently hold 2,757 and 1,936 inmates respectively, over 240% of their intended capacities. Congested cells, lack of infection control measures, and prevalent malnutrition result in a high transmission setting for tuberculosis (TB). Prior to any interventions, a limited antiretroviral therapy (ART) programme was the only healthcare service provided by inadequately trained prison staff.
A 2011 study estimated HIV (41%) and TB (4.4%) point prevalence in central Malawian prisons. In 2014 Médecins Sans Frontières' (MSF) introduced a comprehensive package of interventions to prevent, screen, treat, and monitor HIV and TB in these prisons according to the Southern African Development Community minimum standards for prisons. Auxiliary care includes a nutrition programme, hepatitis B vaccination, mental health screening, outpatient care and referral, health promotion, and advocacy.
This research outlines the unique programmatic tools and structural interventions implemented by MSF, and the impact of these interventions on HIV care and TB transmission in the prisons.

Methods: An overview of the programmatic interventions introduced by MSF between June 2014 and December 2016 in Maula and Chichiri prisons. Data were captured in TIER.Net, analysed using Stata 12.1, and results reported until 31/12/2016.
Results: The HIV point prevalence at Maula and Chichiri prisons was 13.7% (95% CI: 12.4-15.1%) and 20.6% (18.8-22.5%) respectively. There have been no confirmed cases of HIV transmission in the prisons. The UNAIDS 90-90-90 HIV cascade indicators are summarised in the table below:

	Maula Prison	Chichiri Prison
Prisoners screened for HIV in past 6 months	2334/2359 (98.9%; 95% CI: 98.4-99.3%)	1780/1807 (98.5%; 95% CI: 97.8-99%)
HIV positive on ART	363/378 (96.0%; 95% CI: 93.5-97.8%)	397/399 (99.5%; 95% CI: 98.2-99.9%)
On ART eligible for viral load with viral load taken	180/241 (74.7%; 95% CI: 68.7-80.1%)	244/281 (86.8%; 95% CI: 82.3-90.6%)
Viral load <1000 copies/ml	165/180 (91.7%; 95% CI: 86.6-96.2%)	229/244 (93.9%; 95% CI: 90.1-96.5%)

[UNAIDS 90-90-90 HIV cascade indicators in prisons]

The number of inmates with active TB on treatment was 33 (1.2%; 95% CI: 0.8-1.7%) in Maula and 22 (1.1%; 0.7-1.7%) in Chichiri with HIV-TB co-infection of 24.2% (8/33) and 59.1% (13/22) respectively.
Conclusions: The model of care implemented in this challenging setting has been effective in helping to achieve the UNAIDS 90-90-90 goal and can be replicated in similar prison contexts. Active TB case finding and infection control efforts (including isoniazid preventative therapy) need to be intensified to curb transmission.

TUPED1197

Internalized homophobia, HIV/AIDS responsibility beliefs, and HIV knowledge amongst men who have sex with men: correlates of HIV/AIDS discrimination in a setting of institutionalized homophobia

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Background: Men who have Sex with Men (MSM) in Singapore are disproportionately represented in the proportion of prevailing HIV infections, relative to the general population. However, there exists a paucity of research on the psychosocial dimensions of the HIV/AIDS epidemic amongst MSM in non-Western settings such as Singapore due to the criminalization of gay sex and prevailing homosexual stigma. The present study addresses this gap by investigating the significant demographic and psychosocial correlates of HIV/AIDS discrimination amongst MSM. The results will serve to highlight psychosocial barriers to the reduction of HIV/AIDS discrimination against People Living with HIV/AIDS (PLWHA) which is associated with poor antiretroviral adherence, increased risky sexual behaviors, and poor mental well-being when internalized.
Methods: 164 responses from self-identified MSM were obtained through purposive and convenience sampling methods by employing a web-based survey disseminated by two voluntary welfare organizations. Surveys were self-administered and responses were anonymized to protect participants from possible legal repercussions in Singapore, where gay sex is criminalized. The survey sought to measure discrimination against PLWHA, and its association with internalized homophobia, HIV/AIDS personal responsibility beliefs (HAPRB) and HIV knowledge. An ordinary least squares regression model, using a sequential modelling approach, was employed for analysis.
Results: Results indicate that internalized homophobia is positively associated with discrimination against PLWHA. Age and living in private housing are negatively associated with internalized homophobia. Personal income, perception of strong community support, and having no religion are positively associated with HIV knowledge. Being HIV-positive and personal income are positively associated with HAPRB, while having no religion or perceiving strong community support are negatively associated with HAPRB. Internalized homophobia also mediates the relationship between HAPRB and discrimination against PLWHA [Mediated Effect = .24, SE = .11, 95% CI = .03, .46]. This study validates a 13-item internalized homophobia scale (Cronbach's alpha = .86), and a 3-item discrimination against PLWHA scale (Cronbach's alpha = .79) amongst Singaporean MSM.
Conclusions: Community-based interventions in settings of prevailing institutionalized homophobia should recognize internalized homophobia as a barrier to the effectiveness of programs targeted at reducing HIV/AIDS discrimination amongst MSM, which in turn has wider implications for HIV prevention efforts.

TUPED1198

What prevents central Asian migrant workers from accessing HIV testing? Implications for increasing HIV testing uptake in Kazakhstan

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Background: Several barriers prevent key populations, such as migrant workers, from accessing HIV testing. The success of the UNAIDS 90-90-90 goals hinges on the ability to drastically increase the number of people being tested for HIV, particularly among key affected populations with low HIV testing uptake, such as migrant workers. There is a dearth of HIV research on migrants in Central Asia, a region that has one of the fastest growing HIV epidemics in the world. Central Asia also has high levels of migration flows, which may complicate controlling the HIV epidemic in the region. This study identifies the determinants of HIV testing among Central Asian labor migrants (from Kyrgyzstan, Tajikistan, and Uzbekistan) in Kazakhstan.
Methods: Using data from a cross-sectional study among 623 migrant workers (22% female, 78% male) in Kazakhstan, we examined factors associated with HIV testing. Participants completed surveys containing questions related to demographic, economic, legal, sexual risk, and health care access factors. We assessed associations between independent variables and HIV testing using bivariate logistic regression. Significant variables in the bivariate models were simultaneously entered in the multivariate model to identify variables that remained significantly associated with HIV testing.
Results: Overall, 48% of participants had ever received an HIV test. Being female (AOR 2.56; (95% CI [1.48-4.45]), having temporary registration (AOR 1.69; (95% CI [1.12-2.56]), having an employment contract (AOR 2.59; (95% CI [1.58-4.23]), being able to afford health care services (AOR 3.61; (95% CI [1.86-7.03]) having a medical check-up in the past 12 months (AOR 1.85; 95% CI [1.18-2.89]), and having a regular doctor (AOR 2.37; 95% CI [1.20-4.70]) were associated with having an HIV test.
Conclusions: HIV testing uptake among migrants in Kazakhstan falls far short of the UNAIDS 90-90-90 goals. Intervention strategies to increase HIV testing among this population may include initiatives that focus on improving outreach to undocumented migrants, making health care services more affordable, and linking migrants to health care.

TUPED1199

Financial and behavioral economic factors associated with uptake of free HIV testing in AIDS-affected adolescents and households in Uganda: a cross-sectional analysis

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Background: Provision of free HIV counseling and testing services (HCTS) is perceived to remove financial barriers to seeking care. Yet, little is known on whether uptake of free HCTS by households impoverished by AIDS is influenced by financial and behavioral economic factors. Research suggests that individuals experiencing financial distress may be reluctant to seek HCTS with high opportunity costs, but this has not been examined in adolescents and families.
Methods: We used baseline data from the Suubi-Maka randomized experiment in the Rakai and Masaka districts of Uganda. Three hundred forty-six (n=346) AIDS-affected adolescents, aged 10 - 17, and their guardians were enrolled. Multivariate, hierarchal logistic regression was used to examine the association of prior HIV testing with traditional financial measures, such as employment, savings, food and income insecurity. We also examined whether guardians in households affected by AIDS with "present-bias" preferences were more likely to seek free HCTS for themselves, their adolescent orphans, and other household adults. Present-biased individuals were defined by behavioral economics as those who disproportionately weighted the present while discounting the future.
Results: HIV testing was low for adolescent orphans (8%), guardians (59%), and households with at least one non-guardian adult (41%). Household savings were not associated with adolescent testing (OR=0.88, CI:0.32 - 2.46). However, ado-

lescents cared for by present-biased guardians were more likely to be HIV tested (OR=2.64, CI:1.04 - 6.70) than adolescents cared for by guardians who weighted future gains. This suggests that present-biased guardians may have valued HIV testing given the rapid results. Conversely, omitting adolescent HIV testing may have been consistent with future-biased guardians' preferences to avoid present-day costs and reserve resources for the future. Guardians (OR=2.02; CI:1.19 - 3.41) and non-guardian adults (OR=2.38; CI:1.30 - 4.34) in households with cash savings were also more likely to have been tested. Financially-insecure households (OR=0.59, CI:0.35 - 0.97) and those with an employed non-guardian adult (OR=0.49, CI:0.25 - 0.97) were less likely to be tested.
Conclusions: Interventions that address would-be HIV testers' economic needs, including present- or future-behavioral economic biases, may prove beneficial. More research is needed to understand how costs and household economies impact HIV testing behaviors.

TUPED1200

The role of gender norms and masculinity on men's engagement in the HIV care continuum in sub-Saharan Africa: a systematic review

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Background: Men living with HIV/AIDS in sub-Saharan Africa have worse outcomes throughout the HIV care continuum compared to women. Gender norms and masculinity have been hypothesized as key factors in men's poor engagement in HIV care.
Methods: We conducted a systematic review and qualitative synthesis to examine how masculinity influenced men's HIV care engagement in sub-Saharan Africa. In May 2016, we systematically searched PubMed, Web of Science, and PsychInfo for quantitative and qualitative studies examining masculinity/gender norms and HIV care engagement outcomes (HIV testing, support-seeking, linkage to care, treatment adherence, clinic attendance). Studies were first screened for eligibility by title and abstract, then full articles reviewed, and data extracted, with consensus obtained across authors. A content analysis approach was used for qualitative analysis.
Results: Our review yielded a total of 23 qualitative studies from 10 countries that met inclusion criteria. Masculinity was defined similarly across settings, and common themes demonstrated how notions of masculinity can serve both as barriers and facilitators to care engagement across all stages of care. The articles identified several masculine norms as barriers to care engagement: being physically and mentally strong, independent, emotionally inexpressive, and sexually successful with women; and fear that HIV would threaten men's social relationships including their role as husband, father, head of household, provider, worker, and peer. HIV stigma was found to threaten men's fulfillment of these masculine gender roles. Facilitators to HIV care/treatment included: perceptions that care/treatment could restore masculinity through regained physical strength, ability to work/provide, and potential for marriage and children. Studies found that over time some men were able to adopt new masculine identities and roles in the community that were conducive to care engagement.
Conclusions: Our review identifies evidence across sub-Saharan Africa that masculinity plays an important role in men's decision to seek and remain in HIV care. These findings suggest a need for further cross-sectional and longitudinal work to establish the relationship between masculinity related norms and HIV care. Future research should consider integrating a gender-transformative approach into HIV counseling to help reduce the masculinity-related barriers to care.

TUPED1201

Barriers to ART uptake experienced by healthy clients in Malawi under test and treat

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Background: Malawi is one of the first countries in sub-Saharan Africa to implement antiretroviral therapy (ART) regardless of clinical stage or CD4 cell count (Test and Treat). We evaluated barriers and facilitators to ART uptake from the perspective of both asymptomatic newly HIV+ clients and HIV service providers during the first 6 weeks of program implementation.
Methods: Routine data from 5 ART clinics were reviewed to identify clients ≥ 18 years of age testing HIV+ between July 14-September 23, 2016. Individuals were screened to determine if they were asymptomatic at time of testing. In-depth interviews were conducted with asymptomatic clients. Twelve focus group discussions were completed with ART providers (n=31), HIV counselors (n=19), and community-based support staff (n=29).
Results: One hundred and fifty-three clients tested HIV+ and of those 22% (n=33) were asymptomatic. Ninety-one percent of clients identified as asymptomatic completed in-depth interviews (n=30). The most common barriers to ART uptake identified by clients were fear of disclosure (63%, n=19), fear of experiencing side effects while healthy (57%, n=17), work schedules or other commitments that conflict with clinic hours (33%, n=10), and needing time to accept their diagnosis before initiating ART (30%, n=9). Dominant facilitators to ART initiation included the desire to stay healthy to provide and/or care for family members (70%, n=21), motivation to prevent unwanted disclosure by becoming sick (23%, n=7), the desire to extend one's life (43%, n=13), and personal knowledge of others who died from AIDS due to delayed treatment (37%, n=11). Providers identified fear of disclosure, lack of privacy at ART clinics, and poor knowledge about benefits of early ART as primary barriers to uptake among asymptomatic clients. Additionally, providers raised concern that asymptomatic men may not engage in HIV care.
Conclusions: Concern about HIV disclosure, lack of privacy, fear of side effects, and facility hours may limit ART uptake among asymptomatic clients. Patient- and provider-reported barriers closely align. Interventions that improve privacy, support disclosure, increase patient knowledge, and improve access to ART may facilitate ART uptake among asymptomatic HIV+ individuals under Test and Treat.

TUPED1202

Out-of-pocket expenditures associated with HIV treatment and care in the Dominican Republic: results of a community-based research

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Background: Though treatment is free for most people in the Dominican Republic, there are external factors that inhibit individuals to procure treatment or to assist to their regular checkups, such as the inability to pay for transportation, meals, and childcare. Evidence from other countries shows that out-of-pocket (OOP) expenditures can generate significant barriers to access and retention in care for persons living with HIV. The objective of this research was to estimate OOP expenses incurred by persons with HIV, and to analyze characteristics associated with them, including socio-demographic characteristics, current treatment options, vital status, use of health services, and impact of opportunistic infections.
Methods: Data was collected between October and November 2015 with a community based participatory research (CBPR). The sample consisted in 191 randomly selected adults living with HIV, enrolled in ART or pre-ART services across 10 sites in and around Santo Domingo. Researchers conducted individual face-to-face interviews with different themes: demographic characteristics, current visit at health facility, vital status, and OOP expenditures associated with HIV services in the last six months.
Results: Individuals interviewed reported an average total spending on health for the last six months corresponding to US$ 153. Besides, individuals reported an average of US$ 28 spent on transport and housing to access HIV services. When looking at how out-of-pocket expenditures were spent, the two most important categories were hospital stay and nutrition complements, which corresponded to US$35 and US$43 respectively. These important expenses can lead individuals to rely on external financial sources. 17% reported having to sell personal belongings to pay for health expenditures, 35% having to ask a personal loan from family or friend, and 31% having to take a loan from someone outside their personal and family circle.
Conclusions: The costs of transport and housing to access HIV services appeared to be significant for a vast majority of the individuals surveyed (85%). Our results suggest that while the majority of people with HIV reports limited amount of OOP expenditures, the latter could be a significant barrier to access and retention to HIV care and treatment for a minority of individuals facing important expenses in the Dominican Republic.

TUPED1203

Can adolescents and youth in Kenya afford free HIV testing services? A cost analysis

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Background: Voluntary HIV testing among adolescents is critical to curb transmission and limit morbidity and mortality. Although HIV testing is free, other costs to adolescents may be barriers.
Methods: Adolescents and youth ages 14-24 who completed voluntary HIV testing and counseling (VCT) at a large public hospital in Nairobi, Kenya were recruited. Direct non-medical costs (transportation, childcare, and food), indirect costs (missed income), and lost school time were collected. Per capita GDP ($115USD/mo) was used as a proxy for wages for unpaid work. Median and interquartile ranges (IQR) presented for participants with non-zero costs.
Results: Among 189 adolescents, 121(64%) reported non-zero costs; 118(62%) had direct non-medical costs, 19(10%) had indirect costs. Among those with non-zero costs, the median total cost was $1.98. Median direct costs were $1.73. Food and transport were the largest components of direct costs: 79(42%) paid for food (median: $1.98), 98(52%) paid for their own transport (median: $0.59), and 20(11%) paid another person's fare (median: $0.50). Median indirect costs were $7.97; 19(10%) missed a half or full day of work. 78(42%) missed a half or full day of school. Monthly income ranged; 25(13%) of adolescents had any income. Among those with income, median monthly income was $198; 52% reported no income but incurred direct costs; 35% reported no income and no direct costs.
In sex-stratified analyses, males (34%) were more likely to have direct and indirect cost than females (78% vs 53%, 15% vs 7%, respectively). They had similar sources of income, but males were more likely to have a salaried job (15% vs 10%). Males were more likely to pay for their transport than females (63% vs 45%).
Conclusions: The costs of HIV testing may influence adolescent care seeking and HIV detection. Interventions to address cost of seeking HIV testing and time away from school or work should be considered.

N=189	n	%	median	25th percentile	75th percentile
Any direct non-medical costs	118	(62)	1.73	0.69	2.97
Any indirect costs	19	(10)	7.97	5.01	11.38
Has salaried job	23	(12)	148.51	54.46	297.03
Has non-salaried (casual labor) job	15	(8)	49.50	19.80	99.01
Does unpaid work	86	(46)	--	--	--
Has other source of income	11	(6)	19.80	4.95	49.50
Any food and drink outside the house	79	(42)	1.98	0.99	1.98
Paid own transportation costs	98	(52)	0.59	0.40	0.99
Paid another person's transportation costs	20	(11)	0.50	0.30	0.84

[Costs of adolescent care seeking]

TUPED1204

Rethinking the value of pill counts: poor performance of pill counts in correlating with viral suppression in HIV-infected patients on ART at the Mbeya, Tanzania COE

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Background: Pill counting is a labor-intense, time-consuming and logistically challenging process to implement efficiently at high volume clinics. It is susceptibility to unintentional calculation and human errors at the facility and patient level. Given the time consuming nature of the practice, it is important to evaluate the utility of pill counting in our resource limited settings. We evaluated the performance of pill counting in correlating with viral suppression in patients on ART in Mbeya, Tanzania.
Methods: Retrospective review of pill count data and VL results was extracted between January 2015 and May 2016 at the Baylor College of Medicine Children's Foundation - Tanzania centre of excellence in Mbeya, Tanzania. "Viral suppression" was defined as VL <1000 copies. Pill count value of "95-105%" was used to define test result of interest. Pill count data was extracted from the same visit the VL testing was performed. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) was calculated to evaluate the performance of pill count of "95-105%" to identify viral suppression.
Results: Between January 2015 and May 2016, 903 patients had both a documented pill count and VL. Of these, 59% (530/903) were virologically suppressed. In correctly identifying virologically suppressed patients, pill count of "95-105%" had 64% sensitivity, 40% specificity, 60% PPV and 44% NPV. For patients during the routine VL testing era that started February 2016 (n= 575), 63% (364/575) were fully suppressed, and "95-105%" pill count had 63% sensitivity, 38% specificity, 64% PPV and 38% NPV.
Conclusions: Pill count value of "95-105%"performed poorly in identifying virologically suppressed patients on ART. Sensitivity, specificity, PPV and NPV were all low. Clinicians need to be aware of these limitations of pill counts, and critically consider the utility of this practice. Pill counts may be an additional tool, but is not a standalone replacement for adherence monitoring, and our findings should bring to light the risks and pitfalls of relying too heavily on pill counts as the sole measure of adherence.

TUPED1205

Community-based support reduces the risk of virological failure among children with HIV infection: results of the ZENITH trial

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Background: Children have poorer HIV treatment outcomes than adults. We conducted a randomized controlled trial to investigate the impact of community-based support on viral suppression and retention in care.
Methods: Children aged 6-15 years with newly-diagnosed HIV attending 7 primary health clinics (PHC) in Zimbabwe were randomized to receive routine (PHC-based) care (control arm) or routine care plus structured support visits by lay workers (LW) (intervention arm) over 18 months. Primary outcomes were proportion who i)died or had an unsuppressed HIV viral load (VL) (>400 copies/ml) at 12 months post antiretroviral therapy (ART) initiation (only in those who started ART within 6 months of enrolment, and ii)missed ≥2 scheduled clinic appointments within 18 months (all participants). The secondary outcome was a composite of death, VL>400 copies/ml, not initiating ART and loss-to-follow-up at 18 months. Odds ratios for outcomes were estimated using mixed-effects logistic regression, with adjustment for age and sex, LW and clinic and any variables with imbalance between arms at baseline.
Results: We randomised 334 participants (166 intervention; 168 control); median age 11 years and 53% female. Trial retention rates were similar between arms (Table):

	Intervention arm(n=166)	Control arm(n=168)
	n(%)	
Transferred to another clinic	30(18.1%)	23(13.7%)
-Planned	***-28***	***-14***
-Client did not inform clinic	***-2***	***-9***
Died	5(3.0%)	7(4.2%)
Withdrew from trial	0	1(0.6%)
Lost-to-follow-up	6(3.6%)	11(6.5%)

[Trial retention rates]

Within 6 months of randomization 122 intervention arm and 115 control arm participants started ART, and at 12 months post ART initiation in this group the proportion of participants with VL >400copies/ml or death was lower in the intervention arm compared to control arm participants (33.0% vs 48.2%; aOR=0.47, 95%CI 0.24-0.91; p=0.03). There was also a significant difference between trial arms in the proportion who met the composite outcome (43.8% in intervention arm vs 58.0% in control arm; aOR=0.50; 95%CI 0.28-0.89; p=0.02). There was no difference by arm in proportion who missed >2 clinic appointments (17.4% vs 18.2%, aOR=0.92, 95%CI 0.49-1.74; p=0.79).
Conclusions: This is the first trial of an intervention that reduces risk of HIV virological failure in children in resource-limited settings, and has high potential for scaleability.

TUPED1206

Development of a risk score-based on patient's individual factors for predicting non-adherence to antiretroviral therapy

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Background: Adherence remains a key factor in the effectiveness of antiretroviral therapy. Patient-related individual factors that influence adherence are well known. However, we do not have a useful tool to predict adherence considering several risk factors together. The aim of the study was to develop a model to predict the risk of non-adherence in people living with HIV.
Methods: We retrospectively evaluated 349 HIV-infected patients who started antiretroviral therapy in 2012-2015 from a University Hospital in Barcelona, Spain. Adherence was evaluated every 2 months by pharmacy refills and by self-reports. A patient with < 90% of prescribed dose and / or ART interruption for more than one week was considered non-adherent. To test the association of risk factors with non-adherence univariate and multivariate logistic regression (LR) was used. The best cut-off was obtained by means of bootstrapping methodology. To develop an ease to use predictive score, we assigned the risk factors identified by multivariate analysis weighted points proportional to the β regression coefficient values. C statistic was evaluated as measure of performance.
Results: During a median follow-up of 23.13 months, 104 patients (29.8%) were considered non-adherents.
Seven independent risk factors were identified, and each was assigned a value proportional to its regression coefficient: alcohol use (20); current substance use (11); language and cultural barrier (24); unstable housing (13); concerns and negative beliefs about treatment (28); loss of previous appointments (28); Psychiatric disorder (depression, psychosis) (9). We calculated risk scores for each patient adding the values of each risk factor. The optimal cutoff point calculated was 29.7, and to predict non-adherence we found sensitivity 0.87, specificity 0.87, positive predictive value 0.74, and a negative predictive value 0.94. The C statistic was 0.91 (95% CI 0.87-0.94). Viral load < 20 copies / ml was achieved at follow-up by 92.7% versus 33.7% of patients in the adherent and non-adherent group respectively (p:0.000).
Conclusions: A simple risk score was developed to predict non-adherence to antiretroviral treatment with high sensitivity and high specificity. Once validated in another population could be a useful tool to identify the resources needed to achieve the optimal treatment goals.

TUPED1207

Predictors of missed clinic visits in the TREAT Asia HIV Observational Database (TAHOD)

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Background: Missed clinic visits can lead to poorer HIV treatment outcomes and higher risk of mortality. Knowing the determinants of missed visits will allow for appropriate counselling and intervention strategies to ensure continuous engagement in care.
Methods: Patients from TAHOD who have initiated antiretroviral therapy (ART) were included in the analyses. A missed visit was defined as having no clinical visits or laboratory assessments in a six-monthly time period, up to five years after ART initiation. Patients who were lost to follow-up were counted as having a "missed visit" up until 12 months after their last visit date then removed from the analysis dataset. Repeated measures logistic regression (GEE) was used to analyse factors associated with missed visits.
Results: A total of 7100 patients were included from 20 sites in 12 countries in Asia with 2676 (37.7%) having at least one missed visit. There were 4967 males (70%) and 2133 females (30%). The median follow-up time was 5.1 years (IQR 3.2 - 7.4). ART adherence information in the first six months was available in 2541 patients (35.8%). Multivariate analyses indicate that patients with early suboptimal self-reported adherence < 95% in the first six months were more likely to have a missed visit compared to those with adherence ≥95% (OR=2.55, 95% CI(1.81-3.61)). Other significant factors associated with having a missed visit were homosexual (OR=1.45, 95%CI(1.27-1.66)) and other modes of HIV exposure (OR=1.48, 95%CI(1.27-1.74)) compared to heterosexual exposure; using PI-based (OR=1.33, 95%CI(1.15-1.53) and other ART combinations (OR=1.79, 95%CI(1.39-2.32)) compared to NRTI+NNRTI combinations; and being hepatitis C co-infected (OR=1.27, 95%CI(1.06-1.52)). Patients aged older than 30 years (31-40 years OR=0.81, 95%CI(0.73-0.89); 41-50 years OR=0.73, 95%CI(0.64-0.83); and >50 years OR=0.77, 95%CI(0.64-0.93)); female sex (OR=0.81, 95%CI(0.72-0.90)); and being from upper middle (OR=0.78, 95%CI(0.70-0.80)) or high-income countries (OR=0.42, 95%CI(0.35-0.51)), were less likely to have missed visits.
Conclusions: Missed visits occurred in almost 40% of our TAHOD patients. Early ART adherence was an indicator of subsequent clinic visits. Intensive counselling and adherence support should be provided at ART initiation in order to optimise long term clinic attendance and maximise treatment outcomes.

TUPED1208

"Because my life is more important": findings from a qualitative study on adherence to second and third-line antiretroviral therapy regimens in rural Malawi and Kenya

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Background: Little is known about treatment adherence behaviours amongst second- and third-line patients who may have unique experiences associated with reaching ,the end' of their treatment options. We explored influences on adherence to second- and third-line regimens among patients enrolled in HIV programmes supported by Médecins sans Frontières in rural Malawi and Kenya.
Methods: Repeated in-depth interviews were conducted with 29 HIV patients on second- or third-line antiretroviral therapy and 10 HIV health workers with different roles in Chiradzulu, Malawi and Homa Bay, Kenya. Patients were purposively sampled from second and third-line patients receiving their current regimen for 6 months minimum, and ensuring maximum diversity in terms of age, sex, residence, virological outcomes and regimen type. Observations took place in clinics including group education sessions. Interviews were audio-recorded, transcribed and translated into English. Following coding, themes were derived deductively and inductively.
Results: In both settings, many patients' engagement with second and third-line treatment was shaped by experiencing life-threatening illnesses prior to switching regimens and fearing they had reached ,the end' of treatment options, before being given "a final chance at life". These events often catalyzed changes in patients' attitudes to treatment-taking and prompted feelings of responsibility for managing their disease. Transformations reported by patients included giving up drinking, reducing sexual encounters, changing jobs that interfered with treatment-taking, becoming involved in leadership positions in the community and overcoming stigma. This was more evident in the Kenyan programme where the counsellor had received more training in working with patients after regimen changes. Nevertheless, many patients reported the persistence of multiple and interrelated social, economic and health systems challenges that had undermined their adherence to first-line treatments.
Conclusions: While well-established barriers to adherence remain for many second- and third line patients, others experienced a resurgence of hope as they overcame debilitating HIV-related illnesses associated with prior treatment failure. Although this can initially encourage renewed efforts to adhere, the effects may wane over time. Regular, patient-centred counseling or peer-led mentoring following regimen change may help promote and sustain these life transformations and build resilience among patients, supporting adherence and thereby prolonging the life-span of second and third-line regimens.

TUPED1209

Is readiness the key of achieving viral suppression among people newly diagnosis with HIV

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Background: International emphasizes the need of early uptake of antiretroviral therapy (ART) for all HIV-infected patients at any CD4 cell count. Understanding individual´s readiness to initiate lifelong treatment is essential. The study purpose was to determine patient's readiness to take ART impact on HIV viral suppression.
Methods: A prospective longitudinal study was conducted at seven AIDS designated hospitals of Taiwan. Eligible patients were over 20 years old, newly diagnosed with HIV after 2014, and not currently taking antiretroviral medication.
Readiness to take ART is measured by the 10-item HIV medication readiness scale (HMRS) and the score >31.5 referred to ready to take ART.
Readiness and HIV viral load were repeated measured at three time points: baseline, one month (T1) and 6 months (T2) after taking ART.
Generalized estimating equation analysis was used to estimate relationships among readiness, adherence and viral suppression.
Results: A total of 283 patients newly diagnosed with HIV were enrolled, of them 146 (51.6%) had initiated of ART. Of the 137(48.4%) patients received ART, 58.4% had the HMRS score >31.5 referred to ready to take ART, 44.9% had achieved viral load suppression in T2. Factors associated with taking ART were: readiness (OR, 2.07; 95% CI, 1.24-3.46, p=0.005) CD4 cell counts lower than 350 counts/mm3 (OR, 0.567; 95% CI, 0.33-0.98, p=0.042), and viral load >100,000 copies/ml (OR, 1.89; 95% CI, 1-05-3.39; p=0.034). Eighty (54.8%) patients completed three times repeated measure, readiness increased from 61.6% in baseline, 86.2% in T1, and 88.9% in T2. After taking HAART, adherence ≥90% increased from 41.6% in T1 to 92.9% in T2, and viral suppression rate increased from 9.8% in T1 to 44.9% in T2. Factors associated with viral suppression after taking ART were: Readiness (β=0.43, p=0.08), CD4 cell 350-500 counts/mm3 (β=1.11, p=0.07) and greater than 500 counts/mm3 (β=1.82, p=0.002).
Conclusions: Readiness is the key of initiation of ART among people newly diagnosis with HIV, but not the major factors of achieving viral suppression after taking ART. Preparing individual's readiness to initiate lifelong treatment is essential in the era of " treat-for-all".

TUPED1210

Adherence to maternal ART during the 18 months post-delivery in South Africa

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Background: Despite improved policies to prevent mother-to-child HIV transmission (MTCT), adherence to maternal antiretroviral therapy (ART) is low in South Africa. We describe ART adherence amongst a cohort of HIV-positive mothers from six weeks until 18 months post-delivery and identify risk factors for nonadherence.
Methods: Data were collected in 2012-2014 through a nationally representative survey of PMTCT effectiveness. Mother-infant pairs were enrolled during the infant's first immunization visit at 6 weeks. Mothers and HIV-exposed infants (2,811 pairs) were followed to 18 months at 3-month intervals. Mothers who self-reported being on ART at 6 weeks postpartum (N=1572 (55.9%)) were eligible for this analysis and information about their adherence was captured at each interview they attended thereafter. We defined nonadherence within each 3-month interval as self-report of missing >5% of daily ART doses, estimated cumulative adherence using Anderson & Gill analysis for recurring events, and identified risk factors for nonadherence with an extended Cox regression model (separately for mothers and infants) in Stata 13. Results are as yet not adjusted for the study design or non-response and not weighted for live-births.
Results: Cumulative adherence to ART until 18 months was 63.6% among mothers reporting ART use at 6 weeks (95% confidence interval (CI): 60.9-66.2) based on 483 nonadherence events during the 480,715 days of person-time contributed. Risk factors for nonadherence to maternal ART, controlling for other factors, included single status (single vs. married, adjusted Hazard Ratio (aHR): 1.6, 95% CI: 1.1-2.3), young maternal age (16-24 years vs. >35 year aHR: 1.5, 95% CI: 1.1-2.1), and nondisclosure of HIV status to anyone (nondisclosure vs. disclosure: aHR: 1.5, 95% CI: 1.2-1.9).
Conclusions: Maintaining ART adherence until 18 months postpartum remains a crucial challenge with maternal ART adherence <65%. Young, single, and mothers who do not disclose their status should be targeted with messages to improve adherence.

TUPED1211

Impact of mobile technology in improving tracking outcomes in Northern Nigeria

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Background: Retention in ART has remained a serious challenge for HIV treatment programs in northern Nigeria among patients on ART. High rate of Lost to Follow Up (LTFU) among clients on ART constitute a significant challenge to the success of achieving 90% retention rate. This is as a result of difficulty in physically tracking the clients back to treatment due to distance and hard to reach terrains. Thus, most PLHIV who default on ART and are eventually lost to follow up.
Methods: With funding from USAID, MSH's Pro ACT project provided mobile phones to select trained adherence counsellors and trackers in select supported health facilities. These mobile phones are used to track clients who default on appointment and those LTFU. Counseling services are also provided to defaulters and LTFU clients via mobile phones. List of defaulters and LTFU clients are generated from supported health facilities by data clerks and handed over to trained trackers and adherence counsellors for onward tracking using mobile phones. The trackers and adherence counsellors reach the defaulters and LTFU clients at least twice a week through mobile phones. These interventions were conducted in supported health facilities across Kwara, Sokoto and Kebbi states in North Central and North Western Nigeria. A total of 4315 clients comprising of defaulters and LTFU were tracked. This number comprised of 1425 males and 2830 females.
Results: After twelve months of intervention, a total of 2956 clients comprising of defaulters and LTFU were tracked back to ART. This number comprised of 1020 males and 1936 females. Thus, 68.5% of defaulters and LTFU clients were returned to ART using mobile technology.
Conclusions: The use of mobile technology in tracking and provision of adherence counseling services improves clients retention on ART especially among clients from far distance and hard to reach terrains. Thus, there is a need to scale up this intervention especially in rural communities.

TUPED1212

Client and provider perceptions of factors affecting adherence to antiretroviral therapy in Côte d'Ivoire

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Background: HIV is the leading cause of death in Côte d'Ivoire and adult prevalence is 3.5%. In 2012 it was estimated that only 67% of clients were alive and on treatment 12 months after initiation of antiretroviral therapy (ART). A 3-year pilot of an integrated model of chronic care aiming to improve retention and adherence began in 2015 in 42 government facilities across 2 regions of the country. A qualitative evaluation was undertaken to understand patient and provider perceptions of barriers and enablers to adherence to care.

Methods: In May 2016, we conducted a cross-sectional qualitative assessment in one hospital and one health center in one region where the model was being implemented, with matched facilities in a neighboring control region. This included in-depth interviews and focus group discussions with clients, and in-depth interviews with providers. A total of 108 participants were interviewed during 36 discussions after consent was obtained. Ritchie's Framework analysis approach was used to ascertain themes deductively and inductively, and coding of verbatim transcripts occurred in Atas-ti.
Results: Service-level enablers identified included improved access to medicines, provider follow-up with clients, counselling that emphasizes HIV as a chronic condition, confidentiality, presence of a clinical care team, appointment scheduling and encouragement of partner disclosure of HIV status. Client-level barriers included difficulty disclosing status, stigma, missing appointments for social responsibilities; traditional healers discouraging ART use; and transport costs. Service-related barriers were related to staffing and wait times. Facility staff and clients articulated the perception that HIV is a condition that one can live with, similar to other chronic conditions.
Conclusions: The integrated chronic care model has potential to improve social support for PLHIV, facilitate disclosure of HIV status among couples, and may reduce perceived stigma that, for many PLHIV, contributes to difficulties with adhering to treatment. The model aims to decentralize care, contributing to the reduction of transport costs as a barrier, as well as improve facility-level care through instituting appointment systems and integrating services, leading to decreased waiting times and uncoordinated visits for clients.

TUPED1213

Use of digital gaming and Wisepill dispenser technology to measure adherence among HIV-infected adolescents and young adults

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Background: There is an unmet need for effective interventions to improve adherence to antiretroviral treatment (ART) among HIV-infected adolescents and young adults (AYAs). Interventions that utilize user-friendly gaming with motivational components have shown promise for behavior change in AYAs. Currently, the data on the role of gaming and real-time medication adherence monitoring of ART adherence remain limited. This study examined the uptake of interactive smartphone based games interlinked with medication-monitoring device (Wisepill dispenser) among a cohort of HIV-infected AYAs on ART.
Methods: HIV-infected AYAs ages 13-24 years with suboptimal ART adherence (defined as detectable HIV viral load) were eligible. Participants were provided with smartphones containing three digital games with varying levels of difficulty and a Wisepill dispenser, which openings were linked to in-game incentives. Gameplay data, including the numbers of levels completed and Wisepill dispenser openings were tracked using wireless technology. Descriptive statistics were used for data analysis.
Results: Twenty-four participants (mean age=18 years; 12M/12F) were recruited; 17 (10F/7M) completed the 3-month follow up. Participants opened their Wisepill dispensers only 23% of the time based on the prescribed ART frequency (501 actual/2169 prescribed openings). On time Wisepill dispensers' openings (within two hours of self-reported daily medication ingestion times) were observed only 5% of the time (118 actual/2169 prescribed openings). Nearly three-fourths (71%; n=17) decreased the number of Wisepill openings during the study period. Available game data among 3-month follow up participants (n=12; 7M/5F) showed overall little gameplay (mean=12% completion). There were no differences in amount of gameplay by age; however, females showed slightly higher completion compared to males (14% vs. 10%). Among the three games, higher degree of difficulty was associated with lower degrees of completions.
Conclusions: Although a real-time, electronic ART adherence monitoring system interlinked with smartphone gaming was technically feasible, we observed low uptake of this technology among this cohort of HIV-infected AYAs with suboptimal ART adherence. Data from ongoing exit surveys will be used to modify gaming and adherence monitoring design.

TUPED1214

Antiretroviral therapy adherence among HIV-positive breastfeeding women in an implementation research study in Malawi

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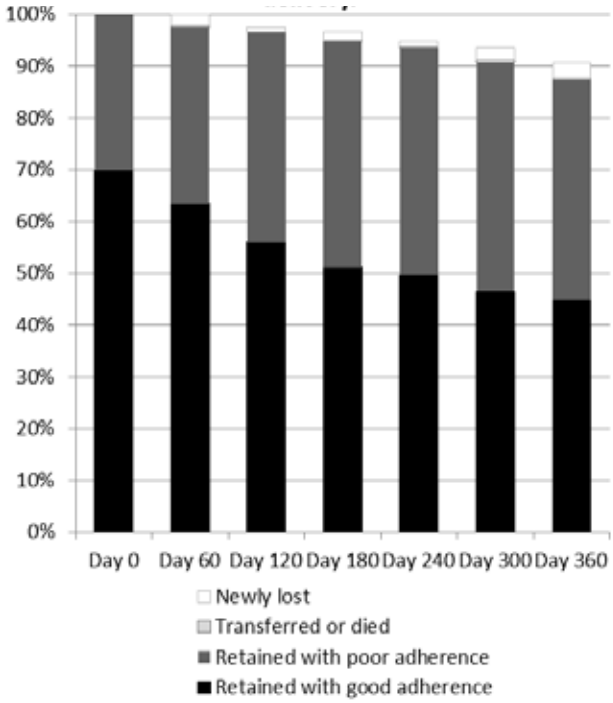
Background: Option B+ has changed the landscape for prevention of mother-to-child-transmission of HIV (MTCT), offering antiretroviral therapy (ART) to all HIV-infected pregnant women for life. To achieve virtual elimination of MTCT, efforts must include evaluating retention in care and adherence to ART. This analysis examines adherence of ART medication possession ratio (MPR) among HIV-positive breastfeeding mothers in Malawi.
Methods: Data from clinical records abstracted as part of the Promoting Retention among Infants and Mothers Effectively (PRIME) study (a cluster randomized controlled trial that examined post-partum retention in care), conducted May 2013-August 2016, were pooled and reanalyzed. Using ART attendance dates, number of pills dispensed, transfers and deaths for every woman, at every visit, the proportion of women with good adherence was assessed, defined by MPR ≥95% of the time while in care, from delivery through 360 days.
Results: Among the 1084 women on ART and in care at delivery (day 0), 70% had good adherence. This proportion decreased to 63% on day 60, 51% on day 180, and 45% on day 360 (p< .001), with the overall proportion retained on day 360 decreasing to 87% (figure 1). By day 360 2% died or transferred and 11% were lost. Women who initiated ART during pregnancy (61%) were more likely to be lost by day 360 than those already on ART prior to pregnancy (14% vs. 6%, RR 2.05, p=0.001). Similarly, women already on ART were more likely to have good adherence (51% vs. 41%, RR 1.24, p=0.002).



[Figure 1. Evolution of good ART adherence (medication possession ratio ≥95%) and retention in care from days 0 to 360 post-delivery]

Conclusions: Although most women were retained in care one year after delivery, less than half had good adherence, much lower than Malawi's goal of achieving good adherence among 90% of patients by 2020. Interventions to keep women in care and ensure good adherence must begin during the antenatal period and be maintained through the postpartum and breastfeeding period.

TUPED1215

Understanding treatment failure amongst patients on second-line antiretroviral therapy regimens: a mixed methods study in Médecins sans Frontières-supported HIV programmes in rural Malawi and Kenya

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Background: Patients' understanding of the relationship between viral load and antiretroviral therapy may influence their adherence to treatment, particularly among those who have experienced treatment failure. We investigated second-line patients' understanding of HIV, treatment and viral load and its association with viral load suppression.
Methods: Quantitative: Adult patients receiving second-line antiretroviral therapy regimens for at least 6 months in Médecins sans Frontières-supported programmes in Chiradzulu (Malawi) and Homa Bay (Kenya) underwent viral load testing and were interviewed to assess knowledge about HIV, treatment and viral load. A knowledge score was calculated by summing the number of correct answers to 9 true/false questions on antiretroviral therapy.
Qualitative: In each site, repeated in-depth interviews were conducted with a purposive sample from the survey participants (Kenya:n=16) and (Malawi:n=13) and 5 health workers to explore experiences and understanding of second-line medication. Interview data were transcribed, translated and coded. Content analysis identified emerging themes from the data.
Results: Quantitative: In Kenya, 299 (51% female) and in Malawi 212 (59% female) were surveyed. Knowledge about antiretroviral therapy was high in both sites, whereas understanding of viral load was more limited, with some differences by site (table 1).

	KENYA			MALAWI		
	VL < 1000 copies/ml	VL ≥ 1000 copies/ml	p value	VL < 1000 copies/ml	VL ≥ 1000 copies/ml	p value
	n(%)	n(%)		n(%)	n(%)	
Total surveyed n (%)	**256(86)**	**43(14)**	**n/a**	**188(89)**	**24(11)**	**n/a**
Good ART knowledge: (8/9 questions correct)	192(75)	31(72)	0,67	186(99)	24(100)	0,61
Doesn't know if ever had VL test	39(15)	9(20)	0,56	9(5)	1(4)	0,64
Doesn't know what VL test is for	43(17)	15(35)	0,006	28(15)	4(17)	0,76
Knows that VL test can check if ART is working	57(22)	7(16)	0,37	122(65)	1(71)	0,56
Knows that VL test can monitor adherence	11(4)	0()		72(38)	9(36)	0,94

[Table 1. Results Knowledge questions]

Qualitative data revealed that moralistic messages from health workers in both settings meant that some patients believed that high viral load results and treatment failure were due to unprotected sex, use of traditional medicine or witchcraft, particularly in Malawi. Many patients did not explicitly link viral load results to their own pill-taking or the effectiveness of their treatment.
Conclusions: Despite excellent knowledge about antiretroviral therapy, many second-line patients have limited understanding of viral load and its relationship to adherence and treatment failure. Counselling sessions should address the missed opportunity to explain this relationship which may promote regular pill-taking. Supportive counselling approaches should be favoured rather than blaming patients' sexual behavior or use of traditional medicine for treatment failure.

TUPED1216

Design of a user-centered strategy to improve ART adherence among MSM living with HIV in Mexico

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Background: Globally, studies show that adherence levels to antiretroviral therapy (ART) among people living with HIV are not optimal. High adherence to ART is key to improving survival rate and reducing AIDS related complications among patients, while also reducing HIV-transmission. The objective of this study was to design a user-centered strategy to improve adherence to ART among MSM living with HIV in Mexico.
Methods: Between October and November 2016, 37 MSM participated in six focus groups discussions held in two Mexican cities, and 9 semi-structured interviews were conducted with health care providers of two HIV-clinics. A team discourse analysis approach was first used to identify themes using MAXQDA software. A "design thinking" approach was then used in order to identify the best elements to design the strategy.
Results: We identified multiple barriers and facilitators to ART adherence, and strategies used by patients to improve their medication intake. We found that these strategies vary in time as patients adjust their routines over the course of treatment. Two key moments were identified as crucial to intervene: treatment initiation and a period of readjustment after an intake routine is established. The former is a stage in which most of the adherence barriers first emerge and is crucial for newly diagnosed patients; the latter is essential for those who have already achieved a routine of medication intake, but this routine is discontinued or about to be.
To address this, we designed a multi-stage intervention strategy. For the first, we focused on the formation of skills to overcome key barriers. For the second, we reinforcement key information regarding HIV and ART, strengthen communication with health personnel, and create safe spaces for MSM living with HIV to share experiences with peers.
Conclusions: Barriers and facilitators to adherence are not static, and might undergo changes throughout different stages of adjustment to ART, thus, different moments and strategies that can be used to improve medication intake should be considered by health personnel.
Daily routine, social context, and cultural factors should be taken into account while designing a strategy to improve ART adherence in MSM in order to make it relevant and effective.

TUPED1217

Assessment of predictors of retention in care HIV-infected women in Ukraine

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Background: HIV-infected women are very affected through stigmatization, social problems and drug abuse. Women initiating ART during pregnancy before implementation of Option B+ have high rates of dropout, particularly after delivery. In this study, we aimed to explore the HIV cascade care in Ukraine and potential barriers to retention HIV infected women.
Methods: We analyze data from medical documentation a retrospective cohort of 839 women who were observed in HIV outpatient clinic in Poltava region of Ukraine in 2003-2016. Three outcome measures related to involvement and retention in care were considered - (1) duration of contact with the HIV-care institution after the initial registration, (2) time of the first CD4 count analysis, (3) start of ART.
Results: Among 839 study participants, were registered in care 121 in 2005 or earlier, 226 in 2006-2008 and 492 in 2009 or later. Proportion of women who were registered in care and not seen by health workers in subsequent years was 25.7% overall and lower (13.2%) in earlier years. Women who inject drugs and those who diagnosed during the pregnancy had higher rates of dropout (OR=1.6, 95%CI 1.1-1.8; OR=1.9, 95%CI 1.5-2.3). Staying in care was best predicted by having any of the clinical complications including oropharyngeal candidiasis (OR=0.6, 95%CI 0.3-0.7), any unknown opportunistic infection (OR=0.5, 95%CI 0.3-0.9), tuberculosis (OR=1.2, 95%CI 1.1-2.8), herpes zoster (OR=0.5, 95%CI 0.3-0.8). Likewise,

patients with diagnosed HIV-infection stage 4 at admission were less likely to drop out (OR=0.5, 95%CI 0.3-0.8). Among those who stayed in care, 538 (64.1%) had their CD4 test within same or next year after registration, 205 (24.4%) did so later on, and 96 (11.4%) never got their CD4 counts. Younger women (29 years or less) had greater risk to never get CD4 counts and to postpone getting the test. Analysis of start ART showed that if any of the above listed symptoms were present, odds of getting ART were greater: OR=2.2, 95%CI 1.4-3.4.
Conclusions: The main predictors of retention in HIV care were revealed appearance of severe opportunistic infections, low level of CD4 counts, older age, drug abuse and diagnosing HIV during the pregnancy before implementation of Option B+.

TUPED1218

The role of peer-to-peer model in achieving 90-90-90 among female sex workers in East Central Uganda

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Background: Female Sex workers (FSWs) have an increased risk of HIV infections due to a number of behavioral and structural drivers. In Uganda, HIV prevalence among FSWs is estimated between 33 and 37 percent, much higher than the national average of 7.3 percent. The objective of presented work was to assess engagement of FSWs in HIV care continuum within Strengthening HIV&AIDS and Tuberculosis Responses in East Central Uganda (STAR-EC) program.
Methods: STAR-EC supported access to and use of TB and HIV services within the East Central Region for the period 2014-2016. The project targeted different populations, including Key populations. STAR-EC trained peer-to-peer- mentor buddies, identified and registered FSWs in brothels, bars, lodges, and truck stops. Registered FSWs were referred to reproductive health and HIV services, including family planning, STI risk reduction counselling, HTC, ART, and adherence counselling, offered at health facilities and outreach clinics. Follow up by health workers to HIV-negative FSWs on a monthly basis was conducted and HIV-positive FSWs received retention support services including CD4 and viral load testing.
Results: A total of 2,815 FSWs were reached by STAR-EC during October 2014 - June 2016. Among them 2,318 FSWs were tested for HIV for the first time and 608 tested HIV positive. Among 608 HIV positive FSWs, 577 (95%) linked to ART, 537 (88%) remained active on ART within the region, 430 (71%) received CD4 and viral load testing and 318 (52%) were virally suppressed.
Conclusions: Peer-to-peer ,mentor buddies' program helped to diagnose HIV positive persons and link them to care. Additionally, the model helped FSWs to be retained on ART program. A lot more is still required to ensure everybody accesses viral load testing and mechanism to be put in place to ensure viral load suppression for FSWs in order to achieve the 90 90 90.

TUPED1219

"I can do this myself": investigating the acceptability of a web-based, HIV self-testing service in South Africa

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Background: While HIV testing rates have improved in South Africa, the majority of HIV positive individuals (65% male, 45% female) are unaware of their seropositivity, which negatively impacts the potential for universal HIV treatment. HIV self-testing (HIVST) has been shown to have high fidelity, feasibility and acceptability, and therefore has the potential to provide testing to individuals who may not use traditional healthcare services, with subsequent opportunities for timely HIV care. This study evaluated individual acceptability of a web-based HIVST delivery service.
Methods: Self-selected participants above 18 years old logged onto the iTest website via a web search. After viewing text and video study information, participants requested an HIVST and were presented with referral options. Following online consent, a courier was notified to deliver the iTest HIVST to the participant's address. A researcher administered a telephonic acceptability questionnaire within two weeks of the HIVST delivery.
Results: 205 (55%) of 372 participants who enrolled were successfully contacted. 141 of these participants (58% female) had completed the HIVST, and 7% were first-time (debut) testers. No adverse experiences were reported. The majority (97%) reported satisfaction with delivery times, which ranged from 2-5 days, with 7 participants reporting non-delivery. Nearly all participants considered the service to be confidential (94%), with an easily understood video (97%) and written information (96%). The service was rated 4.7 out of 5 with 115 (82%) stating that their experience of self-testing was better than facility based testing.
Conclusions: This study demonstrated high acceptability for the web-based HIVST service, with no adverse events reported. The number of debut testers was surprisingly low. Further qualitative research may elucidate the reasons for seemingly lower uptake from debut testers. The study indicates that HIVST available online can complement existing HIV testing strategies by offering a rapid and confidential testing environment.

TUPED1220

Engagement of traditional birth attendants for scaling-up PMTCT coverage in Abia and Taraba States, Nigeria

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Background: Slow effort at integrating Traditional Birth Attendants (TBAs) care has been identified as one of the barriers to scaling up prevention of mother-to-child transmission of HIV (PMTCT) in Nigeria. Under the National Agency for Control of AIDS Comprehensive AIDS Programme with States, we engaged TBAs to scale-up PMTCT coverage in Abia and Taraba States.
Methods: Mapping: Officers-in-charge (OIC) or the PMTCT focal persons in the Primary Healthcare Centres (PHCs) were asked to identify TBAs within their environs.
Capacity building: A two-day meeting was held to train the TBAs on universal precaution and safe assisted delivery and to also get a buy-in on the engagement.
Network formation: Referral and linkage networks were established between TBAs and PHCs.
Service provision: From July to September 2016, the OICs or PMTCT focal persons in the PHCs conducted monthly outreaches while the TBAs mobilized their clientele for the outreaches. The OICs were provided with stipend for the outreaches and the TBAs were also provided with communication stipend to facilitate referral and linkages with the PHCs.
Monitoring and Evaluation: Ad hoc forms were developed for reports on the outreaches. Data were also captured using the national M & E tools and register as appropriate.
Results: A total of 720 TBAs were mapped (Abia 407; Taraba 313). Three hundred and ninety nine TBAs who participated in the capacity building meeting were linked to 115 PHCs in Abia State while 245 TBAs were linked to 27 PHCs in Taraba State. In three months, the outreaches contributed 17% to the number of pregnant women counselled tested and received result (CTRR) (table 1) and 15% to the total positive women identified (table 2). All the positive pregnant women were enrolled into care.

State	TBA outreach	Facility	Total CTRR	% contribution from TBA outreach to total CTRR
Abia	2,053	9,073	11,126	18%
Taraba	1,892	10,154	12,046	16%
Total	**3,945**	**19,227**	**23,172**	**17%**

[Table 1: Pregnant women CTRR]

State	TBA outreach	Facility	Total positive	% contribution from TBA outreach to total positive
Abia	58	270	328	18%
Taraba	22	174	196	11%
Total	**80**	**444**	**524**	**15%**

[Table 2: Pregnant women who tested positive]

Conclusions: If effectively engaged, TBAs can improve the uptake and coverage of PMTCT services by bridging the gap between the communities and the health facilities.

TUPED1221

Effectiveness of community-based HIV testing and counseling in identifying HIV-positive cases and linking to care in a concentrated epidemic in Viet Nam

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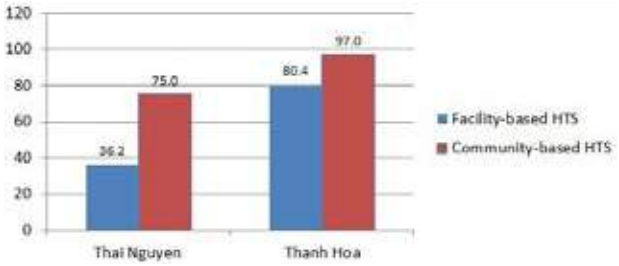
Background: Uptake of HIV testing and counseling services (HTS) at health facilities has been limited among key populations in Vietnam due to various reasons, e.g. fear of discrimination, stigma, need to travel long distance. Community-based HTS (CBHTS) was piloted to test the hypothesis that CBHTS is acceptable to key populations and effective in identifying HIV positive cases and linking them to treatment.
Methods: Pilot description: The pilot was started in January 2015 in Thanh Hoa and in August 2015 in Thai Nguyen province. CBHTS was delivered by trained village health workers in 12 communes in Thanh Hoa, and by trained PWID and MSM peer educators at three sites in Thai Nguyen.
Pilot assessment: A review on CBHTS was conducted in November 2016 to assess the outcomes of the pilot including feasibility and acceptability of CBHTS. Quantitative data were obtained through the reviews of HTS and treatment logbooks. Qualitative data were collected though 33 in-depth interviews and 2 focus group discussion sessions
Results: A total of 1,711 clients received HTS in communities. Forty-four clients were diagnosed as HIV positive and 40 (91%) were linked to ART (Table 1). Better linkage from HIV testing to treatment was achieved compared to facility-based HTS (Figure 1). Both clients and lay providers reported CBHTS is convenient for clients, enhancing demands for HTS; reaching "unreached" key populations, providing prompt and accurate results while ensuring privacy and confidentiality, and supportively linking to care and treatment services.

Clients	# tested	# HIV+ cases (%)	# received ART (%)
Key populations	834	34 (4.1)	30 (88.2)
Partners/children of people living with HIV/people who inject drugs	472	8 (1.7)	8 (100)
Other	405	2 (0.5)	2 (100)
Total	1711	44 (2.6)	40 (90.9)

[Table 1. Results of CBHTS in two piloted provinces]



[Figure 1. Linkage from HIV testing to care and tre]

Conclusions: The results of this pilot demonstrated the appropriateness, effectiveness and feasibility of CBHTS as an additional approach for increasing testing uptake. The results of this pilot informed development of national guidelines for HIV testing in which CBHTS was recommended.

TUPED1222

Provider-initiated testing and counseling: is it still high yield? Yield of routine HIV testing in pediatric and adult inpatient wards in central and southern Malawi

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Background: Routine HIV testing at health facilities (provider-initiated testing and counseling, PITC) is recommended at presumed high yield venues like inpatient wards. Limited recent data exist on testing yield in settings like Malawi with mature Option B+ and active HIV case finding programs. We evaluated inpatient PITC yield at three hospitals in central and southeastern Malawi.
Methods: Data on PITC in inpatient wards (adult, pediatric, pediatric nutritional rehabilitation units (NRU)) were collected from July-Dec 2016 (Salima) and Oct-Dec 2016 (Balaka, Mangochi) using dedicated PITC registers. Per national guidelines, patients one year of age and older underwent rapid antibody testing to determine HIV status; mothers of infants less than one year (or if unavailable, infants) underwent rapid HIV testing to determine HIV exposure. Patients were offered testing if they had never tested for HIV, tested negative >3 months ago, or had no documentation of prior testing. HIV status (known or newly ascertained) and testing outcomes for patients one year of age or older were analyzed to determine ward HIV prevalence and testing yield.
Results: Of 7664 inpatients (3526 pediatric, 4064 adult, 74 NRU) admitted during the evaluation period, 6266 (82%) were assessed for testing eligibility. Of those assessed, 4742 (76%) did not have documented HIV status (including those never tested) or tested negative >3 months ago and were offered testing. Refusal rate was 1.6%.

	Ward prevalence: Known and new HIV+ / (Total Known Status + Total Newly Tested >1yo)	Testing Yield:New HIV+ / (Total Newly Tested >1yo)
NRU	25.5% (13/51)	12.5% (4/32)
Pediatric Inpatient	3.5% (75/2118)	1.1% (19/1799)
Adult Inpatient	23.7% (787/3327)	4.8% (102/2141)

[Ward Prevalence and Testing Yield]

The majority of HIV-positive inpatients knew their HIV status prior to admission (87% in adult wards, 75% in pediatric wards, 69% in NRU). Inpatient ward HIV prevalence was higher than national population HIV prevalence (1.6% 0-14y and 10.6% 15-64y) (Malawi Population-based HIV Impact Assessment 2016). Yield of new HIV testing among inpatients (excluding NRU) was lower than population prevalence.
Conclusions: PITC remains an important approach for HIV case finding and is critical for prompt treatment initiation, however in the setting of Option B+ and active HIV case finding, yield may be decreasing. Contemporary data on PITC yield in various settings and identification of novel high-yield case finding strategies are needed.

TUPED1223

After achieving 90-90-90 in the SEARCH study: who is not achieving viral suppression?

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Background: HIV viral suppression (VS) on a population level can accelerate elimination of new HIV infections. The SEARCH HIV test-and-treat study (NCT01864603), achieved 97% HIV tested/93% on ART/89% suppressed after 2

years in 16 intervention communities (~10,000 persons each). Population-level viral suppression among HIV+ persons was 80%. We assessed demographic and care characteristics to better understand factors contributing non-suppression in the 20% of adults who remain viremic.
Methods: We studied HIV+ adults (≥15 years) in 16 SEARCH intervention communities using streamlined HIV care that included:
(1) nurse-driven triage,
(2) multi-disease care,
(3) viral load (VL) testing and counseling,
(4) 3-month ART refills,
(5) appointment reminders and patient tracking, and;
(6) telephone access to clinicians.
VLs were measured at during annual campaigns and clinical follow-up (June, 2013 - November, 2016). Predictors of viremia (most recent VL>500 copies/ml) were sought with multivariate logistic regression.
Results: Among 8299 HIV+ adults, 5705 (69%) were ≥30 years and 2594 (31%) were aged 15-29 years. Among the 7968 (96%) adults with at least one VL measurement, 1603/7968 (20%) were viremic. Among these viremic adults: 980 (61%) were female, 869 (54%) were ≥30 years, 1082 (68%) were married, 1257 (78%) had attained primary education, 831 (52%) were farmers and 1131 (71%) resided in Kenya. In total, 494 (31%) had never been in care, 512 (32%) were linked to care but lost to follow up (LTFU), and 597 (37%) were actively engaging in care. Predictors of viremia included: age 15-29 years (OR= 2.29 vs. age ≥30, 95% CI 2.02-2.58); male (OR=1.43, 95% CI 1.26-1.61); working in transport (OR=1.49 vs farming, 95% CI 1.01-2.19); being a student (OR=2.27 vs farmer, 95% CI 1.70-3.04), and residing in Kenya (OR= 1.24 vs. residing in Uganda, 95% CI 1.09-1.40).
Conclusions: In the SEARCH Study, after 2 years of a universal HIV test-and-treat intervention, 20% of HIV+ adults remained viremic. One third had never linked to care, 1/3 LTFU and 1/3 were still engaged in care. Youth—in particular young men—and students were the most at risk for viremia. Targeted interventions to support viral suppression are urgently needed for these sub-populations.

TUPED1224

Barriers and facilitators of HIV testing among female sex workers in rural pastoralist communities in Northern Kenya

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Background: Female sex workers (FSWs) in Turkana County, Kenya, are disproportionately affected by HIV compared to the general population and other FSWs in Kenya (36% versus 6% and 29%, respectively). HIV testing is a critical first step in linkage to care and yet uptake is low in this region.
We sought to increase HIV testing through peer-led outreach and determine reasons for low testing uptake among FSWs in Turkana West subcounty, a rural pastoralist community in Northern Kenya.
Methods: The USAID and PEPFAR funded LINKAGES project, in collaboration with TUPADO, conducted hotspot mapping exercises in Turkana West subcounty. We estimated the number of FSWs in the region and formed a community advisory board consisting of FSWs and project staff to help identify a suitable location for a drop-in center (DIC). We trained 30 peer educators to mobilize their peers for intensified HIV testing at least once every quarter. FSWs were tested through referrals to the DIC or through outreach events. We analyzed data collected during programmatic activities for accelerating HIV testing in the run-up to World AIDS Day 2016. Descriptive statistics are used to summarize HIV testing uptake.
Results: A total of 28 hotspots with 1,465 FSWs were identified from October to December 2016. Of 851 FSWs (58%) offered HIV testing services, 162 (19%) accessed the HIV testing centers, of whom 147 (17%) received an HIV test. Sixty-five percent of FSWs tested were ages 15-24 years. The most common reason cited for testing was a need to confirm their HIV negative status. Of the 15 FSWs who accessed the testing center but declined an HIV test, seven (47%) reported a condom burst without access to post-exposure prophylaxis in the previous three months. The most commonly cited reason for not testing was fear of others knowing their status and desire for heightened anonymity.
Conclusions: HIV testing uptake continues to be low among FSWs in this high HIV prevalence region. HIV stigma reduction interventions and heightened confidentiality measures during testing are urgently needed to increase uptake of HIV testing and prevention services among high risk FSW.

TUPED1225

High virological suppression and retention in HIV-infected patients initiated on ART with CD4 above 500 in a program setting in Uganda

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Background: The World Health Organization recommends antiretroviral therapy (ART) for all HIV-infected patients. However, there are concerns that healthy patients especially key populations (KPs) accessing ART in programmatic settings may have poorer rates of virological suppression. We sought to determine the prevalence of lost to follow up (LTFU) and define predictors of viral suppression among HIV infected adult patients initiated on ART with baseline CD4 cell count >500 cells/µl at two high volume urban clinics in Kampala, Uganda.
Methods: In this cross-sectional study, we enrolled patients attending two PEPFAR supported clinics, one of which exclusively serves KPs. Eligible patients were aged ≥18 years, baseline CD4>500 and on first line ART for ≥six months. We obtained data on socio-demographics, ART history, clinic and reasons for ART; using interviewer-administered questionnaires. Plasma HIV RNA was determined with Abbott Real-time© HIV-1assay.Predictors of virological suppression (HIV RNA< 75 copies/ml) were determined using multivariate logistic regression.
Results: Between August 2015 and March 2016, 228 consecutive participants were eligible of which 25 (11%) were LTFU (no visit in prior 90 days). Of the 203 enrolled patients, 106 (52.2%) were sex workers, 9 (4.4%) men who have sex with men, 17 (8.4%) discordant couples, 45 (22.2%) pregnant or lactating women and 26 (12.8%) were other high-risk populations. The median age (IQR) was 30 (25-35) years, median duration (IQR) on ART14.2 (8.4-16.2) months and baseline CD4 (IQR) was 662 (547-774) cells/µl. Virological suppression was achieved in 173/203 (85%; 95% CI, 80.3-90.1) patients, and 192/203 (95%, 95% CI 90-97) had HIV RNA< 1000 copies/ml. In a model adjusting for age, sex, adherence, prior HIV RNA test, reason for ART initiation and clinic, the factors associated with virological suppression were prior HIV RNA monitoring test(s) (aOR 6.98; 95% CI 2.63-18.50; p value < 0.001) and receiving care from a non-KP clinic (aOR 5.41; 95% CI 1.52-19.27; p=0.009). Of the 25 LTFU, 10 were alive and 60% (6/10) of these patients had stopped ART.
Conclusions: HIV infected patients with high CD4 counts including KPs, achieved excellent virological suppression and retention in care in a routine program setting. VL monitoring and clinic type were associated with suppression.

TUPED1226

Why do people delay seeking healthcare for advanced HIV? A qualitative study from a low-coverage setting in Kinshasa, Democratic Republic of Congo (DRC)

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Background: HIV prevalence in DRC is estimated to be 1.2%, and access to HIV testing and treatment remain low across the country. National ART coverage is among the lowest worldwide (23% in 2014). While 64% of the population lives below the poverty line, 43% of health expenditure is made by households. User fees severely limit health-care access, and many people with HIV start ART late or interrupt treatment due to cost. At the Centre Hospitalier Kabinda (CHK) in Kinshasa, median CD4 count at admission was 74 cells/uL and in-patient mortality was 25%; 70% of patients were previously on ART and 50% had interrupted treatment for more than 6 months and 20% were treatment failures not managed accordingly. A qualitative study was conducted to explore why patients arriving at CHK delayed seeking treatment.
Methods: 24 in-depth interviews were carried out with currently- and previously-hospitalised patients, relatives/care-givers of patients and health-care workers in CHK. Patients included those who were ART-naïve and non-naïve. Participant observation was also conducted. Interviews were conducted in French and Lingala. All interviews were translated into English, entered into NVivo, coded and thematically analysed.
Results: Patients, care-givers and health-care workers gave similar reasons for late arrival of patients including lack of training amongst health-care workers on treatment failure management; religious leaders encouraging people not to take ART; poor patient understanding of diagnosis/treatment; stigma and lack of economic

resources to pay for consultations. Stigma prevented patients from disclosing and seeking support from their relatives. Health-care workers felt HIV testing was not offered early enough and that adherence support was insufficient. Clinics were described as ‚boutiques' where every intervention had an additional - often unaffordable - cost.
Conclusions: Cost, stigma, lack of patient and health-care worker knowledge and misinformation by religious leaders causes delays in seeking health-care. These factors jeopardise the assumption that lifelong HIV treatment is feasible in low-coverage settings, and contribute to explain ongoing persistence of advanced HIV disease. Access to free HIV-testing, ART and treatment of opportunistic infections; counselling (disclosure, adherence, treatment failure); training of health-care workers and counsellors; support for care-givers and stigma reduction strategies with churches are urgently needed.

TUPED1227

Access to prevention of mother to child transmission (PMTCT) of HIV service cascade through integrated active case management in 15 operational districts in Cambodia

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Background: Aiming to achieve the goal of virtually eliminating mother-to-child HIV transmission by 2025, Cambodia has implemented integrated active case management (IACM) approach since 2014. This approach is expected to improve detection of HIV positive cases and assure that all HIV positive pregnant women and their HIV-exposed infants receive the full package of PMTCT services. This study aimed to analyse PMTCT cascade data in 15 operational districts (ODs) implementing the IACM in Cambodia.
Methods: A retrospective cohort study design was used to analyse data obtained from IACM program database from 15 ODs implementing IACM between 1 January 2014 and 31 December 2016. We measured key PMTCT cascade indicators including HIV infected pregnant women identified, maternal antiretroviral treatment (ART) during pregnancy, infant antiretroviral (ARV) prophylaxis, infant cotrimoxazole prophylaxis, and early infant diagnosis (EID) of HIV infection by DNA PCR test.
Results: During the study period, 895 HIV positive pregnant women were identified. Among them, 237 (26.5%) were tested HIV positive during pregnancy, 9 (1%) were tested HIV positive at delivery, and 649 (72.5%) were HIV positive women already on treatment who became pregnant. By 31 December 2016, 501 women in the cohort had given birth to 502 infants, as one woman had twins. Among these 502 infants, 496 were live birth infants and 486 reached 6 weeks old or older. PMTCT cascade analysis shows that 92.3% (826/895) of the identified women had access to ART during pregnancy, 85.3% (423/496) of live birth infants received ARV prophylactic treatment, and that 72.8% (354/486) and 70.4% (342/486) of the infants aged 6 weeks or older received cotrimoxazole prophylaxis and DNA PCR test, respectively. Among infants who received DNA PCR test, 2.6% (9/342) was HIV positive.
Conclusions: Gaps in accessing PMTCT of HIV service cascade were still significant in these ODs implementing IACM. Many HIV positive women and their HIV-exposed infants were still not able to receive treatment, prophylaxis, and early diagnosis of HIV. Further research is needed to identify the determinants of access to PMTCT service cascade.

TUPED1228

A program implemented to expand access to HIV testing finds high prevalence and incidence among young MSM in four provinces in Thailand

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Background: HIV prevalence and incidence among men who have sex with men (MSM) remain high in Thailand but HIV testing, an entry point to care, is low. We launched a four-year pilot program to promote HIV testing and link HIV-infected MSM to care in September 2011 in Bangkok, Khon Kaen, Phuket, and Udon Thani, four high-HIV prevalence provinces in Thailand.
Methods: MSM were recruited and trained to promote HIV testing among their peers. Mobile and clinic-based sites were identified to provide HIV testing using three rapid HIV tests, consistent with national guidelines. MSM who tested HIV-positive were referred for care. During HIV testing, health care providers collected demographic and HIV testing history information using a standardized form. We used Poisson regression to determine trends in annual HIV testing and calculated incidence, per 100 person-years of observation, using data from participants who initially tested HIV negative and tested at least one more time (there were 68 incident HIV infections), assuming a uniform probability distribution throughout the interval between the last negative and first positive HIV tests.
Results: A total of 5,629 MSM agreed to HIV testing. Testing increased from 458 in fiscal year (FY) 2012 to 1,832 in FY 2016 (p<0.001). Participant's median age at enrollment was 24 years, 2,299 (41%) were referred by peers, 1,923 (34%) tested at mobile clinics, and 3,412 (61%) were testing for the first time. Almost 100% (5,606) received their HIV test results. HIV prevalence was 21% in FY 2012 and decreased to 17% in FY 2016 (p<0.001). Among HIV-positive MSM, 63% had a CD4 test and the median CD4 count was 284 (interquartile range 143-420) cells/mm^3. The overall HIV incidence was 6.2 per 100 person-years (95% CI, 4.8-7.9) but higher among MSM 15-19 years old (10.1 per 100 person-years) and 20-24 years old (10.9 per 100 person-years) than among MSM >24 years old (3.8 per 100 person-years).
Conclusions: We successfully implemented an HIV testing program among MSM. HIV prevalence and HIV incidence among MSM remains high, particularly among young MSM, highlighting the urgent and ongoing need for comprehensive HIV prevention services for this population.

TUPED1229

Toward the first 90: identifying and testing younger populations for HIV at community outreach events in Kenya

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Background: Low HIV status awareness among children and adolescents, 12,940 new HIV infections among children and rising adolescent AIDS-related deaths in Kenya is a cause for concern given the association of delayed HIV identification with poor health outcomes. This study examined HIV testing outcomes and characteristics of younger (age < 19) populations attending targeted community outreach events (TCOEs).
Methods: In Homa Bay, Migori, and Kisumu counties in Kenya 492 TCOEs with HIV testing and identification were conducted in 148 health facility catchment areas supported by the HIV program Family AIDS Care & Education Services (FACES) over five months from July - December 2015. Aggregated HIV testing (mean number tested), yield (mean number identified HIV positive), and gender among eligible children (age < 15) and adolescents (age 15-19) at TCOEs were captured in a REDCap database. Negative binomial models were used to assess age and gender differences in HIV testing and yield.
Results: Among 14,603 individuals tested at TCOEs, 67% (N=9788) were children (age < 15) and 33% (N=4815) were adolescents (age 15-19). Among children, 54% (N=5291) were female with 0.2% (N=10) HIV positive; 46% (N=4497) were males including 0.2% (N=8) HIV positive. Among adolescents, 51% (N=2457) were female with 0.5% (N=13) HIV positive; 49% (N=2358) were male including 0.2% (N=4) HIV positive. Adolescents were less likely to be tested at TCOEs compared to children (IRR: 0.46; 95% CI: 0.34, 0.62; p<0.01). Although fewer males than females tested overall (IRR: 0.85; 95% CI: 0.78, 0.93; p<0.01), the decrease in males testing from the children age group to the adolescent age group was smaller than in females (IRR: 1.13, 95% CI: 1.02, 1.25, p=0.02). There was no significant difference in age and gender among those testing positive.
Conclusions: Targeted community outreach events reached twice as many children as adolescents for HIV testing and identification and female HIV testing declined in adolescence. The TCOE approach appears useful in reaching children, however a better understanding of what type of community approaches would draw adolescents, particularly females, is needed.

TUPED1230

Gender and power dynamics of social relationships shape willingness to participate in biomedical HIV prevention research among South African adolescents and young adults

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Background: Adolescents and young adults (AYA) are a priority population for HIV prevention initiatives. We explored the social relationships at intimate, family, community and institutional levels that influence AYA participation and potential adherence to protocols in HIV prevention research (e.g., PrEP, vaccine trials, mucosal sampling, medical male circumcision).
Methods: Eight age- and gender-stratified (16-18; 19-24 years) focus group discussions (FGDs) were conducted with 33 male and 42 female participants enrolled in AYAZAZI, a youth-centred HIV prevention study among AYA in Soweto (April-May 2015) and Durban (July 2016). FGDs were co-facilitated by trained qualitative researchers and youth interviewers in English, Sesotho, or isiZulu, audio-recorded and translated verbatim. Data were analysed using grounded theory and ecological systems theory.
Results: Across all levels, gender and power dynamics of AYA's social relationships shaped willingness to participate in research. At an intimate level, vaccine trials and PrEP were favoured by women for access to female-controlled discrete options to protect themselves against HIV and by men who desired to protect themselves and sexual partners (i.e against unfaithfulness; when condoms weren't used).
At the family level, AYA feared that to parents, study participation would suggest risky sexual behavior and expressed concerns about a lack of privacy if asked to collect vaginal or seminal samples at home.
At the community level, AYA feared stigmatization from neighbors and peers for participating in research and men feared physical abuse and teasing. Learning about sexual risks and sharing knowledge with friends to protect them was a motivator to participate for men and women. Some men feared marginalization from their community if they chose medical over traditional circumcision.
Institutional: Both men and women were motivated by the desire to help society. Positive relationships with health care teams (trust, safety, non-judgmental, listening ear) were also motivators to participate in such research.
Conclusions: Large numbers of AYA will be required to demonstrate efficacy and feasibility for future biomedical HIV prevention research. Recruitment and retention efforts are likely to be enhanced through adopting a multi-level relational and gendered approach that considers collective decision making processes such as support, opposition or judgment of family, partners and community regarding study participation.

TUPED1231

High yields attained through HIV household index case testing in Zimbabwe: the case of the FHI 360 Zimbabwe HIV care and treatment project

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Background: FHI360 in Zimbabwe is implementing a USAID-funded, Zimbabwe HIV Care and Treatment Project (ZHCT), to increase the availability and quality of care and treatment services for persons living with HIV (PLHIV), through community-based interventions.
This project compliments the Government of Zimbabwe efforts towards achievement of the first and the third 90s of the UNAIDS Strategy aimed at ending AIDS by 2030.
Methods: The ZHCT project primarily provides household index-case testing (HICT) specifically targeting adolescents, young women, pregnant and breastfeeding women, men and sexual partners. In 2016, ZHCT project was implemented in communities around health facilities with more than 175 patients enrolled on ART in eight districts in 2 provinces of Zimbabwe. Between March and December 2016, HIV- positive index-cases were identified at various service delivery points at these health facilities and were followed up by trained nurse testers. HIV testing services (HTS) were then provided to their sexual partners and children at household levels. Those identified to be HIV-positive were linked to care and confirmed by being recorded in the health facility pre-ART register.
Results: A total of 25,930 people tested for HIV during the period under review and 4383(16.9% yield) were newly identified to be HIV-positive. The yield increased from 8% to 39% over the first year of implementation. A total of 13,057 (50%) of those that tested for HIV were men while (48%) were aged 25-49 years. A total of 1579 (75%) of those identified to be HIV-positive were linked for HIV care.
Conclusions: These findings show that HICT gives a higher yield of HIV-positives identified and linked to HIV care than traditional community based HTS approaches like door to door or outreach. In this project HICT reached the sexually active age group and more men with HIV testing services compared with ~10% at heath facility levels. Based on these findings HICT should be scaled up with a focus on testing of sexual partners and exploring the sexual network in Zimbabwe as the country moves towards attainment of the 90x 90x90 targets and thus reach individuals less likely to test within the conventional health facility testing stream.

TUPED1232

Index client testing: is this the magic bullet to better testing yield in the journey towards the first 90?

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Background: There are estimated 1.6 million Kenyans living with HIV, with 101,560 new HIV infections annually in 2016. Kenya has adopted UNAIDS' 90-90-90 goals, as outlined in the Kenya AIDS Strategic Framework. In order to achieve these, beginning with the first "90", Kenya has embraced innovative HIV testing strategies that target highest risk populations and aim to identify more people living with HIV. Among this was index client testing which is a strategy to identify untested sex partners/spouses and family members of people living with HIV and offer them HIV testing services.
Methods: APHIAPLUS KAMILI is a USAID funded project led by Jhpiego supporting HIV Prevention, Care and Treatment in Eastern and Central Kenya, including HIV testing services (HTS). In year 2016, the project began offering index client testing in 62 HTS sites. Health facility staff and HTS counselors were mentored on the approach, and roles and responsibilities for each were outlined. Client records were reviewed during routine facility visits to identify family members (spouse and children) with unknown HIV status. Clients were educated on the importance of family member testing, and were requested to bring them for testing during their next appointment. In some cases where the client was unable to visit, HTS counselors offered family member testing in the clients' home.
Results: Between January and September 2016, a total of 4,561 HIV client records were reviewed as the index cases. Of these, 8,876 contacts/family members were identified, of which 1,529 had a known HIV status and were excluded. Of the 7,347 with unknown HIV status, 6,047 (82%) were tested, 397 (7%) tested HIV positive, and 363 (91%) were successfully linked with treatment. This yield is significantly higher than the 2.1% HIV positivity at outpatient and 2.5 % at Inpatient HTS observed during the same time period.
Conclusions: The index client testing strategy is a high yield and effective approach to identify undiagnosed HIV-positive clients. This enables programs reach people with a high likelihood of being HIV positive to optimise on HTS services. Jhpiego and other programs should scale up this approach as part of the strategy to achieve the UNAIDS 90-90-90 goals.

TUPED1233

Uptake of HIV services in rural Mozambique: factors associated with retention in care after community-based ascertainment of 12-month outcomes

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Background: In order to end the HIV/AIDS epidemic by 2030, the current gap in case detection needs to be closed through HIV counseling and testing strategies that are locally appropriate and effective in linking patients into care. We aimed to compare the linkage rates between different testing modalities in a semi-rural area in southern Mozambique.

Methods: Between May 2014 and June 2016, a prospective cohort study conducted in the Manhiça District Health Demographic Surveillance System consecutively enrolled adults with a first positive HIV result from three testing modalities: voluntary and provider initiated (VCT and PICT) and home based testing (HBT). Linkage and retention data was extracted from patient clinical charts. Determinants of lost to follow-up (LTFU) at each step of the cascade were evaluated through the Fine and Gray competing risk model. The true attrition rate was ascertained through home visits after 12 months' follow-up.
Results: Among the 1122 enrolled patients, 56.1% were female with a median age of 33 years and 43.7% had linked to care, defined as having a CD4 count available within three months of diagnosis. Among them, median CD4 cell count was 291/mm3 (IQR 173-450) and 69% were ART eligible. When conditioned on the previous step, the testing venue showed no significant difference in linkage, although, it did influence significantly initial enrollment in care (98%, 91% and 36% enrollment for VCT, PICT and HBT respectively, p<0.01). Other factors associated with increased linkage included older age (adjusted sub-distribution hazard ratio (aSHR) 1.56; 95% CI: 1.17-2.09), having a previous HIV test more than a year ago (aSHR 1.85; 95%CI: 1.15-2.27), and being tested with other family/friends (aSHR 1.32; 95%CI: 1.01-1.73). Whereas decreased linkage was associated with showing no intention to disclose their HIV status to partner (aSHR 0.64; 95%CI: 0.43-0.95). One fourth of participants initiating anti-retroviral treatment were LTFU after 12 months of initiation. Among them, 22% were deaths, an additional 29% were transfers and migrations, thus reducing the proportion of true LTFU by half.
Conclusions: Improved linkage will require multiple cascade step-specific interventions and adequate monitoring including ascertainment of true LTFU.

TUPED1234

Contact tracing of HIV-infected individuals, an innovative approach to increase HIV case finding in Angola (pilot project)

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Background: Angola has a generalized heterosexually-driven HIV/AIDS epidemic with an estimated HIV prevalence of 2.41% in adults aged 15-49. An estimated 317,206 people are living with HIV in Angola, more than 50% of whom do not know their HIV status. To achieve the UNAIDS 90-90-90 goals by 2020, additional efforts are needed to identify HIV-positive persons and link them to HIV care and treatment services. Contact tracing has shown success in achieving this goal.
Methods: Strengthening Angola Systems for Health (SASH), a USAID-funded project, together with the National AIDS Institute (INLS), Luanda Health Directorate, and Viana Municipal Health Directorate, implemented a contact tracing pilot project in Viana I Health Center October-December 2016. The goal was to increase the number of HIV-positive individuals who know their HIV status and link them to care and treatment services. All index cases, or ICs, (i.e. all persons newly diagnosed with HIV and/or recently admitted into HIV care) included in the project received counseling and information about the importance of testing contacts. ICs provided healthcare workers with information to reach their sexual contacts and consented verbally to home visits. Contacts were reached via phone or home visits and offered HIV testing at home or at the health facility.
Results: 60 ICs were enrolled in the pilot project, with 80% between 25-49 years. 67% were female. 131 contacts were identified: 64 sexual partners (37 primary partners), 48 children, 2 parents of child/adolescent ICs, and 17 other family members. Male ICs were more willing to provide information about their sexual partners. 50 contacts (38%) were HIV-positive: 30 sexual partners (47%), 8 children (17%), 2 parents of IC children (100%), and 10 other family members (59%). Linkage to HIV care and treatment was successfully documented in 42 (84%) HIV-positive contacts; 30 initiated ART (71.4%).
Conclusions: Contact tracing is an innovative strategy for testing persons at high risk of HIV infection and increasing the number of HIV-positive individuals diagnosed and linked to HIV care and treatment. Contact tracing should be offered to all ICs, although additional work may be necessary to increase future tracing of sex partners, who may be at highest risk.

TUPED1235

Pilot of a community-based hybrid HIV testing program as a strategy to saturate testing coverage in Western Kenya

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Background: Increasing access and uptake of HIV testing services (HTS) is a critical first step for linking individuals to prevention, care and treatment services. In 2015, Homabay County had the highest HIV incidence in Kenya and HIV prevalence was 4.5 times higher than nationally. We piloted a community-based "Hybrid" HTS program entailing community mapping, household census, multi-disease community health campaigns (CHCs) and home-based HTS.
Methods: The pilot was implemented in July-September 2016. HTS eligibility (not previously-diagnosed HIV-positive, age ≥15 years, sexually-active youth <15) and antiretroviral therapy (ART) initiation were based on 2016 national guidelines. Services provided at CHCs included HTS, and screening/referral for tuberculosis, malaria, hypertension and diabetes. Enumerated residents not attending CHCs were tracked to offer home-based HTS. Demographic factors associated with accepting HTS were assessed by multivariate logistic regression.
Results: The Hybrid program reached a total of 28,460 persons: 24,608 enumerated Rusinga and Lambwe residents, and 3,852 non-residents. There were 19,291 persons reached through CHCs (n=14,018) and tracking (n=5,273). Of the 11,352 HTS-eligible individuals, 9,487 (84%) accepted testing, of which 854 (9%) were first-time testers and 124 (1.3%) were newly-diagnosed with HIV. Persons ages 25-34 (aOR=0.86; p=0.047) and those with no prior testing history (aOR=0.23; p<0.001) were less likely to accept HTS. Among eligible residents, HTS was achieved in 76% of adults and 100% of children, yielding 94 new diagnoses. These new diagnoses represent 7% of total 1,336 HIV cases (newly- and previously-diagnosed) among residents attending CHCs or tracked. Sixty-one percent of newly-diagnosed persons identified at the CHCs initiated ART the same day as part of the campaign.
Conclusions: The Hybrid HTS program diagnosed Homabay County residents previously unaware of their HIV-positive status, thereby enabling linkage to care and same-day treatment and reducing onward transmission risk. The pilot was among the first programs in Kenya to implement new national guidelines of ART initiation upon diagnosis. The brief implementation timeframe limited the number of CHCs and duration of tracking activities. Increasing HTS uptake among individuals who never tested or potentially at-risk for infection remains challenging. Lessons learned from this pilot will inform future implementation of HIV testing approaches in sub-Saharan Africa.

TUPED1236

Participant reasons for not initiating antiretroviral treatment despite compelling evidence following early unblinding of the Strategic Timing of Antiretroviral Treatment (START) trial

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Background: START, an international randomized clinical trial, investigated whether immediate initiation of antiretroviral treatment (ART) at CD4 cell counts > 500 cells/μL was superior to deferral until CD4 < 350 cells/μL or development of AIDS in terms of morbidity and mortality. After 3.0 years average follow-up, the data safety and monitoring board (DSMB) unblinded the study due to significant clinical benefit in favor of immediate ART initiation. The DSMB recommended that ART be offered to all participants in the deferred arm not yet on therapy. Despite the DSMB's recommendations, some participants elected not to initiate ART.
Methods: A case report form (CRF) was developed to capture why participants in the deferred arm declined ART. The CRF listed multiple possible reasons, and site staff completed the form following discussion with the participant. The CRF

was available over a 6-month period to allow sites time to contact participants and discuss the study results.
Results: Of the 4685 randomized participants, 2359 were in the deferred arm. At the time of unblinding in May 2015, 48% (1134) of the deferred arm were on ART; six months later, 454 (19%) participants were not known to have initiated ART and were requested to complete the CRF. Of these, 33% (148) reported not wanting to begin ART, 40% (181) elected to or had already initiated ART, and 28% (125) were not able to be contacted.
Of the 148 who declined ART the most common reasons were: not ready to begin ART (57%); high CD4 cell count (37%); low HIV viral load (20%); and, concern about side effects (19%). 40% of participants provided 2 or more reasons. Reasons were consistent across geographic regions.
Conclusions: In START, despite strong evidence of clinical benefit from initiation of ART at high CD4 cell counts, some participants were reluctant to begin ART. The most common reason reported was not being ready to begin ART, which indicates that patient approaches to treatment are more complex than clinical evidence alone. More effort is needed to fully understand why some individuals decline ART. Further study should investigate individuals' personal reasons for making treatment decisions.

TUPED1237

Bridging the HIV treatment gap using a door to door strategy: experience from the community care program in Benue state Nigeria

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Background: To close the HIV treatment gap and facilitate achievement of the UNAIDS 90-90-90 goal, there is need to decentralize HIV services. PEPFAR selected 32 high HIV burden local government areas (LGA) for scale up and saturation of HIV services in a 'test and treat' pilot. The Center for Integrated Health Programs (CIHP) an indigenous non-governmental organization, was mandated to scale up HIV services in 5 of the LGAs in Benue state. To increase antiretroviral treatment (ART) coverage we instituted a door to door initiative across 58 ward councils of the 5 LGAs.
Methods: CIHP mapped the existing HIV treatment clinics and communities within the wards. Door-to-door community care program (CCP) protocol was developed in line with the WHO 'test and treat' strategy. Integrated community engagement approaches were undertaken to get buy-in of the community gate keepers. Community care volunteers (CCVs), which included a pool of unemployed but certified community health extension workers, were engaged and trained to provide HIV services. From January-September 2016, door to door HIV testing were conducted by groups of 3-4 CCVs and newly diagnosed HIV positives started on ART using the 'test and treat' strategy, then linked to the clinics for follow up. Newly diagnosed HIV positive persons were screened for tuberculosis and presumptive cases referred to the clinics. Contact tracing systems were instituted to enhance completion of referrals. Programmatic oversight was provided by trained LGA officials and CIHP technical staff.
Results: Seventy four percent of the communities (1,192/ 1,603) were reached in 9 months of intervention. 385,534 (48% males and 52% females) were tested for HIV and 90% (4,191/ 4,656) of HIV positive started on ART by the CCVs. 93% (3,912/ 4,191) of those initiated on ART were successfully linked to the clinics for follow up HIV care services. 88% (1,647/ 1,870) of the patients linked to the clinics remained in care 6 months post ART initiation.
Conclusions: The door-to-door CCP is a feasible way to take HIV services to underserved communities and bridge the HIV treatment gap. However targeting high risk populations will increase the efficiency of door to door HIV testing.

TUPED1238

Tracking lost to follow-up patients for ART initiation after the introduction of test and start in the North of Haiti

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Background: The incidence of HIV in Haiti is among the highest in the Caribbean but has decreased in the past decade from 6.6% to 2.2%. Despite great progress in the HIV response, retention in care is a national concern as many people living with HIV (PLHIV) are considered lost to follow up (LTFU). In 22 health facilities in northern Haiti supported by MCSP-SSQH/USAID, only 25% (4773) of PLHIV enrolled in care were receiving ART in July 2016. The launch of Test and Start that same month prompted improved efforts between July-September 2016 to track HIV patients LTFU and support them to be initiated on ART.
Methods: A tracking tool was developed and airtime/transportation fees were provided to community health workers/Peer Educators to actively search for and bring back those patients.. The total number of patients active in care and number of clients who were LTFU were inconsistent, and a triangulation between pharmacy, EMR and appointment book registries was necessary. LTFU was defined as patient that missed more than 3 visits. The list of clients who were LTFU was updated weekly as patients returned to the clinic.
Results: As of September 2016 a total of 1182 HIV patients were active in care and 1354 were LTFU. 836 (62%) of patients LTFU had been contacted through phone calls or home visits.225 (27%) were found, and more than 209 (25%) returned for treatment. We were unable to trace 81 patients due to absence of contact information, and the remaining had reportedly travelled to nearby countries in the Caribbean for economic reasons.
Conclusions: In light of the new policy to treat all PLHIV, it is critical to ensure HIV clients who are already in care but were LTFU are re-engaged in care and initiated on ART. Additional efforts are needed to track those clients and reintegrate them back into care to contribute for epidemic control.

TUPED1239

Role of support persons in adolescent and youth voluntary counseling and testing for HIV

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Background: HIV incidence and mortality are high in adolescents and youth (AY), but testing rates remain low. Understanding how support persons influence HIV testing decisions of AY may improve the uptake and quality of testing.
Methods: AY aged 14-24 seeking HIV testing in Nairobi, Kenya completed a post-test survey which assessed the role of support persons in HIV testing. Correlates were evaluated using chi-square tests and multivariate relative risk regression.
Results: Among 1,062 AY, median age was 21 (IQR: 19-23); 306 (29%) were younger (14-19 years), and 756 (71%) were older (20-24 years). Overall, 12.4% reported their decision to test was influenced by a parent, 20% by a partner, and 22% by a peer. Older AY were more likely than younger AY to be influenced to test by partners (23% vs 12%, p<0.001), and less likely by parents (7% vs 27%, p<0.001), health care workers (11% vs 16%, p=0.048), or counselors (9% vs 19%, p<0.001).
Half of AY were accompanied for HIV testing (10% with parent, 11% partner, 23% peer, 4% others, and 2% with multiple types). Support persons were involved in all aspects of testing: 57% were present for pre-test counseling, 64% for finger prick/blood draw, 33% in disclosure of results, and 33% for post-test counseling.
Older AY were more likely than younger AY to present alone (58% vs 32%, p<0.001) or with a partner (12% vs 7%, p<0.001), and less likely to present with a parent (2% vs 31%, p<0.001). Similar proportions of younger and older AY came with a peer or in a group.
Correlates of presenting with a support person included: younger age (RR=1.63 [95%CI=1.37-1.94]), female sex (aRR=1.45 [95%CI=1.21-1.73]), and school enrollment (RR=1.43 [95%CI=1.07-1.92]). Accompanied and unaccompanied AY had similar HIV transmission and prevention knowledge and similar proportions previously tested for STI (p>0.05).
Conclusions: Support persons play an important role in Kenyan AY's HIV testing experience, however support person involvement may vary with age. Leveraging AY support persons may provide interventional opportunities to enhance the uptake and quality of HIV testing for this population.

TUPED1240

Determinants of voluntary HIV testing among female sex workers and men who have sex with men in India: a cross-sectional study

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Background: Regular HIV testing plays a critical role in the HIV prevention effort. Regular testing is not only an indicator of heightened awareness of one's HIV status but also a gauge to assess ownership of his/her own sexual health. However regular HIV testing among High-Risk groups (HRGs) fails to take precedence in certain settings. This study investigates factors associated with HIV testing among FSWs and MSM in the AVAHAN phase-3 project areas in South and Western India.
Methods: A Systematic survey was conducted by field workers in their respective intervention areas using existing lists available with CO and TI and Snow balling technique.The Cross-sectional study was conducted during April - September 2015. It covered 109,366 FSWs and 8594 MSM in the five high-risk states of India. Socio-demographic characteristics, sex work related factors and community involvement were used as independent variables. Outcome indicator used was HIV testing at least twice a year. Multiple regression analysis was applied which was stratified based on the type of HRG.
Results: The Study revealed poor HIV testing behavior among both FSW and MSM groups approximately 63% and 62% respectively. Factors negatively associated with HIV testing among FSW and MSM groups included Younger age(< 25 years), Low monthly income (< 5000Rs), living with parents or alone and alcohol consumption. Factors such as increased years in sex work, higher client load per week were positively associated. Increased involvement with a community organization was strongly associated with testing as per the norm in both FSW AOR (1.464, CI (1.422-1.508) and MSM AOR (2.76, CI (2.37-3.20). FSWs who frequently changed the site of sex work were more likely to go for tests. In contrast among MSM, HIV testing was higher among those who had never changed the place of sex work.
Conclusions: Regular HIV testing among HRGs remains dismal. Special attention needs to be paid on actively engaging with the younger and newer entrants into commercial sex work. Addressing alcohol use among HRGs will be an essential component to consider in the HIV prevention program. The study clearly reiterates the potential of community organizations in improving voluntary testing.

TUPED1241

Improving access to HIV testing among hard to reach and hidden sex workers in India: will uptake of HIV test increase if testing services are provided at the door-step?

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Background: To meet the first UNAIDS 90-90-90 target; India, with a low-level, concentrated but high-burden HIV epidemic, needs to focus on testing most-at-risk populations, who are least likely to test. India's updated National guidelines (Dec 2016) for HIV Counseling and Testing Services (HCTS), provide an enabling environment for novel interventions. We conducted a rapid field-assessment in a high-burden state in western-India, to explore needs, develop and understand feasibility of a community-based HIV testing (CHT) model among female sex workers (FSWs) as a new intervention to "test the untested".
Methods: Between June-September 2016; 3 group-discussions (GD) with FSWs in Kolhapur (urban), Ichalkaranji (semi-urban) and Gadahinglaj (rural) and 2 among Government Integrated Counseling Testing Centre (ICTC) staff and FSW-peers from Targeted Intervention (TI) sites were held. GDs were taped after seeking consent.
Results: Most FSW "accepted" the importance of HIV testing. Urban, semi-urban and rural FSWs availed public-facility based HCTS differentially. Although urban-FSWs, living elsewhere and working in the city, reported high levels of bi-annual HCTS in public-facilities; the testing was primarily driven by ‚peers' from TI programs. Semi-urban FSWs were less likely to access ICTC in public-facility due to "fear of recognition" and all knew many "hidden/secret" FSW who neither interacted with TI nor got tested. Secretive-FSW from less-populous rural areas, said that attending the "highly publicized" ICTC at rural-hospitals, was potentially stigmatizing and a deterrent to testing. All expressed a strong need for community-based anonymous opportunities for screening and opined that "if we are healthy, we can serve better". FSW accepted trained-peers providing pre-HIV-test education; but would not accept a ‚trained-peer' to perform the HIV screening test in the community.
Conclusions: FSW continue to remain less likely to self-initiate conventional HIV-Testing, especially at public facilities, even in the urban ambience offering anonymity. Secretive semi-urban and rural FSWs are less likely to access government HCTS and strongly favor anonymous community-based testing services.These data have helped develop a CHT model, leveraging the local networking of secretive-FSW, to provide anonymous HIV-screening opportunities at conveniently timed, small social-gatherings to "reach the unreached and test the untested" FSWs in rural areas. A demonstration study is planned in 2017-18.

TUPED1242

A user costs analysis for HIV testing among rural communities in Malawi

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Background: HIV prevalence remains high in Malawi, with adult rates of infection at 9% and high testing gap among men. Even if no user fees are charged, direct and indirect user costs of attending health services are increasingly recognized as a barrier to access. We estimated user costs in terms of direct costs, such as transport, and indirect costs such as lost income and child care costs of accessing HIV testing in rural Malawi as part of the HIV Self-Test Africa (STAR) project and analyzed their key determinants.
Methods: A baseline household survey was conducted in southern Malawi as part of a cluster randomized trial of HIV self-testing. The questionnaire was administered to adults (15-49 years) of randomly selected households (n=5,556), of which 25% were randomly allocated an extended HIV testing questionnaire (n=1,387). Further, the respondents who reported having at least one HIV test in the preceding 12 months (14%) completed a module on costs associated with their last test (n=749). To estimate the impact of user and service level characteristics on patient expenditures, while accounting costs being censored at $0, a Tobit model was applied.
Results: Fifty-nine percent of respondents had previously accessed HIV testing at a health facility, 29% reported no user costs. Of those reporting costs, the median cost was $2.08: $2.98 for men and $1.39 for women. Both user and service characteristics were important drivers of costs. Overall, individuals who tested at health care facilities spent twice as much as those who tested within their communities (mobile clinic) with each additional hour spent at the facilities leading to an average of 24% increase in user costs, ceteris paribus.

VARIABLES	Tobit model
Sex (Female)	-0.715**
	(0.293)
Age (Years)	-0.00678
	(0.0138)
Primary Education	0.163
	(0.388)
Secondary Edu.	1.303***
	(0.483)
College/Higher	-0.340
	(2.062)
Number of Children	0.170**
	(0.0683)
ANC Centre	-0.220
	(0.375)
VCT Centre	0.0215
	(0.481)
Community HTC	-2.298***
	(0.477)
Other Place	-1.559
	(1.754)
Test Duration_(Hours)	0.215***
	(0.0603)
Hospital Visit Reason	0.552**
	(0.276)
Wealth	0.0871***
	(0.0121)
Constant	4.601***
	(0.698)
Observations	746

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

[Regression Results]

Conclusions: Observed user costs in rural Malawi were significant, approximately equal to 154% of average daily earnings. This financial burden may provide insights into the existing HIV testing gap, particularly among men.

TUPED1243

Normalizing HIV testing to reach the first 90: PITC at clinic reception - Zambezi NAPPA Clinic, Namibia

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Background: An estimated 28% of people with HIV in Namibia do not know their HIV status and provider-initiated testing and counselling (PITC) is one of several strategies to achieve UNAIDS 90-90-90 goals. Namibia Planned Parenthood Association (NAPPA) operates a clinic in Zambezi region, offering sexual and reproductive health (SRH) services targeted at adolescents and young people. The majority of clients are women and girls seeking family planning and HIV Testing Services (HTS). Despite efforts to boost provider initiation, HTS was largely client-initiated with low uptake and frequent retesting. It failed to reach highest-risk individuals including adolescents.
Methods: In December 2015, PITC was integrated into the clinic registration process for all clients, in an effort to improve HTS uptake and increase case finding. Clients receive group pre-test information, then individually proceed to a private room for registration procedures including blood collection via finger prick. HIV results are given individually along with the services originally sought. Waiting times are the same for all clients, including those who opt out of HIV testing. Clients with negative results in the past 12 months were only retested if they insisted. Data from HTS monthly reports was reviewed, comparing six pre-intervention months (June-November 2015) to the six post-intervention months (December 2015-June 2016). There was no HTS in April 2016 due to test kit unavailability.
Results: In comparison to the pre-intervention period, the post-intervention months showed a remarkable increase in the total number of HIV tests conducted (1211 vs 571), number of provider initiated tests (661 vs 117), number of first time testers (634 vs 276) and most importantly, the number of positive results (119 vs 72). There was a small increase in the number of males tested (212 vs 181). However, a lower positivity yield (9.8% vs 12.6%) was recorded post-intervention. While there was an overall 210% increase in HTS uptake post-intervention, the greatest increase (302%) was observed among persons aged 15-19 years.
Conclusions: Integrating PITC to standard clinic registration process remarkably increased HTS uptake and HIV case finding among SRH clients. The prominent impact observed among middle and late adolescents suggests an added adolescent appeal.

TUPED1244

Targeted health campaign for key populations improves access to HIV testing and initiation on antiretroviral therapy (ART) in Botswana

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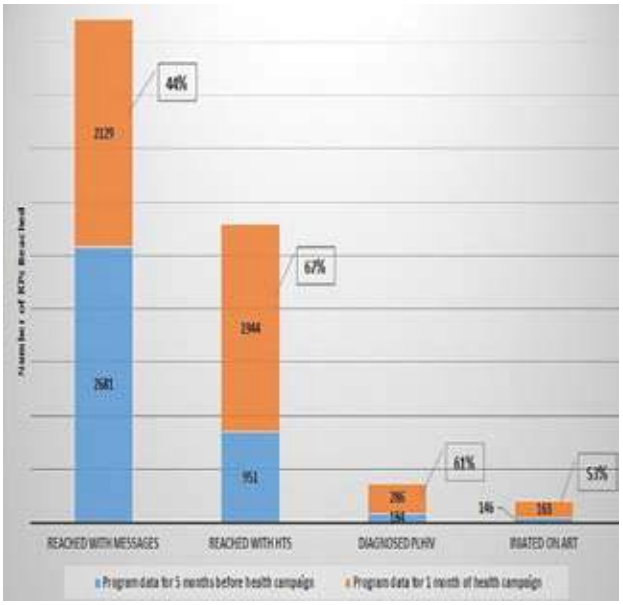
Background: The traditional hot-spot based outreach approach often used to reach key populations (KPs) - including men who have sex with men and female sex workers - with HIV prevention interventions has resulted in low uptake of HIV testing and low positivity yield because of limited penetration of KP networks.
To improve access to new KP networks and increase uptake of HIV testing services (HTS) and ART services by KPs, the USAID- and PEPFAR-funded LINKAGES project conducted a 1 month KP health campaign in the 4 LINKAGES Botswana districts.
Methods: The campaign used social network strategy (SNS), a respondent-driven sampling, to find KPs and link them to clinical services. The strategy used an initial purposive selection of 39 peer outreach workers and mobilizers/recruiters as 'seeds', who were each given 4 referral coupons to share with members of their social networks. When KP members presented with a coupon, they were enrolled in the program, received phone airtime incentive (approximately $10), received a basic package of clinical services, and were given coupons to recruit other KPs. A small airtime incentive was also provided to the recruiter for each KP successfully referred to the campaign site.

Results:



[Campaign results vs project results]

In the 5 months of project implementation prior to the campaign, 951 KPs were tested for HIV and 146 were initiated on ART. During the campaign, 1944 KPs (1665 FSW and 279 MSM), newly tested for HIV. 163 (155 FSW and 8 MSM) were initiated on ART. Incomplete referrals were limited as comprehensive services were available in one spot.
Conclusions: The combination of SNS-based health campaign and same-day service provision increased coverage and uptake of HTS, identified more KPs living with HIV, and improved linkage to ART services among KPs in Botswana. SNS has proven to produce results and other KP focused programs can implement it.

TUPED1245

Saved by angels: a SHIPS for MARPS approach for partner notification services (PNS)

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Background: Partner Notification Services is the act of notifying the sexual partner(s) of a MARP, known as the "index case", who has been newly diagnosed with HIV. It involves contact tracing and index testing of the MARPs partners. In response to the UNAIDS 90:90:90 objective, the SHIPS for MARPs project adopted an index testing strategy into its program implementation in order to ensure that the first and second 90 objective is achieved.
Methods: Once a MARP is tested positive during HIV Testing Services, s/he is provided with post counseling during which their disclosure plan is discussed. The moment the MARP declines or presents fear of status notification to partners due to Intimate Partner Violation, partners Contacts and best time of partner availability are elicited while s/he is linked to the One Stop Shop (OSS) for further management. Cluster testing is conducted in the spots/neighborhood at the times provided by the MARP. Upon identification of the INDEX case, disclosure plan is equally discussed and if the Index client decline, same process is followed.
Results: The project commenced Partner Notification Services in quarter 3 of the Fiscal Year16. The table below shows her progressive achievement in HTS and ART through PNS only;

INDICATOR	QTR 3	QTR 4	QTR 1, FY17
No of elicited partners tested	226	525	413
No of elicited partners tested positive	21	54	219
No of elicited partners enrolled on ARV	1	27	212

[PNS Result]

Conclusions: Great effort and emphasis should be laid on cluster testing for Partner Notification Services as it has proved effective in reducing incidence/cases of Intimate Partner Violation, improved MARPs early knowledge of their status and initiation on treatment (ART) as well as enhanced level of confidence bearing.

TUPED1246

The use of risk-tracking snowball approach to increase HIV testing and HIV case detection among hard-to-reach individuals at higher risk of HIV infection

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Background: This implementation study is to tests whether a Risk Tracing Snowball approach (RTSA) at Non-Governmental Organization (NGO) clinics result in a higher testing and HIV detection rate than among people walked in.
Methods: Between March and August 2016, at two NGO clinics in Phnom Penh Cambodia, RTSA adopted from respondent driven sampling was used to reach hard-to-reach individuals at higher risk of HIV infection. All clients who presented for HIV testing and counselling services, were given the opportunity to be seeds who will recruit other high-risk individuals to get tested for HIV. If recruited individuals presented at either HIV NGO clinic with a valid coupon, screened as being "at risk" for HIV infection, and completed HIV testing, their seeds received $2.5 USD compensation. Recruited individuals were then given the same opportunity as initial clients to be recruiters. Study participant criteria were everybody who came for HIV testing—general population, men who sex with men, transgender women, and female sex workers—and aged 18 years or older, and never tested for past three months. Simple descriptive analysis was used to examine client's type of population, referral network, and study outcome (rate of newly identified HIV positive).
Results: During the implementation period, 2,293 HIV tests were conducted at these two clinics—721 walked-in clients, and 1,572 clients referred by seeds/recruiters. Among tests conducted, newly HIV identified positive via RTSA was lower than walked-in clients (1.8% vs. 3.2%, p-value=0.002). However, the number of total HIV cases were increased compared to the same six-month period prior RTSA implementation (32 vs 52). Also, the rate of newly identified HIV positive cases among those recruited in RTSA were about six times higher than the rate among 35,398 tests of key populations tested by outreach workers at community in 2016 (1.8% vs. 0.6%, p-value <0.001).
Conclusions: RTSA was a promising alternative approach to increased HIV testing uptake (surplus on the routine HIV test), but not increased the newly identified HIV positive rate. However, the HIV case detection rate in RTSA is still an acceptable rate, given the low HIV case detection rate among key population tested by outreach workers at community.

TUPED1247

Making mobile HIV testing available for high-risk MSM in saunas

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Background: Men who have sex with men (MSM) account for roughly half of all new HIV infections in Thailand, but only 1/3 of HIV-positive MSM know their status, which limits the potential impact of HIV treatment as prevention. We aimed to improve testing uptake and HIV case finding in Bangkok, Thailand by offering on-site HIV testing in saunas where high-risk MSM gather to seek partners and engage in sex on the premises.
Methods: Community-based organizational partners identified 4 high-volume men's saunas and, with the support of the venue owners, provided venous blood-based, rapid mobile testing at each venue once per month, following a three-test confirmatory algorithm. Uniformed outreach workers recruited clients in the public areas of the sauna, and a private space was set aside for counselors and laboratory specialists. Standard operating procedures (SOPs) were developed to ensure that mobile testing met quality guidelines, protected clients' confidentiality and did not interfere with sauna operations. All clients were registered and tracked with a Unique ID Code.
Results: From July-December 2016, community partners conducted 20 sauna testing sessions at 4 saunas and tested 224 clients, finding 36 new HIV-positive cases (16.1%), compared to an 10.6% yield for all facility-based testing clients in Bangkok during the same period. 8 clients (22%) were successfully referred to ART services and initiated ARV treatment. 30 clients were screened syphilis reactive using a TPHA rapid syphilis screening test (19 of whom were also HIV-positive); however, only 7 were successfully referred for VDRL confirmation and treatment. Sauna-based testing clients included a higher-than-usual proportion of migrant and non-Thai individuals who were less open to follow-up by community-based organizations.
Conclusions: Sauna-based HIV testing was more accepted than originally anticipated by sauna owners and patrons, though existing SOPs should be modified to accommodate a higher volume of clients with restricted time and space. Elevated seropositive rates indicate testing in these venues access higher-risk subpopulations of MSM. However, ensuring successful referrals to both ARV and STI treatment are significant challenges. Where sauna-based testing is supported, care and support staff should be integrated into the mobile testing team, with rigorous follow-up protocols.

TUPED1248

Comparison of testing of index-case networks with outreach in community hotspots for identification and linkage of HIV-positive clients into care

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Background: Despite aggressive global targets to raise awareness about HIV status among 90% of people living with HIV (PLHIV), HIV testing and counselling (HTC) interventions have not reached most of this group. Tanzania's country operation plan (2014) showed that only 4.3% of PLHIV were being identified through facility-based HTC outlets. In 2016, with CDC funding, IntraHealth International piloted and compared two community-based HTC approaches: 1) Outreach in community hotspots, and 2) home-based index-case testing.
Methods: HTC and treatment databases and participatory social mapping with local leaders were used to identify high transmission areas and social networks. Outreach in community hotspots targeted people with high-risk behaviours for testing with their consent, while the index-case approach started with known HIV-positive clients, contacted by service providers for linking up with their social networks. Individuals who tested HIV-positive were offered an escort for clinic follow-up and enrolment into care and treatment.
Quarterly service data were used to analyse trends in HTC service uptake and enrolment of HIV-positive clients into treatment. Using Excel, manual calculations generated the proportion of clients as well as enrolment rates by service delivery model, age, and sex.
Results: Both community-based approaches were acceptable, but home-based testing of index-case networks was more logistically feasible in urban and semi-urban versus rural settings. Overall, the hotspot approach allowed four times more clients to be tested (117,511) than the index-case approach (27,827).
However, home-based testing of index-case client networks was more sensitive in identifying HIV-positive clients (7.6% of those tested) than testing in hotspot areas (4.3%). Outreach in homes with people sick for unidentified reasons was better for reaching children below 15 years and couples who had never been tested. Both models were effective in enrolling clients into care (82%), but slightly more index-case clients were enrolled into care (79%) compared to individuals in hotspot areas (72%).
Conclusions: Both community approaches are promising to reach people outside clinics for HIV testing, but the index-case approach may be more sensitive in identifying HIV-positive clients.

TUPED1249

HIV care & support program review for India: longitudinal trends in enrolment for antiretroviral therapy (ART)

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Background: The Indian ART program began in 2004 and has grown from 8 to 528 ART centers. It has enrolled approximately 2 million patients and currently provides care to 1.2 million people. Access to treatment has been increased by adopting mul-

tiple strategies like scale-up of treatment centres, revision of national guidelines as per international recommendations, awareness creation activities etc. This paper seeks to
(a) quantify the changes in program performance over time for metrics enumerated below and
(b) evaluate demographic factors that may impact these metrics in order to assist the programme in formulating future strategizing.
Methods: A retrospective analysis was conducted on program data comprised of 15,40,133 (out of 18,01,678) adults (>15 years old) registered into care from January 2004-September 2015 in 519 government ART centres with complete patient records. The annual movement in
(a) patient registrations,
(b) CD4 count at registration,
(c) ART initiations, and
(d) time to ART initiation after registration for eligible patients were evaluated. Eligible patients were defined as patients who were eligible for ART initiation (as per prevailing ART guidelines) at registration based on their CD4 count.
Results: Annual patient enrolments increased from 37,849 in 2005 to 2,03,747 in 2014. Median CD4 counts at registration increased from 165 cells/mm^3 in 2005 to 253 cells/mm^3 in 2015 and proportion of patients presenting with CD4 counts greater than 350 cells/mm^3 increased from 21% to 35%, including 19% with >500/cmm. For all years analysed, it was observed that older and male patients registered with lower median CD4 counts than younger and female patients. 80% (6,93,057) of the 56% (8,68,010) eligible patients were initiated on ART. The proportion of eligible patients initiated increased from 73% to 85% while their median time to initiation decreased from 16 to 6 days.
Conclusions: The program has been successful in diagnosing and treating patients considerably earlier. However, a large proportion of patients still register at a later disease stage (CD4< 350) and males more often than females, necessitating customised strategies and deeper evaluation of causal social factors that needs to be considered before Test and Treat.

TUPED1250

Increased HIV test uptake with comprehensive PITC implementation: findings from 3 district hospitals in Zimbabwe

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Background: Provider-initiated HIV testing and counselling (PITC) and linkage to care are key interventions towards UNAIDS' 90-90-90 objectives in Zimbabwe. A facility-based PITC model was implemented at 3 mission hospitals, deploying dedicated nurse counsellors to offer HIV testing to patients in hospital outpatient departments (OPDs). An "OPD HIV testing tracking tool" was administered from October 1, 2015, to July 31, 2016, capturing clients > 18 years of age attending the OPD, with known HIV-positive status or eligible for testing, the proportion tested, positives identified and linked into care.
Methods: Summary descriptive statistics were used to report the HIV test acceptance and linkage rates, comparing average number of tests performed and positives identified 12 months before and after PITC implementation. Forty-two qualitative interviews were conducted with health care providers, adult clients who declined testing, and key stakeholders. Interviews were thematically analysed to assess respondents' experiences.
Results: Of the 6,951 clients attending OPD and not in OI/ART care we tracked, 95.3% (6,621) accepted HIV testing, with 631 (9.5%) testing positive, and 617 (97.8%) being linked to care. The average number of HIV tests performed per month at the 3 facilities increased from 623 (SD=134.6) in the 12 months prior to introducing PITC, to 1,009 (SD=246.8) in the 12-month period post PITC initiation (p <0.0001). The average number of positives identified per month also increased from 73.8 (SD=13.8) to 89 (SD=19.2), (p=0.0363). Themes from qualitative analysis suggested that primary reasons for refusing testing included patients' preference to consult with partner first, not feeling ready, or the perception that they were not at risk.

Facility performing HIV tests	Pre-PITC Mean (±SD)	Post-PITC Mean (±SD)	Mean Difference	p-value
Makonde Mission Hospital	182.8 (48.8)	336.2(77.9)	153.4	<.0001
St. Paul´s Mission Hospital	182.1 (80.5)	324 (112.7)	141.9	0.0018
St. Luke´s Mission Hospital	258.3 (118.4)	349 (150.6)	90.7	0.1149
Total	623 (134.6)	1,009.2 (246.8)	386.2	<.0001
Facility identifying HIV-positives	Pre-PITC Mean (±SD)	Post-PITC Mean (±SD)	Mean Difference	p-value
Makonde Mission Hospital	22.75 (7.7)	27.3(6.9)	4.55	0.1394
St. Paul´s Mission Hospital	23.8 (2.6)	29.5 (2.67)	5.7	0.144
St. Luke´s Mission Hospital	27.2 (12.5)	32.2 (13.4)	5	0.354
Total	73.8 (13.9)	89 (19.2)	15.2	0.0363

[Average number of tests performed and positives id]

Conclusions: Strengthening PITC resulted in a 62% increase in testing, 21% increase in positives identified and a 97.8% linkage rate. Programs to increase PITC coverage in OPD departments can play a role in reaching UNAIDS´ 90-90-90 objectives in Zimbabwe.

TUPED1251

Values and preferences of adolescent girls and young women in Kenya for three HIV prevention approaches: PrEP, HIV self-testing and HIV partner notification

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Background: Adolescent girls and young women are especially vulnerable to HIV infection in high prevalence settings, underscoring the need to ensure the acceptability and accessibility of HIV testing and preventative services among this population. This study explores the values and preferences of adolescent girls and young women in Kenya for PrEP, HIV self-testing and partner notification.
Methods: This mixed methods study was conducted in five high HIV prevalence counties in Kenya (8.6%-27.1%): Homabay, Siaya, Kisumu, Mombasa and Nairobi. Females 18-24 years old were eligible for the study. Participants were recruited through national and county networks of PLHIV, youth groups, sex workers and PWID. Data was collected from structured questionnaires and focus group discussions (FGDs). FGDs were conducted in a mix of health facilities and community sites. Standard thematic analysis was applied to qualitative transcripts.
Results: 489 adolescent girls and young women participated in structured questionnaires and 240 participated in 20 FGDs. Prior to the study, less than half of all participants had heard of PrEP, HIV self-testing or partner notification. However, respondents reported that all three approaches were acceptable for preventing HIV or learning your HIV status. 59% of respondents felt at risk for HIV. 89% had previously tested for HIV. 49% of 18-19 year-old participants and 29% of 20-24 year-olds did not know their partners' HIV status. 11% of participants reported previously using PrEP. Participants discussed possible adherence challenges for PrEP. It was also observed that many participants confused PrEP with PEP. Lack of confidentiality at health facilities was considered a barrier to accessing services. Participants felt HIV self-testing would provide much-needed privacy. However, some participants worried about forced testing, increased risk behaviors and the potential for oral HIV self-tests to revive misconceptions that HIV is spread through saliva. Partner notification was largely seen as beneficial for both partners to know their status and support each other to access treatment, but there were concerns it could influence household breakups.
Conclusions: Adolescent girls and young women in Kenya had overall positive perspectives on PrEP, HIV self-testing and partner notification. Supportive, confidential service delivery could improve uptake of HIV prevention approaches for this population.

TUPED1252

Men are absent across the HIV continuum of care in a rural area of southern Mozambique

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Background: Loss-to-follow up (LTFU) along the HIV continuum of care leads to increased morbidity and mortality which is not distributed equally by gender. In sub Saharan Africa (SSA), the female-male gap in adult life expectancy has nearly doubled since the scale-up of antiretroviral treatment (ART) in 2004. Although the incidence of new HIV infections is higher in women in SSA, mortality is higher in men.
Methods: Between May 2014 to June 2016, a prospective cohort study conducted in the Manhiça District Health Demographic Surveillance System (HDSS) in southern Mozambique consecutively enrolled 1,122 adults with a first positive HIV result from three testing modalities: voluntary and provider initiated (VCT and PICT) and home based testing (HBT). Linkage and retention data was extracted from clinical charts and demographic data from the HDSS database.
Results: Of the new HIV diagnoses, 43.9% were male with a median age of 33 years. The proportion of males among total clients was higher in PICT and HBT as compared to VCT (39.1%, 34.1% and 26.2% respectively, p=0.05).
However, in a random sample of 10,897 households visited for HBT, men were 3 times more likely than women to be absent from the household (p<0.01) and 1.2 times more likely to have emigrated (p<0.01). Furthermore, the acceptance of HBT was significantly higher in women (84%) than in in men (77%) (p<0.01).
After initial linkage to care, men were twice as likely to be in WHO stages III/IV at first visit (p<0.01) and the median CD4 count was lower (209 vs. 281 c/μL, p=0.03). Of those initially ART eligible, a similar proportion of men and women initiated treatment (81 and 86%, respectively). Both had similar odds of LTFU at pre-ART stage but women were more likely to be retained in ART after 12 months (82.5% vs. 69.9%, p<0.01).
Overall 12 month mortality was almost twice as high in men as compared to women (5.9% vs. 3.2%, p=0.03).
Conclusions: Decreasing the female-male gap in mortality and achieving the 90-90-90 targets will require gender-based strategies. Male-friendly approaches for testing and retention across the continuum care are needed to control the epidemic.

TUPED1253

Linkage Expert Program facilitates timely linkage to care and promotes early retention for people living with HIV

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Background: Timely linkage between HIV diagnosis and treatment services is critical for the health of people living with HIV and transmission prevention. Recent literature demonstrates high rates of loss to follow-up between diagnosis and treatment initiation or enrollment in HIV care services. We developed and evaluated the impact of a novel Linkage Expert Program to facilitate prompt linkage to and retention in HIV care.
Methods: The program was implemented from June 2015 to November 2015 in two government-funded health facilities in central Malawi. Immediately following an HIV+ diagnosis, patients were referred to a community health worker designated as the focal linkage person, or Linkage Expert (LE), who provided intensified post-diagnosis counseling and an escort to HIV services. Patient data was recorded in a linkage register and their enrollment into HIV services tracked. For patients who did not enroll, at least two tracing attempts were made via phone and home visit to follow up.
Results: A total of 515 patients were enrolled in the program, median age (IQR) was 34 (26-42) years and 215 (41.8%) were male. The majority were referred from the voluntary testing and counselling department (51.1%). At the time of identification, 117 (22.7%) reported knowing their HIV+ status, but had not initiated treatment. Of all enrolled patients, 449 (87.2%) were eligible for ART; 384 (85.5%) initiated in a median time (IQR) of 7 (1-10) days. Of those initiated on ART, 345 (89.9%) remained in care three months post enrollment.

Enrolled in Linkage Expert Program	Khombedza Health Centre N= 101 (%)	Salima District Hospital N=414 (%)	Total N=515 (%)
Eligible for ART			
Yes	88 (87.1)	361 (87.2)	449 (87.2)
No	13 (12.9)	46 (11.1)	59 (11.4)
Unknown*	0 (0.0)	7 (1.7)	7 (1.4)
Started ART, n	*n= 88*	*n=361*	*n=449*
Yes	87 (98.9)	297 (82.3)	384 (85.5)
No	1 (1.1)	64 (17.7)	65 (14.5)
Enrolled in HIV Services			
Yes	100 (99.0)	330 (79.7)	430 (83.5)
No	1 (1.0)	84 (20.3)	85 (16.5)
3 Month Outcome			
Alive, enrolled in pre-ART care	9 (8.9)	32 (7.7)	41 (8.0)
Alive, on ART	71 (70.3)	274 (66.2)	345 (67.0)
Died	3 (3.0)	16 (3.9)	19 (3.7)
Refused	5 (5.0)	48 (11.6)	53 (10.3)
Stopped	1 (1.0)	3 (0.7)	4 (0.7)
LTFU	8 (7.8)	26 (6.3)	34 (6.6)
Transferred Out	3 (3.0)	15 (3.6)	18 (3.5)
Missing	1 (1.0)	0 (0.0)	1 (0.2)

*Person was lost to follow up before assessment of ART eligibility.

[Table. Outcomes of patients enrolled in the Linkage Expert Program by health facility]

Conclusions: These findings suggest that in settings with sub-optimal rates of linkage from testing to treatment initiation, a dedicated LE can promote prompt linkage from identification to HIV care with high rates of early retention. Further characterization of clients with known HIV+ status who have not yet initiated treatment may inform development of better strategies to increase treatment coverage.

TUPED1254

High HIV positivity rate in Index Case Testing in Malawi

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Background: In partnership with the Malawi government, the CDC funded DHSS project, implemented by Management Sciences for Health (MSH) and partners, aims to identify people living with HIV and enroll and sustain them in care and treatment. Overall HIV prevalence in Malawi is 10.6%, but HIV positivity rate of HIV testing has declined to less than 5%. This is the result of a high coverage rate of 70% of all people living with HIV on ART.
To increase the HIV positivity rate or yield DHSS introduced Index Case contact testing. All patients attending HIV Care or ART Clinics are encouraged to bring their family members (children, spouses, siblings, and parents) for HIV testing during family testing days organised at each health facility, facilitated by a Family Referral Slip (FRS) which is given to the first member of the family identified (Index Case).
Methods: Routinely collected data from HIV testing registers were used to prepared monthly ‚Index Case Testing' reports from each of the 41 health facilities. We used these reports for further analysis for this paper.
Results: From August - December, 2016, a total of 7,680 adults and children from families living with HIV/AIDS were tested in 41 Facilities in four districts in the south of Malawi (Blantyre, Chiradzulu, Thyolo and Neno). The table gives an overview of the number of tests done, the number HIV positive, and the HIV positivity rate (yield).

	Male			Female			Total		
Age Group	Tested	Positive	Positivity Rate	Tested	Positive	Positivity Rate	Tested	Positive	Positivity Rate
1-4	822	54	7%	870	37	4%	1692	91	5%
5-9	276	38	14%	372	40	11%	648	78	12%
10-14	208	25	12%	236	32	14%	444	57	13%
15-19	181	39	22%	474	66	14%	655	105	16%
20+	2081	789	38%	2160	855	40%	4241	1644	39%
Total	3568	**945**	**26%**	**4112**	**1030**	**25%**	**7680**	**1978**	**26%**

[Results]

Conclusions: Our results indicate that Index Case testing in the Malawi setting shows good results. A positivity rate of 26% is high compared to the overall prevalence and the number of men reached was encouraging. Therefore, case finding through index patients is a promising strategy to maximize HIV case detection.

TUPED1255

Association between a novel telehealth intervention and utilization of HIV services among transgender women of color in Washington, DC, U.S.A

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Background: Transgender women of color (TWC) are an underserved population who often experience HIV and barriers to care, as well stigma, violence, and trauma. Novel ways to improve access for TWC are urgently needed. Telehealth can engage TWC in care, yet this approach has been unexamined. The purpose of this study was to develop a TWC-specific telehealth intervention to increase access to care and assess feasibility of the intervention among TWC.
Methods: Participants were ≥18 years, male at birth, transgender or female identified, a racial/ethnic minority, and with at least one study-defined barrier to healthcare in the last 6m. Following a 3m pre-intervention phase, participants received a 3m intervention with secure, remote access to trained peer health consultants (PHC) via video, email, text, and phone. Utilization of the intervention and outcomes were assessed monthly. Intention to seek care and receipt of care were modeled using generalized estimating equations (GEE) from data obtained from PHC and participants via Computer Assisted Self-Interview (CASI).
Results: Of 25 participants, most were Black (96%), >25y (69%), living with HIV (52%), and reported recent depressive symptomatology (67%).The intervention was acceptable and well-utilized based (Table 1). The intervention was associated with significantly ($p < 0.05$) increased odds of intention to seek TWC-specific care [aOR 1.76 (1.00-3.08)] compared to each person's baseline, while participants with depressive symptoms were significantly more likely to have intention to seek specialty care [aOR 10.53 (1.42-77.97)], HIV-specific care [aOR 2.56 (1.27-5.17)], and mental health care [aOR 2.56 (1.27-5.17)] post intervention. Participants with depressive symptoms had significantly greater odds of having sought HIV care in the past month [aOR 2.31 (1.31-4.06)] post intervention relative to those without.

Characteristic--> Intention to seek type of care in the next month	Post Intervention Period (vs. Pre-Intervention Period) Adjusted OR (95% CI)	Elevated CES-D-8 (vs. Lower CES-D-8) Adjusted OR (95% CI)
Primary care	0.91 (0.52-1.57)	0.99 (0.58-1.70)
Specialty care	0.39 (0.10-1.59) p=0.188*	10.53 (1.42-77.97) p=0.02**
Transgender-specific care	1.76 (1.001-3.08) p=0.049**	1.52 (0.87-2.65) p=0.142*
HIV-specific care (prevention or treatment, as applicable)	0.97 (0.53-1.77)	2.56 (1.27-5.17) p=0.009**
Mental health care	***0.63 (0.28-1.40)***	***2.80 (1.22-6.43) p=0.015****
N=16 with baseline evaluation plus at least one post-intervention assessment		
**p<0.05 *0.05<p<0.25 shown due to hypothesis-generating nature of pilot study.		

[Correlates of Intention to Seek Care]

Conclusions: These data suggest telehealth may be facilitated by PHCs who provide immediate non-clinical consultation; this may be effective in overcoming barriers and improving health of TWC. Telehealth may be an innovative solution to improve outcomes for TWC with barriers to care.

TUPED1256

Finding the hard to reach HIV-infected: respondent-driven sampling as a public health intervention for PWID and MSM

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Background: HIV treatment-induced viral suppression is the most efficacious prevention tool available, so all HIV programs should seek to minimize prevalence of viremia in a community. However, to achieve viral suppression, HIV-infected persons need to be identified, linked and maintained on ART. In hard-to-reach populations such as MSM and PWID, identifying out of care HIV-infected persons remains the biggest deficiency in the HIV care continuum. We hypothesized that respondent driven sampling (RDS) to identify viremic individuals would be cost-effective by leveraging social network connectedness in MSM and PWID.
Methods: Between 9/12-12/13, we recruited 14,481 PWID and 12,022 MSM across 27 sites in India (n~1000 per site) through RDS. To estimate costs, we identified costs from site operations (e.g., rent, staffing), RDS (e.g., compensation for recruiting participants), and HIV testing (market pricing) and excluded research costs (e.g., investigator salaries, travel, sample storage). Cost per viremic person identified was calculated as the total non-research costs at each site divided by the number of viremic persons identified at the site.
Results: From 56 seeds recruiting 26,447 individuals, RDS identified 4,065 HIV-infected individuals (median: 197 per PWID site and 86 per MSM site) of whom 2,825 were viremic (median: 141 per PWID site and 50 per MSM site) and 2,329 were unaware of their HIV infection. The median site cost per viremic individual identified was USD 349 (range: 117-1344). This varied from USD 233 (range: 117-820) for PWID sites to USD 481 (range: 291-1344) for MSM sites. The prevalence of viremia and speed of recruitment were positively associated with the cost per viremic individual identified. The median site costs per unaware HIV-infected PWID and MSM identified were USD 147 and 437, respectively. The additional median cost of identifying a HCV-infected PWID unaware of his/her status was USD 11 (site range: 7-142).
Conclusions: RDS is an efficient way to identify hard to reach viremic HIV-infected MSM and PWID with the potential to transmit HIV, particularly in communities with high HIV burden, poor ART access and strong interconnectedness. RDS appears more cost-effective in PWID compared to MSM, potentially explained by higher HIV burden and poorer ART access.

TUPED1257

Community involvement and targeted approach: increase uptake of HIV testing among family members of PLHIVs - experience from the Global Fund-Supported Vihaan Programme in India

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Background: India HIV/AIDS Alliance implements the Global Fund supported Vihaan programme to deliver care and support services for people living with HIV (PLHIV) through its 361 community-based Care & Support Centres (CSC) across India from 2013 to 2017. Around 1 million PLHIVs were provided care and support services through CSCs. Care and support helps increase treatment adherence, improves quality of life and ensures healthy life for PLHIV. Partner notification and partner testing including family members for HIV still remains challenge.
Methods: Screening to firm up the eligible family members were carried out among 1,019,667 registered clients through 361 CSCs till June 2016. Data were collected using structured client registration form after obtaining consent from the client. Eligible clients were approached individually by 2021 field level outreach workers and peer counsellors for linking with HTC for testing through proper referral slip. Outcome were updated and documented in the CSCs. Clients were followed up to ensure HIV testing and receive results. Intervention also ensured all newly diagnosed PLHIV are linked with treatment center for medication.
Results: Family size of the 1,019,667 registered clients were 2.2 with total family members of 2,276,326. Mean duration of having connected with treatment center is more 3.2 years. 9.4% (n=2,13,298) of family members were identified as eligible for HIV testing but not tested for more than one year or ever. Majority of the eligible family members were spouse/partners (57%), female and age group of 15-45 years. Through regular counselling and motivated family notification, 38% (80,476) of eligible clients were tested for HIV and received results with 10.3% positivity. As a continuum of care, 73% (6,091 vs 8,329) of the newly diagnosed HIV positive clients were linked with ART center for care and treatment.
Conclusions: HIV positivity among family members is higher than the key populations and so focus on this group is most warranted. Community based intensified focused approach on family members especially spouses and partners improve the uptake HIV testing and early linkage with treatment center. Vihaan model may be replicated across world as it yielded high result.

TUPED1259

How should we configure services to maximise uptake of couples HIV testing: results of a qualitative study and discrete choice experiment from rural Zimbabwe

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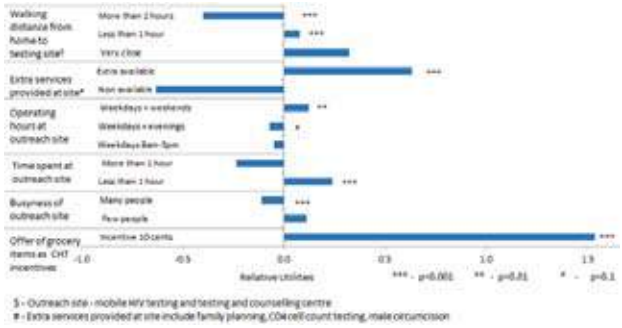
Background: Despite numerous health benefits, uptake of couples HIV testing (CHT) is suboptimal. We conducted a mixed-methods study to identify and evaluate relative preferences for CHT services in a rural Zimbabwean community.
Methods: We systematically identified attributes to explore in the discrete choice experiment (DCE): we conducted mixed-gender focus group discussions (FGDs) and in-depth interviews to explore barriers and facilitators to CHT and identify preferred service delivery characteristics. We used these findings along with structured discussions with programmers/implementers to finalise DCE attributes. The piloted paper-based DCE questionnaire was illustrated pictorially and administered among adults >18 years. DCE data were analysed using the multinomial logit model allowing for preference heterogeneity.
Results: We conducted four FGDs with 8-9 participants each (n=34, 17 women), and 29 in-depth interviews (16 women). Barriers to CHT included:
1) difficulty broaching the subject of CHT for cultural reasons (females not expected to bring up sexuality issues) and discomfort with associated implications of distrust/infidelity;
2) fear of relationship dissolution in case of HIV-positive diagnosis;
3) conflicting work schedules. Men reportedly resisted CHT more than women.
Interventions that "put pressure" to test together, such as CHT at antenatal clinics, reportedly facilitated CHT. Small non-monetary incentives were suggested as CHT facilitators.
We enrolled 300 DCE participants, including 174 women. The final DCE attributes and levels and their relative strength of preferences identified people's optimal CHT service attributes: a nearby, not busy, integrated facility that has short waiting times with weekend opening (figure).



[Relative Utilities for CHT Program Characteristics]

Non-monetary incentives for CHT were highly attractive. Even low value incentives could compensate for perceived shortcomings in other program attributes. In subgroup analysis women had stronger preferences for incentives than men.
Conclusions: Broaching the subject of CHTC is challenging especially for women. Paying attention to strengths of preferences may ensure design of programs which improve CHT. Incentives may help overcome identified barriers.

TUPED1260

Values and preferences of PLHIV and key populations in HIV self-testing (HIVST) and partner notification (PN) in the Middle East and North Africa (MENA)

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Background: In 2016, WHO issued guidelines recommending HIVST and PN. In this context, the WHO Regional Office for the Eastern Mediterranean conducted an assessment of the values and preferences of key populations (KP) in collaboration with two regional networks, RANAA and AFEMENA. The results of the assessment will be used to address low access to HIV testing services (HTS) and antiretroviral therapy in the region.
Methods: Focus group discussions and in-depth interviews were conducted by trained service providers in Morocco, Tunisia, Lebanon and Jordan. Forty people who inject drugs, 34 female sex workers (FSW), 24 men who have sex with men, 24 transwomen (TG) and 72 people living with HIV (PLHIV) were recruited using a convenience sample. Consultation with service providers was conducted virtually. All answers were categorized and analyzed thematically.
Results: HIVST was known to a minority of participants, including service providers. A large proportion of the participants perceived HIVST as beneficial to increase access to HTS and overcome stigma and discrimination (S&D). TG were more skeptical due to lack of awareness in the community. PLHIV with prior bad experiences with HTS favoured HIVST while those with positive experiences tended to reject it. Unacceptance of HIVST was due to overprotection of PLHIV, distrust in rapid testing, fear of self-harm, and lack of counselling and linkage.
Overall, assisted and unassisted HIVST were acceptable especially if supported by population-tailored information and delivered through NGOs, peers via outreach programs, pharmacies or health services.
PN was considered essential by all groups, but less so by FSW due to the difficulty of reaching clients, fear of violence and income loss. Barriers include S&D, limited awareness, loss of partner's trust and fear of HIV status being known by others.
The preferred approaches to PN were dual and contract referral due to the protection and support by the service provider. Few empowered and independent participants preferred the passive referral.
Conclusions: Introduction of HIVST and PN in MENA is acceptable to KP, service providers and PLHIV. Implementation will require advocacy, raising awareness and building capacity among communities and service providers, along with tailoring service delivery to community needs and context.

TUPED1261

Improving quality of care for patients by introducing atazanavir/ritonavir as the preferred second-line protease-inhibitor in Togo

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Background: In 2010, Togo had 24,635 patients on treatment and 5% on second-line (2L). 98% of 2L patients were on LPV/r-containing regimens despite challenges such as poor tolerability, twice-daily dosing schedule, and high pill burden. A new protease-inhibitor, atazanavir/ritonavir (ATV/r), became available in 2013 with benefits over LPV/r including: smaller pill size, decreased pill burden, once-daily dosing, and improved tolerability. ATV/r was also less costly compared to LPV/r.
Methods: In December 2010, the Clinton Health Access Initiative supported the Togo Ministry of Health to develop a comprehensive product introduction process for national rollout of ATV/r in Togo. A National Technical Committee for ARV's and other related commodities for the management of HIV was established and tasked with drafting and disseminating dispensing guidelines for ATV/r administration. A progressive switch of 70% of patients from LPV/r to ATV/r was planned from January 2015 to December 2017. The National Anti-AIDS Committee used mentors to actively engage with facilities to monitor the rapid uptake of ATV/r through dispenser reports providing site-level breakdown.
Results: Starting with 100 patients on ATV/r in the second quarter of 2011, Togo expanded to 2,216 patients on ATV/r by the end of 2014. Between 2010 and 2014, approximately 1,500 patients on 2L treatment switched from LPV/r to ATV/r. By

the end of 2014, 60% of 2L patients were on ATV/r. The success of the ATV/r roll-out was tied, in part, to engagement with community groups as part of the national adoption framework. Additionally, Togo achieved over $1,232,705 in savings from 2011-2014 by preferring ATV/r to LPV/r in 2L.
Conclusions: Successful uptake of new products requires more than adoption into national guidelines. Key interventions in Togo contributing to successful uptake included: comprehensive planning and engagement with stakeholders; a strong regional approach; the use of mentors who had a deep understanding of the realities in the field; and periodic supervisory site visits to monitor dispensation reports, identify sites not implementing, and develop solutions to resolve any bottlenecks.

TUPED1262

Increasing ART initiations with a community outreach health information intervention, a cluster-randomized trial from Zomba, Malawi

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Background: Treatment as prevention is a potentially effective strategy to end the AIDS epidemic in southern Africa. ART is widely available upon diagnosis; in Malawi a test and (immediate) treat policy has recently been implemented. Evidence-based policy to increase uptake of ART is necessary in order to successfully scale up treatment as prevention. We evaluated a community outreach information campaign as a policy to increase HIV testing and ART uptake.
Methods: We conducted a cluster-randomized controlled trial in a rural area of Zomba district, Malawi, with two arms: control villages (n=122) and intervention villages (n=62). In late 2013, we held a 45-minute community health information meeting, conducted by a trained community educator, in every intervention village. On average, 64% of adults attended the meeting (total attendance =7375 adults). We provided the information that ART prolongs life, reverses HIV/AIDS symptoms by suppressing viral load, and is available at a specific nearby health facility.
Results: We collected health facility data on village-level outcomes collected during 12 months post-intervention. We find a significant effect on HIV diagnoses (aOR 1.39, 95% CI 1.04-1.86, control arm mean =2.4 diagnoses/village) and ART uptake (aOR 1.33, 95% CI 1.02-1.75, control arm mean =1.4 initiations/village). The effect of the intervention on ART uptake was heterogeneous, and was larger for villages with higher pre-intervention rates of HIV testing (p=0.06) and ART uptake (p=0.05), and for villages that were further from a health facility (p=0.06). The mean age of clients who initiated ART in the intervention arm was two years younger (p=0.14) and they were 9 percentage points more likely to have a CD4 count taken (p=0.08), which was only indicated for individuals in WHO-stage I or II, suggesting that the intervention may have encouraged early ART initiation. Clients who initiated ART did not differ significantly by gender or weight between the intervention and control arms.
Conclusions: The results demonstrate that lack of information about the benefits and availability of ART is a barrier to ART uptake among adults in rural Zomba, Malawi. An inexpensive, one-time community outreach information campaign is an effective policy to increase ART uptake.

TUPED1263

Men's perspectives of their HIV risk and vulnerability in KwaZulu-Natal, South Africa: formative findings of the 'linkage of men to HIV care' study

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Background: Treatment-as-Prevention requires that a substantial proportion of HIV-positive persons be diagnosed, linked to, and maintained in care. Substantially fewer men than women in sub-Saharan Africa are tested and linked to treatment; addressing this will reduce men and women's risk and vulnerability to HIV. This is one of a handful of studies rigorously evaluating evidence-based strategies to diagnose, link and retain HIV-infected men in care in a high-prevalence context.
Methods: Using a cluster randomized design, eight communities in KwaZulu-Natal, South Africa will be randomised to receive one of:
(1) male-centred mobilization,
(2) a small incentive and male-focused testing, or
(3) standard-of-care health services. Once tested, HIV-positive men will be individually randomized to:
(1) standard-of-care ART,
(2) point-of-care CD4 testing, or
(3) point-of-care CD4 testing combined with personalized male linkage to care.
Finally, we will estimate the joint effect of the structural and individual-level interventions and conduct cost-effectiveness analysis. Formative data were collected in May-July 2016 through key informant interviews with stakeholders working with men (n=10; ages 25-58) to understand risk concepts, potential linkage barriers, and possible intervention strategies. Five focus group discussions were conducted with men (n=42; ages 25-49) to explore gender norms and barriers to HIV testing and treatment. Data were transcribed and translated verbatim, then analysed both inductively and deductively to identify, refine and consolidate emerging themes.
Results: Men articulated their HIV vulnerability as being tied to several complexly interconnected factors, namely
i) unemployment and related struggles with role reversal and failure, lost respect and waning power in sexual relationships;
ii) social disconnectedness and lack of platforms to share and discuss challenges,
iii) inability to engage women partners or healthcare workers about physical, sexual or psychological health problems;
iv) health systems that were experienced as alienating, and where consultations carried huge direct and opportunity costs amid poverty; and v) high alcohol use in a context of stress, poverty and unemployment.
Conclusions: In this setting, determinants of men's HIV vulnerability intersect in complex ways, reiterating that multi-strategy interventions could be the key to effectively diagnosing, linking and retaining men in HIV care.

TUPED1264

Association between intimate partner violence and the prevention of mother to child transmission of HIV

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Background: Prevention of mother to child transmission of HIV (PMTCT) has been prioritized as a key component in ending HIV/AIDS transmission in Sub-Saharan Africa. Intimate partner violence (IPV) is a risk factor for non-adherence to HIV treatment for women, however the evidence on the impact of IPV specifically on uptake of PMTCT services is inconclusive. The aim of this study is to assess the effect of IPV on uptake of PMTCT services and retention in care.
Methods: We used data from a randomized controlled trial that evaluated the effect of conditional cash transfers on retention in and uptake of PMTCT services in which newly diagnosed HIV-infected women, ≤32 weeks pregnant, were recruited at antenatal care clinics in Kinshasa, Democratic Republic of Congo, between April 2013 and August 2014 and follow-up through 6 weeks postpartum. Participants were asked about their IPV experiences in a face-to-face interview at enrollment. The outcome assessed was uptake of PMTCT services (attend all scheduled clinic visits and accept proposed services) through six weeks postpartum and LTFU (loss to follow-up).
Results: Of the 433 participants who were enrolled and randomized, approximately half of the sample (51%) had experienced some form of IPV; 35% had experienced emotional abuse, 29% physical abuse, and 19% sexual abuse. At six weeks postpartum, the proportion of participants who attended all clinic visits and accepted proposed services was 61% and the proportion LTFU was 15%.There were no significant differences between women who had experienced IPV and those who had not experienced IPV in adherence to the PMTCT cascade (61.5% vs. 59.4% (Adjusted Odds Ratio [AOR] =1.14; 95% confidence interval [CI]: 0.77-1.69) or LTFU (15.4% vs. 15.6% AOR= 0.98; 95% CI: 0.58-1.65), controlling for age, marital status, and education level.
Conclusions: Findings from this study indicate that experiencing IPV does not reduce pregnant women's engagement in PMTCT services. The high prevalence of IPV in this population suggests that IPV screening and intervention should be included as part of standard care for PMTCT.

TUPED1265

Utilisation of the social network strategy to reach hidden female sex workers (FSWs) with HIV and health services in Francistown, Botswana

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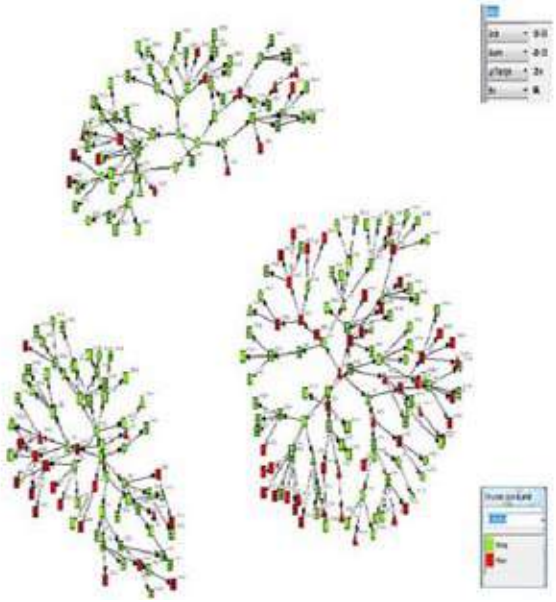
Background: The USAID- and PEPFAR-funded LINKAGES project aims to increase reach to key populations most at risk for HIV, promote HIV testing and counseling, and enroll and retain those with HIV into care and treatment. In Botswana, The LINKAGES team attempted to reach female sex workers (FSWs) with HIV prevention messaging and HIV counselling and testing at "hotspots" where they congregate through peer outreach workers (POWs), but faced challenges identifying HIV+ FSW. To address this, a Social Network Strategy (SNS) was applied to increase access to hard to reach FSWs.
Methods: The SNS followed a respondent driven sampling approach to recruit FSWs within POW networks. POWs, acting as initial ‚seeds' in 4 districts, were given 4 referral coupons to give to FSWs in their social networks. FSWs who presented with coupons at LINKAGES-supported health facilities received clinical services including HIV testing and ART. FSWs received a small incentive of approximately $10 USD airtime for participation. They were also given 4 coupons to recruit additional FSWs in their network, with an added incentive of $5 USD for each successful new FSW referred.
Results:



[Fig 1: Spread of network through SNS strategy]

Data presented here are from Francistown district where three POWs acted as initial seeds. Through SNS, 282 FSWs were recruited within 4 weeks. A total of 261 (93%) were newly tested, 85 (30.1%) diagnosed HIV positive and, of those, 50 (59%) initiated on ART. More HIV+ FSWs were identified as the waves increased within the network. (fig 1)
Conclusions: The SNS method that relies on peers referring others into the program was effective in identifying new FSWs, increasing testing, and enhancing initiation of HIV+ FSWs on treatment. LINKAGES is currently supporting partners with acceleration activities using the same approach to identify new FSWs. The approach can be replicated across LINKAGES countries as it has proven to yield results.

TUPED1266

Does HIV treatment availability improve HIV status knowledge and progression through the cascade of care?

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Background: Expansion of HIV treatment may increase disclosure, reduce stigma, and increase testing leading to improved progression through the cascade of care. However many HIV-infected persons in South Africa, especially men, do not know their status and many patients are lost along the cascade of care. We estimate how a person's ART eligibility affects their household member's HIV status knowledge and progression through the cascade of care.
Methods: We conducted a regression discontinuity analysis that exploits the CD4 count threshold for ART eligibility in South Africa to evaluate the causal intent-to-treat (ITT) effect of ART eligibility. Using data from a large population-based cohort, we compared outcomes among household members of patients who had a CD4 count just below the 200-cell threshold (eligible for ART) with those just above the cut-off (less likely to be eligible for ART). We assessed effects on knowledge of HIV status, and further research will assess cascade of care outcomes including CD4 count of household members when enrolling in pre-ART services, and time to ART enrollment once eligible.
Results: ART led to a 17 percentage point increase in HIV status knowledge among the patient's male household members relative to a baseline level of 7% (17 pp, 95% CI 12, 22). The results were robust to variation in bandwidths and inclusion of covariates. We hypothesize that loss to follow up in enrolling on ART and CD4 count at the time of pre-ART enrollment will be improved by living with an ART-eligible household member, results forthcoming.
Conclusions: Living with someone who is eligible for ART increased men´s likelihood of reporting that they knew their HIV status. Although prior studies have noted a correlation between ART expansion and testing rates, this study is among the first to causally link ART initiation to increased awareness of HIV status among household members. This effect may be due to increased testing, or to updating of beliefs about HIV status based on partner´s status. Ongoing research will determine whether this effect leads to improved progression through the cascade of care.

TUPED1267

The last mile toward elimination of mother to child HIV transmission in Zimbabwe: optimizing resources for subpopulations most at risk

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Background: The first coverage target required for validation of "virtual elimination" of mother-to-child HIV transmission is ≥95% antenatal care (ANC) attendance. Achievement of this target will require strategic allocation of limited resources. We identified subgroups most at need for intervention for the final push toward elimination of PMTCT in Zimbabwe.
Methods: We analyzed data from a 2014 evaluation of the National PMTCT Program that collected population representative data. Eligible women were ≥16 years and had infants born 9-18 months before the interview. Participants were tested for HIV and interviewed about service utilization during pregnancy. We examined the proportion of mothers who would be targeted by various strategies, the number of outreached mothers needed in each strategy to reach one mother without ANC, and the impact on population ANC attendance if 50% of those mothers without ANC were successfully engaged in ANC. We also looked at uptake of other services among women who did not attend ANC.
Results: Two of the five provinces surveyed failed to meet ANC the target, with 6.2% of mothers in Harare and Manicaland reporting no ANC visits. The targeting strategy with the highest impact on overall ANC attendance in these provinces was outreach to mothers of Apostolic religion (reduction from 6.2% to 4.1%). However, 37% of mothers were Apostolic. An alternate strategy, also allowing these prov-

inces to reach the target (reduction from 6.2% to 4.5%), was to target mothers in those provinces with 3 or more previous pregnancies or a previous non-institutional delivery. This group targets only 18% of mothers. Mothers with no ANC were also more likely to have missed other services including; institutional delivery (62.6% vs 11.9%, p<0.0001), immunization (33.5% vs 0.1%, p<0.0001), and EID (48.6% vs 28.8%, p=0.003).
Conclusions: Reaching the last group of women who do not attend ANC will require a significant effort. Women in this group are also less likely to uptake other health services, and targeted outreach to these mothers may have additional benefits if they are engaged in healthcare. These findings demonstrate a data driven approach to optimizing resources to target populations outreach for ANC services.

TUPED1268

Barriers and facilitators of HIV care in recently diagnosed men who have sex with men (MSM) in Lima, Peru: qualitative analysis of bi-directional text messages from an mHealth intervention

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Background: Mobile phone technology in HIV care (mHealth) is a promising tool to increase HIV treatment adherence and retention in the HIV care continuum for high-risk populations. A thorough understanding of barriers and facilitators of engagement and retention in care from the perspective of newly diagnosed MSM is critical to targeting effective mHealth interventions in Lima, Peru.
Methods: From June-December 2015, 28/40 MSM participants were linked to HIV care with an mHealth intervention within 3 months of HIV diagnosis at Via Libre clinic. For 12 weeks, participants agreed to receive weekly short message service (SMS) from an assigned HIV counselor. Text messages were tailored to elicit barriers and facilitators of HIV care while encouraging engagement in conversation. We coded and thematically analyzed 4,559 messages.
Results: Mean age of participants was 29.8 years (2050); with 70% reporting some post-high school education and 73% self-identifying as homosexual. Five categories captured 16 themes related to barriers and facilitators of care that emerged from the data:
1) Psychosocial issues,
2) Medication concerns,
3) Follow-up support,
4) Interpersonal dynamics, and
5) HIV/AIDS knowledge.
Upon engagement in care, psychosocial themes emerged most often. In messages about assimilating an HIV-positive diagnosis, most participants conveyed that "adapting to a new life is the most difficult thing" to overcome. For the majority of participants, "fear of the effects of the drugs they [I] will take" was a barrier to retention. In fact, most patients prescribed antiretroviral therapy (ART) did experience mild to moderate side effects including gastrointestinal upset, headaches, dizziness, and body rashes. The ability to send pictures and ask questions at symptom onset mitigated this retention barrier for most participants and simultaneously facilitated their engagement in care. Proactive themes of re-scheduling appointments and asking about follow-up lab work helped participants navigate their care, with most expressing the sentiment "now I know I am not alone."
Conclusions: For newly diagnosed MSM entering the HIV care continuum, psychosocial and medication related barriers to engagement and retention merit further study. Future mHealth interventions may benefit from anticipating these barriers and producing built-in facilitators to address these concerns.

TUPED1269

Early lessons from a regional scale-up of test and treat in Lubombo, Swaziland

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Background: The Ministry of Health of Swaziland in compliance with WHO HIV management guidelines released in 2015 scaled up "Test and Treat" to all people living with HIV (PLHIV) starting October 2016. Prior to this time, "Test and Treat" was only available to targeted populations. The country ART coverage was 66% The Test and Start initiative serves to increase ART coverage to meet the UNAIDS 90-90-90 targets leading to a reduction in the estimated 8,658 new infections and 3200 AIDS related deaths annually in Swaziland. This paper sought to describe early lessons from the scale up of "Test and Treat" in the Lubombo region.
Methods: Following a national position statement by the Health Ministry, a national mentors training on Test and Start was conducted by the National AIDS Program. In the Lubombo region, a modular training curriculum for test and start was developed for use onsite. A Regional training calendar was developed to improve the coordination of the training, on site trainings were held and post training mentoring support for service delivery and documentation was provided. The public was sensitized through key messaging and community dialogues. Facility support for supply chain management was also provided to cater for the anticipated additional prescriptions.
Results: ART coverage in the region increased from a baseline of 65% at the end of 2015 to 71% by the end of December 2016. Between October and December, ART initiations increased by 20% with 17% of new initiations taking place on the same day as the HIV test. 90% of the health care facilities received training on Test and Start within October 2016 and 85% of health care providers were trained during this time.
Conclusions: A region wide coordinated effort of training and information provision that targeted both providers and recipients of HIV care enhanced the scale up of "Test and Treat". Both clients and providers received targeted messaging enabling demand creation for the service.

TUPED1270

Predictors of loss to follow-up among HIV exposed children within HIV prevention of mother to child transmission cascade, Kericho County, Kenya, 2016

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Background: In 2014 >2.3 million children <15 years were HIV infected with >240,000 new infections occurring annually and majority (>90%) are in sub Saharan Africa. Morbidity and mortality from HIV remain high in Kenya partly due to lost to follow up (LTFU). LTFU results in no or delayed treatment. The study had sought to determine predictors of LTFU among HIV exposed children in Kericho County, Kenya, 2016.
Methods: A hospital based frequency matched case-control study was conducted. Study recruited 44 cases who had missed 3 months of clinic appointments and 88 controls who had adhered to all appointments. HIV exposed infant (HEI) hospital register for the months of September 2014 through February 2016 was used. A structured questionnaire was administered to both cases and controls. Consent was required. Predictor factors were identified using chi-square tests (X^2) at 95% significant levels and logistic regression model to determine independent predictors.
Results: Of the 132 HEIs 71(54%) were male. Median age was 59 weeks (26-93 weeks), cases ranged 29-91 weeks and controls 27-90 weeks. Majority 81 (61%) were aged 12-18 months. A total of 124 (94%) caregivers were biological mothers, 79 (60%) aged < 30 years with 94 (71%) delivering in a hospital. Independent factors associated with mother-infant pair loss to follow up were: fear knowing HEI status (aOR= 12.7 [CI 3.2-50.2]),lack of knowledge HEI are followed up to 18 months (aOR= 12.0 [CI 2.9-48.8]),not wanting partners know HEI status (OR= 11.3 [CI 2.9-44.0]),using traditional treatments (aOR= 6.4 [CI 1.8-22.9]).Protective of HEI status were: HEI mothers knowing own HIV status pre-pregnancy (aOR= 0.2 [CI 0.05-0.71]) and households having health insurance
(aOR= 0.11 [CI 0.01-0.76]).
Conclusions: Non-disclosure of infant exposure status to partner, lacking knowledge of HEI follow up duration and use of traditional treatments significantly contribute to clinic non-adherence. Increased early HIV testing among mothers, disclosure support, health education and partner involvement is advocated. Encouraging households enroll in health insurance schemes could be beneficial. Further qualitative studies to understand care givers knowledge, attitudes and practices relating children HIV and a survey to get the magnitude, impact and reasons for using home treatments.

TUPED1271

The impact of structured mentor mother support on PMTCT retention and viral suppression at 6 months postpartum among HIV-positive women in rural Nigeria

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Background: Nigeria has the 2nd-highest burden and widest gaps in PMTCT globally. Poor PMTCT uptake and adherence remain major challenges. Peer support has reportedly improved PMTCT outcomes; however, evidence on its impact on retention-in-care is limited. Retention implies consistent engagement and treatment adherence. The MoMent study evaluated the impact of structured peer support on postpartum retention and viral load (VL) suppression among rural Nigerian women.
Methods: A total of 497 HIV-positive pregnant women were consecutively recruited at 10 primary healthcare centers (PHCs) with structured Mentor Mother (MM) support (close supervision, detailed documentation of MM activities, close client tracking), and 10 pair-matched PHCs with routine but ad-hoc peer support (PS). Retention was defined by clinic attendance during the first 6 months postpartum. Participants with ≥ 3 of 6 expected monthly visits were considered retained. Women with a 6-month postpartum plasma VL of < 20 copies/mL were considered suppressed. A logistic regression model with generalized estimating equation to account for clustering was used to assess the effect of MMs on retention and viral suppression.
Results: Exposure to structured MM support was associated with higher odds of retention than routine PS (aOR=5.9, 95% CI 3.0-11.6) (Table 1).

Characteristics	All, N=497	Retained in Care n (%)	Multivariate Analysis (aOR, 95% CI)	
Routine PS	237	59 (24.9)	1.0	--
MM Support	260	161 (61.9)	**5.9**	**3.0-11.6**
<secondary education	252	115 (45.6)	1.0	--
≥secondary education	245	105 (42.9)	1.1	0.6-1.9
Muslim	178	66 (37.1)	1.0	--
Christian	319	154 (48.3)	1.1	0.7-1.9
Previously HIV diagnosed	197	95 (48.2)	1.0	--
Newly HIV diagnosed this pregnancy	299	125 (41.8)	1.0	0.6-1.6
aOR=adjusted odds ratio; CI=confidence interval; PS=peer support; MM=Mentor Mother				

[Factors Associated with Retention at 6m Postpartum]

Similarly, the odds of viral suppression at 6 months postpartum were higher for MM-supported women (aOR=4.9, 95% CI 2.6-9.2) (Table 2).

Characteristics	All, N=497	Viral Suppression (n=130); n(%)	Multivariate analysis (aOR, CI)	
Routine peer support	237	22 (9.3)	1.0	--
Mentor Mother support	260	108 (41.5)	**4.9**	**2.6-9.2**
<secondary education	252	51 (20.2)	1.0	--
≥ secondary education	245	79 (32.2)	1.6	1.0-5.6
Efavirenz-based regimen	330	86 (26.1)	1.0	--
Nevirapine-based regimen	156	38 (24.3)	1.0	--
Lopinavir-based regimen	11	5 (45.5)	**3.7**	**1.0-13.2**
Not retained	277	43 (15.5)	1.0	--
Retained	220	87 (39.5)	**2.1**	**1.2-3.5**

[Factors Associated with Viral Suppression]

Conclusions: Closely-supervised, outcomes-focused Mentor Mother support significantly improved postpartum PMTCT retention and viral suppression among HIV-positive women in rural Nigeria. Introduction of structure and close supervision into peer support interventions can significantly improve outcomes of women and children in PMTCT care.

TUPED1272

Trends in the implementation of national policies to improve retention in HIV care: evidence from national policy reviews and health facility surveys in six sub-Saharan countries

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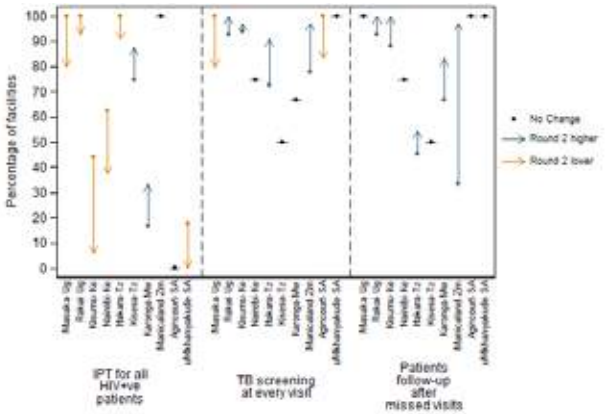
Background: Sub-optimal retention in HIV care in African settings may undermine efforts to reach the "90-90-90" targets. We describe national policies relating to retention in care, and investigate their implementation in selected health facilities between 2013 and 2016.
Methods: A policy extraction tool was used to summarise 120 national HIV policy documents published in Kenya, Malawi, South Africa, Tanzania, Uganda, and Zimbabwe between 2003 and 2016. 145 purposively-sampled health facilities in ten health and demographic surveillance sites in the same countries were surveyed in 2013-15 and 2015-16 using a structured questionnaire to document HIV service provision. A conceptual framework was used to develop 16 indicators to compare policies influencing retention in care with health facility implementation. For each indicator, we assessed whether national policy was explicit or implicit/absent, and calculated the proportion of facilities per site that reported its implementation in each round.
Results: Policy gaps relating to retention in care were observed in all countries in 2013, with little change by 2016. The most frequent policy gaps included referrals for home-based care, nutritional support for HIV patients and drug pick-ups by a designee (noted in 3 or more countries in each case). Only three policies were explicit in all countries by the latter round: home visits/phone calls to patients following missed clinic appointments, tuberculosis screening at every visit, and intermittent preventative therapy for all HIV-positive patients. However, the proportion of health facilities implementing these policies varied across sites and over the two rounds (figure 1).



[Figure 1. Changes in implementation of national policies to promote retention in care from 2013-16]

Furthermore, stock-outs of antiretroviral therapy drugs increased in 5/10 sites, with 34% of all facilities reporting stock-outs in the past year by round 2 (+22%).
Conclusions: Addressing policy implementation gaps and reducing the occurrence of drug stock-outs will be essential if retention in care is to be improved, and HIV elimination goals are to be achieved.

TUPED1273

AllyQuest: engaging HIV+ young MSM in care and improving adherence through a social networking and gamified smartphone application (App)

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Background: HIV disproportionately impacts young men who have sex with men (YMSM) who experience disparities across the HIV care continuum. Technology-based interventions allow the delivery of tailored content specific to each user's context, and offer the unique capability for broad diffusion across geographic locations within the US and globally.
Methods: AllyQuest is a novel, theoretically-based, smartphone app intervention designed to improve engagement in care and antiretroviral therapy (ART) adherence among HIV+ YMSM (target age 16-24 years). The app features address barriers to care among youth, including low HIV health literacy, lack of social support, and internalized stigma. AllyQuest was built on an established gamification platform for patient engagement that embeds social networking and fundamental game mechanics, such as challenges, points, and rewards (unlocking story collections). A medication tracker provides reminders to promote ART adherence via personalized adherence strategies that are user and context specific; a calendar allows for reflection on adherence over time. After iterative development with input from two Youth Advisory Boards, usability testing was conducted to assess app functionality, comprehension of the educational content, use of intervention features, and overall impressions of app relevance and appeal. A 28-day pilot trial was conducted with 20 HIV+ YMSM to evaluate intervention feasibility and acceptability.
Results: Mean age of participants was 21.8 years (range 19-24), 95% were non-white. Mean time using the app was 143 minutes, with a mean of 36.2 log-ins and a mean 21 days of use. There were 225 posts to the daily discussion social wall and 275 total health-focused quests completed. Feasibility and acceptability ratings were high. Overall, participants found the app easy to use and navigate, not intrusive, and had few reported technical issues. Most (15/17) reported greater confidence in reliably taking their ART and feeling more connected to other HIV+ YMSM (14/17). Qualitative exit interviews identified areas for improvement including the need for additional tailoring and personalization.
Conclusions: AllyQuest represents a new, highly scalable solution that is well-suited to meet the specific prevention and care needs of HIV+ YMSM. The development of this intervention is both timely and vital given the urgency of the ongoing HIV epidemic among YMSM.

TUPED1274

Protocol guided adherence counseling by trained patients taking ART: does it make a difference?

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Background: Retention on an Anti-Retroviral Treatment (ART) program and adherence to medication are key to survival of AIDS patients. Shifting of selected tasks, such as counseling, to People living with HIV (PLHIV) is believed to be one way to increase adherence and retention. However, PLHIV-provided counseling services may lack structure or key content useful for encouraging patients to take their medicine and stay on treatment.
Methods: To assess the effectiveness of protocol guided adherence counseling provided by ART-experienced PLHIV in reducing attrition and improving adherence; a two arm cluster randomized, controlled trial with partial blinding was used. Random assignment was made to intervention or control arm at hospital level first. Eligible patients in the intervention hospitals were consented and those who agreed were provided with protocol guided counseling by peer educators. The study subjects were selected from among those who consented and who got the protocol guided counseling randomly. Neither the health care providers nor the peer counselors knew who will be enrolled during the intervention, thus were blinded. In the control sites, standard of care was provided which included counseling by peer educators without the protocol. Retention and adherence to medication were compared at month 2 and 6.
Results: Six hospitals were included in each arm. 433 patients were enrolled in the study (226 in the intervention arm). A significant difference in attrition rates was seen at month-six: 19.4 vs. 37.5 per 100 person-years on treatment in the intervention and control arms respectively (incidence rate ratio 0.52, 95% CI 0.28 - 0.92, P = 0.02). After adjusting for multiple factors, the intervention group had a lower risk for attrition than control group (adjusted IRR 0.47, 95% CI 0.27 - 0.82, P=0.01). The chance of missing medication was much lower in the intervention group at month six (Adjusted IRR 0.44, 95% CI 0.22 - 0.90, P = 0.03).
Conclusions: Retention and adherence to medication were significantly higher among ART patients who were provided protocol-guided adherence counseling compared to those who were provided with unstructured counseling. Provision of protocol guided adherence counseling by ART experienced patients should be considered in all ART settings.

TUPED1275

Navigation and linkage to care outcomes among not-in-care HIV-infected patients identified by three referral sources: clinical providers only, HIV surveillance only and a combination model

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Background: The US CDC supports the use of HIV surveillance data to identify not-in-care (NIC) patients and re-link them to care ('Data-to-Care'). Since 2012, the SFDPH LINCS navigation program has re-linked NIC patients, but the optimal strategy for identifying patients for Data-to-Care is unknown.
Methods: Eligible NIC patients met one of the following criteria: their last viral load (VL) was >1500 and >4 months ago, or they had no VL in 12 months. Referred NIC patients came from three sources:
1) Clinical providers;
2) A query of the SFDPH electronic medical record cross-matched with the SFDPH HIV surveillance registry to remove patients who were already in care (AIC) or who had migrated (EMR-surveillance) or;
3) A surveillance-generated list.
Patients who were incarcerated, psychiatrically unable to participate, had a case manager or who had migrated were considered ineligible for navigation.
Two outcomes were evaluated:
1) Enrollment in LINCS defined as initiating navigation services and;
2) Linkage to care defined as VL or CD4 count reported to surveillance after enrollment.
Results: From 10/1/2015-9/30/2016, LINCS navigation enrolled 40% (127/320) of provider referrals, 30% (32/106) of EMR-surveillance referrals and 9% (17/195) of surveillance-generated referrals (p<0.0001.) Over a quarter of surveillance-generated referrals were AIC, compared to 13% and 2% of referrals from providers and the EMR-Surveillance list, respectively. Of the 176 patients enrolled in navigation, 82% were male, 27% were Black, 27% were Latino, 24% were homeless, and 38% used methamphetamines. Within 90 days of enrollment, 77% of them re-linked to care and 35% were virally suppressed. There were no differences in linkage rates based on gender, race, housing status, drug use, or referral source.

	Clinical Provider		EMR Identified Patients Matched to Surveillance		Surveillance Generated List	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
Enrolled	127	39.7	32	30.2	17	8.7
Already in Care	42	13.1	2	1.9	54	27.7
Refused	35	10.9	11	10.4	13	6.7
Not located	52	16.3	28	26.4	39	20.0
Ineligible	64	20.0	33	31.2	72	36.9
Total	320	100	106	100	195	100

[Linkage Outcomes by Referral Source,10/2015-9/2016]

Conclusions: Provider-identified NIC referrals were more likely to be enrolled in navigation compared to both surveillance-generated and EMR-surveillance referrals. In order to improve the efficiency of Data-to-Care strategies, health departments should consider working closely with clinical providers and refining eligibility criteria for surveillance-generated lists prior to attempting navigation.

TUPED1276

The effect of a mobile health intervention on patient retention during the first year of HIV care: a randomised controlled trial (WelTel Retain)

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Background: Patient retention in the first year of HIV care is critical to ensure the timely initiation of anti-retroviral therapy (ART) and to maximise health outcomes; however, a substantial proportion of individuals in sub-Saharan Africa are lost during the early stages of HIV care. We conducted an open, parallel group randomized controlled trial to determine whether a weekly text-message intervention improved retention during the first year of care.
Methods: Between April 2013 and June 2015, adults testing HIV-positive were recruited at two clinics in low-income areas of Nairobi, Kenya. Participants were randomly allocated to the intervention or control arm at a 1:1 ratio. Intervention arm participants received a weekly text-message check-in and were asked to respond within 48 hours ("OK" or "problem"). Healthcare providers contacted those who responded "problem" or did not respond. The primary outcome was retention in care at 12-months (attendance at the 12-month visit). Participants who did not attend this visit were telephone or community traced. Those in care elsewhere were considered retained. The key secondary outcome was retention in Stage 1 care (the proportion of participants who returned to the clinic within three weeks to complete their ART-eligibility assessment). This trial was unblinded.
Results: Of 1,068 participants screened, 700 were recruited: 349 were allocated to the intervention arm and 351 to standard care only. Out of 17,422 text messages sent, there were 9,303 "OK" responses, 401 indicated a problem, and 7,718 instances of non-response. At 12 months, 276/349 (79.1%) intervention arm participants were retained in care compared to 285/351 (81.2%) control arm participants (non-retention risk ratio (RR) 1.11, 95% confidence interval (CI) 0.826 to 1.499). In Stage 1 care, 301/349 (86.2%) in the intervention arm were retained compared to 310/351 (88.3%) in the control arm (RR 0.98, 95% CI 0.923 to 1.033). The median time to initiation of ART for those eligible at baseline was 27 days in both groups (Kaplan-Meier log-rank test p-value 0.947).
Conclusions: Preliminary analyses indicate that the WelTel intervention did not improve retention in the first year of HIV care. Other secondary outcomes, including satisfaction with care and level of social support, will be presented elsewhere.

TUPED1277

The role of triggering events as a cause of attrition in a cohort of lost to follow-up patients in the DREAM program in Malawi

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Background: Retention in care is crucial for achieving success in HIV programs. A deeper understanding of potential challenges is needed to design appropriate strategies. DREAM is a public health program for HIV care in Malawi. Medical care, laboratory monitoring and adherence interventions (counselling, peer-to-peer educators, phone calls, computerization) are free of charge; these factors lead to retention rates >95%.
Methods: The objective of this study was to investigate the reasons for attrition. Research was conducted in 12 DREAM centres in Malawi (1 in the urban area of Blantyre, 11 in rural settings). Lost-to-follow-up (LTFU) was defined as >90 days from the last visit for a client on ART and was identified through software available within health centres. Community health workers traced every client LTFU and questionnaires were administrated.
Results: From 15.099 clients [10.732 females (71%), 8.561 urban residents (56.7%)] registered before 2. 014, 202 (1.3%) were LTFU in 2014, including 148 females (73%). Tracking results demonstrated that 56 clients were untraceable (37 moved, 19 possibly gave erroneous contact information), 18 died, 26 (12.8%) transferred care to another clinic. Among 102 clients disengaged from care who were interviewed, 51(50%) experienced a "triggering event": a new job, work-related move, marriage, divorce or death of partner, incarceration or acute illness. These events were registered mostly in urban settings (75.4%) and drove to change of residency and difficulty in reaching our clinic. Other reasons were behaviour-related: belief they were in good health (20); turning to traditional healers/prophets (9); failing to disclose his/her status (4). These reasons were mainly reported in rural areas (43% of LTFU), while in clients from urban areas the attrition was due to job related issues in 32% of cases. After the interview, 20 clients (19.6%) returned to care.
Conclusions: In our cohort, 21.7% of clients reported as LTFU were dead or had transferred care, demonstrating the need for further investigation of LTFU. A model of "triggering events" could better explain the LTFU process even in previously adherent patients. HIV treatment programs should take these challenges into account.

TUPED1278

Comprehensive management provision of anal and HPV-related diseases as an HIV retention strategy in low-middle income countries

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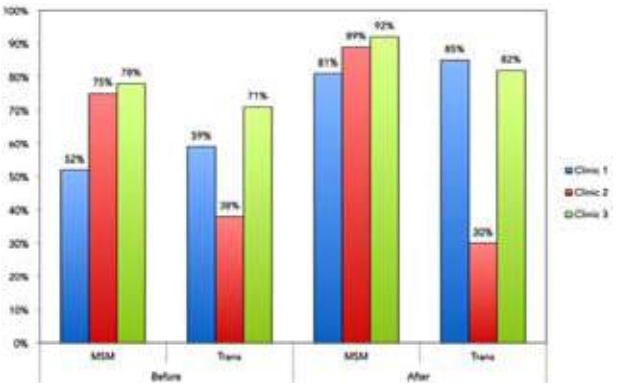
Background: HIV Prevalence in Dominican Republic is estimated of 0.8%; however, this local epidemic is considered to be concentrated among key populations, like Gays, Transgender, and other Men who have sex with men (GTM). This concentrated prevalence reflects an absence of specific services addressing the needs of these populations. The purpose of this analysis was to evaluate the cascade of care among GTM living with HIV that received a comprehensive package of services that included a holistic approach of anal health, and early detection of HPV-related malignancies.
Methods: We selected six (6) HIV clinics from three provinces in the DR (Puerto Plata, Santiago, and Santo Domingo). Out of the total patients we have characterized GTM populations to look over the HIV cascade of care. A training covering anal and HPV health, was offered to all providers in those units. Also, after training a series of mentoring visits were provided, as well as follow-up and referral discussion after the pathology department provided anal results. We used as set point the moment of anal screening, and a 12-month based follow-up was used as a determinant for viral suppression.
Results: We characterized a total of MSM and Trans living with HIV in Puerto Plata (n=33), Santiago (n=128), and Santo Domingo (n=96). None of those before intervention were achieving the 90% goal of HIV viral suppression. After anal screening started we revaluated the HIV cascade of care in Puerto Plata between 82%-92% achieved the 90% goal, in Santiago (30%-89%), and Santo Domingo (85%-81%).



[Figure 1. Cascade of care before and after comprehensive interventions in MSM and Trans populations]

Conclusions: This study suggests that population-specific services for GTM populations can increase opportune ART initiation, linkage to care, and retention in care. Anal screening services, and HPV-related malignancies management in friendly environments seems to induce a better virological suppression among those living with HIV.

TUPED1279

Community outreach and care process improvement to maintain HIV patients in care in Northern Haiti

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Background: In Haiti, UNAIDS estimates[1] that in 2013 the number of people living with HIV (PLHIV) between ages 15-49 was between 130,000 and 150,000 with a prevalence rate of approximately 2%. Haiti has a target to place and retain 80% of PLHIV on antiretroviral therapy (ART) by 2017 as part of its effort to reach PEPFAR's 90-90-90 goals. SSQH-Nord was a USAID-funded project (2013-2015) implemented by University Research Company (URC) which supported the MOH in Haiti in north.
The number of PLHIV lost to follow-up (LTFU) after being enrolled in ART has been rising in Haiti over the past years; PEPFAR Haiti indicates that 7000 patients were LTFU in 2013[2]. The SSQH-Nord project launched an investigation to track these clients as well as to better understand the causes for the LTFU, as a first step to reconnecting these clients to care and treatment (C&T).
Methods: The SSQH-Nord team conducted site visits to the three facilities with the highest volume of PLHIV on treatment between May and June 2015. The team worked with health providers and affiliated Community Health Workers (CHW) to identify the reasons for LTFU and propose ways to return clients to C&T. A list of all clients 822 LTFU were cross checked with medical records. CHWs participated in focus groups to identify reasons that clients discontinued C&T and proposed solutions. Focus groups with providers (doctors, nurses, lab technicians) discussed facility-level reasons for LTFU, mapped the treatment process for PLHIV at the site, identified bottlenecks, quantified the resources allocated to each step and proposed solutions to strengthen their processes. Quality improvement teams analyzed the medical records with the providers to assess the quality of care LTFU received.
Results: Client tracking at the community level and care process improvement at the facilities resulted in locating more than 601 LTFU, re-engaging them and decreasing the percentage of those LTFU. The experience was disseminated and decreased LTFU rate in northern Haiti by August from 26% to 17%[3].
Conclusions: The site visits and associated focus groups show that community-level outreach as well as improved site- and department-level monitoring are key to reducing and maintaining low LTFU.

TUPED1280

HIV ART outreaches achieve more than 90% viral suppression and more client retention compared to the ART clinic in Eastern Uganda

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Background: An efficient antiretroviral therapy (ART) delivery system is necessary for viral suppression. This is a requirement by the UNAIDS 90-90-90 goals to end the AIDS epidemic by 2030 in particular the 3rd 90. HIV ART Outreach is a care model targeting stable patients in the community designed to implement an efficient delivery system to encourage long term retention into care by supporting patients.
The aim of this study is to compare HIV viral suppression and retention among patients receiving care from the ART clinic and outreach and also determine factors associated with detectable viral loads.
Methods: Data from HIV positive patients receiving ART from Soroti clinic and ART outreaches who had had a viral load test by June 2016 were included in the study. Patients' files and open MRS were used to extract clinical and demographic information. Patients were considered lost to follow up if they spent at least ≥91 days without returning to the ART clinic or outreach. Logistic regression was used to determine the factors associated with detectable viral loads.
Results: Of the 447 participants, 293(65.5%) were receiving care from the ART clinic and 154(34.5%) from ART outreaches. HIV viral suppression was achieved in 93.7% overall, being 95.2% in the ART clinic and 90.9% in the ART outreach. There was no statistical difference virological suppression in the ART clinic and outreach, P=0.118. Participants in the ART clinic registered more loss to follow up 22(7.5%) as compared to 1(0.7%) in the ART outreach, P-value 0.002. The independent factors associated with detectable viral load were age, 41-50 years [HR 0.13(95% CI: 0.03-0.56), P=0.006], current WHO stage 3 and 4 [HR 5.12(95% CI: 1.19-22.07), P=0.029], baseline ART regiment containing AZT [HR 4.22(95% CI: 1.14-15.68), P=0.031] and baseline ART regimen containing D4T [HR 5.89(95% CI: 1.16-29.97), P=0.033].
Conclusions: Patients in HIV ART outreaches are achieving more than 90% viral suppression surpassing the UNAIDs target. The same group registered more retention in care compared to clients in the ART clinic. Therefore we need to scale up HIV ART outreach services to suitable populations in order to end the AIDS epidemic by 2030.

TUPED1281

Strengthening community-health facility linkages using expert patients to track and trace HIV-positive clients defaulting ART in Zimbabwe: towards achievement of the third 90 of the UNAIDS targets

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Background: The FHI360 Zimbabwe HIV Care and Treatment Project (ZHCT) is a USAID-funded project implementing community-based interventions with the overall goal of strengthening community-health facility linkages and community level systems to monitor, track and retain PLHIV in care. ZHCT interventions contribute to national efforts towards achieving the last 90 of the UNAIDS targets.
Methods: Between March and December of 2016, ZHCT was implemented in communities around PERFAR Tier-1 and 2 health facilities in eight districts in 2 provinces of Zimbabwe. ZHCT, in partnership with health facilities, identified ART clients who had defaulted on treatment. Expert-patients, who are HIV positive community-based cadres, were trained by ZHCT to track defaulters in their communities and evaluate their ART status in order to link them back to care as necessary. Outcomes were recorded for each defaulter reached and defaulters who were not reached in 3 home visits were considered lost to follow up trained by the ZHCT project.
Results: A total of 8,343 clients who were registered as ART defaulters at the 126 health facilities. Of these 8,143(97%) were tracked while 5,918 (73%) were tracked and traced. A total of 1,492/8,343 (25%) of the clients identified were confirmed to be still in care and 2,430/8,343 (29%) was either lost to follow, dead or had self transfered to other health facilities. Of the 4118 true ART defaulters, 3,144 (76%) were successfully returned to care.
Conclusions: These findings show that using expert patients in this context to strengthen community-health facility linkages achieved high rates of ART defaulters returned back to care. Clients still in care but registered as ART defaulters suggest poor documentation at facility levels. The ZHCT will support health facilities in updating registers such as appointment diaries, pre-ART and ART registers to minimise this challenge as the country moves towards attainment of the 90x 90x90 targets.

TUPED1282

Barriers and facilitators to retention in HIV care and treatment among patients on antiretroviral therapy at the Communicable Disease Centre in Singapore

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Background: As the national referral centre for HIV management in Singapore, the Communicable Disease Centre (CDC) plays an important role in providing clinical care, counselling and support to people living with HIV. In 2014, the clinic observed approximately 15% of missed clinic appointments by patients enrolled in HIV care. To develop interventions to improve retention in HIV care, this qualitative study was conducted to understand the motivators and barriers to accessing and retention in HIV care.
Methods: Twenty-seven in-depth interviews (IDIs) were conducted with healthcare providers and peer support leaders (n=11), people living with HIV who are consistent in care (n=9) and lost to care at CDC (n=7), from April to December 2016. Semi-structured interview guides were used to elicit participants' experiences with linkage to and quality of care at CDC, reasons for staying at or not returning to CDC and recommendations on strategies to improve access and retention in care.

Results: All patient participants reported high quality of care at CDC and that healthcare providers are supportive and caring. However, barriers to care include high costs of antiretrovirals despite financial assistance, perceived stigma associated with visiting CDC which is a known HIV facility, presence of other priorities in life such as work, and long waiting times at the clinic. Patient participants (n=12) shared that they are buying medications from informal sources at much lower prices and thus did not see the need to return to care. To enhance retention in care, healthcare providers reported a need to streamline clinic workflows so as to maximise the value of each patient visit. Use of videoconferencing technology as part of routine clinical consultation (n=13), extended clinic operating hours (n=16) and the use of case managers (n=20) to trace patients lost to care were cited as useful interventions to assist people living with HIV in returning to care.
Conclusions: This study highlights the structural barriers and social factors that needs to be addressed in order to improve retention in care. Healthcare providers at CDC should evaluate current clinic services and explore the implementation of novel methods to enhance access to and retention in HIV care.

TUPED1283

Expert client contribution to achieving the 90-90-90 targets: the Malawi experience

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Background: In 2015 Malawi adopted UNAIDS 90-90-90 treatment targets and instituted the universal test and treat approach. Despite increased identification of HIV-positive individuals and earlier initiation on antiretroviral treatment (ART), retention in HIV care remains sub-optimal, especially in asymptomatic clients. Malawi MOH reports 1 year retention rates on ART of 71%.
Methods: Jhpiego supported the MOH to deploy 619 Expert Clients (ECs) to 52 facilities in 4 districts-Nsanje, Chikwawa, Lilongwe, and Salima—to strengthen retention of clients on ART and re-engage clients lost to follow-up (LTFU). ECs received a 1-week training on HIV basics, HIV testing, ART, PMTCT, early infant diagnosis, viral load testing, adherence counselling, and tracing clients LTFU. ECs utilized ART/PMTCT clinic appointment books, master cards and registers to identify clients LTFU, traced clients by phone/home visits, and physically escorted clients to the clinic. ECs were provided with bicycles, phones, monthly airtime, t-shirts, umbrellas, gumboots and stationary.
Results: Out of 14,426 clients LTFU, ECs traced 8,929 (62%) clients within 12 months of deployment to health facilities in the 4 districts. Of these: 6,187 (69%) were reinitiated on ART; 844 (9%) had died; 1,063 (12%) had silently transferred to another health facility; and 835 (9%) were traced but refused to come back to care. The majority of the 38% of untraceable clients were reported to be Mozambican nationals. Feedback from clients suggests they related to ECs as peers who understood their situation.

District	Total Defaulters	Total Defaulters traced	Total brought back to care/ re-initiated on ART	Total Died	Total Transferred out (silent transfers)	Traced but refused to come back
Chikwawa	4,815	3,628(75%)	2,924(81%)	177(5%)	339(9%)	188(5%)
Lilongwe	3,306	897(27%)	358(40%)	184(21%)	275(31%)	80(9%)
Nsanje	5,545	3,831(69%)	2,469(64%)	448(12%)	383(10%)	531(14%)
Salima	760	573(75%)	436(76%)	35(6%)	66(12%)	36%(6%)
Totals	**14,426**	**8,929(62%)**	**6,187(69%)**	**844(9%)**	**1,063(12%)**	**835(9%)**

[Back to care outcomes per district]

Acknowledgement of ECs by traditional leaders facilitated their acceptance in the community. Their participation in support groups and training gave ECs the knowledge and confidence to talk to clients about the importance of ART adherence.
Conclusions: ECs can play an important role in achieving the UNAIDS 90-90-90 goals, and should be used to re-engage ART clients who are LTFU in all districts in Malawi.

TUPED1284

Retention in HIV care for patients on ART in military health facilities in Zambia

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Background: In responding to the 90-90-90 UNAIDS global targets, the Zambia Defense Force (ZDF) increased the number of sites providing ART resulting in an exponential increase in the number of clients on treatment from 3,208 in 2009 to 6,059 in September 2016. While enrollment into care at ZDF facilities has increased by 53%, retention in care remains a challenge: national rates in Zambia public facilities have been reported to be approximately 75% while retention in care at 12 months after ART initiation at ZDF sites have still not been documented.
Methods: We retrospectively examined routine data (using ART registers and patient files) of HIV positive clients that were enrolled into care from October 2014 to September 2015 at 14 ZDF military sites supported by Jhpiego. The objective was to assess client's outcomes 12 months after ART initiation: retention in care, (defined as client alive and currently active on treatment) as well as, lost to follow up rates, deaths and documented transfers. Data was disaggregated by age and sex.
Results: A total of 1134 (males - 40%, females - 60%) HIV positive clients were initiated on ART in the period October 2014 to September 2015. 93% (1054) of the clients were above the age of 15 years. At 12 months after initiation, retention in care was 91% (1034 clients). Retention rates were similar - 91% in both males (417/458) and females (617/676).
Conclusions: Retention of clients on ART at military health facilities in Zambia supported by Jhpiego is much higher than in the public sector. There is need to further investigate the factors influencing retention at these site and create platforms for sharing learning with public health facilities that provide ART services.

TUPED1285

Characterizing patients´ attrition in a primary healthcare clinic practising test and treat

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Background: Expanding access to diagnosis, treatment and strengthening linkage and retention in care are critical to achieve the 90-90-90 UNAIDs targets. To date, a number of HIV programs report elevated rates of patients' attrition from care. Presently, limited information is available characterising patients' attrition in a test and treat (T&T) setting. We sought to determine the cumulative incidence of loss to follow up (LTFU) and incidence rate of mortality in a primary healthcare clinic practising T&T.
Methods: We retrospectively sampled 600 patients from routine patients' data for HIV patients enrolled into HIV care from January 2012 to December 2014 at Masaka regional referral hospital - Uganda Cares clinic. Cumulative incidence of loss to follow up and incidence rate of mortality were determined and compared across different patients' baseline characteristics using survival analysis and stata version 13.
Results: Of 600 patients in the sample, 50% had initiated antiretroviral therapy (ART) instantly and 64.67% were females with median (IQR) 30.4 (23.8-37.1) years. The overall cumulative incidence of LTFU at 12 months was 8.48% (95% CI, 6.26-11.12%). Compared to the T&T group (12.26%, 95% CI=7.90-17.51 %), cumulative incidence of LTFU was 5.89% (95% CI=3.57-9.02%) in the deferred group (p=0.023). Overall mortality rate was 5.23/100 person years of observation (pyo). Mortality incidence rate was 7.51/100 pyo in males against 3.95/100 pyo in females (p=0.027). Higher mortality was observed in those aged ≥45 years (9.53/100 pyo) than those <18 years (2.91/100 pyo). Furthermore, higher mortality rate was observed in those with a baseline WHO stage of 3 or 4 at baseline (25.15/100 pyo) against WHO stage 1&2 (2.55/100 pyo, p< 0.001). Compared to those with a baseline CD4 of <350 cells/ ml (6.37/100 pyo), mortality rate was 3.49/100 pyo in those with CD4 cell count of 350-499 cells/ml while we observed no mortality case in those with baseline CD4 cell count of ≥ 500 cell/ml.
Conclusions: This study identified higher cumulative incidence of LTFU in those who begun ART instantly. We observed lower incidence rate of mortality in females, patients starting ART with higher CD4 cell count and in those with early stage of HIV infection.

TUPED1286

Retention of HIV-infected children in antiretroviral treatment programs in Benue State, Nigeria: a retrospective review of medical records

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Background: Retention in HIV care programs are key determinants to successful treatment outcomes. Retaining children infected with HIV in care remains a major challenge in Nigeria where the antiretroviral treatment (ART) coverage remains very low. We conducted a review of medical records of HIV infected children in high burden HIV treatment facilities in Benue. In 2014, Benue state had the highest HIV sero-prevalence of 15.4% in Nigeria.
Methods: From July to November 2016, medical records of HIV infected children were reviewed in 3 large HIV treatment facilities in Benue state, Nigeria; General Hospital Otukpo, GH Ugba and GH Adikpo. Retention was defined as proportion of children alive and presenting at the clinics 6, 12, 24 and 36 months post ART initiation; lost to follow up was defined as absence from clinic for more than 6 months. Retention on ART post initiation and factors associated with lost to follow up were estimated through 3 years using descriptive statistics (frequency and proportion), chi square, T-test and binary logistic regression.
Results: Medical records of 455 children across 3 health facilities were reviewed; median age was 48 months (range= 2-169 months). 53.8% (246) of the participants were male while 46.2% (211) were female. The median CD4 count was 470 (range: 123- 2,879). Out of 455 participants, 79.8% (363) were retained at 6 months, 76.7% (349) at 12 months, 73.8% (336) at 24 months and 60.7% (276) at 36 months. There was a statistically significant difference between time spent in getting to the facility and retention at 6 months (p< 0.001), 12 months (p=0.02), 24 months (p< 0.001); Children were less likely to be retained at 6 months (OR=0.99, 95% C.I= 0.987-0.997), 12 months (OR=0.99, 95% C.I= 0.989 - 0.999) and 24 months (OR= 0.99, 95% C.I= 0.990 - 0.999) for every unit increase in the time spent getting to the clinics. There were no significant associations between CD4 levels, age and sex and retention in care.
Conclusions: Retention of children in HIV care programs decreases over time. Reducing distances travelled to the clinics may improve retention of children in care programs.

TUPED1287

SMS messaging to improve adherence to PMTCT/ART: demand for overt HIV-related content among peripartum HIV-infected women in Kenya

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Background: There is growing evidence that mobile health (mHealth) approaches including short messaging service (SMS) can improve antiretroviral therapy (ART) adherence. Concerns about SMS privacy have raised questions about how HIV-related information should be communicated to patients to balance benefits of delivering clear, detailed information against risks of status disclosure. Most interventions have delivered SMS that do not overtly refer to HIV or ART.
Methods: In formative work for the ongoing Mobile WACh-X randomized controlled trial (RCT) evaluating the impact of one-way and two-way SMS on prevention of mother-to-child-transmission (PMTCT) adherence and retention, we conducted 10 focus group discussions (FGDs) with 87 HIV-infected peripartum Kenyan women to determine desirability and preferred terminology of HIV-related content. SMS content for the RCT was developed based on FGD findings.
Results: Roughly half of FGD participants expressed that women would want to receive SMS containing overtly HIV-related terms, such as ‚HIV' and ‚medication'. Participants favoring overt HIV-related content expressed desire for detailed educational messages about ART and PMTCT. Those opposed to overt content expressed concerns about confidentiality. Many participants argued that acceptability of HIV-related content depended on the recipient's disclosure status and others' access to her phone. Based on these findings, both covert and overt SMS were developed. RCT participants who own their phone or have disclosed their HIV status to anyone who accesses their phone may choose one of three options: (1) covert SMS only, (2) overt SMS, only in response to HIV-related questions from the participant, (3) overt SMS routinely, initiated by the study. To date, 545 participants have enrolled in the RCT, of whom 519 (95%) were eligible to receive overt SMS. Of these, 318 (61%) opted to receive routine overt SMS and 64 (12%) to receive participant-initiated overt SMS.
Conclusions: These findings show there is demand for clear, overt HIV-related information by SMS, which outweighs confidentiality concerns if women have disclosed their HIV status or have their own phone. As programmatic efforts to improve ART adherence increasingly incorporate mHealth interventions, our findings highlight that consultation with recipients is key to developing message content that balances confidentiality with delivery of HIV-related information.

TUPED1288

Predictors of loss to follow-up from antiretroviral therapy in Namibia

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Background: Nearly one-third of people living with HIV in sub-Saharan Africa have unknown treatment outcomes within two years of starting ART and are classified as lost to follow-up (LTFU). 18 million PLHIV are on ART globally and as this number continues to increase, the challenge of retaining patients on ART is of paramount importance. LTFU presents a major challenge in achieving high levels of treatment success. Patients LTFU are at high risk for virologic failure due to treatment interruption and for development of drug resistance, both of which increase morbidity and mortality.
Identifying predictors and developing interventions to mitigate LTFU is critical in order for countries to achieve the UNAIDS goals of 90-90-90 and to eliminate HIV/AIDS as a public health threat by 2030.
Methods: An observational cohort study was conducted at seven ART sites selected randomly from seven geographic regions in Namibia. 524 consecutive ART starters in 2012 were administered a baseline survey to collect data on demographic and socioeconomic variables. 12-month outcomes were assessed using clinic records and tracing. Multivariable logistic regression analysis was used to determine independent predictors of LTFU.
Results: The mean age was 36 and 61% were female. 40% had less than secondary school education and 75% reported a monthly income of N$1000 (US$75) or less. Mean baseline CD4 cell count was 222 cells/mm^3, 17% had WHO clinical stage 3 or 4, and 14% were started on efavirenz-based regimen.
In the final multivariable model, significant factors associated with LTFU were: younger age (odds ratio (OR)=1.03; 95% confidence interval (CI)=1.00 to 1.06), male sex (OR=2.34; 95% CI=1.34 to 4.06), difficulty leaving work or home to attend clinic (OR=2.55; 95% CI=1.40 to 4.65), and baseline efavirenz-based regimen (OR=2.35; 95% CI=1.22 to 4.51).
Conclusions: Among a representative sample of HIV patients starting ART in Namibia, several factors were significant predictors of LTFU at 12 months. Interventions to improve retention should be targeted to younger men, especially those who find it difficult to leave their work or home to attend clinic. Efavirenz-based regimens may be a risk factor for LTFU potentially due to side-effects.

TUPED1289

Positive health dignity and prevention (PHDP): an imperative intervention for achieving the second and third 90s of the UNAIDS 90-90-90 goals

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Background: PLHIV default on ART and are eventually lost to follow up (LTFU). There is a significant need to improve the provision of quality community-based PHDP services to PLHIV.A significant challenge to the success of achieving 90% retention rate among clients eligible for ART and subsequent achievement of 90% viral suppression among clients on ART is poor adherence. This is partly a result of service providers' low technical capacity to provide quality Positive Health Dignity

and Prevention (PHDP) services covering risk reduction counseling, condom services, adherence on ART, partner counseling and testing services, and STI and family planning services to PLHIV.
Methods: With funding from USAID, MSH's Pro-ACT project provided small grants to Community-Based Organizations to facilitate the provision of community-based PHDP services to PLHIV at the community level using PLHIV support groups and PHDP home visits. Lists of LTFU clients were compiled from supported health facilities by data clerks and given to trained community-based PHDP volunteers who visit LTFU clients at home, provide them with home-based PHDP services, and link them to support groups. Interventions were conducted in supported communities across Niger, Kwara, Sokoto, Zamfara, and Kebbi states in North Central and North Western Nigeria.
Results: After six months of intervention, 3,490 LTFU clients (1,293 males; 2,197 females) were reached with home-based PHDP services and linked to support groups. 682 LTFU clients (244 males; 438 females) returned to the health facility to continue with ART while a total of 1,154 LTFU clients (334 males; 820 females) joined support groups. 19.5% of LTFU clients returned to ART while 33% of LTFU clients joined support groups. This represents an increase of 12.3% of clients returned to ART and 23.2% of clients who joined support groups when compared to the baselines of 7.2% and 9.8% respectively.
Conclusions: Community-based PHDP interventions can improve clients' retention on ART when strategically tailored to address the factors directly hindering PLHIV from accessing ART and care. There is need to scale up and sustain the provision of community based PHDP for PLHIV in order to achieve the 90-90-90 goals.

TUPED1290

Same-day antiretroviral therapy initiation under the "Treat-All" approach is associated with inferior treatment outcomes in rural Swaziland

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Background: Antiretroviral therapy (ART) initiation at the day of HIV diagnosis and/or HIV care registration reduces pre-treatment loss to HIV care. Randomized controlled trials indicated improved retention in HIV care while PMTCT option B+ cohorts showed increased ART attrition. We compared treatment outcomes for patients initiating ART same-day vs deferred under routine conditions following the WHO Treat-All programmatic approach.
Methods: This is a prospective cohort study of newly diagnosed HIV+ patients (≥16 years) initiated on ART irrespective of CD4/WHO staging criteria in 9 public-sector facilities in rural Swaziland, from 10/2014 to 09/2015. ART initiation was done by clinicians on the day of HIV diagnosis and/or HIV care registration (same-day) or thereafter (deferred). Kaplan-Meier estimates were used to describe ART retention and Cox-proportional hazards models to assess the risk of all-cause ART attrition, adjusted for socio-demographic, clinical (pregnancy, CD4, WHO staging, body-mass-index, TB) and facility factors. We also described the six-month viral load (VL) suppression (< 1,000 copies/ml).
Results: Of 853 patients initiating ART, 634 (74.3%) were females, 248 (29.1%) were pregnant, the median age was 29 (IQR 24-36) years and CD4 count 289 (IQR 133-447) cells/mm^3. 459 (53.8%) patients deferred ART initiation to a median of 10 (IQR 7-21) days after HIV care enrolment and 14 (IQR 8-28) days after HIV diagnosis. The crude retention on treatment was inferior for same-day ART (6 months: 77.6%, 95%CI: 73.1-81.4; 12 months: 74.8%, 95%CI: 70.1-78.8) when compared to deferred ART (6 months: 86.4%, 95%CI: 82.9-89.3; 12 months: 83.4%, 95%CI: 79.6-86.6). In multivariate analysis, patients initiating same-day ART were 62% (adjusted Hazard Ratio: 1.62, 95%CI: 1.11-2.37; p=0.01) more likely to be lost to care. Among 429 patients with a VL test result, VL suppression was similar in both groups (same-day: 92.4%; deferred: 91.6%; p=0.78). It was inferior for same-day ART (53.2% vs 66.0%; p< 0.01) when patients without VL test results and lost to care were assumed virologically non-suppressed.
Conclusions: Same-day ART initiation was associated with inferior treatment outcomes in this public-sector programme applying the "Treat-All" programmatic approach. Timing of ART initiation should be tailored to the patient needs taking patient's choice and ART readiness into account.

TUPED1291

A sampling-based approach to evaluate retention and its barriers across clinics in Zambia

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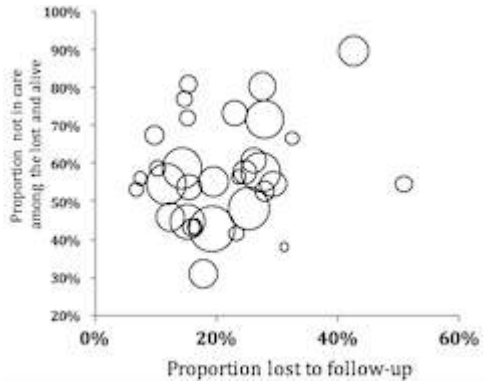
Background: Understanding the frequency, length and reasons for lapses of retention in HIV treatment can drive improvements in the care cascade. We undertook a systematic assessment of outcomes among a random sample of patients lost to follow up (LTFU) of 31 clinics in Zambia to understand the incidence of silent transfers, disengagement from care, as well as to identify patient reported reasons for loss.
Methods: We intensively traced a simple random sample of patients who were LTFU (>90 days from last scheduled visit) as determined from clinic-based electronic medical records (EMR) from a probability sample of facilities. Among patients alive and found in person, we solicited reasons for either stopping or switching care. We coded reasons into structural, psychosocial and clinic based barriers.
Results: Among 54,172 patients starting ART between July 1 2013 and July 31 2015 (63% female, median age 35 years, median CD4 level 266 cells/ul), median LTFU was 26% (IQR: 22-24, range 20 to 40). We randomly traced 18% of lost patients and successfully contacted 75%. Using only data from EMR, retention estimated across all sites was 61% at one year and 42% at two years. After incorporating outcomes ascertained through tracing, retention at one and two years was 86% and 78%. The difference between EMR and corrected estimates did not differ by clinic, unlike the prevalence of patient reported barriers . Among the patients who were not in care, the median prevalence for patient reported structural, psychosocial and clinic level barriers was 45%, 31% and 40% respectively, and were highly variable across facilities.



[Fig 1: Proportion lost to follow-up (x-axis) is not strongly associated with the fraction of alive patients who are not in care (y-axis). Size of marker proportional to clinic volume.]

Conclusions: True patient retention in care is higher than what is estimated across clinics in Zambia. The EMR LTFU estimates do not reflect the actual degree of patient disengagement. Understanding levels of disengagement, facilitators and barriers to care unique to each clinic is needed to improve retention.

TUPED1292

Linkage to ART in an outpatient treatment center in Dakar, Senegal from 1998 to 2016: delay and missed opportunities

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Background: Delaying ART initiation is associated with increased morbidity and mortality and with increased risk of transmission. We describe delay and missed opportunities from eligibility to antiretroviral treatment (ART) initiation among ART-naïve people followed in an outpatient treatment center since the onset of ART access program in 1998.
Methods: This is a retrospective analysis of ESOPE-software computerized medical file data. A total of 3693 ART-naïve individuals aged above 15 years, entering the Fann Hospital outpatient center in Dakar, Senegal from august 1998 to june

2016 were included. Four time-periods were considered according to successive HIV guidelines revisions. Eligibility was defined as clinical stage 3 or 4 or as clinical stage 1 or 2 and CD4 count below 200, 350 or 500 cells/µl for periods 1998-2003 and 2004-06, 2007-10 and 2011-16, respectively.
Results: Out of 2874 ART-eligible individuals, 1720 initiated ART (60%) in the center. Linkage to ART improved markedly with time and reached 87% in the more recent period. Median delay from eligibility to ART initiation was reduced from 4 months during the first time-period (1998-2003) to 2 months in the last one. But the delay is greater than 9 months for at least one quarter of the individuals in all periods. Overall, only 19% initiated treatment immediately, and 14% had at least 5 visits (missed opportunities) from eligibility to ART initiation, even in the last period (2011-2016).
Conclusions: Despite significant progress in linkage to care, strategies to reduce delay and missed opportunities in initiation of ART need to be implemented to achieve the UNAIDS target of 90% of ART coverage. These strategies, based on education campaign, should highlight the benefit of timely linkage to ART to reduce transmission and help end the AIDS epidemic.

	Time-periods				
	1998-2003	2004-06	2007-10	2011-16	Total
ART-naïve, n (%)	1488	969	831	405	3693
ART-eligible, n (%)	991(67%)	784 (81%)	738 (89%)	361 (89%)	2874 (78%)
Linked to ART, n (%)	426 (43%)	456 (58%)	524 (71%)	314 (87%)	1720 (60%)
Median delay [interquartile range]	4 [2-9]	4 [2-9]	3 [1-11]	2 [1-9]	3 [1-9]
Number of additional visits after eligibility					
No visit	17%	17%	14%	33%	19%
1 to 4 visits	72%	69%	67%	52%	66%
5 + visits	11%	14%	19%	15%	15%

[From eligibility to ART initiation (1998-2016)]

TUPED1293

Contributing factors to attrition amongst key and priority population PrEP users: a cross sectional qualitative study of PrEP demonstration project participants in Kenya

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Background: A major programmatic concern in the delivery of PrEP for HIV prevention to key populations at risk of HIV infection is their retention in PrEP programs. For effective prevention of HIV with minimal risk of drug resistance and seroconversion in PrEP programs, retention needs to be sustained. There is limited literature on reasons why PrEP users choose to withdraw from PrEP programs and solutions to address the attrition. This study aimed to describe the reasons for attrition among clients in a PrEP demonstration project in Kenya, and give recommendations on how to address the challenges.
Methods: A cross sectional qualitative study was conducted in November 2016 among 531 PrEP users (166 female sex workers, 103 men who have sex with men and 262 young women) who had missed their monthly appointments by three to ninety days in the PrEP demonstration project. Health service providers (HSPs) at implementing sites contacted the defaulted PrEP users by phone or face to face to document their reasons for missing appointments. In-depth interviews were also conducted with six HSPs on contributing factors that led to the attrition. Data was analysed using open coding approach.
Results: Individual factors that led to defaulting scheduled appointments were: reduced self-perception of risk where project participants reported they were not sexually active at the time (sex break), negative perceptions of PrEP usage, partner discouragement of appointment attendance, non-disclosure of PrEP use to sexual partner and forgetfulness. Socio-economic factors included: relocation from PrEP dispensing site, lack of transport monies and competing time priorities due to employment. Health system factors mentioned were complicated PrEP initiation and follow up process and procedures and long waiting times at the health facility.
Conclusions: These findings are important for program managers in the context of national PrEP rollout in Kenya to address the challenges raised through practical interventions such as correct PrEP messaging during mobilisation, sexual partner engagement and development of simplified standard operating procedures on initiation and follow up of PrEP users clients. Client education on self-risk perception is equally important to ensure retention during actual seasons of high HIV infection risk.

TUPED1294

National-level assessment of patient retention and loss to follow-up under PMTCT test and treat using a random sample of health facilities in Côte d'Ivoire

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Background: Loss to follow-up (LTFU) in PMTCT test and treat programs may occur at multiple stages of antenatal and post-partum care. We estimated the proportion of HIV-positive pregnant women with known retention in care to better understand both LTFU and the information gap between ARV delivery in antenatal care and continued ARV use at and after childbirth.
Methods: We randomly selected a nationally representative, stratified sample of 50 health facilities providing PMTCT services in Côte d'Ivoire. Data collection teams abstracted quantitative data from routine facility-based monthly reports, registries, and patient charts, to estimate the magnitude of LTFU under Option B. We combined data from these sources to determine the proportion of PMTCT patients with documented retention status at childbirth and 6 months post-enrollment.
Results: From November 2014 to October 2015, 92% of pregnant women attending first antenatal care visits had a recorded HIV test; 79% of HIV-positive women were reported to have received ARVs during their antenatal care. Among all HIV-positive women identified in ANC in 2014 and 2015 in our sample, 49% had a patient chart available at the health facility; 72% of 1,207 eligible patient charts had proof of active patient retention at childbirth; and 65% had proof of active retention 6 months from enrollment in care. Variability between health facilities was high for all indicators. Combining the lost to follow up in all of the above steps, the overall aggregate proportion of all HIV-positive women in the sample with a documented active retention 6 months from delivery of ARVs was 29%.
Conclusions: Documented retention in among women on ART in pregnancy is far lower than estimated retention rates based on initiation of treatment. We believe that a focus on improving data quality to understand true retention could improve the effectiveness of service delivery interventions. The high degree of variability among health facilities in LTFU at each stage of the cascade suggests that targeted health facility interventions may provide opportunities to improve performance and reduce LTFU. These may include early interventions to improve data collection quality, consistency, and regular data review.

TUPED1295

Active patient tracking can improve patient retention under PMTCT test and treat: results from a national intervention project in Côte d'Ivoire

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Background: Test and treat models of antiretroviral treatment delivery (including Option B/B+ for the prevention of mother-to-child transmission of HIV (PMTCT)) greatly increase the numbers of HIV-positive women in lifelong antiretroviral therapy. Côte d'Ivoire has faced challenges to retention in care among HIV-positive mothers, including effective measurement of retention.
Methods: This study used a nationally representative sample of 30 health facilities providing PMTCT services in Côte d'Ivoire. An active patient tracking (APT) intervention was rolled out monthly to six-site clusters following a stepped-wedge study design. The APT included a training workshop and an APT data toolkit to be used by an inter-professional APT team made up of site-based health workers. Quantitative data were collected from HIS reports and patient charts to measure changes in on-site chart availability and to estimate changes in patient retention among available charts. Interviews were conducted monthly to record strategies identified as a result of the intervention.
Results: On-site patient chart availability increased significantly (p=0.001) from 57% pre-intervention to 76% during the intervention. The proportion of patients actively in treatment among available charts did not change significantly. Sites

experienced varied fidelity to the intervention with staff enthusiasm and heavy patient load cited as key barriers to implementation and doctor and community counsellor engagement cited as key facilitators. Sites with higher fidelity to the intervention identified new strategies for improving maternal retention, including new tasks/duties, improved information sharing, increased service offerings, and strengthening data systems and sharing.
Conclusions: The APT intervention increased the number of patient charts available to health workers for management of retention. Since the proportion retained in the additional was similar to the smaller number of charts available before the intervention, the overall proportion of patients who were considered actively in treatment increased significantly. The intervention, focusing on collaboration and use of patient chart data, encouraged staff at health facilities to work together to identify strategies to improve patient retention.

TUPED1296

The burden of gynecomastia among men on antiretroviral therapy in Zomba, Malawi

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Background: Many Africans who are on life-saving ART face challenges from a variety of toxicities. After the introduction of a standardized first-line efavirenz-containing ART regimen, reports of gynecomastia in Malawian popular media caused concern, however data on the prevalence and risk factors for gynecomastia from studies in African are scarce
Methods: We conducted a cross-sectional study in males ≥18 years registered on ART at the HIV clinic in Zomba Central Hospital, south-east Malawi. Men who reported to have ever experienced breast or nipple enlargement received a standard questionnaire and underwent physical examination. Questions included perceptions and concerns about gynecomastia. Clinicians confirmed the presence of gynecomastia and severity was determined with a validated score. Routinely collected data on current and previous ART regimens, CD4 count, WHO clinical stage at ART initiation, anthropometric measurements and history of tuberculosis were extracted from the electronic database. We used multivariable logistic regression analysis to determine risk factors for gynecomastia.
Results: We enrolled 1,027 men with median age of 44 years (IQR: 38-52 years). The median ART duration was 57 months (IQR: 27-85); 46.7% were in WHO stage III/IV at ART initiation, 88.2% had exposure to efavirenz and 9% were overweight or obese. The prevalence of self-reported gynecomastia was 6.0% (62/1027) (95%-CI: 4.7-7.7%). Of men with gynecomastia 83.6% reported nipple enlargement and 98.4% enlarged breasts (85.5% bilateral). One-third said they had not previously reported gynecomastia to a health care provider. Over three-quarters mentioned that gynecomastia was an important problem for them, while more than half were embarrassed by it. On examination, gynecomastia was present in 90% (confirmed gynecomastia prevalence of 5.5%; 95%-CI: 4.2-7.0%) and 51.8% had severity grade III or IV. Only history of tuberculosis treatment was independently associated with gynecomastia; adjusted OR 2.51 (95%-CI: 1.05-6.01).
Conclusions: The burden of gynecomastia among men on ART in Malawi was higher than previously reported, and was associated with adverse psychological consequences, calling for increased awareness, a proactive diagnostic approach and thorough clinical management.

TUPED1297

Retention in care of children living with HIV in resource constraint setting: the case of Nepal

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Background: The need for efficient retention in HIV care is more evident than ever because of the expansion of earlier ART initiation and the shift towards ‚Test and Treat'. This study assesses different steps of HIV care cascade (from diagnosis to viral load suppression) among children living with HIV (CLHIV) in Nepal. We also examined retention in care, mortality and Loss To Follow-Up (LTFU) over time by age (0-4 and 5-14 years) and gender.
Methods: We calculated the number of CLHIV using UNAIDS developed Spectrum and Epidemic Projection Package using census, surveillance data and national programme data. We reviewed the program data of all HIV-infected children (1363) registered till the end of 2015 in 65 ART centres in 59 districts of Nepal. The retention in care was defined as the percentage of children alive and on ART at 12, 24, 36 and 48 months. LTFU was defined as having not visited ART centre for 90 days.
Results: Of 1589 estimated CLHIV, 815 (51.3%) were male, and 774 (48.7%) were female. 1363 (86%) of the total estimated children were diagnosed with HIV by the end of 2015. Of the total estimated CLHIV, 76% linked to HIV care. Only half of the CLHIV have access to ART, and one-third (35%) had tested for viral load. Only one-quarter of CLHIV remained virologically suppressed (≤1000 copies/mL) at their most recent tests. The retention rate was 94%, 94%, 89% and 84% at 12 months, 24 months, 36 months and 48 months respectively. No substantial difference in the retention in care was observed by gender, but the difference was observed by age group. LTFU was increased from 3% in 2012 to 6% in 2016, and the substantial difference was observed by age group (≤4 years vs. 5-14 years: 11% vs. 2% at 12 months). Similarly, we found a significant difference in mortality rate over time by age group (≤4 years vs. 5-14 years: 14% vs. 6% at 36 months).
Conclusions: Young children (≤4 years) are experiencing higher LTFU and mortality than children 5-14 years old. Future efforts should improve access to and retention in care of young CLHIV in Nepal.

TUPED1298

Assessing long-term retention in care for patients on antiretroviral therapy in the northern part of Zambia: a cohort study

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Background: Zambia has made significant progress in scaling up antiretroviral therapy (ART) programs in the last decade. Retention in care is critical to achieving HIV viral suppression, improved health outcomes and reduced HIV related morbidity and mortality. This evaluation presents findings from a cohort of 4,417 patients on cART as we seek to define predictors for retention in care.
Methods: This was a retrospective review of medical records of patients initiated on cART between January and December 2009 and followed up for 60 months at nine 2nd level provincial hospitals in Zambia. Kaplan Meier curves were used to determine retention at 12, 24, 36, 48 and 60 months. Retention was defined as not having experienced death, loss to follow up, transfer out or stopped ART. Cox regression was used to determine the predictors of retention and the magnitude of their effect on retention. Factors examined included age, baseline WHO clinical stage, education level, marital status and gender.
Results: The retention rates were 77%, 69%, 61%, 54% and 47% at 12, 24, 36, 48 and 60 months respectively. Females had higher retention at 60 months (50% vs 44%) compared to males: aHR: 0.84 (95% CI: 0.76 - 0.92). Retention was positively associated with various factors such as lower baseline WHO clinical stage I and II: aHR: 0.66 (95% CI: 0.60 - 0.74) and primary education: aHR 0.89 (95% CI: 0.81 - 0.99).
Conclusions: Retention rates for patients in ART care was at 77% after 1 year but dropped to 47% at 5 years of follow up. Patients who are male, with WHO stage III or IV disease and with secondary or tertiary education require intensive adherence counselling and follow up to improve retention in care.

TUPED1299

Sub-group effect heterogeneity of conditional food and cash transfers provided to HIV-infected adults in improving adherence to antiretroviral therapy and retention in care in Shinyanga, Tanzania

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Background: We recently concluded a randomized study in Tanzania which found that short-term conditional cash and food transfers significantly improved HIV-infected patients' possession of antiretroviral therapy (ART) and reduced loss to follow-up (LTFU). We examined whether the transfers had differential effects within key subgroups.
Methods: In the parent study, 805 individuals were randomized to standard of care (SOC) HIV services or food or cash transfers, valued at approximately $11 USD/month and provided for ≤6 months, conditional on clinic visits. Eligibility criteria were: 1) ≥18 years; 2) HIV-infected; 3) food insecure; and 4) initiated ART ≤90 days before enrollment. We compared achievement of 6-month medication possession ratio (MPR) ≥95% and 12-month LTFU between patients receiving the SOC and those receiving food or cash (combined). Heterogeneity was assessed by comparing intervention effects expressed as risk differences (RD) within the following subgroups: sex, age (18-35, ≥35 years), wealth (poorest quartile vs. all others), and time elapsed between HIV diagnosis and ART initiation (≥90, < 90 days).
Results: The intervention improved MPR≥95% and reduced LTFU in subgroups, although effects did not significantly differ between most subgroups (see Table). For example, the intervention's effect on MPR≥95% was non-significantly stronger among females compared to males; those poorest vs. wealthier; and significantly greater for participants with < 90 days elapsed between diagnosis and ART initiation compared to those with ≥90 days. For 12-month LTFU, the effect was non-significantly stronger amongst those poorest vs. wealthier; and in participants with ≥90 days elapsed between diagnosis and ART initiation compared to those with < 90 days.

	Males	Females	Age: 18-35	Age: 35+	< 90 days elapsed between diagnosis and ART initiation	≥ 90 days elapsed between diagnosis and ART initiation	Lowest wealth quartile	Wealthier quartiles
Intervention Effect on 6-Month MPR ≥ 95% (RD, 95% CI)	13.9% (-2.1, 29.8)	21.4% (8.9, 34.0)	16.1% (2.5, 29.7)	21.8% (7.1, 36.6)	24.0% (12.4, 35.7)	3.0% (-14.6, 20.6)	28.2% (5.3, 51.1)	16.4% (5.2, 27.5)
Test for homogeneity	p = 0.51		p = 0.64		p = 0.039		p = 0.27	
Intervention Effect on 12-Month LTFU (RD, 95% CI)	-13.7% (-29.6, 2.2)	-6.4% (-15.7, 2.9)	-9.9% (-21.6, 1.9)	-7.5% (-19.2, 4.1)	-6.8% (-16.2, 2.6)	-15.0% (-32.5, 2.5)	-18.3% (-39.7, 3.1)	-6.4% (-15.2, 2.3)
Test for homogeneity	p = 0.58		p = 0.83		p = 0.13		p = 0.27	

[Table]

Conclusions: This analysis provides preliminary data suggesting that targeting interventions at patients more recently diagnosed with HIV, whose HIV healthcare habits are still being formed, may be worthwhile. Although not powered for subgroup analyses, study results suggest that food or cash transfers may have stronger beneficial effects on HIV care in marginalized population members, particularly the poorest and in women. Future studies to detect subgroup effects with larger sample sizes are warranted.

TUPED1300

Have patient outcomes in South Africa's ART program improved with age? Evidence from an urban HIV clinic under three different sets of ART guidelines

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Background: As HIV treatment programs in resource-limited settings transition to "treatment-for-all", it is important to take stock of successes thus far to guide retention-in-care priorities as larger numbers of healthier patients start treatment. We evaluate short-term outcomes of patients initiating antiretroviral therapy (ART) in South Africa under various treatment guidelines since program inception in 2004.
Methods: We conducted a prospective cohort analysis of ART-naïve adults (≥18) initiating standard first-line ART at a large, public-sector HIV clinic from 04/2004-12/2015. We used Cox proportional hazards regression to evaluate the association between attrition (mortality and loss to follow-up [LTF: ≥3 months late for a scheduled visit] combined) and three ‚guidelines' cohorts: 04/2004-08/2011 (C1:CD4≤200mm^3); 08/2011-12/2014 (C2:CD4≤350mm^3); 01/2015-12/2015 (C3:CD4≤500mm^3). Patients were followed from ART initiation until the earliest of death, LTF, transfer or 12-months follow-up.
Results: 23,654 adults were followed for 19,961 person-years. Median age at ART initiation increased from 36.3 (IQR:31.0-42.8) (C1) to 38.7 (IQR:32.5-46.3) (C3). The proportion of men increased from 37.0% (C1) to 43.1% (C3) and median baseline CD4 count increased from 94 cells/mm^3 (IQR:35-166) (C1) to 156 cells/mm^3 (IQR:50-305) (C3). Attrition at one year declined across the guidelines cohorts from 24.4% to 18.0% (Table 1).

		C1: CD4 ≤200 guidelines N (%)	C2: CD4 ≤350 guidelines N (%)	C3: CD4 ≤500 guidelines N (%)
Patients enrolled		16794 (71.0)	5723 (24.2)	1137 (4.8)
12-month outcomes	Alive, on treatment	12091 (72.0)	4078 (71.3)	825 (72.6)
	Dead	1314 (7.8)	337 (5.9)	67 (5.9)
	Lost to follow-up	2786 (16.6)	855 (14.9)	137 (12.1)
	Transferred	603 (3.6)	453 (7.9)	108 (9.5)
Total Person Years		14,159	4,826	976
Attrition rate per 100 person years**		29.0	24.7	20.9

*≤200 guidelines: April 2004 to August 2011; ≤350 guidelines: September 2011 to Dec 2014; ≤500 guidelines: January 2015-March 2015. **Attrition is defined as those who are dead or LTF

[Table 1: 12-month outcomes of patients initiated on ART at the Themba Lethu Clinical HIV Cohort in Johannesburg, South Africa between 1 April, 2004 and 31 December 2015 by South African ART guidelines]*

However, after controlling for sex, age, anaemia, and baseline ART regimen, no association was observed between attrition and guidelines cohort within CD4 count categories (Table 2).

		Baseline CD4 count <100		Baseline CD4 count 101-200		Baseline CD4 count 201-350		Baseline CD4 count 351-500	
		n/N (%)	aHR (95% CI)	n/N (%)	aHR (95% CI)	n/N (%)	aHR (95% CI)	n/N (%)	aHR (95% CI)
CD4 treatment guidelines**	≤200	2273/7969 (28.5)	1.00	1046/5243 (20.0)	1.00	343/1775 (19.3)	1.00	31/141 (22.0)	1.00
	≤350	448/1708 (26.2)	0.96 (0.84, 1.09)	193/1167 (16.5)	1.01 (0.83, 1.23)	186/1545 (12.0)	0.76 (0.60, 0.96)	26/189 (13.8)	0.51 (0.24, 1.09)
	≤500	75/330 (22.7)	0.84 (0.65, 1.07)	30/155 (19.4)	1.21 (0.82, 1.77)	26/200 (13.0)	0.84 (0.55, 1.29)	15/123 (12.2)	0.50 (0.22, 1.16)

*Models are adjusted for sex, age and anaemia at ART initiation and baseline ART regimen

[Table 2: Adjusted HR for 12-month attrition by baseline CD4 count]*

Conclusions: Overall, immune status of patients initiated under the three guidelines has improved at this facility; however, we still observe high rates of attrition within 12 months on treatment. As South Africa implements "treatment-for-all", focus should be early retention in care to ensure long-term success.

TUPED1301

Evaluating the WelTel service's Grand Challenges Canada "transition-to-scale" for HIV care in Kenya's northern arid lands

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Background: The original WelTel Kenya1 randomized controlled trial showed that weekly text messaging communication between healthcare providers and individuals with HIV improved ART adherence and outcomes. As part of the Canadian Grand Challenges program, in partnership with Amref Health Africa and the USAID-funded APHIAplus IMARISHA project, we implemented and evaluated the WelTel service for HIV patients in Kenya's remote northern arid lands, a pastoral region with major health access issues.
Methods: Patients with mobile phone access seen between April 2015 and September 2016 at the Isiolo County Hospital's Comprehensive Care Clinic (CCC) were prospectively offered enrollment in WelTel. We tracked the number of monthly enrollments, responses to weekly check-in messages, and CCC visit attendance during the study period. Demographic information (age, sex, marital status, individual/shared phone access, and urban/rural residency) was obtained from the hospital's electronic medical records.
Results: Overall, 1,131 patients with demographic information available were seen at the CCC during the study period. Of these, 563 (50%) agreed to receive WelTel, with the majority of participants (350/563, 62%) enrolled within three months. A total of 32,595 messages were sent, with an overall response rate of 36%. Uptake was highest among patients aged 25-49 years (392/711, 55%), those with individual phone access (397/699, 57%), and married patients (277/512, 54%). Uptake was lowest among those aged < 18 years (33/142, 23%), those with shared phone access (42/101, 42%), and single individuals (111/275, 40%). There were no differences based on sex or urban/rural residency. A median of 4 CCC visits were scheduled per patient. As a group, patients on WelTel attended a higher proportion of their visits as scheduled (mean ± standard deviation: 57 ± 30%) than those not on WelTel (52 ± 31%, p=0.02). Patients on WelTel also defaulted on a smaller proportion of their clinic visits than those not on WelTel (8 ± 18% and 12 ± 22% respectively, p=0.01).
Conclusions: The WelTel mobile health program successfully reached half the population of a remote HIV clinic and reduced defaulting. It has been sustainably adopted in additional clinics in northern arid lands.

TUPED1302

Tracking of lost to follow-ups PLHIVs towards increased retention in HIV care: experience from the Global Fund-supported Vihaan Programme in India

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Background: 2,068,097 people registered with ART center for treatment of which 15% are on lost to follow-up (LFU) for the treatment. Bring back the LFU clients for treatment remains challenge. India HIV/AIDS Alliance implements the Global Fund supported Vihaan programme to deliver care and support services for people living with HIV (PLHIV) through its 361 community-based Care & Support Centers (CSC) across India and supports national programme to bring back LFU clients for treatment.
Methods: LFU clients list were shared with CSCs to bring back to the treatment through ART-CSC coordination and data sharing process on monthly basis. LFU clients include ART LFU, Pre-ART LFU, ART missed clients, clients who are eligible but not started ART and missed CD4 testing. Data sharing tool has been developed and used across India uniformly. 2,023 outreach workers and peer counsellors were trained on LFU tracking and tools. Field level community workers tracked back LFU clients and documented the outcome. Brought back line lists were compiled nationally and analysed. Data quality were ensured through on-site data verification and supervisory visits. Descriptive analyses of brought back clients and trend analyses for LFU were carried out.
Results: 256,011 LFU clients were brought back to ART center for treatment and health monitoring between 2013 and 2016. Of which 67% LFU and missed clients on ART and 37% were clients not on ART. On an average, frontline workers of CSC were able to bring clients back to ART centre within 2 months. Among clients brought back to ART centre, average age is 33 years. More than 60% clients are in 20-40 years age category and about 9.3% belongs to < 20 years. Among brought back 54% were male and 46% were female. Through regression analyses of LFU clients for last 2 years showed the there is a significant decrease (p< 0.001) in clients not on treatment (Pre-ART clients) and stabilisation on clients on-ART.
Conclusions: Collaborative effort between national ART progamme and community led outreach programme is effective in bringing back the alive LFU clients for treatment. Long term of this continued efforts will sustain the increased adherence and retention in HIV care.

TUPED1303

Low retention in care among recently diagnosed women enrolled in Option B+ care in Mozambique

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Background: Mozambique adopted the Option B+ strategy in 2013-2014. Reported rates of HIV testing and ART initiation during pregnancy are >90%; however, retention in care has been poor, potentially resulting in uncontrolled viral load (VL) and continued mother-to-child HIV transmission.
Methods: From 07/2015-03/2016, we enrolled an unselected population of Option B+ eligible women from antenatal care at ten clinics in Central Mozambique. Sociodemographic data, medical and obstetric history, and data concerning ART knowledge and self-efficacy were collected at enrollment. Follow-up data were collected by clinic nurses during routine visits at delivery, six weeks and six months post-partum; VL samples were collected at delivery. Retention in care was defined as completion of a routine visit within 45 days of the scheduled date. Baseline factors associated with subsequent retention in care and VL suppression to < 500 copies/mL were identified using generalized estimating equations with clustering by clinic.
Results: 1576 women were enrolled at a median gestational age of 5.9 months. Prior to enrollment, 57% of women had been diagnosed with HIV and 47% had initiated ART. By six weeks post-partum, 46% of women were lost to follow-up; by six months post-partum, 68% were lost to follow-up. Retention in care was associated with presenting to care after the first trimester (OR=1.26,(95%Confidence Interval:1.07-1.47)), and HIV diagnosis prior to study enrollment (OR=1.56,(1.25-1.94)). Of 535 women with samples analyzed to date, 290 (54%) had suppressed VL. Suppression was associated with HIV diagnosis (OR=2.06,(95%CI:1.42-2.98)) and ART initiation (OR=1.49,(95%CI:1.07-2.08)) prior to enrollment. Greater than median self-efficacy score at enrollment was associated with both retention in care (OR=1.31, (95%CI:1.05-1.64) and VL suppression (OR=1.62,(95%CI:1.20-2.18).
Conclusions: Early loss to follow-up from routine care in our study was extremely high, and recently diagnosed women were at particular risk of loss to follow-up and unsuppressed VL. Enhanced strategies are needed to promote retention in care and ART adherence under Option B+ in Mozambique; self-efficacy assessments may provide an opportunity to identify at-risk women.

TUPED1304

Exploring patent medicine vendors (PMVs) in the context of community ART programs in resource poor settings using rural areas of Benue state as case study

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Background: Background
To scale up Antiretroviral Therapy (ART) in 5 PEPFAR prioritized LGA of Benue State, access to HIV treatment must be at the reach of the endemic population in the communities. Patent Medicine Vendors (PMVs) are outlets for selling over-the-counter drugs. Literature review reveals that PMVs are the first point of contact when members of the community become ill. The objective of the study is to examine the contextual factors of involving PMVs in community ART programs
Methods: .A cross-sectional community based survey was conducted across five local government areas in Benue state in December 2015. A total of 191 Patent medicine vendors across 41 ward councils of Tarka, Logo, Gwer West, Katsina Ala and Konshisha LGA were assessed. Data collection was done using a structured questionnaire and analysed using SPSS

Results: A review of the 191 PMVs assessed in the 5 LGs revealed 47.1% had secondary school certificate, 2.6% had tertiary education, and 15.7% had no formal education. No PMVs had record of adverse drug reactions. Hygiene standards revealed 2% had hand washing and 15% had toilet facility respectively. Dispensing worksheet was not in use with only 3% using adhoc drug register to document drugs dispensed. Assessment of Basic Infrastructure to support ART drug pick-up showed that only 24.1% have rooms with audio-visual privacy while 27.2% have adequate patient waiting area. Only 20.9% have PCN (Pharmacists council of Nigeria, the regulating and licencing body in Nigeria) licence while 93.2% were registered with NAPPMED (National Association of Patent and Proprietary Medicine Dealers, the association of medicine vendors in Nigeria)
Conclusions: The study findings demonstrates that PMVs have obvious limitations in participating in community ART programs due to legal issues of PCN licensing, poor infrastructural support and inconsistent level of formal education. Other observations include PMVs retailing alcoholic beverages/ household materials, traditional concoctions and tobacco. To incorporate PMVs into community ART program, effort would be needed to build capacity, provide infrastructural support and advocacy on appropriate licencing for practice

TUPED1305

A randomized controlled study of intervention to improve continuity care engagement among HIV-infected jail detainees

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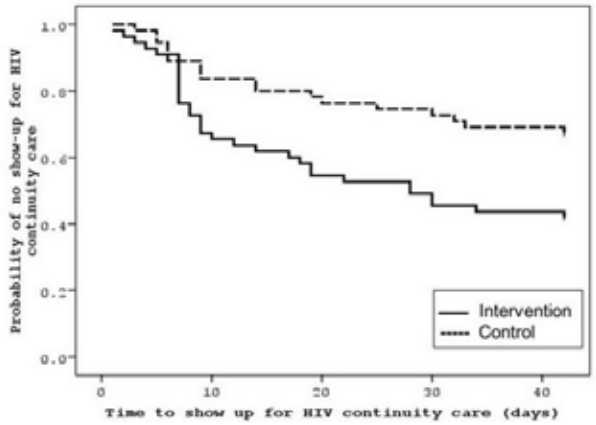
Background: Short-term stay, multiple jail admissions and social and financial difficulties are significant obstacles for continuity care engagement (CCE) after release among HIV-infected jail detainees. The rate of CCE within 6 weeks after jail release has been previously reported to be 25-68%. However, no study has been conducted to evaluate strategies to improve CCE.
Methods: All HIV-infected detainees at Cook County Jail were enrolled during 2011-2014. The detainees were randomly assigned to the intervention group (telephone contact within 2-4 days of release by continuity clinic coordinator), plus standard of care versus the control group, which received only standard of care. Rates of CCE within 6 weeks of jail release were assessed.
Results: There were 166 detainees enrolled, of which 56 were excluded due to being sent to prison (N = 49) or re-incarceration within 6 weeks (N = 7). The final cohort included 55 detainees in each of the groups. Baseline demographic and clinical characteristics of the two groups were similar, except for higher proportion of history of alcohol use in the control group (76% vs. 51%). The rate of CCE within 6 weeks after jail release was significantly higher in the intervention group compared to the control group (58% vs. 33%; P=0.007). By Kaplan-Meier survival analysis, the probability of failure to present for continuity care was significantly higher in the control group ($\chi 2$ = 7.44, P=0.006; Figure). In multivariable logistic regression analysis, being in the control group was the only factor associated with no CCE within 6 weeks (adjusted odds ratio 2.66; 95% confidence interval 1.18-6.00; P=0.02).



[Figure]

Conclusions: A simple contact intervention by telephone to schedule an appointment for HIV continuity care following release from jail, significantly improved CCE among HIV-infected jail detainees.

TUPED1306

Peers counseling at care entry point increase linkage to care among pre-ART HIV-infected patients: a case study

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Background: Mater Misericordiae Hospital is a faith-based institution offering comprehensive integrated HIV services for a decade through PEPFAR funding. As in other countries, linkage and retention in pre-ART care among newly diagnosed HIV infected clients was poor. To address this, the HCT counselor who is PLHIV was mentored in peer counseling, additionally the post-test counseling session for HIV infected clients was modified to include orientation of patients on clinic processes, obtain a commitment to seek care from patients, escorting clients to the next point of service and introducing patients to ART providers same day. Referral follow-up for those referred to other treatment centers was strengthened. This study seeks to evaluate the outcome of this intervention.
Methods: Baseline assessment of the linkage of clients who were identified at the HTC unit of MMH in 2013 was carried out; the intervention started in January 2014. The assessment was repeated end of 2014. All newly identified patients were included in the study. Referred-in clients were excluded from the study. Linkage was assessed using medical records. Complete linkage was defined as having ART number, completed adherence education, baseline laboratory results and WHO staging documented. For clients who were referred to other ART centers, the feedback referral form and the register documentation were the evidence of linkage. Identifiers of patients in HTC registers were traced in all other registers. Additionally, medical charts were reviewed for evidence of services provision.
Results: In 2013, 160 HIV infected clients were identified; 93(58%) were successfully linked to ART care at MMH, 40(25%) stopped during the Pre-ART period, 27(17%) never returned to the facility, totaling 42% lost to care. At the end of 2014, 127clients were identified, 98 agreed to receive ART at MMH, while 29 clients were referred to other centers. All 98(78%) remained in care at MMH and 22(17%) referred clients accessed care at other facilities yielding 95% linkage achievement.
Conclusions: Peer counseling at ART entry points, escort system and orientation of clients on clinic processes increased linkage to care at MMH. Unexpected outcome was improved referral process. Replication of this intervention in diverse settings may prove the strength of this intervention.

TUPED1307

Linkage-to-care among HIV-positive men who have sex with men (MSM) and transgender women (TW) diagnosed via venue-based testing in Lima, Peru

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Background: There is little information available on linkage-to-care processes among MSM and TW in Peru. Existing information is often restricted to individuals who do reach the HIV care facilities, though HIV testing primarily occurs elsewhere. We sought to monitor the linkage process among MSM and TW diagnosed during a venue-based HIV testing study.
Methods: We conducted venue-based HIV testing with 3rd and 4th generation rapid tests at bars, clubs, and sex work walks where MSM/TW congregate. Staff provided pre and posttest counseling and collected contact information. Then the study team maintained contact with the MSM/TW who tested positive to help with linkage-to-care at Peruvian Ministry of Health (MoH) or non-governmental organizations (NGOs) providing HIV care including antiretroviral therapy.
The study also provided funds for initial HIV program visits and testing required for program entry.
Results: Among the 300 MSM/TW tested, 67 (22%) were diagnosed with HIV. Among these 67, only 13 (19%) were able to successfully link to HIV care within 6 months of diagnosis, the number was lower among the HIV positive TW (10% TW vs. 19% MSM were enrolled) though this was not statistically significant. Their time to linkage-to-care was longer at the MoH (median 90 days) vs. NGOs (median 58 days). Another 15/67 (22%) began the linkage process, but remained unlinked 6-months post-diagnosis, most reported a lack of time to attend visits required for linkage or did not feel inclined to begin care yet.

Another 24/67 (36%) did not appear for follow-up HIV linkage visits, although they were contacted repeatedly by study staff. We were unable to contact the remaining group 15/67 (22%) after initial venue-based diagnosis due to non-working contact information.
Conclusions: Although venue-based testing works for case finding, additional interventions are needed to facilitate entry into care. Several individuals did not want to be contacted by the study post-diagnosis because they did not yet feel the need to link-to-care. HIV programs also need to improve understanding of current treatment and work to promote health care seeking. Peer navigator programs should be expanded and HIV care facilities should consider burden-of-care and public health when designing their protocols.

TUPED1308

Enhancing referral to increase linkage to HIV care in rural South Africa: example from the ANRS 12249 TasP trial

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Background: Timely linkage to care following an HIV diagnosis is critical for people living with HIV to initiate antiretroviral treatment as early as possible and thus decrease the risks of HIV-related morbidity, mortality and HIV transmission. Linkage to HIV care is however often challenging and innovative strategies are required to help people accessing HIV care.
We aimed at evaluating the effect of phone calls and home visits following an initial referral on time to linkage to care in the context of a Universal HIV Testing and Treatment (UTT) trial in rural KwaZulu-Natal, South Africa.
Methods: The ANRS 12249 TasP trial was conducted from March 2012 to June 2016 with the aim to evaluate the effect of UTT on HIV incidence. Individuals ≥16 years were offered home-based HIV testing; those identified HIV-positive were referred to nearby TasP trial clinics to receive care and treatment. Starting April 2013, an enhancement strategy combining phone calls and home visits was implemented to re-refer people who did not link to care within three months of first referral. Effect of this strategy on time to linkage to care was studied as a time-varying variable among individuals not in care at first referral using a Cox regression model censored for death, migration and end of study observation.
Results: Among the 7,643 individuals identified HIV-positive at home and referred to TasP clinics, 2,254 (72% female) were not in care at referral and did not link to care within three months of first referral. Among them, 451 (20%) individuals were contacted through phone calls or home visits before migration or death. Probability of linkage to care was significantly higher among individuals re-referred to care compared to those not re-referred (Hazard Ratio 2.25; 95% Confidence Interval 1.83-2.78); significant positive effects were also observed for both genders and all age categories (< 30; 30-39; 40-49; ≥50 years old) after stratification.
Conclusions: Phone calls and home visits aiming at re-referring people to HIV care appear effective in improving linkage to care. Patient-centered strategies should be part of UTT programs in order to achieve the 90-90-90 UNAIDS targets.

TUPED1309

Postpartum transfer of HIV-infected women initiating antiretroviral therapy (ART) during pregnancy in an integrated antenatal care (ANC)/ART service in Cape Town, South Africa: a cohort study

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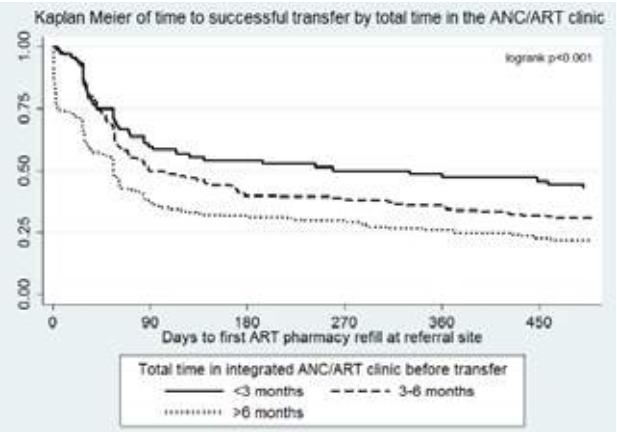
Background: Integrated ANC/ART services are commonplace in high-burden settings and require transfer to general ART care postpartum. Given the challenges in engaging postpartum women on ART, we examined how postpartum transfer of ART services influenced engagement in general ART care.
Methods: Consecutive HIV+ pregnant women initiating ART in an integrated, public-sector ANC/ART service were followed from ART initiation through 20m postpartum in the MCH-ART study. Referral from ANC/ART services occurred 0-13m postpartum, with women referred to their nearest general ART clinic. Data on ART initiation and ANC/ART visits were abstracted from routine records, with time in ANC/ART clinic measured from ART start date to date of postpartum referral to general ART clinics. Electronic ART pharmacy refill (PR) was obtained through 20m postpartum from all ART services in the Western Cape Province. Analyses used product-limit methods and Poisson models to evaluate predictors of successful transfer to ART care (defined as PR ≤3m post-transfer).
Results: Among 486 women included, the median age was 28y and median time in the integrated ANC/ART clinic before transfer was 276d. Overall, 54% of women successfully transferred. Increased time in the integrated ANC/ART clinic was strongly associated with successful transfer (Figure, p< 0.001). After adjusting for age, gestation at ART initiation, relationship status, timing of HIV diagnosis and design effect, each additional month in the integrated ANC/ART clinic increased the likelihood of successful transfer by 7% (RR and 95%CI: 1.07 [1.04-1.10]). Women with >6m in the ANC/ART clinic were 1.52 and 1.28 times more likely to transfer successfully than women in the ANC/ART clinic < 3m and 3-6m (RR and 95%CI: 1.52 [1.07-2.16] and 1.28 [1.04-1.57], respectively).
Conclusions: While successful postpartum transfer appears low, raising concerns about disengagement from care after delivery, these data suggest that increasing total time in integrated ANC/ART services could be an important determinant of successful transfer.



[Kaplan Meier of time to successful transfer by total time in the ANC/ART clinic]

TUPED1310

Early diagnosis and the 2020 goals: the importance of a partnership between civil society orgaizations and the national health system

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Background: According to the latest available data (2014), Portugal shows a proportion of late diagnosis similar to others EU countries, altough this value remains high, regarding the UNAIDS 90-90-90. So, we must evaluate new approaches of early diagnosis and linkage to care, namely those implemented in partnership with civil society organizations (SCO), looking at their potential benefits and replication in other contexts. The aim of the study is to compare, regarding the stage of infection, the MSM population with a new HIV diagnosis (a population growing up in Portugal) admitted in our hospital through an SCO referral (2014-16) with the total of new diagnosed cases in MSM and all the new diagnosed cases, in Portugal.
Methods: We study the MSM population admitted in our center (CHLN-HPV) by CheckpointLX referral (MSM LX) with a new HIV diagnosis between 2014 and 2016 (n=112). We analyze some demographics and HIV infection stage of disease (CD4 cell count, late diagnosis/advanced disease). We compare this results with the national data obtained in: a) new HIV MSM diagnosed cases; b) all new diagnosed cases. The statystical analysis was done using the $\chi 2$ and t-test.
Results: The results are sumarized in Table 1

	MSM LX 2014-2016	MSM PT 2014		Global PT 2014	
	n (%)	n (%)	*p**	n (%)	*p**
Age (mean)	30.4	34.0	***0.0011***	40.5	***<0.0001***
Migrant	31/112 (27.7)	67/389 (17.2)	***0.0033***	161/1101 (14.6)	***<0.0001***
CD4 (mean)	501.7 cells/mm3	427 cells/mm3	***0.0088***	378 cells/mm3	***<0.0001***
CD4 <350cells/mm3	29/110 (26.4)	119/299 (39.8)	***0.0040***	455/926 (49.1)	***<0.0001***
CD4 <200cells/mm3	11/110 (10.0)	61/299 (20.4)	***0.0068***	292/926 (31.5)	***<0.0001***

[Table 1]

* in relation to MSM LX
CD4 (MSM LX): n=110 (2 missed cases).
Conclusions:
1) The HIV positive MSM admitted through ChepointLX referral were significantly younger, had a higher proportion of migrants and less late diagnosis and advanced disease.
2) These data suggest that, at least in the MSM population, this methodology must be followed in other regions and/or other SCO in Portugal.
3) This methodology can contribute to reach the 2020 UNAIDS goals.

TUPED1311

Engagement in economic strengthening activities and retention in care among food insecure people living with HIV (PLHIV) in Ethiopia

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Background: Retention in care, a critical factor for optimal clinical outcomes, is a particular challenge among food-insecure PLHIV in Ethiopia. It is hypothesized that Economic strengthening (ES) intervention designed to address poverty and food insecurity may also have an impact on retention in care positively. This study aims to assess the impact of ES interventions in Ethiopia on retention in care among PLHIV on ART or pre-ART.
Methods: Comparative Cross-sectional design was employed to compare food insecure PLHIV benefitting from the ES project of WFP Ethiopia to food insecure PLHIV not participating in ES. In this study, one is considered as non-retained if he/she misses at least one pre-ART or routine ART appointment in the last 12 months period. Logistic Regression model was employed to estimate the likelihood of missing a health facility appointment. Qualitative data were also collected to complement the quantitative data.
Results: After adjusting for important background characteristics including sex, place of residence, formal education attendance, marital status, numbers of daily ART pills, age and household size, non-participation in ES increases the odds of missing a clinic visit by a factor of 6.74, significant at 0.001 levels. The ES participants explained that the series of trainings, discussions at the saving and loaning association meetings, peer support mechanism and the boost in economic capacity created by the ES intervention have helped them rebuild their confidence, self-esteem, and self-worth which all are quoted as contributors for their consistent retention in care. On the contrary, for the comparison group, forgetfulness, internal stigma and lack of interest (depression) are cited as major constraints that discourage attendance to their appointments. This is reflected in the large difference in mental health scores noted between the ES and the comparison group in favor of the former (67.8 vs. 50.8).
Conclusions: The study suggest that participation in ES contributes to improve retention in care among food insecure PLHIV which may be explained by the effects of the intervention in improving mental health aspects of quality of life and economic well-being. Thus, ES can be taken as a strategy to improve retention in care among PLHIV in resource-limited settings.

TUPED1312

Evaluation of electronic medical records to track patients across health facilities in Malawi: case of women participating in Option B+ program at Bwaila District Hospital

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Background: The introduction of Option B+ program in Malawi has resulted in a large number of women starting antiretroviral therapy (ART). However, it is not easy to accurately trace all lost to follow up (LTFU) and transferred out patients using conventional methods only. Currently, Malawi uses an Electronic Medical Record System (EMRS) developed and maintained by Baobab Health Trust at over 86 health facilities, including all large volume ART clinics. Approximately 40-45% of all ART patients receive care at facilities with EMRS. We evaluated the feasibility of EMRS as a tool for tracing LTFU and transferred out women participating in option B+ across health facilities in Malawi.
Methods: We conducted a retrospective cohort study of HIV-infected pregnant women who enrolled in Option B+ and were LTFU at Bwaila Hospital or were transferred out to EMRS facilities within central Malawi between January 2015 and June 2016. We assessed for matches across all 20 facilities with EMRS in central Malawi. Many-to-one probabilistic record linkage algorithm was employed to assess records for matches using last name, first name and date of birth.
Results: Of 385 women recorded as LTFU, 127(33.0%) records were found at other health facilities other than Bwaila, while 12(48.0 %) of the 25 women documented to have transferred out were found at other facilities within central Malawi. However, none were found at the facilities documented on the transfer. Median time between last visit and registration at the new health facility was 110 days (IQR=72-250) for LTFU and 199.5 days (IQR =179-270) for those transferred out. Sensitivity and specificity for both groups was 60.6% (95%CI: 51.6-69.8) and 88.0% (95%CI: 83.4-91.7) respectively.
Conclusions: Linkage across EMR modules and facilities can identify women who are LTFU, detect those at risk for lost to follow-up and confirm patient transfers. Continued expansion of electronic medical records may improve the ability to track patient outcomes.

TUPED1313

High linkage to ART and HIV RNA suppression among HIV-positive MSM and TG, along with high PrEP uptake among HIV-negative MSM and TG, through community-led health service model in Thailand

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Background: More than half of new HIV infections annually occur among men who have sex with men (MSM) and transgender women (TG) in Thailand. To more effectively and efficiently prevent and treat HIV in these populations, a community-led health service (CLHS) model was established in Bangkok, Chiang Mai, Pattaya and Songkhla to train and mentor peers to provide HIV clinical services as community health workers (CHW) at non-government organizations.
Methods: Thai MSM and TG aged ≥18 years were recruited through six community-based organizations from May 2015 - September 2016. Trained CHWs provided same-day result HIV testing and sexually transmitted infection (STI) screening at baseline. HIV-positive clients had point-of-care CD4 measurements, immediate offers of antiretroviral therapy (ART) and HIV RNA assessments at six-months. Pre-exposure prophylaxis (PrEP) was offered to a subset of HIV-negative clients. We evaluated risk characteristics, HIV diagnosis yield, ART uptake and virologic suppression rates among HIV-positive clients, PrEP uptake, and HIV incidence.
Results: Of 2,497 participants enrolled, HIV prevalence was 18.15% in MSM (n=1,763) and 8.99% in TG (n=734) and incidence was 5.86 (3.90-8.82) per 100 person-years among MSM and 2.48 (0.93-6.61) per 100 person-years among TG. Among 386 HIV-positive participants, median (IQR) CD4 count was 370 (267-504) cells/mm^3 at baseline and 82% initiated immediate ART with a median (IQR) time to ART initiation of 15 (8-22) days. HIV-positive participants were more likely to have: never had HIV testing (66% vs. 45%, p< 0.001), have STIs at baseline (58% vs. 29%, p< 0.001); reported unprotected sex (84% vs. 76%, p=0.002); receptive anal sex (83% vs. 71%, p< 0.001); use of amphetamine-type stimulants (9% vs. 6%, p=0.03) in the past 6 months; and, never heard of PrEP (32% vs. 23%, p< 0.001). Among 70% retained on ART at six months, 93% had HIV RNA <1,000 copies/mL. Of 409 HIV-negative participants offered PrEP, uptake was 40.1%.
Conclusions: The CLHS model is highly feasible and effective, enabling previously unreached high-risk populations to access HIV testing and treatment services early as demonstrated by high HIV yield, rapid linkage to ART, high retention rate, high virologic suppression rates, and high PrEP uptake in this cohort.

TUPED1314

Utility of SMS-based reporting for supply chain management and fast tracking PMTCT intervention: a pilot study in West Bengal

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Background: Under National AIDS Control Program, commodities like testing kits and drugs are procured centrally and supplied to the States for further distribution to the facilities. Monitoring of drugs and testing kits placed at the facility and timely replenishment of stock to the facility is a real challenge to the State AIDS Control Society (SACS). Excel sheet was used to report the stock from the field level status on a weekly basis. In addition, for facilitating linkage of all HIV positive pregnant women to treatment and continuum of care services, real-time information of positive pregnant women detection was utmost required centrally, which could help to minimize linkage loss.
Methods: A mobile sms-based reporting system on stock management and linkage mechanism was developed by SACS in collaboration with State Information Technology cell. Mobile number of identified focal person at each facility was linked to the system and she/he need to send weekly stock report of seven main consumables in single sms syntax to a specified number at the end of every week. Similarly the details of HIV positive pregnant women are sent in specified syntax from mobile number of the focal person of the facility. Web based monitoring of stock and linkage to care services could be conducted by SACS.
Results: The number of facilities reporting stock out of commodities decreased from 10% to 2% and linkage of HIV positive pregnant women to treatment and care services increased from 80% to 95% , after the implementation of the weekly SMS reporting system.
Conclusions: This system being an offline reporting, is easy to implement in rural part of the State. Inbuilt central feedback mechanism ensures that the focal person at the facility upload correct data and in time. This system could be easily replicated across the country and is cost effective.

TUPED1315

Outcomes and predictors of linkage to care among newly diagnosed human immunodeficiency virus (HIV) infected patients in Central Kenya

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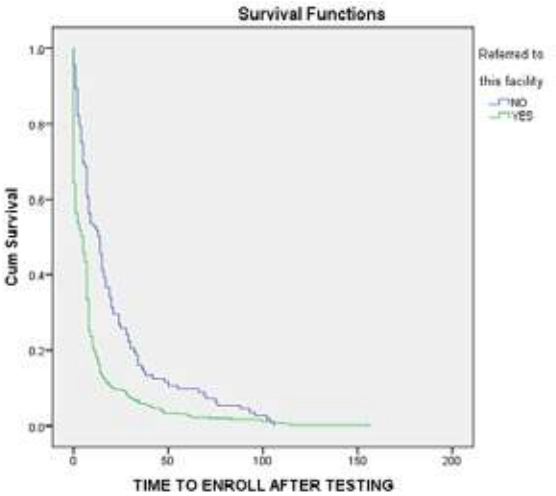
Background: There is substantial loss of HIV infected clients after diagnosis and before enrolment into HIV care in Kenya. The extent of the loss after HIV diagnosis and the reasons for the loss are not well documented in Kenya. This information will help programs to know the extent of the problem and areas to intervene. The aim was to determine the proportion who get linked to HIV care and the predictors of linkage to care among newly diagnosed HIV infected clients in Central Kenya.
Methods: This was a retrospective cohort with a sample of 634 newly diagnosed HIV patients from October 2015 to March 2016. The subjects were selected from Thika, Murang'a, Karatina and Nyahururu Hospitals. Each client was followed for up to three months to determine the outcome of the referral.
A data abstraction tool was used. Proportions were computed for patient characteristics and outcomes. Logistic regression was used to determine predictors of linkage. Kaplan Meier graph was done to show difference in time to enroll.
Results: Of 634 patients, 62.6% were females, 98.9% were referred to HIV care, 96.7% were documented in linkage register, 77% were linked to care, 53.8% were assessed for ART eligibility, 38.8% were eligible and 34.1% were started on ART. Patients diagnosed at inpatient had a 3.5 fold (p<0.05) higher odds of failure to be linked compared to those diagnosed at outpatient. Those diagnosed at HIV clinic were 2 times more likely to link (p<0.05) than those diagnosed at outpatient. Referral to a different facility (OR 2.3, p<0.05), non-documentation on linkage register (OR 2.3, p<0.05) and missing phone number information (OR 3.9, p<0.05) were associated with failed linkage.



[Figure 1. Time to enroll after HIV testing (p<0.05)]

Conclusions: The findings show certain predictors that can be addressed at program level to improve linkage to HIV care.

TUPED1316

Linkage of HIV-positive clients to antiretroviral care and treatment: an assessment of a finance-based linkage system in Nigeria

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Background: Community-based HIV Testing and Counselling (conducted outside of a health facility) has the potential to identify asymptomatic HIV-positive individuals at high CD4 counts. However, linkage to care remains a challenge for those identified at these settings. We assessed the effect of a finance based linkage-to-care intervention in Nigeria.
Methods: A reimbursable coupon mechanism was implemented in Benue, Nasarrawa and the Federal Capital Territory, Abuja, Nigeria in 2016. HIV positive clients identified at outreaches were issued coupons and referred to ART clinics. Data from those who were enrolled into care were abstracted from facility record. Data from a period prior to commencement of the coupon system (pre-coupon phase) were collated for comparison. Descriptive statistics and Chi square tests of comparison for differences between categorical variables were conducted. Logistic regression was used to assess the effect of the coupon system on linkage and enrollment into HIV care and treatment.
Results: A total of 120 and 806 HIV positive clients were referred in the pre-coupon (October-December 2015) and coupon phase (January-March 2016) respectively. Majority of the clients were women (64%). Median age for females was 30 years (interquartile range {IQR}:26 - 35) and 37 years for men (IQR:31 - 40). Overall 87% of the clients received a coupon. Median time to linkage to care was 0 days (IQR: 0-7 days). Enrollment was higher in coupon phase compared to pre-coupon phase (90% vs. 17%; p<0.0001). Enrollment was similar for women (82%) and men (79%;p=0.297). Seventy-one percent compared to only 1% (p<0.0001) of clients provided invalid/wrong phone numbers in the pre-coupon and coupon phase respectively. When controlled for sex and if a client received coupon, logistic regression showed that those who received coupon were 38 times more likely to be linked and enrolled into care [OR: 38.2; 95% CI:22.7 - 64.2, p<0.0001).
Conclusions: The coupon system resulted in 90% of clients being linked and enrolled into care. The coupon has addressed a key barrier to linkage and its strong association to linkage is a promising strategy that must be scaled up. Reaching the UNAIDS 90:90:90 goal is achievable if evidence based and innovative strategies are implemented.

TUPED1317

Strategies for linking adolescents living with HIV (ALHIV) to HIV services: experience from Benue state, Nigeria

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Background: Much progress have been made in the HIV response, however ALHIV are left behind globally. While HIV related mortality has reduced by 25% in the general population, it has increased by 50% in adolescents. An HIV free generation is possible only when adolescents left behind are identified and placed on treatment especially in Nigeria where 10% of ALHIV reside.
Methods: A pilot project was conducted to evaluate approaches to the delivery of comprehensive HIV services for Adolescents and Young People (AYP) in Gboko and Makurdi Local Government Areas (LGA) in Benue state, Nigeria. The pilot had 3 components: intensive demand creation, facility and outreach based HIV testing and counselling (HTC), and referral of HIV positive clients to HIV treatment services. Two approaches were applied to test the most effective strategy for ensuring AYP testing positive were successfully referred to HIV treatment services. Under the same conditions, AYP testing positive during outreaches in Makurdi LGA were referred to HIV services by the use of peer escorts only; while those in Gboko LGA were referred using both peer escorts and SMS message reminders. Effectiveness was measured in terms of the number of HIV positive adolescents and young people who were successfully referred to HIV treatment services.
Results: Overall 401 (97.6%) AYP were successfully linked to HIV services. The use of peer escorts resulted in 208 (98.6%) AYP being successfully linked to HIV services in Markudi, while the use of peer escorts together with text message reminders resulted in the successful referral of 193 (96.5%) AYP in Gboko. (Table: 1). The addition of text messages did not result in a statistically significant rate of successful referral (P>0.05).

Access to follow-up services after HIV test and referral	Peer escort support only (Makurdi LGA)	Peer escort & text message (Gboko LGA)	Total
Yes	208 (98.6%)	193 (96.5%)* *p>0.05	401 (97.6%)
No	3 (1.4%)	7 (3.5%)	10 (2.4%)
Total	211	200	411

[Distribution of AYP Acessing Services]

Conclusions: This pilot highlights that interpersonal communication is an effective means of referral for adolescents and is not significantly augmented by the use of text messages.

TUPED1318

A comparative analysis of barriers and facilitators to HIV service utilization among three key populations in Zambia

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Background: Female sex workers (FSWs), men who have sex with men (MSM), and people who use drugs (PWUD) are key populations (KPs) at high risk of HIV acquisition and transmission. In Zambia, their behaviors are illegal and little information exists about their HIV prevention, care and treatment needs. We compared barriers and facilitators to HIV service utilization among these populations.
Methods: Focus group discussions (FGDs) and in-depth interviews (IDIs) were conducted from July 2013 to September 2015 in nine districts in Zambia. 196 FSWs participated in 65 IDIs and 18 FGDs; 102 MSM in 38 IDIs and 10 FGDs; and 72 PWUD in 28 IDIs and 7 FGDs. Interview guides gathered information on knowledge, attitudes and experiences surrounding existing HIV/STIs service utilization. Thematic content and constant comparative analysis was used.
Results: Four domains emerged as facilitators and barriers to HIV service utilization differing by KP and health facility type- private, public, NGO, and traditional healers.
Interpersonal factors -
(a) need to protect privacy served as a barrier for all KPs;
(b) need to protect themselves and others from HIV was a facilitator among FSWs and MSM; and
(c) fear of HIV test results was a barrier among FSWs and PWUD.
Confidentiality and privacy -
(a) all KPs agreed it was lacking in public but present in private facilities; and
(b) fear of legal prosecution, believing public facilities reveal their behaviors to police, was a barrier for MSM and PWUD.
Patient-centered care -
(a) fear of and experienced stigma and discrimination and
(b) unwelcoming environments were barriers for all KPs in public facilities but not at other facility types.
Accessibility -
(a) available and free services at public facilities facilitated FSWs and PWUD access; high cost at private facilities hindered access by FSWs and MSM;
(b) long waiting times for FSW and PWUD and
(c) lack of support organizations for PWUD served as barriers.
Conclusions: There is need to improve HIV services, especially in public health facilities, for KPs. Furthermore, services must take into account the unique circumstances of each KP in order to adequately meet their HIV prevention, care and treatment needs.

TUPED1319

Reasons for switching from first-line to second-line ART regimen among patients recorded in the APMR database in Swaziland

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Background: In Swaziland, successful scale-up of antiretroviral therapy to near-universal access has led to a need to strengthen patient monitoring to achieve treatment outcomes. Management Sciences for Health (MSH) has supported the ministry of health (MOH) over the past eight years to improve HIV data management and use. This support included the development, implementation, and support of an electronic medical record database, the ART patient management system (APMR) at all HIV treatment sites. In an effort to demonstrate and build capacity of MOH on how routine data stored in the APMR can be used to inform HIV programming decisions, the systems for improved access to pharmaceuticals and services (SIAPS) project worked with MOH to conduct a study to identify reasons for switching from first to second line ART regimen. Knowing the reasons for switching to second line is critical for the ART programme to put in place interventions to prevent unnecessary switches while ensuring timely switching for those who are eligible.
Methods: This was a retrospective-descriptive study aimed at documenting the reasons for switching from first line to second line ART regimen as recorded in the APMR. Data used for analysis of this study was extracted from the national APMR database. Data was analysed using SPSS version 2.0; STATA-12, and presented as descriptive statistics.
Results: A total of 4266 ART patients identified as having switched from first to second line regimen between years 2010 to 2015 were studied. A large proportion of these patients were among the age range 25-44 years (32.6%). 67% of patients who switched had no recorded reasons for regimen switching. 15.3% (N=4266) registered treatment failure as the main reason for regimen switching. Toxicity was recorded in 8% of patients records, clinical reasons (2, 7%), and ‚other' reason were recorded in 5.5% of the patients records.
Conclusions: The findings of this study further support the need for routine viral load monitoring as part of HIV treatment standard of care.There is also a need to strengthen data collection into the APMR system to correctly inform analysis into the reasons for regimen switching.

TUPED1320

An evaluation of the Elizabeth Glaser Pediatric AIDS Foundation supported quality improvement program in Zimbabwe, 2016

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Background: In 2013, the Zimbabwe Ministry of Health and Child Care developed the national HIV Quality Improvement (QI) Program in partnership with Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and HEATLHQUAL International. The program seeks to improve uptake of HIV prevention, care and treatment services in 14 priority areas covering children, pregnant women and general OI/ART clients. From June 2015, EGPAF supported 310 health facilities in 63 districts to implement the HIV QI program. We evaluated the EGPAF supported QI program.
Methods: A one-group pre-test post-test quasi-experimental retrospective review was conducted on 310 health facility records to determine changes in service uptake during QI implementation. The mean differences between indicator performance at baseline (July to December 2015) and during the QI implementation period (January to June 2016) for 13 of the 14 service delivery areas for all the facilities were tested for significance through paired t-testing at a=5%. Data were analyzed using Stata 13. In each facility, the six-month implementation period comprised performance measurement, structured QI coaching by EGPAF staff, planning activities to improve service weaknesses discovered during data review and testing changes to improve uptake.
Results: Overall uptake in 9 out of the 13 reviewed service delivery areas had significantly improved following the QI intervention, p < 0.05. (Table1). These comprised 5 out of 7 adult OI/ART indicators and half of the pediatric HIV treatment and care indicators. These improvements were observed across the entire cascade.
Conclusions: Our findings show that tailored QI interventions can lead to significant improvements in HIV service delivery in a high-prevalence setting such as Zimbabwe. QI should be considered as an effective strategy to increase service uptake and adherence to standard guidelines on HIV management.

QI Indicator	Baseline	Endline	p-value
% HIV- pregnant women retested in 3rd trimester	36.1%	65.2%	<0.001
% HEI with DBS collected age <2 mos	71.2%	77.5%	0.0054
% HEI with DBS <2 mos & result c/in 1 mo	15.6%	26.9%	<0.001
% HIV+ pregnant women start same-day ART	60.4%	69.9%	0.0055
% retained on ART in the past 6 mos	87.2%	90.9%	0.0077
% children start ART <2yrs & retain at 6 mos	3.4%	44.3%	<0.001
% ART clients with adherence assess last visit	78.3%	89.2%	<0.001
% ART clients with routine CD4 monitoring	12.4%	15.8%	0.0084
% HEI initiated on cotrimoxazole prophylaxis	65.8%	74.2%	<0.001

[Table 1: Comparison of service uptak]

TUPED1321

The standardized pediatric expedited encounters for ART drugs initiative: description and evaluation of an innovative pediatric ART health service delivery model in Tanzania

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Background: As countries scale up antiretroviral therapy (ART) for children, innovative strategies to deliver quality services to children are needed. Differentiated ART delivery models have been successful in adults, but no such program has been described in children. We describe the Standardized Pediatric Expedited Encounters for ART Drugs Initiative (SPEEDI).
Methods: We conducted a retrospective cohort analysis for children and adolescents on ART at the Baylor Centre of Excellence (COE) in Mbeya, Tanzania between January 2013 and December 2015 comparing patients with at least one SPEEDI visit to those pre-SPEEDI implementation. Stable children and adolescents on ART for approximately 3 months or longer, no medical or social complications, good adherence to ART, and having a reliable caregiver were eligible for SPEEDI and seen every two-months alternating SPEEDI visits with standard visits. During a SPEEDI visit, patients were fast tracked in triage to collect medications directly. Baseline characteristics and outcomes of the two groups were compared and Kaplan-Meier survival curves and the hazard ratio were calculated in the survival analysis.
Results: 1164 patients utilized SPEEDI, totaling 3493 SPEEDI visits. SPEEDI reached 51.3% (1164/2269) of pediatric ART patients, accounting for 7.7% (3493/44489) of total patient encounters. SPEEDI patients were 52% (605/1164) female, median age of 11.7 years (range 1.2-25.5yr), median time on ART of 21 months (range 4-130 months) and 83.5% (964/1155) categorized as no or mild HIV-associated immunodeficiency. SPEEDI patients had significantly higher percentage of good outcomes (98.8% vs. 94.5%, p<0.001), lower LTFU (0.1% vs. 2.1% p<000.1) and lower mortality rates (0.61 deaths vs. 2.59 deaths per 100 patient-years) compared to pre-SPEEDI patients. There was a statistically significant difference in the survival curves favoring SPEEDI patients (Hazard ratio log rank statistic =1.786, 95% CI 1.271-2.508, p<0.001).
Conclusions: SPEEDI was an effective model for delivering ART to children and adolescents in our setting, leading to good clinical outcomes. The SPEEDI program safely and effectively expedited and spaced out ART visits for children and adolescents, and can serve as an adaptable ART delivery model for other resource limited settings.

TUPED1322

"If I'm not in the club, I have to move from one chair to another." A qualitative evaluation of patient experiences of adherence clubs in Khayelitsha and Gugulethu, South Africa

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Background: Quantitative outcomes of adherence clubs (ACs), an ART delivery model differentiating care for stable adults, have been well described for pilot and scaled implementation in South Africa. ACs are comprised of 15-30 stable ART patients, meet five times per year at their clinic/community location and are facilitated by a lay health-care worker who distributes pre-packed ART. To date, there has been no qualitative evaluation of the ACs. We explored the experiences of AC members and non-members.
Methods: Eleven focus group discussions with 85 participants and 43 in-depth interviews were conducted in Khayelitsha and Gugulethu, Cape Town, South Africa. FGD participants were current AC members and interview participants were stable patients who had never joined an AC and AC members referred back to clinician-led facility-based ‚routine' care due to missed appointments or viral rebound. Both were conducted in isiXhosa, translated and transcribed into English, entered into NVivo, coded and thematically analysed.
Results: ACs saved patients time and money and created peer-support networks. Perceived benefits included fewer clinic visits, longer drug refills and allowing refill collection up to 5 days late or by a ‚buddy'. Perceived disadvantages included reduced regular access to a clinician. Patients talked about membership as an achievement and considered being returned to routine care a ‚failure'. AC removal for missed appointments or viral rebound were acceptable rules to those in ACs, but perceived as unfair by those referred-out. Patients viewed little value in increased clinical support provided after losing AC benefits. Moving between ACs and routine care created frustration and broke down trust in the health-care system and relationships with health-care providers, especially when referral criteria weren't fully understood. Stable patients not in ACs had heard of clubs, but did not feel sufficiently empowered to request enrolment if not directly offered by their clinician, or if offered, did not fully understand the enrolment process.
Conclusions: The AC model was considered acceptable by patients, with specific appreciation for refill collection flexibilities. Improved patient understanding of enrolment processes, eligibility and referral criteria and the role of clinical oversight is essential for building relationships with health-care workers and trust in the overall health-care system.

TUPED1323

The role of community drug distribution point of care model on retention of HIV-positive individuals from a pastoral community in Kigaju, Kalungu district

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Background: Retention in care of HIV-positive individuals residing in pastoral communities is essential for successful HIV management. Mildmay Uganda (MUg) developed a partnership with Bukulala HC IV, Kalungu district to establish a community drug distribution point to facilitate persons living with HIV from a pastoral community at Kagaju to access HIV care and treatment. The purpose of this paper is to highlight lessons learnt from implementation of this care model.
Methods: Mildmay working with Bukulula HC IV, a community drug distribution point of care model was established at Kigaju pastoral village in October of 2011. The health workers at the health facility identified clients residing in a pastoral community. Training sessions on adherence to ART, retention in care, and aim of this care model were given to all clients. The clinical team packs ARV drugs and distributes them to clients on scheduled appointment dates every month. Clinical evaluations would be done by clinicians at Bukulala HC IV every after every 3 months and ART response monitoring using viral load was done every after 6 months.
Results: A total of 139 adult clients on ART were enrolled on this care model. Majority (63%) were female. Majority (81%) consistently kept their clinic appointments and were retained in care. 91% (102/112) reported good adherence on ART. 82 clients were had their viral load test done, and 98% (80/82) were virally suppressed (viral load < 1,000 copies/mL as per national guidelines). There were no new WHO clinical stage 3 or 4 events reported among these clients during the follow-up period.
Conclusions: Community drug distribution point of care model was successfully integrated into HIV program serving a pastoral community. The retention in care of 81% and viral suppression of 98% are encouraging.

TUPED1324

Community-based ART Initiation, delivery and monitoring in rural Southwest Uganda: participant experiences of a differentiated model of HIV care delivery

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Background: In settings of high HIV prevalence and resource scarcity, differentiated models of HIV care refocus clinical resources on symptomatic patients, while providing stable clients with less intensive community-based services. By adapting services for particular patient groups, this client-centered approach can reduce burdens on health care systems. Individuals' experiences of differentiated care will inform how future services are utilized. Using qualitative data from a randomized trial of community-based ART initiation, delivery and monitoring, we describe participant experiences of a differentiated model of ART delivery.
Methods: The Delivery Optimization for Antiretroviral Therapy (DO ART) study is evaluating community-based ART initiation and follow-up compared to clinic-based care in rural southwest Uganda and Kwa-Zulu Natal, South Africa. Fifty DO ART study participants from the Uganda site were purposefully sampled for qualitative research. Sampling aimed to represent a range of experiences across three study arms at different stages of HIV follow-up care. Data collection included in-depth interviews eliciting participants' experiences of initiating ART and receiving follow up. Trained research assistants conducted interviews and transcribed the audio-recordings into English. For this analysis, transcripts were inductively content-analyzed to characterize interviewees' experiences of this differentiated model of care. Results are represented as descriptive categories.
Results: Overall, qualitative interview data reveal a favorable response to community-based care experiences. Compared to clinic-based care, perceived advantages of home ART initiation and community-based follow-up include:
(1) convenience: ART delivery in communities saves time and money otherwise spent on travel to clinics;
(2) personalized services: one-on-one interactions with health workers in communities allow time to address individual questions and concerns;
(3) increased privacy: receiving services at home or in communities (e.g. mobile vans) eliminates the possibility of being recognized at clinics, decreasing disclosure risk; and
(4) responsiveness: focused attention and flexible approaches to care outside clinic settings communicate caring, strengthening patients' commitment to treatment.
Conclusions: These data suggest community-based ART initiation and follow-up is an acceptable and effective approach to HIV service delivery in rural Uganda. Differentiated models of care are a promising strategy for eliminating longstanding access barriers and improving HIV service quality from the perspectives of HIV-infected persons living in rural sub-Saharan Africa.

TUPED1325

Retention and viral suppression outcomes of patients enrolled in family ART adherence clubs in Cape Town, South Africa

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Background: Design and implementation of differentiated antiretroviral therapy (ART) delivery models are important for children as well as adults. Since 2011, HIV positive children (stable on ART) and their caregivers (stable or not on ART) were offered the option to enroll in family ART adherence clubs (FCs) - a healthcare worker managed group model of ART delivery for families with five visits per year.

Patients that require more frequent adherence or clinical follow-up are referred back to clinician-led individual care. We describe retention and viral suppression outcomes of patients enrolled in FCs.
Methods: We conducted a retrospective cohort analysis of children and caregivers on ART enrolled in FCs between March 2011 and December 2014. We linked patients to service access data to validate retention and virologic outcomes and using Kaplan-Meier methods estimated the outcomes: retention, loss to follow up (LTFU), transfers (TFO), mortality and viral load completion and suppression (≤400 copies/mL).
Results: 163 children and 84 caregivers on ART were included in this analysis, contributing 733 person-years of follow up (88% in FC, median 3.7 years). At enrolment, 45% of children were female, median age 8.7 (Interquartile range (IQR), 6.3-11.1) years; and 95% of caregivers were female, median age 37.7 (IQR, 33.5-41.8) years. Cumulatively retention remained high from 12 to 36 months among both children (94-86%) and caregivers (94-90%) (Table 1).

Duration of follow up	n (%)	Loss to follow up % (95% CI)	Transfers % (95% CI)	Retention % (95% CI)
Children	163			
12 months	148	2.5 (0.9 - 6.5)	3.8 (1.7 - 8.3)	93.7 (88.7 - 96.6)
24 months	139	4.5 (2.2 - 9.3)	3.8 (1.7 - 8.3)	91.8 (86.3 - 95.2)
36 months	112	9.0 (5.3 - 15.1)	5.3 (2.7 - 10.3)	86.1 (79.5 - 90.8)
Caregivers	84			
12 months	74	5.0 (1.9 - 12.7)	1.2 (0.2 - 8.2)	93.9 (85.9 - 97.4)
24 months	59	7.6 (3.5 - 16.2)	1.2 (0.2 - 8.2)	91.3 (82.6 - 95.8)
36 months	45	7.6 (3.5 - 16.2)	2.9 (0.7 - 11.3)	89.7 (80.4 - 94.8)

[Table 1: Kaplan-Meir estimates of outcomes]

After 36 months, 86% (95% confidence interval (CI), 78-92) of children and 95% (95% CI, 83-99) of caregivers were virally suppressed, with viral load completion in 98% and 89% of patients respectively.
Conclusions: The FC model ensured simplified, family-centered HIV care and ART refill access for children and their caregivers, supporting high rates of retention and viral suppression. These findings provide evidence that differentiated ART delivery models can safely be provided to stable children and family-centered management is feasible within such group models.

TUPED1326

Breastfeeding practices and infant care engagement among HIV-infected postpartum women on antiretroviral therapy (ART) attending community-based adherence clubs (ACs) in Cape Town, South Africa

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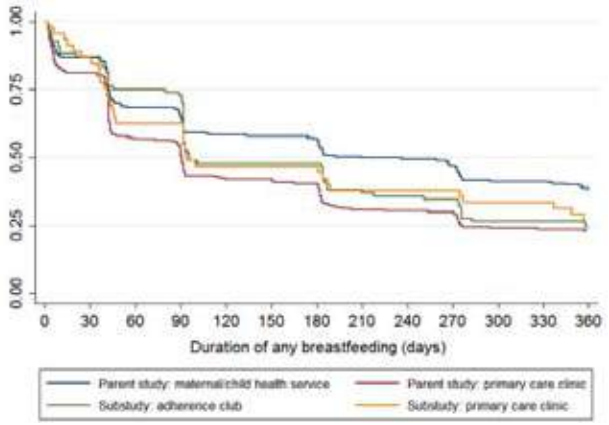
Background: There is an urgent need for effective models to deliver postpartum care to women initiating ART in pregnancy and their infants. ACs have been proposed as one model of differentiated care but the ability of ACs to support newly postpartum women and maximize maternal and child health (MCH) is unclear.
Methods: As a substudy to the MCH-ART trial, we enrolled newly postpartum, breastfeeding women who initiated ART in pregnancy, and asked participants to choose between: (i) ACs or (ii) primary care clinics (PHCs) for postpartum ART care. Women were followed through 12m postpartum with breastfeeding reported at study visits separate from either ART service; evidence of PCR for early infant diagnosis (EID) and immunizations were abstracted from routinely-collected records. In analyses, outcomes were compared to that of a comparator cohort of women randomized in the parent study to either (i) an MCH-focused ART service or (ii) PHCs for postpartum care.
Results: From February-September 2015, 129 postpartum women were enrolled (mean age, 28y), with 65% choosing ACs and 35% choosing PHCs. Median duration of any breastfeeding was 3.2m in ACs and 3.1m in PHCs (p=0.861); the median duration of exclusive breastfeeding was 3.0m and 2.2m (p=0.568), respectively. Breastfeeding duration was similar across women attending ACs and those attending PHCs, but was significantly longer in women attending the MCH-focused service (Figure). Of women attending ACs, 96% had evidence of infant PCR testing < 12w postpartum, versus 93% of those attending PHCs. The proportion of infants with evidence of immunizations received through 10w postpartum was >90% in both services. Compared to comparator cohort, no differences were observed in EID or immunizations across any of the four ART services compared.
Conclusions: Effective strategies for delivering ART and related services during the postpartum period must account for MCH-specific service needs to ensure the health of women and their infants.



[Figure. Time to cessation of any breastfeeding, by postpartum ART service.]

TUPED1327

Service delivery costs for HIV treatment under differentiated models of care for stable patients in Malawi

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Background: Despite gains in improving the efficiency and coverage of antiretroviral therapy (ART), Malawi is expected to face an ART funding gap in coming years. Models of differentiated care may further improve efficiency by streamlining services for stable patients. An analysis was conducted to understand the costs associated with three models of differentiated care in Malawi: multi-month scripting (MMS), fast-track refills (FTRs), and community ART groups (CAGs). The models were compared against a hypothetical model of monthly clinic visits, which is used in many other national ART programs.
Methods: Data were collected in 30 purposefully selected sites that represented a range of facility types and sizes. All sites implemented MMS, while four sites also offered FTRs and eight sites offered CAGs. Patient visit frequency was measured through facility questionnaires and 1,473 observations of visit time and clinic flow. Cost modeling was performed in Excel to identify average unit costs of each model and the expected resources required for scale up.
Results: Annual per patient costs of MMS, FTRs and CAGs are similar and represent an estimated 10% reduction compared with a monthly clinical visit policy. These reductions are largely driven by decreased visit frequency and the delegation of some service delivery tasks to lower level cadres. Monthly clinic visits for all stable patients in Malawi would cost $63.8 million per year. However, $5.8 million per year has been saved with current implementation of differentiated care models. Expanding participation in the MMS model or coverage of the FTR model would lead to $745,000 and $67,000 in additional savings, respectively. Expansion of CAGs is not projected to lead to savings given some limited additional supervision costs required for implementation.
Conclusions: Malawi has already generated efficiencies in ART service delivery by introducing MMS for stable patients. Limited additional savings could be realized by improving MMS coverage and, to a lesser extent, by rolling out the FTR model nationwide. Since the variation in service delivery costs are largely driven by human resource costs, savings would likely be greater in countries where salary levels are higher and represent a greater proportion of overall ART costs.

TUPED1328

Patient and health worker perspectives on implementation of models of differentiated care for stable HIV patients in Malawi

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Background: In Malawi, various models of differentiated care have been launched for stable HIV patients on antiretroviral therapy (ART), including: multi-month scripting (MMS), fast-track drug refills (FTRs), and community ART groups (CAGs). These models introduce adjustments to service delivery standards to ensure that care is efficient and patient-centered. We aimed to understand the patient and health worker perspectives on the challenges and successes of implementing these models of care.
Methods: Qualitative data was collected in 30 purposefully selected ART facilities. All 30 sites offered MMS, and 8 and 4 sites offered CAGs and FTRs, respectively. Semi-structured interviews were held with 32 health workers that manage ART clinics, and 30 focus groups were held with 216 patients receiving the models of care. Interviews and focus groups were audio recorded, transcribed and coded thematically. Dedoose software was used to facilitate analysis.
Results: Patients and health workers reported that these models of differentiated care have yielded key benefits, including: reduced travel and visit times for patients, reduced health worker burden, decongestion of facilities, and enhanced social support. Both health workers and patients suggested that these benefits could lead to improved patient adherence and retention. At the same time, challenges were reported, such as inconsistent stocks of ART and other supplemental drugs like cotrimoxozole, which can restrict the provision of multi-month refills. For CAGs, the group-based nature of the model presented some unique problems, such as conflicts within groups or patient concerns about privacy. For all models, some health workers had concerns that patients would fail to seek care if they became ill between appointments, while patients reported having an understanding of the need to seek care if they felt ill before an appointment.
Conclusions: Overall, differentiated care is strongly supported by both patients and health workers and appears to have significant and immediate benefits. To maximize impact, however, challenges relating to supply availability, model logistics, and patient support should be addressed. Patients are likely to cycle in and out of differentiated care as their needs change and the ability of facility to provide these models may vary, so a one-size-fits-all approach to differentiated care is not realistic.

TUPED1329

Improvements in engagement, retention, and viral load suppression in a mobile outreach retention and engagement (MORE) project at a community health center in Washington DC

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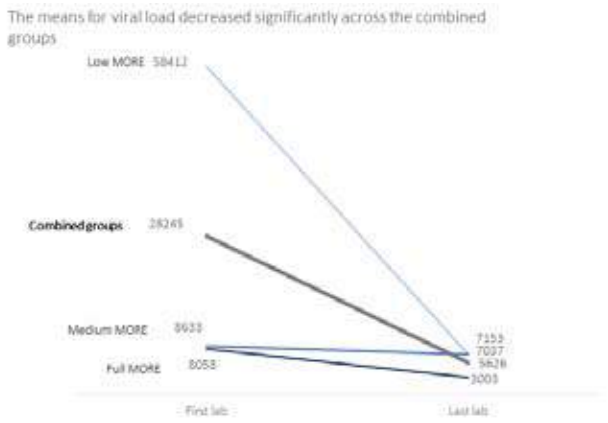
Background: HIV+ individuals on antiretroviral therapy, engaged and retained in services, and who are virologicaly suppressed have improved health outcomes and are less likely to transmit HIV infection, providing the basis for the United Nations 90:90:90 target goals. MORE is a novel community health approach to increase patient engagement, retention, and virologic suppression at Whitman-Walker Health, Washington DC's largest HIV care provider. The MORE team (consisting of community health workers (CHW), care navigators (CN), and a nurse practitioner and physician assistant), offered supportive services and medical care inside and outside the clinic for high-risk HIV+ patients.
Methods: EMR review identified high risk HIV+ patients who were not retained in care (no medical visit in the last 6 months) and/or with a viral load >200 . 258 individuals were approached for MORE and 202 engaged.
Engagement levels were self-selected as:
Low - <3 month intervention with CHW and CN only;
Medium - declined home visits but received increased ongoing care navigation and access to CHW;
Full - medical home visits with coordinated care team in addition to uber travel support.
Results: Study uptake was 78% (202) (26% Full MORE, 18% Medium MORE, 34% Low MORE). Medium and Full MORE participants were more likely to have at least one viral load during follow up. (90% versus 76%). 80% of participants across groups either maintained or decreased their viral load. The mean decrease across groups was significant, with a reduction in community viral load from an average of 28245 copies to 5626 copies.
Conclusions: One year after the initiation of MORE, preliminary evaluation demonstrates increased patient engagement, retention, and decreased community viral load in a select population of high risk patients whom were previously failing to meet treatment targets. MORE is a potential effective intervention to reduce community disease burden and HIV transmission.



[Mean change in viral load]

TUPED1330

Acceptability of interventions to improve retention in HIV care among pregnant women in Johannesburg, South Africa

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Background: Women who initiate antiretroviral therapy during pregnancy in South Africa are at high risk of dropping out of routine HIV care after delivery. We conducted a pilot study of the feasibility of a financial incentive intervention—a one-time R50 (~USD4) supermarket voucher for completing one postpartum visit—to attempt to reduce postpartum losses. We here assess the acceptability of the intervention.
Methods: We interviewed 100 pregnant, HIV-positive women at enrollment. We assessed the acceptability of the intervention as well as respondents' attitudes towards other interventions to improve HIV retention for pregnant and postpartum women.
Results: Median (IQR) respondent age was 28 years (24-31), most (78%) had previously been pregnant, and 31% were employed. Three-fourths (76%) of respondents found the supermarket voucher incentive acceptable and 86% responded that the incentive would motivate them to return to the clinic, with responses such as, "If you know that you´ll get something you won´t miss your appointment" and "I´m not working. If the clinics could offer incentives like these they will help me and my kids so much." Among the 23% who found the intervention unacceptable, the most frequent reason was perceived personal responsibility for one's own health (21/23), with responses including, "People should attend their visits without getting anything" and "It´s like they bribe them for their health." Overall, when asked to rank preferred hypothetical incentive interventions, assistance with social services ranked first (29%), followed by provision of infant formula (22%) and cash (21%); assistance with social services was the top-ranked choice by both those who found the voucher incentive intervention acceptable and unacceptable. To encourage HIV-positive women to remain in care, respondents most frequently suggested health education (32%), counseling (25%), financial incentives (17%) and home visits (12%).
Conclusions: The problem of poor retention in postpartum HIV care is well documented, but few successful interventions have been found. Our results suggest a financial incentive intervention is acceptable, but women frequently expressed pref-

erence for integrated services and improved education and counseling to improve retention in care. Interventions exploring the feasibility and efficacy of education and counseling interventions to improve postpartum HIV care are warranted.

TUPED1331

Effect of incentivizing men for HIV testing on HIV testing behavior of women in rural Uganda

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Background: Despite expansion in HIV testing services, men test for HIV at lower rates than women in sub-Saharan Africa. In a recent randomized trial in rural Uganda, we found that men were more likely to test for HIV when offered a low-cost lottery incentive than a low-cost gain-framed incentive. The indirect (i.e. "spillover") effects of such incentives on close ties like family members are not well understood. We evaluated the impact of offering HIV testing incentives to men on HIV testing behavior of their spouses.
Methods: Following the IBIS-Health Trial (NCT02890459), we conducted a post-hoc analysis among wives of men enrolled and randomized to receive various incentives for HIV testing: low-cost ($1) gain-framed incentives (control), where men were told they would receive a small prize for HIV testing; or lottery incentives, where men who came for HIV testing had a chance to instantly win large prizes. Women were not incentivized to test for HIV. The primary outcome was HIV testing uptake of wives of male trial participants at community health campaigns held between June-July 2016.
Results: Overall, 397 households were included - 397 men and 401 women. Men had significantly higher HIV testing uptake than women (81% vs. 61%, p< 0.001). Although men randomized to lottery incentives were significantly more likely to test than those randomized to gain-framed incentives, there was no difference in testing uptake among their wives by incentive type (123/207 [62%] vs.121/194 [59%], p=0.545). In the lottery group, there was no difference in testing among wives whose husband was a lottery winner vs. non-winner (10/14 [71%] vs. 94/147 [64%], p=0.772).
Conclusions: The type of incentive to which men were randomized had no significant impact on HIV testing uptake among their wives, suggesting a lack of spillover effects. However, the overall lower testing uptake among women compared to men suggests negative spillover, which may be explained by factors such as community perception that the testing campaigns were for men. Clear communication is necessary when delivering incentives to specific population subgroups, and equitable implementation may be needed to avoid negative spillover effects on health behavior of others.

TUPED1332

Behavioral economic incentives supported by SMS messaging to improve antiretroviral adherence among youth in Uganda

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Background: Youth account for nearly half of all new HIV infections worldwide and face specific barriers to optimal ART adherence, yet few interventions target this population. Interventions using behavioral economic insights have proven effective in improving adherence among adults; in this study, we test the use of prize drawings supported by mobile health to improve ART adherence and viral suppression among HIV-positive youth.
Methods: Patients at an urban HIV clinic in Kampala, Uganda aged 17-24 years were randomly assigned in a 1:1:1 ratio to one of two incentive groups or a control group. In the first intervention group, clients were eligible to participate in prize drawings to win mobile airtime with expected value of 5,000 Ush (~$1.50USD) if their electronically measured adherence exceeded 90%. In the second group, drawing eligibility was based on a target of their own choosing (but exceeding 80%); we hypothesize that this novel approach leads to improved adherence through higher intrinsic motivation and identity congruence. All three study groups receive weekly SMS reminders conveying motivational messages aimed at adherence maintenance. Main outcomes are mean dose-taking adherence and viral suppression over the 9 month study period. This trial is registered with ClinicalTrials.gov, NCT02918838.
Results: 211 clients approached enrolled in the study, and only 4 people declined to participate. 2,766 messages were sent and 83.5 percent of these were successfully delivered to the participant's phone. Among the group setting their own adherence goal, fewer than one-third chose the lowest possible adherence target, and two thirds chose 90% or higher. As of January 2017, 94 participants in the intervention groups completed their first clinic visit and 60 percent of these were eligible to participate in a prize drawing.
Conclusions: Prize drawings coupled with SMS reminders are feasible to implement in a low-income setting. A novel finding is that those asked to choose their own adherence targets set high goals for themselves. Subsequent analysis of study data will show whether these findings translate to improved adherence and health outcomes among this vulnerable population.

TUPED1333

A pilot randomized trial of conditional cash incentives to increase pediatric HIV testing

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Background: Pediatric HIV diagnosis is often delayed due to parental reluctance to test children. A systematic offer of pediatric testing to HIV-infected parents in Kenya resulted in 14% uptake, suggesting need for additional approaches. We conducted a pilot study to assess acceptability of incentives to increase pediatric testing.
Methods: Between October-December 2016, we recruited HIV-infected caregivers at Kisumu County Hospital, Kenya, with children of unknown status aged 0-12 years, and randomized them to receive $5, $10 or $15 conditional on child testing within 2 months. We compared proportion testing child(ren), preference for incentive type and impact on test timing.
Results: Of 2,196 recruited, 72(3%) were eligible, 60(83%) randomized; 20 to each arm. Forty three (72%) completed testing; 15(75%), 15(75%) and 13(65%) in the $5 $10, $15 arms, respectively. This uptake was significantly higher than in the recent cohort (72% vs. 14%, p< 0.001). Of 17 not tested, 13 failed to complete testing in 2 months and 4 are pending testing.
Of 54 children tested, median age was 9 years (IQR 5-11), 1 was HIV positive. Median days to testing were 17, 4, and 7 in the $5 $10, $15 arms, respectively. Caregivers reported preferring incentives provided as cash (37%), household goods (14%), agricultural goods (9%), health services or food vouchers (10%); 30% had no preference. Thirty-five (81%) said the incentive influenced testing, and 35(81%) motivated earlier testing. Thirteen (30%) perceived their children were HIV positive before testing but these tested negative. Eighteen (42%) caregivers previously had avoided health care during child illness for fear of HIV testing.

	n(%) or median (IQR) $5 arm	n(%) or median (IQR) $10 arm	n(%) or median (IQR) $15 arm
Completed testing of 1+ child	15 (75) 95%CI (51-91)	15 (75) 95%CI (51-91)	13(65) 95%CI (41-85)
Median (IQR) days to testing	17 (1-28)	4(1-6)	7(2-20)
Number of children tested	18	20	16
Median age of children tested	8.5(4,10)	8(5.5, 10.5)	10.5(7-11)
Preferred cash	7(47)	4(27)	5(38)
Household goods or agricultural items	6(40)	2(13)	2(15.5)
Health services or food voucher	0	2(13)	2(15.5)
No specific preference	2(13)	7(47)	4(31)
Previously avoided health care	8(53)	4(27)	6(46)

[Testing uptake and preference for incentive]

Conclusions: Cash incentives motivated pediatric HIV testing. Confirming HIV negative status may alleviate parental fears and increase uptake of other health services. An efficacy trial with incentive values of $0, $1.25, $2.50, $5, and $10 will begin January 2017.

TUPED1334

Conditional food or cash transfers do not increase purchase of temptation goods among adults living with HIV infection in Shinyanga, Tanzania

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Background: Conditional cash and in-kind incentives are increasingly recognized as effective tools for increasing demand for HIV care and treatment services. However, a common concern is that incentives may increase expenditures on ‚temptation goods' like alcohol and commercial sex. We evaluated this assertion among HIV-infected adults in Shinyanga, Tanzania who received short-term cash or food support.
Methods: We analyzed data from a study of 805 individuals randomized to one of three study arms: standard of care (SOC), short-term cash transfers or short-term food assistance. Eligible participants were:
1) ≥18 years old;
2) HIV-infected;
3) food insecure; and
4) initiated antiretroviral therapy (ART) ≤90 days before enrollment.
Food or cash transfers, valued at approximately $11 USD/month and conditional on attending HIV clinic visits, were provided for up to 6 months and accompanied by a message to use the transfer as needed to improve health. An in-person survey after the incentive period (median ~8 months after enrollment) assessed self-reported expenditures, consumption of alcohol, and purchase of sex.
Results: The study population included 509 (64%) females with a mean age of 37 years. Most incentive group participants reported using transfers for food: on average, household food expenditures among cash recipients increased by 1428 Tanzanian shillings (TSH) (p=0.60), and 96% of food assistance recipients reported consuming the food. Purchase of sex was not reported by any participant.
Median monthly alcohol expenditures did not significantly differ between the SOC and the cash (3000 TSH vs. 6000 TSH, respectively, p=0.94) or food group (3500 TSH, p=0.73). The proportion of participants who reported drinking alcohol in the past month was significantly lower in the cash transfer group (0.35%) compared to the food assistance group (4.2%, p=< 0.01). Alcohol consumption in the past month did not differ significantly between the food and SOC group (3.9%, p=0.90) or cash and SOC group (p=0.11).
Conclusions: In this population of food insecure HIV-infected adults, provision of short-term conditional cash transfers did not increase temptation good usage. Consistent with findings from cash transfer programs for social protection, concerns that incentive programs for people living with HIV infection may increase purchase of temptation goods may be unfounded.

TUPED1335

Social norms messaging to improve antiretroviral adherence among youth in Uganda

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Background: SMS messaging to improve medication adherence has a mixed record of success and has largely focused on adult populations. We report findings from one of the first studies to target youth, and the use of social norms messaging, an approach that to date has not been tested in this population. In one group, we send weekly messages informing participants of their electronically measured adherence to counter over-optimism about their ability to stick to their pill regimen. In the second group, we also send information about group level adherence, which we hypothesize, will create a social norm to which participants in this group will strive to adhere to or even surpass.
Methods: Patients at two HIV clinics in Kampala, Uganda aged 15-24 years (80% female and 20% male) were randomly assigned to one of two intervention groups or a control group. In the first intervention group, participants received a weekly motivational message with information about their adherence level in that week. In the second group, participants in addition received information about the performance of their peers in the intervention. The main outcome is electronically measured mean dose-taking adherence. This trial is registered with ClinicalTrials.gov, NCT02514356.
Results: 147 clients were recruited and attrition over the nine study months was relatively low (17%). While we do not find an overall effect of the intervention, we find important treatment heterogeneity: those with low pre-intervention adherence experience about a 10% increase in mean adherence. Those with already high adherence before the intervention, on the other hand, see their adherence decrease by about 14%. We do not find differential impacts by gender.
Conclusions: The findings in this study suggest that SMS messaging to address over-optimism and creating a social norm is feasible and acceptable for a group of youth in HIV care in Uganda. The impact heterogeneity suggests that participants with lower adherence than the peer norm likely benefit most from such an intervention, and that different messaging may have to be used for those with higher initial adherence. The preliminary results and potential heterogeneity should be confirmed in a larger follow-up study.

TUPED1336

Describing the price differential for condomless sex into HIV prevention programming for female sex workers in Senegal

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Background: There has been significant study of the effectiveness of economic incentives as components of an effective HIV response. Studies to date have observed limited utility of these approaches for female sex workers(FSW). Concurrently, descriptive studies have examined the price differential, defined here as the price difference for condomless sex with FSW. Here, we explore the price differential as a guide for incentive programs aiming to support exclusive condom use during sex work in Senegal.
Methods: 194 FSW aged 18 and older reporting selling sex as their primary source of income for the last 12 months were enrolled into a prospective cohort in Dakar, Mbour, and Thies, Senegal. The cohort participants were originally recruited from a cross-sectional study of FSW recruited using Respondent-Driven Sampling and complete quarterly structured socio-behavioral questionnaires. This analysis presents the preliminary results of the price differential in relation to economic variables from month 6 and month 12 visits (Table 1).
Results: The prevalence of clients offering more money for condomless sex was 27.3%(57/194) and 44.9%(70/156) at months 6 and 12 respectively. The average price differentials at these times were 10,506 FCFA(17.21USD) at month 6 and 11,564 FCFA(18.95USD) at month 12 comparing condomless sex with condom-use sex. On average, client offered twice as much compensation for condomless sex as compared to sex with a condom, characterizing a strong financial incentive to engage in condomless sex and an elevated HIV risk for FSW.

	Month 6 (N= 194)	Month 12 (N= 156)
Individual characteristics		
Registered as FSW (n, %)	58(29.90%)	43(27.56%)
Experience stigma from low financial situation (n, %)	73(37.63%)	101(64.74%)
Compensating differential (XOF)		
Experience a client's offer (n, %)	53(27.32%)	70(44.87%)
Price per vaginal sex (Mean ± SD)		
With condom	7995(±6297)[a]	8663(±9086)
Without condom	17928(±17332)[a]	21628(±21290)[b]
Compensating differential	10506(±13777)[a]	11564(±24260)[b]
Reliance on sex work (XOF)		
Weekly income (Mean ± SD)		
from sex work	39672(±38879)	49404(±55970)
from other profession	8443(±13881)	6760(±13185)
from family/friends	3915(±11058)	5030(±14126)

[a]: number of participants who responded is 77.[b]: number of participants is 39.

[Table 1. Preliminary analysis of economic factors]

Conclusions: The data presented here reinforces the challenges in ensuring condom use during sex work for FSW in Senegal. In combination with condom negotiation difficulties, these data highlight the economic benefits to FSW with condomless sex. While these data suggest that economic empowerment-based HIV interventions should calibrate their effective dosage based on the price differential, they also highlight the importance of comprehensive approaches to addressing vulnerabilities during sex work.

TUPED1337

The use of a performance-based financing approach in the engagement of private health facilities for HIV testing services in Nigeria

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Background: Engagement of the Private Health Sector (PHS) has been identified as one of the key strategies in bridging the huge gap in PMTCT service coverage in Nigeria. With forty three percent (43%) of facility-based deliveries occurring in this sector, there is a consensus among stakeholders that the sector offers an opportunity to expand access to HIV services. Also important is the need to ensure increased value for money and greater accountability in the health system in the face of dwindling resources. So far in Nigeria, d engagement of private health facilities have been limited and accountability in the health system inadequate.
Methods: The Nigerian National Agency for the Control of AIDS with support from the World Bank adopted a performance (PBF) based financing approach to motivate private healthcare providers to provide HIV testing services (HTS) for pregnant women. 390 facilities were to be engaged in the pilot project across 13 states (Lagos, Oyo, Kaduna, Sokoto, Akwa-Ibom, Rivers, Kano, Taraba, Cross-River, Imo, Nasarawa, Benue and the Federal Capital Territory (FCT). Facilities would be reimbursed N2, 750 for every pregnant woman tested. Women who test positive are referred to antiretroviral therapy (ART) centres to which they are linked. Using a developed eligibility criteria, thirty facilities were selected per state for the project. Personnel in selected facilities were trained on HTS provision, data collection and referral. Contracted independent verification agents (IVAs) verify services provided before providers are paid based on achievements.
Results: After four months of programme implementation, 293 facilities (81%) met the eligibility criteria and were engaged. 63,074 pregnant women were tested, 612 (0.97%) women were identified positive and 384 (62.7%) successfully referred for ART. Private health facilities were willing to participate in the scheme. The use of IVAs ensured the linkage of financing to result.
Conclusions: PBF can be used in engaging the private health sector to expand access to HIV services in Nigeria and by extension other similar health service packages in the country.

TUPED1338

Rapid test and early treatment of HIV infection in a community-based sexual health care system associating "the Checkpoint" and "The 190" dedicated to the MSM population in Paris, France

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Background: In France, 40% of new HIV diagnoses occurs in the men who have sex with men (MSM) population and 40% of new diagnoses occur in Paris area. In this context, two community-based sexual health medical centers dedicated to the MSM population were created in 2010 and decided to combine their activities : „the Checkpoint" offering HIV rapid testing, and „The 190" proposing ARV treatment to positive patients. The aim of this study was to evaluate benefits of this coordinated system proposed to the highly exposed MSM in Paris.
Methods: In this retrospective observational study, data of sociodemographic characteristics, stage of HIV infection according to Fiebig classification, delay between the positive test and HAART initiation and efficacy of HAART were collected for patients diagnosed positive at the „Checkpoint" and then came to the „190" for care, between 02/01/2010 and 12/31/2014.
Results: 82 patients were included during the study period. Median age at diagnostic was 30,5 years and 19,5% of the patients were less than 25 years old. 24,4% (20/82) were born outside of France. Socioprofessional group was known for 61 patients: 28% were students and 43% belonged to highly-qualified working people. Interestingly, based on HIV-1 western blot results, 78% (64/82) had an incomplete HIV-1 Western blot and 28% (23/82) were diagnosed at the time of primary infection (Stage III to V Fiebig). Median time between positive test and the first medical consultation was 7 days for 79 patients who came to "the 190" for care. 61 patients (74,4%) had HAART initiation at "the 190" with a median time of 13 days. Among the 23 patients with primary infection, median time for HAART initiation was 8 days. Viral load was undetectable < 50 copies/ml after 6 months for 98,3% patients.
Conclusions: This model, sustaining a sort of rapid "Test and Treat" within a community has shown a strong attractivity for a fairly young MSM population who beneficiate to be diagnosed and treated at a very early stage of HIV infection. That kind of approach could participate to reduce the dramatic epidemic among young Parisian MSM.

TUPED1339

Feasibility and acceptability of delivering prenatal test results at the point-of-delivery through a non-internet dependent mobile health platform

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Background: Community-based strategies for HIV testing have expanded opportunities to increase the proportion of pregnant women who are aware of their HIV diagnosis. In order to use this information to implement evidence-based interventions for the prevention of mother-to-child HIV transmission, these results have to be available to the clinician at the point-of-delivery. Most electronic health records are dependent on the availability of internet connectivity and thus, have limited use in rural and resource-limited settings. The purpose of our study was to (a) determine the feasibility of developing a non-internet dependent mobile health (mHealth) platform that made results from community-based screening programs available to clinicians at the point-of-delivery and (b) the acceptability of such platform by pregnant women.
Methods: We leveraged on existing technology to integrate a database, smartcard technology, and a cell phone-based application. We selected a convenience sample of 240 pregnant women from an ongoing NIH-funded study and obtained consent after explaining the purpose of the smartcards. Each participant who consented was offered a card with their encrypted test result. We used an investigator-administered survey to obtain information on the willingness of participants to allow clinicians to retrieve information from their card. Participants were eligible if they tested positive for at least one of three conditions: HIV, Hepatitis B virus (HBV) infection and sickle cell trait or disease (SCD).
Results: We successfully designed an integrated platform that stored test results on a database, securely encrypted the results on a smartcard and used a cell phone application to read the information on the smartcard, without the need for internet connectivity. Participants were mostly rural dwellers with low education (92%) and economic levels (96%); 23% were HIV-positive, 29% HBV-infected and 59% had SCD. A majority of participants (76%) self-reported access to a mobile phone. All participants (100%) accepted and indicated the willingness to use the smartcards for prenatal and delivery services.
Conclusions: Our findings indicate that it is feasible to develop a non-internet dependent mHealth platform that can make test results obtained through community-based strategies available at the point-of-delivery. This platform is well accepted when the potential benefit of early intervention is explained to participants.

TUPED1340

Enhanced peer mobilization and use of a real-time HIV cascade performance system: on-going lessons in peer-driven interventions and improving HIV yield

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Background: Although HIV testing is the critical entry point for antiretroviral treatment and pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM), fewer than half of MSM in Asia know their HIV status, and outreach-based test promotion has achieved low testing uptake and yield.

We introduced an enhanced peer mobilizer (EPM) model, a peer-driven intervention, to increase rates of HIV testing and strengthen case finding.
Methods: EPM was implemented by community-based organizations in four cities in Thailand. Under EPM, a small team of trained outreach workers manage a wider, informal network of incentivized Peer Mobilizers (PMs) to recruit clients from their social networks. Data on client demographics, risk behaviors, and referrals are collected and shared via a real-time mobile data collection system (eCascade).
Results: From July 2015 to December 2016, 12,599 unique clients were registered under the EPM model, 61% of whom received an HIV test (n=7,717) with an 11% testing yield (n=848) and 285 of whom initiated ART at a collaborating site (34%). Most clients were MSM (64%) between the ages of 15-29 (74%). 86% of clients had not previously been reached with HIV prevention interventions and 56% had never previously been tested for HIV. Of program clients, 8,207 were recruited via contracted outreach workers, 3,281 via clinic walk-in, and 1,576 via peer-driven recruitment. Clients recruited by PMs were more likely to be tested than clients recruited by outreach workers (86% versus 44%), but testing yield varied by site. Peer-driven recruitment overall contributed only about 12% to total program coverage but this also varied by site and target population (in one site, it reached approximately 50%). Only 3% of clients became successful peer mobilizers and, of those, the majority only recruited one additional client. A small number of highly motivated "super mobilizers," using creative strategies within their own personal networks, contributed the majority of peer-driven recruitment.
Conclusions: EPM and the use of real-time HIV cascade performance monitoring offer opportunities to increase efficiencies in outreach, to increase HIV testing and yield, and to adjust strategies to reach higher-risk networks of key population, a common challenge of outreach programs.

TUPED1341

A primary care level algorithm increases yield of HIV-positive adolescents in a community intervention: HPTN071 (PopART) Study, Zambia

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Background: The PopART for Youth (P-ART-Y) study aims to evaluate the acceptability and uptake of a community-level combination HIV prevention package among young people, including UTT. The study is nested within the HPTN071 (PopART) trial, a 3-arm randomized study in 21 communities in Zambia and South Africa. It's delivered through a door-to-door approach by Community HIV-care Providers (CHiPs). HIV prevalence is low among 10-14 year olds, hence to prioritise HCT, a screening tool was used to identify those at risk of being HIV-infected.
Methods: Adolescents contacted at home were offered participation in the PopART intervention. Data were recorded electronically by CHiPs during household visits. For the 10-14 year olds, a screening tool developed and validated elsewhere was used to identify those at risk of being HIV-infected. Screening questions were history of hospital admission; recurring skin problems; poor health in last 3 months; and death of one or both natural parents. A "yes" response to ≥1 question was considered as an HIV infection suspect ("at risk"). We present findings from Zambia for the period, October 2015-August 2016.

[Figure 1. HIV testing in adolescents aged 10-14 year old]

Results: A total of 32,220 adolescents aged 10-14 years were enumerated; 56.0% (n=18,040) participated in the intervention and had their health data recorded (Figure 1). 12.1% (n=2,181) were "at risk". In the at risk group, 4.4% (96/2,181) self-reported as HIV+ compared with 0.5% (74/15,859) in the not at risk group. Among those who did not self-report HIV+, uptake of testing was 69.5% (1,449/2,085) and 49.1% (7,755/15,785) in the "at risk" and "not at risk" groups respectively. HIV prevalence among those tested was 2.4% (35/2,085) in the at risk group, compared with 0.6% (44/7,755) in the not at risk group.
Conclusions: The screening tool identified adolescents in the general population who are at relatively high risk of being HIV-infected, this can be exploited to allow targeted offer of HCT in resource limited settings.

TUPED1342

The effect of community led vulnerability reduction intervention on risk reduction among MSM-TG population across 3 states in India

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Background: The ever growing body of research shows that HIV epidemics are socially and culturally produced and multi-level processes determine an individual's ability to adopt safe sex practices. This has influenced HIV prevention approaches to be designed around structural and social factors that decide individual level risk behaviors and also target the vulnerabilities of communities that are marginalized and at higher risk. Avahan Phase-III program as part of BMGF supported AIDS India Initiative, examines the impact of combined vulnerability reduction intervention coverage (CVRICI) on risk behavior among MSM and TG.
Methods: A systematic process of Member Engagement and Communication was conducted by Field Workers in their respective intervention areas using existing lists available with community organizations (CO) and TI Programs wherever accessible during April - September 2015 covering 8594 MSMs and 2169 TGs across 11 COs from 3 states of Maharashtra, Karnataka and Tamil Nadu. Information was collected on CVRICI, bonding with the CO (COBI) and risk behaviors like condom use etc. The data collected was managed and required comprehensive analysis was conducted using SPSS V 22.0
Results: MSMs and TGs with higher CVRICI reported consistent condom use (CCU) with 1 or all type of sexual partners. [MSM-AOR 2.168, CI (1.908-2.464) and TG-AOR 1.390, CI (1.027-1.881)] The analysis also showed that having a better bonding with the CO (COBS) is also significantly associated with the consistent condom use. But it was seen that above the COBS, CVRICI was more important in showing significant behavior change.
Conclusions: The findings from the study shows that combined vulnerability reduction interventions which focus on crisis response system, social protection and financial security which are community led have significant effects, direct and indirect on sustaining safe sex practices. The findings from the study ascertains the importance of combined approach of vulnerability and risk reduction to bring sustainability in the existing HIV program.

TUPED1343

The cost-effectiveness of HIV testing and treatment engagement initiatives in British Columbia, Canada: 2011-2013

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Background: Recognition of the secondary preventive benefits of antiretroviral therapy (ART) have mobilized global efforts to ‚seek, test, treat and retain' people living with HIV/AIDS (PLHIV) in HIV care. Our objective was to determine the cost-effectiveness of a set of HIV testing and treatment engagement interventions initiated in British Columbia (BC), Canada in 2011-2013.
Methods: Using a previously-validated dynamic, compartmental HIV transmission model, and linked individual-level health administrative data for PLHIV and aggregate-level HIV testing data, we estimated the cost-effectiveness of primary care testing (hospital, emergency department, outpatient), ART initiation and ART retention initiatives, versus a counterfactual scenario approximating the status quo. HIV incidence, mortality, costs (in 2016$CDN), quality-adjusted life years (QALYs), incremental cost-effectiveness ratios were all estimated. Analyses were executed over 5, 10 and 25-year time horizons, from a government-payer perspective.
Results: ED testing was the best value at $30,216 per QALY gained and had the greatest impact on incidence and mortality among PLHIV, while ART initiation provided the greatest QALY gains. Delivered in combination at the observed scale

and sustained throughout the study period, we estimated a 12.8% reduction in cumulative HIV incidence and a 4.7% reduction in deaths among PLHIV at an incremental cost of $55,258 per QALY gained. Results were most sensitive to uncertainty in the number of undiagnosed PLHIV.
Conclusions: HIV testing and ART initiation interventions were cost-effective, while the ART retention intervention was not. Reducing uncertainty in the size of the undiagnosed population and developing strategies to re-engage PLHIV lost to care are priorities moving forward.

TUPED1344

Clients' experiences utilizing a safer conception service: results from a process evaluation assessing knowledge, self-efficacy and perceived value of services among clients accessing care

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Background: Data from safer conception services (SCS) for HIV-affected couples trying to conceive are limited. Experiences from clients utilizing SCS are needed to identify persistent gaps in patient knowledge and self-efficacy in order to optimize service delivery packages.
Methods: A sub-sample of clients attending SCS at Hillbrow Community Health Centre in Johannesburg, South Africa were invited to participate in a process evaluation; stratified sampling was used to ensure clients were sampled across different visits. Clients were asked to rate their perceived knowledge of and self-efficacy to use safer conception methods, such as PrEP, timed condomless sex and self-insemination using visual analog scales ranking success from 0-100. Results are described and trends across visits assessed using linear regression.
Results: Of 556 individuals enrolled into SCS, 117 (21%) were sampled for the evaluation between April 2016-January 2017, including 74 women and 43 men. Participants completed a median of three SCS visits (IQR 2-4) prior to the survey. On a scale of 0-100 (no valueàhigh value), clients strongly valued continuing SCS attendance until pregnancy is achieved (mean score 96% [95%CI 94-98]); results were independent of the number of completed visits. Clients' perceived knowledge and self-efficacy to use safer conception methods are illustrated in Figure 1. For every additional visit completed, knowledge of the fertile window increased by 4 points (sd: 2, p=0.047); no other significant trends in knowledge or self-efficacy were observed over time.

[Clients safer conception knowledge & self-efficacy]

Conclusions: Clients' perceived value of SCS and confidence to reduce conception-related transmission risks were high, and understanding of peak fertile days improved over time. However, understanding of PrEP, identifying peak fertile days and knowledge about preconception STI management could be improved, emphasizing the need for multiple SCS visits rather than a once-off counseling approach. Follow-up counseling should focus on building self-efficacy to apply HIV prevention strategies, including self-insemination for male negative serodiscordant couples.

Wednesday 26 July

Oral Abstract Sessions

WEAA01 The Dance: Virus and Host Factors

WEAA0101

Impaired Nef's ability to counteract SERINC5 is associated with decreased plasma viremia

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Background: It is recently revealed that an HIV-1 accessory protein Nef plays an essential role in virion infectivity by antagonizing a host restriction molecule SERINC5. However, it remains elusive whether Nef's ability to counteract SERINC5 influences viral fitness in vivo. Because Nef is a highly polymorphic protein due to the selective forces by host cellular immunity, we hypothesized that certain immune-escape polymorphisms might affect the Nef function and thereby plasma viremia.
Methods: We collected plasma viral RNA from HLA-typed, treatment-naïve, chronically HIV-1-infected subjects (n=375) and analyzed DNA sequences of Nef-encoding region. Immune-associated Nef polymorphisms were analyzed by a phylogenetic network model. We also introduced several mutations to a control strain and patient-derived Nef clones and tested various Nef functions in vitro, including downregulation of CD4 and HLA class I as well as enhancement of virion infectivity and counteraction of SERINC5.
Results: We identified 112 Nef polymorphisms that were overrepresented within patients sharing the same HLA genotypes. Specifically, two mutations, Tyr-120 to Phe and Gln-125 to His were overrepresented in patients carrying HLA-B*51:01 and HLA-C*14:03 and the number of the two mutations correlated inversely with plasma viral load (p=0.004). Nef functional assays demonstrated that the double mutant Nef impaired in SERINC5 counteraction and enhancement virion infectivity whereas other Nef functions such as CD4 and HLA class I downregulation remained unchanged. Jurkat cells lacking SERINC5 expression lost such functional difference between the parental and mutant Nef clones.
Conclusions: Taken together, these results suggest that naturally occurring immune-associated mutations impair Nef's ability to counteract SERINC5 and enhance virion infectivity, associating with reduced plasma viral load in vivo.

WEAA0102

HIV-1 concentrates and shelters cell-associated infectivity a "viral biofilm"

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Background: Highly Active Antiretroviral Therapy (HAART) does not allow the complete clearance of the virus since it does not target viral reservoirs nor efficiently block HIV-1 cell-to cell transmission in vivo. HIV-1 cell-to-cell spread is thousands fold more efficient than cell-free infection; yet how virions are transferred via cell contacts remains unknown.
Methods: Using a panel of cutting-edge imaging techniques (Cryo-TEM, CL/SEM, CL/FIB and super resolution imaging) to functional assays, we investigated and characterized viral structures involved HIV-1 cell-associated infectivity. We analyzed a range of infected T cells cultures (chronically infected T cell lines, primary CD4+ T cells infected in vitro with virus primary isolates, and CD4+ T lymphocytes from untreated HIV-1 infected patients with a detectable viremia).
Results: We show here that HIV-1 cell-associated infectivity mostly resides at the surface of CD4+ T lymphocytes in a viral biofilm, formed by viral particles aggregated within a scaffold of extracellular matrix (ECM) components. Our set of data demonstrates that (i) biofilm-associated viral particles are more efficient in establishing infection than free viral particles and (ii) they confer HIV with important properties characterizing cell-to-cell spread. This includes the decreased sensitivity to HAART and to the broad neutralizing antibody 3BNC117. HIV-1 regulates biofilm matrix composition that controls both viral particles organization at the cell surface and the resulting cell associated infectivity. The organized clustering of viral particles along an ECM framework locally concentrate virions, favors their collective transfer to target cells and limits their exposure to nAbs. Finally, CD4+ T cells from HIV-1 infected patients produce and transmit viral biofilms, supporting that they may also be involved in vivo.
Conclusions: Thisstudy thus unveils HIV biofilm as a new highly infectious extracellular entity that concentrates, stores, disseminates and shelters HIV-1 infectivity. This may have implications for HIV-1 spread and persistence in host, including for maintaining HIV-1 sanctuaries in treated patients. Our results unveil a new role for the ECM in clustering and protecting HIV-1 at the plasma membrane, and in their collective transfer through virological synapses. Targeting biofilm ECM components could represent a promising approach to favor HIV-1 clearance or to potentiate the effect of available anti-viral therapies.

WEAA0103

Coordinated mTOR-mediated rewiring of nucleotide anabolism regulates HIV-1 infection of CD4 T lymphocytes

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Background: HIV-1 replication is restricted in resting CD4 T lymphocytes. Stimulation of these cells via either the T cell receptor (TCR) or gamma-cytokine receptors up-regulates HIV provirus formation at levels of reverse transcription (RT) and nuclear import. However, the enhancements of both RT and nuclear import are not fully explained by activation-induced changes in known restriction factors. Here, we study a "master regulator" activated by both TCR and gamma-cytokine signaling: the mechanistic target of rapamycin (mTOR) kinase.
Methods: Resting CD4 T cells purified from blood donor PBMCs using immunomagnetic cell separation were stimulated with anti-CD3/anti-CD28 beads, PHA/IL2, or IL7/15. Inhibitors were used before activation to study the role of mTOR. qPCR quantified HIV-1 RT products and 2-long terminal repeat (2-LTR) circles. Flow cytometry after infection with a single-round HIV-1-GFP reporter virus monitored productive infection. Quantitation of dNTPs used ultra-sensitive LC-MS/MS detection. Flow cytometry and immunoblotting assessed effects of treatments on mTOR activity.
Results: mTOR activity induced by engagement of either T cell or gamma-cytokine receptors coordinates expression of transporters for glucose (GLUT1), glutamine (ASCT2), and transferrin (CD71), as well as rate-limiting enzymes for pyrimidine (CAD), purine (IMPDH2), and deoxyribonucleotide (dNTP) synthesis (RRM1). mTOR has been previously reported to govern the expression of nutrient transporters and pyrimidine biosynthetic genes, but this is the first demonstration of this global mTOR-dependent program in activated CD4 T lymphocytes. Pharmacological ablation of mTOR activity suppressed dNTP pool expansion after activation. Multiple chemically distinct catalytic inhibitors of mTOR were found to reduce HIV-1 RT products after TCR-stimulation. Moreover, both TCR and gamma-cytokine-activation induced mTOR inhibitor-sensitive accumulation of 2-LTR circular forms of HIV-1 DNA, indicating that mTOR activity also regulates active, energy (GTP/ATP)-dependent) HIV-1 nuclear import.
Conclusions: CD4 T lymphocyte activation-induced mTOR "metabolic reprogramming" drives increased susceptibility to HIV-1 by expanding key nucleotide substrate and energy pools necessary for both reverse transcription and nuclear import. This adds mechanistic understanding, confirms earlier reports that catalytic inhibitors of mTOR hold promise for improving HIV-1 chemo-therapy and prevention, and suggests continued investigation of mTOR's role in establishment as well as reactivation of HIV-1 infection.

WEAA0104

Membrane-associated RING-CH (MARCH) 1 and 2 are other members of MARCH proteins that inhibit HIV-1 infection

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Background: Membrane-associated RING-CH 8 (MARCH8), which is one of 11 members of MARCH family, downregulates several host membrane proteins (MHC-II, CD86, transferrin receptor, etc.). We have recently reported that this

protein also targets HIV-1 envelope glycoproteins and acts as an antiviral factor (Nat. Med. 21:1502-1507, 2015). It remains unclear whether other family members might have similar antiviral functions to those seen in MARCH8. Here, we show that MARCH1 and MARCH2, are such MARCH family members that reduces virion incorporation of envelope glycoproteins.
Methods: Plasmids expressing family members of MARCH (MARCH1, MARCH2, MARCH3, MARCH5, MARCH6, and MARCH7) were created by RT-PCR-amplifying their mRNAs. The HIV-1 proviral luciferase indicator plasmid was cotransfected with plasmids expressing either HIV-1 Env, or VSV-G, and those expressing MARCH family members including MARCH8, into 293T cells. Supernatants were subjected to assays for infectivity, viral entry, or virion incorporation, and producer cells were used for flow cytometry. Real-time RT-PCR was performed to determine endogenous levels of MARCH1 and MARCH2 expression.
Results: Infectivity assays showed that, two other members of MARCH family, MARCH1 and MARCH2 had the antiviral activity in a dose-dependent manner. The expression of these proteins in virus-producer cells decreased the efficiency of viral entry and indeed downregulated HIV-1 envelope glycoproteins from the cell surface, resulting in reduced incorporation of envelope glycoproteins into virions, exactly as observed in MARCH8 expression. Endogenous expression of MARCH1 and MARCH2 were enhanced in monocyte-derived macrophages by treatment with type I interferon.
Conclusions: As the antiviral MARCH family members, MARCH1 and MARCH2 join a growing list of host factors that inhibit HIV-1 infection.

WEAA0105

Bicaudal D2 facilitates the cytoplasmic trafficking and nuclear import of HIV-1 genomes during infection

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Background: Numerous viruses, including HIV-1, exploit the microtubule network to traffic towards the nucleus during infection. Although numerous studies have observed a role for the plus end microtubule motor dynein in HIV-1 infection, the mechanism by which the viral core containing the viral genome associates with dynein and induce their perinuclear trafficking has remained unclear.
Methods: We utilized CRISPR mediated depletion of the dynein adapter protein Bicaudal D2 (BICD) and monitored the stages of viral replication by qPCR, measured viral trafficking using live cell imaging, and the induction of antiviral gene expression by RT-PCR.
Results: We observe that BICD2 depletion inhibits infection, preventing the nuclear entry of the viral genome, while fusion and reverse transcription are unimpaired. Using live cell imaging, we show that viral trafficking is altered in BICD2 depleted cells, and show that NC-CA tubes bind cellular BiCD2. Finally, we observe that disruption of the CA-BiCD2 interaction in the monocytic cell line THP-1 results in the accumulation of viral genomes in the cytoplasm and the induction of interferon stimulated genes in these cells.
Conclusions: These studies demonstrate that BICD2 is required for efficient HIV-1 infection and reveal the BICD2/CA interaction as a novel target for possible therapeutic interventions designed to increase innate immune activation in response to HIV-1 infection.

WEAA02 Catch Me If You Can: Reservoir Intervention

WEAA0201

Investigating the SHIV reservoir in a non-human primate model following allogeneic bone marrow transplantation

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Background: Three components are thought to have contributed to the Berlin patient's cure following BMT: myeloablative conditioning, graft-versus-viral reservoir (GVVR), and HIV resistance of the donor CCR5D32 cells, yet the contributions of each to reservoir clearance is unknown. Moreover, while the Boston patients' viral rebound suggests HIV-resistance will be key, this has not yet been rigorously determined. To dissect the role of myeloablative conditioning, GVVR and viral resistance on the SHIV reservoir, we have developed the first NHP model for allogeneic BMT in SHIV-infected, cART-treated rhesus macaques.
Methods: We intravenously infected 6 animals with SHIV-1157ipd3N4 and left them untreated for six months, followed by six months of cART (Raltegravir, PMPA and FTC). 3 animals remained untransplanted, and 3 animals received myeloablative total body irradiation (1020 Gy) followed by haplo-identical BMT without ART discontinuation. Donor chimerism was monitored, and viral DNA and RNA were measured by qPCR in ~35 tissues following necropsy.
Results: All animals showed peak viral titers in the range of ~10^7 copies/ml ~2 weeks post-infection, which subsequently reached steady-state. 1 animal controlled viremia before ART initiation (day 184). In the other animals, plasma viral RNA became undetectable 2-3 weeks post cART initiation. The 3 transplanted animals were euthanized at day 47, 29, and 9 post-transplant, due to infection, acute graft-versus-host disease, and renal complications, respectively. Analysis of whole blood and sorted CD4+ T cells showed rapid acquisition of 100% donor blood chimerism, with lower chimerism in multiple tissues. Despite undetectable viremia post-transplant, viral DNA quantification in 35 tissues, including hematopoietic and major organs, CNS, and reproductive organs revealed an increased reservoir in transplanted non-controllers versus untransplanted controls.
Conclusions: Our results indicate that the DNA reservoir significantly increases early after transplant, despite control of peripheral viremia. This suggests that transplant represents a significant initial ‚shock' with loss of anti-HIV immunity contributing to reservoir enlargement, potentially explaining the rebound observed in the Boston patients. We believe that full recovery of anti-HIV immune control may be restored if additional HIV resistance factors and/or anti-HIV strategies are incorporated post-transplant to enhance the targeted killing of infected cells.

WEAA0202

Investigating clinical therapeutics to target infected cells and promote HIV clearance

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Background: Efforts to eliminate the latent HIV reservoir highlight the need for alternative strategies geared towards killing latently infected cells. HIV manipulates host apoptotic pathways in order to sustain the infection cycle and evade immune surveillance. BH3-mimetic inhibitors antagonise pro-survival proteins and promote intrinsic apoptosis.
Here, we employ a novel humanized mouse model of latent HIV infection, together with in vitro cell survival assays, to investigate the usefulness of BH3-mimetics in clearing the latent reservoir and achieving a functional cure.
Methods: Primary human $CD4^+$ T lymphocytes were isolated from healthy donors, activated and infected with HIV-GFP. Infected primary $CD4^+$ T cells were treated with BH3-mimetics and assessed for death of GFP-positive, HIV infected cells.
Briefly, humanized mice were generated as follows: NOD.Cg-Prkdc^{scid} Il2rg^{tm1Wjl}/Sz (NSG) neonates were sub-lethally irradiated in order to achieve myeloablation, followed by injection of human $CD34^+$ cord blood haematopoietic stem cells into the

orbital vein. Mice were assessed for degree and quality of reconstitution at 16 weeks of age before infection with HIV. Virological suppression was recapitulated using a clinically-relevant ART regimen before testing novel interventions.
Results: We first sought to investigate the in vitro sensitivity of actively infected cells to pro-apoptotic interventions. Treatment with the pre-clinical BH3-mimetic ABT-737, which targets pro-survival proteins Bcl-2, Bcl-xL and Bcl-w, resulted in preferential killing of HIV-infected cells in a concentration-dependent manner. A similar outcome was observed using the FDA-approved, clinical-stage Bcl-2 inhibitor Venetoclax.
Our humanized mouse model successfully recapitulates key stages of human disease, including chronic infection, viral suppression, as well as subsequent rebound following treatment interruption. Suppressed mice were administered Venetoclax over three treatment cycles before therapy was interrupted to assess for viral rebound. Humanized mice treated with Venetoclax experienced a substantial delay in rebound up to one week longer than vehicle-treated controls.
Conclusions: These results pave the way for further in vivo studies using a humanized mouse model of HIV latency. Efforts are underway to optimise treatment regimens as well as to investigate the combination of BH3-mimetics with traditional latency-reversing agents. Overall, these findings represent a novel approach to killing latently infected cells and purging the proviral reservoir.

WEAA0203

Inhibiting memory CD4+ T-cell self-renewal to reduce HIV persistence

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Background: Long-lived memory CD4+ T-cells with high self-renewal capacity such as central memory (T_{CM}) T-cells and T memory stem cells (T_{SCM}) are major contributors to the viral reservoir in HIV-infected individuals on antiretroviral therapy (ART). The Wnt/beta-catenin signaling pathway primarily regulates the balance between self-renewal and differentiation of T_{SCM}/T_{CM} and pharmacological manipulation of this pathway offers an opportunity to reduce persistence of latently-infected cells.
Methods: To block self-renewal and promote T_{SCM}/T_{CM} differentiation, we used an inhibitor targeting the Wnt/beta-catenin pathway initially developed to target cancer stem cells (called PRI-724). We evaluated the safety of PRI-724 with a dose escalation study in healthy rhesus macaques (RM). We then conducted an efficacy study in twelve SIV_{mac251}-infected RM treated with ART. After suppression of viremia, 8/12 RM received PRI-724 at 10 or 20 mg/kg/day while 4/12 RM were maintained on ART only. The gene profile of CD4+ memory T-cell subsets was assessed longitudinally by RNAseq analyses. RM were sacrificed on ART following twelve weeks of PRI-724 treatment for assessment of SIV reservoirs.
Results: PRI-724 was well tolerated in both healthy and ART-treated SIV-infected RM, with blood counts, liver function, and renal function within normal limits. No alteration of tri-lineage hematopoiesis was observed in bone marrow. The transcriptomic profiling of genes associated with T-cell differentiation showed an increased expression of the EOMES transcription factor in the CD4+ T_{SCM} of PRI-treated animals as compared to controls. Moreover, Gene Set Enrichment Analyses showed that gene sets distinguishing effector versus memory were significantly enriched in the CD4+ T_{SCM} as compared to the naïve T-cells. Interestingly, this CD4+ T_{SCM} enrichment in effector-like genes was significantly higher in the PRI-treated than in the control RM. These results suggest an effect of PRI-724 on CD4+ T_{SCM} differentiation. PCR analyses in the sorted subsets of memory CD4+ T-cells showed no significant difference in cell-associated SIV DNA levels between PRI-724 treated and untreated RM.
Conclusions: This work provides novel support for the strategy of promoting CD4+ T_{SCM} differentiation by pharmacological modulation of the Wnt/beta-catenin pathway. However, combination strategies targeting stem cell pathways and/or additional anti-reservoir strategies are likely necessary to reduce SIV/HIV persistence.

WEAA0204

PBMCs from patients with chronic myeloid leukemia treated with different tyrosine kinase inhibitors show variable susceptibility to HIV-1 infection: searching for the best therapeutic approach

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Background: Tyrosine kinase inhibitors (TKIs) such as imatinib, nilotinib, dasatinib, bosutinib and ponatinib are currently used for treating chronic myeloid leukemia (CML). Imatinib was the first TKI introduced in clinical practice and is very selective of the chimeric fusion protein BCR-ABL responsible for causing CML. Second generation TKIs nilotinib, dasatinib and bosutinib are 20-, 300- and 200-fold more potent than imatinib against BCR-ABL, respectively. Third generation Ponatinib has been approved for patients resistant to other TKIs. Our group demonstrated that Dasatinib interferes with SAMHD1 phosphorylation, preserving its antiviral activity and avoiding HIV-1 retrotranscription and proviral integration. Therefore, using dasatinib as adjuvant of antiretroviral therapy in HIV-infected patients could reduce the formation of the viral reservoir. In this work, we evaluated which TKI would be the best choice for treating HIV-infected patients.
Methods: PBMCs isolated from 42 CML patients on treatment with imatinib, nilotinib, dasatinib, bosutinib or ponatinib and 44 healthy controls. All patients were treated for >2 years with normal TKI dose; they showed no HIV-1 infection, normal lymphocyte count and general good health.
Results: 1) IC_{50} for inhibiting HIV-1 replication was calculated in vitro for each TKI: imatinib IC_{50}=10μM; nilotinib IC_{50}=10μM; dasatinib IC_{50}=37.5nM; bosutinib IC_{50}=0.5μM; ponatinib IC_{50}=150nM. 2) Ex vivo infection of PBMCs from CML patients showed that imatinib, dasatinib and bosutinib effectively inhibited both early and late reverse transcription ($p< 0.001$). Ponatinib was also very effective but we only recruited one patient. 3) PBMCs from CML patients showed lower SAMHD1 phosphorylation after PHA/IL-2 treatment for 5 days ($p<0.0001$ for dasatinib; $p<0.01$ for bosutinib). 4) Proviral integration was inhibited after treatment with all TKIs, being dasatinib the most significant ($p<0.01$). 5) Synthesis of viral proteins was mostly significantly interfered by dasatinib ($p<0.0001$).
Conclusions: PBMCs from CML patients on chronic treatment with TKIs showed resistance to SAMHD1 phosphorylation after activation with PHA/IL-2. HIV-1 reverse transcription and proviral integration was reduced in these cells. Dasatinib was the most potent against HIV-1 replication, closely followed by ponatinib. Consequently, preserving SAMHD1 antiviral function with TKIs such as Dasatinib could reduce the reservoir size during HIV-1 acute infection.

WEAA0205

Eradication without reactivation: suppression of HIV-1 transcription and reactivation from latency by a Tat inhibitor

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Background: HIV persists in latently infected CD4+T cells in infected individuals even after prolonged periods on suppressive antiretroviral therapy (ART). Transcriptional reactivation from latency is not inhibited by current ART, highlighting the need for novel approaches.
The HIV-1 Tat protein exponentially activates viral transcription, and limited Tat-transactivation correlates with HIV-1 latency establishment. We identified didehydro-cortistatin A (dCA) as a potent Tat inhibitor. Over time, treatment of infected cells with dCA drives HIV-1 gene expression into an induced state of persistent latency, refractory to viral reactivation by a standard panel of latency reversing agents (LRAs), suggesting the HIV promoter is epigenetically repressed. We postulated a strategy for a functional cure, dubbed "block-and-lock", where a specific HIV-1 transcriptional inhibitor would promote a durable state of latency, reduce ongoing viral replication during ART, and inhibit spontaneous reactivation during ART or when ART is discontinued.
Methods: We will present our long-term studies of the activity of dCA in primary human CD4+T cells isolated from aviremic infected individuals, using an optimized approach that maintains cell cultures up to 10 weeks. To explore the in vivo efficacy of dCA we used the bone marrow-liver-thymus (BLT) humanized mouse model of HIV-1 latency.

We will also discuss epigenetic mechanisms regulating dCA induced deep latency in CD4+T memory T cells, as well as mechanisms of viral evasion to dCA.
Results: We demonstrate in CD4+T cells from five suppressed infected individuals that not only combining dCA with ART promotes faster HIV-1 suppression, but more importantly that prior treatment with dCA significantly reduces viral rebound up to 25 days of treatment interruption, even when viral reactivation is stimulated by LRAs.
In the BLT mouse model of latency, we demonstrate that adding dCA to ART suppressed mice, for a period of 14 days, results in a significant 1.5 to 10.5 fold reduction in viral RNA production in all tissues. Experiments assessing the ability of dCA to inhibit viral rebound upon treatment interruption are ongoing and will be presented.
Conclusions: In combination with ART, dCA abrogates residual HIV production from cellular reservoirs, blocks viral reactivation, and may ultimately reduce reservoir replenishment and latent reservoir size.

WEAA0206

Myeloablative conditioning is dispensable for transplant-dependent HIV cure

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Background: Over 10 years ago, hematopoietic stem cell transplant (HSCT) with infection-resistant CCR5Δ32 cells led to cure/remission of HIV infection and leukemia in the Berlin patient. HIV cure was likely a combined result of the conditioning regimen, an allogeneic „graft versus reservoir" effect, and the CCR5Δ32 donor cells. We studied the impact of conditioning and CCR5-edited cells in simian-human immunodeficiency virus (SHIV)-infected macaques suppressed by combination antiretroviral therapy (cART). The goal of this study was to identify the mechanisms by which each facet impacted the latent viral reservoir.
Methods: Pigtailed macaques were challenged with CCR5-tropic, HIV enveloped SHIV, and suppressed by cART following viral set point. In one cohort, autologous HSCT was performed with unmodified stem cells. In a second cohort, animals received CCR5-edited stem cells. Control animals were infected and suppressed, but did not undergo transplantation. Flow cytometry and ELISA were used to monitor changes in immune homeostasis, and quantitative PCR and viral reservoir assays were used to identify virologic changes between experimental and control animals.
Results: The conditioning regimen resulted in a dramatic, but incomplete depletion of CD4+, CD8+ T-cells and B-cells, disrupted T-cell homeostasis, elevated markers of microbial translocation, a significant loss of SHIV-specific antibodies, and increased viral rebound, relative to untransplanted controls. Although CCR5 editing did not reach threshold levels for post-cART control of viremia, correlates of protection were observed: quantitative viral outgrowth, Tat/Rev-induced limiting dilution, and tissue viremia assays showed that the size of SHIV reservoirs was impacted.
Conclusions: Our data identify perturbations of the immune system as a mechanism for the failure of autologous transplantation (without gene-protected cells) to eradicate HIV, highlighting the importance of an intact immune system for viral control after cART withdrawal. We conclude that reduced-intensity conditioning, which is safer and less toxic, should be a focus for transplant-based approaches. Analogous to cutting-edge therapies for cancer patients, next generation HIV cure strategies should balance killing of virus-infected target cells with retention of greater immune function, e.g. with immune modulators. High efficiency gene therapy/gene editing to protect transplanted cells and actively target the viral reservoir during ongoing cART will be essential.

WEAB01 Potpourri of Comorbidities

WEAB0101

Trends and predictors of non-communicable disease multi-morbidity among HIV-infected adults initiating ART in Brazil, 2003-2014

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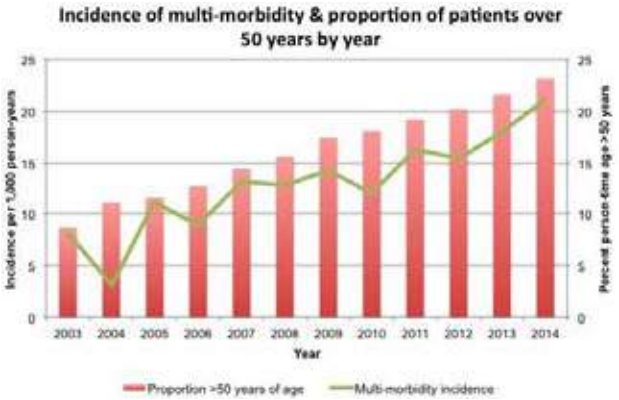
Background: HIV-infected adults on ART experience high rates of non-communicable diseases (NCDs). These co-morbidities can accumulate and older HIV-infected adults often suffer from multi-morbidity. Little is known of the burden of multi-morbidity in HIV-infected adults in low- and middle-income countries.
Methods: HIV-Brazil Cohort is an observational, multi-site study of HIV-infected adults initiating ART between 2003-2014. We studied NCDs and multi-morbidity in patients from seven clinical sites in six Brazilian cities. NCDs included coronary artery disease, cerebrovascular disease, high-grade hyperlipidemia (HLD), diabetes, chronic kidney disease, cirrhosis, osteoporosis, osteonecrosis, venous thromboembolism (VTE), and non-AIDS-defining cancers. Multi-morbidity was defined as the incident accumulation of two or more unique NCDs. We examined incidence trends using Poisson regression and predictors of multi-morbidity using competing risk and Cox regression models.
Results: Of the 5,786 adults included, 388 (7%) developed multi-morbidity during the study period. From 2003 to 2014, parallel to the rise of patients over the age of 50 in the cohort, the incidence of multi-morbidity rose to 21 patients per 1,000 person-years (Figure). HLD and VTE incidence decreased while diabetes and osteoporosis rates significantly increased from 2003-2014. In adjusted Cox models, female sex, age, and low CD4 nadir at baseline were significantly associated with risk of multi-morbidity (Table, also adjusting for education, race, year, hepatitis C). Among all patients with multi-morbidity, the most common NCDs were HLD (87%) and diabetes (59%); however, women with multi-morbidity were more likely to have osteoporosis than men (15.4 vs. 6.8%).



[Figure. Incidence of multi-morbidity & proportion of patients over 50 years by year]

	Adjusted Hazard Ratio [95% CI]	P value
Female sex (ref: male sex)	1.35 [1.06-1.70	0.014
CD4 cell count nadir at baseline (µ/L)		
>200	(ref)	
100-199	1.59 [1.18-2.13]	0.002
<100	1.77 [1.35-2.32]	<0.001

[Multivarbiable Cox proportional hazard model]

Conclusions: Multi-morbidity of NCDs increased from 2003-2014. Females were more likely to develop multi-morbidity in adjusted analyses. Further studies examining sex-specific screening, prevention and management of NCD co-morbidities in HIV-infected adults are needed.

WEAB0102

HIV infection and the risk of peripheral arterial disease

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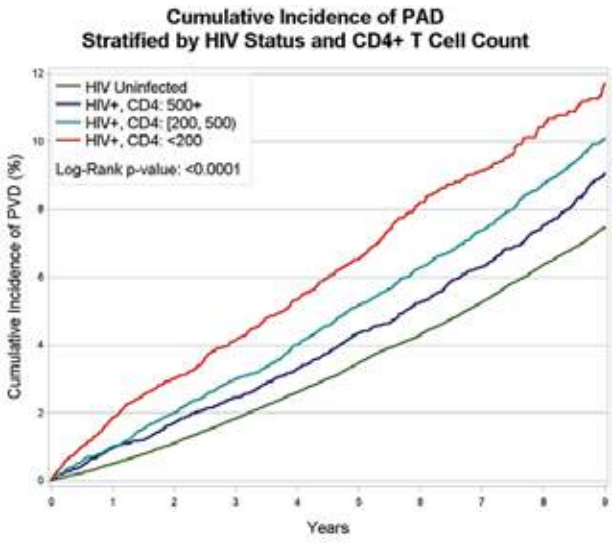
Background: Peripheral arterial disease (PAD) affects ~8 to 10 million U.S. adults annually and is the second most common clinical manifestation of atherosclerosis after acute myocardial infarction (AMI). While the increased risk of AMI and ischemic stroke among HIV infected (HIV+) compared to uninfected people is well documented, data linking HIV to incident PAD events are sparse. We, therefore, compared PAD risk among HIV+ and uninfected veterans.
Methods: We analyzed data on 91,457 veterans (33% HIV+) without prevalent cardiovascular disease from the Veterans Aging Cohort Study (VACS). VACS is an observational, longitudinal cohort of HIV+ veterans matched 1:2 with uninfected veterans on age, gender, race/ethnicity, and clinical site. Participants were followed from their first clinical encounter on or after 4/1/2003 until a PAD event, death, their last follow-up date, or 9/30/2012. We used ICD-9 and CPT codes to identify participants with incident PAD. Cox proportional hazard regression models were utilized to assess the association between HIV, CD4+ T cell count, and PAD adjusting for atherosclerotic risk factors (Table). Finally, we constructed cumulative incidence curves to examine PAD risk stratified by HIV status and CD4 + T cell count.
Results: During a median follow-up of 7 years, there were 5091 PAD events. See Table and Figure for rates and risk of PAD stratified by HIV status and CD4+ T cell count.

Group	N	PAD Events	Rate/1000PY 95% CI]	Unadjusted PAD Risk [HR 95% CI]	Adjusted PAD Risk [HR 95% CI]a
HIV Uninfected	61,498	3103	8 [7.8, 8.4]	1.00	1.00
HIV+, CD4: 500+	10,682	663	10 [9.4, 11.0]	1.23 [1.13, 1.34]	1.31 [1.20, 1.43]
HIV+, CD4: [200, 500)	12,368	835	11 [10.6, 12.1]	1.41 [1.31, 1.52]	1.46 [1.35, 1.59]
HIV+, CD4: <200	6909	490	14 [12.8, 15.3]	1.77 [1.60, 1.95]	1.62 [1.45, 1.80]
a adjusted for age, sex, race/ethnicity, hypertension, diabetes, LDL and HDL cholesterol, triglycerides, HCV infection, smoking status, renal disease, BMI, anemia, cocaine dependence or abuse, alcohol dependence or abuse, and COPD.					

[Rates and risk of PAD by HIV status and CD4+ T cel]



[Figure. Cumulative incidence of PAD stratified by HIV status and CD4+ T cell count]

Conclusions: Conclusions and Relevance: HIV+ veterans have a significantly higher risk of PAD than uninfected veterans.

WEAB0103

Impact of exposure to each antiretroviral treatment (ARV) on the risk of fracture in HIV-1-infected individuals: an analysis from FHDH ANRS CO4

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Background: HIV-infected patients have a lower bone mineral density (BMD) and a higher incidence of fractures compared to the general population of same age and sex. To assess the impact of exposure to each ARV on the risk of osteoporotic fractures, we conducted a nested case-control study.
Methods: Cases were individuals enrolled while ART-naïve, with a first prospectively reported fracture between 01/2000 and 12/2010. Controls were randomly selected after matching on sex, age (±3 years), diagnosis period (< 1997/≥1997) and clinical centre. The risk of fracture was analysed using conditional logistic regression models. Exposure to each ARV was measured either by cumulative duration of exposure (model1), or by exposure yes/no (model2). In a 3rd model, the exposure variable was chosen for each ARV according to the lowest Akaike criterion value. All exposure variables and potential confounders were included in the multivariable models.
Results: Among the 861 reviewed fractures, 261 were osteoporotic fractures, and 254 were matched to at least one control (376 controls). The median year of fracture diagnosis was 2007(IQR 2004-2009), 67% of cases were men, 71% diagnosed with HIV-infection before 1997, median age was 49 years, CD4 436[293-592], nadir CD4 196[82-287], 31% at AIDS-stage, 65% with VL< 50cp/mL, and 49% exposed to tenofovir, 82% to PIs and 37% to efavirenz.
After accounting for transmission group, AIDS-stage, geographic origin, BMI, current smoking, alcohol consumption, exposure to systemic glucocorticoids, and period of enrolment, no association was found between the risk of fracture and exposure to tenofovir (OR for cumulative exposure: 1.03[0.86-1.24], similar results for exposure yes/no), or to NRTIs, or to PIs (exposure to PI overall: OR 1.01[0.92-1.11] or to each PI). Cumulative exposure to efavirenz was associated with a lower risk of fracture in models 1 and 3 (respective OR 0.81[0.69-0.95] and 0.82[0.70-0.96] per year of exposure), while exposure to efavirenz (yes/no) was not (OR 0.84[0.51-1.40]). Sensitivity analyses do not favour the causal nature of the association with exposure to efavirenz.
Conclusions: There was no evidence of excess risk of fracture following exposure to tenofovir or to PIs. This is an important result in the debate about TAF versus generic tenofovir.

WEAB0104

Being HIV-1-infected is independently associated with decreased erectile function among older men who have sex with men

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Background: Several studies have reported that HIV-1-infected men who have sex with men (MSM) more often experience sexual dysfunction compared to HIV-1-uninfected MSM. HIV-1-infected individuals have a higher prevalence of non-communicable comorbidities, which may affect sexual health, compared to HIV-1-uninfected individuals. We assessed whether HIV-1 infection is independently associated with decreased sexual functioning among MSM aged 45 years and older.
Methods: Data from HIV-1-infected and HIV-1-uninfected MSM aged ≥45 years at the time of enrolment into the on-going AGE$_h$IV Cohort Study were used. The questionnaire included 3 questions (representing 3 sexual domains) on sexual functioning from the International Index of Erectile Function (IIEF), addressing erectile

function, sexual desire, and sexual satisfaction (scale 1-5, higher score represents better function). The 3 separate questions were dichotomised using a cut-off of ≤2. Three multivariable logistic regression models were constructed to investigate the association between HIV-1 infection and the 3 domains. Variables associated with both HIV-1 infection and one of the outcomes (at p<0.20) were included in all 3 multivariable models. We explored HIV-1- and ART-related variables in the established multivariable models including only HIV-1-infected individuals.
Results: In total, 399 HIV-1-infected and 366 HIV-1-uninfected MSM were included in the analyses. Decreased erectile function (13.0% vs. 3.4%, p<0.001), decreased sexual desire (7.0% vs. 3.6% p=0.033), and decreased sexual satisfaction (17.8% vs. 11.8%, p=0.019) were more prevalent among HIV-1-infected MSM compared to HIV-1-uninfected MSM. In multivariable logistic regression models including age, ethnicity, waist-to-hip ratio, noncommunicable comorbidities, depression, frailty, use of antidepressants, and antihypertensive medication, HIV-1 infection was independently associated with decreased erectile function (adjusted odds ratio (aOR) 2.53, 95%CI 1.23-5.21), but not with decreased sexual desire (aOR 1.78, 95%CI 0.81-3.92), and decreased sexual satisfaction (aOR 1.35, 95%CI 0.84-2.17). Among HIV-1-infected participants, previous (aOR 3.20, 95%CI 1.52-6.75) and current (aOR 4.71, 95%CI 1.90-11.71) use of lopinavir were independently associated with decreased erectile function.
Conclusions: Among MSM aged ≥45 years, being HIV-1-infected was independently associated with decreased erectile function. Exposure to lopinavir appeared to be an independent risk factor for decreased erectile function. No independent association between HIV-1 infection and decreased sexual desire or decreased sexual satisfaction was observed.

WEAB0105

SHIV infection and drug transporters influence brain tissue concentrations of efavirenz

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Background: Despite antiretroviral (ARV) therapy, there is a high prevalence of HIV-associated neurocognitive disorder (HAND) in HIV-infected individuals. Using CSF data, it has been theorized that inadequate ARV concentrations may contribute. However, information on brain tissue concentrations is sparse. This study compared the concentration of ARVs in four regions of brain tissue with CSF in uninfected and SHIV-infected rhesus macaques.
Methods: In 12 male macaques (6 uninfected; 6 SHIV-infected) dosed to steady-state condition, concentrations of 6 ARVs - tenofovir (TFV), emtricitabine (FTC), efavirenz (EFV), raltegravir (RAL), maraviroc (MVC) and atazanavir (ATZ) were measured by LC-MS/MS in the CSF (LLOQ=0.5 ng/mL) and cerebrum, cerebellum, basal ganglia and parietal cortex regions of the brain (LLOQ of homogenate ranged from 0.002-0.01 ng/mL). Tissue concentrations were converted to ng/g using density of 1.06. To assess the influence of drug transporters on ARV concentration, brain tissue was analyzed for Pgp and BCRP efflux transporter proteins by LC-MS proteomics (LLOQ=0.1 pMol/mg protein). Data are presented as median (range); statistical analysis was by Kruskal-Wallis test.
Results:

	CSF concentration (ng/ml)		Brain tissue concentration (ng/g)	
	Uninfected	Infected	Uninfected	Infected
TFV	0.8 (0.0, 4.6)	2.2 (1.5, 3.0)	55.0 (47.1, 392.1)	34.9 (22.7, 65.1)
FTC	2.1 (0.0, 11.7)	5.7 (3.9, 7.3)	29.9 (19.5, 85.8)	28.4 (14.8, 33.6)
EFV	2.1 (1.4, 3.4)	0.5 (0.5, 1.4)	1615.2 (965.2, 1983.0)	391.6 (239.8, 792.3)
RAL	1.2 (0.6, 1.3)	0.5 (0.5, 0.5)	27.7 (15.8, 78.3)	14.7 (9.7, 21.8)
MVC	2.9 (0.5, 11.1)	0.0 (0.0, 0.0)	57.5 (21.9, 193.0)	48.7 (34.8, 104.8)
ATZ	0.5 (0.0, 40.5)	0.5 (0.5, 0.5)	84.1 (49.7, 554.1)	133.1 (59.4, 138.0)

[Concentration of ARVs in brain and CSF]

CSF concentrations did not differ by infection status (p>0.1). Since there was no difference in ARV concentration in the various regions of the brain (p>0.1), these data were combined. Concentrations in brain tissue were significantly greater than CSF for TFV, FTC and EFV: ranging from 5-times (FTC) to 769-times (EFV) higher. Brain tissue concentration of EFV was 4.1 times higher in uninfected animals. BCRP concentration was 1.7 times higher in infected animals (p=0.02); Pgp concentration did not differ with infection status (p=0.06).
Conclusions: In this study, brain tissue concentration of EFV was 4-fold lower in infected macaques and this may be due to increased BCRP concentrations. Further, we have shown that ARV CSF concentrations may need cautious interpretation when used as surrogate for brain tissue exposure. Based on these data, further investigations are needed to determine how ARV brain tissue concentrations influence HAND prevalence.

WEAC01 PrEP Expectations and Experiences

WEAC0101

Barriers to uptake of pre-exposure prophylaxis among respondents to the Flash! PrEP in Europe survey

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Background: Pre-exposure prophylaxis (PrEP) has been shown to effectively reduce HIV infection risk and is recommended by the World Health Organisation (2015) and the European AIDS Clinical Society (2015). As of January 2017, only two European countries, France and Norway, have authorized prescription and reimbursement of PrEP. In this analysis we identify potential barriers to PrEP uptake across Europe.
Methods: The Flash! PrEP in Europe (FPIE) online survey was a community-based research study aiming to assess interest in and barriers to PrEP uptake amongst respondents from 11 European countries. Data was collected from June to July 2016. Respondents were ≥18 years old and self-reported HIV-negative or unaware of their serological status. A 5-point Likert scale was used to assess potential PrEP uptake barriers, responses were dichotomized (Yes, probably/ Yes, definitely vs Maybe/ No, probably/ No, definitely). To assess barriers amongst different groups, and due to high response rate from Germany, four groups were analyzed separately: German men (GM), other European men (OEM), women and transgender men and women (TMW).
Results: Of 15 461 respondents, there were 10 288 GM, 4201 OEM, 690 women, 245 TMW and 37 did not provide gender information. Among the 10 833 (72.7%) respondents potentially interested in PrEP, the greatest potential barriers were fear of side effects (GM: 53.6%, OEM: 39.0%, women: 55.8%, TMW: 40.0%) and necessary hospital visits for PrEP (GM: 49.1%, OEM: 27.3%, women: 33.0%, TMW: 35.7%). Among respondents not interested in PrEP, a majority (>64% in each group) did not want to take PrEP daily, feared side effects or did not feel the need to change their protection strategy. Fear of getting other sexually transmitted infections (STI) was also predominant particularly among GM (72.8%).
Conclusions: FPIE results highlight high interest but widespread knowledge gaps in relation to PrEP use among potential users. Improved communication on PrEP, including regular STI testing, follow-up for side effects, possibility of event-driven regimen and facilitating PrEP access, may help address some barriers. Better understanding of PrEP uptake barriers may help inform public health policies which meet the needs of at-risk populations.

WEAC0102

Preferences regarding emerging HIV prevention technologies among Toronto men who have sex with men

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Background: New HIV prevention technologies (NPTs) currently in development include long-acting injectables and topical microbicides, and have unique attributes that may appeal differently to different users. We used a discrete choice experiment (DCE), in which participants' choices between hypothetical alternatives are used to infer preferences for attributes, to characterize NPT preferences among men who have sex with men (MSM) in Toronto, Canada.
Methods: MSM undergoing anonymous HIV testing completed a DCE with 12 ‚choice sets' by selecting their preferred option within each set. Each set included "usual methods to prevent HIV infection" (excluding pre-exposure prophylaxis) as

one option and two hypothetical NPT options which differed according to HIV prevention efficacy (50%, 65%, 80% or 99% risk reduction), route of administration, side effects (none or mild), and risk of drug resistance (none, low, or moderate). We used mixed logistic regression to infer relative preferences for NPT attributes and latent class analysis to determine patterns of responses.
Results: Of 306 participants, 54% were White and median (IQR) age was 30 (25, 38). Participants reported 6 (3, 10) partners and 0 (0, 2) condomless receptive anal sex-acts in the preceding six months. Most had heard of post-exposure prophylaxis (80%) and pre-exposure prophylaxis (91%), but only 11% and 5% respectively had used them. We excluded 40 participants who had all missing data or gave invariant responses. An on-demand pill was the most preferred NPT, followed by a daily pill, monthly injection and on-demand rectal gel. Resistance was an important determinant of NPT preference if the risk was moderate, but not if low. The minimum NPT efficacy required for an on-demand pill to be preferred over usual methods was 52.8% (95%CI=46.9-58.7); for a daily pill, injections, and rectal gel, estimates were 60.1% (95%CI=53.8-66.5), 67.0% (95%CI=61.0-73.0), and 78.3% (95%CI=70.9-85.7), respectively. Latent class analysis identified one subset of participants clearly favouring on-demand PrEP (40.5%), and three others preferring usual methods but with an aversion to injections (20.7%), aversion to rectal gels (21.9%), or relative indifference to NPTs (16.9%).
Conclusions: Attitudes towards NPTs among MSM are heterogeneous. Understanding these preferences and aversions may help predict NPT uptake.

WEAC0103

"Early adopters" of PrEP in SEARCH study in rural Kenya and Uganda

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Background: PrEP is now recommended for high-risk persons in Africa. There are limited data on PrEP uptake in Africa outside of clinical efficacy trials. "Early adopters" can provide insights for program strengthening. We report on early PrEP adopters in SEARCH (NCT01864603), an ongoing population-based combination prevention study of 320,000 persons in rural Uganda and Kenya.
Methods: Following mobilization and community education, 2 groups were offered PrEP: i)HIV-uninfected adults at high risk (R) based an HIV risk score that maximized observed seroconversion coverage under a minimized number of persons needed to treat and ii)those who perceived themselves at risk (S) including being in serodiscordant relationship. "Early adopters" were defined as those who started PrEP within 30 days of being offered. To estimate predictor coefficients for early PrEP uptake, we used generalized linear models with binomial distribution.
Results: Of 24,709 HIV-uninfected individuals in six communities, 4622 were identified for PrEP; 2995 based on risk score(Rs) and 1627 as self-referrals(Ss). 2374(51%) scheduled an appointment with 946(20%) initiating PrEP; 916(97%) of these were "early adopters" with a vast majority 712(78%) starting PrEP on the same day. "Early adopters" tended to be Ss (64%), women (52%) and married (68%). Youth accounted for only 29% of "early adopters." Predictors of PrEP uptake among Rs were older age (ref: 18-25, age 36-45 OR 1.6, 95% CI 1.0-2.5, age 46-55 OR 2.1,95%CI 1.2-3.9), polygamy (OR 1.9,95%CI 1.3-2.7), serodiscordant spouse (OR 4.3,95%CI 1.6-11.5), no history of recent migration (ref: 0 months, 1-6 months OR 0.6, 95% CI 0.4-1.0 >6months OR 0.3, 95%CI 0.2-0.7), perceived current risk of HIV (OR 2.2, 95%CI 1.8-2.8). Among Ss, predictors were gender (male vs female OR 0.7,95%CI 0.6-0.9), age >=26(ref: 18-25, age 26-35 OR 1.4,95%CI 1.1-1.9, age 36-45 OR 1.8,95%CI 1.4-2.5, age 46-55 OR 2.4,95%CI 1.7-3.4, age>55 OR 2.0 95%CI 1.3-3.2) and a serodiscordant spouse (OR 2.5, 95%CI 1.0-6.1).
Conclusions: Among the 916 PrEP "early adopters", most started the same day as offered, two-thirds were married and perceived themselves as high-risk. Low participation among certain crucial groups such as youth (18-25 years) emphasizes the need for more effective mobilization.

WEAC0104

Health systems and study design features permitting rapid enrolment of individuals at high-risk of HIV acquisition into a pre-exposure prophylaxis study in Melbourne, Victoria, Australia

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Background: Australia's Medicare system provides clinicians fee-for-service and residents receive free or low-cost health care. Australia's Pharmaceutical Benefits Scheme (PBS) subsidises medication costs. Tenofovir/Emtricitabine (TDF/FTC) is registered in Australia for HIV pre-exposure prophylaxis (PrEP) but is not PBS subsidised, hence individuals must import generic TDF/FTC or pay A$800 monthly. In 2016 we implemented a 2,600-person PrEP demonstration study in Victoria, hypothesising a resultant 33% decline in new HIV infections in men who have sex with men (MSM). We describe the health systems and processes that facilitated rapid study enrolment and concomitant increases in HIV and sexually transmitted infection (STI) testing.
Methods: Victoria's population is approximately 6 million, including an estimated 37,000 HIV negative, sexually active MSM. From January 2016, individuals registered study interest online and nominated which of seven study clinics in Melbourne they would attend, whether they already attended that clinic and whether they were currently using PrEP. At study commencement, on July 26, 2016, 2,198 individuals had registered interest. Key community stakeholders, study clinics, and retail pharmacies were engaged in the study design and service system planning. Clinics were incentivised with A$100/participant, or a study nurse. Australian PrEP guidelines' specified eligible individuals at high risk. Participants were enrolled electronically. HIV/STI test results were extracted automatically using a sentinel surveillance system (ACCESS), extant in five clinics. We report HIV and syphilis testing rates in three of seven clinics across five-month pre-intervention (26/07/2015-26/12/2015) and PrEP-intervention (26/07/2016-26/12/2016) periods.
Results: 1,000 participants were enrolled within 21 days of the study commencing, and one in three participants were using PrEP; 2,350 participants were enrolled in six months. Six clinics chose the A$100 payment per patient. HIV tests increased from 3,009 to 4,952 and syphilis tests increased from 2,926 to 4,704 compared to the same five-month period in 2015, respectively.
Conclusions: In a free healthcare system that provides clinicians fee-for-service, rapid enrolment into PrEP programs appears feasible. A detailed registry of interest, prior use of PrEP, clinic remuneration, electronic enrolment and data extraction and collaborative planning were features of the study's rapid enrolment rate. A substantial rise in HIV and syphilis testing accompanied the study rollout.

WEAC0105

Self-report and medication possession ratio are accurate measures of HIV pre-exposure prophylaxis use in a real-world clinical setting

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Background: Oral, daily pre-exposure prophylaxis (PrEP) prevents HIV acquisition in optimally adherent men who have sex with men (MSM). Given the importance of adherence in PrEP-related outcomes, accurately and affordably monitoring adherence is a priority during implementation. We evaluated two low-burden measurements, self-report (SR) and medication possession ratio (MPR), for concordance with the well-established method of determining tenofovir diphosphate (TFV-DP) levels in dried blood spot (DBS).
Methods:
We reviewed behavioral and DBS data on patients presenting to the Washington University in St. Louis (USA) PrEP Clinic between November 2015 and August 2016. Optimal adherence was defined as TFV-DP ≥700 fmol/punch and was compared to patient 7-day SR and 3-month MPR using pharmacy refill data. Sensitivity, specificity, and negative and positive predictive value (NPV, PPV) for SR and MPR in relation to DBS were calculated.
Results: From 88 MSM, 137 DBS TFV-DP levels were analyzed. Their median age was 27 years; 58% were White, 30% Black, 6% Latino; 69% graduated college; and 71% reported condomless receptive anal sex in the last 3 months. Ten patients had a DBS < 700 fmol/punch. Drug concentration was not related to demography and did not significantly decline over time. By SR, 5 patients took < 4 doses/week, 4 of whom had sub-optimal DBS (NPV 80%), and of the 83 reporting ≥4 doses/week, 77 had optimal DBS (PPV 93%), resulting in 99% sensitivity and 40% specificity. For MPR, 3 patients had a MPR < 0.60 (indicating < 4 doses/week), all of whom had sub-optimal DBS (NPV 100%), and of the 84 with MPR ≥0.60, 77 had optimal DBS (PPV 92%), resulting in 100% sensitivity and 30% specificity. MPR and SR correlated with DBS TFV-DP levels (r=0.55, P< 0.001; r=0.48, P< 0.001). More stringent cut-offs to the strategies produced higher specificity- 60% for SR ≥6 doses/week and 70% for MPR at 0.70.
Conclusions: In a real-world clinical setting, SR and MPR correlated with optimal DBS concentrations despite different measurement windows (past 7, 30, 90 days). Specificity in this sample was improved when more stringent SR and MPR cut-offs were used. Results provide evidence for using low-burden measurements for PrEP adherence monitoring.

WEAC02 PMTCT: We Must Do Better

WEAC0201

Raltegravir vs Lopinavir/r for late-presenters pregnant women

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Background: Late-presenters pregnant women need aggressive antiretroviral therapy to reach a plasma viral load (PVL) <50 copies/ml before delivering. We compared the safety and efficacy of LPV/r and Raltegravir (RAL) in decreasing PVL in late-presenters pregnant women in Salvador, Brazil.
Methods: in this open-label, pilot trial (N=40), we included drug-naïve pregnant women who started antiretroviral therapy (ART) at a gestational age ≥ 28 weeks. They were randomly assigned to receive AZT+3TC+LPV/r or AZT+3TC+RAL. We measured time to reach undetectable PVL, and compared the proportion of women with PVL< 50 copies/ml at delivery, in each group. PVL was measured weekly by Real Time PCR, up to delivery. Frequency of side effects and MTCT rate were assessed. Babies were tested for HIV-1 plasma RNA at 4 weeks of age.
Results: we already enrolled 28 women (14/arm). Groups were comparable for age, education, smoking/alcohol use, number of previous gestations/miscarriages. Most (73%) were black/racially mixed, and single (82%). Twenty-five women already completed the trial. Median baseline PVL was similar for LPV/r (4.26 log_{10}, IQR: 4.02-4.04) and RAL (4.05 log_{10}, IQR: 3.55-4.31) groups, as well as mean gestational age (32.8 ± 11.4 vs 32.9 ± 10.4 weeks, respectively). At delivery, only 1/11 (9%; 95%CI:0.5-37%) women in group LPV/r had PVL< 40 cps/ml, compared with 9/14 (62%; 95%CI:38-86%) in RAL group (p=0.01). The median time to reach undetectable PVL was significantly shorter for RAL (44 days) in comparison with LPV/r arm (69 days, p=0.009). In RAL arm, 2 (14%) patients reached PVL <50 cps/ml at week 1, and 3 (21%) at week 2 of ART. In contrast, in LPV/r arm the first PVL< 50 copies/ml was reached only after 6 weeks of therapy. More gastrointestinal adverse events were observed in LPV/r arm (5/11) than in RAL one (1/14). No case of MTCT was detected.
Conclusions: use of RAL was associated with significantly higher rate of undetectable PVL at delivery and lower incidence of adverse events, in comparison with LPV/r. Time to reach undetectable PVL was significantly shorter in RAL group. RAL should be the preferential option to treat late-presenters pregnant women, to minimize the risk of HIV-1 MTCT.

WEAC0202

Intensification of antiretroviral treatment with raltegravir for late-presenting HIV-infected pregnant women

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Background: The risk of HIV perinatal transmission in HIV-infected pregnant women who are started late on antiretroviral therapy during the third trimester is estimated to be up to 6-10%. Raltegravir, HIV integrase inhibitor, has rapid viral reduction and is recommended by the British HIV Association (BHIVA) guideline for late-presenting HIV-positive pregnant women. This study aims to describe HIV perinatal transmission from high-risk HIV-positive pregnant women who have received raltegravir intensification antiretroviral treatment.
Methods: A prospective cohort study was conducted at the Thai Red Cross AIDS Research Centre. Inclusion criteria were HIV-positive pregnant women with high-risk of HIV vertical transmission defined as (1) Having been started on antiretroviral therapy (ART) at gestational age (GA) ≥32 weeks or (2) Having received ART but having HIV-RNA >1,000 copies/ml at GA 32-38 weeks. Pregnant women received standard 3-drug ART regimen plus raltegravir 400 mg twice daily until delivery and then were continued on 3-drug ART after delivery. Plasma HIV-RNA was performed before adding raltegravir and at time of delivery. The HIV status of infant was determined by HIV-DNA PCR at birth, 1, 2 and 4 months.
Results: From January to December 2016, 57 pregnant women were enrolled. Median CD4 count was 307 cell/mm^3(IQR 155-507). Median plasma HIV-RNA before initiation of raltegravir was 3.6 log_{10}copies/ml (IQR 2.9-4.3). Median GA at time of starting raltegravir was 35 weeks (IQR 33-37). Combinations of ART were 32 EFV-based (56%), 21 LPV/r-based (37%), and 4 others (7%). Median duration of raltegravir was 18 days (IQR 7-28). The proportion of pregnant women who had plasma HIV-RNA < 50 and < 1,000 copies/ml at time of delivery were 47% and 81%, respectively. To date 50 infants were born, 40% by cesarean section and 8% preterm (GA < 37 weeks). HIV perinatal transmission rate was 0% (95%CI 0-6.3). No rash, hepatitis and jaundice in mothers or infants has been reported.
Conclusions: No HIV vertical transmission occurred among high-risk HIV pregnant women who received raltegravir intensification ART. This strategy is feasible and effective, supporting elimination of HIV mother to child transmission.

WEAC0203

Spatial-temporal trend of mother to child HIV transmission in western Kenya, 2007-2013

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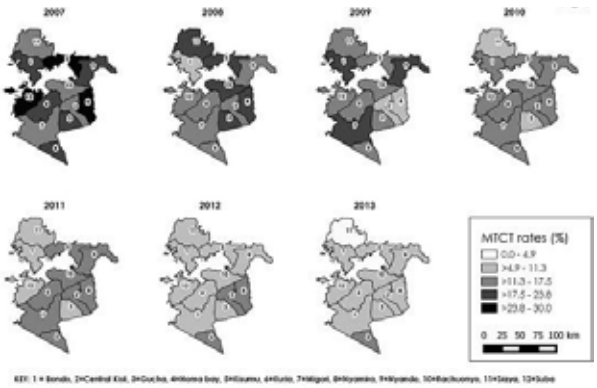
Background: Using spatial-temporal analyses to understand coverage and trends in elimination of mother to child transmission of HIV (e-MTCT) may be helpful in understanding effectiveness of interventions while refocusing e-MTCT programs efforts to the right places to achieve epidemic control. We measured MTCT rates using early infant diagnosis (EID) program data collected from January 2007 to November 2013 in Western Kenya; and assessed associated HIV transmission risk factors within a spatial context irrespective of treatment guideline changes.
Methods: We performed trend analysis for 102,116 HIV-exposed infants (HEIs) using extended Cochran-Mantel-Haenszel stratified test and logistic regression models to determine associations of infant HIV status with maternal and infant characteristics recorded on EID laboratory test request forms. We fitted spatial and spatial-temporal semi-parametric Poisson regression models with infant and maternal covariates to explain MTCT rates. We used R-Integrated Nested Laplace Approximation (INLA) package and Quantum GIS to map raw and fitted estimates.
Results: Median age of HEIs was 2 months, interquartile range (IQR) 1.5 to 6 months. Pooled positivity was 11.8% in the 7-year period, which significantly, spatial-temporarily declined from 17.9% in 2007 to 8.4% in 2013, p< 0.001(Figure 1). Uptake of polymerase chain reaction (PCR) HIV testing ≤8 weeks after birth was under 40% in 2007 and increased to 60% by 2013. A spatial-temporal model with covariates was better in explaining geographical variation in MTCT (deviance information criterion (DIC 296)) than either a non-temporal spatial model (DIC 326) or temporal model without covariates
(DIC 311).
Conclusions: Improved EID uptake and reduced MTCT rates are indicators of success of the e-MTCT program in this low-resource setting. Adding both time and covariates in spatial-temporal analysis provides a robust approach for explaining programmatic impact over time. Geographical disparities in program achievements may signify gaps in spatial distribution of e-MTCT efforts, and indicate areas needing further resources and intervention.



[Fig 1: Spatial-temporal trend of fitted MTCT (%)]

WEAC0204

Cost and cost-effectiveness analysis of a randomized controlled trial evaluating perinatal home visiting among South African mothers/infants

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Background: South Africa faces a high antenatal HIV prevalence and infant mortality rate. Community-based programs involving home visits contribute to reductions in neonatal mortality. However, most low and middle-income countries lack the budget to deliver such preventive interventions by nurses. Therefore, paraprofessional interventionists may be an innovative alternative strategy to healthcare workers. This study assesses the costs and benefits of implementing a home visiting program utilizing community health workers (CHW).
Methods: We conducted an economic evaluation alongside a cluster RCT in Cape Town, South Africa, called Philani+. The trial assessed the impacts of training CHWs to deliver antenatal and postnatal home visits to address maternal and child health risks. Financial costs were collected from the perspective of the health system. We calculated ICERs by dividing the costs of the intervention by the number of low birth weight newborns and cases of infant undernutrition averted among intervention participants compared with controls. These measures are strong indicators of maternal and newborn health. Numbers of averted cases were modelled as the product of intervention subjects and differences in the rates of adverse outcomes between intervention and control groups.
Results: The total cost of the intervention over 24 months was estimated at US$91,574. The average cost of supporting 12 CHWs was $7,631 per CHW and the cost per mother was US$142. The intervention group had higher HIV treatment adherence and longer breastfeeding duration. The intervention was associated with averting an estimated 55 (90% CI: 41-74) cases of low birth weight and 59 (90% CI: 42-83) cases of undernutrition. The estimated cost per low birth weight averted was $1,664 and the estimated cost of averting an undernourished child was US$1,552.
Conclusions: Philani+ was innovative because it integrated HIV care and prevention with activities to improve maternal and child health. The employment of CHWs provides cost savings compared to use of nurses; and builds capacity in a country with a high unemployment rate and shortage of healthcare workers. Finally, Philani+ was able to improve child health at a relatively low cost considering the costs to the health system caused by low birth weight and undernutrition.

WEAC0205

A community-based, household survey to determine mother to child HIV transmission rates and HIV-free survival in Swaziland

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Background: The Joint United Nations Programme on HIV/AIDS (UNAIDS) renewed efforts to virtually eliminate mother-to-child HIV transmission (MTCT) with a target of reducing the mother-to-child transmission rate to 5% or less among breastfeeding populations by breastfeeding cessation, and to 2% or less among non-breastfeeding populations. In Swaziland, although data are available on MTCT rates at six weeks, no study has been performed to determine MTCT and HIV-free survival through the end of breastfeeding.
Methods: The Elizabeth Glaser Pediatric AIDS Foundation performed a national, cross-sectional study of children born 18-24 months prior to the study launch among HIV-infected mothers to determine MTCT rates and HIV-free survival through a community survey in randomly selected constituencies in all four regions of Swaziland. At the time of this cohort's birth, Swaziland had been implementing World Health Organization Option A for prevention of MTCT (PMTCT). We also evaluated the relationship between both maternal and child characteristics and child infection or death.
Results: Most HIV-positive mothers (91.8%) received antiretroviral prophylaxis for PMTCT or antiretroviral treatment during pregnancy. Among 724 known HIV-exposed children between 18 and 24 months, 26 children were HIV-positive and 694 were HIV-negative and alive. Four (all with unknown HIV status at time of death) HIV-exposed children died by 24 months of birth. The overall 18-24-month HIV-free survival among this cohort was 95.9% [95% CI: 94.1-97.2]. At 18-24 months, the estimated proportion of HIV-positive children among known HIV-exposed children was 3.6% [95% CI: 2.4-5.2]. Older maternal age, delivering in a health facility, high maternal CD4 count and receiving antenatal antiretroviral drugs were associated with reduced risk of child infection or death. Child hospitalization was associated with higher rates of child HIV infection or death.
Conclusions: The Swaziland PMTCT program under Option A was largely effective with a high HIV-free survival of 95.9% and low MTCT at 18-24 months of 3.6%. This would be expected to improve further under current Option B+ (universal maternal antiretroviral therapy).

WEAD01 Care for Kids

WEAD0101

Trends in pediatric HIV testing across six African countries

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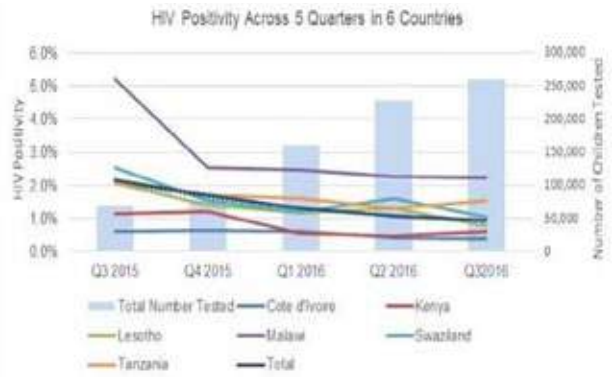
Background: Improving the identification of HIV-positive children is integral to increasing the number of HIV-positive children on lifesaving treatment; however, there is limited current data on the yield of intensified pediatric HIV case finding approaches. Between July 2015 and September 2016, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) scaled-up intensified pediatric HIV case finding in facility and community-based service delivery points (SDP) in six countries (Cote d'Ivoire, Kenya, Lesotho, Malawi, Swaziland, Tanzania). Through this initiative, 791,851 children, aged 0-14, were tested.
Methods: We conducted a descriptive analysis of aggregate pediatric HIV testing data from the six countries to identify cross-country trends in HIV-positivity, including data disaggregated by age group and SDPs, where available.
Results: From July 2015 to September 2016, the number of children tested for HIV and identified as HIV-positive increased by 275% and 60%, respectively. Total HIV-positivity decreased from 2.2% in Q3/2015 to 0.9% in Q3/2016. In Kenya, where SDP disaggregated data is available, outpatient departments (OPDs) represented 63% of children tested and 62% of HIV-positive children identified (0.8% positivity). TB clinics, malnutrition wards, and MNCH services had higher positivity (10.2%, 1.9% and 1.4% respectively). The proportion of HIV-positive children identified in those services was lower than OPD (3%, 2%, and 10%, respectively).



[Pediatric HIV Positivity in 6 Countries]

Conclusions: The rate of HIV-positivity in most countries remained relatively stable, although there was large decrease between Q3 2015 and Q4 2015 in Malawi. Intensified pediatric HIV testing dramatically increased the numbers tested and identified 9,688 HIV-positive children. Overall HIV positivity was relatively low, likely due to effective PMTCT programs in these countries combined with mortality among undiagnosed older children. Testing of higher-risk children (e.g., TB clinics, malnutrition wards, risk-screening in OPDs) as opposed to broad testing, may be a more effective way to identify HIV-positive children in an era of maternal treatment.

WEAD0102

Evaluation of the impact of the accelerating children's HIV/AIDS treatment (ACT) initiative on pediatric and adolescent HIV testing and yield in Western Kenya

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Background: Despite declining new infections, pediatric HIV remains significant, with 150,000 new infections annually and 1.8 million children (< 15 years old) living with HIV globally. We examined whether activities under the Accelerating Children's HIV/AIDS Treatment (ACT) initiative increased testing and identification of children with HIV.
Methods: Family AIDS Care and Education Services (FACES) implemented activities under the ACT initiative in 144 health facilities in western Kenya between October 2015 and September 2016. Interventions targeting pediatric testing included: provision of HIV-testing counselors; renovation/allocation of space for HIV testing and counseling (HTC space); use of a Family Information Table (FIT) and FIT chart audits; community outreach testing; and text message reminders for HIV-exposed infants. We compared the number of children tested monthly and the number of HIV-positive children between intervention and control sites using negative binomial generalized estimating equations. Analyses adjusted for repeated measures, geographic location, health facility tier, and test kit stock-outs.
Results: Mean number of children tested monthly increased across all age groups: From 2.8 to 7.2 ($p<0.0001$) in infants <18 months; from 44.8 to 142.0 ($p<0.0001$) in children 18 months to 9 years; and from 30.1 to 123.3 ($p<0.0001$) in adolescents 10-14 years. Identification of HIV-positive children increased: 0.06 to 0.37 (per month per facility; $p<0.0001$) in infants;0.34 to 0.62 ($p=.002$) in children; and 0.17 to 0.26 ($p=.03$) in adolescents.Use of the FIT was significantly associated with increased HIV testing in infants, incidence rate ratio (IRR)=2.89 (95% confidence interval [CI]=1.53,5.49; $p\leq0.001$) and identification of HIV-positive infants, IRR=8.71 (95% CI=1.45,52.4; $p\leq0.02$). Among children, FIT chart audits were significantly associated with increased testing, IRR=2.15 (95% CI=1.36,3.40; $p\leq0.001$). Among adolescents, HTC space was significantly associated with increased HIV testing, IRR=1.45 (95% CI=1.09,1.93; $p\leq0.01$).
Conclusions: Targeted testing of family members of HIV-positive adults increased both testing and identification of HIV-positive children. Our findings suggest that the one-time investment in improving HTC space may be an effective approach for increasing HIV-testing among adolescents in this context. Significant increases in number of children tested resulted in only a modest number of new children identified with HIV, highlighting the need for multiple testing approaches.

WEAD0103

Disclosure of HIV status to children living with HIV in Malawi: needs assessment and formative evaluation of an intervention intended to help with the disclosure process

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Background: Approximately 10% of people living with HIV in Malawi are children under the age of 15 years. While the World Health Organisation recommends that disclosure of HIV status should take place between the ages of 6 to 12 years, very little is known about the practice of HIV disclosure in Malawi. This study aimed to evaluate the current practice of HIV disclosure to Malawian children and to assess the acceptability of a series of age-appropriate, culturally acceptable story books intended to help with the disclosure process
Methods: Questionnaires, interviews, and focus group discussions were used to collect data from caregivers, healthcare workers, school teachers, adolescents living with HIV, and community leaders across the three administrative regions of Malawi. Data on disclosure of HIV to the child, reasons for non-disclosure, the need and acceptability of the proposed series of story books, the child's mental health, and the family psychosocial characteristics were collected using reliable instruments. Data were analysed using chi-square test, multiple logistic regression, and thematic analysis.
Results: The response rate was 99 per cent: 600 questionnaires, 19 interviews, and 12 focus groups were completed. The prevalence of non-disclosure was 64 per cent. Non-disclosure of HIV status was more likely for younger children (aOR 3.8; 95% CI: 2.1-6.8), those in a farming family (aOR 3.495% CI: 1.2-9.3), and those whose healthcare workers lacked training about disclosure (aOR 7.7; 95% CI: 3.4-11.6). The lack of disclosure guidelines and materials (33%), the child's capacity to cope with the diagnosis (29%), and a lack of confidence to disclose appropriately (19%) were cited as the main reasons for non-disclosure. Ninety-eight per cent of participants supported the idea of developing the proposed series of story books. More than three-quarters of the participants emphasized the need for all stakeholders involved in caring for children living with HIV to work together towards promoting effective HIV disclosure.
Conclusions: The rate of non-disclosure in Malawi is high. The results of this study support the need for the development and rigorous evaluation of disclosure materials and the involvement of all stakeholders to promote effective disclosure and meet the evolving needs of children.

WEAD0104

An assessment of the effectiveness of reaching undiagnosed HIV+ children through community-based testing in Lesotho

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Background: All health facilities in Lesotho offer free, provider-initiated HIV testing and counseling (PITC) and treatment, and the country adopted the WHO-recommended "Treat All" policy in 2016. However, the antiretroviral treatment coverage for children, 0-14 years, is less than 60%, suggesting many children are not regularly accessing services at facilities. Recognizing that testing is the critical first step in initiating HIV+ children to lifesaving treatment, community-based PITC strategies were piloted to understand the effectiveness of identifying undiagnosed children in Lesotho beyond the facility.
Methods: From December 2015 - December 2016, four community-based strategies were utilized: 1) mobile outreach clinics; 2) door-to-door testing; 3) household-based index patient testing; 4) targeted testing events conducted at venues thought to have high-risk children. A mobile application was designed for use by healthcare workers for real-time data collection at point-of-care to capture data on newly identified HIV+ children; this included residence, gender, and age, as well as HIV testing history and health facility attendance history.
Results: Out of 36,121 children tested, 161 were HIV+ (0.44% positivity yield), and 123 were enrolled in the program with a 1:1.2 male-to-female ratio. Only 23.5% of all enrolled patients were known to be previously tested. Overall, 12% were 0-2 years, 25% were 2-5 years, and 63% were 5-14 years. Of the 52% of patients with known facility attendance history, 20% had not been in over one year, 17% had attended within 4 months to 1 year, and 15% had visited a facility within the previous 3 months.
Conclusions: The majority of children testing HIV+ through community-based PITC were 5-14 years, nearly half had unknown facility attendance history, and 9.5% who had been to a facility in the previous year did not receive an HIV test. This establishes the need for investigation into causes of Lesotho's shortcomings in offering facility-based PITC. Additionally, it proves that community-based PITC is a necessary tool in closing the access gap by bringing these lifesaving services to children in need, particularly older children. National scale-up is essential in reaching UNAIDS' first 90 target and is recommended for other countries struggling to achieve widespread coverage for children through facility-based testing.

WEAD0105

The clinical impact and cost-effectiveness of incorporating point-of-care (POC) assays into early infant HIV diagnosis (EID) programs at 6 weeks of age in Zimbabwe: a model-based analysis

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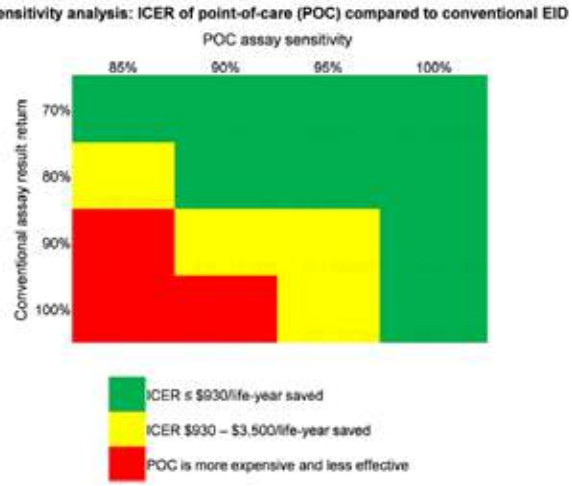
Background: Many EID programs use laboratory-based total nucleic acid (conventional) assays. New POC EID assays are costlier, but may increase access to testing and shorten time to result-return and ART initiation.
Methods: We used the CEPAC-Pediatric model to examine the clinical benefits, costs, and cost-effectiveness of using POC EID assays at 6 weeks of age in Zimbabwe. We simulated two EID strategies: conventional and POC. Positive results led to ART initiation; ART was stopped if a confirmatory assay of the same type and a third conventional assay (all sent pre-ART) were negative. Modeled assays differed in sensitivity (conventional: 100%; POC: 96.9%), specificity (conventional: 98.8%; POC: 100%), time and probability of result-return (conventional: 1-month delay, 71%; POC: immediate, 97%), and cost (conventional: $15; POC: $21). Model outcomes included early survival, life expectancy (LE), and average lifetime per-person cost for HIV-infected infants and all HIV-exposed infants. We calculated incremental cost-effectiveness ratios (ICERs) using discounted (3%/year) costs and LE for all HIV-exposed infants, defining ICERs ≤$930/life-year saved (Zimbabwe per-capita GDP) as cost-effective.
Results: With conventional EID, projected undiscounted LE was 24.95y (HIV-infected infants) and 60.16y (all HIV-exposed infants), at $1,050/HIV-exposed infant (Table). POC EID improved projected undiscounted LE (HIV-infected: 26.58y, HIV-exposed: 60.27y) at $1,120/infant, and increased survival by 4.5% in months 1-2 of life. The ICER of POC vs. conventional was $730/life-year saved (LYS). This ICER remained < $930/LYS if POC specificity was >95% or POC sensitivity was >85%. Large improvements in conventional assay result-return were needed to offset slightly lower POC assay sensitivity (Figure).

Strategy for EID testing at 6 weeks of age in Zimbabwe	Outcomes for HIV-infected infants	Outcomes for all HIV-exposed infants (including HIV-infected and HIV-uninfected infants)				
	LE (years, undiscounted)	LE (years, undiscounted)	LE (years, discounted)	Lifetime per-person costs (USD, undiscounted)	Lifetime per-person costs (USD, discounted)	Incremental cost-effectiveness ratio ($/life-year saved)
Conventional	24.95	60.16	24.84	$1,050	$570	Comparator
POC	26.58	60.27	24.91	$1,120	$620	$730

[POC and conventional EID: modeled outcomes]



[Figure: Sensitivity Analysis]

Conclusions: POC assays for HIV-exposed infants improve survival and life expectancy and are cost-effective compared to conventional assays. EID programs in Zimbabwe should replace conventional testing with POC assays.

WEAD02 When Donors Leave...

WEAD0201

When donor funding leaves: the immediate impact on resources of USAID's withdrawal of support for direct HIV care and treatment at a public health facility in South Africa

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Background: From 2008-2014, USAID-funded organizations were responsible for directly delivering HIV care and treatment via "Comprehensive Care, Management and Treatment" facilities" (CCMTs) in South Africa. Despite USAID having communicated its plans to phase out funding for direct service delivery (DSD) and instead focus primarily on technical assistance, there has been a sense that public clinics were not adequately prepared for the transition.
The aim of this study was to examine the impact on financial and human resources and workloads immediately after the withdrawal of funds for a CCMT at a clinic in Johannesburg.
Methods: In late 2016, we conducted a natural experiment in which trends in budgets and expenditure, clinical staff complements, patient loads, and services rendered were compared at the study clinic before (2007-2012), during (2012-2014), and after (2014-2016) the withdrawal of the clinic's USAID-supported CCMT site. Data were drawn from the country's District Health Information System, local budget and expenditure reports, and staff records supplied by the city. Analysis was conducted in Excel (2013).

Results: Phasing out of the CCMT occurred between July 2012 and June 2015. Reductions in clinic staff occurred in parallel, first by 33% in 2012-2013 and then by a further 29% in 2014-2015. The reduction in staff drastically raised the workload per staff member (i.e. patient-to- staff headcount ratio) in 2013 and 2015.
The withdrawal of the CCMT was not accompanied by an increase in real expenditure. Real expenditure per capita was on average lower after 2012 (ZAR 77) than it had been between 2008 and 2012 (ZAR 85) when the CCMT was providing HIV treatment to patients.
Despite increased workload, service volumes for primary healthcare services at the clinic (HIV counselling and testing, tuberculosis testing, and family planning) did not decrease after the departure of the CCMT.
Conclusions: The phasing out of funding for DSD by USAID at a clinic in Johannesburg negatively impacted on human resources and staff workload while decreasing per capita expenditure. The volume of primary healthcare services delivered at the clinic did not decline; however, the impact on service quality is unknown.

WEAD0202

How changes in United States funding policies could impact the HIV epidemic in sub-Saharan Africa

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Background: The United States is a giant in the global fight against HIV/AIDS. The bipartisan foundation of PEPFAR in 2003 transformed the world´s approach to anti-retroviral therapy in developing countries, and the US is the largest contributor to the Global Fund. However, the isolationism of the Trump Administration may soon place these activities under threat.
Methods: To test the potential impact of changes in American HIV/AIDS funding policies, we employed a mathematical model of the HIV epidemic and response across 18 countries in sub-Saharan Africa. We used financing data from PEPFAR, the Global Fund, and the IMF to estimate the US share of the total HIV/AIDS response historically and in future. We then removed this US share from the total funding available, or changed the way it could be allocated to future prevention efforts, to explore a series of alternative policy strategies that the administration might adopt.
Results: The model finds that US participation in the AIDS response is likely to have averted 2.5 million AIDS deaths and 21 million HIV infections in sub-Saharan Africa between the start of the epidemic and the end of 2016. Looking forward, sustained US funding could avert 300,000 AIDS deaths and 8.4 million HIV infections on the subcontinent between now and 2030. If the US instead withdraws from the funding landscape, for example by defunding PEPFAR in 2017 and breaking its pledge to the Global Fund, the cost could reach 298,000 AIDS deaths and 7.9 million HIV infections by 2030. How funds are disbursed also matters. If the new administration continues to fund PEPFAR but turns a moralistic blind eye to sex workers and gay men, an avoidable 239,000 AIDS deaths and 5.4 million HIV infections could occur.
Conclusions: Our work suggests that the choice before the US government is stark: it can shirk the mantle of global leadership in the AIDS response and thereby reverse the past decade of progress against the epidemic, or it can continue to fund PEPFAR and the Global Fund and potentially save 8.4 million people across sub-Saharan Africa from infection with HIV.

WEAD0203

Estimating the size of the pediatric antiretroviral (ARV) market in 26 low- and middle-income countries (LMICs) through 2025 as prevention of mother to child transmission (PMTCT) initiatives continue to succeed

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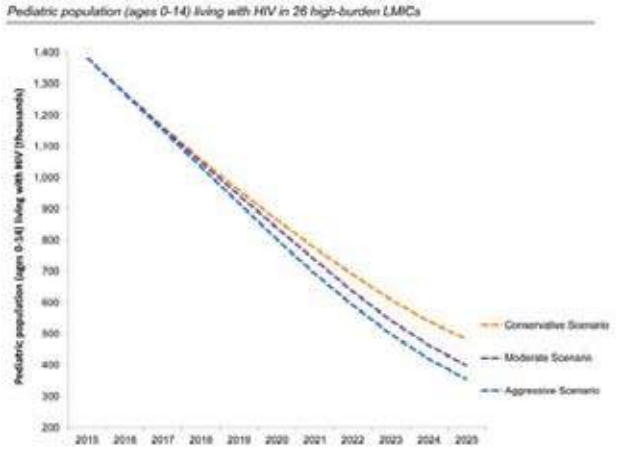
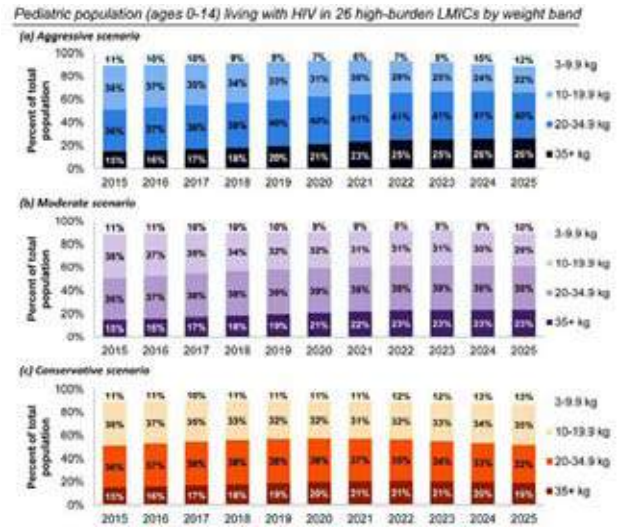
Background: PMTCT initiatives have significantly reduced HIV infections in children, a trend expected to accelerate with the "Start Free, Stay Free, AIDS Free" initiative. Its "Super Fast-Track" targets aim, by 2020, to reduce new perinatal infections to <20,000 annually and achieve universal pediatric ART coverage. Population projections are needed to help optimize supply of pediatric ARVs, especially new formulations.
Methods: Provisional single age band estimates for HIV-infected children (ages 0-14) for 26 high-burden LMICs, provided by UNAIDS, representing ~77% of the global pediatric HIV burden in 2015, were used. For each forecast year, age cohorts were moved from one age bracket to the next, new perinatal HIV infections were added to the age 0 cohort, and the age 14 cohort "aged out" of the market. Annual decreases in AIDS-related deaths were assumed to be similar to 2011-2015, and evenly distributed across age groups.
Three scenarios of the "Super Fast-Track" targets for new infections were modeled: "Aggressive" (targets met), "Moderate" (2 year delay), and "Conservative" (similar decrease as 2011-2015). Resulting cohorts were converted to weight bands using published tables.
Results: The number of HIV-infected children will continue to rise until 2019 before decreasing. By 2025, there could be between 350,000 and 500,000 children living with HIV, needing ART, across the 26 high volume countries. The more aggressive scenarios suggest an increasing proportion of >20kg children.



[Figure 1. Total Ped. PLWHA]



[Figure 2. Weight Distribution]

Conclusions: As pediatric ART coverage increases, more children will need second- or third-line treatment. These population estimates can inform discussions on the development of new pediatric ARV formulations.

WEAD0204

Can differentiated care models solve the crisis in treatment financing? Analysis of prospects for 38 high-burden countries in sub-Saharan Africa

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Background: Rapid scale-up of antiretroviral therapy (ART) in the context of financial and health system constraints has resulted in calls to maximize efficiency in ART service delivery. Adopting differentiated care models (DCMs) for ART

could potentially be more cost-efficient and improve outcomes. However, no study comprehensively projects the cost savings across countries. We model the potential reduction in facility-level costs and number of health workers needed when implementing two types of DCMs while attempting to reach 90-90-90 targets in 38 sub-Saharan African countries from 2016 to 2020.
Methods: We estimated the costs of three service delivery models:
1) undifferentiated care,
2) differentiated care by patient age and stability, and;
3) differentiated care by patient age, stability, key versus general population status, and urban versus rural location.
Frequency of facility visits, type and frequency of laboratory testing, and coverage of community ART support varied by patient subgroup. For each model, we estimated the total costs of antiretroviral drugs, laboratory commodities, and facility-level personnel and overhead. Community-based ART costs were included in the DCMs. We took into account underlying uncertainty in the projected numbers on ART and unit costs.
Results: Total five-year facility-based ART costs for undifferentiated care are estimated to be US$23.33 billion (95% confidence interval [CI] $23.3-$23.5 billion). An estimated 17.5% (95% CI 17.4%-17.7%) and 16.8% (95% CI 16.7%-17.0%) could be saved from 2016 to 2020 from implementing the age and stability DCM and four-criteria DCM, respectively, with annual cost savings increasing over time. DCMs decrease the full-time equivalent (FTE) health workforce requirements for ART. An estimated 46.4% (95% CI 46.1%-46.7%) fewer FTE health workers are needed in 2020 for the age and stability DCM compared with undifferentiated care.
Conclusions: Adopting DCMs can result in significant efficiency gains in terms of reduced costs and health workforce needs, even with the costs of scaling up community-based ART support under DCMs. Efficiency gains remained relatively unchanged with increased differentiation due to some groups requiring more intensive inputs. More evidence is needed on how to translate analyzed efficiency gains into implemented cost reductions at the facility level.

WEAD0205

Characterizing the South African private sector ART market

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Background: South Africa has the largest public sector HIV treatment program in the world, with >3 million clients on ART. It also has one of the most robust and diverse private health care sectors in Africa. We hypothesized that a substantial segment of South African PLHIV are accessing ART through the private sector, especially for 2nd line (2L) treatment regimens. We characterized the private sector ART market indirectly by comparing public and private sector drug procurement data from 2012-2015.
Methods: For the private sector we analyzed IMS Health data from pharmaceutical wholesalers and distributors in South Africa. For the public sector we analyzed data from the Global Price Reporting Mechanism. To avoid double counting, we used regimens with Efavirenz or Nevirapine as a proxy for 1st line (1L) regimens and regimens with Atazanavir or Lopinavir/Rotanivir as a proxy for 2L regimens.
Results: The total patient years of treatment (PYTs) for 1L and 2L regimens in the private sector ART market peaked at 244,760 in 2014 and then decreased to 231,938 PYTs in 2015. Total public sector PYTs for 1L and 2L regimens in South Africa increased more than seven-fold during 2012-2015, from 544k to 4.3 million PYTs.
Rapid growth in public sector ARV procurement, did not appear to significantly displace ARV purchasing in the private sector. Growth in the private sector 1L treatment decreased only 4.2% on average from 2013-2015 while the number of PYTs for 2L treatment in the private sector increased 3.9% on average for the same time period.
Conclusions: Our analysis found a substantial private sector market for ART in South Africa. By 2015 PYTs, the private sector ART market in South Africa would have been the 14th largest treatment program in the world, and the 10th largest in Africa. As public sector treatment budgets reach capacity, there may be opportunities to leverage domestic financing through private sector channels in South Africa. Better landscaping of the private sector ART market is needed to guide future interventions and investments.

Wednesday 26 July

Poster Discussions

WEPDB01 Opportunistic Infections and AIDS-defining Cancers: Can We Do Better?

WEPDB0101

Immediate vs. delayed oral etoposide (ET) among HIV-infected individuals with limited-stage KS initiating ART: A5264/AMC-067 study

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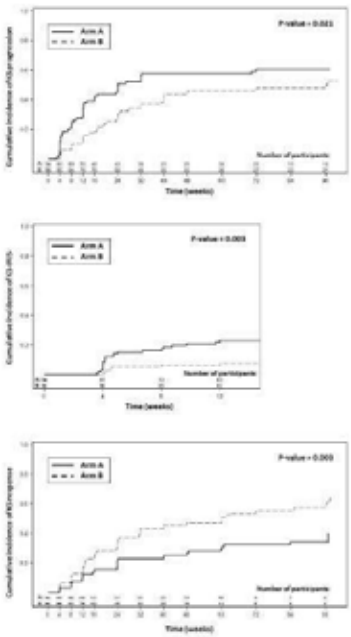
Background: Limited-stage KS often responds to ART alone; the role for adjuvant chemotherapy is unclear. We assessed the impact of immediate vs. delayed oral etoposide (ET) among HIV-infected individuals with limited-stage KS initiating ART.
Methods: ART-naïve, HIV-1-infected adults with limited-stage KS (stage T0 and T1 [minimal oral KS and/or asymptomatic edema]) were randomized to ART (TDF/FTC/EFV) alone (Arm A) vs ART plus up to 8 cycles of oral ET (Arm B) and followed for 96 weeks. Participants with KS progression on ART alone received ET as part of Arm A strategy. Participants who received non-study chemotherapy after ET continued follow-up. Primary outcome was categorical (van Elteren test stratified by CD4): Failure (composite of KS progression, initiation of non-study chemotherapy, lost-to-follow-up, death), Stable, and Response (Partial or Complete) at 48 weeks compared to baseline. Sensitivity analysis excluded receipt of non-study chemotherapy in Failure. Secondary outcomes included times to initial KS progression, suspected KS-IRIS, and KS response (Gray's tests).



[Figure 1. Time to Event Analysis]

Results: Study terminated early for futility after DSMB interim review. Of 190 participants (A=94, B=96); male: 71%; African: 93%; mean age: 35 years; T1:61%. Failure (53.8% vs 56.6%), Stable (16.3% vs 10.8%) and Response (30% vs 32.5%) did not differ between arms (A vs B) among those with Week 48 data potential (N=163, p=0.91). Failure (48.8% vs 38.6%), Stable (16.3% vs 16.9%) and Response (35.0% vs 44.6%) were also not different in sensitivity analysis (p=0.17). Times to KS progression (p=0.021), KS-IRIS (p=0.003), and KS response (p=0.003) favored Arm B (Figure 1). Mortality and adverse events were similar.
Conclusions: Immediate ET showed no benefit compared to delayed ET by the primary endpoint. Pre-specified secondary analyses showed shortened time to KS response, reduced KS-IRIS incidence, and increased time to KS progression with immediate ET, but no effect on mortality or need for additional, non-ET chemotherapy.

WEPDB0102

Implementing CRAG screening in HIV patients initiating ART in rural HIV clinics with regular absence of CD4 testing services in rural Tanzania

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Background: The World Health Organization (WHO) recommends screening for cryptococcal antigen (CRAG) in blood of HIV-infected antiretroviral therapy (ART)-naïve patients with CD4 < 100 cells/μL. CRAG+ persons who receive ART but not antifungal therapy are at a high risk of death. However, absence of reliable or prompt CD4 testing services in rural clinics jeopardizes implementation of CRAG screening.
Methods: We implemented CRAG screening in all primary health HIV clinics in the Kilombero district, southern Tanzania. Point-of-care CRAG lateral flow assay testing was recommended for all ART-naïve HIV-infected persons with criteria for ART initiation or with headache for >5 days. All CRAG+ persons were transported to the Referral Hospital in Ifakara for a meningitis diagnostic workup and antifungal therapy. Patient transport costs, antifungals, and incentives to clinicians were provided.
Results: From November 2015 to November 2016, 723 ART-naïve patients were tested for CRAG in 8 HIV clinics. Of these, 45 (6.2%) were CRAG+, and 26 (58%) were diagnosed at peripheral clinics and referred to Referral Hospital for evaluation. The median age of the CRAG+ patients was 35 years (interquartile range [IQR], 21-55), and 60% (27/45) were women. Lumbar punctures were performed in 41 consenting (91%) patients, and 51% (21/41) of patients were CRAG+ in cerebrospinal fluid (CSF). Among these 21 CSF CRAG+ persons, 3 were asymptomatic (7% of overall CRAG+ persons).
Conclusions: Our CRAG screening algorithm tailored for rural HIV clinics was effective in maximizing cryptococcal detection in advanced HIV patients at a district level in the absence of regular CD4 testing. The high CRAG prevalence found highlights the importance in the absence of CD4 testing of extending CRAG screening to all HIV-infected persons enrolling in care in order to reduce early mortality.

WEPDB0103

High mortality despite high dose oral fluconazole (1600 mg) and flucytosine, and serial lumbar punctures, for HIV-associated cryptococcal meningitis: ANRS 12257 study in Burundi and Ivory Coast

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Background: Mortality from HIV-associated cryptococcal meningitis (CM) remains unacceptably high in low-income countries, where applicable and effective antifungal strategies are needed. In a context where Amphotericine B (AmB) is unavailable, in hospitals lacking intensive care units, we evaluated prospectively the safety and efficacy of an oral combination of fluconazole 1600 mg and flucytosine associated with serial lumbar punctures (SLP) in HIV- associated CM.
Methods: Eligible HIV-infected patients presenting a first episode of CM were enrolled in a one-arm open-label clinical trial in Burundi and Ivory Coast from 2012 to 2015. After inclusion, patients received fluconazole 1600 mg per day in combination with flucytosine 100 mg/kg per day for 2 weeks, followed by fluconazole alone, 800 mg per day for 8 weeks and then 200 mg until the end of follow-up (24 weeks). Intracranial pressure was treated with SLP, according to IDSA recommendations. The primary endpoint was 10-week mortality, expected at 35% +/-15% precision. Secondary endpoints were 2-week and 24-week mortality, early fungicidal activity (EFA) determined by serial quantitative cerebrospinal fluid (CSF) cultures, and safety.
Results: Forty-one (22F/19M) patients were included, 59% being antiretroviral therapy (ART)-naive; 14 (34%) had reduced level of consciousness and 24 (59%) had elevated intracranial pressure at presentation. Overall 10-week mortality was 48.8% (95% CI = 32.9-64.9); 2-week and 24-week mortality were 26.8% (14.2-42.9) and 58.5% (42.1-73.7), respectively. Mean EFA was -0.27 +/- 0.20 log CFU/ml per day, and 16 patients had sterile CSF after two weeks of treatment. The treatment appeared to be well tolerated with no study drug discontinuation. For naive patients, ART was started at a median of 28 days, with no cryptococcal immune reconstitution inflammatory syndrome observed.
Conclusions: Mortality with high dose oral fluconazole and flucytosine associated with SLP was at the upper range of expected values. Oral treatment seems to be less effective than AmB-based combinations, probably due to lower fungicidal activity. Nevertheless, in low-income countries where AmB is not available, this combination appears to be a well tolerated therapeutic option.

WEPDB0104

Comparison of various anal intraepithelial neoplasia screening strategies including standard anoscopy, anal cytology and HPV genotyping in HIV-positive men who have sex with men

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Background: There is no international consensus on anal cancer screening strategy. Guidelines range from digital anorectal examination (DARE) including standard anoscopy (SA) alone (France) to DARE combined with anal cytology (Pap) (IDSA) +/- HPV genotyping in HIV-positive men who have sex with men (HIV+ MSM), to detect high grade intraepithelial neoplasia (HGAIN).
This study aimed at comparing various HGAIN screening strategies yields based on Pap, SA and HPV genotyping alone or in combination in HIV+ MSM.
Methods: Pap, SA and HPV genotyping were performed systematically on consecutive HIV+ MSM attending for the first time a cancer screening consultation between January 2012 and August 2016 in a French hospital. High-resolution anoscopy (HRA) was performed in case of HPV16 positivity or abnormal cytology (ASCUS, LSIL, HSIL). Targeted biopsies were performed when dysplasia was suspected. Screening yield was defined as the number of patients with HGAIN relative to the total number of patients screened. Each strategy was compared with the complete strategy.
Results: 212 patients (median age 51 [IQR:45-57], HIV-RNA< 20 in 84% of patients, median CD4: 682/mm^3 [IQR:491-890]) were screened. The most frequent HPV genotypes were high risk HPV: HPV52 (24.5%), HPV16 (18.9%), HPV53 (18.4%), HPV31 (15.6%) and HPV68 (15.6%). 86/212 (40.6%) patients had at least one positive screening test (Pap+: 62/212(29.2%), HPV16+: 40/212 (18.9%), SA=dysplasia: 19/212 (9.0%)). Screening strategies yields to detect HGAIN compared with the complete strategy and Pap alone are presented above.

Anal cancer screening strategy (N=212)	Number of HRA performed	Number of Biopsies performed	HGAIN at histology: N(%)	Strategy vs Complete strategy: P(Fisher)	Strategy vs Pap alone: P(Fisher)
SA	0	19	7 (3.3%)	<0.001	0.02
HPV16 genotyping	39	26	14 (6.6%)	<0.05	0.47
Pap	59	40	19 (9.0%)	0.27	
SA + HPV16 genotyping	33	40	19 (9.0%)	0.27	1.00
Pap + HPV16 genotyping	75	48	23(10.8%)	0.65	0.63
SA + Pap	51	52	24 (11.3%)	0.77	0.52
SA + Pap + HPV16 genotyping	67	59	27 (12.7%)		0.27

[Table 1]

Conclusions: Pap alone or combinations of two screening tests yielded to similar rates of HGAIN detection than the complete strategy. Compared to Pap alone, Pap + HPV16 slightly improved the number of HGAIN detected but not significantly. Given the limited number of clinicians trained in HRA and the perspective of self-sampling, Pap +/- HPV16 screening might be the best strategy to increase screening acceptance and to identify HGAIN in HIV+ MSM.

WEPDB0105

Human Papillomavirus infection and cervical lesions in HIV-1-infected women on antiretroviral treatment in Thailand

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Background: Rates of Human Papillomavirus (HPV) infections and cervical lesions are both increased in HIV-infected women. The objectives of the study were to estimate the prevalence and factors associated with Human Papillomavirus (HPV) infection, HPV genotypes and cytological/histological high-grade (HSIL+/CIN2+) lesions in HIV-1 infected women receiving combination antiretroviral therapy (cART).
Methods: We conducted a cross-sectional study (PapilloV study, NCT01792973) within a prospective cohort (the PHPT cohort) of HIV-infected women on cART in 24 hospitals accross Thailand. Cervical specimens were collected for cytology and HPV genotyping (Papillocheck®). Any women with High-Risk-HPV (HR-HPV), and/or potentially HR-HPV (pHR-HPV) and/or ASC-US or higher (ASC-US+) lesions were referred for colposcopy. Factors associated with HR-HPV infection and with HSIL+/CIN2+ lesions were investigated using mixed effects logistic regression models.

Results: 829 women were enrolled: median age 40.4 years, on cART (613 on NNRTI-based regimen and 213 on PI-based regimen) for a median of 6.9 years, median CD4 cell-count 536 cells/mm3, and 788 (96%) with HIV-viral load <50copies/mL, 196 (24%) were CDC-stage C and 125 (18%) had history of virologic failure. Of 214 (26%) infected with HPV: 159 (19%) had ≥1 HR-HPV, of whom 38 (5%) HPV52, 22 (3%) HPV16, 9 (1%) HPV18; 21 (3%) had pHR-HPV, 34 (4%) low risk-HPV infection, and 56 (26%) had multiple genotypes. Younger age, low CD4 cell-counts and low education were independently associated with HR-HPV infection. 72 women (9%) had ASCUS+ and 28 (3%) HSIL+/CIN2+ lesions. HR-HPV infection was independently associated with HSIL+/CIN2+ lesions.
Conclusions: The prevalence of HPV infection and of cervical lesions was low. CD4 cell count was inversely associated with the presence of HR-HPV infection, indicating the need for closer gynecological follow-up in case of immunological failure.

WEPDB0106

Screening for tuberculosis with Xpert MTB/RIF versus fluorescent microscopy among people newly diagnosed with HIV in rural Malawi: a cluster-randomized trial

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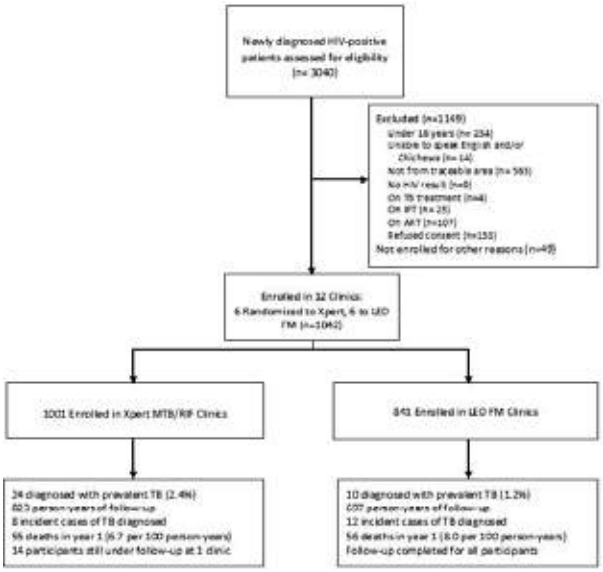
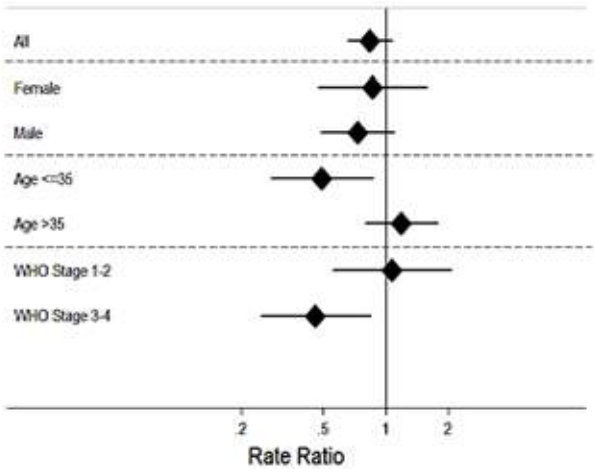
Background: Tuberculosis (TB) is the leading cause of HIV-associated death. Xpert MTB/RIF (Xpert) has greater diagnostic sensitivity than microscopy but also higher costs and infrastructural requirements. Sensitive TB screening following HIV diagnosis could potentially reduce mortality.
Methods: Cluster-randomized trial of point-of-care TB screening using Xpert versus LED fluorescent smear microscopy (LED FM) across 12 primary care clinics in Thyolo District, Malawi (ClinicalTrials.gov NCT01450085). Randomization was constrained (1:1), with a primary outcome of 12-month all-cause mortality. Participants newly diagnosed with HIV underwent TB symptom screening followed by Xpert or LED FM if symptomatic and isoniazid preventive therapy if asymptomatic. Analyses used t-tests of log-transformed cluster-level rates, and Poisson regression.



[Fig 1. Study profile]

Results: Of 1,842 participants recruited (Figure 1), 24/1,001 (2.4%) participants in the Xpert arm and 10/841 (1.2%) in the LED FM arm had TB diagnosed at entry. The primary outcome was similar across arms (overall mortality 6.45 per 100 person-years with Xpert vs 7.80 with LED FM, rate ratio 0.83, 95%CI: 0.63-1.09; p=0.14; see Figure 2). However, a pre-specified secondary analysis among people with WHO stage 3 or 4 disease (n=463) showed significantly lower mortality in the Xpert arm (15.9 versus 34.8 per 100 person-years, rate ratio 0.46, 95%CI: 0.22-0.93; p=0.03). Unadjusted` and adjusted results were similar.



[Fig 2.RR (Xpert v LED FM) for all-cause mortality]

Conclusions: Screening rural adult Malawians recently diagnosed with HIV for tuberculosis using point-of-care Xpert MTB/RIF increased baseline diagnoses of TB and halved mortality among individuals with stage 3 or 4 disease but did not significantly affect all-cause mortality overall.

WEPDC01 It's Time to Focus on STIs

WEPDC0101

STI co-infections at HIV diagnosis in France

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Background: Sexual risk behaviours expose people to HIV infection but also to other sexually transmitted infections (STI). In the context of an increase of STI in France, the aim of our work was to analyse the frequency of STI in people newly diagnosed for HIV between 2012 and 2015.
Methods: Since 2012, mandatory HIV surveillance system in France has collected information on bacterial STI (syphilis, gonorrhea, chlamydia trachomatis infection or lymphogranuloma venereum-LGV). These infections had to be reported if they were concurrently diagnosed at the time of HIV diagnosis or diagnosed in the last 12 months before HIV diagnosis (STI/HIV co-infections).
Results: Information on STI infection was available for 9.207 HIV diagnoses in adults during the period 2012-2015 (52% of all diagnoses). STI/HIV co-infection was globally 14.2% (1.310/9.207), but was more frequent in men having sex with men (MSM) (25.4%) than in heterosexuals born in France (9.0%: 11.1% in men and 6.0% in women) or abroad (3.4%: 5.0% in men and 2.3% in women) and in injecting drug users (6.7%). STI/HIV co-infection was more frequent when HIV infection was diagnosed during acute illness.
STI/HIV co-infection has increased overtime (from 12.9% in 2012 to 16.9% in 2015), but this increase was observed only in MSM (from 22.0% to 30.0%).
Among STI, the frequency of syphilis, gonorrhea, chlamydia and LGV were respectively 74.3%, 15.8%, 15.0% and 1.7%. Chlamydia was the only STI more frequent in heterosexuals compared to MSM.
Conclusions: STI/HIV co-infections affect almost one third of MSM newly diagnosed with HIV in 2015, and most commonly syphilis/HIV. These results highlight the importance to combine HIV testing to other STI, and to offer an HIV test to patients presenting with a STI.

WEPDC0102

Acquisition of sexually transmitted infections among women using a variety of contraceptive options: a prospective study among high-risk African women

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Background: In many African settings, women concurrently face high risk of HIV-1, STIs, and unintended pregnancies. Few studies have evaluated STI risk among users of hormonal implants and intrauterine devices (IUDs) although these long-acting reversible methods are being promoted widely because of their contraceptive benefits. Within a prospective study of women at risk for HIV, we compared the risk of STI acquisition among women using different contraceptive methods.
Methods: MTN-020/ASPIRE was a randomized trial of the dapivirine vaginal ring for HIV-1 prevention that enrolled 2629 women from Malawi, South Africa, Uganda, and Zimbabwe; all were required to use contraception at study entry. Analysis was restricted to 2264 women (50.2% from South Africa) who used DMPA (n=1147), implants (n=692), NET-EN (n=438) or IUD (n=541) at any point during follow-up. Screening and treatment for Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis occurred at baseline, semi-annually, and when clinically indicated.
Results: Over 3,440 person-years of follow-up, 408 cases of C.trachomatis (incidence 11.86/100 person-years), 196 of N.gonorrhoeae (5.70/100 person-years), and 213 cases of T.vaginalis (6.19/100 person-years) were detected. The incidence of C.trachomatis and N.gonorrhoeae were not significantly different across contraceptive methods (Table), although DMPA and implant users had lower incidence than IUD users. The incidence of T.vaginalis was significantly lower for DMPA, implant, and NET-EN users, compared with IUD users. Findings were consistent across South Africa and non-South Africa sites.

Method	*Chlamydia trachomatis*			*Neisseria gonorrhoeae*			*Trichomonas vaginalis*		
	incidence	aHR*	95% CI	incidence	aHR*	95% CI	incidence	aHR*	95% CI
IUD (copper)	12.92	1	-	6.77	1	-	9.07	1	-
Implant	9.19	0.69	(0.47,1.01)	5.92	0.97	(0.60,1.57)	6.01	0.58	(0.39,0.87)
DMPA	12.44	0.86	(0.65,1.16)	5.13	0.74	(0.48,1.14)	4.75	0.37	(0.24,0.59)
NET-EN*	17.35	1.45	(0.94,2.23)	6.55	0.86	(0.48,1.57)	5.84	0.40	(0.20,0.81)

* NET-EN only South African women; hazard ratios adjusted for randomization arm, age, sexual behavior, baseline STIs

[Incidence of STIs by contraceptive method]

Conclusions: Among African women at high risk for HIV-1, we found that risk of cervical infections (N.gonorrhoeae and C.trachomatis) did not differ across contraceptive methods. Significantly lower rates of T.vaginalis among progestin based methods compared to IUD users was seen, likely due to hypoestrogenic states which may not be conducive for persistence of T.vaginalis. Results are reassuring and lend support to current WHO guidance that women should have a wide range of contraceptive options.

WEPDC0103

Differences in biological and behavioral HIV risk before, during and after PrEP use among a national sample of gay and bisexual men in the United States

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Background: Some have expressed concern that gay and bisexual men (GBM) who use pre-exposure prophylaxis (PrEP) will engage in more condomless anal sex (CAS) and acquire/transmit STIs more frequently while on PrEP. Others, however, argue that increases in STIs among men on PrEP result from required STI screening and testing. There has been little longitudinal data to support either conclusion.
Methods: Data were collected from One Thousand Strong, a longitudinal study of 1,071 HIV-negative GBM from across the U.S. Participants were tested for urethral and rectal gonorrhea and chlamydia and asked to report on their PrEP use every 12 months.
Results: In cross-sectional between-group analyses, the 823 PrEP-naïve men had a significantly lower STI infection rate (4.2%) than the 77 men currently (10.4%) or 17 men formerly (11.8%) on PrEP, $X^2(2) = 7.72$, p = 0.02; men currently on PrEP also reported significantly more acts of CAS, H(2) = 37.73, p <0.001. Within-person longitudinal analyses of the 181 men who reported PrEP use indicated slight but non-significant increases in the odds of an STI diagnosis while on PrEP (OR = 1.25, p = 0.55) and after discontinuing PrEP (OR = 1.43, p = 0.53) in comparison to pre-uptake of PrEP. We also saw no significant changes in CAS while on PrEP (OR = 1.09, p = 0.76) or after PrEP discontinuation (OR = 0.48, p = 0.10) compared to pre-uptake levels.
Conclusions: Our findings failed to support the notion that GBM experience an increase in CAS and STIs while on PrEP. Although PrEP-naïve GBM have fewer STIs and report less CAS than current and former PrEP users, these data provide support for the notion that the highest risk GBM are the ones who initiate PrEP use, and their risk behaviors do not change substantially as a result. It is worth noting that most of the men on PrEP in this sample are early adopters, and further research is needed to determine whether behavioral differences may emerge in larger samples of men who may engaging in lower levels of HIV risk behavior at the time of PrEP initiation.

WEPDC0104

Partner notification of sexually transmitted infections among MSM on PrEP: a sub-study of the ANRS-IPERGAY trial

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Background: Sexual partners of people with HIV or other sexually transmitted infections (STI) are at high risk of infection. Partner notification (PN) is a useful public health approach to enhance both targeted testing of those at very high risk, and linkage to care for undiagnosed HIV+ /STI+ individuals. Despite WHO recommendations, PN is implemented differently worldwide. In France, there are no specific guidelines, and information about PN practices is scarce. We used the ANRS-IPERGAY PrEP prevention trial to investigate PN in HIV-negative men who have sex with men (MSM), who reported STI.
Methods: The present sub-study was conducted among 275 participants who completed a specific online PN questionnaire, during the open-label extension study of the ANRS-IPERGAY trial, between April and June 2016. Socio-demographic data were collected at inclusion. Data about their most recent sexual encounter and about preventive behaviours were collected at the follow-up visit prior to filling out the PN questionnaire to define variables to be used as proxies of at-risk practices. Chi-2 or exact Fisher tests were used to select variables eligible for multiple logistic regression analysis.
Results: Among the 275 participants, 250 reported at least one previous STI. Among the latter, 172 (68.8%) had informed their partner(s) of their most recent STI. Of these, 138 (80.2%) had notified their occasional partners and 83 (48.3%) their main partner. There was no significant socio-demographic difference between MSM who notified their partner(s) and those who did not. Multiple logistic regression showed that MSM were less likely to notify their main partner when their most recent sexual encounter was through unprotected anal sex with an occasional partner (aOR[95%CI] 0.31[0.14;0.68], p=0.03). Older MSM were less likely to inform occasional partners (aOR[95%CI] 0.44[0.21;0.94], p=0.03), while those participating in chemsex at their most recent sexual encounter were more likely to inform their occasional partners (aOR[95%CI] 2.56[1.07;6.09] p=0.03).
Conclusions: Unprotected sexual relationships with people other than main partners, and recreational drug use were identified, respectively, as a socio-behavioural barrier to and motivator of PN among a sample of high-risk MSM. These results provide a first insight into the process of PN and might fuel reflection about PN in France.

WEPDC0105

Predictors of genital ulcerations in HIV-serodiscordant couples, Lusaka, Zambia

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Background: Genital ulcers are known risk factors for HIV transmission, and reduction of genital ulcers could reduce HIV incidence. However, little is known about risk factors for ulcers, limiting their early identification and treatment.
Methods: HIV-serodiscordant heterosexual couples (M+F-, M-F+) were followed with censoring at antiretroviral treatment uptake or HIV transmission (1994-2012). Exposures (demographic, clinical, laboratory) were measured every 3 months. Anderson-Gill survival models evaluated associations between exposures measured during the visit prior to the time-to-undiagnosed genital ulcer outcome (defined as incident syphilis diagnosis via rapid plasma regain test or active ulcer on genital exam).
Results: We followed 1393 M+F- couples for 2756 couple-years and 1656 M-F+ couples for 3216 couple-years. The proportion of intervals positive for ulcers were 13.7% for HIV+ men, 5.6% for HIV- men, 8.5% for HIV+ women, and 4.4% for HIV- women. Risk for genital ulcer for HIV- women was associated (p< 0.05) with bilateral inguinal adenopathy (BIA) (adjusted hazard ratio, aHR=1.9), genital inflammation (GI) (aHR=1.5-1.9), man´s non-STI GI (aHR=2.9), and increasing number of previous pregnancies (aHR=1.1). Risk for genital ulcer for HIV+ women was associated with BIA (aHR=1.5), GI (aHR-1.5-2.0), man´s non-STI GI (aHR=2.0), HIV stage III-IV versus I (aHR=1.5), and being pregnant (aHR=0.7). Risk for genital ulcer for HIV- men was associated with man´s BIA (aHR=1.8) and STI GI (aHR=2.9), woman´s ulcer (aHR=1.7) and non-STI GI aHR=1.4), and being uncircumcised (aHR=1.7); being uncircumcised with foreskin smegma was independently predictive (aHR=3.2). Risk for genital ulcer for HIV+ men was associated with man´s STI GI (aHR = 2.8), HSV-2-positivity (aHR=2.5), and HIV stage III-IV versus I (aHR=1.7); being uncircumcised with foreskin smegma was independently predictive (aHR=2.4).
Conclusions: BIA and GI may be early indicators or risk factors for genital ulceration; importantly, partners' non-STI GI is also a strong risk factor, and screening of both partners for BIA and GI is indicated. Uncircumcised men with foreskin smegma were at increased risk for genital ulceration. Interestingly, HSV-2-positivity was only predictive of genital ulcer for HIV+ men. Targeted screening among HIV+ individuals with more advanced stage of disease may be worthwhile.

WEPDD01 Getting to the First 90

WEPDD0101

Community-based testing strategies among sex workers in the transport corridor in Mozambique

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Background: The MSF Corridor project aims to implement a comprehensive intervention for sex workers (SW) along the transport corridor in Mozambique and Malawi. The community-based model incorporates outreach services, HIV testing and counseling, condom distribution, retesting for HIV-negative SWs, and access to STI and HIV care. Sex worker peer educators (SWPE) play an important role in supporting outreach activities, health education and linkage to care. This analysis describes testing, retesting and seroconversion among SWs in Tete and Sofala, Mozambique and explores SWPE perspectives on their role.
Methods: Retrospective analysis of routinely collected data included SWs enrolled in the outreach program between January 2014 and June 2015. The proportion HIV-positive among SWs who initially tested between January 2014 and June 2015 and the proportion of those initially negative who retested within 6 months were assessed. Seroconversion was determined among those who retested within 6 months. Participant and non-participant observations were conducted during SWPE outreach activities in four project sites, along with nine in-depth interviews and two focus group discussions.
Results: 1810 female SWs enrolled, with a median age at first contact of 28 years [23-32]. Among 1207 SWs tested, HIV positivity at initial test was 44%. Overall HIV positivity rate, including 371 additional SWs who self-reported positive, was 57%; 32%, 42%, 61% & 78% among SWs <18, 18-24, 25-34 and ≥35 years, respectively. 42% of SWs initially HIV-negative retested within 6 months and 14 (5%) seroconverted (median time: 114 days). SWPEs described their ability to reach out to their peers, to engage new and 'informal' SWs with health-care services, including HIV testing. Challenges included experiencing prejudice and undervaluation by non-SW colleagues.
Conclusions: Despite stigma and mobility challenges, most SWs contacted agreed to test. Among those negative, almost half retested within 6 months. However retention for retesting remains a major challenge. HIV prevalence and apparent incidence demonstrate the extreme risk among this group and importance of community strategies to access testing, treatment and prevention, including PrEP. SWPEs have a key role in developing trust among their peers and supported uptake of testing and re-testing. Greater efforts are needed to develop their role in SW programs.

WEPDD0102

Views on HIV self-test kit distribution strategies targeting female sex workers: qualitative findings from Zimbabwe

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Background: HIV self-testing (HIVST) may be a suitable strategy to increase HIV testing uptake and frequency among female sex workers (FSW). Optimal ways of distributing test kits to FSW are unclear. We qualitatively explored views on HIVST and distribution methods, amongst FSW and potential self-test kit distributors.
Methods: Focus group discussions (FGD) were held among FSW and peer educators (PE), condom-promoting hairdressers and community female condom sales agents ("Care Promoters"), ≥18 years. Discussions were transcribed and analysed thematically.
Results: From September 2016 to January 2017, 15 FGD were conducted across Zimbabwe with 7-10 participants each: 6 each among FSW (n=54) and PE (n=55); 2 among hairdressers (n=16); and 1 among Care Promoters (n=7).
Though knowledge of HIVST was limited, FSW felt it provides increased privacy and convenience. Most were against PE and hairdressers distributing kits, preferring healthcare workers from dedicated FSW clinics to do so and provide HIVST information. Preference for on-site self-testing at these clinics was expressed. Provision of HIVST vouchers for distribution to other FSW was suggested; some PE agreed, proposing they do pre-test HIV counselling alongside.
PE reported HIVST may empower FSW and provide opportunities to test clients/partners. Most were interested in distributing self-test kits if trained, though some preferred clinic distribution. Like FSW, they felt hairdressers should not be distributors.
Hairdressers showed willingness to distribute kits to FSW even at their households; conversely, FSW and PE views were mixed regarding door-to-door distribution, partly due to low prospects of linkage to post-test services. Some thought Care Promoters were better positioned as they already distribute condoms to FSW. Hairdressers expressed a need to be incentivized, seeing self-test kit distribution as an opportunity for additional income.
Care Promoters felt HIVST may increase testing among FSW. They expressed willingness to distribute kits, and like FSW, proposed a voucher system, redeemable at clinics.
Conclusions: Though all potential distributors demonstrated willingness, FSW and PE preferred HIVST distribution through FSW clinics where support and post-test services are easily accessible. Distribution of HIVST vouchers also emerged as a potential strategy. These findings will inform scale-up of HIVST distribution targeting FSWs in Zimbabwe.

WEPDD0103

Feasibility and acceptability of home-based HIV testing among refugees: a pilot study in Nakivale Refugee Settlement in southwestern Uganda

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Background: Home-based HIV testing may help reach refugees who face obstacles accessing testing in sub-Saharan Africa. We conducted a pilot study to determine the acceptability and feasibility of home-based HIV screening in Nakivale Refugee Settlement.
Methods: From February-March 2014, we visited homes up to 3 times in 3 geographic zones within Nakivale. We enrolled adults ³18 years who spoke English, Kinyarwanda, Runyankore, or Kiswahili and surveyed them about their country of origin, years in the settlement, and reasons for testing acceptance/refusal. We used the proportion of eligible participants present to demonstrate feasibility. The primary outcome was participation in HIV testing and receipt of result. We used logistic regression models with the generalized estimating equation to correlate willingness to test with gender and number of eligible individuals present in the household at time of consent, while taking into account clustering within households.
Results: Of 319 homes visited with 566 eligible individuals reported living in these homes, 292 homes (92%) had 507 (90%) individuals present; 353 (70%) present at visit one, 127 (25%) additional people at visit two, and 27 (5%) additional people at visit three. Home-based HIV testing participants totaled 378 (75%); all received their results and 7 (1.9%) had new HIV diagnoses. Of participants, 134 (35%) were from the Democratic Republic of the Congo, 129 (34%) from Rwanda, 91 (24%) from Burundi, and 23 (6%) from Uganda. Participants were predominantly refugees (93%) and female (56%), with a median age of 30 (IQR 24-40) and a median time of 6 years (IQR 3-8) in Nakivale. Willingness to participate was positively associated with the number of participants at home at time of consent (OR 1.59 [1.17-2.14], p=0.003). Testing was not associated with gender (OR=1.00 [0.71-1.41], p=0.99). The most common reason for testing was: "to know if I am HIV-infected" (91%).
Conclusions: In this home-based HIV testing pilot study, the majority of eligible individuals (75%) participated in HIV testing and received their results. Most participants were reached by the second visit and were more likely to participate when others were present at the time of consent. Home-based HIV testing is feasible and acceptable in a refugee setting.

WEPDD0104

Sex, test and treat: implementing an incentivized community-driven intervention to promote the uptake of HIV testing services among clients of sex workers

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Background: Female sex workers (FSW) and their clients face elevated risks of acquisition and transmission of HIV and other sexually-transmitted infections globally. In Cameroon, HIV prevalence among FSWs is estimated at 36%, and HIV testing uptake among clients of FSW is suboptimal. To increase uptake of HIV testing services (HTS) among FSW clients, the USAID-funded Continuum of HIV/AIDS prevention, care and treatment for Most-at-risk Populations (CHAMP) program developed a community-led referral recruitment approach. FSWs were provided a small incentive to promote HTS to their clients, who could access the services directly at, or near sex work hotspots.
Methods: FSW at high-volume hotspots were given coupons with unique identifier codes (UICs) and basic training to refer clients to an HTS counselor (and lab technician) located in a room nearby. FSW received USD$1 for each client who agreed to take a test. Each client who accessed HTS was assigned a UIC. Quantitative client data were collected via the CommCare digital platform and analyzed for the period September 2015 through December 2016. In addition, the team collected qualitative data via in-depth interviews with 30 clients who attended HTS.
Results: Prior to the implementation of this innovation, HTS uptake averaged less than 100 FSW clients per month. Recruitment and referral through FSW increased HTS uptake among clients dramatically (1,071 clients of FSW were tested in just one month, with a yield of 4.8% living with HIV). Most clients who agreed to be tested noted the discrete environment and time saved as reasons for testing, as compared to mass screening campaigns. FSW expressed satisfaction and pride serving as community mobilizers.

[Clients of FSW - HTC uptake]

Conclusions: Incentivized, FSW community-led referral recruitment approaches may have strong potential to identify clients more likely to be living with HIV, effectively recruit them into the services network, and concurrently engender building of social capital among FSW.

WEPDD0105

Implementing test & start program in a rural conflict affected area of south Sudan: the experience of Médecins Sans Frontières

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Background: Community-based HIV counselling and testing (CB-HCT) and early initiation of antiretroviral therapy (ART) reduce HIV transmission and mortality. Access to HIV care in settings with low ART coverage and/or affected by conflict is low; innovative strategies are needed to increase HIV care and ensure continuation of ART in case of instability. A pilot test and start project was implemented in rural areas of Yambio South Sudan, a chronically conflict-affected area aiming to determine feasibility and acceptability of this intervention.
Methods: Data from July 2015 to December 2016 was analysed. The project involved five mobile teams offering HCT and same day ART initiation at community level. Contingency plan included delivery of key messages on "what to do in case of conflict" during counselling sessions and coordination with community health workers (CHWs) to distribute "run-away bags" with 3 months of ART. Several episodes of acute instability occurred during this period which needed to activate the plan to ensure that patients would not interrupt their treatment.
Results: During this period 13,872 people were tested; 442 (3.2%) was found to be HIV positive and 344 (77.8%) started on ART. 224 (54.4%) where women with a mean age of 33 years, 207 (60.2%) had CD4 count below 500cells/µl. By December 2016, 67 (19.5%) patients were loss of follow up, 8 (2.3 %) died. Retention in care at 6 and 12 months of follow up was respectively 291(84%) and 277(81%) patients. 114 patients with available viral load results (85.7%) had VL less than 1000 copies/ml after 6 months of ART. At 17 months 251 (73%) patients are still under follow up and on ART.
Conclusions: Our program shows a high level of acceptance to HCT and early ART initiation despite rural context and security situation. Early results shows retention in care and virological suppression outcomes comparable with HIV programs at clinic level and without security issues. We believe this strategy could be extrapolated to other contexts with low access to ART and instability.

WEPDX01 Phylodynamics: Tracking Molecules in Populations

WEPDX0101

Phylogenetic, epidemiological and virological insights on the rise of large cluster outbreaks fueling the HIV-1 epidemic among men having sex with men within Quebec

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Background: HIV-1 epidemics remain uncontrolled among Men having Sex with Men (MSM) within Quebec in the era of treatment-as-prevention. Phylogenetics infer two patterns of HIV-1 spread among MSM, each contributing to half of the epidemic. While the majority (95%) of HIV-1 strains lead to self-limiting clusters (size 1-4), thirty-two viruses contributed to micro-epidemics (cluster size 20-140) disproportionately rising from 13%, 25%, and 42% of diagnoses in 2004-2007, 2008-2011, and 2012-2015, respectively. Here, phylogenetic, epidemiological and virological data deduced factors favoring the selective advantage of large cluster variants.
Methods: Population-level phylogenetics across the RT/protease domain deduced temporal dynamics of HIV-1 clustering. Phylogenetics across the viral integrase and V3 loop was performed on representative clusters. Epidemiological data from the SPOT rapid testing site and Montreal primary HIV cohort deduced epidemiological and behavioral risk effects implicated in clustering. Primary HIV-1 strains from MSM associated with large 20+ clusters or singleton/small clusters (cluster size 1-4) were grown in cell culture under dolutegravir (DTG), elvitegravir (EVG) and/or lamivudine (3TC) pressures. Sanger and deep sequencing assessed HIV-1 genotypic changes under drug pressure.
Results: Phylodynamics charted the introduction and spread of 32 large clusters (median cluster size 20-140), over median two year periods. Clusters were concentrated in Montreal with several clusters in Quebec City and Sherbrooke. Three large clusters (cluster size 38, 43, 45), with median transmission dates of 06/2010, 02/2012 and 10/2013, shared a common integrase. Large cluster strains (n=11) were resilient showing accelerated acquisition of resistance within 5-8 weeks to DTG, EVG, and 3TC compared to small cluster strains where resistance arose after 20 weeks. Several large clusters displayed dual X4/R5 tropism. Large clusters were arising in younger persons with 29%, 35% and 41% under 30 years of age over the 2004-2007, 2008-2011 and 2012-2015 periods. Only 48% of infections within large clusters were first genotyped in primary/recent infection. HIV-1 testing habits remain poor and significantly better for persons reporting multiple anonymous partnerships than those reporting low risk behavior.
Conclusions: HIV-1 continues to spread among MSM with an alarming shift towards large cluster outbreaks, emphasizing the need for improved prevention paradigms.

WEPDX0102

Transmission cluster-specific pattern of adaptive evolution of the HIV-1 envelope gp120 protein sequence in a Japanese MSM population

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Background: HIV-1 envelope protein (Env) is the target of neutralizing antibodies (NAbs), which show a potential in the treatment and prevention of HIV infection. To combat against the rapid evolution of the Env gene during the HIV transmission chain, development of various broad NAbs corresponding to the genetic diversity is required. Recently, we've identified unique transmission clusters (TCs) of subtype B circulating in Japan based on their protease-RT gene sequences. In this study, we analyzed adaptive evolution of the Env sequences in the TCs to further characterize the immune escape of the Env gene within a TC.
Methods: We determined 2,673 C2-V5 sequences of Env gp120 from 712 individuals who underwent tropism testing between 2011 and 2015 at Nagoya Medical Center, the second largest medical facility participating in the Japanese Drug Resistance HIV-1 Surveillance Network. The TC of each sequence was identified by searching our TC database, and was confirmed by inferring the phylogenies of gp120 sequences. Neutral evolution of each region within each TC was tested by Kumar's Z-test for the null hypothesis of strict neutrality. Codon-by-codon neutral selection was analyzed by maximum-likelihood computations of synonymous and nonsynonymous substitutions per site using the HyPhy software package.
Results: We identified 89 TCs, 77 of which belong to subtype B associated with the MSM population. The nucleotide diversity of the C3 region was greater than that of the V3 region and was similar to that of the V4 region. Regions with greater diversity exhibited significantly positive selection during the evolution of subtypes, whereas the directions of selection during the evolution of TCs were much more variable. Furthermore, different amino acid sites in the C3 region were under positive selection during the evolution of each TC. Viruses circulating in each TC of gp120 have a distinct substitution pattern to confer escape from NAbs.
Conclusions: Our study indicates that a prevention program targeting a key population using an effective broad NAb may not work efficiently for another patient group. Identification and characterization of the HIV transmission network is thus crucial to choose the most appropriate NAb for an antibody-mediated prevention strategy targeting a local key population.

WEPDX0103

Analysis of U.S. HIV sequence data indicates that recent and rapid HIV transmission is focused among young Hispanic/Latino men who have sex with men

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Background: Although the estimated rate of HIV transmission in the United States is approximately 4 transmission events per 100 person-years, the rate of transmission in some risk networks is likely much higher. Identifying these networks can provide critical data for focusing efforts on populations in need of the most intensive prevention interventions. To describe the leading edge of HIV transmission, we identified molecular clusters with recent and rapid growth, determined the transmission rate for these clusters, and described the persons involved in rapid transmission.
Methods: We analyzed baseline partial HIV-1 polymerase sequences reported to the National HIV Surveillance System through December 2015 by 27 participating jurisdictions for persons with HIV diagnosed during 2013-2015. We calculated genetic distance for each pair of sequences. Using a pairwise threshold of 0.005 substitutions/site, we inferred clusters and identified rapidly growing clusters (those with ≥5 diagnoses during 2015). We used node ages determined through molecular clock phylogenetic analysis to calculate HIV transmission rates for these rapidly growing clusters and compared persons in these clusters to other persons with sequences included in the analysis, accounting for correlation between cases in the same cluster.
Results: Sequences were analyzed for 30,323 persons; 13 rapidly growing clusters were identified. These clusters had a transmission rate of 34/100 person-years. Compared with the 30,127 persons not in these clusters, the 196 persons in these 13 clusters were disproportionately men who have sex with men (MSM) (94% vs. 62%, P< 0.0001), aged <30 years (68% vs. 41%, P< 0.0001), Hispanic/Latino (49% vs. 28%, P<0.0001), and, specifically, young Hispanic/Latino MSM (32% vs. 9%, P<0.0001). The clusters included high levels of transmitted drug resistance (43% vs. 20%, p=0.0006).
Conclusions: This approach identified a small number of clusters with a transmission rate more than 8 times that of previous national estimates. These findings highlight the extent of rapid transmission among young Hispanic/Latino MSM, suggesting the need for prevention efforts that focus on this population. Identifying clusters of active transmission can help programs effectively direct limited public health resources.

WEPDX0104

Phylodynamic insights into HIV epidemic dynamics within Canada

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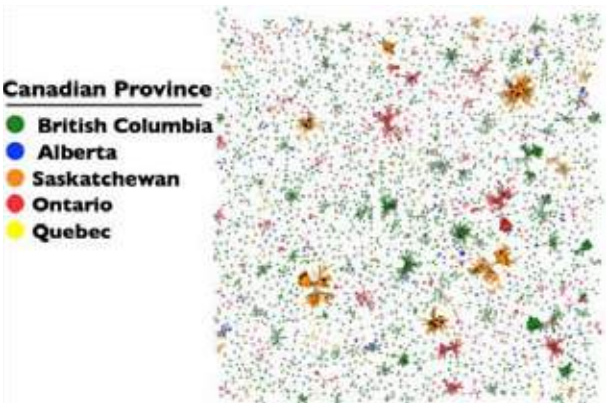
Background: Despite the importance of HIV, the early history, geographic dissemination, and dynamics of the virus within populations across Canada remain unclear. Epidemiological processes stamp measurable signatures on HIV genomes sampled at different places and times. Using statistical phylodynamic approaches applied to HIV sequences sampled from across Canada we test hypotheses concerning past and present HIV epidemic dynamics.
Methods: We compiled 51,493 doubly-anonymized HIV pol sequences from 20,000+ patients annotated with clinical and socio-demographic parameters. Data were available from 5 Canadian provinces: British Columbia, Alberta, Saskatchewan, Ontario, and Quebec. Analyses were restricted to the first sample collected from each patient and drug resistance codons were censored from the alignment. Phylogenetic trees were inferred using FastTree2. Phylogenetic clusters of five or more participants were identified using a tip-to-tip distance cutoff < 0.02 substitutions per site. Diversification rate and phylogeographic analyses were conducted in R and BEAST respectively.
Results: We observed variation among provinces in the proportion of non-subtype B infections, with the Prairies displaying significantly greater numbers of non-B infections ($p < 0.05$). We recovered 285 clusters of size ≥ 5 (Fig.1). Cluster size was associated with proportion of people who inject drugs ($p < 0.004$). Most provinces contain large, primarily province specific, clusters dominated by transmission through injection drug use. Some between-province clustering is observed (n=55 clusters including 3 or more provinces). Association of clusters with more than one province was associated with proportion MSM risk factor ($P < 0.05$). Consistent with other evidence, the Prairies had the highest rates of HIV diversification.
Conclusions: Secondary analysis of genotypic resistance data provides useful epidemiological inferences on a national scale. Different circumstances permitted establishment, dissemination, and growth of the HIV epidemic in Canada at different times within component subpopulations. Our results emphasize the varied challenges facing different regions of Canada in controlling the HIV epidemic in the future.



[Figure 1. Phylogenetic clusters of HIV in Canada.]

WEPDX0105

Phylogenetics between and within hosts along the genome reveals transmission, dual infections, recombination and contamination

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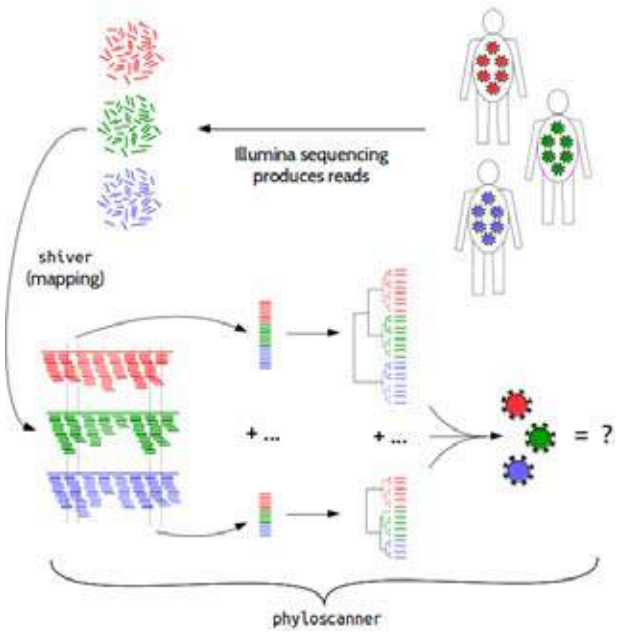
Background: Next-generation sequencing (NGS) has transformed genomics for many pathogens, increasing the availability of sequence data for studying evolution, epidemiology, vaccines and therapeutic design. However on the comprehensive Los Alamos National Laboratory database, more than 90% of HIV sequences were generated with the older method of Sanger sequencing. Widespread adoption of NGS may have been hindered by the technical difficulty of reconstructing and interpreting quasispecies data from reads (short fragments of DNA), given the high diversity of HIV between and within hosts.
Methods: Our public computer program ´shiver´ reconstructs whole HIV genomes using two commands, by mapping (aligning) reads to a reference genome constructed specifically for each sample to maximise accuracy, then finding the consensus of the reads. Our program ´phyloscanner´ interprets mapped reads with a single command. This extracts all patients´ reads in a sliding window of the genome, processes and aligns them, constructs a phylogeny with RAxML, analyses the diversity within and between hosts, performs ancestral host-state reconstruction, and produces a per-patient summary. Contamination is detected by comparing reads between patients and by finding phylogenetic outliers. We used these two programs on new whole-genome NGS data for 24 seroconverters from European and African cohorts: 5 each from subtypes A1, B, C and D, and 1 each from 01_AE, 01_AG, F1 and G.



[Understanding NGS data for HIV]

Results: In our data we found donor-recipient pairs with the direction of transmission suggested by the host-state reconstruction, identifying ancestry between quasispecies. (Unsampled intermediate patients are always possible.) Variability across the genome highlighted the importance of whole genomes and many genomic windows for detecting transmission from sequence data. Dually infected individuals had two distinct phylogenetic clusters of reads. Phylogenetic intermediates showed where these two strains recombined in the host.
Conclusions: Raw NGS data for HIV can be analysed easily and powerfully with our public tools phyloscanner and shiver.

WEPDX0106

Deep analysis of HIV transmission chains: input of ultra-deep sequencing

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Background: Many studies have shown clustering in recently HIV-1 infected Men having Sex with Men (MSM) but few data are available on the link with transmitted drug resistance (TDR). Moreover, the added value of Ultra Deep Sequencing (UDS) over Sanger sequencing (SS) for phylogenetic HIV transmission studies needs to be determined. We explored the epidemiological linkage between HIV infected MSM using both sequencing approaches, and evaluated its impact on TDR detection.
Methods: Reverse transcriptase, protease and integrase sequences were obtained by SS and UDS from 70 HIV-1 infected, treatment-naïve MSM diagnosed between January 2012 and July 2013 in Paris. Maximum likelihood phylogenies were estimated using FastTree and RAxML, with SH-like tests and 1000 bootstrap replicates, respectively with both datasets. Transmission events were identified as clades with branch support ≥70% and intra-clade genetic difference < 2.5%. TDR mutations were recognised from the consensus list of TDR surveillance.
Results: Median time between the HIV-1 diagnosis and date of the sample used for genotypic analysis was 12 days; 5 diagnosis occurred during the acute infection stage.
SS and UDS data concurred in the identification of 7 transmission pairs and 1 cluster of 3 patients. With UDS, direct linkage and direction of transmission was unambiguously inferred in 3/8 and 1/8 clusters, respectively. Sequences from the putative recipient were polyphyletic for 4/8 clusters, suggesting multiple founder viruses and excluding unobserved, intermediary links. By SS, the prevalence of TDR mutations was 5.7% in the unlinked patients and 0.0% in the linked patients (13.2% and 35.3% by UDS, respectively). Minority resistant variants were not shared among the transmissions chains.
Conclusions: While SS and UDS identified the same transmission chains, UDS provided extra information on founder viruses, linkage and levels of TDR. No mutation within the clusters were associated with reduced efficiency of PrEP, even by UDS. Moreover, no sharing of minority resistant variants was observed among the chains of transmission. These results highlight the benefits of UDS data in the phylogenetic identification of transmission chains, allowing the inference of direct linkage and multiplicity of founder viruses in the recipients, and potentially of direction of transmission.

Wednesday 26 July

Poster Exhibition

Interventions to Fight HIV

WEPEA0165

Activity of mannose-binding lectins to enhance virus neutralization by antibodies to V1V2 and V3 loops of HIV-1 envelope

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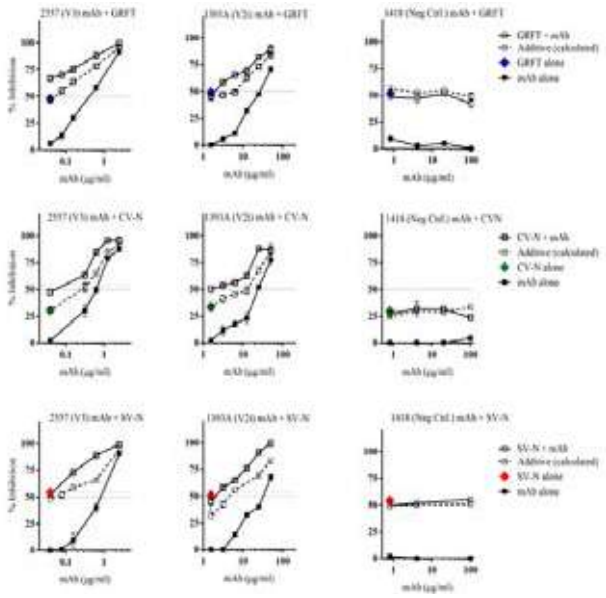
Background: The apex of HIV-1 envelope (Env) trimers, comprising the V1V2 and V3 regions in the Env gp120, contains neutralizing antibody epitopes. However, it is extensively shrouded by N-linked glycans that hinder antibody recognition. The predominant N-linked glycans are of high-mannose ($Man_{5-9}GlcNAc_2$) type and Manα1-2Man terminating glycans are 3-fold more abundant among high-mannose glycans. In this study, we sought to evaluate whether the addition of lectins targeting Manα1-2Man terminating N-linked glycans would affect the virus neutralization activity of antibodies against V1V2 and V3 conformational epitopes.
Methods: HIV-1 pseudoviruses with tier 1 Env of BaL.01, BaL.ec1, and SF162.LS were treated with Manα1-2Man-binding lectins (GRFT, CV-N, and SV-N), monoclonal antibodies (mAbs) to V1V2 (1393A) or V3 crown (2557), or combinations of lectin and mAb, and incubated with TZM-bl target cells. To test the lectin and mAb combination, reagents were added sequentially; one was serially diluted, while the other was kept at a constant IC_{50} concentration. After 48 h, virus infectivity was measured using a β-galactosidase-based assay.
Results: Each of the 3 viruses tested was sensitive to mAbs 1393A and 2557, with median IC_{50} (μg/mL) of 24.86 and 1.25, respectively. The viruses were also inhibited by each of the 3 lectins, with median IC_{50} (μg/mL) of 0.003 for GRFT, 0.15 for CV-N, and 4.07 for SV-N. These IC_{50} values correlate with lectin avidity. Virus neutralization by mAbs was enhanced by the addition of lectins, with GRFT being the most potent, followed by CV-N and SV-N. Neutralization levels were significantly higher than the calculated additive value (Fig 1), indicating synergism. This activity was seen when lectins were added before, but not after, mAbs.
Conclusions: The Manα1-2Man specific lectins potently synergize with poorly neutralizing antibodies. The enhancement in neutralization potency resulted due to stabilization of glycans by Manα1-2Man binding lectins with concomitant enhanced access of antibodies to epitopes.



[Enhancement in the neutralization potency of mAbs]

WEPEA0166

IL-33 enhances the induction, durability, and breadth of the antibody response to a DNA/protein-based HIV Env vaccine

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Background: Induction of a sustained and broad antibody (Ab) response is a major goal in developing a protective HIV vaccine. DNA is an attractive priming strategy when combined with protein or viral vector boosting; however, DNA priming alone fails to induce a substantial Ab response, limiting its potential as a stand-alone immunogen.
Methods: Using the VC10014 DNA/protein vaccine consisting of gp160 plasmids and gp140 proteins derived from an HIV clade B infected subject who developed broadly neutralizing serum Abs, and which has been previously shown to induce Tier 2 heterologous neutralizing Abs in rhesus macaques, we screened a panel of factors in C57BL/6 mice for their ability to enhance the Env-specific Ab response.
Results: IL-33, an alarmin, emerged as the lead candidate. The addition of recombinant IL-33 during the gp160 DNA priming phase dramatically changed the kinetics of the Ab response, inducing serum gp120-specific IgG (>1:12,500 titer) after a single DNA immunization, which was not detectable in mice that did not receive IL-33 ($p<0.0001$). Then following boosting with DNA/protein co-immunization in Alum, gp120-specific IgG levels were extraordinarily durable, remaining stable even at 6 weeks after final immunization compared to mice not receiving IL-33 ($p<0.0001$), in which they rapidly declined. IL-33 also increased the cross-clade breadth and avidity of the serum gp120-specific IgG response.
Conclusions: Analysis of the Env-specific B cell immunoglobulin repertoire and the IL-33 mechanism of action is ongoing. These results demonstrate the profound effect that priming conditions can have on the quality of the Env-specific antibody response.

WEPEA0167

Non-neutralizing antibodies targeting HIV's V1V2 domain exhibit strong inhibitory activities

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Background: Due to the enormous diversity of HIV-1 and other virus escape mechanisms, the development of an effective vaccine has proven to be challenging. Case-control studies of RV144 identified an inverse correlation of HIV-1 infection risk with antibodies (Abs) to the V1V2 region of gp120 with high Ab dependent cellular toxicity (ADCC) activity. Using primary effector and target cells and virus isolates grown on primary PBMCs (peripheral blood mononuclear cells), we studied the inhibitory profile of monoclonal Abs (mAbs) targeting the V1V2 loop, designated V2i mAbs, that were previously isolated from HIV-1 infected patients and display numerous immunologic similarities to the Abs elicited in RV144.
Methods: PBMCs were isolated from donor blood and separated into CD4+ lymphocytes and NK cells using an autoMACSpro. CD4+ cells, infected with primary HIV-1 virus isolates, were incubated with autologous NK cells at a 1:1 ration in the presence or absence of mAbs. Intracellular p24 was measured after 4hrs by flow cytometry. Fc-receptor mediated inhibition of Abs was analyzed on monocyte-derived macrophages, which were infected in the presence of Abs and the percentage of infected cells measured after a single round of infection.
Results: Studying the ADCC profile of several mAbs, we found that the V2i mAbs induce strong NK cell mediated lysis of HIV-1 infected CD4+ cells in our physiologically relevant ADCC model. We also discovered that some non-neutralizing mAbs directed against V2 reached higher levels of ADCC (up to 60%) than some well-known broadly neutralizing Abs such as 3BNC117, 10-1074, and 10E8 (ADCC levels of 23%, 14%, and 10%, respectively).
We also studied the Fc-receptor mediated inhibition of V2i mAbs on macrophages, infected with primary HIV-1 isolates. Several of the V2i mAbs efficiently reduced the infection rate by up to 90% and the addition of anti-Fcγ receptor blocking antibodies partly reversed this inhibition. Thus, V2i mAbs display Fc-receptor mediated inhibition of infection on macrophages.
Conclusions: Our data suggest that in addition to neutralization other inhibitory functions can effectively participate in HIV protection. V2i mAbs display functions that inhibit virus infection and kill HIV-1 infected cells, highlighting the interest in inducing such Abs in future HIV-1 vaccine research.

WEPEA0168

Antibody dependent cell-mediated phagocytic activity is increased in the genital tract mucosae of HIV-infected women with prior tenofovir gel exposure

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Background: Pre-exposure prophylaxis (PrEP) can alter antibody kinetics resulting in delayed antibody binding avidity and reduced titers during the breakthrough and early post-HIV infection periods. However, the effect of prior PrEP on subsequent antibody function remains poorly described.
Methods: Using an in vitro neutrophil-based functional assay, the antibody dependent cell-mediated phagocytic function (ADCP) to p66, p24, gp41 and gp120 were investigated in the blood and genital tracts of women who seroconverted from the CAPRISA 004 1% tenofovir microbicide gel trial at 3; 6 and 12 months post-infection in the tenofovir arm (n=24) and placebo arm (n=24).
Results: Detection of HIV-specific antibody mediated phagocytic responses (phagocytic scores above background) at 3 months post-infection, were higher in the genital tract compared to the blood with a mean of 92% detectability versus 89%, in both arms. In the blood, evolving and significantly increased phagocytic activity mediated through antibodies specific to p66 and gp120 ($p<0.05$) were found from 3 to 12 months post-infection in both arms. However, there were no differences in the magnitude of ADCP activity between the arms. In contrast, the magnitude of mucosal ADCP activity was higher in the tenofovir arm than in the placebo arm over 12 months for p24 ($p= 0.006$) and gp41 ($p=0.01$) specific antibodies. Specifically, at 6 months, mucosal ADCP activity in the tenofovir arm was significantly higher for p24 ($p=0.003$) and gp41 ($p=0.005$) compared to the placebo arm. ADCP activity did not correlate between the blood and genital tracts for either arm, despite the strongly significant inter-compartmental correlations for the profile of HIV-specific antibodies. Irrespective of arm, the genital tract had early and detectable ADCP activity albeit at lower magnitude compared to the blood ADCP activity.
Conclusions: Prior topical tenofovir gel did not diminish antibody-mediated effector ADCP function, as evidenced by the higher mucosal specific ADCP activity in the tenofovir arm relative to the placebo arm. Together, these data inform combination prevention strategies, that parallel PrEP usage can influence humoral immunity, and may even enhance both the ensuing antibody profiles and perhaps diverse antibody-mediated effector functions post HIV vaccination, at the site of vulnerability, the genital tract.

WEPEA0169

HIV-specific B cell frequency correlates with transmitted/founder virus neutralization in patients naturally controlling HIV-infection

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Background: In the absence of antiretroviral therapy (ART), elite controllers (EC) naturally control HIV infection maintaining low to undetectable viral loads. Immune responses, in particular cytotoxic T cell responses, participate in the control of HIV. Increasing evidences suggest that the B cell antibody (Ab) responses might also play a role. Understanding the mechanisms implicated in natural control of HIV infection will help in developing efficient HIV vaccines. In EC, we aimed at characterizing memory B cell compartments and determining the frequency, the specificity and the isotype of HIV-specific memory B cell responses. We asked whether the preservations of HIV-specific B cells could be associated with the capacity to neutralize HIV viruses.
Methods: In EC expressing or not the protective HLA-B*57 allele, patients under ART and HIV-negative individuals, we characterized memory B cell compartments and HIV-specific memory B cells responses using flow cytometry and B cell-ELISPOT. We analyzed the capacity of sera from EC to neutralize a panel of 10 HIV strains including mostly transmitted/founder (T/F) viruses.
Results: EC preserve memory B cell compartments and in contrast to treated patients, maintain HIV-specific responses. HIV-specific B cells mainly express IgG1+ Abs. Importantly, 25% of EC neutralized at least 40% of viral strains tested. Moreover, in HLA-B*57+ EC, effective cross-neutralization was associated with high HIV-specific B cell frequencies.
Conclusions: Preservation of HIV-specific B cells and its association with cross-neutralizing capacities in HLA-B*57+ EC suggest that efficient memory B cell responses could contribute to the natural control of HIV infection.

WEPEA0170

Early recovery of antibody-mediated neutralization and ADCC responses in HIV-positive individuals under dolutegravir-based antiretroviral therapy

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Background: Dolutegravir (DTG) is the newest and most potent member of the integrase inhibitor drug family. No reports of drug resistance have been reported in patients receiving first-line DTG treatment since its FDA approval in 2013. It has been shown that resistance mutations associated with first-line treatment contribute to functionally impaired viruses without compensatory mutations. The impact of DTG-treatment on viral evolution in patients is not clear, but characterization of host immune responses against HIV-1 will shed light on the status of viral infection during suppression achieved by antiretroviral (ARV) therapy.
Methods: Our study is a longitudinal observational study. Sequential serum samples were obtained from patients suppressed with DTG-based or Elvitegravir (EVG)-based therapy (n=8 and n=5, respectively) at one month (T1), two months (T2), and five to six months (T3) after treatment initiation. The antibody-dependent cellular cytotoxicity (ADCC)-mediating potency and virus neutralization titers of the serum samples were measured.
Results: T2 and T3 sera from four individuals treated with DTG- or EVG-based ART (two in each group) were tested for their ability to mediate ADCC activity. The serum dilutions at which 50% of the infected target cells were killed were 48-fold higher at T2 and 11-fold higher at T3 for DTG-treated individuals when compared to EVG-treated individuals. The 50% neutralization titers of the sera were 1:227 at T1, 1:640 at T2, and 1:647 at T3 for DTG-treated individuals and 1:247 at T1, 1:225 at T2, and 1:633 at T3 for EVG-treated individuals.
Conclusions: Patients treated with DTG compared to EVG had more robust levels ADCC responses ($p < 0.01$) and earlier recovery of neutralization titre overtime. These data are consistent with reports of a reduced likelihood of HIV Env evolution following exposure to DTG compared to other drugs.

WEPEA0171

Post-translational processing influences antibody reactivity against the gp120 V2 domain on infected CD4+ T cell

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Background: Following the RV144 vaccine trial, interest in non-neutralizing antibody responses directed against the V2 domain of gp120 has increased. Such responses may contribute to ADCC and other effector mediated anti-viral activities. The V2 domain of gp120 can adopt distinct conformations that influence antibody reactivity. The structure of the V2 domain is strongly influenced by post-translational processing (PTP), including glycosylation. In this study we investigated the influence of PTP on V2 conformation and the reactivity of V2-specific monoclonal antibodies (mAbs).

Methods: To manipulate Env PTP, we cultured HIV infected CD4+ T cells in the presence of Brefeldin A (BreA), an inhibitor of transport between the endoplasmic reticulum and Golgi. BreA treatment of infected cells should increase the proportion of Env expressed on the surface of the cell that is processed in a Golgi-independent manner. Env processed in this way is incorporated into infectious virions, but has no demonstrable function. We then probed the surface of these cells with a panel of V2 mAbs that recognize distinct conformations that differ with respect to neutralization sensitivity.
Results: In the absence of BreA, several mAbs specific for alternative conformations recognize significant fractions of Env on the surface of infected CD4+ T cells. This indicates that alternative conformations are present on the surface of infected cells. Interestingly, for CH58, a non-neutralizing V2 mAb derived from an RV144 vaccine recipient, reactivity was largely unaffected by BreA treatment of infected cells. In contrast, for PG9, a broadly neutralizing mAb that recognizes an alternative glycan-dependent conformation of V2, reactivity was almost completely absent when cells were cultured in the presence of BreA.
Conclusions: Our results indicate that the mAb CH58 recognizes a conformation of V2 that can be processed in a Golgi-independent manner and that this epitope is retained on the surface of infected primary CD4+ T cells. This finding raises the possibility that certain antibodies targeting alternatively processed forms of HIV Env may have added value and contributed to the mechanisms underlying reduced risk of acquisition in the RV144 trial. These findings may have implications for the design of protective HIV vaccine immunogens.

WEPEA0172

A unique N332 supersite directed bnAb from a slow progressor shares characteristics with both CD4bs and V3-glycan bnAbs

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Background: Broadly neutralizing antibodies (bnAbs) can protect from HIV-1 acquisition but it is still poorly understood which factors drive bnAb development in natural infection. Here we report on the development of a potent bnAb response in a slow progressing, subtype B infected individual, Z91, enrolled in the Zurich Primary HIV Infection (ZPHI) study, who controlled viremia at low level (range: 750-40 000 HIV-1 RNA copies/ml) for 9 years before initiation of therapy.
Methods: A potent bnAb, ZPHI-12, was isolated from PBMC of patient Z91. The evolution of the bnAb was studied longitudinally by deep sequencing. Env genes were cloned from plasma viruses at multiple time points and analyzed for sensitivity to autologous plasma and ZPHI-12. Breadth was determined against a 38 multiclade virus panel in the TZM-bl assay. Comprehensive neutralization, binding and competition analyses were performed to map the epitope of bnAb ZPHI-12.
Results: Plasma neutralization breadth in patient Z91 increased from 13% at week 46 to 78% after 7 years of infection. BnAb ZPHI-12, isolated at 5.4 years post infection neutralizes 58% of probed viruses. ZPHI-12 has a 21 amino acid long CDRH3 containing an unusual stretch of 7 tyrosines. Autologous virus quasispecies showed variable resistance and sensitivity to ZPHI-12 during the 8 year observation period. Autologous viral resistance at different time points was differentially influenced by N332 glycosylation and accompanied by mutations in the V3-"GDIR" motif. ZPHI-12 binds both gp120 monomer and trimer and competes with PGT128 and VRC01 bnAbs for binding. Interestingly, ZPHI-12 shows differential binding to the Env core probe RSC3/RSC3d371I similar to CD4-bs directed bnAbs.
Conclusions: bnAb ZPHI-12 shows characteristics of both, CD4bs and V3-glycan site bnAbs. Mutations of the V3-GDIR motif and its surrounding glycans suggest that the bnAb response kept continuous pressure on that target region. While dependent on the N332 in the context of some virus strains, the autologous virus found ways to escape ZPHI-12 while maintaining the N332 glycosylation site.

WEPEA0173

Antibody dependent cellular cytotoxicity and neutralization antibody responses in HIV-1-infected elite controllers

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Background: A small percentage of HIV-1 positive individuals (1%), the "elite controllers" (EC), spontaneously control viremia in the absence of therapy for one year or more. The ability to suppress viral load below the limit of detection by standard assays was associated with more favorable clinical outcomes compared with viremic patients.
Methods: Here, we analyzed the neutralization capability (Nabs) and the antibody dependent cellular cytotoxicity (ADCC) of the plasma of 13 EC. The 13 patients, all immunologically healthy, were therapy naïve with a viral load below the detection limit of standard assay (< 50 cp/ml). The time from diagnosis of HIV-1 infection varied from 1 to 25 years.
Nabs were tested against laboratory (n=2) and primary (n=2) heterologous isolates in a PBMC-based assay. ADCC was performed by Grantoxilux assay using $gp120_{BAL}$-coated target cells and purified NK cells as effector.
Results: Seventy-nine percent of plasma were able to neutralize at least one virus and 30% neutralized at least 2 viruses. In general neutralization titers were low or medium level (1/20-200). Interestingly, five of 13 patients did not neutralize the highly neutralization-sensitive SF162. All plasma samples showed ADCC activity independently from neutralization capacity. Titers of ADCC ranged from 1/1100 to 1/156250 with maximum granzyme B activity varying between 30-88%.
Conclusions: Our results show that plasma neutralizing capacity is frequent but generally of low titer in EC. Interestingly, ADCC is present in all EC tested, suggesting that non neutralizing response could play a role in controlling viremia.

WEPEA0174

Identification and characterization of broadly neutralizing antibodies against founder viruses

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Background: In most cases HIV-1 infection results from the transmission of a limited number of viral variants termed transmitted/founder (T/F) viruses. We propose that the antibodies generated by a preventive vaccine should be able to neutralize preferably the transmitted variants that establish the infection. The objective of this study is the identification and characterization of antibodies capable of neutralizing T/F viruses in a cohort of patients with chronic infection.
Methods: 190 serum samples from a cohort of chronically infected individuals (Hospital Clinic, Barcelona) were analyzed. The neutralization capacity of these sera was determined by neutralization assays against two different panels: a mini-panel of 6 recombinant viruses with envelopes of T/F viruses (Fiebig stages I to IV, subtypes B and C) and a mini-panel of 5 recombinant viruses from chronic infection of several subtypes. The specificities of the neutralizing antibodies were studied using the following techniques: ELISA using mutated gp120 that abrogates antibody binding, neutralization assays with viruses mutated in the antibody binding regions and peptide competition neutralization assays.
Results: We have identified 12 serum samples with broadly neutralizing antibodies against founder viruses, 3 of which are also capable of neutralizing chronic viruses. The remaining 9 sera neutralized only founder viruses and 3 sera neutralized only chronic viruses. In patients displaying broad neutralizing activity, epitope mapping showed that the percentage of sera targeting the CD4 binding site and the V1/V2 domain was higher against the panel of founder viruses than in those with neutralizing responses to chronic viruses. These differences did not reach statistical significance probably due to the small population size.
Conclusions: We have identified a group of neutralizer patients against founder viruses and observed differences in the susceptibility to neutralization between chronic and founder viruses included in the neutralization panels of this study. These results could suggest that there are structural differences between T/F and chronic HIV-1 envelopes and that an effective preventive vaccine should induce antibodies able to neutralize these early viral envelopes.

WEPEA0175

The impact of HIV-genetics on imprinting HIV-1 neutralization and binding responses

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Background: A key question on the way towards an HIV-1 vaccine is the impact of viral genetics on the neutralization response: Will a given HIV-1 envelope immunogen induce the same antibody specificities across vaccinees? Here we addressed this by studying the influence of virus genetics in potential transmission pairs identified within a recently conducted systematic screen of HIV-1 neutralization in 4,484 individuals (Swiss 4.5K Screen; Rusert, Kouyos Nat Med 2016).
Methods: Potential transmission pairs were defined based on HIV-1 pol gene phylogenies and plasma neutralization activity against a 14 multi-clade pseudovirus panel and IgG binding activity to 13 HIV-1 Gag and Env antigens was determined. Neutralization and binding similarity within pairs was determined by Spearman correlation and a range of shuffling tests and similarity measures.
Results: We identified 336 potential transmission pairs within the Swiss 4.5K Screen. For 7/14 pseudoviruses, we observed a significant ($p<0.05$) positive within-pair correlation of neutralization. The average Spearman correlation coefficient across all 14 viruses was weakly ($\rho=0.10$) but significantly ($p_{shuf}<0.001$) positive, even after controlling for viral subtype, infection-length and ethnicity ($p_{shuf}<0.001$). Similarly, binding to different HIV-1 antigens was significantly correlated within pairs (average $\rho_{spear}=0.12$, $p_{shuffling}<0.001$). This similarity was stronger for IgG1-responses (average $\rho_{spear}=0.18$, $p_{shuffling}<0.001$) than for IgG2 (average $\rho_{spear}=0.08$, $p_{shuffling}=0.01$) and IgG3 (average $\rho_{spear}=0.08$, $p_{shuffling}=0.01$). Notably, we found that two elite neutralizers (top 1% of neutralizers) formed a transmission pair and exhibited highly similar neutralization ($\rho_{spear}=0.73$) fingerprints. To generalize this finding, we present a novel systematic approach which could identify pairs with similar neutralization and binding responses.
Conclusions: Our results indicate that viral genetic factors significantly affect the breadth and specificity of the antibody responses to HIV-1. A large proportion of this effect is likely due to the env gene. Not all bnAb Envs may carry the capacity to imprint identical Ab specificity, thus utilizing Envs from bnAb inducers with proven transferability of antibody reactivities as identified here may be the ultimate immunogen candidates to base vaccine design on.

WEPEA0176

Neutralizing antibodies efficiently inhibit HIV transmission from infected T cells to heterologous DC and T cells

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Background: In the semen, both free viruses and infected cells are able to transmit HIV during sexual intercourse. An efficient vaccine should therefore inhibit both infection states. The aim of this study is to analyze the capacity of antibodies (Abs) to inhibit HIV transmission from infected cells.
Methods: We developed an in vitro model aiming to mimic mucosal HIV transmission via infected cells. Briefly, PHA-activated CD4(+) T cells labeled with PKH26 from donor A were infected with HIV-1_{Bal}, HIV-1_{Bx08} or a transmitted/founder virus HIV-$1_{pREJO.}$ As at the mucosal site both CD4(+) T cells and dendritic cells (DCs) have been described to be the first HIV targets, we further co-cultured the infected cells with CD4(+) T cells and DCs from another donor (donor B) in the presence or absence of Abs. The different infected cell populations were identified by PKH26 labelling, membrane marker phenotyping and p24 staining by FACS. Statistic analysis was performed using Mann-Whitney test or one-way ANOVA (Kruskal Wallis test), where $p< 0.05$ was considered significant.
Results: In this DC/T cell co-culture model, we found a significantly increased infection rate ($p< 0.05$) in DCs compared to CD4(+) T cells from donor B after 1 day of co-culture with infected CD4(+) T cells from donor A. In the presence of broadly neutralizing Ab 10-1074, a dose dependent decrease of infected cells was observed at a similar level for both cell types of donor B. Analysis of the inhibitory potential of other HIV-specific Abs is currently in progress.
Conclusions: Overall, our results indicate that DCs are strategic cells efficiently infected in addition to CD4(+) T cells in this heterologous co-culture transmission model. Neutralizing antibodies are potent inhibitors of both infected target cells. Future HIV prophylactic vaccine design should develop immune strategies able to prevent infection of DCs, in addition to the prevention of infection of CD4(+) T cells.

WEPEA0177

Suppression of SAMHD1 in dendritic cells improves antigen presentation and HIV-specific cytolytic T cell response *in vitro*

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Background: Sterile Alfa Motif domain and HD domain-containing protein 1 (SAMHD1) is one of the human host proteins known to block HIV replication in dendritic cells (DCs). Suppression of SAMHD-1 may lead to infection of DCs and efficient antigen processing leading to induction of effective adaptive immune response.
We studied the effect of HIV-2 Vpx induced down regulation of SAMHD-1 in human monocytes derived dendritic cells (MDDCs) on HIV-specific cytolytic T cell response.
Methods: MDDCs generated in vitro from blood monocytes from healthy donors (N=6) were nucleofected using plasmid containing Vpx from HIV-2 ROD9 (for Vpx expression) to suppress SAMHD-1 and subsequently infected with primary HIV-1 isolate (0.01 MOI). These HIV-1 infected MDDCs ($MDDC_{HIV+Vpx+}$) were mixed with autologous T cells (1:10) and cultured for 10 days. HIV-specific cytolytic $CD4^+$ and $CD8^+$ T cell response was assessed by determining the expression of CD107a (a degranulation marker) against HIV-1 gag and env peptide pools using multicolour flowcytometry. $MDDC_{HIV-Vpx-}$ and $MDDC_{HIV+Vpx-}$ were used as the assay controls. Wilcoxon matched paired test was used to check the statistical significance in the comparative analysis.
Results: HIV-specific CTL response generated using $MDDC_{HIV+Vpx+}$ was found to be significantly higher as compared to T cells mixed with $MDDC_{HIV+Vpx-}$. A significantly higher response of CD107a+ expression by CD8+ T cells was seen when stimulated with $MDDC_{HIV+Vpx+}$ (Mean: 4.62%; Range: 0%-23.7%) as compared to CD8+T cells mixed with $MDDC_{HIV+Vpx-}$-(Mean: 0.23%; Range: 0%-0.95%) (p=0.001).
Similarly, CD4+CD107a+ T cells when stimulated using $MDDC_{HIV^+Vpx^+}$ were found to be significantly higher (Mean: 2.0%; range: 0.02%-11.8%) as compared to when stimulated with $MDDC_{HIV^+Vpx^-}$ (Mean: 0.2%; range: 0.01%-0.77%) (P=0.0068).
Conclusions: Vpx mediated downregulation of SAMHD-1 resulted in more efficient antigen presentation and induction of CD4+ and CD8+ CTL responses by MDDCs. This finding may provide a new target for immunological intervention for control of HIV infection, especially during early stage of infection.

WEPEA0178

Impact of a single escape mutation selected by HLA-A*24:02-restricted $CD8^+$ T cells on HIV-1 control by HLA-B*35:01-restricted ones and T cell adaptation

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Background: It is well known that HLA-B*35 is an HLA allele associated with rapid progression to AIDS. Recent studies demonstrated that most prevalent subtype HLA-B*35:01 is a detrimental allele in HIV-1 clade B-infected individuals. However, the mechanisms underlying the detrimental impact of this allele on the clinical outcome of HIV-1 clade B-infected individuals remain unclear. To clarify this mechanism, we sought to identify HLA-B*35:01-restricted epitope-specific $CD8^+$ T cells controlling HIV-1 in HIV-1 clade B-infected Japanese individuals and further analyzed the effect of mutations within the epitopes on the T cell responses and clinical outcome.
Methods: We analyzed 15 HLA-B*35:01-restricted epitope-specific $CD8^+$ T cells in 63 HIV-1 clade B-infected Japanese individuals carrying HLA-B*35:01 using ELISPOT assay. To clarify effects of mutations on the epitope-specific $CD8^+$ T cell responses, we next analyzed HLA-associated mutations within the HLA-B*35:01-restricted epitopes in the Japanese cohort.
Results: The T cell responses to only 4 HLA-B*35:01 epitopes (GagNY9, PolVY10, NefRY11, and NefYF9) were significantly associated with low plasma viral load. However, the control of HIV-1 by YF9-specific T cells are impaired by a single NefY135F mutation selected by RF10-specific CTLs restricted by HLA-A*24:02 which is found in 70% of Japanese individuals. The longitudinal analysis of the YF9-specific T cells showed that the emergence of the virus having this mutation led to the induction of the mutant epitope-specific T cells having entirely different TCR clonotypes from those of the wild type-specific T cells. The ability of mutant-specific T cells to suppress the mutant virus was significantly weaker than that of wild type-specific ones to suppress wild type virus in vitro, suggesting

that the mutant-specific T cells fail to control HIV-1 replication in vivo. Thus, the HLA-B*35:01-restricted T cells adapt to the mutation virus selected by the HLA-A*24:02-restricted ones.
Conclusions: The accumulation of NefY135F mutation selected by the HLA-A*24:02-restricted CTLs and the adaptation of YF9-specific T cells to the mutant virus are key factors in the impairing control of HIV-1 in Japanese individuals having a detrimental allele HLA-B*35:01.

WEPEA0179

Control of HIV-1 by HLA-B*52:01-restricted or C*12:02-restricted cytotoxic T lymphocytes specific for 6 epitopes in an HIV-1-infected Japanese cohort, in which HLA-B*57 and HLA-B*27 are very rare

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Background: Our previous study showed that the HLA-B*52:01-C*12:02 haplotype, which is the most prevalent haplotype in Japan (approximately 20%), was significantly associated with both low plasma viral load (pVL) and high CD4 counts in treatment-naïve Japanese individuals chronically infected with HIV-1, suggesting that these alleles are protective ones in Japan and implying that HLA-B*52:01-restricted or C*12:02-restricted cytotoxic T lymphocytes (CTLs) may control HIV-1 replication. The following study demonstrated the control of HIV-1 replication by 4 HLA-B*52:01-restricted CTLs in the Japanese cohort. However, it is still unclear whether HLA-C*12:02-restricted CTLs control HIV-1.
Methods: We first identified novel HLA-C*12:02-restricted CTL epitopes by IFN-g ELISpot assay using a set of HIV-1 overlapping peptides spanning Gag, Pol, and Nef regions and intracellular cytokine staining assay. We next statistically analyzed correlations between these epitope-specific CTL responses and pVL or CD4 counts in 80 HIV-1-infected HLA-B*52:01$^+$HLA-C*12:02$^+$ Japanese individuals using two-tailed Mann-Whitney test.
Results: We identified 4 novel HLA-C*12:02-restricted epitopes, Gag TH9, Pol KY9, Pol IY11, and Nef MY9. The frequencies of the responders to Pol IY11 or Nef MY9 were over 20% whereas those to Gag TH9 and Pol KY9 were less than 3%. The T cell responses to Pol IY11 or Nef MY9 were significantly associated with both low pVL and high CD4 counts in the Japanese cohort, suggesting that these epitopes were immunodominant ones. The breath of the T cell responses to these 2 HLA-C*12:02-restricted and 4 previously identified HLA-B*52:01-restricted epitopes (Gag MI8, Gag RI8, Gag WV8 and Pol SI8) revealed a significant inverse correlation with pVL and a positive correlation with CD4 counts, indicating that the CTLs specific for these 6 epitope synergistically control HIV-1 replication in Japanese individuals.
Conclusions: The present study highlighted the CTLs specific for 6 epitopes restricted by HLA-B*52:01 or HLA-C*12:02 play an important role on control of HIV-1 in Japanese individuals. These results strongly support our previous finding that the HLA-B*52:01-C*12:02 haplotype had the protective effect on clinical outcomes in Japan.

WEPEA0180

Follicular cytotoxic T cells specifically control the infection in follicular helper T cells

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Background: Follicular helper T (T_{FH}) cells are a specialized subset of CD4$^+$ T cells that reside in B-cell follicles to support humoral immune response. Recently, T_{FH} cells were identified as a major cellular reservoir of HIV-1 in individuals under combination anti-retroviral therapy (cART) and may represent a major obstacle for a functional cure for HIV-1 infection. Cytotoxic CD8$^+$ T cells play a central role in the elimination of virus-infected cells. However, it remains unclear whether a specific subset of CD8$^+$ cytotoxic T cells controls the infection of T_{FH} cells.
Methods: The presence, phenotype and function of CD8$^+$ T cells in B-cell follicles were characterized in human HIV-1-infected human samples and a mouse model of infection with lymphocytic choriomeningitis virus (LCMV).
Results: We identified a specialized group of cytotoxic T cells that expressed the chemokine receptor CXCR5, selectively entered B cell follicles and eradicated infected T_{FH} cells. The differentiation of these cells, termed ‚follicular cytotoxic T cells' (T_{FC} cells), required the transcription factors Bcl6, E2A and TCF-1 but was inhibited by the transcriptional regulators Blimp1, Id2 and Id3. Blimp1 and E2A directly regulated Cxcr5 expression and, together with Bcl6 and TCF-1, formed a transcriptional circuit that guided T_{FC} cell development. We also found the differentiation of T_{FC} cells is regulated by certain cytokines including IL-2.
Conclusions: T_{FC} cells specifically control the infection in T_{FH} cells. The identification of T_{FC} cells has far-reaching implications for the development of strategies to eliminated persistent infection in T_{FH} cells for a functional cure of HIV-1 infection.

WEPEA0181

Low T cell immunogenicity of the yellow fever vaccine in HIV-infected patients: ANRS EP46 NOVAA

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Background: The immunogenicity of the live attenuated Yellow fever vaccine (YFV) in HIV-infected patients even with high CD4 counts has been questioned. We previously reported the good YFV safety in HIV-infected adults with high CD4 cell counts from the NOVAA-AnrsEP46 study and the induction of similar levels of protective specific antibodies compared to uninfected vaccinated. Here we report the T cell immunogenicity of the YFV in this study.
Methods: The prospective NOVAA T cell sub-study included 36 YFV-naïve HIV-infected adults under antiretroviral therapy (ART) with CD4 counts >350/mm^3 and plasma HIV-RNA < 50 cp/ml for at least 6 months, and 16 HIV-negative healthy adults. Patients' characteristics were similar to the whole study. All received one YFV-17D injection. T cell responses were assessed ex vivo at D0, D28, D91 and D364 using an IFN-gamma ELISpot assay and a series of 15-mer peptides from the YF non-structural (NS) NS1, NS2, NS3, NS4, NS5, envelope and core proteins.
Results: YFV-specific T-cells were detected at D28 after vaccination in 21.4% HIV+ and 50% HIV- individuals, (p=0.082) with median cell frequencies of 57.5 [50-2,335] and 125 [50-1,645] SFC/10^{6}PBMC. At D91, YFV-specific T-cells persisted in 14.7% HIV+ compared to 50% HIV- individuals (p=0.01) with similar cell frequencies (65 [50-725] and 107.5 [55-605] SFC/10^{6}PBMC), and decreased at D364 down to 10% in HIV+ and 15.4% in HIV- individuals respectively (p=0.63). The YFV-specific T-cells from both groups recognized a median of one protein [1-3] per individual. NS1 was the most immunogenic protein, recognized in 22.5% cases, followed by NS2 in 10.2%, NS4: 7.8%, Env: 6% and NS3: 4% cases, respectively. Overall during the one year follow-up a specific YFV-T-cell response was detected at least once against at least one YFV protein in 27.8% HIV+ patients compared to 62.5% HIV- individuals (p=0.03).
Conclusions: The T cell immunogenicity of the live attenuated YFV vaccine was significantly lower in ART-treated HIV infected patients than in healthy uninfected subjects, despite high CD4 cell counts and suppressed viral replication, contrasting with similar antibody responses. Such a lower T cell immunogenicity might influence the limited duration of protective antibodies to YFV reported in HIV-infected patients.

WEPEA0182

Heterogeneity of circulating follicular helper T cells during hyperacute HIV-1 subtype C infection impact neutralizing antibody responses

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Background: Seminal studies have described the characteristics of broadly neutralizing antibodies developed during HIV-1 infection, however, the immunological mechanisms responsible for their development is not well understood. Follicular helper T cells (Tfh) are a subset of CD4 T helper cells that support the development of high affinity and long-term B cell antibody responses, but their influence on the initial development of antibody breadth is not well characterized. Here we investigate how hyperacute HIV-1 infection modulates the Tfh phenotype and determined the relationship between Tfh phenotype subsets and neutralization breadth.

Methods: Two groups (HIV negative, n=10 and acute HIV, n=11) were drawn from a cohort of high risk females from Kwazulu-Natal, South Africa and were sampled longitudinally during the first year post infection. Tfh was phenotypically and functionally characterized from PBMCs using multicolor flow cytometry. Furthermore, the HIV-neutralizing ability of the serum was measured at one-year post infection using TZM-bl assay.
Results: An emergence of Tfh (CD45RA- CXCR5+ PD1+ CD4 T cells) was observed within the first week of infection, it peaked by the third month and subsequently declined. Interestingly, when we examined the Tfh subsets, we observed a significant increase in the frequencies of CXCR3+Tfh and a significant decrease of CXCR3-Tfh during hyperacute HIV. Four individuals developed cross reactive antibodies after one year of infection. Furthermore, we observed a trend of higher CXCR3+Tfh frequencies during hyperacute HIV infection among the neutralizers compared to non-neutralizers.
Conclusions: Our results indicate that hyperacute HIV infection alters Tfh subset composition. We also showed an association between higher frequencies of CXCR3+Tfh and the subsequent development of cross reactive anti HIV-1 antibodies. These data are relevant for HIV-1 vaccine strategies seeking to induce broadly neutralizing antibody responses.

WEPEA0183

CD8+ T-cell suppressive capacity directly correlates with peak viral load in a cohort of virally suppressed HIV+ patients on combination antiretroviral therapy

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Background: The combination of potent HIV-specific immune responses and a small latent viral reservoir is likely required to achieve post-treatment control of HIV infection. In this study we investigated correlations between CD8+ T-cell suppressive capacity, HIV reservoir and clinical parameters.
Methods: Fifty-three patients on cART with suppressed viremia (< 55 copies/mL) were recruited. Total HIV DNA and unspliced mRNA were quantified in PBMCs using digital droplet PCR. In a sub-group of patients infected with HIV subtype B, viral transcriptional activity was quantified with the ‚tat/rev induced limiting dilution assay' (TILDA) (N=21) and CD8+ T-cell suppressive capacity was measured against HIV-1 III_B superinfected autologous CD4+ T-cells before and after HIV consensus B Gag peptide stimulation (N=16). The latter assay was also done on six negative donors. Linear regression and student t-test were used for correlation analyses.
Results: Patients had a median: age 45.7 years, time on cART 70 months [IQR: 41 - 130], nadir CD4 count 283 cells/µL [IQR: 191 - 390]. 83% were male. Total HIV DNA was detected in all patients, ranging from 15 to 859 copies per million PBMCs (median: 196). Unspliced HIV RNA was detected in 42/53 patients (79%) ranging from 0.0 to 39.1 copies per million PBMCs (median: 2.8). TILDA values ranged from 0 to 313 cells [IQR: 1.4 - 55.8] with detectable HIV RNA transcripts per million CD4+ T cells after stimulation. Whereas CD8+ T-cell suppressive capacity without peptide stimulation was only observed in one patient, eight of 16 showed suppression with peptide stimulation. Suppression in the negative donors was used to determine the background threshold.
Total HIV DNA correlated directly with usRNA levels ($p< 0.05$). TILDA values tended to be higher for patients with residual versus undetectable viremia ($p=0.071$). Interestingly, a positive correlation between viral suppressive capacity and peak viral load was observed ($p< 0.05$).
Conclusions: In this group of virally suppressed patients, heterogeneity in terms of immune responses and reservoir size was observed, as expected. The remarkable correlation between peak viral load and CD8+ T-cell suppressive capacity after peptide stimulation might reflect the build-up of memory responses as a result of high antigen exposure before treatment initiation.

WEPEA0184

Early antiretroviral therapy intervention in HIV infection can rescue metabolic profiles of *ex vivo* CD8+ T cells

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Background: The molecular and cellular pathways that lead from HIV infection to AIDS are complex, multifactorial and not understood. One immunological phenomenon in HIV infected individuals that has been suggested as a factor for progression towards AIDS is chronic immune activation (CIA). The underlying causative mechanism(s) of CIA in HIV infected individuals are not well understood. The immune dysfunction and dysregulation upon HIV infection, which is characterized by the depletion of CD4+ T cells coupled with the expansion of non functional exhausted CD8+ T cells, confound the search for an underlying factor(s) for CIA. Recent work has established that metabolic programming itself influences T cell differentiation, effector function, persistence and survival into memory. We hypothesize that the chronic nature of HIV infection along with the associated CIA alter the metabolic profiles of effector CD8+ T cells to drive and to maintain their exhausted status.
Methods: Herein we generated metabolic profiles of isolated ex vivo CD8+ T cells from HIV uninfected, HIV Early infected treatment naïve and on treatment, HIV Chronic infected treatment naïve and on treatment, and viral controllers (VCs), who are able to control the HIV viral replication without treatment, by subjected them to Seahorse XF^{e}96 metabolic analyzer.
Results: We show that the baseline oxygen consumption rate (OCR), a readout of oxidative phosphorylation, of CD8+ T cells is enhanced in all the different HIV clinical stages, except HIV Early infected treatment naïve and on treatment, compared with HIV uninfected. The ATP linked and reserve capacity OCRs are also increased in all the different HIV clinical stages other than HIV Early infected on treatment. The overall metabolic profiles of CD8+ T cells from HIV Early infected on treatment is similar to that of HIV uninfected. Surprisingly, the baseline glycolysis rate is enhanced during HIV Early infected treatment naïve and VCs
Conclusions: Thus, the metabolic profile of ex vivo CD8+ T cells from chronic HIV infection was altered compared to HIV uninfected. This alteration can be rescued with early anti-retroviral therapy intervention. Further studies to understand the possible mechanism of the altered metabolic states of CD8+ T cells during HIV infection are currently underway.

WEPEA0185

Unilateral selection of viral mutations for escape from CD8+ T-cell recognition in SIV infection

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Background: CD8+ T-cell responses exert strong suppressive pressure on HIV replication and frequently select for viral escape mutations. Some of these mutations result in loss of epitope-MHC-I interaction, whereas others do not inhibit epitope presentation but disturb CD8+ T-cell recognition. Selection of the latter mutations may induce CD8+ T-cell responses targeting the mutated epitope. In the present study, to investigate these virus-host CD8+ T-cell interaction, we analyzed CD8+ T-cell responses targeting Mamu-A1*065:01-restricted $Gag_{241-249}$ (SSVDEQIQW) epitope and viral genome sequences encoding this epitope in a macaque AIDS model of SIV infection. In our previous study, most Mamu-A1*065:01-positive macaques have been shown to select a mutation resulting in a D-to-E change at the 244th residue in Gag, which does not inhibit epitope presentation but $Gag_{241-249}$-specific CD8+ T-cell recognition.
Methods: We examined viral genome sequences encoding the $Gag_{241-249}$ epitope in Mamu-A1*065:01-positive rhesus macaques infected with wild-type SIVmac239 having Gag244D (n = 9) or mutant SIVmac239 having Gag244E (n = 5). We then investigated CD8+ T cells targeting $Gag_{241-249}$.244D dominantly ($Gag_{241-249}$.244D-specific), $Gag_{241-249}$.244E dominantly ($Gag_{241-249}$.244E-specific), or both equivalently by using wild-type ($Gag_{241-249}$.244D) and mutant ($Gag_{241-249}$.244E) epitope-Mamu-A1*065:01 tetramers.
Results: Wild-type SIV-infected macaques dominantly elicited $Gag_{241-249}$.244D-specific CD8+ T-cell responses in the early phase of infection. These animals showed selection of the 244D-to-244E mutation within a year post-infection and concomitant increases in the frequency of $Gag_{241-249}$.244E-specific CD8+ T cells. In contrast, mutant SIV-infected macaques elicited $Gag_{241-249}$.244E-specific CD8+ T-cell responses in the early phase. Interestingly, however, none of the mutant-infected showed the reverse 244E-to-244D change, although SIV with 244D

has higher in vitro replicative capacity than SIV with 244E. Induction of $Gag_{241-249}$:244D-specific $CD8^+$ T cells was inefficient in these animals.
Conclusions: Selection of escape mutations can result in induction of $CD8^+$ T cells targeting the mutated epitope. However, these $CD8^+$ T cells targeting the mutated epitope do not have the potential to induce the reverse mutation into the wild type. Varieties of epitope peptides may efficiently bind to MHC-I molecules, but this study suggests that only limited numbers of them can form optimal epitope-MHC-I complexes that could be efficiently targeted by potent $CD8^+$ T cells.

WEPEA0186

HLA-C is downregulated by most primary clones of HIV-1, and variation between these viruses is more pronounced for downregulation of HLA-C than HLA-A/B

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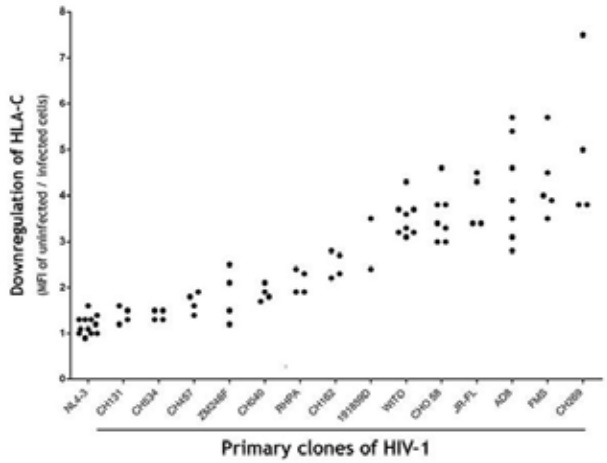
Background: Many pathogens evade CTL by downregulating HLA molecules on infected cells, but the loss of HLA can trigger NK cell-mediated lysis. HIV-1 has been thought to subvert CTLs and preserve NK cell inhibition by downregulation of specifically HLA-A/B but not HLA-C molecules, via the viral Nef protein. However analysis of HLA protein modulation by complete viruses has been largely restricted to the lab-adapted viral isolate NL4-3, and rarely been studied in primary cells.
Methods: Cell surface protein expression levels of each HLA class-I locus were characterized by flow cytometry, on primary CD4+ cells infected in vitro with molecular clones of primary HIV-1. This was enabled by recent advances in the characterization of HLA monoclonal antibody specificity, and in the cloning of primary viruses.
Results: In contrast to the laboratory-adapted NL4-3 virus, which downregulates specifically HLA-A/B, the transmitted founder primary HIV-1 clone WITO also downregulated HLA-C. Chimeric and mutated viruses show HLA-C reduction is mediated by the viral Vpu protein, and confirm Vpu does not contribute to downregulation of HLA-A/B. A screen of primary HIV-1 clones finds that most downregulate HLA-C to some extent (Fig. 1). The primary HIV clones vary in their ability to downregulate HLA-C, with a linear distribution, and show much more frequently significant differences between viruses in magnitude of downregulation of HLA-C than is observed for downregulation of HLA-A/B. This variation is investigated further by characterization of HLA-C downregulation by viruses and Vpu clones from different patients.



[Figure 1]

Conclusions: Downregulation of HLA-C on HIV-infected cells is distinct from the viral modulation of HLA-A/B, as the effects are mediated by different viral proteins and the magnitude of HLA-C reduction varies much more between viruses. Identification of the immune pressure selecting for HLA-C downregulation could represent a target for immune-mediated therapies, particularly as natural variation in HLA-C expression associates with patient viral loads.

WEPEA0187

HIV-1 accessory proteins hijack membrane trafficking to downregulate CD28

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Background: HIV-1 Nef and Vpu lack enzymatic and structural functions, but improve the ability of the virus to replicate and persist within the host by binding to host cellular proteins. One way in which Nef and Vpu increase success of the virus is by downregulating cell surface receptors, such as the key immune cell activator cluster of differentiation 28 (CD28). However, the mechanisms utilized by these viral proteins to downregulate CD28 remains unknown. HIV-1 Nef and Vpu co-opt host cellular membrane trafficking proteins to alter the subcellular localization or levels of various host cellular receptors. We therefore hypothesized that Nef and Vpu subvert membrane trafficking pathways to downregulate CD28.
Methods: We infected CD4+ T cells with pseudotyped HIV-1 viruses expressing Nef, Vpu, or mutated forms of these viral proteins. A combination of flow cytometry and immunoblotting was utilized to determine the fate of endogenous CD28 in the presence of these HIV-1 accessory proteins.
Results: We observed a decrease in both cell surface and total CD28 protein levels, which could be attributed to both Nef and Vpu. Furthermore, impaired CD28 downregulation occurred upon introduction of mutations that impair the ability of Nef to bind to the vacuolar ATPase, an enzyme essential for acidification of the lysosome. This suggested that Nef may facilitate the transport of CD28 to a degradative compartment and was supported by an increase in total CD28 observed upon ammonium chloride treatment, which blocks lysosomal acidification. Additionally, mutation of a motif in Nef known to facilitate interactions with the membrane trafficking protein adaptor protein 2 (AP-2), decreased downregulation of cell surface CD28, implicating AP-2 in the transport of CD28 away from the cell surface. Vpu mutations known to inhibit interactions with specific host cell membrane trafficking proteins were tested for their effect on CD28 downregulation. We demonstrate that, similar to Nef-mediated downregulation, the ability of Vpu to interact with AP-2 is important for CD28 downregulation.
Conclusions: HIV-1 has evolved evolved multiple means to eliminate the immune cell activating receptor CD28 within infected cells. Our data suggest that Nef and Vpu hijack membrane trafficking, specifically AP-2, to reduce CD28 in HIV-1 infected cells.

WEPEA0188

Hide and seek with HIV-1 Nef: gaining super-resolution insights to immune evasion

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Background: A major factor preventing the elimination of HIV-1 lies within the ability of the virus to hide from the immune system. This inherent ability of HIV-1 to confuse the immune system is accomplished by the small accessory protein Nef. Specifically, MHC-I downregulation by the HIV-1 Nef prevents infected cells from cytotoxic T-cell mediated killing. Nef downregulates MHC-I by modulating the host membrane trafficking machinery, resulting in the endocytosis and eventual sequestration of MHC-I within the cell. However, the precise cellular locations and the host proteins mediating these events remain unknown.
Methods: Our study utilized the intracellular protein-protein interaction reporter system, bimolecular fluorescence complementation (BiFC), in combination with super-resolution microscopy to uncover the membrane trafficking route undertaken by Nef and MHC-I. Our analysis describes protein-protein interactions in HIV infected cells in addition to ternary complexes formed by Nef in order to evade the immune surveillance response.
Results: We demonstrate that the Nef-MHC-I interaction occurs upon Nef binding the MHC-I cytoplasmic tail early during endocytosis in Rab5-positive endosomes. Disruption of early endosome regulation inhibited Nef-dependent MHC-I downregulation, demonstrating that Nef hijacks the early endosome to sequester MHC-I within the cell. Super-resolution imaging identified that the Nef:MHC-I BiFC complex transits through both early and late endosomes before ultimately residing at the trans-Golgi network. The membrane trafficking protein PACS-1 was essential to maintain the Nef:MHC-I complex and enhanced the formation of

a ternary complex within vesicles that were positive for adaptor protein-1 (AP-1). Indeed, disruption of the PACS-1 binding site on Nef inhibited Nef:MHC-I complex formation and thereby disrupted Nef's ability to evade immune surveillance.
Conclusions: Together we demonstrate the importance of the early stages of the endocytic network in the removal of MHC-I from the cell surface and its re-localization within the cell and define PACS-1's role and location as a key membrane trafficking regulator allowing HIV-1 to optimally evade host immune responses. Understanding these complex molecular pathways will aid in the development of new inhibitors targeted at crippling HIV-1's ability to evade our own immune surveillance system.

WEPEA0189

Deep sequencing analyses of emergence and maintenance of mutations in CTL epitopes of HIV-controllers with differential control of Viremia

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Background: HIV-Controllers are individuals able to control the viral replication to very low levels. Besides that, lower viral evolution and viral mutations related to escape of CTL response have been observed in HIV plasma sequences from those individuals. The dynamic of emergence and fixation of those mutants in reservoirs could be of great importance to comprehend spontaneous control of infection in HIV-Controllers.
Methods: In order to analyze the mutational profile of HIV and the dynamic of escape mutants we selected 11 HIV-controllers with more than 8 years of infection classified as Elite controllers, with (EEC-n=3) and without (EC-n=3) occasional viral blips, and Viremic controllers (VC-n=5), with persistent low viremia. Proviral DNA from PBMCs related to the earliest (V1) and latter visits (VX) available (mean interval of 50 months) were used to sequence gag and nef genes by using Illumina HiSeq. Reads obtained allowed to map the whole nef gene and the first 1000bps of gag (Medium coverage>200.000X). Consensus of each mapping, or previous sequences for 2 cases with unavailable NGS, were used to assess V1-VX divergence and Geneious Variant-call tool was used to identify variants (Frequency>0,5%).
Results: Deep sequencing analyses of VC showed higher divergence for nef comparing to gag (p< 0,02) and to both genes of EC (p< 0,04 for gag). Both genes showed low and similar divergence in ECs. Quantitatively, SNP analysis showed higher number of variants and variable positions in both genes of VC in comparison to EC and EEC. Analyses limited to CTL-restricted epitopes showed that non-synonymous mutations arose between V1 and VX in most individuals. All VCs had high number of mutations, with major frequency change between V1 and VX, that could be related to escape of immune response. All EC also presented non-synonymous mutation in CTL epitopes, in general, with frequencies lower than 1%.
Conclusions: The genetic conservation of gag and nef of EC indicates that the better viremia control restricts the evolution of both genes. All HIV-Controllers showed mutations on CTL epitopes. However, lower frequencies were observed for EC indicating that potential escape variations arise over time, but most do not fix in their reservoirs.

WEPEA0190

Pre-clinical pharmacokinetics of elsulfavirine/VM1500A long acting injectable formulations

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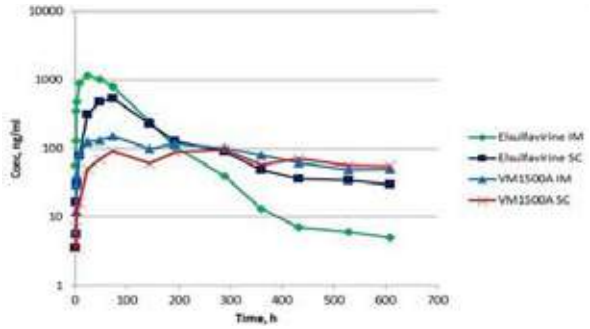
Background: New options for the prevention and treatment of HIV infection that allow infrequent dosing will facilitate adherence and likely improve long-term outcomes. Elsulfavirine (Elpida®, VM1500) is the prodrug of VM1500A, a new, potent non-nucleoside reverse transcriptase inhibitor (NNRTI), currently under review for registration as an oral QD regimen for HIV/AIDS treatment. Unique pharmacokinetic properties ($T_{1/2}$ is ~8 days) of VM1500A suggest a possibility for long-acting formulation development.
Methods: Aqueous nanosuspensions of Elsulfavirine or VM1500A (particle size between 200 and 900 nm) were prepared by wet milling. Different surfactants and drug to surfactant ratios were used. Formulation safety and pharmacokinetics (PK) were studied in beagle dogs, following single (5, 10 or 20 mg/kg) dose administration by intramuscular (IM) or subcutaneous (SC) injection. Three animals were studied per dose and route of administration. Blood samples were collected frequently up to 72 h after administration and every week up to 3 months. Elsulfavirine and VM1500A plasma concentrations were measured using LC-MS/MS.
Results: All studied formulations were well-tolerated at all doses, no adverse reactions were observed, including at the injection site. The PK analysis showed that dosing with VM1500A provided more stable drug plasma concentrations than dosing with the prodrug Elsulfavirine from these administration routes. Following a single 10 mg/kg dose of VM1500A (either IM or SC), its plasma levels were maintained above 50 ng/ml for at least 4 weeks (the latest data point collected at the time of this abstract submission). These levels exceeded the clinically-efficacious VM1500A plasma concentrations. The graph plots VM1500A plasma concentrations over time after single IM or SC injections of 10 mg/kg Elsulfavirine or VM1500A.



[Fig. 1. Dog plasma VM1500A concentrations.]

Conclusions: This study provides proof-of-concept that VM1500A nanosuspensions could be developed into long-acting injectable formulations to enable infrequent dosing. Further pre-clinical development of these formulations is warranted.

WEPEA0191

Generation of phage recombinant single chain variable fragment (scFv) library from pooled PBMCs of HIV-1-infected humans and identification of cross-neutralizing anti-CD4 binding site and N332 glycan dependent scFvs

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Background: More than 50% of HIV-1 infection globally is caused by subtype_C viruses. Majority of the broadly neutralizing antibodies (bnAbs) targeting HIV-1 have been isolated from non-subtype_C infected donors. A recent phase I clinical trial showed for the first time, that passive infusion of a single CD4 binding site directed bnAbs (3BNC117 and VRC01) and also V3 glycan supersite specific bnAb (10-1074) in humans reduced the viraemia in HIV-1 infected donors efficiently. Thus bnAbs against HIV-1 are potential candidates for a safe and effective eradication strategy, by way of prevention, immunotherapy and cure.
Methods: Recombinant antibody technology enables generation of a large repertoire of monoclonals with diverse specificities. It has been proven by studies that engineered antibody fragments can be more effective and can neutralize even resistant HIV-1 strains as they are smaller than full length IgGs. Hence, we constructed a phage recombinant single chain variable fragment (scFv) library, using a novel strategy of pooling peripheral blood mononuclear cells (PBMCs) of six select HIV-1 chronically infected Indian donors whose plasma antibodies exhibited potent cross neutralization efficiency. The library was panned and screened by phage ELISA using two different trimeric recombinant proteins (h-CMP-V1cyc1 gp120 protein and BG505:SOSIP.664 gp140) that mimic the native form of HIV-1 envelope, to identify viral envelope specific scFv clones.
Results: We constructed a phage recombinant single chain variable fragment (scFv) library with a diversity of 7.8×10^8 scFv clones. After bio-panning and screening, three scFv monoclonals D11, C11 and 1F6 were selected from the library. These scFvs cross neutralized subtypes A, B and C viruses at concentrations ranging from 0.09µg/mL to 100µg/mL. All the three scFvs showed distinct sequences and gene usage. The D11 and 1F6 scFvs competed with mAbs b12 and VRC01 demonstrating CD4bs specificity, while C11 demonstrated N332 specificity.

Conclusions: This is the first study to identify cross neutralizing scFv monoclonals with CD4bs and N332 glycan specificities from India. Employing antibody engineering strategies, it is feasible to generate bispecific and chemically-modified antibody reagents that can simultaneously target multiple HIV-1 epitopes with high avidity and can be potential candidates for passive immunotherapy, thereby prevent viral escape.

WEPEA0192

Complete protection of HIV-1 infection by a tandem BiIA in humanized mice and rhesus macaques

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Background: Viral genetic diversity is one of the major obstacles to prevention and immunotherapy against HIV/AIDS. Because none of native broadly neutralizing antibodies (bnAbs) inhibits all HIV-1 strains of genetically divergent subtypes, we aimed to engineer a bi-specific immunoadhesin (BiIA) with improved breadth and efficacy.
Methods: By testing six pairs of HIV-1-specific IAs in combination, we chose the synergistic pair of PGT-128 and Hu5A8 for BiIA construction. We generated two BiIAs, BiIA-DG by "knobs-in-holes" and BiIA-SG by tandem recombination. Their anti-HIV activities were extensively evaluated in vitro, and in humanized mice and rhesus macaques.
Results: In comparison to a panel of bnAbs, we show that BiIA-SG has the most broadly neutralizing activity against all HIV-1 strains tested, including multiple co-circulating subtypes/recombinant forms, transmitted/founder viruses and viral strains naturally resistant to parental IAs. Moreover, BiIA-SG confers complete protection not only against diverse live pathogenic HIV-1 challenges in a humanized mouse model but also against the R5-tropic $SHIV_{162P3}$ in rhesus macaques. Importantly, in vivo delivery of the BiIA-SG gene generates sufficient amount of BiIA-SG that eliminates productively and latently infected CD4 T cells in humanized mice as indicated by adoptive transfer of total splenocytes. In contrast, antiretroviral treated mice display rapid viral rebound after drug termination.
Conclusions: Our findings demonstrate that BiIA-SG is a promising biomedical product for HIV-1 immunoprophylaxis and immunotherapy, which warrants clinical development to control the expanding epidemic with diverse HIV-1 subtypes.

WEPEA0193

Ranpirnase exhibits dose-dependent inhibition of rectal explant HIV infection and inflammatory changes

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Background: Ranpirnase (RNP) is a safe, low molecular weight type III endoribonuclease, isolated from frog oocytes, which demonstrates broad antiviral and antitumor properties. A phase I/II clinical study has just been completed examining the effectiveness of RNP in HPV infections. RNP is stable under harsh conditions and is not a substrate for RNAse inhibitors. We sought to characterize RNP HIV antiviral activity in the in vitro rectal explant challenge model.
Methods: Colorectal tissue biopsies were obtained from healthy, HIV uninfected volunteers (N=6). To determine the potential effectiveness of RNP on tissue based HIV infection, we incubated triplicate colorectal biopsies for 2 hours with $HIV\text{-}1_{Bal}$ in the presence of increasing concentrations of RNP (0-60 µg/mL). After washing, explants remained in culture for 14 days and cumulative p24 levels released into the supernatant were determined by Elisa (AlphaLisa, Perkin Elmer, Waltham MA). Supernatants from explants taken three days after HIV infection were assayed for biomarkers using the Meso Scale Discovery 30-Plex assay (Rockville, MD) for chemokines, cytokines, and proinflammatory agents.
Results: RNP inhibits p24 release in a dose dependent manner, with statistical significance occurring at 6 µg/mL ($p<0.05$) and 60 µg/mL ($p<0.01$). Of the 30 biomarkers measured, 14 demonstrated an RNP dose-dependent decrease vs infection alone, with dose-dependent defined as two or more consecutive doses demonstrating statistical significance ($p<0.05$). Affected biomarkers include the following members of the chemokine panel: IP-10, MDC, MIP-1β, IL-8 and TARC, the cytokine panel: IL-1α, IL12-p40, IL-7, IL-15 and IL-17, and the proinflammatory panel: IFNγ, IL-4, IL-13 and IL-1β.
Conclusions: RNP demonstrates dose-dependent efficacy in mitigating ex vivo HIV infection of colorectal explants, while remaining non-toxic to the tissues at the doses tested. In addition to treating HIV infection, RNP mitigates inflammatory changes associated with HIV infection. Further experiments are needed to determine whether RNP acts only directly on HIV or in addition through its immunomodulatory activity.

WEPEA0194

A comparison study of tenofovir alafenamide (TAF) plus emtricitabine (FTC) in solution and as nanoparticles (NPs) for pre-exposure prophylaxis (PrEP) in humanized BLT (hu-BLT) mice

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Background: The use of oral TAF+FTC has shown positive results for PrEP in a macaque model. However, when TAF+FTC was administered to uninfected women, tenofovir (TFV) + FTC drug levels were low or non-detectable in vaginal tissues. To resolve this issue, we encapsulated TAF+FTC into polymeric NPs and report here improved efficacy in hu-BLT mouse model of HIV-1 PrEP.
Methods: TAF+FTC powders were fabricated into a nanoformulation using an oil-in-water emulsion methodology. NPs were characterized for drug entrapment efficiency and size. Humanized bone marrow, liver, thymus (hu-BLT) mice with >50% human engraftment of peripheral blood by flow cytometry was randomized into control, solution (Sol), or NP dosing (n=5/group). Control animals received saline. TAF+FTC dosage (100 mg/kg) was administered SubQ and mice were vaginally challenged with two strains of HIV-1 (2.5×10^5 $TCID_{50}$). Challenge with HIV-1 occurred on day 4, 7, or 14 after NP administration and on day 4 for Sol and control groups. Plasma for viral load (pVL) was obtained every week starting 2 weeks post-challenge (PC) and determined by real-time PCR for 4 subsequent weeks. Euthanized mice will have organs harvested for in situ hybridization with p24 ribosomes. In parallel, humanized mice ($NSG\text{-}CD34^+$, n=3/time point) received 100 mg/kg NP formulation plasma and organs were harvested at 1, 2, 4, 7, 10, and 14 days post-NP administration for TFV drug levels using liquid chromatography-tandem mass spectrometry (LC-MS/MS).
Results: TAF+FTC NPs were 233 ±12.8 nm in diameter (n=5) and drug entrapment efficiency averaged 38% and 35%, respectively. Controls all became HIV-infected 14 days PC. Sol group became HIV-infected 21 days PC. TAF+FTC NP groups challenged at Days 4, 7, and 14 after SubQ NP administration became HIV-infected at rates of 40%, 60%, and 100%, respectively by day 42 PC ($p< 0.05$, Mantel-Cox test). Mean TNF vaginal tissue levels at 4, 7, and 14 days after NP injection was 140, 35, and 10 ng/mL, respectively.
Conclusions: TAF+FTC at 100 mg/kg as NP formulation produced significantly long-acting protection from HIV-1 compared to Sol. Higher doses of TAF+FTC NP may produce greater PrEP protection.

WEPEA0195

Bevirimat-like compounds overcome HIV resistance and target different infection steps

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Background: Antiretroviral therapy (ART) against HIV-1 encompasses at least two drugs with different targets on the viral replication cycle. ART intensification has been proposed as a strategy to eliminate infection but current antiretrovirals seems to be ineffective, and thus, new drugs should be developed. Bevirimat (BVM) was a first in class maturation inhibitor that failed to enter the market due to the presence of natural resistances.
In this work we study the antiviral effect of selected BVM-like compounds that have been developed with the aim of avoiding viral resistance.
Methods: Anti-HIV-1 activity was evaluated in vitro using a recombinant virus assay. Viral entry was assessed by infections with VSV pseudotyped HIV. Real time PCR was used for the quantification of total and integrated viral DNA. Cell transfection was used to evaluate transcriptional activity. Gag p24 viral protein was measured after transfection to evaluate the effect on HIV protease. Infectivity of new

virions was assessed by a maturation assay. Finally, inhibition of protease inhibitors and BVM resistant virus was evaluated.
Results: Compounds inhibited HIV infection with IC_{50}s values between 1 and 30 µM. Their effect was independent of viral entry since VSV pseudotyped HIV was inhibited with similar IC_{50}s. Compounds diminished the amount of viral DNA, suggesting the inhibition of viral reverse transcriptase but only one, lup-20(29)-en-28-ol-3-one, inhibited significantly proviral DNA integration. All of them inhibited viral transcription and p24 production after viral transfection. Compounds inhibited viral maturation even of BVM resistant viruses and they were active against BVM and protease inhibitors resistant viruses with similar IC_{50}s as wild-type strains.
Conclusions: BVM-like compounds were found to inhibit viral maturation also in BVM resistant viruses. Surprisingly, these compounds showed promiscuity of targets since they inhibited retrotranscription, integration, transcription and/or maturation. This behavior as multitarget drugs have been demonstrated to be effective in reducing the likelihood of drug resistance, drug-drug interactions and toxicities, as well as improving patient compliance. Therefore, this approach could help developing a new generation of anti-HIV agents.

WEPEA0196

Synthesis and properties of novel soluble bifunctional CD4-mimetic small molecules containing pyridine moiety

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Background: CD4 mimic small compounds (CD4MCs), NBD-556 and its analogues bind to the Phe43 cavity of gp120 and inhibit the gp120-CD4 interaction. CD4MCs can also induce conformational changes in the gp120 architecture thereby exposing masked epitopes of neutralizing antibodies (NAbs) on the Env protein and sensitizing infected cells to antibody-dependent cell-mediated cytotoxicity (ADCC) killing. In this study, we reported on the design, synthesis, and screening of a series of pyridine derivatives as potential novel soluble bifunctional CD4MCs, KKN series.
Methods: Twenty KKN compounds were designed and synthesized to improve water solubility and bioavailability using our previously reported method. A chimeric clone containing the primary KP-5mvcR virus isolate (subtype B, R5) gp160 within a pNL4-3 backbone was constructed. The susceptibility of the infectious clone to entry inhibition and neutralization sensitivity to the anti-cryptic V3 NAb KD-247, in the presence of the KKN compounds, was determined using the TZM-bl assay. The results were compared to those of the NBD-556 compound.
Results: We synthesized and tested 20 KKN compounds and found novel CD4MCs KKN-104, KKN-118, and KKN-134, which could inhibit the KP-5mvcR infection in IC_{50} values of 2.3, 3.0, and 2.1 µM, respectively. These compounds exhibited much higher solubility and markedly less cytotoxic than that of NBD-556. To investigate synergistic effect of these compounds and anti-cryptic V3 NAb KD-247, we calculated Combination Indexes (CIs) using the Chow and Talalay method. Combinations of KD-247 with NBD-556, KKN-104, KKN-118, or KKN-134 were highly synergistic, with CI values of 0.66, 0.87, 0.72, or 0.37, respectively. These results suggest that the KKN compounds render the primary HIV-1 sensitive to neutralization by NAbs directed against the V3 region involved in co-receptor binding, similar to the potent NBD-556.
Conclusions: In the present work, we designed, synthesized, and evaluated a series of novel soluble bifunctional CD4MCs containing pyridine moiety. Three compounds, KKN-104, KKN-118, or KKN-134 were strongly synergistic when combined with anti-cryptic V3 NAb KD-247. These findings indicate that KKN compounds might be useful in inhibiting HIV-1 infection not only by directly obstructing viral entry, but also enhancing sensitivity to NAbs.

WEPEA0197

A novel therapeutic approach to prevent AIDS

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Background: Apoptosis has been proposed as a key mechanism responsible for CD4 T cell depletion and immune dysfunction during HIV infection and associated with Aids pathogenesis. We demonstrated that a caspase inhibitor, inhibits spontaneous and activation-induced cell apoptosis of T cells from SIV-infected rhesus macaques (RMs).
Methods: Based on the pharmaco-toxicity and -kinetics of this compound in non-human primate, we performed an in vivo assay by administrating five injections of this drug during acute phase of infection. The therapeutic assay consisted of 20 infected monkeys, 10 of whom received the treatment.
Results: When administered during the acute phase of infection, this compound is associated with
(i) reduced levels of T cell apoptosis,
(ii) preservation of CD4/CD8 T cell ratio in lymphoid organs and in the gut,
(iii) maintenance of memory CD4 T cells, and
(iv) increased specific CD4 T cell response.
Although therapy was limited to the acute phase of infection, RMs showed lower levels of both plasma viremia and cell-associated SIV-DNA as compared to control SIV-infected RMs throughout the chronic phase of infection, and delayed the development of AIDS.
Conclusions: Overall our data demonstrate that injection of this compound in SIV-infected RMs may represent a novel adjunctive therapeutic agent to control HIV infection and delaying disease progression to AIDS.

WEPEA0198

Novel selection approaches to identify broadly neutralizing DARPins targeting the HIV-1 envelope protein

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Background: Broadly neutralizing antibodies (bnAbs) only evolve in a fraction of HIV-1 infected individuals. They have a unique potential to suppress viremia and inhibiting HIV-1 infection and are hence considered as blueprints for vaccine and therapeutics design. bnAbs recognize the HIV-1 Envelope (Env) proteins gp120 or gp41 within the context of the HIV-1 Env trimer rendering the trimer as major interest for HIV-1 vaccine research as target immunogen. Using the Designed Ankyrin Repeat Protein (DARPin) technology we recently generated broad and potent DARPins capable of targeting the membrane external proximal region (MPER) within gp41 and the variable loop 3 (V3) within gp120. The ~10-18kD sized DARPins binding to antigens of interest can be selected from high diversity (~10^{12}) libraries by ribosome display. The HIV-1 Env specific DARPins we isolated have exceptional breadth inhibiting up to 100% of tested HIV-1 strains and exceeding the breadth of bnAbs targeting the same epitopes. Differential recognition of the Env epitopes compared to the related bnAbs and an in part structure dependent binding mode make the Env DARPins highly interesting tools for immunogen characterization besides a use as antivirals.
Methods: To expand the DARPin toolbox we aimed in the current study to select DARPins targeting additional Env domains such as the variable regions 1 and 2 (V1V2). Using a range of stabilized, soluble Env trimers and Env derivatives including scaffold and chimeric envelope constructs presenting diverse V1V2 loops, we sought to yield DARPins targeting quaternary epitopes and/or the V1V2 loop.
Results: In total six different trimer-directed and eight V1V2 focused DARPin selections were conducted. From each obtained sub-library 200 clones were analyzed for specific Env binding and neutralization potential using a 5-virus panel. The screened libraries contained more than 90% Env binders and numerous novel broad and potently neutralizing DARPins that are currently characterized for epitope specificity.
Conclusions: Besides their potential as therapeutic agents by increasing the panel of broadly neutralizing DARPins we have gathered a valuable tool box for the characterization of neutralization sensitive epitopes that may aid in unraveling novel sites of vulnerability.

WEPEA0199

Triterpene-resistant HIV env variants show higher sensitivity to anti-V3 neutralizing antibodies

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Background: It is known that triterpene derivatives such as IC9564 can inhibit human immunodeficiency virus type 1 (HIV-1) entry into the cells. Recently, by screening synthesized triterpene derivatives, we obtained a potent and low toxic, novel triterpene derivative OKS3-019. In the present study, to investigate the mechanisms for viral resistance to triterpene derivatives, we analyzed how HIV-1 can change to resist to previously-obtained IC9564 and newly-obtained OKS3-019, respectively.
Methods: Resistant variants were induced by culture of HIV-1 89.6-infected PM1 cells in the presence of triterpene derivative IC9564 or OKS3-019. We then constructed infectious 89.6 clones carrying mutations selected in the resistant variants. The susceptibility of the infectious clones to the two triterpene derivatives and anti-V3 neutralizing antibodies (NAbs) 447-52D and KD-247 was tested by TZM-bl assay.
Results: In the presence of IC9564, one mutation resulting in F522V substitution was first selected, followed by selection of H72Y mutation. In the presence of OKS3-019, one mutation resulting in R588K was first selected, followed by selection of V68I mutation. Both F522V and R588K are in the N-terminus of Env gp41, while both H72Y and V68I are in the C1 region of Env gp120. HIV-1 carrying both H72Y and F522V was highly resistant to the triterpenes, but single F522V or R588K mutation conferred only moderate resistance on viruses.
Unexpectedly, these triterpene derivative-resistant env variants exhibited higher sensitivity to anti-V3 NAbs 447-52D and KD-247 compared with the wild-type HIV-1 89.6.
Conclusions: In the present study of in vitro induction of triterpene-resistant variants, we found mutations in the region encoding the N-terminal gp41 that contribute to the resistance to triterpene derivatives. It can be speculated that gp41 modification by these mutations may induce structural rearrangements resulting in formation of the CD4-bound like conformation, thereby changing the accessibility of these compounds to the Env. These results provide valuable information for designing novel triterpene analogues inhibitory for HIV-1 infection.

WEPEA0201

New formulation of injectable and removable long-acting dolutegravir is effective in prevention of HIV transmission with high dose vaginal HIV challenges

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Background: Oral pre-exposure prophylaxis (PrEP) is an effective prevention strategy for HIV transmission. Poor adherence decreases PrEP effectiveness. Injectable long-acting (LA) formulations of antiretrovirals (ARVs) represent a viable alternative. Currently available LA formulations cannot be removed. Here we describe a novel injectable in-situ forming implant (ISFI) formulation of dolutegravir (DTG) that:
1) Delivers drug for up to one year,
2) Can be safely removed and;
3) Efficiently prevents vaginal HIV transmission.
Methods: NSG mice (n=20) were used to assess the pharmacokinetic profile of DTG-ISFI in plasma using a validated LC/MS-MS method with a lower limit of quantification of 1 ng/mL. Highly relevant early passage and transmitted/founder viruses ($HIV_{JRC-SF, CH040, THRO}$) were used to 1) evaluate HIV suppression after acute infection, 2) the development of viral resistant mutations and 3) to evaluate protection against high dose repeated vaginal challenges using BLT mice. Statistical analysis was performed using Prism Software.
Results: With the objective of obtaining >30 day sustained release, an ISFI containing 6.5 micro grams of DTG was administered subcutaneously to NSG mice. Remarkably, this ISFI formulation resulted in sustained release of DTG for over 350 days. Importantly, removal of the DTG-ISFI resulted in fast clearance of the drug from plasma. Administration of the DTG-ISFI to accutely infected BLT mice resulted in a transient but statistically significant (1.5 log) reduction in plasma viral RNA levels. Viral rebound was associated with appearance of several amino acid substitution including the well characterized INSTI resistance R263K mutation. In the context of HIV prevention, administration of a single dose of DTG-ISFI resulted in significant protection from high dose vaginal challenges 1 and 7 weeks post ISFI administration (p=0.0128).
Conclusions: Subcutaneously administered DTG-ISFI in BLT mice resulted in sustained levels of DTG in plasma that are dramatically reduced after ISFI removal. The plasma concentration of DTG achieved (>4X IC50) were sufficient to effectively inhibit HIV replication and to prevent vaginal transmission after two high dose HIV challenges.

WEPEA0202

A novel NRTI, EFdA, effectively penetrates and suppresses HIV infection in all individual compartments of male genital tract

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Background: Unprotected intercourse is the most common route of HIV transmission. Despite the success of antiretroviral therapy in suppressing plasma viremia to undetectable levels, HIV sheding persists in the semen from a subset of individuals. Thus, it is imperative to find more effective antiretroviral treatments that effectively suppress HIV in male genital tract (MGT) and prevent seminal HIV shedding. Here we evaluated a novel NRTI 4-ethynyl-2-fluoro-2-deoxyadenosine (EFdA) for suppression of HIV in MGT using a state-of-the-art animal model.
Methods: Reconstitution of MGT compartments of BLT mice including testes, epididymis, seminal vehicles, prostate and penis with human hematopoietic cells (CD4 and CD8 T cells, B cells and macrophages) was assessed by flow cytometry. To evaluate efficacy of EFdA at suppressing HIV infection in the MGT, infected BLT mice were treated orally once daily for 4 weeks. Levels of cell-associated HIV-RNA in the MGT compartments from suppressed BLT mice were analyzed by quantitative PCR and compared to animals not receiving treatment.
Results: All MGT compartments of BLT mice analyzed were reconstituted with human hematopoietic (CD45+) cells and CD4 and CD8 T cells as well as macrophages were readily and reproducibly detected. Cell-associated HIV-RNA was found in all MGT compartments of untreated BLT mice. Four-weeks treatment with EFdA resulted in dramatic reductions in the levels of cell-associated HIV-RNA in all MGT compartments.
Conclusions: BLT humanized mice are an excellent model for assessing HIV infection in all different compartments of the MGT. EFdA can effectively penetrate and suppress HIV replication in all MGT compartments. In current studies we are evaluating the pharmacokinetics of EFdA penetration and HIV suppression in the MGT.

WEPEA0203

Preclinical characterization of a potent D-peptide inhibitor of HIV entry: cholesterol-conjugated PIE12-trimer (CPT31)

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Background: There remains an urgent need for new HIV entry inhibitors given the limited currently approved options. Mirror-image D-peptide inhibitors are protease-resistant and therefore have longer half-lives compared to natural L-peptides (e.g., Fuzeon). Our previously reported D-peptide HIV entry inhibitor, cholesterol-conjugated PIE12-trimer (CPT31) has exceptional potency due to its localization at membrane sites of viral fusion.
Methods: We characterized CPT31's pharmacokinetic properties in rats and NHPs using a sensitive and quantitative LC-MS bioanalytical assay on purified plasma samples. We characterized CPT31's inhibitory activity using TZM-BL reporter cells and an international panel of diverse primary isolates.
We used in vitro passaging studies coupled with deep sequencing to characterize the evolution of drug resistance.
Finally, the rhesus macaque model was used with SHIV-AD8 in prevention (single high-dose rectal challenge) and treatment protocols.
Results: CPT31 has potent and broad-spectrum inhibitory activity (IC_{50} < 1 nM in >90% of primary strains tested). CPT31 drug resistance is slow to develop during in vitro passaging studies and is mediated by mutations in the gp41 pocket residue Q577. Such mutations in isolation significantly hamper viral fitness. Subcutaneously administered CPT31 has a long terminal half-life in rats and NHPs (5.4 and 18 h, respectively). In a PrEP efficacy study, CPT31 dosed at 3.0 and 0.5 mg/kg/day fully protected 4 macaques, while 0.125 mg/kg/day was partially protective. As a therapy in animals with uncontrolled viremia, CPT31 rapidly induced a ~2-log drop in viral load. Virus rebound was also observed and attributed to resistance caused by Q577 mutations. In animals pre-treated with cART to achieve undetectable viremia, CPT31 monotherapy maintains viral suppression for >8 weeks.

Conclusions: CPT31's potent inhibition of diverse strains, strong resistance profile, and efficacy in NHP prevention and treatment models make it a promising preclinical HIV entry inhibitor candidate. Its long half-life and in vivo stability are ideal for sustained-release formulation (e.g., monthly or quarterly depot).

WEPEA0204

RNA-induced epigenetic silencing of HIV-1 involves actin regulators, Arp2 and Formin-like 1 protein

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Background: Antiretroviral therapy (ART) has revolutionized the treatment of HIV-1, however it does not cure the latent reservoir, which is a major barrier to eradication. An alternative to an eradication cure is a functional cure approach, whereby the virus reservoir is locked in latency through RNA-induced epigenetic silencing. We have previously reported the short-interfering RNA (siRNA), designated siPromA, which targets the HIV-1 5' long terminal repeat region, induces potent transcriptional gene silencing (TGS). The RNA interference (RNAi) machinery involved in this process is the RNA-induced Transcriptional Silencing (RITS) complex, comprising siRNA and Argonaute 1 (Ago1) protein. Our previous fixed cell microscopy studies identified filamentous actin (F-actin) as being associated with Ago1 in the RITS complex during TGS of HIV-1, however whether F-actin is directly linked to the trafficking of RITS remains unknown. This project aims to characterize the intracellular trafficking mechanism of RITS complex components in real time during TGS in HIV-1 infected cells and specifically the involvement of F-actin.
Methods: We employed advanced live cell imaging every 90 sec for 12 hr to capture HIV-1 infected HeLa T4+ cells, stably transduced with Ago1-GFP and mCherry-labelled F-actin-LifeAct, and transfected with AlexaFluor647-labelled siRNA, then screened several actin inhibitors for any effect on this process.
Results: Analysis of imaging data using arbitrary line intensity profiles and Pearson's correlation coefficient demonstrated significant nuclear co-localization and correlation of siPromA:Ago1-GFP (PCC=0.85±0.15; p=< 0.0001), compared to cytoplasmic co-localization of a scrambled siRNA control (PCC=0.31±0.3). Relative enrichment over time reported siPromA:Ago1-GFP signal intensity increased to a maximal level upon nuclear translocation compared to the siScrambled control, which showed a consistent signal intensity. Drug inhibition screens and subsequent knockdown studies of actin and actin-related proteins (Arps) revealed the actin nucleation and branching pathway to be essential for RITS complex nuclear translocation.
Conclusions: This study has identified the first known actin regulators, Arp2 and FMNL1 (formin-like 1), to be involved in RNA-induced TGS of HIV and may represent a conserved biological process.

WEPEA0205

Characterization of novel and potent U1 interference RNAs targeting the Gag open reading frame of HIV-1

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Background: HIV-1 replication is critically dependent upon a complex RNA splicing process, whereby over 40 different viral mRNA species are produced by alternative splicing. Assembly of the spliceosome begins with the recognition of splice donor sites by the complementary 5'-end of cellular U1 small nuclear RNAs (U1 RNAs). Recently, modified U1 RNAs, termed U1 interference RNAs (U1i RNAs), have been exploited to suppress HIV-1 production. Modifications of the 5'-end of U1 RNAs can redirect the molecule to specific target sites in HIV-1 RNA, where it can inhibit polyadenylation or induce excessive splicing of HIV-1 RNA transcripts. Our lab has identified novel and potent U1i RNAs targeting a conserved region in the Gag coding sequence of HIV-1 RNA.
Methods: We evaluated the therapeutic potential of our U1i RNAs and those previously designed targeting HIV, by measuring the production of HIV-1 in the culture supernatant of HEK293T cells co-transfected with an HIV-1 molecular clone (pNL4-3) and U1i RNAs. To identify the mechanisms of U1i RNAs targeting Gag, we compared their effects on HIV-1 RNA levels using Northern blots and on Gag processing by Western blots against HIV-1 capsid protein.
Results: U1i RNAs targeting Gag and those that induce excessive splicing were found to be the most potent, with half maximal effective concentrations (EC50s) ranging from 1 to 5 ng/ml, compared to those that inhibit polyadenylation, with EC50s of 50 ng/ml or greater. Like U1i RNAs that inhibit polyadenylation, U1i RNAs targeting Gag reduced RNA levels evenly, suggesting a global RNA inhibition. U1i RNAs targeting Gag were also found to inhibit processing of Gag, like U1i RNAs that induce excessive splicing. Our results suggest that U1i RNAs targeting Gag are acting through different mechanisms compared to previously described candidates and work is in progress to characterize their mechanism(s). We also found that U1i RNAs acting through any mechanism are more potent compared to ribozyme or decoy candidates and are comparable to short hairpin RNA candidates in development.
Conclusions: Overall, our results suggest that U1i RNAs are potent RNA interfering molecules that have the potential to be used in a gene therapy approach to cure HIV-1 infection.

WEPEA0206

A new highly sensitive retinoic acid-based viral outgrowth assay to detect replication-competent HIV reservoir

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Background: Current antiviral therapies (ART) successfully control viral replication in HIV infected subjects; however, the persistence of viral reservoir represents a major barrier for the cure. The development of HIV eradication strategies represents a major research priority. Sensitive assays are needed to assess the efficiency of such strategies.
Here we describe a modified viral out growth assay (VOA) that measures replication-competent viral reservoirs in low numbers of CD4+ T-cells.
Methods: CD4+ T-cells were isolated from PBMCs of HIV-infected individuals with undetectable plasma viral load under ART (HIV+ART). Quantification of integrated HIV-DNA was performed by ultrasensitive PCR. For the VOA, T-cells were stimulated with CD3/CD28 Abs for three days. To ensure optimal cell viability and viral cell-to-cell transmission, cells were split every three days. All-trans retinoic acid (ATRA) was added to facilitate viral reactivation and/or transmission. HIV reactivation was quantified by HIV-p24 ELISA in cell culture supernatants collected every three days and by flow cytometry analysis of intracellular HIV-p24 expression at day 12 post-culture.
Results: In the absence of ATRA, HIV reactivation was detected in CD4+ T-cells isolated from 8 out of 10 HIV+ART individuals. Levels of viral replication varied in different donors and did not correlate with integrated HIV-DNA levels ex vivo. This assay was highly reproducible and results from independent experiments were significantly correlated (r=0.96, p< 0.0001). Of particular importance, ATRA greatly increased and accelerated HIV reactivation efficacy in all donors tested, including those with undetectable HIV reactivation upon TCR triggering alone. The cost of this assay is estimated at 200$ per donor.
Conclusions: We described an easy, sensitive, and highly reproducible VOA that measures replication-competent HIV reservoirs in CD4+ T-cells of ART-treated individuals. This assay may be used to assess the efficiency of HIV eradication strategies and evaluate the risk of viral rebound upon treatment interruption.

WEPEA0207

The PPARγ antagonism inhibits HIV replication while restoring effector functions in Th17 cells

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Background: Mucosal Th17-polarized CD4+ T-cells are the first targets of HIV/SIV infection, with viral reservoirs persisting in long-lived Th17 cells during antiretroviral therapy (ART). Novel therapeutic strategies are needed for the normalisation of Th17 frequency/function toward mucosal immunity restoration in ART-treated individuals. PPARγ controls RORγt-mediated functions and HIV replication in Th17 cells. Here, we investigated the potential use of PPARγ agonism/antagonism for viral eradication and Th17 restoration during HIV infection.
Methods: Peripheral blood memory CD4+ T cells were isolated from HIV- and HIV+ on ART individuals using magnetic beads and stimulated with CD3/CD28 Abs. HIV- T-cells exposed to replication-competent or VSVG-pseudotyped HIV in vitro, as well as T-cells isolated from HIV+ on ART individuals, were cultured in the presence or absence of the PPARγ agonist Rosiglitazone (RGZ) or antagonist T0070907 for 12 days. HIV-p24 and IL-17A levels were quantified by ELISA and

FACS. HIV-DNA integration was quantified by real-time PCR. Gene expression was quantified by real time RT-PCR. The expression of HIV co-receptors CD4, CCR5 and CXCR4 was measured by FACS.
Results: RGZ decreased both HIV replication and IL-17A production. As predicted, T0070907 increased IL-17A production. Surprisingly, T0070907 also strongly inhibited HIV replication. T0070907 regulated HIV replication at multiple levels by reduction of CCR5 expression and HIV transcription, and alteration of lipid metabolism. The T0070907-mediated effects coincided with the induction of cholesterol-25-hydroxylase, an enzyme converting cholesterol into 25-hydroxycholesterol. Of note, 25-hydroxycholesterol is a broad inhibitor of viral infection and was recently identified as an intrinsic agonist of the Th17 master regulator RORγt. Finally, T0070907 inhibited HIV reactivation in a viral outgrowth assay and increased IL-17A production in CD4+ T cells from HIV+ on ART individuals.
Conclusions: We demonstrate that PPARγ antagonism reduces HIV replication in vitro as well as viral reactivation in CD4+ T-cell of HIV+ on ART individuals, while boosting the Th17 effector functions. These effects are mediated in part via the synthesis of 25-hydroxycholesterol. These findings open the path for future studies in animal models and human clinical trials to determine whether PPARγ is an appropriate target for viral eradication and Th17-mediated mucosal immunity restoration in HIV-infected individuals.

WEPEA0208

HIV-1-specific ADCC following anti-latency therapy and analytical treatment interruption

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Background: There is growing interest in utilising antibody-dependent cellular cytotoxicity (ADCC) to eliminate infected cells following latency reversal. A potential barrier is that HIV-1-specific ADCC antibodies decline in patients on long-term antiretroviral therapy (ART). It is unknown whether reactivation from latency with current anti-latency regimens could provide sufficient stimulus to boost HIV-1-specific ADCC. If current strategies are insufficient, we hypothesise that the recrudescence of virus after analytical treatment interruption (ATI) could provide larger antigenic stimulus to boost HIV-1-specific ADCC.
Methods: We analysed plasma samples from 14 subjects of the panobinostat trial, obtained pre- and post-panobinostat and after a short ATI (median 21 days). We also studied plasma from the SMART trial, from 30 subjects who underwent ATI for 12 months and 30 subjects who remained on ART. ADCC activity was measured in two ways:
(i) the binding of recombinant dimerised Fc gamma receptor (FcγRIIIa) to gp120-specific antibodies was used as a surrogate measure of Fc effector function,
(ii) infected cell elimination assays were performed to directly measure ADCC.
Results: Panobinostat or a short 21-day ATI did not increase HIV-specific ADCC, with no changes in FcγRIIIa-binding or ADCC killing. However, for the SMART trial subjects, there was a marked increase in FcγRIIIa-binding antibodies after 12 months of ATI [OD_{450}, baseline 0.331 (0.130-0.470) vs 12 months 0.908 (0.716-1.046), p< 0.0001] and a decrease in subjects who remained on ART [0.490 (0.181-0.750) vs 0.252 (0.097-0.740), p=0.04]. These findings were confirmed with significantly higher ADCC after 12 months of ATI [baseline, 14.4% (5.9-23.2%) vs 12 months 21% (17.5-26.9%), p=0.0002], as compared to the subjects who remained on ART [13.3% (11.8-16.5%) vs 15.7% (12.2-17.7%), p=ns]. Time course analyses showed that 90% of the subjects had increased ADCC antibodies by 2 months of ATI [OD_{450}, 0.331 (0.130-0.470) vs 0.678 (0.429-0.868), p=0.0014].
Conclusions: Our results show that low level viremia after panobinostat does not stimulate ADCC and there is a lag of several weeks between viral recrudescence and the stimulation of ADCC immunity after ATI. These data have implications for the antigenic stimulus required for anti-latency strategies or therapeutic vaccines to induce ADCC and assist in reducing the latent reservoir.

WEPEA0209

Sphingosine-1-phosphate receptor 1 agonists as HIV-1 latency reversing agents

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Background: Various drugs are being tested to reactivate replication-competent HIV-1 in reservoir cells. Yet, many of these HIV-1 latency reversing agents (LRA) are toxic and/or poorly efficient in vivo. We have recently shown that S1P1, a receptor for sphingosine-1-phosphate (S1P), is a G-protein coupled receptor (GPCR) highly expressed in CD4+ T cells and able to dimerize with CCR5. Of note, we observed that S1P1 expression increased HIV-1 replication. Here we analyzed the mechanism responsible for this effect and tested S1P1 agonists as LRA.
Methods: Hela cells were transduced using HIV-1-derived vectors. HIV production was monitored by measuring gag p24 concentration in the culture supernatant. p65 NFkB nuclear translocation was monitored by immunofluorescence. Luciferase activity was quantified using a commercial kit.
Results: In Hela cells stably transfected with a luciferase gene driven by HIV-1 LTR, S1P1 but not LacZ transduction induced luciferase production. This effect was further increased in the presence of the S1P1 agonist SEW2871, indicating that S1P1 signaling results in LTR activation. Transfection of a luciferase gene driven by a wild-type LTR, but not by an NFkB binding site-deleted LTR, into Hela cells transduced with S1P1 induced luciferase production, indicating that NFkB is involved in this phenomenon. Accordingly, S1P1 expression in MT4 cells activated p65 NFkB, and increased the production of an X4 HIV-1 strain, as long as the LTR of this strain contained intact NFkB binding sites.
Finally, S1P1 and SEW2871 induced HIV-1 production by peripheral blood and lymph node mononuclear cells latently infected in vitro (112 ± 94 and 26 ± 21 pg of p24/mL produced by PBMC after 9 days in presence or absence of SEW2871, respectively, p = 0.027).
Conclusions: S1P1 activation, induced by the presence of S1P in the culture medium and reinforced by S1P1 agonists, induces HIV-1 genome expression via NFkB activation. The effect of S1P1 agonists need to be further tested ex vivo on HIV-1 reservoir cells and in combination with other LRA, inasmuch as the S1P1 ligand FTY720 is already used in multiple sclerosis. We have identified two other GPCR presenting with the same characteristics.

WEPEA0210

Monocyte co-culture can reverse pre-activation but not post-activation latency

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Background: The "Shock and kill" strategy aims to activate and eliminate latently infected cells, but not all intact latent viruses are induced, even with potent mitogen or T-cell receptor stimulation. T-cell activation and virus expression from latency may not be directly linked and other stimuli required to activate HIV expression. We hypothesized that responses to latency-reversing agents (LRA) depend on how latency is established and tested virus activation in two models of HIV latency.
Methods: Latency was established in primary CD4+ T-cells using X4 tropic, nef-competent, enhanced green fluorescent protein (EGFP)virus following 1] direct infection of CCL19-treated resting CD4 (pre-activation latency) and 2] infection of naïve T-cells activated with antiCD3/28 (post-activation latency). EGFP-negative cells were sorted 5-7d post-infection and stimulated for 72hrs with Dimethyl sulfoxide (DMSO), allogeneic monocytes (mo, at a ratio of 1:10 to T-cells) +/- antiCD3 (20µg/ml), antiCD3/28 and other LRAs. EGFP expression and T-cell proliferation using cell proliferation dye were measured by flow cytometry. Wilcoxon matched pairs signed-rank test was used for comparisons.
Results: At 5-7d post-infection there were more productively infected cells (EGFP+ cells) in the post-activation compared to pre-activation model (74 and 144 EGFP+/10^4 cells, p< 0.0001, n=8). In the pre-activation latency model, EGFP expression was induced from latency following stimulation with mo/antiCD3 and antiCD3/28 compared to DMSO (43, 22 and 3 EGFP+ cells/10^4 cells respectively, p< 0.001). In the post-activation latency model, the addition of antiCD3/28 but not mo/antiCD3 increased the mean number of EGFP+ cells compared to DMSO (145, 15, 22 EGFP+ cells/10^4 cells respectively, p< 0.001). The magnitude of EGFP expression post-stimulation correlated with T-cell proliferation in the pre-activation latency (r=0.34, p=0.003) but not the post-activation latency model (r=0.05, p=0.72). Following LRA (panobinostat, romidepsin, JQ1) stimulation, an increase in EGFP expression compared to DMSO was observed in the pre-activation latency model (8, 16, 6 and 3 EGFP+ cells/ 10^4 live cells respectively, p< 0.01, n=4-5, paired student t-Test).

Conclusions: Multiple stimuli can reverse latency in a pre-activation model of latency, which differs from a post-activation latency model. The pathway by which latency is established is linked to the efficacy of specific latency reversal strategies.

WEPEA0211

The activation of NF-kB and the subsequent transcription of latent HIV-1 in resting CD4+ T cells is the direct consequence of MVC binding to CCR5

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Background: We have shown that maraviroc (MVC) reactivates latent HIV-1 in resting CD4+ T cells in patients who received 10 days MVC, added to a stable antiretroviral regimen, through activation of NF-kB. To elucidate the mechanism of NF-kB activation by MVC, we have evaluated in an in vitro model if MVC could be acting as a partial CCR5-agonist, with no other mechanisms or pathways involved.
Methods: We used HeLa P4C5 cells, which stably express CCR5. Cells were seeded for 2, 6, 12, 24 and 48h in the absence or presence of MVC (5, 10, 20 and 40mM). NF-kB activation was detected by ELISA. The functionality of NF-kB was analysed by measuring the differential target gene expression by real-time PCR. As controls, we used TAK-779, a CCR5 antagonist, and PMA, a positive control of NF-kB activation. To check if the activation of the NF-kB signalling pathway is due to the binding of MVC to CCR5, HeLa cells, which do not express CCR5, were treated with MVC.
Results: NF-kB activation was observed after 2 and 6h of MVC treatment at all the concentrations tested in HeLa P4C5. We did not detect activation of NF-kB at 12, 24 and 48h at any of the concentrations included. The greatest increase in NF-kB activation levels was observed in the presence of MVC in HeLa P4C5 at 2h, with the maximum peak being induced with 5mM MVC. This significant increase in NF-kB was also observed at 6h in the presence of 5mM MVC. NF-kB activation was not detected in the presence of TAK-779. No activation of NF-kB was found in HeLa at any of the concentrations and times tested, with the exception of PMA. The expression of the target genes was in agreement with the activation observed in NF-kB.
Conclusions: This in vitro study suggests that MVC-induced latency reversal of HIV-1 is mediated by MVC binding to CCR5, acting as a partial agonist, and the subsequent downstream signalling. Taking altogether, the information from the previous clinical trials and this confirmatory mechanistic in vitro study provides a strong background for MVC to be used as a latency reversal agent.

WEPEA0212

Antiretroviral drug transporters and metabolic enzymes expressed in the testes could potentially contribute to low tissue drug concentrations and HIV-1 persistence

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Background: Human immunodeficiency virus (HIV-1) is capable of persistent infection in the testis, where inadequate ARV penetration could be due in part to the functional expression of drug efflux transporters at the blood-testis barrier (BTB). In this study, we characterized the expression and localization of drug transporters and metabolic enzymes in human testes and quantify antiretroviral drug (ARV) concentrations in HIV-infected testicular tissue. Since ligand-activated transcription factors (i.e., nuclear receptors) are known to induce the functional expression of drug transporters and metabolic enzymes in various tissues, we also investigated the regulation of ATP-binding cassette (ABC) efflux transporters expressed at the BTB by pregnane X receptor (PXR) and constitutive androstane receptor (CAR).
Methods: mRNA and protein expression of the ABC and solute carrier (SLC) transporters, CYP450 metabolic enzymes, and nuclear receptors were evaluated in testicular tissue obtained during gender reassignment surgery from uninfected (n=8) and HIV-1 infected (n=5) individuals on ARV therapy, by qPCR analysis and western blotting respectively. Localization of transporters and metabolic enzymes was determined by confocal microscopy. ARV concentrations in testicular tissue or plasma were quantified by LCMS/MS. TM4 Sertoli cells, a continuous cell line representing the mouse BTB, were exposed to nuclear receptor ligands and targeting siRNA. The mRNA and protein levels of efflux transporters were quantified in these cells to determine their regulation.
Results: Expression and localization of ABC (P-gp, BCRP, MRPs) and SLC (OATP, OAT, OCT, CNT, ENT) transporters, as well as CYP3A4 and CYP2D6 were confirmed in human testes. Several ARVs that are known substrates for ABC transporters displayed low testicular tissue concentration. Nuclear receptors, PXR and CAR, were also expressed in human testicular tissue and TM4 mouse Sertoli cells and mediated the induction of P-gp, BCRP and MRP4 at the BTB.
Conclusions: Our findings suggest that drug transporters, metabolic enzymes and nuclear receptors involved in ARV disposition are present in the testes, and could limit ARV tissue penetration in HIV-1 infected individuals; this could potentially contribute to persistent HIV-1 infection and formation of a viral sanctuary in this tissue.

WEPEA0213

Blood CXCR3+ CD4 T cells are enriched in inducible replication competent HIV

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Background: We recently demonstrated that Lymph node (LN) PD-1+/T follicular helper (Tfh) cells from anti-retroviral therapy (ART) treated HIV-infected individuals were enriched in cells containing replication competent virus. However, the distribution of cells containing inducible replication competent virus has been only partially elucidated in blood memory CD4 T-cell populations.
Methods: We have investigated the distribution of 1) total HIV-1 infected cells by Alu PCR and 2) cells containing replication competent HIV using virus outgrowth assay (VOA) within blood memory CD4 T-cell populations defined by chemokine receptor expression i.e CXCR3+CXCR5- (Th1), CXCR3-CXCR5+ (cTfh), CXCR3+CXCR5+ (Th1 cTfh), CCR4+CCR6- (Th2), and CCR4+CCR6+ (Th17) cells in ART treated (0.1-8.2 years) aviremic (< 20 HIV RNA copies/ml) individuals (N=15).
Results: No significant differences in the frequency of integrated HIV DNA in the different memory CD4 T-cell populations were found (P>0.05) However, Th1 cells were significantly enriched in cells containing replication competent virus as compared to any other blood CD4 T-cell population (P< 0.05). The mean frequency of Th1 cells containing inducible replication competent virus was about 13 cells per million as assessed by RNA-Unit Per Million. Blood Th1 cells were also the largest contributor (54%) to the total pool of blood HIV-infected cells containing replication competent virus in the cohort. Interestingly, the fraction of HIV provirus induced by VOA was higher in Th1 cells as compared to any other blood CD4 T-cell subpopulations, suggesting that Th1 cells contained either more intact or more inducible provirus. Of note, blood CD4 T-cell populations were not significantly different in terms of
1) level of activation as assessed by HLA-DR or Ki-67 expression,
2) CCR5 and CXCR4 HIV co-receptor expression and
3) SAMHD1 HIV restriction factor expression (P>0.05).
However, both Th1 and cTfh cells were significantly enriched in PD-1 expressing cells as compared to Th2 and Th17 (46% and 42%, respectively) (P< 0.05), but only the levels of HIV RNA of Th1 VOA culture supernatants directly correlated with the frequency of PD-1 expression on Th1 cells (P< 0.05).
Conclusions: Taken together, these results indicate that blood Th1 cells represent the major blood compartment containing inducible replication competent virus in treated aviremic HIV-infected individuals.

WEPEA0214

Latency reversing agents induce differential responses in distinct memory CD4+ T cell subsets in virally suppressed individuals

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Background: HIV primarily persists in three subsets of memory CD4+ T cells [central (Tcm), transitional (Ttm) and effector (Tem) cells]. Given their functional differences, we hypothesized that HIV latency results from different mechanisms in these three memory subsets and that distinct reactivation strategies might be needed to simultaneously reactivate latent HIV in all cellular reservoirs.
Methods: Histone acetylation (H3K9, H4K5/8/12/16), active NF-κB (pS529), and active P-TEFb (pS175 CDK9) were measured by flow cytometry in Tcm, Ttm and Tem from virally suppressed individuals. We tested the ability of latency reversing agents (HDACi, NF-κB inducers, P-TEFb inducers) at modulating these factors in each subset. HDACi uptake in all the subsets was assessed by LC-MS/MS analysis.
Results: Baseline levels of acetylated H4 were higher in Tem ($p<0.05$) when compared to Tcm and Ttm, whereas no significant differences in baseline levels of acetylated H3 were noted. pNF-κB levels were maximal in Tcm and decreased with the differentiation stage (Tcm>Ttm>Tem, $p<0.05$), whereas baseline pCDK9 levels tended to be higher in Ttm.
Dose responses with a panel of LRAs revealed that vorinostat was more potent at acetylating histones in Tcm than in Tem (median EC50 for H3 and H4: 534 VS 938nM and 502 VS 955nM, respectively), whereas romidepsin was more potent at acetylating histones in Tem than in Tcm (median EC50 for H3 and H4: 15,6 VS 8,6nM and 11,3 VS 7,6nM; respectively).
Of note, HDACi uptake was similar between the subsets. Fold increases at the top plateau showed that NF-κB inducers (bryostatin, prostratin, ingenol) increased NF-κB phosphorylation with a higher efficacy in Tcm ($p\leq0.0002$ for all inducers). P-TEFb inducers (JQ-1, I-BET) had no significant effect on CDK9 phosphorylation, while bryostatin and ingenol readily induced CDK9 phosphorylation, particularly in Tem.
Conclusions: Our results indicate that the baseline levels of cellular factors involved in HIV latency differ between the memory CD4+ T cell subsets that serve as reservoirs for HIV during ART. Importantly, LRAs exert different activities in distinct cellular reservoirs, suggesting that their anti-latency activities may be subset-restricted.

WEPEA0215

A novel strategy to circumvent cytokine release associated with HIV latency reversal

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Background: Antiretroviral therapy (ART) does not cure HIV-1 infection due to the persistence of replication-competent proviruses in long-lived resting T cells. Strategies to target these latently infected cells will be necessary to eradicate HIV-1 in infected individuals. Protein kinase C (PKC) activation is a promising pathway to reactivate latent proviruses and allow for recognition and clearance of infected cells by the immune system. Ingenol derivatives are PKC agonists that reliably induce latency reversal ex vivo. PKC agonists, including ingenols, can induce pro-inflammatory cytokine release and T cell activation. These undesirable properties have precluded consideration of PKC agonists as candidate latency reversal agents to date.
We hypothesized that a kinase inhibitor combined with an ingenol compound could decrease PKC-induced pro-inflammatory cytokine release without affecting latency reversal. This strategy could allow PKC agonists, including ingenol compounds, to be safely tested in pilot HIV-1 eradication trials.
Methods: We performed an in vitro screen of kinase inhibitors to identify compounds that could decrease pro-inflammatory cytokine release induced by ingenol derivatives. Hits were defined as compounds that reduced interleukin-6 (IL-6) by four-fold or greater without altering cell viability compared to cells exposed to ingenol alone. We subsequently tested one screening hit, the FDA-approved Janus Kinase (JAK) inhibitor ruxolitinib, with regard to cytokine release and latency reversal in the presence of ingenol compounds using cells obtained from HIV-positive participants ex vivo.
Results: Kinase inhibitor screening identified several candidate hits that attenuated ingenol-induced IL-6 release. Ex vivo exposure to ruxolitinib, a selective inhibitor of JAK1 and 2, significantly reduced release of pro-inflammatory cytokines but did not impair latency reversal induced by ingenol-3,20-dibenzoate in cells from HIV-1 positive donors on ART. In addition, Ruxolitinib did not induce T cell activation or apoptosis.
Conclusions: Ingenol-3,20-dibenzoate reactivates latent HIV-1 to levels similar to positive control (T cell receptor stimulation) and induces release of pro-inflammatory cytokines ex vivo. Ruxolitinib, an FDA-approved JAK inhibitor, reduced pro-inflammatory cytokine release by >90% but did not diminish latency reversal induced by ingenol. PKC activation combined with JAK inhibition represents a novel HIV-1 eradication strategy that merits in vivo evaluation.

WEPEA0216

Early initiation of long-term ART may favor interventions to eradicate HIV: analysis of cell turnover and persistent HIV reservoir in distinct CD4+ T cell subpopulations in suppressed HIV disease

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Background: HIV persistence during antiretroviral therapy (ART) is predictably dependent upon the relative turnover of CD4+ T cell subpopulations harboring HIV genomes. We present here an analysis of the in vivo turnover and HIV content of various CD4+ T cell subpopulations as a function of the time of initiation and duration of suppressive ART.
Methods: We enrolled 24 participants treated either within 3 months or after 12 months of infection and for <3 years or >7 years. Using established labelling techniques, we measured CD4+ T cell turnover based on in vivo incorporation of deuterium into genomic DNA in sort-purified HLADR-negative CD4 T naïve (TN), stem-cell memory (TSCM), central-memory (TCM), transitional-memory (TTM), effector-memory (TEM), and effector (TEMRA) cells, after oral administration of deuterated water. We also quantified integrated HIV-DNA (Int-DNA) and cell-associated HIV-RNA (caRNA).
Results: Overall, the half-life of CD4+ T-cell subpopulations decreased significantly with increasing maturation status ($p<0.04$), except for TEMRA. A shorter cellular half-life was associated with higher levels of Int-DNA and caRNA content ($r=-0.53$, $p<0.0001$), with enrichment of virus in shorter-lived subpopulations, e.g., TEM, TTM, and TCM ($p<0.019$). Compared to delayed ART, early ART initiation was associated with longer half-lives for TSCM, TCM, TTM, and TEM and decreased Int-DNA levels within TTM ($p<0.037$). Long-term ART was associated with a longer half-life and lower levels of Int-DNA within TTM ($p<0.033$), and a lower relative contribution of infected TSCM and TEMRA to the total HIV reservoir ($p<0.038$), compared to short-term ART.
Conclusions: We conclude that HIV persistence in CD4+ T cells can be maintained within two subpopulations with markedly different characteristics: most of the reservoir is composed of relatively short-lived differentiated cells that proliferate at a high rate while a smaller portion persists within less-differentiated cells that survive for longer periods of time. Notably, long-term maintenance of early ART is associated with a lower contribution to the reservoir load within these latter long-lived subpopulations, and may accordingly favor interventions to eradicate HIV.

Median [IQR] for all 24 participants	TN	TSCM	TCM	TTM	TEM	TEMRA
Half-life (days)	933 [715-1181]	157 [129-196]	128 [104-147]	100 [94-126]	88 [71-127]	249 [207-300]
Integrated HIV DNA (copies/million cells)	28 [8-145]	161 [42-420]	290 [66-1343]	770 [154-2510]	838 [257-3029]	205 [32-973]
Contribution to the reservoir (%)	5 [2-16]	0.6 [0.3-1.3]	34 [17-46]	27 [17-33]	20 [10-28]	2 [1-7]
Cell-associated HIV RNA (copies/million cells)	29 [12-105]	183 [60-578]	590 [91-2533]	1313 [159-4124]	2729 [222-4871]	644 [98-3992]

[HOPE]

WEPEA0217

Replication competent HIV reservoirs resist elimination by CTLs and potent combinations of latency-reversing agents

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Background: Primary-cell models of HIV latency are often used in HIV cure studies. However, these models may not reflect the full complexity of natural viral reservoirs. Here, we investigate whether the "shock-and-kill" paradigm (utilizing immune effectors, in combination with latency-reversing agents (LRAs)), can drive reductions in natural HIV reservoirs. CD4+ T-cells, from HIV+ donors on long-term ART, were treated with LRAs and autologous HIV-specific CTL clones targeting non-escaped epitopes, then assessed for decreases in total and inducible provirus.
Methods: HIV-specific CTL clones targeting known HIV epitopes were isolated from ARV-treated subjects by limiting dilution; killing activities were confirmed by flow cytometric assays. We tested the abilities of these CTLs to reduce viral reservoirs in an HIV eradication assay, using the following LRAs and immunotherapeutics either singly or in combination: HDACi's, bryostatin, JQ1, IL-15SA, Pam$_3$CSK$_4$, anti-PD-1, anti-hTim3, or PMA/Ionomycin. Resting CD4+ T-cells were co-cultured with LRAs and CTLs for 4 days with ARVs, then isolated and assessed for activation/memory phenotypes, and measured for cell-associated HIV DNA (ddPCR) and inducible HIV by quantitative viral outgrowth assay (QVOA).
Results: Most combinations of LRAs with HIV-specific CTL saw significant decreases in cell-associated HIV DNA, with PMA/Ionomycin or bryostatin treated conditions achieving the greatest effects (up to 50% reductions, p< 0.01). Critically, reductions in HIV DNA were not reflected by measurable reductions of inducible virus, regardless of the CTL/LRA combination used (powered to detect >2-fold reductions with 95% confidence). CTL combinations with PMA/ionomycin, also failed to deplete the viral reservoir. Additionally, CTLs degranulated (CD107a) in response to autologous activated CD4+ T-cells that were infected with virus from positive QVOA wells, ruling out a role for immune escape.
Conclusions: This HIV eradication assay utilizes highly functional CTLs that target non-escaped epitopes, and overcomes latency with potent combinations of LRAs and immunotherapeutics. Even after maximal activation with PMA/Ionomycin, CTLs failed to reduce the viral reservoir. These data suggest the existence of additional, previously unknown, barriers to CTL-mediated reservoir elimination. Our recent experiments indicate that Nef-mediated downregulation of MHC-I, may limit CTL action against the intact-inducible reservoir. Discerning and solving these novel barriers is key to successful shock-and-kill interventions.

WEPEA0218

4-Deoxyphorbol derivatives as new drug candidates for "Shock and Kill" therapy with strong activity against HIV-1

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Background: Antiretroviral therapy (ART) cannot eliminate HIV infection due to the persistence of HIV in latently infected cells in the blood and lymphoid organs. Viral reactivation has been proposed as ART adjuvant therapy to eradicate viral reservoirs. To achieve this goal, a new generation of drugs termed "Latency Reversal Agents" (LRA) displaying high potency and low toxicity is needed.
Methods: Anti-HIV-1 and LRA activity of 4-deoxyphorbols were evaluated in vitro in MT-2 cells and human PBMCs using a recombinant virus assay. Receptor expression was evaluated by single-, double- or three-color immunophenotyping in a FACScalibur flow cytometer. HIV reservoir reactivation activity was evaluated in a resting PBMCs based latency model. Pathways involved in the mechanism of action of 4dPE-A were studied by pharmacological inhibition of different isoforms of PKCs and MEK kinases and SAMHD1 phosphorylation was assessed by western blot.
Results: In an initial screening of 4-deoxyphorbols one of them, 4dPE-A, showed the strongest antiviral activity with an IC_{50} of 3 nM in infection with X4-tropic HIV-1 in MT-2 cells and 0.3/0.2 nM in infections with X4/R5 tropic HIV-1 in IL-2 preactivated PBMCs. Specificity index was >10000, and no long-term toxicity was observed in PBMCs even 2 weeks after treatment. The compound was active at different steps of the HIV cycle:
(1) 4dPE-A induced the internalization of CD4, CXCR4 and/or CCR5 lymphocyte receptors and this activity was independent of PKCs and MEK.
(2) As, LRA 4dPE-A was able to trigger NF-kB activity and viral transcription in HIV-1 transfected MT-2 cells and PBMCs at concentrations as low as 10nM. This activity was strongly dependent on the activation of PCK-theta isoform and MEK and thus, different pathways would be involved in 4dPE-A action.
(3) Finally, 4dPE-A induced SAMHD1 phosphorylation in resting PBMCs.
Conclusions: 4dPE-A is a novel compound with a potent dual activity in the HIV replication cycle, both as a viral entry inhibitor and viral reservoir reactivator. 4dPE-A represents a LRA candidate that could be further developed as ART adjuvants to achieve a functional cure in HIV-1 infected people.

WEPEA0219

Stress increases HIV transcription in HIV-infected individuals on antiretroviral therapy: implications for biomarkers of HIV persistence

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Background: Cell-associated unspliced (CA-US) HIV RNA is a measure of transcriptionally active cells and is an important biomarker for quantifying the efficacy of latency reversing agents (LRAs). We recently observed that CA-US RNA levels may vary due to stress, circadian rhythms, or both. We performed an experimental clinical study aimed at defining the impact of stress on HIV RNA production in individuals on antiretroviral therapy (ART).
Methods: Participants were on ART with plasma HIV RNA < 50 copies/ml for > 3 years. All participants underwent a Trier Social Stress Test (TSST), a procedure in which participants are asked to give a speech and perform a math task before an audience that provides no positive verbal or non-verbal feedback. On the TSST day, we obtained blood before and 30 and 65 minutes after the stress tasks. Salivary cortisol was also quantified. We used physiological monitoring to measure autonomous nervous system activity:
(1) respiratory sinus arrhythmia (RSA), a measure of parasympathetic activity, with lower values indicating less parasympathetic tone; and
(2) pre-ejection period (PEP) for sympathetic activity, with lower numbers indicating greater sympathetic tone. On a control day in the absence of the TSST, the identical tests were performed.
Results: Mean cortisol levels immediately post-stressor were 9.63 nmol/L on the TSST day and 4.87 on the control day (n=25; P=0.0003), and RSA and PEP both declined significantly during the stress tasks. There was an estimated 1.49-fold increase in CA-US RNA at the TSST visit relative to the control day (95%CI: 1.15 to 1.93-fold increase, p=0.002). HIV DNA did not change significantly. Decreases in PEP predicted increased CA-US HIV RNA during the TSST (rho=-0.59, P=0.002).
Conclusions: Psychological stress induces an increase in CA-US HIV RNA in a range that would be considered significant in clinical trials of LRAs and needs to be considered in clinical study design. The increase is likely to be related to sympathetic nervous system enhancement of HIV transcription, which is consistent with prior data indicating sympathetic activation may enhance HIV replication. Further understanding of the mechanisms involved may reveal new targets for inducing the latent HIV reservoir.

WEPEA0220

HIV-1 Nef blockade improves the immune recognition and clearance of primary latently HIV-1-infected CD4 T cells by autologous CD8 T cells

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Background: Eradication of the HIV-1 latent reservoir represents the current obstacle towards the development of a cure for AIDS. Latently infected cells persist by effectively evading HIV-specific CD8 T cells that are critical for control of HIV-1 infection. One strategy employed by the virus to promote immune evasion from CD8 T cells is the downregulation of MHC-I from the surface of infected cells mediated by the HIV-1 Nef protein. Indeed, Nef transcripts and protein are detectable in the PBMCs of individuals on suppressive HAART indicating that Nef expression in latently infected cells plays a key role in viral persistence. Thus, we hypothesized that Nef blockade would restore optimal CD8 T cell mediated immune surveillance and result in the elimination of latently infected CD4 T cells.
Methods: In a proof-of-concept study, we have tested a single dose of four recently characterized small molecule inhibitors of HIV-1 Nef: DQBS (diaminoquinoxaline benzenesulfonamide), B9 (diphenylpyrazolyldiazene scaffold) and next-gen B9 analogs JZ-96-21 and JZ-97-21, in an in vitro primary CD4 T cell latency model. We cocultured Nef inhibitor treated latently infected CD4 T cells with autologous HIV-peptide expanded CD8 T cells and measured CD8 T cells' ability towards immune recognition and elimination of latently infected targets
Results: Three out of four compounds significantly enhanced the recognition of latently infected CD4 T cells by autologous CD8 T cells ($p < 0.05$) relative to control in an IFN-γ release assay. Importantly, Nef blockade by each of the inhibitors facilitated significantly greater elimination of latently HIV-1 infected CD4 T cells by HIV-peptide expanded CD8 T cells ($p < 0.05$) as measured by viral outgrowth assays quantitating HIV-Gag p24 via ELISA and flow cytometry following coculture.
Conclusions: We demonstrate for the first time, using primary T cells, that Nef blockade, in combination with HIV-specific CD8 T cell expansion, might be a feasible strategy to target and eradicate the HIV-1 latent reservoir. Our study sets the precedent to test Nef inhibitors for future in vivo studies geared towards a cure.

WEPEA0221

Panobinostat distribution in rhesus macaque lymph nodes following anti-latency therapy

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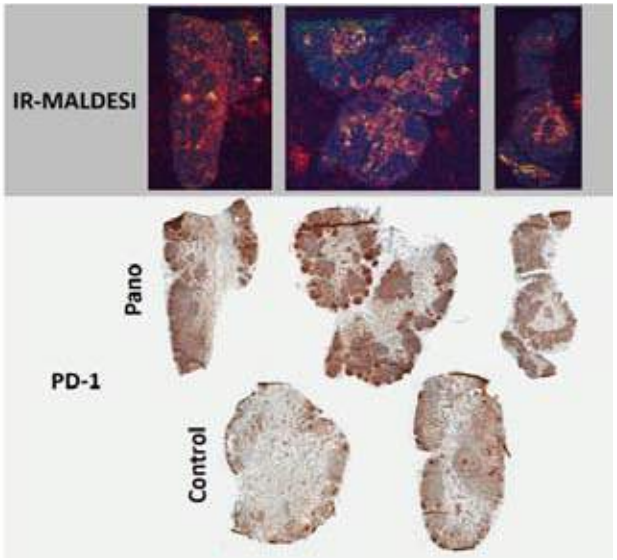
Background: Panobinostat (Pano), a potent HDAC inhibitor, may act as a latency reversing agent within tissue reservoirs. We have characterized the spatial distribution of Pano in RT-SHIV+ rhesus macaques (RM) receiving HAART to evaluate penetration into key tissues using a novel approach to mass spectrometry imaging (MSI).
Methods: 3 RT-SHIV+ RM were administered 44-weeks of HAART with biweekly Pano (0.667 mg/kg (n=2) and 2.0 mg/kg (n=1) for 3 weeks prior to necropsy. 2 control animals on HAART were also sacrificed at week 47. MSI of snap frozen cryosections (10µm) of lymph nodes (LN) were analyzed using an infrared matrix-assisted laser desorption electrospray ionization (IR-MALDESI) source. Response was calibrated by standards on blank tissue, with 88 fg/voxel limit of detection (LOD). Serial sections of tissue were stained for immunohistochemistry (IHC: PD-1, CD3, and CD4 expression), and analyzed by LC-MS/MS (LOD=0.01 ng/ml homogenate) to validate MSI results.
Results: MSI revealed that LN Pano concentrations (LC-MS/MS: 206±34 ng/g) were distributed heterogeneously in tissue (Figure 1). Using IHC microscopy and in silico micro-dissection of MSI results, an estimated 45-68% of total Pano exposure was localized in vasculature. Parenchymal Pano concentrations were estimated to be 86±33 ng/g (260nM, based on tissue density of 1.06 g/cm^3), representing a 1.6 to 4-fold increase over plasma concentrations. Higher (3-fold) Pano dosing marginally increased Pano tissue homogenate concentrations (1.1-fold), but yielded 1.6-fold higher penetration into parenchyma. While parenchymal Pano exceeded concentrations required for in vitro HIV activation (EC50=10nM, EC90=100nM), no difference was found in PD-1 expression intensity between Pano and control tissues (6.1±2e5 and 6.5±0.6e5, respectively).
Conclusions: This study is the first to map the biodistribution of panobinostat in putative viral reservoir tissues following anti-latency therapy. Stimulating dormant virus out of latency requires adequate penetration into tissues where it resides, and IR-MALDESI MSI can provide key information to evaluate the efficacy of treatment strategies.



[Localization of panobinostat in vascular regions of RM lymph node]

WEPEA0222

Vorinostat renders the replication-competent latent reservoir of HIV vulnerable to clearance by CD8 T cells

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Background: Latently HIV-infected cells are transcriptionally quiescent, and thus invisible to clearance by the immune system. We wished to demonstrate that the latency reversing agent (LRA) vorinostat induces a window of vulnerability in the latent HIV reservoir, defined as the triggering of viral protein antigen production sufficient in quantity and duration to allow for clearance of persisting infection.
Methods: We created a latency clearance assay, by modifying the quantitative viral outgrowth assay to allow the addition of immune effectors capable of clearing cells expressing viral antigen. A reduction in the recovery of replication-competent virus recovery following addition of immune effectors provides evidence that LRA exposure leads to sufficient production of viral protein to allow detection and clearance of latent infection.
Results: The 14 participants studied were all suppressed for at least 2 years, with a median duration of suppression of 6 years (range 2-8.5) and a wide range of latent reservoir sizes as measured by the standard quantitative outgrowth assay (median 0.57, range 0.04 to 2.30 infectious units per million resting CD4 T cells). Following a 6 hour exposure of resting CD4 T cells to 335nM of vorinostat, chosen to mimic physiologically achievable levels in vivo, the number of p24+ wells recovered as a percentage of total wells plated was significantly reduced when a variety of immune effectors were exposed to infected cells overnight, and then removed prior to the viral outgrowth step of the assay. Autologous CD8 cells (in some cases), autologous CD8 cells expanded in the presence of viral peptides (HXTCs, ref. Sung JID 2015), or autologous CD8 cells with bispecific antibody-derived molecules (Sung, JCI 2015) all significantly reduced the recovery of replication-competent HIV from resting CD4+ T cells in the latency clearance assay.
Conclusions: We show that a pharmacologically relevant exposure to vorinostat induces viral protein expression in resting CD4 T cells from antiretroviral suppressed, HIV-infected individuals, creating a window of vulnerability within this latent reservoir. In ongoing clinical studies, we will seek evidence that clearance activity assessed in this ex vivo assay using autologous HIV+ participant´s cell can predict in vivo responses.

WEPEA0223

HIV-1 Nef is required for efficient latency reversal in a T cell line

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Background: Nef is a crucial accessory protein that enhances HIV pathogenesis, in part through evasion of host immune responses. Nef is reported to modulate T cell signaling events, which may alter cellular activation status, but Nef's contribution to the establishment and maintenance of viral latency remain elusive. To investigate this, we examined the reactivation efficiency of clonal CEM T cell lines latently infected with HIV strains encoding functional or defective Nef.
Methods: Latent CEM-A*02 (CLat) T cell clones were generated using NL4.3ΔEnv viruses encoding Nef_{SF2}GFP, Nef_{G2A}GFP, or $Nef_{NL4.3}$-IRES-GFP. The nef gene was subsequently disrupted in a selected CLat clone using CRISPR/Cas9. Viral reactivation induced by TNFα, panobinostat or prostratin was assessed using flow cytometry to measure GFP or intracellular Gag-p24 expression. Surface CD4 and HLA-A*02 expression was quantified following reactivation to confirm Nef function.
Results: A panel of CLat-Nef_{SF2}GFP [N=11] and CLat-Nef_{G2A}GFP [N=41] clones with low background GFP expression (< 10%) was generated. For all latency reversal agents tested, we observed that viral reactivation was generally poorer in clones encoding defective Nef_{G2A}GFP compared to those encoding wild-type Nef_{SF2}GFP. In particular, median fluorescent intensity of GFP was lower in reactivating CLat-Nef_{G2A}GFP clones (GFP_{MFI}=133 [IQR 112-151]) compared to CLat-Nef_{G2A}GFP clones (GFP_{MFI}=375 [272-474]; p<0.0001). Additionally, CLat-Nef_{G2A}GFP clones were less responsive to stimulation using histone deactylase inhibitor (panobinostat) compared to CLat-Nef_{SF2}GFP clones (median [IQR] % GFP+ cells: 9 [7-12]% versus 48 [38-62]%; p<0.0001). To overcome potential bias associated with differences in DNA integration site between clones, we disrupted the Nef gene in a CLat clone encoding $Nef_{NL4.3}$-IRES-GFP. As expected, all Nef knockout clones (N=38] lacked the ability to downregulate CD4 and HLA-A*02. Knockout clones displayed variable reactivation profiles (85 [65-99]% GFP+ cells), but notably, the median fluorescent intensity of GFP was lower in Nef knockout clones (GFP_{MFI}=157 [118-229]) than in the parental clone (96% GFP+; GFP_{MFI}=459±16), and fewer Gag-p24+ cells were observed.
Conclusions: These results suggest that HIV-1 Nef contributes to viral reactivation from latency. In addition to Nef's role in immune evasion, our data indicate that Nef can modulate the efficiency of viral reactivation in the context of latency reversal agents.

WEPEA0224

IFITM1 targets HIV-1 latently infected cells for antibody dependent cytolysis

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Background: Antiretroviral therapy (ART) potently suppresses HIV-1, but viral eradication remains unachievable due to the persistence of reservoirs. Current eradication strategies rely on histone deacetylase inhibitors and related compounds, in conjugation with ART, to reactivate and kill infected cells within the reservoir. Components of intrinsic immunity, such as restriction factors possess potent anti-HIV-1 activities by interfering with the virus life cycle.
Methods: Using a well-established ex vivo model we generated latently infected CD4+ T-cells and identified IFITM1, a transmembrane antiviral factor, as being overexpressed in latently infected cells.
Results: We found that the expression of IFITM1 and SAMHD1 were 4-fold and 2-fold increased, respectively, in resting latent cells when compared to reactivated cells. We also tested the capacity of NK cells to recognize and kill IFITM1-expressing cells by antibody-dependent cell-mediated cytotoxicity (ADCC). We detected significant killing of ACH-2 cells labeled with anti-IFITM1 antibody (79±4.5%), when compared to control (25±1.3%) and this was associated with a significant increase (p=0.0286) in the frequency of IFN-γ+CD107a+ NK cells (1.345±1.3%).
Conclusions: Our results reveal an important and unreported finding that suggests a role for IFITM1 during HIV-1 latency. The efficient killing of latently infected cells through the engagement of an anti-IFITM1 antibody may shed light into new strategies for the efficient eradication of latently infected cells. These novel insights could be explored to develop clinical therapeutic approaches to effectively eradicate HIV-1.

WEPEA0225

Early treatment of SIV+ macaques with an $\alpha_4\beta_7$ mAb alters virus distribution and preserves $CD4^+$ T cells in later stages of infection

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Background: SIV infected macaques treated with ART in combination with an anti-α4β7 mAb controlled plasma viremia for up to two years following discontinuation of all therapy. The mechanism of control is unknown.
Methods: We employed whole body immuno-PET/CT imaging to detect the distribution of virus and CD4+ T cells in treated animals both before and after therapy interruption. Flow cytometry and immunohistochemistry was used to confirm PET/CT results.
Results: We were able to detect virus in various lymphoid and mucosal tissues including gut in animals treated with either ART plus control IgG or ART plus anti-α4β7 mAb. Anti-α4β7 mAb promoted a redistribution of virus, with a pronounced decrease in the large intestine. The reduction in viral replication in gut tissues occurred despite the fact that anti-α4β7 mAb treatment did not result in a decrease in $CD4^+$ T cells within the gut.
Conclusions: These results demonstrate that an anti-α4β7 mAb impacts the distribution of virus while promoting the restoration of CD4+ T cell in the gut and other lymphoid tissues following experimental infection and treatment with ART. The redisrtibution of virus and the subsequent CD4+ T cell restoration may underlie the mechanism of viral control in macaques treated with ART plus anti- α4β7 mAb.

WEPEA0226

The central nervous system as a reservoir of HIV-1 variants resistant to broadly neutralizing antibodies

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Background: Clinical studies using broadly neutralizing antibodies (bNAbs) as therapeutic or prophylactic agents are moving forward at increasing pace. The emergence of resistant escape mutants has already been reported. Envelope glycoprotein evolve quickly under the selective pressure by autologous antibodies but also by adaptating to cell tropism in different compartments of the body, as it is the case for compartmentalized viruses isolated in the cerebrospinal fluid (CSF). This could impact the sensitivity to bNAbs. We analyzed the sensitivity to bNAbs of variants isolated from paired CSF and blood samples.
Methods: Paired contemporaneous CSF and blood plasma samples of 6 subjects with HIV-associated neurocognitive disorder infected by HIV-1 strains of 5 different clades were analyzed by single genome sequencing. Pseudotyped viruses expressing envelope glycoproteins representative of the quasi-species present in each compartment were generated. Their sensitivity to neutralization was measured using a TZM-bl assay and bNAbs targeting the N160-V1V2 site (PG16, PGT145), the N332-V3 site (PGT121), the CD4-binding site (VRC03), the membrane-proximal external region (MPER) of gp41 (10E8) and a conformational epitope overlapping both envelope subunits (8ANC195). Sensitivity to sCD4 was assessed as well.
Results: Phylogenetic analyses revealed significant compartmentalization of HIV populations between blood and CSF in 4 out of 6 patients. In 5 patients, we observed major differences of sensitivity to at least one bNAb targeting the N160-V1V2 site, the N332-V3 site or the CD4bs, between blood and CSF variants, even for patients without compartmentalization. The last patient was highly resistant to all bNAbs but a 22-fold resistance to sCD4 of CSF variants was observed. Three patients had CSF variants with enhanced resistance to either PGT121 and PG16 (9 and 43 fold, respectively), PGT145 and VRC03 (15 and 16 fold, respectively), or PGT145 alone (7 fold) compared to blood variants. Sensitivity to 10E8 was similar in both compartments for all patients.
Conclusions: Our data show the presence of bNAbs-resistant viruses in patients naive from bNAbs. Considering the low blood-brain barrier penetration of IgGs and the possible migration of HIV-1 from CSF to blood, these results should warn us on the potential role of CNS as a reservoir for selection of bNAbs resistant viruses.

WEPEA0227

Knockdown of CCR5 expression in antigen-specific CD4 T cells

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Background: Approximately half of memory CD4 T cells are CCR5+ and therefore susceptible to HIV-1 infection. Gene therapy presents an opportunity to modify CCR5 expression. We aimed to investigate use of short-hairpin (sh) RNA to knock-down CCR5 in recall antigen (Ag)-specific CD4 T cells in vitro.
Methods: 30 to 40 million PBMC from healthy HIV-uninfected adults were incubated for 48 hr with recall antigens, CMV lysate or tetanus toxoid, respectively. Non-Treg Ag-specific CD4 T cells were identified and cell sorted using up-regulation of CD25 and CD134 (OX40) and lack of CD39. Purified Ag-specific CD4 T cells were transduced with a lentiviral vector containing shRNA specific for CCR5 under the control of the H1 promoter, and GFP under control of ubiquitin C promoter, in the presence of IL-2 for 3 days. After 3 weeks incubation in IL-2 containing medium in the presence of feeder cells, GFP+ cells were cell sorted and further expanded. Expanded GFP+ cells were analysed by fluorescence microscopy and flow cytometry.
Results: From 10,000 to 30,000 CD25+CD134+CD39neg recall Ag-specific CD4+ T cells were isolated by cell sorting. Approximately 3-10% of purified Ag-specific cells were transduced with GFP, by fluorescence microscopy, compared with 50% transduction of positive control SEB-stimulated PBMC. Autologous monocyte-derived dendritic cells (Mo-DC) were used as feeder cells during expansion, and 4-6 weeks was required to obtain ≥ 2 million GFP+ Ag-specific CD4+ T cells. Using optimized sensitive flow cytometric detection, GFP+ CD4+ T cells were CCR5-negative, and had a Granzyme B+ cytotoxic phenotype.
Conclusions: Using the OX40 assay, Ag-specific CD4+ T cells can be isolated for genetic modification of CCR5 expression via stable transduction with lentiviral shRNA. Cell therapy with in vitro expanded Ag-specific T cells has proved beneficial in the clinical setting of opportunistic infections during lymphopenia following hemopoietic stem cell transplant. Our results suggest that CCR5-negative Ag-specific CD4+ T cells may also be produced in vitro for possible augmentation of immunity in HIV+ subjects.

WEPEA0228

Structures within the coreceptor binding site account for the broad neutralizing activity of single chain variable fragments (scFv) targeting CD4-induced epitopes

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Background: A CD4-induced (CD4i) epitope, which overlaps with the coreceptor binding site, is highly conserved, and is a favorable target for neutralizing monoclonal antibodies (nMAbs). However, the CD4i epitope is hidden inside trimeric Env, before CD4 binds gp120. Moreover, the close physical proximity of gp120 and the cellular membrane blocks the access of anti-CD4i Abs to this CD4i epitope after the CD4-gp120 interaction. In order to overcome this problem, single-chain variable fragments (scFv) of anti-CD4i nMAbs were tested for neutralization to multi-clade HIV-1 strains.
Methods: Single-chain variable fragments (scFv) from three anti-CD4i nMAbs, 16B2, 4E9C and 25C4b, were produced in E. coli, and their neutralization activities were compared with their counterparts. The binding properties of anti-CD4i nMAbs were determined by ELISA using $gp120_{BaL}$ mutants.
Results: The full length IgGs corresponding to the scFvs in this study were unable to neutralize Clade B HIV-1. In contrast, the anti-CD4i scFvs neutralized the tier 2 and tier 3 viruses of clade B. Futhermore, the neutralizing activities of scFvs were significantly higher than those of the corresponding Fabs. Moreover, neutralization assays using 66 pseudoviruses belonging to 7 subtypes revealed broad neutralization coverage by scFvs, 16B2 (100 %), 4E9C (83 %), 25C4b (92 %). Post-attachment neutralization assay, which regulated a fusion process by temperature, showed that the scFvs neutralized viruses resistant to the corresponding IgGs after the virus-cell attachment. Binding profiles of 25C4b against the series of gp120 mutants were comparable to 17b which interacts with the hairpin 1 (H1), hairpin 2 (H1) and requires the V3-base.
On the other hand, binding of 4E9C was found to be dependent of V3-base region. Finally, 16B2 was found to recognize a CD4-bound structure composed of H1 and H2.
Conclusions: Anti-CD4i scFvs can effectively neutralize multi-clade HIV-1 strains after the CD4-gp120 interaction. The gp120 structure induced by CD4-binding targeted by the neutralizing scFvs is associated with conserved regions including hairpins H1 and H2.

WEPEA0229

Jak inhibitors employ novel mechanisms to block reservoir seeding and HIV persistence

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Background: Ruxolitinib is a Jak 1/2 inhibitor (JAKI) that is FDA-approved for myelofibrosis and polythema vera. We evaluated the ability of JAKI to block events preventing eradication, including
1) HIV replication,
2) bystander infection/activation,
3) markers of homeostatic proliferation and reservoir lifespan,
4) reservoir size, and
5) reservoir expansion.
Methods: #CD4 T-cells from HIV^+ donors were cultured for 6 days with JAKI+IL-15 or AZT+EFV+RAL prior to Alu-PCR. pSTAT5, HLADR/CD38, and PD1 were quantified on T cells from HIV^+ individuals ex vivo. MΦ were infected with $HIV\text{-}1_{BaL}$ for 28 days; PMA-induced reactivation +/- JAKI was quantified after 24 hr (p24 ELISA). CFSE-stained CD4 T-cells were infected with LAI +/- JAKI for 3-6 days prior to quantification of non-dividing $p24^+$ cells, bcl-2 and activation markers. pSTATs were measured in CD4 T-cells + IL-2, 6, 7, 10, 15 or IFN-a +/- JAKI. MΦ were infected with $HIV\text{-}1_{BaL}$ for 6 days +/- JAKI prior to quantification of HLADR/CD163.
Results: In vivo (HIV^+ individuals), increased pSTAT5, HLADR/CD38 and PD1 expression correlated with increased integrated HIV DNA ($p< 0.001$). JAKI demonstrated nanomolar inhibition of viral replication in vitro and ex vivo in CD4 T-cells ($EC_{50/90}$ 0.007/0.01μM). JAKI blocked
1) IL-2, IL-7, IL-15 induction of reservoir lifespan marker Bcl-2 in T_{cm}, T_{tm}, T_{em} ($EC_{50/90}$ 0.01/0.3μM),
2) HIV-induced upregulation of CCR5 (CD4 T-cells; $EC_{50/90}$ 0.06/0.2μM) and HLADR/CD163 (MΦ) ($EC_{50/90}$ 0.006/0.2μM),
3) IL-15 or PMA (MΦ) induced reactivation (EC_{5090} 0.006/0.2μM),
4) bystander cell proliferation and infection (CD4 T-cells; $EC_{50/90}$ 0.01/0.2μM),
5) frequency of CD4 T-cells harboring integrated HIV DNA, and non-dividing $p24^+$ CD4 T-cells $EC_{50/90}$ 0.009/0.1μM).
Conclusions: Activation of the Jak-STAT pathway correlates with markers of viral persistence in HIV^+ individuals, including size of the viral reservoir, underscoring therapeutic relevance for blockade of this pathway as a tool to mitigate these events. JAKI significantly reduce markers of viral persistence, including viral replication, HIV-induced activation, inflammation, and reservoir size, maintenance and expansion in vitro and ex vivo in T cells and MΦ. These data suggest that JAKI can act as an immune checkpoint blocker, which may allow for eventual withdrawal of antiretroviral agents in stably controlled infected individuals without viral rebound, which could result in a functional cure.

WEPEA0230

CTL-based vaccine-induced control is associated with induction of high follicular to extra-follicular ratios of virus-specific $CD8^+$ T cells

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Background: There is an urgent need to develop an effective HIV vaccine. We previously showed that during chronic HIV-1 and SIV infections, HIV and SIV replication is concentrated within B cell follicles, whereas HIV and SIV-specific $CD8^+$ T

cells are largely excluded from these sites suggesting that the inability of HIV and SIV-specific CD8+ T cells to fully suppress virus replication may be due to their deficiency in B cell follicles. We hypothesize that a successful HIV vaccine will either prevent HIV seeding B cell follicles or induce high levels of virus-specific CD8+ T cells in B cell follicles.
Methods: Here we investigated whether control associated with three CTL inducing SIV vaccines was associated with levels of SIV-specific CD8+ T cells in follicular (F) and extrafollicular (EF) compartments in lymph nodes of vaccinated animals after challenge with pathogenic SIV relative to a cohort of non-vaccinated chronically infected animals using in situ tetramer staining with MHC Class I tetramers combined with immunohistochemistry. Control was defined a set point plasma viral load of ≤10^4.
Results: We found lower levels of tetramer+ SIV-specific CD8+ T cells in F compared to EF areas of non-controller animals (P<0.0001), but not in controller animals (P=0.13). Although similar levels of tetramer+ SIV-specific CD8+ T cells were detected in F and EF areas between the controller and non-controller animals (P=0.62) and (p=0.51) respectively, the controller animals had significantly higher F: EF ratios of tetramer+ SIV-specific CD8+ T cells (P=0.028). Also, there was a significant inverse correlation between F: EF ratio of tetramer+ SIV-specific CD8+ T cells and plasma VL in the controller (r=-0.75, P=0.0046) but not in non-controller animals (r=0.01, P=0.97).
Conclusions: These results support developing CTL-based HIV vaccines that augment relative levels of virus-specific CTL within B cell follicles.

WEPEA0231

Deciphering the first steps of the local immune response after intradermal vaccination with recombinant MVA

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Background: Live attenuated vectors, such as modified vaccinia virus Ankara (MVA), are considered as powerful cell-based vaccines. In order to better understand the early immune response, which may be crucial for vaccine efficacy, we deciphered dynamics of infection and kinetics of inflammation induced from 0h to 72h after intradermal administration of a MVA based vaccine in a non-human primate (NHP) model.
Methods: NHPs were injected intradermaly with recombinant MVA expressing either eGFP or HIV Gag-Pol-Nef. Blood, skin and draining lymph node samples were collected during 72h following the injection. Inspired by system vaccinology approach, we used a wide set of techniques involving histology, ex vivo and in vivo imaging, flow cytometry, Luminex and transcriptomic assay covering macroscopic to molecular immune events. Using this rich and heterogenic dataset, we then designed a coexpression network, based on significant correlations over the time between studied effectors, dedicated to identify major effectors of this immune response.
Results: MVA was able to infect a wide set of skin cells from 14h to 72h post intradermal injection. The vaccine also induced a strong local inflammatory response. Indeed, we highlighted an important granulocytes and macrophages recruitment associated with pro-inflammatory cytokines releasing such as GM-CSF, IL6, IL1β, MIP1α, MIP1β or TNFα between 24h and 48h post-injection, with an increased diversity at 72h (IL2, TGFα, IL15 but also G-CSF). MVA injection also impacted on the systemic responses, with an early increase of $CD66^{high}$ granulocytes and $CD14^+CD16^+$ monocytes associated with IL6 and IL1ra releasing. Draining lymph node activation was rather characterized by cytokine production than cell subset dynamics. Finally, the coexpression network highlighted a hub of correlation between local and lymph node cytokine productions.
Conclusions: Altogether, this study provided insights to better understand the innate immune response process triggered by MVA, characterizing the innate response in the deep details. The use of an innovative integrative approach showed the complexity and the multiplicity of this response and highlighted several key innate effectors, such as TNFα, TGFα and cells expressing a $CD14^+$MDSCs phenotype, susceptible to lead the first steps of the adaptive response in the draining lymph node.

WEPEA0232

Innate myeloid responses are highly diverse and strongly differ after the priming and the boosting immunizations

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Background: Better understanding the innate immune response to vaccines is required to comprehend and orientate the consecutive adaptive immune response toward a stronger, more efficient protection against pathogens. A better characterization of innate cells populations and a deeper understanding of how vaccination impact them is then highly valuable to rationally optimize future HIV vaccines.
Methods: Here, as animal and vaccine model we used cynomolgus macaques immunized with the recombinant MVA HIV-B vaccine, which is currently tested in phase I/II clinical trial by the VRI. 5 animals were immunized with a homologous prime-boost at two months apart, and blood samples were collected longitudinally at 15 timepoints. We took advantage of mass cytometry technology as well as longitudinal blood sampling and focus on the innate myeloid cells using a 32-markers antibody panel to phenotype them in deep and decipher their dynamics post-immunizations.
Results: Our results unveiled a high phenotypic diversity among blood granulocytes, monocytes and dendritic cells populations. Most of these subpopulations were significantly impacted in number by MVA injections and a large part of them behave differently after the first and second injection. Some populations expanded only after the prime while other ones solely expanded after the boost. Strikingly, subpopulations responding mainly to the boosting injection showed a higher expression of maturation markers such as CD11b, CD32 and CCR7. This shows that innate myeloid responses differ between the first and second vaccine encounter while it is often admitted that innate immunity behaves each time similarly. We hypothesize that the primary memory response and more particularly immune complexes and soluble factors produced by memory T cells in response to their cognate antigen, license innate cells to respond differently at the boost.
Conclusions: These results pave the way for further studies to better understand the reciprocal relationships between innate and adaptive immunity.

WEPEA0233

Novel pDNA prime-boost vaccine strategy combining gag and Env elicits broad cytotoxic T cell and antibody responses targeting conserved subdominant gag and Env epitopes of HIV and SIV

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Background: HIV sequence diversity and the propensity of eliciting immunodominant responses targeting variable regions are hurdles in the development of an effective AIDS vaccine. We demonstrated that a vaccine comprising conserved elements (CE) of HIV-1 $p24^{gag}$ as prime followed by a combination of CE+gag pDNA as boost elicits broad, potent and durable T cell responses targeting these conserved regions, efficiently overcoming the dominance imposed by the Gag variable regions. This vaccine concept is currently developed for a clinical trial HVTN 119. To improve the vaccine efficacy and combine the benefit of cellular and humoral responses, we developed pDNA immunogens encoding conserved elements within SIV gag and the HIV-1 Env protein and evaluated the immunogenicity in macaques.
Methods: DNA plasmids were constructed encoding 7 conserved segments of Gag (p27CE) or encoding 12 conserved segments from HIV-1 Env (Env-CE). Macaques were immunized by IM injection followed by vivo electroporation with p27CE+Env-CE pDNA or with p27CE+gp145 env pDNA. Cellular responses were measured by multi-color flow cytometry, and vaccine-induced antibody responses were measured.
Results: Cellular responses towards SIV Gag CE were severely reduced upon vaccination with a combination of p27CE+gp145 env pDNA, indicating that sequences within Env exert an immunodominant interference with the conserved Gag epitopes. In contrast, macaques immunized with p27CE+Env-CE developed high and

broad cellular responses targeting both Gag and Env CE. Both, Gag and Env CE pDNAs induced antibody responses in immunized animals and these antibodies cross-reacted with the WT molecules. These data demonstrate that a vaccine combining Gag+Env CE pDNA profoundly alters the immunodominance exerted by the variable regions of both Gag and Env, and provides a balanced immune response.
Conclusions: HIV/SIV vaccine regimens comprising CE pDNA prime and CE+gag/env pDNA boost redirects cellular responses to subdominant and more vulnerable viral targets, and augment cytotoxic T cell responses to highly conserved epitopes in the viral proteome maximizing response breadth. The balanced immunity, both cellular and humoral responses, induced by this vaccine regimen makes this an interesting candidate for the prevention of HIV-infection and therapy.

WEPEA0234

Effective priming of CD8+ T cells with ability to suppress HIV-1 replication using STING ligand

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Background: Effective priming of functional HIV-1-specific CD8+ T cells from naïve T cells is crucial for AIDS vaccines and immunotherapy. However, the study of HIV-1-specific CD8+ T cell priming is limited by the lack of established in vitro approaches. Here we sought to establish an in vitro priming method in order to induce functional HIV-1-specific CD8+T cells from naïve T cells.
Methods: CD8+ T cells specific for the HLA-A24:02-restricted immunodominant CTL epitope Nef RF10 were primed from HLA-A*24:02+ HIV-1-seronegative donor-derived PBMCs in the presence of TLR4 ligand (LPS) or STING ligand (3'3'cGAMP) combined with Flt3 ligand. We used specific tetramers to evaluate the induction of RF10-specific CD8+ T cells upon day 11 of priming and established RF10-specific CD8+ T cell lines to investigate various functional properties of primed
T cells.
Results: Consistent priming of RF10-specific CD8+ T cells from naïve T cells was obtained with LPS or 3'3'cGAMP although no significant difference was observed between the two. All primed T cells had ability to produce IFN-g, IL-2, TNF-a, and MIP-1b in response to RF10 peptide. However, LPS primed T cells expressed low level of granzyme B and perforin, and failed to suppress HIV-1 replication. Some of these cells showed also low TCR avidity. In contrast, 3'3'cGAMP primed T cells exhibited higher expression of granzyme B and perforin and carried higher avidity TCRs than LPS primed ones, and a strong ability to suppress HIV-1 replication.
Conclusions: The present study demonstrates that functional HIV-specific CD8+ T cells having ability to suppress HIV-1 can be induced from naïve T cells primed with 3'3'cGAMP, indicating that STING ligand may be a useful adjuvant for the design of AIDS vaccine and therapy.

WEPEA0235

Use of encapsulated NOD2 ligands for increasing germinal centers and enhancing HIV humoral responses

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Background: Recognition of Pathogen-associated molecular patterns (PAMPS), through specific TLR (Toll Like receptors) or NLR (NOD-Like receptor) and identification of synthetic ligands, has opened a new area in adjuvant research. As such molecules could be encapsulated in biodegradable nanoparticles (NP), we could co-deliver to the same Antigen Presenting Cell (APC), either Env Trimer or gag HIV and immune stimulatory molecules.
Methods: Both p24 and BG505 adsorption on NP was optimized, caracterized and modelized. Then SKH-1 and CB6F1 mice have been immunized in order to analyze:
(i) nanoparticles biodistribution by tomography,
(ii) germinal center (GC) responses in the draining lymph node by confocal microscopy,
(iii) immune responses in blood sample by ELISA.
Results: We are able to adsorbed 50 BG505 per NPs and we show that BG505 is adsorbed into NPs through gp41 moities and gp120 epitopes are exposed as in native virion. Using fluorescent nanoparticles, we demonstrate by in vivo tomography that NPs allow a depot effect at the injection site during several weeks, compare to 7 days without nanoparticles. Furthermore, formulation with NPs increases the number of GC in draining lymph nodes. These GC response correlated with an enhancement of humoral responses highlighting the role for adjuvants in programming the durability of HIV vaccine response.
Conclusions: Our results indicate that PRR ligands delivered in biodegradable NPs coupled with BG505 or p24 offer a novel approach to engineer robust and durable humoral affinity with implications for HIV-1 vaccine developpement in humans.

WEPEA0236

Delivery of antigen to nasal-associated lymphoid tissue microfold cells through secretory IgA targeting local dendritic cells confers protective immunity

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Background: Transmission of mucosal pathogens relies on their ability to bind to the surfaces of epithelial cells, to cross this thin barrier, and to gain access to target cells and tissues, leading to systemic infection. This implies that pathogen-specific immunity at mucosal sites is critical for the control of infectious agents using these routes to enter the body. Although mucosal delivery would ensure the best onset of protective immunity, most of the candidate vaccines are administered through the parenteral route.
Methods: The present study evaluates the feasibility of delivering the chemically bound p24gag HIV antigen through secretory IgA (SIgA) in nasal mucosae in mice.
Results: We show that SIgA interacts specifically with mucosal microfold cells present in the nasal-associated lymphoid tissue. p24-SIgA complexes are quickly taken up in the nasal cavity and selectively engulfed by mucosal dendritic cell-specific intercellular adhesion molecule 3-grabbing nonintegrin- positive dendritic cells. Nasal immunization with p24-SIgA elicits both a strong humoral and cellular immune response against p24 at the systemic and mucosal levels. This ensures effective protection against intranasal challenge with recombinant vaccinia virus encoding p24.
Conclusions: This study represents the first example that underscores the remarkable potential of SIgA to serve as a carrier for a protein antigen in a mucosal vaccine approach targeting the nasal environment.

WEPEA0237

HIV-1 conserved mosaics delivered by regimens with integration-deficient, DC-targeting lentiviral vector induce robust T cells

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Background: To be effective against HIV-1, vaccine-induced T cells must selectively target epitopes, which are functionally conserved (present in the majority of currently circulating and reactivated HIV-1 strains) and, at the same time, beneficial (responses to which are associated with better clinical status and control of HIV-1 replication), and rapidly reach protective frequencies upon exposure to the virus. Heterologous prime-boost regimens using virally vectored vaccines are currently the most promising vaccine strategies, nevertheless, induction of robust long-term memory remains challenging. To this end, lentiviral vectors induce high frequencies of memory cells due to their low-inflammatory nature, while typically inducing only low anti-vector immune responses.
Methods: We constructed novel vaccines vectored by DC-targeted, integration-deficient lentiviral vector platform ZVex® delivering conserved regions of HIV proteins designed as bivalent mosaics with a high global HIV-1 match. We characterized the vaccine-induced T cells in mice using the IFN-γ ELIPOT assay and polychromatic flowcytometry.
Results: The novel candidate vaccines ZVex.tHIVconsv1 and ZVex.tHIVconsv2 were individually immunogenic. When administered together in heterologous prime-boost regimens with chimpanzee adenovirus ChAdOx1 and/or poxvirus MVA vaccines to BALB/c and outbred CD1-Swiss mice, they induced median frequency of over 6,000 T cells/10^6 splenocytes, which were plurifunctional, broadly specific and recognized epitope variants beyond those present in the tHIVconsvX immunogens.

Conclusions: These data support further development of a conserved mosaic HIV-1 immunogen-based strategies, utilizing heterologous prime-boost approaches of the ZVex®, MVA and/or ChAdOx1 platforms. For the tHIVconsvX as well as other immunogens, we envisage a panel of vectors delivering the same transgene, which will allow a personalized delivery avoiding known pre-existing anti-vector immunity, multiple heterologous boosts for low responders, a maintenance of protective levels of immunity over a prolonged period of time and more flexibility for combining future effective T and antibody vaccines into one regimen for the best HIV-1 control.

WEPEA0238

Langerhans cells targeted with anti-Langerin monoclonal antibodies fused with HIV antigens promote the differentiation of naïve CD4+ T cells towards Tfh cells

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Background: A rationale approach for vaccine design is to target HIV antigen to specific receptor of dendritic cells (DCs) via fused monoclonal antibodies (mAb) with the intention to favor antigen presentation and activation of HIV-specific T- and B-cell responses. In animal models (Epaulard O. et al JI 2014), targeting of Langerhans cells (LCs) residing in the skin with anti-Langerin mAbs fused with HIV antigens (aLC/HIV) drives antigen-specific humoral responses.
The development of these immunization strategies in humans requires a better understanding of early immune events driven by targeted LCs. The present study investigates the effects of aLC/HIV-Env on the differentiation of naïve CD4+ T-cells.
Methods: Anti-human Langerin recombinant human (Hu) IgG4 antibody fused with HIV-Env antigen at the C-terminus of the H-chain were produced in CHO cells. Purified cord blood CD34+ progenitor cells were differentiated into LCs (Caux C. et al. Blood 1997), briefly incubated with aLC/HIV-Env, and co-cultured with autologous purified naïve CD4+ T-cells. The phenotype of differentiated T-cells was assessed by flow cytometry.
Results: We first show that aLC/HIV candidate vaccine specifically target LCs ($CD1a^{high}$/$CD207^{+}$) as demonstrated by flow cytometry and immunohistostaining on vaginal or skin explants. aLC/HIV mAbs are endocytosed by targeted LCs. We confirm that in vitro CD34-derived LCs exhibit a phenotype similar to ex vivo isolated LCs from human skin. After being treated with aLC/HIV-Env, CD34-derived LCs induce the differentiation of co-cultured autologous naïve CD4+ T-cells towards Tfh-like cells ($CD45RA^{-}$ $CXCR5^{+}$ $PD1^{+}$ $Bcl6^{+}$ $ICOS^{+}$) significantly as compared to culture conditions with control HuFc-IgG4 or aCD40 HIV fusion antibodies. Strikingly, in the same culture conditions, monocyte-derived DCs and BDCA1+ primary DCs does not promote this differentiation of naïve CD4+ T cells.
Conclusions: These results revealed that LCs activated through CD207 promote the differentiation of naïve CD4+ T-cells towards Tfh cells. We are deciphering functional (cytokines/chemokines, co-stimulatory molecules) and gene expression profile of vaccine targeted LC and differentiated Tfh cells. These data support the development of novel DC targeting vaccine approaches.

Comorbidities

WEPEB0476

Concurrent validity of four screening tests for HIV-associated neurocognitive disorders (HAND): sensitivity, specificity, and classification accuracy

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Background: Effective cognitive screening instruments are needed to differentially assess and manage milder forms of HIV-associated neurocognitive disorders (HAND). We assessed concurrent validity of four screening tests against the gold standard for HAND diagnosis in people living with HIV.
Methods: 220 adults (mean age: 51 years; mean education: 14 years; 86% men) attending one HIV outpatient clinic in Toronto were included in our analyses. Four neurocognitive screening tests: Cogstate Brief Battery (CBB), HIV Dementia Scale (HDS), Computer Assessment of Memory and Cognitive Impairment (CAMCI), and Montreal Cognitive Assessment (MoCA) were administered. Impairment was defined as raw score of >10 (HDS), ≥30 percentile (CAMCI), a score of >26 (MoCA), and impairment in two or more domains (CBB). Participants completed comprehensive neuropsychological battery assessing processing speed, attention/working memory, learning/memory, and executive functions. Clinical HAND diagnosis was made according to Antinori (2007) criteria independent of screening test scores. Validity of tests was assessed using sensitivity, specificity, and area under the curve (AUC) estimates against the gold standard.
Results: 129 participants (59%) had a clinical diagnosis of HAND (ANI=20; MND=94; HAD=15). Sensitivity estimates were: 72% (MoCA), 61% (CBB), 42% (HDS), and 31% (CAMCI). Specificity estimates were: 98% (CAMCI), 95% (HDS), 82% (CBB), and 73% (MoCA). AUC estimates were 0.723 (MocA), 0.714 (CBB), 0.682 (HDS), and 0.644 (CAMCI). Combining of any two screening tests (test positive by either one or both tests) resulted in modest classification accuracy improvements (AUC ranges: 0.736-0.758). All four screening tests were better at detecting symptomatic HAND (10%-32% higher AUC) compared to non-symptomatic HAND.
Conclusions: Our results suggest that the MoCA and CBB screening tests have only modest global classification accuracy for assessing mild HAND in people with HIV. Work is underway in our laboratory to determine the clinical utility and generalizability of newer instruments which may have better diagnostic accuracy.

WEPEB0477

The impact of age and time of disease on HIV-associated neurocognitive disorder: a Japanese nationwide multicenter study

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Background: The impact of age and time of disease on HIV-associated neurocognitive disorders (HAND) are still controversial due to multiple variation factors such as language or educational differences. Japanese are suitable population for exploration of the factors and neurocognitive characteristics because they have relatively uniform background.
Methods: We conducted a multicenter, prospective and cross-sectional study of 17 facilities with strict random recruitment manner. The eligible participants completed 14 neuropsychological tests for eight domains. The Frascati criteria were used for diagnosis of HAND.

Results: Of 1399 randomly recruited HIV-infected patients, 729 were eligible and 406 were declined due to the exclusion criteria. Prevalence of HAND was 26.1% [13.7% asymptomatic neurocognitive impairment, 11.0% mild neurocognitive disorder (MND), and 1.4% HIV-associated dementia (HAD)]. Trail Making Test B and Rey-Osterreith Complex Figure Test presented the better diagnostic accuracy for HAND (78.9% and 77.3% by receiver operating curve, respectively).
In multivariate analysis, older than 50 years (OR 2.119, 95% confidence interval (CI) 1.289-3.752), lower education level (OR 1.679, 95% CI 1.006-2.802) and incomplete viral suppression (OR 1.969, 95% CI 1.015-3.819) were risk factors, whereas current ART (OR 0.067, 95% CI 0.025-0.180) and currently employed (OR 0.534, 95% CI 0.311-0.918) were improvement factors.
The prevalence of HAD or MND decreased along the time since diagnosis in the early stage (from 11% in < 2 years to 7% in 2-5 years, p=0.022), then re-increased in the later stage [to 17% in 6-10 years and 21% in >10 years, p=0.020 and 0.009 (vs. 2-5 years), respectively]. Older patients have more often HAD or MND than younger ones in the early stage (27 vs. 9% in <2 years and 20 vs. 4% in 2-5 years, p=0.027 and p<0.001, respectively), while there was no significant difference between them in the later stage (17 vs. 11% in 6-10 years and 23 vs. 13% in >10 years, p=0.441 and p=0.332, respectively).
Conclusions: Executive and visuospatial function are susceptible cognitive domains in HIV-infected Japanese. The prevalence of HAND in Japanese presented biphasic pattern along the time since diagnosis. Older patients are more likely to have neurocognitive decline at early stages of HIV infection.

WEPEB0478

Baseline Framingham risk predicts HAND after two years in HIV+ Ugandan cohort

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Background: Cardiovascular risk factors are hypothesized to be important risk factors for the development of HIV-associated neurocognitive disorder (HAND) in the antiretroviral therapy (ART) era. However, the role of these factors in the development of HAND in Sub-Saharan Africa, where rates of hypertension, hyperlipidemia, and diabetes are much lower than in Western populations, is unknown. We hypothesized that Framingham risk scores would predict HAND in HIV+ adults in rural Uganda.
Methods: 254 HIV+ adults from Rakai District, Uganda, enrolled in a longitudinal cohort of neurological complications of HIV, and were evaluated at baseline and after 2 years of follow-up. All were ART-naïve at baseline, and 92% were on ART at follow-up. Participants underwent sociodemographic interviews, neurological and medical evaluations, and a neurocognitive test battery at each visit. HAND stage was determined using Frascati criteria and normative data derived from 400 HIV- adults in Rakai. ANOVA and logistic regression were used to assess relationships to Framingham scores and HAND.
Results: Participants were 50% male, with mean(SD) age=36(9) and mean(SD) education=5(3) years. 72 participants (28%) had CD4 counts <200 at baseline. Baseline Framingham risk score and HAND were not related (p=0.50). Framingham risk score at the follow-up visit did not vary by HAND stage at follow-up (p=0.06) (Table 1). However, higher baseline higher Framingham risk score was associated with HAND stage at the two-year follow-up visit (p=0.004). Participants with a baseline Framingham baseline risk score of ≥5 had higher odds of symptomatic HAND at their two-year follow-up visit (OR=3.2, p=0.01).

	Baseline Framingham Score [mean (SD)]	p value	Follow-up Framingham Score [mean (SD)]	p value
HAND stage at follow-up				
Normal cognition (n=219)	2.7(2.6)	0.004	2.9(2.8)	0.06
Asymptomatic neurocognitive impairment (ANI) (n=7)	2.3(2.3)		2.6(1.9)	
Minor neurocognitive disorder (MND) (N=24)	5.7(10.0)		5.0(8.1)	
HIV-associated dementia (HAD) (n=4)	4.8(4.1)		3.7(2.9)	

[Table 1]

Conclusions: Cardiovascular risk factors as approximated by the Framingham risk score were associated with subsequent risk of more severe neurocognitive impairment in HIV+ rural Ugandans. This suggests cardiovascular risk factors are important in the development of HAND in patients on ART, even in populations with low levels of traditional risk factors.

WEPEB0479

Neurocognitive decline in people living with HIV in India and correlation with 3T magnetic resonance spectroscopy: a case-control study

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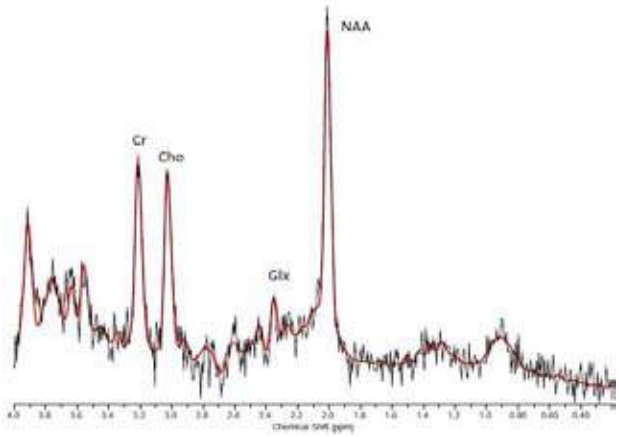
Background: Neurocognitive decline in asymptomatic HIV patients and its correlation with metabolic changes in brain has not been studied in developing countries like India. In the present study we aim to examine the correlation between cognitive decline and changes in brain metabolites using MRS.
Methods: ART naïve HIV-positive patients, in the age group 20-50 years attending ART center of the hospital from July to December 2016 were included in the study. All patients underwent evaluation using MRS of left frontal white matter (FWM) and left basal ganglia (BG). Levels of N-acetyl aspartate (tNAA), choline (tCho), creatine (tCr), lipids and macromolecules at 0.9ppm (Lip09+MM09) were measured. Cognition was tested using a battery validated for Indian population. Locally normalized z-scores were used to calculate brain dysfunction score. Spearman correlation coefficient was used to assess the correlation between two continuous variables. There were 28 (29% female and 71% male) cases and 30 (37% female and 63% male) controls
Results: The mean age was comparable in the 2 groups (33 and 34 years). There was a significant difference (p< 0.05) in the concentration (mmol/kg) of tNAA (9.29±311 vs 7.45±0.64), tCho (2.08±0.70 vs 1.74±0.25), tCr (6.95±2.56 vs 5.43±0.61), in the FWM and Lip09 + MM09 (5.87±1.05 vs 4.80±0.35) in BG, with higher levels in controls. There was no significant correlation between CD4 count and metabolites or overall dysfunction score and metabolites except Cr in FWM with more dysfunction associated with lower concentration. Fig 1 shows MR spectrum acquired from FWM of a patient



[Figure 1]

Conclusions: The results show that HIV-associated changes are present in asymptomatic people which may be contributing to the early neurocognitive decline. Knowledge of metabolic changes within studied brain regions can help understand the pathology and design interventions to cater to this unmet need in people living with HIV.

WEPEB0480

Assessing depression's impact on neurocognitive performance in the Metabolic and Ageing Cohort of the Swiss HIV Cohort Study

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Background: In the era of potent antiretroviral therapy with suppressed blood HIV replication, HIV-associated neurocognitive disorder (HAND) remains a concern. This study aims to analyze the link between the presence of depressive symptoms and HAND in the Metabolic and Ageing Cohort of the Swiss HIV Cohort Study (SHCS).
Methods: The Neurocognitive Assessment in the Metabolic and Ageing Cohort (NAMACO) of the SHCS is an ongoing observational cohort study, which recruited 981 HIV-infected SHCS participants aged 45 years old or more from seven Swiss hospital centers between Jan 2013 and Nov 2016. All participants underwent a comprehensive neurocognitive examination by neuropsychologists and were classified into different categories of neurocognitive impairment based on the revised American Academy of Neurology diagnostic criteria for HAND. Depressive symptoms were assessed with the Center for Epidemiologic Studies Depression (CESD) scale. Demographic and HIV-infection associated characteristics as well as comorbid conditions were extracted from the SHCS database. A cross-sectional multivariate analysis was performed on baseline data using regression models controlling for demographics, after exclusion of individuals with known neurological conditions increasing the risk of cognitive impairment.
Results: 314/878 patients (35.8%) had HAND, including 279/878 (31.8%), 19/878 (2.2%) and 16/878 (1.8%) with asymptomatic neurocognitive impairment, mild neurocognitive impairment and HIV-associated dementia, respectively. The median CESD score was 9 (IQR 4-16). According to a 16/60 reference cut-off, 248/875 patients (28%) suffered from depression. The CESD scale was associated with HAND in the univariate analysis (OR 1.05 [95% CI 1.04-1.06], P <0.001) and in multivariate analysis (OR 1.05 [95% CI 1.03-1.07], P <0.001) adjusting for sex and age (female sex OR 2.33 [95% CI 1.63-3.35], P <0.001, age OR 1.05 [95% CI 1.03- 1.07], P <0.001). Female sex was also significantly related to the CESD scale (P = 0.0003, Wilcoxon rank-sum test).
Conclusions: Depression is an important confounding factor when assessing neurocognitive performance in HIV-infected individuals, even with moderate depressive symptoms. In our study, female sex was a major risk factor for both depression and HAND. Better addressing depressive symptoms, especially in HIV-infected women, might potentially improve the neurocognitive outcome of HIV-infected patients.

WEPEB0481

Prevalence over time and predictive factors of HIV-associated neurocognitive disorder (HAND) in HIV-positive patients

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Background: Despite benefits on morbidity and mortality due to combined antiretroviral therapy (cART), HAND remains common in HIV individuals, with a variable prevalence in different cohorts. Aim of our study was to evaluate prevalence and predictive factors of HAND in more recent years.
Methods: Single-centre, retrospective, cross-sectional analysis of neurocognitive profile in HIV-infected ART-treated patients. All underwent neuropsychological assessment (NPA) by standardized battery of 14 tests on 5 different domains. Persons were classified as having HAND according to Frascati's criteria. Chi-square for trend and multivariable logistic regression were fitted.
Results: A total of 1,289 NPA over 771 HIV-infected individuals were collected from 2009 to 2016. Main characteristics: male 80.2%; MSMs 48.6%; HCVAb+ 18.6%; HIV-RNA < 40 cp/mL at NPA 84.9%; median of 8.6years (3.9-17.6) of infection and 13years (8-15) of education; median of 233 cell/mm^3 CD4+ nadir and 587 (419-772) cell/mm^3 current CD4+. At NPA, 50.7% of pts were receiving NRTI+NNRTI, 28.3% NRTI+PI/r and 3.8% NRTI+INSTI. In 461/1,289 (35.8%) tests a cognitive complaint in deficit of memory, attention or concentration was reported. HAND prevalence was 45.5% in complaining (ANI=24%; MND=18%; HAD=3%) and 14% in non-complaining patients (ANI=11%; MND=3%; HAD=0). Prevalence over time of HAND was stable in complaining (p at chi square for trend=0.134), but decreased in 2013-2016 in non-complaining (p <0.001). Factors associated to HAND by multivariable logistic regression were older age, lower educational level, lower CD4+ count and detectable HIV-RNA at NPA (Table). Patients tested in more recent years show a reduced risk of HAND.
Conclusions: A decreasing prevalence of HAND was observed in more recent years among patients without a cognitive complaint. Better viroimmunological state was correlated to a lower risk of HAND, while worse educational level and older age to a higher one. Besides HIV-related factors, patient characteristics, more than treatment-associated variables, affect risk of neurocognitive impairment.

All study population	N= 1289		
Factors	OR	95% CI	p
Gender (male vs female)	0,85	0,57 – 1,27	0,431
Age (per 10 years increase)	1,18	1,01 – 1,38	0,032
Mode of HIV transmission			
MSM	1,00		
IVDU	0,69	0,40 – 1,17	0,166
Heterosexual	0,78	0,54 – 1,13	0,187
Other/unknown	0,72	0,35 – 1,49	0,374
Years from HIV test			
< 5	1,00		
5-10	0,96	0,63 – 1,44	0,827
> 10	1,21	0,83 – 1,76	0,327
Nadir cd4			
>= 200	1,00		
< 200	1,30	0,95 – 1,78	0,106
HIV-RNA at NPA			
<40 or NR	1,00		
rilevabile	1,70	1,14 – 2,53	0,009
CD4 at NPA			
0-499	1,00		
>= 500	0,52	0,38 – 0,72	0,000
Education (per year more)	0,85	0,81 – 0,88	0,000
HCV co-infection			
neg	1,00		
pos	1,40	0,94 – 2,09	0,101
unknown	1,31	0,67 – 2,55	0,425
Type of current regimen			
NRTI + N NRTI	1,00		
NRTI + PIr	1,47	1,05 – 2,06	0,026
NRTI + INSTI	0,50	0,22 – 1,16	0,106
other	0,75	0,48 – 1,17	0,203
Years of NPA			
2009-2010	1,00		
2011-2012	0,89	0,57 – 1,38	0,597
2013-2014	0,60	0,38 – 0,93	0,024
2015-2016	0,55	0,35 – 0,89	0,014

[Table. Factors predictive of HAND by multivariable logistic regression (p<0.05)]

WEPEB0482

Magnetic resonance imaging of cerebral small vessel disease in HIV-positive and HIV-negative men aged 50 and above

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Background: We assessed whether HIV serostatus was associated with white matter hyperintensities (WMH), a neuroimaging correlate of cerebral small vessel disease, in men aged ≥50 years.
Methods: Virologically-suppressed HIV-positive and demographically matched HIV-negative men aged ≥50 in the multicentre POPPY cohort underwent magnetic resonance imaging (MRI) at 3 Tesla. WMH volume (WMHV) was extracted from volumetric 3D T1 and FLAIR images using automated image processing algorithms and compared between groups (Mann-Whitney test). The association between HIV serostatus and WMHV as a proportion of intracranial volume (ICV; log-transformed) was estimated using a multivariable linear regression model with adjustment for age and associated factors identified in bivariate models (age, waist circumference, high-density lipoprotein concentration).
Results: Forty HIV-positive (median age 59 [interquartile range, IQR 54-64]) and 37 HIV-negative (59 [54-63]) men were included. HIV-positive participants had CD4+ count 570 (470-700) cells/μL and time since diagnosis of 20 (12-24)

years. Clinical characteristics were similar between groups including body mass index 25.4 kg/m^2 (23.4-18.2), waist circumference 91cm (86-100), blood pressure systolic 126 mmHg (116-137) over diastolic 78 mmHg (73-83), total cholesterol 5.0 mmol/L (4.0-5.4) and 10-year risk of cardiovascular disease (Framingham) 6.9% (5.2-9.9). Seventeen (22%) were current smokers and 24 (31%) recently used recreational drugs. Three (7.5%) HIV-positive men reported a history of stroke or transient ischaemic attack (TIA) and five (12.5%) reported ischaemic heart disease (IHD) compared to none of the controls (p=0.24 for stroke/TIA; p=0.06 for IHD). HIV-positive participants had more previous syphilis (47.5% vs. 21.6%; p=0.02) and current hepatitis C (7.5% vs. 0%; p=0.24). There were no differences in WMH between groups (Table). In the multivariable model, WMHV/ICV was not associated with HIV serostatus (p=0.82) but was associated with increasing age (1.7-fold increase in WMHV/ICV per +10 years, 95% confidence interval [CI] 1.1-2.7, p=0.03) and waist circumference (1.3-fold increase in WMHV/ICV per +10 cm, 95% CI 1.0-1.6, p=0.05).

	HIV positive (n=40)	HIV negative (n=37)	p
Median (IQR) WMHV, µL	929 (430-2311)	825 (347-1969)	0.33
Median (IQR) total intracranial volume (ICV), mL	1548 (1458-1601)	1556 (1454-1645)	0.36
Median (IQR) WMHV, % of ICV	0.06 (0.03-0.15)	0.05 (0.02-0.13)	0.31

[White matter hyperintensity volumes (WMHV)]

Conclusions: We found no difference in WMHV between middle aged HIV-positive men and demographically-matched HIV-negative controls.

WEPEB0483

Acceptability and safety of lumbar puncture for research in HIV-positive patients, Rakai, Uganda

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Background: HIV-associated neurocognitive disorders (HAND) are a common neurological sequelae of HIV infection. Collection of cerebrospinal fluid (CSF) by lumbar puncture (LP) is essential for the analysis of CSF biomarkers in research on HAND. However, there are concerns about the acceptability of LPs and post-LP side effects.
Methods: Four hundred antiretroviral therapy naïve HIV-positive patients aged 20-68 years with severe (CD4 ≤ 200; n=200) or moderate (CD4 351-500; n=200) immune suppression participated in a study to assess the neurological sequelae of HIV infection in Rakai, Uganda. Participants were offered the opportunity to have an LP to assess CSF virological compartmentalization and inflammatory markers. Up to 10mls of CSF were collected using the Tro-Spinoject 22 gauge atraumatic spinal needle in consenting participants. Following LP participants received recumbent rest and oral analgesics. We assessed the acceptability and safety of LP by interview and examination. Acceptability of LP was analyzed by key socio-demographic characteristics and baseline CD4 count.
Results: Two hundred seventeen out of 400 (54.3%) research study participants consented to LP.LP acceptance was significantly higher among patients with moderate immune suppression than with severe suppression (65% versus 44%; p< 0.001), but did not differ by age, gender or education. 198 (91.2%) of the LPs were successfully completed. The frequency of any adverse event was 12% and clinically significant adverse events (e.g., transient hypotension) was 0.9%. 11.1% experienced post-lumbar puncture headache, 1.0% backache and 1.0% neck pain. All post-LP effects resolved within a week and none required hospitalization. The risk of post-LP adverse event was unrelated to age, gender, education or immune suppression.
Conclusions: Research using lumbar puncture was acceptable among HIV-positive study participants. Using a 22 gauge spinal needle, the LP procedure can be performed with a very low rate of clinically significant adverse events.

WEPEB0484

Neuronal damage estimated by CSF NFL and association with neurocognition in HIV

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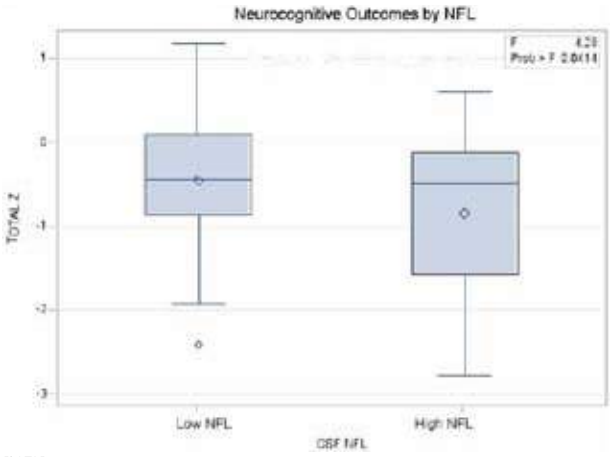
Background: HIV enters the central nervous system (CNS) early and persists in some, resulting in HIV Associated Neurocognitive Disorders (HAND) despite effective antiretroviral treatment (ART). The CNS represents both a compartment and reservoir, and is a barrier to curing HIV. Neurofilament light chain (NFL) is a biomarker reflecting CNS neuronal damage in Cerebrospinal Fluid (CSF), and we assessed the relationship to neurocognitive status in the THINC cohort.
Methods: THINC participants were administered neurocognitive testing (NP) and lumbar puncture (LP) after being on ART for at least one year. The NP battery assessed a number of domains, with summary Total z and GDS scores. NFL was determined in CSF and we assessed the cross sectional relationship to neurocognition.
Results: The 96 participants were 87% male, 60% Caucasian, had a mean (SD) age of 49 (11), education of 14 (3), CD4+ of 540 (253), Total z score -0.60 (.81) and CSF NFL 643 (564). There was a significant correlation between high CSF NFL (>700) and impaired total z score (r=-.21, p< .05). Controlling for age, we found significant (F(1, 92) = 4.04, p< .05) increased neurocognitive impairment in those with high CSF NFL. Similarly, the impaired (GDS >1.33) neurocognition group had significant increase in CSF NFL (847) over neurocognitively normal (CSF NFL (570); F(1,92) = 4.24, p< .05).



[NFL]

Conclusions: Biomarkers reflecting active neuronal damage and the impact on neurocognitive and functional status are important in estimating the CNS reservoir and managing effective treatment in those living with HIV. CSF NFL is a promising biomarker reflecting current neurocognitive functional status. We found a significant relationship between increased CSF NFL and neurocognitive impairment in these HIV participants. Future work could assess the use of CSF NFL as a marker of ongoing neuronal damage due to viral replication or neuroinflammation, and potentially guide treatment.

WEPEB0485

Screening positive for depression and illegal poly-substance use are among the factors independently associated with lower health-related quality of life of people living with HIV in Rio de Janeiro

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Background: The HIV-treatment primary goal of reducing viral load to an undetectable level can improve patients' quality of life. However, multiple factors can affect the Health-related Quality of Life (HRQoL) of people living with HIV/Aids (PLWHA) and influence treatment outcomes. This work aimed to estimate the factors associated with HRQoL among PLWHA in Rio de Janeiro, Brazil.
Methods: This was a cross-sectional study with patients receiving HIV-care at the National Institute of Infectious Diseases Evandro Chagas (INI-Fiocruz) enrolled between 2014-2016. EQ-5D-3L measured HRQoL; PHQ-2 screened depression; and, ASSIST measured substance use. Illegal poly-substance use was considered as the use of more than one illegal substance in the last three months. Structured questions evaluated intimate partner violence, sexual activity, and relationship status. Viral loads were obtained from the clinical cohort database if available within a 6-month interval before and after the study visit. A multiple linear regression model was conducted to estimate factors associated with HRQoL.
Results: The median age of the 1445 participants was 43.09 (IQR: 34.64-50.83) and of EQ-5D-3L scores was 0.80 (IQR: 0.74-1.00). The model results (estimate; p-value) showed that: screening positive for depression (-0.098; <0.001); illegal poly-substance use (-0.076; <0.01); older age [≥60-y vs.< 30](-0.070; <0.001), [40-59-y vs.< 30](-0.030; <0.05), [30-39 vs. <30](-0.002; 0.869); intimate partner violence (-0.059; <0.01); female sex at birth (-0.040; <0.001); detectable viral load [≥50 copies/ml vs. undetectable] (-0.040; <0.001), [missing viral load (22.56%) vs. undetectable] (-0.010; 0.322); 12-month sexual inactivity (-0.034; <0.01); lower educational level [≤ fundamental vs. medium](-0.029; <0.01), [superior vs. medium](0.014; 0.185); tobacco use (-0.027; <0.01); and, not being in a relationship (-0.022; <0.05), were factors independently associated with lower HRQoL.
Conclusions: These results suggest that most of the participants have low impact on quality of life, considering that the weights used for HRQoL calculation were obtained recently from a representative Brazilian general population, and that a EQ-5D-3L of 1.00 represents a "perfect health state". Moreover, regarding the associations in the model, both biological and sociobehavioral factors should be targeted for improving quality of life of HIV patients.

WEPEB0486

Co-prescription of benzodiazepines and opioids on hospitalization rates among people living with HIV in British Columbia, Canada

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Background: Co-prescription of benzodiazepines and opioids, which are prescribed primarily for anxiety and pain, respectively, are associated with various health harms, including mortality. People living with HIV (PLHIV) are often prescribed these medications given the intersections between HIV/AIDS, mental health, pain, and addiction, making them particularly vulnerable to these harms. While studies have examined the use of opioids on hospitalization rates, little is known about the effect of benzodiazepine and opioid co-prescription on this outcome. The objective of this study is to examine whether co-prescription of benzodiazepines and opioids is associated with higher hospitalization rates among PLHIV in British Columbia, Canada.
Methods: Using a comprehensive linked population-level database of PLHIV in British Columbia, we included individuals following their first dispensation of highly active antiretroviral therapy (HAART). Generalized estimating equation regression models were constructed to determine the relationship between co-prescription of benzodiazepines and opioids, which was defined as an overlapping prescription of at least one day of both medications, on all-cause hospitalization rates.
Results: Between 1996 and 2013, a total of 8,993 individuals were included in the study; 1,694 (18.8%) were female and the median age at baseline was 40 years (Q1-Q3: 33-47 years). In a multivariable model adjusted for various demographic and clinical confounders, there was a positive association between the prescription of benzodiazepines and/or opioids and hospitalization rates compared to not being prescribed either medication: benzodiazepine only (adjusted rate ratio [ARR] = 1.36; 95% confidence interval: 1.26 - 1.47); opioid only (ARR = 1.83; 95%CI: 1.70 - 1.97); and co-prescription of both medications (ARR = 1.58; 95%CI: 1.41 - 1.77).
Conclusions: In this study, we found that PLHIV who were co-prescribed benzodiazepines and opioids had higher hospital utilization rates, which consequently exacerbates the burden on the healthcare system. The findings should be interpreted with caution - in particular, co-prescription of these medications is not necessarily always inappropriate. However, these findings demonstrate the need for systems- and policy-level interventions to monitor and tease out inappropriate prescribing practices in this setting.

WEPEB0487

Post HIV status disclosure assessment of behavioral health patterns among adolescents living with HIV: a Nigerian study

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Background: Psychosocial and Mental health needs of adolescents living with HIV are major concerns in the global HIV response as they are major predictors of treatment outcome and prevention of new infections. Nigeria is among the largest contributors to the global HIV burden among adolescents, yet behavioural health patterns of this group in Nigeria are largely unknown.
Methods: In-depth interviews were conducted with care givers of 61 adolescent aged 10-18 years (male 34, female 27) and focus group discussions conducted with the adolescents who were purposively selected. There was comparative assessment of the psychosocial/behavioural health patterns pre and post HIV status disclosure along five themes: academic performance, mood, and participation in activities, relationship with friends and family, and treatment adherence. The information was transcribed, coded and content analysis performed
Results: Majority of the adolescents acknowledged that their status should not affect their education, and expressed worries over bearing the burden of silence in school with the resultant feeling of loneliness. A pattern of occasional withdrawal and low spirit was observed (72%), aggression & depression more in the female, and the older group largely indicated unwillingness to disclose their status not even to their best friends. Poor performance in School was more in the male, "sometimes I wonder why I am going to school" [boy, 17]. Eight (2 boys, 6 girls) engaged in sexual activities, 3 (females) without condom. Poor adherence to therapy was observed as they grew older. All the care givers agreed that it is difficult to hide the status from the adolescents for long, and even more difficult to disclose, "I got tired of lying to him about the drugs, I and the father had to break the news" [a mother].
Conclusions: There is an emergence of large number of adolescent living with HIV, yet the care-givers and most HIV service providers are not adequately prepared to manage the new challenge of HIV infection - mental health. Integrating mental health services into the HIV Program is necessary at this point to secure the wellbeing of the young population and promote right behaviour for effective prevent of new HIV infection.

WEPEB0488

Factors associated with the occurrence of suicide among French people living with HIV in the HAART era: a nested case-control study

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Background: People living with HIV (PLHIV) are at higher risk of dying from suicide than general population. Suicide is the first cause of death among French PLHIV in immunovirological success. The main objective of the present study was to identify factors associated with dying from suicide among French PLHIV.
Methods: It was a multicenter case-control study nested in the French multicenter Dat'AIDS cohort, in the HAART era, from January 2000 to July 2013. Cases were all deceased PLHIV who died from suicide. Control selection (up to four controls for each case) was done using incidence density sampling, allowing to estimate relative risks. Controls were also matched on time from HIV diagnosis and clinical center. The following potential explanatory variables were extracted: date of birth, gender, country of origin, education level, socioprofessional category, marital status, having one or more children, HIV transmission group, Nadir of CD4, CD4 cell count, CDC stage, HIV viral load, antiretroviral therapy, hepatitis co-infections, tobacco use, alcohol use, toxicomania, history of anxious disorder, depression, bipolar disorder, schizophrenia or suicide attempt, and psychotropic drugs use (anxiolytics, anti-depressive, neuroleptics, thymoregulators). Medical files were also checked and multiple imputation was used for dealing with missing data. Univariable then multivariable conditional logistic regression models were performed.
Results: Among 349 patients included in the present study, 70 patients died from suicide and 279 were controls (69 cases had 4 controls, 1 case had 3 controls). By multivariable analysis, having children was protective against the risk dying from suicide (adjusted relative risk (aRR)=0.23, 95% confidence interval (95%CI) [0.10 - 0.70]), whereas active or substituted toxicomania (aRR=3.29, 95%CI[1.10 - 9.85]), alcohol intake >20g/day or history of abuse (aRR=3.56, 95%CI[1.43 - 8.88]), history of depressive disorder (aRR=3.76, 95%CI[1.49 - 9.50]), history of suicide attempt (aRR=5.93, 95%CI[1.58 - 22.24]) and psychotropic drugs intake (aRR=6.37, 95%CI[2.56 - 15.85]) were independently associated with an increased risk of dying from suicide.
Conclusions: Identification of factors associated with an increased risk of dying from suicide may help recognizing PLHIV that may the most benefit from an intervention to prevent suicide.

WEPEB0489

Adjustment disorders predict HIV viral load in patients seeking to improve self-efficacy regarding antiretroviral therapy adherence

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Background: Adherence to the antiretroviral therapy (ART) is a crucial determinant of effective HIV treatment. ART adherence is impacted by socioeconomic, psychological, and health challenges. Previous studies have documented an association between disclosure of HIV status and adherence.
This study examined the relationship between psychiatric diagnosis, adherence, disclosure, and HIV outcomes.
Methods: HIV-infected patients receiving care at Mount Sinai were enrolled in Rango, a program developed by VillageCare Wellness Innovations using technological resources to improve treatment adherence. All participants signed consent approved by the Mount Sinai IRB. Eligibility criteria included HIV infection on ART, NYC residence, and being a Medicaid and/or Medicare beneficiary. Patients completed self-report on mental health, substance use and determinants of adherence including disclosure of HIV status. Data were extracted about mental health disorders and HIV outcomes from both the Rango database and EMRs as per protocol.
Results: 289 patients enrolled in the program during the review period. Participants identified as African-American (41%), Hispanic (41%), White, non-Hispanic (8%), mean age was 50, and the majority was male (60%). One-fifth reported missing HIV medications in the prior 3 days, 35% had a detectable viral load (VL). 15% disclosed their HIV status to all family and friends, while 14% had not disclosed to anyone. White participants were more likely to have disclosed to all family and friends. Half of the participants had a psychiatric diagnosis documented in their electronic health records: 28% unipolar disorder, 14% anxiety disorder, and 9.7% bipolar disorder. Having an adjustment disorder and using substances were associated with missed medications or a detectable VL ($p<0.05$). Logistic regression adjusting for age, gender, race, adherence, HIV disclosure, and substance use showed that patients with adjustment disorders had 5.32 times the odds of having a detectable viral load compared to patients without adjustment disorders (95% CI: 1.25-22.70).
Conclusions: In our cohort, occurrence of adjustment disorders seems to play a prominent role in HIV outcomes compared other psychiatric diagnoses. Despite previous studies, no association was found between virologic suppression, disclosure or having a psychiatric diagnosis. These data suggest that patients with adjustment disorder may benefit from treatment intervention.

WEPEB0490

Effects of adaptive behavioral interventions to reduce alcohol use among HIV-positive patients in primary care: the health and motivation study

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Background: Drinking alcohol at hazardous levels can compromise antiretroviral therapy (ART) response, and increase rates of medical and psychiatric problems, unsafe sexual practices, and mortality for people living with HIV. This randomized controlled trial examined two brief intervention models to reduce alcohol use.
Methods: Participants included 614 HIV-positive patients recruited from a Kaiser Permanente Northern California (KPNC) San Francisco Medical Center primary care HIV clinic. Subjects were eligible if they reported hazardous drinking during the prior year. Participants were recruited by telephone and randomized to either 3-sessions of a motivational interviewing (MI) behavioral intervention with a psychologist to enhance motivation to reduce drinking, emailed feedback (EF) containing information on alcohol use risks via the KPNC patient portal, or usual care alone (i.e., clinic-based alcohol screening/intervention by usual care providers). Participants who reported hazardous drinking at 6 month interviews post-intervention were offered additional (i.e., booster) treatment within the MI and EF arms. The primary study outcome was hazardous drinking rate (any 4+/5+ drinks in a single day for women/men) at 12 month follow-up study interviews; secondary outcomes were based on clinic-based alcohol screening measures. Hazardous drinking by intervention group and other demographic, psychological and substance use predictors (baseline age, education, race, income, sex, marital status, depression, anxiety, marijuana use, and hazardous drinking) was evaluated by multivariable logistic regression.
Results: The sample was 97% male; 63% White, 16% Hispanic, 10% African American, and 7% other ethnicities; with mean age of 49 years. In the 30 days prior to enrollment, 48% reported hazardous drinking, which was reduced to 25% at 12 months; no significant differences were noted by treatment group. Similar drinking reductions were noted for clinic-based alcohol measures. Factors associated with worse survey-reported hazardous alcohol use included younger age ($p=.006$), not being married or partnered ($p=.069$), and greater frequency of hazardous drinking at baseline ($p<0.001$).
Conclusions: Among HIV patients engaged in primary care, substantial reduction in hazardous drinking over time was observed for all 3 study arms. Patient demographic and clinical characteristics were identified that could help target individuals at risk for worse alcohol-related outcomes over time, to enhance future intervention development.

WEPEB0491

Role of basal ganglia in depression in HIV-infected individuals

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Background: Depression is the most common psychiatric comorbidity in HIV+ individuals that has persisted in the era of combination antiretroviral therapy (cART). Major depression is associated with abnormalities in the striatum and frontal cortex, in particular decreased functional connectivity between ventral striatum and ventromedial prefrontal cortex and anterior cingulate cortex. Given that basal ganglia injury is frequent in HIV infection, it could in part explain the higher prevalence of depression in HIV+ individuals. The aim of the current study was to determine if basal ganglia dysfunction (as measured by brain metabolites) is associated with depression and if these brain metabolites differ between HIV+ and HIV- individuals with depression.
Methods: As part of an ongoing longitudinal study of the effect of cART on brain structure and function, thirty-seven treatment naïve HIV+ individuals and 95 HIV- individuals underwent psychological and neuroimaging assessment.
Depressive symptomatology was assessed by the Center for Epidemiological Studies Depression Scale (CES-D). MR Spectroscopy (volume size = 15´15´15 mm^3, TE=35ms, TR = 2000ms) was acquired at basal ganglia region for metabolite concentrations. MRS data was calculated with the linear combination of model spectra. We collected the following metabolite concentrations in our study: glutamate(GLU), N-acetylaspartate(NAA), choline (CHO), myo-inositol(INS), and creatine(CRE).
Results: 37 HIV+ individuals (age 33.2±15.0) and 91 HIV- (age 42.2±14.4) (age p=0.09) were compared. HIV+ individuals prior to starting cART had a CD4 cell count of 500.6 cells/mm^3± 265 cells/mm^3 and viral load 5.08 log_{10} copies/ml ± 5.37 log_{10} copies/ml. Twelve of 91 (13%) HIV- and 17 of 37 (46%) HIV+ individuals prior to starting ARVs had depression (CES-D score ≥ 16) (p<0.01). After 12 weeks of cART, depression persisted in 38% of HIV+ individuals. Of the MRS metabolites, CHO/CRE was elevated in the HIV+ depressed individuals compared to the HIV+ non depressed individuals (p=0.01). HIV- depressed individuals tended to higher levels of CRE and INS (p= 0.057 and p=0.06 respectively.
Conclusions: Basal ganglia dysfunction is associated with depression in HIV+ individuals. The increase in CHO/CRE suggests that glia dysregulation may be contributing to the symptoms. HIV- depressed individuals tend to have less glia dysfunction in the basal ganglia than HIV+.

WEPEB0492

Risk factors associated with aortic stiffness in HIV-positive individuals compared to two HIV-negative groups: results of INI-ELSA-Brasil

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Background: HIV-infected patients are at increased risk for cardiovascular (CV) disease. Aortic stiffness (AS) measured by carotid-femoral pulse wave velocity (cf-PWV) is a marker of subclinical atherosclerosis. We studied the association of risk factors and HIV infection with AS in a cross-sectional analysis.
Methods: Cf-PWV was determined using a validated device. We used multivariable linear regression models to investigate the relationship between traditional and HIV-related CV factors with cf-PWV in a group of 649 HIV+ patients and two comparison groups, separately: 106 HIV-negative individuals and 15105 participants of the ELSA-Brasil study. A marker of poor health management was defined as having hypertension, diabetes or dyslipidemia without treatment at the moment of the clinical visit. Propensity scores (PS) were used to account for imbalances between the compared groups.
Results: Out of 15860 participants, 15622 (98.5%) with complete cf-PWV examinations were included. Overall, 46.0 % were male, median age was 51 [interquartile range (IQR) 45-58] years. Median cf-PWV in m/s (IQR) were 9.3 (8.4-10.5) in males and 8.7 (7.8-9.8) in females (p <0.001). For ELSA-Brasil, HIV- and HIV+ groups, cf-PWV were 9 (8.1-10.2), 8.7 (7.9-10.2) and 8.48 (7.66-9.4), respectively (p<0.001). Most of HIV+ individuals (88.7%) has ever been on ART, and 71.3% were virologically suppressed with a median CD4 count (IQR) of 540(371-741). In the adjusted model, age, hypertension, body mass index, systolic and diastolic pressure, and CD4 count, were associated with increased cf-PWV in HIV+. In the final models HIV+ was not associated with cf-PWV compared to HIV- group (β=-0.05;95%CI=-0.15,0.26;p=0.58), whereas lower levels of cf-PWV were observed when compared to ELSA-Brasil (β=-0.18;95%CI=-0.33,-2.97;p=0.01). Poor management was more frequent in the HIV- group (55.24%), compared to ELSA-Brasil (53.36%) and HIV+ (43.97%) groups (p<0.001) and was significantly associated with AS in the model comparing HIV+ with ELSA-Brasil groups (β=0.33;95%CI= 0.17,4.88;p<0.001).
Conclusions: Traditional CV risk factors and CD4 counts were associated with increased cf-PWV in HIV+ subjects. HIV infection was not a risk factor for increased cf-PWV, which was even higher for the ELSA-Brasil group. Better management of traditional CV risk factors combined with a good virologic control could explain these results.

WEPEB0493

The prevalence of cerebral microbleeds in HIV-infected hemophilia patients

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Background: Several studies have shown that rates of cerebrovascular events in HIV-infected patients are increased in comparison to uninfected individuals. In addition, cerebral hemorrhage represents a serious complication in hemophilia patients. Recently, asymptomatic cerebral microbleeds (CMBs), which can be detected by highly sensitive techniques such as T2*-weighted magnetic resonance imaging (MRI), have emerged as an important marker for predicting symptomatic cerebral hemorrhage. The aim of the present study was to investigate the prevalence of CMBs in HIV-infected hemophilia patients and to evaluate the association between HIV infection and cerebral hemorrhage.
Methods: All of the HIV-infected hemophilia patients (HIV+ HemPts) who visited our hospital from January 2015 to December 2016 were enrolled in this study. In addition, all of the HIV-uninfected hemophilia patients (HIV- HemPts) who visited our hospital in the same period were enrolled as controls. CMBs were assessed using T2*-weighted MRI. The relationship between cerebral hemorrhage and the patients' clinical factors, such as age, the severity of hemophilia, hepatitis virus and HIV infection statuses, hypertension, hyperlipidemia, diabetes mellitus, and smoking status was examined.
Results: Two HIV+ HemPts had symptomatic cerebral hemorrhage during the study period. Twenty-one asymptomatic HIV+ HemPts and 12 HIV- HemPts underwent T2*-weighted MRI. CMBs were observed in 7 HIV+ HemPts and 1 HIV- HemPt. In the logistic regression analysis, HIV infection was the only risk factor for cerebral hemorrhage (Odds ratio: 7.07, p-value: 0.04).
Conclusions: This is the first report to investigate the prevalence of CMBs in HIV-infected patients. The prevalence of CMBs or symptomatic cerebral hemorrhage in HIV+ HemPts was extremely high (39.1%) in comparison to that in HIV+ HemPts (8.3%). Brain screening by T2*-weighted MRI led to more strict management of the blood pressure, re-evaluation of hemophilia treatment, and lifestyle improvements such as smoking cessation to prevent symptomatic cerebral hemorrhage in patients in whom CMBs were detected. The screening test seems to be meaningful for HIV+ HemPts.

WEPEB0494

Vitamin D and progression of carotid intima-media thickness in HIV-positive Canadians

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Background: Based on evidence implicating vitamin D deficiency in the development of cardiovascular disease (CVD) we hypothesized that in HIV-positive Canadians, low 25-hydroxyvitamin D (25(OH)D) concentration would be associated with increased progression of vascular disease. Vitamin D deficiency represents a unique problem in the HIV context. The antiretroviral drug efavirenz may impair vitamin D metabolism, and deficiency has been associated with increased HIV progression, all-cause mortality and carotid artery intima-media thickness (CIMT)-a measure of subclinical vascular disease.

Methods: We prospectively studied the relationship between baseline 25(OH)D (continuous) and CIMT progression (as CIMT change per year) between 2002 and 2011 in the multicentre Canadian HIV Vascular Study. Linear regression models were adjusted for Framingham risk, ethnicity, CD4 count and nadir, and years since HIV diagnosis (parsimonious model; variables included if P ≤ 0.20 in univariable associations). Full models were adjusted for age, sex, smoking, total cholesterol-to-HDL ratio (TC:HDL), ethnicity, BMI, antiretroviral therapies, CD4 nadir, lipid medications, physical activity, years since HIV diagnosis, kidney disease, and season (full model variable selection facilitated by construction of directed acyclic graphs).
Results: Of the 128 participants, 89.1% were men, mean age (SD) was 46.5 (8.2) years, 93.8% were white, and 36.7% were smokers. Mean (SD) annual CIMT follow up was 5.7 years (2.0; min 1.5, max 8.5). Mean CIMT progression (SD) was 0.027 mm/year (0.030 mm/year). Mean (SD) 25(OH)D was 95.0 (46.9) nmol/L. Only 13.3% were vitamin D deficient (25(OH)D < 50 nmol/L), whereas 61.7% met sufficiency status (75 nmol/L). Vitamin D quartiles were inversely associated with BMI (ANOVA, P = 0.034), TC:HDL (P = 0.001), parathyroid hormone (P = 0.003), but not efavirenz exposure (chi-square, P = 0.141). In linear regression analyses, baseline 25(OH)D was inversely associated with CIMT progression in all models (Table 1).

Baseline 25-hydroxyvitamin D (log) estimates for annualized carotid IMT progression weighted by years of follow-up

Models (n=128)	Estimate (95% CI)	Standard error	P value
Univariable	-0.04 (-0.049, -0.031)	0.005	<0.001
Parsimonious	-0.035 (-0.046, -0.024)	0.006	<0.001
Full	-0.04 (-0.052, -0.027)	0.006	<0.001

[Table 1]

Conclusions: Plasma 25(OH)D is associated with CIMT progression in this relatively vitamin D replete, predominately white and male, Canadian HIV positive population. Future research needs to establish causality as this could warrant more targeted screening and/or supplementation.

WEPEB0495

Death after myocardial infarction (MI): incidence and risk factors by MI type in HIV

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Background: People living with HIV (PLWH) are at higher risk for MI. The Universal Definition of MI divides MIs into types. Type 1 MIs (T1MI) result spontaneously from atherosclerotic plaque instability. Type 2 MIs (T2MI) occur in the setting of oxygen demand-supply mismatch, such as with sepsis or cocaine-induced vasospasm. The purpose was to evaluate survival rates after each MI type and predictors of death following MIs in PLWH.
Methods: This study was conducted in the CNICS cohort of PLWH in care at six U.S. sites. MIs were centrally adjudicated and death dates were collected via national registries, death certificates and hospital records. Possible predictors of death after MI included age, sex, race, CD4 count, HIV viral load (VL), diabetes, estimated glomerular filtration rate (eGFR) < 30, statin use, and treated hypertension all assessed prior to the MI event. We compared percentages of those who died within 1 year of T1MI and T2MI with chi-square tests. Predictors of death within 1 year after T1MI or T2MI were tested using relative risk regression.
Results: 643 PLWH had MIs (317 T1MI, 326 T2MI) between 2000-2014; 77% male, 37% white, 54% black, and 7% Hispanic, with a mean age of 50 (SD 10). 26% died within 1 year; the rate was significantly higher for T2MI (37%) than T1MI (14%). PLWH with diabetes had significantly higher risk of death within 1 year of MI than those without for both T1MI (Relative Risk [RR] 1.9, 95% CI:1.1-3.4) and T2MI (RR 1.5, 95% CI:1.1-2.2). For T1MI but not T2MI, additional significant predictors of death were older age (RR 1.7 per 10 years, 95% CI:1.3-2.2), VL>400 copies/mL (RR 2.3, 95% CI:1.3-4.1), eGFR < 30 (RR 2.1, 95% CI:1.1-4.1) and not using a statin (RR 2.0, 95% CI:1.1-3.9).
Conclusions: Death within 1 year of MI was common in PLWH, particularly after T2MI. Predictors of death included modifiable risk factors, suggesting treatments such as statin use and effective ART could be used to prevent death following MI, principally T1MI. The significant differences in the rate and predictors of death for T1MI vs. T2MI enforces the importance of considering these outcomes separately.

WEPEB0496

Distribution and performance of cardiovascular risk scores in a mixed population of HIV-infected and community-based HIV-uninfected individuals in Uganda

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Background: To compare and validate CVD risk profiles with carotid intima media thickness among a population of HIV-infected people on antiretroviral therapy (ART) and age and gender-matched HIV-uninfected people in Uganda.
Methods: We estimated CVD risk and contrasted profiles by HIV serostatus using the 1) Framingham laboratory-based score (FRS-Lipids); 2) Framingham non-laboratory score (FRS-BMI); 3) Reynolds score (RRS); 4) American College of Cardiology and American Heart Association score (ACC/AHA); and 5) the Data-collection on Adverse Effects of Anti-HIV Drugs (D:A:D) score. We compared absolute risk scores and risk categories across each score using Spearman rank correlations, and kappa statistics, respectively. Finally, we fit linear regression models to validate each risk score with common carotid artery intima media thickness (c-IMT) as a surrogate marker of CVD.
Results: Of 205 participants, half were female and the median age was 49 (IQR 46-53). Median CD4 count was 430 cells/mm^3 (IQR 334-546), with a median of 7 years of ART exposure (IQR 6.4-7.5). Compared with HIV-infected comparators, HIV-uninfected participants had a higher median systolic blood pressure (121 mmhg IQR [111-135 mmhg] versus 110 mmhg [100-121 mmhg], P<0.001), and higher prevalence of current smoking (18% versus 4% P=0.001) correlating with higher median CVD risk scores (p<0.003), and evidenced by greater c-IMT (0.68 vs. 0.63 P=0.003). Although all calculators were generally highly correlated (Spearman rank >0.80) and demonstrated increasing c-IMT with increasing risk category, FRS-BMI performed best among HIV-uninfected participants (R^2=0.20, P<0.001). FRS-Lipids, FRS-BMI and D:A:D performed similarly among the HIV-infected (R^2=0.13-0.15, P<0.004). ACC/AHA had the lowest association with c-IMT in both groups (R^2= 0.09, P=0.01). Notably, the HIV-specific D:A:D score categorized a significantly higher proportion of HIV-infected individuals as moderate or high risk (73%), than the other risk scores (9-13%).
Conclusions: A non-laboratory based risk score (FRS-BMI) correlated well with pre-clinical atherosclerosis in both HIV-infected and uninfected individuals, and may be of particular use in low-resource settings. Age and gender-matched, community based HIV-uninfected individuals had higher CVD scores than HIV-infected individuals in care in rural Uganda, and the difference appeared to be driven by modifiable factors such as smoking and high blood pressure.

WEPEB0497

Increasing cardiovascular disease incidence in HIV-positive adults in Asia: projections for 2017-2026

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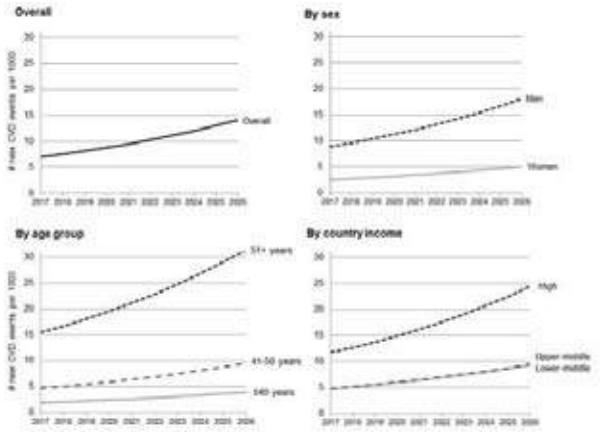
Background: HIV is estimated to increase cardiovascular disease (CVD) risk in HIV-positive people by about two-fold. The number of people experiencing co-morbid CVD is expected to rise as the HIV population ages, but CVD risk and management have received limited attention in HIV-positive adults in Asia. We aimed to project the 10-year incidence of CVD based on a heterogeneous Asian HIV-positive cohort.
Methods: Analyses were based on patients recruited to the TREAT Asia HIV Observational Database (TAHOD), consisting of 20 sites in 12 countries. Patients were included if they started antiretroviral therapy, were alive, had no previous CVD history, and had data available on CVD risk factors. The D:A:D CVD risk equation was used to estimate annual new CVD events for 2017-2026, accounting for age- and sex-adjusted mortality. Projections were stratified by sex, age, and country income level.
Results: Of 3406 patients who met the inclusion criteria, 69% were male, median age was 45 (IQR 39-52) years, and median time since ART initiation was 8.1 (IQR 5.8-12.5) years. We projected that cohort incidence rates of CVD events will increase from 7 per 1000 person-years (/1000pys) in 2017 to 14/1000pys in 2026 (Figure). Stratified projections for 2026 showed a higher CVD event rate in men than women (18 vs 5 events/1000pys), in older patients (31, 9 and 4 events/1000pys in those aged 51+, 41-50 and ≤40 years, respectively) and in high-income countries (24 vs 9 in upper-middle and 9 in lower-middle income countries).
Conclusions: Our projections suggest that CVD incidence rates in Asian HIV-positive adults in our cohort will double in the next decade. Risk screening, specifically in men, older patients and high-income countries, is needed to support timely intervention and to reduce future CVD burden.



[Figure: Estimated CVD event rate for 2017-2026]

WEPEB0498

TLR4 Asp299Gly polymorphism is associated with cardiovascular disease in HIV-infected patients

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Background: Non-AIDS-related events (nADEs), especially cardiovascular diseases (CVDs), are the main cause of morbi-mortality in HIV-patients on suppressive antiretroviral therapy. The association of variants in the lipopolysaccharide (LPS) toll-like receptor 4 (TLR4), with the occurrence of CVDs in non-HIV-population is controversial. In HIV-infected patients, the role of TLR4 variants in the onset of CVDs remains unknown. The objective was to study the impact of the Asp299Gly polymorphism in the onset of CVDs in HIV-infected patients and to analyze the functional consequences of this polymorphism.
Methods: Patients, who consecutively visited the Virgen del Rocío University Hospital in Seville (Spain) between 1989 and 2016, with nADEs recorded information and DNA samples available, were included. TLR4 polymorphism, Aps299Gly (rs4986790), was determined in total DNA by real time PCR. Asp299Gly association with CVDs was analyzed by logistic regression after adjusting for potential confounders. Ex vivo activation and in vitro response after LPS stimulation on classical, intermediate and patrolling monocytes was assessed by multiparametric flow cytometry in a group of healthy donors and HIV-infected patients who carried the TLR4 polymorphism and compared with wild-types with available fresh whole blood samples. The percentage of monocytes producing intracellular IL1α, IL1β, IL6, IL8, TNFα and IL10 was determined. Soluble IL-6 was measured in plasma samples.
Results: From the total 253, 26 patients presented a recorded CVD (10%). Asp299Gly allele was directly and independently associated with the onset of CVDs (OR (IC95%)=3.35 (1.19-9.41), p=0.02) after adjusting with CD4-T-cell nadir, Hepatitis C virus-infection, bacterial pneumonia and diabetes. After LPS in vitro stimulation, healthy donors carrying the polymorphism showed a high percentage of $IL1\alpha^{-}IL1\beta^{-}IL6^{+}IL8^{-}IL10^{-}TNF\alpha^{-}$ intermediate monocytes and $IL1\alpha^{+}IL1\beta^{-}IL6^{-}IL8^{+}IL10^{-}TNF\alpha^{-}$ patrolling monocytes comparing with wild-type subjects (p=0.037 and p=0.046 respectively). IL-6 soluble levels, were correlated with the percentage of $IL1\alpha^{-}IL1\beta^{-}IL6^{+}IL8^{-}IL10^{-}TNF\alpha^{-}$ intermediate monocytes only in carriers (r=0.89; p=0.01). Regarding HIV-infected individuals, patients carrying the polymorphism for TLR4 showed higher percentage of intermediate monocytes expressing proinflammatory combinations of cytokines that included $IL8^{+}$ and $IL10^{+}$ compared with wild-type patients.
Conclusions: TLR4 Asp299Gly polymorphism is a risk factor in the onset of CVDs in HIV-infected patients. The proinflammatory profiles of this variant could be involved in the development of atherosclerotic pathologies.

WEPEB0499

Hypertension does not affect long-term retention on ART in a Ugandan cohort

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Background: A few studies have reported prevalence of hypertension in HIV patients in Sub-Saharan Africa but information on how it affects clinical outcomes in our context is scarce. Here we analyze data on hypertension from a large HIV program in rural Uganda.
Methods: Data from adult patients started on antiretroviral treatment (ART) between January 2001 and November 2016 with at least two blood pressure (BP) measurements was included in the study. We used Kaplan-Meier survival methods to estimate retention on ART, Cox proportional hazards methods to adjust for potential confounders and multivariate logistic regression to identify factors associated to development of hypertension.
Results: 6,244 patients met the inclusion criteria. 65% were women, median age was 35 years and median CD4 was 171 cells. Hypertension was diagnosed in 1,513 patients (24.2%). 70.1% of all cases were diagnosed before ART initiation or during the first year on treatment. Development of hypertension in the first year on ART had a significant positive association with age and weight and negative with CD4 baseline in the multivariate analysis. Treatment with Stavudine (d4T) -containing regimens was also associated to increased risk of developing hypertension during the first year (OR: 1.59 p=0.01 using as reference Zidovudine-containing regimens). Three and five years retention on ART for those that had a diagnosis of hypertension was 92.8 and 88.2% (versus 91.8 and 88% for patients without

hypertension). There was no association between hypertension and attrition when adjusting by age, sex, CD4 baseline, WHO stage, weight and year of ART initiation in the Cox model.

Conclusions: Our analysis, in line with other studies, found that hypertension is common in HIV patients on ART. Development of hypertension in the first year on ART was associated with the use of d4T regimens and with lower CD4 counts. Despite poor BP control, our study found that HIV patients with hypertension have similar outcomes (in terms of long term retention on ART) than normotensive patients. The low prevalence of other cardiovascular risk factors in our context (reducing the morbidity associated to hypertension) and the closer follow up in patients with chronic diseases could partially explain these findings.

WEPEB0500

Comparing CVD risk factors in HIV-infected and HIV uninfected individuals from the general population in Greece

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Background: Although triple antiretroviral therapy substantially decreased mortality in HIV-infected individuals, mortality remains higher compared to general population, mainly due to higher prevalence of non-AIDS related comorbidities, including cardiovascular diseases (CVD). Study compared the prevalence of CVD risk and its factors, and 'Heart age' between HIV-infected and HIV-uninfected individuals in Greece.

Methods: HIV-infected data was derived from the AMACS study (Athens-Multicenter-AIDS-Cohort-Study), and control data from general population from the health examination survey „National Study of Morbidity and Risk factors" (E.ME.NO.). Multistage stratified random sampling based on 2011 census was used; data was collected between 2014-2015 and weighted to reflect Greek population by age, gender, and geographical distribution. All HIV-infected adults with ≥1 visit between 2012-2014 and all E.ME.NO control-group adults were included. 10-year risk of CVD-event was estimated using the Framingham risk score (FRS). Individual estimated risk was used to calculate 'Heart age' described as a person's predicted vascular system age based on his/her cardiovascular risk factor profile. Weighted multivariable logistic, fractional logistic and multivariable linear regression models were applied for analysis.

Results: 5305 HIV-infected (median age:42.7 years, 85.0% males) and 5950 non-HIV-infected (median age:47.9 years, 48.4% males) individuals were included. Crude prevalence of hypertension, diabetes and high FRS was significantly higher in the control group, but adjusted for age, gender and origin, high FRS was significantly higher in HIV-infected individuals with no significant differences between the two groups in hypertension and diabetes. Smoking and dyslipidemia were more prevalent in HIV-infected whereas obesity was more prevalent in the general population. Adjusted mean difference (for white/men/45yrs) between heart and chronological age was higher by 1.7 years in the HIV-infected-individuals (Table).

Conclusions: Dyslipidemia, smoking and increased CVD risk, were more prevalent in HIV-infected compared to the control group. Assessment and management for CVD and its risk factors are of high priority for HIV-infected patients' care, potentially leading to improved health outcomes.

	HIV infected	HIV un-infected	OR (HIV-infected/HIV-uninfected) (95% CI)	p-value
Hypertension (%; 95%CI)	34.2 (31.7, 36.6)	35.1 (32.4, 37.7)	0.96 (0.83, 1.12)	0.598
Diabetes Mellitus (%; 95%CI)	6.2 (5.4,7.0)	5.8 (4.9, 6.8)	1.06 (1.06, 1.07)	0.588
Dyslipidemia (%; 95%CI)	52.6 (50.8, 54,3)	46.9 (44.5, 49.4)	1.25 (1.12, 1.14)	<0.001
Current smoking (%; 95%CI)	66.8 (64.7, 68.9)	46.5 (44.3, 48.8)	2.31(2.04, 2.61)	<0.001
Obesity (BMI>30) (%; 95%CI)	10.2 (8.6, 11.9)	26.7 (24.6, 28.6)	0.32 (0.26, 0.39)	<0.001
High FRS (>20%) (%; 95%CI)	19.6 (16.8, 22.5)	15.3 (13.1, 17.6)	1.35 (1.07,1.71)	0.013
FRS (Mean; 95% CI)	13.1 (13.0, 13.1)	11.9 (11.8, 11.9)	1.12 (1.11, 1.13)	<0.001
'Heart age'-chronological age (years) (Mean; 95% CI)	13.4 (12.6, 14.2)	11.7 (11.0, 12.4)	Adjusted difference:1.72 (0.68, 2.76)	0.001

[Adjusted estimates (Greek/men/45yrs) & odds ratios]

WEPEB0501

cART induced macrophage p90RSK activation: a potential mechanism for cART-associated atherosclerosis

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Background: Increased incidence of cardiovascular disease (CVD) in HIV infected patients is well established, but the role and potential mechanisms that combined anti-retroviral therapy (cART) may play in CVD remains unclear. Endothelial cells and macrophages play a key role in atherosclerosis (AS) and thus CVD. Our previous studies have shown that activation of endothelial p90RSK, a redox-sensitive kinase, is a critical event in the development of AS. Given that activation of macrophage p90RSK has also been reported to affect macrophage function, we have investigated whether cART may affect macrophage p90RSK kinase thus contributing to AS.

Methods: To determine the role of macrophage p90RSK in atherosclerosis, we generated macrophage-specific wild type (WT) and dominant negative (DN) p90RSK transgenic mice, crossed with $LDLR^{-/-}$ mice and fed a high-cholesterol diet.
To investigate the role of p90RSK in human, whole blood monocytes from 25 HIV infected individuals on stable cART for at least 1 year and with viral load ≤50 copies/mL and 53 HIV negative and non-cART treated controls matched for age, gender, environment and Reynolds CVD risk score were analyzed by flow cytometry.

Results: Efferocytosis-related signaling and phagocytic capacity were upregulated and inflammatory gene expression were down-regulated in macrophages in an p90RSK activity-dependent manner; p90RSK directly phosphorylating ERK5 S496 and consequently inhibiting ERK5 transcriptional activity. In mice, we found that p90RSK activation accelerated plaque formation by inducing pro-atherogenic phenotypes such as reduced efferocytotic activity and enhanced M1 polarization. While backbone regimen of tenofovir (TDF) plus emtricitabine (FTC) did not activate p90RSK, the combination with maraviroc (MVC), rilpivirine (RPV) and atazanavir (ATV)/ritonavir (RTV) significantly increased p90RSK activation, reduced efferocytosis, and increased M1-type related gene expression.
In study participants, we found significantly increased p90RSK activation in the cART-treated group, and additional treatment of low dose of H_2O_2 (200 nM) accelerated p90RSK activation more in the monocytes from cART-treated patients than those in controls in vitro.

Conclusions: Our results demonstrate that p90RSK is robustly activated by cART. This activation culminates in reduced activity of macrophage efferocytosis, thereby accelerating atherosclerotic plaque formation. Monocyte/macrophage p90RSK can be a good target and an excellent biological marker to prevent and predict cART-induced CVD.

WEPEB0502

Awareness of the 2013 American College of Cardiology/American Heart Association (ACC/AHA) blood cholesterol guideline by providers who take care of people living with HIV

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Background: Atherosclerotic cardiovascular diseases (ASCVD) have emerged as an important cause of morbidity and mortality among HIV-infected individuals. Statins reduce this risk, but their use among HIV-infected people has been sub-optimal. The ACC/AHA updated the guideline on blood cholesterol management in 2013, but awareness of this guideline among providers who take care of people with HIV is unknown.
Methods: We administered an anonymous online survey to providers who take care of HIV-infected individuals in St. Louis, Missouri. Knowledge of the guideline and agreement with the recommendations were assessed using multiple-choice and case-based questions with Likert scale items. Data were then summarized using descriptive statistics.
Results: Ninety providers responded to our survey, of which 77.3% were physicians and 12.5% were physicians in training. 63.4% were males. Majority of the providers were from Infectious diseases (64.4%), followed by Internal Medicine (25.3%), and Cardiology (4.6%). Majority (95.1%) believed that HIV-infected individuals are at a higher risk for ASCVD. An overwhelming majority (97.5%) were aware of the guideline, and 68.8% agreed with its recommendations. The top 3 identified barriers to prescribing statins were concerns for drug-drug interaction (47.5%), polypharmacy (47.5%), and poor medication adherence (46.3%). Only 35% routinely use the guideline-recommended ASCVD 10-year risk calculator, however, majority (76.3) were aware of the ≥7.5% 10-year risk threshold for discussing statin therapy. The different patient groups identified by the guideline for whom statin therapy is recommended were correctly identified by majority (>72.3%) of the responders, except for the patient group with a low-density lipoprotein cholesterol of 200 mg/dl or more, for whom only 52.7% of the providers would prescribe statins. Majority (80%) believed that following the guideline would lead to an improvement in the cardiovascular outcomes of HIV-infected individuals.
Conclusions: Most providers who take care of HIV-infected individuals have some awareness of the 2013 ACC/AHA guideline, but few routinely use the ASCVD 10-year risk calculator in their patients. Many providers also cite medication-related issues as barriers to prescribing statins. Interventions are needed to address these gaps.

WEPEB0503

Cardiovascular disease (CVD) and chronic kidney disease (CKD) event rates in HIV-positive persons at high predicted CVD and CKD risk: results from the D:A:D study

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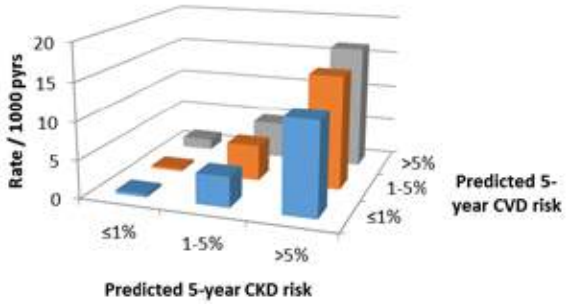
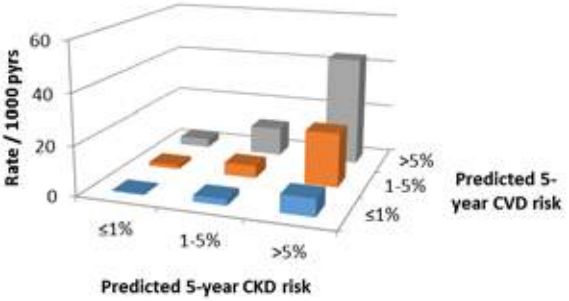
Background: The D:A:D study has developed predictive risk-scores for CVD and CKD (confirmed eGFR < 60 ml/min/1.72m^2) events in HIV-positive individuals. We hypothesised that D:A:D participants at high (>5%) CVD and CKD predicted risk would be at even greater risk for CVD and CKD event outcomes.
Methods: We included all participants with complete risk covariate data, baseline eGFR >60 ml/min/1.72m^2 and ≥3 eGFRs thereafter to calculate CVD and CKD scores. We calculated CVD and CKD event rates by predicted 5-year CVD and CKD risk-strata (< 1%, 1-5%, >5%) and fitted Poisson models to assess whether CVD and CKD risk-strata effects were multiplicative.
Results: 27,215 participants contributed 202,034 person years of follow-up; 74% male, median (IQR) age 42 (36,49) years, baseline year of follow-up 2005 (2004,2008). D:A:D risk equations predicted 3560 (13.1%) participants at high CVD, 4996 (18.4%) participants at high CKD risk and 1585 (5.8%) participants at both high CKD and CVD risk. CVD and CKD event rates by predicted risk-strata were multiplicative **(Figures 1a and 1b).** Participants at high CVD risk had a 563% increase in CKD events (p< 0.001); participants at high CKD risk had a 31% increase in CVD events (p=0.005). Participants' CVD and CKD risk-strata appeared to have multiplicative predictive effects with no evidence of an interaction (p=0.329 and p=0.291 for CVD and CKD respectively).
Conclusions: We found that combining CVD and CKD risk-scores improved prediction of CVD and CKD events, especially CKD. This suggests CVD and CKD risk in HIV positive persons should be assessed in tandem.

Figure 1a. CVD event rate by predicted CKD and CVD risk



[Figure 1a. CVD event rate by predicted CKD and CVD risk]

Figure 1b. CKD event rate by predicted CKD and CVD risk



[Figure 1b. CKD event rate by predicted CKD and CVD risk]

WEPEB0504

Incidence and factors associated with atrial fibrillation in people living with human immunodeficiency virus (PLHIV) in British Columbia, Canada

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Background: Atrial fibrillation (AF) is the most common cardiac arrhythmia in the general population and little is known about its incidence and related factors in PLHIV. The aim of this study was to compare the incidence of AF amongst PLHIV and the HIV negative individuals, as well as to describe its association with markers of HIV infection and treatments.
Methods: A population-based dataset was created via linkage between the BC Centre for Excellence in HIV/AIDS and Population Data BC. PLHIV aged 19 years and older were compared to a random 10% sample of HIV negative population. We used the International Classification of Diseases 9 and 10 codes to identify AF diagnosis from 1996 to 2013. Generalized estimating equation (GEE) models were constructed to examine the relationship between the incidence rate of AF in PLHIV and demographic/clinical variables. The age-adjusted incidence rates were calculated using the age distribution of 2011 Canadian standard population.
Results: 528,859 individuals were assessed; 13,907 were identified as PLHIV and 514,952 as HIV negative individuals. Of those, 265 (1.91%) and 20,244 (3.93%) developed AF respectively during the follow up period (median of 7.15 and 12.42 years). AF occurred at a median age 61 years (Q1, Q3=52, 70) in PLHIV vs 75 years

(Q1, Q3= 66, 82) (P< 0.001) in the HIV negative individuals. The age standardized incidence rate per 1000 person year was 2.88 (95% CI: 2.26-3.50) in PLHIV and 2.68 (95% CI: 2.65-2.75) in the HIV negative individuals with a rate ratio of 1.07 (95% CI: 0.84-1.30). In adjusted models , variables associated with a higher rate of developing AF in PLHIV included: older age, male sex, lower CD4 cells at baseline and having a prior AIDS defining illness. Earlier initiation of antiretroviral therapy (ART) and use of either protease inhibitors or NNRTIs were negatively related to development of AF.
Conclusions: In this study the age standardized incidence rate for AF in PLHIV was similar to the HIV negative individuals. PLHIV had a higher rate of developing AF if they were older, male, and had indicators related to advanced HIV infection, irrespective of their ART.

WEPEB0505

Blood thrombogenicity is increased in antiretroviral-treated HIV infection

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Background: HIV infection is associated with accelerated atherosclerosis and an increased rate of arterial thrombotic complications. This exploratory study was aimed to evaluate quantitative aspects of thrombus as it relates to platelet reactivity, thrombus kinetics, monocyte platelet aggregates (MPA), and monocyte subsets (MS).
Methods: Age and gender matched HIV infected (HIV+) participants (n=15) and seronegative controls (n=14) were enrolled. All HIV+ persons were on suppressive antiretroviral (ART) for >48 weeks. Blood thrombogenicity using the ex vivo Badimon perfusion chamber at low shear rate (LSR; venous) and high shear rate(HSR; arterial), platelet reactivity using light transmission aggregometry(LTA), thrombus kinetics using thromboelastography and fresh whole blood MS and MPA using flow cytometry were evaluated.
Results: HIV infected participants had a median age of 47 years with 53% males and 20% smokers. Controls' median age was 45 years with 50% male and 10% smokers. ART regimens included integrase inhibitor 53%, protease inhibitor 40%, abacavir 20% and NNRTI 13%. As measured by the Badimon chamber, HIV infected participants had increased platelet-thrombus formation as compared to controls at LSR (mean±SD) 6444±932 μ(2)/mm vs 4959±1991 μ(2)/mm, p=0.004 and at HSR 10213±3177 μ(2)/mm vs 7731±3387 μ(2)/mm, p=0.03 and increased platelet reactivity (LTA). Both groups showed similar thrombus kinetics. Although classical(%CD14+CD16-), non-classical(%CD14dimCD16+), intermediate(%CD14+CD16+) MS, and classical MPA (%CD14+CD61+) and non-classical MPA (%CD14dimCD61+) did not differ between HIV+ and controls, platelet-thrombus formation at HSR correlated directly with nonclassical MS (r 0.69; p=0.006) nonclassical MPA (r 0.54; p=0.039), and inversely with classical MS (r -0.57; p=0.032) in HIV+ only.
Conclusions: Compared with age and gender matched controls, HIV+ persons on suppressive ART had increased blood thrombogenicity which may contribute to increased cardiac events observed in this population. Intriguingly, thrombus formation was associated with nonclassical MS and nonclassical MPAs. Nonclassical MS have been shown to highly express tissue factor in HIV+ persons. Future studies are needed to determine the mechanism of increased thrombus formation and to determine the potential clinical benefits of antithrombotic strategies in ART-treated HIV infection.

WEPEB0506

Bone mineral density at the hip declines twice as quickly among HIV-infected women than men

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Background: Initial declines in BMD following ART initiation in HIV are well described, but data on long-term changes and risk factors for decline, particularly among women, are limited.
Methods: HIV-infected men and women in the Modena Metabolic Clinic underwent dual-electron X-ray absorptiometry (DXA) scans every 6-12 months for up to 10 years (median 4.6 years). Mixed methods regression models were created for women and men in combined and stratified models to determine factors associated with BMD. Models included variables described below; CD4 nadir, CD4 total and %, smoking, diabetes, and duration of protease inhibitor use were considered in univariate models but were not significant.
Results: 839 women and 1759 men contributed ≥2 DXA scans. The majority (82%) were ≤ 50 years old; 49% had HIV-1 RNA < 50 copies/mL at baseline; 15% of women were post-menopausal and 7% of men had hypogonadism; 30% and 27%, respectively, had hepatitis C virus co-infection. Significant adjusted average annual declines in hip and spine BMD among women and men were observed; women (hip: -0.008, L-spine -0.012 g/cm²/year) and men (hip: -0.004; L-spine: -0.007 g/cm²/year; all p< .0001). In combined mixed effect models, female sex was associated with lower hip but not spine BMD (p<0.0001). The effects of other variables on BMD are shown (Table). Sex-stratified models yielded similar results with notable exceptions: physical activity (women) and hepatitis C (men) were no longer significant in gender-specific models.

	Hip			Lumbar Spine		
	Estimate	SE	P value	Estimate	SE	P value
Sex (female vs male)	-0.0353	0.00519	<.0001	Not significant in univariate		
BMI (per 1 kg/m²)	.00487	0.00047	<.0001	0.00257	0.000483	<.0001
Duration INSTI (per yr)	0.00003	5.40E-06	<.0001	0.000027	5.32E-06	<.0001
Duration TDF (per yr)	-0.00284	0.00047	<.0001	-0.00295	0.000481	<.0001
Age <55 (vs <35)	-0.0522	0.0123	<.0001	-0.0187	0.0148	0.2069
Age 51-55 (vs <35)	-0.0481	0.0116	<.0001	-0.0354	0.0140	0.0115
Age 46-50 (vs <35)	-0.0330	0.0101	0.001	-0.01752	0.0121	0.1491
Age 41-45 (vs <35)	-0.0078	0.00977	0.425	0.00664	0.0118	0.574
Age 35-40	-0.00336	0.0104	0.746	0.0165	0.0125	0.187
Physical Activity (none vs intense)	-0.00632	0.00293	0.0309	-0.00893	0.00291	0.0022
Physical activity (moderate vs intense)	-0.00071	0.00281	0.8012	-0.00556	0.00279	0.0463
Hypogonadism or post-menopausal	-0.0322	0.00356	<.0001	-0.0460	0.00362	<.0001
AIDS Wasting	-0.0285	0.00465	<.0001	-0.0189	-0.00478	0.0001
Viral load (>50 vs 0 copies/mL)	0.0579	0.00195	<.0001	0.0581	0.00193	<.0001
Vitamin D insufficiency	-0.0152	0.00250	<.0001	-0.0119	0.00254	<.0001
HCV	-0.0130	0.00519	0.0124	-0.0174	0.00627	0.0055

[Table. Effects of covariates on BMD (g/cm²) at the hip and lumbar spine in mixed regression models]

Conclusions: Bone density at the hip, a significant predictor of fracture risk, declined twice as quickly among women compared to men and sex was independently associated with lower hip BMD in adjusted models. In addition, the results further emphasize the importance of bone health evaluation in HIV-infected adults beginning after age 45, and identify modifiable factors that may limit BMD decline.

WEPEB0507

Bone mineral density in HIV-infected patients younger than 40 years: lower peak bone mass and high prevalence of osteoporosis

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Background: It has been observed a lower than expected bone mineral density (BMD) in young HIV-infected patients, especially in those infected perinatally or during adolescence. However, associated factors with reduced BMD and evolution during follow up has not been detailed in those patients with HIV infection acquired in adult age.
Methods: Prospective cohort study of BMD and associated factors in a study about the prevalence of different comorbidities in HIV-infected patients (ComorVIH; NCT 02116751). For the purpose of this study, we selected those patients younger tan 40 years. BMD was evaluated by DXA (Dual X-ray Absorptiometry) and classified according to WHO definition in osteoporosis and osteopenia.

Results: Overall, 279 patients (55 women) had ≤40 yrs and a DXA scan. Mean age was 32.8 yrs, BMI was 23,8 kg/m2, 83% were MSM. Median time of HIV infection was 55 months (32-104), nadir CD4+ count was 250 cells/mmc, and 50% were receiving first-line TAR, TDF-based in 200 cases, for a median time of 36 months. It was observed spine and hip osteoporosis in 14% and 2%, osteopenia in 43% and 42%, respectively. Importantly, osteoporosis was more prevalent in males (21% vs 13% lumbar, 4% vs 0 in hip). According to age strata, there was a marked decrease of BMD after the 20's (1.08, 0.89, 0.84, 0.83, and 0.78, for ≤20, 21-25, 26-30, 31-35, and 36-40 years, respectively). A lower BMD was observed in patients with lower BMI (r=0.35; p<0.01), longer time of HIV (r=-0.31; p=0.03), lower nadir CD4+ (r=0.21; p=0.04), and time on ART (r=-0.21; p=0.03). DXA scan was repeated after a median of 41 months, with worsening of bone status in 60% of cases (spine and hip osteoporosis in 19% and 4%, and osteopenia in 49% and 50%), associated with a longer time between DXAs (r=-0.31; p<0.01) and time on cART including TDF (-0.34; p<0.01).
Conclusions: HIV-infected patients, mostly males, had a lower peak bone mass and a high prevalence of osteoporosis/osteopenia, related with traditional risk factors such as BMI, and HIV-associated factors, especially time of HIV infection and use of TDF.

WEPEB0508

Vertebral fractures in asymptomatic HIV-infected patients older than 50 years: prevalence, relation with osteoporosis and prediction with the use of the FRAX equation tool

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Background: The prevalence of osteoporotic vertebral fractures (VF) in HIV-infected patients has not been widely studied, neither the role of the FRAX equation tool in predicting these morphometric deformities.
Methods: Cross-sectional study of 130 patients ≥ 50 years, asymptomatic, using validated questionnaires about daily calcium intake and physical activity (IPAQ, International Physical Activity Questionnaire), thoracic-lumbar radiographs, bone DXA scan (dual X-ray absorptiometry), and bone biomarkers. VF were diagnosed and classified by semiquantitative morphometric criteria of Genant et al.
Results: Overall, 121 patients (34 women, 28%) were finally evaluated. Mean age was 54,1 yrs (50-75), mean BMI was 23.9 (15.8-33.5), nadir CD4+ was 220 (81-337), and 49% were HCV coinfected. Time of HIV infection was 257 months (205-301), and time on ART was 219 months (150-247). In spite of calcifediol monthly supplementation, 27% had hypovitaminosis D, and 17% had secondary hyperparathyroidism. In the IPAQ, low or moderate physical activity was observed in 80%. DXA scan showed lumbar and hip osteoporosis in 30% and 8%, and osteopenia in 45% and 64%, respectively. There was a significant correlation between the different bone biomarkers (r=0.72-0.75; p< 0.01), higher in case of osteoporosis/osteopenia (Bcrosslaps 0.46 vs 0.42 vs 0.31; p=0.05). Overall, 25 patients had VF (21%), associated with sex male (26% vs 6%; p< 0.01), homosexuality (31% vs 22%; p=0.01), a higher PTH (58.4 vs 50.5 pg/ml; p=0.02), lower serum phosphate (2.9 vs 3.2; p=0.04), and a trend to lower calcium intake (467 vs 578 mg daily), and to lower hip T score (-1.6 vs 1.3; p=0.1). Of note, FRAX was not predictive of VF (10-year risk of osteoporotic fracture, 2.98 vs 2.4; p=0.09; no patient above 10; risk of hip fracture 0.91 vs 0.61; p=0.15; two patients above 3). In a logistic regression analysis, older age (OR 6,2; p=0.02), use of TDF + PI (OR 1,15; p=0.04), a higher PTH (1.05; p=0.04), and time of HIV infection (1.01; p=0.04) were associated with VF.
Conclusions: The prevalence of vertebral fractures in asymptomatic HIV-infected patients older than 50 years is high, is not predicted by FRAX equation tool, and is associated with the use of TDF and secondary hyperparathyroidism.

WEPEB0509

Bone mineral density scanning rates among high-risk US veterans who were new users of antiretroviral treatments for HIV

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Background: The 2015 HIV guidelines recommend dual-energy X-ray absorptiometry (DXA) scans in patients initiating HAART with fracture risk factors including prior fragility fractures, high fall risk, glucocorticoid use, males ≥50, or postmenopausal females. HAART-associated long-term T-score changes remain unclear.
Methods: In a national cohort of US veterans newly-initiating HAART in 2003-2015, we identified DXA procedures and results using procedure codes and natural language processing of radiology reports and clinical notes. We estimated the incidence of DXA scans overall and among high-risk patients and estimated adjusted hazards for DXA with risk factors. Among the subset with baseline and follow-up DXA's, we examined the annual change in T-scores from baseline.
Results: A total of 10,027 patients met eligibility criteria. The mean (SD) age was 50 (10.0), 97% were male, and 31% and 58% were White and African American, respectively. Over an average follow-up of 6.8 years, the incidences of DXA were 26.0 and 31.8 per 1,000 person-years overall and among patients with ≥1 risk factor. Incidences by risk factor and adjusted hazards ratios (HR) are summarized in the table. In general, risk factors increased the likelihood that a patient would be scanned; for example, age 50+ was associated with increased rates of screening in men (HR 1.46, p< 0.0001) and women (HR 3.46, p< 0.0001). However, unadjusted incidences were very small (ranging from 30.8 for prior steroid use to 70.3 for females age 50+). Among patients who received scans at baseline and during follow-up, there was a non-significant adjusted annual T-score increase of 0.15 SD units per year when controlling for age, sex, race, and body mass index.

Risk factor	N (%) of cohort with risk factor	% with DXAs of those with risk factor	Unadjusted incidence per 1000 PY	Adjusted HR (95% CI)	p
Male with age 50+	5150 (551.4%)	19.7%	32.2	1.46 (1.33, 1.61)	<0.0001
Female with age 50+	136 (1.4%)	39.7%	70.3	3.46 (2.60, 4.59)	<0.0001
Prior fragility fracture	169 (1.7%)	20.1%	39.1	0.91 (0.65, 1.28)	0.5917
Steroid use	1872 (18.7%)	19.7%	30.8	1.22 (1.09, 1.37)	0.0007

[DXA scans among 10,027 treated US veterans]

Conclusions: Guideline-recommended DXA screening rates remain very low in the HIV-infected US Veterans. Even though most risk factors were associated with small but significant increases in DXA rates, clinicians may lack awareness of the need to screen high-risk patients. Among the small subset with baseline and follow-up DXA, no significant bone loss could be detected.

WEPEB0510

Staphylococcus nasal carriage and peritoneal dialysis infective outcomes in patients with HIV and end-stage renal failure: a prospective cohort study in two South African hospitals

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Background: Staphylococcal infective complications can cause significant morbidity in HIV-positive dialysis populations. In poorly resourced countries, including those in sub-Saharan Africa, where the HIV is prevalent but access to renal replacement therapy is limited, continuous ambulatory peritoneal dialysis (CAPD) can be a cost-effective option. This study evaluated the effects of HIV infection on the Staphylococcus aureus nasal carriage, staphylococcal peritonitis, and catheter infection rates in patients with end-stage renal failure who were managed using CAPD.
Methods: Prospective cohort study carried out in King Edward VIII and Inkosi Albert Luthuli Central Hospitals, in Durban, South Africa. Follow-up for 18 months, included monthly nasal swabs for Staphylococcus aureus and surveillance for staphylococcal peritonitis (based on clinical presentation, CAPD effluent

staphylococcal culture and white blood cell counts ≥100) and catheter infection (comprising exit-site and tunnel infections) events.
Results: Sixty HIV-positive patients and 59 HIV-negative patients had S. aureus nasal carriage rates of 43.3% and 30.5%, respectively (p = 0.147), while the methicillin-resistant S. aureus (MRSA) nasal carriage rates were 31.7% and 13.6%, respectively (p = 0.018). The S. aureus peritonitis rates were similar in the HIV-positive and HIV-negative cohorts at 0.136 and 0.129 episodes/person-years, respectively, (hazard ratio [HR] 0.96, 95% confidence interval [CI] 0.36-2.60, p = 0.942). The HIV-positive cohort was associated with an increased coagulase-negative staphylococcal peritonitis rate compared with the HIV-negative cohort (0.435 vs 0.089 episodes/person-years; HR 5.27, 95% CI 2.13-13.04, p <0.001). The S. aureus catheter infection rate in the HIV-positive cohort was higher in the S. aureus nasal carriers (0.302 episodes/person-years) compared with the non-carriers (0.036 episodes/person-years) (HR 8.41, 95% CI 1.03-68.74, p = 0.047).
Conclusions: These findings suggest that HIV infection may be a risk factor for MRSA nasal colonization, and that it may increase the risks of coagulase-negative staphylococcal peritonitis and S. aureus catheter infections in association with S. aureus nasal carriage.

WEPEB0511

Low incidence of acute rejection within the six months after renal transplantation in HIV recipients treated with raltegravir: the ANRS 153 Treve trial

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Background: High rates of acute rejection (AR) have been reported during renal transplantation in HIV-infected individuals, probably due to interactions between antiretroviral treatment (ARV), mainly ritonavir-boosted protease inhibitors (PI) and immunosuppressive treatments via the cytochrome P450 system. Raltegravir (RAL) is not a substrate of CYP450 enzymes. We aimed to assess the incidence of clinical AR within the six months after transplantation in HIV recipients treated with ARV including RAL and no PI.
Methods: The ANRS 153 TREVE (NCT01453192) was a multicentre prospective open-label single arm trial in HIV-infected adults with end-stage renal disease, controlled viral load and CD4 count >200/µL, under a three-drug ARV regimen for ≥3 months, with viruses sensitive to RAL, awaiting kidney transplantation. After transplantation, the ARV regimen was based on 3 drugs including RAL and no PI. The trial aimed to demonstrate that the clinical AR rate after transplantation (≥20% increase of serum creatinine plus histology) was < 30%. A blind pathologist reviewed all biopsies.
Time to transplantation, patient survival after transplantation, and allograft survival were compared to a control group of HIV-negative recipients matched on age (±5 years), sex and date of registration on the waiting list (±3 months).
Results: A total of 26 HIV end-stage renal disease participants underwent renal transplantation: 69% were male and 62% were from Sub-Saharan Africa, with median age 48 years and CD4 count 387/µL. AR occurred in 2 participants, leading to an 8% acute rejection rate at 6 and 12 months (Kaplan-Meier estimate, 95%CI: 2-24). One subclinical rejection occurred 10 days after transplantation. HIV infection remained controlled in all patients except one who discontinued ARV transiently.
Median time to transplantation was longer in HIV-infected individuals than in controls (4.3 versus 2.8 years, p=0.002) and was not influenced by blood group. After transplantation, the 3-year survival was 89% in HIV infected individuals and 96% in controls (p=0.197). Three-year allograft survival was 82% in HIV+ and 83% HIV- groups (p=0.991).
Conclusions: After kidney transplantation, ARV including RAL is effective to prevent AR. Patients and kidney allograft survivals are similar to those of HIV negative recipients.

WEPEB0512

Current status of HIV-to-HIV transplants in the United States

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Background: The HIV Organ Policy Equity (HOPE) Act allows transplantation using organs from HIV+ donors for HIV+ recipients in the United States. We evaluated the safety and efficacy of kidney and liver transplantation from HIV+ deceased donors, including those with false positive (FP) HIV antibody (Ab) or nucleic acid tests (NAT).
Methods: HIV+ transplant candidates without active opportunistic infections (OI) on antiretroviral therapy (ART) with CD4 >200 (kidney) or >100 cells/ul (liver) were eligible. HIV+ donors with any HIV RNA and CD4 count were allowed as long as effective ART in the recipient was described. FP donors had discordant HIV Ab/qualitative NAT results and no HIV history; FP status was confirmed by quantitative NAT (Abbott).
Results: Between March and December 2016, there were 3 HIV+ donors (Table1) resulting in 5 transplants (4 kidneys, 1 liver) and 6 FP donors resulting in 15 transplants (9 single-kidney, 1 double-kidney, 4 livers, 1 simultaneous-liver-kidney). FP donors were Ab positive/NAT negative (n=4) or Ab negative/qualitative NAT positive (n=2); all were quantitative NAT negative. No episodes of death, graft failure, or HIV breakthrough have occurred in recipients to date (Table2).

Characteristic	Donor 1	Donor 2	Donor 3
Age (yr)	35	46	31
Race	Caucasian	African American	African American
Sex	Female	Female	Female
Cause of death	Drug Intoxication	CVA/Stroke	Cardiovascular
Organs recovered	Liver, 1 kidney	2 kidneys	1 kidney
Most recent HIV RNA (copies/mL)	<20	475	140
Most recent CD4 (cells/mm^3)	1683	1533	190
Antiretroviral therapy	DTC 3TC DRV^R	TDF FTC ATV^r	FTC+TAF ATV/c

[Table 1. HIV-Positive Donors in US]

HIV-Positive Recipients	
Characteristic	**N = 20**
Age, years, median (range)	53 (26-66)
Female, N (%)	7 (35)
Race, N (%)	
White	2 (10)
African American	14 (70)
Hispanic	3 (15)
Asian	1 (5)
Length of follow up, months, median (range)	4 (1-10)
Undetectable HIV VL at 3 months, N (%)*	8 (100)
CD4 count at 3 months, cells/mm^3, median (range)*	425 (119-651)

*12 recipients have not yet reached 3 months

[Table 2]

Conclusions: We report the first HIV+-to-HIV+ transplants in the United States under the HOPE Act. These cases provide proof-of-concept that organs from HIV+ donors can increase access to transplant providing a public health benefit for everyone on the waitlist and in particular for HIV+ candidates with high waitlist mortality. In addition, the use of organs from donors with FP HIV tests has emerged as an unexpected benefit of the HOPE Act.

WEPEB0513

Optimizing care and improving outcomes in HIV+ kidney transplant recipients

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Background: Kidney transplantation (KT) has increased over the last decade due to a longer life expectancy of HIV+ patients since the introduction of antiretroviral (ARV) treatment. Controversies remain regarding optimal management.
Methods: All KT performed on HIV+ recipients at Duke University were reviewed (2009-2016). Our primary aim was to compare HIV+ KT recipient mortality and graft survival rates against national statistics from UNOS (United Network for Organ Sharing) and data from the literature. Secondary outcomes included comparing HIV and transplant management strategies, rejection rates, and immunologic indices.
Results: 15 KT in HIV+ recipients had been done between 2009-2016, 14 were reviewed. 71.4% were males, with a median age of 48.5 years, 100% were African-American. The underlying diseases were as follows: HIV-AN 64%, hypertension 50%, diabetes 14% and PCKD 14%. 21.5% had a detectable hepatitis C PCR, 7.1% were HBsAg positive. 21% had a history of prior opportunistic infections, the median CD4 count before KT was 512(IQR 382-853). All patients had an undetectable HIV viral load when transplanted. ARV regimens varied: PI-based 29%, NNRTI based 36%, PI and NNRTIs 14%, Nucs 93% and INSTIs 93%. Induction therapy was performed with basiliximab (71%) or thymoglobulin (36%), whilst maintenance immunosuppression consisted of tacrolimus, mycophenolate mofetil and prednisone in all cases. Significant CD4 suppression occurred, especially in the thymoglobulin cohort, yet no postransplant OIs were recorded. 1 patient had acute cellular rejection treated successfully. Delayed graft function (DGF) was observed in 8 patients (57%). Viremia and ARV resistance occurred in only 1 patient, due to poor compliance. All grafts are functional and all patients are still alive to date.
Conclusions: The number of patients with well-controlled HIV, yet chronic renal failure is expected to increase worldwide. This data supports very favorable outcomes of KT in HIV+ recipients. Despite higher rates of DGF, graft and patient survival at one year are comparable to HIV-negative KT rates nationally, and exceed historical HIV-positive comparators. We postulate this is due to a better understanding of the interactions between ARV and immunosuppressive drugs, as well as the broader availability of INSTIs. KT should be considered a life-prolonging therapy for selected HIV+ recipients.

WEPEB0514

Prevalence of and risk factors for low bone mineral density in Spanish treated HIV patients

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Background: There are few published data on bone mineral density (BMD) in the post-HAART era in geographic very sunny areas. Although several studies implicate antiretroviral therapy in the pathogenesis of low BMD, others have not confirmed this association. In this study we analyzed the impact of HIV status, traditional risk factors and antiretroviral therapy in BMD.
Methods: We performed a cross-sectional analysis of 107 individuals infected with HIV and exposed to antiretroviral treatment to estimate prevalence of decreased BMD. Bone mineral density of lumbar spine or femoral neck was measured by dual-energy X-ray absorptiometry. Variables included in a multivariate analysis included HIV status, antiretroviral drugs and traditional risk factors.
Results: Low BMD was diagnosed in 48 participants (44.9%). Factors associated with decreased BMD in the multivariate analysis were an increasing age (b-0.008, p 0.001), a treatment based on IP/r and TDF (b-0.181, p 0.001 in lumbar spine and b-0.083, p= 0.038 in femoral neck) like have been exposed to TDF (b-0.108, p=0.008 in lumbar spine and b-0.122, p=0.004 in femoral neck).
In addition other factors like the intravenous drug users HIV transmission group (b+0,162, p=0,001 and b+0.117 and p=0.003 homosexual and heterosexual versus intravenous drug users respectively) and consumption of 3 alcohol units (b-0.106, p=0.008) were related to a decreased BMD at lumbar spine; while a lower BMI (b-0.007, p=0.037) was related to a decreased BMD at the femoral neck.
Conclusions: In the multivariate analysis we found that the antiretroviral regime based on PI/r and TDF, and the previous exposure to TDF was associated with decreased BMD.

WEPEB0515

Prevalence and risk factors of hypogonadism in HIV-infected young/middle-aged men on effective antiretroviral therapy

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Background: Male hypogonadism (MH) is poorly defined in people living with HIV (PLHIV). Using a reliable free-testosterone (FT) assay, we examined the prevalence and risk factors of MH among PLHIV on effective antiretroviral therapy (ART).
Methods: The total Testosterone level is affected by altered sex-hormone-binding globulin (SHBG) levels in PLHIV, in whom FT measurement is recommended to diagnose MH. Given the limitations of previous studies, we conducted a prospective cross-sectional study, using a reliable FT assay, to determine the prevalence and risk factors of MH in asymptomatic men (no AIDS event), < 50 years old, treated with cART with HIV-RNA ≤ 50 copies/mL. FT was measured twice in the morning. MH was defined as an average serum FT < 70 pg/mL, calculated with the Vermeulen equation. Sociodemographic, anthropometric, bone-densitometric, hormonal, immunovirological, metabolic and therapeutic parameters were collected. The International Index of Erectile Function-5 (IIEF-5) score was used to evaluate erectile function.
Results: We included 250 patients, median age 43 years (IQR 36-47). Median time since HIV diagnosis was 8 years (IQR: 4-13) and median CD4 cell count was 623/mm^3 (IQR: 493-764). The average FT was low (< 70 pg/mL) in 20 patients (8.4%) and SHBG was increased in 119 patients (48%). At inclusion, 236(94.4%), 116(46.4%), 98(39.2%), 54(21.6%) patients were treated by a combination containing NRTI, NNRTI, PI or INSTI respectively. Patients who received no NRTI had a longer median time since HIV diagnosis and more lines of treatment. In multivariate analysis, parameters associated with MH were: an age > 43 years (ORa 3.08, 95% CI 0.98-9.64; p=0.05), a percentage of total fat > 19% (ORa 3.01, CI 95% 1.02-8.84; p=0.05), to receive efavirenz (ORa 4.67, CI 95% 1.55-14.11; p< 0.01) and a nadir of CD4 cell count > 200/mm3 (ORa 0.32, CI 95% 0.11-0.94; p=0.04), to receive nucleoside reverse transcriptase inhibitors (NRTI) (ORa 0.18, CI 95% 0.04-0.94; p=0.04).
Conclusions: In this study, the prevalence of MH is twice the rate reported in the general population of the same age. The three thresholds - the age of 43, 19% total body fat and taking efavirenz - might help to identify patients at increased risk.

WEPEB0516

Increased risk of overweightness and obesity after HCV clearance in patients co-infected with HIV and hepatitis C virus (HCV) (ANRS CO13-HEPAVIH cohort)

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Background: Chronic infection with hepatitis C virus (HCV) in people living with HIV is often associated with systemic inflammation and comorbidities. Although curing HCV can decrease the burden of some comorbidities, overweightness and obesity are important clinical proxies of increased risk of diabetes and other metabolic disorders and constitute an emerging issue in this population. This study aimed to estimate the evolution of overweightness and obesity in HIV-HCV co-infected

patients enrolled in a multicenter prospective cohort, and also the impact of both HCV clearance and time-dependent behavioral factors on patients' body mass index (BMI).
Methods: This longitudinal study used data from the French multicenter cohort ANRS C013-HEPAVIH, which included clinical (medical records updated during follow-up) and socio-behavioral (annual self-administered questionnaires) characteristics. The study sample included patients who completed at least one self-administered questionnaire during follow-up. The outcome „overweightness or obesity" was defined as a BMI ≥ 25 kg/m^2 (annual measures). A mixed logistic regression model helped identify clinical and socio-behavioral factors associated with the outcome in this population.
Results: The analysis included 1,046 patients aged 19 to 80 years old. The prevalence of overweightness and obesity was 18% at cohort enrolment, and 27% in those still followed-up after five years (n=312). In the multivariable analysis, adjusted for both fixed (gender, antiretroviral therapy (ART) duration at cohort enrolment) and time-dependent (time of follow-up in years, HCV clearance, cannabis use) variables, the interaction between follow-up time and HCV clearance post interferon-based treatment was significant, showing an increased risk of overweightness and obesity over time after clearance, with an adjusted odds ratio [95% confidence interval] of 1.74 [1.00 - 3.02] per year.
ART duration at enrolment (0.91 [0.87 - 0.96] per year), female gender (0.42 [0.25-0.71]) and cannabis use (0.22 [0.08 - 0.61]) were independently negatively associated with overweightness and obesity.
Conclusions: Our results suggest that after HCV clearance, HIV-infected patients are at risk of overweightness and obesity. This risk is 50% and 80% lower in women and cannabis users, respectively. Sustained monitoring of HIV-HCV co-infected patients, even after clearance, is needed to control the risk of overweightness and metabolic disorders.

WEPEB0517

Factors influencing time to viral suppression of HIV patients on antiretroviral therapy in a resource-limited setting of Rakai district, Uganda

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Background: The objectives of the study were to determine factors influencing patients' response to antiretroviral treatment by modeling time from start of treatment to viral suppression for patients enrolled in rural Rakai district, Uganda, the average time in months to viral suppression, the effect of different types of regimens, the influence of other co-infections like Hepatitis B and Tuberculosis, the initial levels of CD4, the effect of some demographic factors and how opportunistic infections affect the time to viral suppression.
Methods: We used secondary data from viral load results and other clinical tests from Rakai district of Uganda, We determined time from the start of medication to viral suppression using clinical dates among 1,954 non-hospitalized patients on ART and at least 10 years from 2006 to 2011. Using the Shared Frailty regression model, we assessed factors influencing time to viral suppression, including viral load test results, Initial CD4 count, Hepatitis B and TB co-infections while controlling for demographics (Age at start of medication, Sex), and Risk factors. We also used the Kaplan-Meier curves to compare the survival curves for the time to viral suppression between groups and the Log Rank tests as a procedure to compare the curves.
Results: The average time to viral suppression was 8.9 months with a standard deviation of 6.7 and a range of 65.3. Patients with lower CD4 levels took a longer time to viral suppression. Additionally the rate of recovery for female patients is 0.4 time that of men. RR=0.4, (95% CI, 0.2 - 0.8; P = 0.01). Patients treated of more concomitant infections experienced a shorter time to viral suppression. For example, patients treated of five co-infections had 0.1 times a recovery rate compared to those treated of none. RR=0.1, (95% CI, 0.0 - 0.3; P = 0.00). On the other hand, Hepatitis B, TB, age groups, alcohol and the most commonly used drug combinations were not statistically significant to estimate time to viral suppression.
Conclusions: Like in the developed world (H. Irene, 2013), early linkage to care and treatment of more side infections were associated with faster time to viral suppression..

WEPEB0518

HIV and the dual burden of malnutrition in Senegal, 1994-2012

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Background: Both undernutrition and overnutrition are associated with negative health outcomes among people living with HIV (PLHIV). The aims of this study were to determine the nutritional status of HIV-positive versus HIV-negative adults, to identify differences in the nutrition transition according to HIV status, and to identify predictors of nutritional status among PLHIV.
Methods: We conducted a retrospective study using data from individuals enrolled in previous studies in outpatient clinics in Senegal from 1994-2012. Undernutrition was defined as BMI < 18.5 and obesity as BMI ≥30.0. Logistic regression was used to identify predictors of nutritional status.
Results: We analyzed data from 2448 adults, 1772 were women (72%) and 1471 (60%) were HIV-1 and/or HIV-2 positive. Among PLHIV, the median CD4 count was 282; 24% were on ART. The prevalence of undernutrition among PLHIV decreased from 52% in 1994-1999 to 37% in 2006-2012 and in HIV-negative persons undernutrition decreased from 23% to 5%. The prevalence of obesity among PLHIV increased from 3% in 1994-1999 to 5% in 2006-2012, while among HIV-negative individuals obesity increased from 6% to 22%.
Women had substantially greater odds of obesity (OR 11.4, 95% CI 4.1-31.6; p<0.01), while men had greater odds of undernutrition (OR 3.2, 95% CI 2.6-5.0; p<0.01).
Among HIV-positive women, undernutrition was associated with WHO stage 3 or 4 (OR 3.4; p<0.01), CD4 count <200, (OR 2.4; p<0.01), and lack of education (OR 1.4; p=0.04). Obesity was associated with age>35 (OR 4.0; p<0.01), commercial sex work (OR 3.5; p<0.01) and alcohol use (OR 2.2; p<0.01).
Among HIV-positive men, the strongest predictors of undernutrition were WHO stage 3 or 4 (OR 3.2; p<0.01), CD4 count <200, (OR 2.2; p<0.01) and lack of ART (OR 6.3; p<0.01).
Conclusions: We discovered that both HIV-positive and HIV-negative individuals in Senegal are suffering from a dual burden of malnutrition. Importantly, we found that HIV-positive women are at substantial risk of obesity and would likely benefit from targeted nutrition programs.
Our study highlights an urgent need for the integration of nutrition interventions into HIV programs in Senegal and sub-Saharan Africa.

WEPEB0519

Does the non-alcoholic fatty liver disease (NAFLD) score predict liver fibrosis progression after hepatitis C virus (HCV) treatment in human immunodeficiency virus (HIV)-HCV co-infected patients?

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Background: Steatosis secondary to NAFLD is associated with progression of liver fibrosis in chronic HCV. We aimed to determine the role of the NAFLD score in hepatic fibrosis progression following HCV treatment in co-infected patients.
Methods: The Canadian Co-infection Cohort is a prospective multicentre cohort of 1,693 co-infected patients from 19 sites in Canada. Liver fibrosis progression (regression) was defined as an increase (decrease) of at least one Metavir stage from pre-treatment as determined by FibroScan or aspartate aminotransferase-to-platelet ratio index (APRI). A multivariate logistic model assessed the association of the NAFLD score (which integrates age, body mass index, hyperglycemia, liver transferases, platelet count and serum albumin) with the odds of liver fibrosis regression. A linear model estimated the relationship between the NAFLD score and the percentage change in APRI (the best available proxy for fibrosis) post-treatment.
Results: Overall, 229 participants (185 men, 44 women) with a median age of 49 years; HCV duration 14 years; baseline APRI 1.0 were included. Of the 245 treatment courses, 71% achieved sustained virologic response (SVR). Between 6 and 24 months post-treatment (median 1.4 years), 5% progressed, 25% regressed and 70% remained stable. In the logistic model, the NAFLD score had no effect on fibrosis

regression; however, SVR and pre-treatment APRI were associated with regression (Table 1). In the linear model, the NAFLD score was associated with increases in APRI post-treatment.
Conclusions: SVR was strongly associated with fibrosis regression post-treatment. A high pre-treatment APRI was predictive of recovery, indicating reduction in inflammation or the greater potential for change. After controlling for confounders, a higher NAFLD score appeared to be associated with increases in APRI post-treatment. Management of fatty liver disease following treatment is essential to achieve optimal liver outcomes after cure. Further validation of the NAFLD score in this population is required.

	Odds of liver fibrosis regression*		Percentage change in APRI post-treatment†	
Variable	Odds ratio	95% C.I.	Coefficient	95% C.I.
SVR status indicator post-treatment	3.74	(1.49 ; 10.21)	-0.80	(-0.97 ; -0.62)
Log of pre-treatment NAFLD score	0.47	(0.03 ; 6.70)	1.12	(0.56 ; 1.69)
Log of pre-treatment APRI score	6.23	(3.48 ; 12.05)	-0.58	(-0.69 ;-0.47)
DAA-based treatment indicator	0.88	(0.38 ; 2.02)	-0.10	(-0.28 ; 0.07)
Genotype 3 indicator	0.91	(0.32 ; 2.46)	-0.06	(-0.30 ; 0.17)
HCV duration (per 5 years) at initiation	1.05	(0.83 ; 1.33)	0.04	(-0.01 ; 0.08)
CD4 count (per 100 units) at initiation	1.04	(0.92 ; 1.16)	-0.00	(-0.03 ; 0.02)
Lipodystrophy prior to treatment	0.52	(0.14 ; 1.71)	0.06	(-0.18 ; 0.31)
Waist circumference (cm) at initiation	1.01	(0.97 ; 1.04)	-0.00	(-0.01 ; 0.00)

* The dependent variable for this model was a binary indicator for fibrosis regression, based on Metavir stage
† The dependent variable for this model was the natural log of the percentage change in APRI from pre-treatment to post-treatment
C.I. = Confidence Interval

[Table 1. Regression models]

WEPEB0520

Occult liver cirrhosis diagnosed by transient elastography is frequent and under-monitored in HIV-infected patients: results of a large-scale screening program

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Background: People living with HIV are at increased risk for liver cirrhosis and liver-related death. Unfortunately, the diagnosis of compensated cirrhosis at a preclinical stage is challenging due to the lack of any physical, laboratory and imaging findings. Therefore, we evaluated the prevalence, predictors and evolution of preclinical compensated cirrhosis, defined as occult cirrhosis (OC), diagnosed by liver stiffness measurement (LSM) on transient elastography (TE).
Methods: Unselected HIV-infected patients underwent a TE examination as part of a routine screening program for liver disease. Patients were classified as:
1) OC (LSM ≥13 kPa and absence of any clinical sign of cirrhosis, including no thrombocytopenia, nor signs of advanced liver disease on ultrasound);
2) clinically evident compensated cirrhosis (LSM ≥ 13kPa with any of the previous signs);
3) non-cirrhotic patients (LSM < 13kPa). Predictors of occult cirrhosis were investigated through multivariable logistic regression analysis.
Results: 749 HIV-infected patients were included. In our cohort, the mean age was 50.3 ± 10.6 years, 77.3% were men, the mean CD4 count was 593 ± 266 cell/mm^3, and 90% were on antiretrovirals. HIV/HCV co-infected individuals comprised 22% of our cohort. Overall, liver cirrhosis was present in 11.1% of cases. OC represented 4.4% of the whole patient population and 36.7% of patients with liver cirrhosis. After adjustments, HIV/HCV co-infection (aOR = 7.0, 95% CI 2.28-21.6; p=0.001), longer duration of HIV infection (aOR=1.01, 95% CI 1.0-1.17; p=0.04) and higher BMI (aOR=1.14, 95% CI 1.05-1.24; p=0.002) were factors independently associated with OC. Over a median follow-up period of 21.9 months (interquartile range 12.0-34.8), 6.1% of patients developed hepatocellular carcinoma or liver decompensation. Importantly, patients with OC had fewer ultrasounds and gastroscopies, than patients with clinically evident compensated cirrhosis (see Table).

	Non-cirrhotic	Occult cirrhotics	Clinically evident cirrhotics	p-value
Ultrasound (n ± SD)	1.27 ± 1.23	1.93 ± 1.82	3.10 ± 1.53	0.005
Gastroscopy (n ± SD)	0.16 ± 0.47	0.33 ± 0.73	1.17 ± 1.43	0.007
Surveillance of cirrhosis	NA	11%	45.7%	0.01

[Characteristics of cirrhosis surveillance]

Conclusions: OC is frequent in HIV-infected patients. Importantly, our study shows that HIV patients with OC are under-monitored as compared to those with clinically evident compensated cirrhosis which can lead to the under-diagnosis of cirrhosis complications. Screening HIV-infected patients by TE may prompt initiation of appropriate surveillance and interventions for an otherwise unrecognized condition.

WEPEB0521

Hepatotoxicity in HIV+ postpartum women initiating efavirenz-containing regimens

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Background: Recently hepatotoxicity in HIV+ pregnant African women initiating efavirenz (EFV), was reported. We assessed the incidence and association of hepatotoxicity i.e. liver enzyme elevation (LEE) in postpartum (PP) women initiating EFV in the PROMISE study.
Methods: In PROMISE 1077BF/FF, HIV+ antiretroviral treatment (ART) naïve pregnant women with CD4≥350 and ALT≤ 2.5 ULN were assigned to antepartum (AP) and PP ART strategies to assess HIV vertical transmission, safety, and maternal disease progression. Sites participated between 4/2011-9/2016. In July 2015, based on the START study, participants were recommended to initiate ART, including EFV. LEE was defined as grade 2 (2.6 - 5.0), grade 3 (5.1 - 10.0), or grade 4 (> 10.0) x ULN ALT elevation. Cox proportional hazards models (ratio (HR), 95% confidence interval (CI)) were run for each covariate and entered in a multivariable model. Covariates included age, BMI, ALT, prior ALT elevation, HBsAg, ART regimen prior to EFV, CD4, country, EFV initiation date, time from delivery to EFV initiation, receipt of EFV prior to delivery, NRTI in regimen, and AP and PP randomized assignments.
Results: Among 3575 women, 2318 (65%) initiated EFV, 2267 (98%) PP. At EFV initiation median age was 29.2 yrs and median CD4 was 625, 62% were not on ARVs, 3% had prior ALT elevation and HBsAg+ was 4% (82/2318). After EFV, 7.3% (170/2318) and 2.5% (59/2318) had ≥grade 2 and ≥ grade 3 LEE PP, respectively; with an incidence of ≥ 3 LEE of 2.2 (95% CI 1.9-2.5) per 100-person years. Most were asymptomatic. In multivariable analysis, older age but not CD4 or HBsAg, was significantly associated with increased risk of grade 3/4 LEE PP after EFV initiation (HR per 5 years 1.35 CI (1.06-1.71) and per 50 cells higher 1.04 (0.986,1.086)), other covariates p≥ 0.14. Events occurred between 1-132 wks PP: 2 maternal deaths associated with LEE occurred at 16 and 25 weeks after EFV-ART.
Conclusions: Greater than 7% of PP women initiating EFV had grade 2 or greater LEE. Late-occurring and asymptomatic hepatotoxicity after EFV occurred. The risk of hepatotoxicity underscores the importance of laboratory monitoring for maternal LEE in ART treatment/PMTCT programs.

WEPEB0522

Incidence of hepatotoxicity among HIV-positive pregnant women initiating efavirenz-based ART through Option B+ in Malawi

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Background: Under Option B+, pregnant women initiate ART with tenofovir/lamivudine/efavirenz (TDF/3TC/EFV) without routine liver enzyme monitoring. Previous studies show conflicting results on whether pregnant women have increased risk for hepatotoxicity on EFV-based regimens. With the expansion of Option B+, evidence on hepatotoxicity incidence and timing is necessary for clinical management and patient well-being.
Methods: HIV positive ART-naïve pregnant women attending a public antenatal clinic in Lilongwe, Malawi in 2015-2016 joined a prospective cohort study. All initiated TDF/3TC/EFV through Option B+. Lab values from the first 6 months on ART (enrollment, months 3 and 6) were evaluated for DAIDS Grade 1 or higher alanine aminotransferase (ALT, ≥50 IU/L). We compared differences in ALT elevations by low CD4 count (< 250cells/μL) and WHO Stages ≥2 with Fisher's exact tests.
Results: At enrollment of 299 women, median age was 26 (range 17-40), median CD4 count was 352 cells/μL (range 11-1099), and 95% were in WHO Stage 1. Elevated ALT prevalence was 0.3% at baseline, 0.4% at month 3, and 7.2% at month 6. The 6-month incidence of elevated ALT was 7.9%. Only 3 women (1.1%) had DAIDS Grade 3 or 4 ALT levels; all 3 were postpartum and not taking other hepatotoxic medications. Of those 3 women, one stayed on TDF/3TC/EFV with resolved ALT levels, one switched to a non-EFV regimen, and one died of fulminant hepatitis despite ART discontinuation (presenting total bilirubin=8.2mg/dL, ALT=7; confirmation bilirubin=18.7, ALT=1937). Low CD4 count was not associated with developing hepatotoxicity (p=0.62). A higher proportion of women in WHO Stages ≥2 developed elevated ALT (13.3%) compared to women in Stage 1 (6.7%), but the association was not significant (p=0.28). Viral hepatitis co-infection status was not available.
Conclusions: A small proportion of women who initiated EFV-based ART during pregnancy developed elevated ALT within 6 months of ART initiation, but all toxicities Grade ≥3 occurred postpartum. Neither low CD4 count nor WHO Stage was associated with hepatotoxicity. Our results do not support routine laboratory monitoring in this population; symptom monitoring is likely reasonable under a public health approach. Further follow-up will elucidate postpartum EFV hepatotoxicity timing among Option B+ women.

WEPEB0523

Liver transplantation for HIV-infected patients with hepatocellular carcinoma (HCC)

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Background: In selected patients with HCC, orthotopic liver transplantation (OLT) is a treatment option with high reported survival rates. Yet, OLT is not available to most HIV-infected patients. This study reports the experience of HIV-infected patients with HCC who underwent OLT.
Methods: HIV-infected patients with HCC were retrospectively identified from 1995-2014 in 47 centers in North and South America, Europe, and Australia. Among a total of 392 patients, 37 subjects with OLT were compared to 124 with other curative therapy (radiofrequency ablation, 58; surgical resection, 54; percutaneous ethanol injection, 12).
Results: Compared to 124 patients with other curative therapy, 37 patients with OLT were younger (50.3 vs. 53.4 years, p=0.038) and had higher Child-Turcotte-Pugh scores (6.8 vs. 5.8, p=0.015), but had similar etiology of HCC (HCV 76%, HBV 22%), frequency of alcohol abuse (19% vs. 22%, p=0.69) and control of HIV infection with HIV RNA < 400 copies/mL in 88% vs.82% (p=0.43) and median CD4+ cell count of 322 vs. 425 per mm3 (p=0.37). OLT patients more frequently had multiple tumors (46% vs. 22%, p=0.004), but frequency of early Barcelona-Clínic-Liver-Cancer (BCLC) stages A&B was similar (76% vs. 71%, p=0.58). Five-year survival in all patients was significantly higher for OLT (85%) compared to RFA (73%), resection (51%) and PEI (14%, p< 0.001, log rank). Survival at 5 years was higher for OLT compared to the other curative treatments, both in BCLC stage A (92% vs. 57%, p=0.006) and BCLC stage B (100% vs. 59%, p=0.044), but not in stages C&D (5-yr, 57% vs. 0%; 3-yr, 76% vs. 49%; p=0.31). Among patients with OLT, 5-year survival was superior in those with HBV vs. HCV infection (100% vs. 85%, p=0.013), but it was similar between BCLC stage A and B (92% vs. 100%, p=0.68) and in those who met Milan criteria (n=28, 78%) and those who did not (n=9, 100%).
Conclusions: For HIV-infected patients with HCC, OLT is a therapeutic option with high survival rates which are superior to radiofrequency ablation and surgical resection. The 5-year survival of 85% compares favorably to reported 5-year survival rates of HIV-negative patients with HCC undergoing OLT of 75-80%.

WEPEB0524

Coffee intake modifies the relationship between alcohol consumption and liver fibrosis in patients co-infected with HIV and hepatitis C virus (ANRS CO13-HEPAVIH cohort)

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Background: Alcohol consumption has a strong dose-response relationship with advanced liver fibrosis in patients co-infected with HIV and hepatitis C virus (HCV). In recent years, coffee intake has been shown to modulate both the effect of ethanol on serum gamma-glutamyl transferase (GGT) activities in alcohol consumers and the risk of alcoholic cirrhosis in patients with chronic diseases. In the context of HIV-HCV co-infection, elevated coffee intake (≥ 3 cups/day) was found to be associated with reduced levels of liver enzymes and lower risk of insulin resistance. This study aimed to analyze whether elevated coffee intake modifies the effect of alcohol consumption on advanced liver fibrosis among co-infected patients.
Methods: We used clinical/biological (medical follow-up) and socio-behavioral data (annual self-administered questionnaires) collected during a five-year follow-up in the French national cohort ANRS CO13-HEPAVIH. Patients with decompensated cirrhosis or history of liver transplant were excluded from the analyses. Hazardous alcohol consumption was defined according to the standard AUDIT-C cut-off values (score ≥4 for men or ≥3 for women). Advanced liver fibrosis was defined at each visit as a FIB-4 value > 3.25. Mixed logistic regression models were used to analyze the interaction between elevated coffee intake (≥ 3 cups/day) and alcohol consumption and its effect on advanced liver fibrosis, after adjustment for statistically significant (p< 0.05) clinical (body mass index, CD4 T-cell count, HCV treatment and ART status) and socio-behavioral (chocolate consumption, employment status, having children) factors.
Results: A total of 1,019 patients, accounting for 2,566 visits, were included in the analyses. At first visit, 34.4% of patients reported hazardous alcohol consumption and 27.5% elevated coffee intake. In the multivariable analysis, elevated coffee consumption was significantly associated with lower risk of advanced liver fibrosis, irrespective of the level of alcohol consumption (AOR [95% CI]: 0.46[0.27; 0.77], p=0.0035 for non-hazardous drinking, 0.37[0.19; 0.74], p=0.0049 for hazardous drinking, ref= non-hazardous drinking and low coffee consumption).
Conclusions: Elevated coffee intake modulates the effect of alcohol consumption on liver fibrosis in HIV-HCV co-infected patients. This confirms the need to systematically take into account coffee intake in the evaluation of liver fibrosis progression in this population.

WEPEB0525

Drug related problems and polypharmacy are common among people living with HIV/AIDS

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Background: Although recent advances in antiretroviral therapy have led to simplified regimens resulting in reduced pill burden, polypharmacy still continues to be a challenge for people living with HIV/AIDS (PLWHA). Determination of DRPs may pave the way to properly manage drug related adverse effects in PLWHA and may in turn improve medical care and costs.
We conducted a study to investigate the incidence of DRPs and polypharmacy in a cohort of PLWHA under treatment.
Methods: A prospective study was performed between September 1, 2015 and September 1, 2016 at Hacettepe University Hospitals Infectious Diseases Outpatient Clinic after the ethical committee approval. Pharmaceutical Care Network Europe Foundation version 6.2 (PCNE V 6.2) classification system was used to classify DRPs, causes, interventions and results of interventions. Chi square, Mann Whitney U and logistic regression tests were used in statistical analysis.
Results: One hundred eighty-one patients were included to the study. The mean age of the study group was 40.4 and 26% were older than 50. Fifty-nine (32.6%) had at least one comorbid condition and 12 (6.6%) had three or more comorbidities. The prevalence of polypharmacy in patients with comorbidity was 66.1% whereas, 12.1% in patients without comorbidity (p< 0.005). DRPs were common in PLWHA receiving polypharmacy (38.9% vs 18.9%) (p< 0.005). Based on PCNE classification, the most common DRPs were ´effect of drug treatment not optimal´ (36.2%) and ´adverse drug event (non-allergic)´ (20.7%). Most common reasons for DRPs were inappropriate drug (20.7%), synergistic/preventive drug required and not given (17.2%), inappropriate combination of drugs, or drugs and food (13.8%) and drug not taken/administered at all (13.8%). DRPs were more prominent with advanced age (46 vs 37 years, p< 0.005), longer duration of antiretroviral therapy (45 vs 27 months, p=0.014), and lower education level (p=0.013). Patients receiving intensive ART (>3 ART drug) had more DRPs in the logistic regression model (OR:8.299, %95 CI: 1,924 - 35.803).
Conclusions: This study shows that DRPs are common PLWHA under treatment. Attending physicians should especially take into account DRPs in older and heavily treated patients. Multidisciplinary team including clinical pharmacists is needed to address DRPs in high risk patients.

WEPEB0526

Abdominal obesity, sarcopenia, and osteoporosis are strongly associated with frailty in the MACS cohort

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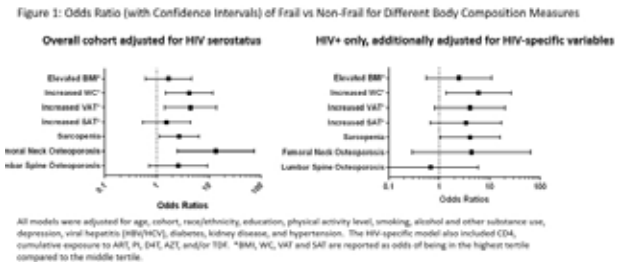
Background: Frailty is more prevalent in HIV-infected (HIV+) adults than in similar HIV-uninfected (HIV-) adults; concurrently, abnormalities in anatomic fat distribution, muscle function/mass, and bone mineral density (BMD) are common among HIV+.
However, the relationships between frailty and fat distribution, sarcopenia, and osteoporosis in older, HIV+ adults are poorly understood.
Methods: HIV+ and HIV- men (50-69 years) in the Multicenter AIDS Cohort Study Bone Strength Substudy were evaluated for frailty (Fried's phenotype) and body composition, including body mass index (BMI), waist circumference (WC), computed tomography-obtained abdominal visceral (VAT) and subcutaneous (SAT) fat volumes, and dual-energy X-ray absorptiometry-obtained appendicular skeletal muscle index (ASMI) and BMD (normal/osteopenia/osteoporosis). BMI, WC, VAT, and SAT were analyzed in tertiles. Baumgartner's definition of sarcopenia (ASMI ≤ 7.26 kg/m^2) was used. Multivariate multinomial logistic regression models determined associations of frailty with body composition.
Results: Of 399 (199 HIV+ and 200 HIV-) men, median age was 60.1 vs 60.0 years and frailty prevalence was 16.1% vs 8.0%, respectively. HIV serostatus was associated with a 2.43 higher odds of frailty (p=0.01). Overall, factors associated with increased odds of frailty included: higher WC, higher VAT, sarcopenia, and femoral neck osteoporosis (figure). In models restricted to HIV+ men and further adjusted for HIV-specific factors, similar trends were observed though some associations lost significance due to reduced sample size (figure). VAT and WC were positively correlated (r=0.63 overall, r=0.56 HIV+, both p<0.0001).



[Figure 1.]

Conclusions: Frailty in HIV+ and HIV- men was strongly associated with measures of visceral abdominal obesity and sarcopenia, but not with BMI or SAT. The association of frailty with WC and the correlations between WC and VAT suggests that, when VAT measurement is not available, WC may serve as surrogate for VAT. Measures to prevent or reverse central obesity and muscle loss may reduce the risk of frailty if these associations are causal.

WEPEB0527

Evolving disease burden at end of life among HIV-infected patients in the southeastern US, 1996-2015

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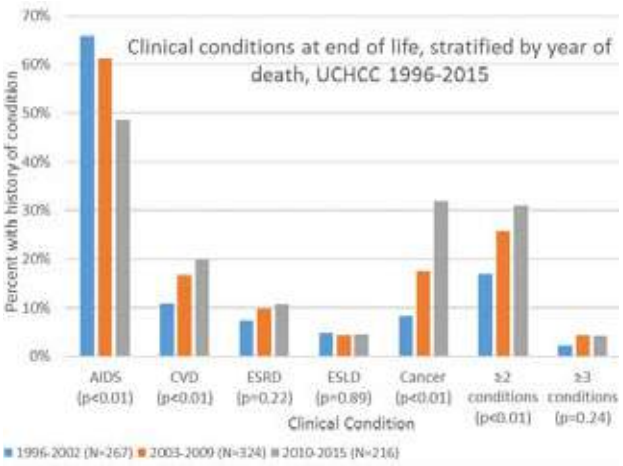
Background: Mortality rates among persons living with HIV (PLWH) have been decreasing. However, little is known about trends in disease burden among HIV-infected patients at the end of life.
Methods: We included patients in the UNC CFAR HIV Clinical Cohort (UCHCC) who died between 1996 and 2015 and had a clinic or laboratory visit < 2 years before death. Analyses were stratified by year of death (1996-2002, 2003-2009, 2010-2015) and patient demographic and clinical characteristics at end of life were contrasted across time using ANOVA and Cochrane-Armitage trend tests. Adjudicated conditions included history of: any AIDS-defining condition, stroke or myocardial infarction (cardiovascular disease, CVD), end-stage renal disease (ESRD), end-stage liver disease (ESLD), and any non-AIDS-defining cancer.
Results: Of 807 deceased patients, 28% were female, 29% men who have sex with men (MSM), and 70% African American (Table).

Characteristic	Total sample (N=807)	Death year 1996-2002 (N=267)	Death year 2003-2009 (N=324)	Death year 2010-2015 (N=216)	p-value
Female, N (%)	223 (28%)	73 (27%)	100 (31%)	58 (27%)	0.47
African American race, N (%)	568 (70%)	195 (73%)	229 (71%)	144 (67%)	0.13
MSM, N (%)	234 (29%)	65 (24%)	97 (30%)	72 (33%)	0.03
HIV RNA<400 copies/mL at death, N (%)	331 (41%)	61 (23%)	125 (39%)	145 (67%)	<0.01
Nadir CD4 count, median cells/mm3 (IQR)	39 (9, 148)	16 (9, 90)	38 (9, 139)	86 (23, 190)	<0.01
CD4 count at death, median cells/mm3 (IQR)	124 (24, 326)	36 (11, 166)	143 (25, 305)	264 (86, 536)	<0.01
Age at death, median years (IQR)	47 (40, 54)	43 (38, 50)	47 (40, 52)	52 (45, 58)	<0.01
Time on ART, median years (IQR)	7 (3, 11)	4 (2, 6)	8 (4, 11)	11 (6, 16)	<0.01

[Clinical and demog. characteristics at end of life]

Most patients (94%) were ART experienced, with median 7 years of ART use (IQR 3, 11). The proportion of MSM and virally suppressed patients increased over time, as did nadir CD4, proximal CD4, age, and ART duration (all p<0.05). Prevalence of AIDS decreased (66 to 49%), while CVD and cancer increased (11 to 20%, and 8 to 32%, respectively) (Figure, all p<0.01). Having 2 or more conditions was also more common in more recent years (from 17 to 31%, p<0.01).



[Clinical conditions at end of life, by death year]

Conclusions: The burden of clinical AIDS at end of life decreased over the study period, while CVD, cancer, and multiple morbidity increased. These findings underscore the need for routine health screening in PLWH.

WEPEB0528

Derivation and internal validation of a mortality risk index for aged people living with HIV: the Dat'AIDS score

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Background: As HIV population is ageing, there is growing interest for specific prognostic tools in aged people living with HIV (PLHIV). The objective was to develop a multivariable prognostic index for 5-years overall mortality integrating classical HIV biomarkers and comorbidities in PLHIV aged 60 or older.
Methods: It was a prospective multicenter cohort study in the Dat'AIDS cohort that involves 12 French hospitals. All HIV-1 infected patients aged 60 years or more actively followed on 1st January 2008 were included. Sociodemographic data, CD4 cell count, CD4 nadir, HIV viral load, history of comorbidities, hepatitis co-infections and laboratory parameters at baseline were considered as potential prognostic variables. The outcome was five-years all-causes mortality. A multivariable Cox model was constructed and a mortality index was derived.
Results: A total of 1415 patients were included. Most patients were male (77.2%) and mean age was 65.7±5.5 years. During the five years of follow-up (6225 patient-years), 154 (10.9%) patients died. Main comorbidities were decreased eGFR (21.1%), diabetes (14.2%), and cardiovascular diseases (12.2%). We derived a score comprising the following predictors: Age (65 - 74: 1 point; ≥75: 8 points), CD4 cell count (200 - 349: 3 points; < 200: 6 points), non-HIV related cancer (6 points), cardiovascular disease (8 points), estimated glomerular filtration rate (30-59 ml/mn/1.73m^2: 5 points; < 30ml/mn/1.73m^2: 16 points), cirrhosis (13 points), low body mass index (10 points), anemia (6 points). Observed score was 7.0 ± 8.0 and ranged from 0 to 45. It allowed to define 4 risks groups for mortality: low risk (0-3 points), moderate risk(4-13 points), high risk (14-19 points) and very high risk (>19 points; 5-year survival probability 0.95 (95%CI [0.93 - 0.97]), 0.90 (95%CI [0.87 - 0.92]), 0.77 (95%CI [0.68 - 0.84]) and 0.54 (95%CI [0.43 - 0.63]) respectively). That score showed good discrimination (c-statistic=0.76) and calibration.
Conclusions: We propose a multivariable prognostic score for mortality among PLHIV aged 60 or over, that will be a predominant population in the future years in western populations. It would be a useful tool for research and for risk assessment by the clinician. External validation is required.

WEPEB0529

Slowing the premature aging process: the benefits of viral control and smoking cessation on leukocyte telomere length (LTL)

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Background: Telomeres shorten over lifespan, and shorter leukocyte telomere length (LTL) is a marker of cellular aging associated with age-related physical morbidities, cognitive aging, and mortality. HIV infection and smoking are both associated with LTL cross-sectionally, but their influence on LTL over time is unclear. This study investigated the relative contribution of HIV and smoking on LTL dynamics in people living with HIV.
Methods: All non-pregnant girls and women ≥12 years old enrolled in the CARMA cohort with available blood specimens were included. For those with >1 sampling ≥1 year apart, the latest specimens were included in longitudinal sub-analyses. LTL was measured by multiplex qPCR. Possible predictors including age, ethnicity, smoking (current, past, never), HIV/viral load (VL) status (HIV-, HIV+/detectable VL, HIV+/undetectable VL), peak VL, and Hepatitis C virus status were considered for inclusion in multivariable models.
Results: LTL was obtained for 287 HIV+ and 211 HIV- participants aged 12-78 years, including 199 HIV+ and 49 HIV- with two specimens 1.0-7.9 years apart. In a cross-sectional multivariable regression, shorter LTL was associated with older age (ß=-0.35, p< 0.0001), current smoking (ß=-0.18, p=0.001) vs. never, and HIV+/detectable VL (ß=-0.13, p=0.004), but not HIV+/undetectable VL (ß=-0.06, p=0.17) vs. HIV-, after adjusting for ethnicity (n=450, R^2=0.25). These results persisted in sensitivity analyses that either excluded ethnicity, restricted ethnicity to the largest group, or restricted age to ≥16 for consideration of smoking status. Longitudinally, LTL attrition rates were greater with current smoking (ß=-0.20, p=0.004) vs. never, but not associated with baseline HIV/VL status, after adjusting for baseline LTL (n=246, R^2=0.11). HIV+ participants with detectable VL who became undetectable at follow-up were more likely to show an increase in LTL and vice-versa (n=57, Fisher's exact test, p=0.043).
Conclusions: These analyses highlight the negative impact of current smoking on LTL, with an effect size larger than even uncontrolled HIV infection. These data suggest that LTL is better preserved in controlled HIV, and stress the importance of smoking cessation and controlling viremia to curb cellular aging.

WEPEB0530

Mutlimorbidity prevalence in South Brazilian HIV cohort (SoBrHIV) and comparison with non-HIV controls: a cross-sectional study

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Background: HIV has become a chronic disease with the use of cART, and life expectancy is quite similar to general population. However, as HIV population ages, non-AIDS related comorbidities are increasingly being reported, which directly interferes with the clinical management of the patient and further enhances morbimortality. The objective of our study was to describe disease burden in a South Brazilian HIV cohort (SoBrHIV) and compare with general population.
Methods: In a cross sectional study, HIV patients (n=78) over 50 years of age and a control group matched by age, race and sex were randomly selected at the Hospital de Clínicas de Porto Alegre Outpatient clinic, in a ratio of 1:1. Prevalence of multimorbidity (defined as the presence of at least 2 non-AIDS related comorbidities)

and individual non-infectious comorbidities were compared using chi-square test. The mean number of chronic diseases was compared using t student or non-parametrical tests. The study was approved by local ethical committee.
Results: The groups were comparable, median age was 57 years, 75% were from Caucasian ethnicity and 57% were men. Prevalence of renal, bone and hepatic disease, as well as multimorbidity, was higher in the HIV group. (Table 1).

	HIV	Non-HIV	p value
Osteopenia/osteoporosis	51.3%	10.4%	0.0001
Hypertension	66.7%	75.3%	0.235
Diabetes Mellitus	24.4%	27.3%	0.679
Cardiovascular disease	8,9%	12,7%	0.4
Renal disease	17.9%	9.1%	0.107
Hepatic disease	17.9%	6.5%	0.03
Lipid abnormalities	85.9%	81.6%	0.467
Multimorbidity (presence of at least 2 non-AIDS comorbidities)	85.9%	76.6%	0.139

[Prevalence of non-AIDS comorbidities]

The mean number of comorbidities was also higher, even when comparing with individuals about 10 years older in the control group. (table 2)

Mean nº of comorbidities	HIV	Non-HIV	p value
Total	2.88	2.31	0.003
51-55 years	2.81	1.84	0.001
56-60 years	2.83	2.62	0.601
61-65 years	2.76	2.44	0.426
>65 years	3.36	3.00	0.369

[Mean number of comorbidities across ages]

Conclusions: This is the first time that a high level of comorbidities is shown in a low/middle income country. Moreover, multimorbidity occurred more often and at younger ages in HIV patients. These initial results are extremely important. They imply that the world will need to build up a more comprehensive care of HIV individuals in order to better deal with their ageing.

WEPEB0531

The growth hormone releasing hormone analogue, tesamorelin, decreases muscle fat and increases muscle area in HIV-infected adults

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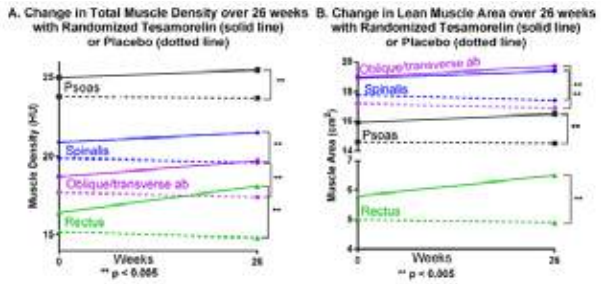
Background: HIV-infected adults have faster physical function decline with aging and a greater amount of muscle fat compared to HIV-uninfected controls. Muscle fat correlates with visceral adipose tissue (VAT) quantity, and is associated with physical function impairment and falls in older populations. Tesamorelin, a growth hormone-releasing hormone analogue, is effective in decreasing VAT in some HIV-infected patients. We hypothesized that tesamorelin would also decrease skeletal muscle fat.
Methods: Participants were selected from two completed, randomized (2:1) trials of tesamorelin vs placebo for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. In tesamorelin responders (defined as VAT decrease of ≥8% and observed in ~70% receiving tesamorelin), and participants in the placebo arm, abdominal (L4-5) computed tomography scans at week 0 and 26 were re-analyzed. Between arm differences were compared for trunk muscle density and area (both total muscle and lean component [excluded intermuscular fat with < 30 Hounsfield units]).
Results: Of 193 tesamorelin responders and 148 persons randomized to placebo, participants were mostly male (87%) and Caucasian (83%). Groups were not significantly different (p>0.10) at baseline in regards to sex, race/ethnicity, age, body mass index, use of lipid-lowering therapy, testosterone use, CD4 T-cell count or HIV-1 viral load, ART regimen, or time since HIV diagnosis. Tesamorelin was associated with significantly greater improvements in total muscle density (less fat), and lean muscle area of the trunk muscle after 26 weeks compared to placebo (Figure; p<0.005). Lean muscle density of the oblique/transverse abdominal and rectus, and total psoas muscle area also increased significantly more in the tesamorelin vs placebo arm (p<0.005).



[Figure]

Conclusions: In HIV-infected adults with excess abdominal fat who have a clinical response to tesamorelin, trunk muscle fat decreased and lean muscle area increased over 26 weeks. The impact of these changes on physical function and long-term durability should be investigated.

WEPEB0532

Impact of the method of measurement (Southern Blot vs qPCR) in the analysis of factors associated with telomere length in HIV-infected patients

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Background: Southern blot has been traditionally used to asses telomere length (TL). Because its complexity, qPCR is used as an alternative (Cawthon RM.2009, Elbers CC et al.2014). We have compared both methods in the study of factors associated to TL in HIV-infected patients.
Methods: Cross-sectional study of HIV-infected patients with suppressed virological replication (HIV RNA < 50 copies/mL for ≥1 year). TL was measured in peripheral blood mononuclear cells using qPCR and Southern. Relative TL was determined by qPCR and run each sample in triplicate. Southern was done using TeloTAGGG™ TL Assay. TeloTool (Gohring J.2014) was used to process Southern images. Multivariate generalized linear models with Gaussian family and log link were used to identify variables independently associated with TL.

Variable	qPCR		Southern Blot	
	exp(β) (95%CI)	p-value	exp(β) (95%CI)	p-value
Age (vs. <45 years)				
45-50	0.90 (0.83-0.98)	0.012	0.86 (0.80-0.93)	<0.001
>50	0.85 (0.79-0.92)	<0.001	0.83 (0.78-0.89)	<0.001
Father's age (per year)	1.004 (0.999-1.009)	0.096	1.003 (0.998-1.008)	0.196
Mother's age (per year)	1.004 (0.999-1.009)	0.160	1.001 (0.96-1.006)	0.668
Sex (female vs. male)	1.04 (0.97-1.11)	0.297	1.03 (0.97-1.10)	0.334
Race (others vs. caucasian)	1.16 (1.03-1.31)	0.015	1.07 (0.94-1.21)	0.289
Transmission (vs. sexual)				
Parenteral	0.99 (0.93-1.06)	0.775	1.05 (0.99-1.12)	0.132
Unknown	0.99 (0.82-1.20)	0.940	1.01 (0.84-1.21)	0.898
Ever IDU (yes vs. no)	0.97 (0.90-1.03)	0.314	1.01 (0.94-1.08)	0.793
Education (vs. primary)				
Secondary	1.05 (0.97-1.13)	0.238	0.96 (0.89-1.03)	0.229
University	1.03 (0.96-1.12)	0.419	0.96 (0.89-1.03)	0.248
Income (higher vs. lower)	0.96 (0.90-1.02)	0.223	0.95 (0.90-1.01)	0.108
Tobacco (pack-years vs.0)				
1-21.5	0.92 (0.85-1.00)	0.038	0.94 (0.87-1.02)	0.133
>21.5	0.92 (0.85-1.00)	0.054	0.92 (0.85-0.99)	0.034
Alcohol (gr-years vs. 0)				
1-163	0.97 (0.90-1.05)	0.467	0.93 (0.87-1.01)	0.074
>163	1.00 (0.92-1.07)	0.897	0.97 (0.91-1.05)	0.488
HCV coinfection (vs. no)				
Active	0.99 (0.91-1.07)	0.735	1.02 (0.94-1.10)	0.690
Past	0.98 (0.90-1.06)	0.612	1.00 (0.93-1.09)	0.904
CD4 nadir (vs. <150 cells/µl)				
150-200	1.00 (0.93-1.09)	0.938	0.93 (0.86-1.00)	0.058
>200	1.01 (0.93-1.10)	0.815	0.92 (0.85-1.00)	0.044
Unknown	1.07 (0.92-1.25)	0.388	0.94 (0.81-1.10)	0.446
AIDS stage (yes vs. no)	0.95 (0.89-1.01)	0.096	1.04 (0.98-1.10)	0.212
Time with HIV (vs. <10 years)				
10-20	0.82 (0.75-0.89)	<0.001	0.93 (0.84-1.02)	0.118
>20	0.85 (0.77-0.92)	<0.001	0.93 (0.85-1.03)	0.148
Time on ART (vs. <10 years)				
10-20	0.89 (0.82-0.95)	0.001	0.95 (0.88-1.03)	0.206
>20	0.85 (0.76-0.95)	0.006	0.94 (0.84-1.06)	0.317
Time on NRTIs (vs. <5 years)				
5-10	0.96 (0.86-1.06)	0.420	0.99 (0.89-1.11)	0.920
10-15	0.90 (0.82-1.00)	0.041	0.97 (0.87-1.07)	0.529
>15	0.89 (0.80-0.98)	0.020	0.96 (0.88-1.06)	0.639
Tenofovir (yes vs. no)	0.96 (0.90-1.03)	0.238	0.97 (0.91-1.03)	0.307
Exposure to PIs (yes vs. no)	0.92 (0.86-1.00)	0.036	0.98 (0.91-1.04)	0.689
Time on PIs (vs. <5 years)				
5-10	0.96 (0.88-1.04)	0.331	0.98 (0.90-1.07)	0.697
10-15	0.95 (0.86-1.05)	0.331	1.00 (0.90-1.11)	0.950
>15	1.03 (0.94-1.14)	0.506	0.97 (0.87-1.08)	0.561

[Table 1. Univariate results for the association of independent variables and telomere length: exponentiated regression coefficients and 95% Confidence Intervals.]

Results: 200 patients included, 72% male, median age 49(IQR 45-54.5). In the univariate analysis, only age was associated with TL with both methods. Assuming results from qPCR, non-caucasian race, longer time of known HIV-infection and longer time on ART were associated with TL. However, with Southern these associations were not statistically significant, but higher CD4 count nadir and tobacco resulted associated, which had been non-significant when analyzed with qPCR. In the multivariate analysis significant predictors of TL, assuming qPCR results, were older age, older parental age at birth, non-caucasian race, and longer time of known HIV-infection. When using Southern, only older age and AIDS stage resulted independently associated to TL.
We compared the assays and we found no correlation between qPCR and Southern (R^2=0.077). The inter-assay coefficient of variation for qPCR was 8.75% and for Southern was 17.1%.
Conclusions: Risk factors for shorter TL in HIV patients were discordant depending on the method used for TL measurement. Southern blot results were less consistent that those obtained by qPCR. Inter-assay variability of Southern blot could play a role in the results we obtained.

WEPEB0533

Risks for COPD in HIV-infected individuals using symptom-based scores and spirometry

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Background: Pulmonary complications are a significant source of morbidity in HIV-infected persons. Due to improved HIV infection treatment and high levels of smoking, chronic non-infectious respiratory co-morbidities have become prevalent among HIV-infected patients. Obstructive lung disease occurs in 7-9% of HIV+ persons, but a third of patients report respiratory symptoms. This project aims to define the relationship between symptom-based scores and pulmonary function tests, chest imaging, tobacco exposure and HIV disease severity.
Methods: HIV-positive and HIV-negative participants over age 30 who are current smokers with at least a 15 pack-year smoking history were enrolled. Pulmonary function tests were performed to assess for obstructive defect. St. George's Respiratory questionnaires (SGRQ) were administered and served as the primary source for symptom-based data. CT scans were performed to evaluate for underlying lung disease. All patients underwent basic demographic data collection as well as HIV disease specific information, including CD4 count and HIV viral load.

Parameter	HIV +	HIV –	p-value
Demographic Characteristics			
N	75	38	
Age, year	49.1 ± 8.0	56.1 ± 7.0	<0.001
Male, (%)	57 (77.3%)	24 (63.2%)	
African American (%)	60 (80%)	29 (76.3%)	
BMI	27.1 ± 6.0	28.8 ± 5.0	0.119
Respiratory Status			
Smoking Pack Year	75 (100%) 27.3 ± 17.9	38 (100%) 46.4 ± 14.4	<0.001
FEV1 % Pred	95.9 ± 15.0	88.3 ± 25.0	0.102
DLCO % Pred	58.3 ± 12.3	56. ±14.4	0.548
FEV1/FVC	0.79 ± 7.5	0.72 ± 13.6	0.008
<0.70 FEV1/FVC	9 (12%)	12 (31.6%)	
SGRQ			
Total	27.1 ± 19.9	28.5 ± 25.4	0.770

[Respiratory status in HIV+ and HIV- individuals]

Results: This study included 75 HIV-infected patients and 38 HIV-negative controls. HIV-infected patients had lower tobacco exposure than HIV-negative patients (27.1 versus 46.4 pack-years), were younger (49.1 ± 8.0 vs 56.1 ± 7.0), and had less obstruction as demonstrated by higher FEV1/FVC ratio. Despite this, symptom-based scores were similar (26.9±20.7 vs 28±25.4, p>0.05), suggesting symptomatology may be a result of complex interactions between smoking, HIV, and COPD. Within the HIV-infected population, SGRQ scores were found to be most associated with pack year smoking history. Decreased FEV1/FVC ratio was associated with age, suggesting that the prevalence of clinical obstruction is likely to increase as overall survival improves.
Conclusions: This study underlines the importance of long-term study in the smoking, HIV-infected population in order obtain a better understanding of the role of HIV, tobacco, and aging in respiratory symptoms and the development of chronic respiratory co-morbidities.

WEPEB0534

HIV-DNA burden in central memory CD4 T cells prior to ART initiation dictates immune recovery

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Background: Despite antiretroviral therapy (ART) fully suppress HIV replication, immune dysfunction - including incomplete recovery of CD4 T-cells - inflammation, and HIV persistence endure for many individuals. Based on a large set of preliminary data, we hypothesized that differential infection of specific CD4 T-cell subsets could further explain divergent CD4 recovery and maintenance of the HIV reservoir during ART.
Methods: 30 HIV-positive individuals were enrolled. Immunologic responders (IR) were defined as having CD4 counts >500 cells/μL ≤2 years after ART initiation; Immunologic non-responders (INR) as having CD4 counts < 350 cells/ μL up to 2 years after ART initiation. Before and during ART, the frequency of total (T) and integrated (I) HIV-DNA was measured in sorted blood naïve, central (CM), transitional (TM), and effector memory CD4 T-cells. T-cell levels, activation/proliferation states, and expression of co-inhibitory receptors (Co-IRs) were analyzed by flow cytometry.
Results: Median age of the cohort was 46; 90% were male and 82.8% were African-American. T and I HIV-DNA content in all CD4 T-cell subsets were significantly higher (P< 0.01) prior to ART and on-ART in INR than IR. The increased HIV-DNA content in INR was associated with higher levels of T-cell proliferation and activation, both at pre- and on-ART (P< 0.05). Expression of Co-IRs such as: PD-1 and TIGIT was significantly increased in memory CD4 T-cells of INR (P< 0.05), with the frequency of these Co-IR-expressing T-cells correlating with levels of I HIV-DNA. HIV-DNA contents in IR were significantly reduced (P< 0.01) on-ART as compared to pre-ART in all CD4 T-cell subsets. Remarkably, INR T and I HIV-DNA levels were significantly more stable in CM and TM CD4 T-cells between pre- and on-ART, and despite INR have been on-ART longer than IR.
Conclusions: When compared to IR, INR demonstrate higher levels of T-cell activation, Co-IRs expression, and viral burden in all memory CD4 T cell subsets, both prior to and on-ART. Furthermore, CM and TM CD4 T-cells harboring HIV-DNA persist longer during ART in INR. These data link levels of inflammation and CD4 T-cell infection prior to ART, particularly in long-lived CD4 T-cell subsets, with immune recovery and HIV persistence.

WEPEB0535

IL-27 is an independent predictor of IRIS: results of a multicenter international prospective study

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Background: Immune reconstitution inflammatory syndrome (IRIS) is a complication of antiretroviral therapy (ART) initiation in lymphopenic HIV patients especially those with an opportunistic infection. Better understanding of pathogenesis and identification of predictors of IRIS is needed.

Methods: We enrolled HIV+ persons with CD4 count < 100 cells/μL starting ART in a prospective international multicenter study in US, Kenya and Thailand (NCT00286767), and followed them prospectively for 48 weeks for the development of IRIS or death. IRIS events were adjudicated by an independent committee using the ACTG criteria. Plasma biomarkers of inflammation, coagulation and tissue fibrosis, were measured. Multivariate and univariate logistic regression and competing risk regression, accounting for death prior to IRIS, were used to investigate the association of baseline biomarkers and the occurrence of and time to IRIS events.
Results: A total of 506 participants were enrolled (206 US, 200 Kenya, 100 Thailand) and there were 109 IRIS events observed and 48 deaths. IRIS patients had lower CD4 and CD8 T cell counts at baseline and lower Hg (Table A).

	All participants (N=506)	IRIS (N=97)	Non-IRIS* (N=409)	P-values
Age (years)	37.0 (31.0-45.0)	37.0 (30.0-44.0)	37.0 (32.0-45.0)	0.2938
Gender				0.8181
Female	199 (39.3%)	37 (38.1%)	162 (39.6%)	
Male	307 (60.7%)	60 (61.9%)	247 (60.4%)	
BMI	20.24 (17.90-23.48)	19.73 (17.85-23.37)	20.48 (17.90-23.48)	0.5121
Hgb	10.90 (9.60-12.40)	10.80 (8.90-11.20)	11.20(9.80- 12.70)	<.0001
CD4 T cells/μL	29 (11-56)	22 (7-49)	30 (12-58)	0.0253
CD8 T cells/μL	458 (273-740)	357 (235-656)	478 (281-747)	0.0287
HIV-RNA (log10 copies/mL)	5.30 (4.89-5.70)	5.37 (5.06-5.70)	5.28 (4.87-5.70)	0.0394

* If IRIS is not observed prior to 24 weeks, the subject drops-out prior to 24 weeks or dies before 24 weeks.

[Table A. Median values with IQR or percent are shown]

In logistic regression adjusting for baseline characteristics and all baseline biomarkers, lower Hg, higher L-27, higher BMI, higher HA and lower IL-17 were significantly associated with increased risk of IRIS. In a similarly adjusted competing risk of death model only lower Hg (P=0.003), higher IL-27 (P≤0.001) and higher BMI (p≤0.001) were associated with increased risk of IRIS. Patients with IRIS did not differ with respect to time to death within 48 weeks, after adjustment for other risk factors, however they had significantly higher CD4 increases from baseline to 24 weeks when compared to subjects without IRIS (P=0.01).
Conclusions: This novel strong association of IL-27 with IRIS may represent an important immune check-point between inflammation and immune regulation in treated HIV infection.

WEPEB0536

Switching from atripla (TDF/FTC/EFV) to eviplera (TDF/FTC/RPV) in virologically suppressed HIV-positive individuals without perceived neuropsychiatric complains improves sleep associated symptoms

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Background: Central nervous system (CNS) toxicity is common with combination antiretroviral therapy and with efavirenz (EFV) use. Concerns exist regarding overt CNS toxicities that are not directly recognized by people with HIV (PWH) on EFV or clinicians, which could have an impact on quality of life. The aim of this study was to determine whether CNS symptoms improve in PWH without overt complains of CNS toxicities when switching off EFV
Methods: PWH receiving Atripla for at least 12 weeks with HIV RNA of < 40 copies /mL, and no self-reported CNS symptoms associated with EFV were enrolled in a prospective study of switching to Eviplera. CNS toxicities were evaluated using CNS and sleep questionnaires. The median CNS score derived from the sum of toxicity of all grades collected in the CNS questionnaires effects (Table), and the median Sleep score were calculated at baseline, and weeks 4 (primary endpoint), and 12 after switching to Eviplera. Cognitive function was assessed at baseline and week 4 using a comprehensive battery
Results: 41 patients (median age 47 y; interquartile range [IQR] 31, 68), predominantly male (92%) and of white ethnicity (80%) were recruited in this 4, and 12 weeks' analysis. A significant reduction in total CNS score was observed at 4 weeks (p=0.028) with a trend towards improvement at 12 weeks (p=0.064). Table summarises the changes in CNS side effects at week 4. Significant improvements in sleep scores at week 4 (p=0.005), and week 12 (p=0.002) were also observed. There were no significant changes in cognitive function at 4 weeks (p=>0.1). HIV-RNA remained undetectable in all patients and there were no clinically significant abnormalities in laboratory parameters throughout the study period
Conclusions: Switching from Atripla to Eviplera in virologically supressed PWH without perceived CNS symptoms, was well tolerated and improved overall CNS score and sleep associated symptoms

CNS side effect n (%)	Baseline n=41	4 weeks n=40	P value
Dizziness	10(24)	2(5)	0.005
Depression	14(34)	14(35)	0.65
Insomnia	23(56)	15(37)	0.05
Anxiety	14(34)	15(37)	0.31
Confusion/ Impaired concentration	14(34)	15(37)	0.52
Somnolence	9(22)	16(40)	0.02
Aggressive mood behaviour	9(22)	7(17)	0.65
Abnormal dreams	22(53)	12(30)	0.003
Headache	12(29)	7(17)	0.04

[Changes in CNS side effects at 4 weeks]

WEPEB0537

Long-term crofelemer use gives clinically relevant reductions in HIV-related diarrhea

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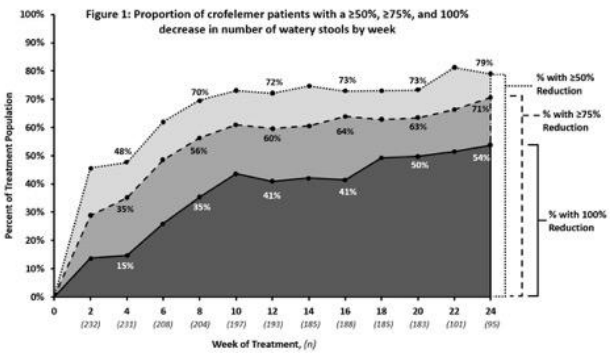
Background: Although the incidence of infectious diarrhea has declined in HIV+ persons due to the increased use of antiretroviral therapy (ART), HIV- and ART-associated diarrhea affect millions of individuals. Crofelemer is the only drug approved for treatment of diarrhea in HIV+ persons. The ADVENT study responder definition typically required a 90% reduction in watery stools per week. Substantial clinical benefits may occur from a 50% or greater reduction in the frequency of diarrheal symptoms.
Methods: Daily diary data were analyzed retrospectively from all persons treated with crofelemer 125mg bid for up to 20 weeks. The average reduction in watery stools from baseline was determined by week. Chi-square tests were performed to detect differences based on protease inhibitor (PI) use or etiology of diarrhea (ART vs. HIV disease).
Results: The baseline diarrheal frequency was 20 watery stools per week among the 274 enrolled persons. Comparing week 4 to weeks 12 and 20, a 100% reduction in weekly watery stools occurred in 15%, 41%, and 50%, respectively; a 75% reduction occurred in 35%, 60%, and 63%, respectively; a 50% reduction occurred in 48%, 73%, and 73%, respectively (Figure 1). There were no significant differences at any week in the proportion of individuals with ≥50%, ≥75%, and 100% reductions based on PI use or diarrhea etiology.



[Figure 1. Proportion of crofelemer patients with a ≥50%, ≥75% and 100% decrease in number of watery stools by week]

Conclusions: Crofelemer use resulted in marked reductions of watery diarrhea in the majority of persons. Therapeutic regimens now include less use of PIs. Results were similar regardless of whether individuals were taking PIs, and whether the eti-

ology of the diarrhea was believed to be secondary to ART or HIV disease. The utility of crofelemer may have been underestimated based upon the previously reported responder analysis. Given the 36 million people worldwide with HIV, this analysis suggests that millions of HIV-infected persons may achieve clinically meaningful reductions in diarrhea by using crofelemer.

WEPEB0538

Metabolic complications in virally-suppressed perinatally HIV infected children and adolescents on tenofovir disoproxil fumarate

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Background: Tenofovir Disoproxil Fumarate (TDF) can exhibit nephrotoxic effects (renal tubular defects, acute kidney injury, chronic kidney disease, bone mineral density changes) among HIV infected children on combination antiretroviral therapy (cART). Maturing perinatal infected children in Jamaica have been on cART since 2002, when the Jamaica Pediatric and Perinatal HIV/AIDS Program (JaPPAIDS) in collaboration with the Jamaica Ministry of Health implemented antiretroviral management protocols congruent with the WHO HIV treatment guidelines. Currently 30% are on 2nd line cART (protease inhibitor based) and have increased exposure to TDF. We aimed to characterize the metabolic disturbances associated with TDF exposure among this perinatally infected cohort.
Methods: Longitudinal data (demographic variables, HIV characteristics, antiretroviral exposure and duration) for HIV-infected children followed between January 1, 2003 and December 31, 2016 in infectious disease clinics of the JaPPAIDS were collated. Adverse outcomes (clinical, laboratory, radiographic) attributable to TDF were described using univariate analyses.
Results: Fourteen of 123 (11%) perinatally infected children exposed to TDF developed metabolic abnormalities. Of the 14, median age 14.50 years (range 8.68 - 20.62), 57% were male, 62% stunted, 50% underweight, 71% CDC category C. Mean duration on cART and TDF was 11.00 years (S.D. 2.06) and 1.58 years (S.D. 1.37) respectively; 78.5% had viral load < 20 copies/ml. Clinical features at presentation included bone pain (7/50%), associated limp (5/39%), altered gait (5/39%), pathologic fractures (5/36%) and asymptomatic (4/29%). Biochemical abnormalities were hypophostatemia (11/79%), elevated alkaline phosphatase (11/85%), acidosis (9/64%), hypokalemia (7/50%), hyponatremia (7/43%), elevated creatinine (7/58%), decreased GFR (7/58%), and urinary wasting of electrolytes. Outcomes were Fanconi syndrome (9/64%), acute kidney injury (3/21%) and metabolic bone disease (13/93%). Resolution of abnormalities followed optimizing cART (substitution of abacavir for TDF), electrolyte replacement for renal losses and vitamin D supplementation.
Conclusions: The maturing cohort of children and adolescents on cART (and achieving viral suppression) is at increased risk for adverse effects attributable to TDF. In the resource-limited setting screening for hypophosphatemia and other biochemical abnormalities is critical. Access to affordable, safer, and equally efficacious cART alternatives (tenofovir alafenamide) must be advocated for these settings which account for majority of paediatric HIV infection worldwide.

WEPEB0539

Switches due to adverse events from integrase inhibitors to other antiretroviral treatments in a clinical practice setting during a 3-year study

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Background: Integrase inhibitors (INSTIs) are recommended as first-line antiretroviral treatment (ART) in HIV patients. However, differences in tolerability have been reported between different INSTIs. The purpose of the study was to assess the frequency and compare switches due to adverse events from the INSTIs in a clinical practice setting.
Methods: Retrospective study including all patients who switched from INSTIs to other ART from our cohort of 1,750 HIV-infected patients from January 2014-September 2016 at a University Hospital in Barcelona, Spain Switches involving other ART than INSTIs were not included. Collected data: demographics, hepatitis C virus-coinfection, previous and new ART. Adverse events were classified as: neuropsychiatric toxicity, dermatologic, gastrointestinal (GI) and others. Chi square test was used to compare proportions.
Results: In total 733 patients were treated with INSTIs during this period: 351 (47.9%) dolutegravir, 223 (30.4%) raltegravir and 159 (21.7%) elvitegravir. The INSTI was switched in 105 patients (14.3%), being in 40/105 (38.1%) due to adverse events, 30(75%) male, age: 49.9 (22-79) years, HCV: 11 (27.5%). Some patients experienced more than one adverse event. The other causes of switching were: Simplification: 42 (40%), low level viremia 18 (17.1%), drug-interactions: 3 (2.9%) and pregnancy 2 (1.9%).

	Raltegravir n=223	Elvitegravir n=159	Dolutegravir n=351	P
Switches due to adverse events (n=40)	8(3.6%)	7(4.4%)	25(7.1%)	<0.001
Adverse events				
Neuropsychiatric	3(1.3%)	1(0.6%)	9(2.6%)	0.002
Dermatologic	0(0%)	0(0%)	5(1.4%)	0.001
Gastro-intestinal	1(0.4%)	2(1.3%)	8(2.3%)	<0.001
Others	4(2.2%)	4(2.5%)	3(0.9%)	<0.001

[Table 1]

Conclusions: Compared with the other integrase inhibitors dolutegravir has a higher proportion of switching due to adverse effects However, only 2.6% of patients treated with dolutegravir had to be discontinued because of central nervous system adverse events, a percentage lower than that reported in other cohorts.

WEPEB0540

An analysis of neurologic and psychiatric adverse events of subjects receiving the investigational HIV-1 maturation inhibitor (MI) GSK3532795/BMS-955176

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Background: GSK3532795/BMS-955176 has been evaluated through Phase 2b clinical trials. In Study 206220 evaluating the electrocardiographic effects (TQTS) of GSK3532795, two subjects receiving supratherapeutic doses of GSK3532795 developed neuropsychiatric serious adverse events (SAE). These isolated SAEs prompted an analysis of neuropsychiatric adverse events (AEs) across all clinical trials.
Methods: Thirteen trials involving healthy and HIV-1 infected adults receiving different GSK3532795 doses (5 mg QD to 240 mg BID) for varying duration (single dose to a maximum of 71 weeks), comparator drug, or placebo were included in this analysis which involved:
1) a clinical summary analysis of neuropsychiatric AEs and
2) an exploratory exposure-response (ER) analysis of most neuropsychiatric AEs in two trials: TQTS (Study 206220) and a Phase 2b study in HIV-1 infected adults (Study 205891).
Results: A total of 784 subjects received at least one dose of GSK3532795; 259 subjects received placebo/other treatments. For neurologic AEs, Grade 1 headache predominated in both groups. For psychiatric AEs, sleep abnormality AEs (abnormal dreams, insomnia, nightmare, sleep disorder, and difficulty sleeping) were the most common in both treatment groups but individually occurred at variable rates across studies. Other psychiatric AEs were infrequent and broadly similar across the two groups. Grade 3 AEs were rare and consisted of two cases at supra-therapeutic doses (240 mg QD and BID) in the TQTS; a single report of acute psychosis in one subject and another subject with homicidal ideation, suicidal ideation, and tachyphrenia. Finally, one HIV-1 infected subject had a Grade 3 nightmare (Study 205892). The ER analysis showed an increasing proportion of subjects having most neuropsychiatric AEs with increasing dose of GSK3532795. However, no significant ER relationship between GSK3532795 AUC(0-24) (Study 206220) or steady state AUC (Study 205891) and neuropsychiatric AEs was observed.
Conclusions: The overall incidence rates of neuropsychiatric AEs (mostly Grade 1) were similar between the GSK3532795 and placebo/comparator treatment arms. No significant ER relationship for neuropsychiatric AEs was observed with GSK3532795. Combined, the data from 13 clinical trials does not suggest a clinically significant signal for neuropsychiatric AEs in adults who receive the MI, GSK3532795.

WEPEB0541

Upregulation of apoptosis pathway genes in peripheral blood mononuclear cells of HIV treatment-experienced individuals with mitochondrial toxicity

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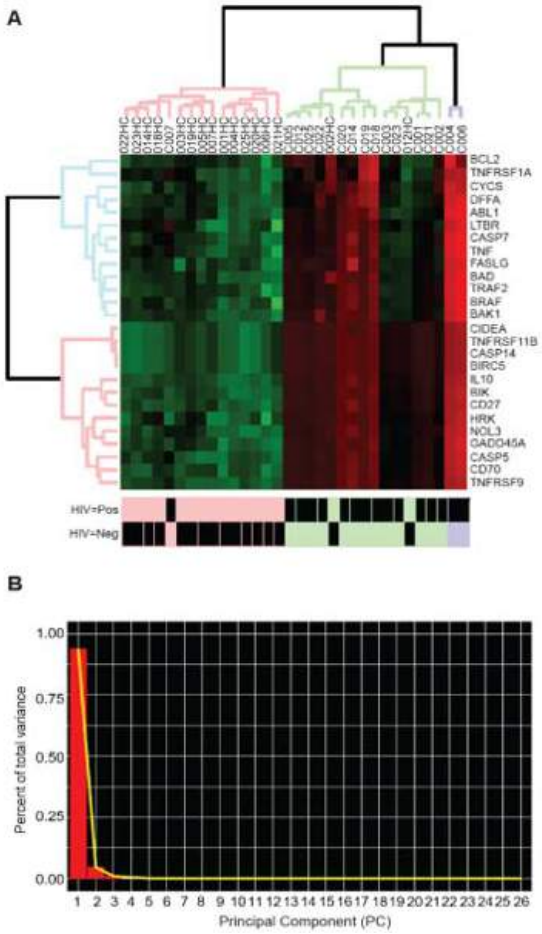
Background: The therapeutic benefit of antiretroviral therapy (ART) is sometimes limited by long-term ART-induced mitochondrial toxicity. There is no universally accepted laboratory tests or clinical definitions that serve as gold standards for diagnosis of ART-induced toxicity. Apoptosis has been implicated as playing a role in ART toxicity. We sought to investigate the differential expression of genes of the apoptosis pathway in HIV-infected patients with ART-associated mitochondrial toxicity versus HIV-uninfected individuals.
Methods: This is a retrospective analysis of data and specimens collected during a prospective, case-control study of ART-induced mitochondrial toxicity. Cases were HIV-infected individuals with ART-associated mitochondrial toxicity (n=16), and controls were HIV-uninfected individuals (n=16). We used an 84-gene Human Apoptosis PCR Array to investigate the differential expression of genes of the apoptosis pathway in peripheral blood mononuclear cells (PBMCs) of study participants.
Results: We identified 26 out of 84 genes that were differentially expressed between cases and controls (Figure 1). Of the 26 genes, 18 were pro-apoptotic (TNFRSF1A, CYCS, DFFA, ABL1, LTBR, CASP7, FASLG, BAD, TRAF2, BAK1, CIDEA, TNFRSF11B, CASP14, BIK, GADD45A, CASP5, CD70, and TNFRSF9); 5 were anti-apoptotic (BCL2, BRAF, BIRC5, IL10, and NOL3); and 3 with overlapping functions (CD27, HRK, and TNF). Using penalized regression analysis, we identified two genes (DFFA and TNFRSF1A) which contributed to the differences in the gene profile between cases and controls. These two genes classified 75% of study participants correctly into either cases or controls.



[Differentially expressed apoptosis pathway genes]

Conclusions: Our findings suggest that apoptosis may be part of the causal pathway of ART-associated mitochondrial toxicity. Further studies are need to assess the utility of DFFA and TNFRSF1A as biomarkers for ART-induced mitochondrial toxicity. If validated, a quantitative PCR assay of these genes could be used to detect and monitor ART-induced mitochondrial toxicity.

WEPEB0542

Uptake of HLA-B*5701 screening and its impact on clinically suspected hypersensitivity reaction to abacavir in the OPERA® Observational Database

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Background: Early phase trials with abacavir sulfate identified a hypersensitivity reaction (HSR). HLA-B*5701 screening to identify patients at risk for HSR entered clinical practice in 2008. This analysis assesses the use and effectiveness of screening in real world practice.
Methods: HIV+ individuals initiating their first abacavir-containing regimen between 01/01/1999 and 01/01/2016 were identified in the OPERA cohort, a collaboration of 79 clinics in 15 US states. Each patient was observed from regimen start until discontinuation of abacavir, loss to follow-up, death, or data freeze (07/31/2016). Patient characteristics, HLA-B*5701 screening, and HSR events were assessed descriptively and compared by testing period (pre-screening; 01/01/1999-08/14/2008 versus post-screening: 08/15/2008-01/01/2016).
Results: Out of 71,627 HIV+ patients, 3,215 from the pre-screening period and 6,404 from the post-screening period qualified for analysis. The proportion of patients screened for HLA-B*5701 ever and prior to abacavir initiation has steadily increased over time. Of patients initiating abacavir-containing regimens in 2015 (the last full year of data), 84.3% were screened prior to abacavir prescription, compared to 40% in 2008 upon approval of the test. Using diagnoses of HSR or symptoms of HSR, 463 (4.8%) patients were identified for review by a physician panel for HSR events (7.2% pre-screening period versus 3.5% post-screening period (p<0.0001)). Following adjudication by the physician panel, whom considered clinical information including symptomatology, potential confounders (such as concurrent medications) and event progression, rates fell to 2.8% pre-screening and 1.6% post-screening (p<0.0001). When these events were limited to those determined to be definite or probable, rates were further reduced to 1.6% pre-screening and 0.5% post-screening (p=0.0005), and median time to event was 23 days (IQR: 13, 36 days) and did not differ between groups.

*[Figure. Proportion of patients HLA-B*5701 screened and definite/probable HSR events by year of abacavir initiation]*

Conclusions: HLA*B-5701 screening has increased steadily from its introduction in 2008 through 2015. Hypersensitivity reactions have decreased in the same time period.

WEPEB0543

Association of sub-optimal antiretroviral therapy (ART) adherence with inflammation in virologically-suppressed, HIV-infected individuals: a sub-analysis of the strategies for management of antiretroviral therapy (SMART) study

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Background: Observational cohort data suggest that variations in ART adherence are associated with enhanced inflammation, even in virologically suppressed individuals. We aimed to evaluate the association of ART adherence with inflammation and activation of coagulation in virologically-suppressed, HIV-infected individuals on ART in the SMART study.
Methods: We evaluated baseline 7-day self-reported adherence and plasma levels of interleukin (IL)-6, D-dimer and high-sensitivity C-reactive protein (hsCRP) in stored samples from virologically-suppressed (< 200 copies/mL), HIV-infected individuals on ART upon enrollment into the SMART study. Adherence was labeled as sub-optimal if a participant reported not taking "all of my pills" in the preceding 7-days for at least one antiretroviral medication. We utilized multivariable linear regression analysis to evaluate the association between adherence and levels of biomarkers at baseline. Data are presented as fold differences in biomarker concentrations in individuals who were sub-optimally vs. 100% adherent.
Results: A total of 3,056 participants (1519 White, 696 Black, 570 Hispanic, 200 Asian, 71 other race) were virologically-suppressed and had 7-day adherence data available at baseline. Of these, 404 (13%) reported being sub-optimally adherent. Median age was 44 (IQR 38-51) years. ART included a PI but not an NNRTI (38%), an NNRTI but not a PI (45%) or other (17%). The number of participants with available plasma levels of each biomarker is shown in the Table. Participants reporting sub-optimal adherence had higher plasma concentrations of IL-6 and D-dimer compared to participants who did not report any missed doses (Table).
Conclusions: Sub-optimal, self-reported 7-day ART adherence was associated with higher concentrations of IL-6 and D-dimer in virologically-suppressed, HIV-infected individuals on ART. Among the possible explanatory mechanisms behind this association could be that sub-optimal adherence triggers episodes of low-level HIV replication (i.e., below the limit of detection of clinical assays), or represents episodes of missed/unmeasured viremia prior to a visit. Maximization of ART adherence beyond viral suppression may result in improved residual inflammation.

Biomarker	Number of Participants	Fold higher level compared to 100% adherence[b]	95% CI	P-value
IL-6	2,776	1.09	(1.01-1.18)	0.02
D-dimer	2,763	1.11	(1.01-1.22)	0.03
hsCRP	2,793	1.04	(0.91-1.17)	0.58

[a]Adjusted for covariates including age, race, gender, body mass index, time on ART, risk group, baseline viral load, baseline and nadir CD4 cells, hepatitis B or C co-infection, smoking and regimen type. [b]100% adherence defined as no report of any missed doses in the preceding 7-day period.

[Table. Adjusted[a] fold difference in baseline inflammatory biomarker plasma concentrations in sub-optimally adherent, virologically-suppressed, HIV-infected individuals on ART enrolled in SMART.]

WEPEB0544

Analyzing the causes that determine the various immune activation profiles observed in HIV-1-infected virologic responders and their consequences: the ACTIVIH study

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Background: The global immune activation (IA) observed in HIV-1-infected individuals is reduced under antiretroviral therapy, but persists, driven by various causes including the presence of HIV and coinfections, microbial translocation, metabolic disorders, Treg deficiency, immune senescence and eventually CD4+ T cell lymphopenia. IA fuels various morbidities in HIV patients with suppressed viremia. We hypothesized that, depending on the causes at work, virologic responders could present with different IA profiles (IAP), and develop thereby different IA-driven comorbidities.
Methods: To test this hypothesis, using 68 soluble and cell surface markers, we quantified activation in circulating CD4+ and CD8+ T cells, B cells, monocytes, NK cells, neutrophils, and endothelial cells, as well as inflammation in 120 HIV-1-infected adults over 45 years of age, aviremic for a mean duration of 102 ± 47 months and with a mean CD4 count of 688 ± 326 CD4+ T cell/microL. We performed a hierarchical clustering analysis to classify these patients according to their IAP. Lipopolysaccharide Binding Protein (LBP) levels were compared using Mann-Whithey test. Logistic regressions were carried out in order to study the relationship between IAP and consequences of IA.
Results: Five different IAP were identified. Regarding the causes of IA, an increase in plasma level of LBP, a marker of microbial translocation, was observed in patients with IAP4 as compared with the other patients (33.9 ± 9.3 and 29.8 ± 8.7 microg/mL, respectively, p = 0.01). Regarding the consequences of IA, IAP2 was linked to marks of metabolic syndrome and with hyperinsulinemia (OR 12.2 [95% CI 1.8-82.9], p = 0.01). Moreover, a past history of Kaposi Sarcoma was more frequent in patients with IAP3, compared with the other groups (OR 4.2 [95% CI 1.2-15.3], p = 0.03).
Conclusions: Various causes of IA might be responsible for the different IAP observed in treated HIV-1 infection, that could drive different comorbidities. Longitudinal studies could unveil biomarkers predictive of these comorbidities. Uncovering molecular mechanisms responsible for the causative link between IAP and comorbidities could unveil new therapeutic targets.

WEPEB0545

Associations between baseline inflammatory markers, lung function, and immediate vs. deferred ART in the START pulmonary substudy

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Background: HIV is an independent risk factor for chronic obstructive pulmonary disease (COPD). Mechanisms by which HIV leads to COPD are not clear, but systemic inflammation is one potential factor. In the START Pulmonary Substudy, immediate ART had no effect on the rate of lung function decline (slope of forced expiratory volume in 1-second [FEV1]) compared to deferred ART. We hypothesized that inflammation would be associated with worse FEV1 at baseline, faster FEV1 decline, and modify FEV1 slope responses to immediate versus deferred ART.
Methods: We enrolled ART-naive, HIV+ adults >25 years old, with baseline CD4+ T-cell counts >500 cells/mm3. Among the 1,026 participants in the study, inflammatory biomarkers (IL-6, hsCRP, and D-dimer) were measured from baseline specimens prior to randomization in 936 (91%). Spirometry was measured at baseline and annually. We tested for associations between biomarker concentrations and FEV1 %predicted at baseline and FEV1 slope during follow-up, adjusted for smoking status. We secondarily tested for a 3-way interaction between baseline inflammatory biomarker concentration, slope of FEV1, and treatment assignment (immediate vs. deferred ART).
Results: Cohort characteristics included (medians): age 36 years, 28% female, CD4+ T-cell count 646 cells/mm3, 29% current smokers, and FEV1 3.4L (97% of predicted normal). Higher baseline biomarker concentrations were associated with lower FEV1 %predicted at baseline but not subsequent FEV1 slope (Table). We found no significant interaction between the randomized treatment arm (immediate vs. deferred ART), baseline inflammatory biomarker concentrations and FEV1 slope for IL-6 (p=0.21), hsCRP (p=0.83), or D-dimer (p=0.73).

	Baseline FEV 1 %predicted	Baseline FEV 1 %predicted	Longitudinal FEV1 slope, mL/year	Longitudinal FEV1 slope, mL/year
biomarker (log 2)	β	p-value	β	p-value
IL-6 (pg/mL)	-1.03	0.04	-0.18	0.96
hsCRP (mcg/mL)	-0.98	<0.001	1.42	0.41
D-dimer (mcg/mL)	-1.62	0.003	-0.63	0.85

[Multivariable linear regression of lung function]

Conclusions: Higher concentrations of IL-6, hsCRP, and D-dimer were each associated with lower lung function at study entry, but not with subsequent rate of lung function decline nor with response to immediate vs. deferred ART. Reasons for the cross-sectional association, but lack of longitudinal association may include limited power, reverse causality, or residual confounding even after adjusting for smoking. We conclude that these particular biomarkers do not appear to have strong utility for predicting lung function decline or lung function responses to ART.

WEPEB0546

Progesterone and mitochondrial DNA (mtDNA) levels in placenta are inversely correlated among HIV+ and HIV- women in the CARMA-PREG cohort

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Background: Women living with HIV are at increased risk of preterm delivery, a contributor to infant morbidity and mortality. Synthesis of pregnenolone, the precursor of progesterone which is central to pregnancy maintenance, is dependent on placental mitochondrial function. Given that many antiretrovirals (ARVs) can affect mitochondrial function, we investigated the associations between placenta mtDNA content, an indicator of mitochondrial health, placenta progesterone levels, and preterm delivery, as these may be related.
Methods: Placental tissue, as well as clinical and sociodemographic data, were collected for pregnant women enrolled in the prospective Canadian cohort CARMA-PREG. Placental progesterone levels were measured by ELISA while mtDNA content was quantified by monochrome multiplex qPCR. Univariate associations between both progesterone and mtDNA measures and the following factors: preterm delivery (< 37w gestation, any etiology), ARV type (unboosted PI vs. ritonavir-boosted PI), and ARV backbone (AZT/3TC vs. ABC/3TC vs. other) during pregnancy were investigated using non-parametric tests.
Results: Placenta tissue was obtained from 136 HIV-infected and 60 HIV-uninfected participants aged 18-45y, of whom 24 (18%) and 9 (15%) had a preterm delivery, respectively. The majority of women living with HIV received a ritonavir-boosted PI (66% vs. 23% non-boosted PI vs. 11% other). HIV-exposed uninfected infants were born at an earlier gestational age (p=0.017), with a lower birth weight (p=0.011) than controls. Within this cohort sample, preterm delivery was high in both groups and showed no association with HIV status, placenta mtDNA or progesterone.
However, placenta mtDNA and progesterone levels were significantly negatively correlated to one another (n=196, rho=-0,242, p<0.0001). In addition, higher mtDNA showed some association with having received a non-boosted PI (vs. boosted PI, p=0.039). The ARV backbone showed no associations.
Conclusions: These preliminary unadjusted analyses suggest a relationship between lower levels of progesterone in the placenta and increased levels of mtDNA, possibly reflecting a compensatory mechanism for mitochondrial dysfunction. Possible associations with preterm delivery etiology and pregnancy complications will be examined once the sample size is larger.

WEPEB0547

MSM sexual orientation predicts stool microbiota composition in the Chicago LAMBCHOP trial

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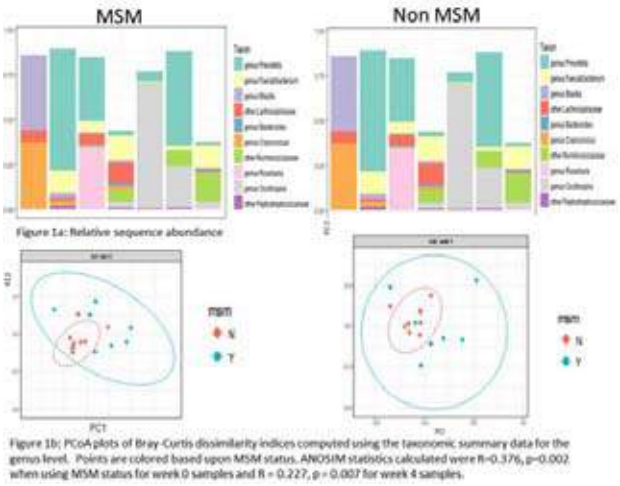
Background: Microbial translocation (MT) from the gut and concomitant immune activation (IA) in controlled HIV infection are associated with mortality in HIV. Attempts to reduce MT/IA have focused on "normalizing" gut microbiota and improving gut barrier function. We present the microbiome analysis of the LAMBCHOP trial, which showed no improvement in MT/IA biomarkers with orally administered lubiprostone, a luminal agent that stimulates recovery of mucosal barrier function via restoration of tight junction protein complexes.
Methods: Stool was collected from 16 HIV infected individuals with suboptimal CD4 recovery and undetectable viral load for 48 weeks, before and after 4 weeks of lubiprostone. Sequence data were processed using a QIIME pipeline. Shannon and Bray-Curtis indices were calculated with default parameters in R using the vegan library. The rarefied genera data, taxonomic level 6, were used to calculated both indices. For Bray-Curtis indices, the rarefied data were filtered to remove any taxon with an abundance of less than 1% of the total abundance in the dataset.
Results: Median age was 49.5 years and median CD4 was 333. 13 were male, 6 were African American, 5 Hispanic and 5 caucasian. 8 were men who have sex with men (MSM). At baseline no taxa correlated, after correction for false discovery rate, with markers of MT/IA: iFABP, zonulin, IL6, sCD163, sCD14 or CRP. MSM status predicted microbiome composition but alcohol/drug use, smoking and pneumocystis prophylaxis did not. After four weeks of lubiprostone the MSM and non-MSM microbiota were more similar, though lubiprostone had no substantial effect on individual taxa. MSM as a risk factor did not predict baseline levels of MT/IA.
Conclusions: MSM status appears to have a substantial effect on gut microbiota. Lack of improvement in MT/IA with lubiprostone may be related to failure to change the gut microbiota, though no particular taxa appeared to drive MT/IA.



[Figure 1]

WEPEB0548

Carotid intima-media thickness in virologically suppressed HIV-infected Thai patients

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Background: The combination antiretroviral therapy (cART) contributes to a significant decline not only in AIDS-related mortality but also the incidence of opportunity infections and AIDS related malignancy. HIV-infected patients with good response to cART have a closer gap of life expectancy to uninfected population. However, the incidences of non-communicable diseases (NCDs), e.g. cardiovascular diseases (CVDs), in HIV infected patients are increasing. Previous studies showed carotid intima-media thickness (cIMT), one of predictors for the risk of CVDs and mortality, was higher in HIV-infected patients than uninfected population. However, there has been no study for a comparison of cIMT of HIV-infected and uninfected adults in Asian population.
Methods: A cross-sectional study was conducted at The HIV Netherlands Australia Thailand Research Collaboration (HIV-NAT) and King Chulalongkorn Memorial Hospital, Bangkok, Thailand. The primary endpoint was the difference in cIMT between HIV-infected patients and uninfected controls. The risk factors for increment of cIMT were determined.
Results: Results: A total 90 adults were enrolled, 60 were HIV-infected. Ninety-six percent of HIV-infected had undetectable viral load with median CD4 of 602 (IQR: 487-811) cells/mL. Eighty-three percent of patients were receiving PI-based regimen. The overall median (IQR) age was 54.1 (52-60) years, and the male-to-female ratio was 1.1:1. The mean overall cIMT of common carotid arteries were not different between groups (0.665 mm vs. 0.649; p=0.277). Hypertriglyceridemia was more prevalent in HIV infected patients (48.3% vs. 26.7%; p=0.049). Serum

high-sensitivity C-reactive protein levels were comparable between groups (1.59 vs. 1.46 mg/dl; p=0.325) and not correlated with increase in cIMT. In univariate analysis, male sex, waist hip ratio, smoking and hypertension were found to be correlated with increased cIMT. In multivariate analysis, male sex and hypertension were correlated with increased cIMT.
Conclusions: Virologically controlled HIV infected patients had comparable cIMT to uninfected Thai adults. HIV-infected patients had significant more hypertriglyceridemia, due to long-term use of protease inhibitors. In this study, traditional risk factors for atherosclerosis correlated with increased cIMT but not HIV risk factor. Interventions to control these risk factors are required to reduce in risk of CVD in HIV-infected patients.

WEPEB0549

Site capacity to screen for and manage renal dysfunction among HIV-infected persons receiving care in low- and middle-income countries (LMICs)

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Background: Acute kidney injury (AKI) and chronic kidney disease (CKD) are more common in HIV-infected, ART-treated adults than in the general population. Markers of renal dysfunction including microalbuminuria, proteinuria, and/or reduced glomerular filtration rate have been associated with increased mortality in HIV-infected patients. With approximately 16 million persons receiving ART in LMICs and limited resources to provide treatment for individuals with CKD and end-stage kidney disease, successful public health approaches require identifying individuals early in their disease risk continuum. Specific data in LMICs on HIV care and treatment site capacity to screen and manage persons at-risk of renal dysfunction is limited.
Methods: Ongoing survey of non-communicable disease (NCD) screening and management capacities and practices among a stratified random sample of HIV care and treatment sites in 36 LMICs within the International epidemiology Databases to Evaluate AIDS (IeDEA). The survey has currently been completed by 70 sites (49%); in 22 countries in Africa, Latin America and Asia. This preliminary analysis focuses on kidney disease screening and management capacity in 53 (75% urban) adult clinics. On site is defined as at this clinic or the same health-facility.
Results: Forty-nine (92%) of 53 sites report screening for kidney disease; with approximately half (58%) providing such services on-site. Serum creatinine and urine dipstick capacity is also available in the majority of sites; with at least 74% and 83% of sites providing these services (Table). A lower proportion of low- (44%) and lower-middle income (43%) sites (compared to 92% upper-middle income) have urine protein quantification services (urine albumin-to-creatinine ratio (uACR)) available. Renal biopsy capacity was extremely limited in low (0%) and lower-middle income (17%) settings.

	Low Income (N =18) n (%)	Lower-Middle Income (N= 23) n (%)	Upper-Middle Income (N= 12) n (%)	TOTAL (N= 53) n (%)
Screening	16 (89)	21 (91)	12 (100)	49 (92)
On-site management	11 (61)	9 (39)	11 (92)	31 (58)
On-site service availability				
Serum Creatinine Measurement	15 (83)	19 (83)	12 (100)	46 (87)
Urinalysis for proteinuria (dipstick)	15 (83)	17 (74)	12 (100)	44 (83)
Urine Protein quantification (i.e. uACR, uPCR)	8 (44)	10 (43)	11 (92)	29 (55)

[Availability by World Bank Income Classification]

Conclusions: The majority of LMIC HIV care sites provide screening for and managing kidney disease onsite. However, tests allowing for identification of earlier stage disease (e.g. uACR) and definitive histopathologic determination (biopsy) are largely unavailable. Such preliminary data provide baseline information to guide the design of future, prospective studies.

WEPEB0550

Prevalence of comorbidities and impact of HIV and comorbidities on health care resource utilization

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Background: The aim of the study was to evaluate the prevalence of comorbidities in HIV patients as well as the impact of HIV and comorbidities on health care resource utilization using the Régie de l'assurance maladie du Québec (RAMQ) public drug plan database.
Methods: Patients who had received antiretroviral treatment (ART) for at least six months from 01/2006 to 06/2012 were selected. HIV-negative individuals from a random sample were matched for age, sex and time of follow-up and compared to HIV-positive patients. Renal, bone and cardio-metabolic comorbidities were defined using diagnosis codes for both cases and controls in the 2 years following cohort entry. Cohort entry was defined for the HIV-positive patients as the date of the first script of ART and for the matched control group of HIV-negative individuals as the date of the first any diagnosis or any prescription recorded in the database. Cases and controls were compared with independent t-test for continuous variables and chi-square test for categorical variables.
Results: A total of 3905 HIV-positive patients were included in the study with mean age of 45.3 and 77.3% being male. In the 2 years following cohort entry, 5.5% had renal, 26% had bone and 41.9% had cardio-metabolic comorbidities, with 17.1% having more than one type of comorbidity. HIV-positive patients had a higher Charlson comorbidity score compared to HIV-negative individuals (3.3 SD=3.3 vs. 0.3 SD=0.8, p< 0.01). HIV-positive patients had a higher mean total health care cost per patient per year in the 2 years following cohort entry than HIV-negative individuals which could be explained mostly by the higher mean number of hospitalization days (2.2 days SD=8.2 vs. 0.9 days SD=6.5, p< 0.01) and the higher number of prescriptions (105.3 SD=202.8 vs. 26.6 SD=71.0, p< 0.01). Similar results were obtained when analysis was restricted to HIV-positive vs. HIV-negative patients both with at least one comorbidity. Among the 1983 HIV-positive patients with at least one comorbidity, the comorbidities associated with the highest burden were renal-related followed by bone and cardio-metabolic comorbidities.
Conclusions: The impact of HIV and associated comorbidities on health care resource utilization was significant when we compared HIV-positive to HIV-negative individuals.

WEPEB0551

Prevalence of cardiovascular risk factors, asymptomatic organ damage and renal disease in hypertensive ART-Naïve HIV-infected patients in Lilongwe, Malawi

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Background: According to the 2009 Malawi national STEPS survey, 36.9% male and 29.9% female participants from the general population had raised blood pressure (BP) or were on antihypertensive medication. As an integrated part of the ongoing prospective LighTen Cohort Study (ClinicalTrials.gov NCT02381275) we aimed at determining hypertension prevalence as well as easy to detect cardiovascular risk factors and organ damage in ambulatory HIV$^+$ patients prior to starting antiretroviral therapy in Lilongwe, Malawi.
Methods: BP values of patients (age ≥18 years) who consented to participate in the study were documented in a standardized fashion together with data concerning BMI, diabetes, smoking and known hypertension or antihypertensive medication. Definite arterial hypertension was defined as treated controlled or uncontrolled hypertension or BP ≥140/90 mmHg independent of hypertension history during ≥2 measurements on ≥2 occasions within 8 weeks after inclusion into the study. An estimated glomerular filtration rate (eGFR) of 30-59 ml/min/1.73m^2 (corresponding to CKD stage 3) or pulse pressure (PP) ≥60 mmHg in patients ≥60 years were considered as asymptomatic organ damage while eGFR < 30 ml/min/1.73m^2 or dipstick positive proteinuria were considered as established renal disease.
Results: Data from 1387/1415 HIV$^+$ patients (794 females, 593 males, mean age 36.0±9.3 years) could be analyzed. Definite hypertension was confirmed in 103 cases (61 females, mean age 43.8±9.6 years; 42 males, mean age 44.0±8.5 years) for a total prevalence of 7.4%. Among them, 34 had a BMI ≥30kg/m^2, 5 were smok-

ers and 5 presented with diabetes mellitus type 2. PP ≥60 mmHg was found in two patients and CKD stage 3 in 12 cases while 6 patients suffered from established renal disease. At least two additional cardiovascular risk factors were found in 15 men and three women, respectively.
Conclusions: Testing renal function and further diagnostics revealed additional cardiovascular risk factors in approximately 35% of HIV+ patients with an established diagnosis of hypertension. Systematic measurements of arterial blood pressure and kidney function together with integrated patient instruction, education and treatment programs at HIV centers may be helpful in reducing the burden of hypertension and its sequelae in settings like Malawi.

WEPEB0552

Looking beyond viral suppression: findings from The Well Project's 2016 user survey on factors influencing the health, well-being, and quality of life of women living with HIV

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Background: The HIV care continuum has become the predominant framework for assessing progress in HIV treatment and prevention, with viral suppression as the ultimate outcome of interest. This is codified in the UNAIDS "90/90/90" campaign, adopted by numerous countries. But for women living with HIV, viral suppression may not be the only outcome of interest, as psycho-social factors—including those related to gender, HIV identity, and mental health—significantly affect their overall health, well-being, and quality of life.
Methods: In 2016, we conducted an online survey of The Well Project's (TWP) users to ascertain factors influencing experiences of women living with HIV (WLHIV) along and beyond the care continuum. TWP is a non-profit organization leveraging technology to facilitate information access, community support, and advocacy for WLHIV globally. Respondents were recruited through TWP's website, newsletters, virtual flyers, and social media, as well as outreach by TWP's CAB members and community partners.
The survey was administered through Survey Monkey and included closed- and open-ended questions. The total sample with complete survey data was 229 women and men. We report here on findings from the subsample of 136 self-identified WLHIV.
Results: WLHIV respondents came from North America (85.3%), Africa (11.7%), Asia (1.5%), and Europe (1.5%); average time since HIV diagnosis was 16.3 years. 97.8% reported seeing an HIV healthcare provider; 97.7% said they were currently taking ART. 77.3% self-reported having an undetectable viral load. Notwithstanding these high levels of engagement in care and viral suppression, WLHIV identified other important factors affecting their overall health, well-being, and quality of life that require further attention. These included stigma and discrimination inside (49.6%) and outside (62.7%) the healthcare system, experiences of trauma (76.5%), and additional mental, emotional, and behavioral health issues (39.8%) that hindered their access to or engagement in HIV care.
Conclusions: While viral suppression is a meaningful outcome for WLHIV, they do not perceive it as the only measure of their health and well-being. Other psychosocial factors, including trauma, stigma and discrimination, and behavioral health issues are important additional influences that must be addressed in order for them to achieve optimal quality of life.

WEPEB0553

The role of psychological flexibility and self-compassion in mental health and quality of life of HIV-infected adults

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Background: Living with HIV may be a stressful and emotionally demanding experience. People living with HIV (PLWH) face a range of issues impacting their mental health, namely anxiety and depression, and quality of life (QoL). Two newly constructs are particularly promising as buffers against the distress that individuals experience when confronting HIV. Indeed, psychological flexibility and self-compassion have been consistently associated with increased psychological well-being. In the HIV context, studies assessing the associations between these two constructs with mental health and QoL are scarce.
Therefore, the aim of this study was to examine the association between psychological flexibility and self-compassion and the mental health (anxiety and depression) and QoL in HIV-infected adults.
Methods: The sample of this cross-sectional study consisted of 89 adults infected with HIV (55.1% male), with a mean age of 41.69 years (SD=10.80; range: 19-65). Participants completed an online survey, between January 2016 and January 2017. Participants completed a self-reported questionnaire on sociodemographic and clinical information, the Acceptance and Action Questionnaire-II, the Self-Compassion Scale, the Hospital Anxiety and Depression Scale, and the EUROHIS-QOL 8-item index.
Results: On average, participants reported approximately 11 years (M=11.42; SD=8.15) since HIV diagnosis. Overall, 79.8% of the participants were HIV asymptomatic, and 77.5% reported a compliance of 100% to antiretroviral treatment in the last month. Both psychological flexibility and self-compassion were significantly and negatively correlated with anxiety and depression, and positively correlated with QoL. Regression analyses indicated that psychological flexibility and self-compassion were significantly associated with reduced levels of anxiety and depression, and higher QoL (the explained variances ranged between 40.7% and 50.4%). Self-compassion presented significant unique variance above and beyond psychological flexibility across study outcomes (the additional variance ranged between 4.8% and 9.9%).
Conclusions: The results of this study revealed that psychological flexibility and self-compassion were significantly associated with mental health outcomes and QoL. This study strengthens that third wave cognitive-behavioural approaches, as acceptance and commitment therapy and compassion-focused therapy, focused in increasing both psychological flexibility and self-compassion may hold promise in the search for effective interventions aimed at improving the mental health and QoL of PLWH.

WEPEB0554

Beyond viral suppression: the quality of life of people living with HIV in Sweden

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Background: Sweden is the first country to reach the UNAIDS ‚90-90-90' target: it is estimated that 90% of HIV cases are diagnosed, 99.8% of people living with HIV (PLHIV) are linked to care and 95% on antiretroviral treatment (ART) achieve viral suppression. It has been argued that viral suppression should not be the ultimate goal of treatment and that the wellbeing of PLHIV is equally important. Therefore, a ‚fourth 90' was a suggested addition to the 90-90-90 target, representing quality of life (QoL). The overall aim of the study was to investigate what factors are related to QoL among PLHIV in Sweden.
Methods: A nation-wide survey was conducted in 2014. It reached a representative sample of 17% of PLHIV in Sweden and consisted of an anonymous, self-reported questionnaire. Fifteen collaborating hospitals, clinics or needle-exchange centres, representing 75% of all known HIV patients, participated in the data collection. The questionnaire was developed in collaboration with Swedish HIV patient support organisations and was available in 10 different languages. When the study was conducted, the law forcing PLHIV to disclose their HIV status to sexual partners regardless of condom use or viral load, had just been modified to include important exemptions.
Results: In total, 1096 individuals responded to the questionnaire of whom 70% were men and 29% were women. About half of the respondents were born in Sweden and the most common routes of transmission were through sex between men (40%) and heterosexual sex (32%).The majority, 60%, reported QoL scores of 7-10 out of 10. Regression analysis showed that strong feelings of hopelessness, HIV-related stigma, taking medications against depression/anxiety, psychological side-effects of ART, drinking more alcohol than one wants to, injecting drug-use and self-medication with pharmacy drugs were associated with lower QoL. Negative change in one's sex life and low income were also significantly associated with lower QoL. Interestingly, gender, sexual orientation, country of birth and age were not significantly associated with QoL in this analysis.
Conclusions: Overall PLHIV in Sweden report high quality of life. Yet, HIV-related stigma and other HIV-related psychological stressors continue to compromise the QoL of PLHIV.

Women

WEPEB0555

Pharmacokinetics of Rifampin and Isoniazid during pregnancy and postpartum in South African women

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Background: Physiological changes during pregnancy may alter drug pharmacokinetics. Trimester differences in rifampin (RMP) and isoniazid (INH) exposure have not been described. We explored the effects of pregnancy gestation on RMP and INH pharmacokinetics in tuberculosis-infected women.
Methods: P1026s is an ongoing, non-blinded, phase IV, prospective study of antiretroviral and antituberculosis pharmacokinetics in HIV-infected and uninfected pregnant women. Intensive steady-state 24-hour pharmacokinetic profiles of RMP and INH were performed during the 2nd trimester (2T), 3rd trimester (3T) and 2-8 weeks postpartum (PP). Daily antituberculosis fixed-dose combination tablets were given according to WHO-recommended weight-banded dosing guidelines. RMP and INH plasma concentrations were measured using High Performance Liquid Chromatography (HPLC); detection limits being 0.117 µg/ml and 0.098 µg/ml, respectively. The pharmacokinetic parameters were characterized using non-compartmental analysis and compared to published non-pregnant South African adult data.
Results: Preliminary pharmacokinetic data are available for 10 South African participants; 7 African, 2 mixed descent and 1 Indian. All were sampled more than once. Eight women were HIV-infected (7 on efavirenz and 1 on lopinavir/ritonavir). The median age at 3T was 31 years (range 21-40) and median weight at 3T was 58.6 kg (range 49-99). Median gestational age at delivery was 38 weeks (range 36-41). RMP and INH pharmacokinetic data were available in 5, 8 and 3 women in 2T, 3T and PP. See Tables 1 and 2 respectively.

Parameter	2nd Trimester	3rd Trimester	Postpartum	Historical Control
No. evaluated / No. HIV-infected	5 / 5	8 / 6	3 / 2	87 / 9
AUC_{0-8} (µg·h/ml)	27.48 (25.74-33.68)	31.34 (21.15-39.74)	16.24 (13.21-33.12)	21.5 (15.3-31.7)
C_{max} (µg/ml)	7.23 (6.63-8.38)	6.11 (4.67-8.46)	4.88 (3.82-7.84)	5.9 (4.2-8.4)

[Table 1. Rifampin PK Parameters, Median(IQR)]

Parameter	2nd Trimester	3rd Trimester	Postpartum	Historical Control
No. evaluated / No. HIV-infected	5 / 5	8 / 6	3 / 2	141 / 14
AUC_{0-8} (µg·h/ml)	7.10 (4.85-13.03)	8.96 (7.06-12.29)	8.90 (5.32-20.51)	25.0 (18.9-32.8)
C_{max} (µg/ml)	3.27 (2.24-4.8)	3.44 (3.27-4.59)	3.73 (2.61-5.63)	6.5 (4.9-8.7)

[Table 2. Isoniazid PK Parameters, Median(IQR)]

Compared to a non-pregnant South African adult cohort (45% male, 10% HIV-infected not receiving antiretrovirals, McIlleron et al. 2006), RMP exposure was similar or higher in 2T and 3T. INH exposure was below the 25th percentile across all stages of pregnancy. Small sample size and unavailable comparator raw dataset prohibited formal statistical testing.
Conclusions: RMP concentrations in pregnancy compared well to non-pregnant concentrations. However, INH exposure was reduced throughout pregnancy. If confirmed with larger sample size, these data suggest that an increased dose of INH may be needed during pregnancy.

WEPEB0556

Pregnancy outcomes among HIV-infected women who conceived on antiretroviral therapy

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Background: As the availability of ART expands in resource-limited settings, it is critical to understand the impact these drugs may have on pregnancy and birth outcomes among women who conceive on ART.
Methods: We conducted a secondary analysis of women prospectively enrolled across three ART prevention or treatment trials (HPTN 052, ACTG A5208 and ACTG A5175). Included women who were on ART at conception, had reliable LMP dating and a recorded pregnancy outcome. Primary outcome was live birth versus other (spontaneous abortion; stillbirth; elective abortion; or ectopic pregnancy). Preterm birth (birth < 37 weeks) was a secondary outcome. Analyses used Cox proportional hazards regression models with time-varying covariates
Results: 359 women had pregnancies during the study period. 253 women (70%) met inclusion criteria and were included: 114 (45%) from HPTN 052, 89 (35%) from A5208, and 50 (20%) from A5175). 127 (50%) were taking NNRTI-based ART, 118 (47%) were taking PI-based ART, and 8 (3%) were taking 3-NRTIs at conception. Of women on NNRTI-based ART, 76% were taking an efavirenz-based regimen. Pregnancy outcomes are in Table 1. The median birth weight among 68 live born infants was 2900 g [IQR: 2500-3400 g]. In multivariable analysis adjusted for region, study, and pre-pregnancy ART class, older age was significantly associated with increased hazard of non-live birth [HR 1.05; 95% CI: 1.001-1.09; p=0.047]. In both univariable and multivariable analysis, no variables were significantly associated with preterm birth among women with a live birth.
Conclusions: Women who conceived on ART had very high rates of preterm birth and other poor obstetric outcomes. A limitation of our study is that the estimated due date (EDD) was not determined by ultrasound but by LMP. New studies that are specifically designed to investigate ARV drug exposure and birth outcomes are urgently needed and will have implications for maternal child health programs in settings with high HIV prevalence

WEPEB0557

Pre-treatment antiretroviral drug resistant mutations (DRM) and subsequent viral rebound on antiretroviral therapy (ART) among pregnant and postpartum women in Cape Town, South Africa: a nested case-control study

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Background: Viral rebound (VR) occurs frequently after initial viral suppression (VS) among women initiating ART during pregnancy in sub-Saharan Africa. However, the aetiology of VR and the role of pre-treatment drug resistance mutations (DRM) are not well understood in this patient population.
Methods: We examined associations between pre-ART DRM and VR>1000cps/mL in a routine primary care cohort. Intensified VL monitoring was conducted separately from routine care, with stored specimens every 2-3m for retrospective VL assessment. All women included here initiated TDF+FTC+EFV in pregnancy and achieved VS≤50cps/mL. After initial VS≤50cps/mL, cases experienced VR>1000cps/mL up to 12m postpartum while incidence-density matched controls maintained VS≤50cps/mL throughout follow-up. Using pre-ART specimens, the

RT region was amplified and sequenced with next-generation Miseq sequencing; consensus sequences containing at least 0.02% of the total reads for that sample were included, and DRM were based on >5% of consensus sequences. Analyses (i) compared DRM in cases/controls, (ii) estimated associations between DRM and time to VS and VR and (iii) calculated population attributable fraction (PAF) for VR associated with DRM.
Results: Cases experiencing VR>1000cps/mL after initial VS (n=103) were significantly younger versus controls who maintained VS (n=80); pre-ART VL was similar (median=4.0 log_{10}cps/mL). Cases were more likely to report previous ARV exposure either through short-course PMTCT (30%) or ART (10%) versus controls (14% and 1%, respectively; p<0.05). DRM were found in 10% of cases and 3% of controls (exact p=0.070) with only NNRTI mutations detected (K103N,K101E,V106M,G190E). DRM were strongly associated with previous ART use (p<0.001). Time to VS was not associated with pre-ART DRM (p=0.899), but women with pre-ART DRM had twice the rate of VR after initial VS versus women without (adjusted hazard ratio=2.15; 95%CI=1.08-4.30). Based on these data, DRM may be involved in the aetiology of 6% of all cases of VR>1000cps/mL after initial VS (PAF uncertainty interval=4-13%).
Conclusions: Pre-ART DRM appear uncommon among pregnant women in this setting, but when present are significantly associated with VR>1000cps/mL after initial VS≤50cps/mL. At a population level, pre-ART DRM account for a small minority of VR, suggesting that non-adherence may play a greater role in early VR during pregnancy and postpartum.

WEPEB0558

Maternal outcomes of pregnancies complicated by HIV: preliminary results of a retrospective matched cohort study from 2004 to 2014

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Background: Although pregnancy in HIV-positive women is complicated by medical and psychosocial comorbidities, maternal pregnancy outcomes are understudied. To test the hypothesis that maternal morbidity is higher in HIV-positive pregnancies, we conducted a retrospective matched cohort of HIV-positive pregnancies at MedStar Washington Hospital Center (MWHC).
Methods: We included all HIV-positive pregnancies delivered at MWHC from 2004-2014, excluding multiple-gestations and abortions. For each HIV-positive pregnancy, we identified two HIV-negative pregnancies, propensity-score matched on age, race, parity, zip-code and insurance status within a year of delivery. Data collection is ongoing. We used chi-squared and Fisher's exact tests for categorical variables and t-tests for continuous variables.
Results: 420 HIV-positive pregnancies met inclusion criteria. We have collected data on 326 HIV-positive pregnancies and 530 HIV-negative controls. Mean maternal age was 27. The majority were African-American (88%) and multiparous. The majority of HIV-positive women acquired HIV through sexual transmission(36.5% vs. 7.4% perinatally-acquired vs. 55.8% unknown).
HIV-positive women were less likely to be married (19.8 vs. 12%, p<0.001) and more likely to be homeless (7.1 vs. 2.5%, p=0.002), unemployed (50 vs. 37%, p<0.001), enrolled in government-sponsored insurance (77 vs. 61%, p<0.001), have social services involvement (5.2 vs. 0.4%, p<0.001), and children in foster care (3.1 vs. 0.6%, p=0.009). They had greater past history of domestic-violence (15.6 vs. 4.5%, p<0.001), sexual abuse (10.4 vs. 4.3%, p=0.001), depression (19.9 vs. 4.9, p<0.001), anxiety (8 vs. 0.9%, p<0.001), and substance use (41.4 vs. 26.6%, p<0.001). Current pregnancies complicated by HIV, had increased depression (12 vs. 2.5%, p<0.001) and substance drug use (27.3 vs. 15.5%, p< 0.001).
Sexually transmitted infections were higher in HIV-positive pregnancies (29.1 vs. 12.5%, p<0.001), as were urinary tract infections (19.6 vs. 9.4%, p<0.001), and pneumonia(1.2 vs. 0%, p=0.041).There was no difference in overall preterm-delivery, however, spontaneous preterm-delivery was higher in HIV-positive pregnancies(8.9 vs. 4.3%, p=0.002). Cesarean deliveries were also higher (55.6 vs. 32.1%, p<0.001), with increased wound cellulitis(1.8 vs. 0.2%, p=0.027).
Conclusions: This is the largest single-site cohort of HIV-positive pregnancies in the United States. HIV-positive pregnancies were more likely to be of lower socioeconomic status with challenging social situations and striking psychosocial comorbidities. HIV-positive pregnancies were at increased risk of infectious morbidity and spontaneous preterm-delivery.

WEPEB0559

Is tenofovir use in pregnancy associated with preterm delivery? A Canadian perinatal HIV surveillance program analysis

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Background: Tenofovir-based cART was associated with significantly higher rates of very preterm delivery and infant death in the recently published PROMISE trial (which compared outcomes from women treated with zidovudine/single-dose nevirapine, zidovudine/ lamivudine/lopinavir-ritonavir or tenofovir/lamivudine/ lopinavir-ritonavir). We assessed rates of preterm delivery according to cART components in the Canadian Perinatal HIV Surveillance Program (CPHSP).
Methods: Data collected annually from 22 pediatric and HIV centres participating in the CPHSP were reviewed for 1997-2015, including: rates of preterm (< 37weeks) delivery, antiretroviral choice, maternal demographics and clinical parameters.
Results: Among 2787 cART-treated mother-infant pairs from 1997-2015, 1703 (61.1%) received zidovudine, 574 received abacavir (20.6%) and 496 received tenofovir (17.8%). Tenofovir use in pregnancy began in 2004 (0.77% of pregnancies) and increased every year since up to 54.1% in 2015; conversely, zidovudine use decreased from 100% in 1997 to 14.7% in 2015. The overall preterm delivery rate was 16.0%, with a significantly higher rate in mothers treated with tenofovir-based versus non-tenofovir based cART (19.4% vs 15.2%, p=0.024). Preterm delivery was not associated with abacavir-based vs non-abacavir-based cART (16.0%) vs 15.9%) or with zidovudine-based vs non-zidovudine-based cART (15.5% vs 16.7%) There was no difference in proportion of preterm delivery among women exposed to tenofovir with versus without a protease inhibitor (19.3% vs. 19.5%), non-nucleoside reverse transcriptase inhibitor (18.0% vs 19.6%) or integrase inhibitor (17.8% vs 19.3%). Other significant predictors of preterm delivery included: race/ethnicity (Indigenous 26.9% vs White 17.2% vs Black 13.0%, p< 0.001), maternal risk factor (intravenous drug use 27.6% vs sexual 13.8% vs other 12.1%, p< 0.001), and viral load (VL) closest to delivery (detectable 24.7% vs undetectable 15.5%, p< 0.001), but not once-daily combinations or trimester of cART start. Multivariate analysis (restricted to 2006-2015 when VL data was more complete) revealed tenofovir (p=0.021) and zidovudine use (p=0.019), IVDU (p=0.009), and detectable VL (p=0.015) as predictive of preterm birth.
Conclusions: In Canada, there was a higher risk of preterm delivery amongst mothers treated with tenofovir-based versus non-tenofovir-based cART. Allowing for biases of observational cohort studies, this finding warrants further investigation to determine the safest antiretroviral treatment in pregnancy.

WEPEB0560

Antiretroviral therapy (ART) during pregnancy is associated with increased placental inflammation and small for gestational age neonates: a prospective study

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Background: While antiretroviral treatment (ART) for HIV-infected pregnant women can significantly reduce mother-to-child HIV transmission and improve maternal survival, prolonged in-utero exposure to antiretrovirals may have adverse effects on birth outcomes and neonatal development. However, there is scant data on the impact of ART exposure on fetal development and birth outcomes, particularly from sub-Saharan Africa. Working within a larger birth cohort in Cape Town, South Africa, we report on a nested sub-study of the impact of ART use during pregnancy on placental pathology and birth outcomes.

Methods: Histopathology of placentas after delivery were examined from two groups: HIV-infected mothers receiving stable ART commenced before pregnancy (n=33) and women initiating ART at ±20w gestation (n=45). All placentas were fixed in 10% formalin and examined for stage/grade of chorioamnionitis (maternal inflammation), cord/plate vessel vasculitis (fetal inflammation), focal infarction and meconium exposure.
In analysis, we examined associations between chorioamnionitis and appropriate (AGA)- or small-for-gestational age (SGA <10th centile) and pre-term (PT≤34 weeks) deliveries.
Results: There were equal proportions of pre-term births in the stable ART and initiating ART groups (9%), but a higher proportion of SGA births in women on stable ART than in those initiating ART (18.2% vs 6.5%; p=0.0153). This was associated with a greater proportion of stage 1 chorioamnionitis in placentas from women on stable versus initiating ART (15% vs 4%; p=02) along with evidence for prolonged exposure to meconium (21% vs 9%; p=0.015). Placentas from women initiating ART showed relatively more plate vessel vasculitis (20% vs 9%; p=0.04), but less focal infarction (4.4% vs 12%; p=0.065) when compared to women on stable ART.
Conclusions: HIV-infected pregnant women commencing ART before pregnancy experienced relatively high levels of SGA deliveries. This may be due to maternally-derived inflammation of the placenta, fetal distress and possibly disrupted blood supply due to infarction. Interestingly, placentas from pregnant women initiating ART showed evidence of fetal inflammation, but this was not associated with SGA deliveries.

WEPEB0561

Factors associated with non-disclosure among females accessing a safer conception service in Johannesburg, South Africa and outcomes following disclosure support

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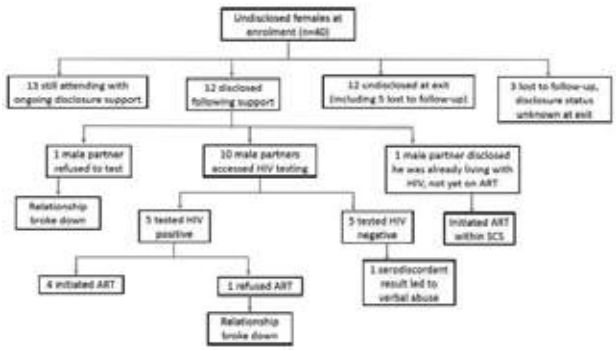
Background: Safer conception services (SCS) enable HIV-affected couples to minimise horizontal and vertical HIV transmission risks during conception efforts. However, non-disclosure within couples planning pregnancy creates difficulties including ethical challenges for healthcare providers, lower partner engagement in care and sub-optimal risk reduction strategy use. Understanding drivers of non-disclosure is critical to strengthening programming. We describe factors associated with disclosure among female SCS clients in Johannesburg and outcomes observed following a disclosure support intervention.
Methods: All SCS clients completed a baseline assessment, including disclosure status. Undisclosed clients received ongoing disclosure support including counselling and opportunities for couples' HIV-testing. Baseline characteristics between disclosed and undisclosed women were compared using chi-squared statistics and t-tests. Undisclosed clients' clinical records were reviewed for disclosure-related events.
Results: From June 2015-January 2017, 362 women, median age 33yrs (IQR 30-37yrs), enrolled. Forty (11%) were undisclosed at enrolment, of which 8 (20%) had detectable viral loads (>200 copies/ml[3]). At baseline, undisclosed women reported shorter relationships than disclosed women (3.1 vs 6.6yrs, p<0.001), were less likely to have any child with their partner (2% vs 28% disclosed, p=0.001), and were less likely to report always using condoms in the month before enrolment (26% vs 44% disclosed, p=0.043). Age, nationality, income, employment, education, years since HIV diagnosis, ART uptake and duration and CD4 cell count nadir were not associated with baseline disclosure status. Following disclosure support, 12 women disclosed (Figure 1).



[Figure 1: Disclosure outcomes following support]

Conclusions: Non-disclosure of HIV-status remains common, even amongst couples actively planning pregnancy. Disclosure is significantly less likely if a woman has no children with her current partner, but increases with relationship duration. Disclosure support can assist with disclosure, leading to increased male testing, diagnosis and ART uptake. However, many women remain unable to disclose and pressured disclosure may introduce risks including relationship breakdown, gender-based violence and withdrawal from care.

WEPEB0562

Uptake of safer conception strategies among women living with HIV in Canada who report pregnancy with an HIV-serodiscordant partner

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Background: Safer conception strategies reduce sexual HIV transmission, while allowing for pregnancy. Canada is one of three countries with national safer conception guidelines, but little is known about uptake. We measured prevalence, types, and correlates of safer conception among women living with HIV (WLWH) who reported pregnancy with an HIV-serodiscordant partner.
Methods: We analysed retrospective questionnaire data from the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS; 2013-2015). Cis-gender women who reported ≥1 pregnancy after HIV diagnosis were included. Among women reporting an HIV-serodiscordant
(i.e., HIV-negative or HIV status unknown) pregnancy partner, we assessed uptake of safer conception strategies during the most recent pregnancy. Multivariable logistic regression examined independent correlates of safer conception among women who reported planned pregnancies.
Results: Of 288 participants (20.2% of 1,425 enrolled), 67% (n=194) reported an HIV-serodiscordant pregnancy partner. Among these women, current median age was 38 years (IQR: 33,43), median years between most recent pregnancy and study enrolment was 4 [IQR: 2-11], and 64% of pregnancies were unplanned. Overall, 26% reported using a safer conception method, with higher uptake among women with planned (41%) versus unplanned pregnancies (17%) (p< 0.01). Among women with planned pregnancies (n=70), reported safer conception methods included: viral suppression with antiretroviral therapy (ART) (34%); manual insemination (31%); timed condomless sex to peak fertility (17%); partner PrEP (7%); sperm donation (7%); sperm washing (< 5%); and artificial insemination (e.g. IUI) (< 5%). In addition, 76% reported being on ART prior to pregnancy although viral suppression status was unknown. Having ever discussed reproductive goals with a healthcare provider after HIV diagnosis [AOR: 23.3 (95% CI: 2.19, 249)] was the only covariate independently associated with safer conception uptake.
Conclusions: One-quarter of WLWH who had an HIV-serodiscordant pregnancy partner reported using safer conception, including 41% with planned and 17% with unplanned pregnancies. However, nearly three-quarters of women reported ART use prior to pregnancy and thus likely benefitted from lowered sexual HIV transmission risk without awareness of this as a safer conception strategy. Discussions of reproductive goals and options are essential to routine HIV care for WLWH to support pregnancy planning and facilitate uptake of safer conception.

WEPEB0563

Beyond HIV-serodiscordance: four types of partnership discordance that affect engagement in safer conception care

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Background: Many men and women living with HIV and their partners want to have children. For those in HIV-serodiscordant partnerships, condomless sex to conceive introduces HIV transmission risks. We conducted in-depth interviews with men and women living with HIV and their HIV-uninfected or unknown-serostatus partners to inform safer conception programming.
Methods: To explore acceptability and feasibility of safer conception methods among HIV-affected couples in Uganda, we recruited couples through HIV-positive men and women on antiretroviral therapy ("index") who reported
(1) an HIV-negative/unknown serostatus partner ("partner"),
(2) HIV-serostatus disclosure to partner, and
(3) personal or partner desire for a child within two years.
We conducted in-depth interviews with 40 individuals from 20 couples to assess awareness and acceptability of five safer conception strategies: antiretroviral therapy for the infected partner, pre-exposure prophylaxis for the uninfected partner, condomless sex timed to peak fertility, manual insemination, and male circumcision.
Results: The 20 index participants had a median age of 32.5 years and median of 2 living children; 11 were women and 80% had plasma HIV-RNA < 400 copies/mL. Awareness of HIV prevention strategies beyond condoms and abstinence was limited and precluded assessment of safer conception method acceptability. Thematic analysis revealed four types of partnership discordance as primary barriers to safer conception practices:
(1) HIV-serostatus disclosure: Although disclosure to partner was an inclusion criterion, disclosure was often incomplete and/or unilateral.
(2) Childbearing intention: Participants often had divergent childbearing plans from partners and made incorrect assumptions about the partner's wishes.
(3) HIV risk perception: participants had disparate ideas regarding risk of HIV transmission and the acceptable level of HIV-acquisition/transmission risk to meet reproductive goals.
(4) Nature of the relationship: discord in understanding the nature of the relationship (e.g. exclusive vs. non-exclusive) complicated decisions about safer conception plans.
Only 2 of 20 partnerships in our sample were concordant across all four domains.
Conclusions: Enthusiasm for safer conception programming is growing. Our findings highlight the importance of addressing communication around gendered discordant partnership goals, knowledge, and perceptions in addition to offering technical safer conception advice to maximize reach, uptake, adherence to, and retention in safer conception programming.

WEPEB0564

Menopausal status and symptoms in women living with HIV in the UK: results from the PRIME study

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Background: There remains a paucity of data on HIV and the menopause. We present preliminary data on menopausal status and symptomatology among women living with HIV (WLHIV) in the UK.
Methods: An analysis of data on the first 400 participants recruited to the PRIME Study; a prospective cohort of WLHIV aged 45-60. Menopausal status was based on self-reported menstrual pattern and categorized according to modified STRAW+10 criteria. Postmenopausal status (PostMP) was defined as last menstrual period [LMP]>12 months; perimenopausal status (PeriMP) as LMP≤12 months with menstrual irregularity. Menopausal symptoms were captured using the Menopause Rating Scale.
Results: Median age of the study population was 49 years (interquartile range: 47-52).The majority were Black African (n=282, 72.5%), with low rates of smoking (n=35, 9.1%) and drug use (n=9, 2.4%). Almost all women (n=381, 97.4%) were on antiretroviral therapy; a minority had a CD4 count< 200 cells/mm^3 (n=37, 11.4%) or detectable HIV viral load (n=46, 12.6%). The majority were PeriMP (n=186, 46.5%) or PostMP (n=140, 35.0%); a fifth were premenopausal (PreMP, n=74). Women reported high levels of somatic (n=349, 88.6%), psychological (n=305, 77.8%) and urogenital (n=259, 67.6%) symptoms. The most frequently reported symptoms were physical and mental exhaustion (63.9%), muscle and joint problems (66.3%), sleep disturbance (63.1%) and hot flushes (63.0%). PeriMP and PostMP women reported symptoms more frequently than PreMP women (p<0.005). Less than half (n=101, 47.9%) of PeriMP and PostMP women with vasomotor symptoms had heard of hormone replacement therapy (HRT), with less than 10% using HRT (n=13). Less than 5% of those with urogenital symptoms reported using topical oestrogens (n=8, 3.9%). Over half of all participants (n=195, 52.0%), stated they had not received sufficient information about the menopause.
Conclusions: This is the largest study to date of menopause symptomatology in WLHIV in the UK. We report high levels of somatic, psychological and urogenital symptoms. PeriMP and PostMP women were most likely to report symptoms in all domains. Despite high levels of somatic and urogenital symptoms, very few women were using hormonal treatment, and there was evidence of significant informational need. We suggest development of services to support to WLHIV through the menopause.

WEPEB0565

Experience of hormone replacement therapy (HRT) in postmenopausal women living with HIV

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Background: One-third of people living in the United Kingdom are female and increasing numbers of women with HIV are reaching menopause. Hormone replacement therapy (HRT) is beneficial to HIV positive women who are symptomatic and/or with early menopause and may improve bone health. At King's College Hospital 40% of HIV positive patients are female and 625(63%) are aged >45 years. Postmenopausal women referred to an HIV medical gynaecology clinic for review and HRT counselling.
Assess the uptake of HRT in HIV positive postmenopausal women, the effectiveness of HRT in treating menopausal symptoms and demographic and HIV characteristics of those with early, premature or natural menopause
Methods: Retrospective case note review of post-menopausal women with HIV attending the medical gynaecology clinic between 1st Jan 2011-31st Dec 2016. Menopause was classified by age at menopause as premature (< 40 years), early (40-45 years) or natural (>45) and baseline characteristics and management described.
Results: Of the 579 women referred to medical gynaecology, 73(12%) were postmenopausal (88% black ethnicity, 95% undetectable on treatment, median(IQR) current and nadir CD4 630(435,780) and 259(111,396) cells/μl respectively) The age range at menopause was between 36-53 years; 11(15%) had premature and 15(21%) early menopause. There was no evidence of a difference between demographic/HIV characteristics between menopause categories (P< 0.5 for all). There was a trend to higher parity among natural menopause compared to early or premature (median IQR) parity 2(1,2) vs. 1(0,2) and 1(0,1) respectively, p=0.02). 69 women attended; 49(71%) to discuss menopause management , of which 28(57%) accepted HRT. 23(82%) were prescribed systemic HRT; 19(83%) had continuous or sequential oestrogen patch or gel plus micronized progestogen. 11(58%) required oestrogen up-titration to improve symptoms. 4 experienced side effects (bleeding N=3, mood disturbance N=1). All women had symptomatic relief within 6 months of starting HRT; 4 discontinued due to side effects and anxiety about breast cancer. 24 underwent bone mineral density evaluation, 15(62.5%) were osteopenic and 2(8%) had osteoporosis.
Conclusions: HRT was acceptable to the majority of women with HIV who were counselled and offered treatment. All women had symptomatic improvement and adverse effects were rare. Dose adjustments were required in the majority patients.

WEPEB0566

Examining the relationships among antimullerian hormone and leukocyte telomere length in HIV-positive and negative women enrolled in the Children and Women: antiRetrovirals and Markers of Aging (CARMA) cohort

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Background: HIV infection is associated with younger age at menopause and shorter leukocyte telomere length (LTL), a marker of cellular aging. Anti-Mullerian hormone (AMH) levels decline with age and can estimate ovarian reserve. We sought to examine the associations among LTL, AMH and HIV to better understand the relationship between cellular and ovarian aging in women living with HIV (WLWH).
Methods: The study included 233 WLWH and 154 HIV-negative non-pregnant women ≥12 years of age enrolled in the CARMA cohort with available blood samples. Relative LTL and AMH were measured by multiplex qPCR and ELISA, respectively. Generalized linear models with log links to account for the non-normal distribution of AMH were used. Possible predictors included age, HIV status, LTL, body mass index (BMI), smoking (current vs. past vs. never), current opioid use, CD4 nadir, peak HIV viral load (VL), current detectable VL and antiretroviral therapy (naïve vs. not). Likelihood ratio tests were used to assess variable importance.
Results: In our cohort, WLWH had shorter LTL (7.2 vs. 7.5 p=0.004) and lower AMH levels (1.9ng/mL vs. 3.1ng/mL p=0.01) compared to HIV-negative controls of similar age (35.0y vs. 34.6y p=0.52). As both AMH and LTL decline with aging, a significant relationship between them (p< 0.0001) did not remain after adjusting for age (p=0.12). WLWH were more likely to be Black (25.8% vs. 5.8% p< 0.001), currently smoking (45.1% vs. 30.5% p=0.01), currently using opioids (25.8% vs. 13% p=0.003) and of higher BMI (26.2 vs. 25.3 p=0.03), than HIV- controls. In analyses omitting ethnicity due to collinearity with HIV status, smoking and opioid use, HIV status (p< 0.0001) and age (p<0.0001) were significantly related to AMH levels, with HIV seropositivity decreasing AMH by 39% at any given age. Among WLWH, age (p< 0.0001) and current opioid use (p=0.01) independently predicted lower AMH levels which were 40% lower in opioid users.
Conclusions: Our data support previous work demonstrating lower AMH levels in WLWH compared to controls. Although LTL was not a significant predictor of AMH in this population, we show that, in addition to HIV infection, opioid use may be associated with decreased ovarian reserve in WLWH.

WEPEB0567

Residual activation/inflammation and HIV-associated co-morbidities do not predict premature ovarian ageing in cART-treated HIV-infected women

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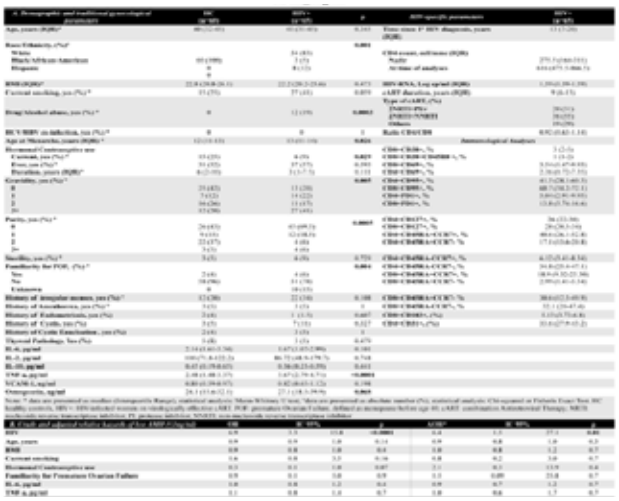
Background: Early menopause and lower circulating anti-Mullerian Hormone (AMH), ovarian ageing marker, have been described in HIV+ women. During suppressive cART, heightened immune-activation/inflammation persist and associate with premature ageing. Little is known on the effects of the hormonal milieu on immune activation/inflammation and on HIV-associated co-morbidities in ageing HIV-infected women. Thus, we aimed to investigate circulating AMH and the possible association(s) with markers of immune activation/inflammation and cardiovascular/bone damage in a cohort of HIV-infected women on effective cART.
Methods: Population: 65 HIV+ women on cART (HIV-RNA< 40 cp/ml) aged 25-50years; 60 age-matched healthy women (HC). Epidemiological, gynecological, HIV-related data were collected. We measured: (i) plasma AMH, IL-6 (ELISA), IL-2, IL-10, TNFa, VCAM-1, osteopontin (Luminex) (ii) CD4/CD8 activation (CD38/CD69), apoptosis (CD95), exhaustion (PD1), maturation (CD45RA/CD45R0/CD127/CCR7), recent thymic emigrants (CD31/CD103) (flow cytometry). Mann Whitney, Chi-squared were used. We defined low AMH ≤1ng/ml. Univariate and Multivariate Logistic Regression Analyses were used to assess factors associated with lowAMH (≤1ng/ml).
Results: Compared to HC, HIV+ women were more frequently non-Caucasian, drug/alcohol abusers, with history of late menarche, lower hormonal contraceptive use, higher gravidity and lower parity (Table.1a).
HIV+ showed significantly lower AMH (0.93 [0.81-1.59] vs 1.45 [1.11-1.78]; p=.004) and higher circulating TNFa (Table.1a).
HIV infection was the only factor independently associated with a 6- fold increased risk of low AMH in both uni- and multivariate logistic regression (Table.1b). In HIV-infected women, no other clinical, HIV-related and immunological parameters resulted associated with circulating AMH.



[Table 1. Demographic/gynecological/HIV-related features of the study population and risk factors for AMH ≤1ng/ml]

Conclusions: Despite effective cART, HIV+ women still display an increased risk of low circulating AMH versus age-matched peers, indicating premature ovarian ageing. The lack of associations with residual immune activation/inflammation, indicates that the higher probability of poor ovarian reserve in successfully treated HIV+ women is mediated by factors that are not captured by pro-inflammatory and cardiovascular/bone damage markers, and that might include tissue HIV reservoirs or co-infections.

WEPEB0568

Contraceptive utilization and fertility preferences among Cameroonian women with and without HIV infection

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Background: HIV prevalence is high in sub-Saharan Africa and the majority of residents living with HIV are of reproductive age. Family planning and the utilization of contraceptives play a significant role in preventing vertical and horizontal HIV transmission. However, decision-making around contraception is poorly understood in many African nations, including Cameroon. Considering this critical knowledge gap, we examined associates of modern contraceptive utilization among Cameroonian women with and without HIV infection.
Methods: De-identified medical records were identified from women screened for cervical cancer as part of the Cameroon Baptist Convention Health Services Women's Health Program in 2007-2013. Bivariate analysis compared personal characteristics and contraceptive practices between HIV-positive and HIV-negative women. Multivariate analysis used logistic regression to model the use of modern methods of contraception.

	N / % HIV + N=2,876	N / % HIV - N=16,662	χ^2
Use Modern Methods*	740 / 34.51%	4,141 / 31.15%	χ^2=9.64 p<0.01
Desire to Become Pregnant Soon* (Yes)	470 / 30.13%	2,830 / 31.66%	χ^2=1.49 p=0.47
Polygamous* (No, 0 Cowives)	757 / 73.78%	7,861 / 82.36%	χ^2=48.89 p<0.001
Polygamous* (Yes, 1+ Cowives)	184 / 17.93%	1,065 / 11.16%	
Parity (0)	210 / 7.30%	1,695 / 10.17%	χ^2=204.49 p<0.001
Parity (1-2)	854 / 29.69%	3,419 / 20.52%	
Parity (3-4)	698 / 24.27%	3,254 / 19.53%	
Parity (5+)	1,114 / 38.73%	8,294 / 49.78%	

[Table 1. Bivariate Results of HIV+ and HIV- Women]

Results: The study included 19,538 women with age 16-45 years. Modern contraceptive utilization was low at 31%. See Table 1 for bivariate results. Women living with HIV had 85% higher odds of modern contraception use (OR: 1.85, p<0.001).

As expected, women with higher parity and higher education levels had higher odds of using modern contraception (OR 1.17, p<0.001 for parity; OR: 3.37, p<0.001 for post-secondary school attendance). Polygamy was negatively associated with modern contraception use; women with three or more cowives had 63% lower odds of modern contraception use (OR: 0.37, p<0.001). All reported odds ratios are adjusted. *Percentages are affected by missing data.
Conclusions: Although it is encouraging that HIV-infected women in Cameroon utilized modern contraceptives at a higher rate than HIV-uninfected women, only one of three women in either group used modern contraceptives during the study period. Some used less reliable, traditional methods (e.g. natural family planning). There are opportunities to improve family planning efforts to reduce vertical and horizontal HIV transmission. Further research is needed to elucidate the decision-making process pertaining to modern contraceptive utilization in sub-Saharan Africa.

WEPEB0569

High prevalence of bacterial vaginosis among women seeking contraception in Kenya

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Background: The prevalence of bacterial vaginosis (BV), which has been associated with increased risk of HIV acquisition and transmission, is high among young women in sub-Saharan Africa, a region that bears the largest incidence of new HIV infections. Women seeking contraceptive services have an opportunity to be evaluated and managed for BV. We sought to determine the prevalence and correlates of BV among women desiring contraception.
Methods: Women screening for a study to evaluate the effects of a contraceptive vaginal ring on vaginal microbiota in Thika, Kenya were assessed. BV diagnosis was made using Amsel's clinical criteria. Factors associated with BV were analyzed using multivariate logistic regression techniques.
Results: Of the 363 women, 246 (69%) were aged < 30 years and 195 (54%) had more than eight years of education. More than three-quarters of the women (280 (78%)) reported having an income and 42 (12%) reported weekly consumption of alcohol. Of the 247 (69%) women who reported having a main sex partner, 132 (53%) were living with this partner. Median number of reported sex acts in the prior month was 3 [IQR 1-8], with 60 (20%) of the women reporting condom use every time they had sex. Daily vaginal washing and use of vaginal lubricants were reported by 215 (60%) and 32 (9%) women, respectively. Close to half (42%) of the women reported an abnormal vaginal discharge.
One hundred and sixteen women (34.6%) had BV. Living with a main sexual partner was associated a reduced likelihood of having BV (OR 0.43 (95% CI 0.20, 0.92). Additionally, having an abnormal vaginal discharge (p < 0.001), lesions in the genital area (p = 0.04) or having a yeast infection (p = 0.02) were also associated with having BV. Vaginal washing and condom use were not significantly associated with BV.
Conclusions: The prevalence of BV among young women seeking contraception was high. Reproductive health workers have an opportunity to evaluate, manage, and educate women who want to use contraception about BV and associated risks, and this may reduce their risk of acquiring HIV.

WEPEB0570

Desire to prove fertility and contraceptive misconceptions delay family planning and condom use until after pregnancy among Kenyan adolescents

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Background: Adolescent girls have a high risk of unintended pregnancy and HIV acquisition in Kenya. We conducted a mixed methods study to characterize contraceptive knowledge and determinants of use among postpartum adolescents.
Methods: We recruited postpartum HIV-uninfected adolescents from 2 maternal-child health clinics in Western Kenya to participate in a survey and focus group discussion (FGD); 4 FGDs were conducted, stratified by site and age (14-18, 19-21). We also recruited health care providers offering family planning (FP) services to participate in a survey and 2 FGDs (1/site).
Results: Overall, 32 adolescents and 28 providers participated. Median provider age was 36 (interquartile range [IQR]: 31-47), and median number of years providing FP was 5 (IQR: 3-10). Misconceptions about FP and HIV risk were common among both providers and adolescents. Nearly half (40%) of providers believed intrauterine devices (IUDs) increased risk of HIV acquisition, and 63% believed they were unsafe to use among HIV-infected women. Adolescents were familiar with condoms for HIV and pregnancy prevention, but believed condoms were only appropriate when a partner was known to be HIV-infected, rather than when partners HIV status was unknown or concordant negative. Providers identified lack of training, experience, and counseling time as barriers to offering the full range of FP methods; they limited counseling to short-term methods when there were long queues or if they lacked knowledge or experience with other methods. Limited counseling options coupled with lack of training and experience with implants and IUDs contributed to lower use of these methods among young women at risk for HIV. Prior to marriage and/or childbearing adolescents lacked family and community support for FP, but adolescents also said they did not use FP because they felt it was important to prove their fertility prior to childbearing. However, after they became mothers adolescents received encouragement and familial/community support to use FP and had increased awareness of FP benefits.
Conclusions: Adolescents would benefit from novel strategies to receive better contraceptive support and education prior to childbearing (including dual method use with condoms) and improved provider training to prevent unintended pregnancies and HIV transmission.

WEPEB0571

Differences in genital tract HIV RNA shedding by injectable progestin contraceptive (IPC) exposure among antiretroviral therapy (ART)-naïve and ART-using HIV-infected women in Cape Town, South Africa

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Background: IPCs may increase female-to-male sexual HIV transmission risk. ART use reduces genital tract HIV shedding. Few data exist regarding IPC use and shedding in ART-naïve and ART-using women. We compared genital tract HIV viral load (gVL) and recent IPC exposure among women by ART use.
Methods: Within a larger trial of intrauterine device use among HIV-infected women, we enrolled:
(i) ART-using (>6 months) women with recent (<12 months) plasma VL (pVL) <1000 copies/dL and;
(ii) women not yet eligible for ART by local guidelines (pre-ART). All women underwent reproductive tract infection (RTI) testing and treatment within 1 month of enrollment, and at enrollment completed questionnaires on contraceptive history and provided specimens for pVL and gVL (via menstrual cup). IPC exposure was defined as depot medroxyprogesterone acetate (DMPA) or norethindrone enantate (Net-En) use within 120 days before enrollment; enrollment was timed to coincide with next IPC dose. Associations between IPC and detectable gVL were analyzed using exact tests and logistic regression, stratified by ART status.
Results: Of 199 women (132 ART-using, 67 pre-ART), 39% reported recent IPC use. ART-using women were less likely to have detectable gVL or pVL (Table 1; p=0.002); detectable pVL was strongly correlated with detectable gVL (AOR=5.28, 95% CI=1.93-14.5) only among ART users.

Variable	Pre-ART	ART	Recent IPC Exposure	No Recent IPC Exposure
Age (median, IQR)	30 (26, 34)	32 (28, 36)	32 (28, 36)	31 (27, 34)
IPC use in last 120 days (%, n)	39% (26)	42% (51)	---	---
Any RTI* at screening (%, n)	36% (24)	24% (32)	27% (21)	29% (35)
Baseline detectable gVL (%, n)	64% (40/63)	16% (21/130)	36% (26)	30% (36)
Baseline detectable pVL (%, n)	95% (63/66)	20% (26/130)	44% (33/75)	46% (56/121)
Baseline log10 plasma VL (median, IQR)	3.91 (3.17, 4.48)	2.73 (2.01, 3.44)	3.07 (2.44, 3.66)	3.21 (2.52, 4.01)

**Neisseria gonorrhea, Chlamydia trachomatis, Trichomonas vaginalis, & bacterial vaginosis.*

[Table 1. Key participant characteristics]

For ART users, recent IPC was associated with detectable gVL (Table 2) and remained independently associated when adjusted for age, RTI, and detectable pVL (AOR=3.27, 95%CI=1.16-9.21; p=0.025). Among ART users, the difference was strongest for women reporting recent Net-En use (Table 2).

Bivariate comparison of genital HIV shedding with recent exposure to and specific type of IPC, by ART status								
	Recent vs. No Recent IPC use	p-value	DMPA vs. Net-En	p-value	Net-En vs. No Recent IPC Use	p-value	DMPA vs. No Recent IPC Use	p-value
Pre-ART	58% (14/24) vs. 67% (26/39)	0.593	64% (9/14) vs. 50% (5/10)	0.678	50% vs. 67%	0.465	64% vs. 67%	1.00
ART-using	25% (12/49) vs. 11% (9/81)	0.052	21% (8/38) vs 36% (4/11)	0.427	36% vs. 11%	0.046	21% vs. 11%	0.167

[Table 2.]

Conclusions: These novel data suggest recent IPC use may be associated with increased gVL in ART-using women. Given widespread concern about potential for IPC to enhance HIV transmission, this association warrants further investigation, with attention to potential differential effects of Net-En vs. DMPA.

WEPEB0572

Tolerability and satisfaction of levonorgestrel versus etonogestrel contraceptive implants among women living with HIV

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Background: In Uganda, uptake of contraceptive implants remains low, possibly due to fear of side effects. We present data on side effects and satisfaction related to the levonorgestrel (LNG) implant versus the etonogestrel (ENG) implant among Ugandan women living with HIV.
Methods: Two studies evaluated LNG or ENG implant pharmacokinetics and tolerability. Each study enrolled 60 women into three groups (n=20/group): efavirenz-based ART, nevirapine-based ART, or ART-naive. Tolerability and satisfaction data were combined across ART groups. At each visit, participants were asked about implant-associated side effects using a structured questionnaire; and contraceptive satisfaction was assessed using a Likert scale. Occurrence of side effects (graded by DAIDS severity tables) and the frequency of being "very satisfied" with the implant at weeks 4, 12 and 24 were compared between the studies by chi-square.
Results: In total, 120 consenting adult women were enrolled in the studies. Three women were excluded from the analysis by week 24 (ART initiation, study nonadherence, and consent withdrawal). Baseline characteristics were similar between studies. There were no statistically significant differences between studies at any visit, except for increased headache at week 12 and increased metrrohagia weeks 12 and 24 in the ENG group (Table, p=0.03, 0.01 and 0.02, respectively). All reported side effects were Grade 1, except two in the LNG study (both weight gain) and three in the ENG study (one metrorrhagia; two dysmenorrhea), which were Grade 2. Overall, lower satisfaction with menstrual symptoms at week 4 and overall satisfaction at week 12 were observed with LNG compared to the ENG implant (Table, p< 0.001 and p=0.04, respectively).

Side effect or satisfaction	LNG Week 4 (n=58)	LNG Week 12 (n=58)	LNG Week 24 (n=57)	ENG Week 4 (n=60)	ENG Week 12 (n=60)	ENG Week 24 (n=60)
Nausea	7 (12.1%)	4 (6.9%)	3 (5.3%)	10 (16.7%)	5 (8.3%)	8 (13.3%)
Headache	16 (27.6%)	12 (20.7%)*	13 (22.8%)	25 (41.7%)	24 (40.0%)*	15 (25.0%)
Weight gain	15 (25.9%)	23 (39.7%)	18 (31.6%)	14 (23.3%)	17 (28.3%)	29 (48.3%)
Breast tenderness	4 (6.9%)	3 (5.2%)	3 (5.3%)	4 (6.7%)	4 (6.7%)	3 (5.0%)
Menorrhagia	10 (17.2%)	18 (31.0%)	11 (19.3%)	16 (26.7%)	16 (26.7%)	11 (18.3%)
Metrorrhagia	3 (5.2%)	6 (10.3%)*	2 (3.5%)*	5 (8.3%)	19 (31.7%)*	11 (18.3%)*
Amenorrhoea	23 (39.7%)	23 (39.7%)	26 (45.6)	18 (30.0%)	14 (23.3%)	20 (33.3%)
Satisfaction with menstrual symptoms	29 (50.0%)*	35 (60.3%)	44 (77.2%)	52 (86.7%)*	46 (76.7%)	53 (88.3%)
Overall satisfaction	49 (84.5%)	44 (75.9%)*	51 (89.5%)	55 (91.7%)	54 (90.0%)*	54 (90.0%)

[Table]

Conclusions: Ugandan women living with HIV had high levels of satisfaction and low rates of Grade 2 adverse events with both implants. Women on ART using contraceptive implants are unlikely to experience greater than mild adverse events in the first 24 weeks.

WEPEB0573

Initial regimen duration in female patients taking integrase strand transfer inhibitors (INSTI) in the OPERA® observational database

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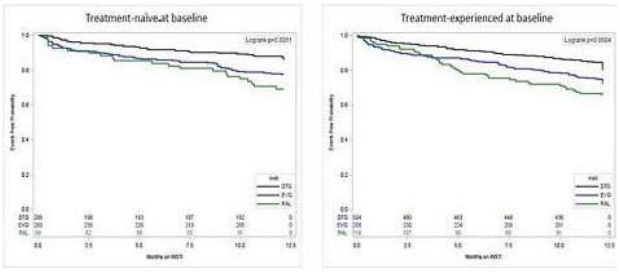
Background: Women face unique complexities with antiretroviral therapy. This analysis compares durations of initial INSTI-based regimens in HIV+ females.
Methods: HIV+ women initiating their first INSTI-containing regimen between 08/12/2013 and 11/30/2015 were identified in the OPERA cohort, a collaboration of 79 clinics in 15 US states. Each patient was observed from regimen start until discontinuation, loss to follow-up, death, or data freeze (11/30/2016). Time to discontinuation was evaluated using Cox regression and Kaplan-Meier estimates.
Results: Out of 73,406 HIV+ patients, 537 treatment-naïve (dolutegravir (DTG):39%, elvitegravir (EVG):48%, raltegravir (RAL):13%) and 878 treatment-experienced (DTG:57%, EVG:29%, RAL:13%) women qualified for analysis.
In the first twelve months after initiation, women taking RAL or EVG were more likely to discontinue their initial INSTI than those taking DTG among both treatment-naïve (adjusted hazard ratio EVG vs. DTG: 1.61(95% CI: 1.09, 2.39); RAL vs. DTG: 2.27 (1.37,3.76)) and treatment-experienced women (EVG vs. DTG: 1.39 (1.03, 1.87); RAL vs. DTG: 2.11 (1.47, 3.02)).
Among women who switched to another regimen during all of follow-up (naïve DTG: 32%, RAL: 62%, EVG: 42%; experienced: DTG: 39%, RAL: 59%, EVG: 44%), a third of treatment-naïve women (DTG:33%, RAL:37%, EVG:36%) and over a quarter of treatment-experienced women (DTG:24%, RAL:27%, EVG:45%) switched to another INSTI.
Treatment interruptions of >45 days were also commonly observed immediately after discontinuation of the initial INSTI (naïve DTG: 30%, RAL: 19%, EVG: 31%; experienced DTG:26%, RAL: 13%, EVG: 19%).



[Figure. Kaplan-Meier estimates of time to discontinuation of first INSTI-based regimens in the first twelve months of treatment]

Conclusions: In a large cohort of HIV+ women in care, INSTI-based regimens were effective throughout the first year of follow-up for treatment-naïve and treatment-experienced women. Women receiving DTG were the least likely to discontinue during this period and over all of follow-up. Intra-class switching from initial INSTIs and drug interruptions suggest that women may be discontinuing for reasons other than virologic failure, and that access may be a major issue.

WEPEB0574

Uptake and correlates of cervical cancer screening among HIV-infected women attending HIV-care in Uganda

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Background: Sub-Saharan Africa has the highest burden of cervical cancer globally and HIV infected women are at particularly high risk. Integration of cervical screening into HIV care is recommended but service uptake is rarely tracked. We assessed the uptake and correlates of cervical cancer screening among HIV infected women in care in Uganda.
Methods: A nationally representative sample of HIV infected women in care were interviewed in a cross-sectional survey conducted August-November 2016. Structured interviews were conducted with 5198 HIV infected women 15-49 years, from 245 HIV clinics. Knowledge of cervical cancer and uptake of cervical

screening were determined. Correlates of uptake of screening were assessed with modified Poisson regression model to obtain prevalence ratios (PR) using Stata version 12.0.
Results: Overall, 94.0% (4858) ever heard of cervical cancer and 66% (3732) knew a site for cervical screening. However, 47.4% (2302) didn't know the schedule for screening and 50% (2409) did not know the symptoms of cervical cancer. A third, (33.7%; 1719) rated their risk of acquiring cervical cancer as low while 16.8% (857) rated the risk as high. Uptake of screening was 30.3% (1561), ranging from 18.6% in the central region to 39.1% in Kampala. Women who never screened cited lack of information (29.6%; 1059), no time (25.5%; 913), lack of screening facilities (14.0%; 501), and information about procedure being painful 10.5% (376). Majority of the 245 health facilities (64%; 153) offered cervical cancer screening. Delivery at health facilities (adj.PR 1.69, CI 1.00-2.87), receipt of HIV care at HCII and private facilities (adj.PR1.55, CI 1.07-2.26 and adj.PR 1.96, CI 1.15-3.34, respectively), knowledge of cervical cancer (adj.PR 1.69, CI 1.29-2.21), where to screen from (adj.PR 8.31 CI 4.47-15.45) and low risk perception (adj.PR 1.50, CI 1.12-2.01) increased likelihood of screening. HPV vaccination was very low at 2%, but higher among adolescents 15-19 years, at 8%.
Conclusions: Cervical screening uptake was very low among HIV infected women in care in Uganda, especially in the central region. Improved awareness about cervical cancer, sources of services and addressing risk perception may increase uptake of cervical screening in this population.

Key populations

WEPEB0575

Perceived HIV stigma among men who have sex with men (MSM) patients with HIV in a single hospital in Northern Taiwan

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Background: HIV-related stigma is a common obstacle facing the care in those people living with HIV especially among MSM. We attempt to measure HIV / AIDS-related stigma as experienced by patients from a hospital in Northern Taiwan.
Methods: The HIV stigma scale, as developed by Berger [1] and modified by Lindberg [2] in 2014 was used to measure HIV-related stigma on 68 MSM patients who visited MacKay Memorial Hospital in Taipei, Taiwan. The scale consisted of four subscales in Personalized Stigma, Disclosure Concerns, Negative Self-Image, and Concerns with Public Attitudes. These 39 items were answered with Likert scale responses. Patient's responses were analyzed using T-test for equality of means.
Results: Sixty-eight patients participated in the study. The mean age was 33. Majority of the patients had college level education (64.71%) and diagnosed more than 24 months (66.18%). 47.06% of the patients had a fixed partner. Most of the patients reported that at least one family member, partner or friend knew about their disease while greater than 50% of patients felt that other people were supportive or very supportive after finding out about their disease. Patients reported HIV-related stigma in all four dimensions of the HIV stigma scale, especially Diclosure Concerns.

Dimensions	Score	Standard Deviation
Personalized Stigma	2.46	0.86
Disclosure Concerns	3.18	0.75
Negative Self-Image	2.37	0.79
Concerns with Public Attitudes	2.97	0.79

[Table 1. HIV Stigma Scale Scores]

Statistical analyses revealed that patients who were received very supportively or supportively by others when others learnt of their disease were less likely to suffer from Personalized Stigma (p=0.002) and Negative Self Image (p=0.003).

Dimensions	Scores in Those with Supportive Contacts	Scores in Those with Unsupportive Contacts	P value
Personalized Stigma	35.38	43.59	0.002
Disclosure Concerns	27.87	29.24	0.224
Negative Self-Image	17.60	21.59	0.003
Concerns with Public Attitudes 19.91	19.91	21.94	0.051

[Table 2. Analysis]

Conclusions: In general, people living with HIV in Taiwan reported HIV-related stigma in all four dimensions of the HIV stigma scale, especially Disclosure Concerns. Patients who reported more support from family and peers experienced significantly less stigma in the areas of Personalized Stigma and Negative Self Image. Healthcare professionals should be address HIV-related stigma concerns when providing care for MSM patients with HIV.

WEPEB0576

Social capital and depression in HIV-infected young black men who have sex with men

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Background: Social capital, the sum of an individual's resource-containing, reciprocal, and trustworthy social network connections, has been proposed as an important facilitator of successful HIV care engagement. Depression, on the other hand, has been shown to negatively impact clinical outcomes among people living with HIV. We sought to explore relationships between social capital, depression and engagement in HIV care in a sample of young Black gay, bisexual and other men who have sex with men (YBMSM) in Atlanta, USA.
Methods: We recruited 81 HIV-infected YBMSM from the Grady Infectious Disease Program clinic. Each participant completed a survey including measures of social capital and depression. Social capital was measured with a modified Personal Social Capital Scale; which included items about the amount and types of support offered through social networks and community involvement. Depression was measured using the Centers for Epidemiologic Studies-Depression (CES-D) scale. Clinical outcomes (appointment attendance and HIV-1 viral load) were extracted from the medical record.
Results: Our sample ranged in age from 18-24 years (Mean=22, SD=1.5). Forty-nine percent (49%) had attended at least 75% of their scheduled appointments over the past year. Sixty-five percent (65%) were virally suppressed (HIV-1 VL ≤ 50 copies/ml). The median social capital score was 25, similar to prior research in other populations. Forty-seven percent (47%) had a positive depression screen. Depression affected viral suppression differently in YBMSM with lower (below median of 25) vs. higher social capital (p = 0.046, test for interaction). There was no association between depression and viral suppression among those with higher social capital (OR= 0.63; p=0.52). However, the odds of viral suppression among YBMSM with lower social capital was 93% lower in depressed vs. non-depressed participants (OR= 0.07, p= 0.002).
Conclusions: Depression was very common in our sample of HIV-infected YBMSM; nearly half of our participants had a positive screen. For these patients, social capital was an important protective factor, as the detrimental effect of depression on viral suppression was worsened among those with low social capital. Our results suggest a need for innovative network-level interventions to augment social capital among HIV-infected YBMSM, particularly those who are depressed.

WEPEB0577

Risky sexual behavior in French HIV-positive men who have sex with men (MSM): ANRS DRIVER study

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Background: High risk sexual behavior is rising in MSM reflected by an increase in sexually transmitted infections (STI). The aim of the ANRS DRIVER study is to estimate the prevalence of asymptomatic STIs in HIV positive MSM and create a risk score of STI. We report the behavioral data.
Methods: Between April and December 2015, HIV positive MSM were enrolled in 13 Paris area hospitals. Sexual behavior was assessed using self-reported outcomes: risky sexual behavior was assessed using 2 scales - the Sexual Compulsivity Scale (SCS) and the Sexual Sensation Seeking Scale (SSSS) - as well as by ways of re-

sponses to a behavioral questionnaire inquiring about drug, alcohol, and condom use in several sexual situations. Chlamydia trachomatis and Neisseria gonorrhoeae were tested by PCR on urine, pharyngeal and anal swabs; syphilis by serum antibodies.
Results: 485 asymptomatic patients at their HIV semi-annual follow up visit were included (median age: 47 years, average time living with HIV: 13 years, undetectable viral load in 94%, average CD4+: 679/mm3. Nearly 63% had a history of STI (genital warts in 39%, syphilis in 45%), and 18% within the previous 12 months. An ongoing STI was found in 13.6% (syphilis 6%, CT or NG infection 8%). Risky behavior in sex, drugs and alcohol use are tabulated.

Risky sexual behaviors in the last six months: N=485	%
Use of Grindr networking application	46
Poppers use	40
Non protected anal intercourse	38
Non protected group sexual intercourse	31
Alcohol use during sexual intercourse	31
Cannabis use	23
Cocaine use	15
GBH use	8
Sex for money	7

[Table 1]

Fifteen percent of patients had an SCS score above 20 (vs 5-6% in the general population) reflecting high compulsivity. Respondents reported thinking about sex at work (16%), thinking about sex more frequently than they would like (14%), frequent uninhibited behavior (30%), seeking new sexual experiences (42%) and unprotected sex (42%). The median score of the SSSS was 22.8. The SSSS was positively correlated with the SCS (R = 0.58).
Conclusions: Risky sexual behavior and sexual compulsivity are common in the French HIV-positive MSM population.

WEPEB0578

Unusual and unique distribution of anal high-risk human papillomavirus among men who have sex with men living in the Central African Republic

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Background: High-risk Human Papillomavirus (HR-HPV) infection is the causal agent of anal cancer in men who have sex with men (MSM). The prevalence of HR-HPV was evaluated by molecular biology in MSM living in Bangui, the capital of the Central African Republic (CAR).
Methods: Forty-two MSM attending the Centre National de Référence des Infections Sexuellement Transmissibles et de la Thérapie Antirétrovirale (CNRISTTAR) were prospectively enrolled and tested for HPV. Genomic DNA was extracted using the DNeasy Blood and Tissue kit (Qiagen, CA, USA). Human beta-globin DNA was detected by PCR. Anyplex II HPV28 (H28) HPV Genotyping Test (Seegene, Seoul, South Korea) was used for HPV genotype distribution in human beta-globin DNA positive samples.
Results: . Among the 42 anal specimens, 29 (69% [95% CI: 55.0-83.0%]) were positive for HPV DNA. Multiple genotypes infections were frequent in 86.2% (25/29; 95% CI: 73.6-98.7%) of positive anal samples and 88% of them were infected by an average of 2.5 HR-HPV (range, 1 to 8 genotypes per anal specimen). 13.8% of anal samples were infected with a single type of HPV and all of them were high-risk types. HPV-31 was found in 65% of single HPV infection. HR-HPV type 35 was the most prevalent genotype (27.5%), followed by HPV-42 and HPV-53 (24.1%), HPV-58 and -59 (20.7%) and HPV-31 and -61 (17.2%). Interestingly, HR-HPV -16 and -18 were poorly represented in 13.8% (4/29) and 10.3% (3/29), respectively. Only one sample was simultaneously infected by HPV-16 and HPV-18. Low-risk (LR) HPV-6 and HPV-11 were observed in 2 and 3 anal samples, respectively.
Conclusions: HR-HPV-35, LR-HPV-42 and LR-HPV-53 were the most prevalent genotypes in anal samples. These findings demonstrate unusual and unique distribution of HVP genotypes in the MSM population of Bangui, and indicate that the currently available 9-valent HPV vaccine would be poorly effective in this at-risk population.

WEPEB0579

Anal high-risk HPV persistence and risk factors in Thai, Indonesian and Malaysian MSM

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Background: Persistent anal infection with high-risk HPV (HR-HPV) is a major risk factor for anal cancers among MSMs. Knowledge about anal HR-HPV persistence in Asia is very limited. We studied anal HR-HPV persistence and its associated factors among MSM in Thailand, Indonesia and Malaysia.
Methods: MSM aged ≥18 years were enrolled from Bangkok, Jakarta, Bali and Kuala Lumpur and followed up 6 monthly intervals for 12 months. A Dacron swab was used to collect anal samples for HPV genotyping. Persistence anal HR-HPV was defined as the presence of HR-HPV type(s) at all three visits. Incidence anal HR-HPV was defined as new detection of HR-HPV type(s) at months 6 and 12 without HR-HPV type(s) at baseline. Baseline demographic data, risk behavior and HIV clinical data were included in the logistic regression models to identify factors associated with persistent anal HR-HPV infection.
Results: Of 392 (235 HIV-positive) MSM enrolled, HIV-positive MSM were older [mean age 35.8(SD 9.0) vs. 32.1(SD 9.2) years], more likely to have a history of sexually transmitted infections (27.7 vs. 18.5%), have had unprotected sex in the past 6 months (26.0 vs. 42.7%), and were less likely to be circumcised (35.3 vs. 45.9%). Of the HIV-positive MSM, 63.0% were taking antiretroviral treatment for a median (IQR) time of 3.0 (1.8-5.8) years.
High-risk HPV types were detected more frequently in HIV-positive MSM than HIV-negative MSM at baseline (66.5 vs. 50.8%, p=0.004). Overall persistence of any HR-HPV types was 33.3%, while the incidence was 8 per 100-person-months. HPV-16 was the most prevalent HR-HPV type (16.9%) at baseline, had the highest incidence (5.1 per 100 person-months), and the highest persistence (9.9 %).
Being HIV-positive (OR 3.66, 95%CI 1.84-7.26, p<0.001), living in Kuala Lumpur (OR 3.49, 95%CI 1.45-8.42, p=0.005), and employed (OR 2.01, 95%CI 1.22-3.33, p=0.007) increased the risk for the overall persistence of HR-HPV. Persistent HPV-16 was associated with being HIV-positive (OR 3.93, 95%CI 1.34-11.53, p=0.01) and living in Kuala Lumpur (OR 5.98, 95%CI 1.70-21.03, p=0.005).
Conclusions: More than half of MSM in South-East Asia had anal HR-HPV infection. HPV-16 was the most common incident and persistent HR-HPV type. HIV-positive status significantly increased the risk of persistent infection of HR-HPV types, including HPV-16.

WEPEB0580

Multidisciplinary management of MSM patients practicing chemsex and slam, in a LGBT-community sexual health clinic

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Background: Chemsex (use of drugs before or during sexual intercourse) and slam (chemsex with intravenous drugs injections) emerged since late 2000's in the gay community. The main complications are addictions, psychiatric disorders, and infectious diseases (HIV, HCV). Few data were published on this field, particularly treatment's guideline.
The objective of the study was to describe our focused healthcare program and evaluate quantitatively his efficiency.
Methods: This study is a retrospective analysis of participants who have recorded for addiction in a LGBT-community sexual health clinic in the center of Paris, the "190". For each participant, the frequencies of chemsex practice (daily, weekly, monthly, quarterly, on occasion, past, or none) at the first and the last consultation were recorded and compared. Participants who had a follow-up (defined as at least 3 consultations and at least 3 months of follow-up during the study interval) were included in the efficiency evaluation.
Results: From 2013 to 2016, 144 participants consulted because of chemsex, generating 1120 addictologic, psycho-sexological, or psychiatric consultations. All were men, average age 39 years, 59% were HIV-infected, 45% practiced slam, with a weekly or daily frequency for 2/3 of them. Among them, 79 MSM practicing chemsex initiated a follow-up for this reason: average age 39 years, 63% HIV-infected, 54% practicing slam, with a daily or weekly frequency for 3/4 of them. The follow-

up was mainly multidisciplinary (67%), mostly addictologic (89%) and psycho-sexo-logical (73%) but also psychiatric for 25%. The average of follow-up was 14 months and 12 consultations. Half of the patients involved in a follow-up reduced (39%) or stopped (9.9%) chemsex or slam practices.
Conclusions: The multidisciplinary management set up in the "190" satisfies a strong demand. Despite severe addictologic profiles, this follow-up has a positive quantitative impact since half of the participants reduced or stopped chemsex or slam consummation. It seems necessary to develop this kind of healthcare programs in structures receiving MSM.

WEPEB0581

Communication outlets of men who have sex with men in Nigeria and implications for program planning and interventions

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Background: Men who have sex in Nigeria communicate in fearful and harsh environment where being gay has been criminalized. An understanding of common means of communication of Men who have Sex in Nigeria will provide insight on communication platform where HIV prevention interventions should focus for maximum impact. The objective of the study was to identify common means of communication outlets among men who have sex with men in Nigeria for intervention purpose.
Methods: A total of 6,114 key informant interviews were conducted. Population size estimates was incorporated into a mapping and characterization which took place between July and September 2015 across 20 Local Government Areas (LGAs) in Lagos, Nigeria. We utilized the capture-recapture method to identify MSM who were engaged in key informant interview. Data were also triangulated to ensure accurate estimate of three hidden and highly stigmatized populations in Lagos, Nigeria.
Results: In the capture phase, 329(25.4%) used emails, 1623(83%) used phone, 1543(78.6%) communicated through friend while the highest percentage of MSM 1816(86.2%) used the social media (Instagram, Facebook, twitter, SMS, WhatsApp, MSM parties and 2-go chat). In the recapture phase, 161(26.8%) used email as means of communication, 715(81.7%) used phone, 799(84.9%) communicated via a friend while 873(87.8%) used the social media.More than one quarter (27.3%) of MSM were interviwed in internet cafes during the study.
The commonest means of communication was the social media including 2-go, Instagram, MSM parties SMS, WhatsApp and Twitter 86.2% and 87.8% of MSM reported to have used these social media outlets in the capture and recapture phases respectively.
Conclusions: Overall, a high proportion of MSM in Nigeria utilized the social media as the commonest means of communication and meeting male sex partners online. The information in this study can be used to direct and target interventions or how best to model delivery of HIV prevention messaging to these MSM, who represent a young, highly educated and highly stigmatized group. These data suggest that further research assessing the feasibility and acceptability of social media interventions will be increasingly important to addressing the HIV epidemic among MSM across Nigeria.

WEPEB0582

Is access to direct-acting antivirals (DAA) universal? A comparison of socio-behavioral characteristics between pegylated-interferon treated and DAA-treated patients in the French ANRS CO13-HEPAVIH cohort of HIV-HCV co-infected patients

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Background: Direct acting antivirals (DAA) have dramatically increased the efficacy and safety of hepatitis C virus (HCV) infection treatment in HIV-HCV co-infected patients. However, their high costs translate into reduced access to HCV treatment for specific groups of patients. This study aimed at comparing the socio-behavioral characteristics of patients initiating pegylated-interferon (Peg-IFN)-based HCV treatment with those initiating DAA-based treatment, in a French hospital-based cohort of HIV-HCV co-infected patients.
Methods: ANRS CO13-HEPAVIH is a national multicenter prospective cohort started in 2006, which enrolled 1,850 HIV-HCV co-infected patients followed-up in French hospital outpatient units. Both clinical/biological (medical records) and socio-behavioral (self-administered questionnaires) data were collected during follow-up. We selected patients with socio-behavioral data available before HCV treatment initiation. Univariable (Chi2 test) and multivariable (logistic regression) analyses were performed to compare pre-treatment characteristics of patients initiating Peg-IFN based with those initiating DAA-based treatment.
Results: A total of 596 patients were included in this analysis. Among them, 367 initiated peg-IFN-based treatment, and 229 DAA-based treatment. There were significant differences between both groups regarding patients' mean age (45 years ±6 for the Peg-IFN group vs. 52 years ±8 for the DAA group, p<0.001), unstable housing (21.1% vs. 11.3%, p=0.034), drug use (43.9% vs. 30.1%, p=0.0008), regular or daily use of cannabis (24.1% vs. 15.9%, p=0.0004) and history of drug injection (68.8% vs. 38.8%, p<0.0001).
In multivariable analysis, patients initiating DAA-based treatment were older than their Peg-IFN-based treatment counterparts (aOR=1.17; 95%CI [1.13; 1.21]). The former group were less likely to report unstable housing (aOR=0.50; 95%CI [0.26; 0.95]), cannabis use (regular or daily use: aOR=0.53 [0.3; 0.95]; non-regular use: aOR=0.44 [0.24; 0.81]), and a history of drug injection (aOR=0.60; 95%CI [0.39; 0.91]).
Conclusions: Although in this co-infection cohort, it is possible that a majority of patients with socio-economic problems and advanced disease were treated for HCV in the Peg-IFN era, it seems that prescription of DAA concerns fewer patients with more unstable lifestyles. As HCV treatment is prevention, improving access to DAA, in particular to individuals with high-risk behaviors, remains a major clinical and public health strategy.

WEPEB0583

Reasons for initiation and experiences related to sexualized drug use in a sample of HIV-positive men who have sex with men

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Background: High prevalence of sexualized drug use(SDU) has been described in several samples of HIV-positive (HIV+) patients. However, motivations to engage in SDU are still poorly studied. We aimed to describe the reasons for starting and participating in SDU in a sample of HIV+ patients in Madrid (Spain).
Methods: We used an anonymous survey to explore magnitude and factors related to SDU (mephedrone, ketamine, GHB, crystal meth, MDMA, cocaine and/or amphetamine) in a sample of HIV+ MSM attending in 22 HIV clinics in Madrid 2016. The survey was conducted using REDCap™. From May to December 2016 a total of 511 participants completed the survey. The present analysis includes the group of patients who referred SDU during the past year. We described sociodemographical characteristics, type of drugs and proportions of patients who referred each type of reason for starting or getting engaged in SDU.
Results: We analysed the responses of 190 patients who referred SDU in the last year. Most of them were middle aged (Mean(SD)=37.8 (7.5)), 72% Spanish born, 71% had salaries above 1000 euros, and 88% were on ART. The drugs more commonly used were: GHB (53.2%), Cocaine (51.6%), Mephedrone (50%), MDMA (21.1%) and crystal methanphetamine (18.4%).
Table 1 shows frequencies of patients by reasons of consumption the first time of engaging in practices associated to SDU (Table 1). Motivations that led to SDU subsequent times are shown in Table 2.

REASONS	N(%)
Get new pleasurable experiences	126 (66.3)
Try new drug uses	63 (33.2)
Facilitate painful sexual practices	39 (20.5)
Having sex with someone liked	37 (19.5)
Avoid negative feelings	23 (12.1)
Feeling accepted/included with others	15 (7.9)
Less concern about HIV-diagnosis	14 (7.4)
Do practices that others asked	3 (1.6)

[Table 1. Table 1. Reasons for SDU (first time)]

REASONS	N(%)
More arousal during sex	147 (77.4)
Sexual disinhibition, different practices	89 (46.8)
Longer sexual response/sessions	93 (48.9)
Avoid negative feelings	34 (17.9)
Overcoming shyness/insecurity	28 (14.7)
Make painful practices	26 (13.7)
Less concern about HIV-diagnosis	26 (13.7)
Feeling accepted/included with others	14 (7.4)

[Table 2. Reasons for SDU (any time)]

Conclusions: Most HIV+ MSM in our sample referred SDU to enhance and facilitate sexual practices. However, a relatively high proportion of patients had SDU to avoid unpleasant feelings or face problematic situations.

WEPEB0584

Unmet contraceptive need in HIV-positive Kenyan female sex workers

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Background: Public health interventions designed to reduce HIV and STI incidence in female sex workers (FSWs) often overlook their broader reproductive health needs. Unintended pregnancy is a major occupational risk factor for FSWs. The objective of this study was to examine the prevalence and correlates of unmet contraceptive need in this key population.
Methods: We examined data collected at enrollment of HIV-positive women entering the Mombasa Cohort, a prospective cohort study of FSWs in Kenya. Unmet contraceptive need was defined as intending to delay the birth of the next child, or not wanting any more children, yet not using modern contraception other than condoms alone. Poisson regression was used to calculate unadjusted and adjusted prevalence ratios (PRs) for factors associated with unmet contraceptive need.
Results: Of the 376 HIV-positive FSWs enrolled between October 2012 and December 2016, 216 (57.4%), 95% confidence interval [CI]: 52.3%-62.5%) had unmet contraceptive need. In multi-variable analysis, increasing age and experiencing physical abuse in the past 12 months were associated with a higher prevalence of unmet contraceptive need (Table 1). In the subset of 333 women who denied currently trying to become pregnant, desire for another child in the future was also associated with unmet contraceptive need after adjusting for age, workplace, and history of physical abuse (adjusted PR 1.32, 95%CI 1.13-1.54, p< 0.001).

Characteristic	N	Unmet need n (%)	PR (95% CI)	p-value	aPR (95% CI)	p-value
Age (years)				0.096		0.003
20-25	31	12 (38.7)	1		1	
26-35	131	71 (54.2)	1.40 (0.87, 2.24)		1.57 (0.96, 2.58)	
36-45	182	110 (60.4)	1.56 (0.99, 2.47)		1.95 (1.19, 3.20)	
>46	32	22 (68.8)	1.78 (1.08, 2.93)		2.33 (1.36, 3.98)	
Physical abuse in past year				0.095		0.039
No	241	190 (55.7)	1		1	
Yes	35	24 (68.6)	1.23 (0.96, 1.57)		1.28 (1.01, 1.62)	

[Table 1.]

Conclusions: This study demonstrated a high prevalence of unmet contraceptive need in HIV-positive FSWs. Interventions are needed to improve contraceptive access and uptake as a component of comprehensive HIV care for this population.

WEPEB0585

HIV risk and outcomes in transgender patients enrolled in a large integrated health care system

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Background: Data on HIV risk and HIV related outcomes in transgender individuals is lacking. We sought to compare rates of HIV virologic suppression between transgender and cisgender HIV-infected patients in an integrated health care system in the United States. To estimate risk of HIV infection in the HIV-uninfected transgender population, we also examined history of sexually transmitted infections (STI).
Methods: We conducted an observational retrospective cohort study of HIV-infected adults and uninfected transgender patients who received care during 2010-2015 in Kaiser Permanente Southern California. History of STI diagnoses in HIV-uninfected transgender patients were ascertained using electronic medical records. HIV virologic suppression was defined as having at least one measurement of HIV RNA <200 copies/mL, and sustained suppression was defined as having 2 consecutive values of HIV RNA <200 copies/mL. Modified Poisson regression models adjusted for age and gender were used to assess the impact of transgender status on HIV RNA suppression and sustained suppression during the 12 months after entry into the cohort, as compared to HIV-infected cisgender patients.
Results:

Characteristics		Transgender HIV+ adults N=79	Non-transgender HIV+ adults N=11,427	P-value
Age, n (%)	18-39	34 (43.0)	3,633 (31.8)	0.0587
	40-59	42 (53.2)	6,626 (58.0)	
	60+/unknown	3 (3.8)	1,168 (10.2)	
Gender*, n (%)	Male	1 (1.3)	10,385 (90.9)	<0.0001
	Female	78 (98.7)	1,042 (9.1)	
Race/ethnicity, n (%)	Non-Hispanic White	13 (16.5)	4,629 (40.5)	<0.0001
	Hispanic	34 (43.0)	3,706 (32.4)	
	Non-Hispanic Black	21 (26.6)	1,909 (16.7)	
	Other/unknown	11 (13.9)	1,183 (10.4)	

*Among transgender patients, gender refers to transgender male and transgender female.

[Demographic Characteristics of Transgender and Non]

Among 3,286 HIV-uninfected transgender persons, the proportions of those ever had a diagnosis of syphilis, gonorrhea, or chlamydia were 1.52, 0.94 and 1.58 %, respectively. We identified 11,427 non-transgender and 79 transgender HIV-infected patients during the study period (Table). Compared to HIV-infected cisgender patients, HIV-infected transgender patients had a similar likelihood of achieving both virologic suppression (adjusted relative risk, aRR: 1.02, 95% CI: 0.92-1.12) and sustained suppression (aRR: 1.03, 95% CI: 0.90-1.17).
Conclusions: Amongst a diverse HIV-infected transgender cohort, no differences in HIV virologic outcomes were observed when compared to cisgender HIV-infected patients. Rate of STIs were high in the HIV-uninfected transgender group; therefore proactive HIV risk-reduction strategies in this population may be warranted.

WEPEB0586

High levels of treatment non-adherence due to concerns for interactions between antiretroviral therapy and feminizing hormones among transgender women in Los Angeles, CA

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Background: Feminizing hormone therapies (HT) are critical to harmonizing gender identity and expression for transgender women (TW), and antiretroviral therapy (ART) is essential for HIV-infected (HIV+) individuals. However, both HT and ART have potential side effects, and drug-drug interactions (DDI) exist between some ART and HT. Despite this, limited data exists addressing knowledge of ART-HT side effects and DDIs among TW. We assessed knowledge of HT and ART side effects and DDIs, including effects on treatment adherence, among HIV+ and HIV- uninfected (HIV-) TW.
Methods: From March-July 2016, self-identified TW were recruited from APAIT, a community-based AIDS service organization in Los Angeles, California, for a cross-sectional study assessing HIV, HT and access to and engagement in health care. Participants reported sociodemographics, medical history and knowledge of ART-HT DDIs. All HIV+ TW were on ART.
Results: Participants (n=87; Table 1) had mean age 45 years; 62% were Hispanic, 54% HIV+ (mean CD4+ T lymphocyte count 555 cells/mm^3) and 69% were on HT. ART use included 40% integrase inhibitor-, 32% protease inhibitor- and 28% NNRTI-based ART. Most (77%) had a regular healthcare provider, although 25% (HIV- 13%, HIV+ 34%) reported unsupervised HT and only 68% (HIV- 78%, HIV+ 61%) discussed potential HT side effects with their provider. Although 57% of HIV+ TW reported concern for ART-HT interactions, only 49% discussed ART-HT DDI with their provider and 40% cited this concern as a reason for not taking ART (n=5), HT (n=5) or both (n=7) as directed.

	HIV- (n=40; 46%)	HIV+ (n=47; 54%)
Age (years)	43 (12)	48 (10)
Hispanic ethnicity	65%	60%
Black/African American race	13%	21%
No healthcare insurance	21%	33%
Current feminizing HT use	65%	72%
Planned future feminizing HT use	26%	16%
Substance Use (last 90 days)	25%	47%

*Mean and standard deviation or percent reported. HT=hormone therapy.

[Table 1: Participant Demographics]*

Conclusions: TW frequently have concerns about potential ART and HT side effects and DDIs that, coupled with sub-optimal provider engagement, contribute to both ART and HT non-adherence. Improved clinician and patient engagement and education are needed to address these concerns and optimize care for TW. Future research will address ART-HT interactions and side effect risk for TW, and investigate approaches to mitigate risk.

WEPEB0587

Factors associated with medical doctors' intention to discriminate against transgender patients in Kuala Lumpur, Malaysia

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Background: Transgender people (TGP) are frequent targets of discrimination as a result of their stigmatized social status. Discrimination in the context of healthcare is an important and understudied phenomenon that can lead to poor health outcomes. TGP who face stigma and discrimination are at an increased risk for depression, suicide, and HIV. In fact, transgender women have the highest HIV burden of any at-risk group, including men who have sex with men and injection drug users. The current study explores factors associated with medical doctors' intention to discriminate against TGP in Malaysia.
Methods: A total of 436 medical doctors at two major university medical centers in Kuala Lumpur, Malaysia, completed an online survey. Sociodemographic characteristics, stigma-related constructs and intentions to discriminate against TGP were measured. Bivariate Pearson correlations were performed to examine the associations between stigma-related constructs and discrimination intent. Bivariate and multivariate linear regression was used to evaluate independent covariates of discrimination intent.
Results: Medical doctors who felt more fearful of TGP and held more shameful attitudes about TGP expressed greater intention to discriminate against TGP, whereas doctors who endorsed the belief that TGP deserve good care were less likely to intend to discriminate. The final model accounted for 54% of the variance in discrimination intent, with 46% accounted for by stigma-related constructs and 8% accounted for by socio-demographic characteristics.
Conclusions: Constructs associated with transgender stigma play an important role in medical doctors' intention to discriminate against transgender patients. Future development of interventions to improve medical doctors' knowledge and attitudes of TGP may reduce discriminatory intent in the setting of medical care and improve quality of healthcare delivery for this important patient group.

WEPEB0588

Importance of addressing gender identity in HIV prevention and treatment services: HIV outcomes among transgender women compared with cisgender men who have sex with men in eight sub-Saharan African countries

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Background: There is growing body of evidence that transgender women bear a heavy and disproportionate burden of HIV globally. Across Sub-Saharan Africa, there has been an increased awareness of the importance of addressing the needs of key populations, however, transgender women are often ignored or included as men who have sex with men (MSM). Preliminary data from three West-African nations found that HIV burden among transgender women was nearly three times that of cisgender MSM (19%vs7%, P< 0.01). Characterizing the specific HIV prevention and treatment needs among transgender women compared to cisgender MSM can guide the development and implementation of these programs.
Methods: Transgender women (n=937) and MSM (n=3,649) living with HIV were included who completed HIV testing and a structured survey instrument accrued with similar methods using respondent-driven sampling in Burkina Faso, Cote d'Ivoire, The Gambia, Lesotho, Malawi, Senegal, Swaziland, and Togo. Student t-tests were used to compare the proportions of each care continuum variable for transgender women and MSM.
Results: Transgender women (78%) were significantly more likely than MSM (74%) to have ever been tested for HIV (p=0.04) and to have been tested in the prior 12 months (50% versus 44%, p=0.004). A significantly greater proportion of transgender women (11%) compared with MSM (4%) had been told they had HIV by a doctor (p< 0.001). However, on HIV testing, 25% and 14%, respectively were HIV-positive (p< 0.001). Of those who were aware of their HIV status, 67% of transgender women and 42% of MSM were currently being treated (p=0.002).
Conclusions: These data confirm that transgender women across SSA demonstrate a heavy and disproportionate burden of HIV, even when compared with cisgender MSM. Moreover, the determinants of engagement in care differ between cisgender MSM and transgender women further reinforcing the need for specific implementations considerations for HIV prevention and treatment programs even in the more generalized HIV epidemics across Sub-Saharan Africa.

WEPEB0589

Migrants and virological rebound on ART in France: role of socioeconomic factors

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Background: Achievement of the 90:90:90 UNAIDS target is conditioned by a sustained viral suppression on cART. Some studies in Western countries have suggested that virological rebound (VR) is more frequent in migrants.
Methods: We included 158 migrants from sub-Saharan Africa (SSA), 53 other migrants (OTH) and 288 French natives (FRA) enrolled from 2004 to 2008 in the French ANRS-COPANA cohort, who started a first cART (2 NRTIs with PI, NNRTI or II) and achieved viral suppression (VS) defined by viral load (VL) <50 cp/ml within one year. Probability of a subsequent VR, defined by one VL>1000 cp/ml or two consecutive VL between 50-1000 cp/ml, was compared between FRA, SSA and OTH by Kaplan-Meier survival analysis. Determinants of VR were assessed by using Cox models including geographical origin, demographic, clinical, biological and various socioeconomic data updated at the time of first VS, among which educational level, employment, income, self-reported financial difficulties, partnership, HIV status disclosure.
Results: cART was started a median time of 1.2 (0.3-2.9) years after HIV diagnosis and lead to VS within a median time of 4.2 (2.8-6.2) months. VR occurred in 116 persons (23%). The 4-year probability (95%CI) of VR was 15% (9-21) in FRA HSH, 16% (8-24) in FRA heterosexuals, 33% (25-41) in SSA and 30% (16-44) in OTH (p<0.001). Migrant status (HR, 2.44 (95%CI, 1.16-3.61) for SSA, 1.74 (0.96-3.18) for OTH, vs. FRA), female sex, type of cART, HIV non-disclosure, low educational level, financial difficulties, unemployment and not being owners/renters of their house were associated with VR, while calendar period, VL and CD4 count at cART initiation were not.
In multivariate analysis, HIV status non-disclosure (aHR 1.69, 1.05-2.70) and PI including-cART (aHR 1.76 (1.13-2.75) versus other cART) remained associated with VR. Migrants were no longer at a higher risk of VR after adjustment for sex, type of cART, educational level, financial difficulties and HIV disclosure. These last three factors had the biggest impact on changes between the crude and aHRs in migrants.
Conclusions: Social factors are strong determinants of the sustainability of the viral response on ART and must be addressed in a global HIV care strategy.

WEPEB0590

Should abacavir be a first-line option for adults with HIV in sub-Saharan Africa?

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Background: Despite a poor toxicity profile, zidovudine supersedes abacavir as a first-line agent in many international treatment guidelines due to concerns about HLA-B*57:01-related abacavir-hypersensitivity. An important question is whether abacavir should become a first-line option in resource limited settings where HLA-B*57:01 is sufficiently rare.
In one of the largest HLA-typing efforts in sub-Saharan Africa, we assessed HLA alleles among 581 HIV-infected patients in Kampala (n=81) and Mbarara (n=500) to guide regional clinical decision-making.
Methods: Specimens were drawn from the UARTO cohort, including 81 pilot subjects enrolled from Kampala during 2002-2004 and 500 subjects enrolled from Mbarara during 2005-2010, just prior to antiretroviral therapy initiation. HLA-typing was performed using Roche/454/Fluidigm HLA Typing Kits following the Roche protocols. HLA alleles and genotypes were called using the Conexio ATF 454 HLA typing software.
Results: Samples from 52 (64%) individuals in Kampala, and 461 (92%) individuals in Mbarara yielded successful HLA-genotyping results. HLA-B*57:01 was not observed in the 52 Kampala subjects. In the main Mbarara cohort, one subject was heterozygous for HLA-B*57:01 among 461 subjects (0.2% prevalence). This subject did not receive abacavir during study observation from 2006 - 2011. Overall, during the entire follow up duration from 2005-2015 in Mbarara, only two other patients ever-used abacavir (0.4% usage rate); neither had HLA-B*57:01. The low prevalence of HLA-B*5701 is consistent with other smaller studies conducted in sub-Saharan Africa.
Conclusions: Given the low prevalence of HLA*B57:01 carriage in our cohort and others in sub-Saharan Africa (Table 1), the cautious use abacavir-based therapy may be more advisable than zidovudine-based therapy when tenofovir is not a viable option. The benefits of abacavir over zidovudine-based therapy should be considered in regional guidelines given abacavir has superior efficacy, once-daily dosing, and has been studied as a component of regimens containing integrase strand transfer inhibitors.

Country	Region/ Ethnicity	Sample size	Allele frequency	Received abacavir?	Abacavir hyper-sensitivity reaction rate	References
Kenya	Nandi	240	0.0083	No	NA	Cao, 2004
Kenya	Luo	265	0.0076	No	NA	Cao, 2004
Mali	Dogon	138	NA	No	NA	Cao, 2004
Uganda	Kampala	161	0.0311	No	NA	Cao, 2004
Zambia	Lusaka	44	0.0114	No	NA	Cao, 2004
Guiné-Bissau	NA	65	0	No	NA	Spinola, 2005
Uganda	Kampala, Entebbe	300	0	Yes	6/300 (2%)	Munderi, 2011
Uganda	Kampala	52	0	No	NA	This study
Uganda	Mbarara	461	0.001	No	NA	This study

*[Table1. Prevalence of B*5701 in sub-Saharan Africa]*

WEPEB0591

Early results of universal test and treat implementation in a large Zambian correctional facility

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Background: High HIV prevalence is an ongoing challenge in Zambian correctional facilities. To provide inmates with the benefits of treatment as prevention (TasP), generate evidence to tailor universal test and treat (UTT) in correctional settings, and coordinate tuberculosis screening among HIV-infected inmates, we launched a UTT implementation research study at Lusaka Central (LC), one of Zambia's largest correctional facilities. We present interim findings here.
Methods: We offered immediate ART to inmates with newly diagnosed HIV or previously diagnosed HIV not yet on ART, regardless of CD4 or WHO stage. To enable UTT, we strengthened the LC health system by: training corrections officers and health workers; hiring a study nurse and clinician; and supporting routine HIV testing services (HTS) and viral load (VL) testing. To evaluate impact, we strengthened routine data systems, and prospectively collected data along the HIV cascade for a cohort of HIV-positive inmates consenting to immediate ART.
Results: From June—December 2016, 1,662 inmates were offered and 1,413 (85.0%) accepted HTS; 198 (14.0%) were found HIV-infected [177 men (89.4%), 21 women (10.6%)]. 172 (86.9%) were referred to the study for immediate ART with 149 (86.6%) meeting study eligibility criteria; 149 (100%) enrolled and 149 (100%) started ART [135 men (90.6%), 14 women (9.4%)] within 1 day (IQR:1-5 days). Mean age was 33.2 years (sd:7.8 years). Median baseline CD4 was 284 cells/mm^3 (IQR:191-401). Prior to ART, 144 (96.6%) inmates underwent TB screening, 7 were diagnosed with tuberculosis by Xpert and 3 clinically; all 10 (100%) started anti-tuberculosis treatment. After 5 months, 88 (59.1%) inmates receiving immediate ART remained in study follow-up and 61 (40.9%) had been released or transferred, with non-significantly more women (n/N=9/14, 64.3%) than men (n/N=79/135, 58.5%) retained in the cohort (p=0.68). Of 13 inmates with VL testing after ≥3 months on ART, 11 (84.6%) were suppressed (VL≤40 copies/ml).
Conclusions: Implementing UTT within a large correctional facility resulted in high uptake of HTS and immediate ART for inmates with advanced immunosuppression, and facilitated tuberculosis screening, diagnosis and treatment. Logistical complexities posed by the Zambian correctional setting, including frequent inmate transfer and release, threaten to interrupt the HIV care continuum for HIV-positive inmates.

WEPEB0592

A high mortality among male HIV-infected patients after prison release

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Background: Outside North American settings, data on treatment outcome and vital status of HIV-positive former inmates are scarce. French Guiana is a South American French territory, where HIV prevalence consistently exceeds 1% in the adult population. In 2014, it fluctuated around 4%in the only correctional facility. After describing the population of HIV-positive inmates, we aimed to evaluate mortality after release, and to identify its predictive factors.
Methods: All HIV-infected adults released from an incarceration of 30 days or more, between 2007 and 2013, were enrolled in a retrospective cohort study. Mortality was described over time, using Kaplan-Meier estimates. Factors associated with mortality were identified through a non-parametric survival regression model.
Results: Of the 147 former inmates included, 82.3% were male. The median age was 37.3 years. The majority were migrants, 25.8% were homeless, 70.1% suffered from substance abuse. On admission, 78.1% had an early HIV-stage infection (CDC-stage A), with a median CD4 count of 397.5/mm3. Upon release, 74 (50.3%) were on ART, and 84.5% of them had a viral load≤200copies/mL. The main reasons for not being treated were: not fulfilling the criteria (74.6%), and refusing ART (15.1%). After release, 8.2% of the cohort had died, with a crude incidence of 33.8/1000 person-years. All recorded deaths were males, with an incidence of 42.2/1000 person-years. Comparing with the age-specific mortality rates for males in French Guiana, the standardized mortality ratio was 14.8.
In multivariate analysis, factors associated with death were age and a low CD4 count before release.
Conclusions: Despite access to ART while incarcerated, with good virological outcome, the post-release mortality was very high for males, almost 15 times what is observed in the male general population living in French Guiana, after age standardization. Access to ART in correctional facilities may be a necessary, but not sufficient condition to protect male inmates from death after release.

WEPEB0593

Real time monitoring adherence for HIV patients with recurrent virological failure: an opportunity to improve linkage to care in vulnerable population (ANRS 950113)

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Background: Five to 10% of HIV patients taking antiretroviral therapy experienced recurrent virological failure (rVF). These patients have frequently serious social and psychological problems and caregivers are often helpless.
Now, adherence data can be transmitted wirelessly through cellular networks and paired with individually tailored interventions in real time. Feasibility about real time adherence monitoring in this specific HIV population is unknown.
Methods: A pilot multicenter (3), prospective study was conducted from 2015 to 2016. Patients living with HIV, > 18 years old with ≥ 2 separate events of virological failure were included. All study participants received a real-time adherence monitor (Wisepill Technologies) and were followed for 6 months. Patients received an SMS only if no signal was received from the monitor within 2 h of the expected dosing time. If no signal was received for more than 48 h, a mail notification was sent to caregivers (nurse and physician). Questionnaires about quality of live and real time monitoring were completed.
Results: Fourteen patients were included: mean age (years)=48.5, sex ratio H/F=6, median CD4 cells=382/mm^3, mean duration (years) of HIV infection=16.7. The mean number of line therapy was high (7) and half of them suffered from mental illness. Initially, viral load was > 50 cp/mL for nearly all patients (12/14=86%). One patient has stopped the study and 6 were lost to follow up (42%). After 3 months, viral load was < 50 cp/mL for 7 patients. After 6 months, among 7 remaining patients, only 2 were still undetectable. In first month, mean adherence was 74.3% before reminder and 84.8% in 2 hours following SMS-reminder. Mean adherence decrease along the study to 50% (59% with SMS-reminder) after 5 months (32% for patients with virological failure). After 6 months, 4PAS score (to assess therapeutic relationship between patient and caregivers) was high (40.8/44). Two patients reported real time monitoring as an intrusion into their private life.
Conclusions: Real time adherence monitoring appears to be acceptable and feasible in vulnerable HIV population with rVF. Further studies are needed to understand reasons to decrease adherence after 3 months and improve automatic and caregivers interventions.

WEPEB0594

E-cigarette use among persons living with HIV

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Background: Cigarette smoking is common, but little is known about e-cigarette use among people living with HIV (PLWH). The goal of this study was to evaluate this.
Methods: This study was conducted in the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) cohort of PLWH in primary care. We included PLWH from six sites across the U.S. who reported having ever smoked cigarettes. E-cigarette use (daily, less than daily, none) as well as other cigarette and drug use and risk behaviors were collected via their most recent CNICS clinical assessment of self-report measures completed between 5/15-8/16 on touch-screen tablets at routine clinical care visits. Illicit drug use, at-risk alcohol use, depression, antiretroviral therapy (ART) use, ART adherence, and unsafe sex rates were compared between e-cigarette users and non-e-cigarette users with logistic regression models adjusted for age, sex, race, and cigarette smoking status.
Results: Of 2,956 PLWH in the sample, their mean age was 47; 87% were male, 53% white, 29% black, 14% Hispanic, and 51% current cigarette smokers. In the past year 4% reported daily, 22% less than daily, and 73% no e-cigarette use. Compared to non-users, e-cigarette users were younger (mean 44 vs. 49) and more likely to be white (61% vs. 50%), current cigarette smokers (69% vs. 44%), current opiate users (5% vs. 3%), current marijuana users (40% vs. 33%), not on ART (8% vs. 6%), and less adherent to ART (mean adherence 91% vs. 94%) (all p values < 0.05 in adjusted models). Those reporting less than daily e-cigarette use were more likely to currently smoke cigarettes (74%) than those who never smoked e-cigarettes (44%) and those with daily e-cigarette use (43%).
Conclusions: E-cigarette use is common among PLWH and associated with high rates of deleterious health behaviors. This highlights the importance of assessing e-cigarette use as part of care and recognizing users may include PLWH that need additional support to reduce risky behaviors such as illicit drug use. While cigarette smoking was less common among daily e-cigarette users, it was still high (43%), raising concerns about the effectiveness of PLWH using e-cigarettes for smoking cessation.

New Approaches and Tools for HIV Prevention

WEPEC0896

Bacterial vaginosis among sexually experienced young women in South Africa: prevalence, covariates and syndromic management

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Background: Young South African women remain among the highest risk groups for HIV acquisition. Bacterial vaginosis (BV) increases HIV risk and may compromise efficacy of tenofovir gel pre-exposure prophylaxis (PrEP). In South Africa, treat-

ment of BV and other genital tract infections (GTIs) follows WHO-recommended syndromic management, which may underestimate cases, particularly among young women. We compared BV prevalence by symptom- and laboratory-based assessment among sexually experienced female youth, and investigated socio-behavioural and clinical correlates of prevalent infection.
Methods: We analyzed baseline data from female youth (aged 16-24) who reported HIV-negative or unknown status at enrolment in a youth-centred cohort in Durban and Soweto (n=425; Nov 2014-May 2016). Interviewer-administered surveys assessed demographics, behaviors, and presence of GTI symptoms. BV prevalence was assessed via reported symptoms and vaginal swab collection for Gram stain diagnosis (Nugent's score >6). We assessed sensitivity and specificity of syndromic screening compared with laboratory confirmation. Multivariable logistic regression identified independent covariates of BV.
Results: Among 195 sexually experienced females (median age 19), 46.9% had been previously pregnant, 35% had a sexual partner ≥5 years older, and 80% reported vaginal douching ≥1 time/week.
Thirty (15.4%) reported any BV symptom. In contrast, clinical tests identified BV in over half of young women (53.7%). Chlamydia prevalence was 18.1%, candidiasis 9.9%, Mycoplasma genitalium 8.8%, trichomoniasis 8.3%, gonorrhoea 6.7% and HIV 5.1%.
Overall, 21/30 participants reporting BV-associated symptoms had clinically-confirmed BV; however of 103 with confirmed BV, 82 were asymptomatic (sensitivity 20.3%, specificity 89.8%).
In adjusted analyses, women with BV had higher odds of co-infection with HIV [aOR: 7.83; 95% CI 0.90-68.0], M. genitalium [aOR: 38.2; 3.08-473.5], and lower gravidity. BV was non-significantly associated with having an intergenerational sex partner [aOR: 1.78; 95% CI 0.88-3.60].
Conclusions: BV prevalence among young women in South Africa is high, and often asymptomatic or unrecognized. Syndromic BV management has poor sensitivity and is thus suboptimal for this population. Associations of BV with HIV, sexually transmitted infections, and other markers of sexual experience highlight an urgent need for linked biomedical, clinical, and structural youth HIV prevention and sexual health approaches, which are resourced to incorporate laboratory-based services.

WEPEC0897

Preclinical evaluation of griffithsin/carrageenan fast dissolving insert in rhesus macaques and murine models

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Background: Griffithsin (GRFT) is a lectin with potent anti-HIV activity. The combination of GRFT with carrageenan (CG) results in synergy against herpes simplex (HSV) and also a potent activity against human papillomavirus (HPV).
Methods: Mice size FDI formulations containing 0.5% GRFT and 1.5% CG (n=6 per formulation/ PK time-point) were inserted vaginally in mice. Vaginal fluid (VF) was collected at baseline and different time-points post FDI insertion. ELISA was used to quantify GRFT in VF. The same formulations in addition to placebo controls (containing hydroxyethyl cellulose) were tested in the HPV16 PsV and HSV vaginal murine models. The formulations were applied vaginally 4 h before challenge with either virus. Fisher's exact test was used for comparison of mouse infection after challenge with HSV-2 and the Mann Whitney U test was used in the HPV16 PsV mouse model. RMs size FDI formulations containing 0.5% GRFT and 1.5% CG (n=6 per formulation/ PK time-point) were inserted vaginally in RMs. VF and plasma were collected at baseline and different time-points post FDI insertion. Vaginal biopsies were also collected at 4h post FDI insertion to measure ex vivo anti-SHIV activity. ELISA was used to quantify GRFT in VF. Curve-fitting analysis was used to calculate the EC_{50} of VF samples against HIV-1 using the TZM-bl assay. Correlations between levels of GRFT and anti-HIV activity in VF were calculated. Vaginal explants were challenged with SHIV SF162P3, washed, and cultured for 14d. Infection was monitored by HIV gag qRT-PCR. SOFT and CUM endpoint analyses were performed.
Results: GRFT concentrations above 2 µg/mL were found in mouse VF 4h after FDI insertion. There was a significant decrease in HSV-2 infection after GRFT/CG FDIs application (60%-73% uninfected, $p < 0.0052$ vs. placebo). GRFT/CG FDIs also significantly decreased HPV-16 PsV infection ($p< 0.0001$). GRFT was not detected in RMs plasma. No significant tissue-associated anti-SHIV activity was detected but GRFT concentrations and EC_{50} values against HIV in RMs VF were strongly correlated ($r=0.9691$; $p< 0.0001$).
Conclusions: GRFT/CG FDI showed a promising PK/PD profile for an on-demand vaginal microbicide and was effective at inhibiting HIV in vitro and HSV and HPV infection in vivo.

WEPEC0898

Partner and peer influence on young South African women's female condom use

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Background: Young women aged 15-24 are the new "face" of HIV, particularly in South Africa, amongst whom one in four new infections occur. HIV interventions have largely failed to curb infection in this group and non-adherence was a key barrier to their PrEP uptake in three trials. The female condom (FC) is a viable alternative to use of male condoms and PrEP, especially in South Africa which has the largest public-sector FC distribution program world-wide. This study investigated theory-driven predictors of FC use among young South African women who participated in a FC promotion intervention.
Methods: Data were drawn from a sample of young women participating in a FC intervention who were randomized to a grouped-based behavioral skills or one-session didactic condition. Eligibility criteria were: ≥18 years; full-time students; self-reported HIV-negative/unknown serostatus; not pregnant or wanting to become pregnant in the next 9 months; and reported condomless vaginal intercourse in the past 2 months. We examined associations between demographic characteristics, FC beliefs of self/partner, gender-role beliefs, history of sexual coercion, and FC use five months post-intervention among 199 women with complete FC use data using backward stepwise regression for the final model.
Results: Participants were Black; mean age was 20.4 years. In the final model, experience of sexual coercion (aOR)=4.11; p=.005), having a friend who had used the FC (aOR=1.95; p=.075), believing that one's partner has positive FC attitudes (aOR=1.55; p=.008), and greater use of FC for vaginal sex at prior assessment at 2.5 months post-intervention (aOR=1.12; p=.030) predicted FC use 5 months post-intervention. Women in the behavioral skills intervention were 2.5 times more likely to report FC use 5 months post-intervention (aOR=2.58; p=.030).
Conclusions: Perceived influence of partners and friends on young women's FC use suggests that their social networks could be an effective conduit for promoting positive FC norms and increasing initial and continued FC use. The higher odds of FC use among women with prior use and practice opportunities highlights the importance of skills-enhancement in FC use and partner negotiation.

WEPEC0899

Efficacy of a single session counseling program to promote safer sex among young Black MSM in the United States: a counseling option for patients taking PrEP

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Background: Among young Black men who have sex with men (YBMSM), to determine the 3-month efficacy of a single-session, clinic-based intervention that promoted the consistent use of condoms for anal and oral sex.
Methods: A pre-test, post-test randomized controlled trial was conducted, using a 3-month period of follow-up observation, in STI clinics. YBMSM (n = 347) completed both baseline and 3-month follow-up assessments between 2012 and 2015. The experimental condition comprised a single-session, one-to-one, evidence-based program (Focus on the Future) designed for tailored delivery in STI clinics. All study protocols were approved by internal review boards at participating institutions.
Results: Among HIV-uninfected YBMSM (n=265) receiving the intervention, 11.2% reported any condomless anal insertive sex at follow-up; compared to 20.6% among YBMSM in the control condition (rate ratio = .54, P = .04). Also among these same HIV-uninfected YBMSM, 12.0% reported any condomless anal receptive sex at follow-up; compared to 21.6% among YBMSM in the control condition (rate ratio = .55, P = .03). When combining insertive and receptive anal sex for

HIV-uninfected YBMSM, 18.3% receiving the intervention reported any condomless sex; compared to 31.1% among those in the control condition (rate ratio = .59, P = .01). Frequency of condomless oral sex among HIV-uninfected YBMSM was also significant. Among those receiving the intervention, 45.8% reported any condomless oral sex at follow-up; compared to 63.2% among YBMSM in the control condition (rate ratio = .72, P =0.03).
Significant findings, for these same four measures, among 92 YBMSM living were HIV were not observed.
Conclusions: This analysis of data from a Phase III RCT suggests that a single-session, clinic-based behavioral intervention may effectively promote the consistent use of condoms for anal and oral sex among HIV-uninfected YBMSM. The single-session program may be a valuable counseling tool for use in conjunction with quarterly clinic appointments for YBMSM using pre-exposure prophylaxis.

WEPEC0900

A cohort of new female condom acceptors: protected sex acts and mixing female and male condom use

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Background: The female condom (FC) is key to increasing HIV protection options for women and men, and is the only female-initiated HIV prevention barrier method. However, despite increased FC distribution globally it remains significantly low compared to male condoms. Although many acceptability studies have been conducted with FC users, data from long-term users are lacking.
Methods: A cohort study of new self-selected FC acceptors (n=598) and a subsample of their male partners (n=60), evaluated longitudinal assessment of key outcomes related to FC and MC use, HIV-related behaviours, and relationship characteristics. Semi-structured in-person interviews were conducted at baseline, and at 1, 6, and 12 months for women and at 1 and 12 months for men. Women aged 18-45 were enrolled from four public-sector health facilities in KwaZulu-Natal, South Africa. Follow-up was completed in 2016.
Results: The mean age for the cohort of new users was 28 years, 50% were unemployed, and 98% had a regular partner. 30% of the women reported that they were HIV-positive and 36% believed that they would "probably or definitely become HIV infected". Most women who tried an FC (78%) said they were confident to use FCs after between 1-3 uses. Cohort data indicated that condom use at last sex using either an FC or MC increased from 56% to almost 90% from baseline to one year. At one year 65.7% of FC users said they felt the FC was better or much better than the MC. "Partner refused to use FC" and "FC was difficult to use" were the main reasons given by women who reported not using the FC at follow-up visits.
Conclusions: Data indicates generally positive experiences of women who chose to accept FC as a method of STI/HIV and pregnancy prevention. Counseling on correct use and how to negotiate use with partners was key to continued use.

WEPEC0901

ShangRing circumcision in boys and men with topical vs. injectable anesthesia: results from a randomized controlled trial

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Background: Circumcision devices can facilitate scale-up of voluntary medical male circumcision (VMMC) programs for HIV prevention in Sub-Saharan Africa. The ShangRing, a single-use circumcision device, is safe, simple to use, and well-accepted by men and boys. We conducted a randomized controlled trial to compare the safety, effectiveness, and acceptability of topical vs. injectable anesthesia for ShangRing circumcision.
Methods: We enrolled men and boys 10 years and older seeking VMMC at two sites in Kenya. Participants were randomized 2:1 to 2.5% lidocaine/2.5% prilocaine topical cream vs. the current practice of 1% injectable lidocaine. Circumcisions were performed using the no-flip ShangRing technique, with follow-up at 7 and 42 days' post-circumcision. The primary outcome was maximum pain experienced during the circumcision, as reported by participants immediately after the procedure, using a visual analogue scale (0=no pain, 10=worst possible pain).
Results: 344 men and boys underwent no-flip ShangRing circumcision between November 2015 and June 2016: 227 in the topical group and 117 in the injectable group. All circumcisions were successfully completed using the ShangRing. 9.3% of participants in the topical group required supplementation with injectable anesthesia before the procedure began. The highest degree of pain during the procedure reported by participants did not differ (p=0.14) between the groups; mean pain scores were 0.2±0.6 vs. 0.1±0.4 in the topical and injectable groups, respectively. There were no allergic reactions or anesthesia-related adverse events in either group and no differences between groups in procedure time, need for supplemental anesthesia during the procedure, or difficulty completing circumcisions. The majority of participants in both groups said there was nothing they disliked about the ShangRing circumcision, and they were very satisfied with the cosmetic results.
Conclusions: Topical anesthesia was effective, safe, and acceptable for use with ShangRing circumcision in males 10 years and older. There were no safety concerns or other adverse effects associated with switching to injected anesthesia in cases where topical was not effective. Use of topical anesthesia may further simplify the no-flip ShangRing technique, minimize needle phobia (potentially attracting more men and boys), decrease risk of needlestick injuries, and increase demand for VMMC in Africa.

WEPEC0902

Evaluating the profile of VMMC clients in order to increase yield in HIV testing for voluntary medical male circumcision (VMMC) programs

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Background: In Tanzania, fewer men than women test for HIV. The WHO VMMC minimum service package includes HIV testing, an opportunity to test this hard-to-reach population in a male-friendly setting. VMMC programs target HIV-negative males, but all men get services regardless of HIV status or age. Little is known about HIV prevalence among males in different age groups receiving VMMC. We examined the profile of clients likely to yield HIV positive results in the VMMC program in Tanzania.
Methods: We conducted a retrospective analysis of VMMC client-level data from September 2009-June 2016 at USAID/Jhpiego-supported VMMC sites in Tanzania. We assessed HIV testing trends and prevalence by age group to identify characteristics associated with high positivity.
Results: In total, 553,514 males were circumcised during this period. 429,270 (77%) were aged 10-19 years and 502,745 (90.8%) received HIV testing; 4,997 (0.99%) were HIV positive, 3,407 of these (68.2%) being newly-diagnosed. Compared to clients aged 10-14 those aged 20-24 (aOR=2.1), 25-29 (aOR=8.7), 30-34 (aOR=16.8), 35-49 (aOR=19.8) and 50+ (aOR=16.2) had a significantly higher HIV prevalence. Clients aged 15-19 (aOR=0.8) were least likely to test positive. Age group 25-29 was most likely to test HIV positive in the VMMC age bracket (15-29 years). Data on sexual activity was available for 144,756 (26%) clients, 23,397 (16%) reporting being sexually-active within 3 months prior to VMMC. 11.4% of the clients were married or cohabiting. HIV prevalence was higher among those sexually-active (aOR= 1.8), cohabiting (aOR=12.2) or married (aOR=1.3) even after adjusting for age.

Age group (years)	VMMC clients (#)	Tested for HIV (#, %)	HIV positive (#, %)	Newly diagnosed (#, %)
10-14	274,677	248,160 (90.35%)	1,133 (0.46%)	716 (63.20%)
15-19	155,986	143,473 (91.98%)	380 (0.26%)	265 (69.74%)
20-24	61,244	55,755 (91.04%)	465 (0.83%)	415 (89.25%)
25-29	25,443	22,853 (89.82%)	704 (3.08%)	591 (83.95%)
30-34	16,325	14,644 (89.70%)	810 (5.53%)	575 (70.99%)
35-49	16,654	14,988 (90%)	1,261 (8.41%)	727 (57.65%)
50+	3,185	2,872 (90.17%)	244 (8.50%)	118 (48.36%)
Total	553,514	502,745 (90.83%)	4,997 (0.99%)	3,407 (68.18%)

[Table 1: HIV Testing in VMMC by Age Groups]

Conclusions: Most clients were < 20 years, but HIV prevalence was higher in clients ≥25 years. VMMC programs target men aged 15-29 years, a lower prevalence group among VMMC clients in Tanzania. Targeting HIV testing services to those at high-risk (i.e. 25-29 year-olds, sexually-active, married or cohabiting) is an important strategy for improving HIV yield in VMMC settings.

WEPEC0903

Voluntary medical male circumcision (VMMC) as a platform to test more men for HIV and link them to care and treatment in Eastern and Southern Africa

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Background: Voluntary medical male circumcision (VMMC) has been scaled-up in fourteen Eastern and Southern African countries since 2009. The VMMC service package includes HIV testing, which offers a unique opportunity to reach men and realize the UNAIDS 90-90-90 goals. According to WHO, 10.5 million men were circumcised in these countries through December, 2015. However, little is known on HIV testing and linkage to care for clients who test HIV-positive in these programs.
Methods: This was a multi-country, retrospective study of VMMC services implemented in Botswana, Mozambique, Namibia, Tanzania, and Zambia, under respective ministries of health, with support from PEPFAR and Jhpiego. We reviewed client-level databases for the period September 2009 through December 2016, though countries initiated VMMC services at different times during this period (Table 1). Data were analyzed to determine HIV positivity rate, new HIV diagnoses, and successful linkage to HIV care and treatment.
Results: Cumulatively, 1,225,083 men received VMMC in the five countries, of which 1,157,240 (94.5%) were tested for HIV. Among the five countries, 13,534 (1.2%) males tested HIV-positive, ranging from 1.0 - 7.2% with Namibia having the highest positivity rate. For four countries, Botswana, Namibia, Mozambique, and Tanzania, 12,952 HIV positive clients were identified with 11,196 (86.4%) being newly-diagnosed, and 8,772 (78.4%) of those newly diagnosed linked to HIV care and treatment.

Country	Time Period	# VMMC clients	# tested (%)	# Tested HIV-positive (%)	# New HIV-positive (%)	# Linked with HIV care/ treatment (%)
Botswana	Jan 2014- Dec 2016	14,538	14, 298 (98.4%)	242 (1.7%)	242 (100%)	76 (31.4%)
Mozambique	Oct 2009 - Nov 2016	589,415	580,231 (98.4%)	7,519 (1.3%)	7,519 (100%)	6,215 (82.7%)
Namibia	May - Nov 2016	2,917	2,576 (88.3%)	186 (7.2%)	27 (14.5%)	17 (63.0%)
Tanzania	Sept 2009- Sept 2016	557,570	504,545 (90.5%)	5,005 (1.0%)	3,408 (68.1%)	2,464 (72.3%)
Zambia	Apr 2015- Oct 2016	60,643	55,590 (91.7%)	582 (1.1%)	not reported	not reported
Total		1,225,083	1, 157, 240 (94.5%)	13, 534 (1.2%)	11,196	8, 772 (78.4%)

[Table 1: HIV Testing and Linkage in VMMC]

(NB: Total tested HIV positive is underreported for Mozambique and Botswana since they only reported newly diagnosed HIV positive clients).
Conclusions: VMMC provides a unique opportunity to offer HIV testing for men who are hard-to-reach through other HIV testing approaches. Although overall yield may be relatively low (1.2%), VMMC is successful at identifying new HIV infections among clients who did not previously know their status and linking them to HIV care and treatment. Stronger data on linkage from VMMC to HIV treatment is needed, and additional efforts should be made to ensure better linkages across the prevention, care and treatment continuum.

WEPEC0904

One arm, open label, prospective, cohort field study to assess safety and efficacy of a new PrePex male circumcision technique performed by nurses in resource-limited settings for HIV prevention

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Background: This study is conducted as part of WHO prequalification process for an update to the PrePex circumcision technique. The updated technique involves removing of the foreskin shortly after PrePex device placement. This technique maintains the PrePex advantages while resolving some of the procedure limitations, including anaerobic environment that may be prone for anaerobic bacteria growth, odor and foreskin hygiene. This study will assess the safety and efficacy of this updated technique in real life environment.
Methods: Rwanda National Ethics Committee approved the study. The study is conducted at Rwanda Military Hospital (RMH). Study includes a sample size of 500 men age 13 and above. Nurses with previous experience in PrePex technique are trained on the updated technique in a 30 minutes instruction course. The updated technique includes the following modifications: 30 minutes after device placement the foreskin is removed till the edges of device are visible, without use of injected anesthesia. All other PrePex steps are same as current technique. The removal of foreskin 30 minutes after placement is different from the current technique where removal of the foreskin is after 7 days.
Results: The study started in January 2017, to date only 12 subjects were enrolled and were followed until device removal on day 7. Numbness of the foreskin was achieved within 25 to 35 minutes from device placement. There was no need of anesthetic injection. Removal of the foreskin after device placement was reported to be easier than removal on day 7. During the 7 days of wearing the device, there was no adverse event reported and no complain on pain or odor. Removal of the device on day 7 was reported to be as simple as the removal of device with the current PrePex technique.
Conclusions: This study is in its early stage and we expect to gather data of 500 men by end of April 2017 and to report statistical conclusions. At this stage it is possible to state that the updated technique seems to be simple to perform and acceptable by clients.

WEPEC0905

Unusual discomfort as reported by clients receiving PrePex™ device circumcision in a pilot study in Mozambique: programmatic implications

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Background: WHO and UNAIDS recommend voluntary medical male circumcision (VMMC) as a priority intervention in high HIV prevalence settings, such as Mozambique, for considerable reduction of sexual transmission of HIV. In Mozambique, VMMC has been provided as surgery since 2009. This requires certified providers and rigorous biosafety measures, making challenging the achievement of the MOH goal of 2 million males circumcised by 2017. PrePex™does not require injectable anesthesia or suturing circumcision. Using such devices could reduce staff needs, procedure time and costs, and increase the acceptability of VMMC. In 2013, a pilot study of the PrePex™ device was started in Mozambique to assess the safety and acceptability of VMMC of this particular device among providers and clients.
Methods: At removal of the PrePex™ device, at day 7 post-placement, 111 clients were randomly asked for in-depth interviews about their experience, and whether they would recommend. The interview was repeated at the 28th day (control visit). Interview transcripts were entered, coded and scrutinized in ATLAS.Ti™, to identify issues with PrePex™ not included in the client information package, and thus classified as "unusual".
Results: In the interviews, 85.8% of the recipients of PrePex™ circumcision indicated they had a good experience with the device and 91.3% of the clients who used PrePex™ would recommend it to others. The interviews identified the occurrence of four presentations of discomfort not foreseen by the providers of device circumcision. The most frequent discomfort was the difficulty to keep the penis upright, followed by the tendency of the penis skin to adhere to underwear (complicating the act of urinating), quick soiling of the bandages before the scheduled visit, and need for frequent hygiene and cleansing due to odor when in bed. The complaints

were associated with embarrassment in public (e.g., on a bus) and interference with social life.
Conclusions: Although satisfaction is high, unusual discomfort with PrePex™ may affect its acceptability. Therefore, appropriate measures should be considered when implementing large scale device circumcision, including information for clients on how to handle such situations need to be offered to device clients, and questionnaires to monitor the presence of forms of discomfort.

WEPEC0906

Safety first: remarkable improved quality of care despite rapid scale-up of five years VMMC Program in Lesotho

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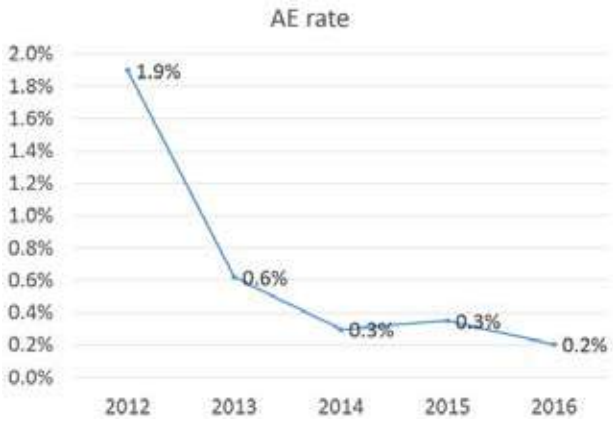
Background: Voluntary Medical Male Circumcision (VMMC) reduces the chances of HIV infection from females to males by approximately 60%. Lesotho adopted VMMC as a priority HIV prevention strategy in 2012. Focusing on outcome of care, programs are advised to implement mechanisms in which health care services will be systematically monitored and evaluated for access, quality and continuity of care. We reviewed the outcome of care through quality aspects of the program including by examining follow-up and adverse event rates and trends.
Methods: We conducted a retrospective review of the VMMC client database from September 2012 to September 2016. Reported follow-up and adverse events were categorized and reviewed by fiscal years and the overall trend summarized in a graph.
Results: A total of 129,982 clients were circumcised during the review period. Of these, 92,041 clients (75.8%) returned for at least one follow-up visit. The overall follow-up rate dropped at the second year of the program but improved gradually over time to 2016. In addition, the AE rates dropped gradually from 1.9% in FY12 to 0.2% in FY 16. In general, there was a remarkable improvement of the safety parameters over the review period.



[AE Rates VMMC Lesotho 5 Years]

Conclusions: Our review revealed significant improvement on follow-up rates and a drop in adverse event rates in over 5 years of program implementation. One of the explanations for these observations could be the regular refresher trainings to providers and counselors so that safety and quality of service become priorities. Mobilizers and community volunteers are also trained in all aspects of VMMC program including quality of care. Both clinical and demand creation teams need to take into account clients' satisfaction and care. Improved quality and perceived safety will increase demand for services from the community.

WEPEC0907

Using predictive analytics and cellular phones to book VMMC for HIV prevention among 18 - 35 years old South African males: the SWHP experience

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Background: In 2010, the South African government introduced voluntary medical male circumcision (VMMC) as part of its national HIV prevention policy - to achieve a targeted 4.3 million circumcisions by the end of 2016. In their strategy to help government reach this target, the SACTWU Worker Health Programme (SWHP) offered VMMC as one of their free services. This is done at their clinics, mobile clinics, and government health care facilities. To improve VMMC uptake, innovative and effective approaches are needed. The objective of this pilot study was to examine the efficacy of using a free Unstructured Supplementary Service Data (USSD) number on their mobiles to book VMMC services.
Methods: Using behavioural economics, SWHP developed a demand creation campaign to boost the uptake of VMMC services among 18 - 35 years old males. Booking an appointment was made easier by dialing the number, *134*450# for free. Men would follow a few simple steps to make an appointment at a convenient date at a health care facility. This booking is followed by a confirmation SMS and a reminder SMS a day before the appointment. This data was used to predict and meet demand in areas where it was most needed. This study was piloted in three of the nine South African provinces: KwaZulu-Natal, Free State and Western Cape. The efficacy of this system was assessed at two months.
Results: From October to December 2016, 48 525 persons accessed the USSD number. A total of 11 533 (24%) were circumcised. The average age of the participants was 18. Most males (74%) were circumcised at clinics, followed by circumcision camps (26%). The most circumcisions took place in KwaZulu-Natal (80%), followed by the Free State (10%) and Western Cape (9%).
Conclusions: Our findings suggest that the integration of a nudge in the form of a carefully designed free USSD booking system into SWHP VMMC demand creation interventions was a success. Our results are also consistent with behavioural economics studies showing that small nudges can modify health behaviours. The effect of this novel intervention should now be tested on a broader scale and in different contexts.

WEPEC0908

The effect of the two Tetanus Toxiod (2TT) dose policy on voluntary medical male circumcision (VMMC) service delivery in Masaka region, Uganda

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Background: VMMC is a proven HIV prevention intervention for men. Nine cases of tetanus infection that resulted into 6 deaths were reported and MoH recommended 2TT doses 28 days apart before circumcision.
We have observed a decline in VMMC uptake which could affect cost per circumcision and the number of infections that would be averted.
Modeling done in Rakai showed that the number of surgeries required preventing one infection over 10 years ranged between 19-58.
We assessed the effect of the 2TT dose policy on VMMC uptake, cost per circumcision, and number of new HIV infections averted over 10 years.
Methods: VMMC service data collected between April and November 2016 from Masaka region was used for this analysis. Between April and June (Period 1) all men received one TT dose and were circumcised on the same day. The 2TT dose policy was fully implemented between August and November 2016 (Period 2) and all men received 2TT doses before circumcision.
We used chi-square test to compare VMMC uptake and cost per circumcision before and after the introduction of the TT policy and estimated the number of new HIV infections that could occur over 10 years.
Results: Of all men who got TT1 in period 1, 99.3% (15,211/15,317) were circumcised compared to 56.2% (9,565/17,017) in period 2 ($p < 0.0001$).
During period 1 (TT1 only), the total number of surgeries done was 15,211, an average of 5,070 circumcisions per month. In period 2 (2TT doses), 9,565 circumcisions were done, an average of 2,391 per month. The difference in monthly circumcisions

between the 2 periods was 2,679 (52.8%) which translates into 10,716 missed circumcisions in 4 months and 32,148 in a year, despite availability of funds.
The operation cost per circumcision in period 2 increased by 55% compared to period 1.
The number of HIV infections that we would fail to avert over ten year's range from 554 to 1,692.
Conclusions: In Masaka region, the Ugandan TT policy led to a more than 50% reduction in the number of men receiving circumcision, increased the cost per circumcision, and can reduce the number of HIV infections averted.

WEPEC0909

Monitoring adverse events in a new mature male circumcision client cohort in Namibia

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Background: Jhpiego and the Namibian Ministry of Health and Social Services launched voluntary medical male circumcision (VMMC) services in Erongo Region Namibia in May 2016. Ninety percent of clients have been aged 20 years and above, in contrast to other regions in Namibia and other countries in East and Southern Africa, where the majority have been aged 10-19 years. A 2012 meta-analysis of 10 studies assessing safety of VMMC across 6 African countries found post-operative adverse event (AE) rates ranging between 0.7% and 37.4%, with an overall pooled proportion of 2.3%.
Methods: As part of routine service delivery, after receiving the full VMMC service package clients were advised to return for follow up at Days 2, 7, and as indicated thereafter. Clinical follow up data were extracted from client records of males circumcised between 13 May - 31 July 2016.
Results: Of 1,155 males who returned for at least one follow up visit, 67 (5.8%) experienced at least one mild (19, 1.6%), moderate (45, 3.9%), or severe (3, 0.3%) AE. Fifty four percent of post-operative AEs were wound dehiscence, and of those 20.6% presented on days 5-7 post-op, 57.1% on days 8-14, and 22.3% on day 15 or later.

Age (years)	VMMC clients returning for at least one follow-up visit n	Wound Dehiscence AEs n (%)	Other AEs n (%)	Cumulative AEs (all types) n (%)
15-19	67	2 (3.0)	3 (4.5)	5 (7.5)
20-24	309	9 (2.9)	6 (1.9)	15 (4.9)
25-29	327	13 (4.0)	10 (3.1)	23 (7.0)
30-34	211	8 (3.8)	2 (1.0)	10 (4.7)
35-39	116	1 (1.0)	4 (3.4)	5 (4.3)
40-44	75	2 (2.7)	4 (5.3)	6 (8.0)
45+	50	1 (2.0)	2 (4.0)	3 (6.0)
TOTAL	1155	36 (3.1)	31 (2.6)	67 (5.8)

[Table: AE rates recorded at VMMC services, Erongo Namibia, 13 May - 31 July 2016]

Conclusions: Observed AE rates exceed the pooled rate in the 2012 meta-analysis. Although further investigation is needed to isolate the cause(s) of high rates of AEs in general and wound dehiscence in particular, the highest concentrations of AEs align with ages of prime sexual activity. A hypothesis for investigation is many AEs resulted from early resumption of sexual activity (intercourse and masturbation) as the majority had onset later than the routine follow-up schedule. VMMC programs may be underestimating AE rates and should consider an extended follow-up schedule to avoid missing late-onset AEs.

WEPEC0910

Impact of a combination behavioural change communication programme on HIV risk reduction via service up-take in a fishing community in Rakai, Uganda

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Background: Multi-channel behavioural change communication interventions are believed to be effective in scaling up the up-take of HIV prevention services, thus a reduction in the HIV risk. There is limited evidence of the effects these interventions on population-level interventions.
Combination behavioural change communication was assessed if it increases services uptake such as Voluntary Medical Male Circumcision (VMMC), HIV Counselling and Testing (HCT), and HIV Care and Treatment targeting HIV risk reduction in a fishing Community with high HIV prevalence (~ 41%) in Rakai District, Uganda.
Methods: Combination behavioural change communication (CBCC) strategies including sensitisation meetings/seminars, village "town hall" meetings, drama/theatre shows, film/video shows, health education in bars, and meetings for most at risk populations were provided to residents of Kasensero fishing community along lake Victoria, between November 2011 and May 2015. All strategies were packaged with HIV risk reduction messages.
Evaluation of the impact of CBCC on HIV incidence, risk behaviours and HIV prevention services utilisation among residents aged 15-49 was done through the Rakai Community Cohort Study (RCCS), a population-based longitudinal study.
A total of 2,744 participants (1,343 females and 1,401 males), and 3,061 (1,547 females and 1,514 males) were interviewed at baseline and follow up visits respectively. Data was collected using structured interview and analysis done using stata version 13. Chi-square test for trends was used to determine change in uptake of HIV prevention services.
Results: ART coverage among HIV-positive individuals increased from 54.6% (124/227) in 2011 to 75.1% (410/546, p=0.001) among women in 2015 and from 49.3% (71/144) to 62.4% (262/420, p=0.006) in men for the same period. VMMC coverage among non-Muslim men increased from 27% (322/1206) in 2011 to 53.1% (753/1418, p=0.001) in 2015. The proportion who had never tested for HIV decreased from 18.5% (284/1343) to 4.8% (74/1547, p=0.001) among females and from 32.8% (460/1401) to 5.7% (86/1514, p=0.001) among males.
Conclusions: Combination behavioural change communication interventions in HIV high risk communities increase uptake of HIV risk reduction services. Multi-channel messaging helps to support and reinforce each other in delivering the right message and should be recommended to other programming implementing services uptake for HIV risk reduction.

WEPEC0911

Willingness to use pre-exposure prophylaxis (PrEP): an empirical test of the information-motivation-behavioral skills (IMB) model among high-risk drug users in treatment

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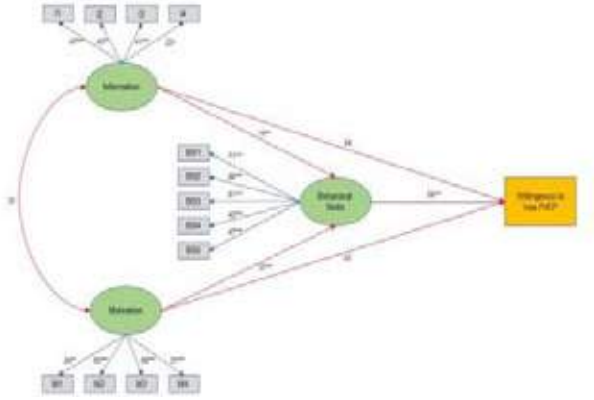
Background: With a rapid increase in the amount of research on the efficacy of PrEP for HIV prevention, complementary research on the willingness to use PrEP has grown, especially among MSM, with limited research focused among people who use drugs (PWUD). As part of the formative process, we utilized the Information-Motivation-Behavioral Skills (IMB) model of health behavior change to characterize and guide intervention development for promoting PrEP uptake among high-risk PWUD.
Methods: We recruited 400 HIV-negative, opioid-dependent individuals enrolled in a methadone maintenance program and reporting drug- and/or sex-related HIV risk. Participants reported on IMB model-based measures related to PrEP using an audio-computer-assisted self-interview. We evaluated the full IMB model of willingness to use PrEP using structural equation modelling in Mplus.

Results: As hypothesized, PrEP-related information and motivation were not significantly related to one another. Paths from information to behavioral skills (β=0.15, p=0.016) and from motivation to behavioral skills (β=0.37, p<0.001) were significant and in the predicted direction. Also as predicted by the IMB model, the path from behavioral skills to willingness to use PrEP was significant (β=0.58, p<0.001) and in the anticipated direction. The overall fit of the model was good according to standard model fit indices: $\chi 2$ (72, N=400)=113.08, p=0.024, CFI=0.95, TLI=0.93, RMSEA=0.09 (90% CI:0.05-0.14), SRMR=0.045), with the model accounting for approximately 36.6% of the variability in willingness to use PrEP (Figure 1).



[Figure 1: IMB model of willingness to use PrEP]

Conclusions: The results provide evidence as to the utility of the IMB model to increase willingness to use PrEP among high-risk PWUD. It therefore makes an important contribution to our understanding of the applicability of theoretically-grounded models of willingness to use PrEP among high-risk PWUD, who are one of the key risk populations who could benefit from the use of PrEP.

WEPEC0912

Using conjoint analysis to measure the acceptability of pre-exposure prophylaxis (PrEP) use for HIV prevention among high-risk drug users in treatment

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Background: Pre-exposure prophylaxis (PrEP), the use of antiretroviral medication prior to exposure, could greatly reduce HIV infections. Despite unequivocal evidence of PrEP efficacy, its uptake remains strikingly low and inadequately scaled to need among most-at-risk populations, particularly people who use drugs (PWUD). This study illustrates the use of conjoint analysis (CA) method, an innovative method for systematically estimating consumer preferences across discrete attributes, to assess PrEP acceptability and the impact of PrEP program characteristics on acceptability.
Methods: 400 HIV-negative individuals, enrolled in a methadone maintenance program, and reporting drug- and/or sex-related HIV risk behaviors participated in a conjoint preferences for PrEP with different attributes. Eight hypothetical PrEP scenarios varying across six dichotomous attributes were constructed using a fractional factorial experimental design (Table 1). Participants rated acceptability of PrEP scenarios from 1 ("most likely to use") to 8 ("least likely to use"). We used conjoint procedure in SPSS, which utilizes a set of linear regressions, to generate acceptability of PrEP scenarios and relative importance (RI) of PrEP attribute levels.
Results: PrEP acceptability ranged from 30.6 to 86.3 on the scale of 0 - 100 across the eight hypothetical PrEP program scenarios (Table 1). The PrEP program scenario with the highest acceptability (scenario 1) had the following attribute levels: insurance covered, daily use, 95% effective, no side effects, treatment at HIV clinic and HIV testing needed every 6 months. The cost associated with PrEP was the most important attribute (RI=38.8), followed by efficacy (RI=20.5) and side effects (RI=11.9); other attributes had no significant effect.

		PrEP Attributes					
Scenarios	PrEP acceptability	Cost	Dose	Efficacy	Side Effects	Treatment Location	HIV Testing Needed
1	86.3	Insurance covered	Daily use	95%	None	HIV clinic	Every 6 months
2	82.1	Insurance covered	Before sex	95%	Nausea/ Dizziness	Drug treatment clinic	Every 3 months
3	70.7	Insurance covered	Daily use	75%	None	Drug treatment clinic	Every 3 months
4	57.2	Insurance covered	Before sex	75%	Nausea/ Dizziness	HIV clinic	Every 6 months
5	51.4	Out of Pocket	Before sex	95%	None	Drug treatment clinic	Every 6 months
6	39.8	Out of Pocket	Daily use	95%	Nausea/ Dizziness	HIV clinic	Every 3 months
7	31.5	Out of Pocket	Before sex	75%	None	HIV clinic	Every 3 months
8	30.6	Out of Pocket	Daily use	75%	Nausea/ Dizziness	Drug treatment clinic	Every 6 months

[Table 1: Acceptability of PrEP scenarios]

Conclusions: Our findings reported a high acceptability of PrEP in response to different PrEP program scenarios with different attribute profiles. As the result of having this information, researchers and policy-makers will be better equipped for evidence-informed targeting and dissemination efforts to optimize PrEP uptake among this underserved populations.

WEPEC0913

Survey of early barriers to PrEP uptake among clients and community members in the SEARCH study in rural Kenya and Uganda

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Background: Barriers to the uptake of open-label pre-exposure prophylaxis (PrEP) offered in a population-based context in high HIV prevalence settings have yet to be studied and could include additional barriers to those identified in prior studies in targeted populations.
Methods: SEARCH (NCT01864603) is a combination prevention study in 32 communities of ~10,000 persons each in rural Kenya and Uganda. The study is offering targeted PrEP to individuals age ≥15 years at risk for HIV based on an empirically-derived risk score for HIV seroconversion or self-identified risk for HIV, including serodiscordant partnership. We studied barriers to PrEP uptake via 1) surveys of clients who expressed interest in PrEP but did not start,
2) surveys of community members, and
3) discussions with PrEP counselors and providers in SEARCH.
Surveys consisted of open-ended questions about reasons for declining PrEP and perceptions about PrEP.
Results: In 6 communities, we surveyed 63 community members (40% men, 35% women, 25% youth) and 42 clients who did not start PrEP (38% women, median age 28 years [range 16-53], 45% at risk for HIV by empiric score, 43% self-identified at risk). Barriers to PrEP uptake were identified at multiple levels (Figure 1), including individual (pill attributes, side effects, specimen collection, low perceived risk of HIV acquisition, misconceptions about PrEP use), partner/household (need to consult with and receive approval from a spouse or parent prior to starting PrEP), structural (work or school attendance, distance to clinic, transport costs, mobility), and community (stigma, community beliefs). Many individuals expressed a preference for non-daily medication taken pericoitally or during holidays.

Level of Influence	Category	Barrier
Individual	Pill attributes Daily medication	Pill size is too large Difficulty swallowing pills Pills look like HIV medications Prefer to take medication periodically or during holidays Prefer periodic injections like family planning
	Fear of side effects or specimen collection	Food insecurity – cannot take drugs on empty stomach Fear of body weakness, nausea, and dizziness Blood draws required Shipment of specimens outside community for testing Hair is collected because PrEP causes brain damage
	Perception of low HIV risk Not ready to take PrEP	Not currently at risk Need time to think about decision to take PrEP
	Misconceptions about PrEP Mistrust	Protects against other sexually transmitted infections Taking for 1 month confers long-term HIV protection Can share PrEP with partner during encounters Treats or causes erectile dysfunction Reduces sexual desire, causes infertility May cause harm during pregnancy or breastfeeding If PrEP is effective, why is HIV testing needed? Concern that PrEP is offered to those who are HIV-infected
	Other HIV prevention strategies	Will decrease use of condoms, other safer sex practices Prefer to use condoms
Partner/ Household	Partner Parent/family	Need to consult partner prior to taking PrEP, fear reaction Intimate partner violence; women lack control of encounters Partner will think PrEP is contraceptive Youth fear asking parent for approval PrEP suggests promiscuity
Structural/ organizational	Health center	Distance to travel to health center Cost of transportation Wait times at clinic
	Work School Mobility	Loss of wages; unable to take time off to go to clinic Difficult to access or take PrEP while away at school Unable to access PrEP if working away from community
Community	Stigma Community beliefs	Fear of being seen getting PrEP at health centers PrEP suggests "misbehaving," will encourage premarital sex PrEP will be perceived as HIV treatment Limited knowledge of PrEP creates misconceptions Fear that religious institutions will not support PrEP use

[Figure 1: Multi-level barriers to PrEP Uptake]

Conclusions: In communities offered targeted PrEP in this population-based study, multi-level barriers to PrEP uptake, including structural/organizational, were identified. Strategies are needed to address these barriers, such as community sensitization, expanded provision of information on PrEP, and community-based delivery mechanisms to facilitate access to PrEP.

WEPEC0914

Perspectives on PrEP among men who have sex with men (MSM) and transgender women (TGW) prior to PrEP rollout in Singapore: a qualitative study

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Background: A PrEP acceptability study was conducted prior to PrEP rollout in Singapore to understand the potential motivators, concerns and barriers to the use of PrEP as a novel HIV prevention method among HIV-negative high-risk MSM and TGW in Singapore.
Methods: Seven focus group discussions (FGDs) (n=48) were conducted between August and September 2016. A semi-structured interview guide was used to explore and identify community perceptions of and concerns regarding the use of PrEP. All FGDs were audio-recorded and transcribed verbatim. Data was analysed using qualitative thematic analysis.
Results: Majority of the participants were unaware of PrEP. Few had heard about PrEP from friends and social media or mistook it as post-exposure prophylaxis (PEP). All participants reported concerns about the efficacy and effectiveness of PrEP, and risks of side effects such as kidney function issues. Additionally, TGW participants highlighted that PrEP might complicate their hormonal treatment.
The cost of PrEP was cited as a huge barrier; most were only willing to spend approximately USD200 for a three-monthly prescription and follow-up visits to the healthcare provider. For TGW participants, paying for rent and hormonal treatment were their priorities. Other barriers include the stigma associated with taking PrEP and HIV-testing, fear of disclosure and being labelled as HIV-positive.
With regard to PrEP dosing schedules, MSM participants preferred on-demand PrEP and to visit private clinics while TGW participants preferred obtaining daily PrEP from transgender-friendly community-based organisations, so as to avoid facing stigma and discrimination from healthcare providers.
In general, PrEP was perceived as an additional protection against HIV infection as condoms were still considered more cost-effective in preventing HIV and sexually-transmitted infections. To raise awareness on PrEP, participants felt that social media would be a useful channel and preferred for PrEP to be introduced to the general population, to avoid further stigma towards the MSM and TGW community.
Conclusions: Findings from this study showed that there is a critical need to develop clinical and educational guidelines on the use of PrEP, for both providers and users, respectively. Similarities and differences in perspectives of MSM and TGW will require different implementation and marketing approaches of the PrEP service.

WEPEC0915

Limited implementation of HIV pre-exposure prophylaxis among public health departments in North Carolina, United States

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Background: Expansion of HIV pre-exposure prophylaxis (PrEP) access could help alleviate the disproportionately high burden of HIV infection in the Southern United States. This study characterizes activities, barriers, and necessary resources for PrEP implementation in North Carolina (NC) public health departments, which frequently serve clients at risk for HIV infection.
Methods: In May 2016, health directors of all county health departments in NC were invited to complete a web-based survey assessing PrEP-related activities, perceived barriers to PrEP implementation, and desired PrEP-related resources.
Results: Of 85 county health departments in NC, health directors of 56 (66%) responded to the survey. Of these departments, 2 (4%) reported PrEP prescribing, 7 (13%) externally referred for PrEP services, and 11 (20%) were considering or preparing to initiate PrEP-related activities at the time of the survey. Among the 54 departments not prescribing PrEP, the most frequently cited reasons were concerns about the cost of PrEP (n=25, 46%), lack of formal prescribing protocols (n=21, 39%), and belief that PrEP would be better managed at a primary care or specialty clinic (n=19, 35%). The two departments that reported prescribing PrEP did not identify any barriers to maintaining their activities. Among the 47 departments not prescribing or referring clients for PrEP, the most frequently cited reasons for lack of referral were absence of PrEP providers to whom referrals could be made (n=29, 62%), lack of PrEP awareness or knowledge among health department staff (n=13, 28%), and perceived lack of PrEP candidates (n=12, 26%). Among all respondents, the most frequently requested PrEP-related resources were training to help identify clients who might benefit from PrEP (n=39, 70%), training on PrEP prescribing and management (n=38, 68%), and PrEP education and outreach materials for clients (n=37, 66%).
Conclusions: PrEP prescribing and referral among public health departments in NC remains extremely limited. However, widespread interest in guidance for PrEP implementation among health directors suggests potential for future expansion. Increased PrEP-related training and support for public health department-based providers could enhance PrEP access for NC residents at risk for HIV infection, especially in rural and underserved areas.

WEPEC0916

Baseline characteristics of women and men enrolled in the US Sustainable Healthcenter Implementatation PrEP Pilot (SHIPP) study, 2014-2017

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Background: Daily oral preexposure prophylaxis (PrEP) with FTC/TDF (Truvada) is recommended for all adults at substantial risk of HIV acquisition in the US but use has been highest initially in urban, white, middle-aged gay and bisexual men who have sex with men (MSM). New models of sustainable PrEP delivery are urgently needed to reach additional populations that will benefit from PrEP use.
Methods: The SHIPP study provided FTC/TDF for PrEP to men and women who met CDC guidelines criteria at community healthcenters in neighborhoods with high HIV infection rates including: 2 in Chicago, IL; Philadelphia, PA; Washington,

DC; and Jackson, MS. All PrEP participants (observational cohort) were followed with medical record abstraction to monitor clinical outcomes. A subset who consented to participate in a medication adherence substudy (MAS) completed quarterly computer-assisted interviews about behaviors and attitudes, and had blood collection to assess tenofovir drug levels.
Results: From October 2014 to- December 2016, 1207 persons enrolled in the MAS, including 103 cis-gender women (8.5%), 37 TGW (3%), and 1012 MSM (84%). Mean age was 33 years, with 22% <25 years. The population was diverse: non-Hispanic white 464 (43%), non-Hispanic black 372 (35%), Hispanic 158(13%), and 213 (18%) of other race/ethnicity. Seventeen percent had a high school diploma or less education, 73% were employed full or part-time, 34% had health insurance, and 58% reported condomless anal or vaginal sex in the month before enrollment, with a mean of 9 reported sexual partners in the 6 months before enrollment. Fourteen percent had a regular partner with HIV; 79% reported concern about high rates of HIV infection among people like themselves. The most common reasons for deciding to start PrEP were: not using condoms as often as they should (30%); not trusting that using condoms alone would protect them (25%); and worry that they would get HIV infection without PrEP (22%).
Conclusions: The SHIPP Study successfully enrolled a racially, geographically, and gender diverse cohort receiving PrEP as clinical care in a large, observational community cohort with data from objective measures of medication adherence. These data will inform healthcare delivery models for underserved PrEP populations in the US.

WEPEC0917

Impact of targeted pre-exposure prophylaxis strategies for men who have sex with men (MSM) in the United States

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Background: Pre-Exposure Prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) has been demonstrated in various studies as effective HIV prevention, including among MSM. We aimed to estimate the impact of different prevention strategies using FTC/TDF for PrEP (FTC/TDF_PrEP).
Methods: CDC data were used as primary sources for epidemiological and behavioural assumptions, with an estimate of 3.9% of US adult males being MSM. The model was calibrated to 2010-2013 estimates of HIV prevalence, by age and race. PrEP efficacy-adherence relationship was derived from the iPrEx-OLE study and real world PrEP uptake, adherence and discontinuations from the PrEP DEMO project. Outcomes evaluated at 5 years included: (1) Number needed to treat (NNT) to prevent one transmission; (2) Percent reduction in HIV Prevalence (PRP) from 2015; (3) Public health benefits (PHB) measured as percentage of all avoided HIV infections that are among non-PrEP users.
Each of the following FTC/TDF_PrEP prevention strategies was considered: PrEP for MSM with CDC HIV Risk Index (HIRI-MSM) ≥10 (MSM-10+), PrEP for black MSM with HIRI-MSM ≥10 (BMSM-10+), PrEP for young (age < 25) black MSM with HIRI-MSM ≥10 (YBMSM-10+), and PrEP for MSM with HIRI-MSM ≥20 (MSM-20+).
Results: The proportion of FTC/TDF_PrEP eligible HIV-negative MSM in the US under each preventive strategy would be: 50.5%/21.6%/5.1%/2.3% with all MSM-10+/all MSM-20+/BMSM-10+/YBMSM-10+, respectively.
PrEP uptake and adherence among eligible MSM are predicted to be lowest in YBMSM-10+ (uptake: 66.2%; adherence: 63.1%). The NNT to prevent one new HIV infection is 70 if FTC/TDF_PrEP is targeted to all MSM-10+. This is reduced to 33, 10, and 48 if targeted to BMSM-10+, YBMSM-10+, and MSM20+, respectively. PrEP availability to MSM-10+ would reduce HIV incidence by 50.0% and prevalence by 17.8% over 5 years, while the PRP with the other preventive strategies would be 4.0% for BMSM-10+, 2.9% for YBMSM-10+, and 9.4% with MSM-20+. PHB are estimated to be highest among YBMSM-10+ (37.8%).
Conclusions: Offering FTC/TDF_PrEP to MSM based on sexual risk, age and/or race, optimizes the NNT and increases PHB. Strategies that assist with uptake and utilization in populations most at risk will be most impactful.

WEPEC0918

Compliance to and safety of tenofovirDF/emtricitabine/rilpivirine in post-exposure prophylaxis

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Background: Post-exposure prophylaxis (PEP) is used to decrease the risk of HIV acquisition after risk exposure and all guidelines recommend a regimen duration of 28 days. The choice of antiretroviral regimen should maximize acceptability and completion rates. Since October 2016, French guidelines recommend TenofovirDF/emtricitabine/rilpivirine (TDF/FTC/RPV) as first choice of PEP, although data with this regimen in the setting of PEP are limited.
Methods: Prospective, observational, open-label, multicenter study conducted in 4 centres of Pays de la Loire area (western France) to evaluate safety, tolerability, adherence and efficacy of a 28-day course of TDF/FTC/RPV (1 pill/day with food) within 48 hours of potential exposure to HIV. At Week (W) 4, all participants were contacted to collect adherence, side effects and completion of the regimen. Blood samples for biological and/or serological data were prescribed at W2, W4, W8 and W16.
Results: From 1st March to 31 December 2016, 129 subjects (130 PEP) were enrolled. Exposure was sexual in 117 subjects (heterosexual intercourse n=51, MSM n=66) and non sexual in 12 subjects (occupational n=7: percutaneous injury n= 6, non-intact skin exposure n= 1; non occupational n=5). Subjects' characteristics are detailed in Table1.

	Total	Non sexual risk	Sexual risk		
				Heterosex.	MSM
N=	129	12	117	51	66
Male, %	75.2	33.3	79.5	52.9	100
Age, years, median(IQR)	29 (25-38)	32.5 (26-43)	29 (25-37)	29 (24-34)	29 (26-40)
Born in France, %	82.9	83.3	82.9	74.5	89.4
High level education, %	71	70	71.1	67.5	74
In employment, %	64.3	58.3	65.6	58.5	71.4
Known HIV+ Source,%	16.9	41.7	14.5	5.9	21.2
Condomless exposure, %	-	-	50.8	46	54.5

[Table 1]

At 31 Dec 2017, 124 subjects reached W4: 104 subjects completed the 28-day course of TDF/FTC/RPV, 12 were lost to follow-up, and 8 subjects prematurely stopped treatment (source patient HIV negative in 4 cases, patient's decision in 1 case at D1, discontinuation for adverse event in 3 cases: asthenia in 1 case at D25 and gastro-intestinal disturbances in 2 cases at D3 and D15). No participant acquired HIV through W16 of follow-up.
Conclusions: Tolerability of TDF/FTC/RPV as once daily PEP was good with low rate of discontinuation for adverse event. These results validate the positioning of TDF/FTC/RPV as preferred regimen for PEP in France.

WEPEC0919

Changes in truvada (TVD) for HIV pre-exposure prophylaxis (PrEP) utilization in the United States: (2012-2016)

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Background: Truvada (TVD) for pre-exposure prophylaxis (PrEP) was approved by the FDA in July 2012 to reduce the risk of sexually acquired HIV-1 in adults at high risk.
In this study we describe the changes over time in TVD for PrEP utilization in the United States and characteristics of the individuals who started TVD from January 2012 through September 2016.
Methods: We used a nationally representative sample of blinded data from a US prescription claims database to assess individuals who received a TVD prescription, representing >80% of retail pharmacies in the US. The data warehouse also contains medical claims, including diagnosis, procedures and patient and provider demographics. We utilized a validated algorithm to identify the use of TVD for the PrEP indication by excluding use for HIV treatment, post-exposure prophylaxis and

off-label chronic Hepatitis B treatment. Logistic regression with linear splines was used to identify changes over time and compare HIV and PrEP characteristics.
Results: Between January 2012 and September 2016, a total of 98,731 unique individuals were identified as starting TVD for PrEP: 5,853 in 2012; 6,547 in 2013; 16,117 in 2014; 33,484 in 2015 and 36,732 in the first three quarters of 2016. Three distinct periods have been observed, the first from 1Q2012 to 1Q2014 of slow growth (9% per quarter); the second of rapid growth from 2Q2014 to 4Q2015 (17% per quarter) and a stabilization period from 1Q2016 to 3Q2016 (growth < 1% per quarter). The first and second periods had statistically significant (p< 0.001) increases (positive slopes), but not the third. In the first period, there were a greater proportion of women (41.6%), which declined to 11.5% and 9.8% in the second and the third periods respectively. When compared to HIV positive patients, uninfected individuals receiving TVD for PrEP were 2.59 times less likely to be female (95% CI 2.5-2.6), and 1.17 times more likely to be younger than 25 years old (95% CI 1.16-1.17).
Conclusions: There has been a steady and substantive uptake in starts of TVD for PrEP across the US with more than 11,000 subjects initiating therapy in every quarter of 2016.

WEPEC0920

Differences in attitudes toward pre-exposure prophylaxis (PrEP) among three key populations: awareness, willingness and anticipated condom use among serodiscordant couples in Taiwan

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Background: In August 2016, Taiwan approved emtricitabine/ tenofovir disoproxil fumarate (Truvada) for use as pre-exposure prophylaxis (PrEP) against HIV. HIV-negative partners within serodiscordant couples are the key targets for PrEP but little is known about differences in attitude toward PrEP among key populations. We compared awareness, willingness to use PrEP and anticipated condom use between couples and differences in three key populations: heterosexuals, men who have sex with men (MSM), and people who inject drugs (PWID).
Methods: A cross-sectional study was conducted in an AIDS designated hospital in Taiwan. Demographics, awareness and attitudes toward PrEP, and sexual behaviors in the previous 3 months were collected. A total of 105 pairs of HIV serodiscordant couples were enrolled: 31 heterosexual pairs, 64 MSM pairs, and 10 PWID pairs.
Results: Overall, 39.5% are aware of post-exposure prophylaxis, 46.7% are aware of PrEP, and only 13.3% of HIV-negative partners of serodiscordant couples were willing to take PrEP. Most of participants (34.8%) favor "on demand" oral PrEP rather than daily PrEP (19.0%). Among the three key populations, MSM couples had the highest awareness (MSM: 60.9% vs. heterosexual: 19.4 % vs. PWID: 40%) and willingness of PrEP (MSM: 33.6% vs. heterosexual: 16.1 % vs. PWID: 5.0%). Agreement of willingness to use PrEP between HIV serodiscordant couples is moderate (Cohen´s Kappa coefficient: 0.37). 81.0% would like to self-pay for PrEP if monthly cost less than 30 US$. Majority of participants (83.8%) were less likely to use condoms if taking PrEP and heterosexual couples had the lowest rate of anticipated condom use. Willingness to use PrEP was associated with MSM (aOR: 2.62, 95% CI: 1.02-6.71), people aged below 30 (aOR: 2.66, 95% CI: 1.18-5.99), full-time job (aOR: 5.07, 95% CI: 1.40-18.37), with history of sexual transmitted diseases (aOR: 7.44, 95% CI: 2.93-18.88), heard PrEP experience from others (aOR: 2.68, 95% CI: 1.04-6.93) and less likely to have risk compensation (aOR: 4.20, 95%CI: 1.92-9.18).
Conclusions: MSM serodiscordant couples had the highest awareness and willingness to use PrEP than heterosexual and PWID. Policy makers need to consider the differences among key populations in order to scale-up PrEP implementation.

WEPEC0921

Self-perceived HIV risk and attitudes towards PrEP affected the decision to take PrEP among Thai MSM and transgender women

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Background: With an HIV incidence of >3% annually, Thai men who have sex with men (MSM) and transgender women (TG) represent populations who should be offered Pre-Exposure Prophylaxis (PrEP) according to WHO guidelines. Characteristics of MSM and TG who should be targeted by PrEP programs in Thailand are unknown. We explored factors associated with the decision to take PrEP when offered among Thai MSM and TG.
Methods: Thai MSM and TG, aged ≥18 years, with unprotected anal sex with a man at least once within the past 6 months were offered PrEP at four community-based clinics in Bangkok and Pattaya. Self-administered questionnaires were provided at baseline and logistic regression was performed to identify factors associated with decisions to take PrEP.
Results: Of 409 participants who were offered PrEP, 40.1% decided to take PrEP. Mean (±SD) age was 27.1 (6.8) years. In the past six months, 5.6% used amphetamine-type stimulants and 11.0% had group sex. PrEP users were more likely than other participants to have: previous HIV testing (54.9% vs. 42.5%, p=0.02), moderate/high risk perceptions for HIV infection (56.7% vs. 41.3%, p=0.001), and multiple sexual partners (91.5% vs. 82.0%, p=0.04). PrEP users felt less embarrassed (0.6% vs. 7.0%, p=0.002) and less anxious (19.1% vs. 35.7%, p<0.001) to take PrEP, and had less dislike of taking any pills (6.1% vs. 22.5%, p<0.001).
Based on logistic regression, self perceptions of moderate (OR 3.39, 95%CI 1.21-9.50) or high (OR 5.75, 95%CI 1.74-18.96, p=0.03) HIV risk and not feeling anxious to take PrEP (OR 2.68, 95%CI 1.37-5.25, p=0.004) were associated with increased PrEP uptake, while the dislike of taking pills (OR 0.20, 95%CI 0.08-0.52, p=0.001) was associated with decreasing PrEP uptake.
Conclusions: PrEP campaigns in Thailand need to target MSM and TG who perceive themselves to have moderate/high risk of acquiring HIV, while also addressing stigma around PrEP use in the community. Studying alternative administration routes of PrEP, such as the use of long-acting injectables, is crucial as substantial proportions of MSM and TG dislike taking oral pills.

WEPEC0922

Behavioral and socio-demographic correlates of PrEP side effects in a national sample of U.S. men who have sex with men (MSM)

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Background: Consistent oral PrEP adherence is necessary for maximal efficacy, but medication side effects (SE) may attenuate adherence. Identifying those most likely to experience an SE can inform intervention efforts.
Methods: An on-line survey was mounted on 2 popular sexual networking sites during March 2016 to assess sociodemographics, sexual behavior, PrEP knowledge, attitudes and use. Factors independently associated with experiencing a SE after PrEP initiation were evaluated using multivariable logistic regression with backward selection.
Results: Of 4,698 respondents, 21% were 18 to 24 y.o. and 38% were 40 or older. Almost half (47%) identified as White, 25% as Black, 11% as Latino/Hispanic. About 2/3 reported condomless anal intercourse (C.A.I.) at least once in the prior 3 months. Despite this, only 15% reported prior PrEP use. Almost all (91%) PrEP users rated taking PrEP as somewhat or very easy. Among PrEP users, 44% re-

ported a SE, with the most common being increased flatulence (17%), nausea (12%), and anorexia (7%). Although the SE disappeared within two weeks for 54% of the respondents, 26% indicated that the SE persisted and were present when they took the survey. Of those who reported SE, 10% discontinued PrEP because of them; 14% discontinued PrEP for other reasons, and 76% remained on PrEP. Black MSM had an increased odds of reporting SE: aOR 1.7 (95% C.I. 1.1, 2.9), p=0.027, compared to White MSM. Older MSM and those reporting chlamydia in the prior year had a decreased odds of reporting SE: aOR 0.4 (95% C.I. 0.2,0.9), p=0.027, compared to 18-24 y.o., and aOR 0.5 (95% C.I. 0.3,0.8), p=0.007 compared to those without an STI in the prior year, respectively.
Conclusions: In this online MSM sample, gastrointestinal SE were common among PrEP users, but few MSM discontinued PrEP as a result of SE. The increased odds of SE among Black MSM suggests that SE education, proactive clinical support, and evaluation of other PrEP modalities are indicated in order to potentially increase uptake and adherence in this population.

WEPEC0923

Opportunities and challenges of using pre-exposure prophylaxis to prevent HIV infection among men who have sex with men in Hong Kong: awareness, acceptability and potential issues

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Background: Pre-exposure prophylaxis (PrEP) is an effective evidence-based biomedical HIV intervention strongly recommended to MSM by the World Health Organization (WHO). The HIV epidemic has been worsening among MSM in Hong Kong. Effective means of interventions are greatly warranted. This study aimed to provide proactive understanding on awareness, acceptability and potential issues related to PrEP among local MSM.
Methods: A cross-sectional survey was conducted. Participants were Hong Kong Chinese MSM aged 18-60 years old. Those self-reported as being HIV positive were excluded. A total of 403 participants were recruited and completed the anonymous self-administered questionnaire.
Results: Of all participants, 26.6% had heard of PrEP, while only 1% had ever used PrEP. After being briefed about the facts of PrEP (i.e., efficacy, WHO recommendation, potential side effects and dosing requirements), 45.2% showed behavioural intention to use daily PrEP in the next six months if it was provided for free by governmental hospitals or clinics. Whereas, 28.0%, 13.9% and 3% would reduce condom use with male regular sex partners, male non-regular partners and female sex partners after using PrEP, respectively. Moreover, 57.6% would not take up regular HIV testing (every three months) after using PrEP, while 25.1% would stop using PrEP without consulting doctors.
After adjusting for these significant background variables, significant factors associated with behavioural intention to use free daily PrEP included: 1) prior awareness of PrEP (Adjusted odds ratio, AOR: 1.92; 95%CI: 1.19, 3.08), 2) perceived risk of HIV infection (AOR: 1.47, 95%CI: 1.13, 1.91), 3) perceived benefit of PrEP (AOR: 1.18, 95%CI: 1.06, 1.31), 4) perceived barriers of using PrEP (AOR: 0.67, 95%CI: 0.58, 0.76), 5) perceived self-efficacy of using free daily PrEP (AOR: 1.55, 95%CI: 1.38, 1.74), and 6) receiving support from peers for using PrEP (AOR: 2.88, 95%CI: 1.01, 8.59).
Conclusions: PrEP is still new for local MSM as their awareness and utilization are low. Future health promotion modifying perceptions and using peer influence may be useful to promote PrEP. Some critical issues need to be addressed before implementation, such as non-adherence, regular testing and risk compensation. More research is needed to prepare for future demonstration study.

WEPEC0924

Knowledge and willingness to use Pre-Exposure Prophylaxis (PrEP) among African Americans in the United States: results from the National Survey on HIV in the Black Community (NSHBC)

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Background: In the United States, 44% of estimated new HIV diagnoses were among African Americans, who comprise only 12% of the population. Yet, few data exist regarding willingness among African Americans to use pre-exposure prophylaxis (PrEP) to prevent HIV infection. This study explores knowledge of and willingness to use PrEP among a nationally representative sample of African Americans.
Methods: From February to April 2016, an online survey assessing sociodemographic characteristics, HIV risk behaviors, HIV beliefs, knowledge of and willingness to use PrEP was administered to a nationally representative sample of African Americans aged 18 to 50.
Results: 868 individuals completed the survey [mean age = 33.6 (±9.2); 43.7% male]. Among all respondents, 14.8% were aware of PrEP, and 26.2% would be willing to take PrEP. In bivariate analysis including all respondents, those who had not seen a health care provider within the last year and those who reported experiencing racial discrimination were less willing to use PrEP. In multivariate analysis controlling for age, education, gender, HIV risk status, and depression, not seeing a health care provider remained significant [AOR 0.5, 95%CI (0.4, 0.8), p< 0.002]. Among high-risk participants (reporting anal sex, condomless sex with more than one partner, transactional sex, and/or MSM, N=331), 15% knew that there was a pill to prevent HIV, and 26.5% would be willing to use PrEP. The most common reasons for lack of willingness among high-risk respondents were: "I'm not at risk of HIV infection" (73%) and "I don't believe it would work" (29%). Among high-risk women, 15% were aware of PrEP, and 33% would be willing to take PrEP. Among high-risk males, 28% were aware of PrEP, and 41% would be willing to take PrEP. No difference in willingness to take PrEP was noted by gender, and there was no significant difference in willingness to take PrEP between MSM and high-risk heterosexual males.
Conclusions: Among a nationally representative sample of African Americans, few high-risk individuals were aware of and would be willing to use PrEP. Interventions to increase HIV risk awareness and improve access to health care are needed to increase PrEP use among African Americans.

WEPEC0925

Feasibility, acceptability and adherence with short term PrEP in female sexual partners of migrant miners in Mozambique

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Background: Oral pre-exposure prophylaxis (PrEP) offers great promise for HIV prevention. The use of PrEP for short-term protection has not been assessed. We evaluated the feasibility, acceptability and adherence with short-term PrEP among female sexual partners of migrant miners in Gaza, Mozambique.
Methods: HIV-negative women who reported being a sexual partner of a male migrant miner were offered daily TDF/FTC for 6 weeks concurrent with when miners return to Gaza. Study visits occurred at baseline, Week 4, 6 and 8 (2-weeks post PrEP cessation). Dry blood spots (DBS) were collected at Week 4 and 6.
Results: Seventy-four women (median age: 42 years) participated, the majority (95%) reported one sexual partner and 80% reported never or rarely using condoms. At baseline, 41% had never tested for HIV and 65% reported being unaware of partners' HIV status. Over half (53%) anticipated no difficulties in taking PrEP and 80% cited protection from HIV as reason to participate. Of all women, 72 (97%) initiated PrEP. At Week 4, most common side effects were dizziness and headache. Seven participants (10%) discontinued PrEP before Week 6, but only one due to side effects. Missed doses in the last 7 days were reported by 8% at Week 4 and 3% at Week 6. Of the 65 (90%) women with DBS at Week 4, 79% had detectable tenofovir-diphosphate (TFV-DP) and 44% had levels consistent with ≥4 pills/week (TFV-DP levels≥700 fmol/punch). Of the 63 (88%) women with DBS at Week 6, 76% had detectable TFV-DP and 42% had levels consistent with ≥4 pills/

week. At Week 6, 86% reported not disclosing PrEP use to partner mostly due to fear "that he would not let me take part in study/take pills." By the end of the study, 98% were willing to continue taking PrEP to protect themselves from HIV.
Conclusions: This is the first study to assess use of short-term PrEP among female partners of migrant workers. Short-term PrEP was found to be feasible and acceptable. A high proportion of women had detectable TDF-DP levels during follow-up. Short-term PrEP offers promise for populations who are at high-risk for HIV during specific periods.

WEPEC0926

Low awareness and uptake of HIV pre-exposure prophylaxis among male sex workers in the Northeastern United States

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Background: Male sex workers (MSW), who exchange sex for money with other men, have nearly 25 times the risk of HIV compared to other men, and could benefit from using pre-exposure prophylaxis (PrEP) for HIV prevention. In order for broad implementation, awareness of and interest in PrEP among those at highest risk must be fostered. We examined awareness of and interest in using pre-exposure prophylaxis (PrEP) among MSWs.
Methods: MSW with 3+ clients in the prior month were recruited through community-based organizations and outreach efforts in Massachusetts (MA) and Rhode Island (RI) in 2014-2016. Men underwent a comprehensive quantitative assessment which included sociodemographics, sexual risk behaviors, substance use, and PrEP awareness and interest. Variables associated with PrEP awareness and with interest in using PrEP were evaluated using separate multivariable logistic regression models.
Results: A total of 100 men (MA:49, RI:51) underwent the assessment (mean age:33.6 years). Forty percent identified as White, 32% as Black, and 19% as Latino/Hispanic. Thirty-six percent identified as gay. Sixty-five percent were unemployed and 43% had unstable housing. Most (90%) reported being "high" on drugs and 26% reported injecting drugs in the past six months. Sixty percent screened positive for clinical depression and 43% for alcohol dependence. In the past month, participants reported an average 2.2 CAS acts with male clients and 6.9 CAS acts with non-paying partners. Over half (56%) had previously heard of PrEP; 13% reported ever taking PrEP. After reading a brief description of PrEP, 80% indicated that they would be interested in taking PrEP to prevent sexual transmission of HIV. In multivariable models, low PrEP awareness was significantly ($p< 0.05$) associated with: not identifying as gay (aOR=2.99;95%CI=1.03,8.64), being unemployed (aOR=4.05;95%CI=1.35,12.19) and fewer CAS with clients (aOR=0.68;95%CI=0.49,0.95. Low PrEP interest was associated with: soliciting clients on the street (vs. online only) (aOR=5.32;95%CI=1.08,26.26) and having stable housing (aOR=4.88;95%CI=1.17,20.23).
Conclusions: MSW are at high risk for HIV infection, and could benefit from PrEP. MSW who do not identify as gay and those who are unemployed may benefit from PrEP education programs and tailored messaging. PrEP implementation efforts and interventions are needed to improve PrEP uptake among MSWs.

WEPEC0927

Shifting HIV prevention methods among men who have sex with men in Montreal: pre-exposure prophylaxis treatment among former post-exposure prophylaxis users

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Background: Post-Exposure Prophylaxis (PEP) treatment has been offered at Clinique médicale l'Actuel (Montréal) since 2000. In 2013, Pre-Exposure Prophylaxis (PrEP) was integrated into the counselling service for PEP patients at l'Actuel.
We aim to describe the proportion of patients beginning PrEP following PEP and compare their risk profiles to PrEP patients without prior PEP use.
Methods: We use retrospective PrEP and PEP databases to describe the proportion of MSM patients beginning PrEP following PEP treatment from January 2013 to November 2016. Patients who reported PEP use prior to 2013 were excluded. Demographic and behavioural traits of individuals on PrEP with and without prior PEP use were compared using chi-square and two-sided t-tests with 95% confidence intervals (CI). Co-variates include age, income, education, number of sexual partners, drug use and STI history.
Results: 1758 MSM received PEP treatment(s) since 2013 and 392 patients (22.3%) subsequently began PrEP. These patients were compared with 814 PrEP patients who never received PEP. Former PEP users tended to be younger (35.3 vs. 37.2), report higher rates of antecedent Chlamydia (58.7% vs. 50.0%) and more frequent HIV testing (64% report HIV testing every six months vs. 49% in PrEP patients who never received PEP).

		Prior PEP use, N=392 (N, %)	Never used PEP, N=814 (N, %)	P-value
Age (mean, 95% CI)		35.3 (34.3-36.3)	37.2 (36.4-37.9)	**<0.01**
Education	Secondary	11.8%	17.2%	0.06
	College	21.1%	22.3%	
	University	67.1%	60.5%	
Annual revenue	<20 000	21%	17%	0.36
	20 001-35 000	11.3%	14.1%	
	35 001-55 000	21.6%	23.5%	
	55 001-75 000	21.6%	18.2%	
	>75 000	24.5%	27.2%	

[Table 1: Cohort sociodemographic characteristics]

		Prior PEP use, N=392 (%)	Never used PEP, N=814 (%)	P-value
Number of sexual partners during the 12 months prior to PrEP start (Mean, 95% CI)		25.5 (18.1-32.8)	25.2 (19.3-31.1)	0.95
Sex under the influence of druges/alcohol during the 12 months prior to initiating PrEP		80.3%	77.4%	0.14
History of STIs prior to initiating PrEP (overall)		81.4%	77.4%	0.14
Antecedent Chlamydia		58.7%	50%	**0.02**
Frequency of HIV testing prior to PrEP	Every six months	63.7%	48.5%	**<0.01**
	Once a year	30.3%	36.3%	
	Once every two years	5%	5.9%	
	Once every 5 years	0.7%	5.3%	
	Only once or twice ever	0.3%	4%	

[Table 2: Cohort risk factors]

Conclusions: Individuals who have sought PEP are receptive to recommendations for PrEP. PrEP users with and without former PEP use report similar traits, indicating that PrEP services are successfully reaching patients with risk factors for HIV infection. PrEP should be offered systematically to MSM through the primary care system to reduce emergency PEPs and HIV transmission.

WEPEC0928

A latent class analysis of preferences for pre-exposure prophylaxis among men who have sex with men in Ukraine

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Background: Ukrainian men who have sex with men (MSM) remain a highly stigmatized group with HIV prevalence as high as 23%. Despite documented effectiveness of pre-exposure prophylaxis (PrEP), PrEP remains unavailable in Ukraine. The aim of this study was to elicit MSM preferences for PrEP to inform the future development of a PrEP program with the highest likelihood of uptake and retention among Ukrainian MSM.
Methods: In March 2016, 1184 MSM were recruited through social networking applications to complete a stated preference [choice-based conjoint (CBC)] survey. Respondents completed 14 choice tasks presenting experimentally-varied combinations of five attributes related to PrEP administration (dosing frequency, dispensing venue, prescription practices, adherence support, and costs). Latent class analysis (LCA) was used to both estimate the relative importance of attributes and preferences across nine possible PrEP delivery programs and classify MSM into distinct clusters based on response to CBC survey.

Results: Participants were in their late 20s (mean=28 years), college-educated (75%), employed full time (49%), did not live independently (69%) and struggled to meet the most important needs with their income (26%). Over half (52%) of participants screened positive for depression and religion was at least moderately important for 39% of participants. Participant preferences clustered into five distinct groups. PrEP affordability was the most influential attribute across groups, followed by dosing strategy. Only one group preferred injectable PrEP (n=216), while other four groups disliked daily PrEP and strongly preferred the ‚on demand' option. One group (n=258) almost exclusively considered cost in their decision making. One group (n=151) had very low level of interest in PrEP initiation correlated with low self-perceived risk for HIV (p<0.05). The two most at-risk groups (n=415) were also more sensitive to changes in program delivery.
Conclusions: PrEP uptake among MSM is most likely to be successful when PrEP is affordable, its' implementation is targeted, and provided as "on-demand" with associated education, and when more thorough medical care and related testing is provided to at-risk populations. The introduction of PrEP as a HIV prevention tool will need affirmation by the Ukrainian government, and framed around guidelines that reflect safety, efficacy, and patient preferences.

WEPEC0929

Optimizing access to Pre-exposure Prophylaxis based on preferences of Men Who Have Sex with Men in the United States: a latent class analysis

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Background: Despite documented effectiveness of pre-exposure prophylaxis (PrEP), PrEP uptake remains low among men who have sex with men (MSM), the population bearing the highest HIV burden in the United States. Little is known about factors that influence MSM likelihood of engagement in PrEP. Consequently, we elicited MSM preferences on components of a hypothetical PrEP program to inform development of future initiatives aimed at increasing uptake of PrEP among MSM.
Methods: Between May and August 2015, 554 MSM in the U.S. were recruited through social networking applications to complete a stated preference [choice-based conjoint (CBC)] survey. Respondents completed 14 choice tasks presenting experimentally-varied combinations of five attributes related to PrEP administration (dosing frequency, dispensing venue, prescription practices, adherence support, and costs). Latent class analysis was used to estimate the relative importance of each attribute and preferences across seven possible PrEP delivery programs.
Results: Overall, the median age was 40 years (range = 21-53 years). Subjects were primarily white (87%), college-educated or higher (64%) and employed full-time (72%). The majority of respondents lived in an urban area (67%) and the geographical distribution of the sample lived in the Midwest (18%), Northeast (21%), Southeast (16%), Southwest (16%), and West (28%). Preferences clustered into five groups. PrEP affordability was the most influential attribute across groups, followed by dosing strategy. Only one group liked daily and on-demand PrEP equally (n=74) while the other four groups disliked the on-demand intermittent option. Monthly injectable PrEP is preferred by two (n=210) out of the five groups, including young MSM. Two groups (n=267) were willing to take PrEP across all the hypothetical programs. One group (n=183) almost exclusively considered costs in their decision making. Participants in the most racially diverse among groups (n= 88) had very low level of interest in PrEP initiation.
Conclusions: : Our data suggest that PrEP uptake will be maximized by making daily PrEP affordable to MSM and streamlining PrEP consultation visits for young MSM. A successful PrEP program should allocate resources towards alleviating structural barriers to PrEP access educating MSM of color on PrEP benefits, and should emphasize protection of privacy to maximize uptake among rural/suburban MSM.

WEPEC0930

Awareness, utilization and willingness to use PrEP among Japanese MSM using geosocial-networking application

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Background: The efficacy and effectiveness of pre-exposure prophylaxis (PrEP) for HIV prevention have been established in many studies, and WHO guidelines recommend daily oral PrEP for those at substantial risk, including men who have sex with men (MSM). However, PrEP has neither been implemented nor approved yet in many Asian countries, including Japan.
Methods: In this study, we investigated the awareness, utilization of, and willingness to use PrEP among Japanese MSM using geosocial-networking-app..
A nationwide, self-administered internet survey about relationship, sexual life, and mental health for Japanese MSM who use gay specific geosocial-networking-app was conducted between September 22th and October 22th 2016.
Results: Among 10,544 respondents, 7,587 completed all questionnaires (completion rate 72%, median age; 34 [IQR=15]). Analyzed samples included men who have sex with a man and did not report being HIV-positive (N=7,054). Of these, only 10.4% were aware of PrEP and 0.1% had used PrEP before, though more than two-thirds (68%) of participants reported they would like to use PrEP for HIV prevention if available.
Main reported concerns for PrEP were; cost (93.3%), toxicity (90.7%), effectiveness (81.2%), accessibility (68.1%), durability and sustainability (57.7%), and drug resistance (46.6%). Less than a third (29.9%) reported that they would be likely to decrease condom use while on PrEP.
Conclusions: These findings suggest that many Japanese MSM would be willing to take PrEP, though the levels of awareness and utilization are still low. There is thus a need to disseminate information appropriately about PrEP to the Japanese MSM community.
Furthermore, implementation studies will be needed to assess the feasibility and acceptability among this community.

WEPEC0931

PrEP uptake, safety and efficacy in a hospital-based clinic in Paris

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Background: TDF/FTC was approved for PrEP in November 2015 in France in individuals at high risk of sexual acquisition of HIV. Both daily and on-demand PrEP are allowed for MSM. We wished to assess PrEP uptake, safety and efficacy in our hospital-based clinic .
Methods: We conducted a prospective cohort study from November 10, 2015 to November 30, 2016 of all people coming to our clinic to get TDF/FTC for PrEP. Individuals were seen every 3 months with HIV tests and creatinine plasma levels. Counseling by a peer-community member was offered at each visit. Screen tests for sexually transmitted infections (STIs) were performed at the physician's discretion. We assessed PrEP uptake, safety, and the incidence of HIV and other STIs.
Results: Overall 801 individuals were seen, with a mean of 61 new individuals per month. Six (0.75%) had HIV-infection at the first visit and 785 started PrEP accumulating 215 person-years of follow-up. All but 6 were MSM with a median age of 37 years. Most individuals (78.6%) started PrEP on demand. During the study period, 24 (3%) were lost to follow-up, 16 (2%) moved to another PrEP clinic, 13 (1.7%) discontinued PrEP, and 3 acquired HIV-infection (incidence: 1.4 per 100 py). All 3 breakthrough HIV-infections were diagnosed at the second visit in individuals who either did not start or discontinued PrEP, one of whom had a virus harboring the M184V mutation. At the 6-month visit 113/136 individuals (83%) had tenofovir detected in plasma.
During follow-up, 97 adverse events were reported, mainly gastro-intestinal AES (72%) with no drug discontinuation. A single participant (0.1%) had a decrease in plasma creatinine clearance <60 ml/mn. The proportion of participants reporting condomless sex at their last intercourse increased from 52.8% at baseline to 77.4% at the end of follow-up.

During follow-up 233 new STIs were diagnosed (30 syphilis, 101 chlamydia, 100 gonorrhea, and 2 HCV infections) in 175 patients with an incidence of 81.3 per 100 py.
Conclusions: PrEP uptake is high among MSM with a high retention rate. Rare breakthrough HIV-infections occurred in non adherent patients despite a high rate of STIs.

WEPEC0932

High interest in pre-exposure prophylaxis with truvada among female sex workers: baseline data from the Senegal PrEP Demonstration Project

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Background: Recent breakthroughs in antiretroviral (ARV)-based prevention provide new opportunities to rethink HIV prevention strategies, especially for key populations such as female sex workers (FSWs). As more and more pre-exposure prophylaxis (PrEP) demonstration projects are being initiated, more information is needed about levels of interest and characteristics of individuals who elect to take PrEP in real-world clinical settings for future scale-up plans.
Methods: The Senegal PrEP Demonstration Project is a prospective, open-label cohort study assessing the delivery of oral Truvada (emtricitabine/tenofovir DF) PrEP to FSWs in 4 Ministry of Health (MoH)-run clinics in Dakar, Senegal. This is within a context of regulated sex work, where FSWs can register with the system for monthly HIV/STIs visits in MoH-run clinics. Adherence was assessed through self-report, pharmacy records, drug levels at specified visits, and using Medical Event Monitoring System (MEMS). Participants were assessed for eligibility and offered up to 12-months of emtricitabine/tenofovir DF for PrEP. Predictors of enrollment were assessed, and characteristics of enrolled participants described.
Results: Between July and November 2015, 350 individuals were approached, 325 (92.9%) were preliminarily eligible, and 271 (83.4%) were enrolled. Eight (2.3%) had undiagnosed HIV infection at screening. The average age of those enrolled was 37.7 years (standard deviation=8.9). Most FSWs were Senegalese (96.7%), and never attended school (61.3%). Uptake was very high, with 83% of eligible participants choosing to enroll and take PrEP. Unregistered sex workers were significantly more likely to enroll than registered sex workers (RR = 1.16; 95% CI: 1.06 - 1.26; p = 0.004). Overall, 91.82% (101 out of 110) of eligible unregistered FSWs chose to enroll in the PrEP versus 79.44% (170 out of 214) of eligible registered FSWs. We did not find significant differences of uptake by site, age, education, or marital status.
Conclusions: Interest in PrEP was very high among FSWs when offered in Ministry of Health (MoH)-run clinics in Dakar, Senegal. This highlights the role that these clinics can play in expanding PrEP access nationwide.

WEPEC0933

Acceptability of a dapivirine vaginal ring among US adolescent females in Phase 2a safety trial (MTN 023)

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Background: Modest protection against HIV infection for women over age 25 in sub-Saharan Africa has been reported in recent Phase III trials of a vaginal ring (VR) continuously releasing the antiretroviral drug dapivirine. No protection was found for women under 21 years likely due to poorer adherence. Better understanding of VR acceptability and adherence is needed for younger women.
Methods: Ninety-six 15-17 year old adolescents from four U.S. cities were enrolled in a Phase 2a placebo-controlled safety trial of the dapivirine VR. Of these, 21 were randomly selected for in-depth semi-structured interviews (IDI) at their final clinic visit. Participants used the VR for either 12 or 24 weeks. Trained interviewers conducted visual web-interviews. Open-ended questions covered participant overall experiences and feelings using the VR, and her reports of partner attitudes and experiences with the ring, including during sexual intercourse. Interviews were digitally recorded, transcribed verbatim, entered into Atlas TI, and analyzed using thematic content analysis.
Results: The 21 IDIs were conducted with 5 and 16 adolescents on study for 12 and 24 weeks, respectively. Most participants reported initial concern with the size of the ring but few reported discomfort or concerns after insertion. Few removed the ring or experienced expulsion, but when removal occurred, reasons were hygiene (to clean it) or curiosity (to check or show partner). Many reported the partner could feel the ring during sexual activity. Concerns raised about using the ring included hygiene, discharge ascribed to the VR, and discomfort about sex because partner could feel it. Nevertheless, most reported not feeling the ring much while in situ nor paying attention to it.
Conclusions: Our findings indicate there may be high acceptability of VR as a HIV prevention method for US adolescent females. Principal concerns for young women are partners' feeling the ring during sex and hygiene issues - issues that may be managed proactively by clinic staff to help increase acceptability and adherence.

WEPEC0934

Safety and efficacy of tenofovir disoproxil fumurate-based HIV pre-exposure prophylaxis in a patient with a solitary kidney

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Background: The safety and efficacy of emtricitabine-tenofovir disoproxil fumarate (FTC-TDF) is unknown for HIV preexposure prophylaxis (PrEP) in persons with preexisting renal disease. PubMed literature review found no citations of PrEP using FTC-TDF in patients with a solitary kidney and only two reports of treatment in HIV-infected patients with a solitary kidney.
Methods: Case report of 32 year old male with a solitary kidney presenting for evaluation and initiation of PrEP using FTC-TDF.
Results: Our patient, a 32 year old caucasian male kidney donor (2011), sought evaluation for PrEP when he was diagnosed with rectal chlamydia. He identified HIV acquisition risk as male-to-male condomless anal intercourse, reported one serving of alcohol/week, denied current or past substance use, denied concurrent medications, and denied body building supplementation. Physical examination was remarkable for a left hydrocele. At baseline, June 2016, the patient was normotensive, weighed 174#, height of 5´8", and body mass index of 26.4 kg/m2. Serum creatinine (SCr) was 1.21 mg/dL, estimated creatinine clearance (eCrCl) based on the Cockroft-Gault equation was 97.28 mL/min. Hepatitis B serologies confirmed immunity as a result of vaccination. Daily FTC-TDF was initiated after a shared decision-making process. Renal function monitored every two weeks for the first month, then monthly for three months, then quarterly if serum creatinine remained < 1.6 mg/dL. The patient was counseled to avoid NSAIDs and maintain adequate hydration. Two weeks after initiation, SCr was 1.18 mg/dL and eCrCl was 98.83 mL/min. At four weeks, SCr was 1.36 mg/dL and eCrCl was 86.74 mL/min. At nine weeks, SCr was 1.2 mg/dL and eCrCl was 98.3 mL/min. At sixteen weeks, SCr was 1.2 mg/dL and eCrCl was 98.3 mL/min. At twenty-four weeks, SCr was 1.32 mg/dL and eCrCl was 86.86 mL/min.
Conclusions: FTC-TDF was well tolerated at 24 weeks in an otherwise healthy HIV-negative male with a solitary kidney. The variation of estimated creatinine clearance was assessed as clinically insignificant. Follow up HIV Ag/Ab screenings were nonreactive. This case report suggests oral daily FTC-TDF PrEP may be safe and effective for persons with decreased renal function but more research is required.

WEPEC0935

Dysbiotic vaginal bacteria induce altered tenofovir pharmacokinetics

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Background: Antiretroviral pre-exposure prophylaxis (PrEP) trials to prevent HIV infection have produced widely varying results in women. Adherence has been postulated for the diverse trial outcomes, however little is known about what biological factors contribute to this variability. Vaginal dysbiosis is characterized by a change in microbial communities from predominantly healthy Lactobacillus spp. to diverse anaerobic bacteria, including Gardnerella vaginalis. We have recently demonstrated that vaginal bacteria can metabolize tenofovir (TFV), and here we investigate the

mechanism(s) underlying this. We hypothesize that dysbiotic bacteria alter drug uptake pharmacokinetics (PK) and damage target cells.
Methods: To elucidate the mechanisms for negative consequences of dysbiotic bacteria on PrEP, we cultured Jurkat cells with G. vaginalis, Lactobacillus spp., as well as supernatants from cultures, in the presence of TFV. Controls included cells alone, TFV alone, TFV + cells. To determine uptake, loss of TFV was measured extracellularly, while adenine (the major metabolite of bacteria-driven TFV metabolism) and TFV-diphosphate (target cell uptake) were measured intracellularly. Mass spectrometry was used to determine TFV and its metabolites.
Results: We demonstrated how vaginal bacteria alter drug PK. We observed a rapid decline in TFV (p=0.0004), significantly less formation of TFV-DP (p=0.0042), and more formation of adenine (p< 0.0001) after being cultured with G. vaginalis when compared with Lactobacillus and Jurkat cells. We also demonstrated inhibition of drug uptake into target cells with just G. vaginalis supernatant alone (p=0.0004). Of interest, Lactobacillus, did not inhibit drug uptake, prevent formation of the active metabolite TFV-DP, or biodegrade TFV into adenine, but maintained levels similar to negative controls.
Conclusions: Here we demonstrate that dysbiotic bacteria alter drug PK by inhibiting target cell uptake and metabolizing TFV preventing therapeutic levels from being reached. In contrast, healthy vaginal mucosal bacterial communities (Lactobacillus) do not interfere with TFV PK. Low levels of TFV-DP formation with G. vaginalis incubations highlight how vaginal bacteria play a role in PrEP efficacy. The inhibition of uptake with G. vaginalis supernatants potentially demonstrate how bacterial products may directly impact epithelial cells and alter PrEP efficacy. These in-vitro experiments provide mechanistic insights into how vaginal dysbiosis may lead to decreased PrEP efficacy.

WEPEC0936

Dynamic sexual risk behaviours during pregnancy and post-partum periods in Cape Town, South Africa: implications for PrEP delivery in pregnant and breastfeeding mothers

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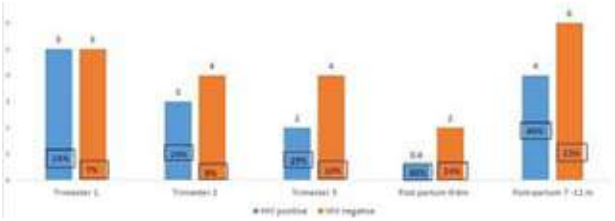
Background: HIV acquisition during pregnancy and breastfeeding contributes significantly toward pediatric HIV infection. PrEP in pregnancy/breastfeeding women is gaining interest, but little is known about sexual behaviors during pregnancy/postpartum to help target PrEP interventions.
Methods: Sex-PP is a cross-sectional study in pregnant/postpartum women attending primary care services. Interviewer-administered questionnaires investigated demographic and sexual behaviors associations of these during and after pregnancy were assessed bivariately and with multivariable logistic regression stratified by serostatus.



[Figure 1. Mean frequency of sex acts per month by pregnancy and postpartum status and HIV status (bars) and % sex acts with condom used (boxes) (n=377 pregnant and postpartum women)]

Results: We enrolled 377 women (mean age, 28 years; 56% pregnant; 60% HIV-). Overall 44% were in a steady relationship with the father of the index pregnancy/child (FOC). Most HIV- women reported the same serostatus as the FOC (64%) or didn't know (35%); 19% of HIV+ women reported being serodiscordant, 44% didn't know (p<0.05). Alcohol use during pregnancy was reported by 32% of HIV+ and 27% of HIV- women of whom 35% and 43% reported drinking ≥6 drinks on ≥1 occasion, respectively. During pregnancy, 98% women reported sex, compared to 35% and 88% during the periods 0-6 and 7-12 months postpartum, respectively; 18% of pregnant and 13% of postpartum women reported ≥1 partner in past 12-months. More frequent mean sex acts were reported in the first trimester of pregnancy and >6 months postpartum than other periods. Condom use varied by trimester, postpartum period and serostatus (p<0.05) (Figure 1). In multivariable models, HIV- pregnant women had increased odds of condomless sex during pregnancy (aOR=3.24; 95% CI=2.03-5.17) and decreased odds of knowing their partner's serostatus (aOR=0.27; 95% CI=0.09-0.34) than HIV+ women adjusting for age and alcohol use.
Conclusions: Significant HIV transmission and acquisition risk during pregnancy/postpartum periods were identified including alcohol use, multiple partners and lack of knowledge of partner's serostatus. Sexual risk behaviors change significantly across pregnancy and postpartum periods, presenting previously unrecognized challenges to prevention efforts, including PrEP delivery.

WEPEC0937

Structural barriers, mental health, and PrEP initiation/non-initiation and adherence among Black MSM in 3 U.S. cities - HPTN 073 study

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Background: Black men who have sex with men (BMSM) have substantial disproportionate HIV infection burden in the United States. Research has indicated that structural barriers relate to increased vulnerability to HIV for BMSM; however, few studies have investigated the relationships between structural barriers, mental health, and PrEP initiation/non-initiation and self-reported adherence among BMSM.
Methods: HPTN 073 was an open label PrEP demonstration study where at risk HIV-uninfected BMSM from 3 US cities (Los Angeles, CA, Washington DC, and Chapel Hill, NC) were offered once daily oral FTC/TDF at no personal cost, client-centered care coordination, and were followed for 12 months between August 2013 and September 2014. Logistic regression was used to test for unadjusted and adjusted associations between baseline structural factors (education, employment status, income, housing status, not having enough money, and access to health care insurance) and mental health characteristics (depression symptoms, social support) predicting PrEP initiation/non-initiation and self-reported adherence (≥ 60%) at week 26 with site as a covariate. Factors with p value ≤ 0.3 were included in the adjusted model.
Results: Of the 226 BMSM enrolled, 178 (79%) participants accepted PrEP. Those who were employed or reported having enough money (rent, food or utilities) were more likely to initiate PrEP (Table 1). Having enough money was significantly associated with PrEP initiation in the adjusted model. Self-reported PrEP adherence was 78% (108/139) among those who initiated PrEP. Self-reported high adherence was significantly associated with full-time employment and two-year or higher educational degree.

	PrEP Acceptance OR (95% CI)	PrEP Acceptance AOR (95% CI)	PrEP Adherence OR (95% CI)	PrEP Adherence AOR (95% CI)
2 year degree or higher vs. ≤ HS Some college/vocational vs. ≤ HS	0.86 (0.38, 1.96) 1.23 (0.51, 2.96)		4.56 (1.41, 14.77)* 1.24 (0.65,2.38)	5.10 (1.19, 21.90)* 0.88 (0.38, 2.59)
Employed FT vs. unemployed PT or self-employed vs. unemployed	2.30 (1.02, 5.20)* 2.47 (1.10, 5.59)*	1.89(0.75, 4.81) 2.32 (1.00, 5.41)	8.37 (2.39,29.28)* 1.65 (0.64,4.31)	11.60(2.43,55.29)* 1.87 (0.62,5.63)
Income 20K - 40K vs < 20K Income 40K or greater vs < 20K	1.87 (0.77, 4.57) 1.38 (0.57, 3.31)		2.19 (0.78,6.11) 1.92 (0.66,5.59)	1.26 (0.37,4.22) 0.29 (0.06,1.35)
Unstable Housing	0.59 (0.13, 2.63)		1.17 (0.13, 10.87)	
Not enough money	2.12 (1.08, 4.16)*	2.25 (1.02, 4.97)*	1.13 (0.49, 2.63)	
Incarceration	1.07 (0.53, 2.18)		1.88 (0.78, 4.50)	
Healthcare Coverage	0.74 (0.35, 1.55)		1.29 (0.56, 2.96)	
Depression Symptom	1.03 (0.96, 1.10)		1.00 (0.94, 1.07)	
Social Support	0.96 (0.91, 1.02)	0.94 (0.88, 1.00)	1.02 (0.95, 1.09)	

Footnote: * Indicates <0.05 significance.

[Table 1]

Conclusions: Our findings suggest that integrating strategies that address structural barriers and mental health needs are critical in strengthening PrEP program development and implementation efforts for BMSM. These efforts may facilitate access to a broader reach of BMSM to meet their unique needs related to PrEP uptake and adherence.

WEPEC0938

Barriers and facilitators to potential future long-acting biomedical HIV prevention strategies for transgender women

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Background: HIV prevalence is high among Latina (49.6%), African-American (48.1%), and White (3.5%) transgender women (TGW) in New York City (NYC). Additionally, NYC TGW have the highest proportion of newly identified HIV-positive test results (20.0%) of any U.S. risk group. Long-acting delivery methods of pre-exposure prophylaxis (PrEP) show some promise in clinical trials. Effective implementation of long-acting HIV prevention strategies requires understanding the challenges and facilitators associated with use, especially for unique populations, such as TGW. This study aimed to identify TGW's barriers/facilitators and likes/dislikes about the following potential future long-acting HIV prevention strategies: biodegradable PrEP implant, non-biodegradable PrEP implant, long-acting PrEP injection.
Methods: Four focus groups were completed with HIV-negative (ascertained by OraQuick Advance rapid HIV test) TGW to understand the acceptability and feasibility of PrEP implants and injections. Strategies were presented through a series of short videos and companion text summaries that featured photos of each method. Themes discussed in focus groups about products included participants' likes/dislikes, barriers/facilitators, strategies to overcome uptake/adherence challenges, ideal implant/injection sites, preferred dosing schedules, number and size of implants/injections, side-effect tolerability, perceived compatibility with hormone regimens, and strategies to promote these tools among TGW. Data were independently analyzed by two coders.
Results: Participants found non-daily dosing of PrEP favorable. TGW emphasized that ensuring the absence of interactions between PrEP and feminizing hormones is essential for uptake. Specifically, for many TGW, hormones are a priority; compromising their short or long-term effects is unacceptable. Several participants expressed concern about the 30-day oral pill lead-in and preferred the removable implant, which would not require this. Others were apprehensive about the inability to remove the injection and biodegradable implant, but acknowledged that the oral lead-in would identify issues with drug tolerability/allergy. Several TGW favored the injection, since its administration is similar to hormone replacement therapy. Some participants felt that developing strategies to administer injections without provider visits could improve acceptability and/or adherence, since additional office visits impose additional cost and inconvenience.
Conclusions: It is necessary to diversify the types of available HIV prevention methods, since different products appeal to different TGW. Long-acting methods appear to be promising, despite challenges.

WEPEC0939

One-year experience with pre-exposure prophylaxis (PrEP) implementation in France with TDF/FTC

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Background: FDA approved TDF/FTC for PrEP in adults at high risk of sexually-transmitted HIV on July 2012. In 2015, the French Medicine Agency (ANSM) initiated a Temporary Recommendation for Use (RTU) to allow the use of TDF/FTC for PrEP in France in January 2016.
Methods: The RTU is a specific French procedure that secures and regulates an off-label indication of a medicine for unmet medical needs. PrEP RTU protocol allowed TDF/FTC use in adults at high risk of sexual HIV acquisition, using a daily or an on-demand regimen (as prescribed in the ANRS IPERGAY trial). Subject registration is mandatory within the RTU framework. Data are collected by physicians using a dedicated and secured web subject monitoring interface. The RTU protocol provides 3 forms to monitor the use of TDF/FTC for PrEP: initiation form with baseline characteristics, HIV seroconversion form, adverse events and pregnancies form. Data are analyzed and reported to ANSM every 3 months.
Results: From January 2016 to December 2016, 2805 subjects were registered by 199 prescribers in more than 130 clinics in France. Median age was 36 (30-44, IQR), 98.6% were males and 97.4% of them were MSM. The on-demand regimen was prescribed to 59% of subjects. In the 12 months prior to PrEP initiation, 30.6% had ≥ 2 STIs, 10.9% used post-exposure prophylaxis and 19.9% used psychoactive drugs. Four HIV seroconversions occurred for a total follow-up time of 1100 patient-years; rate: 0.36/100 patient-years, CI95% [0.07-7.20]. Two acute HIV seroconversions occurred before inclusion in the RTU with no resistance-associated mutation (RAM). One presented HIV seroconversion at month 1 visit with a 500 cp/ml HIV RNA and a M184I RAM. One presented HIV seroconversion 2 months after PrEP was interrupted by the patient with no RAM detected.
Conclusions: The RTU framework provided the first data in real life setting in France for TDF/FTC for PrEP. All subjects were at high risk of sexual HIV acquisition, most of them were MSM and used an on-demand regimen. Low rate of seroconversion after initiation of TDF/FTC for PrEP was reported underlining the need for close monitoring of these high risk individuals.

WEPEC0940

End-user research on Multipurpose Prevention Technologies (MPT) for HIV and pregnancy prevention: young women's ratings of three delivery forms in a randomized, cross-over study in Kenya and South Africa

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Background: End-user input is needed to inform development of MPT products, combining PrEP and contraception, to maximize uptake and use. We compared ratings of three placebo MPT delivery forms after use among young women in Kenya and South Africa and examined factors associated with product ratings.
Methods: The TRIO Study enrolled 277 HIV-negative, sexually active, non-pregnant women aged 18-30 in a randomized cross-over study to use each placebo MPT (daily oral tablets, monthly vaginal rings and monthly injections) for one month. At the end of each use period, we asked participants to rate how much they liked the product on a 5-point Likert scale (1=low) and assessed participant opinions of product attributes. We compared mean ratings for each product using paired t-tests and used multivariable linear regression to examine attribute- and behavior-related characteristics associated with ratings for each product, adjusting for age, site and randomization group.
Results: Mean age was 23.2 years. Mean product ratings increased for all products after the one-month period of use, with the greatest increase (1 point, $p< 0.001$) for rings, the least familiar product. After use, mean rating were significantly higher for injections (4.3 [SD=1.0]) compared with tablets (3.0 [SD=1.3]) and rings (3.3 [SD=1.4]) ($p< 0.001$); mean ratings for rings were significantly higher than for tablets ($p=0.015$). Ratings did not vary by age, but Kenyan women (vs. South African) reported a higher rating for tablets (3.2 vs. 2.7, $p=0.005$) and a lower rating for rings (3.1 vs. 3.5, $p=0.042$). In multivariable analysis, acceptability of key product characteristics (look, ease of use and interference with normal activities) were each associated with a significant increase of ≥1 point in the mean rating across all three products ($p\leq0.001$). Product use without partner knowledge was associated with a higher mean rating for rings ($b=0.50$; $p=0.006$) but not for tablets or injections.
Conclusions: After a one-month period of use, young women rated injections most highly among three placebo MPT delivery forms, and rated rings more favorably than tablets. The acceptability of product attributes contributed significantly to the rating of all products, highlighting the value of choice in HIV prevention to accommodate diverse users.

WEPEC0941

PK and effect on HIV ex-vivo infectivity of elvitegravir in postexposure prophylaxis

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Background: The most common way of HIV transmission is through mucosal tissues. Characterizing pharmacokinetics (PK) , ex vivo efficacy on HIV infectivity and effect on immune system of Elvitegravir (EVG) could be informative for optimizing postexposure prophylaxis (PEP).
Methods: This is a substudy of a clinical trial (n=160) comparing tolerability of 2 PEP strategies: tenofovir/emtricitabine plus ritonavir-boosted lopinavir or cobicistat-boosted elvitegravir received during 28 days. PK (in blood, rectal fluid and rectal tissue), ex-vivo HIV-1 infectivity (estimated using antigen p24 quantification in HIV-1 strain BaL-1 infected explants) and effect on rectal mucosa immune system of EVG were assessed at day 28 and day 90 (considered as baseline).
Results: Overall EVG was well tolerated and there were no serious adverse effects during the study. EVG concentrations in plasma, rectal fluid and rectal tissue were 1200ng/mL, 770ng/sb, 1124ng/g, respectively. A strong correlation on EVG levels were found between different compartments (r=0.4, p= 0,028).
No significant differences were observed in infectivity between day 28 (last dose of PEP) and 90 (60 days after PEP was discontinued) (p= 0.4).
Infectivity was inversely correlated with activation of CD8-T cells in rectal mucosal tissue [CD38+DR+ (r= -0.87, p<0.005), HLA-DR+ (r= -0.85 p<0.007), and CCR5+ (r= -0.9 p<0.002)].
Conclusions: We found that EVG PK levels on different compartments were correlated. However, EVG did not prevent ex vivo infection on human rectal explants after 28 day of PEP. On the other hand, activation of CD8-T cells in mucosa seems to hinder infectivity in our model. Further studies are needed to validate these results.

WEPEC0942

Cost-effectiveness of pre-exposure prophylaxis for HIV prevention during conception

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Background: Pre-exposure prophylaxis (PrEP) for HIV serodiscordant couples seeking conception provides modest prevention benefits when the HIV-infected partner is on anti-retroviral therapy (ART). Further, the relative benefits and costs of PrEP compared to assisted reproductive technologies are not known.
Methods: We developed a Markov cohort simulation to compare six HIV prevention strategies for serodiscordant couples seeking conception: ART alone and with PrEP, both with and without intercourse limited to ovulatory period; intrauterine insemination (IUI); and in vitro fertilization (IVF). We considered a scenario in which the male partner was suppressed on ART, and another in which he was not reliably suppressed. Outcomes included HIV transmissions to mother and baby, discounted quality-adjusted life years (QALY), discounted lifetime medical costs, and incremental cost-effectiveness ratios (ICERs). Data from PARTNER, HPTN 052, and Partners PrEP informed transmission parameters. We assumed a lifetime horizon, and healthcare sector cost perspective (2015 $US).
Results: Limiting unprotected intercourse to the ovulatory period provided better outcomes than non-targeted intercourse and was cost saving. Adding PrEP to ART with targeted intercourse prevented 3 HIV transmissions per 10,000 women and added 0.0016 QALYs.
However, IUI provided still better outcomes than PrEP with targeted intercourse, at a lower cost per QALY gained. The ICER of IUI compared to ART with targeted intercourse was > $3 million/QALY. Similarly, the ICER of IVF compared to IUI was >$5 million/QALY. With non-reliably suppressed male partners, reproductive technologies provided greater benefit than PrEP at lower cost/QALY gained. Sperm wash with IUI was cost-effective at $99,432/QALY.
Only when the male partner was not reliably suppressed and IUI not available did PrEP with targeted intercourse become economically attractive (ICER = $161,645/QALY).

Risk reductive strategy	HIV+ women/ 10,000	HIV+ babies/ 10,000	Life expectancy (Undisc.)	QALY (Discounted)	Lifetime costs (Discounted)	ICER ($/ QALY)
cART (b) intercourse limited to ovulation	10.4	0.16	42.682	19.9558	$139,475	--
cART (a) non-targeted ovulation	14	0.21	42.680	19.9542	$139,579	dominated
cART + PrEP (b) intercourse limited to ovulation	7.7	0.12	42.683	19.9575	$147,748	dominated
cART + PrEP (a) non-targeted ovulation	8.9	0.13	42.683	19.9567	$147,783	dominated
cART + IUI	1.6	0.02	42.686	19.9608	$157,876	$3,658,462
cART + IVF	1.6	0.01	42.686	19.9608	$173,816	dominated

[Effectiveness, cost, & cost-effectiveness]

Conclusions: From a U.S. healthcare sector perspective, PrEP for serodiscordant couples seeking conception is best employed in scenarios in which the male partner is not reliably suppressed on ART and assisted reproductive technologies are not available.

WEPEC0943

Retention in care outcomes associated with pre-exposure prophylaxis implementation science programs in three United States cities

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Background: Few studies have evaluated long-term PrEP use and retention in care outcomes in real-world clinical programs outside of research settings.
Methods: We analyzed data from a longitudinal cohort of men who have sex with men (MSM) prescribed PrEP at clinical programs in three United States cities: Providence, Rhode Island (RI); Jackson, Mississippi (MS); and St. Louis, Missouri (MO). Demographic, behavioral, laboratory and insurance characteristics were reviewed. We assessed retention in PrEP care at three, six and 12 months. Multivariate analyses were used to predict variables associated with retention in PrEP care. We also assessed HIV seroconversions in patients prescribed PrEP.
Results: A total of 505 (RI: 197 MS: 156; MO: 152) MSM were prescribed PrEP; 90.7% filled prescriptions (RI: 85.3%; MS: 92.3%; MO: 96.1%; p=0.001). Patients in MS and MO were more commonly African American than in RI (66.7% and 26.3% vs. 6.1%, respectively), but less frequently Hispanic/Latino (1.3% and 6.6% vs. 22.2%, respectively). Among 336 patients prescribed PrEP for at least 12 months, 78.6% were retained in care at three months (RI: 77.9%; MS: 74.0%; MO: 84.4%; p=0.20), 66.4% were retained in PrEP care at six months (RI: 63.6%; MS: 66.0%; MO: 70.8%; p=0.51), and 48.5% were retained in PrEP care at 12 months (RI: 45.0%: MS: 42.0%; MO: 60.4%; p=0.02). Multivariate analyses revealed no differences in age, race, ethnicity, income, education, and insurance on 3- and 6-month retention, but uninsured MSM were less likely to be retained at 12 months (aOR=0.38, 95% CI=0.18, 0.79). A total of 1.2% (6/505) of patients became HIV infected while in PrEP care including one in RI who had suspected acute HIV infection at baseline, three in MO who were sub-optimally adherent, and two in MS who had stopped taking PrEP.
Conclusions: Retention in care trends varied by setting but generally declined over time; having health insurance was an important predictor of 12 month retention in care outcomes. Further research is needed to identify the individual, social and structural factors that may impede or enhance retention in PrEP care.

WEPEC0944

Mental health vulnerabilities mediate effects of socio-cultural factors on PrEP initiation/non-initiation and adherence among Black MSM in 3 U. S. cities - HPTN 073

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Background: Black men who have sex with men (BMSM) constitute the largest proportion of new HIV infection rates in the U.S. Socio-cultural factors (e.g., the negotiation of racial and sexual identities combined with internalized homophobia) serve as culturally specific psychosocial issues for BMSM. This study tested the hypothesis that mental health factors (depressive symptoms, social support) mediate the relationship between socio-cultural factors (ethnic identity, racial/sexual identity congruence, internalized homophobia) and PrEP initiation/non-initiation and self-reported PrEP adherence/non-adherence among Black MSM. We hypothesized that men who demonstrated higher mental health vulnerabilities would intersect with socio-cultural factors in relation to PrEP outcomes.
Methods: HPTN 073 was an open label PrEP demonstration study where HIV-uninfected BMSM from 3 U.S. cities (Los Angeles, CA, Washington DC, and Chapel Hill, NC) were offered once daily oral FTC/TDF, client-centered care coordination, and were followed for 12 months between August 2013 and September 2014. Logistic regression was used to examine associations between baseline socio-cultural factors and mental health factors predicting PrEP initiation/non-initiation and self-reported adherence (≥ 60%) at week 26 with site as a covariate. Significance of the indirect effect was tested using Proess.sas macro.
Results: Of the 226 BMSM enrolled, 178 (79%) participants accepted PrEP. Those who scored higher for ethnic identity and internalized homophobia were less likely to initiate PrEP in both unadjusted and adjusted models (Table 1). At week 26, self-reported PrEP adherence among the 139 who initiated was 78% (108/139). None of the social-cultural factors were significantly associated with PrEP adherence. Baseline depression symptoms and social support seem to mediate the relationship between internalized homophobia and PrEP acceptance.
Conclusions: To our knowledge, this represents the first study to examine socio-cultural influences of PrEP initiation and adherence among BMSM in the U.S. which contributes to new empirical and conceptual frameworks to enhance future PrEP prevention programs. Our findings suggest that socio-cultural factors involving ethnic and sexual identity affirmation need to be considered for in the development and implementation of PrEP biomedical prevention strategies for BMSM.

	PrEP Acceptance OR (95% CI)	PrEP Acceptance AOR (95% CI)	Total Indirect Effect (95% CI) on PrEP Acceptance	PrEP Adherence OR (95% CI)	Total Indirect Effect (95% CI) on PrEP Adherence
Ethnic Identity	0.54 (0.31, 0.92)**	0.55 (0.31, 0.96)**	-0.04 (-0.19,0.06)	0.90 (0.48, 1.65)	0.03 (-0.12, 0.21)
Internalized homophobia	0.95 (0.90, 1.01)*	0.94 (0.88, 0.99)**	0.02 (0.00, 0.05)+	0.99 (0.92, 1.06)	0.00 (-0.03, 0.03)
Social support	0.96 (0.90, 1.02)*	0.95 (0.88, 1.01)*	Mediator	1.00 (0.94, 1.08)	Mediator

***Indicates p value <0.05 significance; *indicates p-value <0.10; +indicates marginal indirect effect*

[Table 1]

WEPEC0945

The impact of messaging on the PrEP cascade among female sex workers (FSWs): a case study of SWOP-Kenya

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Background: PrEP is a new prevention technology that has been proven to significantly reduce HIV infections among populations at high risk, though its effective delivery to FSWs had not been well documented. We conducted a pilot project whose aim was to provide evidence to inform the deliverability of PrEP as part of HIV combination prevention package among the FSWs in Nairobi, Kenya. More specifically, it set out to develop strategies and messages for reaching out to the FSWs to promote uptake and sustained adherence to PrEP.
Methods: The overall project used a prospective cohort design. A hot spot based peer led model was used for awareness creation and linkage for PrEP uptake. A complementary qualitative aspect through in-depth interviews and focus groups with PrEP users and peer educators were then conducted at different points in time to inform and address implementation challenges that were encountered.
Despite the demand creation activities, enrollments were slow at project onset and additional strategies had to be adapted to facilitate faster patient accrual. These changes were made based on data generated through IDIs and FGDs.
Results: PrEP Cascade - A total of 2044 FSWs were reached with information on PrEP. However, only 36.2% (739) visited the facility to inquire about PrEP, with 78.5% (580) being screened for eligibility. 99.3% (576) were found eligible but only 346 were initiated on PrEP. 148 FSWs are still active on PrEP while 155 have been exited and 43 discontinued.
The qualitative studies revealed that our messaging was poor due to inadequate IEC materials, disjointed demand creation activities, conflicting information being delivered by different Peer Educators, usage of technical terms in the materials and the selected persons used for delivering the messages.
Conclusions: Use of a peer led model for awareness creation and subsequent linkage to PrEP uptake proved successful but poor messaging was a challenge. We therefore recommended an effective information and demand creation strategy with standardized materials for both health care workers and Peer Educators for PrEP scale up.

WEPEC0946

"Be-PrEP-ared ": a PrEP demonstration project among men who have sex with men in Belgium - preliminary results

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Background: In Belgium, HIV incidence is still high among MSM and new prevention approaches are needed. The Be-PrEP-ared study aims to assess uptake and feasibility of different PrEP regimens to reduce HIV acquisition among MSM at high risk for HIV.
Methods: An open-label prospective cohort study enrolling 200 MSM at high risk for HIV with a mixed method social science component. Study participants receive daily or event-driven Truvada for 18 months based on their choice, and they are allowed to switch, discontinue or restart regimens at the three-monthly visits. At each visit, participants receive preventive counselling. Biomedical data (i.e. blood, urine, anal and pharyngeal samples for kidney-, liver function, HIV- and STI testing) and self-reported behavioural data are collected (i.e. sexual behaviour, adherence). Participants report their daily sexual behaviour and pill use on a web-based diary.
Results: From 09/ 2015 - 12/2016, 219 persons were screened and 200 enrolled (197 MSM; 3 transgender women). Mean age at screening was 39 years (range 22 - 70 yrs) and 79% were Belgians. Gonorrhoea, chlamydial infection and syphilis were detected in 11%, 11%, and 8% respectively. At enrolment, 23% reported anal sex with more than 15 anonymous partners, 61% reported the use of recreational drugs before sex and 63% reported participation in group sex in the last 3 months. Twenty-one percent had used Post Exposure Prophylaxis in the last 12 months.
Initially, 76% chose daily and 24% event-driven PrEP. After a total of 96 follow-up years, no new HIV infection was observed. The incidence of N. gonorrhoeae and C. trachomatis was respectively 37 and 39 per 100PY. Thirty-one participants (15%) switched regimens or discontinued PrEP during follow-up at least once. Main reasons for switching includes changes of life/partner situations, frequency of sexual contacts, simplicity, travel and side effects of Truvada. Updated results of longitudinal data will be presented at the conference.
Conclusions: Among this population at high risk for HIV, daily PrEP use is most popular as first choice. However a large proportion of participants switch regimens, tailored to their individual needs. Despite high rates of STI during follow up, no new HIV infections were observed.

WEPEC0947

One case of HIV-1 infection with M184I mutation despite pre-exposure prophylaxis (PrEP)

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Background: The results of randomized controlled trials on Preexposure Prophylaxis (PrEP) demonstrate nearly 100% prevention efficacy in men who have sex with men (MSM) when adherence to PrEP is high. In January 2016, the French Medicine Agency (ANSM) set up a Temporary Recommendation to Use (RTU) TDF/FTC as a PrEP (daily or an on-demand regimen) in adults at high risk of sexual HIV infection.
Methods: When PrEP is prescribed, data are collected on a web subject monitoring interface including an HIV seroconversion form. We report here the first case of a MSM who seroconverted with a FTC/3TC resistant HIV-1 strain after 1 month of PrEP, despite clinical and pharmacokinetic data that suggested adherence to TDF/FTC.
Results: Between January and December 2016, 2805 subjects were included in the french RTU protocol. Only 1 subject presented an HIV-1 seroconversion at month 1 visit. This 31-year-old MSM had an HIV negative serology on March 9. He initiated PrEP (2 pills on Day 1 then 1/day) on March 19. On April 9 his serology was discordant (Biomerieux neg/Diasorin pos). On April 13 he seroconverted with a plasmatic viral load (pVL) at 766 copies/ml (2.88 log) and a western-blot showing reactivities to p24 and slightly to p18/p52. A viral load was retrospectively performed on serum on March 3 and was under threshold's detection. Genotype resistance testing revealed a CRF60_BC recombinant virus with a M184I mutation and polymorphism mutations on the protease (10I, 15V, 69K, 89I). This man has been probably infected at a ChemSex week-end on March 25-28 with multiple partner relationships, mostly passive behavior and psychoactive substance intake. He was considered as treatment adherent with the elements of questioning and plasma dosage performed on April 9 and 13. According to the sequence of events and to the french epidemiological data on HIV strains in acute infection most probably the selection of M184I mutation appeared under TDF/FTC pressure.
Conclusions: In the real-life context of PrEP in France, 1 early HIV seroconversion was reported, emphasizing the need for a very close monitoring when taking in charge patients at high risk of sexual infection.

WEPEC0948

Effect of menses and tampon use on the pharmacokinetics of Dapivirine Vaginal Ring

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Background: Dapivirine Vaginal Ring (DVR), containing 25mg dapivirine, has been shown to be safe and efficacious in two Phase III clinical trials. This trial investigated the effect of menses and tampon use on local and systemic pharmacokinetics of dapivirine delivered by DVR.
Methods: An open-label, randomised, cross-over trial was conducted among 22 healthy, HIV-negative women, aged 18-40 years. Participants received 3 treatments, separated by washout periods of 28 days, according to a randomly assigned treatment sequence: DVR with menses, without tampon use; DVR with menses, with tampon use; DVR with no menses. Oral contraceptives were used to regulate onset or absence of menses between Days 14 and 19 post-ring insertion. Dapivirine concentrations were determined in plasma and vaginal fluid (VF), and residual dapivirine was assessed in used rings.
Results: Both plasma and VF concentrations decreased after onset of menses. For plasma, $AUC_{11\text{-}21days}$ was 6% lower during menses with or without tampon use, relative to no menses (ratio: 0.94; 90% CI: 0.88-1.00). At the end of menses, concentrations increased to levels associated with no menses by Day 28. Menses and tampon use had a greater impact on VF concentrations: $AUC_{11\text{-}21days}$ was reduced by 35% during menses without tampon use (ratio "menses/no menses": 0.65; 90% CI: 0.53-0.80), and by 48% during menses with tampon use (ratio "menses/no menses": 0.52; 90% CI: 0.42-0.65). The lowest mean VF concentrations occurred on Day 15: 4797 and 7701ng/g for menses with and without tampon use, compared to 38350ng/g (no menses), but were well above the in vitro IC_{99} in cervical tissue (3.3ng/mL). VF concentrations subsequently increased to levels associated with no menses by Day 21. Ring residual levels seemed unaffected by menses and tampon use, with mean values of 20.3, 20.7 and 20.2mg following menses without tampon use, menses with tampon use, and no menses, respectively.
Conclusions: Plasma dapivirine concentrations were marginally lower during menses. VF concentrations were markedly reduced during the first 2 days of menses; at the end of menses, levels rapidly increased to pre-menses concentrations. A greater reduction in VF concentration was observed with tampon use; however, the lowest mean value was >1400 times above IC_{99}.

WEPEC0949

Network meta-analysis of post-exposure prophylaxis (PEP) randomized clinical trials: a rankogram for PEP

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Background: Compliance of 28 day course of PEP is often limited by frequent drop-outs and the toxicity of antiretroviral drugs which could limit its efficacy. Several studies have been conducted searching for better tolerated regimens as a priority. In order to evaluate which PEP regimen has the best completion rate we performed a meta-analysis of 5 randomized clinical trials (RCT) comparing different PEP regimens reporting outcomes on 1,105 PEP initiations.
Methods: Three out of the 5 selected RCT compared previous standard of care (SOC) ritonavir-boosted lopinavir (LPV/r) versus a different antiretroviral (ARV) in each trial: atazanavir (ATV), cobicistat-boosted elvitegravir (ELV/c) and raltegravir (RAL), and versus maraviroc (MVC) in 2 RCT. We conducted a network meta-analysis to estimate the pooled odds ratio (OR) for LPV/r versus MVC and the probability of each treatment for showing a better 28 day PEP completion rate. We also plotted a rankogram based on the probability of each treatment being at a particular order (the best, second, third, fourth and the worst).
Results: Non-occupational exposure to HIV was the main reason for PEP, being this an inclusion criterion in 4 studies. In the remaining study, 30 occupational exposures were described. A 3-drug regimen was prescribed in all studies, where tenofovir-disoproxil/emtricitabine was the most frequently used backbone. All studies followed European recommendations on prescription and follow-up. 454 (41%) PEP non-completion were reported for any reason. The OR for each ARV compared to LPV/r was: ATV: OR 0.95 95% CI 0.58-1.56; EVG/c: OR 0.65 95% CI 0.30-1.37; RAL: OR 0.68 95% CI 0.41-1.13, and since only for MVC comparison there were more than one RCT, the only pooled OR was for MVC: OR 0.69 95% CI 0.47-1.01. We estimated the probability of each treatment of being the best. Since the outcome is PEP completion, the best treatment is that with the highest (most positive) treatment effect (table 1). This rankogram showed that EVG/c has 45.6% probability of being the best treatment, followed by MVC, RAL, ATV and LPV/r.
Conclusions: Newly antiretroviral drugs, particularly as a single tablet regimen, showed a better PEP completion rate than previous SOC.

WEPEC0950

Institutional barriers to post-exposure prophylaxis access and related services among survivors of sexual violence in Gaza Province in Mozambique: a qualitative study

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Background: The timely provision of health care services for survivors of sexual violence is crucial to prevent HIV transmission. The government of Mozambique approved implementation of the national integrated care plan, which includes a recommendation to provide post-exposure prophylaxis (PEP) for sexual assault survivors. There are indications that there may be gaps in the implementation of that plan, because it is a multi-sectoral issue (health facility, police sector and community), meaning it should be everybody's or nobody´s responsibility. Un study done in Mozambique showed that only about 31% of survivors arrived at health facility was administered PEP within 72 hours of the sexual violence incident. The objective of this study was to identify institutional barriers that affect access to PEP in six districts of Gaza province, Mozambique.
Methods: Twenty eight in-depth interviews were conducted with personnel involved in sexual assault survivors care that we called "key actors" (15 health workers, four police, and nine community leaders) recruited in six heath facilities supported by EGPAF, through convenience sampling in August 2015. The interviews were conducted in Portuguese and in Changana (local language). The interviews were

audio-recorded and transcribed in Portuguese. The transcripts were codified and a thematic analysis was done using the MAXqda12 program.
Results: Reported institutional barriers that affect access to PEP, in order of most mentioned,
include: lack of coordination between the cadres of key actors; lack of integrated (police and health assistance) sexual assault services at the health facility; lack of transport to bring survivors from communities to police stations or health facilities; unavailability of all sexual assault assistance services available 24 hours a day at the health facility; and lack of key actors trained in care of survivors.
Conclusions: Although the implementation plan for the national integrated care program is already
in place and PEP is available free of charge in all health facilities, there are still challenges that need to be overcome in order for PEP access to be effective. Strategies that ensure that key actors are adequately informed, working cohesively, and equipped to respond to the needs of survivors should be a national priority.

WEPEC0951

Understanding PrEP demand among adolescents/young adults and HIV discordant couples in SEARCH: qualitative findings

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Background: Pre-exposure prophylaxis (PrEP) is a vital new prevention tool, yet, while much is known about PrEP adherence in clinical trial populations, there are critical knowledge gaps to inform open-label implementation in sub-Saharan African populations.
Methods: This qualitative study sought to inform introduction of PrEP to communities participating in a test-and-treat trial in Kenya and Uganda (SEARCH, NCT01864603). Focus group discussions (FGDs), conducted September-October 2016 in two communities, explored risk perceptions, attitudes, norms, and preferences, in six groups: males and females aged 16-24 and HIV-infected and -uninfected female and male members of HIV-discordant couples. Recordings were transcribed and translated for theory-informed analyses.
Results: Adolescents were excited, curious, yet held misconceptions and fears about PrEP. Many mistrusted medical authorities and wanted ‚proof' of PrEP efficacy (via others' testimonies). Young men discussed PrEP as a vehicle for reducing risks while pursuing opportunities for sex, reflecting a normative masculinity valorizing sexual conquest. Young women were more conflicted: they debated engaging in unprotected transactional sex, and discussed PrEP as a means to reduce risks with older male ‚sponsors'. Adolescents reported talking openly with peers about HIV, but not parents, whose disapproval they feared. They requested designated areas or days for PrEP, separate from ART clinics.
Members of sero-discordant couples using PrEP encouraged others to overcome fears. HIV+ members desired to protect partners and ensure their children have a future caregiver. Those with supportive spouses credited couples-VCT and care-provider support for their harmony. Others described marital conflict; HIV+ women feared husbands' affairs would lead to infection and they would be blamed. HIV- members were anxious about HIV risk, with some women angry about husbands' affairs; condom use was rare and disliked by most men and some women. Participants openly discussed extramarital affairs; transactional sex was normal for women when husbands couldn't provide for children. Women feared other women's gossip, while men reported speaking freely with one another.
Conclusions: Population-specific messaging could build demand for PrEP to address motivations and needs of at-risk populations. Couples-based prevention and treatment services are critically important, while education and improving parent-child communication/support may be needed to overcome barriers to PrEP uptake among adolescents.

WEPEC0952

No HIV infections despite high-risk behaviour and STI incidence among gay/bisexual men taking daily pre-exposure prophylaxis (PrEP): the PRELUDE demonstration project

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Background: In randomized clinical trials, PrEP efficacy among GBM was high, but few studies reported about PrEP implementation. Here we report the primary outcomes - HIV incidence, STI incidence, PrEP adherence, and sexual behaviour - in the PrEP demonstration study PrELUDE in Sydney, Australia.
Methods: PrELUDE was a demonstration single-arm, open-label study which evaluated the daily regimen of oral tenofovir/emtricitabine as HIV pre-exposure prophylaxis (PrEP) among high-risk gay/bisexual men (GBM). Participants were enrolled from November 2014 to August 2015 and were followed till December 2016. HIV/STI testing was conducted 3-monthly plus as clinically indicated. Online surveys collected detailed information about sexual practices and medication adherence 3-monthly.
Results: PrELUDE enrolled 317 males; 309 (97.5%) identified as GBM. The median age was 37 (range 22-70) years. Expected HIV incidence was 4 per 100py. No HIV infections were identified during 381.3 person-years (py) of follow-up (HIV incidence 0%, 95% CI:0-0.96 per 100py). While 45 (14.1%) wanted PrEP only for specific events and 64 (20.1%) for short periods around exposure, self-reported daily PrEP adherence was 94.4%, 92.9% and 90.3% at Months 1, 6 and 12, respectively. At enrolment, 42 GBM had HIV-positive regular partners; 40 (95.2%) reported condomless anal intercourse (CLAI) in preceding 3 months (no change over time). With HIV-positive/unknown-status casual partners, CLAI in the last 3 months increased from 80.0% at baseline to 91.1% at 12 months on PrEP (p-trend< 0.01). At enrolment, 16.8% were diagnosed with ≥1 STI (3.3% with anogenital gonorrhea (aGN), 9.5%, anogenital chlamydia (aCT) and 0.7% infectious syphilis (SYP)). The overall incidence of these STIs during the study follow-up was 92.0 (82.2-102.6) per 100py (aGN: 32.4 (26.7-38.9), aCT: 50.2 (42.0-60.2), and SYP: 9.5 (6.5-13.3) per 100py). 13.5% of all STIs were diagnosed between regular assessments, upon symptomatic presentations.
Conclusions: No HIV infections occurred during the study period, despite increases in high-risk CLAI and high incidence of STI. Thus PRELUDE demonstrated that high-risk GBM used daily PrEP appropriately, though they remained at substantial risk of STIs. Longer follow-up is necessary to better understand the real-life adherence, sexual practices and STI rates among PrEP users over longer duration of PrEP use.

WEPEC0953

HIV prevention is not all about HIV efficacy: how the uptake and effectiveness of HIV prevention products may rely on pregnancy and sexually transmitted infection prevention

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Background: In sub-Saharan Africa, considerable HIV-burden exists amongst women. It is hoped that new anti-retroviral (ARV) based prevention technologies could decrease this burden, but this will depend on user behaviour. Uptake of new products could be improved if they protect against pregnancy or sexually transmitted infections (STI).
Methods: We use a discrete choice experiment to project the likely uptake (% of women that use a product) of oral pre-exposure prophylaxis (PrEP), vaginal rings, injectable long-lasting ARV agents (4-12 weekly injection), and gel-based ARV products (with/without diaphragm) amongst adolescent and adult women, and how uptake could depend on whether the product protects against pregnancy or STI acquisition. For different product scenarios, and assuming baseline condom use of 50%, a simple model was used to determine how the uptake of different products could decrease an individual's average HIV transmission risk.
Results: In adolescent women, analyses suggest there will be limited uptake (< 7% use) and impact (< 8% decrease in HIV transmission risk) of any new product unless they also provide pregnancy protection, which could triple the level of use and impact achieved by a product. Conversely, adult women have lower preference for these additional benefits, with moderate use (≤16% for each product) and impact (12-16% decrease) being projected if the products only protect against HIV-

acquisition. In terms of product preference, both adult and adolescent women have highest preference for injectable ARVs, with oral PrEP having high preference if injectable ARVs are not available. The ring will also be used by adult women, with lower predicted use by adolescents. Gel-based products were popular with adolescent women if they provided pregnancy protection when no other products did. However, even in the most favourable scenario, where all five prevention products are available and provide pregnancy and STI protection, projections still suggest that >20% of women will remain unprotected and one-third of the baseline transmission risk will remain.
Conclusions: Incorporating multiple prevention components into new ARV-based prevention products could dramatically increase their uptake and impact in certain sub-groups. The development of multipurpose technologies could be important for tackling the heightened burden of HIV amongst women.

WEPEC0954

First year of PreP in a Parisian hospital STIs clinic: prevention must go on

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Background: Effectiveness of PrEP using TDF/FTC for prevention of sexually acquired HIV infection has been demonstrated in trials and open-label studies; however, few data on sexual behaviors, STIs or chemsex practices have been reported among PrEP users outside clinical studies.
Methods: We describe characteristics of individuals evaluated for PreP initiations, reasons for not starting PreP, rate of retention in care, incidence of HIV, other STIs and practice of chemsex in a PreP Unit (Tenon hospital- Paris) from January 2016 (beginning of the Temporary Recommendation for Use which allow TDF/FTC for PreP in France) through January 2017. We used a multidisciplinary approach to provide clinical monitoring, treatment, adherence support by infectious disease physicians, counselors, nurses, and administrative staff.
Results: About 337 referrals for Prep, there were 313 PrEP initiatons (92,9%); mainly reasons for not starting PrEP included low risk for HIV (3,3%), HIV infection diagnosed at baseline (1,5%), postexposure prophylaxis initiation (0,9%), estimated creatinine clearance ≤60 mL/minute (0,3%). Mean age was 38 years [20-66] and 319 (94,7%) were MSM. In the last 3 months, median of sexual partners was 15 [0-250], median of unprotected sexual intercourses was 4 [0-400], 202 (59,9%) reported chemsex whose 12 (3.6%) of slam at least once during follow-up, with mainly amphetamine (42,8%) and synthetic cathinones (35,31%). The last intercourse was receptive anal sex in 52,2%, unprotected in 54%, under chemsex in 24,63%. During the follow-up, the rate of declarative good PreP observance was 95.5%, 134 individuals (39,8%) were diagnosed with at least 1 STI for a total of 251 STI diagnosed with 94,1% asymptomatic. There was only 1 HIV diagnosed during the follow-up at 1 month in an individual with a resistance of FTC (M184I). There were only 3% lost of follow-up.
Conclusions: In one year, there was only one new HIV infection despite high rates of non symptomatic STIs and use of chemsex. With the implementation of PrEP in the MSMs community, a better understanding of "risk compensation" is needed to understand how changes in sexual behavior may impact risk for HIV and other STIs among PrEP users.

WEPEC0955

HIV prevention method preferences within sexual partnerships reported by HIV-negative MSM in Tijuana, Mexico

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Background: To assess potential uptake of pre-exposure prophylaxis (PrEP) and risk compensation (i.e., decreased condom use) among men who have sex with men (MSM), we examined HIV prevention method preferences within sexual partnerships reported by MSM in Tijuana, Mexico.
Methods: To date (3/2016-12/2016), 309 HIV-negative MSM recruited via respondent-driven sampling and venue-based sampling have completed surveys designed to collect socio-demographic, behavioral, and psychosocial data, as well as information on up to 20 sexual partners in the past 4 months, including their preferred HIV prevention method during sex with each partner if PrEP and condoms were available for free (i.e., PrEP only, condoms only, or PrEP with condoms). Multinomial logistic generalized linear mixed models were used to identify individual and partnership characteristics associated with HIV prevention method preferences within partnerships with male or transgender partners.
Results: Participants had a median age of 39 years (interquartile range [IQR]=29, 46; 28% under 30 years) and mostly identified as male (97%), Latino (94%), and bisexual (54%) or gay (33%). Participants reported on 927 partnerships with male or transgender partners in the past 4 months (median=2; IQR=1, 4), of which 50% had engaged in condomless anal intercourse (CAI). Using PrEP with condoms (56%) was preferred to using condoms only (27%) and using PrEP only (17%) for HIV prevention during sex within partnerships. After adjusting for individual and partnership characteristics, compared to using condoms only, using PrEP with condoms was preferred within partnerships reported by gay-identifying participants (adjusted odds ratio [AOR]=2.0, 95% confidence interval [CI]:1.1, 3.6), while using PrEP only was preferred within partnerships reported by participants who perceived themselves to be at risk for HIV (AOR=2.5, 95% CI: 1.1, 5.7) and partnerships that practiced CAI in the past 4 months (AOR=5.7, 95% CI: 2.7, 11.8).
Conclusions: Using PrEP with condoms was the preferred HIV prevention method during sex within partnerships reported by MSM in Tijuana suggesting that future PrEP uptake could be high within this population. Encouragingly future PrEP uptake may not lead to risk compensation given that preferring PrEP only was most common in the context of high-risk partnerships that already engage in CAI.

WEPEC0956

Acceptability of TMC278 LA: long-acting injectable pre-exposure prophylaxis (PrEP) in HPTN 076

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Background: Continuing high HIV incidence and low adherence to daily oral and topical HIV prevention agents in clinical trials among African women underscore the need for HIV prevention products that are more acceptable and easier to use. Strong global demand for injectable contraception suggests that new, long-acting, injectable HIV Pre-Exposure Prophylaxis (PrEP) formulations could meet this need. HPTN 076, a randomized, controlled trial comparing the safety of TMC278 LA to placebo, administered every eight weeks over a forty-week period, provided an opportunity to examine and compare acceptability of a long-acting injectable PrEP product among HIV-uninfected women in Zimbabwe, South Africa and two United States (US) sites.
Methods: We compared the acceptability of injectable study product attributes, prevention preferences and future interest in injectable PrEP by site (African versus US) and arm via quantitative surveys administered at the first, fourth and sixth injection visits. Focus Group Discussions (FGDs) were also conducted after completion of the sixth injection visit.
Results: The study enrolled 136 (100 African, 36 US) participants with a median age of 31 years [IQR 25-38]. Most participants (≥75%) rated injectable attributes (number, quantity, location, frequency) as very acceptable. While few reported rash or other side effects, 61-67% reported pain with injection, with non-significant differences over time and between arms; and during FGDs, participants described initial fear of the injectable and variable experiences with pain. Although half of participants desired no changes in the mode of injection, others reported a preference for one injection, rather than two, and/or for injection in the arm rather than buttock. Nonetheless, most preferred injectable PrEP to daily oral pills (56-96% versus 4-25%). This preference was significantly higher among participants from the African than US sites, and increased over time in all sites. FGD discussions provide further context for both product acceptability and trial-related experiences.
Conclusions: This study provides evidence that a long-acting injectable PrEP product is highly acceptable among young women in both African and US settings. It also provides insights into women's motivations for product use and trial participation, as well as product preferences and concerns that could inform future product development, trial implementation and introductory efforts.

WEPEC0957

Structural barriers and reasons why we are still failing to stop HIV in an era of effective pre-exposure prophylaxis (PrEP): *a mixed-method study*

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Background: Despite a growing armamentarium of HIV prevention strategies, HIV continues to spread among subpopulations at risk such as Black men who have sex with men (BMSM). Structural barriers to services (cost, location of services, stigma, and lack of culturally competent providers) are associated with poor diffusion of interventions, resulting in severe healthcare access disparities. Emblematic of this is that BMSM, who have the highest HIV rates in the US, are among those least likely to be prescribed PrEP. Examining correlates of structural barriers to PrEP is critical to inform ways to disseminate potentially life-saving medications.
Methods: This was a mixed method study of HIV-negative BMSM ≥18 years old with at least one study-defined structural barrier to uptake of HIV prevention services. Participants (N=75) completed both qualitative in-depth interviews and quantitative surveys regarding uptake of HIV prevention interventions. An additional N=93 BMSM participated in an online survey to test concepts identified and N=25 BMSM participated in a longer qualitative interview alone. Interviews were thematically coded based on grounded theory. Quantitative data were analyzed using descriptive statistics and logistic regression. Concepts derived from the interviews were mapped along the PrEP continuum.
Results: As shown, data from the N=193 participants reached saturation on key structural barriers to uptake of PrEP. Qualitative and quantitative findings echoed one another to provide a comprehensive examination of barriers to PrEP uptake among BMSM including reduced disclosure of risk to providers and knowledge about PrEP, barriers to accessing sites where drug is offered, and adherence.

Awareness of and Willingness to Be Prescribed PrEP [Qualitative example] "My Doctor never asked me "Are you having sex with men?" I just asked for it. And he said, ‚Oh okay' and then circled something on a piece of paper." "I think they wasn't aware. Or they probably thought that it wasn't a concern for them to ask that question, first of all."
Access to Healthcare [Qualitative example] "Interviewer: So, what about your check ups? Do you go... what do you do for your checkups? Respondent: Check ups as in? Interviewer: Like your physical checkups or your annual checkups. Respondent: I don't actually do any of that" "I know particularly a lot of my friends that are black and gay don't go to the Doctor that regularly. I think it's kind of a stigma.
Likely to Be Tested for HIV [Quantitative example] "They don't do that there. I always thought that they just do it automatically. I just never been offered it. I just assumed that they just check everything. They take blood. Oh I am guessing they're checking for HIV and different illnesses."
Likely to Receive PrEP Prescription [Quantitative example] Only general health / preventive services were significantly associated with having health care insurance, not HIV prevention services (p<0.05) Health insurance did not eliminate substantial barriers to prevention in this population (p<0.05) Community clinics better than other care settings for HIV prevention options (p<0.05)
Likely to Be Adherent to PrEP [Qualitative example] "Yeah, you're in the moment of that movie, so you don't want to push pause because you know, you'll lose it. So that's what it is..." "Of course they made the condom up and they done did this and they done did this, a pill, da-da-da-da, but a person, say for instance I'm negative and this person have HIV I'm not going to have sex with that person if I know they have HIV so they're not going to tell me that they have HIV." "People may be starting to get ideas about you having HIV because you're in the study or because they see you taking the study drugs. And to be honest, and I just kind of leave them on my dresser or inside my medicine cabinet, and people will ask me "Oh why do you have all these pill bottles?"
*Selected samples only due to word count constraints. Additional data analyzed and available; presentation will include additional text extracts and adjusted Odds Ratios (95% CI) associated with each step along the continuum.

[Barriers along the PrEP Continuum]

Conclusions: These data suggest myriad systematic changes must be made to leverage PrEP. These include outreach to those at risk beyond the clinic walls, teaching providers to engage in sexual health conversations, support engagement, and provide adherence support.

WEPEC0958

Preliminary focus group findings on PrEP product acceptability and key attributes: people who inject drugs and female sex workers

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Background: Pre-Exposure Prophylaxis (PrEP) has the potential to prevent HIV infection among high-risk groups, including female sex workers and people who inject drugs. A range of new products are in development that may address key barriers to acceptability and adherence among these vulnerable populations. The objective of this research was to qualitatively explore acceptability around three different PrEP product types: new subcutaneous implants, new injectable forms as well as existing pill based methods.
Methods: We conducted focus groups (n=9) over a 3-month period in Baltimore City, USA among street based female sex workers and people who inject drugs (male and female). Non-probability sampling was used to recruit participants. Questionnaires were used to collect demographic information and risk behaviors on all participants. Group facilitators led participants (between four and nine participants per group) through a 45-minute focus group guide, supported by product description videos and handouts. The guide explored each PrEP method and sought feedback on comparisons and preferences. Analysis was conducted using a framework method.
Results: Sexual risk taking was high across all groups, particularly females who inject drugs where 49% reported recent sex without a condom. PrEP knowledge was low amongst all groups. Pill method of delivery was associated with feelings of agency and control. However, of the injectable and implant methods, long lasting forms were preferred. Participants were interested in methods that did not require too many repeat administrations over a short-time period and methods that were minimally invasive and perceptible. Socio-structural barriers, including regular health care access and structural vulnerabilities such as homelessness, emerged as relevant to the acceptability of all three delivery methods.
Conclusions: The findings from this study provide the first data on the attributes and acceptability of new forms of PrEP delivery amongst two high-risk populations that are both currently in need of effective HIV prevention technologies. Results of this research will inform the future development and testing of injectable and implant forms of PrEP.

WEPEC0959

Effective contraceptive use and PrEP adherence among East African women in HIV serodiscordant couples partnerships

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Background: In sub-Saharan Africa, women at high risk of HIV may also want to delay pregnancy and be at risk for unintended pregnancy. For these women, concurrent use of daily oral pre-exposure prophylaxis (PrEP) and an effective contraception are recommended. However, little is known about how the use of effective contraception influences PrEP adherence.
Methods: We analyzed data from 334 Kenyan and Ugandan HIV-uninfected women from the Partners Demonstration Project, an open-label study of the integrated delivery of PrEP and antiretroviral therapy (ART) for HIV serodiscordant couples. In this delivery model, HIV-uninfected women were offered PrEP at quarterly visits and encouraged to discontinue PrEP once the HIV-infected partner used ART for ≥6 months. Effective contraceptive use (including implants, IUDs, injectable, oral, or surgical methods) was self-reported at all visits. In multivariable generalized estimating equations, we modeled the association between effective contraceptive use and high PrEP adherence (≥80% of expected MEMS caps openings) and discontinuation since the prior visit.

Results: Among the 311 women who did not have immediate fertility desires at baseline, 115 (37.5%) women were using effective contraception: 15.1% injectables, 11.9% implants, 5.1% pills, and 2.3% IUD. All of these 311 participants initiated PrEP during the study and high PrEP adherence was reported at 73.1% of visits following PrEP dispensation. 56 (18.0%) of women remained on effective contraceptive throughout study follow-up and 162 (52.1%) were never on a contraceptive method during the study. After adjusting for fertility desires, ART use by the HIV-infected partner, and condom use, high PrEP adherence was as likely during visits following report of effective contraceptive use (37.8%) as visits without (32.4%), adjusted RR [aRR]=1.06; 95% CI=0.91-1.25; p-value=0.44.
Conclusions: Among African women at high risk of HIV infection, effective contraceptive use did not appear to impact adherence to PrEP.

WEPEC0960

Acceptability of emerging technologies for sustained, long-acting HIV pre-exposure prophylaxis (PrEP) among young men who have sex with men (MSM) in the U.S.

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Background: Approximately 67% of all diagnosed HIV infections occurred in MSM in the U.S. in 2014, with adolescent and adult MSM experiencing an increase in number of HIV infections. The CDC recommends oral PrEP for populations at high risk of HIV infection, such as young MSM. Given adherence challenges in daily pill-taking, alternative strategies are under investigation.
The aims of this study were to: a) understand attitudes toward the use of sustained, long-acting injections and implants to deliver PrEP; and b) identify key attributes for future product development.
Methods: From June to August 2016, 6 focus groups were conducted in a Chicago, IL. A convenience sample of young MSM (18-29 years old; mean = 23.4 years) were recruited through Facebook, community-based organizations, and research participant databases. The majority (56%) were non-White (24% African American; 16% Asian) and 20% reported a Hispanic ethnic background. The sample included current PrEP users and non-users. The study team used thematic analysis to identify themes and patterns across the data.
Results: Similar themes emerged across the focus groups in their attitudes toward the use of injections and implants to deliver PrEP. With regard to injections, participants favorably discussed privacy and familiarity with injection procedures. Some were concerned about the danger of not being able to remove the medicine in the event of HIV infection. Key attributes were:
a) duration of 2-6 months; and
b) 1-3 injections per dose.
With regard to implants (biodegradable and non-biodegradable), participants favorably discussed privacy and duration. For the non-biodegradable implant, participants were apprehensive about multiple surgical procedures (insertion and removal). For the biodegradable implant, participants were concerned about whether or not it could be removed in the event of HIV infection. Key attributes were:
a) duration of 6-12 months; and
b) 1-2 implants per insertion.
Conclusions: Future research should continue to develop technologies to improve PrEP adherence and effectiveness, particularly among young MSM. Proposed injections and implants are acceptable to the extent that they are private, long lasting, and convenient. With less frequent adherence requirements, uptake of sustained, long-acting PrEP technologies could be enhanced by aligning development with user preferences.

WEPEC0961

Differences between regimen choices and types of exposure in HIV post-exposure prophylaxis before and after the guidelines implementation in Brazil

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Background: Post-exposure prophylaxis (PEP) is one of the main tools to prevent HIV infection. Although it was first made available in Brazil in 2010, the guidelines for prescription were published in 2015 as part of the combination prevention strategy. The guidelines simplified PEP prescription and defined TDF+3TC+ATV/r as the preferential regimen choice. The objective of this study is to characterize PEP use according to regimen and type of exposure and assess the differences before and after the guidelines implementation.
Methods: We included in the analysis programmatic data from PEP dispensation in Brazil, between 2014 and 2016. Data were described using proportions. Chi-square tests were used to investigate the association between PEP regimen and the year of dispensation and type of exposure.
Results: Between 2014 and 2016, 120,347 PEP treatments were delivered for people aged 15+ and 55,175 (46%) of them were made in 2016. Non-occupational exposure dispensations increased approximately 136% between 2014 and 2016, before and after the PEP guidelines implementation. Sexual exposure was the reason 28,244 people (51%) sought for PEP in 2016 (compared to 30% in 2014 - 7,786 dispensations). In 2016, 85% of the regimens dispensed due to sexual exposure consisted of TDF+3TC+ATV/r (compared to 0.5% in 2014) and 4% of AZT+3TC+TDF (compared to 55% in 2014). Other regimens delivered due sexual exposure, in 2016 were TDF+3TC+LPV/r (4%) and AZT+3TC+LPV/r (2%). There was an increase in the dispensation of TDF+3TC+ATV/r among those who had an occupational exposure as well, from 24% to 79%.
Conclusions: Up to a few years ago, local services focused the PEP delivery mainly on occupational and sexual violence exposures. With the implementation of the guidelines, the Ministry of Health focused on the expansion of PEP delivery for occasional sexual exposure. Furthermore, the implementation was paired with the promotion of the right to access PEP regardless of type of exposure. We observed that the changes proposed by the current guidelines were absorbed and implemented by health providers, especially regarding the preferential regimen. Besides, the roll out of PEP delivery for everybody without moral judgments regarding the type of exposure referred by the patient was also accomplished.

WEPEC0962

InterPrEP (II): internet-based pre-exposure prophylaxis (PrEP) with generic tenofovir DF/emtricitabine (TDF/FTC) in London - analysis of safety and outcomes

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Background: The PROUD and IPERGAY trials demonstrated an 86% reduction in new HIV diagnoses from PrEP. However, PrEP is not available on the National Health Service (NHS) in England. Consequently, people are buying generic versions of TDF/FTC via websites such as www.iwantprepnow, which is legal under UK import laws. In February 2016, we enabled people buying PrEP online to test regularly for HIV, hepatitis B/C and sexually transmitted infections (STIs) and to monitor renal function and antiretroviral drug concentrations. We have recorded a 40% reduction in new HIV diagnoses at the 56 Dean Street Clinic in London, from 2015-2016, in parallel with the introduction of generic PrEP. However, concerns remain about STIs and the quality of PrEP purchased online.
Methods: Notes review of HIV-negative individuals on generic PrEP attending 56 Dean Street from February 2016 - January 2017. Patients were given risk reduction advice and evaluated for HIV, hepatitis B/C, renal function and STIs (gonorrhoea, chlamydia and syphilis) and offered 3-monthly follow-up. Plasma Therapeutic Drug Monitoring for TFV and FTC was also offered. Drug concentrations were measured by ultra-performance liquid chromatography.
Results: Of the 398 individuals on PrEP, 99.7% were Male, 81% White; 87.5% took PrEP daily and 12.5% event-driven; 85% of individuals were on generic TDF/FTC from Cipla Ltd (Tenvir-EM). Adequate drug levels were seen in 96% (335/346). Baseline eGFR (>60ml/min) and/or urinalysis was normal in 99% (318/320) with no deterioration in 100% (150/150) of individuals attending follow-up. 42% of patients reported using "chems" in the 12 months before starting PrEP and 25% reported this whilst taking PrEP. During follow-up, 36% of patients were diagnosed with an STI. There were no new cases of HIV diagnosed on PrEP (0%, 95% C.I.: 0.0 - 4.0%). There were no new cases of hepatitis B and one new case of hepatitis C.
Conclusions: Despite 36% of patients being diagnosed with a new STI while taking generic PrEP, there were no new cases of HIV over the duration of this observational study. Concentrations of TFV and FTC were similar to those in individuals on branded Truvada from Gilead. Strategies to reduce incident STIs remain crucial.

WEPEC0963

PrEP awareness, interest and engagement among Baltimore female sex workers

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Background: In the U.S., women account for nearly one fifth of new HIV cases but only 11% PrEP prescriptions in 2015. Female sex workers (FSW) experience high burden of HIV globally, and a recent meta-analysis of 14 U.S. studies of FSW reported a pooled HIV prevalence of 17.3%. We examined PrEP awareness, interest and correlates of interest among cis-FSW.
Methods: In 2016-2017, a prospective cohort of street-based FSW were recruited through time-location sampling in Baltimore. Participants completed a structured survey and rapid HIV testing (OraQuick©).
Results: Among HIV-negative FSW (N=235), mean age was 36 years, 66% were non-Hispanic white, 52% did not graduate high school, 66% engaged in daily sex work, 39% had condomless vaginal/anal sex with clients, 64% were recently homeless, 81% had health insurance and 33% had disclosed engaging in sex work to a clinician. Lifetime experiences of physical or sexual client violence were prevalent (39% and 32%). Most (78%) had not previously heard of PrEP, only 3% had talked to doctor/nurse about PrEP and none had ever taken PrEP. However, 72% reported that they were interested in "taking a pill every day to prevent HIV." A large majority reported ease in taking the pill (83%) and visiting their doctor for a blood test every 3 months (77%). The majority (83%) would still take PrEP if they had to use condoms "to fully protect from HIV." Bivariate associations with interest in daily oral PrEP included daily sex work (OR=2.1,95%CI=1.2-3.8,p=0.01) and lifetime physical client violence (OR=1.8,95%CI=1.0-3.3,p=0.06). Daily sex work was independently associated with interest in daily oral PrEP after adjusting for age (aOR=2.3,95%CI=1.2-4.3,p=0.009).
Conclusions: Street-based FSW are a high HIV risk population in the U.S. The majority are interested in taking PrEP even in the context of regular doctor visits and condom use with higher interest among FSW who work daily or have experienced client violence. Interventions to engage FSW and their healthcare providers are warranted.

WEPEC0964

The invisible product: preferences for long-acting injectable and implantable PrEP among South African youth

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Background: Uptake and sustained adherence to HIV prevention methods is a widely recognized challenge that long-acting injectable and implantable approaches aim to overcome. Youth are a key end-user target population for these methods. Examination of product attributes and preferences that might impact youth's adherence provides an opportunity to inform product development and optimize the potential impact of long-acting HIV prevention methods.
Methods: In Cape Town, 50 in-depth interviews with male (n=18) and female (n=32) youth aged 18-25 were conducted in English or Xhosa by trained social scientists. Interview guides used a socio-ecological framework to explore external factors at the individual, interpersonal, and structural levels influencing uptake of and adherence to prevention technologies as well as preferences for specific product attributes. We purposively selected youth with a variety of HIV prevention product experience including oral PrEP (n=28; 10 female); injectable PrEP (12 female), or the vaginal ring (10 female), to ensure participants could provide opinions rooted in actual experience.
Results: Participants averaged 22 years of age, 97% have sex only with men (14 male, 31 female). Irrespective of previous method-use experience, gender, or sexual orientation, participants expressed preference for injectables and implants, compared to other methods, because of their longer duration, increased discretion and reduced stigma. Systemic absorption ("it stays in the body") resonated with youth. Attributes suggesting dimensions of "invisibility" were favored: e.g. effortless flow through the body for extended periods; pain-free with no side effects; products that would not be noticed or felt by friends, family, partners or community-members nor necessitate disclosure.
Although still favored, implants were perceived as less "invisible" due to concerns that rods would move inside the body or cause visible scarring that would reveal usage. Several youth expressed concerns about gang members attacking an implant-user to cut out, steal and smoke the drug in the implant.
Conclusions: Several attributes of long-acting HIV prevention methods were perceived as important to young South African end-users, and will be used to quantitatively assess relative preferences and attribute trade-offs in a follow-on discrete choice survey. End-user preferences of attributes can be used to inform product development and testing to optimize adherence among youth.

WEPEC0965

A structural driver of HIV risk behaviors among street-based, cis-female sex workers in Baltimore, Maryland, USA: police encounters

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Background: Three decades into the HIV epidemic, high HIV rates persist among female sex workers (FSWs) worldwide. Structural factors, including law enforcement responses to sex work and engagement with FSWs are increasingly recognized as driving FSWs' HIV vulnerability. We examined correlates of unsafe sex with clients among street-based cis-FSWs (N=250) in Baltimore, Maryland, USA.
Methods: A prospective cohort of cis-FSWs were recruited through targeted time-location sampling throughout Baltimore city from April 2016-January 2017. Participants completed a baseline structured survey administered via CAPI and rapid HIV testing (OraQuick©). We examined frequencies of demographic, drug use and police encounter variables as well as HIV status. We also examined a multivariate model of recent (past 3 months) unprotected vaginal or anal sex with clients. All analyses were conducted using Stata/SE 14.2.
Results: The mean age was 34 years, 67% were non-Hispanic white, 53% did not graduate high school, 66% engaged in daily sex work, 63% were homeless, and 70% were ever incarcerated. 76% reported having injected drugs and 86% reported smoking crack in the past year. 39% reported any unprotected sex with clients (past 3 months) and 6% tested HIV-positive. Women had frequent and varied police encounters in the past year, having experienced: bullying/intimidation (37%); sexual or inappropriate comments on appearance (34%); threatened with a weapon or had one used against them (11%); and physically forced to have vaginal/anal sex with police (2%). Police rarely (40%) explained their reasons for stopping participants. Controlling for relevant demographic variables, recent unprotected vaginal and anal sex with clients was associated with: police officers not explaining their reasons for stopping participants (aOR=2.0,95%CI=1.1-3.7,p=0.027) and recent homelessness (aOR=1.9,95%CI=1.0-3.5,p=0.036).
Conclusions: The study indicates high levels of human rights abuse against FSWs at the hands of police. These abuses were associated with unsafe sexual practices with clients, elevating women's HIV risk. Structural interventions are needed to target police and hold them accountable for their actions.

WEPEC0966

"Test and Treat" among people who inject drugs: results from a demonstration project in Vietnam

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Background: In Vietnam, injecting drug use is the leading cause of HIV transmission. Mathematical models suggest periodic HIV testing and counselling (HTC) and initiating antiretroviral therapy (ART) irrespective of CD4 count in people who inject drugs (PWID) can markedly reduce new HIV infection and AIDS deaths. Programme experience with this approach in resource-limited countries had been limited. A demonstration project was conducted in two high-burden provinces to assess feasibility and inform policy development.

Methods: HTC was recommended to PWID every six months and immediate ART, i.e. initiation irrespective of CD4 count, was offered to HIV positive PWID upon consent. PWID were followed for 12 months, and retention, HIV viral load (VL), and risk behaviors were monitored. Retention in care was compared before and after immediate ART was introduced.
Results: From April 2014 to July 2015, 287 HIV positive PWID started immediate ART. The majority (98%) were men, 32% had baseline CD4 count greater than 350 cells/mm^3 and median baseline VL was 4.8 (interquartile range 4.2-5.2) $\log_{10}$ copies/ml. 238 participants (83%) were retained on ART after 12 months (28 died and 21 lost-to-follow-up). Retention was 80.4% and 88.2% among PWID with baseline CD4 counts below and above 350 cells/mm^3, respectively. Current employment, marriage, CD4 counts > 100 cells/mm^3, no history of imprisonment and receiving methadone maintenance were associated with higher retention. Retention in care after 12 months following introduction of immediate ART intervention (83%) was significantly higher than the rate in the preceding period (ART initiated at CD4 count ≤ 350 cells/mm^3) (78%), primarily due to much lower attrition during pre-ART care. Among 222 PWID who had VL tested at 12 months, 205 (92%) achieved viral suppression (< 1000 copies/ml). Viral suppression was 94% and 90% among PWID with baseline CD4 counts below and above 350 cells/mm^3, respectively. There was improvement in consistent condom use and no decline in clean needle use within the 12 month follow-up.
Conclusions: Early ART initiation resulted in improved retention and comparable viral suppression among PWID without increasing self-reported risk behaviors. The results informed the national guidelines development to recommend immediate ART among key populations.

WEPEC0967

HIV transmission from condomless anal intercourse differs by initial ART regimen in HIV-infected MSM

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Background: INSTI-based cART is associated with rapid viral decay. Sexual transmission of HIV is correlated with viral load. This study explores the impact of INSTI, NNRTI, or PI-based regimens in treatment naïve MSM on the probability of HIV transmission (P-HIV-Tr) using mathematical modeling.
Methods: We used discrete event simulation modeling to estimate P-HIV-Tr during W0-8 and W8-24 after initiation of cART. We modeled 10^6 theoretical patients from each of three naïve treatment studies. P-HIV-Tr was modeled using inputs from recent meta-analyses and from MSM in the START trial. VL decay was modeled from the databases of SINGLE (DTG vs. EFV), SPRING-2 (DTG vs. RAL) and FLAMINGO (DTG vs. r/DRV). We assumed no change in behavior after cART initiation; partner PrEP use and STIs are not considered.
Results: VL data included men from SINGLE (277 EFV, 298 DTG), SPRING-2 (317 RAL; 317 DTG), FLAMINGO (179 r/DRV; 200 DTG). Compared to no treatment, EFV led to 34% and 71% fewer HIV-Tr events during W0-8 and W8-24; DTG led to 42% and 73%. In SPRING-2, DTG led to 55% and 74% fewer events, and RAL led to 55% and 73%. In FLAMINGO, r/DRV led to 53% and 70% fewer events, and DTG led to 62% and 73%. All pair-wise comparisons of HIV-Tr between agents compared in each study, and with no treatment were highly statistically significant in our model (p< .001), with the exception of RAL vs DTG (**See Table**).
Conclusions: VL decay kinetics have important implications for HIV-Tr from ncAI. During W0-8, DTG-based cART reduced HIV-Tr events compared to EFV and r/DRV-based cART. The differential effect was maintained between W8-24. All regimens reduced HIV-Tr substantially compared to no treatment. Regimen selection, and initial use of INSTI's in particular, has the potential to impact HIV horizontal transmission early treatment.

	Week 0-8			Week 8-24		
	Single	Spring-2	Flamingo	Single	Spring-2	Flamingo
No. of simulated patients	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000
No. of simulated partners	1,835,268	1,837,437	1,832,443	3,647,164	3,640,660	3,664,716
No. of simulated sexual encounters	6,159,937	6,147,470	6,130,875	12,398,157	12,390,029	12,438,933
Simulated partners per patient	1.84	1.84	1.83	3.65	3.64	3.66
Simulated sexual encounters per partner	3.36	3.35	3.35	3.40	3.40	3.39
	DTG	DTG	DTG	DTG	DTG	DTG
No. of simulated new infections	478,608	370,819	313,264	419,038	415,295	427,609
Simulated infections per 100 partners (%)	26.08	20.14	17.10	11.49	11.41	11.67
Simulated HIV-Tr events per patient	0.4786	0.3700	0.3133	0.4190	0.4153	0.4276
Proportion of HIV-Tr events compared with no Rx	0.5703	0.4467	0.3791	0.2666	0.2649	0.2715
	EFV	RAL	r/DRV	EFV	RAL	r/DRV
No. of simulated new infections	543,449	371,446	384,642	457,794	425,679	463,531
Simulated infections per 100 partners (%)	29.61	20.22	20.99	12.55	11.69	12.65
Simulated HIV-Tr events per patient	0.5434	0.3714	0.3846	0.4578	0.4257	0.4636
Proportion of HIV-Tr events compared with no Rx	0.6567	0.4485	0.4655	0.2913	0.2715	0.2957
	No Rx	No Rx	No Rx	No Rx	No Rx	No Rx
No. of simulated new infections	827,559	828,253	826,296	1,571,683	1,567,963	1,567,532
Simulated infections per 100 partners (%)	45.09	45.08	45.09	43.09	43.07	42.77
Simulated HIV-Tr events per patient	0.8276	0.8281	0.8263	1.5717	1.5680	1.5675

* A very small number intercourse events among MSM in the START trial were reported to be with women
** In both periods, all pair-wise comparisons of HIV-Tr between agents compared in each study, and with no Rx were statistically significant (P<.001)

[Table. Probability of HIV transmission during W0-8 and W8-24 after initiation on INSTI, NNRTI or PI in treatment naive MSM]*

WEPEC0968

Is there an effect of universal ART on sexual behaviours in rural KwaZulu-Natal, South Africa? ANRS 12249 treatment-as-prevention (TasP) trial

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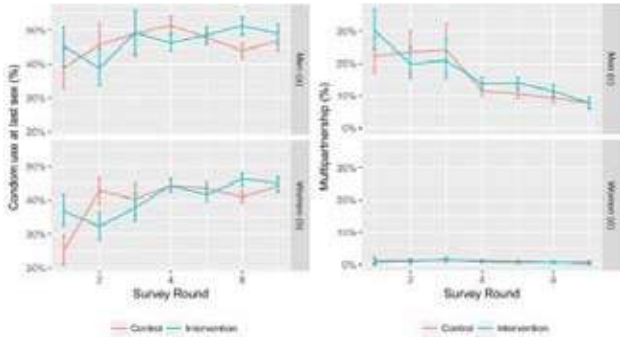
Background: There are concerns that the implementation of Universal Test and Treat (UTT) could increase population-level sexual risk behaviours. We analysed the effect of universal ART vs CD4-guided ART (start at CD4≥350 then ≥500) on sexual behaviours over time, in the context of the cluster-randomised TasP trial.
Methods: As part of the 6-monthly home-based survey rounds conducted in 11x2 clusters, a sexual behaviour questionnaire was administered to all residents ≥16 years. We used GEE modelling stratified by gender, to compare reported condom use at last sex (CLS), and multi-partnership (≥2 sexual partners) among those sexually-active in the previous six months across trial arms. We tested whether the sexual behaviours changed over time differently in each arm by inclusion of an interaction term between survey round and arm, using the Quasi-likelihood Independence Criterion (QIC) statistic to compare models.
Results: The analysis included 43,106 reports of partnerships (22,974 control, 20,132 intervention) across 7 survey rounds (SR), between 03/2012 and 06/2016. There were no consistent or substantive changes in CLS over time neither by gender nor by arm (fig 1a, 1b); inclusion of an interaction term improved the model fit, reflecting small differences between arms in CLS over time. Less than 1.5% of women reported multiple partnerships at any SR, too few for modelling (fig 1d). The proportion of men reporting multiple partnerships decreased significantly during the study (aOR 0.79, 95% CI 0.75, 0.83), p< 0.001), similarly for each arm (interaction not significant), with overall a small, but significant higher proportion reported in the universal ART arm (13.7%) vs CD4-guided ART (12.1%) (OR=1.15, 95% CI (1.03, 1.27), p=0.02 (fig 1c).



[Figure 1]

Conclusions: There is no evidence of increased unprotected sex with universal ART in this South African population. Continued monitoring of population-level sexual behaviour indicators, in particular multiple partnerships, is needed as the UTT strategy is rolled out.

WEPEC0969

The evolution of HIV prevalence in North-Eastern France and future estimates with increased levels of antiretroviral therapy

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Background: "Treatment as Prevention" (TasP) aims to reduce new HIV infections through higher enrolment on suppressive antiretroviral therapy (ART). We describe the current epidemic and possible impact of TasP in North-Eastern France.
Methods: Socio-demographic, clinical and laboratory variables were collected in an electronic medical database (Nadis®) during follow-up of HIV-infected patients in North-Eastern France. The numbers of individuals living with HIV in each year were estimated from diagnoses up to that year minus recorded deaths for each gender, transmission mode, country of birth and treatment status.
Results: From 1985 to the present, 6995 individuals were diagnosed with HIV in North-Eastern France, of whom 72% were men; men were significantly older (mean 37.6 versus 34.7 years, p<0.0001); CD4 count at diagnosis did not differ by gender (median 401 for men vs 379 for women). Unprotected sexual intercourse was the main mode of transmission, 87% for women and 89% for men with 61% of transmissions to men through MSM. Women were more likely to be immigrants (45% versus 13%), whereas men were more likely to have been born in France (52% versus 27%). Individuals born in foreign countries ('Other') tended to show CD4 <300 cells/mm^3 at diagnosis (46% versus 31% for those born in France).
Diagnoses were more likely to be correlated with untreated rather than treated prevalence in each group. Although country of birth did not impact dependence of MSM diagnoses on estimated prevalence (ρ=0.23 diagnoses/year per untreated MSM living with HIV, p<0.0001), heterosexual diagnoses were better correlated with prevalence within country groups; male (untreated) prevalence to female diagnoses: ρ=0.29 (born in France), ρ=0.73 (Other); female prevalence to male diagnoses: ρ=0.36 (France), ρ=0.19 (Other). Using these transmission rates, mathematical modelling estimated that enrolling ≥35% of untreated individuals per year onto ART was required to reduce future HIV diagnoses. Enrolling 75% of untreated individuals per year would decrease diagnoses ten-fold by 2021; prevalence in 2021 would be 10% lower than with 35% ART enrollment.
Conclusions: Increased enrolment of individuals on ART can substantially impact numbers of new HIV infections in this region of France.

WEPEC0970

HIV exposure and infant feeding mode impacts on T cell vaccine responses and memory maturation in early life

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Background: Advances in prevention of mother-to-child transmission (PMTCT) of HIV-1 have prevented HIV infections in almost 97% of infants born to HIV-infected mothers. Of concern is the effect of increasing numbers of HIV-exposed, uninfected infants (HEU) on higher rates of infection-related morbidity and altered responses to standard childhood vaccines. This study addresses the effect of HIV exposure and feeding modality on T-cell responsiveness to acellular Pertussis (aP) vaccination, memory maturation and cell activation.
Methods: Infants were recruited immediately after birth. Blood was collected at birth, day 4, weeks 7, 15 and 36 and 250ul was stimulated with and without Pertussis (aP) antigen in a 12-hour whole blood assay. Cells were then fixed and cryopreserved for banked analyis by multiparameter flow cytometry. An 11 colour panel was used to stain for memory maturation, activation and polyfunction: CD3+CD4+CD8+CD45RA+CD27+HLA-DR+Ki67+ cell antigens and expression of IFNγ, IL-2 and TNFα cytokines. Data analysis was completed using Flow.Jo V9, GraphPad prism V6, Pestle 1.7 and Spice V5.33.
Results: There was a greater frequency of early (CD45RA-CD27+) and late (CD45RA-CD27-) differentiated CD4+/CD8+ memory cells in HEU infants in the first week of life relative to HU infant controls. Additionally, HEU infants had lower frequencies of aP-specific CD8+, any cytokine expressing T-cells at week 7, but higher frequencies of single expressing aP-specific CD8+ IL-2 and IFNγ cells at week 15 compared to HU infants. There was also an added impact of formula feeding (FF), where HEU FF infants had higher levels of CD8+ activation and memory differentiation but lower levels of CD4 memory differentiation at week 7 compared to breast fed HEU infants. These infants also possessed higher aP-specific CD8+ cells expressing overall cytokines and single TNFα expressing CD8+ T-cell at week 7 and week 36.
Conclusions: Collectively, our data suggest that exposure to maternal HIV impacts T-cell ontogeny early in life and that cytokine responsiveness to antigen can be altered by feeding practise. Changes due to HIV exposure appear transient, as by week 36, there are no differences between HEU and HU infants. However, FF causes long-term cell activation and higher aP vaccine responses.

WEPEC0971

Immunogenicity and safety of 4 prime-boost combinations of HIV vaccine candidates (MVA HIV-B; LIPO-5; GTU-MultiHIV B) in healthy volunteers: ANRS/INSERM VRI01 phase I/II randomized trial

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Background: Heterologous prime-boost strategies are considered among the most promising HIV vaccine strategies. We hypothesized that the priming component is important for induction of strong immune responses and that an innovative trial design allows for rapid selection of promising strategies.
Methods: ANRS/INSERM VRI01 is an open-label randomized multicenter trial of 3 candidate vaccines administered as prime or boost: MVA HIV-B (coding for Gag, Pol, Nef); LIPO-5 (lipopeptides from Gag, Pol, Nef); and GTU$^{\Diamond}$-MultiHIV B (DNA coding for Rev, Nef, Tat, Gag, gp160 clade B). Healthy volunteers were randomized 1:1:1:1 to four parallel groups: G1 (M2L2): MVA HIV-B (Wks 0, 8) then LIPO-5 (Wks 20, 28); G2 (L2M2): LIPO-5 (Wks 0, 8) then MVA HIV-B (Wks 20, 28); G3 (D3L2): GTU$^{\Diamond}$-MultiHIV B (Wks 0, 4, 12) then LIPO-5 (Wks 20, 28); G4 (D3M2): GTU$^{\Diamond}$-MultiHIV B (Wks 0, 4, 12) then MVA HIV-B (Wks 20, 28). Vaccine responders were defined by a positive IFN-γ-ELISPOT to ≥1 HIV peptide pool measured 2 Wks after each injection. Co-primary endpoints were safety and the proportion of IFN-γ-ELISPOT responders at Wk30, aiming to discard strategies with ≤ 50% responders.
Results: Nighty-two volunteers were randomized (mean age 30 years, 54% male) and received ≥1 injection. Four, 0, 6 and 1 SAEs possibly related to vaccination were reported in G1, G2, G3, G4, respectively, including one myelitis possibly related to LIPO-5.
Frequency of IFN-γ-ELISPOT responders and median SFC/10^6 PBMC among responders post-prime were: 59% and 328 SFC (G1 post-prime MVA); 5% and 323 SFC (G2 post-prime LIPO-5), 0% (pooled G3+4 post-prime GTU$^{\Diamond}$-MultiHIV B). Following boosting, at Wk30 (primary endpoint, ITT analysis) these responses were 33% and 250 SFC (M2L2); 43% and 528 SFC (L2M2), 0% (D3L2); and 67% (P=0. 06 for superiority to 50% threshold) and 324 SFC (D3M2). In Wk30 per protocol analyses D3M2 was significantly above the predefined minimum immunogenicity level: 74% responders (P=0.02 for superiority to 50% threshold).
Conclusions: This optimized trial design helped to identify MVAHIV-B as a safe and immunogenic T-cell vaccine given as either prime or boost in various combinations. GTU$^{\Diamond}$-MultiHIVB/MVA HIV-B met the pre-defined minimum immunogenicity criterion to pursue clinical development.

WEPEC0972

First report after early termination of ANRS COV1-COHVAC cohort of healthy volunteers from preventive HIV-1 vaccine trials

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Background: The ANRS COV1-COHVAC cohort aims to describe the long-term safety of preventive HIV-vaccines administered in 17 phase I and II clinical trials to healthy volunteers. COHVAC stopped prematurely at the end of September 2016 due to the absence of safety signal.
Methods: 488/496 volunteers were included in the cohort and 355 agreed to participate in prospective follow-up. Data were collected retrospectively from first vaccine administration and prospectively (one visit/year). At each visit, health events evoking neurological, ophthalmological and immunological disorders (any grade) and other grade 3/4 events were collected; questionnaire about behaviors was self-administered and HIV ELISA was done. Age and sex-adjusted mortality and incidence rates (SMR, SIR) were studied in relation to the French population.
Results: Mean total follow-up after first vaccination was 10.1 years (0.1 to 24.3). As of November 2016, targeted events occurred in 56% of participants. Among events of interest, 27% of volunteers had neurological impairment (mostly sciatica, migraine), 14% had an ophthalmologic event (cataract, glaucoma) and 1.6% an autoimmune disease. Among cancers, breast cancer was the most frequent (n=6), however its incidence in COHVAC was not different from that of women in the French population (SIR=1.47, IC95%=[0.54, 3.20]; p=0.45). The mortality of women in COHVAC was not different (SMR=0.73; p=0.41) while that of men was significantly lower (SMR=0.22; p=0.0003) from the French population. At last follow-up visit, 19 volunteers still presented vaccine induced seropositivity. All of them had received rgp160 in median 23 years (17 to 24) previously. Participants were mostly in couple, aged 58 in median at last follow-up and had mostly high social level and involvement. The main motivations of participation in the trials were altruism, proximity to an HIV-infected person and the future generation. Analysis of self-administered questionnaires (Year 0 to Y3) revealed a stable and low percentage (men: 7%, women: 1%) declaring risky sexual practices.
Conclusions: No long-term safety alert was identified during follow-up. Vaccine induced seropositivity may persist for more than 23 years after vaccination. Participation in vaccine trials did not imply increased risk-taking with regard to HIV infection.

WEPEC0973

ADCC and neutralizing antibody responses in HIV-1-infected children

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Background: RV144 vaccine trial showed a modest protection against HIV-1 infection and an inverse correlation with antibody dependent cellular cytotoxicity (ADCC) activity. To inform vaccine development we studied in HIV-infected children ADCC, the development of neutralizing antibodies (NAbs) against autologous and heterologous viruses as well as of antibody reactivity to Env epitopes and childhood vaccination antigens.
Methods: Fifteen vertically infected Italian children were included in the study. Seven developed a severe immune suppression (CDC3) before two years of age and six thereafter. The remaining two children were not classified as CDC3 for at least five years. Plasma were tested for the presence of autologous NAbs in a PBMC-based assay to several primary isolates obtained during disease follow up. Heterologous Nabs were revealed by TZMbl assay to 4 Tier 2 PSVs with plasma at years three to five if autologous Nabs were observed. ADCC was detected by Grantoxilux assay using gp120BAL-coated target cells. Seroreactivity to HIV-1 gp41, autologous gp120 V3-loop peptides and tetanus and diphtheria toxoid by ELISA.
Results: Newborns displayed antibodies, of maternal origins, to an HIV-1 gp41 epitope but did not neutralize the transmitted virus. NAbs developed usually within 1 year of age to the early virus concomitantly with anti-V3-loop antibodies. Ten of 15 children developed Nabs against one or more autologous isolate during the follow-up, which persisted throughout disease but showed emergence of escape variants. All children except one developed heterologous NAbs to at least one Tier 2 virus of 4 tested. All children except one developed ADCC during follow-up within 2 years of age, which persisted thereafter. In general, the antibody titers to tetanus and diphtheria antigens were higher during the first 18 months of age and eventually dropped thereafter. These data suggest that HIV-1 infected children can mount immunodominant antibody responses.
Conclusions: Autologous NAbs develop usually within 1 year of age to the transmitted virus, persist throughout disease but induced viral escape. Heterologous neutralization against at least one Tier 2 virus as well as ADCC activity were common in children within 2 years.

WEPEC0974

HIV population-level adaptation can rapidly diminish the impact of a partially effective vaccine

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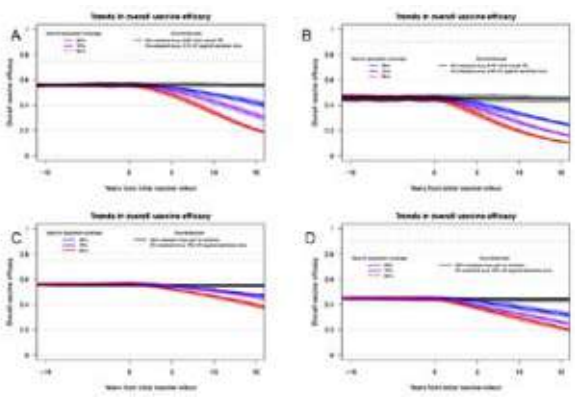
Background: Development of an HIV vaccine is considered essential to ending the HIV/AIDS pandemic. However, vaccines can result in the emergence and spread of vaccine-resistant strains, a consequence that is largely ignored in previous mathematical modeling of the potential impact of an HIV vaccine. Analyses of breakthrough infections in the marginally successful HIV vaccine trial, RV144, identified HIV genotypes with differential rates of transmission in vaccine and placebo recipients. We therefore hypothesized that, for HIV vaccination programs based on partially effective vaccines similar to RV144, HIV adaptation will diminish vaccine impact.
Methods: We developed two individual-based stochastic models of HIV dynamics, one calibrated to the South African epidemic and one calibrated to US men who have sex with men (MSM). We simulated large-scale vaccination programs and, critically, included HIV strain diversity with respect to vaccine response. We varied population vaccine coverage (50%, 70%, or 90%), vaccine efficacy (75% or 90%), and the proportion of vaccine-resistant viruses (25% or 50%).



[Figure 1. Trends in overall vaccine efficacy (VE) from heterosexual (panels A and B) and MSM (panels C and D) models. Panels depict results from scenarios with an initial resistant strain proportion of 25% (panels A and C) and 50% (panels B and D) and sensitive virus VE of 75% (panels A and C) and 90% (panels B and D)]

Results: Population-level viral adaptation was observed in all model scenarios, leading to decreased overall vaccine efficacy (Figure 1) and substantially fewer infections averted by vaccination. Compared to scenarios without viral evolution, 7%-25% fewer cumulative infections are averted within ten years of vaccine roll-out among MSM, and 10%-39% fewer cumulative infections are averted in South Africa. Translating this to the epidemic in South Africa, this represents up to 600,000 new infections within 10 years of vaccine rollout that are due solely to HIV adaptation.
Conclusions: These findings suggest that approaches to HIV vaccine development, program implementation, and epidemic modeling may require attention to potential viral evolutionary responses to vaccination.

WEPEC0975

Engaging underserved key populatios in Kyrgyzstan: what works?

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Background: From 2010 to 2014, HIV incidence almost doubled in Kyrgyzstan (Republican AIDS Center, 2015). Experts recognize that one of the possible reasons for the growth of HIV is limited coverage of vulnerable groups. The aim of this study is to investigate the factors influencing the motivation of members of key populations to participate in HIV prevention programs.
Methods: Main method was - semi-structure in depth interview (N=105).
Additional method -interview "face to face" (N=345). Total- 450 representatives of 3 key populations have been studied (IDU, SW, LGBTIQ), aged 18 and >, having experience of participation in HIV prevention programs, 10 outreach workers and 4 managers of non-governmental partners organization.
Data collection has been carried with the help of trained interviewers, representatives of the communities.
Results: Available services satisfy the respondents partly because they do not completely cover all the needs and requirements of respondents, the exception of educational materials. Providing medicines and medical equipment (syringes, condoms), complex medical examination, legal support , employment, recovery of documents of permanent residence are very popular services, but in most cases are not being on desired and sufficient level.
Outreach workers are the main source of information about prevention programs, HIV and TB infection and about medical organizations (87%-IDU, 61%-SW and 51%-LGBT) and the medical equipment syringes, condoms and lubricants (81%-IDU, 68%-LGBT, 84%- SW). They enjoy sufficient authority and trust among community members (more than 80% per groups). SW and LGBT noted that outreach workers need to more often contact (78%-LGBT, 54%-SW, 29%-IDU). It is crucial that they are representatives of the community, because they exactly know all the details.
Conclusions: Outreach work must be valued as key tool to reach and encourage members of key populations to participate in HIV prevention programs. Motivating outreach workers will increase the quality of their work, resulting in higher coverage of vulnerable groups, and leading to more effective HIV prevention programs. Factors as fear of being identified, harassment by law enforcement officials, the mismatch between demand and supply of inaccessible services were identified as the main barriers to receiving preventive services.

WEPEC0976

Evaluating urine with dried blood spots to assess tenofovir levels for HIV pre-exposure prophylaxis adherence

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Background: Antiretroviral pre-exposure prophylaxis (PrEP) effectively prevents HIV when taken daily. However, there are limited ways to objectively monitor adherence in the clinic. Urine is highly correlated with plasma tenofovir (TFV) levels. Urine TFV levels >1000ng/mL demonstrate recent (last 1-2 days) adherence, levels 10-1000 demonstrate inconsistent dosing in the previous week, and levels < 10 indicate no TFV in the previous week. In this study, we determined the sensitivity of urine TFV levels with dried blood spot (DBS) values.
Methods: Fifty-three paired urine-DBS specimens were obtained from 53 patients enrolled in a PrEP adherence study at Washington University in St. Louis (USA) between May and August 2016. Sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated for urine TFV >1000ng/mL, using DBS as a gold standard with DBS TFV-disphosphate (DP) ≥700 (4 or more doses/week) and ≥1250 (7 or more doses/week) fmol/punch and DBS emtricitabine-triphosphate (FTC-TP) levels (dosing within 48 hours).
Results: Patient median age was 29 years, 92% were male, 53% white, 91% MSM, and median time on PrEP was 11 months. 92% of patients had urine TFV >1000ng/mL, 2% had 10-1000ng/mL, and 6% had < 10ng/mL. Majority (94%) had ≥700 fmol/punch DBS TFV-DP. Urine TFV levels >1000ng/mL demonstrated sensitivity of 94% (95% CI: 83-99) and PPV was 96% (95% CI: 86-100) for ≥700 fmol/punch and 100% (95% CI: 90-100) and 71% (95% CI: 57-83) for ≥1250 fmol/punch. Urine TFV´s specificity and NPV were not reported for DBS given high levels of adherence among the patient sample. Urine TFV >1000ng/mL had a sensitivity of 98% (95% CI: 89-100) and PPV was 96% (95% CI: 86-100) for detectable DBS FTC-TP. Urine TFV specificity and NPV were 60% (95% CI: 15-95) and 75% (95% CI: 19-99) for DBS FTC-TP.
Conclusions: Clinic settings would benefit from rapid and objective PrEP monitoring. Urine TFV levels had high sensitivity and PPV compared to DBS TDF-DP and FTC-TP in a sample of very adherent PrEP patients. Both measures contribute to a growing toolbox of adherence biomarkers to improve PrEP care by identifying patients in need of intensified counseling.

WEPEC0977

Venue-based HIV-testing: an effective screening strategy for high-risk populations in Lima, Peru

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Background: Improving access to and uptake of HIV testing is an important strategy for HIV prevention. Currently, only a small proportion of high-risk men who have sex with men (MSM) and transgender women are screened for HIV in accordance with WHO recommendations in Lima, Peru. Venue-based sampling methods may improve identification of new HIV infections.
Methods: We offered onsite HIV testing at several locations popular among MSM and transgender women communities in Lima. A survey of risk-behavior, HIV testing history, and testing preferences was also administered. Participants who refused testing completed a survey inquiring reasons for refusal and received coupons for free HIV testing at HIV testing centers. All fieldwork was completed in 2016. We used a multivariable Poisson regression to create a model calculating Prevalence Ratios (PRs) for factors associated with HIV infection.
Results: We tested 303 participants for HIV, 29% were transgender women. Only 26% reported testing every six months in accordance with WHO recommendations, and 19% had never been tested for HIV previously. Of those tested, 90% reported they would test for HIV more frequently if testing were offered in alternative venues; with the majority (56%) expressing a preference for public places (e.g. parks, plazas). We identified 69 new cases of HIV infection 23% (95% CI 18-28%). Prevalent HIV infection was independently associated with reporting recent receipt of money in exchange for sex (PR=1.12; 95% CI 1.02-1.23), sex with a partner of unknown serostatus (PR=1.19; 95% CI 1.10-1.29), and a versatile sex role for anal sex (PR=1.15; 95% CI 1.04-1.26) when compared to insertive alone; the model was also adjusted for number of male sex partners. Of the 282 participants who refused onsite testing, the most common reasons for refusal were insufficient time (35%), and preference for a more discrete location (27%). Participation was 59% overall ranging from 33% at disco and a sauna to 89% at a street-based venue and a small video-club.
Conclusions: A high proportion of MSM and transgender women remain inadequately screened for HIV. Venue-based testing can improve screening uptake among under-screened high-risk populations in Lima Peru, and is effective for case finding.

WEPEC0978

Choice, use and persistence with three delivery forms (tablets, ring, injections) among young African women

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Background: Preventing HIV and unintended pregnancies are key health priorities in young women. To understand attributes of future Multipurpose Prevention Technologies associated with adherence, we evaluated three placebo delivery forms in a cohort of Kenyan and South African women.
Methods: HIV-negative, sexually active, non-pregnant women aged 18-30 were enrolled and randomized to use each placebo product (daily oral tablets, monthly injections and monthly vaginal rings) for one month (N=277). At their Month-3 visit (M3), participants chose one product to use for two additional months. We assessed the following components of adherence during the usage period: Initiation/compliance with two injections of 1ml saline in the gluteus. For tablets/rings we assessed regimen initiation and completion (last dose/ring in situ at return visit) by direct observation at the clinic, and execution (correct use) by questionnaire. Non-persistence was measured by the proportion of women who switched product at their Month-4 visit (M4). We examined demographic and behavioral correlates of non-persistence by multivariable logistic regression.
Results: Ninety percent (N=249) reached M3, and 89% (N=247) completed the study (M5). Mean age was 23.2 years, 49% were Kenyan and 51% South African. At M3 all chose a product (64% injections, 21% tablets, 15% ring) and >99% initiated use. At M4, >80% completed their tablet/ring regimen. For each product, initiation, execution and completion levels were similar at M4 and M5. Fifty women (20%) were non-persistent. The top reasons for switching were: wanting to gain experience with another product, preference for another mode of administration, and perceived side effects. Only one mild ring-related adverse event (vaginal pruritis) was documented during the usage period. Choosing injections at M3 (versus ring) was associated with a substantial reduction in the odds of non-persistence in South Africa only (AOR=0.2, p=0.012).
Conclusions: All participants agreed to choose and use a placebo product, a majority appeared adherent and all products were safe. Injections were chosen most often, used with perfect compliance, and in South Africa, were associated with higher persistence. Larger multisite studies with active products are needed to further inform the tolerability of and persistence with these delivery forms across settings.

WEPEC0979

Young African American MSMs speak out: recommendations for enhancing retention in PrEP care for US implementation science programs in the Deep South

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Background: Young African American men who have sex with men (YAAMSM) in the Deep South are retained in PrEP care at disproportionately lower rates than their White counterparts. Little is understood about how to effectively retain young African American MSM in PrEP care in real-world settings.
Methods: We conducted a two-phase qualitative study that included key informant interviews and two focus groups. We used grounded theory and purposeful sampling strategy to guide this study. Participants included YAAMSM enrolled in a real-world PrEP implementation science program in Jackson, MS. Interviews and focus groups with 43 YAAMSM explored factors that enable or pose barriers for retaining YAAMSM in PrEP care, including social, structural, clinical and behavioral factors. We solicited normative recommendations for developing interventions focused on enhancing retention in PrEP care for YAAMSM. We concluded recruitment when saturation was met and common themes emerged.
Results: Structural factors such as cost and access to financial assistance for medications and clinical services undermined retention in PrEP care. Social factors such as stigma associated with being perceived as gay or HIV positive posed barriers to retention in care. Behavioral factors including changing sexual risk behaviors and low perceived HIV risk prompted some participants to discontinue PrEP. Clinical factors including both perceived and actual side effects prompted some participants to discontinue PrEP. Participants commonly solicited "PreP wrap-around services," suggesting that PrEP navigators could offer important support services for enhancing retention in care for YAAMSM. Participants also recommended extending clinic hours, offering transportation support services and behavioral counseling, providing text message reminders about clinical appointments, providing culturally competent care and reducing copayments for medications and related clinical services.
Conclusions: Social, structural, behavioral and clinical factors contribute to retention in PrEP care for young YAAMSM. PrEP navigators who help patients overcome these challenges may enhance retention in care for YAAMSM enrolled in PrEP programs in the Deep South of the US.

WEPEC0980

Reasons for non-adherence to the dapivirine vaginal ring during MTN-020/ASPIRE: results of the MTN-032/AHA study

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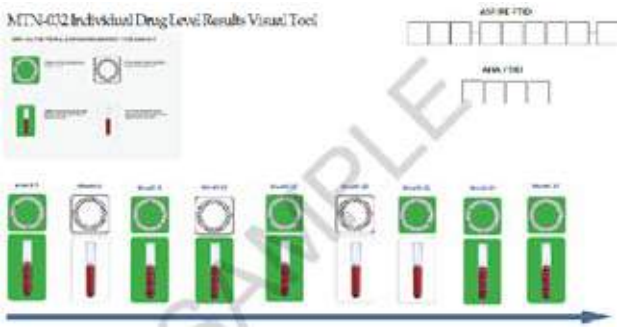
Background: MTN-020/ASPIRE and IPM-027/Ring Study recently proved the dapivirine vaginal ring was safe and effective with consistent use. To optimize the impact of this promising female-initiated prevention method, adherence barriers must be understood and addressed. MTN-032 explored women's ring use challenges through open-ended discussion of their objective adherence data.
Methods: Former ASPIRE participants were stratified by age group (18-21; 22-45) and randomly selected at 7 sites in Malawi, South Africa, Uganda and Zimbabwe, 12-17 months after trial exit. Young women were intentionally over-sampled because they were less adherent and not protected by the ring in ASPIRE. Using in-depth interviews or focus groups, ring use challenges were explored using structured guides and visual tools including individual-level depictions of dapivirine levels detected in plasma and returned rings.



[abstractpic2]

Results: 187 participants aged 19-48 were enrolled; 37% were 18-21 at ASPIRE enrollment. Although many (24%) had concordant plasma and residual ring results suggesting consistent use at every visit measured, most women (73%) had results suggesting inconsistent use throughout ASPIRE. Visual tools elicited participant descriptions of many instances of non-adherence, including removals ranging from short-term (for sex or bathing), to multiday (menses) to multi-week (often with reinsertion 1-3 days before the next visit). Reasons for non-use included influence from peers and communities mistrusting researchers (particularly foreign); worries about ring causing cancer or infertility; non-disclosure to partners and partner objections; and experience of discomfort or side effects. Young women's non-adherence was most commonly attributed (by themselves and older women) to being less "serious" about the future, HIV prevention and the study (and motivated predominantly by benefits); more fearful of childbearing/fertility-related consequences; and to having less control over their relationships.
Conclusions: When presented with objective adherence data, participants provided explanations for ring non-adherence during ASPIRE. These data can be used to pre-emptively mitigate adherence challenges in future ring studies/activities, e.g. MTN-025/HOPE.

WEPEC0981

Very high adherence to HIV PrEP over one year confirmed by four measures in an open-label demonstration project (PRELUDE) in NSW, Australia

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Background: The efficacy of HIV pre-exposure prophylaxis (PrEP) depends upon adherence.
Daily PrEP adherence was assessed over 12 months using two biological measures and two measures of self-report (SR). Drug concentrations in plasma and peripheral blood mononuclear cells (PBMC), and patient SR to clinicians and via online surveys were evaluated. Concordance between SR and biological measures was assessed.
Methods: PRELUDE is an open-label PrEP demonstration project of 327 high-HIV risk, predominantly (96%) gay/bisexual men in New South Wales (NSW), Australia. Participants self-reported the number of tablets taken in the previous week to clinicians, and the last three months via online surveys. SR adherence required daily dosing, as prescribed. Blood was collected from 108 consecutively presenting participants 1, 6 and 12 months post-PrEP initiation. Liquid chromatography-mass spectrometry was used for drug quantification. Biological adherence was defined as plasma tenofovir (TFV) ≥40.0 ng/mL and PBMC tenofovir-diphosphate (TFV-DP) ≥16.8 fmol/10^6 cells, indicative of daily dosing in the three days and one week prior to blood collection, respectively. Results were analysed using descriptive statistics and ANOVAs with Bonferroni's post-hoc correction. Kappa tests were used to determine measurement agreement.
Results: Amongst participants with blood samples from all three time points (n=87), mean adherence was 92% (95% confidence interval 88 - 95%) across all measures (Table 1). Median (interquartile range) PBMC TFV-DP concentrations significantly decreased between months 1 (100 (64 - 176) fmol/10^6 cells) and 6 (61 (40 - 94) fmol/10^6 cells; p<0.001), and months 6 and 12 (51 (29 - 74) fmol/10^6 cells); p=0.01), but not in plasma or SR data (p>0.05). Concordance between PBMC TFV-DP and plasma TFV, survey SR, and clinician SR was 87%, 92%, and 87% respectively.
Conclusions: Very high levels of daily adherence to PrEP amongst early adopters were confirmed using four different measures, although there was a decrease in PBMC TFV-DP over time. Strong concordance between blood drug concentrations and SR data suggests that SR may be a suitable measure of adherence in clinical practice. To ensure effective ongoing PrEP use, longer-term observation is required.

WEPEC0982

Adherence intentions, long-term adherence and HIV acquisition among PrEP users in the PROUD open-label randomised control trial of PrEP in England

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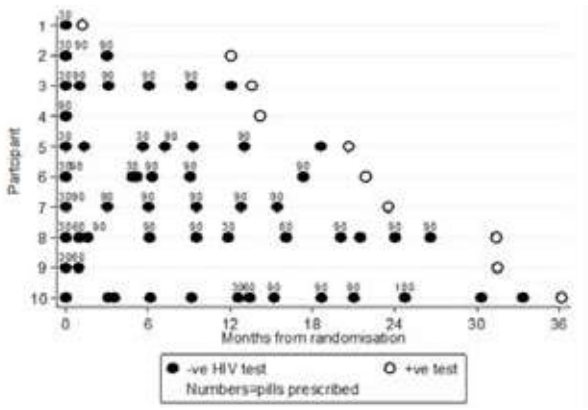
Background: PROUD demonstrated an 86% reduction in HIV-acquisition among participants offered PrEP in the first year of follow-up, with high levels of adherence. Relatively little is known about long-term PrEP adherence. We report adherence intentions, long-term adherence and HIV-acquisition among PrEP users in PROUD.
Methods: We tabulated data from the 'end-of-study-questionnaire' (EoS), which asked about adherence intentions. We calculated the medication possession ratio (MPR) as the number of pills prescribed, divided by number of days elapsed since PrEP initiation. We describe sero-conversions among participants who initiated PrEP.
Results: PROUD ran from Nov12 to Nov16, enrolled 544 participants and accumulated 1,253.3 person years of follow-up. Of 310 participants who completed the EoS, 86% aimed to use PrEP daily during the study, reducing to 61% wanting to use it daily after the trial. 98% thought their adherence was ‚good enough' during periods of risk. 36% reported intentionally interrupting/stopping PrEP. Of 481 participants who initiated PrEP, 327(68%) received a prescription within the last 6-months of the study. The MPR from PrEP initiation to end of first-year of use was high at 92%, reducing cumulatively to 82% and 76% from initiation to end of years 2 and 3. We observed 10 HIV infections among participants who initiated PrEP. One participant acquired HIV before baseline, four stopped attending clinic without providing a reason, two stopped attending clinic after reporting changing to on-demand dosing or stopping PrEP, and three attended clinic but did not collect PrEP (Figure 1).



[Figure 1. HIV tests and PrEP prescriptions for the 10 participants who acquired HIV after starting PrEP]

Conclusions: In this study, which recommended daily-dosing, the majority of participants intended to use PrEP daily, over a third reported intentionally interrupting PrEP and a third stopped using PrEP within 4-years of initiation. When attending clinic, adherence was high but declined over time. The seroconversion data highlights the urgent need for interventions to help people know when to cycle on and off PrEP.

WEPEC0983

Making health a priority: the influence of family structure and household composition on youth's PrEP use in Cape Town, South Africa

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Background: PrEP constitutes a key HIV prevention tool, yet PrEP initiation and adherence is shaped by numerous factors, including an individual's ability to prioritize health behaviors. Existing literature describes the effects of HIV prevention and treatment behaviors on family structure and household composition; however, the inverse is not well elucidated. For youth, in particular, family/household factors could have important effects on PrEP use. We examine these relationships using qualitative data from iPrevent, an end-user study designed to explore factors that optimize PrEP adherence among youth in South Africa.
Methods: Fifty former PrEP trial participants (32 females: 10 vaginal ring, 12 injectable, 10 tablet; and 18 males: all oral PrEP), from informal communities in Cape Town completed in-depth interviews if they were HIV negative, sexually active, and aged 18-24 years. We explored how household environment and family support affected sexual and reproductive health (SRH) decision-making, partner disclosure regarding PrEP use and sustained PrEP use through trial participation. We analyzed transcripts following a framework analysis approach.
Results: Two broad types of families emerged: a loosely-knit family, where intimate discussions around sex, SRH and PrEP use were absent; and a close-knit family where these topics were openly discussed. These two family types defined and shaped how youth navigated health issues, generally, including PrEP use. Family

support positively affected youth's abilities to view health as a priority and hence adopt protection against HIV. Youth from loosely-knit families where support was absent found it difficult to use PreP, and were more likely to seek partner support, including disclosure of PrEP use, to partners as a substitute. While this enabled them to engage in HIV prevention, their partners made key decisions around sex. Youth from close-knit families typically disclosed PrEP use to their families, and not partners, and were accorded familial support. They described greater autonomy in sexual decision-making.
Conclusions: Youth are a unique key population and the manner in which they navigate PrEP use is critical to prevention. We found support to be fundamental to PrEP use; however, family support empowered youth more than partner support, highlighting its important role in adoption of HIV prevention behaviors.

WEPEC0984

Changes in ART adherence among Rwandan youth following a trauma-informed cognitive behavioral intervention

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Background: Like most of sub-Saharan Africa, Rwandan youth are at the epicenter of the AIDS epidemic accounting for 40% of infections. ART adherence is a global health priority, as poor adherence may lead to virus resistant strains, limited future treatment options, and continued new transmissions. High levels of adherence have been reported among adults, but studies of adolescents suggest youth are less adherent, achieve less viral suppression, and have larger viral rebound than adults. Evidenced-based interventions for youth are sorely needed to increase ART adherence. Recognizing the role of the genocide in Rwanda's HIV epidemic, this study evaluated the efficacy of an adherence-enhanced, trauma-informed cognitive behavioral intervention (TI-CBTe) to improve adherence.
Methods: Participants were 360 14-21 year old HIV-infected Rwandan males (49%) and females in care at one of the two HIV clinics in Kigali. Youth were recruited by research staff and guardian consent and youth assent were obtained. Youth completed baseline assessments and were randomly assigned to TI-CBTe or the clinic's standard of care (SOC). Six sessions, each two hours, were delivered once a week by young adult peers. Youth completed 6-month follow-up assessments and reported on their adherence to ART in the past 30 days on a scale from 1 to 6 and their symptoms of trauma.
Results: Analyses compared youth who received TI-CBTe versus SOC on self-reported ART adherence and trauma at 6-month follow up. Groups did not significantly differ at 6-months in adherence for the full sample, but boys who received TI-CBTe reported significantly greater improvement in adherence than boys in the SOC, F (1, 109) = 4.194, p = .043. Similarly, trauma symptoms were not associated with change in adherence overall, but for youth who reported higher trauma at baseline, those who received TI-CBTe reported greater improvement than youth in the SOC, F (1, 36) = 4.925, p = .033.
Conclusions: Findings suggest that a culturally-adapted adherence-enhanced cognitive behavioral intervention can improve ART adherence for Rwandan males and youth with elevated trauma symptoms. Future research should examine whether these positive changes are sustained beyond 6-months and how to enhance treatment efficacy for females.

WEPEC0985

Seeking casual sex partners via the internet, Bangkok MSM cohort study, 2006-2016

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Background: The internet has changed how men who have sex with men (MSM) seek sex partners. We investigated factors associated with meeting casual sex partners via the internet among participants of the Bangkok MSM Cohort Study (BMCS).
Methods: We enrolled Bangkok MSM aged ≥18 years into BMCS between April 2006-November 2010. Participants were followed every four months for up to five years. We collected demographic information at enrollment and behavioral data at every visit using audio computer-assisted self-interview. Participants were asked about casual sex partners and how they met these partners during the past four months. We used Generalized Estimating Equations (GEE), accounting for repeated measures correlations within participants, to model factors associated with meeting casual sex partners via the internet.
Results: From April 2006-February 2016, we enrolled 1,744 MSM in BMCS; 1,590 (91%) had at least one follow-up visit. At enrollment, 37% (638/1,744) reported having casual sex partners and having met partners via the internet. Among 1,375 MSM who reported having casual sex partners in at least two visits, seeking partners via the internet was significantly higher among MSM who—at the time of enrollment—were full-time or part-time students (adjusted Odds Ratio [aOR] 1.3, 95% Confidence Interval [CI] 1.1-1.6) and self-identified as non-heterosexual (aOR 6.2, 95% CI 2.8-13.5). At each individual follow-up visit, seeking partners via the internet was more common among participants who reported age 18-29 years at initial enrollment (aOR 1.8, 95% CI 1.5-2.2), recreational drugs use (aOR 1.3, 95% CI 1.04-1.5), erectile dysfunction drug use (aOR 1.6, 95% CI 1.3-1.9), having group sex (aOR 1.9, 95% CI 1.6-2.2), and inconsistent condom use with male casual partners (aOR 1.2, 95% CI 1.02-1.3), when compared with the rest of the cohort. Using the GEE also found that at each four months the proportion of men meeting sex partners via the internet increased by 1.1% (aOR 1.011, 95% CI 1.008-1.014).
Conclusions: About one third of participants in BMCS had casual sex partners and met these partners via the internet. This behavior increased significantly over time. Meeting casual partners via the internet was associated with high-risk behaviors for HIV acquisition

WEPEC0986

Is it necessary to validate key population hotspots on a regular basis? An experience from Burundi

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Background: LINKAGES is a USAID- and PEPFAR-funded project that is improving access and links to HIV prevention, care, and treatment services for key populations (KPs). Accurate information on hotspots where KPs congregate is critical to focusing outreach and prevention efforts. A hotspot list for Burundi was available from a 2013 PLACE study, a methodology that identifies priority prevention areas but that cannot be conducted frequently due to cost and time requirements. LINKAGES Burundi conducted a rapid programmatic mapping exercise to systematically update and validate the hotspots identified by PLACE 2013 and to identify new ones to facilitate rapid program start-up.
Methods: The project employed 20 female sex workers (FSWs) and 10 men who have sex with men (MSM) to visit all hotspots and conduct interviews among primary (KPs) and secondary (pimps, taxi drivers, vendors, shop owners) key informants in five districts in Burundi from October to November 2016. A structured tool was used to collect information on the size of the population in each hotspot, peak time and days of operation, KPs' use of social media and mobile phones, services available, mobility of the population, and new sites where KPs congregate.
Results: Of 830 (724 FSW and 96128 MSM) sites identified by PLACE in 2013, only 413 (50%) (363 FSW and 50 MSM) were still active. While conducting this validation, we also identified 436 (388 FSW and 48 MSM) new sites that emerged since 2013, for a total of 849 active sites, 59% of which were in the capital province of Bujumbura. The most prevalent type of hotspot was bar/night club (73%) followed by lodge/hotel (10%).
Conclusions: Fifty percent of KP hotspot sites from 2013 were no longer active in 2016—an indication that repeated programmatic mapping is essential for program planning with highly mobile KPs. The results of our validation exercise enable effective distribution of resources, microplanning by local NGOs working with peer outreach workers, and rapid scale-up of programs.

WEPEC0987

Intention toward HIV testing among men who have sex with men in Taiwan: a survey-based on health belief model

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Background: The 90-90-90 targets might eliminate the HIV epidemic in Taiwan. However, 25% of people living with HIV don't know their HIV status currently. Men who have sex with men (MSM) are the most affected population and account for the majority of newly diagnosed HIV infections. We conducted the survey which was based on Health Belief Model (HBM), a health behavior change theory, to understand the health beliefs to HIV testing among MSM in Taiwan.
Methods: An anonymous survey was conducted between April and May, 2016. We recruited participants from eight MSM community health centers located in different regions. Intention toward HIV testing, demographic characteristics, sex-related behaviors, and HBM constructs, of MSM were collected via questionnaires. We performed multi-variate logistic regression to identify the factors associated with testing intention among MSM.
Results: A total of 1,393 responses were included for final analysis. The high testing intention group consisted of 911 (65.4%) MSM. Logistic regression showed that MSM who were 25-34 years-old (AOR=1.52), had anal intercourse experience (AOR=2.09), had more than two casual sexual partners per year (AOR=1.65), experienced chem-sex (AOR=3.88), used geosocial apps (AOR=1.55), received HIV testing before (AOR=3.81), were more likely to have high testing intention in the next year. In contrast, MSM who used condoms during last anal sex (AOR=0.68) had lower testing intention.
MSM perceiving high (AOR=2.16) and moderate (AOR=1.95) risk of HIV had higher intention toward HIV testing than MSM with low perceived risk. High (AOR=1.68) and moderate (AOR=1.59) perceived benefits, high (AOR=2.15) and moderate (AOR=4.26) self-efficacy were associated with higher testing intention. MSM with high perceived severity had higher HIV testing intention (AOR=1.66) than those with low perceived severity, but moderate perceived severity were not significantly associated with testing intention.
Conclusions: Several demographic characteristics related to testing intention of MSM were identified from this study. We could design targeted HIV testing campaign to those MSM more effectively. Besides, we also find out various facilitators to testing intention. This findings could help us to implement HIV testing programs and increase the uptake of HIV testing among MSM in Taiwan. Therefore, the 90-90-90 targets could be achieved.

WEPEC0988

Barriers to HIV-testing and linkage to care among Latino youth in Atlanta

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Background: Latinos account for 24% of new HIV diagnosis in the US with a significant increase in incidence between 2010-2014 among young gay and bisexual men. Georgia's Latino population grew by 96% from 2000 to 2010, with the biggest increase seen in youth. Despite an overall increase in testing and HIV prevention efforts, HIV-infected Latinos progress to AIDS faster than any other US racial or ethnic group. Understanding barriers for testing and linkage to care among Latino youth (LY) is therefore increasingly important.
Methods: We conducted quantitative surveys and five exploratory qualitative focus groups with LY, ages 18-24 years, from the Atlanta Metropolitan Statistical Area. Audio Computer-Assisted Self-Interviewing surveys gauged HIV testing preferences, and risk factors for avoiding testing and/or medical care. Using computer-assisted thematic analyses, we examined focus group responses addressing barriers to HIV testing, treatment, and counseling.
Results: Of 29 study participants, 52% were male, 58% were from Mexico, 59% had ≤ high school education; 79% lived with their guardian; mean age was 19.6 years (SD: 1.74 years). Eighty-nine percent disliked the idea of venue testing, 69% preferred the oral swab as a method of HIV testing, and 69% perceived that HIV-positive LY defer entering medical care despite knowing their status. Reasons cited included fear of medical treatment (59%), depression, denial and fear of discrimination (55% each), and being unaware of available services and treatment venues (35%). Three themes were identified as barriers for testing:
1) fear of rejection,
2) the need to normalize testing, and;
3) stigma.
Treatment affordability and existential attitude were identified as potential barriers for treatment among HIV-positive youth. Upon providing the results of an HIV positive test, the participants emphasized the need to receive information about their disease and the next steps to follow.
Conclusions: Venue testing may not be the best strategy for increasing HIV screening of at-risk LY. Normalizing testing and structuring an empathetic disclosure process that addresses potential misconceptions and fears, and offers a clear pathway to successful treatment is essential to improving linkage to care among LY.

WEPEC0989

Quantifying the ability to capture transgender identities in existing data systems

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Background: Although transgender individuals are recognized as a population disproportionately impacted by HIV, quantifying the number of transgender people living with HIV is difficult due to underreporting of gender identity. In 2016, the U.S. Health Resources and Services Administration mandated reporting of gender identity. The Houston Health Department (HHD) initiated a project to investigate data systems' ability to document transgender identification.
Methods: Data on 30 transgender persons of color were extracted from the most comprehensive HIV surveillance database in the Houston, Texas area. The HHD further investigated these individuals for transgender identity in five care systems and one public access database, all of which are used for identifying, locating, and re-linking out-of-care HIV-positive persons into care.
Results: Only three care systems captured transgender identity in pre-defined fields. Three care systems and one public access database only had a field for birth sex; consequently, it often captured birth sex and current gender. Discrepant pairs were assumed to be transgender. Three care systems could record transgender identity in a notes section. Given a total of six data systems and 30 individuals, a total of 180 outcomes were possible. Given variations in data system purpose, individuals were not necessarily found (65 outcomes) in every system. There were 72 outcomes where only birth sex was recorded in a respective data system compared to 39 outcomes where transgender identity was discovered. Four outcomes were inconclusive. Given the multiple fields and/or notes sections per data system for potential transgender identification, including potential aliases, a total of 28 fields and/or notes sections needed to be searched per person to properly assign a transgender outcome. Even then, transgender status could be concluded only 22% of the time.
Conclusions: The current schema of these data systems inadequately identifies transgender persons, limiting the ability to serve this population. These record searches are resource intensive yet necessary to inform HIV prevention programs of a potentially transgender, HIV-positive individual needing critical assistance. More education is needed to clearly define these fields for accurate data collection. Additional cultural training among healthcare workers may encourage transgender persons to disclose their identity, improving documentation and data quality.

WEPEC0990

Consistency in multiple estimates of the population size for persons who inject drugs (PWID) in Hai Phong, Viet Nam

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Background: Good estimates of the sizes of "key populations" are critical for ending concentrated HIV epidemics, particularly in resource-limited settings where efficient allocation of resources is necessary. We conducted two capture/recapture studies to estimate the size of the persons who inject drugs (PWID) population in Haiphong, Vietnam.
Methods: In Sept. 2014, we conducted a respondent driven sampling (RDS) survey of 603 PWID in Haiphong utilizing standard RDS procedures. A fingerprint reader was used to identify unique participants and prevent multiple enrollment. Current injecting drug use was verified through examination of injection marks and urinalysis. In Oct. 2016, 600 uniquely marked lighters were distributed to PWID in drug use "hotspots" in Haiphong. Beginning one week later, we conducted another RDS survey,
N = 1385, following standard RDS procedures. A fingerprint reader was again used to identify unique participants and match 2014 RDS participants with 2016 participants. Questions were added to the 2016 survey to identify PWID who had received lighters. The 2014 RDS survey and the distribution of lighters to PWID served as two separate "captures," and the 2016 RDS survey served as the "recapture" for both "captures." UNAIDS Technical Guidelines capture/recapture formulae were used for estimating population size.
Results: A total of 1385 participants were included in the 2016 RDS "recapture" survey. They were predominantly male (94%), average age was 39 (SD 9); 100% injected heroin (80% daily) and 47% used non-injected methamphetamine. HIV prevalence was 30%, HCV prevalence 70%.
144/603 participants in the 2014 RDS study were "recaptured" in the 2016 RDS study, giving a population estimate of 5799 (95% CI 5016-6581) for the 2014 RDS-2016 RDS capture/recapture. 152/600 PWID who had received lighters were "recaptured" in the 2016 RDS study, giving a population estimate of 5467 (95% CI 4758-6176) for the lighter/2016 RDS capture/recapture study.
Conclusions: Even with a two-year period between RDS surveys and a week between the lighter distribution/RDS survey, the two capture/recapture studies show great consistency in the estimated PWID population size for Haiphong. The lighter recapture method is an inexpensive method for estimating population size when done in conjunction with an RDS survey.

WEPEC0991

Using risk assessment to better identify female sex workers living with HIV in Luanda, Angola

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Background: In October 2015, the USAID- and PEPFAR-funded LINKAGES project began providing HIV services to female sex workers (FSW) in Luanda, Angola. Early testing data yielded an HIV-positive rate of only 2.91% (57/1956) between November 2015 and May 2016. Limited data are available for FSWs, though one region reported an HIV prevalence rate of 7.2%. As Angola faces periodic stock outs of HIV test kits, HIV programs needed to prioritize HIV testing for those most at risk of being infected with HIV. Risk assessment tools exist nationally but are fully not utilized.
Methods: To better identify FSWs living with HIV, LINKAGES Angola designed a 17-question risk assessment tool that was administered by FSW peer educators with their FSW service beneficiaries from June to December 2016. Risk scores were calculated on three of the 17 questions focusing on age, number of clients per day, and use of condoms. Peers prioritized HIV testing referrals to higher scoring FSWs. All other FSWs, regardless of having had answered the risk assessment or having had obtained a high risk score, were offered HIV testing.
Results: Out of 5,856 FSWs, 5,740 (98%) accepted to take the risk assessment 676 (12%) scored high risk, 2696 (47%) medium, and 2368 (41%) scored lower Twenty-five percent (1433/5740) accepted an HIV test. HIV results by risk group showed HIV rates of 7.61% (21/276), 5.51% (42/762), and 5.82% (23/395), respectively. The overall HIV rate was 6% (86/1,433), an increase of 3.09% compared to the previous period (2.91%) when the risk assessment was not used.
Conclusions: Applying an HIV risk assessment in a resource limited context with FSWs, where little or no data are available, and where there is no culture of asking questions related to risk, LINKAGES Angola was able to improve overall HIV positivity yield within its FSW program. Further analysis of risk data also showed higher rates of HIV in higher risk group. The data showing similar HIV rates for medium- and low-risk FSWs demonstrates the need to further analyze the risk questions to develop a more accurate scoring system that correlates score with elevated risk of HIV infection in FSWs in Angola.

WEPEC0992

Assessing risk for HIV infection among adolescent girls in South Africa: a validation of the VOICE risk score

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Background: Adolescent girls and young women in sub-Saharan Africa face a disproportionately high risk for HIV infection, accounting for 75% of young people living with HIV. As a result, novel biomedical prevention interventions, such as pre-exposure prophylaxis (PrEP), are being implemented among women at highest risk for infection. In attempts to quantify risk, Balkus et al. (2016) developed and validated a risk assessment tool from the VOICE study and two additional PrEP trials (HPTN-035 and FEM-PrEP) among African women (Mdn age=24-26 years). With implementation trials currently underway investigating PrEP efficacy among adolescent girls under 18-years, this research was aimed at validating the risk score for use in adolescent populations.
Methods: Data from HPTN-068, a 3-year randomized controlled trial to assess the impact of a cash transfer, conditioned on school attendance, on HIV incidence among rural South African adolescent girls (Mdn age=15 years), was utilized for this analysis. The risk score, which incorporates factors such as age, married/living with a partner, partner providing financial or material support, partner having other partners, alcohol use, and HSV2 serostatus, was calculated at baseline for participants who completed at least 1-year of follow-up, with possible values ranging from 0-10. The risk score excluded detection of curable STIs. A proportional hazards model was used in the analysis of baseline risk score and incident HIV infection.
Results: Among the 2318 HPTN-068 participants included in the analysis, there were 105 HIV seroconversions during 4986 person-years of follow-up (2.11% incidence). 74% of the sample received a risk score of 5 (range=2-9). Scores ≥5 identified 79% of incident infections from 88% of the sample, compared to the VOICE sample in which scores ≥5 identified 91% of incident infections from only 64% of participants. With each unit of increase in risk score, participants experienced a greater risk for HIV infection (Hazard Ratio=1.332, 95% CI 1.01 -1.75, p=.041).
Conclusions: Findings revealed that the risk score had limited variability in the HPTN-068 study population, but may still be predictive of HIV incidence. To further inform HIV prevention efforts among adolescents, research is needed to better understand how the unique developmental milestones of adolescence might influence risk.

WEPEC0993

PoCT (point of care) HIV/STI testing at after-hours SOPV (sex on premises venues) theme parties

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Background: Sexual 'theme parties' have become more popular among MSM (men who have sex with men) over time. They are typically attended by more 'sexually adventurous' MSM and associated with alcohol/other drug use. These factors may

constitute heightened risks for HIV/STI transmission. Operating a regular, rapid HIV/STI testing service during theme parties (within a high-risk setting), represents a novel approach to health promotion and more accessible testing. This research sought to establish 'proof of concept', and evaluate the uptake and feasibility/acceptability of routine HIV/STI testing for MSM in a novel outreach environment.
Methods: Weekly HIV/STI PoCT (Alere, UniGold) was offered by trained peer-testers on Friday and Saturday nights from 9pm-midnight, in a private room at the venue. Patrons requesting tests were asked to complete an evaluation survey after testing. Verbal consent was provided and ethics approval was obtained for the evaluation. The testing processes were conducted per TGA guidelines.
Results: To date, 122 MSM have participated in PoCT (majority identified as ‚gay'; average age 36, range: 18-66) over a six month period (indicating 4 reactive syphilis tests; nil reactive HIV); recruited via information within the venue and social media). Salient findings indicate: All (100%) participants reportedly felt comfortable with the community outreach testing; 96% reported peer-led testing would increase the frequency of testing; 20% ‚would not have had a test' if the service did not exist; and 34% reported to have 'never had' an HIV test. Further qualitative comments reflecting acceptability included: accessibility; feeling comfortable; easy and quick testing—conducted by friendly and 'relatable' staff members. Secondary analyses regarding socio-demographic features associated with testing patterns, substance use, sexual activity and harm reduction strategies will also be highlighted.
Conclusions: This project has demonstrated acceptability and feasibility within a key MSM sub-group—regarding novel health promotion delivered by a peer-based PLHIV organisation. Implications for further health promotion efforts and future research with sexually adventurous MSM will be discussed in light of main findings. Rapid PoCT technologies foster opportunistic HIV/STI testing uptake amongst MSM in a high-risk setting, and create opportunities for qualitative follow-up; the research will inform the lens through which drug use among gay men and other MSM is contextualised within a sexual context.

WEPEC0994

HIV testing promotion and follow-up with MSM through online dating apps in Cambod

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Background: HIV prevalence in Cambodia of men who have sex with men (MSM) is estimated at 2.3% but this low prevalence belies substantial high risk and potentially high HIV incidence in the future. Despite numerous diverse peer outreach and web-based interventions, a majority of MSM report low intervention exposure, thus necessitating more innovative communication channels and behavior change strategies to promote HIV testing.
Methods: We conducted an assessment of on-line application (app) usage among MSM in Cambodia. One MSM-oriented app reported 23,654 unique users, with users in Cambodia accessing the app on average 7.3 times a day and spending 75 minutes each day on the application. Based on this information, we initiated on-line informal counseling or "chats" on two apps with individuals interested in hearing more about HIV, their risk behaviors, and opportunities for HIV testing. Those who expressed interest were referred to community clinics nearby.
Results: Between October-December 2016, 420 MSM were engaged in on-line counseling via the two apps. Among these, 68 (16.19%) MSM were successfully referred to rapid HIV testing at a community clinic. Ten (14.7%) were found to be HIV reactive through Determine rapid test. 7 of these individuals (70%) were successfully referred to confirmatory HIV testing, and all were initiated on ARV treatment within 3 months. During the same period, traditional outreach and peer-drive interventions in the same community reached 1471 MSM, with 945 (64%) accepting an HIV test and 15 (1.6%) of them screening HIV+.
Conclusions: The intervention strongly indicated that MSM-oriented apps can and should be used to reach high-risk and hard-to-reach MSM, in this case reaching a higher percentage of HIV+ MSM than traditional outreach. The results further showed that active case management is needed to ensure that clients are not lost to follow up along the HIV cascade, particularly for confirmatory HIV testing.

WEPEC0995

Social network approaches to locating undiagnosed HIV cases are more effective than RDS recruitment or outreach models

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Background: Diagnosing HIV cases is essential for providing health care and for Treatment as Prevention. We hypothesize that social network recruitment is superior both to community outreach testing and respondent driven sampling at case finding in Odessa, Ukraine.
Methods: We compared three studies. Odessa TRIP used network sampling to recruit extended risk networks of Recently-infected and longer-term infected (LTs) seeds in 2013-2016. (Participants were classified as "Recents" if Limiting Antigen Avidity (LAg) assay, past testing history, and viral load data indicated they had been infected in the last 6 months. Other HIV+ participants were classified as LTs). IBBS2013 used respondent driven sampling to recruit people who inject drugs (PWID). SYREX provides data on HIV among PWID tested at community outreach sites, 2013-2016.
Outcomes (percent testing positive who self-reported as previously undiagnosed) were compared between TRIP arms; TRIP vs. IBBS2013; and TRIP vs. SYREX.
Results: TRIP networks contained 1270 men, 344 (21%) women; IBBS2013 328 men, 72 (18%) women; SYREX 9669 men, 4267 (31%) women. TRIP networks had a higher yield of undiagnosed positives (14.6%) than IBBS2013 (5.0%) or SYREX (2.4%); ORs 3.24 (CI 2.06, 5.12) vs. IBBS2013, 7.02 (CI 5.91, 8.34) vs. SYREX. Findings remained significant with odds ratios high when these comparisons were conducted separately by sex and when PWID in TRIP networks were compared with SYREX and IBBS2013. Within TRIP, Recents' networks contained higher rates of undiagnosed positives (14.6%) than LTs' networks (9.3%); OR 1.66 (CI 1.10, 2.49); this remained true among PWID subsets. Both TRIP subsets located significantly higher rates of undiagnosed positives than either IBBS2013 or SYREX. In TRIP Recents' networks, women (20.1%) were more likely to be undiagnosed positives than men (13.3%); OR 1.64 (CI 1.12, 2.40). 36.4% of PWID women in Recents' networks were newly diagnosed positives.
Conclusions: TRIP's network recruiting techniques, and paying particular attention to the networks of the recently infected, should become part of standard case finding and treatment as prevention practice. They may be particularly important for finding undiagnosed women. Research is needed on whether these findings hold in other social and epidemiologic contexts.

WEPEC0996

Screening for PrEP eligibility during rapid HIV testing in high-risk neighborhoods in Philadelphia

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Background: Daily, oral pre-exposure prophylaxis (PrEP) has been shown to reduce the risk of HIV in diverse populations. While PrEP implementation studies are emerging, few have focused on screening high-risk populations for PrEP eligibility during community-based rapid HIV testing.
Methods: HIV negative individuals, 18 years of age or older, were recruited from 4 community-based rapid HIV testing sites in Philadelphia. We developed a 6-question PrEP eligibility screening tool based on the 2014 CDC PrEP clinical guidelines. The tool was incorporated into a cross-sectional study assessing PrEP knowledge and attitudes among individuals undergoing community-based rapid HIV testing. Descriptive statistics were used to assess PrEP knowledge, eligibility, and intention to use PrEP.
Results: The sample (n=168) is 68.5% male, with race/ethnicity Black (45.2%), Hispanic/Latino (34.5%) and White (15.5%), with mean age of 42. Among participants, 60.7% were heterosexual, 17.9% were men who have sex with men (MSM), 14.9% reported injection drug use, and 11.3% engaged in transactional sex. The majority (74.4%) of participants had not heard of PrEP. Overall, 31% of our total sample was eligible for PrEP: 34.3% of all sexually active heterosexual men and women, 56.7% of MSM, and 64% of persons who inject drugs (PWID). 37.9% of

heterosexual men in comparison to 27.8% of heterosexual women were eligible for PrEP, but this was not statistically significant (p=.30). 64% of PWID were eligible for PrEP in comparison to 25.2% of non-PWID participants (p<0.01). 56.7% of MSM were eligible compared to 25.4% non MSM (p<0.01). Among participants eligible for PrEP, 63.5% indicated that they were somewhat or extremely likely to use PrEP in the future.
Conclusions: We identified a diverse at-risk population through community-based HIV testing and counseling. Most participants were unaware of PrEP, but those who were eligible expressed intention to use PrEP in the future. Having rapid HIV testers screen for PrEP eligibility and educate clients about PrEP is an effective way to increase PrEP awareness and could increase PrEP uptake in diverse, high-risk populations.

WEPEC0997

Reaching the unreachable: the effectiveness of social media networks to recruit hidden MSM populations to an HIV prevention intervention in Kenya

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Background: Despite having significantly higher risk of HIV infection than the general population, men who have sex with men (MSM) in Kenya remain a largely hidden population because of stigmatization and criminalization. Previous interventions driven by health workers exhibited modest success in recruitment and retention of MSM in HIV programs within Nakuru county. The USAID- and PEPFAR-funded LINKAGES program, implemented in Kenya by FHI 360, aimed to accelerate recruitment of MSM to a peer-led comprehensive HIV prevention program using social media.
Methods: Through partnership with a local peer-led community-based organization with preexisting social networks in Nakuru county, we recruited volunteers for peer education training via outreach on a private Facebook page used exclusively by MSM. Volunteers underwent a five-day peer education training on HIV prevention and risk reduction strategies. Peer educators reached out to their peers primarily via WhatsApp with HIV education messages, provided condoms and lubricants, and referred them for HIV testing and screening for sexually transmitted infections (STIs). We used descriptive statistics to summarize recruitment outcomes.
Results: We trained 15 peer educators who subsequently enrolled 371 MSM (82.4% of target) between July and September 2016. Median age was 24 years (IQR: 22-27). Thirty-two (8.6%) tested for HIV and 81 (21.8%) were screened for STIs. Overall prevalence of HIV and STIs was 6.3% and 3.7%, respectively.
Conclusions: Though use of social media was effective in identifying and enrolling MSM in our program, uptake of HIV testing remained low. Leveraging social media networks for HIV programming presents an innovative and cost-effective mechanism for accelerated recruitment of MSM. However, strategies addressing barriers to HIV testing are needed to increase testing uptake.

WEPEC0998

"Dear Mrembo [Beautiful]": development, testing and finalization of a theory-driven, human-centered mobile phone intervention to prevent pregnancy and HIV/STI among female sex workers in Mombasa, Kenya

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Background: Female sex workers (FSW) have high unmet need for contraception and high incidence of unintended pregnancy and HIV. Interventions using text messaging -ubiquitous among FSW - can improve sexual and reproductive health (SRH) knowledge and behaviors. Yet, few mobile phone programs target FSW in Africa. This presentation describes the participatory development, usability testing, and final content of a theory-driven mobile phone intervention that is being evaluated in a cluster-randomized controlled trial in Kenya.
Methods: Content was developed and tested for relevancy, actionability, and comprehensibility. Six participatory development workshops (n=42 women) and 12 in-depth interviews were conducted with FSW recruited from sex work hotspots. Participants were 16-44 years old, not currently pregnant, owned a mobile phone, and text messaged. Interview guides covered preferred health topics, wording and language, tone, delivery format and timing, and system usability. Discussions were audio-recorded, translated, and thematically analyzed. Final content was compiled for staged delivery over 12 months.
Results: FSW preferred simple, informational text messages in English with some motivational content in Swahili; and sharing "education-entertainment" role model stories portraying pertinent, tricky situations and health-promoting resolutions (Table 1). Behavioral constructs from stages of change and social cognitive theory resonated with FSW. The resulting intervention alternates 160-character messages delivered three times/week for a month, with a unique role model story delivered in five installments over the next month. The intervention delivers 77 messages and 6 role model stories in total.

Topic	Recommendations	Example Results
Health Content	Pregnancy risk, contraception methods especially long acting, condoms, dual protection, alcohol abuse, violence, STIs, HIV testing, ARVs, PMTCT, rights, partner communication	"I need to be informed on alcohol to make the right decisions when negotiating with a client on the use of family planning or condoms for protection." (Workshop 5) "[Start] with HIV because one has to know her status and how to prevent STI infection using condoms, then family planning messaged on child spacing, then do not drink to avoid drama." (Workshop 4)
Behavior Constructs	Self-efficacy, social support, knowledge, self-evaluation, self-liberation, reinforcement	It has given me information about preventing unplanned pregnancies and [where] I can get services that are near me." (Interview 9) "Send us the messages all the time so that we can remember and feel encouraged." (Workshop 6) "Sex workers should know their rights and also teach other women in the community." (Workshop 4)
Language and Tone	Friendly, caring, some Swahili Simple, fact-based, English content	"Kiswahili can have different meanings for one word while simple English is the best." (Workshop 5) "As sex workers we like to be loved and being called names like ,darling, hi dear'. We should put sweet phrases before the messages ...." (Workshop 3) "The messages are short and link to a place where I can get more information, and it's friendly." (Interview 12)
Format	Text strongly preferred, voice perceived as forgettable Role model stories highly relatable, engaging	"Reading about it now as a text message, you can have time and digest on it unlike when you are taught and can forget." (Interview 12) "This thing [in role model stories] happens to sex workers and it has happened to me, too." (Workshop 3)
Timing	Messages about 3 times/week, sent morning or before work in afternoon	"In the morning so that it can remind me of the choices I should make." (Workshop 2) "I prefer receiving messages on weekdays - Monday, Tuesday and Thursday. Wednesday and weekends I am busy." (Workshop 3)
Usability	High comprehension of mobile phone messages by most FSW On-demand content requires clear instructions and prompts	"It is a very good application and can be understood, the way I have engaged with it gives me alerts and more information." (Interview 9) "Messages are short; language is simple and pull option enables one to get information she wants. It is very interactive." (Interview 10)

[Design recommendations from workshops, interviews]

Conclusions: The final intervention prioritizes contraception and condom information, motivation, service alerts, and role model stories, and also addresses HIV/STIs, alcohol abuse, gender-based violence, and stigma and rights. Messages are sent in a pre-determined order, and participants can text any time for additional SRH content. A staged, social cognitive, and participatory approach to mobile phone intervention design for FSWs may improve intermediate pregnancy and HIV/STI behavior outcomes and biological endpoints.

WEPEC0999

Social media interventions to promote HIV testing, linkage, adherence and retention among key populations: a systematic review and meta-analysis

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Background: Social media is increasingly used to deliver HIV interventions for key populations (KPs) worldwide. However, little is known about the specific roles and effects of social media in HIV interventions. This systematic review examines the effectiveness of social media interventions to promote HIV testing, linkage, adherence, and retention among KPs.
Methods: We used the PRISMA checklist and Cochrane guidelines and the study was registered on PROSPERO. We systematically searched six databases (without time limits) and three conference websites (2015 and 2016). Search terms were related to HIV, social media, and KPs. We included studies where:
(a) the intervention was created or implemented on social media platforms;
(b) study population included KPs as defined by the WHO; and
(c) outcomes included promoting HIV testing, linkage, adherence, and retention.
Meta-analyses were conducted by Review Manager version 5.3. Pooled relative risk (RR) and 95% confidence intervals (CI) were calculated by random-effects models.
Results: Among 981 manuscripts identified, 27 studies met inclusion criteria. These studies were implemented in ten countries (19 studies from high-income countries). Eight were randomized controlled trials (RCTs) and 19 were observational studies. Twenty-six studies used social media to promote HIV testing among MSM or transgender individuals. Seventeen studies used social media to disseminate HIV test information, 12 to build online interactive communities to encourage HIV testing, and seven to provide HIV self-testing or self-sampling services.
Of the studies providing HIV self-testing/sampling services, 39.6% of participants requested HIV testing kits from social media platforms (95% CI 38.99, 40.13). Existing social media platforms such as Facebook (n=13) and the gay dating app Grindr (n=11) were used most frequently. In the seven RCTs promoting HIV testing, uptake was higher in the intervention arm than the comparison arm (RR 1.55, 95% CI 1.21, 1.99). In the four studies with baseline and post-intervention results, HIV testing uptake increased after social media interventions (RR 1.50, 95% CI 1.28, 1.76).
Conclusions: Social media interventions are effective in promoting HIV testing among MSM and transgender individuals in many settings. Social media interventions to improve HIV services in low- and middle-income countries and among other KPs should be considered.

WEPEC1000

Discordance of self-perceived HIV infection possibility, reported HIV sexual risk-taking, and voluntary HIV testing among social media-using black, Hispanic, and white young-men-who-have-sex-with-men (YMSM)

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Background: Discordance between self-perceived and actual HIV risk may impede efforts to promote HIV testing among young adult men-who-have-sex-with-men (YMSM). Among this higher HIV risk population, we compared YMSM's self-perceived possibility of having an undiagnosed HIV infection against their reported sexual risk-taking and history of voluntary HIV testing.
Methods: HIV-uninfected 18-24-year-old black, Hispanic, and white YMSM were recruited from across the US through multiple social media websites. Participants were queried about their HIV testing history, self-perception of having an undiagnosed HIV infection, and condomless anal intercourse (CAI) history. We assessed the association between self-perceived possibility of being HIV infected and previous CAI. Cochran-Mantel-Haenszel testing was performed to assess if participant self-perception of HIV infection was concordant with their reported history of CAI in relationship to their HIV testing status. Odds ratios (ORs) with corresponding 95% CIs were estimated.

Results:

		Association between self-perceived and reported HIV risk by HIV testing status		
	Association Between Self-Perceived and Reported HIV risk	Previously Voluntarily Tested for HIV	Never Voluntarily Tested for HIV	Mantel-Haenszel Combined
	OR (95% CI)	*OR (95% CI)*	*OR (95% CI)*	*OR (95% CI)*
CAI with any Man	2.10 (1.61-2.73)	2.11 (1.51-2.91)	2.45 (1.49-2.02)	2.21 (1.70-2.87)
___White___	1.95 (1.30-2.88)	2.04 (1.23-3.32)	2.08 (0.97-4.34)	2.05 (1.39-3.02)
___Black___	1.68 (0.91-3.04)	1.69 (0.81-3.45)	2.87 (0.71-11.24)	1.91 (1.07-3.43)
___Hispanic___	2.88 (1.78-4.61)	2.65 (1.46-4.75)	3.50 (1.43-8.45)	2.90 (1.84-4.57)
CAI with Main Male Partner	1.31 (1.06-1.61)	1.46 (1.15-1.85)	1.00 (0.63-1.60)	1.34 (1.10-1.65)
___White___	1.41 (1.02-1.95)	1.68 (1.15-2.44)	0.92 (0.45-1.87)	1.45 (1.06-1.99)
___Black___	1.51 (0.96-2.37)	1.72 (1.05-2.80)	1.18 (0.31-5.08)	1.62 (1.06-2.52)
___Hispanic___	1.07 (0.75-1.52)	1.05 (0.68-1.60)	1.05 (0.50-2.22)	1.05 (0.74-1.49)
CAI with Exchange or Casual Male Partner	1.82 (1.48-2.24)	1.65 (1.30-2.08)	2.94 (1.82-4.78)	1.86 (1.52-2.28)
___White___	1.83 (1.33-2.52)	1.60 (1.10-2.31)	3.54 (1.64-8.02)	1.89 (1.38-2.59)
___Black___	1.52 (0.95-2.42)	1.47 (0.88-2.45)	2.35 (0.61-9.33)	1.58 (1.01-2.47)
___Hispanic___	2.12 (1.49-3.01)	1.89 (1.25-2.83)	3.11 (1.43-6.75)	2.12 (1.51-2.98)

[Main results]

Of the 2,275 18-24-year-old YMSM (19% black, 36% Hispanic, and 45% white), 21% had never been tested for HIV, 87% reported CAI, and 77% believed that it was at least possible they could have an undiagnosed HIV infection. Perception of having an undiagnosed HIV infection was greater for those who reported CAI, yet there were differences by race/ethnicity. Per the Mantel-Haenszel analyses, YMSM who reported CAI with casual or exchange male partners had a greater self-perception of possibly being HIV infected if they had not been tested for HIV. However, this relationship was not observed for CAI with a main male partner.
Conclusions: Self-perception of possibly being HIV-infected was not higher for YMSM who had never been tested for HIV, but was greater for those who reported CAI. However, self-perception, reported HIV risk and testing were not uniformly concordant across sexual partner type and race/ethnicity. Interventions to promote self-realization of HIV risk and translate that into seeking or accepting voluntary HIV testing should be the focus of future interventions.

WEPEC1001

healthMpowerment: effects of a mobile phone-optimized, Internet-based intervention on condomless anal intercourse among young black men who have sex with men and transgender women

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Background: In the United States (US), young, black men who have sex with men and transgender women (YBMSM/TW) are the only populations with increasing HIV incidence. healthMpowerment (HMP) is a mobile phone optimized, Internet-based intervention designed to reduce sexual risk behaviors among HIV-positive and HIV-negative YBMSM/TW by providing information, resources, tailored feedback, game-based elements and rewards. The objective of this research was to determine the effect of HMP on self-reported condomless anal intercourse (CAI) at 3 months post-intervention.
Methods: Between 2013 and 2015, 474 YBMSM/TW, age 18-30 years, who lived in North Carolina, and reported having at least one episode of CAI in the past 6 months, were randomized to intervention (HMP) or control (information-only) group in a 1:1 allocation. Participants completed computer assisted self-interviewing assessments at baseline, 3, 6 and 12 months. In intention-to-treat analysis (ITT), a zero-inflated mixed-effects Poisson model was used to estimate the relative rate of CAI in the treatment group compared with controls at 3-months post baseline. The complier average causal effect (CACE) was also estimated with compliance defined as ≥60 minutes of intervention exposure during the 3-month intervention period.
Results: Median time using HMP was 13.5 minutes; 50 participants (25.8%) used HMP for ≥60 minutes between baseline and month 3. In the ITT analysis, those randomized to HMP had a significantly reduced rate of CAI in YBMSM/TW com-

pared to those randomized to the control condition (0.76, 95% CI: 0.69,0.83). In CACE analysis, comparing those compliers in each group, use of HMP led to a 38% reduction in the rate of CAI (0.62, 95% CI: 0.55, 0.70). Notably, individuals in the intervention group with higher CAI rates at baseline also had the highest usage at month 3.
Conclusions: Technology-based interventions can reduce risky sex behaviors and represent a new mechanism for the delivery of HIV prevention interventions. The temporal association between higher CAI and usage of HMP suggests that, when given the choice, individuals do engage with an online intervention in a way consistent with their risk needs. Future research will examine the durability of these findings as well as mediators/moderators of intervention effects.

WEPEC1002

MSM user preferences for a smartphone app to accompany HIV & syphilis self-testing

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Background: HIV self-testing is increasingly used in the US and Europe. Although user acceptability is high, concerns remain regarding proper use, handling of HIV-positive results, and linkage-to-care. Some of these concerns could be mitigated with a designated smartphone app. We report on MSM user preferences for content and capabilities of a smartphone app to accompany HIV and syphilis self-testing.
Methods: MSM who regularly engage in condomless anal intercourse used the SMARTtest, a smartphone-based prototype device to test themselves for HIV and syphilis. Instructions were provided via an app with dual (video and pictorial step-by-step) directions. Participants then completed an in-depth interview that explored their experience using the device and recommendations for additional app content related to instructions, results, information, and linkage-to-care.
Results: To date, 20 participants (total N will be 60) have completed the study. Participants strongly approved of the dual instructions and a results screen that clearly states "positive" or "negative" test results. Almost all participants want the option to save test results on the app for personal reference or to show partners. They also want the option to send results to others, primarily partners but also physicians. A few participants were enthusiastic about widely sharing their HIV-negative test results via social or sexual networking sites. Linking test results to sexual networking sites was seen as offering a verified HIV status versus a self-report. Recommendations on HIV and syphilis information to include focused on symptoms, prevention, and next steps if results were positive. Ideas for how and when the information should be provided ranged from basic text on a separate tab to brief videos embedded into the testing process. Participants strongly recommended providing referrals for follow-up care in case of positive results, ranging from listings of clinics with contact information to geospatial mapping of nearby clinics, and automatic scheduling of clinic appointments. In general, participants of higher socioeconomic status had greater demands for app design, functionality, and interactivity than those of lower status.
Conclusions: Smartphone apps can support HIV/STI self-testing to provide clear instructions and prevention information, assist with linkage-to-care, and facilitate disclosure of results to providers and sexual partners.

WEPEC1003

Feasibility of using Hemaspot dried blood spot kits for at-home collection of blood to quantify viral load among an online sample of U.S. HIV-positive MSM

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Background: Sub-optimal adherence to antiretroviral therapy (ART) can impede suppression of HIV, which presents a major public health challenge due to the probability of further transmission. U.S. men who have sex with men (MSM) accounted for 70% of new HIV infections in 2014. Recent online studies of MSM have shown relatively high uptake of home collection of biomarker data. Improved home dried blood spot (DBS) collection has been developed (HemaSpot™), streamlining blood collection. The aim of the study was to assess the feasibility of using HemaSpot kits to obtain home-collected blood specimens for quantifying HIV viral load among an online national sample of HIV-positive MSM.
Methods: From 09/01/2016-01/11/2017, HIV-positive MSM completing a 12-month follow-up survey for an online HIV risk reduction intervention were invited to enroll in a study to collect an at-home DBS specimen. Consenting participants were mailed a Hemaspot kit and instructed to return it directly to a laboratory for analysis. HemaSpot samples were eluted in Abbott DBS Elution Buffer and processed using the m2000_1.0ml_HIV_DBS_Quant protocol.
Results: Of 764 MSM who were emailed an invitation, 578 opened the email and visited the study website; of those, 502 (87%) consented to participate. Overall, 69% were White, 15% Black, and 16% Hispanic. Median age was 39; 91% reported being in HIV care; among individuals on HIV treatment (n=464), 51% scored < 90% on ART adherence on the 3-item Wilson adherence scale. Of consenting participants, 474 (94%) received the Hemaspot kit and 308 (65%) mailed it back to a research laboratory. As of 1/11/2017, 166 kits were tested for HIV-1 RNA; of those, 26 had insufficient blood, and 6 had a lab processing error. Of the 134 samples quantified for HIV-1 RNA, 47% had detectable viremia (35% had >832 copies per ml).
Conclusions: HIV-1 RNA quantification of Hemaspot home-collected samples from HIV-positive MSM is feasible. The majority (65%) returned kits, and 81% of laboratory-tested samples were quantifiable. Despite self-reported engagement in treatment and care, 51% had detectable viremia, signaling the need for novel HIV prevention strategies that include biomarker data in order to better engage HIV-positive MSM who struggle with ART adherence.

WEPEC1004

Risk behaviors and HIV prevention perceptions in a national online sample of men who have sex with men (MSM) in Brazil

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Background: Although national efforts for prevention, new HIV infections among MSM continue to increase in Brazil, especially among the youngest. Social media apps are becoming the main venue for casual sexual encounters. This study aims to describe risk behaviors and HIV prevention knowledge among MSM using two geosocial-networking apps in Brazil.
Methods: This was a cross-sectional online survey among MSM population from ten Brazilian capitals. The questionnaire was created on SurveyGizmo® website and advertised in two apps for MSM population (Hornett and Grindr). Inclusion criteria included ≥18 years-old, cisgender men and HIV negative.
Results: A total of 5,065 completed the survey: median age was 30.0(IQR:25-26), 3,194(63.1%) were white, 3,106(61.3%) completed at least college and 2,504(49.4%) had ≥5 minimal wage monthly income. Most were homosexual/gay (4,468;88.2%), 1,029(20.3%) reported to have a steady partner. Prevalence of tobacco and marijuana smoke in last 6 months was 32.6% and 33.1%, respectively, while binge drinking was reported by 71.8%. The majority of MSM (3,363;66.4%) had ≥10 points (high risk) on CDC MSM risk index, but only 1,083(21.4%) considered to have 50% or more chances to get infected by HIV in one year. Daily and weekend use of apps for sex was reported by 1,798(35.6%) and 678(13.4%), respectively. Regarding prevention, most MSM (4,488;85.4%) had an HIV test lifetime and 464(9.2%) used PEP in the previous year. The awareness and willingness to use HIV prevention strategies are described on.

	Awareness	Willingness
Condoms	-	3,733(73.7%)
HIV self-testing	1,346(26.6%)	2,589(51.1%)
PEP	2,907(57.4%)	3,325(65.7%)
PrEP (1 pill per day)	2,932(57.9%)	2,653(52.4%)
PrEP (on demand)	-	1,751(34.6%)
PrEP (During short periods or vacation)	-	4,652(91.8%)
PrEP (Injection twice a month)	-	2,405(47.5%)
Would never use PrEP	-	239(4.7%)
Would pay for PrEP	-	2,587(51.1%)

[Table 1]

Conclusions: Considering the CDC index, most of the sample would have an indication for PrEP, but only 57.9% have heard about this strategy. In addition, awareness, willingness and use of PEP - which is available in Brazil since 2009 - were also low. National efforts to increase awareness of prevention strategies are urgently needed and inclusion of PrEP in public health system is very important in the context of combined prevention.

WEPEC1005

Effects of SMS reminders on key population appointment adherence and retention: our success story

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Background: The University of Nairobi/University of Manitoba collaboration has been providing services to sex workers for slightly over 30 years. Over the years, a recurring problem has been ensuring adherence to scheduled appointments by clients, as well as a high rate of loss-to-followup (ranging from 32% to 74%). In 2005 we carried out a study on the use of cellphone sms reminders to improve adherence to HAART, the results of which demonstrated a clear link between the two[1]. In the light of this, we decided to widen the scope of the reminders to routine clinic appointments.
[1] Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial.
Methods: Using a home-grown EMR system in the 7 clinics we run in Nairobi, we capture appointment dates prospectively, in addition to client demographic data. We equipped each clinic with a prepaid GSM modem and sms gateway software, enabling the EMR system to send out regularly scheduled coded sms reminders of clinic appointments. The system sends 2 appointment reminders, one 7 days prior and the other a day prior to the appointment date.
Results: We introduced the appointment reminders in the year 2014. In the previous year, out of 5,956 enrolled clients, 1,851 (31%) were still visiting the clinic a year later. After introduction of the reminders, out of 3,478 clients enrolled in the year 2014, 1,925 (55%) were still visiting the clinic a year later. Without attributing the increase solely to the sms reminders, we believe they have had a significant impact.
Conclusions: By improving adherence to clinic appointments (and medication implicitly), sms reminders have proven to be a low-cost way to:
i) Enhance viral suppression
ii) Improve health-seeking behavior
We would recommend the implementation of sms appointment reminders for all programs serving Key Populations in the country as well as further afield in any setting where the usage of mobile telephones is widespread.

WEPEC1006

The demonstrable impact of a new anonymous partner notification tool

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Background: Partner notification (PN) is a key public health strategy than can reduce the cost to diagnose infections. Up to one quarter of partners of HIV index patients are found to have the infection; however, it is difficult to deliver this important work. A new tool was developed to support PN delivery and to capture patient reported outcomes. We therefore tested if this tool could be used to deliver PN for index patients diagnosed with HIV.
Methods: Analysis of the PN tool focused on the number of index patients, total partners, contactable contacts, the number of partners told and tested, either reported by the patient or captured via healthcare worker (HCW) verification using the PN tool. The key performance indicator (KPI) target for STIs has been set as 60 partners seen and tested within four weeks for every 100 index patients (i.e. 0.60), and this was used as a benchmark.
Results: PN data was captured for 105 index patients [58 MSM (36 White, 16 Black or mixed, 8 Asian or other ethnicity), 21 females (15 Black & mixed, 6 White ethnicity), 20 Heterosexual males (13 Black, 6 White, 1 Asian ethnicity) and 6 patients had no demographics captured] with an HIV diagnosis. PN for two or more infections was simultaneously done with 24 (23%) patients and two were diagnosed with Chlamydia, Gonorrhoea, Syphilis and HIV at the same time.
These index patients reported 212 partners and 130 (61%) were contactable; 18 (14%) of these were contacted by the PN tool and not declared to the clinic. Of the contactable contacts told, 65 (50%) were seen and tested [27 (42%) via the PN tool (16 at clinic, 11 reported by the partner) and 38 reported by the patient]. The KPI overall since the launch of the tool is 0.62 for HIV.
Conclusions: The new tool delivers HCW initiated and verified PN and supports providers to simply capture outcomes and achieve the KPI for HIV and other infections. Future developments and research are required to optimize the number of contacts told and support high public health value partners to be seen and tested.

WEPEC1007

Recruitment and enrollment results from a randomized controlled trial of an eHealth, behavioral HIV preventive intervention for HIV-negative male couples in the U.S.

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Background: The use of web-based technologies (i.e., eHealth) and social media (e.g., Facebook) to recruit and enroll male couples into online HIV prevention studies has increased in recent years. However, challenges remain with the online eligibility and enrollment process that could be improved for future eHealth, HIV preventive interventions with this population. To better understand how and where to improve eligibility and enrollment rates for online HIV preventive interventions, the present study uses data collected from a nation-wide, randomized controlled trial (RCT) of an interactive, self-guided, eHealth toolkit aimed to help reduce HIV-negative male couples' risk for HIV.
Methods: Targeted Facebook advertisements were used to recruit the study sample over a period of 5 months. Among the 7,956 individuals who completed the eligibility screener, 28% were ineligible (n=2,191), 69% (n=5,468) were eligible but failed to verify their relationship and/or complete the baseline assessment (i.e., baseline non-completers), and 3% (n=298) were eligible, consented, and verified to represent 149 HIV-negative male couples enrolled into the online RCT (i.e., baseline completers). Comparative statistics, which accounted for the dyadic nature of the data, were conducted to assess differences between ineligible, eligible baseline non-completers, and eligible baseline completers.
Results: For ineligibility, many were disqualified because of living with HIV (41%) or had a partner who was HIV-positive (36%). Compared to those who were eligible, ineligible individuals were more likely to be: older ($p < .0001$); a racial minority ($p < .0001$); Hispanic ($p < .0001$); living in the South ($p < .0001$); non-gay ($p < .001$). Among the eligible participants, baseline completers were more likely to be younger ($p < .0001$), living in the Midwest ($p < .001$), and have a shorter relationship duration ($p < .0001$) yet less likely to live in the Northeast ($p < .0001$) compared to baseline non-completers.
Conclusions: From a primary and secondary HIV prevention perspective, future eHealth HIV preventive interventions should target and include all male couples, irrespective of their HIV serostatus. Broadening this inclusion criteria will help increase enrollment rates among minority couples. Determining whether familiarity of using web-connected devices and the amount of time needed to complete enrollment procedures should also be considered and explored.

WEPEC1008

Alpha and beta testing of a trauma-informed HIV and substance abuse prevention mobile health application for teens who have experienced interpersonal violence: the eHEARTT toolkit

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Background: Teens who experience interpersonal violence (IPV) are more likely to engage in HIV-sexual risk behaviors and to develop substance use disorders than their non-IPV-exposed counterparts. Prevention of HIV and substance use for IPV-exposed youth may be best addressed from a 'trauma-informed lens'—addressing the overlap in IPV and risk behaviors in the context of trauma-focused treatment.
Prevention-focused m-health tools that can be incorporated into the delivery of evidence-based treatments are low-cost and highly-efficient; readily updated for content; and align with consumer-preferred methods of accessing health information. However, despite the rapid proliferation of HIV oriented web- and smartphone-based interventions, little is known about their effectiveness, and less is known about how they need to be tailored to diverse populations to maximize relevance, reach, and benefit. The purpose of the study was to utilize a qualitative analytic approach to guide the refinement of the eHEARTT application.
Methods: In this NIH-funded study in the US, alpha testing in the format of focus groups and individual qualitative interviews is currently underway with end users (trauma-exposed teens, caregivers, and clinicians) to assess reactions and obtain direct input regarding design, content, and functionality. Alpha testing results are

being used to guide refinements of eHEARTT, resulting in a "beta" version of the tools. Beta testing involves evaluation of the refined tool for functionality.
Results: Through NVivo 9 qualitative analyses software, common themes will be identified through transcriptions of the focus groups and interviews as they relate to the specific toolkit applications and to specific populations. Initial and secondary coding passes will be conducted to identify descriptors of the user's reactions to the tools, to refine theme classifications as they emerge, and to impose a data-derived hierarchy to the nodes identified. Interclass correlation coefficients will be computed across coders. Results will be presented—including how these findings are being used to refine the applications.
Conclusions: eHEARTT is a mobile application that will provide clinicians working with trauma-exposed teens the capacity to deliver state-of-the-art HIV prevention content. The formative research to be presented in this poster is a critical step in ensuring the toolkit is user-friendly and ready for efficacy evaluation in preventing HIV.

WEPEC1009

Pilot testing a social media campaign to increase HIV testing among Indonesian men who have sex with men: a community-based participatory research

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Background: In Indonesia, many men who have sex with men (MSM) avoid HIV testing due to fear of getting an HIV-positive result. To improve HIV testing uptake in this group, we exploited the rapid growth of social media use to develop a social media campaign. This pilot study in an urban setting of Indonesia sought to determine whether such an approach can reach MSM and encourage this hard-to-reach group to undergo HIV testing.
Methods: The ‚Gue Berani' (I am Brave) campaign went online in May 2015. This campaign was developed through community-based participatory research and guided by the Health Belief Model. For a period of ten months, starting from two weeks after the launch, we used a self-administrated questionnaire collected from 1733 MSM who took an HIV test at one of eight clinics. We applied multilevel logistic regression to examine association between participants' characteristics and influence of the Gue Berani (GB) campaign for HIV testing, and to see whether the influence varied by clinic.
Results: Of all participants, 51.8% reported having heard about the campaign. Over a third (31.8%) indicated that information from the GB campaign had brought them for HIV testing. When controlling for age and education, first-time testers had higher odd of getting tested because of the campaign than the experienced testers (AOR=1.34; 95% CI: 1.07-1.69). Getting tested because of the GB campaign were more likely reported among men who felt at risk for HIV than among those who tested due to a curiosity of their HIV status (AOR=1.37; 95% CI: 1.07-1.76). The degree to which this campaign was successful significantly varied across clinics. Similar to information received from peers (32.1%), information provided by the GB campaign appeared to be more successful at encouraging MSM to get tested than other information sources, including outreach workers (25.7%).
Conclusions: This pilot study demonstrates that a social media campaign can indeed reach MSM and refer them to HIV testing, primarily those who had never tested for HIV before. This type of intervention is particularly appropriate for MSM in urban settings who are not being reached through conventional approaches, and who look for HIV information online.

WEPEC1010

Virtual and new physical venues are changing the modes of operation and HIV risk among female sex workers and MSM in sex work in India

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Background: In India, targeted HIV interventions among female sex workers (FSWs) and MSM in sex work, are currently hotspot based. The mid-term evaluation of National AIDS Control Programme found a sharp decline in the number of key populations visiting hotspots, and recommended using technology to reach them. To design such newer interventions, PIPPSE of PHFI conducted this rapid assessment to understand the current ways by which FSWs and MSM in sex work meet paying partners.
Methods: In 2016, this exploratory qualitative study was conducted in 6 cities across four states in India: Chennai, Trichur, Pandalam, Mumbai, Santacruz and Margao. We conducted 9 focus groups (N=85 participants) among a purposive sample of 44 FSWs and 41 MSM in sex work, and 9 key informant interviews with leaders/staff of community agencies. Data were explored using narrative thematic analysis.
Results: Participants reported using Internet-based mobile apps (e.g., Whatsapp, Grindr), dating websites (e.g., Planet Romeo), and online classifieds (e.g., Locanto) to meet potential paying partners. Emerging physical venues for meeting paying partners included: certain massage parlors, spas, dance bars, gay parties and gyms. High volume of clients, relative safety and confidentiality, and higher income were stated as the reasons for preferring online over offline venues. Participants felt that the condom use could be relatively better among sex workers who use phones/Internet, when compared to street-based sex workers, because of better negotiation power of the former. However, violence and extortion were reported from paying partners met online. Certain barriers prevent virtual and new physical venues from being used for HIV-related health promotion. For example, phones/apps were seen as useful to get clients, but not to receive HIV-related information.
Conclusions: Emergence of new physical and virtual venues means need for newer strategies (e.g., virtual outreach) to reach sex workers for providing HIV-related information/services. Further research need to focus on HIV risk among sex workers who use smart phones/Internet and testing and scaling up of effective phone-/internet-based HIV prevention interventions, which could augment the traditional hotspot-based interventions.

WEPEC1011

The user experience: perspectives from MCH providers, laboratory providers, and HIV+ mothers enrolled in the HITSystem

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Background: The HITSystem is an innovative, web-based system seeking to improve quality and efficiency of early infant diagnosis (EID) services by utilizing algorithm-based electronic alerts for EID providers and text messages for mothers overdue for services. Compared to national data and reported standard of care outcomes, preliminary data at HITSystem sites suggest shorter turnaround times (TAT) for HIV DNA PCR samples, improved retention in care through 18 months, and more rapid ART initiation. This study aims to assess users' (mothers', providers', and lab technicians') experiences with EID services and the HITSystem.
Methods: A trained researcher conducted semi-structured interviews with HIV+ mothers (n=40) and providers directly utilizing the HITSystem (n=4 MCH and n=3 lab providers) at intervention site hospitals (n=3) and central laboratories (n=2) in a randomized controlled trial evaluating the HITSystem. Interviews were recorded, transcribed, and coded into a priori and emergent themes.
Results: Findings emphasized the recognized value of EID services: providing information, support, and conclusive knowledge of infants' HIV status. Participants identified significant barriers to EID (limited resources, opportunity cost of attend-

ing appointments, distance to hospital, stigma, and fear of disclosure). Providers identified HITSystem-driven improvements in EID experience at a systematic level (fewer lost samples, faster TAT for results, result notification, and ART initiation), while mothers identified improvements at the individual level (cues to action for appointment attendance, reduced hospital visits, and reduced anxiety through shorter waiting periods). HITSystem-facilitated communication between hospital and laboratory providers increased collaboration, problem-solving, and motivated performance through enhanced accountability. Participants described increased patient engagement in care as a result of HITSystem-generated text messages, facilitating increased provider-patient communication (notification of result availability and retesting needs) and opportunities for provider and partner support. No unintentional disclosure from HITSystem participation was reported. Provider suggestions for optimizing HITSystem utilization included addressing network challenges, delaying data entry to improve workflow, enhancing report-generating capabilities, and linking with other national EMR systems.
Conclusions: Individual and systemic barriers to EID services remain. Yet, the HITSystem maximizes the benefits of EID by reducing systematic inefficiencies and motivating retention in care. HITSystem adaptation can further address barriers identified.

WEPEC1012

"How do we as young black gay men stand strong?" The healthMpowerment online intervention as a space to engage with stigma related to HIV, sexuality, and race

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Background: In the United States, young Black men who have sex with men (YBMSM) experience increased HIV infection. HIV incidence is linked to sexuality, race, and HIV stigma, as stigma may inhibit protective behaviors (condom use, HIV status disclosure) and deter care utilization (HIV testing, pre-exposure prophylaxis use, HIV care). An internet-based HIV risk reduction intervention for HIV-negative and HIV-positive YBMSM included access to online forums where YBMSM could share experiences and garner social support.
Methods: In the healthMpowerment (HMP) randomized controlled trial, intervention arm YBMSM (n=232) read and posted content in three support spaces: a discussion Forum, an HIV physician question and answer area (Ask Dr. W), and a multi-media stories area (Getting Real). Informed by gender and sexuality, race, and HIV stigma theories, we systematically content coded all of participants' posts and then thematically analyzed all stigma-related posts.
Results: Sixty-two participants (mean age 24.4, 28 HIV-positive) contributed 1497 posts, of which 61.1% (n=915) were stigma-related. 80.1% (733/915) contained gender- or sexuality-related stigma, 22.1% (202/915) race-related stigma, and 21.4% (196/915) HIV-related stigma (posts could receive multiple codes). Characterizing stigma, 75.3% (689/915) of posts challenged stigma, 14.5% (133/915) relayed stigma experiences, and 8.9% (81/915) expressed anticipatory stigma. Comparing areas, the Forum had a higher proportion of posts challenging stigma (76.0%, 610/803), while Ask Dr. W had a higher proportion of anticipatory stigma (45.5%, 15/33) posts. 46.9% (429/915) of posts - distributed equally across all three spaces - were coded as perpetuating stigma. YBMSM utilized HMP to respond to stigma in five broad ways: correcting misinformation/stereotypes; seeking information and support; promoting positive norms; interrogating stigmatizing media portrayals; and helping other YBMSM.
Conclusions: HMP fostered dialogue about multiple stigmas. While user posts overwhelmingly challenged stigma, almost half also perpetuated stigma. Social media-based interventions for YBMSM should be attentive to opportunities to challenge stigma, while ensuring that measures to reduce stigma perpetuation are in place. Future studies should examine the efficacy of strategies YBMSM use to challenge stigma in online spaces and test how online support might utilize these strategies to ameliorate the impacts of multiple stigmas on HIV risk.

WEPEC1013

"She thought I instantly had AIDS": how media representation influences perception and stigmatization of race, sexuality and HIV among young black men who have sex with men

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Background: Media portrayals of young Black men who have sex with men (YBMSM) may perpetuate racial and homophobic stigma among HIV positive and HIV negative YBMSM, thus heightening experiences of discrimination and HIV disparities. Characterizing how news and social media influence stigma and how YBMSM engage with these portrayals may offer opportunities to confront stigma and develop media-driven stigma reduction interventions.
Methods: Qualitative data were collected from 12 months of user-created posts on an Internet-based HIV intervention aimed at reducing sexual risk behaviors among 474 HIV-positive and HIV-negative YBMSM. Participants posted and commented on a discussion forum, physician question and answer space, and a space for sharing multi-media content (e.g. YouTube videos, newspaper links). Three independent researchers qualitatively coded all participants' posts. All posts with stigma content were identified and coded for race & ethnicity, gender & sexuality, and HIV stigma content. Then thematic content analysis was conducted on all posts with race/ethnicity stigma or intersectional (layered stigmas) codes to identify interactions among YBMSM in relation to shared media.
Results: 62 participants, 28 of whom were HIV positive, contributed 1497 posts. 323 posts were coded with race/ethnicity or intersectional stigma relevant themes. Within these conversations, 59.7% (193/323) of posts contained media content or commentary. Participants engaged highly with these posts discussing the limited presence of YBMSM in popular television shows and sharing examples of LGBTQ portrayals in television and film that were largely positive. Participants also felt that media portrayals reinforced stereotypes, including the perceived interconnectedness of flamboyance, sexuality, AIDS and the experience of coming out. In participants' discussions these portrayals were linked to discrimination within and outside of the gay community.
Conclusions: YBMSM perceived media portrayals as reinforcing and perpetuating stereotypes, which influenced experienced stigma and stigma by association. While this stigma may hinder access to HIV prevention services and engagement with healthcare providers, YBMSM also used social media to challenge stigma, suggesting opportunities to develop media-driven stigma reduction interventions. Structural approaches, including training media on stigma-reduction and HIV advocacy, could lessen perceived and experienced stigma, and ultimately improve the health of YBMSM.

WEPEC1014

Ending HIV through a multi-phased health campaign approach for men who sex with men and the whole of population

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Background: The END HIV campaign was developed due to rising rates of HIV in Queensland and under the umbrella of the Queensland HIV Strategy 2012-2015. The initial challenge/opportunity for the health promotion campaign was to educate, inform and persuade publics to be actively involved in prevention, testing and treatment of HIV. In 2013, the initial campaign was design as a singular phase.
As the campaign developed, the need for an ongoing response to HIV within Queensland became apparent. Consequently, END HIV was extended and further expanded to be a multi-phased response to HIV in Queensland.
Methods: The campaign was developed to target both men who have sex with men (MSM) and whole of population (WOP). Audience research/insights inform branding, messaging, creative and content and ensure targeting on corresponding platforms and channels. These include stakeholder/community engagement, traditional and digital advertising such as hook up apps i.e. Grindr.
A four-pronged message approach focuses on prevention (condoms, PrEP and PEP), testing, treatment and stigma. Third party formative research and evaluation of the campaign is conducted annually through qualitative and quantitative meth-

ods. Findings from these evaluations are considered and synthesized for ongoing development of strategies and tactics.
Results: The campaign is measured by changes in awareness, attitude and behaviour. Results and findings from 2016 evaluations are divided into MSM and WOP segments. Key findings show 83% of MSM state taking some form of action as a direct result of campaign, compared to 67% in 2013 and includes testing which was undertaken by 43%. Key findings among WOP include 12% talking about HIV with other people, compared to 2% in 2013. And 15% stating being more vigilant about safe sex practises. In addition, behaviour showed a 30% increase in testing in gay friendly GPs and a reduction of 38% new transmissions of HIV in Brisbane since 2014.
Conclusions: The END HIV response to HIV in Queensland showed a direct correlation to awareness, attitude and behaviour change. These findings are supported by data showing an increase in testing and a reduction of new transmissions in Brisbane.

WEPEC1015

To get to zero, we must also get to men: UNAIDS review on men and HIV, eastern and southern Africa regional focus

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Background: Men and boys in Eastern and Southern Africa are dying at disproportionately higher rates than their female counterparts because they are underrepresented in HIV testing and are less likely to initiate and adhere to treatment. As part of broader efforts to increase male engagement in the HIV response, UNAIDS commissioned a review to examine effective strategies to increase male engagement in the prevention of and response to HIV.
Methods: An extensive review of available peer-reviewed and grey literature was completed during 2015, informed by additional expert input from UNAIDS, relevant nongovernmental organisations and academic institutions. Evidence presented covers:
(1) the HIV epidemic in Eastern and Southern Africa among men and boys;
(2) men's current use of HIV services;
(3) barriers to men's linkage into the HIV cascade of care;
(4) proven and promising practices to address these gaps; and
(5) a set of recommendations to engage men in HIV prevention and treatment strategies.
Results: Men's low utilisation of HIV prevention and treatment services reflects a combination of factors:
(1) behavioural factors linked primarily to rigid gender norms that discourage uptake of health services;
(2) policy and structural level factors, such as services that are not inclusive of men and boys in all their diversities, and;
(3) insufficient commitment from governments and development partners to fund and implement strategies to scale.
Key recommendations from this review include: development of new policies and policy guidelines that incorporate male engagement as clients and supportive partners; health provider sensitization; mass scale up of male circumcision and male involvement in antenatal care; community-based testing services including self, partner, and workplace testing; extended or varied clinic hours; gender transformative small group and mass media interventions; and community mobilization strategies for uptake of HIV services.
Conclusions: The Fast-Track targets to end AIDS by 2030 outlined in the 2016 Political Declaration on HIV and AIDS cannot be reached unless scaled up and effective strategies to increase male engagement in the HIV response and for gender equality are employed. This review highlights the need for urgent action across multiple levels and sectors, and provides a clear roadmap for how to achieve it.

WEPEC1016

Sex communication at home: parents and health providers as conduits of sexuality-inclusive HIV information for gay, bisexual, and queer adolescent males

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Background: Sex communication interventions have been proven to facilitate positive sexual health outcomes with heterosexual adolescent samples. The same has yet to be established for male youth with same-sex attractions, behaviors and identities. Our study aimed to describe the experiences of gay, bisexual and queer-identifying adolescent males with parent-child sex communication, their assessment of parents' efficacy as sex educators and to identify the role the healthcare system can play during these discussions.
Methods: In this descriptive qualitative study, we conducted 30 in-depth semi-structured interviews with a diverse group of 15 to 20 year-old males. Participants varied by sexual orientation (23 gay, 5 bisexual, 2 queer), school level (5 high school, 6 technical school, and 19 college) and race/ethnicity (11 White, 10 Hispanic/Latino, 4 Black, 4 Asian, and 1 multiracial). Interviews lasting 60-90 minutes were transcribed and iteratively coded on NVivo11. Themes were identified using standard thematic and content analysis techniques.
Results: Themes emerged regarding the frequency and content of sex communication, parents´ knowledgability and rating as sex educators, and the role healthcare providers play in initiating and sustaining these talks. Sex communication with parents occurs rarely and is heteronormative in content prior to sons' disclosure as GBQ. After disclosure, parents are reactionary in their approach and provide information to sons based on stereotypes that equate this population with negative health outcomes. The findings are mixed regarding perception of parents' knowledge about GBQ-specific information; more mothers than fathers addressed sex and sexuality with their sons, and both parents were rated poorly as sex educators by their GBQ sons. Healthcare providers were identified as a crucial resource for GBQ sons and their parents, both before and after disclosure.
Conclusions: Sex communication with parents throughout adolescence that excludes GBQ males' same-sex concerns are missed opportunities for targeted HIV risk reduction. There are multiple ways healthcare providers can assist parents to plan age-appropriate, sexuality-inclusive, home-based discussions about sex for this group.

WEPEC1017

Confronting GBV as a barrier to women accessing HIV services including elimination of vertical transmission of HIV in a peri-urban settlement in Lusaka district

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Background: Bwafwano Integrated Services Organization implemented a project aimed at addressing Gender Based Violence as a barrier to women accessing maternal and child health services and as a factor fueling vertical transmission of HIV. The project sought to eliminate vertical transmission of HIV and provided a platform for improving knowledge, tackling GBV, stigma and discrimination in the community and also improving access to services needed by women living with HIV during pregnancy and delivery.
Methods: This community-based intervention was set in a densely populated peri-urban settlement between 2009 and 2016. 60 men were identified and trained as Champions against GBV and a further 50 Community Volunteers trained in maternal and child health. Working in collaboration with local community leadership, 4,000 men and women were mobilized as couples and engaged through ongoing small group meetings to access information on maternal and child health and to identify barriers to health services among women. A structured questionnaire was also used to identify barriers to services and results analyzed using SPSS. HIV Counseling and Testing services were also provided and 3,798 couples were tested for HIV with 482 being found to be infected HIV with 120 being pregnant.
Results: 82% of the 2,000 women respondents to the questionnaire indicated that they would not disclose their status to their spouses for fear of being divorced while 56% of men felt the same. 120 pregnant women involved in the project gave birth to HIV free babies as compared to 23 babies that contracted HIV in a comparison site which was not targeted under this project. Also, women in this project complied and adhered to treatment compared to those in the comparison site.
Conclusions: Inclusion, GBV is an emerging issue and if not addressed will retard the gains recorded so far in HIV prevention, treatment, care and support especially among women and the implications will be an upswing of vertical transmission despite the availability of OPTION B+.

WEPEC1018

From guideline to implementation of oral pre-exposure prophylaxis for HIV prevention in Taiwan

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Background: Pre-exposure prophylaxis (PrEP) for prevention of human immunodeficiency virus (HIV) infection was proved to be effective and has been widely implemented worldwide. This article introduced guideline development of PrEP use and the implementation of PrEP use in Taiwan.
Methods: The Taiwan Pre-exposure prophylaxis (TW PrEP) guideline writing group was established by Taiwan AIDS Society in 2015. The writing group searched published randomized controlled trials and global guidelines using keywords as pre-exposure prophylaxis, preexposure prophylaxis, antiretroviral hemoprophylaxis, PrEP, Truvada, tenofovir, HIV, and HIV incident through Medline, PubMed, Cochrane Database, EmBase and ClinicalTrials.gov database. The writing group applied Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to draft TW PrEP guideline. Internal and external reviewers independently evaluated TW PrEP guideline draft using the Appraisal of Guidelines for Research and Evaluation (AGREE II).
Results: Of all, 3 systemic reviews and 26 original articles were reviewed by 2 guideline writers. Final recommendations for PrEP use were stratified by 4 key groups: strong evidence and strong recommendation for men who have sex with men and transgender women, as well as serodiscordant couples, intermediate evidence and weak recommendation for people who inject drugs, while low evidence and weak recommendation for at-risk heterosexual men and women. Taiwan CDC released TW PrEP guideline in May 2016. Following the guideline release, Taiwan Food and Drug Administration (TFDA) approved the indication of PrEP for Truvada® in August 2016 and 41 hospitals in Taiwan further provided the service of PrEP since November 2016. Among them, 5 hospitals were selected as demonstration project sites supported by Taiwan CDC.
Conclusions: Taiwan is the first country in Asia to develop local PrEP guideline and to implement PrEP for population at risk of HIV infection nationwide.

WEPEC1019

The effect of child apprehension on sexual HIV/STI risk negotiation with marginalized women sex workers: possible pathways from trauma to HIV/STIs

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Background: Limited research on sex workers who are mothers show that child apprehension by Child Protective Services (CPS) is a commonly experienced phenomenon. While there is emerging literature identifying child apprehension as a source of trauma and adverse health outcomes in women, there is a paucity of information on the health consequences for sex workers, including HIV/STI vulnerability, and on implications for HIV prevention programs. Building on prior studies showing traumatic events to be predictive of HIV vulnerability, this study examined the potential role of child apprehension in shaping pathways from trauma to HIV/STI vulnerability.
Methods: Analyses drew on a longitudinal community-based cohort AESHA (An Evaluation of Sex Workers' Health Access) of street/off-street sex workers in Vancouver, Canada. We used logistic regression with generalized estimating equations (GEE) to examine the independent effect of child apprehension on client condom refusal among women sex workers who ever had a live birth, as well as potential mediating pathways between child apprehension and HIV/STI risk.
Results: Among 466 women, 180 (39%) had experienced one or more child apprehensions (median =1), with Indigenous women experiencing the highest burden of child apprehension (58%). In a multivariable GEE logistic regression model, women sex workers experiencing child apprehension were 1.70 times more likely (95% confidence interval: 1.06, 2.73) to report client condom refusal. In separate models, there was evidence that drug use may mediate the relationship between child apprehension and HIV/STI risk, and physical or sexual violence may be a partial mediator of this relationship.
Conclusions: This research suggests that child apprehension is a traumatic experience for marginalized women with health consequences evidenced by a direct and possible mediated effect on HIV/STI risk through drug use and violence. There is an urgent need to move away from criminalized approaches to sex worker-led trauma-informed, gender-focused and harm reduction centered policies and programs that respond to the needs of sex workers who are mothers and their families (e.g. family-centered housing). The overrepresentation of child apprehension among Indigenous sex workers highlights the need for decolonizing, cultural and equity-informed approaches to ensure Indigenous women receive tailored supports.

WEPEC1020

The role of violence in migration and displacement patterns, unsafe sexual practices under the influence of non-injected drugs and vulnerability to HIV in the Mexico/Guatemala border region

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Background: In a context of increasing drug trafficking, there has been an increase in local substance use along the Mexico-Guatemala border. The area is also distinguished by migration, towards the United States but also regional circular migration. Among diverse populations around the world, a relationship between use of illicit drugs during sex, unsafe sexual practices, and exposure to HIV/AIDS has been established.
However, the Mexico-Guatemala border region is also distinguished by a context of discrimination of migrants and violations of their human rights, arising from structural, symbolic and direct violence, making migrants particularly vulnerable to acquiring HIV/AIDS or having difficulty in accessing available services.
Methods: This qualitative research is based in a case study in the Mexico-Guatemala border city of Tapachula (Mexico), and embedded within the infrastructure of a mixed methods study, "Crossing Borders". 50 in-depth interviews were conducted, during 2013 and 2016, with a targeted sample of men from Honduras, El Salvador and Guatemala en route to the United States with undocumented status, who have commercial sex with men and/or women under the influence of non-injected drugs use and professionals in migration, drug addiction and HIV fields. Three weeks of field observation were included in 2016.
Results: We analyzed direct, structural and symbolic violence as socio-cultural and economic health determinants, related to migratory/displacement patterns and vulnerability to HIV of study population regarding inconsistent condom use and drug consumption during sexual work, in two public areas of Tapachula. Results highlight four levels of macro and intermediate health determinants:
a) the role of direct violence from organized crime, in origin/transit Central American countries and Mexico, in migratory/displacement mobility.
b) Discrimination and lack of social and economic opportunities as undocumented migrants.
c) Economic extortion and harassment from police and migratory agents, and reduced access to public health services.
d) Praxis and Social-representations through the violence of unequal negotiations of safe encounters, about non-condom and drug use in sexual work transactions.
Conclusions: There is a need to increase understanding and improve local interventions within social, economic and cultural determinants of unsafe sexual praxis under the influence of non-injected drug use in this migratory/displacement context.

WEPEC1021

Feasibility, acceptability, and preliminary efficacy of the bio-behavioral community-friendly health recovery program (CHRP-BB): a combination approach for primary HIV prevention among high-risk drug users

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Background: Despite unequivocal evidence supporting pre-exposure prophylaxis (PrEP), few - if any - researchers have reported incorporating it into an existing HIV prevention program, particularly among people who use drugs (PWUD). Based on our formative work, we integrated the biomedical component (PrEP) into the evidence-based behavioral intervention (Community-friendly Health Recovery Program: CHRP). Moreover, we incorporated specific behavioral strategies (e.g., mHealth technology, cognitive remediation tools) within the new combination approach - now called CHRP-BB - to accommodate those with neurocognitive impairment such that primary prevention benefits - including PrEP adherence and HIV risk reduction - can be maximized among PWUD. Here, we report the feasibility, acceptability, and preliminary efficacy of the CHRP-BB intervention among high risk PWUD in methadone maintenance program (MMP).
Methods: Using a within-subjects pre/post/follow-up design, we implemented the CHRP-BB intervention within a group of high risk, HIV-negative MMP clients who had started taking PrEP in the past week (n=23). Participants completed four 50-minute intervention sessions, and reported on demographic, behavioral, and psychosocial characteristics at baseline, immediately post-intervention, and 1-month post-intervention. Furthermore, following the completion of the intervention phase, we administered a process measure among treatment providers and administrators (n=12) at the MMP clinic.
Results: Our pilot study affirmed feasibility, acceptability, and preliminary efficacy of the CHRP-BB intervention. We assessed feasibility based on participant engagement (e.g., attending groups and completing assessments), which was outstanding, with 100% retention through the 1-month post-intervention follow-up. The mixed methods data analysis showed that participants were highly satisfied and perceived the CHRP-BB intervention as valuable and acceptable (82.7%). Post-intervention feedback also indicated that the content delivered in the group sessions, during the mHealth text messaging, and the overall CHRP-BB intervention was helpful in addressing PrEP adherence and HIV risk reduction. In terms of efficacy, PrEP adherence, PrEP-related knowledge and behavioral skills, drug-related risk behaviors, and demonstrated HIV risk reduction skills improved significantly from Pre- to Post-intervention, and the improvement persisted at the 1-month post-intervention Follow-up point.
Conclusions: This pilot study argues for the potential of the new CHRP-BB approach to increase adherence to PrEP and reduction in HIV risk behaviors among high risk PWUD in treatment.

WEPEC1022

Combination prevention in key populations' social venues: a Brazilian experience in partnership with NGOs

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Background: To address the many determinants of HIV epidemic, a multisectoral response is required, operating in individual, social and programmatic levels. The 'Live Better Knowing' project, characterized by the association of HIV prevention interventions targeted at the most at-risk groups, has been considered an assertive combination HIV prevention strategy. This study aims to provide a snapshot of key populations' HIV prevalence and prevention behaviors based on data collected by the strategy.
Methods: The project offers rapid oral fluid HIV testing (DPP HIV-1/2 Bio-Manguinhos/Fiocruz), counseling, prevention education, supplies distribution, referral to PEP and monitored linkage to health services for treatment and care. Testing is free and held in social venues where key populations meet. The targeted population reached by the initiative between June 2015 and October 2016 was also invited to answer a structured questionnaire containing sociodemographic data and information about their risk and prevention behaviors.
Results: Among the 54.476 participants, 62% were nonwhite and 60.3% aged 20 to 40 yo. 61.9% reported drug use and 16.9% drug use and commercial sex combined. 51% reported condom use at last sexual intercourse and 9% reported STI symptoms in the last 12 months. Overall, 47.3% had been tested for HIV at least once before the strategy. The general HIV prevalence found was 1.6%. Among cis-women, transvestites, transsexual women, transsexual men, MSM and heterosexual men it was 0.9%, 6.8%, 5.3%, 1.5%, 3.5%, and 0.9% respectively.
Conclusions: Transvestites and transsexual women constitute a high-risk population for HIV in urgent need of responses able to tackle the vulnerabilities related to the HIV acquisition in these groups. The participation of the key populations, composing the NGOs teams, in the execution of the strategy was crucial to impact structural variables in addition to improve the uptake of prevention technologies trough biomedical and behavioral interventions.

	Cis women (n=23790)	Transvestites (n=1572)	Transsexual women (n=872)	Transsexual men (n=459)	MSM (n=10950)	Heterosexual cis men (n=16883)	Total (n=54476)
	%	%	%	%	%	%	%
Race (n=54476)							
White	33,7	31,5	34,7	41,8	31,7	30	32,2
Black	13,8	19,8	13,6	14,8	17,6	15,7	15,3
Asian	2,0	1,8	1,4	2,8	1,4	1,8	1,7
Brown	48,6	44,9	48,2	40,3	46,5	50,7	48,6
Indigenous	1,5	2	1,8	0	1,9	1,7	1,7
Not informed	0,3	0	0,2	0,4	0,9	0,3	0,4
Age (n=54476)							
15 to 19	23,3	15,0	19,2	18,7	21,1	25,1	23,1
20 to 25	28,3	29,2	37,5	30,9	31,9	25,3	28,3
26 to 40	32,9	43,4	34,6	34,9	33,0	28,7	32
41 to 59	13,4	11,3	7,6	13,1	12,3	16,9	14,1
>=60	2,0	1,1	1,1	2,4	1,7	4,1	2,6
Drug & Commercial sex (n=54476)							
None	22,0	2,5	8,7	19,0	15,3	17,3	18,4
Drug use only	48,9	17,2	30,5	58,2	72,2	79,6	61,9
Commercial sex	4,3	12,4	10,0	3,7	1,6	0,2	2,8
Drug use and commercial sex	24,9	67,9	50,8	19,2	10,9	2,9	16,9
Condom use in the last sexual intercourse (n=54476)							
Yes	50,4	71,7	66,7	42,9	55,9	46,1	51,0
Ever tested for HIV (n=54476)							
Yes	51,7	65,4	65,5	47,7	54,4	33,7	47,3
Had any STI symptom during the last 12 months (n=54476)							
Yes	10,9	8,9	11,2	9,6	11,6	5,7	9,4
HIV prevalence							
Positive	0,9	6,8	5,3	1,5	3,5	0,9	1,6

[Live Better Knowing Descriptive Table]

WEPEC1023

Impact of risk perception trajectory on PrEP and condom use among men who have sex with men during the open-label-extension of the ANRS-IPERGAY trial

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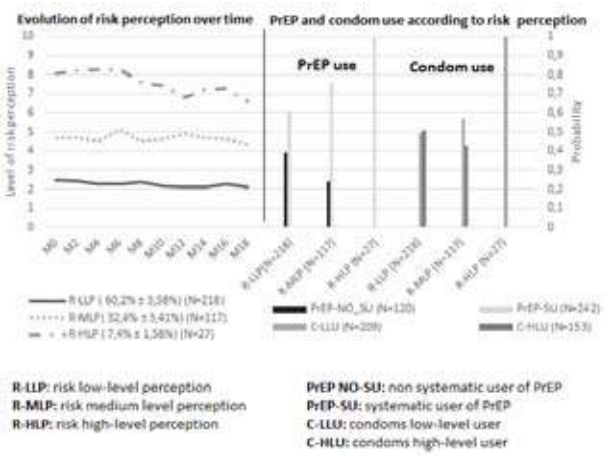
Background: First results of the Open-Label-Extension (OLE) of the ANRS-IPERGAY trial showed greater use of PrEP than condoms. We assessed whether participants' risk perception trajectories impacted PrEP and condom use during the OLE.
Methods: Two-monthly follow-up was performed during ANRS-IPERGAY OLE (M0 to M18) and included online questionnaires focusing on sexual behaviours, condom use, risk perception and PrEP uptake at most recent anal intercourse encounter. A longitudinal multi-trajectory model was implemented for three outcomes: level of risk perception (10-point scale), PrEP use (correct/suboptimal versus no PrEP) and condom use for anal sex (yes versus no). Dual trajectory models helped estimate probabilities of PrEP and condom use according to risk perception.
Results: Data for 362 participants were analysed. Three trajectories of risk perception (low, R-LLP; medium, R-MLP; and high, R-HLP; see left-side figure below), two trajectories of condom use (low-level, C-LLU; high-level, C-HLU), and two trajectories of PrEP uptake (systematic, PrEP SU; non-systematic, PrEP No-SU) were identified. The R-HLP trajectory declined over time. Dual models (see right-side figure below) showed that condom use probability decreased with increased risk perception level: 50% of R-LLP, 40% of R-MLP, and 0.2% of R-HLP were high-level condom users. Estimated PrEP uptake probabilities highlighted that

greater PrEP use compensated for low-level use of condoms, with probabilities increasing with increased risk perception. Specifically, 60% of R-LLP, 75% of R-MLP, and 100% of R-HLP were systematic PrEP users.
Conclusions: In the ANRS-IPERGAY OLE, risk perception contributed to explain PrEP uptake levels. Systematic PrEP users appeared to be less worried about risk over time. Psychosocial factors might explain the barriers to condom use and the success of PrEP uptake. To reduce HIV infection, special attention must be paid to understand factors influencing risk perception and accordingly PrEP uptake.



[Risk perception trajectory and duals model]

WEPEC1024

Men who have sex with men (MSM) in Egypt: high-risk sexual and injecting behaviors

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Background: In Egypt, Key Populations (KPs) especially Men who have Sex with Men (MSM) face severe discrimination from the society. In 2013, FHI 360, with support from the Drosos and the Ford foundations, established the Network of Associations for Harm Reduction (NAHR) to provide KPs with a comprehensive package of HIV/AIDS prevention and harm reduction services through the Comprehensive Care Centers (CCCs).
Methods: Street-based outreach was used to refer MSM to six NAHR CCCs where they received voluntary, anonymous and free of charge harm reduction services promoting safe sex and safe injection. Socio-demographic and behavioral data addressing the sexual and injecting behaviors were collected and analyzed between March 2013 and September 2016 in Greater Cairo and Alexandria.
Results: A total number of 12492 males visited the CCCs, of which 4523 (36.2%) were MSM. Almost half of them (47.3%) were in the age group of 16-24 years, about 44.4% received some university education, more than half of them (52.6%) were employed and 13.0% were currently married. Condom use at last sex was reported by 13.4% with a non-steady partner and 11.2% with a steady partner. About 91.0% were willing to use condom in the future. More than one quarter (27.7%) of MSM ever injected drugs and Heroin injection in the last month was reported by 41.0%. Among injecting MSM, more than half (51.2%) shared needles, 59.2% shared syringes, and 46.1% shared paraphernalia in the last month. Moreover, about 6.0% of MSM exchanged sex for drugs and 17.2% had sex with a sex worker in the last year. The HIV prevalence among MSM was 8.7%.
Conclusions: The comprehensive care package of services provided in NAHR CCCs succeeded is addressing the overlap of risky behaviors among MSM. Replicating the Egyptian integrated model with an adapted harm reduction approach may offer an attractive and practical solution to reaching MSM in similar conservative societies.

WEPEC1025

Use of HIV services increases with targeted HIV campaigns among adolescent girls and young women in a multicountry survey in sub-Saharan Africa

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Background: Adolescent girls and young women (AGYW) have one of the highest HIV incidence rates globally. Lack of access to health services, including Sexual and Reproductive Health (SRH) and HIV testing and low condom use have been indicated among the reasons to explain this situation. In April 2016, AIDS Healthcare Foundation (AHF) commissioned a multi-country survey among AGYW to better understand specific challenges facing this group and identify interventions to address them.
Methods: The survey, among female 16-24 years-old in Uganda, Nigeria and South Africa, used Short Message Service (SMS) technology and comprised of 50 questions covering access to health services, sexual behavior, family planning, HIV testing and information on HIV. Independent covariates of access to HIV related services and condom use were assessed by multivariate logistic regression analysis.
Results: Overall 1,600 participants were included in the survey, 62 % were sexually active, 76 % had used condom in the last sexual intercourse and 81 % claimed to know their HIV status. 72 % of the participants have visited a health facility for HIV or SRH related services. In the multivariate analysis, consistent condom use was higher in those that knew their HIV status and lower in married AGYW (Adjusted Odds Ratio [aOR]: 0.3, 95%Confidence Interval [95%CI]: 0.1-0.6). Access to HIV and SRH services increased with age and onset of sexual activity, and was higher in those whose main source of information was family (aOR: 1.4, 95%CI: 1.2-1.5) versus school and in participants that had recently seen HIV messages/campaigns relevant to them (aOR: 2.6, 95%CI: 1.8-3.9) and decreased when distance to the closest facility was more than 5km (aOR: 0.6, 95%CI: 0.5-0.6).
Conclusions: We found a higher than expected use of health services and uptake of HIV testing. It is also significant that those that received messages on HIV that were relevant to them had more than double the odds to seek HIV health services, highlighting the importance of tailored communication strategies for this group. Regarding condoms, the lower use reported in married AGYW (with the existing evidence of ongoing HIV transmission) calls for new prevention efforts in this context.

WEPEC1026

Attitudes about PrEP among physicians who participated in the open-label extension of the ANRS-IPERGAY trial: a qualitative study

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Background: The ANRS-IPERGAY trial recruited physicians to prescribe PrEP. No scientific data currently exists about physicians' specific experience of prescribing medical HIV prevention treatment.
Methods: A novel, original psychosocial sub-study examined the subjective experience of prescribing physicians during the trial. Between March and June 2016, data were collected during an open-label extension study through interviews with physicians (9 generalists, 7 infectologists and 2 internists). Interviewees came from all participating ANRS-IPERGAY centres. The standard interview grid collected information on experience of PrEP prescription, attitudes about PrEP, treatment of seronegative people and the physician-patient relationship. Text analysis was performed using IRaMuteQ, an open-source automated statistical software package.
Results: Analysis of 18 interviews highlighted that attitudes about PrEP were based

on: i) medical and scientific knowledge (side effects, protocol, impact on public health), which comprised 35% of physicians' discourse, and;
ii) personal experiences with PrEP users and with participating volunteers from the HIV patient association AIDES (personalized support, PrEP use in real life, sex practices, drug use), comprising 65% of their discourse.
The ANRS-IPERGAY experience impacted physicians' practices. They became more favourable to promoting risk reduction practices (39% of interviewees). They also changed their consultation style, becoming more attentive to their patients' needs and opinions. They were required to be more benevolent and non-judgemental, given the delicate nature of the themes discussed (55.5% of interviewees). The physician-patient relationship was a central element for successful PrEP consultation as was the relationship with AIDES' volunteers (for 72% of interviewees). Globally, physicians' participation in ANRS-IPERGAY led to a positive change in their personal representations of PrEP and its users.
Conclusions: This novel study highlights the positive outcome of the ANRS-IPERGAY trial on participating physicians. They gained in-depth knowledge about the MSM community, risk-taking behaviours, PreP users' concerns, and more generally, related public-health issues. The feedback from this trial will help to draw-up guidelines for future professionals prescribing PrEP.

WEPEC1027

Brisbane, capital city of Queensland is the first Australian city to see a significant drop in HIV diagnoses due to new prevention methods

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Background: Brisbane is the first Australian city to report a significant reduction of HIV notifications in 2016. Data reports HIV notifications have decreased by 38% since 2014, following a period where HIV diagnoses had doubled over the 10 previous years. In response, the Queensland HIV Strategy 2012-2015 provided strategic direction focusing on 4 key pillars: comprehensive preventative approach; increase voluntary testing; increase treatment uptake; and addressing stigma and discrimination. With Government commitment to work towards the virtual elimination of HIV and achieving the UN 90-90-90 targets in Queensland, a multi-pronged approach was implemented. The HIV Foundation Queensland was established and tasked with providing leadership, coordination and support to the HIV public health response.
Methods: Stakeholders and partnerships with community, clinicians and academics were mobilised. A peer-led HIV rapid testing clinic and outreach services were established and the growth of Queensland led innovative research and programs was supported. International partnerships with British Columbia were developed and treatment as prevention strategies implemented to promote and improve access to early HIV treatment, PrEP and PEP. The END HIV campaign was launched and demonstrated a shift from one off campaigns to a multi-phased approach.
Results: The peer led HIV rapid clinic and outreach services were well received by MSM and quickly became the busiest testing service in the city with 99% client satisfaction ratings. Gay friendly General Practices also reported significant annual increases (30%+) of HIV testing. Evaluations of forums with community, health professionals, academics and policy makers demonstrated significant shifts in understanding treatment as prevention strategies and willingness to promote and prescribe early treatment, PrEP and PEP. There was an increase in PEP prescriptions and it is estimated that approximately 300 + people at risk of HIV in Brisbane were accessing PrEP through a small demonstration project and self-importation.
Conclusions: Political commitment, clear strategic direction and the mobilisation of all stakeholders and partnerships to work towards the common goal of ending HIV laid the foundation for implementation of innovative strategies. Brisbane is yet to see the full benefit of PrEP, which means the current data present an even more promising outlook for Brisbane.

WEPEC1028

Evaluating HIV testing strategies: a randomized trial of Opt-out versus Opt-in testing among at-risk women in Russia

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Background: Young women are disproportionately affected by HIV which is a major concern in countries with increasing HIV incidence, such as Russia. Testing is a promising prevention strategy particularly for young women who intend to become pregnant or may have limited control over condom use. However, evidence to support effective testing remains low with majority of studies utilizing pre/post or cross-sectional design and data on Russian women are lacking.
The objective of this study was to evaluate Opt-in vs. Opt-out testing among at-risk Russian women.
Methods: The study was conducted in primary care setting in Russia and utilized a mixed methods adaptive design that included a two-arm randomized clinical trial followed by a survey. A total of 868 women of childbearing age were screened; 200 at-risk women who had not completed HIV testing in 12 months were recruited and assigned to either Opt-in or Opt-out testing conditions. Laboratory tests included a rapid HIV screening test and, in Opt-out condition, a multi-health screening (cholesterol, hemoglobin, and blood glucose). Immediately after the trial procedures, participants completed a face-to-face health risk survey. Testing was available after the survey for testing non-acceptors. The outcomes of interest were modeled using Generalized Estimating Equations and Generalized Linear model.
Results: Participants had mean age of 23.5 and 23.4 years in Opt-in and Opt-out groups, respectively. Testing acceptance rates were 86% (Opt-in) and 90% (Opt-out). After participating in the survey, additional 4% (Opt-in) and 6% (Opt-out) accepted testing, totaling to 90% of participants in Opt-in and 96% in Opt-out groups. Education, age, and having children had significant effect on testing behavior. The odds of accepting testing were lower for those who were younger, had any children, and had higher education. When controlling for these characteristics, the odds of acceptance of HIV testing were 3.8 times higher in Opt-out group compared to Opt-in group (OR=3.779, 95% CI:1.169, 14.795, p=0.036).
Conclusions: Removing barriers and offering HIV rapid testing is an effective strategy to increase HIV testing uptake. The specific effect of Opt-out vs. Opt-in testing on testing acceptance provides information necessary to estimate effects of scaling up HIV testing among at-risk women in Russia.

WEPEC1029

Evaluating the impact of combination HIV prevention approaches on service uptake among adolescent girls and young women in Lilongwe, Malawi

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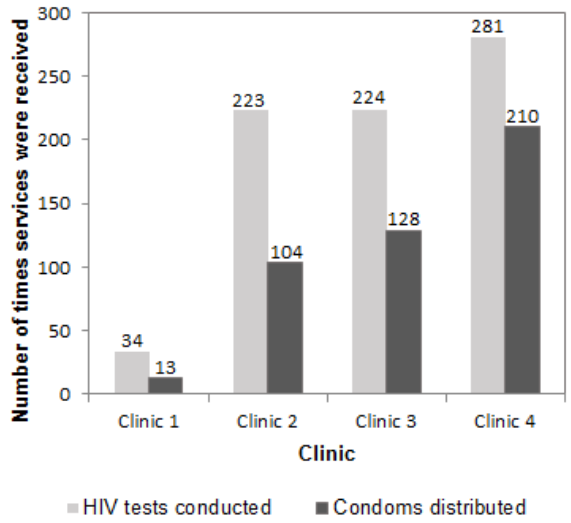
Background: Although multi-level combination HIV prevention has been promoted for adolescent girls and young women (AGYW) in sub-Saharan Africa, there is limited evidence on how clinical, behavioral, structural, and multi-level interventions compare to one another and to no intervention.
Methods: Girl Power is a study assessing four different models of service delivery for AGYW in Lilongwe, Malawi:
1) standard of care (no intervention),
2) youth-friendly health services (YFHS) (clinical intervention),
3) YFHS + empowerment (clinical + behavioral interventions),
4) YFHS + empowerment + cash transfer (clinical + behavioral + structural interventions).
Four comparable public sector clinics were selected and randomly assigned to one model of service delivery. During the six-month enrollment period, the four clinics were compared for uptake of HIV testing and counseling (HTC) and condom uptake (number of times a participant received any condoms). Number of times services were received per 100 AGYW were calculated and compared across clinics.
Results: 250 AGYW 15-24 years old were enrolled in each clinic (N=1000 total). Median age was 19 years. Rates of HTC uptake were 14, 89, 90, and 113 per 100 AGYW at clinics 1, 2, 3, and 4, respectively (p<0.001); rates of condom uptake were 5, 42, 51, and 84 per 100 AGYW in clinics 1, 2, 3, and 4, respectively (p<0.001). Uptake was higher in clinic 2 than clinic 1 for both HTC (p<0.001) and condoms (p<0.001).

Uptake was similar at clinics 2 and 3 for both HTC (p>0.999) and condoms (p=0.116). Uptake was higher in clinic 4 than clinic 3 for both HTC (p=0.009) and condoms (p<0.001).



[Figure 1. Number of times services were received]

Conclusions: A YFHS clinical package contributed to high rates of HTC and condom uptake. A cash transfer contributed further. For AGYW in sub-Saharan Africa, combination prevention programs can substantially impact HIV service uptake.

WEPEC1030

Feasibility, uptake and yield of household-based tuberculosis active case finding within the combination prevention package in the HPTN 071 (PopART) intervention in high TB/HIV burden communities in South Africa

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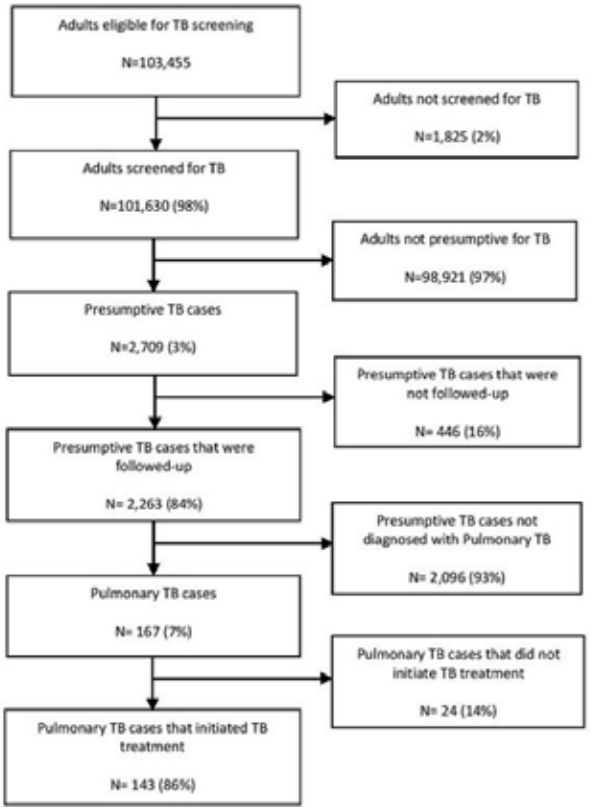
Background: HPTN 071 (PopART) is a community-randomised trial of a combination HIV prevention intervention, which includes home-based HIV counselling and testing and tuberculosis (TB) screening, delivered in four annual rounds by Community HIV-care Providers (CHiPs) in Zambia and South Africa. We evaluated the feasibility, uptake and yield of household-based TB active case finding (ACF) within a combination HIV prevention intervention.
Methods: We report data from the second annual round (06/2015-08/2016) from six South African communities. Adults (≥18 years) that consented to participate were eligible for TB screening if not on TB treatment. CHiPs administered electronic TB screening questionnaires (weight loss, cough ≥2 weeks, night sweats) and enquired about persons with TB in the household or at work. Two sputum specimens were collected from adults with presumptive TB (≥1 symptom or in contact with TB). Diagnosis of bacteriologically confirmed pulmonary TB (PTB) was based on Xpert MTB/RIF®, smear microscopy, or culture. PTB cases were referred to the local health care facility for treatment. Multivariable logistic regression was used to determine the association of sex and age with different outcomes within the TB cascade of care.
Results: 103,455 adults were eligible for TB screening. 101,630/103,455 (98%) adults received TB screening (43% males, median age 31 years). 2,709/101,630 (3%) were presumptive TB cases. 2,263/2,709 (84%) were followed up. 167/2,263 (7%) were PTB cases. 143/167 (86%) initiated TB treatment (See Figure 1). Adults aged ≥55 were more likely to be presumptive TB cases compared to younger age groups (P-value <0.01). Females were less likely to be presumptive TB cases (aOR 0.78, 95%CI 0.72-0.84) and less likely to be diagnosed with PTB (aOR 0.67, 95%CI 0.49-0.93) compared to males.



[Figure 1: Flowchart for TB active case finding]

Conclusions: ACF through household TB screening within a combination HIV prevention intervention is feasible. CHiPs were able to identify undiagnosed cases in the community and refer adults for treatment.

WEPEC1031

HIV testing strategies as opportunities to identify new and long-standing HIV infections: implications for linkage to care

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Background: Multiple HIV testing recruitment strategies have been endorsed as effective by the US CDC, including social network strategies and routine clinical based testing, but it is unknown how each strategy performs in engaging patients in the care continuum. This study aims to evaluate HIV testing strategies and downstream care continuum metrics.
Methods: We evaluated two HIV testing programs operating in Chicago between 2013-2015 that utilize routine testing (RT) and the social network strategy (SNS). For each method, we determined seropositivity rate of new and existing HIV diagnoses, linkage to care and time to linkage to care for new HIV diagnoses using programmatic and Department of Public Health data.
Results: RT performed 31,921 HIV tests in 30,225 individuals, with 203 total positive tests and 81 new HIV diagnoses for a new seropositive rate of 0.27%, while SNS tested 508 individuals with 208 positive tests and 38 new HIV diagnoses for a new seropositive rate of 7.5% (χ^2 (1, N = 30,733) = 673.7, p<0.001). Of new cases diagnosed by RT, 56 (69.1%) were male and 71 (87.7%) were African American (AA) with a mean age of 31.8 years. In RT, median CD4 count and viral load at diagnosis were 279/μL and 4.91 log units, respectively. New diagnoses in SNS were 92.1% male and 100% AA with a mean age of 24 years. In SNS, median CD4 count and viral load were 400/μL and 4.69 log units. Median time to linkage to care was 22 days for RT and 41 days for SNS.
Conclusions: HIV elimination will require identifying approaches that engage individuals in HIV care and prevention. In this analysis, SNS had a higher seropositivity rate, while RT had a faster time to linkage to care. Multiple integrated testing approaches may be necessary to identify individuals with HIV and at risk for HIV. Next steps will be to determine downstream metrics in the continuum of care, including retention in care and viral suppression.

WEPEC1032

PrEP cohort results from MP3 youth combination HIV prevention pilot study

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Background: Young women remain at high risk of HIV in sub-Saharan Africa. PrEP is an effective biomedical intervention for HIV prevention in combination with behavioral and structural interventions, to reduce the risk of HIV among young women. The MP3 youth pilot provides real-world evidence on delivering PrEP to young women in Kenya as part of an age-sex-HIV risk combination HIV prevention package.
Methods: Eligible girls were offered PrEP (TFV-DP) for 12 months. Eligibility included clinical and behavioral criteria (HIV-negative, not-pregnant, 18-24, not enrolled in school, met risk criteria). Enrolment was during mobile events and follow-up was in-person and via SMS survey, monthly for the first 6 months, and 3-monthly for the next 6 months. Adherence was measured by refill visits, self-report, and having >600 fmol/punch of TFV-DP in a dried blood spot (DBS) sample.
Results: Based on eligibility, 40 girls were screened and 28 were enrolled. Participant retention was high in month one (92%), and decreased by month 9 (64%). Ninety-three percent of participants returned at month 9 for endline sample collection. Self-reported adherence was high (87.7%) and congruent with drug levels. Based on DBS drug levels, most girls were adherent (67% (14/21)) at month 2, and even more adherent (78% (7/9)) at month 9. There were no HIV seroconversions and no serious adverse events. Three pregnancies occurred.
Conclusions: PrEP can be initiated in the field after a clinical assessment. Girls need high interaction during follow-up for good retention. The majority of the participants who were non-adherent to PrEP were identified in month one. PrEP may not be the solution for all, but 50% of girls in the study took PrEP consistently, with high levels of adherence. Girls continued to engage in unprotected sex, as evidenced by the pregnancies. Additional research is needed to identify PrEP retention strategies.

WEPEC1033

Participatory package for improving HIV and reproductive health knowledge of HIV-infected and affected adolescents in Myanmar

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Background: Comprehensive knowledge on HIV and reproductive health (RH) is essential for HIV infected and affected adolescents in order to prevent them from adopting RH risk behaviours. Applying participatory package could be more beneficial for young adolescents to learn health knowledge than usual way of providing health education.
Methods: Pre and post intervention design was applied to assess the effectiveness of participatory discussions on HIV and RH among HIV infected and affected adolescents. Participatory package comprising body mapping, two-way discussion using case scenarios and meditation practice were applied during the 3 months intervention period. Baseline and post assessment at 3 months after the intervention were conducted using both quantitative and qualitative research methods.
Results: A total of 80 HIV infected and affected adolescents included in the study. Mean age of the adolescents was 12.8±1.9 years and ranged from 10 to 16 years. Nearly one-fourth (23.7%) of the adolescents were currently out of school, 36.2% stayed with extended family members and 76.2% were either single or double orphans.
At the start of intervention, body mapping exercises were conducted separately for male and female where reproductive organs and puberty changes were discussed. Although the adolescents were aware of puberty changes for their respective gender, most of them could not mention about the opposite gender. Many of them did not know the connection between menstrual cycle and conception. Improvement in knowledge scores on RH regarding puberty changes (2.7±1.3 vs. 4.2±0.7, p<0.05), adolescent pregnancy and consequences (4.0±1.0 vs. 5.0±0.5, p<0.05), contraceptive measures (3.2±1.4 vs. 4.1±0.8, p<0.05) and STI (3.0±1.1 vs. 4.1±0.8, p<0.05) were seen at post-intervention assessment.
Increase in HIV knowledge scores was also seen among the adolescents (4.0±0.9 vs. 5.0±0.5, p<0.05). Overall knowledge scores on RH was significantly increased (18.1±3.4 vs. 22.0±2.3, p<0.001).
Furthermore, majority of the adolescents could apply the knowledge gained from the intervention package and could highlight the adverse consequences of HIV/STI and adolescent pregnancy during group discussion on case scenarios.
Conclusions: Improving in knowledge of RH and HIV/STI among HIV infected and affected young adolescents were achieved by applying such kind of participatory package.

WEPEC1034

Community-led education interventions for human papillomavirus vaccination: a model for future HIV vaccination campaigns?

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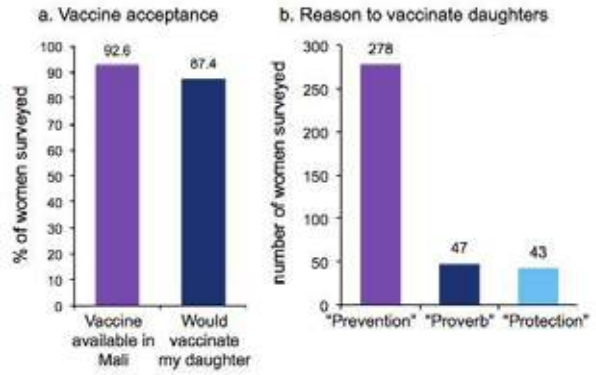
Background: HPV-associated cervical cancer is one of the major causes of morbidity for HIV-infected women, worldwide. Existing HPV vaccines are safe and effective and increasingly accessible in developing world settings. The success of the local community-based intervention on HPV knowledge, desire for CC screening and HPV/CC vaccine uptake described here suggests that a similar approach could be employed for HIV vaccine campaigns.
Methods: Beginning in April 2015, GAIA launched a 6-month campaign using community outreach workers dressed in a West African-style printed cloth with a pattern specifically designed to illustrate the connection between HPV and CC. Outreach workers and midwives led weekly education sessions in 4 neighborhoods and 5 clinics. Women seeking CC screening at the clinics were offered a survey to determine effectiveness of this and other (radio-based) communication methods on knowledge about HPV and CC and willingness to permit their daughters to be vaccinated with HPV vaccine.
Results: 13% of the 500 survey participants knew what HPV was, but 75% knew about CC. 87.4% wanted their daughter HPV/CC vaccinated, when asked why, 84% quoted "Prevention", "Protection", or cited the Malian proverb that was used in the design of the cloth "It is better to prevent than to cure". 38% indicated that their knowledge was derived from clinic-based education sessions, while 8% of participants reported radio and 9% reported national TV ads as a source. During the 6-month campaign, CC screening rates increased 5-fold at the clinics, and a total of 3,271 women received free screenings.



Desire for vaccination is high. (a) Result from a survey where women answered whether they wanted the vaccine available in Mali and if they would vaccinate their daughters. (b) Number of women who wrote in specific reasons for vaccinating their daughters

[Desire for Vaccination]

Conclusions: Community-led education proved more effective than TV and radio outreach. This community-based approach could similarly be applied to HIV prevention, by linking education efforts to testing and treatment services. Community-based education is a successful means of increasing disease awareness and may also improve vaccine coverage when used in conjunction with the introduction of novel vaccines.

WEPEC1035

Risks, benefits and sustained change associated with participating in a social network-based community-level HIV risk reduction intervention for crack users: participant perspectives

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Background: In the realm of HIV prevention, research indicates that HIV risk reduction behavioral interventions that only target individual behavior change have failed to reduce the rate of new HIV infections (Coates, Richter, & Caceres, 2008; Vermund, 2010). Experts have made a call for the implementation and testing of combination biomedical and behavioral multi-level interventions at the level of the community. The objectives of the project are to understand the motivations of research participants to participate in a social network-based community-level combination HIV risk reduction intervention, their experiences as research participants and drawbacks to research participation.
Methods: Eighty participants were recruited to take part in a survey and 20 to take part in a semi-structured interview. The mean age of participants was 33.08 years (SD = 12.83, range 18 to 64 years). The median monthly income reported was $85.00. Approximately 54% did not have a stable residence, 87.2% reported to be heterosexual and 6.4% reported to be HIV Positive. Participants answered a survey after participating in the last session of a risk reduction behavioral intervention. In addition, the survey assessed reactions to research participation, motivations to participate in research, mistrust of research, mistrust of the health care system, health care access, internalized drug use and HIV stigma.
Results: Participants were motivated to participate in the research for a variety of reasons including feeling part of a community and receiving advice from the research staff. Regarding associations, the following correlations were significant: Motivation to participate to help others and substance use (r = .29, p = .01); Positive attitudes towards research and personal satisfaction of participating in the study (r = .40, p = .001); and positive attitudes towards research and HIV and Crack use stigma (r = -.23, p = .01).
Conclusions: Participants were motivated to participate for a variety of reasons, reactions to research participation indicated few drawbacks and benefits at the personal and group level, and importantly, particulars of the research context were significantly associated with motivation, reactions, and effectiveness. The significant associations point to the potential importance of considering the particulars of the research context by researchers and ethics boards.

WEPEC1036

Evaluation of a training aimed at building capacity for outreaching to men who have sex with men and transgender women in Indonesia

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Background: High turnover of outreach workers (OWs) can hamper the effectiveness of HIV outreach programs. Yet this problem might be overcome if programs offer comprehensive, consistent training to new OWs. This study aimed to develop, implement, and evaluate a training package for increasing OWs' knowledge and skills for outreaching to men who have sex with men (MSM) and transgender women.
Methods: Using a one-group pretest-posttest study design, we evaluated an OW-informed training program aimed at helping OWs execute their job responsibilities. We analyzed longitudinal data from 75 OWs from seven Indonesian cities using one-way within-subjects ANOVA to examine the effects of the training program on participants' knowledge and perceived skills over time.
Results: Average overall knowledge among participants increased from pretest to immediate posttest ($p < 0.001$) and from pretest to 2-month posttest ($p < 0.001$), especially in the following knowledge areas: HIV and STIs; condoms and lubricants; sexual and reproductive health and rights; sexual orientation and gender identity and expression; and stages of behavior change. Average overall perceived skills increased significantly from pretest to 2-months posttest ($p=0.018$), especially in the following areas: creating innovative outreach approaches; building effective teamwork; and coordinating with healthcare providers.
Conclusions: This training package increased knowledge and perceived skills among outreach workers, and may help organizations overcome the negative consequences of frequent OW turnover.

WEPEC1037

Stigma, shame and despair as drivers of low HIV testing among transgender women in Lima, Peru

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Background: Globally, transgender women (TW) are 50 times more likely to acquire HIV vs. the general population. In Peru, TW are the population most affected by HIV, with 30% prevalence. Only 50% of TW are aware of their HIV status. Limitations of the Peruvian and Latin American public health system regarding the offer, delivery, and quality of prevention strategies for TW have been previously described. However, there is a to understand the drivers at the individual level that decrease TW´s access to prevention strategies and services.
Methods: Between 2015-2016 theoretical sampling was used to recruit participants to a qualitative study consisting of 15 in-depth interviews and a brief demographic survey. Peers invited participants according to demographic patterns that emerged from the ongoing collected information. Audio files were transcribed verbatim and analyzed using grounded theory, to describe pathways linking TW experiences regarding HIV to the outcome (reduced access to testing).
Results: TW had a mean age of 27 years, 64% had migrated to Lima from the Amazonian region, and 42% reported sex work as their primary source of income. TW conceive HIV as something that will occur at some point in their lives. Through jokes that signal HIV positive peers, messages associated with fear of disease and death are spread within the community. At the same time, the shame about being HIV positive (regarding their families, friends or partners) reduces TW´s agency to decide to get tested and becomes a deterrent for status awareness. Thus, TW don´t internalize existing prevention and treatment options as options available for themselves.
Conclusions: Misinformation linked to HIV stigma, shame and despair are deeply rooted among Peruvian TW, decreasing their ability and willingness to access HIV testing. Peruvian public health prevention strategies designed for key populations are currently dissociated from TW´s understanding of the HIV epidemic. Biomedical interventions with demonstrated efficacy need to urgently add behavioral components (such as HIV stigma reduction) to reach TW and to decrease HIV transmission among this population.

WEPEC1038

Cognitive testing of an instrument to evaluate acceptability and use of PrEP products among women

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Background: As diverse HIV prevention products (i.e., oral pills, vaginal rings, injections and gels) are developed to meet women's needs, a standardized tool could facilitate comparisons of product acceptability and use across geographic, trial and user contexts. We developed a draft instrument to assess product use and trial experience. We conducted a cognitive evaluation of the instrument to assess comprehensibility, salience and completeness of items and domains, and revised the instrument in accordance with our findings.
Methods: We conducted three rounds of interviews in English and isiXhosa among 28 South African women who had recently participated in clinical trials of injectable/oral PrEP and vaginal rings. Participants responded to each question and then described how they determined their response. They were invited to provide alternative wording for questions and response options. Following each round, the study team identified items with low response variability and unclear, embarrassing, or difficult-to-answer questions/response options. The questionnaire was successively modified to reflect participant input until smooth administration was achieved.

Reason for change	n	Examples
Response variability	1	"How easy is the product to use?" → "How difficult..."
Unclear wording		
Question	7	"stigmatized" → "that people looked at you differently"
Responses	8	Rarely, Frequently → Less than half the time, More than half the time
Embarrassment	4	"The last time you had vaginal/anal sex..." → Two separate questions
Difficult to answer		
Question	4	"How many times did you use..." → "How often did you use..."
Responses	4	"Did you use a male/female condom..." Yes/No → Yes, male/Yes, female/No
Administrative	16	Skip patterns, framing throughout

[Table 1. Changes to items]

Results: The final instrument contained 41 items, including five new items that improved construct validity; 22 items were modified for clarity. See Table 1 for types of changes made.
Conclusions: This rapid, low-cost cognitive interview study provided valuable insight into participants' understanding of PrEP acceptability questions, enabling us to further refine the instrument for use in the South African setting. Further validation of the instrument in other geographic settings will improve our ability to examine and compare women's preferences and needs for PrEP across multiple contexts.

WEPEC1039

Integrating microenterprise and behavioral economics for HIV prevention in U.S. urban poor young adults: study design and intervention development of the EMERGE project

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Background: Economic vulnerability contributes to HIV risk among racial and ethnic minorities in the U.S. who are disproportionately infected. Yet, low-income U.S. young adults are largely excluded from HIV-focused economic empowerment initiatives. This presentation discusses the protocol and preliminary findings for study design and intervention development of the EMERGE Project, a microenterprise intervention with integrated behavioral economic text messages to prevent HIV in homeless, out-of-school, and unemployed (HOU) African-American young adults.
Methods: Three formative research methods were used to inform the design and development of the EMERGE project. One, we conducted a systematic review of intervention materials of prior successful HIV-focused microenterprise models, most of which were conducted in low-income countries. This enabled us to identify gaps in study measurement and implementation needs for economics-based prevention science. Secondly, we developed a conceptual framework of the potential effects of an HIV-focused microenterprise intervention, drawing on literature from traditional behavior change models as well as traditional and behavioral economic theory. Thirdly, to include participant perspectives in the study and intervention design, we conducted formative in-depth interviews with HOU youth on perceived gains and losses of engaging in HIV-preventive behaviors using a traditional and behavioral economics perspective.
Results: The EMERGE study will be designed to encourage micro-business start-up, financial self-sufficiency, and positive sexual behaviors to prevent HIV in HOU African-American young adults, aged 18 -24. We will use training workshops, start-up grants, business mentoring, and text messages. An integrated conceptual framework of the hypothesized causal pathways will be presented. We will also discuss the use of text messages to address a current gap in study designs of repeated, longitudinal measurements of sexual and economic outcomes. We will conclude with an overview of the integration of behavioral economic concepts (delay discounting, loss aversion and endowment effect) in HIV-focused microenterprise curriculum and text messages to address study gaps in this area.
Conclusions: The design and implementation of HIV-focused microenterprise interventions, most of which have been conducted in low-income countries, may be informed by experiences working with economically-disadvantaged U.S. youth. Expanding prevention science studies to include behavioral economic theory and text-based longitudinal measurement may also prove beneficial.

WEPEC1040

Research ethics capacity of selected health institutions involved in HIV/AIDS counseling and testing, treatment and research in Nigeria

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Background: Research Ethics Committees (RECs) should review, approve and monitor HIV/AIDS research to ensure the rights, safety and integrity of vulnerable groups are protected. This abstract highlights the institutional capacities for ethical review of and oversight for HIV/AIDS treatment/care interventions and research in Nigeria given: the HIV/AIDS epidemic and increasing HIV/AIDS research and care programmes; that research is one of the major mandates of all Federal and State Ministries of Health (FMoH/SMoH) departments, agencies, and other tertiary health institutions (THIs); and many HIV/AIDS researches target groups vulnerable to abuse and exploitation.
Methods: A cross-sectional study of 41 institutions including FMoH/SMoH, THIs and local government (LGAs) departments of health involved in HIV/AIDS counseling and testing, treatment and research was conducted in 7-randomly selected States and Abuja, the Federal Capital Territory of the country, using semi-structured questionnaires. Data were analysed using SPSS version 20.
Results: Of 41 institutions surveyed, oversight for health research was lacking in many (61.0%) of the institutions. Only 39.0% have established and functional RECs [FMoH (100.0%); States (62.5%); THIs (100.0%); LGAs (4.3%)]. Reasons for non-existent of RECs in the States and LGAs included: perceived non-involvement in research (36.0%); unawareness of need for RECs (20.0%); no provision for RECs (16.0%); and lack of staff with research ethics knowledge/skills (12.0%). Only 1.2% of 8,349 staff of studied institutions have had research ethics training. Such trainings in the 16 established RECs were mostly received at workshops/seminars (68.8%), in-house/hands-on (18.8%), online course (12.5%) and as degree course (12.5%). Only 9 (22.0%) of studied institutions have ever obtained ethical clearance for researches conducted internally. Sources of proposals for ethical review by those having RECs included: researchers/lecturers/health professionals (93.8%); students (68.8%); government agencies (18.8%); development partners (12.5%); and non-government organisations (12.5%).
Conclusions: Most institutions studied lack functional RECs for effective research oversight. The need to address identified capacity gaps is critical in strengthening RECs operations in Nigerian health institutions particularly at State and LGA levels in safeguarding research participants' rights/welfare and harnessing research for evidence-informed policies and sustaining science integrity as well as public confidence in research and standard of care on HIV/AIDS to achieve the 90-90-90 goal.

WEPEC1041

A community-based program to end HIV criminalization, promote public health and defend human rights

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Background: The Supreme Court of Canada requires that people living with HIV (PLHIV) disclose their HIV-positive status to their sexual partners before sexual acts that pose a "realistic possibility" of transmission which means, for the Court, that viral load is low (< 1500 Copies/mL) or undetectable (< 40 Copies/mL) **and** a condom is used. Although there is no evidence that criminalization is effective in preventing transmission, criminal law is often used in the name of public health. Convinced that criminalization could in contrary harm prevention and human rights (Supreme Court decisions are hardly compatible with scientific advances which demonstrate that treatment prevents transmission, increases discrimination against PLHIV and can lead to rights violations), COCQ-SIDA Human Rights Program (the "Program"), in collaboration with other organisations, conduct advocacy strategies to end criminalization.
Methods: The program is part of a Working group on criminalization which includes representatives of Public Health, Justice and Security Departments which advise government in the light of scientific data and legal principles. The program also organises workshops for PLHIV and service providers, plus training for lawyers and prosecutors. Finally, the Program tracks Criminalization cases and provides individual support to defense lawyers and people charged in Quebec.
Results: The Program has written a policy statement on criminalization, which represents COCQ-SIDA member's position and has been calling for prosecutorial guidelines to limit the impact of criminalization. Also, it has participated in three cases at the Supreme Court, given individual support in fifteen files as well as track-

ing all of the various prosecutions throughout Quebec. The Program has given more than one hundred workshops for PLHIV and service providers in addition to two trainings for lawyers and prosecutors.

Conclusions: The Program will continue its different actions and develop new advocacy strategies especially to demonstrate that criminalization could harm prevention and human rights if in contradiction with scientific advances and public health prevention messages. As the impact of the Program's actions on the prosecutions and the decisions reached is difficult to evaluate, the development of a formal evaluation is in process.

WEPEC1042

HIV and access to rights for sub-Saharan immigrants in France: results from the ANRS Parcours Survey

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Background: In France, HIV-positive foreigners can obtain a residence permit for medical reasons (RPHR) (a 1-year renewable permit). However, associations for immigrants' rights have claimed that RPHR holders had more difficulty to access long-term permits than other immigrants although they are entitled to them. In this study we assess whether HIV-positive persons are discriminated in the access to long-term permits because of their holding RPHR.

Methods: We use data from the ANRS Parcours quantitative survey which was led in 2012-2013 among 1705 randomly-sampled Sub-Saharan immigrants living with HIV/Aids or Hepatitis B in Paris area. This biographical survey allows us to reconstitute the entire history of residence permits. With discrete-time logistic models, we study the determinants of the access to long-term permits and the effect of RPHR on this access. Control variables are included to take the instruction level, the reason of migration, the period of arrival and length of stay into account.

Results: The RPHR has a negative impact on the access to long-term residence permits (aOR between 0.15 and 0.27 according to the group, p<0.01), thus RPHR holders are discriminated in their access to long-term permits in France. Additionally, our results reveal an increasing difficulty to access long-term permits since 2005 (aOR= 0.16 [0.07-0.41] for men in the Hepatitis group, same tendency in other groups), reflecting the hardening of migratory policy in the last decade.

	HIV		Hepatitis B	
	Men N=185 (2094 p.years)	Women N=320 (2791 p.years)	Men N=238 (2682 p.years)	Women N=90 (635 p.years)
	aOR[CI95%]	aOR[CI95%]	aOR[CI95%]	aOR[CI95%]
Period of arrival in France				
Before 1996 (ref)	-	-	-	-
1996-2004	0,54 [0,28; 1,04]	0,52 [0,27; 1,00]	0,35 [0,20; 0,61]	0,90 [0,25; 3,32]
2005-2013	0,57 [0,26; 1,26]	0,70 [0,42; 1,18]	0,16 [0,07; 0,41]	0,26 [0,06; 1,17]
Length of stay (t)*	1,06 [0,99; 1,13]	1,07 [1,02; 1;13]	1,05 [0,99; 1,10]	1,16 [1,01; 1,32]
Has had a resident permit for health reasons	0,20 [0,11; 0,36]	0,19 [0,13; 0,28]	0,15 [0,07; 0,32]	0,27 [0,11; 0,66]

[Table 1. Factors associated with the access to 10-year residence or French nationality, year by year, per sex and study group. Odds ratios in bold are significant at 5%. (adjusted on age, region of origin, to have been diagnosed or not, having a child a given year, level of instruction and reason for coming to France) Source : ANRS Parcours Survey 2012-2013]

Conclusions: These results quantitatively measure the discrimination in access to long-term permits towards Sub-Saharan immigrants holding a permit for health-care reasons and they claim for a sustainable legal status for ill foreigners in Europe.

WEPEC1043

Ethical and human rights considerations for inclusion of minors who sell sex in epidemiological, prevention, and other research: evidence from female sex workers in Abidjan, Côte d'Ivoire

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Background: Parental permission may not be appropriate or feasible for research with minors less than 18 years old who sell sex, who are understudied and at high risk for HIV acquisition, particularly in sub-Saharan Africa. Research with adult female sex workers (FSW) who started selling sex as minors can illustrate ethical and human rights issues related to parental consent for epidemiological and prevention research with this vulnerable group.

Methods: FSW >17 years old recruited through respondent-driven sampling in Abidjan, Côte d'Ivoire completed an interviewer-administered survey that included a question asking the age at which they first sold sex. This variable was dichotomized to assess the prevalence and correlates of selling sex under age 18 through multivariable logistic regression using Stata 14/SE. The Johns Hopkins School of Public Health Institutional Review Board and the Comite National d'Ethique et de la Recherche in Côte d'Ivoire approved the study.

Results: Specific numeric results are presented in the tables. Over one quarter (27.9%, 130/466) of participants started selling sex before age 18. Those who sold sex as minors were more likely than those who started as adults to have given birth before age 18 and been orphaned before age 18. They were more likely to have been raped by anyone before age 18 and raped or physically assaulted by a family member ever. Those who sold sex as minors were more likely to report that a parent or family member knew they sold sex but also more likely to report stigma from their family due to selling sex.

Age of start of selling sex	Tested positive for HIV in the study	Gave birth before age 18	One or both parents died before participant was 18 years old	Ever told one or both parents they sold sex	Someone in their family knew they sold sex though they did not voluntarily disclose
Under 18	12.6% (16/127)	33.9% (44/130)	47.3% (61/129)	10.1% (13/129)	45.7% (59/129)
18+	10.4% (34/326)	22.2% (74/333)	32.9% (109/331)	4.2% (14/334)	29.5% (99/336)
Age-Adjusted Odds Ratio (95% Confidence Interval)	2.0 (1.0-4.1)	2.2 (1.4-3.5)	1.7 (1.1-2.5)	2.4 (1.1-5.5)	2.2 (1.4-3.4)

[Correlates of selling sex as a minor in Abidjan]

Age of start of selling sex	Was raped before age 18	Ever told family they were raped (among those raped before age 18)	Was ever raped by family member	Was ever physically assaulted by family member	Ever felt excluded from family gatherings due to selling sex	Ever felt family members spoke badly of them, made discriminatory remarks or gossiped about them because they sold sex
Under 18	43.9% (57/130)	36.8% (21/57)	6.9% (9/130)	17.7% (23/130)	15.4% (20/130)	43.1% (56/130)
18+	6.6% (22/335)	40.9% (9/22)	2.4% (8/336)	9.2% (31/336)	6.0% (20/336)	14.9% (50/336)
Age-Adjusted Odds Ratio (95% Confidence Interval)	10.0 (5.7-17.6)	0.9 (0.3-2.5)	3.5 (1.3-9.7)	2.3 (1.2-4.2)	2.9 (1.5-5.8)	4.5 (2.8-7.3)

[Violence/stigma correlates of selling sex <18]

Conclusions: Women who started selling sex as minors experienced substantial health and social risks for HIV acquisition before age 18. Obtaining parental consent for participation in research about selling sex under age 18 for this population would likely be unreasonable due to parents' death, lack of disclosure of sexual violence or sex work, and violence or stigma from family.

WEPEC1044

"I think the parent should be there because no one was born alone": Kenyan adolescents' perspectives on parental involvement in HIV research

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Background: AIDS is the leading cause of death among African adolescents. Yet there are substantial gaps in knowledge of how to curb the epidemic among adolescents, in part because they are persistently underrepresented in HIV research. Further, ethical guidance for conducting research among youth under 18 is lacking. One ethical issue is the degree to which parents should be involved in the research process. Much of the existing discourse is theoretical and focuses on negative consequences of parental involvement, particularly in sexual health research. We use empirical data to describe Kenyan adolescents' perspectives on parental involvement in consent and disclosure of HIV test results in a research study context.
Methods: We conducted two rounds of focus group discussions with 40 adolescents (15-19 years old) in Western Kenya. Half of the adolescents were female and one-fifth identified as HIV-positive. We used semi-structured guides to ask hypothetical questions about minor adolescent participation in HIV research and parental involvement. We analyzed data using codes and matrices.
Results: Kenyan adolescents were largely in favor of having their parents involved during the research process. More than half of all participants, and a majority of HIV-positive participants, who spoke about permission felt minors must seek their parents' permission to participate in HIV research. Further, an overwhelming majority of adolescents felt that parents of minors should be present for part or all of HIV testing and disclosure, even among those who felt conflicted about or against mandatory parental permission for minors. Youth primarily wanted to have their parents present during HIV testing and disclosure because they wanted their support. Such support was perceived as particularly important for youth receiving an HIV-positive diagnosis.
Conclusions: Our findings depart from existing discourse and provide an important contextualized perspective from Kenyan youth on benefits of parental involvement. From this perspective, involvement of parents in research extends beyond obtaining their permission to participate to providing essential support for youth, regardless of HIV status, during and beyond the course of research. Ethical guidelines that prioritize adolescent autonomy in research must take into account reasons to involve parents considered important by adolescents themselves, particularly in low-resource settings.

WEPEC1045

Ignoring the ban: blood donation among young adult MSM at risk for HIV

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Background: In the US, men who have sex with men (MSM) were banned from donating blood from 1983 to 2015 in effort to prevent transfusion transmitted HIV infection. In December 2015, the US FDA replaced the ban, permitting MSM to donate if they reported no sex with another man in the prior year. Qualitative evidence suggests that MSM who choose to donate blood despite the ban likely base this decision on self-perceived risk, although data on this topic are limited. We aimed to identify blood donation practices and their relationship with HIV risk in a population of young adult MSM (YMSM) believed to be at higher risk for HIV who previously donated blood.
Methods: In 2014, 18-24-year-old black, Hispanic, and white, HIV-negative YMSM were recruited from across the US through multiple social media platforms to complete an online survey. The survey queried about blood donation history, HIV testing history, self-perceived HIV risk, and sexual behavior, particularly condomless anal intercourse (CAI). Among YMSM who ever donated blood, we conducted a multivariable logistic regression analysis estimating the odds of donating blood in the past year, adjusting for age, race/ethnicity, geographic region, education, and if they had a primary care provider.
Results:

	Total (n=1,093) aOR (95% CI)	Black (n=195) aOR (95% CI)	Hispanic (n=385) aOR (95% CI)	White (n=513) aOR (95% CI)
Never had CAI	1.84 (1.24-2.73)	2.81 (1.16-6.85)	3.41 (1.65-7.05)	1.20 (0.69-2.09)
No CAI in the last 12 months	1.16 (0.84-1.60)	1.74 (0.82-3.69)	1.49 (0.86-2.57)	0.93 (0.58-1.49)
Perceived likelihood of having HIV "Not possible at all"	1.57 (1.14-2.16)	1.61 (0.74-3.50)	1.80 (1.07-3.01)	1.55 (0.97-2.49)
Had HIV test in last 12 months	1.23 (0.90-1.67)	1.59 (0.68-3.71)	1.45 (0.86-2.43)	0.97 (0.63-1.48)

[Adjusted odds of donating blood in the past year]

Of the 2,261 YMSM surveyed (19% black, 36% Hispanic, 45% white), 49% had previously donated blood, and 13% had donated blood within the past year. Among YMSM who ever donated blood, past year blood donation was more likely among those who never had CAI and had a lower perceived likelihood of being HIV infected. Past year blood donation was related to ever having had CAI, self-perceived HIV infection likelihood, and past year HIV testing for black and Hispanic but not white YMSM.
Conclusions: Black, Hispanic and white YMSM donated blood with a surprisingly high frequency despite the ban in the US. Although the choice to donate for some YMSM was congruent with HIV risk, white YMSM in particular appeared to donate despite self-perceived HIV risk, sexual behavior, and HIV testing utilization.

WEPEC1046

'From one pill a day to no pill a day': perceptions of HIV cure research among people living with HIV: qualitative findings from focus groups in 4 U.S. cities

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Background: Biomedical HIV cure research is advancing in the United States and elsewhere around the world. Little is known, however, about perceptions and acceptability of various HIV cure research strategies or willingness to participate in studies to test these strategies among people living with HIV.
Methods: We undertook focus group discussions with people living with HIV at four (4) Martin Delaney collaboratory HIV cure clinical research sites in the United States: Seattle, WA; Los Angeles, CA; San Diego, CA and Durham, NC. We conducted 10 focus group discussions January - June 2016 and subsequent thematic analysis.
Results: 76 individuals (60.5% males, 35.5% females, 2.6% transgendered individuals, 1.3% non-binary/queer) participated. The sample was ethnically diverse (40.8% Caucasian/White, 39.5% African American/Black, 9.2% Hispanic/Hispanic descent, 10.5% other). Main narratives centered on meanings of HIV cure (e.g. not having to take medications and not being able to infect sexual partners) and deterrents and motivators to participation in HIV cure research. There was a preference for a sterilizing cure (eradication) compared to a functional cure (remission) across all 4 sites. Participants expressed anxiety with interrupting HIV medication in the context of HIV cure research and preferred knowing that they were controlling the virus at all times. Further, there were concerns about potential clinical side effects of HIV cure strategies. Participants who experienced several HIV treatment regimens to become undetectable appeared less willing to take part in risky cure studies. One thread that emerged was the impact of stigma, and the belief that a sterilizing cure would be the only way to eradicate stigma. Additional narratives focused on expectations of HIV cure biomedical investigators, recruitment of special populations - including women, and practical issues involved in the conduct of HIV cure studies. Some anxieties were expressed around being cured, including losing disability insurance (financial burden). The need for better education around HIV cure research emerged as a strong theme.
Conclusions: This community participatory project begins to fill a gap around perceptions of HIV cure research among people living with HIV. Qualitative results can help inform a patient-centered HIV cure research agenda.

WEPEC1047

What would an HIV cure mean to you? Ascribing meaning through an HIV cure tree

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Background: Interest and investment in HIV cure research has been increasing since the apparent cure of Timothy Brown 10 years ago through a bone marrow transplant from a donor homologous for the CCR5-delta 32 mutation. While his experience has not yet been replicated and is still not fully understood, it spawned the burgeoning field of HIV cure research. An HIV cure holds the possibility of being transformative societally as well as medically. Little has been explored about the meaning and value individuals ascribe to a cure.
Methods: Volunteers from the Community Advisory Board (CAB) of the Martin Delaney Collaboratory (MDC), a US National Institutes of Health initiative funding multiple HIV cure research collaboratories created an "HIV Cure Tree" at the 2016 IAS Conference Global Village in Durban, South Africa. MDC CAB volunteers asked a convenience sample of Global Village attendees from around the world to write on paper leaves their answers to the question, "What would an HIV Cure Mean to You?" Respondents included clinicians, researchers, people living with HIV, activists, and others. Leaves were later sorted into themes.
Results: We collected 244 leaves. The two dominant themes that emerged were freedom and hope. Freedom was a stand-alone concept, and also included multiple sub-themes, such as freedom from taking medication, freedom from stigma, freedom from worry, and freedom to enjoy making love. Other significant themes clustered around personal meanings, such as, "My precious time with my children-LIFE," and "All my dreams come true," while others were more societally focused, such as, "An AIDS-free generation" and, "A world full of happy people." Some saw a cure as "Victory" or an end, while others saw it as a new beginning. Other significant themes that emerged included no more stigma, happiness, fulfillment, a better future, ending suffering, love, prosperity and relief.
Conclusions: People see an HIV cure as liberating for both individuals and societies. Many perceive it as the best route to ending stigma and a key element contributing to ending AIDS. Cultural context contributes to the meanings people ascribe to a cure. There is significant global support for continuing to search for an HIV cure.

WEPEC1048

Adolescent girls´ understanding of consent and views on waiver of parental consent regarding HIV self-testing

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Background: Adolescent girls (AGs) aged <18 years are often omitted from biomedical research because of requirements for parental consent. Thus, there is paucity of knowledge regarding whether interventions that are effective in adult women also work for AGs. We assessed if AGs ages 15-17 years can understand a consent document and explored their views regarding waiver of parental consent.
Methods: We conducted a mixed-methods study with AGs accessing HIV testing services in western Kenya. After enrollment, a study staff administered a second consent for a planned study in which AGs would be offered multiple HIV self-tests for use with their sexual partners. A second staff asked participants 22 multiple-choice questions to assess understanding of various aspects of the second consent, including: purpose, eligibility, procedures, risks and benefits, confidentiality, voluntarism, and rights. We also used semi-structured interviews to explore participant´s views on waiver of parental consent. Participants' response were audio-taped, coded, and analyzed.
Results: We interviewed 33 sexually-active HIV-negative AGs. Sixteen had some primary education and 17 had some secondary education. The proportion of participants who understood each question was ≤25% for 2 questions, 26-50% for 3 questions, 51-75% for 10 questions, >75% for 7 questions. Questions on ,who to contact if rights are violated' and ,IRB with ethical oversight over the study' scored lowest while sample size, age eligibility, voluntary participation, benefits, and reasons for contacting researchers scored highest. Thirty-two participants preferred the consent document read to them, and most felt that parental consent should not be waived when the study is about HIV generally (77%), HIV testing (83%), STIs (77%), pregnancy (83%), contraceptives (67%) and ART (90%). However, when informed that the consent document for studies on these topics could mean that their parents learn of their sexual activity, 64% preferred waiver of parental consent and another 31% preferred that the mother should provide consent.
Conclusions: AGs can understand consent documents fairly well and believe parental consent should not be a requisite for their participation in research if their sexual behavior could be involuntarily disclosed. There is need to also get views from ethics bodies and parents regarding waiver of parental consent.

WEPEC1049

Characterizing the role of gender-based violence and mental health in mediating use of condoms among female sex workers in Cameroon

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Background: Female sex workers (FSWs) face high burdens of gender-based violence (GBV) and associated HIV risk globally. Depression is consistently associated with both GBV and HIV risk behaviors in other populations, yet remains poorly understood or researched among FSWs. We examined the relationship between GBV and mental health for FSWs, and how the relationship may mediate consistent condom use with clients.
Methods: We analyzed data from Cameroon-based FSWs (n=2,265), recruited via respondent-driven sampling across five sites in 2016. Eligible participants were aged 18 and over, and had to report having sold sex within the past year. The women were given tablet-based structured interviews, which included questions about violence, condom use, and the Patient Health Questionnaire 9 (PHQ9) to screen for depression. Survey respondents were linked to HIV tests conducted on site.
Results: HIV prevalence was 24% (548/2,250) and inconsistent condom use with clients was 28% (508/1,841). Violence was prevalent; 25% (561/2,261) reported physical violence and 33% (739/2,263) reported sexual violence. Forty-five percent (934/2,059) of respondents scored a 5 or higher on the PHQ9 scale, signaling some level of depression. Sexual violence was significantly associated with inconsistent condom use among both casual (p=0.009) and regular clients (p=0.000). The PHQ9 depression levels were significantly associated with condom use, with higher PHQ9 depression scores associated with inconsistent condom use (regular clients: p=0.007, casual clients p=0.002). PHQ9 depression levels were significantly inversely associated with experiencing sexual violence (p=0.000).

	Total, N/N	Total, %	inconsistent condom use, reg client, N/N	inconsistent condom use, reg client, %	Chi squared p-value	inconsistent condom use, casual client, N/N	inconsistent condom use, casual client, %	Chi squared p-value
PHQ9 Depression Score								
No depression (0-4)	1125/2059	54.64	183/926	19.76	0.007	139/1008	13.79	0.002
Mild (5-9)	678/2059	32.93	136/606	22.44		96/621	15.46	
Moderate (10-14)	181/2059	8.79	33/142	23.24		42/166	25.30	
Moderately Severe (15-19)	59/2059	2.87	21/55	38.18		12/55	21.82	
Severe (20-27)	16/2059	0.78	6/15	40.00		4/15	26.67	
Violence								
Experience of physical violence	561/2261	24.81	120/506	23.72	0.204	92/537	17.13	0.349
Experience of sexual violence	739/2263	32.66	179/659	27.16	0.000	129/686	18.80	0.009

[Condom Use, Violence, and Depression Among FSW]

Conclusions: Both sexual violence and depression are prevalent and shape condom use with clients among FSW in Cameroon. The large proportion of FSW with reported depression is highly connected both to sexual violence and inconsistent condom use. This highlights the need for interventions to address the structural- and individual-level mental and physical impacts of GBV for FSWs to reduce HIV acquisition and transmission among FSW.

WEPEC1050

A videogame intervention for sexual risk reduction in minority adolescents: a randomised controlled trial

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Background: HIV disproportionately impacts minority youth. Interventions to decrease HIV sexual risk are needed. We hypothesized that an engaging theory-based videogame intervention, would improve sexual health outcomes in adolescents.
Methods: Randomised controlled trial in 12 community programs. Participants were randomised 1:1 to up to 16 hours of the intervention videogame or attention/time control videogames over six weeks. Assessments were conducted at six weeks, three, six and 12 months. Primary outcome was delay of initiation of vaginal/anal intercourse. Secondary outcomes included delay of initiation of sexual activities (composite of vaginal/anal intercourse, oral sex, and touching), sexual health attitudes, knowledge, and intentions. We examined outcomes by gender and age. Analyses of 24-month outcomes are underway and will be presented.
Results: Between February 26, 2013 and May 16, 2014, we randomised 333 participants to play intervention (n=166) or control games (n=167): 90% were racial/ethnic minorities, 53% were boys, and the mean age was 13 years. At 12 months: for the 258 (84·6%) participants with available data: 122/129 (94·6%) in the intervention group vs. 123/129 (95·4%) in the control group delayed the initiation of intercourse (p > 0·99). Eighty-seven percent of participants in both groups delayed the initiation of sexual activities (p > 0·99). We have just completed 24-month follow-up and analyses are underway. This longer duration of follow-up in this age group may demonstrate higher event rates in the initiation of sex. Over 12 months, the intervention group, compared to the control group, demonstrated: improved sexual health attitudes overall (p=0·04), in boys (p=0·01) but not in girls (p=0·63) (treatment by gender interaction, p=0·09), in younger participants (p=0·009) but not in older participants (p=0·97) (treatment by age interaction, p=0·06); increased sexual health knowledge overall (p < 0·001), in boys, girls, younger (≤12 years) and older (> 12 years) participants (p < 0·01 for all comparisons); no differences in intentions to delay the initiation of intercourse or other sexual activities between the two groups (p= 0·59).
Conclusions: A videogame intervention improves sexual health attitudes and knowledge in minority adolescents.

WEPEC1051

Impact of integrating evidence-based behavioral interventions (EBIs) and economic empowerment into HIV/STI prevention programs for slum-dwelling adolescent girls and young women in Kenya

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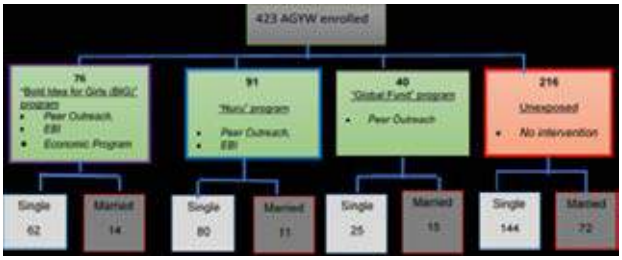
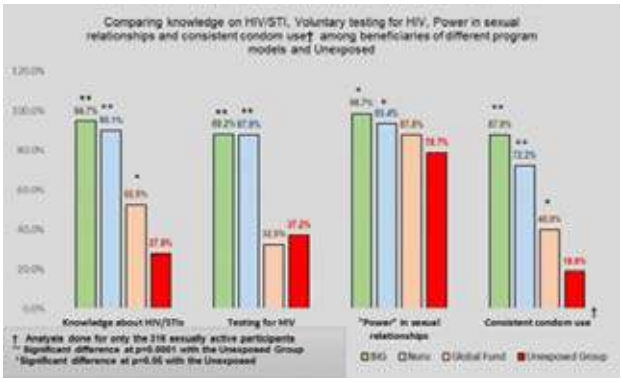
Background: Slum-dwelling Adolescent Girls and Young Women (AGYW) are highly vulnerable to HIV infection. Almost 7,000 new infections occur among AGYW in Eastern and Southern Africa. There is inadequate evidence on which health promotion models elicit sustainability of required behaviors. The objective of the study was to assess Knowledge, Attitude and Behavior (KAB) of AGYW residing in Mukuru Slums, Nairobi who had previously (2011-2014) participated in three different HIV/STI prevention programs. The study shows the potential sustainability of the interventions after three years.
Methods: A total of 423 AGYW were identified through stratified random sampling and enrolled into this retrospective cohort study. These included 207 former beneficiaries of the three different program models and another 216 who had not participated in any HIV Prevention program. The figure below shows those enrolled and the components of the different program models.



[Number of AGYW Enrolled]



[Comparing KAB aspects among programs' beneficiaries]

Conclusions: Integrating EBIs and economic empowerment aspects in HIV/STI prevention programs for slum dwelling AGYW seems to have efficacy in sustaining knowledge, attitude and protective behaviors.

WEPEC1052

"It's almost like gay sex doesn't exist." The nature of sex communication according to sexual minority adolescent males

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Background: Forty years of research on sex communication between parents and children in the home has led to empirically-based HIV and STI prevention interventions. Minimal research on this process prevents the formulation of similar interventions that would benefit adolescents with same-sex attractions, behaviors and identities. We sought to describe the perspectives of gay, bisexual, and queer (GBQ) adolescent sons on how sex communication with parents was initiated and their reactions to these conversations. These data will be inform future home-based HIV and STI intervention work for this population.
Methods: We conducted 30 semi-structured interviews with 15-20 year-old male youth from September 2015 to March 2016. Our participants included 23 gay, 5 bisexual, and 2 queer males. The transcribed data were analyzed iteratively on NVivo11 using standard thematic and content analysis techniques.
Results: We identified four central themes focused on how sex communication was experienced by these adolescent males: Prompts and triggers (when sons initiate the conversations, when parents observe signs of sons' physical maturation or social milestones, when family stories are being shared, and talks that evolve from teachable moments), parents' approaches (informing, lecturing, bargaining or joking), sons' reactions (compliant, mortified, dismissive, isolated, or offended), and the underlying functions they assigned to sex communication (to seek answers to questions of a sexual nature, to gauge parental opinion and acceptance, to keep parents informed, to educate parents, and to maintain a relationship for future support). We describe similarities to sex communication with mostly heterosexual samples and highlight intervention points for the sexuality-sensitive education of sons with same-sex attractions, behaviors, and identities.
Conclusions: Gay, bisexual, and queer males' informational needs about sex are not adequately addressed in the home. Parents are in an opportune position to provide sexuality-sensitive information because of the premium sons place in the parent-child relationship. Parents can be sources of reliable sexual health information and may be leveraged for future HIV/STI risk reduction interventions.

WEPEC1053

The feasibility and acceptability of a technology-based HIV preventive intervention in an urban youth-centered community health clinic in the United States

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Background: HIV among youth remains a significant public health concern in the United States. HIV testing among adolescents is underutilized despite federal recommendations to screen adolescents for HIV infection and risk behaviors. Efficacious technology-based interventions aimed at improving HIV testing and preventing and reducing HIV risk behaviors among adolescents in clinic settings are limited. To fill this gap, we developed Storytelling 4 Empowerment (S4E), a theory-driven, culturally congruent, technology-based HIV preventive mobile application (app) for delivery in the clinic setting.
Methods: Employing a multi-method research design, we examined the feasibility and acceptability of S4E among clinicians and adolescents in an urban youth-centered community health clinic. S4E aimed to improve clinician-adolescent HIV communication and self-efficacy. Once adolescents completed the intervention, clinicians were provided adolescent risk behavior scores via the S4E app, aimed at facilitating adolescent-clinician HIV risk communication, and link adolescents to care and prevention services. We recruited 5 clinicians and 20 adolescents from an urban youth-centered community clinic to test the feasibility and acceptability of the intervention. Quantitative data were analyzed by computing mean scores and qualitative analyses followed the tenets of content analysis.
Results: Among eligible participants, 86.9% of adolescents and 85.7% of clinicians enrolled in the study, suggesting the feasibility of recruiting participants from the targeted clinic. Among the clinicians, 83% identified as non-Hispanic white and 66.7% female. Among the adolescents, 70% identified as non-Hispanic white, 30% African American, 50% female, and the mean age was 19.6 (SD=1.5, Range= 16-21). Findings indicate the participants' high acceptability of S4E (CSQ-8 mean sum= 25.2, SD= 4.8, Range= 17-29). Qualitative themes revealed that participants perceived the S4E app prepared them to discuss HIV risk and reduced their feelings of discomfort associated with initiating HIV communication, facilitated targeted and tailored HIV prevention services, and assisted with linkage to care.
Conclusions: Findings demonstrate the feasibility and acceptability of S4E in an urban community-based clinic setting. A next important step is to examine its efficacy in improving HIV testing and preventing and reducing risk behaviors among adolescents.

WEPEC1054

Participants' perceptions of the extended repeat HIV testing and enhanced counseling (ERHTEC) intervention for primary HIV prevention of pregnant and lactating women in Uganda

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Background: The ‚Primary HIV Prevention among Pregnant and Lactating Ugandan Women' (PRIMAL) study aimed to assess an extended HIV testing and enhanced counseling (EHRTEC) strategy among 820 HIV-negative pregnant and lactating women aged 18 to 45 years and 410 of their male partners to address the first pillar of the World Health Organization global strategy for the prevention of mother-to-child HIV transmission (PMTCT).
Methods: We carried out qualitative research to evaluate the acceptability of ERHTEC and understand its effect on risk reduction, couple communication and support. We conducted 6 focus group discussions and 44 key informant interviews involving health care providers, pregnant/lactating women and their male partners in Mulago, Uganda's National Referral Hospital in urban Kampala, and in a rural hospital in Kitgum, Northern Uganda between July and September 2015. We used Nvivo10 for coding and thematic analysis.
Results: In both sites, participants mentioned that counselling had been helpful in risk reduction. The majority of participants enrolled as couples felt counselling had improved understanding, faithfulness, and support within their relationship. Another counselling benefit frequently mentioned was improvement of couple communication and negotiation for decision making for daily matters as well as sexual issues, family planning and condom use. Most participants felt the information provided on HIV prevention, family planning, and nutrition had supported them to remain HIV-negative and take better care of their children. Participants appreciated the combination of regular HIV testing and counselling, and were helped by the frequent reminders to come for quarterly follow-up. Some participants explained community members approached them for advice on HIV prevention and marital problems. They stressed the importance of providing counselling to all couples, and providing these services at village level. In Kitgum, participants felt couple counselling was the best way to address risk-reduction. In Kampala, participants recommended individual sessions in addition to couple counselling, in order to address personal challenges and concerns.
Conclusions: This study shows how an enhanced repeat testing and counselling PMTCT program with a focus on HIV risk reduction, couple communication, family planning and nutrition can support risk reduction, and improve support, communication and decision-making about sexual and reproductive health in HIV-uninfected mothers.

WEPEC1055

The effect of schooling on partner age difference and number of sexual partners among young women in rural South Africa enrolled in HPTN 068

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Background: Attending school may prevent sexually transmitted infections among young women as they may belong to safer sexual networks, manifested by fewer sex partners who are closer to their own age. In this paper we investigate this hypothesis using longitudinal sexual behavior data on young women.
Methods: We used data from the HIV Prevention Trials Network (HPTN) 068 randomized controlled trial in Agincourt, South Africa. We used "having a partner five or more years older" and "number of partners in the last 12 months" as outcomes. We measured the association of these outcomes with three different schooling situations: women attending >=80% of school days versus < 80%; women in school versus women who had dropped out; and women ever repeating a grade versus never repeating. We used inverse probability of exposure weighted Poisson models with generalized estimating equations. For the binary outcome, a Poisson model was used to approximate the binomial model.
Results: Of the 2,360 young women age 13 to 23 with a follow-up visit, 5.4% (N=270) attended less than 80% of school days and 3.8% (N=190) dropped out of school over the study period. Young women with low attendance had a higher one-year risk of having a much older partner (RD: 13.0%; 95% CI: 6.3%, 19.7%) and more partners (RD: 18.1%; 95% CI: 7.2%, 29.1%) than women with high attendance. Young women who dropped out of school had a higher risk of having a much older partner (RD: 13.7%; 95% CI: 5.1%, 22.3%) and more partners (RD: 36.1; 95% CI: 21.4%, 50.9%). Grade repetition was not associated with either behavior.
Conclusions: Young women who stay in school or attend more days of school have partners closer to their own age and fewer partners than young women who attend less school or drop out. The lack of association with grade repetition suggests that the effect of school on sexual behaviors is more strongly related with frequency of time spent in a school environment than with educational success.

WEPEC1056

Adapting an evidence-based HIV prevention curriculum for native american adolescents

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Background: Native American (Native) adolescents are at risk for HIV infection attributed to various biological, economic, and social factors, and high-risk behavioral factors. The lack of substantive and culturally appropriate HIV evidence-based prevention interventions for Native youth is evident within the literature. Effective

scientific prevention methods require tailoring fundamental interventions to respond to both immediate risks and underlying causes of vulnerability for Native adolescents. This article presents a feasibility study that adapted and modeled an existing HIV evidence-based preventive intervention for Native adolescents.
Methods: Becoming A Responsible Teen (BART) is a community-level, education and behavior skills training designed to reduce risky sexual behaviors and improve safer sex skills among African American adolescents. This adolescent HIV evidence-based prevention curriculum; was adapted in three phases for Native adolescents:
1) ascertaining feedback and guidance from a Native Advisory Board (N=5 experts);
2) modifying the BART curriculum and creating an adolescent workbook to be culturally appropriate and consistent with Native ideologies, language, symbols, practices, and pedagogy; and
3) conducting the BART prevention curriculum to test for both efficacy and effectiveness, with 14 urban inter-tribal Native adolescents.
Examination of acceptability and cultural congruence between the adapted intervention and the youth's culture was captured with Likert-scale ratings and qualitative focus group narratives. A pre-post HIV knowledge survey was conducted to measure HIV knowledge gains.
Results: The adolescents consistently rated each session has highly acceptable. There was difference in pre-survey (M=13.93, SD=3.08) and post-survey (M=17.14, SD=2.25) conditions; t(13) = 4.166, p <0.0005. Qualitatively respondents preferred the Native cultural content and activities as a curriculum format in assisting and clarifying their individual HIV knowledge, sexual ideals, and decision-making practices.
Conclusions: Few HIV evidence-based prevention feasibility studies have been developed, adapted, and/or evaluated for Native adolescents. This study demonstrates that an adapted BART curriculum would be culturally appropriate for dissemination or implementation beyond the population and modalities in which it was originally created and studied.

WEPEC1057

Sharing circles with indigenous women: understanding perceptions of HIV to inform the scale-up of behavioural change strategies in Quebec, Canada

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Background: As a result of historical and structural processes, Canadian Indigenous women are disproportionally affected by the HIV epidemic. Although Indigenous women (First Nations, Métis, Inuit), are 4.3% of the Canadian female population, they represent 30.6% of new female diagnosis. Counter to national trends, available data suggests that the HIV-epidemic among Indigenous women in Quebec is not as widespread.
This research was undertaken to better understand Quebec Indigenous women's perceptions of HIV, and prevention and care services. The overall goal is to identify innovative, culturally safe behavioural intervention for HIV prevention specific to Indigenous women in Quebec.
Methods: This research is embedded within the Canadian HIV Women's Sexual and Reproductive Health Cohort Study - Prioritizing the Health Needs of Positive Aboriginal Women (CHIWOS-PAW). From December 2015 to December 2016, four full-day research retreats were conducted with 14 Indigenous women, led by Indigenous researchers in Quebec. Drawing on Indigenous Methodologies, and under the guidance of an Indigenous Elder, sharing circles, reproductive justice-based sexual health workshops, and arts-based behavioural change strategies were conducted. Research participants then collaboratively interpreted and confirmed the findings in an interactive closing circle.
Results: Fourteen Indigenous women, 24-74 years of age, participated. Inuit, Métis and First Nations were represented from 12 different communities, and seven distinct languages were spoken. Self-reported HIV-status included HIV-positive, HIV-negative, and HIV-status unknown. In the sharing circles, emphasis was placed on root causes of HIV, including gendered violence, unequal relationships, and intergenerational trauma. Recommendations for improving prevention and care included ensuring safe spaces for women to meet, share, and learn from one another, with peer and youth led programming. Strategies to ensure confidentiality within health care settings, and when seeking risk reduction services should be improved. Education regarding HIV must also be prioritized to communicate transmission risks, to dispel persisting HIV misconceptions, and to reduce stigma and discrimination. During the circles, women also shared self-care strategies and tools for building self-esteem as part of overall health.
Conclusions: Peer-led design and delivery of HIV-prevention and care programs are key to ensuring a response that meets Indigenous women's needs, including addressing structural factors which impact their health and healthcare seeking.

WEPEC1058

Unsuccessful behavioral risk reduction contributed to HIV seroconversion as well as high STI incidence among newly diagnosed HIV-positive MSM and TG in a facility-based Test and Treat cohort in Thailand

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Background: Facility-based Test and Treat model for Thai MSM and TG has proved successful in identifying and linking new HIV cases to ART. However, long-term behavioral risk patterns among these HIV-negative and HIV-positive MSM and TG are unknown.
Methods: Thai MSM and TG aged ≥18 years were recruited through 4 clinics/hospitals. Self-administered questionnaires and HIV testing were performed at baseline and every 6 months. Syphilis, gonorrhea and chlamydia were screened at baseline and every 12 months. We studied risk behaviors over a 24-month period among participants diagnosed HIV-positive, seroconverted, or remained HIV-negative. Factors were modeled by Cox proportional hazard for HIV incidence.
Results: Of 696 MSM and 112 TG enrolled, HIV prevalence was 16.4% and HIV incidence was 5.3 per 100 person-years. 85% initiated ART within a median (IQR) time of 8(4-22) days. HIV RNA was < 40 copies/mL in 80.4%, 93.4%, 94.8% and 97.2% at months 6, 12, 18 and 24 after ART, respectively.
Newly diagnosed HIV-positive participants significantly reduced, from baseline to months 6, 12, 18 and 24, unprotected sex (76.4% to17.3%, 14.0%, 13.5%, 15.1%, p<0.001), having multiple partners (60.9% to32.3%, 31.2%, 34.0%, 31.4%, p< 0.001), and amphetamine-type stimulants (ATS) use (10.9% to5.8%, 2.0%, 2.1%, 1.5%, p<0.001). Participants who remained HIV-negative also reduced unprotected sex (50.5% to 34.7%, 32.9%, 35.4%, 29.2%, p<0.001) although not to the level of HIV-positive participants. HIV seroconverters, however, remained practicing unprotected sex (79.1% to 62.8%) and having multiple partners (61.9% to 69.7%) from baseline until seroconverted, and increased ATS use at seroconversion (7.0% to 11.6%). Unprotected sex (HR 3.15, 95%CI 1.31-7.57, p=0.01) and having baseline STIs (HR 2.08, 95%CI 1.10-3.91, p=0.02) increased risk of HIV seroconversion.
HIV-positive participants had higher STI incidence (per 100 person-years) than HIV-negative participants: syphilis (13.4 vs. 1.6, p<0.001), gonorrhea (16.4 vs. 6.0, p<0.001), and chlamydia (18.1 vs. 5.7, p<0.001).
Conclusions: Behavioral risk reduction was not always successful. Continued risks contributed to HIV seroconversion and STI incidence which could affect the ending AIDS goal. Integrating effective use of pre- and post-exposure prophylaxis and regular STI screening into programs for populations with high-risk behaviors are urgently needed.

WEPEC1059

Addressing issues impacting safe and consistent use of an HIV prevention intervention: development of a social benefits-harms (SBH) tool

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Background: In HIV prevention trials, male partners have influenced women's ability to safely and consistently adhere to trial products, including vaginal rings as demonstrated in the MTN 020/ASPIRE trial. Validated scales can be useful tools to systematically measure complex constructs, such as those related to male partner engagement. Building onto an open-label microbicide vaginal ring trial called MTN025/ HOPE, the CHARISMA intervention tailors HIV prevention and em-

powerment counseling to study participants' relationship contexts and monitors the social benefits and harms (SBH) of the intervention on women's agency to use microbicides. Part of the intervention involved development of a SBH tool.
Methods: Based on a literature review and conceptual framework, we identified and refined 127 potential items representing intimate partner violence, agency and social support. A structured survey (n=309), including SBH items among other variables was administered to former microbicide trial- and non-trial participants. We conducted exploratory factor analyses (EFA), examining solutions for three to nine factors, to identify a reduced set of constructs and items to screen women who might experience social harms or benefits related to vaginal ring use. We examined associations with other survey variables to assess content and construct validity.
Results: Several EFA solutions produced conceptually relevant factors with good to strong reliability. We retained five constructs with particular theoretical relevance for the tool. They included:
Traditional Values (13 items, α=.84);
Partner Support (10 items, α=.81);
Partner Abuse and Control (9 items, α=.81);
Partner Resistance to HIV Prevention (5 items, α=.80);
and HIV Prevention Readiness (5 items, α=.68).
The SBH tool is currently being piloted at the Johannesburg MTN 025/ HOPE site; after further validation, rollout to other African sites is anticipated. Administered electronically, women whose scores indicate low partner support and/or high resistance or abuse are identified as potential recipients of tailored counselling and/or referrals.
Conclusions: Our brief, electronically-administered tool assists trial providers to assess women's perceptions of partner support or opposition to using HIV prevention products, including the risk of IPV. Beyond trial settings, such a tool could assist clinic staff to efficiently tailor risk reduction, empowerment and adherence counseling for microbicides and other services.

Sustainable Financing

WEPED1345

The cost and effectiveness of achieving universal HIV treatment coverage in Africa: a modeling analysis of scaling up "treat all" in Zambia

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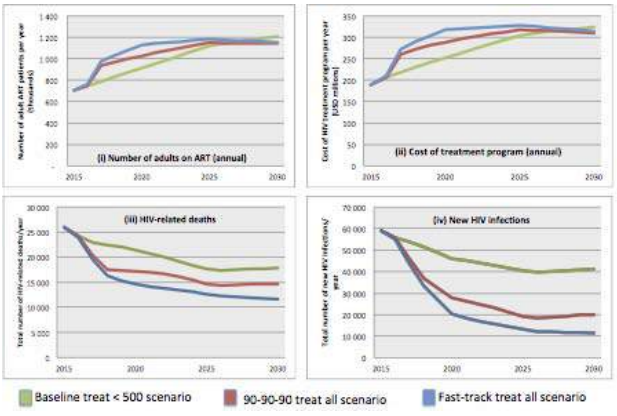
Background: To achieve "90-90-90" targets, many countries have adopted "treat all" with no eligibility threshold for ART. We modeled the impact of adopting treat all in Zambia on total cost and HIV incidence and mortality, to inform policy choices and resource mobilization.
Methods: We used existing Zambian Spectrum AIM and GOALS models and new data on HIV program coverage, ART effectiveness, and current local unit costs to estimate the impact and costs of implementing treat all under three scale-up scenarios:
(1) "baseline" (500 CD4 threshold for ART eligibility, treatment coverage of 70% by 2020 and 82% by 2030);
(2) "90-90-90" (treat all, reaching 81% in 2020 and 90% in 2030);
(3) "Fast Track" (treat all, reaching 90% in 2020 and 95% in 2030, with scaled-up prevention interventions).
Results: Figure 1 presents resulting changes in:
(i) ART patient numbers,
(ii) costs,
(iii) HIV-related deaths, and;
(iv) HIV infections.
Adult patient numbers increase by 45% and 60% by 2020 in scenarios 2 and 3, respectively. New infections and deaths both decline under scenarios 2 and 3, averting 3,000-5,000 more deaths per year and 20,000-30,000 more new infections per year than scenario 1 by 2030. Treatment costs rise from $261 million/year in 2015 to $398 million, $411 million or $443 million by 2020 in the three scenarios, respectively. Annual costs for scenarios 2 and 3 plateau around 2025 and then fall below baseline due to reduced transmission. Compared to baseline, the incremental cost per infection averted over the period was $281 for Fast Track and (-$466) (cost saving) for 90-90-90.



[Zambian Cost & Effectiveness of Treat All scale-up]

Conclusions: Scaling up treat all in Zambia has the potential to save thousands of lives and reduce new infections, but costs will increase dramatically. Domestic and international financing initiatives will need to be explored, with greater efforts to ensure sustainability.

WEPED1346

Uganda: the cost and effectiveness of achieving universal HIV treatment coverage. A modeling analysis of scaling up "treat all"

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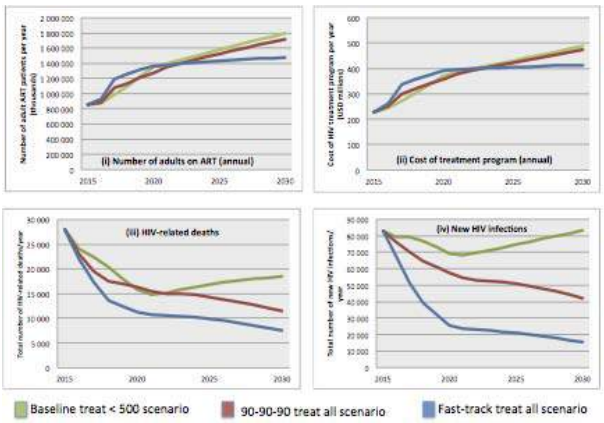
Background: To achieve "90-90-90" targets, many countries have adopted "treat all" guidelines with no eligibility threshold for ART. We modeled the impact of adopting treat all in Uganda on cost, HIV incidence and mortality.
Methods: We used existing Ugandan Spectrum AIM and Goals models and new data on HIV program coverage, ART effect on incidence, and current local unit costs to estimate the impact and costs of implementing treat all under three scenarios: (1) "baseline" (500 CD4 threshold for ART eligibility, treatment coverage of 70% by 2020 and 82% by 2030); (2) "90-90-90" (treat all, coverage of 81% in 2020 and 90% in 2030); (3) "Fast Track" (treat all, coverage of 90% in 2020 and 95% in 2030, plus expanded prevention interventions).
Results: Figure 1 presents resulting changes in (i) ART patient numbers, (ii) costs, (iii) HIV-related deaths, and (iv) HIV infections. Adult ART patient numbers increase by 49% and 59% by 2020 in scenarios 2 and 3, respectively. New infections and deaths both decline under scenarios 2 and 3, averting 2,000-6,000 more deaths per year and 20,000-50,000 more new infections per year than scenario 1 by 2030. Treatment costs rise from $228 million/year in 2015 to $372 million, $358 million or $391 million by 2020 in the three scenarios, respectively. Annual costs for scenarios 2 and 3 decline around 2025, while the Fast Track costs could fall below baseline due to reduced transmission. Compared to baseline, the incremental cost per infection averted over the period was $1,022 for Fast Track and (-$281) (cost saving) for 90-90-90.



[Cost and effectiveness of "Treat All" in Uganda]

Conclusions: Treatment costs in Uganda will increase steadily regardless of scenario, but the 90-90-90 and Fast Track scenarios have the potential to avert thousands more deaths and new infections. Sustainable financing opportunities will be needed for treatment program expansion to achieve the benefits of the treat-all scenarios.

WEPED1347

Global fund funding transition readiness in middle-income countries

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Background: In the Global Fund's (GF) new funding model, countries become ineligible for support as their economies grow or disease burden decreases. This loss of funding may constitute significant operational and budgetary challenges. This analysis evaluates the domestic capacity to provide HIV services, particularly for key populations (KPs), in countries expected to graduate from GF funding by 2025.
Methods: We analyzed eleven countries projected by GF to lose eligibility for HIV funding by 2025. GF support as a share of country resources for HIV was taken from the first year of support listed in each country's most recent GF funding application, stratified by module. Data on civil society organizations' (CSO) program implementation were compiled from UNAIDS National Commitment and Policy Instruments. Criminalization data for same-sex acts, sex work and illicit drug use and evidence of extralegal action were taken from country criminal codes and monitoring organizations.
Results: GF support constitutes on average almost one-third of total HIV budgets in the eleven nations expected to transition to country ownership by 2025. All of these nations have concentrated HIV epidemics in KPs. On average, 35% of GF grant budgets were designated for KP-specific activities, ranging from 0-67%. Services for KPs are largely provided by CSOs, which implement more than 75% of HIV services for at least one KP in six countries. Despite this critical role, six countries have imposed legal barriers on CSO funding and activities, and government harassment of CSOs has been reported in at least three countries. Criminalization of same-sex sexual acts, sex work, or illicit drugs is common.
Conclusions: GF is a major funder of HIV services, particularly for KPs, in this group of middle-income countries. CSOs are important implementers of KP programs, but are dependent on international funding and experience significant barriers to operation in the majority of these countries. In preparation for transition, GF and governments must improve CSO operational and funding environments as well as strengthen advocacy to remove the legal obstacles to sustaining the progress that has been achieved in reducing HIV in these nations.

WEPED1348

Beyond Global Fund: transitioning to sustainable funding for HIV prevention: the case of harm reduction programs in Eastern Europe

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Background: After the Global Fund's new approach to resource allocation was introduced in 2014, there was a decrease in funding available for middle-income countries with concentrated epidemics. Discussions took place on how to ensure the successful transition and sustainability of HIV programs from Global Fund support to national funding, especially interventions that targeted key populations.
In 2016, the Eurasian Harm Reduction Network conducted 5 case studies in Albania, Bosnia & Herzegovina, Macedonia, Montenegro and Romania to evaluate the readiness for transition of harm reduction services, analyse the transition-related processes and possible consequences for the sustainability of such services.
Methods: A standardized approach was used to analyze the situation in each country. The Transition Readiness Assessment Tool (TRAT) was developed. Experts were hired to use the tool to conduct a comprehensive transition readiness assessment which included collection of quantitative and qualitative data through a desk review and interviews with key informants to assess and score benchmarks for each indicator in each thematic area of transition. TRAT was updated based on the results of this field-testing.
Results: In the majority of countries, transition planning processes didn't take place at all or started too late to have any impact. Mostly, governments had neither a tenable plan, nor sufficient human and/or financial resources in place to maintain its HIV program. Governments did not prioritize HIV prevention programs among people who inject drugs. As a result, programs that deliver services for key populations have no resources to continue their work after the end of Global Fund support and, in most cases, collapse.
Conclusions: The transition processes should begin well in advance of the Global Fund's withdrawal, at least 2 allocation periods beforehand. Services delivered by NGOs are at special risk of termination within the transition period, especially without the existence of state mechanisms for contracting NGOs to provide HIV prevention services.

WEPED1349

Sustainable integrated collection logistics management information system reports: collecting HIV/AIDS and malaria LMIS reports using local government area officers and roll back malaria focal persons in Nasarawa State, Nigeria

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Background: Uninterrupted service delivery for any programme is achieved by Commodity Security/availability and this can only be attained by a sustainable timely submission of quality Logistics Management Information System (LMIS) reports. Previously in Nasarawa State, LMIS reports were collected using cluster review meetings. This method of report collection was donor driven and as such not sustainable. This is because of the number of supported facilities and cost of paying individual program focal persons for HIV and Malaria.
Methods: Twenty eight (28) Local Government Area (LGA) officers and Roll Back Malaria (RBM) focal persons representing 13 Local Government areas were recruited to collect both HIV and Malaria LMIS reports.
This group comprised of eight (8) females and twenty (20) males. The selected focal persons were oriented on the LMIS report collection tools used by both programs. This was to enable them validate reports collected from health facilities. At the end of the orientation exercise, the 28 officers were provided with all LMIS tools for report collection, list of facilities offering both services to clients at their LGAs and the names of their focal persons. They were mandated to collect Malaria and HIV/AIDS LMIS reports from the listed facilities. The timelines for usual collection and submission of LMIS reports; first week of each reporting month, was also shared with them.
Results: The cost for integrated collection of HIV and Malaria LMIS reports reduced from twelve thousand eight hundred and five US Dollars (12,805 USD) using the cluster review meeting mechanism to three thousand four hundred and eighteen US Dollars (3,418 USD) using the LGA officers mechanism. In addition, these LMIS reports were collected timely and used to inform resupply of HIV and malaria commodities to health facilities.
Conclusions: Integrated collection of LMIS reports for all program areas using Local Government Area and Roll Back Malaria officers mechanism is a cheaper and more sustainable method of LMIS data collection which can be transitioned to State governments.

WEPED1350

Standing on our own feet: reducing donor dependence and ensuring self sufficiency and self reliance

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Background: Community Organisations (COs) of key populations in India are witnessing a substantial decrease in funding from Government and donor agencies for HIV/AIDS works. The future of this funding is not certain in the years to come due to various reasons, including change in priorities of Government, shift in focus of donor agencies and growing competition between local NGOs and COs for limited funding opportunities. Long term sustainability of COs and the community's agenda is possible only if they are able to raise resources locally. Most of them are not strong enough to sustain on their own due to limited skills and knowledge of key staff and board members about resource mobilization.
Methods: Swasti, Vrutti and CMS manages the Avahan Phase III initiative (2014-2017), funded by Bill & Melinda Gates Foundation, and supports 74 COs on resource mobilization for their long term sustainability. The project covers about 121,000 key populations (FSW, MSM & TGs) across 5 states of India. Capacities of key leaders and staff of COs is built to raise resources. COs are provided handholding support to implement a range of context (and capacity specific) activities to raise resources, which include conducting cultural events, lucky draws, selling

products and seeking donations. They are also equipped to raise resources in kind and also reduce their costs through a range of cost cutting measures. Standing on own feet, a tool to calculate total yearly core cost estimate and choose strategies for achieving the same has been developed and have been tracked on a monthly basis.
Results: Substantial efforts on resource mobilization have started yielding results, with 74 Organizations raising USD 370,462 cumulatively since April 2014. Systematically planned and organized methods of resource mobilization can result in enhanced fundraising required for sustainable HIV/AIDS prevention program.
Conclusions: With right tools, capacity building, facilitation and local leadership, it is possible to mobilize local resources, and this is vital for success of HIV/AIDS prevention and vulnerability reduction programmes. Crises are also opportunities to bring in a sense of urgency. Raising local resources also tests the connect with the Community and relevance of Community services.

WEPED1351

The hidden costs of HIV: what about costs to users?

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Background: Côte d'Ivoire, like many PEPFAR supported countries, has mandated that antiretrovirals, clinical tests, consultation and other fees related to HIV testing, care and treatment, be provided free of charge to patients. In practice, however, patients incur substantial out of pocket costs directly and indirectly related to HIV care and treatment.
This analysis explores the economic consequences of ill-health amongst people living with HIV (PLHIV) in Cote d´Ivoire.
Methods: From July-September 2016, a phone survey was administered to 320 PLHIV recruited from 16 health facilities in N'zi-Ifou and Indenie Djuablin regions of Cote d´Ivoire. The survey included modules on socioeconomic and demographic characteristics, HIV, facility-based services (including direct and indirect costs), equity and financial risk. Data entry occurred using RedCAP and data were analyzed using Stata 13.0.
Results: A total of 317 interviews were completed: 196 (61%) from urban health centers and 124 (39%) from hospitals. 62% of respondents were female; 76% were 35 years of age or older; 55% were married or lived together; 34% reported not having had any education; and 44% were shopkeepers or vendors. 45% of respondents incurred $0.00 cost for their most recent visit to the health facility. Amongst the 55% that incurred a cost, the median cost was US$1.91 and comprised primarily of transportation costs (median $1.61). Transportation costs were significantly higher amongst women, individuals in higher socioeconomic strata, and those receiving care at hospitals. Wages lost and informal payments to be seen first were reported by 9% and 2% of patients, respectively. Direct costs for clinical services were reported by 5% of respondents and included consultation fees and clinical exam fees. Amongst the sub-sample (61%) who received clinical exams during their last visit, 6% incurred costs for blood tests (median $4.04), TB sputum (median $11.20), and/or chest x-rays (median $8.07).
Conclusions: Finding highlight the importance of understanding the consequences of indirect costs to households of PLHIV, including transportation. Strategies which promote community-based distribution of ARTs are likely to reduce indirect costs to patients and lesson the burden on providers. Costs for tuberculosis tests, while infrequent, were high amongst those incurring any cost.

WEPED1352

The fast track to achieve the 90-90-90 target: a review of a costed national plan and expenditure in Nigeria from 2013-2015

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Background: Despite the progress made in addressing the epidemic, the pace at which new HIV infections is declining globally and in Nigeria is slow. It is globally accepted that achieving the 90-90-90 targets is a step towards ending AIDS . The 2017- 2021 Nigeria National Strategic Framework (NSF) was developed to provide direction towards ending AIDS in Nigeria by 2030.As such priorities for achieving the 90-90-90 target in Nigeria have been identified in the NSF. To reach the 90-90-90 target, it is important to look at a previous national plan so we can avoid the pitfalls from past years.
Methods: This paper reviews the goals and estimated cost for attaining these goals in the President Comprehensive Response Plan for HIV/AIDS (PCRP) 2013-2015. It compares the estimated cost in the PCRP with what was spent during the period. HIV/AIDS expenditure was obtained from National AIDS Spending Assessment (NASA) 2013- 2014.
Results: The estimated cost in the PCRP for providing 80 million Nigerians with access to HCT for the 2013-2015 period was 640,202,344USD. NASA revealed that only 44,001,049USD was spent in 2013 and 2014 on HCT. So from 2013-2014 only 7% percent of the estimated HCT cost was spent. In addition only 4,077,663 and 6,716,482 persons respectively were tested in 2013 and 2014 (13% of the target). Also it was estimated that it will cost 181,518,583USD to reach 4million young people and 500,000 MARPS with combination prevention for the 2013-2015 period. NASA however showed that 49,397,478USD (27% of the estimated cost) was spent on sexual prevention within the same period.
Conclusions: The huge funding gap significantly slowed down progress in the implementation of national targets in the past. The goal of 2017-2021 NSF will suffer similar set back if this gap is not addressed. Therefore the fast track to attaining the 90-90 -90 target in the current NSF is dependent on Nigeria's ability to provide cost efficient programs and mobilize resources to bridge this gap.

WEPED1353

Individual and healthcare supply-related barriers to ART initiation in HIV-positive patients followed up as part of the Cameroonian antiretroviral treatment program (ANRS-12288 EVOLCam survey)

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Background: The increasing demand for HIV services and the reduction of international financial support observed in the last decade compromise the sustainability of antiretroviral therapy (ART) programs in developing countries. This translates into limited patient access to ART and reduced capacity of HIV services to promptly initiate treatment. We aimed to investigate whether individual and healthcare supply-related factors were associated with the time of ART initiation (ART-I) in patients eligible for ART within the context of the Cameroonian ART program.
Methods: We used data from a cross-sectional survey conducted among 2141 HIV-positive adults attending 19 HIV services in Cameroon (EVOLCam ANRS 12288). Socio-behavioural, psychosocial, medical and facility-related data were collected. The analysis was carried out on the 1727 (81%) patients eligible for ART at the time of HIV-diagnosis, according to national guidelines. The time elapsed between diagnosis and ART-I was the main outcome. A multi-level Cox model was implemented to investigate healthcare supply and individual factors associated with the time of ART-I.
Results: Among the 1727 patients (women 73%, median age 40 years [Interquartile Range (IQR) = 34-48]), median time elapsed between HIV diagnosis and ART-I was 2.4 months ([IQR= 0.7-12.3]) with large variability across HIV services ([min-max = 0.7-10.6] months). ART-I was slower for patients followed up in the Littoral region (Hazard Ratio (HR): 0.76, 95% Confidence Interval (CI) [0.62-0.90]), in private HIV services (HR [95% CI]: 0.79 [0.67-0.92]) and in HIV services with a higher number of ART patients per medical staff member (HR [95%CI]: 0.99 [0.99-1.00]). Conversely, faster ART-I was associated with the availability of health education activities (HR [95%CI]: 1.83 [1.63-2.04]). With regard to individual factors, having a CD4 count ≥100cells/mm^3 (HR [95%CI]: 0.85 [0.73-0.98]), being HIV-diagnosed without presenting medical symptoms (HR [95%CI]: 0.63 [0.51-0.76]) and having a history of tuberculosis (HR [95%CI]: 0.86 [0.74-0.98]) were all associated with a slower ART-I.
Conclusions: Our findings suggest that health system constraints may delay ART initiation, thereby compromising the second target of the 90-90-90 objective. The development of educational interventions is necessary but insufficient to improve linkage to treatment, and should be complemented with global strengthening of health-based human resources.

WEPED1354

Trends in healthcare expenditure among individuals with HIV/AIDS in the United States: 2002-2011

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Background: While previous studies have examined HIV cost expenditures within the United States, the majority of these studies focused on data collected prior to or shortly after the advent and uptake of antiretroviral therapy, focused only on a short time frame, or did not provide cost comparisons between HIV/AIDS and other chronic conditions. It is critical that researchers provide accurate and updated information regarding the costs of HIV care to assist key stakeholders and decision-makers with economic planning, policy development and adjustments, and resource allocation.
Methods: We used data from the Medical Expenditure Panel Survey-Household Component for the years 2002-2011, which represents a nationally representative U.S. civilian non-institutionalized population. Using generalized linear modeling, we estimated the adjusted direct medical expenditures by HIV/AIDS status after controlling for confounding factors.
Results: Data were from 342,732 people living with HIV/AIDS. After adjusting for socio-demographic factors, comorbidities and time trend covariates, the adjusted incremental cost of total direct expenditures for HIV/AIDS was increased by $31,147 (95% CI $23,645-$38,648) when compared to those without HIV/AIDS. Based on the adjusted mean, the aggregate incremental cost of HIV/AIDS was approximately $10.7 billion higher than the costs for those without HIV/AIDS.
Conclusions: Our estimates of cost expenditures associated with HIV care over a 10-year period show a financial burden that exceeds previous estimates of direct medical costs. There is a strong need for financial investment and comment to socio-structural interventions to reduce the financial burden on those most impacted by HIV and facilitate longer and healthier lives.

WEPED1355

Methods for standardizing sector-wide health budgets to improve allocative efficiency and government ownership in the HIV response: lessons from Malawi

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Background: Achieving 90-90-90 depends on the availability and efficient allocation of limited resources. In many developing countries, fragmentation and information asymmetry constrain governments' ability to coordinate resources across the HIV response.
Malawi is one of the poorest and most donor-dependent countries in the world; in FY2015/16, 99% of all HIV resources financed by donors. In 2012, the Government of Malawi, supported by CHAI, set out to test the hypothesis that annual standardization of health budget data could improve allocative efficiency and optimize the use of HIV resources.
Methods: Developing the annual resource mapping database requires all donors and implementers to complete individual Excel-based submissions with detailed forward-looking budget data, which are consolidated into a single sector-wide database. The data is disaggregated by intervention category, project, activity, financing source, geographical area, cost category, and fiscal year.
Results: Since initiation, resource mapping has repeatedly been used for investment planning, resource mobilization, and coordination of Malawi's diverse HIV investments. Leveraging estimations of the available budget, the Ministry and its partners have been able to:

- Conduct detailed gap analyses to mobilize and allocate new funding. Comparing planned resources against the costed HIV National Strategic Plan, an activity-based gap analysis identified ARVs as experiencing the most severe funding shortfalls. This led to over US$360M in targeted donor investments toward ART.
- Identify and address allocative inefficiencies caused by poor coordination and lack of transparency. By listing funders and implementers of each NSP intervention, resource mapping helped identify duplication of VMMC activities between donors and informed reprogramming of US$15M to 18 underfunded districts.
- Identify technical inefficiencies in planned spending caused by fragmentation. Resource mapping evidence estimated the inefficiency of Malawi's parallel supply chains at US$11M per year. The quantified need for harmonization informed a decision by DFID to channel funding through the national system, saving up to US$3M annually.

Conclusions: Since 2012, resource mapping has become an indispensable tool to ensuring efficiency in Malawi's national HIV response. By enabling comprehensive analysis of HIV commitments over the next five years, resource mapping has increased transparency and country ownership, equipping country stakeholders with evidence for investment planning, coordination, and resource mobilization.

Health Systems Strengthening

WEPED1356

Improved implementation of policies pertaining to antiretroviral therapy access between 2013 and 2016 in six sub-Saharan African countries

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Background: Revisions in World Health Organisation (WHO) guidelines on use of antiretroviral therapy (ART) are aimed at increasing ART uptake and improving treatment outcomes among people living with HIV. As many African countries adopt "test and treat", it is essential to assess their progress in implementing previous WHO recommendations, at the facility level. We assessed changes in the implementation of policies influencing ART provision and other service delivery indicators from 2013-2016.
Methods: Two cross-sectional surveys were conducted in health facilities located within 10 Health and Demographic Surveillance Systems in Uganda, Kenya, Tanzania, Malawi, Zimbabwe and South Africa. Standardised questionnaires were administered to in-charge personnel in 2013/2015 (round 1) and 2015/2016 (round 2). We used descriptive statistics to compare these indicators across the rounds.
Results: Overall, 145 facilities were surveyed in both rounds. The proportion of facilities providing ART services increased between rounds, with most providing ART free of charge (97% in round 1 and 96% in round 2). The proportion of facilities providing ART within two weeks of initiating TB treatment remained over 90% in both rounds.
In 2013, WHO recommended ART initiation with a CD4 count of < 500 cells/μL, and this was implemented in 12% of the facilities in round 1, ranging from 0% in Uganda, Kenya and Malawi to 41% in South Africa. In round 2, the proportion of facilities implementing this recommendation increased to 68%, with 91% implementation in South Africa. In Zimbabwe, the proportion of facilities that did not require laboratory testing to initiate ART increased from 27% to 63% across rounds, whereas overall increase was from 22% to 32%. The proportion of facilities that provided recommended first line WHO 2013 ART regimen increased from 42% in round 1 to 87% in round 2. Occurrence of stock-outs of this regimen decreased from 19% in round 1 to 12% in round 2. However, proportion of facilities providing same-day ART initiation remained low in both round 1 (5%) and 2 (8%).
Conclusions: The sustained reductions in ART stock-outs and an increased adoption of revised WHO ART regimens and ART eligibility criteria signifies an apparent readiness to implement test and treat approach.

WEPED1357

Enhancing ownership of the HIV response in a devolved system of governance: lessons learnt from Kenya

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Background: The Constitution of Kenya 2010 fundamentally changed the governance framework for the multi-sectoral HIV response. Unlike the other three plans which were designed and implemented in the old constitutional dispensation, the current Kenya AIDS Strategic Framework (KASF) 2014/15-2018/19 is aligned to the Constitution and takes cognizant of the devolved system of governance.

KASF is the strategic guide for the country's response to facilitate universal access to comprehensive HIV prevention, treatment and care services. The development of the Strategic Framework was highly consultative and evidence informed. Forty Seven counties have since developed county specific HIV plans guided by this framework with a focus on diseases burden, population and geographical disparities of the counties.
Methods: The process involved the following: Consultation with leadership at the Ministry of Health and Council of Governors; Involvement of other key stakeholders across sectors and levels of government including development partners; Development and dissemination of the KASF; Development of 47 County HIV and AIDS Strategic Plans; Mainstreaming of HIV and AIDS in other key policy and strategic documents and establishment of effective coordination, Monitoring and Evaluation structures at national and county levels.
Results: By implementing KASF, the following key results have been realized between 2013 and 2015;

- 24% Reduction in new HIV infections among the population with 49% decline among children (less than14 years).
- 37% Increase in number of people who received ART treatment.
- 38% Reduction in AIDS related deaths.
- 8% Increase in domestic financing of HIV response; Counties have funds earmarked for sustainable HIV programming through the Medium Term Expenditure Framework.
- Better HIV programming and enhanced ownership of the HIV response by government leaders and implementers; HIV and AIDS activities have been mainstreamed in key Sector and County documents.

Conclusions: Strategic planning, prioritization, effective political engagement, partnership and inclusion of key stakeholders is indispensable in achieving ownership of the HIV response through defining of local priorities for investment, establishment of accountability and enhancing efficiency for sustainability.

WEPED1358

Opt-out HIV testing in out-patient setting

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Background: Under-diagnosis of HIV is often linked with barriers to HIV testing, including tedious informed consent in some settings, lengthy counseling and stigma associated with selection for HIV screening. Opt-out approach can overcome these barriers, but such practice has not been integrated into the healthcare system. In addition, previous studies in hospitals reported acceptance rates as low as 21%, with most patients excluded due to severe illness. Our study attempts to overcome these barriers by using an outpatient setting where extra venipuncture is unnecessary. We aim to evaluate the feasibility and acceptance of opt-out HIV testing in this patient population.
Methods: This is a cross-sectional study. All adult patients attending a selected specialist clinic in Hong Kong over a 7 month period were offered HIV test during routine blood-taking. Patients were surveyed for collecting their demographics and reasons for refusing HIV testing. Factors associated with HIV test refusal were analyzed by multiple logistic regression.
Results: Between June 2015 and January 2016, 963 out of 1069 subjects enrolled in the study with a response rate of 90.1%. Of 952 patients included in the analysis, 361 were females and 591 were males. Acceptance rate was 62.0% (590/952). Of the remaining patients who refused, the most common reason was perceived low risk of infection (57.8%). A small proportion of patients declined because they did not want to know test result (3.7%), fear of venipuncture (2.8%) or fear of stigma (1.8%). The remaining 33.9% declined due to other factors, such as inconvenience. Factors significantly associated with refusing HIV test included older age (58-77 years old) and birth in Mainland China, while males were associated with accepting HIV test. All blood tests showed HIV-negative results.
Conclusions: Pilot data from our study shows that opt-out HIV testing in an outpatient setting is feasible and acceptable to most patients.

WEPED1359

Monitoring delays in adopting WHO HIV treatment guidelines in low- and middle-income countries

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Background: Countries use the World Health Organization (WHO) HIV treatment guidelines to revise their national policies. We quantify the time in the adoption of the October 2009, June 2013, and September 2015 WHO guidelines in low- and middle-income countries (LMICs).
Methods: International Association of Providers of AIDS Care's (IAPAC) website www.hivpolicywatch.org includes 326 published national policies from 122 countries. Using the site database, we abstracted date of publication and antiretroviral therapy (ART) eligibility criteria from 215 policies from 91 LMICs (92% of 2015 global HIV burden). We excluded nine countries that have reported moving to WHO 2009, 2013 or 2015 guidelines but their latest policies are not available. Numbers of months taken to adopt the WHO 2009, 2013, and/or 2015 guidelines were calculated for the remaining 82 countries (91% burden) to determine the average time lag in adoption of the WHO guidelines.
Results: Of 82 countries, 17 (39% burden) recommend the new WHO 2015 ‚treatment for all' recommendation, 38 (39% burden) recommend ART at WHO 2013 CD4 criteria (≤500 cells/mm^3), and 27 (13% burden) at WHO 2009 CD4 criteria (≤350 cells/mm^3). The average time lag to WHO 2009 guidelines adoption in the countries was 12 months (n=68 countries). The countries that have adopted WHO 2013 guidelines took an average of 8 months (n=53 countries), a number that will increase to 19 months assuming the remaining countries move to CD4 ≤500 cells/mm^3 or earlier by December 2016. On average, the 17 countries recommending 'treatment for all' adopted this recommendation 3 months before the release of WHO 2015 guidelines in September 2015. The average time lag in adoption of the WHO 2015 guidelines was the highest in sub-Saharan African region.
Although the time to adoption of the 2015 guidelines appears accelerated, if the trajectories for the adoption of WHO 2009 and 2013 guidelines are followed, it may take many years for the new WHO 2015 guidelines to become national policies, especially for high burden countries.
Conclusions: There is an urgent need to shorten the time lag in adoption and implementation of the new WHO guidelines recommending ‚treatment for all' to achieve the 90-90-90 target by 2020.

WEPED1360

Accessing drug abuse treatment for PLHIV in the Philippines: attitudes of HIV care providers and drug abuse treatment providers

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Background: The Philippines has one of the fastest growing HIV epidemics in the world. Recreational drug use is common among HIV patients. The combination of substance abuse and HIV/AIDS poses special challenges for medical providers. There are currently no services in the Philippines catering to the needs of PLHIV who use drugs. Compounding this issue, the Philippine President declared an "all-out war on drugs" and more than 7,000 drug-related extrajudicial killings occurred between July 2016 and January 2017, prompting international concern for human rights.
Methods: A survey of HIV care and drug abuse treatment providers collected data about provider attitudes toward HIV, drug use, and harm reduction. The survey was distributed by email and social media to more than 140 organizations/facilities nationwide; 47 responses were received.
Results: The majority of respondents opposed aspects of the "war on drugs": 91% disagreed or strongly disagreed with the statement that people who use drugs should be killed, and 63% opposed imposing harsher penalties for drug use. 54% of respondents disagreed or strongly disagreed that health care providers should report patients' illicit drug use to law enforcement. 75% of respondents agreed that health care providers should provide sterile needles and syringes to HIV patients who use drugs. Opposition to needle provision was higher among drug rehab providers (22% opposed) than it was among HIV care providers (8%). 65% of respondents agreed or strongly agreed that health care providers should inform people who use drugs about safer practices for the use and administration of drugs.
Conclusions: There is a need to capacitate HIV care and drug abuse treatment providers about harm reduction practices. An issue of concern is that a significant proportion of providers (46%) either supported reporting or were unsure about

whether they should report their patients' illicit drug use to law enforcement. This raises concerns for the safety of patients who access treatment related to their drug use and may discourage them from disclosing illicit drug use to their HIV primary care providers. It is a priority to create a network of providers who can provide safe spaces and high quality care for PLHIV who use drugs.

WEPED1361

'Yes' to recreational drugs but 'no' to life-saving medications: unpacking paradoxical attitudes about HIV treatments

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Background: Recent research into motivations and barriers to ART uptake and adherence uncovered a puzzling phenomenon: despite the well-known life-preserving benefits of ART, some people are declining potentially life-saving treatment while still being prepared to use potentially dangerous recreational drugs. Unpacking and understanding this paradox will provide insights into core beliefs regarding antiretroviral medication and will enable better models of care to be created.
Methods: In-depth interviews were conducted with adults living with HIV in the Gold Coast region of Australia. Interviews explored perspectives of living with HIV and the role of medical and non-medical treatments, supplements and other substances (including recreational drugs). Data were audio recorded, transcribed and analysed using a 'grounded theory' approach.
Results: This study reports data collected from 27 participants (phase 1 of the study). The majority of participants were gay, male, 40 years or older and contracted HIV through unprotected sex. Participants had been living with HIV from 1 month to 23 years and were currently receiving ART. Eleven participants who reported current recreational drugs use; all used prior to diagnosis; the majority reported increased use after diagnosis. Participants spoke of the benefits of non-medical treatments: relief from stress of living with HIV; potential health benefits of CAM without side effects; self-control as being able to influence disease progression. Participants also expressed concerns regarding ART toxicity, and financial, emotional and physical burdens imposed by treatment. The burden of treatment appears to be a strong motivator for declining, while positive views towards recreational drugs appear to justify use, particularly for mitigating negative states-of-mind.
Conclusions: Decisions regarding living with HIV are complex and appear to be influenced by internal factors such as beliefs about ART, CAM and recreational drugs as well as external factors such as the communities within which they live. Optimal models of care for people with HIV must take into account treatment reservations and people's desires to go beyond what orthodox medicine currently offers.

WEPED1362

Examining Malawi's rollout of universal treatment: policy implementation and provider perceptions

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Background: In July 2016, Malawi implemented universal treatment for all adults (Test and Treat) with no baseline CD4 cell count. We summarize early experiences with the rapid implementation of Test and Treat in 4 districts in Malawi 3 months after the policy change. Provider perceptions of successes and challenges are shared.
Methods: A facility-level survey was conducted at 53 mid- and large-level health facilities across central and southern Malawi. The facility in-charge, lead HIV testing and counseling (HTC) provider, and lead antiretroviral therapy (ART) provider at each site completed a survey. Twelve focus group discussions were completed with providers across 6 health facilities (n=79).
Results: The majority of providers were informed about Test and Treat through a Ministry memo and briefings by facility supervisors. Three months after policy implementation, 96% (n=51) of facilities offered Test and Treat. Two sites had not started because providers felt they had inadequate training. Ninety-one percent (n=48) of Test and Treat sites offered same-day initiation for adult clients. Seventy-seven percent (n=41) of providers reported improved client flow due to the elimination of CD4 count; however, 68% (n=36) experienced heavy workloads due to the increase in ART initiates. Forty-percent (n=21) believed asymptomatic HIV+ clients were not ready to initiate ART. Only 15% (n=8) felt the policy was confusing for clients because it contradicted previous messaging about ART eligibility.
In focus group discussions, providers reported that the policy was easy to implement because it simplified initiation protocols. Providers were concerned that healthy clients were not ready to start ART due to fear of stigma, the burden of taking ART for life, and being unaware of the new policy before testing. While same-day start was believed to be critical for initiation, providers raised concern about increased defaulter rates among healthy clients who initiated ART before feeling ready.
Conclusions: Three months after national rollout, nearly all facilities surveyed provided Test and Treat, with most offering same-day initiation. Data indicate that minimal training and supervision are needed to implement this new policy. Monitoring of provider workload will be needed as patient numbers increase. More research is needed to understand barriers to engaging healthy clients.

WEPED1363

Countrywide epidemiology of B, C and Delta hepatitis in Burkina Faso: the ANRS 12270 clustered cross-sectional study

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Background: At a time when control tools for hepatitis B (vaccination) and C (direct antiviral agents) are available, reliable data of the hepatitis epidemiology are mandatory to inform local health policies and resource allocation. We present the results of a nationwide clustered cross-sectional survey on hepatitis B, C and Delta in the adult population of Burkina Faso.
Methods: Data of the 2010 Burkina Faso Demographic and Health Survey (DHS) were merged to the results of serologic hepatitis assays on 14,886 dried blot spot samples collected during this survey for HIV testing and stored at -20°C. Hepatitis prevalence were estimated, for the general community and for each gender, according to demographic and geographic parameters. Hepatitis prevalence confidence intervals accounted for the multistage clustered design of the study.
Results: The HCV estimated prevalence was 3.6% (95%CI 3.3-3.8) overall, 3.9% (95%CI 3.4-4.5) among males and 3.2% (95%CI 2.8-3.7) among females. HCV prevalence age-class distribution was increasing on males (40-44yrs group: 6.0%, 95%CI 4.0-8.0) suggesting an ongoing HCV epidemic. The HBsAg prevalence was 9.1% (95%CI 8.5-9.7) overall, 10.5% (95%CI 9.6-11.4) among males and 7.8% (95%CI 7.1-8.6) among females. HBV prevalence age-class distribution was decreasing suggesting that HBV infection is mostly acquired at birth, during infancy or horizontally in early childhood. Among HBsAg carriers the Delta hepatitis prevalence was 1.1% (95%CI 0.6-1.6) overall. Strikingly high HCV prevalence (13.2%, 95%CI 10.6-15.7) and HDV prevalence in HBsAg carriers (8.7%, 95%CI 2.5-15.0) were identified in the South West region.
Conclusions: This very large, nationwide study classify Burkina Faso as high endemic for HBV and low-intermediate for HCV and identified an high HCV epidemic in a region of the country which deserves further epidemiological investigation. This study illustrates the very added value of DHS surveys with viral hepatitis immune markers on DBS to obtain precise countrywide and intra-country prevalence estimates for epidemic follow-up, prevention and care programs and evaluation of national health policies.

WEPED1364

The DRIVE Project to "End the HIV Epidemic" among people who inject drugs in Haiphong, Vietnam: importance of the evolving policy environment

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Background: The DRIVE project aims to "end the HIV epidemic" among people who inject drugs (PWID) in Haiphong, Vietnam through public health-scale HIV and substance use treatment. Vietnam's HIV epidemic is concentrated among PWID and other key populations. Like other countries, Vietnam is experiencing reductions in donor support for its HIV/AIDS response and changing its approach to substance use treatment so DRIVE will provide a useful test case. Its success depends on two policy pillars:
1) shift from donor-funded HIV outpatient clinics (OPC) to public facilities and expansion of health insurance (HI) for PLHIV; and
2) implementation of the government's "Renovation Plan" for substance use treatment.
Methods: We describe DRIVE's policy baseline, drawing on interviews and focus group discussions with key stakeholders, policy documents, and data on OPCs.
Results: 52% of ART patients in Haiphong receive care in donor-funded OPCs and 48% in public facilities; 53% of ART patients have HI. All patients will have to move to public clinics when donor-funded OPCs close. Public facilities may be more convenient for some patients but the care is perceived to be inferior. In addition, many patients have difficulty meeting the requirements for free or subsidized HI and producing the ID papers needed to obtain HI cards and receive care in public clinics.
The Renovation Plan aims to transition Vietnam from compulsory drug detention to voluntary, community-based treatment. In Haiphong, compulsory center population has dropped sharply (7300 in 2013 to 200 in 2016) and the number of methadone maintenance treatment (MMT) clinics and patients has increased (currently 12 clinics with 4,000 clients).
However, powerful interests still oppose the Renovation Plan and some conflicting policies persist. Some MMT patients have difficulty making required copayments and dropout rates are substantial. Voluntary treatment besides MMT is very limited. No treatment is available for amphetamine type stimulant (ATS) use, which has surged in Vietnam.
Conclusions: Both policy transitions are underway but face challenges and the policy environment is fluid. DRIVE will monitor the policy environment and its effects on project implementation and outcomes and advocate for improvements in policies and programs based on project data.

WEPED1365

Legal and policy regulatory barriers to effective health and HIV services for key populations in the East African community region

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Background: Evidence suggests that vulnerable and key populations (KPs) are disproportionately affected by HIV and AIDS and other health challenges. Many of these communities remain under-served, particularly along cross-border zones. While anecdotal evidence have mainly implicated unfavourable legal and regulatory frameworks that criminalise activities of these populations, the evidence remains weak. As part of a larger project to support harmonisation of policies across the East African Community (EAC) region, this study reviewed the legal and regulatory frameworks and identified the key barriers to effective and efficient health, HIV and AIDS service delivery for KPs in EAC.
Methods: A critical structured review of key government documents - laws, policies, strategic and investment plans, and monitoring and evaluation frameworks - of five EAC states together with published technical reports on HIV and health services provision for cross border KPs. A predefined structured search criteria guided literature search. Analysis was guided by ‚Decision Model' framework focusing on five core domains targeting KPs: policy and legal framework; budgets and planning for services, community partnerships for service delivery, legal environment and the design of intervention, access, and implementation of policies and programs for KPs.
Results: Major gaps exist in EAC partner states' legal and policy commitment and implementation with regard to services for key populations. Contradictions in legal and policy provisions hamper service providers' ability to respond to the needs of key populations. For instance, in cases where same-sex sexual relations and sex work have not been formally criminalized, public health authorities and policymakers have largely ignored the needs of KPs and detainees.
Conclusions: Although there are improvements in the policy and regulatory framework for health and HIV service provision for KPs, significant gaps remain that hinder effective service delivery towards meeting UN 90-90-90 global goals. EAC bloc countries have committed to harmonising these laws and policies. This process should be hastened to ensure KPs enjoy standard health rights. Harmonisation will also reduce conflicts within laws and curb criminalization of HIV transmission in some member state laws. Finally, the development of regulatory frameworks should ensure full involvement of KPs.

WEPED1366

Who, where, and how? Developing scenarios for the rollout of oral PrEP in Zimbabwe

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Background: As Zimbabwe plans for oral PrEP introduction, questions remain about how to rollout PrEP across districts and populations. While epidemiological and cost-effectiveness modeling traditionally guide decisions, these analyses often require significant time and resources. New rapid analytical methods can complement modeling to accelerate implementation planning, product introduction, and impact.
Methods: We reviewed district-level data and Spectrum model estimates on HIV incidence, population demographics, and demonstration projects to identify districts with greatest impact and cost effectiveness potential for oral PrEP roll-out.
Results: This analysis identified 8 scenarios for oral PrEP rollout in Zimbabwe - 4 scenarios defined by HIV incidence and 4 scenarios defined by target populations (see chart below). The four scenarios targeting high incidence districts range from rollout in 13 districts (adult population 1.6M) covering 39% of new HIV infections to rollout in 38 districts (adult population 6.0M) covering 85% of new infections. The scenarios defined by target populations would prevent significantly fewer new infections, but could leverage existing delivery channels to reach sero-discordant couples (22% of adult new infections) or sex workers, farmworkers, mineworkers, and truck drivers (~15% of new infections).

[Oral PrEP Rollout Scenarios]

The analysis showed that while HIV is not highly geographically concentrated in Zimbabwe, focusing on districts with highest HIV incidence and/or new HIV infections (Scenarios 1-4) will likely be most impactful. Between these scenarios, greater resources available for PrEP will enable greater coverage of new infections. Rollout limited to key populations would cover far fewer new infections than a general rollout in the highest incidence districts and should be pursued only if limited resources demand this approach.
Conclusions: Rollout scenario analyses using existing data can inform oral PrEP implementation planning in Zimbabwe. While this approach does not replace the need for further modeling, it provides timely guidance that can inform planning while more robust analyses are developed.

WEPED1367

Use of residual bio-specimens in research: guidance for Zimbabwe

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Background: Residual bio-specimens are an invaluable resource in improving health care, scientific advancement focused on patient care and research on HIV. However, regulations on secondary use of bio-specimens collected in clinical settings are not explicit or are non-existent in most African countries. It is unclear who determines the fate of such specimens. As such, secondary use of residual bio-specimens has been steeped in legal and ethical controversies, which can be detrimental to research and the advancement of medicine. Explicit guidance should be given internationally and nationally.
Methods: A descriptive desktop review of journal articles, guidelines and legislation on secondary use of bio-specimens was conducted, i.e. Google scholar, Pubmed, JSTOR, Hinari and also Ministry of Health websites were accessed. Journal articles focusing on secondary use of residual bio specimen, including consenting, privacy, confidentiality, bio-banking and ownership were selected and analyzed to determine existence of uniformity or concordance in the recommendations. Guidelines and legislation on secondary use of residual bio specimen collected from clinical and research settings were also searched for, an assessment of areas covered, recommended type of consent and uniformity in guidance given by developed and developing countries. Also an assessment of the common areas addressed by the guidelines was also carried out. The outcome of the analysis was used as grounds for the researcher to make recommendations on the position that could be adopted by regulators and policy makers in Zimbabwe, with regards to secondary use of bio-specimens.
Results: There is a paucity of guidelines that are specific to use of residual bio-specimens. Locally and internationally, an all-encompassing guideline on the collection, ownership, use and storage of residual bio-specimens does not exist. There is also lack of sufficient information on the recommended type of informed consent to be given for such use.
Conclusions: Residual bio-specimens are a valuable resource in medical research, HIV research and health care. There is a need for uniform guidelines that regulate secondary use of residual bio-specimens as international collaboration in research and sharing of bio-specimens is on the rise. Zimbabwe needs specific guidance on secondary use of bio-specimen collected in clinical settings.

WEPED1368

Additional yield of HIV cases through provider initiated testing and counselling in RNTCP in Telangana State, India

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Background: According to the national framework for TB/HIV coordination in India, all the diagnosed TB cases must be tested for HIV. In 2013, the concept of PITC (provider initiated testing and counselling for HIV) has been introduced in the country. Telangana, a high HIV prevalence state, initiated PITC meticulously through successful state, district and field level coordination with National AIDS Control Programme. This study attempts to find out the utility of PITC in field.
Methods: PITC is implemented since Jan 2013 in all the districts of Telangana State, India through all ICTC (Integrated Counselling and Testing Centres) across the state. Towards this all the lab technicians in RNTCP (Revised National Tuberculosis Control Programme) were trained on HIV testing and co-location of ICTC and DMC services was ensured.
Results: Of 39,072 registered TB patients were tested for HIV among the total of 41,827 (93.4%) in year 2013 and 41,672 were tested among 42,661 (97.7%) in year 2014. This resulted in identification of 2,763 (7.1%) and 2,571 (6.2%) HIV +ve cases in year 2013 and 2014 respectively.
A total of 1,43,127 presumptive TB cases (which includes diagnosed TB patients) were tested for HIV as part of PITC among the total of 1,91,081 (75%) in year 2013 and 1,96,494 were tested among 2,21,000 (89%) in year 2014. The analysis demonstrated that there is an additional yield of 6,502 (2.4 times) HIV cases in year 2013, of 10,972 (4.3 times) in 2014, of 8,239 (4.0 times) in 2015 and of 3,561 (2.0 times) in 9 months of 2016 as a result of implementation of PITC.
Conclusions: Provider initiated testing and counselling must be implemented in all high HIV prevalent settings and can contribute to early detection of HIV cases which can help in early initiation of Co-trimoxazole prevention therapy and Antiretroviral therapy to those diagnosed and thus reduce morbidity and mortality among PLHIV. This can in turn contribute to reduction in transmission of TB as the risk of getting TB is very high in PLHIV.

WEPED1369

Challenges faced by transgender/hijra community in public and private health care set up in India

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Background: In India, the Transgender and Hijra communities are marginalized population vulnerable to stigma and discrimination in the Health care sector, which has been identified as a significant barrier to effective HIV prevention, care, treatment and support. Health Care Providers are positioned to respond with needed services and treatment, however prejudicial, ignorant, and discriminatory attitudes coupled with lack of knowledge of trans-issues acts as a barrier toward providing adequate care and services.
Objective: To understand the experiences faced and to address myths, misconceptions and barriers stated by Transgender/Hijra Community in seeking health-care services across Public and Private health care settings in Mumbai.
Methods: In 2013, Five Key Informant interviews and Seven Focus Group Discussions were conducted with Transgender/Hijras Community people. Focus groups and interviews were transcribed and analyzed thematically using NVIVO.
Results: Transgender/Hijra reported experiencing varying levels of stigma and discrimination in Public as well as Private Healthcare settings e.g. Outing of their HIV status (writing their report in red ink, mentioning the status on the file), lack of awareness of Transgender/Hijra anatomy, hesitation in performing physical check-ups, issues with allocation of space if hospitalized, and sex of the examining health-care practitioner affecting the interaction etc. Transgender/Hijra also perceived a differential and biased attitude towards them by the healthcare professionals in government settings based on the language and tone employed along with the long waiting hours. However, Transgender/Hijra also preferred public health settings for its affordability and for addressing their "major" health concerns and local clinics/private practitioners in their areas for other minor health concerns. Transgender/Hijra reported accessing over-the-counter hormonal treatments from chemists and compounders in unlicensed clinics and being over-charged for the services in private health care set up as compared to the general population.
Conclusions: Despite experiencing Stigma and Discrimination, in health care set up, Transgender/Hijra will continue to access Public as well as Private health care set up. The lack of knowledge and training on Transgender/Hijra healthcare issues among the HCPs and Institutions calls for enhanced level of training and awareness among the Health Care Providers from Public and Private health care institutions to address Transgender/Hijra health care needs.

WEPED1370

Georgia's path towards HCV elimination

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Background: Hepatitis C (HCV) infection represents a major public health concern globally and especially in Eastern Europe and Central Asia. HCV is hyper-endemic in People Who Inject Drugs (PWID) throughout the world, with 60-70% chronically infected. HCV prevalence among PWID is in the same range in Georgia. Latest Bio-Behavioural Surveillance Survey among PWID reveals that HCV prevalence among HIV-infected individuals equals to 91%. In 2015, the Government of Georgia introduced a new initiative, that entails provision of HCV treatment free of charge to the the entire population with completed HCV diagnostic testing. Ongoing monitoring of program implementation and awareness on facilitators and barriers to diagnosis and treatment services is necessary to assure success of the program.
Methods: We conducted a qualitative study to investigate individual, societal and health system barriers and facilitators of HCV testing and treatment among PWID in Georgia in 2016. In depth semi-structured interviews were held with key informants, service providers and 40 program beneficiaries purposively selected from 6 main cities to with different HCV testing and treatment status. Data analysis was performed in NVivo-11.
Results: The program had high political support that resulted in smooth management and uninterrupted implementation of the program that was accompanied by public awareness campaign. Risk perception and knowledge about the disease, free

access to expensive treatment, that was previously unavailable in the country, triggered PWID to seek the treatment services. Unavailability of treatment services in some geographic areas, requirement of co-financing for diagnostics prior to inclusion in the program, skepticism about new drugs negatively affected decision to seek treatment. Facilitators to adherence to HCV treatment were supportive environment from family and friends, conducive physical infrastructure and caring staff in treatment facilities, successful treatment experience from peers and short course of treatment with quick recovery. Some factors that hindered decision to seek and adhere to treatment were continuously resolved during the program implementation.
Conclusions: Although the HCV elimination program is underway, the study showed more facilitators rather than barriers to program services among beneficiaries. The study revealed important individual, societal and health system factors supporting program effective implementation that might be useful information for other countries.

WEPED1371

Expanding access to HIV treatment services, the role of government policy in Akwa Ibom State, Nigeria

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Background: Expanding access to HIV treatment and care services for HIV positive individuals in rural communities of Akwa Ibom State remains fundamental to reducing the spread and impact of the virus. HIV positive clients identified within the rural communities through outreaches are referred to government owned facilities where registration fees are required for positive clients before enrollment into care. The poverty level of most positive living HIV (PLHIV) limits their ability to afford registration fees before commencement of treatment, these constitute a barrier to treatment services.
Methods: Akwa Ibom has experienced expansion in comprehensive treatment centers from 4 in 2010 to 61 as at 2016 through support from USAID and Global fund. State government developed policies to support treatment uptake; in 2013 a government policy of free health care for pregnant women and children under five years was adopted and in 2015 a government policy for free registration fees for poor PLHIV who are either pregnant women or children under 5 years and cannot afford registration fees at health facilities was also introduced. An assessment of this policy on treatment uptake across health facilities were evaluated using desk review of program data in the State.
Results: : Of the 42,982 (as at June, 2016) PLHIV currently on ARV in the State, more than 60% could not afford registration fees in health facilities at first visit in 2015. Between 2014 and 2015 after adoption of the policy waiver by government, about 48% of those enrolled in care were poor and could not afford registration fee in secondary health facilities. Also percentage of pregnant women who access HTC services at antennal clinics increased by 80% in 2015 from 37% in 2010, infection rate for children deceased from 8% 2010 to 5% in 2015. Overall this contributed to more PLHIVs and their dependents accessing treatment care and support services through enabling government policies.
Conclusions: HIV program implementer to extend evidence based advocacy interventions to host government leaders in Africa and faith based institutions for adoption of enabling policies to improve access to ART services in State and Nigeria.

WEPED1372

Recommendations for the rapid expansion of HIV self-testing in fast track cities

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Background: Globally, 40% of people living with HIV were unaware of their status in 2015. Cities are heavily impacted by HIV and, by necessity, have served as first responders to the epidemic. Accelerated access to HIV self-testing is critical to closing the diagnosis gap in high HIV burden Fast-Track Cities worldwide.
Methods: IAPAC and ASLM convened an expert Advisory Panel from Africa, Asia, Europe, South America, and North America. The U.S. Centers for Disease Control and Prevention systematically searched for articles from 2000 to 2016 using multiple search terms in two areas: (i) HIV descriptors and (ii) self, home, or rapid testing (5542 citations). The recommendations were drafted by the co-chairs and technical writing team, and reviewed, revised, and approved by the Advisory Panel.
Results: The Panel developed nine recommendations for Fast-Track Cities and their stakeholders:
1) support access to HIV self-tests for use at home and/or in assisted settings;
2) ensure quality-assured, affordable HIV self-tests for everyone, especially for vulnerable populations;
3) lower the price of HIV self-test kits through price reductions, market diversification, pooled procurement, price transparency, market forecasting, and subsidized pricing or for free;
4) monitor expansion of HIV self-tests as part of achieving the UNAIDS 90-90-90 targets by 2020;
5) accelerate regulatory and supply chain processes by identifying and addressing obstacles;
6) support monitoring and evaluation measures to assess individual barriers to HIV self-testing;
7) develop communication, educational and marketing efforts designed to encourage HIV self-testing;
8) optimize service delivery self-refer after HIV self-testing
9) remove government technical and administrative barriers to improve access to HIV self-testing.
Conclusions: apid implementation of HIV self-testing in Fast-Track Cities requires changing HIV policy and regulations, smart programming to increase uptake, and ongoing programmatic adaptation. The recommendations will assist high HIV burden cities to realize the potential of self-testing to achieve the 90-90-90 target and end AIDS as a public health threat.

WEPED1373

Stock-outs of HIV testing and treatment resources in Eastern Zimbabwe: a longitudinal analysis from 2013 to 2015

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Background: Great progress has been achieved in scaling-up national HIV care programmes in Zimbabwe. However, the capacity of local health systems to cope with the increasing number of patients requiring services is of increasing concern, as eligibility for antiretroviral treatment (ART) is expanded through the adoption of WHO's ‚test and treat' policies.
Methods: Between August 2013 and July 2015, two rounds of a survey of thirty-six (36) purposively sampled health facilities were completed in two districts in Eastern Zimbabwe. Data were collected on health facility characteristics, including human resources, and both the frequency and duration of stock-outs in HIV test-kits, first-line ART drugs and prophylactic treatments for opportunistic infections (OIs). Trends in demand for and stock-outs of testing and treatment resources were determined. Facility-level factors were examined for associations with stock-outs.
Results: A large proportion of facilities reported at least one stock-out of HIV test-kits, although this number fell slightly from 69% in 2013 to 61% in 2015. Stock-outs were primarily prominent amongst large district hospitals who reported a notable increase in the mean number of HIV tests conducted over the prior 3 months from 508 in 2013 to 1326.5 in 2015. Amongst facilities that reported stock-outs of HIV test-kits, the mean duration was reduced from 54.5 days in 2013 to 17 days in 2015. Despite the expansion in ART eligibility and expected rise in demand for first-line drugs, no facilities reported experiencing stock-outs of ART drugs in 2015, compared to 1 facility in 2013. Larger facilities and district hospitals were more likely to have experienced a stock-out of prophylactic drugs for OIs, however, no significant difference in the frequency or duration of these stock-outs was found across the two study rounds.
Conclusions: While the impact of changing ART guidelines on ART stock outs could not be directly evaluated, there have been significant improvements in test kit availability over time despite a rise in demand. This may indicate improved supply chain management and an increase in the provincial availability of resources for HIV testing as more initiatives are developed to improve linkage to care.

WEPED1374

Who, where, and how? Developing scenarios for the rollout of oral PrEP in Kenya

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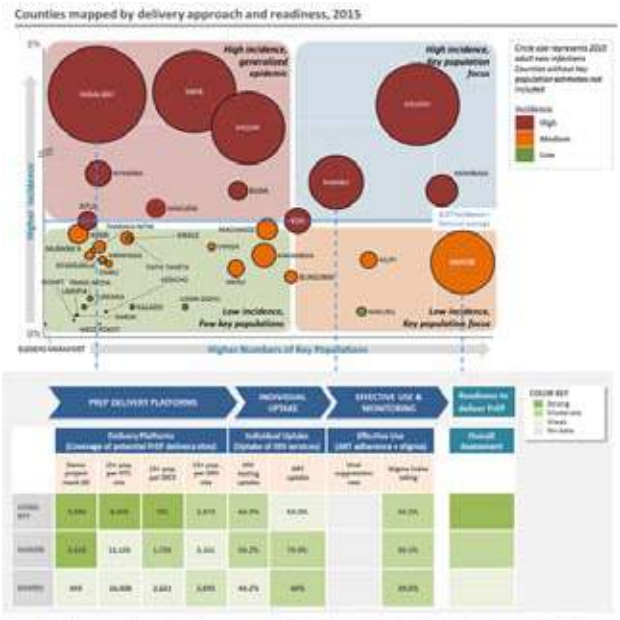
Background: As Kenya plans for oral PrEP (PrEP) introduction, questions remain about how to rollout PrEP across counties and populations. While epidemiological and cost-effectiveness modeling traditionally guide decisions, new rapid analytical methods can complement modeling to help accelerate planning, product introduction, and impact.
Methods: We analyzed existing county-level data on HIV incidence, population demographics, demonstration projects, and uptake of HIV testing, ART, and contraception to assess counties for potential impact and cost of PrEP and develop multi-county scenarios for PrEP rollout.
Results: Counties in Kenya vary greatly by HIV incidence and concentration of key populations. Together, these dimensions define several delivery approaches for PrEP - high-priority general population rollout, high-priority key population rollout, and targeted/limited rollout (see graphic below).
In addition, analysis of county capacity to deliver PrEP along a five-factor value chain suggests that readiness to rollout PrEP effectively varies by county. Counties with high capacity across these factors (e.g., Homa Bay) may be early PrEP adopters while those with lower capacity (e.g., Kiambu) may require additional investment before introducing PrEP.



[Kenya Rollout Analysis]

Promising scenarios included rollout to four highest incidence counties to leverage high existing delivery capacity and meet a great need (~45% of new infections) and rollout to seven counties with the most new HIV infections (~60% of new infections) with general population rollouts in three counties and key population-focused rollouts in four counties. Rollout to all nineteen counties with above-average incidence would have greater impact (covering ~85% of all new infections) but require significantly larger investments, while rollout limited to key populations would reach only ~15% of new infections.
Conclusions: Rollout scenario analyses using existing data can inform oral PrEP implementation planning in Kenya. While this approach does not replace the need for further modeling, it provides timely guidance that can inform planning while more robust analyses are developed.

WEPED1375

Predictors of social security disability benefits use in HIV-infected adults

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Background: The proportion of adults living with HIV receiving social security disability benefits (SSDB) is considerably higher compared to general population. We aimed to investigate the predictors of SSDB use in our adult HIV population.
Methods: A retrospective cohort study was conducted among our HIV+ adult population followed at Penn State Milton S. Hershey Medical Center. The study population comprised all patients seen between January 1st 2014 to December 31st 2015. Patients' employment status was determined by reviewing each patient's profile individually. Demographic and clinical data were obtained from our patient database that included basic demographics, recent CD4+ cell counts, year of HIV diagnosis, cardiac disease, cardiac disease risk factors (diabetes, hypertension, hyperlipidemia, tobacco use, and family history of cardiac disease), chronic hepatitis C infection, history of injection drug use, history of AIDS defining complication(s), county of residence (rural vs. urban), bronchodilator use, opioid use, psychiatric medication use (antidepressants, antipsychotics), and mood stabilizing agent use was obtained to identify risk factors for SSDB use among these patients.
Results: Of the total 866 patients analyzed, 357 (41.2%) were working full-time or part-time, and 313 (36.1) were receiving social security disability benefits. Employment/SSDB could not be determined for the remaining 196 patients. Predictors of SSDB use were Hispanic ethnicity (odds ratio [OR], 3.66; 95% confidence interval [CI], 1.95-6.87), psychiatric medications use (OR, 2.94; 95% CI, 1.96-4.40), African - American race (OR, 2.44; 95% CI, 1.53-3.9), rural county residency (OR, 2.34; 95% CI, 1.40-3.89), history of AIDS defining complication(s) (OR, 2.02; 95% CI, 1.30-3.12), tobacco use (OR, 1.82; 95% CI, 1.24-2.67), injection drug use (OR, 1.81; 95% CI, 1.18-2.77), and older age (OR, 1.03; 95% CI, 1.01-1.05). SSDB use was not related to CD4+ cells counts and other non-tobacco use cardiac risk factors, chronic hepatitis C infection, and cardiac disease.
Conclusions: In our adult HIV population SSDB use was more among racial and ethnic minorities, rural population, smokers, injection drug users, those with a history of AIDS defining complication(s) and older age. Specific interventions may be required to promote return to work for people with HIV/AIDS whose health has been restored by antiretroviral therapy.

WEPED1376

The relation of HIV stigma to satisfaction with health service: a lesson learnt in HIV task-shifting pilot project in Thailand

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Background: The task-shifting of HIV services to primary health care is a global strategy that aims to expand access to anti-retroviral therapy (ART). This represents one of the national goals in Thailand the country with the highest HIV-burden in Southeast Asia. In Thailand, health care workers usually say "close to the house, close to the heart", yet this is not really the case for people living with HIV (PLHIV). PLHIV are afraid of becoming known within their community as being infected with HIV. This stigma forms a barrier to the provision of ART within the primary care setting. This study aimed:
(1) to explore the levels of ‚perceived stigma' in PLHIV attending district hospitals and primary care units (PCUs), and;
(2) to find out the relation between HIV stigma and the satisfaction of patients with their health service.
Methods: In this cross-sectional study, two matched PLHIV receiving routine health care service were recruited for every PLHIV attending a PCU. A total sample of 198 participants was recruited with informed consent. The levels of the participants ‚perceived stigma' and ‚internal shame' were measured applying validated Thai version instruments. The level of the participants' satisfaction was measured applying the Patient Satisfaction Questionnaire 18 (PSQ18). The relationship between the PLHIV's satisfaction with their health service and their ‚perceived stigma' and ‚internal shame' was examined using multivariate robust regression models. Levels of ‚perceived stigma' and ‚internal shame' were measured using two different instruments and analyzed using two different regression models.

Results: 'Perceived stigma' and 'internal shame' levels did not differ significantly between task-shifted PCUs attendants and the district hospital HIV clinic attendants (P>0.05 MANOVA). However, a higher level of patient satisfaction was independently associated with a lower level of 'perceived stigma' (β -5.9, 95% confidence interval (-7.7 to -4.1)) and a lower level of ,internal shame' (β -5.7, 95% CI (-8.3 to -3.2). (P< 0.001)) among PLHIV.
Conclusions: PLHIV's satisfaction with their ART service may serve to relieve their 'perceived stigma' and 'internal shame' regardless of where the ART is received. Health professional education improving HIV services and patient's satisfaction may minimize the HIV related stigmata.

WEPED1377

Addressing clinician-induced barriers to INH prophylaxis for persons living with HIV in South-Eastern Nigeria

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Background: The HIV/AIDS epidemics in Nigeria is complicated by the high tuberculosis (TB) burden. Nigeria ranks 9th among the 22 high-burden TB countries in the world and one in four incident TB cases are co-infected with HIV. Despite these facts, only 57% of HIV-positive registered cases in Nigeria were screened for TB in 2010; while 4712 (2.5%) out of the 185,708 individuals newly enrolled ART in 2013 started Isoniazid Preventive Therapy (IPT). The 2014 Nigeria GLOBAL AIDS RESPONSE Country Progress Report (GARPR) also included reluctance of Clinicians to initiate HIV positive patients on IPT due to perceived fear of Isoniazid (INH) resistance and difficulty with diagnosing active TB in HIV setting as some of the barrier that limit access to TB preventive services for PLHIV.
Methods: Review of INH uptake at HIV treatment centres showed poor access to IPT services. Clinicians were provided with targeted technical assistance (TA) to address the barriers hindering access to IPT for PLHIVs. This include continuous medical education, hands-on mentoring, monthly data feedback and quarterly review of program performance. Excel and Statistical Package for the Social Sciences were used to analyze IPT data captured at the supported treatment centres.
Results: The rate of INH uptake ranged from 0%, to 61% between Jan-Dec, 2014. Targeting 70% of eligible clients (3092); after intervention IPT uptake increased from 11% (348) in Jan, 2015 to 110% (2,356) in Dec 2015.
Conclusions: The TA given to the clinician resulted in sustained increased in the rate of IPT uptake at the HIV treatment sites; relative to achievement in 2014. It is therefore recommended that continuous engagement of the fore front clinicians should encouraged to sustain INH access for eligible clients

WEPED1378

Expanding the provider base: HIV and hepatitis C clinical preceptorships in New York State

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Background: In 2014, New York State (NYS) Governor Cuomo announced a three-point plan to end the AIDS epidemic by 2020. The subsequent blueprint outlined several recommendations highlighting the important role of clinicians. Recent advances in Hepatitis C (HCV) treatment have emerged making it possible for patients to be cured. Despite these developments, there is a dearth of competent HIV and HCV clinicians in many counties throughout NYS, impacting access to quality care. There is a need for experience based medical education for clinicians practicing in at-risk communities.
Methods: From October 2015 to November 2016, three preceptorship programs were held (two on HIV, one on HCV) in New York City. These programs combined didactic presentations, case-based discussions, clinic observations, and support materials. Interested clinicians completed an application. Acceptance criteria included NYS region, intention to improve HIV/HCV care services, and current HIV/HCV knowledge and confidence. Applicants from the upstate regions were provided financial assistance. At the conclusion of the program, attendees provided reflective notes of their clinic observations and completed an exit survey.
Results: Over 200 NYS clinicians applied and 31 clinicians were selected including 12 nurse practitioners, 7 physicians, 7 registered nurses, and 5 physician assistants. More than half (58%) practiced in upstate NYS. The majority of accepted attendees had limited knowledge or were somewhat confident in HIV/HCV treatment and prevention. Reflective notes revealed that clinic observations included screening potential PrEP candidates, HIV resistance testing, HCV treatment selection, and drug-drug interactions. Of exit survey respondents, 100% either "agreed" or "strongly agreed" that they could apply the information learned. The majority of attendees indicated enhanced knowledge and/or confidence in managing newly diagnosed HIV/HCV patients as well as prescribing treatment.
Conclusions: This program provided a needed resource and may be a tool to identify and support future HIV/HCV clinical leaders. Challenges include limited number of participation spots, coordination of preceptor schedules, and long-distance travel for upstate attendees. Long-term impact of this program on workforce capacity is unclear until additional evaluation measures are taken. As advances in HIV/HCV prevention and treatment emerge, programs will need to be revised and resources identified in order to stay relevant and sustainable.

WEPED1379

PrEP implementation in New York State: challenges and solutions in clinical practice

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Background: Despite the evidence that pre-exposure prophylaxis (PrEP) is an effective HIV prevention option, it remains underutilized given the estimated 1.2 million people in the United States for whom PrEP is indicated. Healthcare provider perceptions are often a barrier to implementation. More research is needed to understand the challenges and barriers perceived by healthcare providers and to identify potential solutions to educate and support them in implementing PrEP. New York State (NYS) is uniquely situated to lead PrEP scale-up, given Governor Cuomo's three-point plan to end the AIDS epidemic by 2020 includes point three: provide access to PrEP for high-risk persons to keep them HIV-negative.
Methods: Five PrEP implementation workshops were held throughout NYS with a large sample of interdisciplinary healthcare providers (n=137). A regional and agency-level ,SWOT' (strengths, weaknesses, opportunities, threats) analysis of PrEP implementation was conducted at each workshop. Researchers performed a preliminary conventional content analysis of this data to identify major themes discussed by participants.
Results: Initial results from this conventional content analysis fall into two large regional and agency-level categories (weaknesses/threats; strengths/opportunities). Consistent themes cited by healthcare providers as weaknesses or threats to PrEP implementation include: clinician willingness and knowledge, funding/reimbursement, patient access and knowledge, clinic protocols, staff buy-in, stigma, and organizational capacity. Themes classified as strengths or opportunities include interagency networking, NYS progressive policies, outreach, utilizing multidisciplinary teams, and marketing opportunities.
Conclusions: As PrEP awareness increases, healthcare organizations will need to create or scale up their PrEP programs. This analysis examining healthcare provider perceptions of PrEP implementation demonstrates that many clinical settings do not have key elements necessary to deliver PrEP (e.g. policy and procedure, staff buy-in). Findings from this analysis also show that insurance navigation concerns, clinical capacity, and a lack of ongoing support are hindrances to implementing PrEP. However, we also see that healthcare providers in NYS are able to identify, and feel bolstered by, strengths and opportunities. The level of information sharing and resources provided during the workshops has enabled them to think strategically about providing PrEP services. Disseminating results from these workshops may help other healthcare settings purposefully and effectively develop their own PrEP programs.

WEPED1380

PEP and PrEP clinical cards: translating New York State (NYS) clinical guidelines into practical tools

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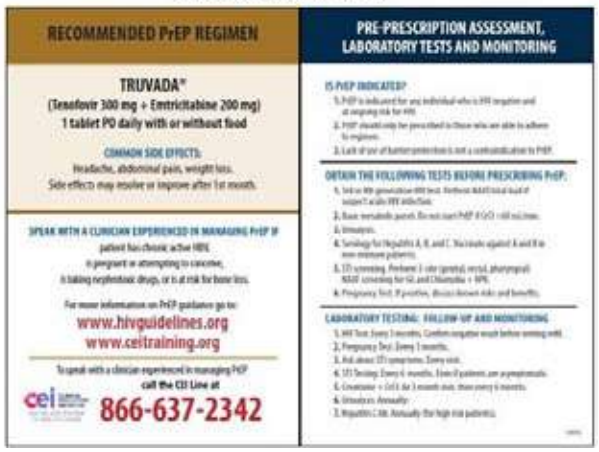
Background: Pre- and post-exposure (PrEP, PEP) clinical guidelines are tools to assist clinicians with HIV preventive care. While this information exists online, clinicians have limited time to review and process lengthy documents during patient visits. PEP/PrEP should be offered by all clinicians; however, many are hesitant due to perceived difficulty in understanding guidelines. PrEP and PEP clinical cards offer a way to disseminate guidelines while providing a portable quick reference.
Methods: PrEP and PEP clinical cards were designed based on the NYS clinical guidelines and included the recommended regimens, lab tests, evaluation, clinician help line, and the NYS guidelines and Clinical Education Initiative websites. Each

card is the size of a credit card and can be attached to a clinician's name tag. Cards were distributed free of charge via online mail order, during clinical conferences/trainings, and preceptorship programs. Due to their clinical content, cards were intended only for physicians, physician assistants, nurses, nurse practitioners, dentists, and pharmacists.

PrEP Card (front and back)



[PrEPClinicalCard]

Results: From August 2015 - January 2017, over 26,000 cards were distributed (12,915 PEP cards and 13,258 PrEP cards). In the first ten months of distribution, over 9,000 PEP and PrEP cards were simultaneously distributed to clinicians practicing in a number of settings including community clinics, hospitals, local health departments, and private practice. Qualitative data suggests strong favorability of the cards and content presented.
Conclusions: As we move toward ending the AIDS epidemic by 2020, it is critical that NYS clinicians have PEP/PrEP guidelines easily available. Clinical cards fill a gap in guideline access and could be used to address other topics including HIV and Hepatitis C screening. Barriers include delivery to the wrong address, torn envelopes, and cards being taken by non-clinicians. While highly popular, future cards will need to be updated when guidelines change and distribution expanded in order to reach clinicians across NYS.

WEPED1381

Strengthening governance, leadership and managerial capacity of district and regional health managers to improve health service delivery in Uganda

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Background: Inadequate management competences among lower level managers is a major challenge to healthcare delivery in low- and middle-income countries. Capacity strengthening initiatives for managers are still limited and primarily focused on individual competences, with limited attention to the governance challenges faced by managers. In this paper we share experiences implementing a District Capacity Building Program that utilizes a team approach to equip local government managers with skills in governance, leadership and management to improve service delivery.
Methods: We implemented a **9-months** work-based, action learning Fellowship for **health managers** that offered trainees short workshops with mentorship at their work stations. Trainees enrolled as teams and as part of training, each team implemented a project addressing governance, leadership and management challenges affecting service delivery at their workplace. Teams introduced changes including; establishing reporting systems, quality improvement structures, coordination structures, community engagement platforms, and staff performance management systems to improve service delivery. A total 134 managers (52 teams) were enrolled: 33 District Health Officers, 67 Regional Performance Monitoring Teams, 30 Regional Referral Hospital managers and 4 Principal Medical Officers of Urban Authorities.
Results: Within 6 months, weekly epidemiological surveillance reporting in 10 districts improved from an average 55.1% to 90.5%; completeness, accuracy and timely reporting of data in 29 facilities improved from 49% to 91.3%, 36% to 81.5%, and 64% to 100% respectively; Measles and DPT3 immunization coverage in 5 districts improved from 58% and 55% to 90% and 94%, respectively; and retention of HIV infected mothers in care at 15 facilities improved from 48% to 63%. Linkage of HIV positive clients to care in 2 districts improved from 55% to 95% and TB case notification in 2 districts improved from 46% to 55%. Managers acquired competences in motivating teams to produce results, data analysis and use for decision-making, strategic planning, negotiation, resource mobilization, and coordination of partners.
Conclusions: Developing governance leadership and management skills of managers empowers them to create organizational change that improves service delivery. The work-based, action learning training model that situates the training in the local context facilitates application of concepts in real life situations and creates immediate improvements in service delivery.

WEPED1382

Workforce development with an innovative HIV training program for nurse practitioners

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Background: In order to achieve the 90-90-90 targets set forth by UNAIDS in 2014 and achieve the U.S. National HIV/AIDS Strategy goal of increasing access to care and improving health outcomes for people living with HIV (PLWH), there needs to be an adequate workforce of providers who are skilled in HIV medical care. To address the potential shortage of HIV primary care providers in the U.S., the Health Resources and Services Administration (HRSA) issued a funding opportunity to establish nurse practitioner (NP) and physician assistant (PA) HIV/AIDS primary care education programs designed to train NPs and PAs in HIV/AIDS care and treatment.
Methods: The Duke University School of Nursing (DUSON) developed a distance-based HIV training program for NPs who wish to provide primary medical and HIV specialty care to PLWH in the U.S. A 12-credit HIV specialty concentration was designed and implemented in the fall semester of 2014. Students enrolled in the specialty complete online didactic instruction in HIV epidemiology, pathogenesis; HIV pharmacology; and HIV psychosocial, political, legal and ethical issues, followed by a clinical management course and 392 hours of supervised clinical practice in an HIV treatment center. Online instruction is complemented by two on-campus learning intensives with an inter-professional focus.
Results: Since inception of the program in August 2014, 43 degree-seeking students, and 4 licensed nurse practitioners have enrolled in the specialty. Most are women (68%), and white (68%) though there is representation from various ethnic groups including Filipino American, African, Cuban American, African American and Hispanic. Thus far 16 degree-seeking students and 3 licensed nurse practitioners have successfully completed the program; of these, 11 (58%) are employed in HIV specific settings providing primary and HIV specialty care and/or sexual health care to PLWH in the U.S., including 5 graduates who are employed in resource limited settings. Four recent graduates are currently seeking employment in HIV specific clinics.
Conclusions: The DUSON has developed and implemented an innovative and replicable HIV training program for NP students. The school has graduated NPs with expertise to provide primary HIV medical care and substantially contributed to the expansion of the HIV workforce.

WEPED1383

An innovative preceptor education training program for nurses and midwives to promote clinical competencies for accelerated scale-up of HIV treatment in Malawi

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Background: In 2013, ICAP at Columbia University developed the Preceptor Education Training Program (PETP) as part of its Nursing Education Partnership Initiative (NEPI). PETP was designed to enhance nursing education by improving the mentorship skills of preceptors at clinical teaching sites linked to nursing schools in Malawi. The six-week PETP included didactic and clinical training to equip nurse-mentors with student-centered clinical teaching competencies and enable them to model competent clinical skills, attitudes and evidence-based practice, with a focus on nurse-initiated and managed antiretroviral treatment (NIMART). In 2016, we assessed the skills of PETP-trained mentors and solicited feedback from nursing students regarding their mentors' performance.

Methods: 126 nurses completed the PETP between 2013-2015. In 2016, trained evaluators observed 25 purposively sampled PETP trainees using a standardized patient and clinical scenario to evaluate clinical teaching competencies in six NIMART domains. In each domain, teaching performance was assessed via a five-point-scale from "not-at-all descriptive" (1) to "very descriptive" (5). In addition, 50 students were randomly selected to complete a self-administered online survey. They were asked if their preceptors demonstrated teaching competencies in 23 domains, using a five-point scale from "disagree" (1) to "agree" (5). They were also asked to assess their preceptors' contribution to their learning, using a five-point-scale from "did not contribute" (1) to "contributed a great deal" (5). Data were analyzed in EXCEL™.
Results: The 25 observed PETP trainees received a median score of 4.0/5.0 for their teaching performance. 53% were "very descriptive" in teaching clinical principles, and 59% were "very descriptive" in teaching key steps in ART initiation. 44 nursing students (88%) completed the online survey, giving their preceptors' teaching competencies a median score of 3.7/5.0 for the 23 domains. 31 students (70%) felt their preceptors contributed to their acquisition of NIMART competencies.
Conclusions: PETP-trained mentors performed well, receiving high scores from trained observers. The majority of students felt their preceptors contributed to their mastery of NIMART competencies. Lessons learned will inform improvements to the PETP curriculum, to ensure production of competent preceptors able to build clinical skills and HIV/AIDS competencies of the next generation of nurses and midwives.

WEPED1384

The road to excellence: journey of the first public health laboratory in West Africa to achieve International Organization for Standards (ISO) 15189 and 15190 accreditation

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Background: The Laboratory of Virology (LBV) at Cheikh Anta Diop University (CADU) in Dakar, Senegal, is a National Reference Laboratory for Human Immunodeficiency Virus (HIV). LBV offers specialized testing for HIV, including HIV serology, CD4, viral load, and early infant diagnosis (EID). LBV also currently serves as a regional provider of external quality assessment (EQA), offering HIV related proficiency testing (PT) services for many laboratories.
In 2010, with assistance from the International Laboratory Brach (ILB) at the Centers for Disease Research and Prevention (CDC) and Westat; LBV began making preparations for achieving international ISO15189 accreditation. After 5 years, through implementation of a quality man- agement system (QMS) for laborato- ry services and carefully addressing identified gaps and deficiencies, the laboratory successfully achieved its goal. In October 2015, LBV was of- ficially recognized by the Institute of Quality Management in Healthcare (IQMH) as one of the first public health laboratories in West Africa to achieve ISO15189 accreditation.
Methods: LBV first initiated efforts to implement a laboratory QMS in the immunology molecular biology, and virology units in 2011. In 2012, the CDC ILB supported training on the World Health Organization (WHO) Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) program. Continued internal and external audits based on ISO15189 technical and management requirements were also conducted which identified additional gaps and areas for improvement from which corrective action plans were developed and tracked to ensure compliance.
Results: Baseline SLIPTA assessments scores ranged from 55-64% (Level 0/1); and increased to 85-94% (indicating Level 4 status) within the first 2 years of implementation. Follow up assessments were conducted based on ISO15189 checklist; which included detailed requirements for technical and management compliance under ISO15189. After addressing areas in need of improvement, the labo- ratory submitted an application for ISO15189 accreditation to IQMH.
Conclusions: The road to ISO15189 accreditation is a major challenge for public health laboratories, and in particularthose within resource limited settings. Key factors for success include management commitment, team effort, mentorship, and financial resources to support infrastructure improvements, service contracts for equipment preventative maintenance and calibration, and procurement of needed equipment and supplies.

WEPED1385

Nurturing community-based organizations of MSM, transgender and hijra (MTH) communities to take ownership in reducing vulnerability to HIV and AIDS

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Background: Since October 2010, The Humsafar Trust (HST), a community based organization (CBO) in Mumbai, has been implementing a GFATM-fund program (Round 9), Pehchan (Identity) across five states in west/central India. Pehchan is unique in its design and approach because it is community-driven and focuses on advocacy and capacity building to create an enabling environment for MSM, TG and Hijra (MTH) populations in unreached districts to access services.
Methods: In addition to strengthening existing organizations, Pehchan focused on setting-up CBOs in districts without HIV interventions. HST worked in 34 districts with low or no visibility of the MTH community due to stigma and discrimination. The project with support from a community advisory board identified community members from various districts, conducted the proto-CBO meetings and provided technical assistance to the members to form and register a CBO. These organizations were then provided with classroom and field level training to deliver the projects effectively.
The program has been able to register 73442 new MTH populations, 47327 have been tested for HIV of which 714 tested positive. Advocacy sessions were conducted with various stakeholders to strengthen their work and conducted 20 community based activities such as TG/ Hijra Habba, Solidary events, state level consultations which provided a platform for the community to mobilize together and also interact with state level stakeholders. A crisis response team comprising of lawyers, doctors, and community leaders helped address 700 crisis situations majority of which were reported post the Supreme Court judgement recriminalizing homosexual acts.
Results: Communities take ownership when there is a platform available.
Sustainability comes with experience and efforts. Advocacy when used as a tool can bring the social pillars of Judiciary, Law enforcement, Media, and Health to stand with the community in crisis situations.
Conclusions: Newly-nurtured CBOs have successfully accessed unreached MTH populations, motivated them to access health services, and empowered the community to fight stigma and discrimination. Strengthened capacities of these organizations has ensured sustainability of HIV programme for MTH population.

WEPED1386

Collaborative capacity building initiatives by two national programs through conventional and distance learning seminars for effective roll out and optimal uptake of services

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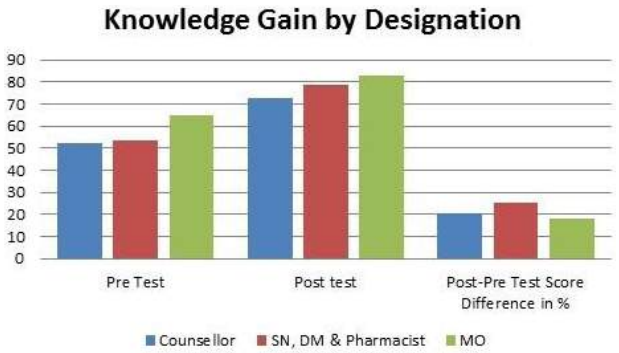
Background: TB is one of the most common opportunistic infections and causes of morbidity and mortality in PLHIV. Assessment and field visits suggested a need to strengthen infection control practices at the ART center. National AIDS Control Organisation(NACO) and Central TB Division(CTD)approved the provision of daily Anti-TB Treatment(ATT), and measures of Intensified Case finding(ICF) for TB, provision of Isoniazid Preventive Treatment(IPT), implementation of Airborne Infection Control(AIC) practices(3I's) at treatment centersto strengthen TB infection control practices.
It was necessary to build the capacity of the staff at service delivery sites for optimal implementation at HIV care settings.
Methods: Standardized training package was developed based on the principles of adult learning followed by one Training of Trainers(TOT) and 21 down training batches over a period of three months June to September 2016. The master trainers comprised of officials from both the HIV and TB programs, clinicians and state level program officials.
Distance learning seminars in local languages were used to train the staff on comprehensive guidelines for prevention and management of TB at ARTCs with detailed guidance on the activities and measures to identity TB in PLHIV, initiate early ART/ATT, and implement 3I´s.
Results: 956 ARTC staff including 429 doctors and 527 Nurses & Counsellors were trained from 510 ARTCs.The pre test scores under all category confirmed a limited baseline knowledge of the participants and there was a 25-30% increase in post test evaluations.



[Knowledge gain by designation]

In 40 distance learning session 3714 staff were oriented about the new guidelines. Post training, the roll out picked well within 3 months with 12 states have started dispensing daily ATT drugs, 6 states have rolled out provision for IPT, 17 states have all their centers linked to CBNAAT facilities and 508 centers havestarted doing 4S screening.
Conclusions: Collaborative and focussed capacity building by HIV and TB programs has positive impact on implementation.

WEPED1387

Reducing viral load sample rejection rates in health facilities of Kabarole district of western Uganda through onsite mentorships and coaching

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Background: To attain the third 90 in line with the UNAIDS strategy, Uganda has scaled up the use of Viral load monitoring for all ART patients however VL sample rejection remains one of the major hindrances to the achievement of VL coverage. Kabarole district in western Uganda registered a high rejection of VL samples. Poor quality of samples and incomplete filing of the sample requisition form for VL were the leading causes for sample rejection. A project was started to reduce the rejection rate of VL samples through mentorship and coaching of health workers. The project set out to build the capacity of health workers to collect quality samples and correctly fill in the requisition forms to reduce the rejection rates.
Methods: 15 sites with VL rejection rates above 5% were selected for the project, a team of competent clinical mentors in VL monitoring were identified and teamed up with the 15 health facilities. A total of 5 teams each comprising of a clinician and a laboratory technician were formed. The mentors worked with health facility staff providing mentorship and coaching for three days for each round of mentorship. Each facility received 4 rounds of mentorship, 2 for each quarter. Health facility staff were monitored by the mentors attached to the sites. Data on the rejection rates were reviewed quarterly for 9 months.
Results: There was a decline in the rejection of VL samples in all 15 health facilities, however the decrease is gradual over time. Health workers were more competent in sample collection and VL sample requisition. Non laboratory health care workers were able to do DBS phlebotomy which reduced client waiting time at the ART clinics. An increase in the rejection rates was observed in some of the sites when new staff attempted to do DBS VL phlebotomy for the first time, however this improved with more coaching and mentorship.
Conclusions: Mentorship and coaching is critical to building skill in the collection of VL samples using DBS and filing of the sample requisition VL form. Follow up of is critical to the effectiveness of the mentorship and acquisition of skill.

WEPED1388

The importance of community: development of a novel pharmacy-based HIV POCT program (the APPROACH study)

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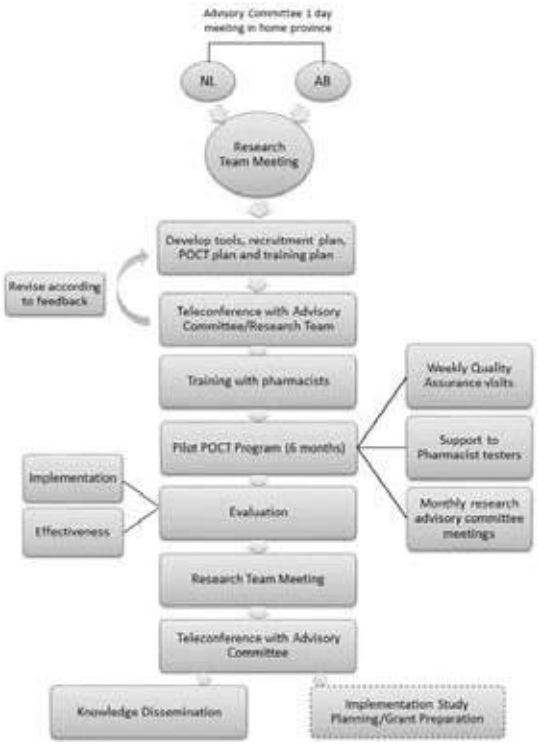
Background: Approximately 21% of HIV-infected Canadians are unaware of their status. In smaller provinces and rural communities, barriers include lack of access to testing, privacy concerns, and stigma. The availability of HIV point-of-care testing (POCT) is limited and variable across Canada. Pharmacists are well-positioned to address these barriers by offering HIV POCT and facilitating linkage to care (LTC).
Methods: The APPROACH study uses a type II hybrid Implementation-Effectiveness design to build a pharmacy-based HIV testing model to assess the acceptability, feasibility, and effectiveness in reaching at-risk individuals. In each province, we created provincial advisory committees (PAC) comprised of stakeholders from community-based organizations (CBOs), health providers, provincial laboratories, and policy/decision makers. PAC consultations informed selection of testing sites, client recruitment strategies, and local resources to support LTC plans in each region.



[APPROACH study - Team Development and Governance]

Results: PAC consultations have identified system and policy gaps including regional disparity in access to testing, which will impact LTC plans. We have devised creative solutions to provide client support using existing resources, including CBO and provincial mental health support lines. LTC plans are tailored for each testing site making best use of existing community and healthcare resources. PAC members facilitated client input and feedback on recruitment materials. PAC members are championing this multifaceted project and are vital to its implementation and sustainability.
Conclusions: Stakeholder engagement has proven critical to ensure the testing model developed is appropriate and responsive to each community's needs. Even in these initial stages of the project, PAC involvement has identified issues of importance beyond this specific study that will impact policy decisions, such as scope of practice and systemic barriers to HIV/STI testing in rural areas. When the testing program begins, PACs will play a critical role in supporting ongoing client recruitment and interpreting study results in the local context of communities.

WEPED1389

South Africa HIV and TB implementation research: a national agenda setting process

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Background: South Africa (SA) has the largest HIV epidemic, the sixth largest TB burden, and the highest prevalence of HIV/TB co-infection in the world[i],[ii]. The SA government has adopted UNAIDS 90-90-90 goals for HIV and is committed to strengthening its TB program. In order to provide guidance the SA National Department of Health (NDoH) convened a SA HIV/TB Implementation Research (IR) Advisory Committee consisting of experts from the government, WHO, academia, program implementers, and healthcare providers. The Committee developed a list of national priority HIV/TB IR questions.
Methods: In January 2015 NDoH convened the IR Advisory Committee to advise on IR goals outlined in the National Strategic Plan on HIV, STIs and TB (NSP). The Committee developed an IR Agenda through this process:
· A list of IR questions submitted by stakeholders was assembled with over 300 questions focused on HIV Prevention, HIV Care and Treatment, Tuberculosis, Health Systems Strengthening, and Strategic Information, Laboratory, and Civil Society. Questions were ranked as "High Priority", "Priority", "Not a Priority".
· February 2016: The Advisory Committee developed a Scorecard with 8 Criteria ranked on a 4 point scale: Burden, Impact, Cost and Cost Effectiveness, Sustainability, Scalability, Available Research, Research Resources, and Policy Alignment. The Committee disseminated the scorecard of "High Priority" and "Priority" questions to over 100 experts in Microsoft Excel and Google Forms formats. The average score for each question was calculated.
· April 2016: The Advisory Committee convened a workshop with 80 stakeholders to clarify, support or dispute results from the exercise.
Results: Experts at the workshop endorsed the high priority IR questions and acknowledged that the highest ranking questions reflect priority HIV/TB IR topics. Participants noted that some questions could be addressed in multiple studies that investigate a larger topic. They recommended that HIV/TB IR also focus on findings and lessons learned from underperforming implementation efforts.
Conclusions: The list of IR questions reflects and complements SA HIV/TB priorities. The SA government and the Committee will continue to pursue related objectives of broader dissemination and capacity building for IR. This includes the use of IR findings for improved effectiveness and efficiency of SA's HIV/TB programs.

WEPED1390

Effect of community-led vulnerability reduction intervention on condom use among female sex workers in India

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Background: Implementation Research Study was conducted under Avahan Phase III (April 2014 - September 2017) program as a part of BMGF supported India AIDS Initiative, to examine the impact of Combined vulnerability Reduction Intervention Coverage Index (CVRICI) on risk behavior among FSWs, and answer the research questions, whether vulnerability reduction increases Consistent Condom Use (CCU)? what is its contribution? and what is the pathway through which vulnerability reduction may impact CCU?
Methods: A systematic process of Member Engagement and Communication was conducted by Field Workers in their respective intervention areas using existing lists available with Community Organizations (COs) and Targeted Intervention Programs, as a part of social network including peer network, and conventional snowball method during April - September 2015, covering 109,366 FSWs across 71 COs from 47 districts of high risk states, Andhra Pradesh, Karnataka, Maharashtra, Tamil Nadu and Telangana.
Variables such as CVRICI, potential mediator CO Bonding Index (COBI) and outcome indicator, CCU with clients were operationally defined and measured using composite scales. SPSS V22.0 was used for Multiple Regression Analysis to explore whether CVRICI was associated with outcome indicator CCU and with mediator variable, COBI. Pathway analysis conducted by testing mediation, explored the degree to which effects could be attributed to CVRICI.
Results: FSWs with high level of CVRICI were more likely to report CCU with clients, AOR = 1.74, 95% CI = 1.66 - 1.81. Similarly, they were more likely to report high degree of COBI, AOR 2.30, 95% CI = 2.17 - 2.45. COBI was epidemiologically associated with CCU, AOR = 1.80, CI = 1.71 - 1.89. Pathway analysis conducted through Multiple Regression suggested that CVRICI acted above and beyond COBI to increase CCU, attributable to CVRICI leading to prevention of STI and HIV.
Conclusions: Findings reveal that vulnerability reduction interventions focusing on social protection, financial security, safety, security, justice among FSWs and institutional development support to community led organizations have both direct and indirect effect on increasing CCU beyond that of community mobilization (CO bonding) as potential mediator. Holistic approach of integrated vulnerability and risk reduction interventions may contribute to the sustainability of accelerated HIV Prevention program.

Monitoring and Evaluation

WEPED1391

Geo-prioritisation of HIV services: a direction for future interventions in Mumbai, India

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Background: HIV prevention and care services including targeted interventions should be easily accessible to communities. We designed the present study to examine the association between geographical locations of intervention programmes and HIV infected individuals in Mumbai, India.
Methods: We categorised the 24 wards in Mumbai into high (A), medium (B), and low (C) based on the proportions of key population (KP), bridge population (migrants and truckers), current HIV infected individuals, and slums in each ward. We used the Poisson Regression Model for count data for estimating the association.
Results: Fifteen wards were categorized as A, seven as B, and two as C respectively. The mean proportion of HIV infected individuals (total and active), HRGs, and slums was significantly different across these categories of wards (Table 1). In general, the median number of HIV-related services was highest in Category A wards; however, the median number of bridge population targeted interventions (TIs) was highest in Category C (Table 2). In the poisson regression models, we found that a unit increase in the proportion of KPs across wards was associated with a 10% increase in the number of KP TIs; this association was statistically significant (Rate Ratio [RR]: 1.10, 95% Confidence Intervals [CI]: 1.03, 1.18; p=0.008). Furthermore, a unit increase in the proportion of bridge population was associated with 5.7% increase in the number of Bridge Tis; however, this was not statistically significant (RR: 1.05, 95% CI: 0.98, 1.16, p=0.22).

Group	Total HIV %	Active HIV %	Key population %	Bridge population %	HIV/TB co-infection %	Slum %
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
A (15)	5.03 (1.36)	5.03 (1.36)	5.45 (3.62)	5.55 (7.21)	4.17 (2.10)	4.78 (2.74)
B (7)	3.18 (0.94)	3.29 (0.97)	2.38 (0.82)	2.32 (3.40)	4.87 (3.62)	4.05 (3.26)
C (2)	1.15 (0.54)	0.76 (0.36)	0.77 (0.95)	0.27 (0.38)	1.68 (0.00)	0.14 (0.20)
p value	< 0.001	< 0.001	0.04	0.35	0.33	0.03

[Table 1: Proportion of select variables]

Categories	HIV testing centres	PPTCT centres	ART centres	STI centres	KP TIs	Bridge population TIs
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
A (15)	3 (2, 3)	3 (2, 3)	1 (1, 2)	2 (1, 2)	3 (1, 3)	0 (0, 1)
B (7)	2 (1, 3)	1 (1, 3)	1 (1, 1)	1 (1, 2)	2 (0, 3)	0 (0, 1)
C (2)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	1 (1, 1)	0.5 (0, 1)
p value	0.28	0.09	0.18	0.53	0.28	0.88

[Table 2: Median number of Service Centres across t]

Conclusions: Even though, the number of KP TIs increased with a higher proportion of KPs in the wards, this pattern was not observed for the Bridge population. Thus, it will important to relocate some of the Bridge population TIs or add new services in wards with a high proportion of bridge population.

WEPED1392

Understanding pregnant women´s uptake and retention in mother to child prevention of HIV transmission in Papua, the most HIV-affected province of Indonesia

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Background: Papua is the most affected province in Indonesia with an HIV prevalence of 2.3% (IBBS, 2011) among the general population, most infected through unprotected heterosexual sex. Treatment for the prevention of mother to child transmission (PMTCT) of HIV is available in Papua, but results are suboptimal following five years of implementation. There is evidence of increased coverage of women received PMTCT treatment, but little is known about determinants for (not) uptake and (not) retention. This research investigated facilitators and barriers to PMTCT uptake and retention of HIV-positive women in Jayapura, Papua.
Methods: In-depth interviews were conducted toward 20 HIV-positive women, and 20 health workers providing PMTCT service. Women participants were registered in ANC care between January 2015 and August 2016; half completed PMTCT uninterrupted and the remainder had interrupted program. PMTCT completion is defined as ART adherence until infant HIV status is established.
Results: All women interviewed accepted PMTCT program at first offer for personal and infant health reason; expectating to have HIV-uninfected child and to maintain physical health to take care of their children. However, during the pregnancy course, some women discontinued the treatment and returned again approaching childbirth, while some others diligently followed the recommendation until HIV status of the baby was declared. All women in both groups had good knowledge of HIV, ARV, and PMTCT. For women completing PMTCT, health gains following ARV treatment and belief in efficacy of ARV helped overcome barriers such as lack of support from partner, risk of unwanted HIV status disclosure, financial burden, geographical challenge, as well as stigma and discrimination. Meanwhile, PMTCT interruption in the second group was mainly due to fear of HIV status exposure; it occurred among women who were not fully motivated to uptake PMTCT since the beginning.
Conclusions: Results suggested that PMTCT success is dependent upon women's personal belief on ARV effectiveness and the strength of her motivation to stay healthy and to have a HIV-negative child. Further research is needed to understand how HIV-positive pregnant women's existing knowledge could be transform into belief that drives compliance behaviours in order to improve retention in PMTCT program.

WEPED1393

Designing a monitoring and evaluation system for oral PrEP in South Africa

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Background: In late 2015 the South African National Department of Health (NDoH) undertook development of policy and guidelines for oral Pre-Exposure Prophylaxis (PrEP) implementation to prevent HIV acquisition for groups at high risk. This was in line with WHO guidance and following Medicines Control Council (MCC) approval of Truvada for use as PrEP. Development of a comprehensive monitoring and evaluation (M&E) framework, tools and templates was a critical part of this effort.
Methods: PrEP M&E development undertook a two-pronged approach. Standardized clinical forms were designed to support longitudinal, cohort-based client management and intrinsically linked to the design of a standard system to support routine data collection. The M&E system was planned with a limited, carefully-considered set of data elements and indicators. Additional operational metrics were included in routine monitoring to support program evaluation. Three M&E trainings have been conducted, in addition to individual site visits to support M&E. Formalized trainings and site visits drove adjustments to existing tools to improve client management and routine reporting.
Results: On 1 June, 2016, oral PrEP implementation began at ten sites in South Africa that work largely with sex workers. By December 2016, twelve sites were implementing oral PrEP, all using the developed M&E tools. From June through December, 2016, the 12 implementation sites initiated management of 729 individuals using the developed M&E tools, representing 235 client-years of data. Program data has informed adjustments to the M&E tools, including capture and management of missed appointments and program evaluation, including assessment of why/how certain sites have maintained higher rates of uptake and retention.
Conclusions: PrEP program design and services were comprehensively and proactively designed with intrinsic considerations for M&E. This has led to robust data availability from program inception. The data have supported adjustments to the M&E approach and evaluation of PrEP services, enabling the program to adjust in near real-time. Inclusion of additional operational metrics, as part of the two-pronged approach, has identified areas of focus for further programmatic and M&E evaluation. This allowed for critical review of data elements required for longer-term M&E where the quantity of data captured will be further limited.

WEPED1394

Remaining causes of mother to child HIV transmission (MTCT) in Thailand: barriers to achieving an MTCT rate of <1%

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Background: Thailand validated the elimination of mother-to-child transmission (MTCT) of HIV in June 2016 (meeting WHO target < 2%). Thailand's National HIV strategy aims to reduce MTCT rate to < 1% by 2020. To understand current causes of MTCT and better focus prevention activities, we analyzed data from an established national prevention of MTCT active case management network (ACC).
Methods: A Department of Health (DOH) case manager is notified when an HIV-infected infant is reported to the ACC. The case manager sends a standardized case investigation form to the Hospital Director where the HIV-infected infant was identified to assess potential causes of MTCT. We analyzed data collected from August 2014 to December 2016. Infants at high risk for MTCT were defined as infants whose mothers had viral load (VL) >50 copies/mL at gestational age >36 weeks or received antiretroviral therapy (ART) for < 4 weeks prior to delivery.
Results: A total of 168 HIV-infected infants were reported. Of these, 102 (61%) infant case investigation forms were completed. Among the 102 HIV-infected mothers, mean age was 26 years with mean CD4 count 466 cells/mm^3. Only 28 (27%) had VL testing near delivery. Mean gestational age at first antenatal visit was 21 weeks and at delivery was 37 weeks.
Among the 102 HIV-infected infants, 82 (80%) were classified as high risk for MTCT. Mean age at first positive PCR was 86 days. Potential maternal risk factors for MTCT reported included presentation at ≥32 weeks or no antenatal care 35 (34%), poor antiretroviral adherence or suspected viral resistance 28 (27%), incident HIV infection (e.g., a woman who seroconverts to HIV-positive late in pregnancy or post-partum) 15 (15%), poor service delivery (e.g., delayed ART initiation) 13 (13%), lost to follow-up 7 (7%), and others 4 (4%).
Conclusions: To reduce MTCT rate to < 1%, Thailand should identify pregnant women with a high risk of MTCT by increasing uptake of VL monitoring prior to delivery, provide ART intensification for mothers with high VL and late-presenters, promote couples HIV testing and counseling to identify HIV discordant couples, and support HIV-infected pregnant women to adhere to ART and remain in care.

WEPED1395

Assessment of the effectiveness of PMTCT program in service delivery points in North-Central Nigeria

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Background: Prevention of mother-to-child transmission(PMTCT) is essential in HIV/AIDS control as mother to child transmission account for the majority of Paediatric HIV infections. Despite over 12 years of HIV programming in Nigeria, there is a paucity of data as to the effectiveness of PMTCT programs in Nigeria. We executed this study to explore the effectiveness of PMTCT in selected sites in Nigeria.
Methods: We conducted a secondary data analysis at eight of supported Service Delivery Points in Abuja and Nassarawa States. Ethical review was received, and all identified PMTCT cases from 2012 - 2016 were included in the study. Mother-infant pairs data were extracted and analyzed using a tailored data collection tool. Data on early infant diagnosis(EID), final outcome and relevant test results were reviewed. We also examined the predictors of HIV transmission from mother-to-child in these centers. SPSS V23 and OpenEpi were used for data analysis.
Results: We retrieved 1,454 mother-infant-pair data from eight centers, but 83% (1207) were from secondary level facilities. While 89.5% (1302) positive pregnant women (PPW) and 92.2% (1340) of HIV-exposed infants received antiretroviral prophylaxis/treatment and 88.4% (1285) were breastfed with 32.5% still on breast milk as at the time of DBS collection. EID-PCR positivity rate was 3.5% (range: 0.0 - 11.1%). Facility of delivery (X=24.99, p<0.00), mother on ARV (X=48.8, p<0.00), mother received ARV prophylaxis (X=89.59, p<0.00), infant received ARV prophylaxis (X=58.56, p<0.00) and baby received cotrimoxazole (X=55.24, p<0.00) were all significantly related to positive EID-results. However, mode of delivery, place of delivery and breastfeeding were not significantly associated with positive EID results.
Conclusions: PMTCT services minimized the transfer of HIV from infected mothers to HIV exposed infants(HEI). To eliminate HIV in our generation and achieve zero new infections, every HIV-positive pregnant woman should receive ARV prophylaxis and supported post-delivery to prevent transfer of infection to the new born. Also, HEI should receive timely ARV and cotrimoxazole prophylaxis.

WEPED1396

Evaluation of the South African national female condom programme: overview of key findings in the progress of female condom rollout in the public and non-public sector

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Background: South Africa (SA) has one of the largest and best-established, national public-sector male and female condom (MC and FC) programmes worldwide. The first comprehensive evaluation of the FC programme has recently been completed, with the primary objective of describing and evaluating FC distribution and promotion approaches.
Methods: This multi-component evaluation included a national survey in public and non-public health sectors, including interviews with providers (n=278) and female clients who had ever used the FC (n=424), and an anonymous female and male client survey (n=4442); review of District Health Information System data; key informant interviews with policy and programme managers; and 12-month follow-up of new FC users (n=598) and a sub-set of their male partners. The existing National STI sentinel site surveillance sample was used for the public-sector evaluation.
Results: Nationally, 256 public and 28 non-public sector facilities participated in the evaluation. Between 2014-2016, FC distribution more than doubled to over 27 million, exceeding the 2016 target of 25 million. All surveyed sites reported ever having distributed FCs, with 4.8% reporting a stock-out on the day of assessment. The anonymous client survey indicated that nearly 90% of women and men had heard of the FC, around 20% had ever used it, and two-thirds knew that FCs were available at their facility. Three-quarters of providers had been trained in FC provision and viewed introduction of new FC products (three FC types available in SA) favourably. Distribution across sites differed widely, with some sites distributing <50 FCs per month while others distributed over 10,000. A third of sites distributed FCs to other sites (e.g. taverns, NGOs, garages). HIV-positive women were well represented in both the cross-sectional client data (30%) and cohort (42%) data. Cohort data indicated that condom use at last sex using either an FC or MC increased from 56% to almost 90% from baseline to one year.
Conclusions: Distribution is increasing year on year, however varies significantly between sites, and around a third of clients are unaware of FC availability in their local facilities. Information that the FC is now available along with MCs in the programme is a priority to ensure access.

WEPED1397

The PrEP cascade: initiation of pre-exposure prophylaxis (PrEP) and retention in care in a clinic-based cohort of men who have sex with men (MSM)

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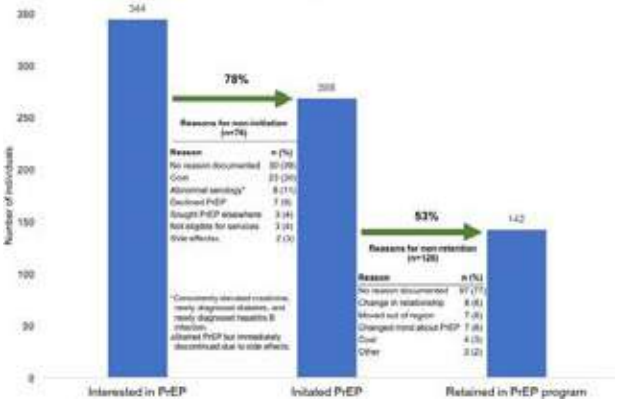
Background: Addressing the PrEP cascade is crucial to optimize its clinical and public health benefits. In a community-based clinic serving MSM, this study characterized key steps of the PrEP cascade (i.e., seeking services, initiating PrEP, and retention in care) and identified predictors of non-retention.
Methods: Between November 2014 and August 2015, MSM were enrolled in a PrEP clinic in San Francisco. Follow-up visits were one month after enrollment and quarterly thereafter. Baseline sexual risk (i.e., self-report and STI diagnoses), stimulant use in the last 12 months (i.e., cocaine, crack, methamphetamine), and binge drinking (i.e., ≥ 5 drinks on one occasion) in the last month were assessed. PrEP initiation was verified at the 1-month follow-up. Non-retention was defined as failure to return within 30 days of a scheduled follow-up after initiating PrEP without evidence of transferring care.
Results: Among the 344 patients who sought PrEP services, most (95%) reported condomless sex and 14% were diagnosed with an STI (i.e., syphilis, rectal gonorrhea or rectal chlamydia). At enrollment, half reported binge drinking (50%) and one-fourth (27%) reported stimulant use. Of those who sought PrEP services, 268 (78%) initiated PrEP. Cost was the most commonly cited reason for not starting PrEP (see Figure). Among patients who initiated PrEP, median follow-up time was 389 (range 112-488) days. Cumulative incidence of non-retention at 13 months was 38%. Men with an STI diagnosis at enrollment had a 79% greater rate of non-retention (Adjusted Hazard Ratio [aHR]=1.79, 95%CI=1.06-3.01). Binge drinking (aHR=1.07, 95% CI=0.73-1.57) and stimulant use (aHR=1.00, 95% CI=0.64-1.56) were not associated with non-retention.



[Figure 1. PrEP cascade: proportion of individuals who sought PrEP, initiated care, and were retained in care]

Conclusions: Barriers to PrEP initiation among MSM are multifactorial, and cost remains a key concern. Non-retention is also prevalent. Although some PrEP discontinuations may be appropriate, expanded efforts are needed to support retention of those with STI diagnoses such as syphilis that increase risk for HIV seroconversion.

WEPED1398

Near real-time tracking of PMTCT gaps in three districts of KwaZulu Natal province, South Africa

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Background: Over the past decade South Africa's prevention of mother-to-child transmission (PMTCT) of HIV programme has seen significant reduction in early-infant transmission from >20% to < 2%. Understanding PMTCT gaps that continue to fuel transmission rates will fast-track the last mile to elimination of mother-to-child transmission (eMTCT) of HIV and mobile health technologies hold the key to rapidly identifying gaps for intervention.
We describe findings from an operational follow-up study that investigated in near real-time, PMTCT gaps among HIV-infected infants aged < 18 months in KwaZulu-Natal Province.
Methods: Between May-September 2016, PMTCT co-ordinators from eThekwini, uMgungundlovu and uMkhanyakude districts received daily email notifications of all HIV PCR-positive results in their district, including patient identifying details. Co-ordinators reviewed facility records for each infant to answer five questions to identify gaps in PMTCT care (maternal age, timing of maternal HIV diagnosis, maternal treatment history, maternal viral load (VL), infant prophylaxis). Data was submitted via cellphone short-message-service using Rapid Pro technology and analyzed in STATA 14.
Results: 400 infants tested HIV PCR-positive during the study period and 367 (91.8%) had data for analysis. 258 (70.3%) were from eThekwini, 58 (15.8%) from uMgungundlovu and 51 (13.9%) from uMkhanyakude. Data was received within a median of 12.5 days (interquartile range [IQR]: 6-23). Median maternal age was 25 years (IQR 22-30) with no significant difference in PMTCT gaps observed between 48 teenage (15-19 years) and 293 older (20-34 years) mothers. 220 (60.0%) mothers were first diagnosed prior to conception or at their first antenatal clinic (ANC) visit and 127 (34.6%) at or after delivery. 137 (37.3%) women transmitted despite receiving >12 weeks cART with 48.9% diagnosed prior to conception. 257 (70.0%) women had no VL result documented, despite 62 (24.1%) being on cART for >12 weeks. Amongst 110 women with a documented VL, 75 (68.2%) received cART for >12 weeks with 35 (46.7%) virologically suppressed. No statistically significant differences in PMTCT gaps were observed between districts.
Conclusions: Findings highlight the need to improve services during ANC, prevention of maternal infections postpartum and prioritization of maternal VL monitoring. We intend using improved technology to streamline data collection and reporting towards eMTCT.

WEPED1399

What is the benefit of the Basic Care Package (BCP) in the era of test and treat of all people living with HIV?

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Background: Uganda has the highest prevalence of HIV in East Africa (7.3%) with about 2363 persons getting infected every week (UNAIDS 2013). Uganda aims to have at least 90% of persons diagnosed with HIV are enrolled on ART by 2020. The question is whether it's necessary to complement ART with BCP. PACE implemented the Positive Living Project (PLP) from 2010-2015 to provide BCP which was a combination of items (water treatment, mosquito net, and condoms) and messaging to People Living with HIV (PLHIV) enrolled in care and their families to adopt a Positive Living Life style (PLL). The goal was to reduce HIV transmission, opportunistic infections. Over 580,000 BCP kits were distributed accompanied with messaging about the PLL. An evaluation was done to establish the effect of complementing ART with BCP on incidence of OIs.
Methods: A retrospective review of clinical records to compare incidence of OIs for three categories of PLHIV i.e.
i) Enrolled on BCP but not on ART
ii) enrolled on ART but not enrolled on BCP, and
iii) Enrolled on both ART and BCP.
Patient records for 12 months after enrollment into each group were reviewed. The achieved samples for the 3 groups were 1110, 1676 and 1815 respectively.
Results: Key findings: In the 12 months follow-up period, a higher proportion of patients on ART-only reported OIs compared to those on both BCP and ART, 41% vs 29%, p value = 0.0002. Similarly, those on BCP-only reported OIs compared to those on both BCP and ART, 34% vs 29%, p value = 0.002. Overall incidence of OIs during the 12 months of follow-up was higher significantly in the ART-only group than other groups. All the 3 interventions have immediate reduction of incidence of OIs within the first three months which wanes by the end of the sixth month to similar levels.
Conclusions: The BCP is critical in the reduction of OIs in the first six months. A combination of both BCP and ART should be prioritized in the first six months of enrollment on ART for effective results.

WEPED1400

Challenges and innovations in monitoring HIV prevention programs for key and priority population

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Background: Integration of HIV prevention programs targeting key and priority populations (KP and PPs) has been advocated and implemented globally. However, the M&E system used to monitor its performance is constrained by a number of issues. This abstract presents key challenges faced and innovations in the M&E system for KP/PP programs implemented in Eastern and Western Uganda.
Methods: Between 2014 and 2016, Baylor Uganda is implementing HIV prevention programs in Eastern and Western Uganda targeting key and priority population including female sex workers, MSM, truckers, sero-discordant couples and adolescents among others. As part of the program, we designed appropriate M&E tools including the framework, data collection and reporting tools, longitudinal registers. Mapping of KPs and PPs was done; Focal persons at all service delivery points received appropriate training and mentorship in data management. Routine support supervision and action plans developed to address identified gaps. A computerized information system was designed and records assistants oriented on using the system. On quarterly basis, data coordination meetings and facility based meetings are conducted to review performance, share experiences and develop work plans. Additionally, quality improvement projects were initiated based on specified gaps. We reviewed data for 34 sites providing KP and PP services and interviewed focal persons on M&E issues; experience, challenges and innovations.
Results: A total of 5,767 KPs and PPs were served including; female sex workers (17%), MSM(1%), fisher folks(63%), truckers (6%) and sero-discordant clients (13%). Key innovations were; the development of new data systems which improved program performance tracking; Use of innovative staffing patterns and KP peers in providing prevention services and updating registers; Collaboration and partnership between stakeholders including project staff, health workers, KP/PP peer groups strengthened the continuity and quality of services. Key challenges included: Transportation of health workers at night for moonlight activities; lack of unique identifiers leading double counting; unreliable Internet connectivity; Lack of tracking system for mobile KPs/PPs leading to missing longitudinal data;
Conclusions: HIV Programmers need to adopt innovative M&E strategies for improved monitoring of the KPs and PPs programs; Standardize and integrate Prevention M&E tools in national M&E system; design a web-based and unique identifier system.

WEPED1401

Predictors of mother to child transmission in women on ART: results from a national evaluation of Malawi's PMTCT program

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Background: In 2016, high ART uptake in HIV infected pregnant women was documented by the National Evaluation of Malawi's PMTCT Program (NEMAPP), and early infant transmission reduced to less than 2% in women on ART. Understanding factors associated with infant transmission in women on ART becomes increasingly important as countries seek to reach virtual elimination of mother-to-child transmission (eMTCT).
Methods: NEMAPP was implemented at 54 health facilities in 10 districts. A stratified cluster sampling design was used to identify a nationally representative sample of 4-12 week old infants. Mothers were consecutively consented and screened for HIV while attending an under-5 clinic, and all identified HIV-exposed infants underwent HIV-1 DNA testing. Structured interviews collected data on sociodemo-

graphic and clinical characteristics. Complex weighted survey design analysis was conducted using STATA.

Results: Of the 2125 HIV-infected women enrolled, 1,865 (88.5%) were on ART at the time of enrollment. Early infant transmission was lower in mothers who started ART prior to pregnancy in comparison to those who started in pregnancy (2.3% vs 3.5%, p=0.014) and women who disclosed their status to their partners (5.8% vs 2.0%, p=0.008).

In multivariable analysis for the subgroup of woman on ART, early infant transmission was almost twice as likely if a woman started ART during compared to before their pregnancy (aOR 1.9;p=0.032). Additionally, partner's HIV status disclosure to mother was significantly protective against early infant transmission (aOR 0.39; p=0.011), although maternal disclosure to spouse was not. Maternal self-reported health status, mother's self-reported missed ART, exclusive breastfeeding and infant receiving nevirapine syrup were not associated with early transmission in this sub-group of women on ART.

Conclusions: Women who have not openly discussed their partner's HIV status are more likely to transmit the virus to their child, indicating that disclosure between partners may mediate the effectiveness of PMTCT, potentially through the mother's adherence to antiretrovirals. This is the first time HIV status disclosure between partners has been documented to affect vertical transmission at national level.

WEPED1402

Sexual health clinics successfully improve efficiencies and increase access to HIV testing among gay and bisexual men

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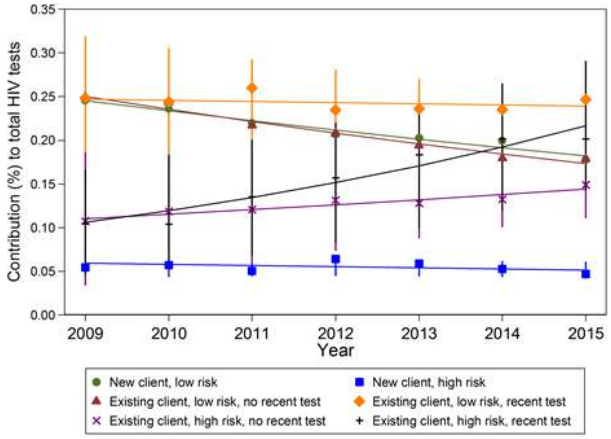
Background: In the past 5 years, public-funded sexual health clinics (SHCs) in New South Wales (NSW) have introduced a range of largely information-technology initiatives to improve efficiencies in their existing services including express-clinics, online booking, self-registration and SMS reminders. We analysed temporal trends in HIV testing among gay and bisexual men (GBM) attending SHCs in this period and if testing was targeted to high-risk GBM.

Methods: We used retrospective data from 32 SHCs in NSW participating in a sexual health surveillance network. HIV-negative GBM were categorised based on client type (new or existing), risk status (using partner numbers and/or recent rectal sexually transmitted infection), and recent HIV testing (past 6 months for high-risk, past 12 months for low-risk GBM). We used repeated measures Poisson regression to assess trends in testing and contribution to total tests by GBM categories.



[Proportional contribution to HIV tests by category]

Results: From 2009-2015, 58,377 HIV tests were done, 74% in existing clients and 35% in high-risk clients. The number of HIV tests increased 2.5-fold (4,779 in 2009 to 12,173 in 2015) with significant increase in all categories and the greatest increase in high-risk existing clients. Over time, high-risk existing clients with recent (past 6 months) testing had an increasingly larger contribution to total tests (13% annual increase, 95%CI: 8-18%, p< 0.001). There were no changes in contribution by other high-risk categories. There was a simultaneous annual decline in contribution to total tests by low-risk new clients (5% annual decline, 95%CI: 2-7%, p< 0.001), and low-risk existing clients with no recent (past 12 months) testing (6% annual decline, 95%CI: 5-7%, p< 0.001; see Figure).

Conclusions: Sexual health clinics in NSW have successfully increased HIV testing among GBM, with testing remaining targeted to high-risk men. Strategies to improve efficiencies in existing clinics, rather than establishing new ones, should be adopted more widely.

WEPED1403

Data for decision making to increase HIV testing among MSM in Kiambu county, Kenya: the Kuja clinic campaign

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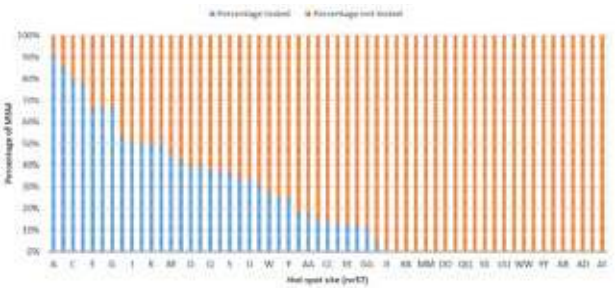
Background: Men who have sex with men (MSM) in Kenya are at high risk of HIV and are a priority population for HIV interventions, including HIV testing. However, MSM underutilize testing services due to stigmatization and discrimination. Through the USAID- and PEPFAR-supported LINKAGES project, we used routinely collected data from the project's efforts in Kiambu County, Kenya to identify gaps in HIV testing among MSM and implement an individualized HIV testing outreach intervention, the Kuja Clinic campaign.

Methods: MSM were recruited into the LINKAGES program through peer-led outreach and referred for HIV testing at community-based centers. At enrollment, all participants were assigned a unique identifying number and were assigned to the peer educator who identified them. We reviewed routine program data, including the number of hot spots from which MSM were recruited, number of MSM enrolled, and number of MSM who did not test for HIV. Data were disaggregated by hot spot to allow for individualized tracking of participants. We used descriptive statistics to summarize HIV testing gaps within the program.

Results: We enrolled 533 MSM from 63 hotspots between July and November 2016. Overall, 361 (68%) MSM spread across 57 hot spots did not test for HIV. HIV testing gaps across hot spots ranged widely from 9-100% (Figure 1). Hot spots with >75% testing gap (n=34) were prioritized for more intensive follow up of MSM through outreach by peer educators.



[Testing Gaps]

Conclusions: Analysis of routine program data revealed gaps in testing by hot spot and allowed for individualized HIV testing mobilization by peer educators. The ongoing Kuja Clinic campaign demonstrates the need for data-driven targeted HIV responses for strategic planning in KP programming to optimize service uptake in resource constrained settings.

WEPED1404

HIV testing strategies in primary health care centres: Indicator condition, risk-based or universal offer. Which strategy is the best?

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Background: Primary health care centres are a key piece to reduce the amount of people who don´t know their HIV status. The aim was to describe the effectiveness of three HIV testing strategies: Indicator condition, risk-based and universal offer in primary care centres.
Methods: Quasi-experimental multicenter study in primary care in the Community of Madrid (Spain). Study population were 18-64 years old patients attending health care centres. We selected centres using a multi-stage cluster sampling from HIV high incidence areas. We randomly assigned one strategy by centre. In 30 centres three strategies were implemented (10 centres by each strategy).
HIV test was indicated according each strategy:
1. Indicator condition offer (IO): in people with HIV indicator disease according 'HIV in Europe platform' recommendations, reminders in the electronic clinical record of patients were implemented.
2. Risk-based offer (RO): focus on the most-at-risk behaviours and vulnerable populations (men sex men, migrants, multiple sex partners, no condom use).
3. Universal offer (UO): for everyone for whom a blood analysis is requested.
We analyzed, by strategy: HIV test uptake, new HIV diagnosis and effectiveness (new HIV diagnosis/ HIV test uptake) with 95% confidence interval (CI).
Results: The study was completed in August 2016, one year after strategies implementation. In 30 centres, 320 professionals (family physicians and nurses) indicated HIV test to 4,044 patients. According strategies, the largest number of tests was performed in UO: 2,358 HIV tests (895 tests in IO and 791 in RO). There were 13 new HIV diagnosis, 9 of these patients with CD4>350 cell/µl. Global effectiveness: 0.32% (95%CI: 0.14-0.51). The most effectiveness strategy was IO: 0.78% (95%CI: 0.15-1.42), followed by RO: 0.51% (95%IC: 0.14-1.29) and finally UO: 0.08% (95%CI: 0.01-0.31).
All new HIV diagnosis had history of indicator disease in the last five years.
Conclusions: Although with routine offer strategy it is possible to carry out many HIV tests, indicator disease offer was the most effective strategy to new HIV diagnosis in primary care centres. So it would be necessary the strengthening of this strategy to reduce HIV hidden infection.

WEPED1405

Afro-Caribbean community HIV rapid testing in France: an opportunity for untested population?

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Background: Community-based HIV testing initiatives has been launched in France since 2010. They target most-at-risk populations, including the afro-caribbean community. We aimed to evaluate how a mobile programme promoting and offering rapid HIV testing in outdoor can attract untested persons.
Methods: Between 2014 and 2015, the programme served 6565 persons in the Paris metropolitan area. Each participant answered to an anonymous questionnaire about sociodemographic characteristics, sexual behaviour and history of HIV testing. Characteristics of untested and already tested persons were compared by Chi-squared or Fisher tests for qualitative variables and by t-tests for quantitative variables. All analyses were stratified by sex. Analyses were conducted using STATA 13.
Results: 1829 participants (28%) had never undergone an HIV test before, more men than women (30.0% vs 23.4%). For both sex, undergoing a first HIV test was associated with younger age (< 25 years), being born in France metropolitan and not having health insurance (22.1% vs 15.9% for women and 27.0% vs 17.2% for men). Men tested for the first time declared less often having multiple partners in the past year and unprotected sex with casual partner.
Men and women declared more often to have decided to be tested when they passed by the programme than those who have ever been tested (15.1% vs 9.1% for women and 16.3% vs 7.9% for men).
Among all participants 40 had an HIV rapid test positive (positivity rate: 0.6%). Among them, 16/40 were tested for the first time (positivity rate among first time testers: 0.9%): 9 were men, 12 were born in sub-Saharan Africa and 8 did not have health insurance. Positivity rate between first time testers and people already tested was slightly different (0.9 % vs 0.5%).
Conclusions: This community programme attracted a substantial number of persons who have never been tested probably because it offers multiple and more attractive, accessible and convenient testing locations than conventional healthcare settings. It may increase access to HIV testing by persons unaware of their HIV serostatus and particularly those without health insurance.

WEPED1406

Distributing HIV self-test kit by vending machines to raise serostatus awareness among high-risk populations in Taiwan: a pilot study in 2016

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Background: According to the surveillance data in Taiwan, up to 90% all new HIV cases are attributed from unsafe sexual behaviors. High-risk sero-unaware individuals with concerns about venue-based testing might benefit from novel private, self-testing methods such as In-Home HIV Test. The purpose of the study was to evaluate the feasibility for distributing the HIV self-testing kit in Taiwan and the HIV-positive rate among users.
Methods: From September-December 2016, we undertook a pilot study to examine the feasibility for HIV self-testing kit targeting vulnerable populations in Taiwan. Taiwan Centers for Disease Control applied for special permission to distribute HIV self-testing kit at NGOs or health stations, through vending machines at LGBT health centers, health stations, and gay sauna. Besides, only Hualien county provided extra route that pay-at-pickup services provided by chained convenient stores (only at Hualien County). Clients paid 6 US dollars to get the kit, and could receive full redeem after logging their test results online. Also, they could join a lottery activity for convenient store coupons (3 US dollars) after completing a questionnaire.
Results: In total, 4,812 kits were sold: 2,526(52.5%) through vending machines, 1,990(41.4%) distributed by LGBT health centers and health stations. At Hualien County, 88.1% (296/336) kits were distributed through pay-at- pickup services provided by chained convenient stores. Of 2,249(46.7%) who logged their test results anonymously on the website, 22 (1%) of respondents reported being newly tested HIV-positive. Of 1,341 who completed the questionnaire, 1,170(87.3%) were males, and 688(51.3%) reported being homosexuals, 179(13.4%) being bisexuals; 521(38.6%) reported that this was their first time to do HIV testing. About the satisfaction survey, 1,203(89.7%) claimed it was convenient to get the kit, 1,253(93.4%) said the service price was acceptable or cheap. For future access to the kits, 883(65.9%) said they'd like to get the kit from vending machines, 559(41.7%) through pay-at- pickup services at convenient stores.
Conclusions: The two novel delivery services were well-accepted and led to a substantial proportion of first-ever HIV testing. Both distributing methods were feasible to facilitate HIV self-testing and their access should be expanded in the upcoming programs.

WEPED1407

Low rates of HIV testing and multiple barriers to care in a large online sample of MSM across India: implications for scale-up of treatment and prevention

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Background: HIV serostatus awareness is a critical initial step to optimize treatment and prevention. Because little is known about current HIV related behaviors in Indian MSM, we sought to determine factors associated with HIV-testing in a national online sample.
Methods: In January 2017, sexually-active MSM, aged 18 years or older, recruited via social-media and MSM mobile dating sites across India, completed an online-survey in English or Hindi, assessing HIV testing and sexual behaviors, and sociodemographics. We used summary statistics and multivariable logistic regression to identify factors associated with HIV-testing.

Results: The 3,637 (59%) MSM completing the survey, came from all states, 17% from rural areas; 18% responded in Hindi. Their median age was 26, most (82%) completed college, and 15% were categorized as being in poverty and 21% in lower class; 49% identified as homosexual, 47% as bisexual, and 4% as heterosexual; 43% had not disclosed their sexual-identity to anyone, and most (77%) had never disclosed same-sex behaviors to any healthcare provider. In the past year, 31% had used drugs/alcohol during sex and 7% were diagnosed with an STI. In the past six months, participants had a median of 5 sexual partners and 42% had condomless anal sex (CAS). Overall, 46% had never had an HIV test and 47% among those reporting CAS (n=1,520), Among those previously tested (n=1,964), 5.4% were HIV positive, and 25% last tested over 12months ago; 59% tested at a private lab or clinic, 23% at a public-hospital, and 8% at a testing-counseling center. Among those never tested, reasons for not testing included not being at risk (43%), feeling scared (20%), and not knowing where to test (14%). In multivariable analysis, never being HIV-tested was associated (p<0.01) with younger age, lower income, less education, CAS, not using drugs/alcohol, lacking access to comfortable testing-sites, non-disclosure of their sexual-identity, and never disclosing same-sex behaviors to any healthcare provider.
Conclusions: In a large demographically diverse Indian MSM sample, large proportions were at-risk and unaware of their HIV status, particularly those engaging in CAS. Local and national programs need to increase access to culturally-competent, non-judgmental services and increase educational outreach to MSM online.

WEPED1408

Implementation of routine HIV testing program in University Infectious Diseases Centre: four-year analysis

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Background: HIV transmission remains of major concern in Eastern Europe, and too many people are diagnosed late. Expanded testing strategies and early and appropriate access to care are required. Infectious diseases departments might be a target for expanded HIV testing owing to intense passage of people belonging to key populations and carrying indicators for HIV disease.
Objectives: To describe implementation and outcomes of integrated nontargeted opt-out rapid HIV screening program in an urban teaching Infectious Diseases Hospital.
Methods: A retrospective cross-sectional study was conducted from October, 2010, through December, 2014, in Vilnius University Hospital Infectious Diseases Centre. The program was divided into two periods:
(1) from October 2010 to December 2012 (pilot study), and
(2) from January, 2013, to December, 2014.
The pilot study consisted of routine HIV screening of patients aged 18-55, hospitalized in one inpatient department. In the second period the decision to enlarge eligibility for screening was made with indication to test all inpatients aged 18-65. Physician-directed testing was conducted in the second inpatient department during the pilot study and in the outpatient department during both periods.
Results: During the pilot study, 2203 patients were hospitalized, 1314 (59.6%) were eligible, 954 (72.6%) were tested, 3 (0.31%) were HIV positive. In the second period, 4911 patients were hospitalized, 3727 (75.9%) were eligible, 3303 (88.6%) were tested, 7 (0.21 %) were HIV positive.
A total of 2800 physician-directed tests (10.1% out of 27 673 admitted/consulted patients) were performed, and 4 (0.14%) found HIV positive. All 14 diagnosed patients were linked to care in the centre.
Comparing cumulative groups of routine (n=4257) and physician-directed testing (n=2800), the HIV prevalence was 0.23% vs. 0.14%, p=0.40. HIV prevalence (0.23%) was above the cost-effectiveness threshold of 0.1 % (p=0.012). A lower proportion of advanced disease (CD4 < 200/mm^3) was found in the routinely tested group (2/10 vs. 4/4, p=0.015).
Conclusions: Routine HIV testing in Infectious diseases admissions is acceptable, feasible, sustainable, and cost-effective. Routine testing helped to discover more patients in earlier stages, compared to physician-directed testing. Furthermore, expanded testing in infectious diseases settings is favourable for linkage to care process.

WEPED1409

Integrated surveillance for HIV, syphilis, HBV & HCV in pregnant women attending ANC sentinel surveillance sites in Eritrea, 2016

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Background: Countries monitor their HIV epidemic using ANC sentinel surveillance sites. Though, HIV surveillance in pregnant women is well advanced, surveillance on Hepatitis B and C is far behind. To determine prevalence and distribution of these infections, HBsAg and Anti-HCV testing were nested in the HIV surveillance.
Methods: A cross-sectional, anonymous and unlinked sentinel surveillance survey was conducted in Dec. 2015-Feb 2016. It covered a total of 46 health facilities from urban and rural areas. Pregnant women, 15-49 years old, attending ANC for their first visit in current pregnancy were consecutively recruited and interviewed followed by drawing blood for HIV, Syphilis, HCV and HBV testing at the National Reference Laboratory.
Results: A total of 5019 pregnant women with 62% from urban and 38% from rural ANC sites were enrolled. Majority (57%) were in the age group 20-29 with the median age of 27 years. Almost all (94%) were married with 87% of them house wives. The overall prevalence of HIV, syphilis and HBV was 0.84% [95%C.I: 0.6, 1.1], 0.56% [CI: 0.4%, 0.8%] and 3.01% [95%CI: 2.6%, 3.5%], respectively. Multivariate analysis showed that age, residence, marital status and occupation of respondents were the most important variables that determined HIV infection. HIV peaked in the age group 25-29 and was more common in urban, in those not married and unemployed. Unlike HIV, HBV and syphilis were more common in rural. Though, region, age and marital status determined syphilis prevalence, region was important factor that determined HBV infection. Anti-HCV was negative in all the pregnant women tested, while co-infection was not evident from the study.
Conclusions: The integrated surveillance showed that the overall prevalence of HIV, syphilis, HBV and HCV is low in Eritrea. However, these infections were relatively higher in some regions and population groups and with no co-infection. Relatively higher prevalence in some regions, age groups and occupations may indicate presence of practices that expose these pregnant women. Therefore, in-depth researches are recommended to understand why certain sub-groupsare more vulnerable to these infections. Moreover, existing HIV sentinel surveillance sites can be used to monitor HBV and HCV infections, generate important data for decision making.

WEPED1410

Coverage of HIV testing among HIV-exposed infants in the context of option B+ in Malawi

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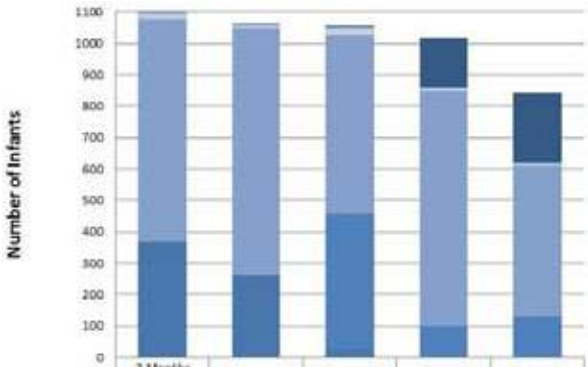
Background: Early infant diagnosis is critical for the survival of HIV-Exposed Infants (HEI), yet testing rates remain low in resource-limited countries. Malawi recommends testing of HEIs by HIV Polymerase Chain Reaction (PCR) by two months and by HIV rapid antibody test (RT) at 12 and 24 months or after cessation of breastfeeding. This analysis estimated the proportions of HEIs tested for HIV at 2, 12 and 24 months in the context of option B+.
Methods: Data were analyzed from the "Promoting Retention among Infants and Mothers Effectively (PRIME)" study, a 3-arm cluster randomized trial assessing the effectiveness of service integration and SMS-reminders on HEIs and maternal retention. The trial was conducted from 2013 to 2016 in 30 health facilities in southern Malawi. HEIs were enrolled at birth and followed up to 24 months. Data on HIV tests, deaths and transfer-outs were extracted from routine health facility records. Infants were considered censored if they did receive the full 24 months of follow-up.
Results: Figure 1 illustrates the testing coverage at 2, 6, 12, 18, and 24 months. A total of 1085 HEIs were enrolled, of whom 369 (34%) received PCR testing by 2 months, 433 (42%) and 130 (16%) receiving 12 and 24 month RT tests, respectively. A total of 59 (8%) received all three recommended tests. Twenty-seven infants (2%) tested HIV-positive; 24 (2%) died, and 50 (5%) transferred-out. A total of 207 (19%) were never tested.
Conclusions: Low coverage was found at all testing points, and PCR testing was notably conducted late. Additionally, very few infants were re-tested, despite continued exposure via breastfeeding. Continual follow-up of HEIs is necessary to ensure testing at all time points is conducted. Though transmission rates were low, interventions targeting longer follow-up of HEIs through the end of breastfeeding are needed to avoid post-natal transmission.



	2 Months (DNA PCR Test Required)	6 Months	12 Months (Rapid Test Required)	18 Months	24 Months (Rapid Test Required)
Censored	0	0	0	156	221
Died	12	5	5	1	1
HIV-Positive	8	5	8	2	4
Transferred-out	13	7	16	10	4
Not tested	708	783	570	747	482
Rapid tested	0	0	433	101	130
PCR tested	369	264	24	0	0

[Figure 1. Infants tested for HIV from birth through 24 months]

WEPED1411

Treat All and the 1st 90: exploring changes in HIV test rates and yields among adults following implementation of test and treat in Bulilima district, Zimbabwe

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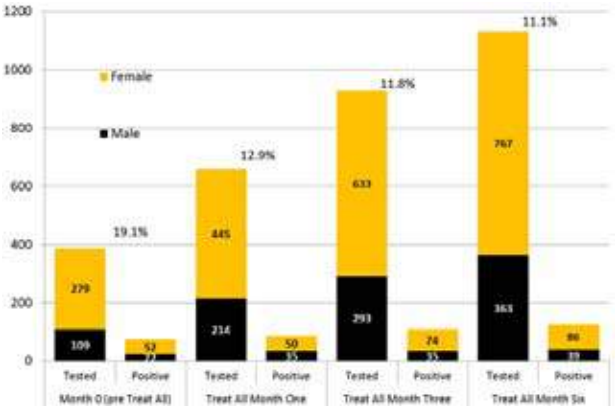
Background: At 22.3%, Matebeleland South Province has the highest HIV prevalence in Zimbabwe. The impact of test and treat strategies on demand and uptake for HIV testing are unknown in high prevalence, resource-limited settings. Our objective was to explore changes to HIV test rates and test yields among clients accessing facility-based care in Bulilima District, Matebeleland South Province, following start of Treat All.
Methods: We conducted a retrospective cohort analysis of clients accessing HIV testing services after Treat All implementation. All clients accessing HIV testing services at 11 purposively selected health facilities in Treat All inception district, Bulilima, from May 2016 (month 0) and 1, 3 and 6 months after Treat All implementation were traced through multiple registers to document HIV test results disaggregated by age, sex and entry point.
Results: Among 3,101 individuals tested for HIV over the period of interest, the majority tested were women (68%). A significant 290% increase in HIV test uptake was observed from pre-Treat All to Month 6. While HIV test yields decreased (19-11%), the absolute number of new positives identified increased by 68% due to increased test rates.



[HIV test rate, new positives and yield (%)]

Within age groups, young women aged 15-19yrs and 20-24yrs had significantly higher test yields than men of the same age (8% vs 2.2%; p=0.02 and 14.5% vs 8%; p=0.04 respectively). Adult men aged 25-49 had the highest test yield (23.2%).

Conclusions: We observed increased HIV test rates and number of new positives identified following implementation of Treat All. Tests rates remained low among men compared to women. In high prevalence settings such as Zimbabwe, our findings highlight the value of offering HIV testing to all individuals with unknown HIV status presenting to health facilities. Evidence-based differentiated models of care to increase testing uptake among high yield groups (young women, older men) are required to reach the 1st 90.

WEPED1412

The test of time: An interrupted time series analysis of HIV testing following service changes at a community-based rapid HIV testing service in Melbourne, Australia

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Background: PRONTO!, a peer-led community-based rapid HIV testing service, was established in Melbourne, Australia in 2013 to increase testing frequency among gay and bisexual men (GBM). In response to evaluation data attributing low return-testing rates to the lack of integrated STI testing, STI (gonorrhoea, chlamydia, syphilis) testing and SMS reminders were implemented. Using a quasi-experimental design, we quantified changes to return-testing following these service-level interventions.
Methods: Implementation of STI testing and SMS reminders occurred in February 2016. Return HIV testing rates were compared between pre-intervention (January 2015-January 2016) and post-intervention (February 2016-December 2016) periods. All HIV tests between 01 July 2014 and 31 December 2016 were included in analyses (2014 tests allowed six months of lead time to assess returning). Using monthly aggregate data a segmented linear regression assessed changes in the percentage of tests per month with a previous test within 91 days (3m return testing) and 182 days (6m return testing). We report regression coefficients: percentage of 3m and 6m return tests at baseline (January 2015, β0), return-testing trend (pre-intervention slope, β1), and return-testing trend from pre-to post-intervention (change in slope, β3). A change in slope (β3) p<0.05 was considered a significant change in return testing.
Results: Over 24 months, 4959 HIV tests were conducted among 3339 individuals (median tests/month=201, range 178-243). Post-intervention, ~100 SMS reminders were sent per month and 60% of clients accessed STI testing. Overall, 3m and 6m return testing increased by approximately 50% in the ten months post-intervention. At baseline, 3m return testing was estimated at 12% (β0), decreasing by 0.4% per month (β1) during the pre-intervention period. Post-intervention, 3m return testing increased an average of 0.8% per month (β3, 95%CI:0.3-1.3, p<0.01), from 7% to 15%. Baseline 6m return testing was estimated at 23% (β0), remaining stable pre-intervention (β1=-0.2%). Post-intervention, 6m return testing increased an average of 1.1% per month (β3, 95%CI:0.7-1.6, p<0.01), from 22% to 35%.
Conclusions: Implementation of STI testing and SMS reminders increased frequent testing. However, less than one in five clients were testing quarterly post-intervention, well below recommended frequencies. Despite improved convenience in this client-centred testing service, compliance with high frequency risk-based HIV testing guidelines remains a significant challenge.

WEPED1413

Pooled PCR testing of dried blood spots (DBS) for HIV early infant diagnosis is cost-efficient and accurate

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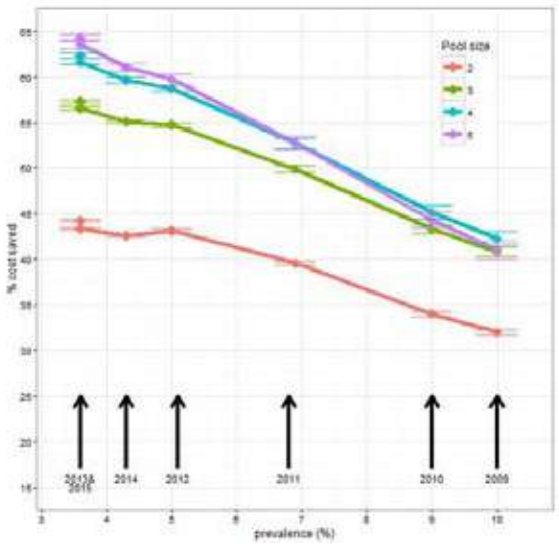
Background: Access to qualitative HIV PCRs for early infant diagnosis (EID) is restricted in resource limited settings due to cost. We hypothesised that pooling of dried blood spot (DBS) samples, defined as combining multiple patient samples in a single assay run with subsequent individual testing of positive pools, would be cost saving while retaining acceptable clinical accuracy compared to individual patient whole blood testing.
Methods: Cost savings: A model was developed to simulate reagent and consumable cost saving of pooled compared to individual sample testing. The number of pools requiring deconvolution (individual testing) was set to the expected number

of positive pools based on a binomial distribution. To validate the model, daily sample/result data and reagent costs of a public health laboratory in South Africa for the period January 2009 to July 2015 were used.
Clinical sensitivity: 1,170 patient samples were tested in pools of five 50µl DBS. Negative pools comprised 5 DBS previously tested in single reactions; positive pools included 1 positive sample. All tests were performed with the Roche CAP/CTM Qual assay.
Results: Overall sensitivity of pooled testing was 98.8%; 100% for strongly reactive pools (Table 1). One pool tested false positive but would not impact clinical specificity as individual patient testing is performed prior to reporting.

		Pooled samples result, n (%), 5 samples per pool		
		Positive	Negative	Total
Whole blood reference result	Positive pools	149 (100)	0	149
	Low positive pools	16 (89)	2 (11)	18
	Negative pools	1 (1.5)	66 (98.5)	67
	Total	166	68	234

[Table 1. Clinical performance of pooled testing]

Pooling would have resulted in saving 65% of laboratory EID costs in 2015 (Figure 1). The model is published as an R-based web tool, into which the user enters sample/positivity estimates and workflow management parameters to obtain cost saving estimates at an optimal pool size.



[Figure 1. Cost savings by pool size / prevalence]

Conclusions: Pooled PCR testing for EID remains accurate and dramatically reduces costs in settings with moderate to low prevalence rates.

WEPED1414

Scale-up of HIV care and ART use over a decade for children in 4 African countries

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Background: Expanding access to HIV care and treatment for children has been critical to combating the HIV epidemic. We report attrition pre and post-ART among children enrolled in care at 349 health facilities in Ethiopia, Kenya, Mozambique and Tanzania over 10 years.
Methods: We describe characteristics of children (0-14years) enrolled in care at PEPFAR-funded ICAP-supported clinics in four countries 2005-2014. We report proportions of children starting ART by year and estimate attrition (loss to follow-up(LTF) and death) pre-ART initiation using competing risk estimators (ART as competing risk) and post-ART initiation with Kaplan-Meier. LTF was defined as no visit within 12 months for pre-ART and 6 months post-ART start. We compared outcomes by year using Cochran-Armitage tests, Kendall Tau coefficients, log rank tests and unadjusted sub-distributional hazards models.
Results: From 2005-2014, 72,120 children were enrolled at 349 facilities: median age 4.1 years[IQR 2-8], 10.4% were < 1year and 46.9% were >=5years; 41.6% were WHO stage3/4 and median CD4+ count for children 5-14years was 362cells/mm³[IQR146-654](51.5% missing). Overall, 43,255 (60.0%) children started ART at median age of 4.9 years[IQR 2-8.7]; 53.0% were WHO stage3/4. The proportion of children starting ART increased from 53.1% in 2005-06 to 72.9% in 2013-14(p<0.0001); for children < 1year, the proportion starting ART increased from 24.3% in 2005-06 to 86.7% in 2013-14 (p<0.0001).
Median CD4+ for children 5-14years at enrollment was 240[104-414] in 2005-06 and increased to 439[193-724] in 2013-14(p<0.0001); median CD4+ at ART start was 197[77-351] in 2005-06 and 314[139-550] in 2013-14(p<0.0001).
Pre-ART attrition overall at 12 months was 27.1%(95%CI 26.7-27.4); it decreased from 34.3%(33.3-35.3) in 2005-06 to 15.5%(14.4-16.6) in 2013-14 (p<0.0001).
Attrition post-ART at 12 months was 22.3%(21.9-22.7) and increased from 15.8% (14.8-17.0) in 2005-06 to 28.4%(26.9-30.1) in 2013-14 (p<0.0001).
Conclusions: Over 10 years, more than 72,000 children enrolled in care and 60% started ART. Over time, a higher proportion of children in care initiated ART and at higher CD4+ count. Attrition decreased among pre-ART patients and increased among those on ART, the latter may reflect higher LTF among children who initiated ART at higher CD4 counts. Innovative efforts are needed to enhance retention among children on ART.

WEPED1415

Initiation of cART: a nationwide overview of variation between HIV treatment centres in the Netherlands

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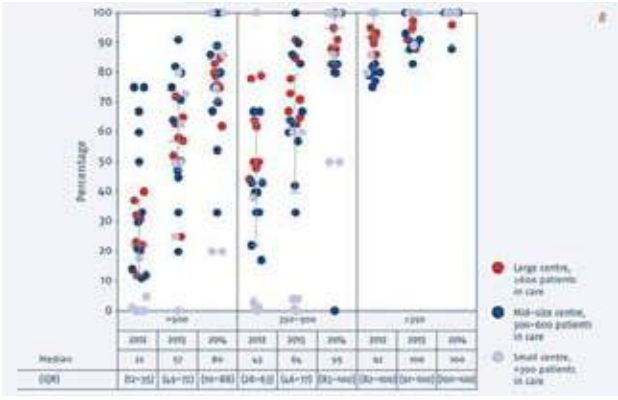
Background: We explored variation in combination antiretroviral therapy (cART) initiation between all 26 acknowledged HIV treatment centres in the Netherlands.
Methods: We assessed the annual proportion of HIV+ adults starting cART within 6 months after entering care, according to CD4 count at entry into care and centre size (>600,300-600,< 300 people in care). We used logistic regression adjusted for CD4 count at entry into care, calendar year and socio-demographic differences between patients at centres (sex, age, HIV-transmission route, region of origin, socio-economic status).
Results: In 2012, 2013 and 2014, 957, 942 and 784 people, respectively, entered into care and had ≥6 months follow-up. A median 62% of the people who entered into care in 2012 started cART within 6 months, increasing to 76% in 2013, and 91% in 2014. Starting cART within 6 months was significantly more likely after entering in 2014 compared to 2012: aOR 5.47; 95%CI 4.22-7.10; p< 0.0001.
People with < 350 CD4 cells/mm³ when entering into care initiated cART earlier, compared to those with ≥350 CD4 cells/mm³ (figure). This difference decreased in 2014, although considerable variation between centres remained, particularly for patients with >500 CD4 cells/mm³.



[Initiation of cART]

People at small centres were less likely to initiate cART within 6 months compared to those at large centres, also after adjusting for CD4 count, socio-demographic differences and calendar year (aOR 0.68; 95%CI 0.48-0.96; p=0.028). People with 350-500 CD4 cells/mm³ entering into care in small centres were less likely to initiate cART within 6 months, compared to those in large centres (aOR: 0.49; 95%CI 0.27-0.90, p=0.005).

Conclusions: Following guideline recommendations, increasing numbers of HIV+ people initiated cART within 6 months. However, differences between centres of different size were observed. Patients with 350-500 CD4 cells/mm^3 entering care in small centres were less likely to start cART within 6 months compared to large centres.

WEPED1416

Persistent high burden of advanced HIV disease in South Africa: data from a longitudinal nationwide laboratory cohort

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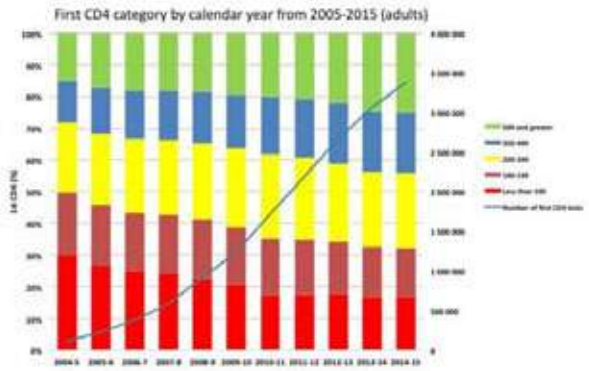
Background: The South African national HIV programme has achieved substantial coverage of antiretroviral therapy (ART) over the last decade, supported by policy changes allowing for earlier ART initiation. However, individual clinic reports suggest the proportion of patients entering care with advanced (< 200 cells/mm^3) and very advanced (< 100 cells/mm^3) HIV disease has remained constant in recent years. We assessed this using nationwide laboratory data.
Methods: We constructed a cohort utilizing nationwide laboratory records containing CD4 counts from 2004-2015. Using standard linkage methods, we determined first CD4 cell count at entry to care. We estimated numbers and proportions of adult patients with first CD4 in the following categories: < 100, 100-199, 200-349, 350-499 and ≥500 cells/mm^3.
Results: In total, 8,4 million first CD4 count tests were identified. From 2004-2011, the % patients with CD4 count < 200 cells/mm^3 entering into care declined from 50% to 35% of all tests (Figure 1). However, from 2011 onwards the % patients entering ART care with low CD4 counts has remained relatively unchanged. In 2015, over 230,000 patients entered care with advanced HIV disease, of whom around 120,000 had very advanced HIV disease. The proportion of men entering care with advanced HIV disease was nearly twice that of women.
Conclusions: The proportion of patients presenting with advanced HIV disease remains consistently high despite ART scale up, representing a large avoidable burden of HIV morbidity, medical costs, and onward transmission. Testing campaigns focused on early HIV-diagnosis and linking patients to ART care should be prioritised, particularly among men. CD4 testing for patients presenting with advanced disease, including rapid ART initiation and screening and prophylaxis for opportunistic infections remains critical.



[Figure 1.]

WEPED1417

Ten-year treatment outcomes of a cohort receiving comprehensive HIV care at Newlands Clinic, Zimbabwe (TENART cohort)

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Background: Data on long term outcomes of patients receiving antiretroviral therapy (ART) in resource limited settings are important but few, particularly in Sub-Saharan Africa. We describe 10 year outcomes of patients enrolled into the Newlands Clinic cohort between 2004 and 2006 and received comprehensive care including psycho-social and adherence support.
Methods: In this retrospective cohort study, data collected during routine care of patients were accessed from an electronic medical record using Microsoft SQL Server Studio 2012 and analysed using Stata version 12.1. We describe baseline characteristics, virological and clinical outcomes, attrition rates, and treatment adverse effects after 10 years from enrollment. We defined virological suppression as HIV viral load < 50 copies/ml and virological failure as >1000 copies/ml after ≥6 months of ART.
Results: Between 2004 and 2006, 605 patients were enrolled into comprehensive care and commenced on ART, 404 (67%) being female and 161 (27%) < 24 years old. Baseline characteristics are listed in Table 1.

Characteristic	Male n (%)	Female n (%)	Total n (%)
Study Participants	201 (33.2)	404 (66.8)	605 (100)
Baseline Age (years) - Median (IQR)	34 (12-40)	35 (27-42)	34 (17-42)
WHO Stage			
Stage 1	10 (5.0)	38 (9.4)	48 (8.0)
Stage 2	55 (27.4)	113 (28.0)	168 (27.8)
Stage 3	107 (53.2)	191 (47.4)	298 (49.3)
Stage 4	29 (14.3)	61 (15.1)	90 (14.9)
Baseline CD4 Count - Median (IQR)	114 (47-200)	131 (63-211)	121 (57-195)

[Baseline demographic and clinical charact]

Patients were followed up for 5823 person-years (median:10.7 years, IQR:10.1-11.4). At enrollment, 129 (21.3%) patients had a history of pulmonary tuberculosis (PTB) and 66 (11%) developed PTB, and 24 (4%) developed extrapulmonary tuberculosis while in care. During follow up, 385 (63.6%) patients experienced ≥1 treatment adverse event, the most frequent being stavudine-induced peripheral sensory polyneurophathy (n=252, 41.7%). After a median ART duration of 10.8 years (IQR:10.5-11.6), 474 (78.3%) patients were still in care, 428 (90.3%) being virologically suppressed, and 21 (4.4%) virologically failing. While 483 (79.8%) remained on first line, 122, (20.2%) were switched to second line ART. Fifty-nine patients (9.8%) were transferred to other ART facilities, 45 (7.4%) were lost to follow up, 25 (4.1%) died, and two stopped ART.
Conclusions: Comprehensive HIV care can result in low mortality, high rates of retention in care and virologic suppression in resource limited settings.

WEPED1418

Adherence to antiretrovirals in Medicaid-insured patients living with HIV: predictors and economic consequences

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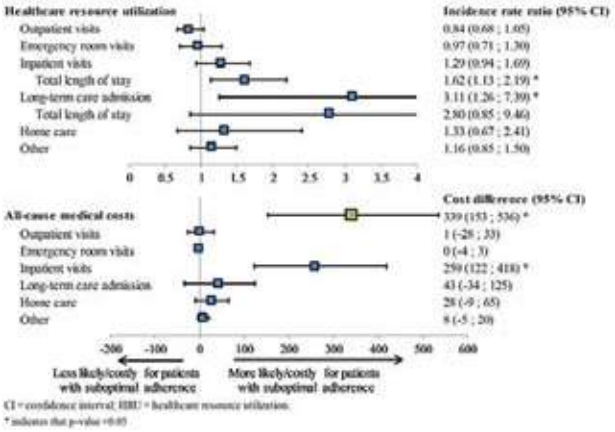
Background: Adherence to antiretrovirals (ARVs) is critical to achieving durable virologic suppression and preventing drug resistance. This study assessed predictors of adherence in Medicaid beneficiaries living with HIV initiating ARVs, and compared healthcare resource utilization (HRU) and costs between patients with suboptimal and optimal adherence.
Methods: Multi-state Medicaid administrative data (05/2012-03/2015) was used to identify adults with HIV-1 who initiated commonly used ARV regimens (index date) and had ≥6 months of observation pre- and post-index. Adherence was measured using proportion of days covered (PDC). A multivariable logistic regression was used to assess risk factors of poor adherence (PDC< 80%) at 6 months post-index. HRU and costs were compared between patients with suboptimal (80%≤PDC< 95%) and optimal (PDC≥95%) adherence using Poisson and ordinary least square models, respectively, and inverse probability of treatment weighting to control for confounding.

Results: Among the 2,683 patients included, 51% had poor, 19% suboptimal, and 30% optimal adherence. Younger age, non-capitated or dual Medicaid/Medicare insurance coverage, no prior ARV treatment, and asymptomatic HIV were associated with higher risk of poor adherence (Table 1). Patients with suboptimal adherence had longer hospital stays, more long-term care admissions, and higher medical costs compared to patients with optimal adherence (Figure 1).
Conclusions: Suboptimal adherence was associated with higher HRU and costs compared with optimal adherence. Poor adherence to ARVs was observed in over half of Medicaid patients. The risk of patients being poorly or suboptimally adherent should be a consideration when selecting an ARV regimen.

Risk factor	Odds ratio (95% CI)	*P*-value**
Age 18-29 (vs ≥50)	1.58 (1.19 ; 2.11)	0.002
Non capitated insurance coverage	1.40 (1.16 ; 1.69)	<0.001
Dual Medicaid and Medicare coverage	5.98 (4.39 ; 8.16)	<0.001
No prior ARV medication use at baseline	1.98 (1.62 ; 2.41)	<0.001
Asymptomatic HIV	1.37 (1.13 ; 1.68)	0.002

ARV = antiretroviral; CI = confidence interval; PDC = proportion of days covered.
*PDC at 6 months was defined as the sum of non-overlapping days of supply of any ARV during a fixed period of time post-index date (i.e., 180 days) divided by the length of the period (i.e., 180 days).
** Only factors with a p-value<0.05 were presented. Other predictors in the multivariable logistic regression model included: gender, race, state, urbanicity, year of index date, Quan-Charlson comorbidity index, specific baseline comorbidities (chronic pulmonary disease, diabetes, hypertension, psychoses, substance-related and addictive disorders, and any other mental comorbidity except substance-related and addictive disorders).

[Table 1. Risk factors of poor adherence to ARVs (PDC <80% at 6 months)]*



[Figure 1. Comparison of monthly HRU and costs during the observation period between patients with suboptimal (80%≤PDC<95%; N=652) vs. optimal adherence (PDC≥95%; N=661)]

WEPED1419

Changes in antiretroviral therapy (ART) and maximal viral suppression over time by age, sex, race/ethnicity, and HIV risk among HIV-infected patients in an integrated health system in the United States

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Background: ART prescription and viral suppression vary by age, gender, race/ethnicity, and HIV risk, even in integrated health systems such as Kaiser Permanente Mid-Atlantic States (KPMAS), which has pharmacy financial assistance available and equal access to care. KPMAS implemented physician reports to address these disparities and program-wide emphasis (including physician conferences, patient outreach) on reducing these disparities. We sought to determine if we had reduced such disparities.
Methods: Retrospective cohort analysis of adult (≥18 years) HIV-infected patients receiving care in KPMAS during 2014-2016. The primary outcomes evaluated were ART use (≥2 fills of ART in year) and HIV RNA as maximally suppressed ("BLQ", defined as HIV RNA< 200/mL at last measure of year; if not performed then not BLQ). We computed percentages achieving BLQ by age group, sex, race/ethnicity, and HIV risk for each calendar year (see Table). Odds ratios (OR) were obtained from a logistic model using GEE, adjusting for the patient demographics in Table 1b.
Results: Higher percentages achieving BLQ were observed for age group 50-64, Whites, and men having sex with men (MSM) (see Table 1a). While Blacks had improving odds of BLQ each year, Blacks have persistently lower odds of BLQ or ART compared with Whites. Asians had the lowest odds BLQ compared with Whites. As for age, 30-49 and 50-64 had improving likelihood of ART each year but all ages had lower odds BLQ compared with 65+. Conversely, women had persistently lower odds of ART than men, but no significant difference in BLQ. There were no significance differences in ART or BLQ where risk group was known.

Table 1a	Raw Data: N of Subpopulations and % BLQ					
	2014		2015		2016	
	Number patients	% BLQ	Number patients	% BLQ	Number patients	% BLQ
Total	2293	76.0%	2589	76.7%	2830	78.9%
Age: 65+	163	78.5%	200	80.5%	222	81.1%
18 - 29	255	65.9%	290	66.6%	335	71.6%
30 - 49	953	74.0%	1098	74.1%	1129	77.1%
50 - 64	922	80.4%	1061	81.3%	1144	82.4%
Sex: Male	1631	76.5%	1820	76.6%	1965	79.6%
Female	662	74.8%	769	76.9%	865	77.3%
Race/Ethnicity: White	369	88.9%	406	86.2%	409	87.0%
Asian	42	50.0%	46	50.0%	53	52.8%
Black	1710	74.2%	1938	76.1%	2110	78.5%
Hispanic	88	85.2%	108	83.3%	143	81.1%
Risk: MSM	758	79.8%	867	79.8%	946	81.8%
Heterosexual	803	76.1%	937	78.4%	1065	79.2%
IV Drug User	243	76.5%	280	72.9%	313	83.7%

Table 1b	Odds Ratio (95% CI) of BLQ and ART Compared with Reference Group 2014 and within Subpopulation Change over Time*			
	BLQ to Reference	BLQ Over Time	ART to Reference	ART Over Time
Age: 65+	Reference			
18 - 29	0.54 (0.44, 0.67)	1.05 (0.83, 1.32)	0.63 (0.40, 1.00)	1.27 (0.97, 1.65)
30 - 49	0.56 (0.41, 0.77)	1.02 (0.84, 1.24)	0.71 (0.48, 1.05)	1.34 (1.08, 1.67)
50 - 64	0.72 (0.54, 0.95)	1.01 (0.82, 1.23)	0.91 (0.62, 1.33)	1.30 (1.05, 1.62)
Sex: Male	Reference			
Female	0.99 (0.83, 1.19)	0.99 (0.88, 1.11)	0.76 (0.62, 0.92)	1.03 (0.92, 1.15)
Race/Ethnicity: White	Reference			
Asian	0.15 (0.08, 0.29)	1.21 (0.94, 1.57)	0.71 (0.35, 1.44)	0.80 (0.59, 1.10)
Black	0.41 (0.30, 0.56)	1.26 (1.06, 1.49)	0.57 (0.44, 0.73)	1.17 (0.99, 1.39)
Hispanic	0.92 (0.50, 1.69)	0.94 (0.67, 1.30)	0.70 (0.45, 1.09)	0.98 (0.71, 1.36)
Risk: MSM	Reference			
Heterosexual	0.87 (0.74, 1.02)	1.01 (0.89, 1.16)	1.02 (0.82, 1.27)	1.13 (0.99, 1.30)
IV Drug User	0.92 (0.75, 1.13)	1.20 (1.00, 1.45)	0.86 (0.66, 1.11)	1.17 (0.96, 1.42)

*--Main effects from models including only significant interaction terms ($p < 0.05$) are shown.

[Table 1a and 1b]

Conclusions: While we see improvement in ART and BLQ over time, particularly among Blacks, many groups still fall short compared with reference populations, and some other populations had declines over time. Novel efforts to improve ART prescription and viral suppression are needed.

WEPED1420

Implementation of point-of-care (POC) HIV viral load (VL) monitoring during antenatal care at a primary care clinic in Cape Town, South Africa

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Background: POC VL testing could increase access to virologic monitoring and help improve viral suppression on antiretroviral therapy (ART). However, limited data is available on the use of POC VL monitoring during pregnancy, implementation challenges in field settings and the acceptability of the device to patients.
Methods: We conducted an implementation science study using the Alere q POC device (input 25µL whole blood; results available in approximately 55 minutes) at a large public sector primary care facility. POC VL testing was conducted for pregnant women initiating ART or requiring routine VL monitoring. As part of the implementation, possible benefits of receiving a POC result were explained to patients; POC results were returned if patients chose to wait. Analysis examined the rate of errors and successful result-return, acceptability to patients and impact of POC VL monitoring on patients' HIV knowledge (determined using a standardized 8-item scale).
Results: Overall 356 tests were completed between January-November 2016. POC tests were completed as a baseline assessment of VL for 103 women initiating ART and in addition to laboratory-based testing for 253 women undergoing a routine VL. Error results were displayed for 5% of tests (n=18) and 3 machine breakdowns occurred meaning 43 eligible participants did not receive a POC test. POC results were returned to 78% of women; rates of result return did not vary by

age, VL result, time on ART, education, mode of transport, gravidity or time of diagnosis. HIV knowledge improved for 62% of women who received a baseline POC (mean score 5.4 vs 6.1, p=0.005) and was significantly higher at time of VL testing than those who did not receive a baseline POC test (mean score; 5.6 p=0.007).
Conclusions: POC VL monitoring appears feasible in a busy primary care, resource limited setting. Most women who received a POC test waited for their result, allowing healthcare providers to act immediately during a high-risk window for mother-to-child transmission of HIV. POC VL testing during pregnancy has potential to improve adherence but further research is required to facilitate the adoption of this technology in low-resource settings.

WEPED1421

Low level of virological success in decentralized HIV care sites in Cameroon

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Background: In many resource-limited countries, access to viral load (VL) monitoring remains scarce due to the difficulty to access a laboratory able to perform VL measurements, and patients followed in decentralized area have even more limited access. The goal of this study was to evaluate the rate of virological success at 12, 24 and 36 months of ART in patients followed in decentralized area in Cameroon.
Methods: Cross-sectional evaluation of patients on first line ART followed in 12 decentralized HIV care sites in three regions of Cameroon (East, North-West and Centre), 12 (11-15), 24 (23-27), and 36 (35-39) months of ART initiation. All patients contributed to two dried blood spot cards transferred to the IRD-CREMER laboratory in Yaoundé (Cameroon) for VL measurement and HIV drug resistance genotyping in patients with VL >1000 cp/mL.
Results: From September 2015 to June 2016, 398, 339 and 204 patients were virologicaly evaluated at 12, 24 and 36 months of ART, respectively. Overall, 72.9% of them were women, this proportion did not differ by evaluation month (p=0.22). Median age at ART initiation was 40 years, and constant across evaluation month (p=0.40). Median CD4 level at ART initiation was 200 cells/mm3, and did not differ by evaluation month (p=0.26).
At the threshold of 1000 cp/mL, the proportion of patient sin virological success was 67.3%, 63.0% and 59.8% at 12, 24 and 36 months of ART, respectively. At all evaluation month, patients who missed no clinical visit planned in the national protocol had a significantly higher risk of virological success. Only at 12 months was another factor associated with virological success; shorter distance between home and hospital was significantly associated with higher chance of virological success. HIV drug resistance is undergoing.
Conclusions: In this cross-sectional evaluation, the proportion of patients in virological success was lower than the standards expected by the WHO. This low rate of virological success is worrisome. Strong efforts must be made so that patients adhere to clinical care. The result from HIV drug resistance genotyping will indicate whether the low level of virological success is due to lack of adherence to ART, or to ART failure.

WEPED1422

How much does it cost to achieve HIV viral suppression?

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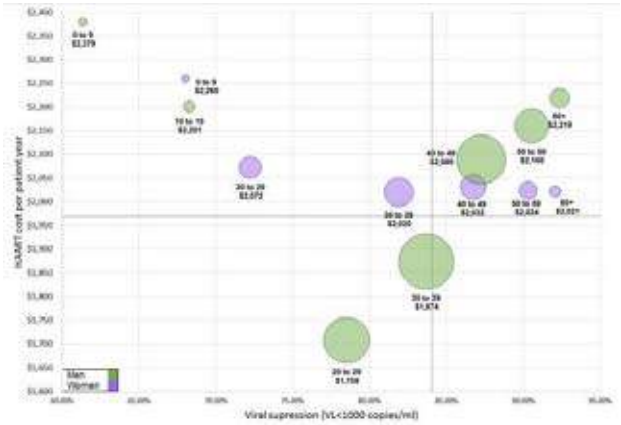
Background: 66% of PLWH on HAART in Mexico receives care through the Mexican Social Protection System in Health which includes ARV access. We wanted to estimate the cost-effectiveness of State HIV Programs.
Methods: Cross-sectional analysis of 78,624 PLWH treated in 32 Mexican states on January 1, 2017 and registered at the national database ‚SALVAR'. We estimated annual HAART cost per patient using ARV prices negotiated by the Mexican government and the recorded therapy. Effectiveness was defined as the percent of PLWH with a last viral load < 1000 copies/mL in the last year.
Results: The mean cost per patient-year across the 32 states was $1,973 ppy (min-max $1,774 - $2,208 ppy) and 83.8% viral suppression (min-max 74 - 91%). Significant differences of up to 17% were found in the percentage of viral suppression between State HIV Programs with similar costs. We found a significant $108 ppy difference (p<0.05) between men and women, and a positive correlation between the cost of treatment and age, as well as time in treatment (p<0.05). Lowest regimen costs were observed at 20 to 29 age group ($1,776) especially in men.



[Mean cost PPY & viral supression by age & sex]

The difference in the mean cost of the regimens without efavirenz vs. with efavirenz was $1,095 ppy higher. The cost ppy at Hospitals was significantly higher ($133; p<0.05; 95%CI 110.59-156-40) than in HIV clinics. Nevertheless, HIV Clinics viral suppression was 2.9% higher (p<0.05; 95%CI 2.21-3.62). Median time at HAART was 0.57 years higher at Hospitals than HIV Clinics (p<0.05), and 0.65 higher in women than men (p<0.05).
Conclusions: It is possible to achieve higher viral suppression rates at a lower cost, with potential savings of up to $ 2 millions. It´s important to take into consideration the time in treatment and ageing of the epidemic.

WEPED1423

Experience of living with HIV: diagnosis & disclosure - findings from the Positive Perspectives study

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Background: While treatment advances have dramatically improved the life-expectancy of people living with HIV (PLHIV), a number of important needs remain. We conducted an international survey of PLHIV to explore the impact of living with an HIV diagnosis on outlook and aspirations; rate the impact and sources of emotional support at diagnosis compared to today and assess the extent of disclosure.
Methods: Qualitative in-depth interviews were performed with PLHIV & partners to identify key hypotheses. A steering group developed the study questions which was fielded online from November 2016 to March 2017 in nine countries. A mixed sampling/recruitment approach was used to ensure a broad cross-section of PLHIV. Respondents were screened via telephone interview prior to accessing to the online survey instrument.
Results: As of January 2017, 819 PLHIV had been recruited. 20% were women, 32% age ≥ 50 years, 11% recently diagnosed, ≥ 80% reporting > 1 co-morbidity. 90% believe their quality of life will improve with advances in treatment though 26% tend not to plan too far ahead into the future because of their status. At time of diagnosis, 26% did not receive any emotional support/guidance from their health care provider (HCP) with 48% seeking support from a close friend. In the last 12 months, 75% continued to experience some level of stigmatisation with social (20%) & self-stigma (28%) very/quite often reported. 63% believe that improved education of the general public would help with this while 25% feel that better training of physicians, nurses and other HCPs would reduce stigma in the healthcare setting. 93% have disclosed their status to their primary care doctor with main drivers being the acknowledged need to keep them fully informed and avoiding drug-drug interactions.

Conclusions: In this large international survey, PLHIV believe that advances in treatment will improve their quality of life. Support from HCPs at time of diagnosis is not always provided. Widespread stigma is still experienced with education of public and HCPs seen as potential remedies.

WEPED1424

Explorative data analysis to assess the Decentralized Pharmacovigilance System's potential to monitor adverse drug reactions in South Africa's HIV treatment programme

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Background: A robust pharmacovigilance programme is indispensable in South Africa for its massive antiretroviral public health treatment programme, which is the largest globally. It plays a key role in the healthcare system through discovery, assessment, monitoring and prevention of adverse drug reactions, toxicities and interactions amongst drugs and their effects on those receiving treatment. This study undertakes an explorative analysis of Adverse Drug Reactions (ADR) data related to antiretroviral HIV treatment that was entered into the Decentralized Pharmacovigilance System between 01 May 2013 and 31 March 2016.
Methods: Data were retrospectively analysed from anonymised suspected adverse drug reaction reports submitted by healthcare professionals from the ART programme in South Africa. A descriptive quantitative analysis of relations between ADR, SOC, and antiretroviral drug by age and sex of person receiving ART was conducted. These included the most suspected ADR-causing medicines, System Organ Class (SOC) involved and drugs responsible for the adverse events in each SOC. These were further disaggregated by age and sex.
Results: Reports (5063) received from the ART programme were assessed, analysed and reviewed.
Of all analysed ADR cases (5063), Stavudine was the main antiretroviral responsible for ADR (30%), followed by Tenofovir (20%). Nevirapine accounted for 3% of all reported ADRs. Females (79%) reported a significantly higher percentage of ADRs to nevirapine than males (18%). ADRs from the various age groups correlate well with the percentage on treatment. The most common SOCs found in relation to reported ADRs were metabolic and nutrition disorder (19%) and nervous system disorders (10%). The programme found low numbers of ADRs with cardiac disorder (0.1%) and endocrine disorder (0.2%) SOCs.
Conclusions: This analysis was the first comprehensive exploration of this data set. The exploration of the data set shows the wealth of data collected and the potential that the decentralised pharmacovigilance programme has for the monitoring and evaluation of drug safety in South Africa´s treatment programme. It is therefore crucial to ensure that HCP enter data correctly, that quantitative and qualitative ADR data is analysed regularly and that those findings are systematically used to inform South Africa´s treatment programmes.

WEPED1425

Perceptions on co-morbidities and research participation in HIV-positive individuals

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Background: Treatment with ART has significantly reduced morbidity and mortality among persons living with HIV (PLWH). It is critical to educate this population on potential co-morbidities, and alert them to available research focused on disease management and cure. Although previous studies have explored perceptions regarding risk of acquiring HIV, little is known about what HIV-infected individuals understand about diseases that are more prevalent with HIV, or their willingness to participate in research.
Methods: We conducted a cross-sectional survey of 106 consecutive PLWH from the Washington University Infectious Diseases Clinic. Questions covered potential co-morbidities, and attitudes towards HIV-related research specifically exploring their perception of cure research, medication safety, tolerable side effects, and willingness to participate in research.
Results: Study participant were mostly Black (66%) and male (71%). The majority of participants had at least high school education (86%), and almost all participants reported currently taking ART. Depression was the most common comorbidity believed to be more prevalent among PLWH (72.3%). Malignancy was also recognized as being common, with half of participants correctly reporting high risk of lymphoma (49%) and anal cancer (46%), although 39% incorrectly report higher risk of colon cancer among PLWH. The majority (98%) of participants reported that HIV-related research has improved the lives of people who have HIV, with high expectations for finding a cure. Only 12% believed a cure would never be found, and 31% recognized that one patient has already been cured. High rates of interest in research were noted, with 49% being very interested in participating in cure research even without direct benefit. Two thirds of patients were willing to undergo side effects to potentially cure HIV, with 13% willing to risk severe side effects including death for a chance for cure. Cure research is a priority to many patients, although they are less likely to prioritize participation the longer they are infected with HIV, and if not Caucasian.
Conclusions: Perceptions of long term comorbidities associated with HIV infection are not completely accurate, indicating a need for continuing education in this aging population. Research is viewed favorably, and PLWH are more willing to participate than had been expected.

WEPED1426

At what stage of disease progression are HIV-infected patients initiated on antiretroviral therapy? A retrospective cross-sectional analysis of patients initiated on ART in Masvingo District, Zimbabwe

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Background: The 2013 Zimbabwe National ART guidelines expanded ART eligibility from a CD4 count of 350 to ≤500 cells/µl. Limited evidence has documented stage of disease severity at which ART naïve persons are initiated following implementation of the guidelines. Our objective was to describe the demographic, clinical and immunologic characteristics of adult HIV positive people newly initiated on ART.
Methods: A retrospective cross-sectional assessment was conducted using data from 325 non-pregnant adults (≥15 years) initiated on ART from January to June 2016 at 7 high volume priority public health facilities in Masvingo District. Demographic, baseline CD4 count and WHO staging data at initiation were abstracted from the ART-registers. The Mann-Whitney U test was used to compare baseline CD4 cell counts between different age groups and sex. Logistic regression was used to identify patient and institutional factors associated with initiating ART with advanced disease (CD4 cell count< 200 cells/µl).
Results: Out of the 325 people initiated on ART (Jan-Jun 2016), 289 (6%:15-24, 82%:25-49 and 12% ≥50 years; Females:51%) initiated ART with a median CD4 cell count of 237 cells/µl (IQR:107-402 cells/µl). Younger adults (15-24 years) had a higher baseline CD4 cell count (median= 372 cells/µl, IQR:311-505 cells/µl) at initiation compared to older adults (25-49 years) (median=238 cells/µl, IQR:107-401 cells/µl, p=0.005), and the elderly (≥50 years) (median=161 cells/µl, IQR:87-357 cells/µl, p=0.003). There was no significant difference in CD4 cell count between males and females. One hundred and twenty (40.5%) people initiated ART with advanced HIV disease. Factors associated with higher odds of initiating with advanced disease were initiating ART at an urban health facility [adjusted odds ratio (AOR = 1.09; 95% CI:1.09-3.17) and older age ($AOR_{50+ vs15-24}$=7.87; 95% CI: 1.88-32.95).
Conclusions: Three years following the expansion of the ART eligibility criteria, the majority of adults initiate ART at low CD4 cell counts below the previous threshold. Elderly people and urban dwellers are at increased odds of starting ART with advanced disease. Our findings, particularly relevant as many low resource countries transition to Test and Treat, underscoring the importance of increasing demand for timely uptake of HIV testing and treatment services to optimise treatment outcomes.

WEPED1427

HIV community viral load as an additional tool to monitor effectiveness of treatment and prevention in Eastern European programs

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Background: Community viral load (CVL) has been proposed as a useful measure to monitor HIV treatment effectiveness and quantify its influence on transmission rates. First reports on CVL were published in 2009; however, until now there have been no publications on CVL from Eastern Europe. This evaluation is the first of an ongoing monitoring process of CVL.
Methods: We analyzed electronic medical records of 22417 patients from 20 clinical sites in Russia, 23050 patients from 23 clinical sites in Ukraine and 226 patients from Linda Clinic in Estonia. All data have been taken from databases created and maintained by AHF. CVL was defined as the average mean of the most recent viral loads of all HIV-positive individuals who were under care in all AHF-supported clinical programs in Russia, Estonia and Ukraine for the 12-month period starting from December 1st 2015 until November 30th 2016. CVL has been calculated for each geographical location and country in general.
Results: Coverage of patients in care on ARV's in Russia, Ukraine and Estonia were 63%, 84% and 88% respectively. Within this coverage, 50% of patients in Russia were virally suppressed, 42% in Ukraine, and 40% in Estonia. 88% of patients in Russia, 81% of patients in Ukraine and 98% of patients in Estonia had at least one of viral load test performed in the above-mentioned period. Average CVL in Russia was 61 223 copies/ml, with a minimum of 7699 copies/ml in the clinical program in Chelyabinsk and maximum of 146722 copies/ml in Vsevolozhsk (Leningrad Oblast). Average CVL in Ukraine was 28793 copies/ml, with a minimum of 5127 in Kherson Regional AIDS Center and maximum of 66702 copies in Ternovka (Dnepropetrovsk region). Average CVL in Estonia is was 26501 copies/ml.
Conclusions: The results reflect current situation with HIV prevention and treatment in our programs in Russia, Estonia and Ukraine. These results will serve as a baseline for evaluation of effectiveness of HIV prevention and treatment interventions in communities in Eastern Europe. We will continue to measure CVL in 6 month intervals for further analysis and present the results.

WEPED1428

Self-reported antiretroviral use in rural South Africa: a validation study

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Background: Accurate estimates of antiretroviral therapy (ART) coverage among HIV-positive individuals are critical for policy planning and program implementation. However, few studies have been able to validate self-reported ART use (SR-ART) with data on biological exposure to ART (BE-ART). We conduct a validation study of SR-ART use among aging HIV-positive adults in South Africa.
Methods: The Health and Aging in Africa: Longitudinal Studies of an INDEPTH community in South Africa (HAALSI) Study is a cohort of adults aged 40 and above in Agincourt, South Africa. The baseline survey was conducted in 2014-2015 and includes socio-demographic data, self-reported HIV status and ART use. All participants underwent HIV antibody and viral load testing. HIV-positive participants by antibody also underwent dried blood spot testing for emtricitabine (FTC) and lamivudine (3TC), two medications that have been included in all first- and second-line ART regimens nationally. We use this information to determine the sensitivity and specificity of self-reported ART use overall and stratified by age and sex. We also calculate and graph the positive predictive value (PPV) and negative predictive value (NPV) by the prevalence of ART use. Finally, we use multivariable regression to determine any associations between accurate SR-ART use and demographic characteristics.
Results: The HAALSI cohort includes 1,048 (23%) HIV-positive participants, among whom 662 (64%) were positive for at least one of the two ART medications included in the BE-ART testing. In the BE-ART group, 450 (68%) self-reported ever accessing an ART program. The sensitivity of SR-ART use was thus 68% (95% CI: 64-72%) and the specificity 87% (95% CI: 83-90%); the PPV was 90% (95% CI: 87-93) and NPV 61% (95% CI: 56-65). The associated Figure 1 shows PPV and NPV over the full range of prevalence of ART use. Accurate SR-ART use was not associated with age, gender, educational attainment or wealth in regression analyses.
Conclusions: Many people on ART will accurately self-report their ART use. Thus, SR-ART is a useful approximation of actual ART use in the absence of biological exposure data and can be used to assess ART uptake and inform program planning.

WEPED1429

Refusal to provide healthcare to sub-Saharan African migrants living in the Paris region: a comparison according to their HIV and HBV status

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Background: Refusal to provide care has recently emerged as a preoccupation in France. Different situation surveys have demonstrated that two categories of patients were frequently denied: those infected by the HIV and/or the poorest (whose insurance status force professionals to ask them flat care fees). We aim to compare the frequency of reported denial of care in sub-Saharan African migrants living in the Paris region, according to their HIV and HBV status.
Methods: The ANRS PARCOURS is a life-event survey conducted in 2012-2013 in health-care facilities in the Paris region, among three groups of sub-Saharan migrants recruited in primary care centres (N=763; reference group), in dedicated centres for HIV care (N=923) and in centres for chronic hepatitis B care (N=778). The participants were questioned about their experiences of refusal of health care since their arrival in France.
Results: In the reference group, 6% reported denied health care (3% by a general practitioner, 1% in a hospital and 3% in a pharmacy). This proportion was twice as high in migrants living with HIV (12%; 6% by a general practitioner, 3% in a hospital and 5% in a pharmacy) and in migrants living with chronic HBV (10%; 5% by a general practitioner, 3% in a hospital and 6% in a pharmacy, p< 0.001).
The main reason for denial of care was their health insurance status (either for the poor or for the undocumented migrants) (40%, 30% and 52% of refusal for reference, HIV and HBV group respectively), followed by the HIV status (in 29% of cases for the HIV group). Other reasons concerned other health insurance problems, lack of financial resources or problems with supporting documents.
Conclusions: Our results show that public specific health insurance plans for poor people and for undocumented migrants, as well as infection by HIV, may lead to refusals of care in sub-Saharan African migrants in France.

WEPED1430

Continuation of HIV care postpartum among Zimbabwean mothers following implementation of option A

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Background: With the implementation of Option B+, understanding predictors of sustained engagement in HIV care postpartum is critical. Continuation of HIV treatment during breastfeeding is key is of particular importance as 5 to 20% of infections are estimated to occur then. Support of male partners may also be key to continued engagement in care following birth.
Methods: In 2014 we conducted a community-based serosurvey of mother-infant pairs residing in the catchment areas of 157 health facilities randomly selected from 5 provinces in Zimbabwe. Eligible mothers were ≥16 years old and had infants born 9-18 months before the survey. We collected questionnaires, blood samples, and verbal autopsies. We estimated the proportion of mothers who were receiving HIV treatment following pregnancy and predictors of remaining on anti-retroviral medications (ARVs) through the postpartum period.

Results: We enrolled 9619 mother-infant pairs with maternal HIV test results, of whom 1176 (12.2%) were HIV-infected. Among HIV-infected mothers, 34.3% reported testing HIV-positive prior to their pregnancy and 32.2% had taken ARVs prior to pregnancy. Overall, 69% of HIV positive mothers reported ARV use during the pregnancy and 66.4% reported ARV use at 9-18 months postpartum. Among the subset of mothers who reported taking HIV medication prior to pregnancy, 99.2% reported taking ARVs postpartum. Among those who had taken medication prior to, or during pregnancy, 95.0% of those who were still breastfeeding reported current ARV use, compared to 86.3% among those who were no longer breastfeeding. In logistic regression, continuing ARV use postpartum was associated with older age (OR 1.05 95%CI1.0, 1.11 per additional year), being on treatment prior to pregnancy (OR13.2 95%CI 4.0, 43.4) and current breastfeeding (OR 2.8 95% CI 1.5, 5.2) whereas women who had a husband/partner who was HIV infected and not receiving treatment were less likely to remain on treatment (OR 0.2 95%CI 0.07, 0.6).
Conclusions: These results indicate that although uptake of ARV during pregnancy is not complete, the majority of women in Zimbabwe who reported taking ARVs prior to or during pregnancy continue ARVs during breastfeeding. These data provide further compelling evidence of the importance of involving male partners in PMTCT programs.

WEPED1431

Estimating the number of HIV patients currently on antiretroviral therapy and others HIV care indicators in Chad: results from a prospective nationwide survey

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Background: Effective monitoring, evaluation and planning of HIV care activities requires reliable health data. It was identified recurring weaknesses in reported data system in HIV facilities in Chad. These weaknesses negatively impacts the quality of data and leads to less-effective decision-making. To overcome these barriers, this study was carried out to evaluate multiple indicators of HIV care activities.
Methods: A prospective study was conducted in 84 of the 90 HIV facilities functioning in Chad during March to July 2016. Repeated data of HIV patients on ART attending HIV facilities during this period was collected. These data included sociodemographic, clinical and biological informations notified in the patient form at different visits. Statistical methods were used to estimate retention on ART care, number of patients regularly on ART, median CD4 evolution, and frequency of patient visits.
Results: During the study period, individual data for 34,142 ART patients were collected. Among them, 70.5% were women. At ART initiation, overall median age was 35 years (IQR:29-43) and median CD4 count was 266 cells/mm^3 (IQR:169-383). Median CD4 count at ART initiation increased from 209 cells/mm^3 before 2007 to 306 cells/mm^3 after 2013 among women and from 218 to 255 cells/mm^3 in the same period among man. About 30.0% of ART patients delayed medical consultation. In the past 12 months before the study period, the proportion of ART patients with at least one measure of CD4 cell count was 34.0% and the proportion with at least one viral load test was 0.2%. Survival analysis indicated that by July 2016, retention at 12 months on ART was 67.8 and 34.7%, respectively among adults and children. The average number of patients receiving ART in Chad at 31 July 2016 was estimated to 38,872 (95% CI:38,486-39,159).
Conclusions: This study provides accurate core indicators that will help HIV national programme to assess progress accomplished to track the HIV epidemic and to identified new strategies to overcome barriers to retention in HIV care.

WEPED1432

Predictors of survival, loss to follow-up among HIV-infected children on cART at Livingstone Central Hospital: 2005-2015

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Background: In 2015, 61% of Zambian children in need of combination Antiretroviral therapy (cART) accessed the treatment which is a big increase from 33% in 2013. Despite this expanded ART coverage, there is paucity of information on effectiveness of pediatric cART programs in reducing morbidity and mortality. We aim to evaluate treatment outcomes among children commenced on cART at a dedicated pediatric center of excellence clinic at Livingstone Central Hospital (LCH), Zambia.
Methods: Using a retrospective cohort study design, we abstracted routinely collected clinical data from medical records of children enrolled in HIV care between 2005 and 2016. Our main and secondary outcomes are death and lost follow up respectively. We carried out descriptive analysis of the baseline characteristics and plotted Kaplan Meier to estimate survival distributions. We performed Cox Regression to assess predictors of mortality and loss to follow-up.
Results: A total of 1,100 children aged below 15 years enrolled in HIV at LCH from 2005 to 2016. 49% of these children were female and 53% had lost both parents. At least 18% of these children enrolled in care before their first birthday. The median age at cART initiation was 3.6 years (IQR;1.3-8.6) and the median duration on cART was 3.9 years IQR (1.2-6.5). 67 (6%) of the children died while in care and 150(13.6%) were lost to follow-up. The children who died were younger at baseline with median age of 6 months (IQR; 2 months to 6 years). The survival probability at 1 year was 0.95, at 2 years; 0.94, at 5 years; 0.93 and 0.89 after 11 years of follow-up. The probability of loss to follow-up was 0.92 at 1 year of follow-up, 0.90 after 2 years, 0.82 after 5 years and 0.70 after 11 years.
Conclusions: Attrition due to mortality was low after 11 years of follow up. Probability of loss to follow up decreases over time. These findings demonstrate that pediatric care is feasible in low resource settings. There is need to strengthen care within the first year of treatment.

WEPED1433

145 National HIV treatment cascades compared by region, HIV prevalence, conflict and GDP

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Background: In 2014, UNAIDS and partners set the 90-90-90 targets. Reaching these targets may be more difficult in lower prevalence countries with ongoing military conflict or resource constraints. We assessed how close countries and regions are to reaching these targets, and analysed outcome predictors.
Methods: Country-level HIV treatment cascade data from 2010-2015 were extracted from national reports, published papers and the www.AIDSinfoOnline database and analysed. Weighted least squares regression was used to assess predictors of cascade achievement (diagnosis, ART coverage and viral suppression) by: region, HIV prevalence, Gross Domestic Product (GDP/capita) and the 2016 Global Peace Index, which measures societal safety, militarization and conflict.
Results: Data were available for 145 national cascades. The percentage of PLHIV diagnosed ranged from 90% (Sweden) to 3% (Madagascar), while ART coverage ranged from 83% (Sweden) to 2% (Madagascar) and viral suppression ranged from 79% (Sweden) to 4% (Pakistan). Regions with the lowest ART coverage rates were South East Asia & Pacific (36%), Eastern Europe & Central Asia (17%) and Middle East & North Africa (13%). Within Africa, countries with higher HIV prevalence had higher rates of ART coverage (p=0.002) and viral suppression (p=0.002) but not diagnosis (p=0.317). Outside Africa, countries with higher HIV prevalence had higher diagnosis rates, ART coverage and viral suppression (all p< 0.001). Countries with higher GDP/capita had higher ART coverage (all p< 0.001). Furthermore, countries with lower levels of peace (Global Peace Index) had lower ART coverage (p< 0.001). 7/11 countries with the lowest ART coverage had the highest conflict levels: South Sudan, Afghanistan, Somalia, Yemen, Sudan, Pakistan and Russia.

Region	Sample Size [PLHIV]	% of PLHIV Diagnosed [Range]	% of PLHIV On ART [Range]	% of PLHIV Virally Suppressed [Range]
Oceania	30,695 [3 countries]	85% [55%-86%]	65% [26%-68%]	62% [62%-62%]
Western Europe	687,720 [11 countries]	80% [75%-90%]	67% [44%-83%]	60% [40%-79%]
South America	1,301,200 [11 countries]	71% [39%-89%]	50% [29%-61%]	40% [12%-50%]
United States of America	1,201,100 [1 country]	86%	37%	30%
South East Asia & Pacific	4,696,578 [16 countries]	54% [23%-85%]	36% [7%-74%]	29% [5%-70%]
Sub-Saharan Africa	25,532,002 [37 countries]	59% [3%-87%]	42% [30%-69%]	29% [5%-70%]
Central America & Caribbean	615,320 [13 countries]	67% [62%-77%]	45% [30%-69%]	23% [10%-40%]
Eastern Europe & Central Asia	1,758,146 [14 countries]	55% [31%-87%]	17% [14%-44%]	13% [11%-37%]
Middle East & North Africa	654,340 [14 countries]	26% [11%-74%]	13% [3%-37%]	6% [4%-30%]

[Regional Data]

Conclusions: Only 1 country has reached the UNAIDS 90-90-90 targets, with three years left. Regions lagging behind should target resources to their cascade breakpoints. Difficulty meeting these targets is associated with lower GDP/capita, lower HIV prevalence and higher conflict levels.

WEPED1434

HIV care continuum outcomes: does Ethiopia meet the UNAIDS 90-90-90 targets?

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Background: Ethiopia has pledged to the UNAIDS 90-90-90 framework in 2015. However, the progress towards achieving this target has never been assessed. We assessed HIV care continuum outcomes as surrogate markers for the 90-90-90 targets.
Methods: A retrospective cohort study was conducted over 12 years period. Complex surrogate makers were used to assessing the HIV care continuum outcomes, an overall proxy surrogate for UNAIDS targets. For measuring the UNAIDS diagnosis target, prevalence rate of early HIV diagnosis was considered as a surrogate marker. For the treatment target, number of people on ART, number of people who discontinued from ART or transferred out, and number of people who had fair or poor adherence were used as surrogate markers. For the viral suppression target, number of CD4 counts and/or WHO clinical stages were used to assess immunological, clinical and treatment successes and further show the viral suppression. Descriptive statistics was undertaken and estimated survival time was calculated using Kaplan-Meier.
Results: 8172 patients were enrolled for HIV care between June 2003 and March 2015. For the diagnosis target, the overall prevalence of early HIV diagnosis among patients on ART was 34.5% (females contributed to 35.7%) showing that 34.5% patients knew their status timely. For the treatment target, 5299 (64.8%) received ART and females accounted for 54.6%. For the virological suppression target 65.8% of patients had treatment successes, displaying that an estimated 65.8% of patients achieved the target.
Conclusions: The 35-65-66 performances of 90-90-90 targets of Ethiopia seem very far from achieving the target. This underscores the need for rigorous innovative methods, community distribution of ART, runaway packs during conflict, and use of GenXpert for HIV viral load testing would significantly help to hit the target.

WEPED1435

Uniquely identifying HIV cases: a comparison of deterministic and probabilistic matching for HIV case-based surveillance in the absence of a national unique persons' identifier in Kenya

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Background: In Sub-Saharan Africa, HIV case-based surveillance (CBS) has not been widely implemented, yet it is recommended for 2nd generation HIV surveillance. CBS is important for monitoring HIV treatment cascade including the UNAIDS Fast-Track 90-90-90 targets through individual tracking of HIV cases to understand who is getting diagnosed, linked to HIV care, accessing treatment; virally suppressed, dead, or lost-to-follow-up. In the absence of a national unique persons' identifier (NUPI), record linking and de-duplication of cases in surveillance systems may be dependent on name-matching algorithms. We present a comparison of deterministic and probabilistic algorithms in uniquely identifying cases in a CBS pilot in Kenya.
Methods: We used HIV case-based surveillance pilot data from 124 facilities in two high HIV-burden counties (Siaya and Kisumu) in Western Kenya. For de-duplication, we investigated three scenarios to account for patients' movement within the treatment cascade: HIV testing services (HTS), HTS-to-care, and within care. We included Soundex of first name, surname, sex and year of birth to create a unique key and matching identifier. For deterministic matching, we included medical record number in HTS-to-care and master facility list code (MFL) in within care scenarios. For probabilistic matching, we used a variety of string edit distance calculation methods; Jaro, Jaro-Winkler, Levenshtein and Damerau-Levenshtein implemented in R stringdist package.
Results: We abstracted 12,157 cases from 124 facilities, of which 4073 (33.5%) were from HTS, 1091 (9.0%) HTS-care and 6993 (57.5%) within care. Using the deterministic process 11,722 unique cases were identified, yielding 435 (3.6%) duplicate records. Of these, 67 (1.6%) of HTS records, 164 (15.0%) of HTS-care and 204 (2.9%) within care. Jaro-Winkler probabilistic matching yielded 615 (5.1%) duplicate records; 268 (6.6%) within HTS, 151 (13.8%) within HTS-care and 196 (2.8%) within care. Jaro probabilistic matching yielded 600 (4.9%) duplicate records overall while Levenshtein and Damerau-Levenshtein yielded 519(4.3%) duplicate records each.
Conclusions: Jaro-Winkler probabilistic matching yielded highest the number of duplicate records. In absence of a universal NUPI, we suggest Jaro-Winkler probabilistic matching. Kenya needs a standard national deduplication and persons-matching algorithm to improve accuracy in monitoring the Fast-Track 90-90-90 targets.

WEPED1436

Epidemiology and early childhood outcomes of HIV-infected children in Zimbabwe: a secondary data set analysis, 2015

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Background: Delays in pediatric HIV diagnosis are associated with high morbidity and mortality. Highly centralized testing leading to long turnaround time (TAT) of results contributes to delays in HIV early infant diagnosis (EID). EGPAF hosts an EID electronic database (EDB) utilized by 1223 sites in Zimbabwe. The EDB tracks EID results and facilitates prompt issuing of positive results and fast tracked commencement on ART. Analysis of this national dataset has potential to provide insight into the national and local-level EID steps, which may inform critical interventions to enable ending pediatric AIDS in Zimbabwe.
Methods: In 2016, a retrospective secondary data set analysis was conducted by EGPAF. Excel was utilized to generate frequencies, medians, interquartile ranges and graphs. The dataset had a total of 2740 EID entries with unique identifiers. Records with critical information missing were not considered in the dataset analysis. Confidentiality was assured and maintained through coding of data to exclude personal variables, password protection and no patient identification information was analysed.
Results: The median age at dried blood spot (DBS) specimen collection was 14 weeks (Q_1=7;Q_3=43). Out of 63 districts, three major cities and one peri-urban district contributed 20% yield of DNA PCR positive results. Overall median TAT was 35 days (Q_1=21; Q_3=62), with the laboratory incurring the largest length of time in the TAT process, at 15 days (Q_1= 10; Q_3 =21). The median time from sample collection to ART initiation was 8.8 weeks (Q_1=5.1; Q_3=10.7). By August 2015, 50% were on ART, 4% lost to follow, 2% transferred out, 6% died whilst 38% of the entries had a pending outcome.
Conclusions: High median age at testing, long TAT and late ART initiation has potential to contribute to high early morbidity and mortality. As program implementers in Zimbabwe focused on the care and treatment of HIV-positive children, we need to further decentralize EID services and introduce point-of-care diagnostics to reduce TAT to better meet the needs of children infected with HIV. MOHCC should consider targeting high yield geographic areas such as major cities with pediatric HIV prevention services to avert new infections.

WEPED1437

HIV treatment cascade among female entertainment and sex workers living with HIV in Cambodia: impact of amphetamine use and an HIV prevention program

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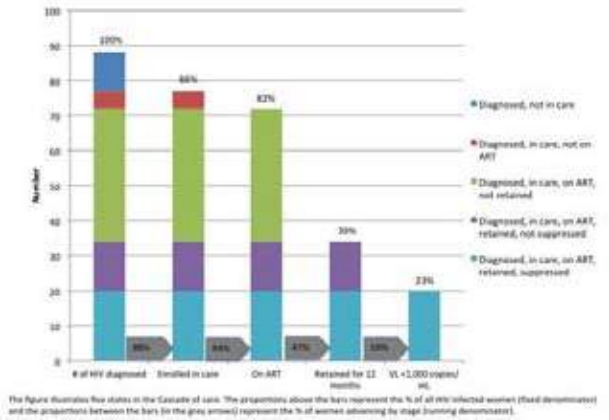
Background: A successful HIV continuum of care (COC) is key to effective clinical care and prevention. Few studies have examined this in female entertainment and sex workers (FESW). FESW in Cambodia have high risk of HIV associated with amphetamine-type stimulant (ATS) use. We examined COC outcomes among HIV-positive FESW participating in a comprehensive HIV prevention intervention that was integrated into the existing SMARTgirl HIV prevention platform in 10 provinces in Cambodia.
Methods: From 2013 to 2016, 1,198 FESW who reported multiple sex partners and/or transactional sex were recruited in 10 provinces in Cambodia; 88 women were identified with HIV at baseline. COC outcomes examined included: enrollment in care, antiretroviral therapy (ART) uptake, 12-month retention in care and viral suppression. Data on ATS use and other risk exposures were obtained from study surveys Logistic regression analyses examined correlates of 12-month retention in care.
Results: Median age was 32 years (interquartile range (IQR)) 28, 35). 50% of the women reported working in entertainment venues and 50% were freelance/brothel based; Overall, 88% were enrolled in care, 82% were on ART, 39% were retained in care, and 23% were virally suppressed at 12 months (Figure 1).



[HIV continuum of care in Cambodian FESW]

Women who screened positive for ATS substance use disorder had a 91% lower odds of 12-month retention in care (AOR 0.09; 95% CI 0.01, 0.97). Women who were engaged in SMARTgirl had 4-fold greater odds of 12-month retention in care (AOR=4.16, 95%CI: 1.27, 13.69)
Conclusions: The majority of women living with HIV were successfully linked to HIV care but retention and viral suppression were low. Tailored programs like SMARTgirl, targeting the broader population of HIV-positive FESW including those using ATS could optimize the clinical and population health benefits of HIV treatment.

WEPED1438

The road to 90-90-90: the HIV cascade of care in Portugal

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Background: The 90-90-90 strategy is a key element to help end the AIDS epidemic. To reach this goal, each country must build, monitor and evaluate their own "HIV cascade of care" (HCC). Consistently with this strategy, this is the first HCC in Portugal, contributing to define the major issues and challenges to be addressed and overcome by 2020 in Portugal.
Methods: 1) Data reports to 2014, latest full epidemiological/clinical data available; 2) The number of people living with HIV (PLWH) and the number of PLWH diagnosed were estimated with ECDC HIV Modelling Tool (incidence method); 3) The remaining steps were analyzed according to the national hospital-based HIV information system (SIVIDA) that collects data from more than 90% of HIV-infected people followed in Portugal.
Results: According to ECDC HIV Modelling Tool, we estimate that, in 2014, the number of PLWH in Portugal was 45501 (44470-46508) and 41073 (40660-41504) were already diagnosed (**90.3%**). According to SIVIDA data, 33529 (81.6%) were retained in care and, from those in care, 26513 were on treatment (ART) (79.9%), meaning that a total of **64.6%** of diagnosed people were on ART. Of these, 22430 (**84.6%**) had undetectable viral load (UVL < 200copies/mL). In summary, at the end of 2014, 49.3% of PLWH had undetectable viral load.
Conclusions:
1. In Portugal (2014), the proportion of PLWH with undetectable viral load was similar or slightly lower than other european countries.
2. Portugal may have already reached the first „90-90-90" goal. However efforts regarding early diagnosis must be pursued.
3. Contrary to what was thought, linkage and retention in care and early ART are now the critical challenges to reach the „90-90-90" goals.
4. Strategies to improve the suboptimal proportion of people on ART with UVL need to be reinforced to overcome the last „90" goal.
5. The next HIV cascade of care must evaluate already the impact of the strategy of „treat all irrespective of CD4 cell count", adopted in 2015.

WEPED1439

National 90-90-90 and HIV care continua for key populations

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Background: Men who have sex with men (MSM), people who inject drugs (PWID) and female sex workers (FSW) bear disproportionate burdens of HIV but often have the least access to HIV services. We review the published national HIV care continua for these key populations (KPs) to track progress towards the UNAIDS 90-90-90 target.
Methods: For 2010-2016, we searched the Internet, PubMed, surveillance reports, UNAIDS country reports, PEPFAR country operational plans, and conference abstracts for officially reported nationally-representative HIV care continua for KPs. We collected data on and methods to derive the estimated number of KPs (a) living with HIV, (b) diagnosed, (c) on ART, and (d) with viral suppression. The continua were graded high, medium or low quality based on the methods to derive the indicators.
Results: We found 24 care continua (12 for MSM, seven for PWID, and five for FSW) from 12 countries. HIV diagnosis, ART coverage and viral suppression varied between (a) 5-85%, 2-73% and 1-72%, respectively among MSM; (b) 54-97%, 14-78% and 8-66%, respectively among PWID; and (c) 27-63%, 8-16% and 2-14%, respectively among FSW. Among the KPs, progress toward 90-90-90 for FSWs was the lowest. HIV diagnosis, ART coverage, and viral suppression for MSM and PWID in European countries (Denmark, Netherlands, UK, and France) were comparatively higher and they are likely to achieve 90-90-90 for MSM and PWID well before 2020. The rates of HIV diagnosis were high (>85%) in Kazakhstan (PWID) and the United States (MSM and PWID), however, access to ART and viral suppression were relatively low (< 40% and < 35%, respectively). Continua from two countries (Denmark and Netherlands) used data from national cohorts and were ranked as using high quality methods to determine the continua.

Conclusions: Even though a few countries are close to achieving 90-90-90 for select KPs, data in the public domain are limited. Considerable additional efforts are likely needed to achieve this target for KPs in countries with high HIV burden and limited resources. Improved monitoring and evaluation with meaningful community engagement will be required to construct more reliable and standardized continua for KPs in order to promote accountability and data-driven programs.

WEPED1440

Data accessibility as a barrier towards achieving the UNAIDS 90-90-90 goals in the HIV cascade of care among men who have sex with men (MSM) in Buenos Aires, Argentina

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Background: The HIV cascade of care has become an important tool for central assessment of treatment as prevention (TasP) strategy to stop the HIV epidemic. This study presents data of the HIV cascade among men who have sex with men (MSM) diagnosed with HIV in the main testing center for MSM in Buenos Aires, Argentina.
Methods: Recruitment was done by spontaneous demand of rapid HIV test (RHT), available for free in the testing center (Nexo NGO) from April-2014 to March-2015. HIV diagnosis was performed with finger-stick samples (Alere Determine HIV-1/2) after signing an informed consent. During the post-test interview, confirmatory/complementary studies (Ag/Ab ELISA, HIV viral load and CD4T cell count) were offered to RHT-reactive-individuals. A blood sample was withdrawn by venipuncture from those who accepted and delivery of results was planned at 10 days. All RHT-reactive individuals were contacted (via email and/or mobile phone) one year after HIV diagnosis in order to collect information about retention in care, HAART and viral suppression.
Results: 1496 MSM were tested at Nexo reaching an HIV prevalence of 12.5%. Among the RHT-reactive individuals, 83.4% (156/187) accepted to do confirmatory/complementary studies and 82.8% of them picked the results up, received counseling and were linked to care. A total of 62.0% had less than 500 CD4T cell/ml. At one year, 55.1% (103/187) could be contacted, 92.2% (95/103) were on HAART, 55.8% (53/95) remembered their last VL, and 83% (44/53) were virologically suppressed. The individuals that could not be contacted did not answer neither emails nor cell phone calls and messages.
Conclusions: Our data reveals that the first steps in the engagement in care were successful with more than 80% of the individuals linked to care through the confirmation of reactive RHT, the picking up of the results and the visits to the physician. Among those whose data were obtained, high frequency of retention in care, HAART and virologically suppression was observed. However, efforts should be concentrated on increasing strategies to collect data in countries, like Argentina, where follow up information is not centralized in national data bases due to the coexistence of different health care systems.

WEPED1441

Plugging the leaks; strengthening relay and documentation of viral load results and quality of pediatric care necessary to achieve the last 90

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Background: Ongoing review of the quality of care and treatment programs is necessary to achieve the last two of the 90-90-90 targets. In a quality of care review, we sought to assess retention on HAART and 12-month viral suppression among patients enrolled for care in decentralized ART sites in Ndhiwa Sub-County, Kenya.
Methods: In December 2016, as part of routine program quality improvement, we conducted file reviews for 879 patients drawn from 26 facilities (1 hospital, 2 clinics, 20 dispensaries, 3 health centers) in a rural sub-county. Patients started on ART between June to November 2015 were included. Summary statistics were used to describe the cohort and chi-square test to assess association between various determinants and viral suppression at 12 months.
Results: Of 878 patients, 68.4%(602) were female, the median age at ART initiation was 28 years (IQR 22 - 36) and 10.4% (91/873) were aged 14 years or below. Viral load results were documented in the files of 42% (95% CI, 38.9% - 45.6%) and were less likely to be documented in the hospital (8/113, 7.1%) and health centers (29/124, 23.4%) compared to dispensaries (328/630, 56.1%), p<0.05. Viral suppression varied with age from 65%, 50% and 55.5% among those aged 0-4, 5-9 and 10-14 up to 89.7% and 91.6% among those aged 15-24 and 25+, respectively. There were no gender differences in viral suppression; males 86.2% vs females 87.9%, p=0.63. Viral suppression among individual facilities ranged between 60% and 100% with 9 of the 26 facilities having a 12-month viral suppression above 90%. Overall at 12 months, 81.9% (95% CI, 79.1% 84.4%) were alive and on ART; clinics 81.2% (95% CI, 48.2% - 97.7%), dispensaries 84.1% (95% CI, 81.0% - 87.0%), health centers 76.5% (95% CI, 67.8% - 83.8%) and the hospital 75.2% (95% CI, 66.2% - 82.9%).
Conclusions: Coverage of viral load was very low. To reliably assess progress towards achieving the 90-90-90 goals, there is need to strengthen relay, file documentation and utilization of viral load results. A focus on improving quality of care for children is necessary to achieve the 90% viral suppression target.

WEPED1442

What will it take to reduce HIV incidence in the United States: a mathematical modeling analysis

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Background: UNAIDS has set ambitious "90-90-90" targets for population level HIV diagnosis, ART initiation and viral suppression to help end the AIDS epidemic. However, there is a paucity of data to inform program level care-continuum thresholds that are likely to translate to broader population-level epidemiologic goals.
Methods: We used a previously validated mathematical model of HIV transmission and care-engagement in the US to characterize care continuum parameters (including annual rates of screening, linkage to care after diagnosis and annual rates of retention in care) that would translate into achievement of population-level epidemiologic goals. We simulated the model multiple times - using different, randomly-selected care continuum parameters for each simulation - to ascertain the parameter values necessary to achieve target reductions HIV incidence. Primary outcomes were the projected HIV incidence and viral suppression among all people living with HIV [PLWH] after 10 years, compared to a base-case scenario of the current US continuum of care.
Results: Among 100,000 simulations that successfully achieved a 50% reduction in new HIV transmissions over 10 years, the median percentage virally suppressed among all PLWH was 80%. Retention in care was the primary driver of viral suppression, and thus, achievement of incidence targets. To achieve 80% population level viral suppression, the rate of annual disengagement from care (i.e. loss to follow-up), amongst those diagnosed and in care, could not exceed 8% per year, even at high rates of returning to care at later time-points. Among simulations that exceeded this annual rate of care disengagement, we found a median of 48% of PLWH achieving viral suppression, corresponding to an 18% reduction in incidence by 2025. By contrast, when 95% of individuals in care remained engaged each year, the median percent suppressed among PLWH was 84%, and the median percent reduction in incidence was 59%.
Conclusions: Our results suggest that long term retention in care is critical to achieve high levels of viral suppression and sustained reductions in HIV incidence. Health systems should aim to retain at least 95% of PLWH in care per - corresponding to at least 80% population viral suppression - to halve HIV incidence over the next decade.

WEPED1443

Monitoring and comparison of HIV cascade for MSM & TGH in Mumbai, India

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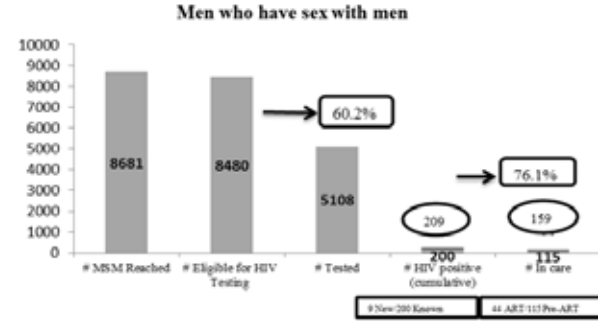
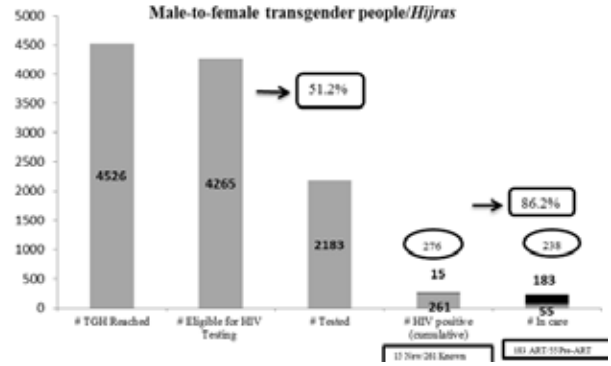
Background: In India, men who have sex with men (MSM) and male-to-female transgender people/Hijras (TGH) are provided HIV prevention services by NGO-run targeted intervention (TI) programs, and are referred to Government facilities for testing and treatment. We assessed differences in the HIV cascade of services in a sample of MSM and TGH in Mumbai, India in order to design appropriate interventions.
Methods: We evaluated service data for cohorts from10 TIs, five focused on MSM and five on TGH. Specifically, we reviewed data from October 2015 through March 2016 on numbers tested for HIV, tested positive, and linked to Care, Support, and Treatment (CST) centers. We used chi-squared test to assess the difference in proportions, and estimated the odds ratio (OR) and their confidence intervals (CI).
Results: Sixty percent of MSM (Figure 1) and 51% of TGH (Figure 2) eligible for an HIV test during the six-month period had tested. About 76% of the MSM and 86% of the TGH who tested HIV positive were linked to CST. Thus, eligible MSM were significantly more likely to undergo HIV testing compared with TGH (OR: 1.44, 95% CI: 1.34, 1.56, p<0.001). TGH who tested HIV positive were significantly more likely to be linked to CST compared with MSM (OR: 1.97, 95% CI: 1.20, 3.24, p=0.004).



[Cascade of services for men who have sex with men]



[Cascade of services for male-to-female transgender]

Conclusions: There is an urgent need to increase HIV testing for TGH, potentially by introduction of community-based testing facilities. Furthermore, linking HIV positive MSM to CST through peer navigation will be useful to achieve 90-90-90 in these groups.

WEPED1444

Scaling up and reaching the 3rd 90 with community testing and counselors support

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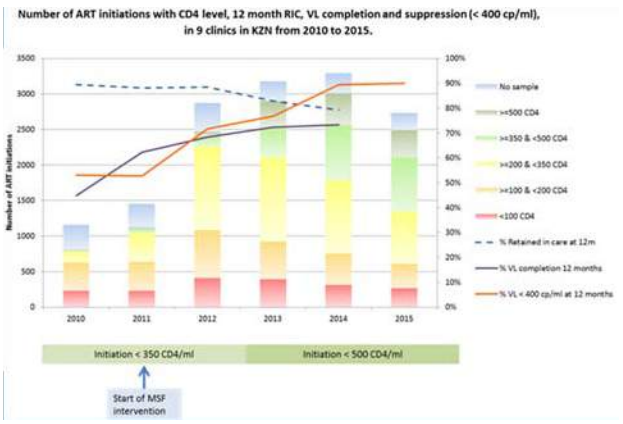
Background: In Kwazulu-Natal (KZN), South Africa (SA), HIV prevalence is 25% in adults and up to 50% in women at 35 years. Since 2011 MSF, in collaboration with the department of health of KZN has implemented community interventions (rural population of 114000) aimed at reducing HIV incidence and reinforcing the HIV cascade of care. Community testing includes mobile and fixed-testing units, and door-to-door testing. Activities focusing on the 3rd 90 include initiation and adherence counseling, and clinical mentoring.
Methods: Twelve month retention in care (RIC), Viral Load (VL) completion (9 to 18 months after initiation) and suppression (VL < 400cp/ml) were calculated for all patients treated >= 6 months initiated between 2010 and 2015.
Results: The total number of active ART patients increased from 3601 to 12150. In 2010, 1157 patient were initiated, 54% of them with a CD4 <200. Only 53% of initiated were suppressed after one year. In 2012, community testing was introduced and initiations doubled. Retention in care decreased to 80% without decrease of the overall cohort. VL completion increased from 45% up to 73%. In 2014, 90% (1671/1869) of patients were suppressed after one year of treatment. Among those initiated <200 CD4/ml, the proportion suppressed increased to 83%. Among all active patients on ART >=6 months at the end of 2015, 85% (9390/10995) had a viral load done in time and among those, 90% (8498/9390) were suppressed. In the overall cohort, 5.75% patients (699/12150) were on 2nd line regimen.



[BG AIS 2017]

Conclusions: With "Test and Treat" introduced in SA in 2016, these results show that, with focused interventions on testing, adherence and support to the quality of care, it is possible to scale up initition and increase VL completion and suppression. Such strategies have supported achievement of the 3r 90, and will support the achievement of the first two 90's.

WEPED1445

Achieving 90-90-90 in the WHO Eastern Mediterranean region: key issues for people who inject drugs

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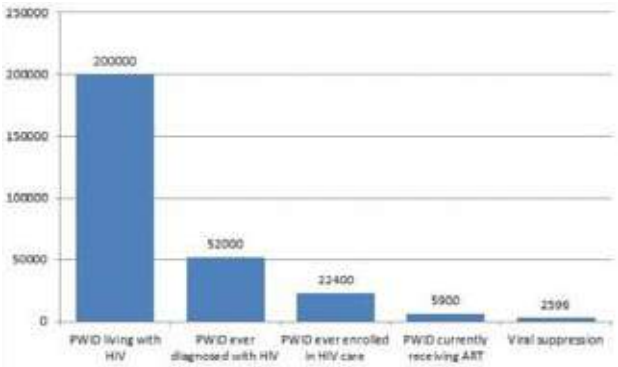
Background: There are 22 countries in the WHO Eastern Mediterranean (EM) Region which has the lowest coverage of ART worldwide. Use of contaminated injecting equipment by people who inject drugs (PWID) is the second most common route of transmission. PWID represent approximately one third of PLHIV in the region.
Methods: A systematic review of published and unpublished data, primarily from National AIDS Programme and other government reports, was conducted to estimate the population size of PWID in EM countries, number of PWID-LHIV who know their status, PWID-LHIV in care and on ART and PWID-LHIV achieving viral suppression.

Results: The number of PWID in the region is estimated to be 790,000 (range: 616,000-999,000; data from 8 countries) with 200,000 living with HIV. An estimated 52,000 PWID-LHIV have been diagnosed with HIV; 22,400 have ever been enrolled in HIV care; 5,900 were currently receiving ART. The proportion of those currently receiving ART who were virally suppressed was only available from 1 country; this proportion was used to estimate a regional figure for number virally suppressed of 2,596 (see Figure 1).



[Figure 1. HIV treatment cascade for PWID in WHO Mediterranean Region.]

Conclusions: While data is limited, results indicate that most PWID-LHIV in the region are unaware of their HIV status. For those diagnosed, there is poor linkage to ART services and treatment initiation is often delayed or denied. Retention in care and subsequent viral suppression are problematic. Achieving the 90-90-90 targets for PWID in EM countries requires higher coverage of simplified testing algorithms and focus on lay-provider and self-testing approaches integrated with peer-led assisted referral to navigate HIV treatment services. Attention should be paid to differentiated ART delivery approaches, service integration and better inclusion of NGOs and peer-led interventions. Stigma, knowledge and attitude of health care providers, local authorities and public security must be addressed.

WEPED1446

Trends and determinants of viral suppression among persons on HIV care in Italy

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Background: The HIV Continuum of Care is a useful framework to monitor access to care for people living with HIV and the potential contribution of cART to control HIV epidemic. Few studies however analyzed progress over time toward the UNAIDS 90-90-90 target of the CoC, especially the last about viral suppression.
Methods: We analyzed data of adult patients receiving clinical care in 2011-2015 in 42 Italian centers included in the ICoNA cohort. For each year of the study we computed the proportion of patients prescribed cART and of those with viral suppression (VS) in the last available viral load for that year (HIV-RNA< 200 copies/mL). Logistic regression models were set up for each year to identify clinical or demographic characteristics associated with cART-prescription or VS.
Results: The number of persons included in the analysis increased from 4,915 to 7,548 (2011-2015). Overall cART-prescription increased from 75.0 to 86.9% (p<0.001), in particular for patients with CD4>500/mmc (from 57.9 to 77.7%) and for foreign-born persons (from 67.1 to 83.2%). Recent HIV diagnosis, younger age, being foreign-born, higher CD4-cells count and lower HIV-RNA were associated with a lower probability of being on cART. The strength of the association with these three latter factors decreased during the study period (Table). Overall, VS increased from 68.5 to 84.3% (p<0.001) and, among those on cART, increased from 89.3 to 94.9%. Determinants of not obtaining VS were recent cART initiation (< 1 year), being foreign-born or IDU patients, higher HIV-RNA before cART.

	cART Prescription Adjusted OR (95% C.I.)		VL suppression among pts on cART Adjusted OR (95% C.I.)	
	2011	2015	2011	2015
Mode of Transmission/Gender				
Het/F	Ref	Ref	Ref	Ref
IDU/F	0.97 (0.62-1.53)	0.95 (0.58-1.56)	0.36 (0.22-0.59)	0.23 (0.14 – 0.40)
Other/F	0.65 (0.40-1.06)	0.94 (0.49- 1.80)	0.66(0.32- 1.82)	0.69 (0.36- 2.21)
Het/M	0.70 (0.54-0.91)	1.14 (0.88-1.48)	1,18 (0.84-1.66)	1.24 (0.87 – 1.81)
IDU/M	0.77 (0.56-1.05)	0.89 (0.64 -1.24)	0.66 (0.45-0.97)	0.55 (0.40- 0.86)
Other/M	0.53 (0.42-0.67)	0.96 (0.77- 1.19)	1.36 (0.98-1.88)	1.36 (0.97- 1.92)
MSM	0.39 (0.26-0.59)	0.87 (0.60 – 1.27)	2.22(1.06-4.62)	1.65 (0.89- 3.26)
Foreign Born	0.61 (0.49-0.77)	0.83 (0.68-1.02)	0.44 (0.33-0.59)	0.60 (0.42 – 0.74)
Age (per 10 years increase)	1.51 (1.39-1.63)	1.25 (1.17-1.34)	1.03 (0.92-1.15)	1.09 (0.98-1.21)
Recent HIV diagnosis (< 1 year)	0.11(0.08-0.13)	0.12 (0.10-0.14)	—	—
Recent cART initiations (< 1 year)	—	—	0.26 (0.21-0.31)	0.16 (0.13- 0.19)
CD4 cells/ml				
<200	Ref	Ref	Ref	Ref
200-349	0.71 (0.48-1.03)	0.83 (0.61-1.14)	1.09 (0.82- 1.45)	0.95 (0.68- 1.22)
350-500	0.18 (0.12-0.25)	0.59 (0.44-0.79)	1.31 (0.92-1.85)	1.27 (0.89 -1.81)
>500	0.07 (0.05-0.10)	0.23 (0.17-0.30)	0.70 (0.46-0.94)	1.14 (0.78-1.67)
HIV-RNA cp/ml				
$<10^4$	Ref	Ref	Ref	Ref
10^4-10^5	1.58 (1.36-1.86)	1.91 (1.61-2.28)	0.91 (0.67- 1.24)	0.77 (0.55-1.08)
$>10^5$	2.57 (2.00-3.29)	2.49 (1.99-3.11)	0.66(0.46- 0.91)	0.54 (0.36-0.77)
AIDS	0.97 (0.62-1.54)	0.55 (0.37-0.81)	0.89 (0.52-1.36)	0.74 (0.45 – 1.22)

In the analysis of cART prescription, baseline CD4 cells count and plasma HIV-RNA were included in the model.
In the analysis of VS, CD4 cells count and plasma HIV-RNA at cART initiation were included in the model

[Table. Factors associated with cART prescription and viral suppression among persons on care for HIV in Italy 2011-2015 - Multivariable logistic regression analysis]

Conclusions: The proportion of persons with VS has significantly increased among adults on care for HIV in Italy. Expanding indications for and access to cART and increased effectiveness of treatment may have contributed to this trend. Further interventions may be needed to improve access to treatment and its outcomes among some subpopulations, such as foreign-born and IDU patients.

WEPED1447

Assessment of pediatric HIV testing and linkage to HIV care and treatment in Lesotho, 2014

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Background: In 2015, 13,000 children were living with HIV in Lesotho, which has the second highest global HIV prevalence. Lesotho's HIV program has made substantial progress; however, challenges to achieve universal treatment access persist. As such, challenges across the pediatric HIV care continuum-testing uptake, timely linkage to care, and immediate ART initiation-need to be identified and addressed.
Methods: A Presidents Emergency Funding for AIDS Relief (PEPFAR)-funded evaluation was conducted from May-June 2016. Routine data was abstracted from HIV testing and counseling (HTC), pre-ART, and ART registers and HIV care cards for children age 0-14 years receiving services in 2014 in 62 facilities in five high HIV burden districts prioritized for the Lesotho Accelerating Children on Treatment (ACT) initiative. Data was limited to services provided within the testing facility, as no system for tracking inter-facility transfers exists. Descriptive and univariate analyses were conducted to identify factors associated with testing and testing positive. Statistical analyses accounted for clustering by health facility, using generalized linear mixed models.
Results: HTC registers recorded 24,443 children tested in 2014-3% positive, 97% negative, and < 1% indeterminate. Most tested were aged 10-14 years (37%). More boys were tested than girls (56% vs. 44%) and among those tested, females were more likely to test HIV-positive (2.9% vs. 2.4%, p=0.028). Positivity differed by age-< 1 year: 2.8%, 1-4 years: 2.9%, 5-9 years: 3.1%, 10-14 years: 2.1% (p=0.047). Including non-HTC register data, 674 children tested positive and 436 (65%) were enrolled in care at the same facility. Of the 436 in care, 333 (76%) initiated ART; 53% (167/317) initiated within one month. Children initiated on ART were more likely to be active in care than those not initiated (68% vs. 11%, p<0.0001).
Conclusions: Poor retention observed among children not started on ART suggests that successful implementation of immediate ART initiation should be prioritized to increase retention. More boys were tested likely due to the voluntary medical

male circumcision program that includes boys aged 10-14 years. Opportunities for testing more females aged 10-14 should be identified to support HIV prevention among adolescent girls and young women by providing a forum for prevention messaging/counseling.

WEPED1448

Reaching the first 90 among key population in India: whether this will be reached?

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Background: UNAIDS launched the ambitious "90-90-90" targets in 2014 to help end the AIDS epidemic as a public health threat by 2030. First target i.e. by 2020, 90% of people living with HIV will know their HIV status, fundamental to achieve the other two 90's, is often considered as the most challenging to achieve. This paper aims to report status of first 90 among key population in India from a large scale national Integrated Biological and Behavioral Surveillance (IBBS).
Methods: Data from first National IBBS, a probability based survey, implemented during 2014-15 was analyzed. IBBS enquired about HIV testing amongst key populations.. IBBS recruited 27,007 female sex workers (FSW) out of 670,000, 23,081 men who have sex with mem (MSM) out 247000 and 19,902 people who inject drugs (PWID) out of 132000 across 187 study domains spread across India. Unlinked anonymous testing with informed consent testing strategy was used.
Results: Among FSWs, 79.5% [95% Confidence Interval (CI) 78.2%-80.7%] reported to ever tested for HIV while 78.9% [95% CI 77.6%-80.1%] reported to undergone HIV testing in 12 months preceding the survey; 85.8% of HIV positive FSWs [95% CI 79.0%-90.6%] reported to be tested for HIV at least once. Among MSM, 74.5% [95% CI 72.9%-76.0%] reported to ever tested for HIV while 73.6% [95% CI 72.0%-75.1%] reported to undergone HIV testing in 12 months preceding the survey; 85.5% of HIV positive MSM [95% CI 79.9%-89.8%] reported to be ever tested for HIV. Among PWIDs, 62.2% [95% CI 60.5%-64.0%] reported to ever tested for HIV while 57.2% [95% CI 55.4%-59.0%] reported to undergone HIV testing in 12 months preceding the survey; 58.4% of HIV positive PWID [95% CI 53.8%-62.9%] were tested for HIV at least once.
Conclusions: National AIDS Control Programme (NACP) promotes routing HIV counselling and treatment (HCT) among key population through peer educator led interventions and offers free HCT at widely distributed Integrated Counseling and Testing Facilities. Clearly, NACP strategies had delivered and target that at least 90% of people living with HIV tested at least once is within striking distance among FSWs and MSM; however, coverage for HCT among PWID needs to be strengthened.

WEPED1449

Expanding HIV cluster observed in Indigenous population in Australia

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Background: We report on an expanding cluster of new HIV cases amongst the Indigenous population in Cairns, Australia. Over the last 20 years, Indigenous Australians experienced similar rates of HIV diagnosis to the non-Indigenous population despite higher rates of other STIs, an increasing proportion of cases of HIV acquired through injecting drug use, and a higher proportion of cases diagnosed among women and heterosexual people. We report on a four-fold increase in the rate of new cases of HIV in this Indigenous population.
Methods: We collected data on all new HIV diagnoses at the Cairns Sexual Health Service from 2014-2016. Cases were reported according to Indigenous status, and further examined to identify any concomitant diseases and cultural/socioeconomic factors that might contribute to this expanding cluster of new HIV cases.
Results: Since 2014 there has been a significant increase in the rate of diagnosis of HIV among the Indigenous population in Cairns, accounting for almost 50% of all new HIV diagnoses. Pre-2014, there were approximately 15 new diagnoses of HIV annually in Cairns, with 1-2 cases occurring in the Indigenous population (range: 6.5%-13%). In 2016, we observed an expanding cluster of new cases of HIV in the Indigenous population with 14 Indigenous diagnoses out of a total of 30 new cases of HIV (47%). Currently, 43 Indigenous patients are engaged with our service; 37 are on treatment (86%), but 8 (22%) remain detectable. In addition, 64% (9 of 14) of Indigenous individuals diagnosed with HIV in 2016 presented with syphilis or chlamydia. There were almost no new local cases of HIV among the non-Indigenous population during this time. We attribute this to high rates of testing among the non-Indigenous population, treatment as prevention (TasP), and recent uptake of Pre-exposure prophylaxis (PrEP).
Conclusions: We observed a 4-fold increase in the rate of new HIV diagnoses in the local Indigenous population over a 2-year period, coinciding with a local outbreak of syphilis. Cultural issues cannot be underestimated in this local epidemic. Early detection and culturally sensitive education will diminish the risk of HIV being further transmitted to outlying communities, with potentially devastating consequences for Indigenous Australians.

WEPED1450

Using fingerprinting to de-duplicate program data for MSM and transgender women in Guatemala

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Background: Country-level 90-90-90 monitoring requires quality data that tracks individuals across multiple observations and sites. For this purpose, the Guatemalan Ministry of Health created a unique identity code (CUI) based on the participant's sex, birthdate, nationality, birth municipality, birth department, and initials for use by HIV prevention and treatment service providers. We designed a computerized fingerprint recording and monitoring software to better identify and track individuals receiving HIV testing. We compared the effectiveness of the CUI to biometric fingerprint data for correctly de-duplicating MSM and transgender women receiving these HIV services.
Methods: We tested the fingerprint tool in MSM and transgender women who participated in a community-based prevention program package (behavior change, condom distribution, STI diagnosis and treatment, HIV testing and linkage to care) in 19 of the 21 departments of Guatemala. Following informed consent, trained educators from 6 CBOs entered the information to create the CUI as well as recording a middle finger right-hand fingerprint of the participant. The software captures the fingerprint image, extracts unique minute data, encrypts the data, and identifies matching fingerprints, thus serving as a gold standard to identify nonmatching CUI for the same individual.
Results: During August of 2016, we registered 3,017 individual fingerprints of MSM and transgender women participants in 91 municipalities. 86 participants (2.7%) refused to provide their fingerprint, so only the CUI was entered. The fingerprint software identified 114 instances of multiple observations for the same person that were entered with different (inconsistent) CUIs. These nonmatching CUIs occured due to inconsistent or changed data for: 39 (34%) birth dates, 26 (22%) birth municipality, 31 (26%) birth department, 21 (18%) initials. The unique fingerprint identified an additional 333 repeat obsevations on the same person that were also correctly identified as duplicates by the CUI.
Conclusions: Fingerprint monitoring was accepted by service providers and 97% of service recipients. It was far more accurate than a "unique" idntification code in identifying multiple observations of the same individual. This technique has great potential for improving accuracy of tracking data to monitor the HIV treatment cascade for key populations in resource limited settings with high stigma.

WEPED1451

Extended PMTCT cascade and implications for PMTCT program coverage in the era of lifelong ART for pregnant and breastfeeding women living with HIV: Rwanda national impact study 2011-2012

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Background: Lifelong ART for all pregnant and breastfeeding women living with HIV (Option B+) to prevent MTCT (PMTCT) is broadening the traditional PMTCT cascade in resource limited settings. We assessed coverage and determinants across a traditional PMTCT cascade and an extended (pre-pregnancy, pregnancy and postpartum) PMTCT cascade.

Methods: We abstracted data from a national Option B/B+ PMTCT impact study conducted in Rwanda (July 2011 - June 2012). We included all infants aged 6-10 weeks and their mothers. We constructed for the traditional PMTCT cascade a standard package (SP) (maternal ART + infant ARV), and three incremental packages (a, b and c): package a= SP + early attendance to first ANC; package b= package a + early retention on ART up to 6-10 weeks; and package c= package b + planned index pregnancy. We estimated coverage of each PMTCT package and assessed its determinants (health system and maternal) using logistic regression models in STATA.
Results: The analysis included 1,521 mother-infant pairs. Coverage for the SP, packages a, b and c was 88%, 61%, 56% and 29% respectively. Mothers who attended first ANC visit during the first/second trimester were twice as likely to receive SP during pregnancy and delivery compared to mothers attending first ANC after second trimester (adjusted Odd Ratio - aOR = 2.0; 95% CI 1.3-3.0). Mothers who were married and those who were cohabiting were respectively 2.9 times (aOR = 2.9; 95% CI 1.4-6.3) and 3 times (aOR = 3.1; 95% CI 1.5-6.3) more likely to complete package c compared to single mothers. In addition, mothers who had four to six household assets were twice as likely
(aOR = 2.1; 95% CI 1.2-3.5) to complete package c compared to mothers who had no household assets. By contrast, mothers who had no source of income were 70% less likely to complete package c compared to mothers who were employed (aOR = 0.4; 95% CI 0.2-0.9).
Conclusions: Rwanda PMTCT program should address the specific needs of single mothers and those from poorer households. Interventions aiming to increase access to income for women and mothers could significantly improve coverage across the extended PMTCT cascade.

WEPED1452

Progress towards 90-90-90 along the paediatric HIV care continua in South-East Asia

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Background: The WHO South-East Asia region has an estimated 180,000 children (0-14 years) living with HIV. But in a setting where the epidemic is concentrated among key populations, paediatric HIV is largely overlooked. We construct HIV care continua for children living with HIV and assess progress towards the 90-90-90 target for them in the region and its 10 Member States.
Methods: We searched the Internet, PubMed, UNAIDS global AIDS response progress reports, PEPFAR country/regional operational plans, and conference abstracts/presentations for data on HIV care interventions for children. We also contacted the WHO country offices and Ministry of Health. We collected data on the following indicators to construct national HIV care continua for children:
(a) estimated children living with HIV,
(b) diagnosed,
(c) on antiretroviral therapy (ART),
(d) tested for viral load (VL), and
(e) with viral suppression.
Results: For 2015, of the 10 countries, we obtained data on at least one indicator from seven (~100% of the regional paediatric HIV burden). Proportion of children living with diagnosed HIV (first 90) was unavailable since countries do not use unique identifiers and it is challenging to estimate this number from data on cumulative HIV cases ever diagnosed. ART coverage among children living with HIV for the region was 38%, ranging between 22%-95% across countries. The regional ART coverage is less than the global average of 49% [42%-55%]. Also, the region is far from achieving the second 90 target, which translates into 81% of children living with HIV on ART by 2020. Availability of VL is limited in majority of the countries - only 44% [3%-86%] of children on ART received VL testing in the four countries reporting data on this indicator. Viral suppression among children on ART (third 90) was high at 86% [67%-89%].
Conclusions: Limited data from the region show that getting to 90-90-90 by 2020 in paediatric HIV requires intensified efforts to expand HIV services for children, especially early infant diagnosis and immediate ART irrespective of CD4/VL count or WHO clinical stage. Additionally, monitoring and evaluation systems need to be strengthened so that progress towards 90-90-90 for children can be evaluated for data-driven decision-making.

WEPED1453

Diversity of ART treatment site decisions by HIV-positive Thai MSM challenges HIV cascade monitoring

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Background: Although timely treatment initiation and adherence lead to better health outcomes for individuals living with HIV and reduced likelihood of ongoing HIV transmission, only 1/3 of known HIV-positive men who have sex with men (MSM) in Thailand are receiving antiretroviral therapy (ART). We introduced Unique Identifier Codes (UICs) and real-time, mobile data collection (eCascade) to follow a cohort of MSM clients across the HIV cascade, track linkage to care and treatment, and increase ART uptake.
Methods: eCascade is implemented by a collection of community-based organizations and private clinics across 4 sites in Thailand. Clients are registered via outreach contact or clinic walk-in, provided with HIV testing, and referred to ART services at participating clinics. Data on treatment initiation are recorded in eCascade and tracked over time, and community-based care, support and treatment officers follow-up regularly with HIV-positive clients.
Results: Between October 2015 and September 2016, 340 clients registered in eCascade were tested HIV positive, but only 40% were successfully tracked to an ART providers (n=137). 60% (n=203) of all newly diagnosed HIV-positive clients in eCascade were considered lost to follow-up (LTFU). However, follow-up revealed that 43% (n=88) of those "LTFU" patients were receiving ART from providers not affiliated with the service utilization network connected to the real-time monitoring system, eCascade. An additional 36% of LTFU clients had still not initiated ART; reasons included structural and policy barriers, the need to wait for additional test results, and being "unready" for treatment. 42 clients (21%) could not be contacted to ascertain their treatment status.
Conclusions: Real-time HIV cascade monitoring provides valuable insights into programmatic performance, but the diverse ARV treatment site decisions of clients can contribute to misleading conclusions. In this case, the "true" rate of successful linkage to care, support and treatment services was 66%, or twice the national rate. To provide a clearer picture of cascade functioning, monitoring systems must account for numerous service delivery points, including those external to the project's network. However, gaps in data collection cannot account for all "leaks" in a cascade. Significant work also remains to reduce structural barriers and increase patient willingness to access ART.

WEPED1454

Care trajectories among people living with HIV and followed within a universal test and treat programme in rural South Africa (ANRS 12249 TasP trial)

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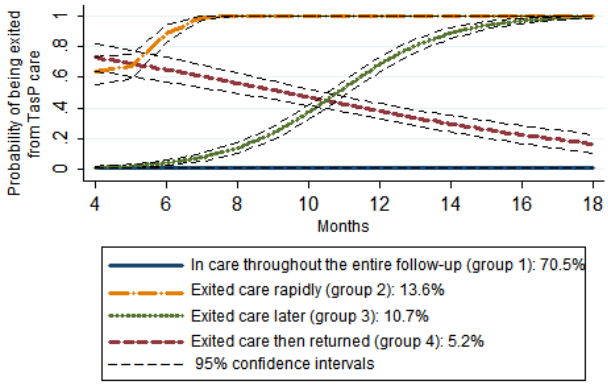
Background: Retention in care is essential to optimize antiretroviral treatment (ART) impact on viral suppression and ensure the success of the universal test and treat (UTT) strategy. We aimed to identify care trajectories and associated factors among ART-eligible patients within the UTT cluster-randomized TasP trial.
Methods: Following home-based HIV testing, HIV-positive individuals were referred to TasP clinics and offered immediate ART (intervention arm) or according to national guidelines (control arm). This analysis included all patients ART-eligible at their first clinic visit ≥18 months before the trial end. Monthly clinical follow-up was offered in TasP clinics. A patient was considered exiting care if ≥3 months late for the last appointment, transferred-out or dead.

Care trajectories, assessed over 18 months of follow-up, and their associated factors were identified using a group-based trajectory model (Nagin, 2005, Harvard University Press).
Results: Among the 787 ART-eligible patients who attended TasP clinics, four trajectory groups were identified: 70.5% remained in care throughout the entire follow-up period (group 1), 13.6% exited care rapidly (median 4 [IQR 4-6] months after first visit) (group 2), 10.6% exited care later (11 [9-13] months) (group 3) and 5.2% exited care then returned after 4 [3-9] months (group 4) (Figure 1). The risk of exiting care (groups 2&3) was higher in newly diagnosed patients and those ≤29 years. The "returning group" members (group 4) were more likely male, with CD4 >350 cells/mm^3 at first visit, living in high HIV prevalence clusters (>34%) with the lower nurse-patient ratio, and less likely to have initiated ART.
Conclusions: Although most patients remained in care over the 18-month period, a significant proportion exited care at different follow-up times. Particular attention should be paid to men, young and newly diagnosed patients, and those with CD4>350 in order to improve retention in care and maximize the effect of UTT strategies.



[Figure 1. Care trajectories in TasP clinics over 18 months of clinical follow-up among ART-eligible patients at the first visit (ANRS 12249 TasP trial, n=787)]

WEPED1455

A case for age and gender disaggregation in Malawi

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Background: Malawi's routine monthly reporting from site-level does not enable reporting of age- and sex-disaggregated data. Subsequently, variations in service provision across different age groups are not well understood. A health facility assessment analysed routine health service statistics to estimate coverage of HIV and reproductive health services among patients aged 10 to 24 years.
Methods: Stratified random sampling was used to select 61 urban and rural facilities, representing 22% of health facilities in 8 high HIV burden districts. Age- and sex-disaggregated data for April-September 2016 were collected from clinic registers and included ANC rates, known HIV status, treatment, STI rates and contraceptive use. Counts and frequencies were used to analyze the data with MS Excel and SPSS.
Results: 21,946 pregnant women registered for ANC during July- September 2016, and a 100% had their HIV status ascertained. Of the 2020 clients who tested positive, 7.2 % were aged 10-19 years, 23.7% were 20-24 years, and 69.1% were 25 years and above. ART coverage within ANC increased with age, ranging from 40% among 10-19 year olds, 49% for 20-24 year olds and 58% in those 25 years and above. HTC coverage was lowest among 10-14 year old non-pregnant females at 22%, yet this subgroup had the highest positivity rate at 6% compared to both genders in the 15-19 year, and 20-24 year age bracket who had the average HIV prevalence of 3.4%. Although ART initiation was lowest among 10-14 year olds (56%), they had better ART retention at 3 and 6 months (91% and 85%) than 15-19 year olds (84% and 80%). Of note, retention was lowest among females aged 15-19 years. STI infection is again disproportionately higher among females aged 15-19 years at 74% than in males of the same age at 26%.
Conclusions: Adolescents are exposed to significant risk of contracting HIV, but are less likely to know their HIV status or access treatment. The magnitude of the problem is masked by the absence of age- disaggregated data. Data disaggregation by sex and age will provide a better understanding of where to intensify HIV service delivery to achieve the 90-90-90 goals.

WEPED1456

Sexual orientation, HIV retention and mortality among people living with HIV in rural Mozambique

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Background: HIV-related outcomes among persons of same-sex orientation are poorly documented in sub-Saharan Africa. We investigate program performance along the HIV continuum of care among persons of minority sexual orientation in rural Mozambique.
Methods: This is a large retrospective cohort study of HIV-infected adults with bisexual, homosexual, and heterosexual preferences (n=49,058) receiving care in a comprehensive HIV program in Zambézia Province, Mozambique. We compared linkage to care, time to initiation of antiretroviral therapy (ART) and CD4+ cell count at enrollment using chi-squared and Wilcoxon rank sum tests. Pre- and post-ART loss-to-follow-up (LTFU), as well as patient mortality, was compared using Cox regression analysis and the Gray test.
Results: From 2014 to 2016, 49,058 HIV-infected patients reported their sexual preference (heterosexual [n=47,780, 97.4%], homosexual [n=1013, 2.1%], bisexual [n=256, 0.5%]) through routine data collection at treatment initiation. Among pre-ART patients, sexual orientation was significantly associated with higher LTFU at one year using Cox regression (p=0.02). Homosexual pre-ART patients (but not bisexual patients) had a significantly higher hazard of LTFU (Hazard Ratio: 1.27 [1.06, 1.51]) vs. heterosexual pre-ART patients. Among ART patients, sexual orientation was not associated with LTFU in the first year of treatment (p=0.20). At one year, homosexual (4.5% [95% confidence interval: 6.7%, 2.3%]) and bisexual (7.2% [13.1%, 0.9%]) patients had a higher rate of mortality vs. heterosexual patients (3.1% [3.4%, 2.8%]), but this difference was not statistically significant (p=0.11).
Conclusions: We found sexual orientation to be an important factor predicting LTFU among pre-ART patients but not among those enrolled on ART. Of concern is the trend toward higher mortality rates among our bisexual and homosexual populations, compared to individuals with heterosexual preferences. Our analysis was limited by the incomplete documentation of sexual preference in the clinical records coupled with reluctance to disclosure sexual preference due to social stigma. This likely creates an invisible population of bisexual and homosexual people living with HIV. HIV programs in Mozambique need to actively engage sexual minority patients and health agents to prioritize addressing underlying social mechanisms and norms that limit their uptake and retention in HIV services.

WEPED1457

Dynamic modelling of the HIV care cascade in the United States: where are people leaving the cascade and where should we intervene?

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Background: Only 30% of people living with HIV/AIDS (PLWHA) in the US are virally suppressed. The US HIV care cascade shows that large numbers of PLWHA are not retained in care, but it assumes unidirectional progression and fails to capture cascade dis/re-engagement. We used a dynamic model of the US care cascade to identify weak points where most PLWHA disengage from the cascade, and evaluate the effects of targeted interventions.
Methods: We developed a deterministic compartmental model of the HIV care cascade which allowed PLWHA to enter and leave care, start and stop antiretroviral therapy (ART), and achieve and lose viral suppression. We modelled movement of PLHIV through the US HIV care cascade from 1995 until 2015. The model was parameterised using published estimates of transition rates between different care cascade stages and calibrated to data from 1995-2012 on the number of people at each cascade stage. We used the calibrated model to identify where most people are lost, and to assess the impact upon viral suppression of strengthening different parts of the cascade.
Results: The calibrated dynamic cascade model suggested that failure to retain PLWHA in care after linkage significantly contributes to the low numbers achieving viral suppression, consistent with the static cascade. The dynamic model additionally suggested that a substantial proportion of people not in care have previously achieved viral suppression. Improvement of patient retention rates gave the largest improvement in viral suppression: 50% greater retention rates would have improved the proportion of PLWHA with suppressed viral load by 11 percentage points in 2012 (from 31% to 42%); increasing rates of testing, linkage rates, or re-

engagement by 50% only increased suppression in 2012 by 2-3 percentage points. Simultaneous 50% improvements in linkage, retention and re-engagement rates were additive, giving an 18-percentage point increase in the proportion virally suppressed in 2012 (from 31% to 49%).
Conclusions: Although the dynamic model of the US HIV care cascade gives additional information about how PLHA transition through care, the overall conclusion agrees with that from the static cascade: that improving retention in care is crucial to optimise the US HIV care cascade.

WEPED1458

Global status report of HIV care continua and the 90-90-90 target

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Background: The 2014 UNAIDS 90-90-90 target specifies that by 2020, 90% of individuals living with HIV will know their HIV status, 90% of people with diagnosed HIV infection will receive antiretroviral treatment (ART), and 90% of those taking ART will be virally suppressed. Consistent methods and routine reporting in the public domain are necessary for tracking progress towards the 90-90-90 target.
Methods: For 2010-2016, we searched PubMed, UNAIDS country progress reports, World Health Organization (WHO)/UNAIDS reports, national surveillance and program reports, United States President's Emergency Plan for AIDS Relief (PEPFAR) Country Operational Plans, and conference presentations and/or abstracts for the latest available national HIV care continuum in the public domain. Continua included the number and proportion of people living with HIV (PLHIV) diagnosed, on ART and virally suppressed of the estimated number of PLHIV. We ranked the described methods for indicators to derive high, medium and low quality continuum.
Results: For 2010-2016, we identified 55 national care continua with viral suppression estimates representing 21.8 million (59%) of the 2015 global estimate of PLHIV. Of the 55, six (2% of 2015 global HIV burden) were high quality, using standard surveillance methods to derive an overall denominator and program data from national cohorts for estimating steps in the continuum. Only nine countries in sub-Saharan Africa had care continua with viral suppression estimates. Of the 55 countries, the average proportion of PLHIV from all countries on ART was 48%, and Virally suppressed was 40%. Seven countries (Sweden, Cambodia, United Kingdom, Switzerland, Denmark, Rwanda and Namibia) were within 12% and 10% of achieving the 90-90-90 target for on ART and Viral suppression, respectively.
Conclusions: Relatively few national continua of care are available in the public domain and there is wide variation in methods for determining progress towards the 90-90-90 target. A standardized monitoring and evaluation approach could improve the use of scarce resources to achieve 90-90-90 through improved transparency, accountability and efficiency.

WEPED1459

12 months virological outcomes among HIV-1-infected patients initiated on first-line combination antiretroviral therapy in the Zambian national ART program

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Background: There is scarce data on Viral load (VL) suppression and HIV drug resistance (HIVDR) especially in the sub-Saharan region; a region mostly affected by HIV and where there has been unprecedented roll out of HIV combination antiretroviral therapy (cART) . Achieving a high level of viral suppression among individuals on cART is important for achieving the third 90-90-90 goal - 90% of people on ART virally suppressed by 2020. Such a goal is important as it reduces HIV transmission and has individual health benefits. We thus assessed the VL suppression and HIVDR among HIV-1 infected individuals at 12 months of first line cART in the Zambian national ART program.
Methods: We conducted a cross sectional survey among HIV-1 infected individuals at 12 months (± 3 months) of first line cART. Sampling of clinics was performed using systematic sampling to generate probability proportional to proxy size samples. 20 clinics were selected based on the random starting-point, sampling interval and cumulative population size giving a sample size of 460. Eligible patients had their blood specimens collected for VL and CD4 count testing. Specimens with VL ≥ 1,000 copies/mL were genotyped to determine HIVDR status. Proportions for each outcome at linearized standard error 95% confidence interval and summary estimates were determined.
Results: Of the 476 patients enrolled, 98% were on TDF/3TC/EFV and 2% on TDF/3TC/NVP. At 12 months of cART 90.27% were virologically suppressed (VL <1000 copies/mL) and the median CD4 was 375 cells/mm^3 (IQR: 236-563) whereas the BMI was 22.7 kg/m^2 (IQR:19.1-25.6). Current BMI > 18.5 kg/m^2 and CD4 > 100 cells/mL were significantly associated with virologic suppression (OR 1.8, CI:1.12-3.02, P=0.017 and OR 2.2, CI:1.19-4.11, P=0.012 respectively).
Among individuals with VL>1000copies/mL, 83.3% had either NRTI and/or NNRTI associated mutations whereas 6.7% had no mutations at all and none had PI associated mutations.
Conclusions: Patients on 12 months of first line cART had achieved more than 90% of the recommended virologic suppression target. Not all patients with virologic failure had HIVDR mutations. In the absence of routine viral load monitoring, low BMI and low CD4 would aid in targeting viral load testing.

WEPED1460

Quality assessment of national strategic plan targets

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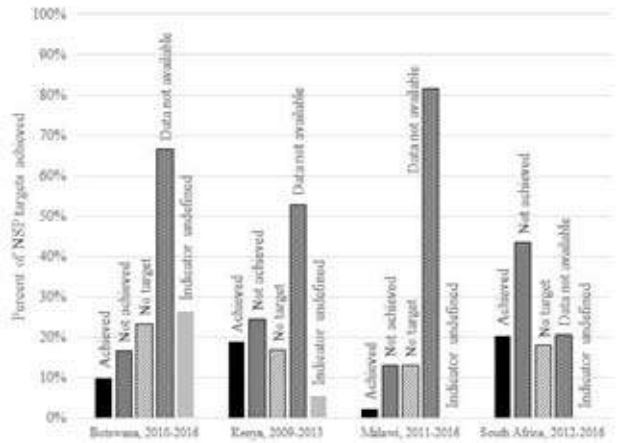
Background: National Strategic Plans (NSPs) for HIV have become foundational documents that frame national responses to HIV. Both Global Fund (GF) and PEPFAR require coordination with NSPs as part of their processes. Despite this role of NSPs in planning, no rigorous assessment of NSP targets and performance exists. We performed a quantitative analysis of the quality of NSP indicators and targets, and an assessment of achievement of historical NSP targets.
Methods: We extracted all identifiable targets and indicators from publicly available NSPs from 32 countries with generalized HIV epidemics and GF support eligibility for HIV in 2017. Targets and indicators were evaluated for specificity, measurability, and achievability. Additionally, progress toward achieving targets was evaluated using historical NSPs from four countries with available NSP progress reports.
Results: On average, 21% of country's NSP indicators were disaggregated by sex, age, or population group. The average percent of indicators that included numeric targets or baselines was 69% and 46%, respectively; 38% identified data sources for either measure. Targets were a 165% increase (or decrease) relative to baselines (IQR = 75.4% - 208.3%). Achievement of historical NSP targets ranged from 2% of targets in Malawi to 21% in South Africa. Assessment of achievement was limited by lack of numeric targets, available data, and well-defined indicators.

	Mean	Minimum	Maximum
Number of indicators	84.5	8.0	232.0
Have numeric target	69.0	0.0	100.0
Have numeric baseline	45.7	0.0	91.5
Percent change baseline to target (for non-missing)	167.8	15.5	646.6
Indicators identify data source for baseline and/or target	38.3	0.0	100.0
Target or baseline has a disaggregate (age, sex, high-risk population)	21.2	0.0	76.6

[Table 1. % Indicators/targets with each criterion]



[Figure 1. Progress toward NSP targets.]

Conclusions: Country NSPs are limited by a lack of specific, measurable, and achievable targets. The low achievement of targets in historical NSPs corroborates that targets are often poorly defined, aspirational, and not linked to available data sources. The use of NSPs for country planning, grant applications, and monitoring and evaluation is limited by low quality target setting.

WEPED1461

Health provider perspective on the pediatric HIV referral system in Lesotho

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Background: Lesotho has the second highest adult HIV prevalence in the world, and 13,000 children living with HIV in 2015. While progress has been made towards universal access to HIV treatment, multiple barriers persist. As part of Lesotho's Accelerating Children's HIV/AIDS Treatment Initiative, we interviewed health care providers to obtain their perspective on the existing referral system for children living with HIV and HIV-exposed infants (HEI).
Methods: Interviews were conducted from May-June 2016 with health facility level providers involved in pediatric HIV-related referrals to identify gaps in the system. Guidelines, standard operating procedures, and monitoring and evaluation tools were reviewed. Descriptive analyses were conducted.
Results: We interviewed 101 individuals from 27 health facilities. Among health facility staff, 96% used the HIV testing and counseling (HTC) register to document pediatric HTC, while the Under-5 (74%), tuberculosis (59%), and pediatric inpatient (30%) registers were also used. Patient escort was the primary mechanism used for within facility referrals (72%). Decisions on where to make inter-facility referrals is primarily made through provider knowledge (70%) while few (5%) used a referral directory. Most providers made inter-facility referrals using the standard patient referral form (88%) and writing referral information on the patient's personal medical record book (64%). Twenty-eight percent of providers indicated there was a system to confirm referral completion, with the most common method a phone call to the receiving facility (62%); 45% indicated no referral follow-up is done. Fifty-four percent of health facilities used a referral protocol. Multiple tools were used to document prevention of mother-to-child transmission (PMTCT) services and to track HEI.
Conclusions: A variety of mechanisms were used for within and inter-facility pediatric referrals, which can lead to poor linkage and retention. Consistent use of client escort to ensure within facility linkage, establishment of a standardized referral directory, and a system to conduct and document referral completion are needed to strengthen the referral system. Until a national unique patient identifier is implemented, a unique number within facilities to enable longitudinal tracking of women living with HIV and HEI across different service points is needed.

WEPED1462

Stock-outs of antiretroviral and tuberculosis medicines in South Africa: a national cross-sectional survey

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Background: Stock-outs of antiretroviral medicines (ARVs) and tuberculosis (TB) medicines in treatment facilities limit the capacity of national programs to treat growing numbers of patients successfully and prevent the development and spread of antimicrobial resistance.
The aim of this analysis was to determine the magnitude of stock-outs of ARVs and TB medicines in public health facilities in South Africa.
Methods: This was a cross-sectional study using structured telephonic interviews with healthcare workers in all public health facilities providing ARVs and TB services in South Africa between October and December 2015. Data included the existence of stock-outs of ARVs and TB medicines on the day of the call and in a three-month period preceding the contact. When stock-outs were reported, questions were asked about the medicines out-of-stock, the duration of the stock-out and solutions the facility proposed to patients presenting during the stock-out.
Results: Out of 3547 facilities identified, 2804 (79%) could be reached, of which 2463 (88%) participated and 2370 (96%) were analysed. Nationwide, 36% (864/2370) and 20% (285/2370) of facilities reported at least one ARV and/or TB medicine stock-out during the three month period prior to contact and the day of contact, respectively. Out of 1467 stock-outs reported in three months, 74% were adult ARVs, 20% paediatric ARVs and 7% TB-related medicines. 70% (532/763) of resolved stock-outs had lasted over one month. In 25% (366/1449) of stock-out cases patients did not receive treatment or an incomplete ART regimen. Stock-outs occurrence, duration and mitigation mechanisms varied widely between provinces. While 24% (348/1476) of facility stock-outs resulted from a nationwide stock-out of adult lopinavir/ritonavir, 76% (1128/1476) of cases happened while the medicines were available in country. The national stock-out resulted from inability of the single supplier to meet demand. Legislative reform should ensure market access for multiple suppliers of lifesaving medicines. In-country, province-specific supply chains should be evaluated and improved. Independent alert mechanisms could reduce stock-out duration and impact.
Conclusions: Stock-outs of ARVs and TB medicines in South Africa affect patient and threaten national ambitions to end the epidemics. Patient-centred action is needed from multiple stake-holders to stop stock-outs.

WEPED1463

HIV treatment cascade assessment of a community-based test and start model for key populations in Lagos, Nigeria: where are the gaps?

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Background: Targeted community-based test and start (TAS) models have shown potential to improve clinical outcomes for key populations because they provide unrestricted access to comprehensive HIV services. We assessed the performance of a TAS model for key populations (KP) in Lagos along the UNAIDS 90/90/90 cascade.
Methods: Men who have sex with men (MSM), female sex workers (FSW), and persons who inject drugs (PWID), >14 years of age were recruited through peer-referral for HIV testing services (HTS) at a community-based KP-friendly clinic in Lagos between June 2015 and September 2016. The clinic provides comprehensive HIV services, including HIV treatment. Those who test positive are enrolled and provided with TAS services. Using routine service data, we determined the performance along the 90/90/90 cascade.
Results: In total, 8,812 KPs comprising MSM (51.6%), FSW (32.7%) and PWID (15.7%) were tested during this period. About one-half (46.4%) were young KP (15 - 25 years). The majority (76.1%) were male, single (86.1%), almost all (99%) had at least primary school level education, and about one-quarter (25.1%) were employed. Among MSM, 506 (11.1%) tested positive, 276 (54.5%) were initiated on ART, of whom 155 conducted viral load testing and 88 (56.7%) had achieved viral suppression (< 1000 copies per milliliter). Among FSW, 88 (3.1%) tested positive, only 28 (31.8%) were initiated on ART, of whom 15 conducted viral load testing and 9 (60%) achieved viral suppression. Among PWID, of 15 (1.1%) who tested positive, only 2 (13%) were initiated on ART and none had conducted viral load testing.
Conclusions: The current community-based model shows excellent capacity to achieve the first 90 goal among target KP communities. However, linkage to care and treatment, adherence, and retention remain significant challenges in achieving the second and third nineties at the community level.

WEPED1464

Are health systems addressing comorbidities in people living with HIV? An assessment of key European HIV guidelines and monitoring mechanisms

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Background: Widespread access to antiretroviral therapy has brought about major reductions in HIV-related morbidity and mortality in much of the WHO European Region, but non-AIDS related comorbidities now impose a large burden of disease on people living with HIV (PLHIV). It is unclear whether health systems have sufficient information about comorbidity prevention and treatment in PLHIV, or whether they are effectively monitoring service delivery issues related to comorbidities.
Methods: We selected nine non-AIDS-related comorbidities that are prevalent among PLHIV in Europe, based on recent literature. Two researchers independently used a three-point grading system to assess the extent to which each is addressed in the WHO European clinical protocols for HIV (2012), European AIDS Clinical Society (EACS) guidelines (2016) and the 2016 Dublin Declaration Questionnaire developed by the European Centre for Disease Prevention and Control (ECDC). Discrepancies in grades were reviewed by two other researchers and resolved through consultation.
Results: The WHO protocols deal only with liver diseases and to some extent depression. EACS guidelines address physical comorbidities in a concise yet comprehensive manner, but do not address prevention of neurocognitive and mental health issues. The Dublin questionnaire does not ask for information on specific comorbidities other than tuberculosis. It does ask if there are "effective systems in place to ensure that" PLHIV are linked to care and services in very broadly defined areas, such as "mental health" and "chronic disease" (Table 1).

Type of comorbidity	Addressed in WHO/Europe HIV clinical protocols	Addressed in European AIDS Clinical Society guidelines	Access to services monitored via Dublin questionnaire	Comorbidity burden monitored via Dublin questionnaire
Non-AIDS malignancies	C	B[1]	C	C
Cardiovascular disease	C	A	C	C
Renal disease	C	A	C	C
Hepatitis B virus	A	A	A	C
Hepatitis C virus	A	A	A	C
Liver diseases other than chronic viral hepatitis	A	B	C	C
Neurocognitive disorders	C	B[2]	C	C
Depression	B	B[2]	B	C
Drug dependence	C	B[2]	B	B

[1] Vaccination and screening only. [2] Treatment only (i.e., not prevention). [3] Burden of HIV disease monitored in people who inject drugs.

A = addressed sufficiently
B = addressed but not sufficiently
C = not addressed

[Table 1. Analysis of how comorbidities are addressed in the WHO/Europe clinical protocols for HIV, European AIDS Clinical Society guidelines and the 2016 Dublin Declaration Questionnaire]

Conclusions: When revising WHO/Europe and EACS HIV clinical guidelines, greater attention to non-AIDS-related comorbidities will help to inform healthcare officials and providers about the full range of PLHIV health needs. Likewise, ECDC might consider consulting countries on the need to monitor the burden of specific comorbidities and to expand the list of specific types of care and services to which access is being monitored.

WEPED1465

Using effective and flexible M&E systems for timely and accurate data in HIV/AIDS programming: bridging data quality gaps

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Background: In the era of "last mile" HIV programming to meet the UNAIDS 90-90-90 targets, strategies to increase HIV service coverage have been widely advocated for and implemented. However less attention has been given to strengthening M&E systems for tracking and decision making. This abstract presents evidence based M&E best practices for improved data quality and challenges.
Methods: Baylor Uganda is implementing three HIV/AIDS/TB projects in 266 health facilities in Uganda. M&E related interventions implemented include; onsite training, mentorship, support supervision, M&E financing, provision of data tools, computerization, leadership training and human resource support. In 2014, we implemented additional interventions: monthly onsite data review meetings, district coordination meetings and data quality improvement projects. In this study 54 sites had their M&E systems assessed before (2014) and after additional interventions (2016). We reviewed reports, registers and compared reported data versus actual count. Open-ended interviews were held with supervisors. Indicators selected to assess accuracy were: HIV positive individuals identified, started ART and 12 month ART retention. Odds ratios were estimated using SAS 9.2.
Results: Results showed a great improvement in data quality and data use for decision making as a result of the interventions. Reporting rates increased from 83% to 100% and timely reporting from 70% to 95%. The odds of facilities reporting accurately after the additional interventions were higher than before by 4.1 times (OR=4.1 95%CI, 2.97-7.15), report completeness was higher by 2.3 times (OR=2.3, 95%CI=1.71-6.19) and consistency was two-fold better (OR=2.12, 95%CI=1.32-3.74). The average time of generating reports improved from 7-10 days to 1-3 days. Ten out of 15 supervisors indicated that they used data to make a decision. The proportion of sites that had action plans tracked and updated increased from 25% to 60%. All facilities had a dedicated person for data management, However sustainability and Irregular supply of data tools were their main challenges.
Conclusions: Scale-able and effective M&E best practices resulted in improved data quality and data-use for decision making. Program implementer need to plan for prioritized implementation and innovate strategies for sustainability.

Monday 24 July

Late Breaker Abstracts

Oral Abstract Sessions

MOAA01 Hide and Seek: Biology of Reservoirs

MOAA0106LB

Enrichment of the HIV reservoir in CD32+ CD4 T cells occurs early and is closely associated with immune checkpoint receptor expression

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Background: CD32 has been identified as a marker of a substantially enriched HIV reservoir. Here we explore the relationship of CD32 expression on CD4 T cells with other correlates of reservoir size including time to viral rebound after treatment interruption.
Methods: CD32 expression was measured by flow cytometry on PBMCs (n=39) and tonsillar tissue (n=1) from individuals who initiated ART during primary HIV infection (PHI), and uninfected controls (n=10). Co-expression with immune checkpoint receptors (ICRs), lineage, memory and T follicular helper (Tfh) markers was measured. HIV DNA was quantified in bulk and sorted CD32+ and CD32- populations.
Results: One-year post-ART initiation, the frequency of CD32+ CD4 T cells was 1.5% (range 0.2-6.4), and did not differ from controls. CD32+ CD4 T cells were found predominantly within differentiated memory subsets (transitional, effector memory, and T_{EMRA}) compared with CD32- CD4 T cells (all p< 0.001) for HIV+ (n=20) and controls. CD32+ CD4 T cells were highly enriched for HIV DNA compared with CD32- cells (average 103-fold, n=6, p=0.03), although CD32 percentage did not correlate with reservoir size (n=29). In a subset of individuals (n=19) who interrupted ART after 48 weeks, CD32+ CD4% did not predict viral load rebound, although all three individuals with persistently undetectable viraemia had CD32+ CD4% below the median.
CD32+ CD4 T cells from blood had higher expression of PD-1, Tim-3 and TIGIT (all p< 0.0001) and a higher density of CD2 (p=0.001) than CD32- cells in HIV+ participants (n=20) and controls. Tonsil CD32+ CD4 T cells (n=1) showed a similar pattern of memory distribution and ICR expression as the periphery. Although tonsillar CD32+ CD4 T cells had higher individual expression of Bcl-6, ICOS and CXCR5 than CD32- cells, the co-expression pattern was not consistent with a Tfh phenotype.
Conclusions: We confirm the role of CD32 as a marker of the HIV reservoir, and show that this may occur early during PHI on more differentiated CD4 T cells and is highly co-expressed with ICRs. That expression is similar between HIV+ and HIV- individuals suggests that preferential infection or survival of CD32+ cells, rather than CD32 up-regulation, is responsible for the observed enrichment.

MOAB01 Antiretroviral Therapy - ART: Season One

MOAB0105LB

A phase 3 randomized controlled clinical trial of bictegravir in a fixed dose combination, B/F/TAF, vs ABC/DTG/3TC in treatment-naïve adults at week 48

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Background: Integrase strand transfer inhibitors (INSTIs) are recommended as first-line antiretroviral therapy in combination with 2 nucleoside reverse transcriptase inhibitors. Bictegravir (B), a novel, potent INSTI with a high in vitro barrier to resistance and low potential for drug interactions, has been coformulated with emtricitabine (F) and tenofovir alafenamide (TAF) as a fixed-dose combination (B/F/TAF). We report results from a blinded phase 3 study comparing B/F/TAF to coformulated abacavir, dolutegravir, and lamivudine (ABC/DTG/3TC).
Methods: HIV-infected, treatment-naïve, HLA-B*5701-negative, HBV-uninfected adults with estimated glomerular filtration rate (eGFR) ≥50 mL/min were randomized 1:1 to receive blinded treatment with fixed-dose combination B/F/TAF (50/200/25 mg) or ABC/DTG/3TC (600/50/300 mg) with matching placebos once daily. The primary endpoint was proportion of participants with HIV-1 RNA (VL) < 50 c/mL at W48 (FDA snapshot). Noninferiority was assessed through 95.002% confidence intervals (CI) (12% margin). Secondary endpoints were safety (adverse events [AEs] and laboratory abnormalities) and pre-defined analyses of changes from baseline in bone mineral density (BMD) and measures of renal function, including eGFR and proteinuria.
Results: 629 participants were randomized and treated (314 B/F/TAF, 315 ABC/DTG/3TC): 10% women, 36% Black, 16% VL >100,000 c/mL, 11% CD4 < 200 cells/mL. Median baseline characteristics: age 32 yrs, CD4 count 444 cells/μL, and VL 4.47 log10 c/mL. At W48, B/F/TAF was noninferior to ABC/DTG/3TC, with 92.4% on B/F/TAF and 93.0% on ABC/DTG/3TC achieving HIV-1 RNA < 50 c/mL (difference -0.6%; 95.002%CI -4.8% to 3.6%, p=0.78). No resistance mutations emerged in either group. Comparing B/F/TAF to ABC/DTG/3TC throughout, the most common AEs were diarrhea (13%, 13%), headache (11%, 14%), and nausea (10%, 23%). Few participants (0 vs 4 [1%]) had any AEs leading to premature study drug discontinuation. At W48, mean % changes from baseline in BMD were -0.83% vs. -0.60% (p=0.39) [lumbar spine] and -0.78% vs. -1.02% (p=0.23) [total hip]. No differences between treatments were noted in changes from baseline for eGFR and proteinuria at W48.
Conclusions: At W48, B/F/TAF achieved virologic suppression in 92.4% of treatment-naïve adults and was noninferior to ABC/DTG/3TC, with no emergent resistance. B/F/TAF was safe and well tolerated with less nausea than ABC/DTG/3TC. Bone and renal safety profiles were similar between groups.

MOAB0106LB

Dual therapy with darunavir/ritonavir plus lamivudine for HIV-1 treatment initiation: week 24 results of the randomized ANDES study

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Background: Following the results of the GARDEL trial, dual therapy (DT) has been explored in different studies. Generic fixed dose combinations (FDC) of Darunavir/ritonavir (DRV/rtv) 800/100 mg and Tenofovir/Lamivudine(TDF/3TC)

are available in Argentina. This study compares DRV/rtv plus 3TC to standard-of care triple therapy (TT) based on these same drugs plus Tenofovir (TDF).
Methods: ANDES is a randomized, open-label, phase IV study, designed to assess the antiviral efficacy, safety and tolerability of DT with DRV/rtv (800/100 mg) FDC, plus 3TC (300 mg), compared to TT with DRV/RTV (800/100 mg) plus TDF/3TC (300/300mg) FDC in treatment-naïve HIV-1 infected patients. Primary endpoint: proportion of patients with viral load (pVL) <50 copies/mL at week 48. Preplanned analyses at week 24, measured by the proportion of patients with pVL <400 copies/mL (ITT-exposed analysis, FDA snapshot algorithm) are reported. ClinicalTrials.gov Identifier:NCT02770508.
Results: Out of 182 patients screened, 145 were randomized to receive: DT (n:75) or TT (n:70). Screening failure rate 20%. At baseline: 91% were male; median age 30 years; CDC stage A: 92%; 24% had pVL >100,000 copies/mL. At week 24, 94.7% (n:71) of patients receiving DT and 97.1% (n:68) receiving TT were responders (pVL < 400 copies/mL), difference -2.5 % (95% CI:-7.9-2.9) Patients with baseline pVL >100,000 copies/mL (n:35) showed 100% response in both arms. One patient had virological failure at W24 due to non-compliance (control arm). Mean CD4+ increases were similar in both arms (DT=206 cells/mm3; TT=204 cells/mm3).Sixty-seven grade 2-3 possible/probable related adverse events (AEs) were reported in 51 patients (36%), most frequent were gastrointestinal (22%) and rash (14%). AEs incidence was similar in both arms; one patient was discontinued due to a drug-related grade 3 adverse event (rash).
Conclusions: A generic combination of DRV/RTV in fixed-dose plus 3TC showed non-inferiority to a generic triple drug regimen of DRV/RTV plus TDF/3TC at 24 weeks. These results, if confirmed at week 48, may provide further evidence about the potential efficacy of dual therapy based on 3TC and a drug with a high genetic barrier.

MOAD01 What's Different about Differentiated Care and Service Delivery?

MOAD0106LB

Retention in community versus clinic-based adherence clubs for stable ART patients in South Africa: 24 month final outcomes from a randomized controlled trial

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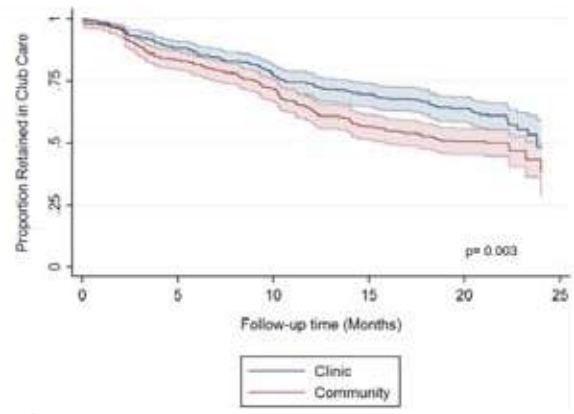
Background: Adherence clubs, where groups of 25-30 patients stable on antiretroviral therapy (ART) meet for counselling and medication pick-up, is an innovative model to retain patients in care and facilitate task-shifting. Adherence clubs can be organized at a clinic or community venue. We performed a randomized controlled trial to compare club retention between community and clinic-based adherence clubs.
Methods: Stable patients with undetectable viral load at Witkoppen Clinic in Johannesburg, South Africa, were randomized to a clinic- or community-based adherence club. Clubs were held every other month. All club participants received annual viral load monitoring and medical exam at the clinic. Patients were referred back to standard clinic-based care if they missed a club visit without ART pickup within 5 days, had two consecutive late ART pickups, developed a comorbidity requiring closer monitoring, or had viral rebound. We assessed the proportion referred back to routine care by 24 months following randomization.



[Figure]

Results: From February 2014-May 2015, we randomized 775 adults into 12 pairs of clubs—376 (49%) clinic-based, and 399 (51%) community-based. Characteristics were similar by arm: 65% female, 89% on fixed-dose combination ART, and median CD4 count of 506 cells/mm^3. The proportion referred back to standard clinic-based care was greater among community-based (47%, n=191) compared to clinic-based clubs (37%, n=140, p=0.003) (Figure).
Adjusted for age, gender, employment and baseline CD4 count, community-based club participants had an increased risk of loss from club (aHR 1.43, 95% CI:1.15-1.79, p=0.001). Main reasons for return to clinic-based care were missing ART pickup (59%, n=198) or pregnancy (11%, n=36), and were similar by arm. Among those referred to standard care, 63% and 80% made a visit within 60 and 90 days respectively of their last club visit.
Conclusions: By two years, drop-out from adherence club participation was high (43%) and higher among community-based compared to clinic-based clubs.

MOAX01 Just Do It Yourself: Preferences and Performances of HIV Self-testing

MOAX0105LB

HIV self-testing among female sex workers in Zambia: a randomized controlled trial

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Background: HIV self-tests (HIVST) may help increase HIV testing coverage to meet the 90-90-90 target in female sex worker (FSW) populations. We report the results of a randomized controlled trial of HIVST among FSW in Zambia.
Methods: Trained peer educators in Kapiri, Chirundu, and Livingstone, Zambia each recruited 6 FSW participants. Peer educator-FSW groups were randomized to: 1) direct distribution of an oral HIVST from the peer educator, 2) distribution of a coupon for an oral HIVST available from a health clinic/pharmacy, or 3) referral to standard HIV testing. HIVST-arm participants received one HIVST at baseline and another three months later. Participants completed baseline, month-1, and month-4 questionnaires.
Results: 965 participants were enrolled between September-October 2016; 20% had never tested for HIV. 98.3% of direct distribution arm participants reported using their HIVST at month-1, compared to 86.3% in the coupon arm (P=0.001); this difference had disappeared by month-4. There was no significant difference in reported past-month testing for HIV at month-1 or month-4, although rates were highest for the direct arm at both timepoints. At month-1, 94.9%, 84.4% and 88.5% of direct-, coupon- and standard-arm participants reported testing in the past month (P=0.10 direct vs. standard, P=0.29 coupon vs. standard). At month-4, past-month testing coverage was 84.1%, 79.8% and 75.1% (P=0.11 direct vs. standard, P=0.42 coupon vs. standard).
Of 144 participants reporting a positive HIV test at month-1, 51.0% and 52.8% in direct- and coupon-arm participants reported linking to care, compared to 74.6% in the standard arm (P=0.07 direct, P=0.12 coupon). At month-4, of 235 participants reporting a positive test, 71.6%, 76.6% and 85.7% of direct-, coupon-, and standard-arm participants reported linking (P=0.13 direct, P=0.17 coupon). Three cases of HIVST-related intimate-partner violence (IPV) were reported, despite 60% of participants reporting IPV in the previous year.
Conclusions: HIVST provision via peer educators to Zambian FSW led to high test uptake and rapid linkage to care, including amongst those who had never previously tested, without a significant increase in IPV. HIVST should be considered as part of an intervention package to maximize HIV protection for FSW populations.

MOAX0106LB

Performance and usability of INSTI, a blood-based rapid HIV self test for qualitative detection of HIV antibodies in intended use populations in Kenya

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Background: HIV self testing is rapidly gaining acceptance as an effective method to reach undiagnosed individuals in sub-Saharan Africa, however there is very little documented data on performance of blood-based self tests in diverse intended-use populations. The self testing concept was approved in Kenya in 2015, but no products were available.
Methods: The Kenya Medical Research Institute (KEMRI) completed a study of the blood-based 60-second INSTI HIV Self Test to measure its performance, usability and readability in 688 consenting adults with broad demographic diversity, from Matayos, Bumutiru, Khunyangu, Aterait and Asinge villages in Busia County, Western Kenya. All subjects participated in the performance study, comparing INSTI results to 4th generation EIA results from venous blood collected from each subject. Portions of the study subjects also participated in qualitative usability and readability studies to assess label comprehension, ease of use and result interpretation.
The study was conducted between 22nd March and 11th April 2017, under ethics approval by the KEMRI Ethical Review Committee.
Results: Compared to the bioelisa HIV-1+2 Ag/Ab (Biokit S.A., Barcelona, Spain) EIA test, the specificity of the INSTI HIV Self test was 99.26% and sensitivity was 98.51%. Negative predictive value was 98.89% and positive predictive value was 99.00% for the study population. From the 350 subjects in the usability study, 98.00% found the test instructions easy to follow; 99.71% successfully added the blood droplet into INSTI bottle 1; 97.71% indicated willingness to use the test again; and 98.29% would recommend the kit to a partner. For the 91 subjects in the readability study, 100% correctly interpreted the positive, negative and invalid results, while 65.93% were unsure how to interpret the weak positive result.
Conclusions: INSTI is unique for its use of a "hanging" fingerstick blood drop, without the need for a collection device. This first field study of such a fingerstick blood-based self test provides strong evidence that the INSTI HIV Self Test is accurate, acceptable and easy to use by self testers with diverse backgrounds in sub-Saharan Africa. Modifications to the kit instructions to include a visual of a weak positive result would provide a more consistent interpretation.

MOAX02 Co-Chairs' Choice

MOAX0201LB

A randomized controlled trial for the treatment of HIV-associated cryptococcal meningitis in Africa: oral fluconazole plus flucytosine or one week amphotericin-based therapy vs two weeks amphotericin-based therapy. The ACTA Trial

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Background: Cryptococcal meningitis (CM) accounts for 10-20% of HIV-related deaths and >100,000 deaths/year. Amphotericin (AmB) plus flucytosine for 2 weeks is considered the gold standard but is unavailable in resource-limited settings where fluconazole treatment predominates.
Methods: Based on phase II studies, we tested, against 2 weeks AmB-based treatment, 2 new strategies, which could be sustainable in Africa, and more effective than fluconazole: optimized oral therapy of high dose fluconazole plus flucytosine, and short (1 week) induction with AmB-based treatment. In the AmB arms we compared fluconazole and flucytosine as adjunctive treatments.
Between 2013 and 2016, 721 participants from 9 centres in Malawi, Zambia, Cameroon, and Tanzania with first-episode CM were randomized to:
Oral (238): fluconazole (1200mg/day) plus flucytosine (100mg/kg/day) for 2 weeks.
1-week (240): AmB (1mg/kg/d), plus fluconazole (1200mg/day), or flucytosine (100mg/kg/day) (ratio 1:1), for 7 days. Days 8-14, fluconazole 1200mg/day.
2-weeks (243): AmB (1mg/kg/d) plus fluconazole (1200mg/day), or flucytosine (100mg/kg/day) (ratio 1:1), for 14 days.
After 2 weeks, all received standard fluconazole consolidation. ART was started, or restarted, at 4 weeks, and patients followed-up to 10 weeks.
Results: Only 4 participants were lost-to-follow-up. Mortality at 2 and 10 weeks for oral, 1-week, and 2-weeks was 18%, 22%, 21%, and 35%, 36%, 40%, respectively. The upper 1-sided 95%CI limits for the difference in mortality comparing oral and 1-week against 2 weeks AmB-based treatment (primary endpoint) were 3.0% and 6.8%, below the pre-specified 10% non-inferiority margin. Hazard ratios (95%CI) were 0.82 (0.54-1.25) and 1.01 (0.68-1.51) at 2, and 0.83 (0.61-1.13) and 0.89 (0.66-1.21) at 10 weeks, for oral and 1-week vs 2-weeks, respectively. As adjunctive treatment with AmB, flucytosine was superior to fluconazole [HR(95%CI): 1.62(1.19-2.20) p=0.002]. One week AmB plus flucytosine had the lowest 10-week mortality (24%), significantly lower than all other AmB arms [HR(95%CI): 0.56(0.35-0.91) comparing 1-week with 2-weeks AmB plus flucytosine]. Side effects were more frequent with 2 weeks AmB than with 1 week AmB, or oral therapy.
Conclusions: One week AmB plus flucytosine and the oral combination provide safe, effective and sustainable induction therapy in resource-limited settings. Flucytosine should be made widely available for treatment of cryptococcosis.

MOAX0202LB

Dolutegravir / tenofovir / emtricitabine (DTG/TDF/FTC) started in pregnancy is as safe as efavirenz / tenofovir / emtricitabine (EFV/TDF/FTC) in nationwide birth outcomes surveillance in Botswana

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Background: Global rollout of DTG-based antiretroviral therapy (ART) has been hampered by lack of safety data in pregnancy.
Methods: We captured birth outcomes data at 8 government hospitals throughout Botswana (~45% of all deliveries) starting August 2014. In 2016, Botswana changed first-line ART from EFV/TDF/FTC to DTG/TDF/FTC, including for pregnant women. This analysis included women initiating either EFV/TDF/FTC (delivered August 2014 to August 2016) or DTG/TDF/FTC (delivered November 2016 to April 2017) during singleton pregnancy. Outcomes included combined endpoints of any adverse outcome (stillbirth, preterm birth [< 37 weeks], small for gestational age (SGA)[< 10th% weight-for-gestational age], or neonatal death [< 28 days]) and severe adverse outcomes (stillbirth, neonatal death, very preterm birth [< 32 weeks] and very SGA [< 3rd% weight-for-gestational age]). We fit log-binomial regression models, controlling for maternal age, gravidity and education, to estimate adjusted risk ratios (aRRs). Congenital abnormalities were detected by maternity nurse surface exam.
Results: Maternal characteristics were similar for women starting DTG/TDF/FTC (N=845) or EFV/TDF/FTC (N=4593), including age, education, occupation, parity, alcohol/tobacco use, history of adverse birth outcome, delivery site, gestational age at presentation for antenatal care, and CD4 cell count. ART was initiated at median [IQR] 19 [15, 25] weeks gestation for DTG/TDF/FTC and 21 [16, 27] for EFV/TDF/FTC. There were no significant differences in stillbirth, neonatal death, preterm or very preterm birth, SGA or very SGA by regimen (Table 1). Comparisons of any adverse birth outcome (aRR 1.0, 95%CI 0.9,1.1) and severe outcomes (aRR 1.0, 95%CI 0.8,1.2) were similar by regimen. Among 512 first-trimester ART initiations (116 DTG/TDF/FTC, 396 EFV/TDF/FTC), one major congenital abnormality was identified (skeletal dysplasia in an EFV-exposed infant).
Conclusions: Adverse birth outcomes were similar for DTG-based ART and EFV-based ART when started during pregnancy. Further studies are needed to determine the safety of DTG exposure from conception.

	Tenofovir/ emtricitabine/ DOLUTEGRAVIR (DTG/TDF/FTC) N=845	Tenofovir/ emtricitabine/ EFAVIRENZ (EFV/TDF/FTC) N=4593	Adjusted Relative Risk (95% CI) DTG/TDF/FTC vs. EFV/TDF/FTC
Any Adverse Outcome	291 (34.4%)	1606 (35.0%)	1.0 (0.9,1.1)
Severe Adverse Outcome	92 (10.9%)	519 (11.3%)	1.0 (0.8,1.2)
Stillbirth	18 (2.1%)	105 (2.3%)	0.9 (0.6,1.5)
Neonatal Death (<28 days)	11 (1.3%)	60 (1.3%)	1.0 (0.5,1.9)
Preterm Birth (<37 weeks)	149 (17.8%)	844 (18.5%)	1.0 (0.8,1.1)
Very Preterm Birth (<32 weeks)	35 (4.2%)	160 (3.5%)	1.2 (0.8,1.7)
Small for Gestational Age (<10th %tile weight for gestational age)	156 (18.7%)	838 (18.5%)	1.0 (0.9,1.2)
Very Small for Gestational Age (<3rd %tile weight for gestational age)	51 (6.1%)	302 (6.7%)	0.9 (0.7,1.2)

[Birth Outcomes by regimen started in pregnancy]

MOAX0203LB

Weekly oral MK-8591 protects male rhesus macaques against repeated low dose intrarectal challenge with SHIVC109P3

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Background: MK-8591 (4'-Ethynyl-2-Fluoro-2'-Deoxyadenosine; EFdA) is a potent and long-acting nucleoside RT translocation inhibitor (NRTTI) in clinical development for the treatment of HIV-1 infection. Single 10 mg doses of MK-8591 resulted in suppression of viremia in HIV-1 infected patients for at least 10 days as have weekly doses of 3.9 mg/kg or greater in SIV-infected rhesus macaques (RM).
Methods: Two groups of 8 male RM were given 5 mL/kg of 10% Tween80 with (treated) or without (placebo) 3.9 mg/kg MK-8591 by oral gavage on day 0, day 7 and weekly thereafter for a maximum of 14 doses or until SHIV infection was confirmed. All animals were challenged intrarectally (IR) with 1 ml of 50 $TCID_{50}$ of SHIVC109P3, a viral stock derived from the third passage in RM of the molecular clone SHIVC109F.PB4, which contains an HIV Env initially derived from a newly HIV-infected Zambian. Challenges occurred on day 6 and weekly thereafter for a maximum of 12 challenges or until infection was confirmed. Prior to weekly challenge, blood was drawn to determine infection status and drug levels. Infection was confirmed by real-time RT PCR amplification of viral gag sequences in plasma on 2 consecutive samples. Proviral DNA was measured by PCR and virus-specific antibody responses were assessed. Intracellular levels of MK-8591-triphosphate (TP) were measured by LC/MS/MS.
Results: All placebo animals became infected after 1-4 challenges (median 1, mean 2). All treated animals remained uninfected after 12 challenges and were followed through week 24 without evidence of infection as determined by the absence of plasma viremia, proviral DNA and seroconversion. MK-8591-treated macaques had a 41.5-fold lower risk of infection (95% C.I 7.3, 237.9) compared with placebo macaques (p<0.0001, log-rank test). Mean trough concentrations of the active MK-8591-TP at the time of challenge were 4.07 mM (range: 2.26-5.17) and compare favorably with the level achieved by a weekly oral dose of 10mg in HIV-1-infected humans.
Conclusions: MK-8591 is a potent NRTTI that completely protected against repeated low-dose IR challenge in this SHIVC109P3/RM model with intracellular active drug concentrations readily achieved in humans. These results support the potential use of MK-8591 for HIV prophylaxis.

MOAX0204LB

Substantial progress in confronting the HIV epidemic in Swaziland: first evidence of national impact

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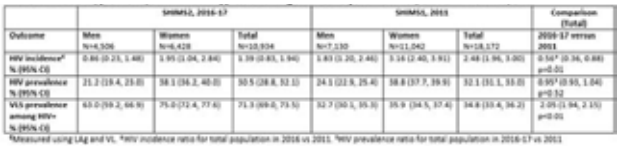
Background: Swaziland has the highest national HIV incidence and prevalence in the world. In response, the Swazi government extensively scaled-up national HIV prevention and treatment services. The 2016-17 Population HIV Impact Assessment (PHIA) Swaziland HIV Incidence Measurement Survey (SHIMS2) provides the first measure of the impact of national HIV programs scale-up on the epidemic's trajectory since the previous SHIMS1 survey conducted in 2011.
Methods: A nationally representative sample of individual ≥15 years (y) underwent household-based, rapid HIV testing from August 2016-March 2017. All HIV-positive samples were tested for HIV RNA and limiting antigen (LAg) Avidity. WHO criteria for HIV incidence estimates were used (LAg < =1.5 ODn and HIV RNA >1000 copies/ml). Viral load (VL) suppression (VLS) was defined as < 1000 copies/ml. Weighted measures of national HIV incidence, HIV prevalence, and population VL (among all HIV+, regardless of HIV knowledge or ART use) were compared with SHIMS1 results among adults 18-49 year.



[Table. HIV incidence, prevalence, and viral load suppression among adults 18-49 years in SHIMS2, 2016-17 and SHIMS1, 2011]

Results: A total of 10,934 participants ≥15y were tested, 3,003 tested HIV+, with HIV prevalence [95% Confidence Interval] of 27.0% [25.7, 28.3], and HIV incidence of 1.36% [0.92, 1.81]. Among adults 18-49y incidence was 1.39% [0.83, 1.94], a 44% decrease from the 2011 incidence estimate of 2.48% [1.96, 3.00]. Adult HIV incidence was higher among women 1.95% [1.04, 2.84] than men 0.86% [0.23, 1.48], with 38% and 53% decreases in women and men, respectively, from 2011. VLS among all HIV+ participants was 73.1% [71.3, 75.0]. Among HIV+ adults 18-49y, VLS was 71.3% [69.0, 73.5], a two-fold increase from the 2011 VLS of 34.8% [33.4, 36.2].
Conclusions: Since 2011, VLS prevalence in Swaziland has doubled and national HIV incidence has decreased by nearly half. These remarkable findings in a high prevalence setting provide the first direct measure of the national impact of expanded HIV prevention and treatment programs. Sustaining these achievements will be paramount to Swaziland's success in curbing its severe HIV epidemic.

MOAX0205LB

Safety and efficacy of long-acting CAB and RPV as two drug IM maintenance therapy: LATTE-2 week 96 results

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Background: Long-acting (LA) injectable nanosuspensions of cabotegravir (CAB) and rilpivirine (RPV) are being developed. At the LATTE-2 W32 primary endpoint, response rates were statistically comparable between injectable every 4 weeks (Q4W), injectable every 8 weeks (Q8W) LA arms and daily oral CAB 30 mg + ABC/3TC (PO) dosing.
Methods: Phase 2b, multicenter, parallel group, open-label study in ART-naïve HIV infected adults. Patients with plasma HIV-1 RNA <50 c/mL during the 20-week Induction Period on once daily oral CAB + ABC/3TC were randomized 2:2:1 to IM CAB LA + RPV LA Q4W, Q8W or PO in the Maintenance Period (MP). Evaluations included; antiviral activity < 50 c/mL (FDA snapshot analysis), protocol defined virologic failure (PDVF), and safety at the pre-specified W96 secondary endpoint in MP (ITT-Maintenance Exposed (ME)).

Week 96 Snapshot Study Outcomes (ITT-ME) **	CAB LA + RPV LA Q8W[δ] (n=115)	CAB LA + RPV LA Q4W[δ] (n=115)	Oral CAB 30 mg + ABC/3TC (n=56)
%HIV-1 RNA <50 c/mL at W96: Diff in Proportions (95%CI)	94% (10.0: -0.6, 20.5)	87% (3.0: -8.4, 14.4)	84%
Snapshot Virologic Non-response	**5 (4%)**	**0**	**1 (2%)**
Data in window not <50 c/mL	2 (2%)	0	0
Discontinued due to lack of efficacy	1 (<1%)	0	1 (2%)
Discontinued due to Other Reasons while Not Suppressed	2 (2%)*	0	0
Snapshot No Virologic Data	**2 (2%)**	**15 (13%)**	**8 (14%)**
Discontinued due to AE or Death*	1 (<1%)	9 (8%)	2 (4%)
Discontinued due to Other Reasons while Suppressed	1 (<1%)	5 (4%)	6 (11%)
Missing Data During Window but on Study	0	1 (<1%)	0
Other Results			
Number of injections	3160	5419	NA
Number of ISR events	1925	2435	
Grade 1 – mild (%)	1543 (80%)	2105 (86%)	
Grade 2 – moderate (%)	359 (19%)	314 (13%)	
ISR Duration ≤7 days	1718 (89%)	2172 (89%)	
Median CD4+ cells/mm³			
Baseline	449	499	518
Change from Baseline at W96 (IQR) ‡	+239 (111, 359)	+226 (145, 393)	+317 (214, 505)

Intent to Treat- Maintenance Exposed (ITT-ME)
BL = baseline (last value prior to first Induction Period dose at Week -20)
IQR = Interquartile range
**W96 represents 116 weeks on study (20 Week Induction Period with oral CAB 30 mg + ABC/3TC followed by 96 Weeks of Randomized Maintenance Period Therapy)
δQ8W: CAB LA 600 mg + RPV LA 900 mg IM every 8 Weeks; Q4W: CAB LA 400 mg + RPV LA 600 mg IM every 4 Weeks
* Includes one subject with withdrawn consent due to intolerance to injections
* Q8W: ISR/chills/body pain (n=1); Q4W: Hepatitis C (HCV) (n=1), rash (n=1), depressive reaction (n=1), psychotic state (n=1), Churg Strauss vasculitis (n=1), epilepsy (death) (n=1), mesenteric vein thrombosis (n=1), QT prolongation/Sinus Tachycardia (n=1), met liver stopping criteria (n=1); PO: Acute HCV (n=1), Drug Induced Liver Injury (DILI) (n=1)
‡ Based on observed values at Week 96 (Q8W: n=109; Q4W: n=100; Oral: n=47)

[Table]

Results: 309 patients were enrolled (ITT-Exposed): 91% male, 20% non-white, and 19%>100,000 c/mL HIV-1 RNA. 286 patients were randomized into the MP. At W96, 94% (Q8W), 87% (Q4W) and 84% (PO) remained suppressed (ITT-ME). Three ME patients had PDVF through W96; two Q8W (one at W4 and one at W48 with NNRTI/INI mutations) and one PO at W8. SAEs occurred in 10% (Q8W), 10% (Q4W) and 13% (PO) patients, none were drug related. Excluding injection site reactions (ISRs), 2% (Q8W) 4% (Q4W) and 2% (PO) reported drug-related AEs ≥ grade 3. Only two patients had ISRs leading to discontinuation through W96. Majority of ISRs were mild/moderate pain and discomfort with < 1% of ISRs classified severe. Emergent lab abnormalities ≥ Grade 3 occurred in 19% (Q8W), 29% (Q4W) and 21% (PO).
Conclusions: LA injectable 2-drug therapy given either Q8W or Q4W IM demonstrated high rates of virologic response and was well tolerated through 96 weeks. Difference in virologic success between Q8W and Q4W is primarily due to non-virologic reasons. Phase 3 studies are evaluating Q4W dosing.

MOAX0206LB

Treatment of chronic hepatitis C genotype 1, 2 and 4 in patients with or without HIV and living in Central or West Africa: the TAC ANRS 12311 trial

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Background: With the advent of highly effective direct antiviral agents against chronic hepatitis C (CHC) and the recent World Health Organization commitment, HCV elimination has become realistic. However, in sub-Saharan Africa (SSA) the HCV epidemic remains a neglected issue and access to care and treatment is almost inexistent. The TAC ANRS 12311 trial is an international multicenter open label trial aimed to assess the feasibility, efficacy and safety of q combination of interferon-free DAA in HCV-infected patients in the SSA setting.
Methods: Adult patients with treatment-naïve CHC were recruited in Senegal, Côte d'Ivoire and Cameroon. Patients without decompensated cirrhosis received a 12 week-combination of sofosbuvir plus weight-based ribavirin (SOF+RBV) if infected with genotype (GT) 2 or sofosbuvir/ ledipasvir (SOF+LDV) if infected with GT1 or 4. This trial included 120 participants (40 per GT). We present here the outcomes in the first 110 participants (GT-1, n=33; GT-2, n=40; GT-4, n=37).
Results: Among the participants (male 55%, median age 58 years [IQR 48-63], median plasma HCV-RNA 6.0 logIU/mL [IQR 5.5 -6.5]), 32 were HIV-coinfected (median CD4: 624/mm3, IQR 442-844), all with plasma HIV-RNA< 200 copies/ MI. Eleven patients were cirrhotic (APRI score>2). All but one patient completed the 12-week treatment course, and the remaining one discontinued treatment for personal reason (travel abroad). No patient died or was lost to follow-up. No severe adverse event occurred. Four patients had a haemoglobin decrease between 85 and 100 g/L, and two had a consequent reduction of RBV dosage. HCV-RNA was measured at week 24 (documenting SVR12) and 98/110 (89%) had undetectable viral load (threshold of detectability 12 or 25 IU/mL): 29 (88%) in GT-1, 36 (90%) in GT-2, and 33 (89%) in GT-4. Three out of 12 failing patients were cirrhotic at baseline. Viral strains of failing patients are currently been sequenced.
Conclusions: In this interim analysis, HCV treatment appeared to be feasible, safe and effective in sub-Saharan Africa including in HIV co-infected patients. With the growing access to HCV drugs at generic price worldwide, it is time to prompt scaling up of HCV care and management in Africa.

Tuesday 25 July

Oral Abstract Sessions

TUAA01 The Wrestling Match: Virus Versus Immune Cells

TUAA0106LB

Efficacy of epithelial stem cell-based AIDS vaccine to induce mucosal immune responses offering protection against SIV challenge in macaques

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Background: A key obstacle limiting the development of an effective AIDS vaccine is the inability to deliver antigen for a sufficient period of time resulting in weak and transient protection. HIV transmission occurs predominantly across mucosal surfaces; therefore an ideal vaccine strategy would be to target HIV at mucosal entry sites to prevent infection.
Methods: We developed a SIV single cycle vaccine under the control of the involucrin promoter (pINV-SIVsc), which was tested for its ability to drive SIV expression in terminally differentiated epithelial cells, induce mucosal immune response, and offer better protection against SIV challenge. A total of 20 naïve young Rhesus macaques were selected (10/20 expressed MHC class I Mamu-A*01 allele). The pINV-SIVsc vaccine was administrated intravaginal (n=12) at week 0. Animals were monitored overtime for specific immune responses in blood and various tissues (n=4). Eight animals were challenged at week 12 (n=4) or at week 24 (n=4) using repeated pathogenic SIVmac239 and monitored for specific immune responses in blood and various tissues. Eight additional animals were infected with repeated SIVmac239, and served as unvaccinated Controls. Complementary approaches were used to characterize SIV-specific immune responses in blood, vaginal secretions, LN, and vaginal biopsies collected at various times.
Results: This vaccine induced strong mucosal IgA and IgG responses and specific T cells expressing a4ß7 homing to the mucosa. Repeated challenges revealed significant delay and lower viremia with 3-4 logs reduction at peak, 4-5 logs-reduction at set-point, and undetectable viremia by week 10-14 post-SIV in vaccinated females compared to Controls. Following challenge, we demonstrated a positive correlation between the generation of mucosal and systemic T cell responses and control of viremia, an Inverse association between viremia and post-infection vaginal IgA/IgG responses.
Conclusions: We have obtained evidence, within the limitation of the small animals´ number studied, that macaques vaccinated with pINV-SIVsc can generate strong mucosal SIV-specific T cell responses and local antibody responses (IgA/IgG). We demonstrated the efficacy of an epithelial stem cell-based SIV vaccine to serve as antigen delivery system suggesting an important role in protection against mucosal Infection.

TUAB01 Antiretroviral Therapy - ART: Season Two

TUAB0104LB

Fixed dose combination of doravirine/lamivudine/TDF is non-inferior to efavirenz/emtricitabine/TDF in treatment-naïve adults with HIV-1 infection: week 48 results of the Phase 3 DRIVE-AHEAD study

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Background: Doravirine (DOR) is a novel non-nucleoside reverse transcriptase inhibitor (NNRTI) with once-daily (QD) dosing. In the phase 3 DRIVE-FORWARD study in HIV-1 treatment-naïve adults receiving 2 NRTIs, DOR 100mg QD was non-inferior to darunavir+ritonavir on efficacy, and demonstrated a more favorable lipid profile.
Methods: DRIVE- AHEAD compared doravirine with efavirenz (EFV) in an ongoing phase 3, multicenter, double-blind, non-inferiority trial. Eligible participants were antiretroviral treatment-naïve adults with HIV-1 infection and pre-treatment HIV-1 RNA ≥1,000 c/mL. Participants were randomized (1:1) to a once-daily fixed-dose regimen of DOR 100mg, lamivudine 300mg and tenofovir disoproxil fumarate 300mg (DOR/3TC/TDF) or EFV 600mg, emtricitabine 200mg and TDF 300mg (EFV/FTC/TDF) for up to 96 weeks. Randomization was stratified by screening HIV-1 RNA (≤/>100,000 c/mL) and hepatitis B/C co-infection (yes/no). Primary efficacy endpoint was % of participants with HIV-1 RNA < 50 c/mL at week 48 (FDA Snapshot approach). Predefined non-inferiority margin was 10%. Primary safety endpoint was % of participants with prespecified neuropsychiatric adverse events (dizziness, sleep disorders/disturbances, altered sensorium).
Results: Of 734 participants randomized, 728 received study drug (364 in each treatment group) and were included in the analyses (mean age 33 years, 85% male, 48% white). At week 48, HIV-1 RNA < 50 c/mL was achieved by 84.3% (307/364) of DOR/3TC/TDF recipients and 80.8% (294/364) of EFV/FTC/TDF recipients (difference 3.5%, 95%CI [-2.0, 9.0]). The incidence of dizziness, sleep disorders/disturbances, and altered sensorium (table) was lower in DOR/3TC/TDF recipients than in EFV/FTC/TDF recipients (p< 0.001, p< 0.001, and p=0.033, respectively). Fasting LDL-C and non-HDL-C (table) were reduced by DOR/3TC/TDF and increased by EFV/FTC/TDF (both p< 0.0001).
Conclusions: In HIV-1 treatment-naïve adults, the efficacy of DOR/3TC/TDF at week 48 was non-inferior to EFV/FTC/TDF and similar regardless of baseline HIV-1 RNA. DOR/3TC/TDF was generally safe and well tolerated, with significantly fewer neuropsychiatric events than EFV/FTC/TDF and a favorable lipid profile.

Week 48 Efficacy & Safety Outcomes

HIV-1 RNA <50 copies/mL	DOR/3TC/TDF n/N	DOR/3TC/TDF %	EFV/FTC/TDF n/N	EFV/FTC/TDF %	Difference % (95% CI)
Overall†	307/364	84.3	294/364	80.8	3.5 (-2.0, 9.0)
Baseline HIV-1 RNA ≤100,000‡	251/277	90.6	235/258	91.1	-0.5 (-5.5, 4.4)
Baseline HIV-1 RNA >100,000‡	56/69	81.2	59/73	80.8	1.0 (-12.4, 14.3)
Baseline CD4 ≤200 cells/mm³‡	29/42	69.0	36/43	83.7	-14.6 (-33.2, 3.9)
Baseline CD4 >200 cells/mm³‡	278/304	91.4	258/288	89.6	1.8 (-3.0, 6.5)

Adverse Event (AE) Summary	DOR/3TC/TDF (N=364)	EFV/FTC/TDF (N=364)	Difference % (95% CI)
One or more AE	82.7 %	90.7 %	-8.0 (-13.0, -3.1)
Drug-related AE	31.0 %	62.9 %	-31.9 (-38.6, -24.0)
Serious AE	3.6 %	5.8 %	-2.2 (-5.5, 0.9)
Discontinued due to AE	3.0 %	6.6 %	-3.6 (-6.9, -0.5)
Dizziness	8.8 %	37.1 %	-28.3 (-34.0, -22.5)
Sleep disorders/disturbances	12.1 %	25.5 %	-13.5 (-19.1, -7.9)
Altered sensorium	4.4 %	8.2 %	-3.8 (-7.6, -0.3)

Fasting Lipids, Change from BL	N	Mean Δ	N	Mean Δ	Difference (95% CI)
LDL cholesterol (mg/dL)	330	-1.6	305	+8.7	-10.0 (-13.5, -6.5)
Non-HDL cholesterol (mg/dL)	333	-3.8	314	+13.3	-17.0 (-20.9, -13.2)

† FDA Snapshot method; 95% CI for treatment difference based on stratum-adjusted Mantel-Haenszel method. Non-inferiority bound pre-specified as -10 percentage points.
‡ Observed Failure (OF) approach for missing data.

[Week 48 Efficacy & Safety Outcomes]

TUAB0105LB

Superior efficacy of dolutegravir (DTG) plus 2 nucleoside reverse transcriptase inhibitors (NRTIs) compared with lopinavir/ritonavir (LPV/RTV) plus 2 NRTIs in second-line treatment: interim data from the DAWNING study

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Background: DAWNING is a non-inferiority study conducted to compare a protease inhibitor-sparing regimen of DTG+2NRTIs with a current WHO-recommended regimen of LPV/RTV+2NRTIs in HIV-1 infected subjects failing first-line therapy of a non-nucleoside reverse transcriptase inhibitor (NNRTI) + 2 NRTIs (ClinicalTrials.gov: NCT02227238). An Independent Data Monitoring Committee (IDMC) performed periodic reviews of data to protect the ethical and safety interests of subjects.
Methods: Adult subjects failing first-line therapy, with HIV-1 RNA ≥400 copies(c)/mL, were randomised (1:1, stratified by Baseline plasma HIV-1 RNA and number of fully active background NRTIs) to 52 weeks of open-label treatment with DTG or LPV/RTV combined with an investigator-selected dual NRTI background, including at least one fully active NRTI. An IDMC review was performed, which included data from 98% (612/627 randomised) of subjects through 24 weeks on therapy.
Results: At Week 24, 78% of subjects on DTG versus 69% on LPV/RTV achieved HIV-1 RNA < 50 c/mL (adjusted difference 9.6%, 95% CI: 2.7% to 16.4%, p=0.006 for superiority). The difference was primarily driven by lower rates of Snapshot virologic non-response in the DTG group. The safety profile of DTG+2NRTIs was favourable compared to LPV/RTV+2NRTIs with more drug-related adverse events (AEs) reported in the LPV/RTV group, mainly due to higher rates of gastrointestinal disorders.
Following review of Week 24 data and large subsets of data from Weeks 36 and 48, the IDMC recommended discontinuation of the LPV/RTV arm due to persistent differences in rates of Snapshot virologic non-response and protocol-defined virologic failure (PDVF) favouring the DTG arm.

Week 24 outcomes	DTG (N=307)	LPV/RTV (N=305)
Snapshot virologic success	240 (78%)	210 (69%)
Snapshot virologic non-response	36 (12%)	64 (21%)
Data in window not <50 c/mL	33 (11%)	59 (19%)
Discontinued for other reason while not <50 c/mL or change in ART	3(1%)	5 (2%)
Snapshot no virologic data	31 (10%)	31 (10%)
Discontinued due to AE or death	5 (2%)	14 (5%)
Discontinued for other reason or missing data during window but on study	26 (8%)	17 (6%)
PDVF	5/312 (2%)	12/312 (4%)
Drug-related AEs	45/314 (14%)	107/310 (35%)

[Week 24 outcomes]

Conclusions: The IDMC recommended discontinuation of the LPV/RTV arm due to superior efficacy of DTG+2NRTIs and the potential to harm subjects on LPV/RTV based on available data. Final Week 24 results of this study will be presented. DAWNING provides important information to help guide second-line treatment decisions in resource-limited settings.

TUAB0106LB

HIV-specific broadly-neutralizing monoclonal antibody, VRC01, minimally impacts time to viral rebound following treatment interruption in virologically-suppressed, HIV-infected participants who initiated antiretroviral therapy during acute HIV infection

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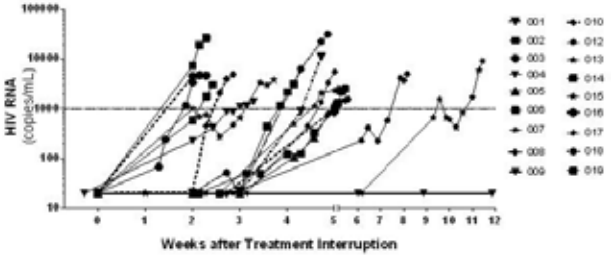
Background: We present interim, blinded data exploring kinetics of viral load (VL) rebound in a randomized, placebo-controlled trial of VRC01 following analytic treatment interruption (ATI) in adults who initiated antiretroviral therapy (ART) during acute HIV infection (AHI). Study arms will be unblinded in June 2017.
Methods: Virologically-suppressed adults who initiated ART during AHI underwent ATI and randomization (3:1) to receive VRC01 40mg/kg or placebo intravenously every three weeks for up to 24 weeks. If virologically-suppressed at 24 weeks, observation continued off all therapies. Participants were monitored every 3-7 days for VL rebound and resumed ART for confirmed VL >1000 copies/ml or CD4 < 350 cells/mm^3.
Results: Twenty-three Thai males were enrolled. Four received no study product and one experienced grade II generalized urticaria during the first infusion, terminating study participation without ATI. These analyses include 18 participants who initiated ART during Fiebig I (n=1), II (n=10), or III (n=7); underwent randomization and ATI; and met a study endpoint (Table and Figure). As of May 9, 2017, one participant remained off ART with an undetectable VL for 32 weeks. All other participants experienced VL rebound, restarted ART, and re-achieved virologic suppression. Ten participants had detectable VL via single copy assay (range 0.44-2.1 copies/mL) at median 10 (range 7-29) days prior to rebound >20 copies/mL. There were no serious adverse events.

Baseline Participant Characteristics (n=18)	Median	Range
Age (years)	28	21-50
Duration of ART (years)	3.0	2.3-6.6
CD4 Count (cells/mm^3)	716	402-1,032
Key Results (n=17; excluding one participant without VL rebound)		
Time to Rebound Viral Load >20 copies/mL (days from ATI)	21	9-65
First Detectable Viral Load (copies/mL)	447	21-7,395
Highest Viral Load (copies/mL)	3,845	1,401-31,807
Time to Viral Load <20 copies/mL (days from ART resumption)	21	6-34

[Participant Characteristics and Key Results]



[Clinical Viral Load Assessments]

Conclusions: Participants who initiated ART during AHI and received VRC01 or placebo during ATI mostly experienced rapid VL rebound. Early ART alone or with VRC01 during ATI appears insufficient to delay time to VL rebound in most individuals.

TUAC01 Updates from PrEP Clinical Trials

TUAC0106LB

Safety, tolerability and pharmacokinetics of long-acting injectable cabotegravir in low-risk HIV-uninfected women and men: HPTN 077

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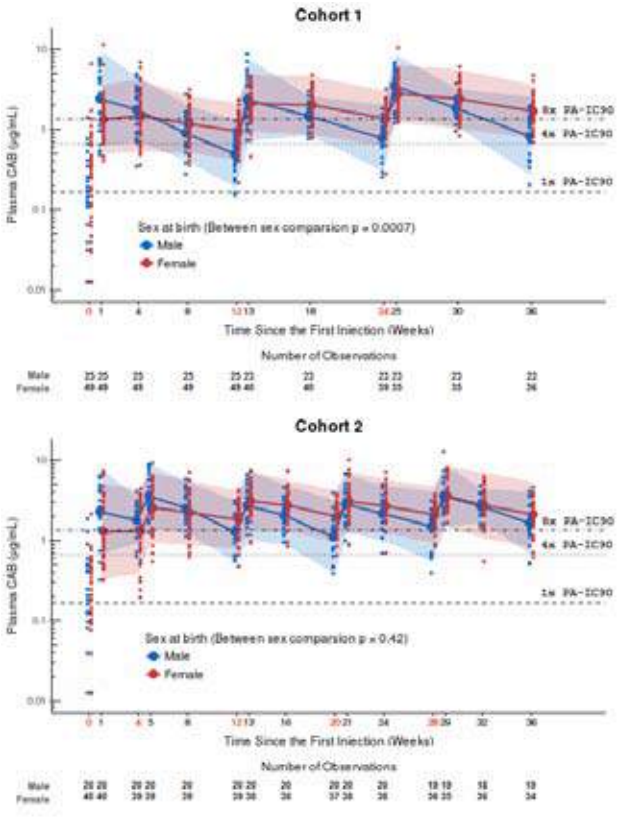
Background: Cabotegravir (CAB) is a novel strand-transfer integrase inhibitor, available as a long-acting injectable nanosuspension, under development for HIV treatment and prevention.
Methods: HPTN 077 is a Phase 2a, randomized double-blind placebo-controlled study of CAB at two doses. Participants were low-risk HIV-uninfected individuals at eight sites globally, randomized (3:1) to daily oral CAB 30mg (or placebo [PBO]) for four weeks(W), followed by CAB (or PBO) 800mg IM at W5, 17, and 29 (Cohort 1[C1]) or 600 mg IM at W5, 9, 17, 25, and 33 (Cohort 2[C2]).
Results: 110 participants enrolled in C1, 89 in C2. Median age 31y (IQR: 24,40), BMI 27 (IQR: 23,32), 66% female, 41% Black, 27% White, 24% Latino, 8% mixed/other. Overall, 94% completed the oral phase, 89% received at least one injection, and 75% completed all injections, which did not differ by arm, cohort or sex (**Table**). Over 41W, injection site pain and injection site reactions (ISR) were more common in CAB vs. PBO. No other differences were found in safety or tolerability. ISR led to injection discontinuation in 2/134 (1.5%).

	Overall (n=199)		Cohort 1 (n=110)		Cohort 2 (n=89)	
	CAB	PBO	CAB	PBO	CAB	PBO
Enrolled	151	48	82	28	69	20
Male	51 (34%)	16 (33%)	28 (34%)	10 (36%)	23 (33%)	6 (30%)
Female	100 (66%)	32 (67%)	54 (66%)	18 (64%)	46 (67%)	14 (70%)
Completed Oral Phase	143 (94%)	45 (94%)	78 (95%)	27 (96%)	64 (93%)	18 (90%)
Male	48 (94%)	15 (94%)	28 (93%)	10 (100%)	22 (96%)	5 (83%)
Female	94 (94%)	30 (94%)	52 (95%)	17 (94%)	42 (91%)	13 (93%)
Received ≥1 Injection	134 (89%)	43 (90%)	74 (90%)	25 (89%)	60 (87%)	18 (90%)
Male	45 (88%)	15 (94%)	25 (89%)	10 (100%)	20 (87%)	5 (83%)
Female	89 (89%)	28 (88%)	49 (91%)	15 (83%)	40 (87%)	13 (93%)
Received All Injections*	114 (75%)	36 (75%)	59 (72%)	20 (71%)	55 (80%)	16 (80%)
Male	42 (82%)	13 (81%)	23 (82%)	8 (80%)	19 (83%)	5 (83%)
Female	72 (72%)	23 (72%)	36 (67%)	12 (67%)	36 (78%)	11 (79%)
At least one ≥G2 AE§,¶,#	122 (91%)	38 (88%)	64 (87%)	23 (92%)	58 (97%)	15 (83%)
Male	40 (89%)	12 (86%)	21 (84%)	8 (80%)	19 (95%)	4 (80%)
Female	82 (92%)	26 (93%)	43 (88%)	15 (100%)	39 (98%)	11 (85%)
ISR (any grade)#¶	121 (90%)	13 (30%)	68 (92%)	6 (24%)	53 (88%)	7 (39%)
Male	41 (91%)	3 (20%)	24 (96%)	2 (20%)	17 (85%)	1 (20%)
Female	80 (90%)	10 (36%)	44 (90%)	4 (27%)	36 (90%)	6 (46%)

[Table. Outcomes of Study PPTs by Cohort/Sex]

One seizure (participant with previous seizures) and one seroconversion (48W post last injection) occurred in CAB participants; CAB levels at the time of events were 278 ng/mL and < 25 ng/mL (LLQ), respectively. C2 dosing consistently achieved plasma trough targets; C1 dosing did not (Figure).



[Figure. Geometric Mean Conc and 90% Pred Interval]

Conclusions: CAB was well tolerated among low-risk HIV-uninfected men and women. Pharmacokinetics support the development of CAB for HIV prevention using 600mg IM every 8 weeks with a 4-week loading dose for all sexes.

TUAC02 Prevention and Adolescents

TUAC0206LB

Safety and acceptability trial of the dapivirine vaginal ring in U.S. adolescents

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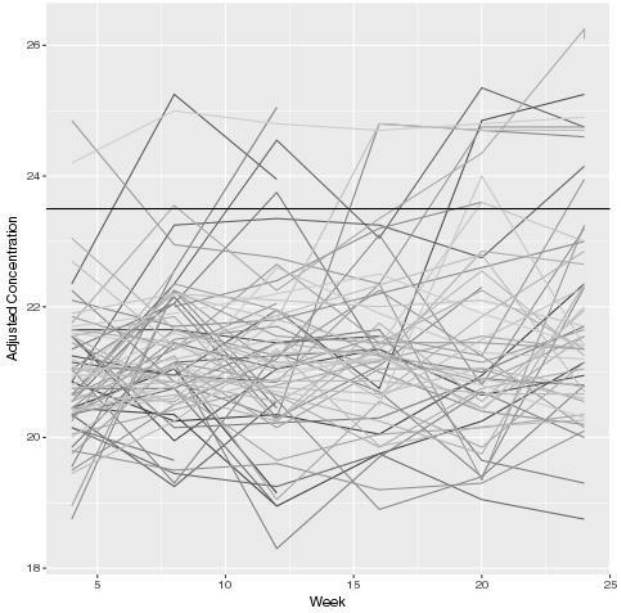
Background: Young women ages 15-25 years are disproportionately affected by the HIV epidemic. Two phase 3 trials of a 25 mg dapivirine vaginal ring demonstrated HIV-1 risk reduction in adult women over 21, but not in those ages 18-21. Lack of protection was correlated with low adherence.
Methods: A Phase 2a randomized, double-blind, placebo-controlled trial of the dapivirine ring was conducted in sexually active females, ages 15-17. Participants were randomized 3:1 to a dapivirine or placebo ring to be inserted monthly for 6 months. Safety endpoints included grade 2 product-related adverse events (AE) and grade 3 and higher AEs. Adherence to ring use was assessed through self-report, plasma dapivirine concentrations and residual levels in used rings. A plasma dapivirine concentration >95 pg/mL was used to define short- term adherence

(hours); a dapivirine residual level < 23.5 mg was used to define long term adherence (monthly). Acceptability was assessed through computer assisted self-interviews.
Results: Ninety six participants were enrolled across six US sites. The mean age was 16.3 years; 59% were black and 34% white. Adherence to study visits was 97%. There were no differences in safety outcomes between treatment arms. By self-report 42% (95% CI 32, 52) of participants reported that they never removed the ring except to replace it monthly. In the dapivirine group, drug levels indicated adherence in 87% of plasma samples and 95% of rings. Participants noted no discomfort due to the ring at 87% of visits and "liking" the ring at 93% of visits. The most frequently cited concern (28%) involved their primary sex partner feeling the ring during sex.



[Spaghetti Plot of Residual Dapivirine Concentration]

Conclusions: The dapivirine vaginal ring, a promising microbicide approach, is safe and acceptable in this population. By self-report and objective measures, adherence was high. Discussing potential partner concerns with participants prior to ring use may positively influence adherence.

TUAC0207LB

Pluspills: an open label, safety and feasibility study of oral pre-exposure prophylaxis (PrEP) in 15-19 year old adolescents in two sites in South Africa

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Background: South African adolescents are at risk for HIV acquisition. PrEP is licensed and being offered to key populations, but not yet to adolescents. This open-label 12-month PrEP study examined uptake, safety and adherence to PrEP and assessed sexual risk behaviour among adolescents in Soweto and Cape Town, South Africa
Methods: Sexually active, healthy, HIV negative, adolescents (15-19 years) participated in a study of Tenofovir/Emtricitabine PrEP. Participants were asked to take daily PrEP for at least 3 months, were seen monthly, after which they could opt-out of PrEP if preferred. At subsequent 3-monthly follow-up visits, participants could decide to stay on or off PrEP per preference. Laboratory and clinical safety monitoring occurred at each visit, including HIV and pregnancy testing. Plasma and dried blood spots (DBS) were serially collected for tenofovir (TFV) and tenofovir diphosphate (TFV-DP) levels at every PrEP refill visit. Plasma TFV levels were offered at each visit as part of adherence counselling.
Results: 244 individuals were screened and 148 were enrolled (median age 18,67%F). 3(1%) had undiagnosed HIV infection and 9 (6%) were pregnant at screening. STI diagnosis at baseline was high (40%) and remained high throughout. 26 (18%) participants opted out of PrEP at 12 weeks. Thereafter PrEP opt-out (and opt-in) at months 6 and 9 included 41% and 43% (5% and 7%) of the cohort respectively. PrEP was safe and reasonably well tolerated. Plasma TFV levels were detectable in 57% of participants at week 12, 38% at week 24 and 38% at study end. One HIV seroconversion occurred on study (0.76/100 person-years) in a 19 year old woman who had stopped PrEP 24 weeks prior to diagnosis
Conclusions: Pluspills enrolled a cohort of self-selected adolescents at high risk of HIV acquisition and offered an opportunity to engage on ethical norms for adolescent research. PrEP was safe and tolerable in those who persisted. However PrEP usage decreased and adherence diminished over time, when visits became less frequent. STI diagnoses remained constant and HIV incidence was low. SA adolescents need access to PrEP with tailored adherence support and potentially augmented visit schedules.

TUAC04 Prevention: It's Not Just about PrEP

TUAC0406LB

Increasing knowledge of HIV status among men: a cluster-randomised trial of community-based distribution of oral HIV self-test kits nested in four HPTN 071 communities in Zambia

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Background: HPTN071 (PopART) is a community-randomised trial evaluating the impact of a combination HIV-prevention intervention on HIV incidence. Overall, this intervention has reached the first UNAIDS 90, yet men and younger adults still have lower knowledge of HIV status. We nested a cluster-randomised trial of oral HIV self-testing (HIVST) in addition to rapid finger-prick HIV testing (HIVFP) offered door to door by lay counsellors (CHiPs) within HPTN071 to evaluate the impact on knowledge of HIV status.
Methods: Four of the Zambian HPTN071 intervention communities were randomised by CHiP zones, with an average of 471 households per zone. In HIVST zones (n=33/N=66), individuals aged ≥16 years who did not self-report being HIV-positive, were offered a choice of HIVST or HIVFP. Secondary distribution of HIVST was offered for absent partners. A population-average logistic regression model was used to estimate the effect of the HIVST intervention on knowledge of HIV status (definition: self-report HIV-positive or accepted HIV testing services), using total population enumerated as the denominator, adjusting for community, sex and age, and accounting for clustering by zone.

Characteristic	Enumerated in non-HIVST Zones	Knows HIV-status in non-HIVST Zones	Percent (%)	Enumerated in HIVST Zones	Knows HIV-status in HIVST Zones	Percent (%)	Odds Ratio	95% Confidence Interval	p-value
Total	13,383	8,203	61.3	12,852	8,139	63.3	1.25	1.01-1.56	0.04
Sex: Male	6,311	3,171	50.2	6,200	3,412	55.0	1.30	1.07-1.60	0.01
Sex: Female	7,072	5,031	71.1	6,652	4,727	71.1	1.03	0.85-1.25	0.74
Age (yrs): 16-29	6,841	4,541	66.4	6,565	4,508	68.7	1.24	1.01-1.53	0.04
Age (yrs): 30 and above	6,542	3,662	56.0	6,287	3,631	57.8	1.20	0.97-1.48	0.10
Community 1	3,670	1,971	53.7	3,585	1,933	53.9	1.01	0.79-1.29	0.93
Community 2	1,567	715	45.6	1,650	992	60.1	1.99	1.39-2.85	<0.001
Community 3	4,150	2,477	59.7	4,604	2,784	60.5	1.17	0.88-1.55	0.29
Community 4	3,996	3,040	76.1	3,013	2,430	80.7	1.45	0.68-3.10	0.34

[Knowledge of HIV status in non-HIVST & HIVST zones]

Results: Between February 1st and April 30th 2017, 63.3% (8,139/12,852) of adults enumerated in the HIVST arm knew their HIV status compared to 61.3% (8,203/13,383) in the non-HIVST arm, adjusted OR 1.25 (95% CI 1.01-1.56, p=0.04). Women had high knowledge of HIV status (71.1% in both HIVST and non-HIVST, adjOR 1.03, 95%CI 0.85-1.25, p=0.74). Among men, knowledge of HIV status was 55.0% in HIVST compared to 50.2% in non-HIVST (adjOR 1.30, 95%CI 1.07-1.60, p=0.01), with strong evidence that the effect of the HIVST intervention was different for men and women (p=0.004; Table).
Conclusions: Introducing HIVST for 3 months in communities already exposed to door-to-door HIV-testing services for 3 years, increased the proportion of the population who knew their HIV status. This effect was seen most markedly in men.

TUAC05 The Key to Key Populations

TUAC0506LB

HIV treatment prevents HIV transmission in male serodiscordant couples in Australia, Thailand and Brazil

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Background: Prospective data on the association of HIV transmission and undetectable viral load (UVL) in homosexual male HIV-serodiscordant couples (HM-SDC) are extremely limited. We report the final results from the Opposites Attract cohort study of HM-SDC in Australia, Bangkok and Rio de Janeiro.
Methods: HM-SDC were recruited through clinics. Information on sexual behaviours was collected at each visit from the HIV-negative partner (HNP). HNPs were tested at baseline and follow-up for HIV antibodies/sexually transmitted infections (STIs), and positive partners (HPPs) for HIV viral load/STIs. Phylogenetic analysis of pol and env genes was performed to identify linked HIV transmissions within couples based on genetic distance and monophyletic grouping. Incidence was calculated per couple-year of follow-up (CYFU), and stratified by pre-exposure prophylaxis (PrEP) use and by whether different forms of condomless anal intercourse (CLAI) were reported. UVL was defined as < 200 copies/mL. One-sided upper 95% confidence limits (UCL) were calculated.
Results: By end 2016, 358 HM-SDC were enrolled: 157, 105 and 96 from Australia, Thailand and Brazil respectively. There were 591 CYFU in 343 couples with at least one follow-up visit of whom 57.4% reported anal sex with outside partners during any point in follow-up. At baseline, 79.9% of HPPs were on anti-retroviral therapy (ART) and 77.9% had UVL; STI prevalence was 14.3%/11.7% in HPPs/HNPs respectively. There were 318 CYFU in periods where CLAI was reported with a total of 16,889 acts of CLAI. There were 3 new HIV infections but no linked transmissions. The overall UCL of the transmission rate when CLAI was reported was 1.16/100 CYFU, and it was 1.56/100 CYFU when there was UVL.

	Linked transmissions (n)	Couple-years of follow up (CYFU)	CLAI acts (n)	Incidence per 100 CYFU (95% CI)
Overall	0	591.2	16,889	0 (0-0.62)
Any CLAI	0	318.0	16,889	0 (0-1.16)
Any CLAI, no daily PrEP	0	241.3	12,928	0 (0-1.53)
Insertive CLAI	0	210.0	8,389	0 (0-1.76)
Receptive CLAI	0	132.1	4,569	0 (0-2.79)
UVL (VL <200)	0	236.2	12,638	0 (0-1.56)
VL >200	0	5.17	290	0 (0-71.4)
STI diagnosed	0	23.2	1,007	0 (0-15.9)
First 6 months ART	0	10.0	341	0 (0-36.9)

[HIV incidence by category of CLAI]

Conclusions: There were no linked HIV transmissions in almost 600 CYFU involving close to 17,000 acts of CLAI in HM-SDC. Our results provide strong support for the hypothesis that undetectable viral load prevents HIV transmission in homosexual men.

TUAD01 Treat All: How to Make It Happen and Can We Afford It?

TUAD0106LB

Index partner testing and targeted case finding in northern Haiti

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Background: In Haiti, national guidelines recommend HIV testing for partners of people living with HIV (PLHIV), but uptake and documentation have been low. While some healthcare providers recommend partner testing, it is not prioritized and delivery is inconsistent. HIV-positive women may be reluctant to notify their partners for fear of abuse or abandonment, and additional strategies are needed to increase case finding, particularly among men.
Methods: Jhpiego-Haiti, through the USAID-funded Maternal and Child Survival Program, and in collaboration with the National AIDS Control Program (PNLS), attempted to strengthen index partner testing by introducing training and documentation at 20 health facilities in northern Haiti. The 2-day training, conducted in October 2016, addressed targeted case finding, and strategies for supporting index clients living with HIV to refer their partners for testing. Counselling and communication skills were reinforced, and data collection and reporting tools were presented. Providers offered counselling on partner testing to all newly diagnosed HIV-positive clients, and submitted monthly reports on key indicators for partner testing.
Results: From October 2016 - March 2017, a total of 593 index clients tested HIV-positive in 20 health facilities in northern Haiti, 63% of whom were women. 519 index clients (88%) accepted counselling for partner testing, and 112 (22%) of those agreed to refer their partners. Only 61 partners attended the clinic for HIV testing, 30 (49%) of whom were HIV-positive, and 31 of whom were in discordant couples. The primary reason partners were not referred is because index clients were afraid to disclose their status for fear of their partner's reaction and stigmatization.
Conclusions: Training providers, equipping them with monitoring tools, and supporting them to counsel newly diagnosed PLHIV on partner testing can lead to the identification of HIV-positive partners and discordant couples. Further efforts to strengthen this targeted testing approach, including ongoing counselling and support for index patients to disclose, are needed to achieve the UNAIDS 90-90-90 targets in Haiti.

TUAD02 Decisions, Decisions, Decisions: Behavioural Economics

TUAD0206LB

Willingness and ability of OST clients to pay for some OST services in Odesa region in the light of the Ukraine crisis

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Background: Odesa region is one of the highest burden of HIV in Ukraine. HIV epidemic is mainly concentrated among key populations (PWIDs, CSWs and their partners, MSMs). The international donors' support of OST programs for PWIDs are currently in the process of financing reduction. The economic crisis in Ukraine complicated the nationwide state financing of OST programs in Ukraine. The implementation of the alternative financing models such as co-payment is optimal way to secure critical for PWIDs services. The aim of the study is to assess the willingness and ability of current OST clients to pay for some OST services.
Methods: Cross-sectional study was conducted in Odesa city in 2016 among current OST clients in Odesa city. Random sampling strategy was used for respondent recruitment. Structured questionnaire was used for data collection. The study protocol received an approval of IRB at Ukrainian Institute on Public Health Policy. Bivariate analysis was used to estimate correlates of clients' willingness to pay for some OST services.
Results: A total of 161 clients of OST programs (125 (77.6%) males and 36 (22.4%) females) were interviewed. The average age of the respondents was 41.98 years (SD=8.0). 66.5% of interviewed OST clients in Odesa city had a secondary education and 14.9% had a higher education. Half of the respondents (49.7%) had a single

marital status. 74% of respondents uptake OST program for more than 12 months. Overall 89% of respondents (n=143) demonstrate willingness to pay for some OST services in Odesa. The willingness to co-pay for some OST services is higher among clients listed "possibility to uptake additional medical care at OST site" as personal benefit of OST participation. The willingness is also correlated with income per family member (p=0.009), self-assessment of financial well-being (p=0.008) and perceived social support (p=0.014).
Conclusions: Clients of OST program in Odesa region demonstrated willingness and ability to pay for some OST services despite on economic crisis in the country. Their willingness depends on socio-economic status of PWID and his/her family. These important correlates of willingness and ability to pay should be considered for design and implementing OST co-payment service delivery model in Odesa region.

Wednesday 26 July

Oral Abstract Sessions

WEAA01 The Dance: Virus and Host Factors

WEAA0106LB

Identification of a new factor involved in DNA methylation-mediated repression of latent HIV-1

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Background: DNA methylation is an epigenetic mechanism of HIV-1 latency. The methylation profile of the latent viral 5'LTR is heterogeneous in latency model cell lines and in patient cells in which it increases progressively during cART. Moreover, we previously reported that the DNA methylation inhibitor decitabine (5-aza-2'deoxycytidine) induces different levels of HIV-1 reactivation in latently-infected T cell lines and ex vivo patient cell cultures. However, the mechanism of DNA methylation-mediated HIV-1 silencing remains unclear.
Methods: Sodium bisulfite sequencing, EMSAs, ChIP-qPCR assays, RNA interference, GFP fluorescence FACS, p24 ELISA experiments and purification of primary cells from HIV+ patient blood.
Results: To explore this mechanism, we took advantage of two latently-infected J-Lat cell lines (the 8.4 and 15.4 clones) representing distinct integration sites and showed that these two cell lines exhibited similar levels of 5'LTR CpG methylation in basal conditions but different DNA demethylation extents in response to decitabine. Demethylation at CpG dinucleotides following decitabine-induced reactivation of HIV-1 production occurred at specific and reproducible CpG positions that differed depending on the two J-Lat cell lines studied. Interestingly, a site comprising one of this hotspot for decitabine-induced demethylation was shown to bind UHRF1 (Ubiquitin-like PHD and ring finger domain-containing protein 1), only in one of the J-Lat cell line, whereas DNMTs were recruited to both J-Lat cell lines. Treatment with decitabine caused a decreased in vivo UHRF-1 recruitment to the 5'LTR. UHRF1 knockdown using RNA interference or pharmacological approaches showed increased levels of HIV-1 transcription and production that were accompanied by an increased recruitment of RNA polymerase II to the 5'LTR. We are currently studying UHRF1 functional role in latently-infected primary cells from aviremic cART-treated HIV+ patients.
Conclusions: We have identified UHRF1 as a factor recruited to the HIV-1 5'LTR in a methylation- and integration-dependent manner during latency and which plays a functional role in DNA methylation-mediated repression of HIV-1 gene expression. UHRF1 is known to regulate and maintain heterochromatic equilibrium via its combined action on both DNA methylation and histone modifications. This factor has not previously been identified as a regulator of HIV latency and might thus constitute a new therapeutic target for HIV cure strategies.

WEAB01 Potpourri of Comorbidities

WEAB0106LB

Zoledronic acid is superior to TDF-switching for increasing bone mineral density in HIV-infected adults with osteopenia: a randomised trial

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Background: Tenofovir disoproxil fumarate (TDF) reduces bone mineral density (BMD) and probably increases fracture risk in HIV-infected adults. Proven strategies for improving BMD in HIV-infected adults on TDF are TDF switching or bisphosphonate therapy; which strategy is superior is unknown.
Methods: We randomised virologically-suppressed, HIV-infected adults on TDF with low BMD (T score < -1.0 at hip or spine by dual-energy x-ray absorptiometry [DXA]) to either switch TDF or to continue TDF and receive intravenous zoledronic acid (ZOL) 5mg every 12 months. Calcium (all patients) and vitamin D (if serum 25OH vitamin D was < 50 nmol/L) were supplemented. The primary study outcome was change in lumbar (L1-L4) spine BMD at 24 months by intention-to-treat analysis. Secondary outcomes included femoral neck and total hip BMD, fractures, safety, and virological failure (confirmed viral load ≥400 cp/mL).
Results: We randomised 87 patients (44 to TDF switch and 43 to ZOL): mean age 50 years (SD 11), 96% men, mean TDF duration 5.9 years (SD 3.1), 22% on a boosted PI, mean spine and hip T scores -1.6 and -1.3, respectively. TDF switches were mostly to abacavir (62%) or raltegravir (19%). Adherence to each strategy was high: four switch patients (10%) recommenced TDF at a median of 9 months; 98% of ZOL doses were administered. Mean spine BMD changes at 24 months were 7.4% (SD 4.3%) with ZOL vs. 2.9% (4.5%) with TDF-switching (mean difference 4.4%, 95%CI 2.6-6.3; p< 0.001). Mean left femoral neck BMD changes were 4.1% (3.8%) and 2.1% (4.6%), respectively (mean difference 2.0%, 95%CI 0.2-3.8; p=0.03). Mean left total hip BMD changes were 4.6% (2.6%) and 2.6% (4.0%), respectively (mean difference 1.9%, 95%CI 0.5-3.4; p=0.009). There was 1 fracture in the ZOL group (1 patient) and 7 separate fracture events in the TDF switch group (4 patients). Serious adverse events occurred in 9 (19%) ZOL patients and 6 (14%) TDF-switch patients; none was related to study drugs or procedures. Virological failure occurred in 1 TDF-switch patient and no ZOL patient.
Conclusions: ZOL is more effective than TDF switching at increasing BMD in osteopenic adults on TDF, and may result in fewer fractures.

WEAC01 PrEP Expectations and Experiences

WEAC0106LB

Pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) in the Netherlands: motives to choose for, switch to, or stop with daily or event-driven PrEP

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Background: Proper implementation of pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) requires a clear understanding of the reasons why MSM choose one PrEP-dosing regimen over another in real-life settings. Therefore, we aimed to gain insight into the motives for choosing or switching between daily and event-driven PrEP or (temporarily) stopping PrEP use.
Methods: We used data from the Amsterdam PrEP (AmPrEP) demonstration study (June 2015-February 2017), where both daily and event-driven PrEP (dPrEP and edPrEP, respectively) are offered. MSM's motives to choose a regimen were measured at baseline among 376 participants of whom 273 chose dPrEP and 103 chose edPrEP. Motives to switch or stop were recorded at every 3-monthly follow-

up visit. Standardized closed- and open-end items were used. Open answers were coded and analyzed following qualitative research methods.
Results: Among the reasons to use dPrEP were the convenience of daily routine (n=133), perceived higher dPrEP efficacy (n=34), and fear of side-effects relating to edPrEP re-initiation (n=5). Perceived toxicity and burden of daily medication were reasons to choose edPrEP (n=38). Infection risk was also considered: dPrEP was preferred for unplanned and/or frequent sexual risk behavior (n=79), while edPrEP was chosen when risk was more predictable (n=57). Some chose for, or switched to, edPrEP to inhibit sexual risk behavior (n=4), while others chose for, or switched to, dPrEP to gain more sexual freedom (n=17). Other reasons to switch to edPrEP included experiencing side-effects (n=14), having less sex than anticipated (n=20), experimenting with another regimen (n=2) and receiving negative reactions from the environment (n=1). Doubts about edPrEP's safety (n=2), inability to plan sex (n=13) and desire for more structure (n=9) were motivators to switch to dPrEP. Motives to temporarily stop dPrEP (n=99) were situational (e.g. medical issues or vacations). Changed life circumstances (n=2) and reduced sexual risk (n=6) were motives to completely stop with PrEP use (n=12).
Conclusions: A great variety of personal and contextual factors determine the choices for PrEP regimens, related switches and stops. In order to successfully support future PrEP users, a tailored approach, addressing choices for PrEP regimens as a continuum of flexible and changeable choices, is essential.

WEAD01 Care for Kids

WEAD0106LB

The cost-effectiveness of integrating maternal ART into maternal & child health (MCH) services during the postpartum period in South Africa

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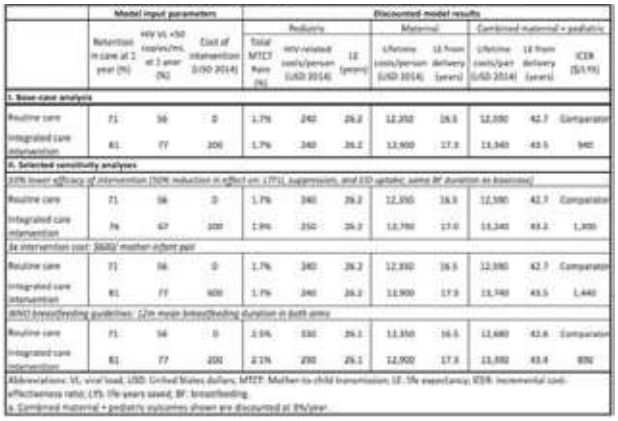
Background: Despite improved PMTCT services in South Africa, poor retention in care and low maternal ART adherence after delivery increase risk of postnatal MTCT and adverse maternal outcomes. We projected the clinical and economic impact of the MCH-ART trial, which evaluated integrated, co-located maternal and pediatric care throughout breastfeeding in Cape Town.
Methods: Using the CEPAC model, we simulated HIV-infected women initiating ART during pregnancy and their infants (mean maternal age: 28.6y, median CD4: 354 cells/μL). We compared two strategies: routine care (referral to local clinics after delivery for separate adult ART and well-baby care) and integrated maternal/pediatric care in the MCH service through weaning (median: 8m, then referral to local clinics). Trial-derived inputs included: primary trial outcomes of 12-month maternal retention (routine: 71%, integrated: 81%) and virologic suppression (routine: 56%, integrated: 77%); breastfeeding duration (routine: 6m, integrated: 8m); and infant HIV testing uptake at 6-10w (routine: 78%, integrated 82%). We assumed an intervention cost of $200/mother-infant pair and equal monthly LTFU and ART failure rates in both strategies after 12 months. Model outcomes included MTCT rates, maternal and pediatric life expectancy (LE), and lifetime HIV-related per-person costs (2014 US$). We calculated incremental cost-effectiveness ratios (ICERs) from discounted (3%/year) maternal + pediatric LE and costs, defining "cost-effective" as an ICER < $6,500/life-year saved (South Africa 2014 per-capita GDP).
Results: Compared to routine care, integrated care was projected to decrease maternal 1-year mortality (1.7% vs. 1.5%), increase maternal LE (27.0y vs. 28.6y, undiscounted), and result in an ICER of $940/LYS. Modeled pediatric outcomes were similar between arms. The intervention remained cost-effective with lower intervention efficacy (50%: Table), higher intervention costs (up to $4,650), and longer breastfeeding duration (12m).
Conclusions: Integrated maternal-pediatric care, co-located in MCH services through the end of breastfeeding, is a cost-effective strategy to optimize postpartum maternal and infant outcomes in South Africa.



[Table. Results of clinical and economic analysis of integrated postpartum maternal-infant care intervention in South Africa]

WEAD02 When Donors Leave...

WEAD0206LB

Cost-effectiveness of routine viral load monitoring in low and middle income countries: a systematic review

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Background: Routine viral load (VL) monitoring for HIV-1 management of persons on ART has been recommended by the WHO to identify treatment failure. However, VL testing represents a substantial cost in resource constrained health care systems. The central challenge is whether and how VL monitoring may be delivered such that it maximizes health gains across the population for the costs incurred. We hypothesized that key efficiency assumptions about program design and cost drive the cost-effectiveness of programs with viral load monitoring.
Methods: We conducted a systematic review of studies on the cost-effectiveness of viral load monitoring in low and middle income countries (LMIC). We followed the Cochrane Collaboration guidelines and the PRISMA reporting guidelines.
Results: We identified 18 studies that evaluated the cost-effectiveness of viral load monitoring in HIV treatment programs. Overall, we identified three key factors that make it more likely for viral load monitoring to be cost-effective: 1) Use of lower cost, robust approaches to viral load monitoring; 2) Ensuring the pathway to health attainment is established and that viral load results are acted upon; 3) Viral load result is used to simplify HIV care in patients with viral suppression (i.e. differentiated care, with fewer clinic visits and longer prescriptions); viral load monitoring in differentiated care programs provides evidence that reduced clinical engagement, where appropriate, is not impacting health outcomes.
Conclusions: The cost-effectiveness of viral load monitoring critically depends on the context. To achieve this goal of being cost effective, viral load monitoring will need to facilitate scale up of differentiated care approaches to HIV treatment - introducing viral load monitoring without differentiated care is unlikely to be cost-effective in most settings and results in lost opportunity for health gains through an alternative use of limited resources. As countries scale up differentiated care programs, data on clinical outcomes and cost are essential to evaluate the on-going cost-effectiveness of viral load monitoring as utilized in practice.

Monday 24 July

Poster Discussions

MOPDC01 Anti-virals and Pregnancy

MOPDC0106LB

Breast milk dapivirine pharmacokinetics and estimated infant exposure during dapivirine intravaginal ring use among lactating women

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Background: The 25 mg dapivirine (DPV) vaginal ring (VR) can reduce women's risk of acquiring HIV infection. Most studies of HIV prevention products exclude lactating women, despite global recommendations for breastfeeding and continued risk for HIV acquisition during lactation. MTN-029/IPM 039 was a Phase I, open-label study of pharmacokinetics; safety and tolerability, and adherence associated with DPV VR use.
Methods: Between January 2016 and March 2017, 16 healthy, HIV-uninfected women aged 18 or older were enrolled in Pittsburgh and Birmingham, USA. Eligible women had weaned infants from breastfeeding before enrollment, but were able to pump breast milk. Participants were instructed to wear the VR continuously for 14 days. Milk and blood plasma samples were collected (pre-insertion, Hour 3, Hour 6, Hour 24, Day 7, Day 14 after ring placement, and two days after ring removal) and analyzed for DPV using validated ultra-performance liquid chromatography-tandem mass spectrometry assays, with lower limits of quantification of 10 pg/mL and 20 pg/mL for milk and plasma, respectively. We estimated infant DPV intake assuming 150 mL/kg/day milk ingestion. Adverse events (AEs) were collected at all participant contacts.
Results: All participants had detectable DPV in milk and plasma. Median DPV concentrations in milk and plasma rose gradually to relatively steady concentrations on Day 7 and Day 14, followed by falling concentrations after ring removal to approximately 40% of Day 14 concentrations by Day 16. Median (interquartile range) peak concentration for milk and plasma were 676 pg/mL (443, 924.5) and 327 pg/mL (274.5, 378), respectively. Time-adjusted median milk/plasma ratio was 1.70 (1.38, 1.86). Estimated daily infant exposure was 68.0 ng/kg/day (53.0, 85.1). Estimated terminal concentration half-life after ring removal was 39.0 hours (27.1, 53.4) and 35.2 hours (29.8, 46.4) for milk and plasma, respectively. Six of 16 (38%) participants experienced eight total AEs, most of which were mild.
Conclusions: In this first study of DPV exposure during lactation, DPV VR use was associated with low levels of detectable DPV in milk and plasma, very low estimated levels of infant exposure, and a favorable safety profile. Future DPV VR studies should evaluate longer periods of use among breastfeeding mother-infant pairs.

Tuesday 25 July

Poster Discussions

TUPDB01 HIV Reservoirs: Ups and Downs

TUPDB0106LB

Viral and host characteristics of a child with perinatal HIV-1 following a prolonged period after ART cessation in the CHER trial

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Background: In the 6-year CHER trial (2005-2011), HIV-infected infants were randomized to deferred antiretroviral therapy (ART) or early limited ART for 40 (ART-40W) or 96 (ART-96W) weeks; ART reinitiation was based on CD4 and clinical criteria. We describe a child, randomized to ART-40W in 2008, who on long term follow-up, maintains an undetectable viral load after 8.5 years off-ART.
Methods: Studies conducted to describe immunological and viral characteristics included: ultrasensitive qualitative nested and quantitative semi-nested PCR assay to assess HIV DNA reservoir; co-culture of CD4 cells with MOLT-4/CCR5 and CD8-depleted phytohaemagglutinin-activated lymphocytes to detect replication-competent virus.
Results: HIV diagnosis was confirmed by HIV-DNA PCR+ at age 32 days, and on days 39 and 60, VL was >750,000 and 151,000 copies/ml respectively. ART started at age 8.7 weeks and was interrupted at 40 weeks post randomisation. On ART, VL declined to < 50copies/ml at week 24 and was < 20 copies/ml post-interruption .During later follow-up 6-monthly VLwere also < 20copies/ml. At age 9.5 years, the child was clinically asymptomatic with CD4 802 cells/µl. Qualitative DNA PCR was negative. HIV-antibody by ELISA was negative but was weakly reactive to Gag p40 and p24 on Western blot; a weak Gag-specific CD4 T-cell response was detected by whole blood intracellular cytokine assay. Proviral DNA was positive by ultrasensitive nested (int) PCR and HIV DNA reservoir size was estimated at 2.2 copies/10^6 PBMCs by semi-nested quantitative (RT) assay. DNA sequencing of Gag confirmed subtype-C virus. No replication-competent virus was detected in culture supernatants by day 22 using p24 ELISA and ultrasensitive nested RT-PCR. All HLA loci were heterozygoous (A*30:02:01/66:01; B*08:01:01/44:03:01; C*04:01:01/07:01:01; DRB1*12:01:01/13:02:01; DPB1*01:01:01/18:01; B1*05:01:01/06:09:01). The KIRAA1 genotype included both full-length and truncated KIR2DS4. Immunophenotyping showed few CCR5-expressing CD4 T-cells (6.6%), low CCR5 density, low immune activation (HLA-DR, TIGIT), high PD-1expression and high % naive CD8 T-cells.
Conclusions: To our knowledge, this is the first case of sustained virological control from a randomized trial of ART interruption following early treatment of infants. Further investigation may expand our understanding of how the immune system controls HIV replication and inform future research strategies for ART interruption after early ART.

TUPDB02 Late Breaker Poster Discussion Session

TUPDB0201LB

Phase 3 randomized, controlled clinical trial of bictegravir coformulated with FTC/TAF in a fixed-dose combination (B/F/TAF) vs dolutegravir (DTG) + F/TAF in treatment-naïve HIV-1 positive adults: week 48 results

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Background: In a phase 2 study, bictegravir (BIC, B), a novel, potent integrase strand transfer inhibitor (INSTI) with a high barrier to resistance, was directly compared with dolutegravir (DTG), each given with the recommended N(t)RTI combination of emtricitabine and tenofovir alafenamide (F/TAF) in treatment-naïve, HIV-infected adults. Both treatments demonstrated high efficacy and were well tolerated through Week (W) 48. We now report results from a phase 3 study of this comparison of BIC and DTG, each with F/TAF, utilizing a single-pill coformulation of B/F/TAF.
Methods: Treatment-naïve, HIV-infected adults with estimated glomerular filtration rate (eGFR)
≥30 mL/min were randomized 1:1 to receive blinded treatment with fixed dose combination B/F/TAF (50/200/25 mg) or DTG (50 mg) + F/TAF (200/25 mg) with matching placebos once daily through W48. Chronic hepatitis B and/or C infection was allowed. The primary endpoint was the proportion of participants with HIV-1 RNA < 50 copies/mL (c/mL) at W48 (FDA snapshot). Noninferiority was assessed through 95.002% confidence intervals (CI) using a margin of 12%. Secondary endpoints were safety measures (adverse events [AEs] and laboratory results).
Results: 645 participants were randomized and treated (320 B/F/TAF, 325 DTG + F/TAF): 12% women, 31% Black, 19% viral load (VL) >100,000 c/mL, 12% CD4 < 200 cells/μL, median age 34 yrs, CD4 count 440 cells/μL, and VL 4.44 log10 c/mL. At W48, B/F/TAF was noninferior to DTG + F/TAF, with 89.4% on B/F/TAF and 92.9% on DTG + F/TAF achieving HIV-1 RNA < 50 c/mL (difference -3.5%; 95.002%CI -7.9% to 1.0%, p=0.12). At W48, proportion of participants with HIV-1 RNA ≥50 c/mL was < 1% in each arm. No study subject in either treatment arm developed resistance to any of the study drugs. The most common AEs were headache (13% B/F/TAF, 12% DTG + F/TAF) and diarrhea (12% for both). Few participants (5 [2%], 1 [< 1%]) had AEs leading to premature study discontinuation. Lipid changes were not significantly different between study arms. No renal discontinuations and no cases of proximal renal tubulopathy were reported.
Conclusions: After 48 weeks, B/F/TAF achieved virologic suppression in 89.4% of treatment- naïve adults and was noninferior to DTG + F/TAF. B/F/TAF was safe and well tolerated.

TUPDB0202LB

Single doses as low as 0.5 mg of the novel NRTTI MK-8591 suppress HIV for at least seven days

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Background: MK-8591 is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) in early clinical development for the treatment of HIV-1 infection. MK-8591-triphosphate (MK-8591-TP), the active phosphorylated anabolite of MK-8591, exhibits a half-life of ~150-160 hrs in human PBMCs. Here we describe antiviral efficacy and tolerability of single doses of 0.5 mg to 30 mg MK-8591 over 7 to 10 days in HIV-1 infected subjects in an ongoing Phase 1b monotherapy proof-of-concept efficacy study.
Methods: In an open-label study in HIV-1-infected subjects naïve to antiretroviral treatment (ART), subjects are being administered a single dose of MK-8591 across a range of doses. Blood samples are being collected for viral load (VL), MK-8591 PK, and MK-8591-TP PK at prespecified time points up to 7 to 10 days post-dose. Following completion of Day 7 or Day 10 procedures, subjects are being offered standard of care ART. Safety, PK, and VL data from the doses of 0.5 mg, 1 mg, 2 mg, 10 mg, and 30 mg (N=6/panel) are available.
Results: Single doses of MK-8591 across the entire tested range were associated with a rapid and robust reduction in VL. At 168 hours postdose, a mean (95% CI) placebo-corrected VL reduction of 1.18 log10 (0.95, 1.46) was observed for 0.5 mg. For the 30 mg dose, mean VL continued to decline through Day 10 with a mean placebo-corrected reduction of 1.57 log10 (1.34, 1.85), with no evidence of recrudescence at any dose. In samples with sufficient VL for testing (14/24), no common mutant strains, including M184V/I, were detected. All doses were generally well tolerated, with a limited number of mild/moderate adverse experiences reported. MK-8591 plasma and MK-8591-TP PBMC PK were similar to previously observed data in healthy subjects.
Conclusions: MK-8591 suppressed HIV replication for at least seven days when administered as a single dose as low as 0.5 mg. The antiviral potency, human pharmacokinetics (PK), and physical properties of MK-8591 have the potential to open new paradigms for extended duration HIV treatment and prophylaxis approaches.

TUPDB0203LB

Pharmacokinetics, pharmacodynamics and pharmacogenomics of efavirenz 400mg once-daily during pregnancy and postpartum

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Background: Antiretroviral dose reductions may compensate for the finite global manufacturing capacity and allow access programmes to reach larger numbers of HIV-infected patients. The ENCORE-1 study showed that efavirenz 400mg (EFV400) is non-inferior to the standard adult dose. WHO clinical guidelines now recommend EFV400 as an alternative first-line agent, however with a disclaimer that no data on EFV400 during the third trimester of pregnancy (TT) exist. This study investigated the pharmacokinetics (PK), efficacy and CYP2B6 pharmacogenetics of EFV400 in women living with HIV (WLWH) during TT and post-partum (PP) with a view to removing the disclaimer and allowing wider EFV400 use in first-line.
Methods: Open-label, multicentre study (UK and Uganda) in WLWH receiving tenofovir disoproxil fumarate (TDF), emtricitabine (FTC) and EFV 600mg with an undetectable viral load (VL), who switched to TDF/FTC/EFV400 was performed. Weekly therapeutic drug monitoring (TDM), steady-state PK profiles during TT and PP, safety, virologic efficacy and polymorphisms in CYP2B6 (516C>T; 938T>C) were evaluated.
Results: 22 WLWH of African origin were enrolled, baseline median (range) age and CD4 were 30 (18-41) years and 548 (190-882) cells/mm^3, respectively. All had VL< 50 copies/mL at baseline, which was maintained throughout the study (only 2 blips were observed but confirmed < 50, when repeated). None of the children were HIV-infected. No WLWH were excluded from the study because of low EFV400 TDM results (< 800 ng/mL in >3 consecutive visits). Geometric mean (GM) ratios (TT/PP; 90% confidence intervals) of EFV400 Cmax, AUC, and C_{24h} were 0.86 (0.68-1.09), 0.74 (0.59-0.94), 0.62 (0.47-0.83). GM C_{24h} was 1256 ng/mL (coefficient of variation 79%). 20/22 WLWH were carriers of the CYP2B6 516G allele and only 2 were slow metabolisers. EFV400 was well tolerated during pregnancy with no grade 3 or 4 laboratory abnormalities.
Conclusions: Cmax, AUC, and C_{24h} in TT were 14%, 26% and 38% lower compared to PP but within ranges of those measured for EFV600 during TT by Schalkwijk et al. (2016) and those measured in ARV-naïve patients on EFV400 in ENCORE-1 (Dickinson et al. 2015). All subjects maintained a VL< 50, suggesting that EFV400 can be used in pregnant WLWH.

TUPDB0204LB

Universal sputum testing vs. symptom-based testing for tuberculosis (TB) in HIV-infected pregnant women: a cluster-randomized implementation trial in South Africa

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Background: TB in HIV-infected pregnant women is a leading cause of maternal and infant morbidity and mortality. Currently-recommended symptom-based screening of HIV-infected pregnant women may be insensitive.
Methods: We conducted a cluster-randomized trial to compare universal sputum TB testing of HIV-infected pregnant women against standard symptom-based testing. Sixteen public-sector antenatal clinics in two health districts were assigned to either strategy by constrained randomization. HIV-infected pregnant women without currently diagnosed TB were eligible. In universal testing clinics (UC), all HIV-positive pregnant women were asked to produce a sputum sample. In symptom clinics (SC), only those with WHO criteria for TB testing (cough, fever, night sweats, or weight loss) were asked to produce sputum. Sputa were tested by Xpert MTB/RIF and midway through the study liquid MGIT culture was added. Women and infants were followed through 2 months postpartum. Cluster-adjusted results are shown.
Results: From 5/2015 through 3/2017, 937 and 1095 HIV-infected pregnant women were enrolled in the UCs and SCs, respectively. Median age was 30 years, median gestational age 24 months, 11% had prior TB, 90% were on ART, with no significant differences by arm. At baseline 17% of UC women and 22% of SC women had ≥1 TB symptom (p=0.40).
In UCs and SCs, respectively, 35 and 4 women were diagnosed with TB during pregnancy (UC prevalence = 3.7%, SC 0.37%, adjusted p=0.01). Two months post-partum, infant mortality in UCs was 0.9% vs. 2.1% in SCs (adjusted p= 0.06). Miscarriages and stillbirths were similar in both arms and two women died in the SCs .
MGIT culture identified more TB than Xpert: 25/487 samples (5%) were MGIT+ vs 19/1400 (1.4%) Xpert+ (p< 0.05). 440 samples were tested with both assays, 4 were Xpert+/MGIT+, 412 negative for both, 3 Xpert+/MGIT-, and 21 Xpert-/MGIT+.
Conclusions: Universal TB screening of all HIV-infected pregnant women increased case detection 10-fold and was associated with reduced early infant mortality. MGIT identified more TB than Xpert in women whose pregnancy may mask TB symptoms. Our data support sputum testing all HIV-infected pregnant women for TB in high burden areas such as South Africa. Cost-effectiveness studies of universal testing are needed.

TUPDB0205LB

Sub-study 202094 of SWORD 1 & SWORD 2: switch from TDF containing regimen to DTG+RPV improves bone mineral density and bone turnover markers over 48 weeks

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Background: Loss of bone mineral density (BMD) has been attributed to traditional risk factors for osteoporosis, HIV infection and antiretroviral therapy (ART), in particular tenofovir (TDF). 202094, a sub-study of the international, multicenter SWORD 1 & 2 studies, evaluated change in BMD (by DEXA) following switch from a triple ART regimen containing TDF to the 2-drug regimen (2DR) dolutegravir (DTG) + rilpivirine (RPV). Week 48 SWORD data demonstrated maintenance of suppression with DTG+RPV and noninferiority to continuing current ART (CAR).
Methods: Subjects were HIV-infected adults, with HIV-1 RNA< 50c/mL and who received ART containing TDF both for ≥ 6 months prior to randomization to DTG+RPV or CAR on Day 1 through Week 48 in SWORD-1/2. Hip and lumbar spine BMD were measured by DEXA scans which were centrally read. The primary endpoint was the percentage change in total hip BMD. Secondary endpoints included change in lumbar spine BMD and bone turnover markers. The ANCOVA BMD analysis of the intent-to-treat population adjusted for baseline parameters (see Table 1).
Results: The results at Week 48 are shown in Table 1. DTG + RPV patients had an increase from Baseline to Week 48 in hip (1.34%) and spine BMD (1.46%) which differed statistically significantly (p=0.014, p=0.039, respectively) from CAR patients. (Table 1). Consistent with this, DTG + RPV patients had a decrease from Baseline to Week 48 in bone specific alkaline phosphatase, procollagen type 1-N-propeptide, osteocalcin and Type I Collagen C-Telopeptide bone turnover markers which differed statistically significantly from the CAR group (p range from < 0.001 to 0.029 across markers).

Treatment Assignment in Parent SWORD Study	DTG + RPV	CAR	p value
Evaluable subjects at Baseline and Week 48(a)	46	35	
Primary Endpoint: Total Hip(b) BMD			
Mean adjusted % change from Baseline to Week 48 (95% CI)(c)	1.34 (0.68, 2.01)	0.05 (-0.71, 0.82)	
Difference in adjusted % change from Baseline to Week 48 between treatment groups (95% CI) and p value(c)	1.29 (0.27, 2.31)		p = 0.014
Secondary Endpoint: Lumbar Spine(d)BMD			
Mean adjusted % change from Baseline to Week 48 (95% CI)(c)	1.46 (0.65, 2.28)	0.15 (-0.79, 1.09)	
Difference in adjusted % change from Baseline to Week 48 between treatment groups (95% CI) and p value(c)	1.32 (0.07, 2.57)		p = 0.039
a. Subjects having evaluable BMD data at both Baseline and Week 48 had their DEXA scans performed within the predefined time period for the study visit b. Total hip includes the femoral neck, trochanter and intertrochanter areas c. BMD is expressed as areal density. Estimates and associated p-values are from an ANCOVA model adjusted for Baseline BMD value, age at study entry, and Baseline BMI d. Lumbar spine includes the first lumbar vertebra (L1) to the fourth lumbar vertebra (L4)			

[202094 Week 48 Results: ITT-Exposed Population]

Conclusions: Switch to the 2 drug-regimen of DTG+RPV is associated with significant improvement in bone mineral density and markers of bone health compared to continuation of a TDF-based 3 drug regimen, and provides a robust option for preserving bone health while continuing suppressive HIV treatment.

TUPDB0206LB

Earlier treatment and lower mortality in infants initiating antiretroviral therapy at < 12 weeks of age in South Africa: The International epidemiologic Databases to Evaluate AIDS Southern Africa (IeDEA-SA) Collaboration

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Background: The context of HIV prevention and treatment for children in South Africa has significantly improved and there is a recent shift toward birth early infant diagnosis and early infant antiretroviral therapy (ART). We describe the characteristic and outcomes of children initiating ART in the context of changing paediatric HIV testing and treatment guidelines in South Africa.
Methods: A retrospective cohort analysis was conducted using data from the IeDEA-SA collaboration. HIV-infected children initiating combination ART at < 3 months old, from 2006-2016 were included. We described changes in characteristics of children starting ART and mortality, loss to follow-up (LTFU) and transfer out by 12 months on ART.

Results: Among 1380 infants, the median age at ART initiation was 62 days (interquartile range (IQR) 37-79); median time on ART was 13.6 months (IQR 4.0-34.5). The median age at ART start decreased from 67 days (IQR 53-81) in 2006-2009 to 48 days (IQR 9-74) in 2013+ (p<0.001). There was a decline in median log viral load at ART initiation from 5.9 (IQR 5.4- 6.4) in 2006-2009 to 5.4 (IQR 3.9-6.3) in 2013+ (p<0.001). The median absolute CD4 count (cells/μL) increased progressively from 888 (IQR 380-1703) in 2006-2009 to 1526 (IQR 659-2231) in 2013+ (p<0.001). Among infants with data on WHO disease staging (n=865), 84% (n=299) started ART with WHO disease stage 3/4 in 2006-2009 compared to 39% (n=279) in 2013+ (p<0.001). After 1 year on ART, 11% (median age 68 days (IQR 55-75)) and 4% (median age 60 days (IQR 25-83)) of children died in 2006-2009 and 2013+ respectively (p<0.001). LTFU increased from 7% in 2006-2009 to 21% in 2013+ (p=0.002) and transfer out declined from 20% in 2006-2009 to 12% in 2013+ (p<0.001).
Conclusions: Children are starting ART earlier, with less progressive disease and associated declines in mortality; however mortality and LTFU in infants starting ART remains unacceptably high. In view of the scale up of birth PCR testing in South Africa, a significant proportion of children still start ART with advanced disease, highlighting the need for a focused approach to early infant HIV testing and follow-up on ART.

TUPDC01 TRANScending Barriers for Prevention

TUPDC0107LB

High level of retention and adherence at week 48 for MSM and TGW enrolled in the PrEP Brasil demonstration study

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Background: PrEP Brasil is a demonstration study to assess feasibility of daily oral tenofovir-disoproxil-fumarate plus emtricitabine (TDF/FTC) provided at no cost to high-risk men who have sex with men (MSM) and transgender women (TGW) within the Brazilian public health system. We report week 48 PrEP retention, adherence to daily pill use, trends in sexual behavior and incidence of HIV and sexually transmitted infections.
Methods: PrEP Brasil was initiated on April/2014; participants were followed for 48 weeks. Adherence was evaluated based on tenofovir diphosphate (TFV-DP) concentrations in dried blood spot samples. Logistic regression models were used to quantify the association of socio-demographic, behavioral and clinical variables with high levels of adherence (≥4 doses/week).
Results: 450 participants initiated PrEP, of which 376 (83%) were retained through 48 weeks. At week 48, 73.7% (277/376) had protective levels consistent with ≥4 doses/week. Higher odds of achieving protective levels was observed among participants from São Paulo (adjusted odds ratio [aOR] 2.01, 95% confidence interval [95%CI] 1.16-3.47), as well as among those who reported sex with HIV-positive partners (aOR 1.77, 95%CI 1.03-3.04), and those who had protective levels of TFV-DP at week 4 (aOR 3.26, 95%CI 1.87-5.68). The prevalence of rectal chlamydia and rectal gonorrhea ranged from 8.0% and 4.9% at enrollment to 7.7% and 3.7% at week 48, respectively (p=0.88 and p=0.42). Syphilis incidence was 9.0/100PY (95%CI 6.5-12.5). The mean number of sexual partners slightly decreased from 11.0 to 8.6 (p=0.20) whereas the proportion of participants engaging in condomless receptive anal sex slightly increased from 44.7% to 47.8% (p=0.37). Two individuals seroconverted during follow-up (HIV incidence 0.51 [95%CI 0.13-2.06] infections/100PY); both had undetectable TFV-DP levels at seroconversion.
Conclusions: Our results show high levels of retention and adherence to PrEP corroborating PrEP's feasibility in a real-life setting of a middle-income country. Moreover, sexual behavior and STI incidence remained stable over time, suggesting a lack of risk compensation in this population.

Wednesday 26 July

Poster Discussions

WEPDC01 It's Time to Focus on STIs

WEPDC0106LB

Are associations between HIV and HPV transmission due to behavioural confounding factors or biological effects?

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Background: Epidemiological studies suggest 2 to 5 fold unadjusted increased risk of newly detecting HPV infection for HIV-infected individuals and of HIV acquisition following HPV detection. Meta-analyses of the latter association, using estimates adjusted for behavioural risk factors, estimate ~2 fold increased risk. We conducted a mathematical modelling study to assess whether confounding behavioural factors and network effects are sufficient to explain associations between HIV and HPV infection status, without biological interactions.
Methods: MicroCOSM, a dynamic individual-based network model, was used to simulate epidemics of HIV and 13 oncogenic HPV types. Heterogeneity in sexual risk behaviour was represented by distinguishing relationship types and allowing for variation between individuals in their rate of partner acquisition and propensity for concurrent partnerships. No biological effects were assumed to modify transmission parameters of HIV in the presence of HPV infection and vice versa. Bayesian methods were used to calibrate the model to South African HIV and type-specific HPV prevalence data. Medians of the posterior distributions of the model parameters were used to simulate cohorts with bi-annual HIV and HPV testing from 2010 to 2015. Cox proportional hazards models were used to estimate hazard ratios for each of 100 simulated cohorts and mean hazard ratios were calculated.
Results: The 2010 mean HIV prevalence and oncogenic HPV prevalence among adults aged 15-49 in the 100 cohorts are 20.1% (95% CI 18.7-21.4%) and 38.9% (95% CI 36.5-41.2%), respectively. The modelled mean unadjusted hazard ratio of HIV acquisition following detection of an oncogenic HPV type is 3.2 (95% CI 2.6-3.8). The mean unadjusted hazard ratio for the effect of HIV on newly detected HPV is 3.7 (95% CI 3.4-4.1). Model findings are similar for different years of study enrolment and frequency of testing.
Conclusions: Model results are comparable to unadjusted results from observational studies, even when no biological effects are included. This suggests that observed associations between HPV and HIV transmission could be attributed to confounding by behavioural factors and network-level effects, implying that primary prevention of HPV (for example by vaccination) may not play a significant role in HIV prevention.

WEPDD01 Getting to the First 90

WEPDD0106LB

Accelerating progress towards the first 90 among men: a trial of the peer-based distribution of HIV self-test kits in Bulisa, Uganda

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Background: Too few men living with HIV are aware of their status, particularly in fishing communities around the great lakes of Africa. HIV self-testing (HIVST) addresses barriers preventing men from testing. But current approaches to distributing HIVST kits (e.g., through health facilities) only reach a subset of the men requiring HIV testing. We conducted a pilot trial of the distribution of HIVST kits through peer networks of fishermen.

Methods: We recruited seed participants among male patients of a TASO-supported facility. We introduced them to HIVST, and asked if they would distribute HIVST kits to peers who have not recently been tested for HIV. If so, we provided a package containing up to 5 HIVST kits (OraQuick), instructions and scripts addressing questions their peers may ask about HIVST. Recruited peers were referred to the study using a coupon with a unique number, and were asked to return the HIVST kit (used or unused). We conducted audio computer assisted self-interviews with seeds and recruits to measure a) the occurrence of adverse events (e.g., coercion) and b) the uptake of HIVST kits. The accuracy of HIVST was measured against a confirmatory HIV test conducted by a health worker.
Results: A total of 19 seeds offered an HIVST kit to 115 men, and 95 (82.6%) accepted the offer. Among those, 29 had never been tested (25.8%), and 42 (44.2%) had tested more than a year ago. According to confirmatory testing, HIV prevalence was 4.3% among recruits (4/94). Compared to this standard, the sensitivity of HIVST was 100%. Three men living with HIV learned of their infection through HIVST (yield = 1 new diagnosis per 6.3 seeds). The specificity of HIVST was 93.3% (88/94). The 6 false positives were due to a faint grey line appearing on the test location of the OraQuick kit. No recruit reported coercion, but one seed experienced hostility from family members of a recruit.
Conclusions: A novel network-based distribution model of HIVST had high uptake and yield among men in this pilot study. It could constitute a crucial tool in reaching the 90-90-90 targets in under-served fishing communities in Uganda and elsewhere.

Monday 24 July

Poster Exhibition

MOLBPEA01

Majority of HIV virions exclusively express either functional or nonfunctional forms of Env

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Background: HIV is one of the most variable viruses because of its high mutation rate and the conformational plasticity of env. The rapid evolution of this virus, in particular of its envelope (Env), within an infected individual allows it to evade host cellular and humoral immune responses. The correct conformation of Env is critical for the HIV infection.
In this study, we investigate the conformation of Envs on individual virions using our new technology "flow virometry" and a panel of antibodies that discriminate between various gp120 conformations.
Methods: To analyze native HIV virions individually we used magnetic nanoparticles (MNPs) coupled with anti-HIV antibodies to capture HIV virions, followed by staining of resultant complexes with different combinations of fluorescent "detection" antibodies recognizing different conformations of Envs. The resultant complexes were separated in a strong magnetic field using magnetic columns, and analyzed with a flow cytometer. To investigate how Envs of different conformations may affect viral infection we depleted HIV preparation of viruses carrying trimeric Envs recognized by PG16 antibodies or of virions carrying Env stumps recognized by 4B3 antibodies. We then infected tonsillar tissue blocks ex vivo with these depleted preparations or mock depleted preparation and monitored infection for 12 days by measuring p24 released in culture medium.
Results: We found that the majority of virions did not carry defective and trimeric spikes simultaneously. Accordingly, the depletion of the virions that carry defective Envs only mildly decreased the infection of human lymphoid tissue. 4B3-MNPs depleted viral preparation infected human lymphoid tissues ~40% less (60.8±15.5%, n=6) than the control preparation. In contrast, viral preparations depleted with PG16-MNPs or VRC01-MNPs were significantly less infectious (p=0.01 and p=0.03, respectively). These preparations infected human lymphoid tissue to the level of 28.6 ±8.8% (n=6) and 19.5%±2.7 (n=5) of control, respectively.
Conclusions: The observed lack of mosaicism for the majority of infectious virions suggests that this all-or-nothing viral strategy likely aids immune evasion by subverting the focus of humoral responses to generate multiple non-neutralizing antibodies at no cost to infectious virions.

MOLBPEA02

Natural amines inhibit activation of human plasmacytoid dendritic cells through CXCR4 engagement

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Background: Plasmacytoid dendritic cells (pDC) are the first line of host defence against viruses and bacteria and link innate to adaptive immunity. These immune cells are activated after recognition of pathogen nucleic acids by sensors such as Toll-like receptors (TLR). TLR activation triggers production of type I interferon and proinflammatory cytokines. RNA viruses, such as human immunodeficiency virus type 1 (HIV-1) induce high secretion of type I interferon. However, prolonged pDC activation and consequently massive type I interferon production may have adverse effects in the chronic phase of AIDS. Therefore, modulating pDC function and understanding the mechanisms underlying this pDC regulation is of great clinical interest. It was shown that Histamine strongly inhibits cytokine production by Influenza A-activated pDC and inhibits type I interferon production by activated pDC from psoriasis patients.
Methods: Human pDC were purified from healthy donors and cultivated in presence of HIV overnight. IFN-a production by pDC was quantified by ELISA and relative mRNA levels of different interferons, ISG and pro-inflammatory cytokines

were measured by RT-qPCR. We tested natural (histamine, spermine, serotonine) and synthetic (clobenproppit) amines on pDC activated by HIV. siRNA was performed successfully for the first time on primary human pDC to evaluate the implication of the proteins of interest (Smith et al., 2016). 29S8 mice were infected by inhalation with influenza in presence or not of the amines and IFN levels in bronchoalveolar fluids were measured.
Results: Here we show that natural and synthetic monoamines and polyamines inhibit type I interferon production, membrane TRAIL expression and interferon-stimulating genes (ISG) by HIV-stimulated pDC and PBMCs in vitro. Furthermore, IFN production was fully inhibited in a mouse model of influenza infection. Surprisingly, histamine receptors are not required for pDC inhibition. We show that the positive ammonium moiety is essential for the inhibitory activity and we identify CXCR4 as the unexpected common link between amine effect and pDC inhibition.
Conclusions: Our study establishes a functional link between natural amines and the innate immune system and identifies CXCR4 as a potential 'on-off' switch of pDC activity and therefore as a promising therapeutic target in HIV chronic phases (Smith et al., 2017).

MOLBPEA03

Higher levels of NK cell phenotypic diversity and transcriptional activation prior to HIV-1 infection are associated with increased set point viral load

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Background: Natural killer (NK) cells are innate lymphocytes expressing a diverse set of activating/inhibitory receptors that drive their effector activity. Transcriptional signatures differentiate NK cell functions, however, the significance of this functional diversity remains unknown. NK cells are critical for antiviral responses and are generally considered to participate in the control of HIV-1, yet the mechanism remains unclear. A better understanding of NK cell diversity during acute HIV-1 infection (AHI) may be important in the development of treatment and vaccine strategies to eradicate HIV-1.
Methods: NK cell immunophenotyping was evaluated in 24 participants from the RV217 early capture HIV-1 acute infection cohort. PBMC, collected prior to infection and 7-8 time-points over the first 60 days of infection, were thawed and stained to characterize activation, differentiation, homing, and activating/inhibitory receptor expression of NK cells using flow cytometry. In addition, longitudinal NK cell transcriptional signatures were defined in 12 of these donors using Fluidigm BioMark multiplex qPCR.
Results: Throughout AHI, coincident with viral expansion, NK cell counts increased from a median 228 cells/μl (49-589) to 317 cells/μl (100-864)($p< 0.01$). Nevertheless, the kinetics and magnitude of NK cell expansion showed marked variability indicating substantial donor diversity in response to AHI. Analysis of 10 surface receptors revealed broad phenotypic diversity, and there were clear signatures of NK cell activation and trafficking. Moreover, we identified unique transcriptomic fingerprints, related to NK cell effector activity including direct cell recognition, response to cytokines, and antibody dependent cellular cytotoxicity. None of these aspects of NK cell biology were associated with viral control. Interestingly, an index of receptor diversity, prior to infection, trended to a correlation to set point viral load ($r=0.37$, $n=23$, $p=0.1031$). Furthermore, at baseline, expression of 54 genes associated with NK cell effector activity strongly correlated to set-point viral load ($r>0.578$, $n=12$, $p< 0.048$).
Conclusions: Together, this data shows novel phenotypic and transcriptomic signatures associated with NK cells involved in the early responses of HIV-1 infection. Importantly, while NK cell activity can contribute to control of HIV-1 viremia, we observe distinct signatures prior to infection that may be associated with higher set point viral load and worse clinical outcome.

MOLBPEA04

Expanded clones in SIV-infected macaques on antiretroviral therapy recapitulate key features of expanded clones in HIV infection: implications for evaluation of "HIV Cure" interventions

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Background: Residual sources of HIV that persist despite seemingly effective combination antiretroviral therapy (cART) and can give rise to recrudescent infection when cART is stopped ("viral reservoir") include expanded clones of CD4+ T cells, characterized by identical proviral integration sites. These cells can be broadly distributed anatomically, and may contain replication competent proviruses that can contribute significantly to the total viral reservoir.
Methods: To assess whether SIV infected rhesus macaques (RM) receiving cART recapitulate the biology of expanded clones in HIV infected humans, and thus might serve as a useful animal model in this important research area, we analyzed SIV integration sites in RM and human CD4+ T cells infected in vitro, and compared them to HIV integration sites in in vitro infected human CD4+ T cells. We also extensively analyzed integration sites in blood and tissue samples (lymph node, spleen) from four SIV-infected RM started on cART 4 weeks post-infection, and treated for one year.
Results: SIV integration sites in RM and human CD4+ T cells infected in vitro with SIV showed the same overall patterns observed for HIV integrations in human CD4+ T cells (preference for integration into the bodies of highly expressed genes in gene-rich regions), with extensive overlap in the top 500 genes identified as integration hot spots for both viruses. For in vivo specimens, of 997 integration sites documented, 31% represented expanded clones and 7 of the 10 most frequently identified clones were found in at least two different tissues, similar to findings for HIV-infected humans.
Conclusions: These results indicate that SIV integration in RM cells recapitulates essential features of HIV integration in human cells, in vitro and in vivo, including the formation of expanded clones with identical integration sites, and should provide a useful animal model for studies of this critical viral reservoir component. Key questions for future studies include demonstration of the replication competence of at least some of the expanded SIV proviral clones, the role of antigen specific proliferation in their establishment and maintenance and initial evaluations of the impact of appropriate "HIV cure" strategies on this compartment.

MOLBPEA05

Oxidative stress-related PML nuclear body degradation: a novel pharmacologically druggable mechanism behind the establishment of latency during acute infection

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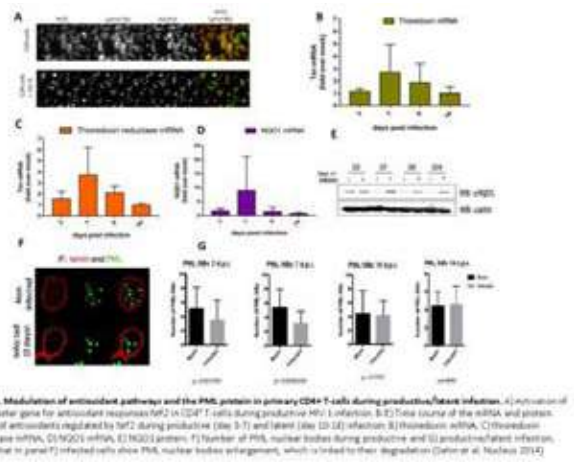
Background: Unravelling the mechanisms establishing HIV-1 latency may provide new therapeutic tools. Latent HIV-1 resides proximally to nuclear bodies, and their main component, the PML protein, is susceptible to the anticancer drug arsenic trioxide, resulting in latency reversal [Lusic et al. 2013]. We here investigated, in primary $CD4^+$ T-cells, the redox modulation of PML degradation/reformation during transition from acute/productive to latent HIV-1 infection, and its potential therapeutic implications.
Methods: Primary $CD4^+$T-cells were used to model the productive/latent infection transition. Cells were activated with α-CD3-CD28, ex-vivo infected with wild-type NL4-3 HIV-1 and kept in culture for 14 days to revert to a resting state. Viral production was measured by qPCR and FACS. Integrated HIV-1 DNA was measured by ALU-gag PCR. Transcriptomic profiles were obtained by microarray and the results validated by qPCR and western blot. Single cell (co)localization of PML and HIV-1 DNA were assessed by 3Dimmuno-DNA FISH. Data were analyzed with the Graphpad, Volocity and "R" software.
Results: Acute/productive infection (days 3-7 post-infection) was characterized by increased oxidative stress (decreased reduced/oxidized glutathione ratio) and concomitant upregulation of the master gene for antioxidant responses (Nrf2) and its

downstream targets. Particularly, expression of thioredoxin, thioredoxin reductase, and NQO1 peaked 7 days post-infection. Generation of oxidative stress was accompanied by PML degradation and decreased nuclear bodies number (P<0.001).



[NRF2 pathway-PML dynamics during HIV-1 infection]

These effects were reverted during the transition to latent infection (days 9-14 post-infection). Conversely, establishment of latency was prevented both by drug-induced PML degradation and by glutathione depletion using BSO, which selectively induced dose/time dependent death of productively HIV-1 infected cells.
Conclusions: Productive HIV-1 infection activates Nrf-2/antioxidant pathways and leads to PML degradation. These effects are reversed upon latency establishment and can be pharmacologically exploited using pro-oxidant drugs to selectively kill infected cells, thus providing a new tool to hamper latency establishment during acute infection.

MOLBPEA06

Estimating the contribution of proliferation to HIV-infected lymphocyte persistence

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Background: Despite suppressive antiretroviral therapy (ART), HIV persists in infected individuals as provirus integrated into the genomes of resting memory CD4+ T cells. The relative importance of intrinsic longevity versus homeostatic proliferation of provirus-containing cells in maintaining this stability remains unknown. To understand how lymphocyte proliferation contributes to reservoir stability, we developed a statistical method to infer dynamical parameters of the HIV-infected lymphocyte population and applied this method to integration site data.
Methods: Recent investigations of HIV integration sites provide a window into the dynamics of resting memory CD4+ T cells. Because HIV integrates randomly into the human genome, the frequency of multiple integrations at the same site is extremely low, implicating clonal proliferation in these observations. Here, we developed a method to use the observed distribution of proviral integration clone sizes to infer the dynamics of cells tagged by these integrations. Using a branching process model and a Bayesian statistical framework, we inferred proliferation and death rates of these cells.
Results: Integration site data from 5 individuals obtained from the Retrovirus Integration Database yielded median a posteriori estimates of proliferation rates in the range of 1.5-5.3 divisions per year, significantly larger than the net rate of latent reservoir decay (~0.2/year). The integration site data were consistent with a model of homogenous dynamics with occasional bursts of proliferation, possibly due to antigenic stimulation of a small subset of T cell lineages. Finally, we connected the statistical uncertainty in our method to sample size and timing in order to guide future studies.
Conclusions: Our results provide a quantitative estimate of resting memory T cell proliferation in individuals with HIV. Because the efficacy of strategies designed to bias the turnover of latently infected cells towards extinction depends critically on this population's intrinsic dynamics, this work is a first step towards evaluating these strategies. Given our model, a reduction in proliferation of latently infected cells could substantially decrease the half-life of the reservoir. In an individual with a latently infected cell proliferation rate of 5 divisions per year, a 90% reduction in proliferation would decrease the half-life of latently infected cells to 1.8 months.

MOLBPEA07

Increased levels of HIV-1 specific IgG antibody in the presence of HLA-DPB1*13 in three HIV-1 vaccine trials

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Background: IgG antibodies to HIV-1 Envelope (Env) amino acid positions 120-204 (reference sequence HXB2) were identified as a predictor of decreased risk of infection in the RV144 vaccine trial (Haynes et al. NEJM 2012). Env (120-204)-specific IgG antibody levels were a correlate of protection only in the presence of a specific HLA class II allele: DPB1*13 (Prentice et al. STM 2015). Two recent HIV-1 vaccine trials in Thailand, RV305 and RV306, employed the same vaccine regimen as RV144 with additional boosts. This presented a unique opportunity to further examine effect of HLA genotype on vaccine induced IgG responses to HIV- 1 Env.
Methods: HLA-DPB1 was genotyped in 137 and 316 vaccinated individuals from the RV305 and RV306 studies, respectively. IgG binding was detected to scaffolded subtype B and CRF01-AE Env antigen, consisting of the variable loops 1 and 2 flanked by partial regions of the first and second conserved domains. Association of HLA-DPB1*13 with Env (120-204)-specific IgG responses at the timepoint coinciding with peak immunogenicity in RV144 were computed using linear regression adjusted for gender.
Results: In RV306 higher levels of Env (120-204) IgG antibody directly correlated with the presence of HLA-DPB1*13 (P=0.03, q=0.07). The association was stronger when considering only Env-specific IgG responses directed to Env antigen from the CRF01-AE subtype dominant in Thailand (P=0.01, q=0.04). In RV305 association of HLA-DPB1*13 with higher levels of Env (120-204) IgG showed a similar strength association which trended to significance in this smaller sample size (P=0.06, q=0.19).
Conclusions: Presence of a specific HLA class II allele associated with the only protective immune correlate identified to date in a HIV-1 vaccine trial. We were able to replicate this finding in independent donors from two subsequent HIV-1 vaccine trials. HLA-DPB1*13 is known to be expressed at high levels on the cell surface and could modulate CD4+ T cell stimulation of antibody production by B cells in an HLA class II restricted manner. Transcriptome analysis is being performed to identify specific differences in vaccine-induced responses elicited by individuals with HLA-DPB1*13. Understanding this mechanism of protection of the vaccine will enable improved HIV vaccine design.

MOLBPEA08

Cervicovaginal bacteria and HIV acquisition in young South African women

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Background: Increased inflammation in the female genital tract (FGT) is associated with an elevated risk of HIV infection. The role of cervicovaginal bacteria in HIV susceptibility has not been fully elucidated.
Methods: We characterized the gut and cervicovaginal microbiome of HIV-uninfected South African women aged 18-23 years using 16S rRNA gene and DNA/RNA virome sequencing. We performed flow cytometry and Luminex/ELISA to measure numbers of activacted CD4+ T cells and cytokine concentrations in the FGT of these women, as well as in the FGT of mice intravaginally inoculated with low- and high-risk bacteria and in a 3D in vitro model of the FGT. We also used single-cell sequencing to assess the effect of bacteria in vivo.
Results: Women with Lactobacillus-deficient anaerobic cervicovaginal bacterial communities, which constitute the majority of healthy black South African women, had 4-fold higher risk for acquiring HIV than those with Lactobacillus crispatus-

dominant communities. This finding was independent of STIs and HIV risk behaviors. Unlike bacteria, highly prevalent alphapapillomaviruses, Anelloviridae and bacteriophages did not form distinct communities and were neither associated with bacterial communities nor with HIV acquisition. Women with low Lactobacillus abundance, high-diversity bacterial communities had up to 17-fold higher numbers of cervical HIV target cells, providing a biological mechanism for the observed increase in HIV infection. We further identified specific bacterial taxa associated with HIV infection, showing that L. crispatus, but not L. iners, was linked to lower HIV incidence, while genera including Prevotella and Sneathia were associated with elevated inflammation and HIV acquisition. We additionally identified relationships between vaginal and rectal colonization of high-risk bacteria. Finally, germ-free mice intravaginally inoculated with high-risk bacteria had increased numbers of activated mucosal CD4+ T cells.
Conclusions: Our results indicate that cervicovaginal bacteria modulate HIV infection risk and that the predominant microbial communities of South African women place them at increased risk for acquiring HIV. High-risk bacteria engender inflammation through innate sensing by epithelial and mucosal antigen presenting cells in the FGT. These findings and the identification of specific targets within the genital bacterial microbiome may inform future prevention strategies to reduce HIV acquisition in women living in sub-Saharan Africa.

MOLBPEA09

Medroxyprogesterone acetate, unlike norethisterone, increases R5 HIV-1 replication in ecto- and endocervical explant tissue and PBMCs, at physiologically relevant concentrations, by a glucocorticoid receptor-dependent mechanism

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Background: The synthetic progestins, depo-medroxyprogesterone acetate (DMPA) and norethisterone enanthate (NET-EN), are widely used in developing countries as injectable contraceptives, where HIV-1 prevalence is high. Recent epidemiological data show that MPA, unlike NET, increases HIV-1 acquisition in women (HR 1.4), although data for NET-EN are limited. We have previously shown that MPA has relatively potent glucocorticoid (GC)-like activity, unlike NET. We hypothesized that MPA and NET would differentially affect HIV-1 replication due to their differential GC-like actions in HIV-1 target cells, at physiologically relevant concentrations.
Methods: Infection assays were performed in the absence and presence of progestins using HIV-1BAL-RENILLA IMCs in both peripheral blood mononuclear cells (PBMCs) and cervical tissue explants from HIV-1-negative women not on contraception. The GR antagonist RU486 was used to investigate the involvement of the GR in modulating ligand-specific effects.
Results: We show for the first time that MPA, unlike NET, significantly increases HIV-1 replication in human endo- and ectocervical explant tissue at 10 nM (3.8 ng/mL) concentrations detected in the serum of DMPA users. Dose response analysis shows similar effects in PBMCs, with an EC50 of about 15 nM. The results support a mechanism whereby MPA, acting via the glucocorticoid receptor, directly increases HIV-1 replication in HIV-1 target cells and tissue, unlike NET.
Conclusions: The results suggest that the effects on HIV-1 of MPA in injectable contraceptive users are likely to be due, at least in part, to its GC-like actions and unrelated to hypoestrogenism. Collectively, the data suggest that NET, unlike MPA, would be a safer choice of injectable progestin contraceptive in young women in high risk areas for HIV-1 infection.

MOLBPEA10

HIV-1 up-regulates endogenous Galectin-3 to facilitate virological synapse formation and CD4+ T cell-to-cell transmission

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Background: Galectin-3 (Gal-3), a β-galactoside-binding lectin, promotes HIV-1 budding via associations with Alix and Gag. Gal-3 localized in membrane lipid rafts regulates dendritic cell migration. Researchers have shown that HIV-1 spreads between T cells by forming supramolecular structures called virological synapses (VSs), which crucially depend on lipid rafts for integrity and cell-to-cell HIV-1 transmission. We hypothesized that Gal-3 may also play a role in cell-to-cell HIV-1 transmission.
Methods: Immunofluorescent assay and memebrane flotation assays were used to evaluate the colocalization Gal-3 with Gag, Alix and GM1 and virological synapse (VS) formation in Gal-3 expression or knockdown CD4+ T cells. Cell-to-cell transmission assay and FACS were used for valuation of regulating effect of Gal-3 on HIV-1 transmission via VS. Mass spectrometry was conducted to analyze the lipid raft components alteration by Gal-3.
Results: Immunofluorescence staining and immunoblotting data indicate that HIV-1 infection induces Gal-3 up-regulation in CD4+ T cells; translocates with Alix, Gag, and GM-1 to cell-to-cell interfaces, and facilitates VS formation. Time-lapse confocal images show the co-transfer of Gal-3 with Gag between HIV-1 effector and target cells. Membrane flotation data indicate that Gal-3 expression regulated the coordination of Alix, Gag, and flotillin-1 into plasma membranes fractions. Functional cell-to-cell transmission data suggested a significant correlation between HIV-1 transmission efficacy and Gal-3 levels in CD4+ T cells. Other results indicate that Gal-3 expressed in effector cells plays a more important role in facilitating HIV-1 cell-to-cell transmission, than the protein present in target cells. Mass spectrometry and cholesterol quantification data indicate higher levels of sphingomyelin, phosphatidylcholinesphosphatidylcholine, and cholesterol in the membrane lipid rafts of Gal-3-positive CD4+ T cells compared to CD4+ T cells subjected to Gal-3 knockdown. In short, we found evidence that endogenous Gal-3 up-regulates lipid raft components of CD4+ T cells and facilitates intercellular HIV-1 transmission
Conclusions: This study indicates that endogenous Gal-3 is up-regulated by HIV-1 and further facilitates HIV-1 cell-to-cell transmission. We suggest that endogenous Gal-3 is a potential target for HIV-1 intervention.

MOLBPEA11

Colorectal distribution of lymphocytes and cell-free HIV surrogate in autologous seminal plasma following simulated anal intercourse

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Background: Unprotected anal intercourse remains the greatest HIV sexual transmission risk for men who have sex with men (MSM). Rational design of topical rectal antiretroviral microbicides depends critically on understanding the spatiotemporal distribution of HIV infectious elements throughout the colorectal space. The objective of this study was to explore the luminal distribution and clearance of cell-associated (lymphocytes) and cell-free (seminal plasma) HIV surrogate within the distal colon following simulated receptive anal intercourse.
Methods: Six healthy, HIV-uninfected men were recruited and gave semen samples in sterile containers. Samples were centrifuged and the supernatant (seminal plasma) collected and frozen. Peripheral blood lymphocytes were harvested from subjects via apheresis and labeled with ^{111}Indium (In)-oxide on the dosing day. ^{111}In-labeled autologous lymphocytes and ^{99}Technetium (Tc)-sulfur colloid (HIV surrogate) were reconstituted with 3 mL of autologous seminal plasma. Reconstituted seminal plasma was inserted into the rectum using a phallic device with artificial urethra; the device was manipulated to simulate the physical stresses of coitus. Distribution of radiolabels in time and space was assessed with SPECT/CT at 3 timepoints.

Analysis of radiolabel distribution was performed using a flexible principal curve algorithm in R. Pharmacokinetic distance parameters were defined as follows: Dmin (most distal signal, closest to the anorectal junction); DCmax (point of greatest luminal concentration); Dave(average distance, similar to mean residence time); & Dmax (most proximal signal, furthest from the anorectal junction).
Results: Quantitative colonic luminal distance parameters are summarized in the Table for the 1 hour SPECT/CT scans. Differences between cell-free and cell-associated HIV surrogates were not statistically significant; neither were differences among 1, 4, and 8 hour images.

	Cell-Associated (Lymphocytes; In)		Cell-Free (Sulfur colloid; Tc)	
PK Distance Parameter at 1 hour	N	Median (IQR) (cm)	Median (IQR) (cm)	p-value (t-test)
Dmin	6	0.95 (-0.08, 3.45)	1.73 (-0.08, 2.92)	0.75
Dave	6	6.13 (5.15, 8.44)	7.12 (5.23, 7.23)	0.77
DCmax	6	6.15 (5.22, 8.51)	7.08 (5.45, 7.57)	0.73
Dmax	6	14.59 (13.63, 15.78)	16.46 (13.73, 16.92)	0.76

[Distribution of HIV Through Colorectum]

Conclusions: Cell-free and lymphocyte-associated HIV distribution throughout the rectosigmoid can be quantified spatiotemporally. Both autologous lymphocytes and HIV surrogate particles in seminal plasma distribute to a maximal distance of approximately 15 cm from the anorectal junction, with a maximal concentration approximately 6 cm from the anorectal junction. This provides a target anatomic distribution for topical rectal microbicide product development.

MOLBPEA12

Development and *in silico* evaluation of a novel formulation of oral long-acting antiretroviral therapy

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Background: Global access and adherence to antiretroviral therapy (ART) is limited by high pill burdens. Investigational long-acting formulations exist, but administration requires injection or implantation. Here we sought to develop an oral system for long-acting ART, and create a mathematical-modeling framework to guide the development of extended-release formulations.
Methods: A polymer matrix capsule loaded with ART was engineered, and evaluated in large swine. Device stability and drug release kinetics were measured longitudinally. To predict in vivo therapeutic outcomes with this formulation, we developed a multi-scale model of ART within individual patients. The pharmacokinetic component predicts drug disposition throughout the body (e.g. plasma, lymph; population mean/variance) by simulating absorption, distribution, metabolism, and excretion using physiochemical principles. The pharmacodynamic component relates instantaneous drug levels to suppression of viral replication using ex vivo efficacy measurements. The viral dynamics component tracks active and latent infection, with drug-level-dependent infectivity rates. Drug-sensitive and resistant viral strains interact by mutation and selection, and are defined by existing laboratory or clinical identification of resistance pathways. To model PrEP, we also developed and calibrated a mechanistic model of HIV transmission.
Results: Our device continually released drug (DTG, RPV, CAB) for 7+ days post-dosing in pigs and maintained plasma concentrations well above the daily trough levels of immediate-release formulations. Based on these findings, we used our model to evaluate the therapeutic potential of weekly oral long-acting ART. We predict that long-acting DTG and RPV for maintenance monotherapy is similarly effective as daily formulations, for a range of adherence levels, and substantially more effective if individuals who missed scheduled doses can restart any day of the week. The fraction of treatment failures accompanied by resistance increases with long-acting RPV but not DTG. For PrEP, our model reproduces the dose-dependent efficacy of TFV-based regimens, and predicts that DTG could be highly-effective as PrEP, with over 95% relative-risk-reduction in transmission with perfect adherence and over 50% up to 10 days after the last dose.
Conclusions: This work presents the first pre-clinical development of an orally-delivered long-acting ART formulation, and provides a modeling framework for risk-benefits analysis of these dose regimens and prioritize them for clinical evaluation.

MOLBPEA13

Ledgins hamper the establishment of a reactivation competent HIV reservoir

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Background: Since HIV integrates into the host genome, it can persist for life in a latent reservoir. HIV integrase uses LEDGF/p75, a host co-factor, to target integration towards transcription units. LEDGINs were developed to block this interaction, but they also allosterically inhibit integrase and lead to aberrant progeny virus. Since a sterilizing cure remains elusive and integration sites may influence viral latency, we investigated if LEDGINs could alter integration site distribution and thus affect the latent reservoir.
Methods: Integration sites were amplified by linker-mediated PCR and sequenced using 454/Roche pyrosequencing. To test reactivation potential, we infected with various cell lines (SupT1, MT4 and Jurkat cells) and primary activated CD4+ T cells, with a double-reporter virus (OGH, Chavez et al., 2015). LEDGINs were either added during infection with or production of the virus. We reactivated cells with TNFα and measured viral reactivation by flow-cytometry to detect reporter gene expression. Finally, we infected primary activated CD4+ T-cells with wild type NL4.3 virus and treated them with LEDGIN or raltegravir. Cells were reactivated with PMA and PHA and virus production was measured by p24 ELISA.
Results: In cell lines, LEDGIN treatment during infection strongly reduced infectivity. Residual proviruses were shifted out of transcription units in a dose-dependent manner. LEDGIN treatment during both infection and virus production increased the latent fraction of the residual reservoir and made the reservoir less prone to reactivation.
In activated CD4+ T-cells, both LEDGIN and raltegravir hindered HIV infection, but only LEDGIN treatment made the residual reservoir refractory to reactivation.
Conclusions: LEDGINs strongly inhibit viral integration and replication and retarget residual integration sites out of transcription units. The resulting reservoir is significantly smaller, more latent and refractory to reactivation. LEDGINs will thus be useful to study latency in vitro. In vivo, LEDGINs may help silence the latent reservoir when administered as part of PrEP or early during acute infection. This could contribute to longer treatment intervals or HIV remission, although this remains to be tested. Further investigation is also need to determine if LEDGINs could also influence the reservoir in chronic infection.

MOLBPEA14

A subset of bnAbs exhibit broad binding to primary CD4+ T cells infected with reactivated reservoir HIV *in vitro*

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Background: Broadly neutralizing antibodies (bNAbs) against HIV are defined by their breadths of reactivity against globally diverse HIV isolates. These bnAbs hold potential as curative therapeutics if they can bind to reactivated latent reservoirs, targeting these for elimination by natural killer and phagocytes. We evaluated the binding of bnAbs to reservoir virus that had been reactivated from participant CD4+ T-cells. Intra- and inter- participant breadths of reactivity were assessed with a panel of bnAbs by testing binding to multiple reservoir viruses each from 6 individuals.
Methods: Quantitative viral outgrowth assays (QVOAs) were performed with CD4+ T-cells from participants on long-term ART. A panel of bnAbs were conjugated with fluorophores, and tested for surface binding to cells from p24+ QVOA wells.
Results: We observed substantial heterogeneity in the binding of different bnAbs to cells infected with reactivated reservoir virus. The V3-Glycan antibody 10-1074 and the V1/V2 antibody PG9 exhibited potent and highly-specific binding to HIV-infected (Gag+) cells from 4/6 participants. PG9 additionally bound to a subset of viral isolates from the 2 remaining participants, while 10-1074 showed mixed binding to viruses from one and a lack of binding to viruses from the other. PGT-121 (V3-Glycan) exhibited particularly strong binding to HIV-infected cells for all 35 viral isolates (6 participants), but also appreciable binding to bystander cells (Gag-). The CD4 binding site bnAb 3BNC117 and the MPER bnAb 2F5 each exhibited specific binding to infected cells in 2/6 individuals. The remaining antibodies exhibited either little binding or limited specificity for Gag+ cells for each of the viruses tested in this in vitro assay (2G12, VRC01, VRC07, N6, 10E8, 4E10, PGDM1400, CAP256.VRC26.25).
Conclusions: BnAbs exhibit distinctive binding profiles for HIV-infected primary CD4+ T-cells, which may not fully parallel neutralization potency. Encouragingly, the bnAbs which bound well to HIV-infected cells exhibited substantial coverage

of reactivated reservoir virus with PGT121, PG9, and 10-1074 binding to 35/35, 31/35, and 27/35 isolates, respectively. Our results add further support to the idea that bnAbs may contribute to 'kick and kill' strategies, and provide guidance on the selection of bnAbs based on magnitude, specificity, and breadth of binding.

MOLBPEA15

Rapid CTL recognition of HIV-1 latently infected cells depends on the levels of inducible viral reactivation and CTL activation status

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Background: HIV-1 "shock and kill" cure strategies depend on the induction of viral transcription in HIV-1 latently infected cells by latency-reversing agents (LRAs), and the clearance of reactivated cells by cytotoxic T-lymphocytes (CTL). However, the therapeutic window of opportunity between HIV-1 latency reversal and CTL recognition is unknown. Here, we aimed to investigate the kinetics of CTL recognition and killing of HIV-1 reactivated cells by LRAs.
Methods: We developed an HIV-1 "Resting-Like model" (RELI) to measure HIV-1 inducible reactivation and CTL killing in the presence of LRAs. We assessed the kinetics of CTL recognition and killing at 3, 6 and 20 hours after coculturing LRAs-treated cells with HLA-matched CTLs. We measured CD107a, MIP1β and IFNg secretion as a surrogate marker of CTL activation and reduction of intracellular p24 in cocultures as readout of killing. We monitored the impact of continuous antigenic exposure in CTL exhaustion by PD1/LAG3/TIM3/CD39 expression and we evaluated changes in the killing of LRAs reactivated cells by CTL.
Results: We detected HIV-1 reactivation in RELI cells after LRAs treatment with SAHA (4-fold; p<0.005) and Panobinostat (2-fold; p<0.05). LRAs-driven reactivation increased CTL clearance of HIV-1 infected cells (p<0.05). In terms of kinetics, we observed killing of reactivated cells by CTLs from 3 hours in SAHA and SAHA/Bryostatin conditions (p<0.05). By contrast, Panabinostat reactivated cells exhibited slower kinetics of CTL killing which magnitude increased with the addition of Bryostatin. The kinetics of CTL activation showed an augment in CD107a and MIP1β expression and a reduction of IFNg production from 3 hours post-coculture. In addition, Bryostatin-treated cells induced higher levels of CTL cytokine expression in the absence of virus reactivation. Upon continuous antigen exposure, up-regulation of LAG3/TIM3/CD39 by CTLs was associated with reduced killing of reactivated cells (p<0.05).
Conclusions: LRAs induce viral proteins expression and increase CTL recognition and killing of HIV-1 reactivated cells. Rapid killing of HIV-1 reactivated cells by CTLs depends on the LRAs potency and the CTL pre-activation status, which can be modulated by Bryostatin. Our results have direct implications for the optimization of "shock and kill" therapeutic strategies.

MOLBPEA16

CXCR5-transduced primary rhesus macaque CD8 T cells accumulate in B cell follicles in a novel *ex vivo* B cell follicle migration assay

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Background: CD8 T cells are crucial for controlling both human and simian immunodeficiency virus (HIV/SIV) infections. Low levels of virus-specific CD8 T cells within B cell follicles permit ongoing replication of HIV and SIV. The B cell homing molecule, CXCR5, is required for homing to B cell follicles. We hypothesize that engineering virus-specific CD8 T cells to express CXCR5 will enable them to home to B cell follicles and suppress viral replication. To begin to test this hypothesis we developed a novel ex vivo B cell migration assay.
Methods: We first determined the optimal time that lymph node tissue slabs could be incubated and maintain follicular morphology. Next we evaluated whether CD8 T cells engineered to express CXCR5, accumulated within B cell follicles. We transduced CD8 T cells from SIV infected rhesus macaques, with a control vector or a CXCR5 transducing vector, labeled with a live cell dye CTV, layered these cells onto 300um thick fresh tissue slabs and incubated for six hours. Sections were then fixed and stained via IHC with anti-CD20 to stain B cell follicles. Sections were imaged using a confocal microscope and CTV labeled cells were quantified inside and outside of B cell follicle.
Results: We determined that follicular morphology was maintained after 4 and 6 hours of incubation, but was lost after overnight incubation.
Preliminary migration results showed a fivefold increase in the follicular to extra follicular ratio (F: EF) of CTV labeled cells in the CXCR5 transducing vector samples compared to control samples.
Conclusions: We successfully created an ex vivo B cell migration assay. Preliminary results using this assay suggest that CXCR5 transduction induces T cell migration into B cell follicles.

MOLBPEA17

Detection and activation of naive B cells expressing the germline precursors of protective antibodies

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Background: Various strategies are being pursued to identify and characterize the precursors of bNAbs, as a way to guide HIV immunogen-design approaches. In many cases, the precursors of bNAbs do not bind Env, which limits the design of appropriate immunogens. b12 is a CD4 binding site antibody that neutralize ~40 % of circulating HIV-1 strains. However, none of the 80 recombinant Envs that we screened bound germline b12 (glb12).
Methods: To overcome this obstacle, we developed anti-idiotypic antibodies against the predicted glb12 and obtained crystal structures of two anti-idiotypic antibodies, ib2 and ib3 in complex with glb12.
Results: The structures revealed that the two antibodies contact germline b12 in different manners. Interestingly, ib2 interacts with glb12 heavy chain only, similarly to gp120 interactions with b12. ib2 CDRH3 inserts between glb12 CDRH3 and CDRH1 in an identical manner as the CD4 binding loop of gp120 CD4 interacts with b12. ib3 contacts glb12 with a different angle, facing the glb12 combining site. We then used the ib2 anti-idiotypic antibodies to isolate very efficiently germline b12-like antibodies from HIV-1 negative patients, something that is not feasible using recombinant Env.
Conclusions: In conclusion, anti-idiotypic antibodies against predicted glb12 can be used to isolate glb12-like antibodies and the knowledge of their interactions with glb12 should guide further immunogen design.

MOLBPEC25

The impact of mass incarceration of African American men on HIV acquisition among African American women: an agent-based modelling study

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Background: The United States has the highest incarceration rate in the world, with significant racial disparities. Incarceration can increase HIV risk behaviors and may be a driver of HIV acquisition for women. Our objective was to estimate the impact of mass incarceration of African American men on HIV acquisition among African American women.
Methods: An agent-based model simulated HIV transmission in a dynamic sexual-contact network representing all heterosexual African American men and women living in Philadelphia from 2005-2015. The model was calibrated using epidemiologic surveillance data. Informed by current literature, incarceration and partner incarceration increased the number of sexual partners and decreased HIV care engagement for men post-release. To quantify the impact of incarceration, we compared a status quo scenario (i.e., calibrated model with current incarceration rates) to one in which there was no incarceration. Since there is a pronounced racial disparity in incarceration rates, we also compared the status quo model to one in which the incarceration rate for African American men was equal to that for white

men in Philadelphia. Our outcome was the average number of HIV transmissions among African American women during the study period.
Results: On average, the status quo scenario resulted in 1,775 (95% Simulation Interval [SI]: 1,480-2,140) new HIV infections among women over ten years. The scenario with no incarceration decreased HIV transmissions to 1,638 (95% SI: 1,380-1,990), resulting in 137 averted infections, while the scenario without racial disparities in incarceration resulted in 1,709 (95% SI: 1,410-2,030) HIV transmissions, and 66 averted infections. A sensitivity analysis increasing the duration of male post-release high-risk sexual behavior from six to twelve months intensified the impact of incarceration: 169 infections were averted in the no incarceration scenario, and 77 infections averted in the no disparities scenario.
Conclusions: The mass incarceration of African American men increases HIV acquisition among African American women. Our findings emphasize the importance of ending mass incarceration and the impact of substantial racial disparities in incarceration rates. Future research should evaluate points of intervention that may lessen the impact of incarceration, such as improving HIV care engagement post-release.

MOLBPEC26

Estimated hepatitis C prevalence and key population sizes in San Francisco: a foundation for elimination

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Background: Initiated in 2016, End Hep C SF is a comprehensive initiative to eliminate hepatitis C (HCV) infection in San Francisco. The introduction of direct-acting antivirals (DAAs) to treat and cure HCV provides an opportunity for elimination. To properly measure progress, a baseline estimate of HCV prevalence, and of the number of people in various subpopulations infected with HCV, is required to target and measure the impact of interventions.
Methods: Our estimates are based on triangulation of data found in case registries, medical records, cohort studies, and published literature from 2010 through 2017. We stratified the population by sex, age and/or HCV risk group, and estimated the population size and HCV prevalence in each group. When multiple sources of data were available, we calculated a weighted average using inverse variance weighting. Credible ranges (CRs) were derived from 95% confidence intervals of population size and prevalence estimates.
Results: We estimate that 23,311 residents of San Francisco are HCV seropositive (Credible Range: 11,281-43,997), representing an overall seroprevalence of 2.7% (CR: 1.3%-5.1%). Of these, 17,517 are estimated to be viremic (CR: 7,114-38,968), but this estimate includes treated (and cured) cases. People who inject drugs (PWID) represent 69.9% of viremic HCV infections. Of those MSM with HCV viremia, 1,656 (CR: 823-2,748), or 73% (CR: 73-75%) are estimated to be co-infected with HCV and HIV. Results are summarized in the table.

Subpopulation	# HCV seropositive (CR)	HCV seroprevalence (CR)	% of citywide HCV seropositives (CR)	% of citywide HCV viremics (CR)
PWID	15,988 (8,852-23,592)	65.3% (63.1-67.5)	68.6%	69.9%
MSM	3,057 (1,634-4,535)	4.4% (2.4-6.4)	13.1%	12.9%
HIV+ MSM	***2,269 (1,634-3,455)***	***15.7% (8.8%-22.7%)***	***9.7%***	***7.1%***
Transgender Women (low SES)	211 (132-299)	22.1% (14.9-29.5)	0.9%	0.9%
Baby Boomers	8,917 (4,256-16,221)	4.4% (2.2-7.5)	38.3%	37.8%
Men	16,872 (8,503-29,261)	3.8% (2.0-6.5)	72.4%	71.7%
Women	6,228 (2,645-14,447)	1.5% (0.6-3.4)	26.7%	27.3%
Total	***23,311 (11,281-43,997)***	***2.7% (1.3-5.1)***	***100.0%***	***100.0%***

[Summary of Estimated HCV Burden by Subpopulation]

Conclusions: Our estimate provides a useful baseline against which the impact of End Hep C SF can be measured. We estimate approximately 9,000 more HCV seropositive cases than are included in the San Francisco HCV case registry.

MOLBPEC27

The impact of HIV self-testing on recent testing, status knowledge, and linkage to care among female sex workers in Kampala, Uganda: a randomized controlled trial

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Background: HIV self-testing (HIVST) is a promising new testing strategy for female sex workers (FSW) because it has the potential to reduce testing barriers for this population, i.e. provider stigma and discrimination. We explored the impact of HIVST via different delivery platforms on recent testing, status knowledge, and linkage to care among FSW in Kampala, Uganda.
Methods: FSW peer educators each recruited and enrolled 8 eligible participants. Peer educator-participant groups were randomized to one of three study arms:
(1) distribution of a HIVST,
(2) distribution of a HIVST coupon (exchangeable at specified clinics), or;
(3) referral to standard testing services, all by the peer educator.
Participants in the intervention arms received two HIVSTs or coupons, one after enrollment and one three months later. Participants completed baseline, one-month, and four-month assessments. HIV status knowledge was assessed at four months with a perceived conditional cash transfer; participants received ~1 USD if their reported HIV status matched the results of a rapid test.
Results: 960 participants were enrolled from October to November 2017; median age was 28 years (IQR: 24-32). Relative to the standard arm, recent HIV testing was more common in the HIVST arm at one-month (95.2% HIVST vs. 71.5% standard, P=< 0.001) and both intervention arms at four-months (45.9% standard; 59.5% HIVST, P=0.04; 62.3% coupon, P=0.008). There were no significant differences in correct HIV status knowledge across study arms at four-months (88.0% standard; 88.1% HIVST, P=0.96; 86.9% coupon, P=0.73). Among those testing positive, there was no difference in linkage to care between HIVST and standard arms. Linkage was lower in the coupon arm compared to the standard arm at both follow-up assessments (one-month: 24.1% coupon vs. 64.1% standard, P=0.001; four-months: 49.2% coupon vs. 75.0% standard, P=0.02).
Conclusions: HIVST is acceptable among FSW in Kampala, Uganda. Compared to standard testing, HIVST increased rates of recent testing, but did not change correct HIV status knowledge and resulted in decreased linkage to care among HIV-positive participants who received HIVST coupons. In order for HIVST to reduce gaps in the HIV treatment cascade, additional efforts are need to ensure individuals correctly interpret the HIVST results and link to care.

MOLBPEC28

The impact of a real-world pre-exposure prophylaxis program on HIV transmission among men who have sex with men: an agent-based modelling study

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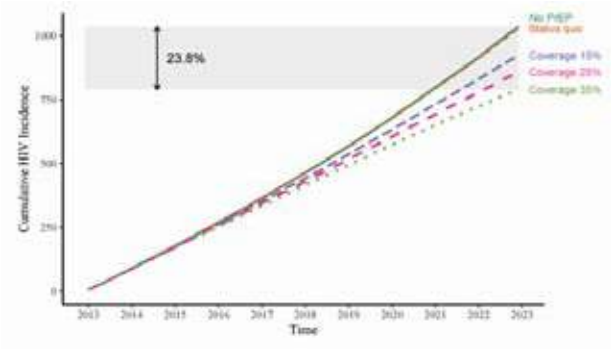
Background: In the United States, men who have sex with men (MSM) continue to be disproportionately impacted by HIV. Pre-exposure prophylaxis (PrEP) has emerged as an important preventive intervention, but the impact of PrEP implementation on population-level HIV incidence remains unknown.
Methods: We used an agent-based model to evaluate the impact of a real-world clinical PrEP program which provides the majority of PrEP care in the state of Rhode Island. We simulated HIV transmission among all MSM (N = 23,815) in the state between 2013 and 2023. In a status quo scenario, PrEP was scaled up until 2023 based on the initiation rate and partner number distribution observed within the current PrEP program. Several hypothetical scenarios were modelled to determine the scale-up required to substantially reduce HIV incidence. We compared incidence across scenarios and calculated the person-years on PrEP per averted infection (PYPAI). Estimates are presented as medians with 95% simulation intervals (SI).

Results: A total of 203 prescriptions were provided to MSM between February 2013 and October 2016. Assuming linear scale-up, 1.3% of the at-risk MSM population is projected to be on PrEP after 10 years. In the absence of PrEP, 1037 (95% SI: 917.9, 1163.0) new infections would occur by 2023 (Figure). Under the status quo, approximately 7.2 infections would be averted (95% SI: -121.8, 127.3), amounting to 191 PYPAI (95% SI: 10.9, 1381.8). With 35% of MSM taking PrEP by 2023, 247.2 (95% SI: 149.2, 337.3) transmissions would be avoided, nearly a 24% decrease, resulting in 162 PYPAI (95% SI: 119.1, 269.2).



[Cumulative HIV incidence over 10 years]

Conclusions: Among MSM in this setting, current PrEP implementation programs are having a modest impact on HIV incidence. To achieve a 25% reduction in new infections, dramatic and sustained scale-up of PrEP is required.

MOLBPEC29

A field safety and acceptability study of PrePex male circumcision device when removing the foreskin shortly after device placement

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Background: This study was designed to validate the safety and efficacy of an adjusted PrePex procedure of removing the foreskin shortly after device application on day 0 (FRP). An initial assessment in Rwanda showed this procedure is feasible without injected anesthesia 30 to 60 minutes after device placement.
We validated that the updated procedure maintains the device non-surgical advantages while resolving some of the procedure limitations, such as anaerobic environment that may be prone for anaerobic bacteria growth, odour and foreskin hygiene.
Methods: Between March 2017 to May 2017, study procedures were performed in 2 mobile offices close to health care facilities in Lusaka and Livingstone, Zambia. 500 eligible male subjects scheduled for circumcision ages 13 to 49 were enrolled, the average age was 22.7 years (SD6.7).
The study was conducted in 2 phases:
Phase 1 (Establishing FRP protocol), 119 subjects.
Phase 2 (Validating the procedure), 381 subjects.
Results: For all 500 subjects, there was no need for injected anaesthesia for the FRP, 96.4% reported no pain at all, the average reported pain for the remaining 4.6% was 2.66 (VAS of 0 to 10 was used to evaluate subject reported pain).
The average waiting time from placement to FRP was 36 minutes.
During the 1st phase, while the FRP protocol was not yet established, there were 5 bleeding events (AE rate of 5%), 4 requiring device removal and sutures. At the 2nd phase, with an established FRP protocol, there were 2 bleeding events only, 1 requiring device removal and sutures (AE rate of 0.5%).The difference between the AE rates of both groups was statistically significant (p< 0.003).
Conclusions: This study demonstrates that removing the foreskin after device placement is safe and easy to perform while eliminating some of the device limitations, most importantly per WHO guideline it puts the device at the same tetanus risk level as surgical circumcision reducing the requirements for 2 tetanus toxoid contacting vaccine prior to PrePex.
This study will significantly contribute to the continuation of PrePex implementation in VMMC programs halted in 2016 following WHO tetanus guidelines.

MOLBPEC30

The impacts of a demand-side VMMC incentives program on the male circumcision rate in 2 districts in Malawi: a synthetic control approach

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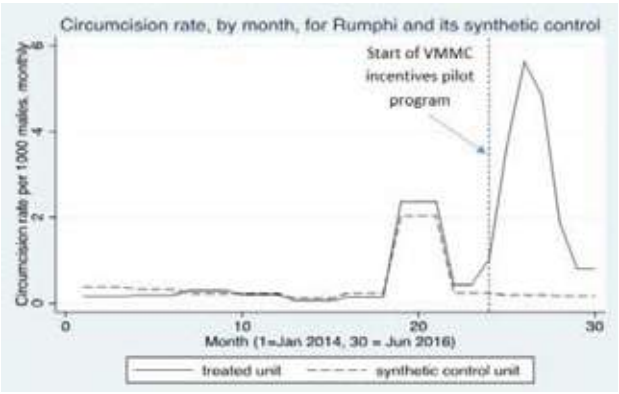
Background: Voluntary Medical Male Circumcision (VMMC) is an effective HIV prevention intervention. The Malawian government responded to the need to increase VMMC, but progress has been slow and innovative solutions were needed to increase VMMC uptake. In this light, the Malawi National AIDS Commission undertook a study of using incentives to create VMMC demand in Mchinji and Rumphi districts. This pilot program, implemented from Oct 2015 to April 2016, extended in-kind incentives to primary and secondary schools, as well as school-based mother groups, with the value determined by the number of young men voluntarily undergoing VMMC at their District Hospital.
Participating organizations also offered vouchers to potential circumcision clients and their caretakers - and a second set to hand out to their friends and caregivers - that covered the cost of transport for them and their caregiver for the procedures and two follow-up visits.
Methods: Synthetic control methods are used to estimate the causal effect of the program on the circumcision rate of males 14-34 years old. Information on VMMC rates for the two years before study onset, as well as district-level socio-demographic and health information, inform the synthetic counterfactual for each of the study districts. Permutation tests establish the robustness of impact estimates.
Results: The program led to a substantial increase in circumcisions: an additional 16.05 male circumcisions per 1,000 adult males in Rumphi (see Figure 1), and an additional 9.15 in Mchinji. Overall, an individual who received a voucher was 7 times more likely to be circumcised than someone who had not received one. Complementary qualitative findings suggest that mothers' groups were more effective in motivating young men due to personal attention, and that caregivers play an important supportive function in the circumcision decision.



[Figure 1 - Rumphi results]

Conclusions: Despite implementation challenges, VMMC incentives are highly effective in increasing the circumcision rate from low baseline levels.

MOLBPEC31

No change in health-related quality of life for at-risk U.S. women and men starting HIV pre-exposure prophylaxis (PrEP): findings from HPTN 069/ACTG 5305

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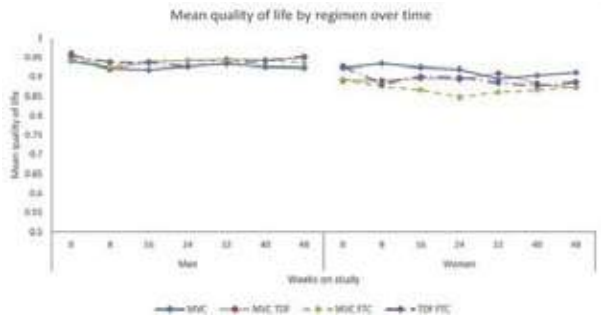
Background: Tenofovir (TDF)-containing PrEP is effective for HIV prevention, but its effect on health-related quality of life (QOL) is unknown. Using data from HPTN 069/ACTG 5305, a randomized trial of potential PrEP regimens comparing maraviroc (MVC) alone, or together with TDF or emtricitabine (FTC), to TDF/FTC (control), we evaluated the impact of these regimens on QOL in at-risk HIV-uninfected U.S. women and men.
Methods: QOL was measured at baseline (before starting medications) and every 8 weeks until week 48 using the EQ-5D, a validated instrument. Responses were converted to health utilities, on a scale from 0.0 to 1.0, using published valuation weights. Mean utilities were compared between groups at each time point using nonparametric statistical testing. Multivariable linear regression was used to adjust for potential confounders.
Results: We analyzed data from 186 women (median age 35 years, 65% black, 17% Hispanic) and 405 men (median age 30 years, 28% black, 22% Hispanic), including 9 transgender participants analyzed based on phenotypic sex. Mean baseline QOL was 0.91 for women and 0.95 for men. There were minimal changes in mean QOL for any regimen from baseline over time (Figure). Mean QOL did not differ significantly by regimen at any time point, both unadjusted and after adjustment for age, race/ethnicity, alcohol use, opiate use, other substance use, or adherence. There were no significant differences between participants who continued the regimen (n=396) compared to participants who discontinued (n=107).
Conclusions: QOL in at-risk individuals starting candidate HIV PrEP regimens in a clinical trial is similar to the general population and maintained over time. This finding did not vary among regimens or when adjusted for demographics, adherence, and substance use. Our findings are the first to show that starting a candidate PrEP regimen in at-risk HIV-uninfected U.S women and men was not associated with significant changes in QOL.



[Figure - Mean Quality of Life by Regimen Over Time]

MOLBPEC32

HPTN 076: safety and pharmacokinetics of rilpivirine LA through week 76 in HIV-uninfected women

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Background: Long-acting injectable agents may be an alternative to daily oral tablets for pre-exposure prophylaxis (PrEP). HPTN 076 evaluated safety and pharmacokinetics of the long-acting injectable form of rilpivirine (RPV LA) for 76 weeks.
Methods: HPTN 076 was a phase 2, double-blind, 2:1 randomized trial comparing the safety of 1200mg RPV LA (LA) to placebo (P) in low risk, sexually active HIV-uninfected women in the United States (US), South Africa and Zimbabwe. After four weeks of daily oral product, participants received the injectable product every eight weeks. Each dose consisted of two gluteal, intramuscular (IM) injections, the last dose was at Week 44 and participants were followed until Week 76. All samples collected on the same day as injection administration were obtained prior to dosing.
Results: Of 136 enrolled women, 122 (80 LA, 42 P) received ≥ one dose; 98 (64 LA, 34 P) received all six. From Week 4 to 76, there were 16 product discontinuations (10 LA, 6 P); 6 (8%) LA and 2 (5%) P were due to AEs. There were no significant differences between two arms in AEs, including liver abnormalities, and one seroconversion occurred in the P arm. Three LA and no P arm participants developed Gr ≥3 injection site reactions.
The median plasma RPV trough concentration (C_{Trough}) at Week 52, was 92 ng/mL, 94% > PA-IC_{90} (12.5ng/mL); at Week 76, plasma RPV concentration (C_{W76}) was 44.2 ng/mL, 92% > PA-IC_{90}. Among participants receiving all six injections, the median plasma C_{W76} was 47.7 ng/mL, 100%> PA-IC90. In five women who received only the first injection at Week 4, C_{W76} < PA-IC90, but only one was below detectable level (1.0 ng/mL). Week 36/44 C_{Trough} in cervico-vaginal fluid (N=80) and vaginal tissue (N=16) had medians of 90 and 60 ng/g respectively, moderately correlating with contemporaneous plasma concentrations (Spearman correlation ρ=0.53, 0.32, p=<0.0001, 0.23).
Conclusions: RPV LA, 1200 mg IM every eight weeks was well tolerated and safe through 76 weeks in African and US women. RPV plasma concentration at Week 76 was above the PA-IC90 in 92% and detectable in 99% of participants.

MOLBPEC33

Tenofovir enema as HIV PrEP for receptive anal intercourse: safety, pharmacokinetics, pharmacodynamics and acceptability (DREAM 01)

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Background: Unprotected receptive anal intercourse (uRAI) carries a high risk of acquiring HIV. Large trials demonstrate efficacy of oral tenofovir (TFV)-based pre-exposure prophylaxis (PrEP), though poor adherence reduces efficacy and systemic drug exposure has associated toxicities. Pericoital douching is commonly practiced with uRAI. Therefore, a behaviorally-congruent pericoital medicated enema could provide uRAI PrEP for those who struggle with oral PrEP or prefer topical methods.
Methods: Six healthy, HIV-uninfected men received a single 125 mL rectal enema containing 220mg TFV. Plasma, PBMCs, rectal fluid, and colon tissue were sampled for TFV and activated TFV-DP concentration. Four participants re-

ceived a ^{99}Tc-DTPA labelled enema to assess colonic distribution using SPECT/CT imaging. Colon biopsies assessed ex vivo explant susceptibility to HIV infection. Acceptability was assessed via questionnaire.
Results: No related Grade 2 or higher adverse events were observed. All participants said they would be likely or very likely to use the enema, especially applying it before uRAI, if it protected against HIV. Drug concentrations (median [range]) are presented in the Table.

Post-Dose	Plasma TFV	Tissue TFV	Tissue TFV-DP	Tissue Cell TFV-DP
Hours	*ng/mL*	*ng/mg*	*fmol/mg*	*fmol/10^6 cells*
1	1.9 (0.4, 9.1)	94 (39, 150)	907 (135, 1680)	1100 (793, 1407)
3	4.3 (1.0, 21.7)	16 (13, 992)	562 (BLQ, 1855)	4081 (16, 24782)
24	0.8 (BLQ, 1.9)	10 (1, 95)	82 (BLQ, 200)	1799 (823, 2670)
72	BLQ (BLQ,BLQ)	2 (1, 3)	111 (BLQ, 221)	103 (BLQ, 206)

[DREAM 01 Pharmacokinetic Summary]

From 1-24 hours post-dose, median colon cellular TFV-DP concentrations exceeded target concentrations by 1.1-1.7 $\log_{10}$. (Target: TFV-DP 83 fmol/10^6 colon tissue cells, estimated as the TFV-DP level associated with iPrEx IC_{90} dose frequency of 4 doses/week). Observed concentrations were consistent with steady-state daily dosing of 1% TFV rectal gel. SPECT/CT indicated radiolabel distribution from rectosigmoid to splenic flexure in all subjects. Compared to pre-drug baseline, biopsies collected from 1-24 hours after dosing reduced viral replication in ex vivo colon tissue explants by median (quartiles) 0.77 $\log_{10}$ (0.20, 0.81) ($p< 0.01$).
Conclusions: Tenofovir enema is a novel, behaviorally-congruent delivery method for uRAI PrEP. A single dose was safe, well-tolerated, acceptable, and reduced HIV replication in ex vivo explants. Colon cell TFV-DP exceeded by >10-fold the steady-state colon mucosal cell concentrations associated with >90% efficacy (based on modeling iPrEx and smaller pharmacokinetic studies), yet with minimal systemic TFV exposure.

MOLBPEC34

Pooled efficacy analysis of two phase III trials of dapivirine vaginal ring (DVR) for the reduction of HIV-1 infection risk in HIV uninfected women in sub-Saharan Africa

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Background: Efficacy of the DVR in reducing the risk of HIV-1 infection via vaginal intercourse in HIV-1 uninfected women has been demonstrated in two independent, well-controlled Phase III trials, IPM 027 and MTN-020, conducted in four countries in sub-Saharan Africa. DVR is meant to be used in combination with safer sex practices. The pooled efficacy results of these two trials are presented.
Methods: In the pooled efficacy analysis, HIV-1 infection as measured by HIV-1 seroconversion was the primary endpoint. The efficacy analysis was repeated using the time of first detection of HIV-1 RNA as the endpoint. Adherence to DVR use was defined as ≤23.5 mg of residual dapivirine levels in used rings and dapivirine plasma concentrations of ≥95 pg/mL, measures that indicate at least some DVR use during the prior month.
Results: The rate of HIV-1 seroconversion per 100 person-years was 3.7 (95% CI, 3.1 to 4.3) and 5.0 (95% CI, 4.2 to 5.8) in the dapivirine and placebo ring groups, respectively, resulting in a statistically significant reduction in the risk of HIV-1 infection by 27.4% (95% CI, 8.6 to 42.3%; p=0.0063) relative to placebo. This risk reduction was statistically significantly higher (p=0.026) in participants older than 21 years (39.8%, 95% CI, 20.2 to 54.6%) than in participants 21 years or younger (-4.8%, 95% CI, -57.3 to 30.2). Using time of first detection of HIV-1 RNA, use of the DVR showed a statistically significant reduction in the risk of HIV-1 infection of 29.9% (95% CI, 11.8 to 44.3; p=0.023) relative to placebo. For periods in which participants were defined as adherent to at least some DVR use, HIV-1 infection risk reduction improved to 45.3% (95% CI, 27.4 to 58.8%; p<0.0001).
Conclusions: The pooled results of two independent well-controlled Phase III trials of DVR, which achieved similar and statistically significant results, resulted in an overall HIV-1 risk reduction of 27.4%. Higher HIV-1 risk reduction was observed with increased adherence to product use. The maximum level of HIV-1 infection risk reduction from vaginal exposure with consistent ring use cannot be determined based on the available data.

MOLBPEC35

Potential healthcare insurance and provider barriers to PrEP utilization among YMSM

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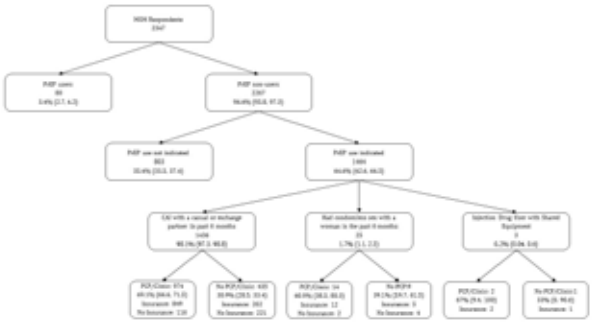
Background: Given the relative low utility of pre-exposure prophylaxis (PrEP) compared to its need, we examined potential healthcare insurance and provider barriers to its utilization among black, Hispanic, and white young adult MSM (YMSM).
Methods: Social media was used to recruit 18-24-year-old black, Hispanic, and white HIV negative YMSM for an online survey on sexual behavior, healthcare access and previous use of PrEP. We identified PrEP-eligible YMSM based on US Centers for Disease Control and Prevention guidelines (condomless anal intercourse (CAI) with men, condomless sex also with women, and injection-drug use with equipment sharing). Multinomial logistic regression was used to identify potential barriers to PrEP usage based on having healthcare insurance and a primary care provider (PCP)/clinic for healthcare.
Results: Of the 2,347 YMSM surveyed, 3.4% had previously used PrEP. Of the non-PrEP users, 65% were PrEP eligible, and of these 59% had both healthcare insurance and a PCP/clinic.



[PrEP Eligibility and Healthcare Access]

In the multinomial regression analysis, age, race/ethnicity, years of formal education, and US geographic region of residence were associated with greater healthcare insurance and PCP/clinic barriers to accessing PrEP among YMSM who were PrEP eligible.

Reference group is full access to care-have both PCP/clinic and healthcare insurance (n=863)

	No PCP/Clinic & No Healthcare Insurance (n=226) OR (95% CI)	No PCP/Clinic, but have Healthcare Insurance (n=208) OR (95% CI)	Have PCP/Clinic, but No Healthcare Insurance (n=118) OR (95% CI)
Age	1.19 (1.08, 1.23)	1.07 (0.98, 1.18)	1.18 (1.05, 1.33)
Race			
White	1	1	1
Black	1.53 (0.96, 2.42)	1.10 (0.72, 1.69)	2.40 (1.38, 4.17)
Hispanic	3.47 (2.43, 4.95)	1.29 (0.91, 1.82)	2.81 (1.74, 4.53)
Education			
Less than high school	2.69 (1.19, 6.08)	1.06 (0.45, 2.49)	6.20 (2.45, 15.68)
High school/GED	4.03 (2.35, 6.91)	1.37 (0.80, 2.36)	2.29 (1.01, 5.18)
Less than bachelor degree	1.34 (0.86, 2.08)	0.75 (0.51, 1.11)	1.91 (1.04, 3.49)
Bachelor degree or higher	1	1	1
Region			
Northeast	1	1	1
Midwest	1.56 (0.91, 2.68)	1.49 (0.89, 2.50)	2.10 (0.93, 4.74)
South	2.08 (1.29, 3.35)	1.52 (0.94, 2.44)	3.16 (1.51, 6.58)
West	1.34 (0.76, 2.37)	2.13 (1.26, 3.60)	3.30 (1.49, 7.31)

[Factors impacting healthcare insurance and provide]

Conclusions: PrEP uptake was low in this population of YMSM, although the potential for expansion is high. Scale up efforts must address potential healthcare insurance and provider barriers related to age, race/ethnicity, geography and education levels.

MOLBPEC36

HVTN 100: the effects of a 12-month booster on immune responses in healthy HIV-uninfected adults vaccinated with ALVAC-HIV (vCP2438) and bivalent subtype C gp120/MF59® in South Africa

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Background: HVTN 100 evaluated an HIV clade C pox-protein vaccine regimen. A 12-month booster was included in the regimen to extend and, ideally, enhance vaccine-induced immune responses. We present effects of this booster on peak post-boost and memory vaccine-induced immune responses.
Methods: We conducted a phase 1-2 randomized, double-blind, placebo-controlled trial administering clade C ALVAC-HIV (vCP2438) (months 0, 1) and the latter plus Bivalent Subtype C gp120/MF59® (months 3, 6, 12). Cellular and humoral immune responses were evaluated at peak (month 6.5 and 12.5) and at durability (month 12 and 18) time-points. IgG binding antibody responses (magnitude and breadth) were measured by HIV-1 binding antibody multiplex assay (BAMA). Intracellular cytokine staining (ICS) measured HIV-specific T-cells expressing interferon-gamma and/or interleukin-2.
Results: Of 252 participants (210 vaccine/42 placebo), 231 samples were available at month 6.5. For all other time-points, samples from a subset of 70 vaccine-recipients and 5 placebo-recipients were evaluated. Antibody responses following the 12-month booster were higher in magnitude and more durable than those following the month 6 vaccination; ICS responses were similar. However, significant waning of binding antibody responses, especially to V1V2 antigens, was seen at month 12 and 18 durability time-points. Evaluating paired samples, month 18 response rates were significantly higher than month 12 for most gp120 (10/13), most gp140 (7/9), and 5/18 V1V2 antigens (p's <0.04). Month 18 magnitudes were significantly higher than month 12 (p<0.04) for all gp120 and gp140 antigens, and for 13/18 V1V2 antigens (p's <0.04) with geometric mean fold-difference 4.32; magnitude/breadth scores were significantly higher as well (p's<0.001). Response rates for Env-specific CD4+ T cells expressing interferon-gamma and/or interleukin-2 declined from 62.1% at month 6.5 (95% CI 50.1%-72.9%) to 35.9% at month 12 (95% CI 25.3%-48.2%; p=0.0003), but increased after the booster to 69.7% at month 12.5 (95% CI 57.8%-79.4%; p<0.0001), and measured 56.9% at month 18 (95% CI 44.8%-68.2%; p=0.275).
Conclusions: A 12-month booster extends binding antibody responses to 18 months after initial vaccination and prolongs robust CD4+ T-cell responses.

MOLBPEC37

Online HIV self-testing: a tool to expand first HIV testing for young high-risk MSM in Brazil

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Background: UNAIDS indicates that less than 50% of men who have sex with men (MSM) have been tested for HIV in Brazil. E-testing is an online, anonymous and free-of-charge HIV self-testing (HIVST) strategy designed to expand HIV testing among MSM in Curitiba, Brazil.
We describe the socio-demographic and behavior profile of E-testing MSM users, as well as the prevalence of and factors associated with first-time testing among HIVST users in this population.
Methods: We developed an online platform for HIVST request/delivery for MSM in 2014. Data were collected between February 2015 and February 2017. The CDC HIV Incidence Risk for MSM scale was used to stratify risk behavior. Logistic regression was performed to assess factors associated HIVST usage as first HIV test.
Results: Over 23,000 unique visitors accessed the online platform and 6040 questionnaires were completed and fulfilled inclusion criteria for HIVST request. Most individuals (72%; n=4356) self-identified as MSM, median age was 25 years, 73% had at least enrolled into college and 31% were first-time testers. The majority of first-time testers (59.4%) were classified as high risk, although 51.5% perceived themselves as having a low chance of acquiring HIV infection in the following year (Table).

	Total, n=4356(%)	Previously tested, n=3002(%)	Never tested, n=1354(%)	P-value*
Age -median(IQR)	25 (21 -29)	26 (22-30)	22 (21-29)	<0.001
Self-reported as white	3324 (76.3)	2332 (77.7)	992 (73.2)	0.004
College education (Complete/incomplete)	2566 (58.9)	1779 (59.3)	787 (58.1)	<0.001
Post-graduation	607 (13.9)	503 (16.8)	104 (7.7)	
Reported a STI diagnosis (prior 6 months)	380 (8.8)	304 (10.1)	76 (5.7)	<0.001
High risk score (prior 6 months)α	2591 (59.5)	1787 (59.5)	804 (59.4)	0.476
Perceives low chance of HIV infection in the next year	2321 (53.3)	1624 (54.1)	697 (51.5)	<0.001
Answered questionnaire between Feb'15-Feb16	2341 (53.7)	1571 (52.3)	770 (56.9)	0.005

The most frequent categories are presented, except for schooling. *Chi-square or rank sum test. αScore ≥ 10 in the CDC HIV Incidence Risk for MSM scale

[Socio-demographic and risk behavior profile of MSM]

Factors associated with being a first-time tester included: being 18-28 vs. ≥41 years (adjusted Odds ratio- aOR- 2.2; CI95% 1.3-3.5), having completed high school or less vs. post-graduation (aOR 2.5; CI95% 1.9-3.2) and college vs. post-graduation (aOR 1.7; CI95% 1.3-2.2), and not having a STD diagnosis in the prior 6 months (aOR1.9; CI95%1.4-2.5). CDC incidence risk score was not statistically associated with first time testing.
Conclusions: The E-testing strategy proved to be an acceptable and feasible approach to expand HIV test coverage among MSM in Curitiba, Brazil. E-testing is now being introduced in other Brazilian cities to reach young MSM who have not previously accessed HIV testing.

Tuesday 25 July
Poster Exhibition

TULBPEB18

Incidental lung cancers and positive CT images in HIV-infected individuals: results from the Copenhagen Co-morbidity in HIV Infection (COCOMO) study

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Background: Several authorities currently recommend lung cancer screening in current or former smokers from the general population. Such recommendations may not be applicable in people living with HIV (PLWHIV).
Methods: We performed low dose chest CT scans (LDCT) and assessed prevalence of histologically proven lung cancers and positive CT images (i.e. pulmonary non-calcified nodules). These outcomes were accessed in the entire cohort and in the high risk group (>50 years and >30 pack-years).
Results: In total, 901 PLWHIV underwent a LDCT. Lung cancer was diagnosed in two individuals, both in the high risk group, constituting 1.8% (95%CI 0.5-6.2) of the high risk subgroup. A positive CT image was identified in 3.1% (2.2-4.5) of the primary cohort and in 9.7% (5.5-16.6) of the high-risk subset. A positron emission tomography was carried out in 10/28 of those with a positive image, 14/28 individuals had one follow-up CT scan, 8/28 individuals had two follow-up CT scans, and 1/28 had three follow-up CT scans. Invasive diagnostic procedures were performed in eight patients. Three localized pneumothoraxes occurred of which none required intervention.

After controlling for age and cumulative smoking, a current CD4 count< 500 cells/μL and CD4 nadir count< 200 cells/μL were each associated with an increased odds of a positive image (OR 2.32 [1.01-5.13, P=0.04] and OR 2.63 [1.13-6.66, P=0.03], respectively).

	All individuals (n= 901)	Individuals with positive CT image (n=28)	Univariate OR (95% CI) for factors associated with positive CT image	P-value
Age (years), n (%)				
- >55	293 (32.5)	18 (64.3)	Ref	
- 45-54	345 (38.3)	9 (32.1)	0.41 (0.17-0.90)	0.03
- 35-44	197 (21.9)	1 (3.6)	0.07 (0.00-0.38)	0.01
- < 35	66 (7.3)	0 (0.0)	--	--
Male, n (%)	783 (86.7)	21 (75.0)	0.44 (0.19-1.13)	0.07
Caucasians, n (%)	777 (86.2)	24 (85.7)	0.95 (0.36-3.29)	0.94
Tobacco use, n (%)				
- Current	251 (27.9)	11 (39.3)	Ref	
- Previous	321 (35.6)	15 (53.6)	1.07 (0.49-2.43)	0.87
- Never	310 (34.4)	2 (7.1)	0.14 (0.02-0.53)	0.01
Cumulative smoking > 30 pack years, n (%)	18 (6.5-32.0)	30 (14-37.5)	2.62 (1.15-5.90)	0.02
Current CD4 count (cells/μL), n (%)				
- <350	67 (7.4)	7 (25.0)	Ref	
- 350-500	131 (14.5)	4 (14.3)	0.27 (0.07-0.93)	0.04
- >500	694 (77.0)	17 (60.7)	0.22 (0.09-0.57)	<0.01
CD4 nadir <200 cells/μL), n (%)	373 (41.4)	20 (71.4)	3.53 (1.59-8.61)	<0.01
HIV RNA > 50 copies, n (%)	44 (4.9)	0 (0.0)	--	--
Years of known HIV, median (IQR)	13.8 (6.9-21.3)	14.8 (7.2-24.4)	1.02 (0.97-1.06)	0.46
Prior AIDS defining event, n (%)	157 (17.4)	12 (42.9)	3.94 (1.78-8.59)	<0.001
History of PCP, n (%)	59 (6.5)	5 (17.9)	3.29 (1.07-8.37)	0.02

[Table 1. Characteristics of study population]

CD4/CD4 nadir	CT findings	Invasive diagnostic procedures	Lung cancer/differential
Non calcified nodule(s)			
553/72	Multifocal nodules	TFFNB and VATS	No
1110/360	Multifocal nodules	Bronchoscopy/TBBx	No
172/2	Nodules (8 and 9 mm)	Bronchoscopy/TBBx	Vulvar and anal cancer#
580/140	Nodules (6 and 7mm)	Bronchoscopy/TBBx	NSCLC, adenocarcinoma (IIIa)
845/368	Nodule (15 mm)	Bronchoscopy/TBBx and VATS	No
Non-nodular lesions			
590/140	Mediastinal mass	UGNBx/VATS	Thymoma B2
570/550	Atelectasis, consolidation	Bronchoscopy/TBBx	No
1100/186	Endobronchial mass	Bronchoscopy/TBBx and VATS	NSCLC, adenocarcinoma (IIa)

[Table 2. All invasive procedures]

Conclusions: Lung cancer prevalence and prevalence of positive CTs in PLWHIV at high risk for lung cancer was comparable to screening rounds in the general population. LDCT screening seems to be feasible although data from interventional trials are lacking.

TULBPEB19

People living with HIV and HIV-negative individuals with similar lifestyles show greater age advancement compared to healthy blood donors

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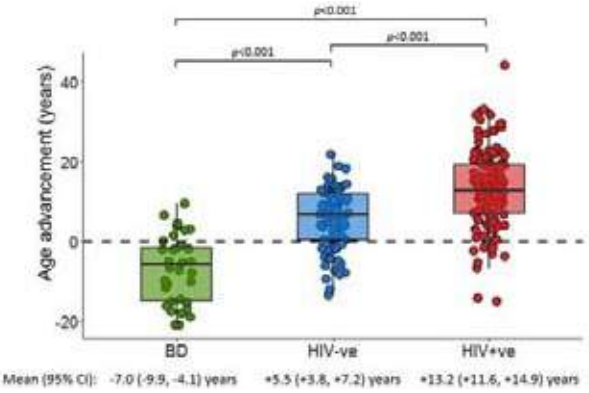
Background: It is suggested that HIV, even when treated, may be associated with premature aging. We investigated relationships between established ageing biomarkers and HIV infection, and explored factors associated with age advancement among participants in the COBRA Collaboration (www.fp7-cobra.eu).

Methods: Biological age was derived in 134 ART-treated and virally-suppressed HIV+ve (median 56 years, 93% male, 88% white) and 79 demographically-lifestyle-comparable HIV-ve (median 57 years, 92% male, 97% white) study participants, and 35 age-matched blood donors (BD, median 59 years, 51% male) using 10 ageing biomarkers (www.markage.eu). Associations between 'age advancement' (biological minus chronological age) and HIV-status/parameters, lifestyle, cytomegalovirus (CMV), hepatitis B (HBV) and hepatitis C (HCV) infections were investigated using linear regression.

Results: Age advancement was significantly greater in the HIV+ve persons than in both other groups, but also in HIV-ve participants compared to BD (Figure).



[Age advancement in BD, HIV-ve and HIV+ve people]

No significant associations were found between age advancement and lifestyle, but anti-CMV IgG titer, chronic HBV and CD8+ T-cell count were each associated with increased age advancement, independently of HIV/group (Table).
Among HIV+ve persons, age advancement was increased by 3.5 (95% confidence interval 0.1-6.8) years among those with nadir CD4+< 200 cells/μL (p=0.04) and by 0.1 (0.06-0.2) years for each additional month of exposure to saquinavir (p<0.001).

Conclusions: Both treated HIV+ve and lifestyle-comparable HIV-ve individuals show signs of age advancement compared to BD, to which persistent CMV and HBV co-infection, and CD8+ T-cell activation may have contributed. Age advancement remained greatest in HIV+ve people and was related to prior immunodeficiency and cumulative saquinavir exposure.

Variable	Regression coefficient (95% CI)	p-value	Regression coefficient (95% CI) Adjusted for HIV-status/Group	p-value
HIV-status/Group				
HIV-ve vs HIV+ve	-7.8 (-10.2, -5.3)	<0.001		
BD vs HIV+ve	-20.2 (-23.5, -16.9)	<0.001		
Total anti-CMV IgG titer [per 1 log(AU)]	3.5 (2.2, 4.8)	<0.001	2.1 (0.7, 3.4)	0.002
HBV vs no HBV infection	14.5 (6.1, 22.8)	<0.001	9.1 (2.4, 15.8)	0.008
CD8+ T-cell count [per 100 cells/μL]	0.9 (0.5, 1.3)	<0.001	0.4 (0.1, 0.9)	0.020

[Increase (if pos) or decrease (if neg) in age adv.]

TULBPEB20

Raltegravir (RAL) 1200 mg once daily (QD) versus RAL 400 mg twice daily (BID), in combination with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in previously untreated HIV-1 infection through week 96

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Background: In the ONCEMRK study, RAL 1200mg (2x600mg reformulated tablets) once daily had non-inferior efficacy and similar safety and tolerability to RAL 400mg BID at Week 48. Here we report final (Week 96) results from this study.

Methods: ONCEMRK is a phase 3, multicenter, double-blind, randomized, controlled trial to evaluate if reformulated RAL 1200mg QD is non-inferior to RAL 400mg BID. Treatment-naïve HIV-1-infected adults were assigned (2:1) to reformulated RAL 2x600mg QD or RAL 400mg BID, both with TDF/FTC, for 96 weeks. Randomization was stratified by screening HIV-1 RNA and chronic hepatitis B/C status. The primary efficacy endpoint was the proportion of participants with HIV-1 RNA < 40 copies/mL at Week 48 (Non-Completer=Failure); the non-inferiority margin was 10 percentage points.

Baseline Characteristics	RAL 1200 mg QD (N=531)	RAL 400 mg BID (N=266)	Total (N=797)
Mean (SD) HIV-1 RNA, log_{10} c/mL	4.6 (0.7)	4.6 (0.7)	4.6 (0.7)
HIV-1 RNA >100,000 c/mL	28.1 %	28.9 %	28.4 %
Mean (SD) CD4+ T-cells/mm^3	407.6 (213.7)	428.9 (217.3)	414.7 (215.0)
Efficacy & Safety Outcomes, Week 96	**RAL 1200 mg QD**	**RAL 400 mg BID**	**QD–BID (95% CI)**
HIV-1 RNA <40 c/mL, All participants (NC=F)	81.5 %	80.1 %	1.4 (-4.4, 7.3)
Baseline HIV-1 RNA >100,000 c/mL (OF)	84.7 %	82.9 %	1.8 (-8.2, 13.6)
Baseline ≤200 CD4+ T-cells/mm^3 (OF)	79.0 %	80.0 %	-1.0 (-17.2, 18.6)
HIV-1 RNA <200 c/mL, All participants (NC=F)	85.3 %	82.7 %	2.6 (-2.9, 8.1)
Integrase resistance	0.8 %	0.8 %	n/a
Mean Change (95% CI), CD4+ T-cells/mm^3 (OF)	261.6 (242.9, 280.3)	262.2 (236.4, 288.0)	-0.6 (-32.8, 31.6)
One or more clinical adverse events	90.2 %	93.2 %	-3.0 (-6.8, 1.3)
Drug-related clinical adverse events	26.0 %	26.7 %	-0.7 (-7.4, 5.6)
Serious clinical adverse events	9.2 %	15.8 %	-6.6 (-11.9, -1.8)
Discontinued due to any adverse event	1.3 %	2.3 %	-0.9 (-3.6, 0.9)

Data are % of participants, unless otherwise specified.
NC=F: Non-Completer=Failure, as defined by FDA snapshot approach (all missing data treated as failures).
OF: Observed Failure approach.

[ONCEMRK Week 96 Results]

Results: Of 802 participants randomized, 797 received study therapy and were included in the analyses. The study population was 84.6% male, 59.3% white, mean (SD) age 35.9 (10.5) years. 694 participants (86.5%) completed 96 weeks of treatment (87.6% QD; 84.4% BID) with low rates of discontinuation due to lack of efficacy (1.1% for both groups) and adverse events (1.3% QD; 2.3% BID). At Week 96, RAL 1200mg QD was non-inferior to RAL 400mg BID (HIV-1 RNA < 40 copies/mL in 81.5% and 80.1%, respectively, Δ(QD-BID)=1.4%, 95% CI [-4.4, 7.3]). Resistance to raltegravir was infrequent, occurring in 4/531 (0.8%) and 2/266 (0.8%) in the QD and BID groups, respectively. Increases in CD4+ T-cell counts from baseline were comparable for the two treatment regimens. Both treatment regimens were generally well-tolerated with low rates of discontinuation due to adverse events (table).
Conclusions: In HIV-1-infected treatment-naïve adults receiving TDF/FTC, RAL 1200mg QD demonstrated non-inferior efficacy compared to RAL 400mg BID that was durable to Week 96. RAL 1200mg QD was well tolerated with a safety profile similar to RAL 400mg BID through Week 96.

TULBPEB21

ACTG A5353: a pilot study of dolutegravir (DTG) + lamivudine (3TC) for initial treatment of HIV-1-infected participants with HIV-1 RNA < 500,000 copies/mL

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Background: DTG+3TC has attractive attributes for initial HIV-1 treatment, but limited data exist particularly in individuals with high pre-treatment plasma viral load (VL).
Methods: A5353 is a phase II, single-arm, pilot study of once-daily DTG (50mg) + 3TC (300 mg) in treatment-naïve HIV-1-infected participants with VL ≥1000 and < 500,000 copies/mL (cpm). Active hepatitis B or integrase, reverse transcriptase or major protease resistance mutations were exclusions. Primary outcome of virologic efficacy (VL < 50 cpm by FDA snapshot algorithm) was estimated using a two-sided exact 95% confidence interval (CI). Secondary as-treated analysis focused on participants who remained on DTG+3TC. Comparisons between entry VL (≤100,000 versus >100,000 cpm) used Fisher's exact tests. Virologic failure (VF) was defined as confirmed VL >400 cpm at week 16 or 20, or confirmed VL >200 cpm at/after week 24. DTG plasma levels and resistance testing were performed at VF.
Results: Of 120 participants who initiated study treatment, 37 (31%) had VL > 100,000 cpm. Majority were male (87%); median age 30 (IQR: 24, 41) years; 40% Black, 28% White, 27% Hispanic. Median entry VL and CD4 count were 4.61 (3.94, 5.05) log_{10} cpm and 387 (288,596) cells/mm^3. Virologic efficacy at week 24 was 108/120 (90%, CI [83%, 95%]) with no significant difference between the low and high VL strata: 90% [82%, 96%] and 89% [75%, 97%], respectively (p>0.99). In the as-treated population, 108/112 (96% [91%, 99%]) had VL < 50 cpm, with no difference between the VL strata (99% [93%, 100%] vs. 92% [78%, 98%], p=0.10). Median CD4 change from entry to week 24 was +167 (86, 275) cells/mm^3. The three participants (2 in low, 1 in high VL strata) with VF had plasma DTG levels below the limit-of-quantification around the time of VF. There were no integrase mutations; M184V was detected in one participant at VF off study treatment. Two participants experienced Grade 3 possibly/probably treatment-related adverse events, however no Grade 4 adverse events or discontinuations occurred.
Conclusions: In this pilot study of treatment-naïve HIV-1-infected participants with VL < 500,000 cpm, once-daily DTG+3TC was effective and well tolerated. Randomized trials of this regimen versus standard-of-care are warranted.

TULBPEB22

ABX464 decreases total HIV DNA in PBMC's when administered during 28 days to HIV-infected patients who are virologically suppressed

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Background: ABX464, the first drug candidate from Abivax's proprietary antiviral platform, inhibits HIV replication through a novel mechanism (i.e. the modulation of RNA splicing) which may have a sustained antiviral effect as shown in preclinical testing. In an earlier Phase IIa study, the results of which were presented at CROI 2016, ABX464 showed dose-dependent viral load reductions in treatment-naïve HIV-subjects and a good safety and tolerability profile.
Methods: Multi-center, randomized, double-blind, placebo-controlled Phase IIa trial in Spain, Belgium and France. Subjects with VL< 50 copies/mL under boosted darunavir monotherapy for at least 8 weeks prior to enrolment were randomized (3:1) to add ABX464 QD or placebo to boosted darunavir monotherapy during 28 days. At the end of such 28 days, all treatments were interrupted. Viral load was regularly measured and ART was reinstalled when viral load was > 1000 copies/ml. Safety was the primary endpoint of the trial. Blood samples (D0 and D28) were taken to assess the potential effect of ABX464 on the HIV reservoir (Total HIV DNA in PBMC's). A significant reduction HIV reservoir (i.e. Responders) was defined as subjects who had a minimum reduction of 50 copies and a greater than 25% decrease in total HIV DNA copies.
Results: 30 subjects (29 males, 1 female) were included. They had been infected with HIV-1 for 10.2 years and on ART for 5.6 years. ABX464 was well tolerated. There were no serious adverse events reported in the treatment group. Mean time to viral load rebound was 14 days (placebo) and 13 days (ABX464). Amongst subjects with validated viral DNA results (4 placebo and 15 ABX464-treated subjects), an important reduction in viral DNA was observed in 8/15 (53%) ABX464 treated subjects (mean change of -38%, ranging from -27% to -67% and a mean decrease of 185 copies [-434; -82] / Mio PBMC's. No responders were observed in the placebo group.
Conclusions: This is the first time we see a signal with any therapeutic candidate that it may be possible to reduce HIV reservoirs in patients. Further clinical trials with longer treatment duration are needed to further understand the mechanisms and implications of these findings.

TULBPEB23

Allogeneic stem cell transplantation in HIV-1-infected individuals - the IciStem Consortium: the role of lymphocyte populations

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Background: The primary aim of the Icistem Project is to guide clinicians involved in allogeneic HSCT procedures in HIV infected individuals. The scientific aim is to understand the causes for the only successful intervention to cure HIV to date. This requires the identification of immunological mechanisms and predictors of the restriction or eradication of the HIV reservoir as well as the innate and adaptive responses before and after HSCT.
Methods: The study includes 28 HIV positive patients with hematological malignancies. 22 of these patients received an allogenic transplant (8 x CCR5Δ32 donor). PBMC samples were collected longitudinally before and after HSCT and were analyzed via multicolor flow cytometry. The first panel focuses on the possible reservoir CD4 T cell populations such as central, transitional and effector memory cells, Tregs and their cytotoxic CD8+ counterpart. On these populations we measure the expression of HIV coreceptors (CCR5, CXCR4), the activation (CD38, HLA-DR and Ki-67) as well as the level of exhaustion (PD-1) and capacity to migrate to the gut (α4β7 integrin). In a second panel we focussed on unconventional T cell populations (γδT cells, MAIT cells, NKT cells) and NK cells that share the capacity for a quick immune response whithout prior clonal expansion.
Results: Seven patients passed the 12 months follow-up after HSCT and 10 patients have died after transplantation. Preliminary analysis shows systematic reduction of HIV-1 reservoirs to very low levels post SCT. Three patients show no detectable virus in blood independent of CCR5 expression. Overall we found a significant reduction in the frequency of naïve CD4 and CD8 T cells after HSCT, an inverted CD4/ CD8 ratio, a loss of MAIT cells as well as an inverted ratio of Vδ2/Vδ1 cells in comparison to healthy controls. Preliminary results show a high immune activation of NK cells in one of the patients without detectable viral load. Further correlation to clinical data and the HIV reservoir size is ongoing, which will help to characterize "beneficial" anti viral immune responses.
Conclusions: The immune composition and activation of the graft might contribute to the clearance of the viral reservoir independent of the CCR5 status of the donor.

TULBPEB24

No association between duration of implant use and pregnancy among HIV-positive women using concomitant efavirenz-containing antiretroviral therapy

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Background: Concomitant use of efavirenz-containing antiretroviral therapy (ART) among HIV-infected women using contraceptive implants leads to an increased risk of pregnancy. Since the contraceptive hormone concentration decreases gradually after implant insertion, we conducted a retrospective cohort study to investigate whether implant failures (i.e. pregnancies), especially among efavirenz users, was associated with the duration of implant use.
Methods: We analyzed electronic medical record data from the East Africa International Epidemiology Databases to Evaluate AIDS. HIV-positive women 15 to 45 years of age using implants while enrolled in HIV care between January 2011 and December 2015 were included. Pregnancies identified in the records were confirmed, along with implant insertion dates, by phone interviews with the women. We used pooled logistic regression generalized estimating equation models to generate odds ratios (ORs) for implant failure associated with ART, implant type, and time from implant insertion, categorized into 6-month intervals.
Results: We conducted 788 phone interviews among implant users and identified 51 (6.5%) women who became pregnant while using an implant, of which 36 (71%) women were concomitantly using efavirenz-containing ART. Of these 51 women, 39 (76%), 11 (22%), and one (2%) became pregnant while using levonorgestrel, etonogestrel, or unknown type of implant, respectively. The median time to implant failure was similar for levonorgestrel (24.9 months; IQR 13.0, 37.2) and etonogestrel (21.1 months; IQR 4.2, 26.6) users. Compared to the first 6 months of implant use, the ORs for pregnancy did not differ significantly for each subsequent 6-month interval for either levonorgestrel or etonogestrel implants (Table 1; p>0.05 for each comparison). The OR for pregnancy was not statistically different among levonorgestrel vs. etonogestrel users (1.61; 95% CI 0.83, 3.14). Efavirenz- vs. nevirapine-containing ART was associated with a significantly increased OR for pregnancy (6.27; 95%CI 2.92, 13.49). Models including interaction terms with ART revealed no significant effects.
Conclusions: Contraceptive implant failures among HIV-infected women, including those using efavirenz, do not appear to be associated with the duration of implant use. Replacing implants prior to the approved length of use is unlikely to prevent implant failures among women using efavirenz, and alternative strategies to improve contraceptive effectiveness need to be explored.

TULBPED38

Determination of OraQuick® HIV self-test result stability with delayed visual re-reading: an external quality assurance analysis

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Background: HIV self-testing (HIVST) is being evaluated globally as an innovative approach to reach the 40% of people living with HIV who don´t know their status. No external quality assurance (EQA) systems have been established to support HIVST implementation. We evaluated the visual stability of late re-reading of used OraQuick® kits exposed to different environmental conditions to determine whether re-reading of returned kits may offer an accurate quality assurance approach.
Methods: A panel of 444 OraQuick® kits was established using a plasma matrix comprising HIV high-reactive (n= 148), weak-reactive (n=148) and HIV non-reactive (n=148) results. Kits were read at 20 minutes by three independent readers blinded to the initial results and each other. Subsequently, kits were incubated under four different conditions: temperature low/ humidity low, temperature low/ humidity high, temperature high/ humidity low, temperature high/ humidity high. Baseline condition was defined as temperature of 30°C, humidity 20%. Kits were re-read daily for a week, weekly for a month, and monthly for six months. Consensus between two or more readers was taken as the true result. Test result transition hazards between states were estimated using a multi-stage Markov model.
Results: Over six months, 43 of the 144 non-reactive kits (29.24%) changed to a weak-reactive result across all conditions. The earliest changes were seen on Day 4 (n=9 kits). There was dynamic movement between non-reactive and weak-reactive states over time, but no kits with initially reactive results changed over time. Compared to the baseline conditions there were no statistically significant differences in the hazard of transition between storage conditions for any group.
Conclusions: We found a high incidence of OraQuick® results changing from 'true non-reactive' to 'false reactive' results over 6-months, making late re-reading an inaccurate option for EQA monitoring. Studies using returned used HIVST kits for 'late' visual re-reading for monitoring test results may overestimate true HIV positivity rates. Programmes scaling up HIVST need to ensure clear messaging regarding the correct read times to avoid misinterpretation of results by self-testers who fail to dispose of kits after having conducted the test.

TULBPED39

Stock outs of ARVs cause catastrophic expenditures and further impoverishment of ART patients in South Africa

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Background: The Republic of South Africa (RSA) has the largest ART cohort in the world with over 3.3 million clients. Unfortunately the country faces substantial ARV stock-outs at point of service, with 20% of public health facilities reporting at least one ARV out of stock the day of the national survey. This economic analysis aims at estimating the economic impact of ARV stock-outs on patients.
Methods: We use a modelling approach utilizing already-existing data, combining the stock-out national survey database with data from literature review of ART services in South Africa. Prevalence and duration of ARV stock-outs are combined with unit costs and patients' characteristics. Analyses are run by category of ARVs at provincial level using 2015 data.
Results: In 2015, 709 stock-outs of ARV were reported nationwide, resulting in 33,189 ART clients leaving their facility with no medicines, a shortened supply or an incomplete regimen. Our findings further suggest that 80,440 ART clients would have been affected if facilities had not managed to (informally) borrow ARVs from each other's and change patient regimen.
A patient affected by an ARV stock-out therefore bore the financial burden of an extra visit, estimated to an average ZAR 68 (USD 5.6). This cost can be considered as a catastrophic expenditure for at least 50% of ART clients (median income of ZAR 972), and as an impoverishing expenditure for at least 40% of ART clients (already facing financial distress for monthly ART services).
Conclusions: Extra cost resulting from stock outs of ARVs significantly increase financial distress on thousands of ART clients in South Africa, further impoverishing the poorest and jeopardizing their access to care. The 90/90/90 objective results in a dramatic increase in the number of ART clients, and therefore in the number of patients potentially affected. In addition, the RSA spent ZAR 8.9 Billion (USD 850.3 Million) in 2013/14 on HIV treatment activities. Addressing stock-outs and ensuring ARV availability at point of service should therefore be a priority.

TULBPED40

Reaching the first 90 in Philippines: community-based screening: a strategy to increase HIV coverage and testing

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Background: Globally, the number of new HIV cases has declined by 33 percent in 2013. However, the Philippines bucks this downward trend. Despite the significant increase in the number of new cases, program coverage and testing remains low particularly for the MSM and TG population who are the key drivers of HIV epidemic in Philippines. To address this gap and fast-track the country's progress towards first 90, Save the Children through its Global Fund program piloted the Community-based screening (CBS) approach in 3 geographical regions. CBS is a testing option that is envisioned to help increase testing uptake with the support of community based organizations. It is not meant to replace diagnostic testing options in the country, rather increases the screening and testing options to clients.
Methods: Quantitative analysis of the HIV testing data for MSM and TG in the 3 priority areas: NCR, Cebu City and Davao City for the pilot phase i.e. 3 months was done.
Results: A total of 70 motivators were engaged. A total of 777 MSM and TG were Reached and 774 (99.6%) were motivated to be screened in the 3 areas. Average positivity rate was at 5% among those who were screened. The highest rate was noted in NCR and Cebu which are 2 of the highest prevalence areas in the country (Table 1).

Indicators	NCR	Cebu	Davao	Total
Total Reached	438	140	199	777
Total Screened	436	140	198	774
Total Screened Reactive	24	9	8	41
Rate of Reactive Screened Clients	6%	6%	4%	5%

[Indicator dis-aggregation per site]

Conclusions: The rise in HIV cases in the Philippines is alarming. One of the bottleneck is the low testing of high risk population due to fear of the testing clinics and lack of manpower for testing. The scale-up of CBS strategy in the next GF funding cycle will be a major intervention to reach the first 90 based on the following: First, In the 3 months of implementation, it yielded a 5% positivity rate compared to the 1-2% positivity rate of the ongoing outreach activities. Second, 99% of the clients who were reached were motivated to be tested compared to the average 70% testing rate of the outreach activities. Third, based on feedback from clients, they are more likely to submit to screening due to rapport established with the motivators.

TULBPED41

Predictors of linkage to and retention in HIV care following release from Connecticut, USA jails and prisons

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Background: One in six people living with HIV (PLH) in the USA transition through prisons/jails annually. During incarceration, people may engage in HIV care, but transition to the community remains challenging. Linkage to care (LTC) post-release and retention in care (RIC) are necessary to optimizing HIV outcomes, but have been incompletely assessed in prior observational studies.
Methods: We created a retrospective cohort of all PLH released from a Connecticut jail or prison (2007-14) by linking Department of Correction demographic, pharmacy, and custody databases with Department of Public Health HIV surveillance monitoring and case management data. We assessed time to LTC, defined as time from release to first community HIV-1 RNA test, and viral suppression status at time of linkage. We used generalized estimating equations to identify correlates of LTC within 14 or 30 days after release. We also described RIC over three years following initial release, comparing recidivists to non-recidivists.
Results: Among 3302 incarceration periods from 1350 unique PLH, 21% and 34% had LTC within 14 and 30 days, respectively, of which >25% had detectable viremia at time of linkage. Independent correlates of LTC at 14 days included incarceration periods >30 days (adjusted odds ratio [AOR]=1.6; p< 0.001), higher medical comorbidity (AOR=1.8; p< 0.001), antiretrovirals prescribed before release (AOR=1.5; p=0.001), transitional case management (AOR=1.5; p< 0.001), re-incarceration (AOR=0.7; p=0.002) and conditional release (AOR=0.6; p< 0.001). The 30-day model additionally included psychiatric comorbidity (AOR=1.3; p=0.016) and release on bond (AOR=0.7; p=0.033). RIC after release declined over one year (67%), two years (51%) and three years (42%). Recidivists were more likely than non-recidivists to have RIC but, among those retained, were less likely to be virally suppressed (Figure 1).
Conclusions: For incarcerated PLH, both LTC and RIC are suboptimal after release. Targeted interventions and integrated programming aligning health and justice goals may improve post-release HIV treatment outcomes.

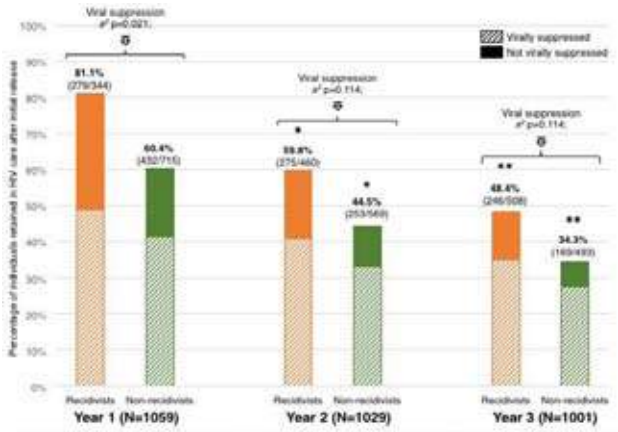

Figure 1. Longitudinal sustained retention in HIV care at one, two, and three years post-release, based on frequency of HIV-1 RNA viral testing, stratified by whether individuals were reincarcerated at some point during the follow-up period.

* statistically significant decline (McNemar's test p<0.0001) compared with initial one-year rates. ** statistically significant decline (McNemar's test p<0.0001) compared with sustained two-year rates. ❖ statistically significant difference (χ^2 p<0.0001) in retention rates between recidivists and non-recidivists across all time points. Among those retained, non-recidivists had significantly higher viral suppression rates compared to recidivists at the end of year 1 (p=0.021) and year 3 (p=0.048).

[Figure 1]

TULBPED42

PrEP in Zimbabwe: an integrated approach

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Background: Zimbabwe has one of the highest burdens of HIV with a prevalence rate of 16.7% in adults aged 15-49 years. PSI/Z offers comprehensive HIV/SRH integrated services through a social franchise network called New Start. Services on offer include HTS, including self-testing, HIV care & treatment services, family planning, cervical cancer screening, TB screening and treatment, and IPT. PrEP was introduced at New Start in August 2016 for use as an additional HIV prevention strategy by all at substantial risk of HIV.
Methods: Programme data from August 2016 to April 2017 was analysed for trends. PrEP is offered through 6 New Start centres across Zimbabwe. Data was collected using PrEP programme M&E tools - registers, client visit tracker.
Results: 1,255 clients were enrolled on PrEP between August 2016 and April 2017. The age/sex disaggregations are outlined in the table.

Age (Years)	10-14	15-19	20-24	25-49	50+	Total
Male	0	1	30	77	6	114
Female	1	132	380	621	7	1141
Total	1	133	410	698	13	1255

[Number of Clients Enrolled on PrEP by Age and Sex]

Client categories include female sex workers (58%), MSM (2%), HIV-negative partner in serodiscordant relationships (15%). 8% of clients includes those answering "Yes" to transactional sex. The remaining clients have risk profiles that put them at substantial risk of HIV. 34 clients stopped PrEP for reasons including side effects (7), pressure to stop from family (2), relocation to areas with no PrEP services (7), challenges with adherence (2), and no longer at risk - partner tested HIV-negative, abstinence, no longer in relationship with an HIV-positive partner, regular condom use.
Since inception, programme data shows poor retention of clients on PrEP as shown in the cohort analysis table.

[PrEP Cohort Analysis]

Conclusions: Despite being at substantial risk of HIV, clients on oral PrEP are not returning for resupply as expected. More needs to be done in terms of information dissemination of the benefits of PrEP to the public.

TULBPED44

Costs of HIV viral load testing using POC and central laboratories: assessing an efficient viral load testing network in Kenya

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Background: Kenya´s HIV care guidelines stipulate universal coverage of routine viral load (VL) monitoring for people receiving ART. Reaching UNAIDS 90-90-90 targets will incur significant costs given the 826,000 adults receiving ART and additional scale-up required to reach 1.5 million people living with HIV.
Methods: We applied Activity-Based-Costing methods for VL testing on point-of-care (POC) and central laboratory (CL) platforms. Costing included a probability sample of 21 health facilities in Siaya County and their affiliated central lab at Kenya Medical Research Institute (KEMRI) in Kisumu. Unit costs were calculated for the Alere™ q and Cepheid GeneXpert IV POC platforms, and the Abbott m2000 RealTime, Roche Cobas AmpliPrep, and Cobas TaqMan CL platforms. Cost inputs included equipment, human resources, reagents, supplies, training, transportation, quality assurance, and recurrent costs.
Results: Average VL unit costs were US$29.74 using POC platforms, compared to US$24.63 at central labs. Reagent procurement accounted for the largest proportion of unit costs; 74% for VL-POC L and68% for VL-CL. Human resource costs were low due to little hands-on time needed for workflows at high testing volumes. Deploying a dedicated POC technician to ensure VL testing on-site increases the unit cost to US$31.93. Low demand constrains performance and increases unit cost; estimating the cost of deploying VL-POC to the 21 facilities in Siaya County showed average unit cost of US$47; seven high-demand facilities could achieve costs below $40, while four low-demand facilities are likely to exceed US$120 per test, somewhat challenging the conventional wisdom that POC technology is best suited to low-demand rural settings.
Conclusions: Building an efficient network to monitor VL suppression requires a cost-effective equipment mix to delivering timely test results, hastening ART assessments and linkages to care. VL-CL testing involves technology-intensive production but can realize economies of scale if working near full machine capacity. Reagents have potential for cost savings through negotiating volume-based procurement prices and pooling samples for testing. Decisions on which VL platform to deploy and where should be guided by evaluations of patient demand for testing, facility staffing and financial capacity to pay for same-day results.

TULBPED45

Brief didactic educational session increases willingness to prescribe HIV pre-exposure prophylaxis among health professionals

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Background: Pre-exposure prophylaxis (PrEP) is recommended for HIV prevention in at-risk populations as part of routine primary care services. However, awareness and prescribing of PrEP by health providers is low. We evaluated whether brief educational sessions for providers impacted their willingness to prescribe or discuss PrEP.
Methods: Between July 2014 and October 2016, we conducted 20-minute PrEP didactic educational sessions (components: local epidemiology, CDC guidelines, local patient/provider resources) at 18 organizations in four cities (Missouri, USA). Pre- and post-session surveys, completed by 244 attendees, assessed awareness, willingness to prescribe or discuss, and concerns regarding PrEP on 5-point Likert scales. Outcomes included changes in willingness to prescribe or discuss PrEP and predictors of unwillingness to prescribe or discuss. Wilcoxon signed-rank test and multivariable logistic regression were performed.
Results: A total of 343 health professionals attended sessions; 18% physicians and 12% nurse practitioners, physician assistants, or pharmacists (prescribers); 6% nurses and 43% social workers, case managers, or counselors (non-prescribers). Pre-session PrEP awareness was 89% among all participants, and 14% of prescribers had written a prescription for PrEP. More non-prescribers (95%) were comfortable discussing sexual health with patients than prescribers (77%). Willingness to prescribe or discuss PrEP increased from 64% to 84% overall ($p< 0.001$) and +28% among prescribers ($p< 0.001$). Twenty-one percent of all attendees changed their willingness to prescribe or discuss PrEP from unlikely (pre-session) to likely (post-session) (95% CI:16%-27%). Forty health professionals (16%) remained unwilling to prescribe or discuss post-session. Perceived organizational-level barriers to prescribing or discussing were low; perceived prescribing feasibility (82%) and support from administration for PrEP prescribing (66%) were high. When adjusting for organization type, location, and baseline PrEP awareness, perceived support from administration was a predictor (Adjusted OR=0.06; 95% CI:0.00-0.81; p=0.04) for unwillingness to prescribe or discuss (post-session) among attendees. The main post-session concern was poor patient follow-up (35%).
Conclusions: A brief educational session for health professionals significantly improved their willingness to prescribe or discuss PrEP. However, perceived lack of support at an organizational level was identified as a barrier. These findings suggest future educational interventions should be aimed at both providers and administrators in order to strengthen PrEP implementation.

TULBPED46

Scale-up of antiretroviral therapy was associated with decreased community HIV incidence in Rakai, Uganda, 1999-2016

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Background: There are limited data on the impact of ART scale-up on HIV incidence at the community level. We assessed associations of community ART coverage with community HIV incidence in Rakai, Uganda.
Methods: Using population-based surveys (1999-2016) in 30 communities, community-level ART coverage, sociodemographics, sexual behaviors, and HIV incidence was estimated over four time periods: prior to ART availability (1999-2004), early ART and medical male circumcision (MMC) program (2004-07), mature program (2007-13), and further ART scale-up (2013-16). To isolate the effect of ART and exclude the impact of MMC scale-up on community HIV incidence, the outcomes are community-level incidence *in uncircumcised men* and *in women* who would not benefit from MMC, respectively. Multivariable Poisson regression with generalized estimating equations was used to estimate adjusted incidence rate ratios (adjIRR) associated with ART coverage in the opposite sex.
Results: From period 1 to 4, median community ART coverage rose from 0 to 47% in men and to 57% in women. Median community HIV incidence declined from 1.31 to 0.31 per 100-person-years (PYs) in uncircumcised men, and from 1.25 to 0.80 per 100-PYs in women. For uncircumcised males, each 10% increase in female community ART coverage was associated with an adjIRR of 0.88 (95%CI 0.83-0.93, p<0.001), suggesting 100% female ART coverage could reduce community HIV incidence by 73% compared to zero ART coverage. For females, the adjIRR associated with each 10% increase in male community ART coverage was 0.92 (CI 0.86-0.98, p=.006), and 100% male ART coverage could reduce female community incidence by 59%. Table 1 shows the adjIRRs associated with categorized ART coverage.

ART coverage in women	adjIRR (95%CI) associated with community incidence in uncircumcised men		ART coverage in men	adjIRR (95%CI) associated with community incidence in women	
≤10%	ref	P-value	≤10%	ref	P-value
10-20%	0.89 (0.65- 1.23)	0.48	10-20%	1.09 (0.88-1.36)	0.42
20-30%	0.79 (0.55-1.11)	0.18	20-30%	0.92 (0.68-1.25)	0.59
30-40%	0.73 (0.43-1.26)	0.26	30-40%	0.93 (0.74-1.17)	0.54
40-50%	0.54 (0.27-1.07)	0.08	40-50%	0.69 (0.50-0.96)	0.027
>=50%	0.42 (0.28-0.62)	<.001	>=50%	0.56 (0.36-0.88)	0.011

[Table 1.]

Conclusions: Increasing community ART coverage in the opposite sex was significantly associated with lower community HIV incidence in uncircumcised men and in women, but universal ART coverage alone could not reduce HIV incidence by 90% which is needed to end the HIV epidemic by 2030. Combination prevention including MMC, behavioural risk reduction is needed to end the HIV epidemic in Rakai.

TULBPED47

Acceptability of door-to-door rapid HIV testing among sub-Saharan African men and women living in the Paris region

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Background: Recent modelling estimates indicate a high prevalence of undiagnosed HIV infections among individuals born in Sub-Saharan Africa (SSA) living in the Paris region (~1 per 100). To reduce undiagnosed HIV infections, innovative testing services are needed. Door-to-door HIV testing is often used in low- and middle-income countries, but rarely in high-income countries. A study was developed to evaluate the acceptability of door-to-door HIV testing among men and women born in SSA and living in the Paris region.
Methods: A pilot study was implemented to offer outreach rapid HIV testing in deprived neighbourhoods of three cities (Sevran, Bagnolet, Saint-Denis). The targeted population was SSA-born individuals. Field workers knocked on apartment doors and after oral consent asked the inhabitants to complete a short survey on country of birth and HIV testing. They offered rapid testing either at home or in a mobile van temporarily parked outside tower blocks. Reasons given for refusal were collected. Statistical comparisons between genders were performed using Pearson's chi-square test.
Results: Between November 2016 and February 2017, 290 SSA-born inhabitants (147 women, 143 men) were reached during 31 door-to-door outreach events. Sixty-two men (43.4%) and 55 women (37.4%) reported an HIV test in their lifetime (p=0.30). Fifty-six men (39.2%) and 48 women (32.7%) (p=0.25), were interested in getting tested for HIV. Among them (n=104), 46.4% of men (vs. 50.0% of women) were more interested in being tested at home and 41.1% (vs. 39.6% of women) in the van, with no significant gender differences. Among all, 24 men (16.8%) and 24 women (16.3%) were tested at home. One woman had a reactive test. Among individuals not interested in getting tested for HIV (n=186), most common reasons given for refusal were "not feeling at risk or not interested" (70.1% for men vs 66.7% for women, p=0.61) and "already tested" (42.5% for men vs 29.3% for women, p=0.06).
Conclusions: To our knowledge, this is the first time that door-to-door rapid HIV testing was implemented in Europe. It was an acceptable HIV testing strategy for individuals born in SSA. Implementation on a larger scale is necessary to study its potential impact on the HIV epidemic.

TULBPED48

Benchmarking 90-90-90 and HIV care continuum data and methodology in 9 Fast-Track Cities

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Background: The Fast-Track Cities initiative supports cities to achieve the UNAIDS 90-90-90 target by 2020. Grounded in the principle of data transparency, the initiative includes a public domain web-based monitoring and evaluation platform-the FTC Global Web Portal- which allows cities to measure and monitor progress towards the 90-90-90 target on city-specific dashboards.
Methods: HIV Care Continuum data and methodologies were considered for nine Fast-Track Cities that have reported data on their online dashboard, and were reviewed in accordance with IAPAC's 2015 Guidelines for Optimizing the HIV Care Continuum. Data were collected on the following indicators: estimated people living with HIV (PLHIV), PLHIV diagnosed, on antiretroviral therapy (ART) and virally suppressed. Based on the indicator rankings, the care continuum was graded as high, medium or low quality.
Results: Melbourne and Miami reported state and county data, respectively, in place of city data. Of the 9 Fast-Track Cities, two (Amsterdam, Melbourne) have achieved the 90-90-90 target in 2015. Five cities (Amsterdam, Melbourne, New York City, San Francisco, Denver) have achieved the "first 90" target; two (Amsterdam, Melbourne) have achieved the "second 90" target; and five (Amsterdam, Melbourne, New York City, Denver, Paris) have achieved the "third 90" target.
Along the care continuum, proportions ranged from 51-94% diagnosed, 23-85% on ART, and 19-79% virally suppressed among the estimated PLHIV. Majority of the cities had medium quality continuum, using standard surveillance methods, estimates and/or modeling to derive the indicators along the continuum.

[Continuum & 90-90-90 data for 9 Fast-Track Cities]

Conclusions: Fast-Track Cities are benchmarking 90-90-90 and care continuum data to address gaps across their HIV care continua. Two cities have attained the 90-90-90 target and four others have attained or surpassed one or more of the 90-90-90 targets. The Fast-Track Cities initiative supports cities to standardize metrics and strengthen methodologies for measuring the HIV care continuum, and to align programmatic efforts towards attaining 90-90-90.

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