9th International Workshop on HIV & Women

From Adolescence to Menopause

2 – 3 March 2019, Seattle, WA, USA

Abstracts

1

INSTI Exposure and Neural Tube Defects–Data From Antiretroviral Pregnancy Registry

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Background: Dolutegravir (DTG) is an integrase strand transfer inhibitor (InSTI) with once-daily dosing, good viral efficacy, high barrier to resistance, and good tolerability. Preliminary data from the NIH-supported Botswana birth defects surveillance project (Tsepamo study) reported a potential increased risk of neural tube defects (NTD) in infants born to HIV-positive women receiving DTG-based antiretroviral therapy (ART) prior to conception, compared to non-DTG ART or to uninfected women (0.9%, 0.1% , and 0.09%, respectively). Using data from the Antiretroviral Pregnancy Registry (APR), a voluntary, international, prospective exposure-registration cohort study with independent Advisory Committee oversight, we describe central nervous system (CNS) defects and NTD in infants born to women receiving InSTIs.

Materials & Methods: Data on prospectively enrolled pregnancies through 31Jan2018 with birth outcome are summarized. Birth defects are reviewed by a dysmorphologist, coded according to modified Metropolitan Atlanta Congenital Defects Program criteria, classified by organ system and assigned timing of exposure to each InSTI (DTG, elvitegravir [EVG], raltegravir [RAL]). Birth defects within the CNS organ system include both NTDs and encephalocele, which is reported separately from NTD.

Results: A total of 19,688 pregnancies resulted in 20,026 fetal outcomes including 18,658 live births. APR reports come from North America (75%), Europe (8%), Africa (7%), South America (6%) and Asia (4%). There were 1,021 live births with an InSTI exposure at any time during pregnancy, of which 507 had ongoing exposure at conception, 111 had exposure later during the first trimester, and 403 had exposure during the second/third trimester. The 507 with InSTI exposure ongoing at conception include 121 DTG, 155 EVG, and 231 RAL live birth outcomes. There were no NTD or other CNS birth defects among prospective cases for any InSTI drug exposure at any time during pregnancy.

Conclusions: No occurrences of CNS defects or NTDs were observed among 1,021 prospective live birth outcomes with InSTI exposure at any time. This frequency is consistent with the observed low prevalence of NTD in developed countries (~0.1%), as most APR reports (83%) come from North America and Europe where food is supplemented with folate, which reduces NTD prevalence. However, InSTIs are a newer class of ARVs and the number of pregnancies with InSTI exposure in the APR to date is insufficient to draw definitive conclusions about a potential association between DTG and NTD, or to look at specific geographic regions. Healthcare providers are encouraged to continue to report pregnancies with prospective antiretroviral exposures to the APR.

2

Congenital Anomalies in Infants of Canadian Women Exposed to Antiretrovirals, Including Dolutegravir

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Background: Dolutegravir is recommended worldwide as one of the first line antiretroviral therapies (ART) for individuals living with HIV, resulting in a dramatic increase in dolutegravir use internationally. In Botswana, it has been used as a first line agent since 2016, including among women of reproductive potential and in pregnancy. Data from an interim analysis of a birth surveillance study found that, of 11,558 women living with HIV in Botswana who became pregnant, 0.9% of babies born to the women taking dolutegravir at conception had a neural tube defect (NTD) (4/426), compared with 0.1% of babies born to mothers taking other antiretroviral combinations (14/11,173). We reviewed national surveillance data of outcomes from women living with HIV (WLWH) exposed to ART to determine our rates of congenital anomalies, particularly NTD's.

Objective: The aim of this study was to examine rates of congenital anomalies in infants born to WLWH in Canada who received ART in the first trimester.

Methods: Data was extracted from the Canadian Perinatal HIV Surveillance Program (CPHSP) from 2007-2017. CPHSP consists of 22 sites, 19 HIV referral health centres and 3 health departments from all Canadian provinces and territories. Descriptive analyses were conducted to determine the demographics of pregnant WLWH, and the incidence of congenital anomalies among women exposed to dolutegravir, and other antiretrovirals, during pregnancy.

Results: From 2007-2017, there were 2,591 live infants born to WLWH in the CPHSP, of which 2,423 had congenital anomaly data. 1,311 women (56.4%) were on antiretrovirals at the time of conception, and another 204 (8.8%) started in the first trimester. Of 98 cases of anomalies (4.04%; 95% CI: 3.30-4.91%), 12 were associated with chromosomal abnormalities (0.5%), resulting in a non-chromosomal congenital anomaly prevalence of 3.5%, with no difference across gestational age exposure groupings (p=0.915). There were 3 cases of neural tube defects, an overall incidence rate of 0.12%, two of whom were born to women who were taking ART at conception: tenofovir, emtricitabine, and ritonavir boosted atazanavir; and zidovudine, lamivudine, abacavir, and ritonavir boosted atazanavir. There were 80 cases with dolutegravir exposure in the first trimester with 4 cases of non-chromosomal congenital anomalies, giving a rate of 5.0% [CI: 1.4%-12.3%] These included anomalies in the following systems: urinary tract (n=2), circulatory system (n=1) and musculoskeletal system (isolated polydactyly) (n=1). Three of the 28 infants exposed to elvitegravir had congenital anomalies; the urinary, musculoskeletal systems, and in multiple systems (10.7%) [CI:2.3%-28.2%].

Conclusion: This data demonstrates no safety signal for congenital anomalies amongst pregnancies with dolutegravir exposure in the first trimester, with the overall rate of NTDs (0.13%) being only slightly higher than Canadian population data (0.04%) and comparable to the baseline rates in Botswana in non-dolutegravir exposed pregnancies (0.1%). There was, however, a small number pregnancies with elvitegravir first trimester exposure with a rate of non-NTD anomalies of 3/28 (10.7%). There were no other safety signals for other ART exposure in pregnancy. This data should ideally be combined with other global data to further understand any potential risks of ART exposure in pregnancy.

3

Evaluation of Neural Tube Defects After Exposure to Raltegravir During Pregnancy

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Background: The purpose of this comprehensive review is to evaluate the risk of neural tube defects (NTDs) after exposure to raltegravir during pregnancy.

Methods: Exposures to raltegravir during pregnancy reported cumulatively through 31-May-2018 to the company safety database were reviewed. This database includes all reports of pregnancy from Merck-sponsored clinical trials, spontaneous post-marketing and non-interventional data sources, including the Antiretroviral Pregnancy Registry (APR). Reports were classified as prospective (exposure report prior to knowledge of pregnancy outcome) or retrospective (report after knowledge of pregnancy outcome). Pregnancy reports were further reviewed to identify cases of NTDs. We also reviewed data from two ongoing pregnancy cohorts.

Results: A total of 2426 pregnancies with reported outcomes were identified among women exposed to raltegravir: 1238 from the Merck safety database and 1188 from United Kingdom/Ireland and French pregnancy cohorts. Among all 2426 pregnancy reports, 1991 were prospective. No cases of NTDs were identified among the prospective pregnancy reports, of which 767 were first trimester, including 456 in the periconception period (at or within 28 days after conception). Among the 435 retrospective reports, four NTD cases per APR criteria were identified, of which only one (myelomeningocele) was among exposures in the periconception period. Given the inherent limitations and bias of retrospective reports, it is not appropriate to calculate an incidence rate.

Conclusions: Prospectively collected pregnancy outcome data do not suggest an association between raltegravir exposure in the periconception period and NTDs.

4

Clinical Development Strategy to Inform Dosing of Antiretroviral Drugs in Women: Dolutegravir as a Case Study

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Background: Male and female differences in body size/composition, concomitant medication use, and physiological changes associated with endogenous hormone or pregnancy may result in different pharmacokinetics (PK) and drug response in women compared to men. Antiretroviral drug development guidelines encourage early enrollment of women in clinical trials to ensure that adequate safety and efficacy data are collected in the female population. For this to occur, various staged clinical pharmacology evaluations must be completed to characterize PK and exposure-response relationships and confirm an appropriate dose regimen for women

Materials & Methods: The dolutegravir (DTG) clinical pharmacology strategy was reviewed to illustrate type and timing of studies needed to understand PK and inform dosing in women. After early non-clinical reproductive risk assessments, the PK and safety of single and multiple ascending DTG doses were initially assessed in healthy men and women of non-child bearing potential. These studies were followed by a proof-of-concept study and 17 clinical drug-drug interaction (DDI) studies in men and women, including an oral contraceptive DDI study in women only, and a female genital tract distribution study. Knowledge of the contraceptive interaction potential along with later stage nonclinical reproductive toxicity results, supported enrollment of women of child-bearing potential on hormonal contraceptives into Phase 2b/3 trials. Two population PK analyses of sparse samples from 3 treatment-naïve and 3 treatment experienced Phase 2b/3 trials (N=1037; ~20% women) were undertaken to examine the effect of gender and other patient intrinsic factors (e.g., weight, age, race) on DTG PK. DTG PK was also assessed in pregnant women, first in three Phase 3b study participants who became pregnant while on study; later in larger external investigator-led clinical trials.

Results: The initial DTG clinical development program included 452 females of which 143 participated in clinical pharmacology studies. Although population PK modeling showed that gender was a statistically significant covariate predicting bioavailability (F), gender had small effect on steady-state DTG plasma exposures (<32% increase in AUC, Cmax, Cmin) that was not considered clinically significant based on a wide therapeutic index and further supported use of the same DTG dose in women as men. Importantly, co-administration with DTG did not affect norelgestromin or ethinyl estradiol PK, indicating that common hormonal contraceptives and DTG can be co-administered. DTG is present in the female genital tract with AUCs in cervicovaginal fluid, cervical and vaginal tissues ranging from 6-10% of plasma. During pregnancy, DTG plasma exposures tend to be lower during the 2nd and 3rd trimester compared to post-partum. However, these exposures were still in the same range previously observed for non-pregnant Phase 3 trial participants and therefore efficacious DTG exposures are achieved in pregnancy with standard dosing.

Conclusions: Appropriately timed acquisition of clinical pharmacology data in diverse populations, including women, during drug development (i.e., PK, DDI, exposure-antiviral/safety relationships) provide valuable evidence informing the dose for women is appropriate. These data enabled administration of the standard DTG dose to women, including those on hormonal contraceptives or in the last two trimesters of pregnancy, in later stage efficacy/safety or PMTCT trials.

5

HIV Risk and Characteristics of Women Seeking PrEP in a US Demonstration Project

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Background: Little information is known about the risk profiles of women who initiate pre-exposure prophylaxis (PrEP) for HIV prevention in the US. We analyzed baseline risk factors of women in a PrEP demonstration project using tenofovir diphosphate/emtricitabine to assess correlates of PrEP uptake.

Methods: Adherence Enhancement Guided by Individualized Texting and Drug Levels (AEGiS) is a PrEP clinical trial in Southern California of 136 HIV-negative cisgender women ≥18 years old at risk for HIV who completed enrollment. At baseline, women were surveyed for sociodemographics and risk behaviors with testing for STIs. Women in three primary HIV risk groups according to main partner type ([1] serodiscordant partnerships (SD), [2] sex workers [SW], and [3] risk attributable to known and unknown partner behavior [UP]) were compared using Fisher's exact or Kruskal-Wallis tests to determine differences by risk group.

Results: Of 136 women enrolled, median age was 40 (IQR 32-47) with 38% non-Hispanic Black, 22% non-Hispanic White and 19% Latina. Sixty-four women (47%) were grouped in the SD risk group, 21 (15%) in SW and 51 (38%) in UP. SW were less likely to be Latina (p=0.003) and more likely to report unemployment or inability to work (p=0.016) compared to SD and UP. Despite SW reporting significantly more sex partners than SD or UP, overall baseline STI rate was low at 8% with no difference by risk group. SW were more likely to report problem drinking and drug use (p=0.002) and history of intimate partner violence in the last year (p<0.001) compared to SD and UP. HIV literacy was higher among SW vs. the other risk groups (p=0.023). Nearly all SW (95%) and most UP women (83%) wanted to take PrEP to protect themselves from HIV vs. only 33% of SD (p<0.001). There were no differences between groups in depression score or HIV risk perception. Of 103 women reporting a main partner, 80% were aware of their partner's HIV status. Among the 51 women reporting an HIV+ partner, 96% thought their partner was on ART and 71% were suppressed. Black women were less likely to know if their partner was HIV+ compared to White and Latina women (p=0.032). Black and Latina women vs. White women (p=0.006), and SW and UP vs. SD (p<0.001) more frequently suspected partner infidelity.

Conclusions: Women enrolled in this PrEP demonstration project were predominantly in serodiscordant relationships but many had partners of uncertain risk and almost one in six were engaged in sex work. We found differences between individuals in the three HIV risk groups by race/ethnicity, employment, HIV knowledge and risk behaviors, PrEP motivations and main partner dynamics. Interventions to increase PrEP uptake among women may need to be customized based on the varying partnership types found among women at risk for HIV.

6

Optimizing HIV Service Delivery for Young Women Who Sell Sex: A Discrete Choice Experiment

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Background: Data from Zimbabwe estimate that >40% of sex workers (SW) begin selling sex at <25 years of age, representing a substantial proportion of the SW population. Young women who sell sex (YWSS) are disproportionately affected by HIV, with higher incidence and lower engagement in HIV services than their older counterparts. How best to deliver HIV and sexual health services to YWSS, in order to maximize their engagement, remains unclear. As we gather evidence from the DREAMS program in sub-Saharan African countries, it is vital to consider feasible next steps in programming for this high-risk group.

Methods: We conducted a discrete choice experiment (DCE) to estimate the relative strengths of YWSS preferences for service delivery characteristics of the DREAMS program in Zimbabwe. A pictorial, paper-based DCE questionnaire was developed through focus group discussions and cognitive interviews with YWSS, stakeholder input, and pretesting.

Attributes/levels investigated were based on a HIV prevention cascade framework, exploring demand, supply, and adherence factors of service delivery. Seven attributes were explored: availability of HIV services (testing co-located with post-test PrEP/ART services or not); services offered in addition to clinical (educational/skills training, gender-based violence, both); distance to referral services (walkable, requires transportation with cost provided or not); type of facility (sex worker, adolescent, or general population clinic); respectfulness of providers; appointment reminders (call, text, none); and price ($0, $1, $2). YWSS from two sites where DREAMS was implemented chose between two hypothetical programs over nine choice sets. DCE data were analyzed using random-parameters logit models, stratified by site.

Results: 438 YWSS completed the DCE, 210 in Mutare and 228 in Bulawayo. Median age was 22 (range 18-25), 58% had a secondary education, and 79% considered sex exchange their main source of income. There was significant variation by site in terms of marital status, HIV risk perception, and number of sexual partners. Provider respect was the most important attribute driving program choice at both sites, followed by preference for an appointment reminder and availability of education/skills training ($p<0.001$ for all). Some differences by site were identified in relation to preferences around price and facility type. Women in Mutare preferred services to be free ($p<0.001$), while in Bulawayo price did not influence choice of program ($p=0.83$). Women in Bulawayo preferred accessing services at either sex worker- or adolescent-dedicated facilities ($p=0.001$) whereas women in Mutare had no preference for facility type ($p=0.63$).

Conclusions: Optimizing engagement of YWSS in HIV and other health services is a critical step in reaching global HIV goals. Our DCE has identified key and achievable elements of service delivery for YWSS, with provider respect being most important. Despite demographic variation, preferences were largely consistent across sites. Some consideration of setting may be required with program implementation for YWSS, due to varying preference by site identified for certain attributes. Based on a prevention cascade framework, this research offers evidence of how best to implement services to optimize engagement of YWSS, a population whose engagement is critical to epidemic control.

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High PrEP Uptake Among HIV-Exposed Women with Pregnancy Plans in South Africa

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Background: Women who choose to conceive while exposed to HIV need prevention strategies to mitigate HIV acquisition risks. We are conducting a longitudinal study to evaluate use of tenofovir/emtricitabine (TDF/FTC) as PrEP among HIV-exposed women planning for pregnancy in KwaZulu-Natal, South Africa.

Methods: This longitudinal study offers counseling on safer conception strategies, with the option to initiate PrEP. We enroll HIV-uninfected women aged 18-35 years, who are not pregnant, in a stable relationship (≥6 months) with a partner living with HIV or of unknown serostatus, and personal or partner plans for pregnancy in the next 12 months. Safer conception counseling occurs at each study visit; PrEP users participate in adherence counseling at quarterly visits. We follow women for one year; those who become pregnant are followed through pregnancy outcome. The primary objective is to evaluate uptake of and adherence to PrEP during periconception and pregnancy periods. In this analysis, adherence is the number of bottle openings divided by number of days of expected PrEP exposure based on MEMS cap electronic pill cap data downloaded at the first three-month follow-up visit. We present screening and enrollment data for the first 136 participants and adherence data for the first 50 participants completing 3-month follow-up.

Results: Between 26 October 2017 and 31 October 2018, we screened 297 women and enrolled 136. 58 (20%) were screened out citing a lack of interest. Among the 239 interested women, main reasons for exclusion included: known HIV-uninfected partner (N=26, 11%); using long-acting contraception (N=14, 6%); HIV-positive serostatus (N=4, 2%); infertile based on reproductive screening (N=11, 5%); unable to attend study visits (N=3, 1%); above the enrollment age (N=2, 1%); not wanting to have a child (N=7, 3%); and pregnancy (N=1).

Among 136 enrolled women, median age is 25 (range 18-35) years and all identify as black South African. Partner HIV-serostatus was reported as unknown by 124 (91%) women. The majority, 81 (64%) reported condomless sex at last intercourse. Among 107 women who completed the safer conception counseling intervention at the time of analysis, 64% (N=69) women chose to initiate PrEP. Among these 69 women, 43 completed at least one follow-up visit during which adherence data were collected from an electronic pill cap. Median adherence was 69% (IQR 47%, 81%) with a quarter (26%) of participants achieving adherence of at least 80%.

Conclusion: Nearly half (46%) of screened women had personal or partner plans for pregnancy and were at-risk for HIV acquisition. Most did not know their pregnancy partner's HIV-serostatus and 64% initiated PrEP as a safer conception strategy. Preliminary data suggest challenges to PrEP adherence for this population of women at risk for acquiring HIV. The study is ongoing and final analysis will include biological markers of adherence, adjust for condomless sex, and include qualitative evaluation of barriers to and promoters of adherence.

8

Innovative Intervention for Pregnant and Breastfeeding Adolescent Mothers to Enhance Viral Suppression in Homa Bay County, Kenya

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Background: There were 184,718 HIV infected young people aged 15 to 24 in 2017 in Kenya. HIV prevalence among that age group was 1.34% for male and 2.61% for female. Annual new HIV infections of 15-24 year old male was 5,200 against 12,500 female. New HIV infections among adolescents 10-19 was 8,200. Homa Bay County comes 2nd in both HIV prevalence rate and new infections in the country at 20.7% prevalence and 4,558 new infections respectively. Homa Bay County led in new HIV infections among young people 15 to 24 years at 1,852. Homa bay also has the 3rd highest teenage pregnancy rates at 36%. PMTCT coverage in Kenya is about 77%. EGPAF initiated an intervention for adolescent mothers in Ndhiwa Sub County in Kenya.

Materials and Method: EGPAF supported 5 facilities in the sub-county to implement HIV infected adolescent mothers' intervention in 2018. The intervention included: immediate ART initiation for HIV infected pregnant and breastfeeding adolescents as per the guidelines, intensified adherence counselling and close viral load monitoring for intervention to high viral load clients; HIV infected adolescent mother's specific clinic days and support groups with a peer or adolescent friendly mentor mother; strengthened Health care providers capacity on specialized HIV and SRH needs of pregnant adolescents with talking points and a "one on one approach"; encouraged adolescents to bring their sexual partners for testing, supported the entire PMTCT cascade to ensure negative baby and healthy mother. The PSSG topics included: elimination of mother to child transmission of HIV, adherence, risk reduction, gender based violence, child and partner testing, breast feeding options, family planning and option of secondary abstinence and disclosure to sexual partner. The groups were sensitized on economic empowerment and shared ideas on chicken keeping, kitchen gardening etc. The group slogan is "Know your status plus all your contacts, I will not infect another person, I will not be re-infected". EGPAF documented the intervention.

Results: All the 101 HIV infected adolescent mothers are on ART and support groups. 38 of the adolescents, who had partners with unknown status brought their partners for testing, of which 19 were found to be in discordant sexual relationships (50% discordance), 7 of the negative male partners have also joined the groups. Only 18 out of the 101 are not yet supressed (82% suppression rate compared to 40% at the onset of the intervention); the 18 have been put on intense adherence support and will have follow up viral load testing. 6 of the adolescents have been supported to return back to school. The intervention is being scaled up in other facilities

Conclusions: Immediate ART initiation for HIV positive pregnant and breastfeeding adolescents, plus intensified adherence counselling enhances viral suppression.

HIV infected adolescent mother's specific clinic days and support groups with a peer or adolescent friendly mentor mother encourages participation in the PSSG which enhances retention.

Strengthening Health care providers' capacity on addressing specialized HIV and SRH needs of pregnant adolescents is key for success of interventions targeting HIV positive adolescent mothers.

9

Non-Vaccine Oncogenic HPV Persistence Among HPV-Vaccinated Women Living with HIV

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Background: HPV vaccines are now available and have promising safety and immunogenicity data in women living with HIV (WLWH). However, it is critical to understand what the residual burden of oncogenic HPV is within WLWH in order to inform post-vaccination cervical screening needs for this population. The objective of this analysis is to assess rates of incident persistent infection with non-quadrivalent HPV (qHPV, i.e. HPV6/11/16/18) oncogenic HPV types in our cohort of qHPV-vaccinated WLWH.

Materials & Methods: WLWH were scheduled to receive three doses of qHPV vaccine in a multi-centre study. Participants provided health data and HPV DNA samples tested by Linear array assay. Persistent cases of HPV were defined as new HPV in samples from ≥2 consecutive visits or as HPV present in the last sample. Participants had to be DNA negative for the relevant HPV type at screening and baseline. HPV31/33/35/39/45/51/52/56/58/59/68/82 were considered because they may have oncogenic potential. HPV31/33/45/52/58 are contained within the nonavalent vaccine. Median follow-up time was 4 years post initial vaccine dose.

Results: 284 participants were eligible for this analysis with 1205 person-years (PY) of follow-up (≥1 dose of vaccine, ≥1 HPV DNA result post-vaccination), reflecting an intention-to-treat population. At baseline, median age was 38 years (IQR: 32-44), median CD4 count was 499 cells/mm3 (IQR: 375-680), median CD4 nadir was 230 cells/mm3 (IQR: 120-338), and 71% had a suppressed HIV viral load (<50 copies/mL). The highest incidence of persistent infection was with HPV51 (1.38/100PY), followed by HPV52 (1.18/100PY), and HPV39 (1.06/100PY).

Conclusions: qHPV-vaccinated WLWH continue to face a burden of persistent oncogenic HPV infection. While the nonavalent vaccine could alleviate some of this burden, two of the top 3 persistent oncogenic HPVs in this cohort are not contained within any available vaccine. This highlights the need for ongoing cervical screening in HPV-vaccinated WLWH.

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Dolutegravir Pharmacokinetics During Pregnancy and Postpartum

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Background: Although dolutegravir (DTG) should be avoided around conception and until the first 8 gestational weeks due to potential neural tube defects, a place for DTG remains in the treatment of pregnant women thereafter in several scenarios, such as late presentation or as salvage regimen. Adequate antiretroviral (ARV) exposure is important to prevent the development of resistance and mother-to-child transmission of HIV. However, pregnancy-related physiological changes may alter ARV exposure. As limited data are available on PK of DTG during pregnancy, we present data on 3rd trimester DTG exposure in HIV-positive pregnant women.

Methods: Multi-centre phase IV study in HIV infected pregnant women recruited in European HIV treatment centers. Patients treated with DTG 50mg QD during pregnancy had 24-hour PK profiling in the 3rd trimester (T3) and 3-7 weeks postpartum (PP). Paired cord (CB) and maternal (MB) blood samples were taken at delivery. Safety and virological data were collected. DTG plasma concentrations were determined with a validated LC-MS/MS method (LLOQ of 0.01mg/L). Geometric mean ratio (GMR) T3 PK versus PP with 90% confidence interval (CI) was calculated for AUC0-24h, Cmax and Ctrough.

Results: 14 patients (10 black, 4 white/other), median (range) age 32 (21-42) yrs were included. 5 patients did not attend at postpartum, 1 patient was excluded from PK analysis because of invalid plasma concentrations. Median (range) GA at delivery was 39 wks (34-40); birth weight was 3258 gr (2120-4040). Peri-delivery all patients had HIV VL<50cps/mL. 10 children were HIV un-infected (4 unknown status).One intrauterine fetal death (34 weeks GA) occurred due to cholestasis pregnancy syndrome, 1 infant had hypospadia, 1 had polydactily (as other members of her family). Two maternal hospital admissions occurred to exclude pre-eclampsia.
Ratios T3/PP (GMR (90%CI), n=8) were: 0.88 (0.67-1.16) for AUC0-24h; 0.94 (0.75-1.18) for Cmax; 0.74 (0.50-1.09) for Ctrough. One patient had a subtherapeutic Ctrough (<0.3 mg/L) in the T3 of pregnancy. Median (range) CB:MB ratio was 1.4 (1.1-1.8; n=8).

Conclusion: Although variability is high, DTG AUC0-24h seems similar in pregnancy and postpartum. In T3 DTG plasma Ctrough was above the efficacy level of 0.3 mg/L in all but one patient. These findings, coupled with the undetectable viral loads at delivery, support standard dosing of DTG during pregnancy.

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Intimate Partner Violence, Depression, and Mortality Among a Cohort of Women Living with HIV Marginalized by Socio-Structural Inequities in Vancouver, Canada

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Background: Globally, intimate partner violence (IPV) has significant health impacts on women, including worsening mental health. The United Nations Sustainable Development Goals are committed to reducing IPV and increasing support for women experiencing IPV. Among women living with HIV (WLHIV), few studies have examined prevalence, consequences (i.e., mortality), and correlates of IPV.

Methods: Using cross-sectional survey data from the Longitudinal Investigations into Supportive Ancillary Health Services (LISA) study from 2007-2010 in Vancouver, Canada, we examined the prevalence, consequences, and correlates of any IPV (emotional, and/or sexual, and/or physical) among individuals living with HIV faced with socio-structural inequity. Of the 1,000 LISA participants, 251 were WLHIV who responded to violence-related questions. IPV was self-reported by asking women if they had experienced any emotional (verbal), sexual, and/or physical partner violence in their lifetimes. With linked longitudinal clinical data from British Columbia's HIV Drug Treatment Program and mortality captured by the provincial vital statistics registry (up until December 31, 2017), potential correlates of shortened survival time, including IPV, were examined using multivariable Cox proportional hazards regression models. Subsequently, HIV viral suppression (<50 copies/mL), food insecurity, potentially problematic alcohol use, history of injection drug use, depression diagnosis (lifetime), and adherence to antiretroviral therapy were examined as potential correlates of IPV using logistic regression models

Results: Among the 251 women in this sample, 150 (60%) reported any IPV in their lifetime. Sixty-three participants (25%) died during follow-up where 28% of women who experienced any IPV died compared to 20% of women who did not experience IPV. The relationship between any IPV and mortality was non-significant (adjusted hazard ratio [HR]=1.11, 95% confidence interval [CI]=0.82-1.50). However, in multivariable models, depression was significantly associated with mortality (aHR=1.37, 95%CI=1.03-1.82). In multivariable logistic models, the following correlates of any IPV were identified: a diagnosis of depression (adjusted odds ratio [OR]=1.91, 95% CI=1.09-3.37) and a history of problematic alcohol use (aOR=2.54, 95%CI=1.40-4.61); 136 (54%) participants had ever been diagnosed with depression, and half (51%) had a history of potentially problematic drinking.

Conclusion: There is a high prevalence of lifetime IPV among WLHIV who are marginalized by socio-structural inequities. Given that IPV was independently associated with depression and that depression was associated with reduced survival time, screening for IPV in treatment programmes, and efforts to prevent IPV and ensure trauma and violence aware care for WLHIV are essential.

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Vaginal Microbiome and Associations with Tenofovir Diphosphate and Lamivudine Triphosphate in Cervical Tissues of Ugandan Women

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Background: Multipurpose prevention that combines delivery of contraception and HIV prevention therapy are an appealing option for women of child-bearing age who are also at risk of HIV infection. Effective concentrations of antiretrovirals in the female genital tract (FGT) are critical for success. Previous studies have suggested that, when topically applied, tenofovir (TFV) disposition in the FGT may be altered by the vaginal microbiome. TFV disposition following oral dosing does not seem similarly affected, however few studies have directly measured the active metabolite tenofovir diphosphate (TFV-DP). In addition, despite widespread lamivudine use, the association between lamivudine triphosphate (3TC-TP) exposure in FGT and the vaginal microbiome is unknown. We sought to describe TFV-DP and 3TC-TP disposition in cervical tissue of women orally dosed with tenofovir disoproxil fumarate and lamivudine (TDF/3TC). Users of depot-medroxyprogesterone (DMPA) and non-hormonal contraception (non-HC) were included to elucidate the interactions between hormonal contraception, the vaginal microbiome, and drug disposition.

Materials/Methods: HIV-positive, virologically suppressed, non-pregnant women, receiving combination TDF/3TC as part of antiretroviral therapy, were recruited in Kampala, Uganda. Women receiving DMPA (n=25) or using non-HC (n=25) participated in a single visit study. Cervical biopsies were obtained for quantification of TFV-DP, 3TC-TP, and endogenous dATP and dCTP using liquid chromatography with tandem mass spectrometry. Blood plasma was collected to assess medication adherence. Vaginal swabs were collected on polyester swabs from the mid vaginal wall. DNA was extracted from swabs and 16S rRNA gene sequencing was performed to characterize the vaginal microbiome. Microbial diversity was compared between contraceptive groups using the Shannon index of alpha diversity. Associations between vaginal microbiome profiles and drug exposure in cervical tissues were evaluated using canonical correspondence analysis.

Results: Fifty women aged 21-34 years were enrolled between November 2017 and March 2018. Women receiving DMPA had lower bacterial alpha diversity compared to the non-HC group (mean Shannon diversity 1.36 vs 2.00, p=0.035). 3TC-TP and dCTP concentrations were correlated with relative abundances of Lactobacillus (Spearman r = 0.32 and 0.30; p=0.033 and 0.044). No vaginal genera were significantly correlated with cervical TFV-DP or dATP however relative abundances of Fusobacterium were inversely correlated with TFV plasma concentrations (Spearman r = -0.32, p=0.033). TFV-DP was inversely correlated with Shuttleworthia abundances within DMPA users (Spearman r = -0.43, p=0.040) but not within non-HC users (Spearman r = -0.14, p=0.5).

Conclusions: Our findings that TFV-DP concentrations in cervical tissue following oral dosing are not significantly correlated with vaginal microbiome profiles is consistent with clinical trials of oral TFV-based PrEP that found no efficacy differences based on microbiome status. These data do, however, provide further evidence of an interaction between hormonal contraception and the vaginal microbiome that may influence drug exposure. In addition, these are the first data to describe the association between 3TC-TP concentrations in cervical tissues and the vaginal microbiome. These data contribute to our understanding of how interactions between exogenous hormones and the vaginal microbiome influence drug disposition in the FGT and will be essential in facilitating development of multipurpose prevention for contraception and HIV.

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Women's Involvement in Clinical Research: Women Included in Dolutegravir Clinical Trials Versus Collaborative Studies

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Background: The importance of considering gender differences in clinical decision-making is crucial. However, it has been acknowledged in recent decades that clinical trials have not always adequately enrolled women or analysed gender-specific differences in the data. As these deficiencies have hindered the progress of understanding women's response to medications; agencies, academia and pharmaceutical companies, including ViiV, have worked towards the inclusion of women in clinical trials and appropriate analysis of gender-specific data from clinical trials. This review outlines ViiV efforts and progress of women's inclusion in randomised clinical trials (RCTs) and collaborative studies (CSs) for prescription drugs and presents considerations for researchers, clinicians, and academicians on this issue. The objective of this analysis is to describe the number of women included in RCTs and CSs and characterise its implications for prescription and use of novel ARVs

Methods and Materials: Analysis of the number and proportion of women living with HIV (WLWHIV) included in eleven ViiV sponsored Phase III RCTs of dolutegravir (DTG) development programme, and its comparison with the number and rate of WLWHIV included and being included in worldwide DTG collaborative studies

Results: Since 2009 the number of WLWHIV included in ViiV studies increased, including the design and development of a 100% women study and establishment of women targets in Phase III RCTs. 1871 women were included in 11 RCTs and 1,075 were exposed to DTG. In the context of collaborative studies, women rates are significantly higher shadowing the epidemiological characteristics of the territorial areas where the studies are performed, women inclusion rates reached up to 70%. The same phenomenon has been seen when RCTs are performed in the context of co-infections like tuberculosis where WLWHIV inclusion rate rise to 41%, and in second line regimens assessed in low and middle-income countries where rates of 35% were achieved.

Conclusions: Interestingly, the inclusion patterns describe the epidemiological characteristics of the region and highlights potential clinical and scientific knowledge gaps and needs. The HIV community, healthcare-professionals, regulators and drug innovator companies all have an interest in ensuring appropriate enrolment of women in clinical trials and gender specific analysis. It is critical that data from women are available when decisions on dosing, safety, and efficacy of therapeutic agents are being made. There has been a shift in philosophy in how to best protect public and global health but further efforts towards women inclusion are needed.

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Altered Levels of Bioactive Lipids in HIV and cART-Exposed Pregnancy

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Background: Pregnant women living with HIV are at an increased risk of developing adverse birth outcomes including preterm birth and fetal growth restriction. The mechanisms that underlie these are not fully understood. Lipid mediators derived from arachidonic acid (ARA) play a pivotal role in the maintenance of pregnancy and in fetal development. High levels of ARA and its downstream metabolites, 5-, and 15-hydroxyeicosatetranoic acids (HETE) have been linked to pregnancy complications. Lipid abnormalities are common in people living with HIV (HIV+) and are accentuated in those receiving combination antiretroviral therapy (cART). HIV infection has been linked to overstimulation of the ARA pathways. Our objective was to investigate the effects of HIV infection and cART use during pregnancy on the levels of pregnancy-related bioactive lipids in maternal and cord plasma.

Methods: Maternal plasma (gestational week 33-38), cord plasma, and placental tissue were collected from HIV+ (n=55) and HIV-negative (n=40) pregnant Canadian women followed prospectively throughout gestation. We quantified the levels of 60 lipid mediators in maternal and cord plasma using an unbiased, quantitative liquid chromatography tandem mass spectrometry (LC-MS-MS) based lipidomics approach. The placental expression level of cytochrome P450 2J (CYP2J) was quantified using real-time quantitative polymerase reaction.

Results: Birth weight centiles were lower in the HIV+ compared to the HIV-negative group [median (IQR); 24.3 (8.9–57.0) vs 53.5 (30.8–70.8), p=0.001]. Twenty-two bioactive lipid mediators were significantly different throughout pregnancy between the two groups. Levels of ARA were significantly higher in maternal blood of the HIV+ group [median (IQR); 741.3 ng/mL (522.2–1014) vs 486.4 ng/mL (392.3–679.5), p=0.0002]. The levels of downstream metabolites of ARA 5-, 11-, and 15-HETE were also higher in the maternal blood of the HIV+ group ($p<0.01$), while levels of 5,6-, 8,9-, and 11,12- dihydroxyeicosatrienoic acids were lower in the cord blood of the HIV+ group ($p<0.0001$). The placental expression of CYP2J, an enzyme involved in the metabolism of ARA, was 1.5-fold higher in the HIV+ group (p=0.005).

Conclusions: Our data suggest that exposure to HIV/cART during pregnancy is associated with lipidomic profile alterations, including overstimulation of the metabolism of pregnancy-relevant bioactive lipids of the ARA pathways. Studies are underway to determine the association of these alterations to birth outcomes.

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Double-Dose Levonorgestrel Implant Does Not Fully Overcome Drug-Drug Interaction with Efavirenz

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Background: We previously described 57% lower levonorgestrel (LNG) exposure in women receiving the LNG subdermal implant (standard dose, 150mg) with efavirenz (EFV)-based antiretroviral therapy (ART) compared to ART-naïve women. Three of 20 women (15%) had an unintended pregnancy within 48 weeks of LNG-EFV combined use, with observed LNG concentrations ≤ 303pg/mL at the visit prior to pregnancy. Among women receiving LNG-EFV, 18 (90%) had any LNG concentration ≤ 303pg/mL during the study. We hypothesized this interaction could be overcome by doubling the LNG implant dose; specifically, LNG 300mg exposure over 48 weeks in women receiving EFV-based ART would be similar to ART-naïve women receiving LNG 150mg.

Materials & Methods: This was a pharmacokinetic evaluation of double-dose (300mg) LNG implants in Ugandan women receiving EFV-based ART with an undetectable HIV-RNA (DoubLNG group; n=28). LNG implants, one in each arm, and a copper intrauterine device were placed at entry. Historical controls were ART-naïve Ugandan women (n=17) who received standard-dose (150mg) LNG implant at entry. Plasma was collected at 1, 4, 12, 24, 36, and 48 weeks. LNG concentrations were analyzed by a validated LC-MS/MS method (range 50-1500pg/mL), summarized as median (IQR), and compared between groups by geometric mean ratio (GMR) with 90% CI. The proportion with LNG ≤ 303 pg/mL was compared by Fisher's Exact test.

Results: All women were Black African. The DoubLNG group had a median age of 33 years and median weight of 58 kg; the control group was 29 years and 69 kg, respectively. After 1 week, LNG concentrations were 44% lower in the DoubLNG group compared to the historical control group: 571 (466, 894) pg/mL in the DoubLNG group versus 1073 (744, 1586) pg/mL in the control group [GMR (90% CI) 0.56 (0.52, 0.61)]. At weeks 4, 12, 24, and 36, LNG concentrations in the DoubLNG group were 33-39% lower than the control group. After 48 weeks, LNG concentrations remained 39% lower compared to the control group: 373 (319, 540) pg/mL in the DoubLNG group versus 651 (469, 879) pg/mL in the control group [GMR (90% CI) 0.66 (0.61, 0.72)]. During the study, 18% (n=3) in the control group and 46% (n=13) in the DoubLNG group had any LNG value ≤ 303 pg/mL (p=0.06).

Conclusions: We observed 33-44% lower LNG concentrations over 48 weeks in women receiving EFV-based ART plus LNG 300mg implants compared to ART-naïve women on LNG 150mg implants. Relative to our prior study, the magnitude of the interaction with EFV at week 48 was smaller with double-dose LNG (34% lower) vs standard-dose LNG (57% lower). Also, fewer women receiving EFV-based ART had an LNG ≤303 pg/mL in the double- vs standard-dose group (46% vs 90%, respectively; p=0.002). Doubling the dose of LNG implants did not fully overcome the interaction with EFV compared to our historical control group, and the contraceptive effectiveness of this approach remains uncertain.

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Lopinavir (an HIV Protease Inhibitor) Impairs Uterine Remodeling During Pregnancy

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Background: Exposure to protease inhibitor (PI) based combination antiretroviral therapy (cART) during pregnancy; especially Lopinavir (LPV) based cART during periconception, increases the prevalence of preterm delivery and low birth weight. PIs may contribute to these adverse events by lowering progesterone (P4) levels. P4 plays a central role in uterine preparation for pregnancy, and a critical P4-dependent process in early pregnancy is remodeling of the uterine endometrium to form the decidua. The key events of this process include decidualization of endometrial stroma, and remodeling of decidual spiral arteries into highly dilated vessels to adequately supply maternal blood to the placenta and fetus. As PI-cART causes P4 dysregulation, we hypothesized that decidualization and spiral artery remodeling are likely to be impaired upon exposure to LPV based cART. Hence we investigated the effects of PIs on the decidua.

Methods: Human HIV-negative decidua and placenta tissue was collected from elective first trimester terminations. The placenta-decidua co-culture model was used to investigate the effects of PIs on spiral artery remodeling by immunohistochemistry. The placental villous explant culture was used to study extravillous trophoblast (EVT) invasion across matrigel. A primary decidual cell culture system was used to assess PI-induced changes in soluble and intracellular protein factors using ELISA and multiplex approaches. Flow cytometry was used to examine the viability of various decidual cell types.

Results: Treatment with LPV impaired the EVT outgrowth as well as remodeling of decidual spiral arteries. A dysregulation of decidualization was observed, marked by reduced stromal expression of prolactin and IGFBP1, the key biomarkers of decidualization. The viability of uterine NK (uNK) cells was affected, concomitant with changes in the secretion profile of uNK and stroma cell specific growth-factors and cytokines/chemokines such as VEGF, PlGF, IL-15, MMP-9 and CXCL16. The effects of LPV treatment could be attributed to a decrease in the expression of transcription factor STAT3, known to regulate decidualization.

Conclusion: Overall, our data reveal that LPV based cART causes dysregulation of decidualization and impairment of spiral artery remodeling, thereby possibly contributing to inadequate placentation and poor birth outcomes. Our findings suggest a possible mechanism to explain why LPV exposure from conception may be associated with higher rates of adverse birth outcomes.

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Adverse Pregnancy Outcomes in HIV-Positive Pregnant Women on ART in Kenya

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Introduction: While antiretroviral treatment (ART) is essential for the elimination of mother-to-child transmission (MTCT) and improved health outcomes for women living with HIV (WLWH) globally, adverse pregnancy outcomes (APO) among pregnant women on life-long ART are a growing concern.

Methods: A total of 1225 pregnant WLWH enrolled in the Mother-Infant Visit Adherence and Treatment Engagement (MOTIVATE) study from 24 clinics in a high HIV prevalence region in southwestern Kenya between January 2015 to January 2018 were included. MOTIVATE is a cluster-randomized trial testing the impact of two behavioral interventions (community mentor mothers (CMMs) and text messaging) on retention in care and antiretroviral treatment (ART) adherence among HIV-positive pregnant/postpartum women. Women with an APO (miscarriage, stillbirth, neonatal death, infant death, preterm delivery, low birth weight) were compared with women with live birth at least 30 days postpartum without APO. Maternal deaths were excluded from analysis. Multivariable logistic regression was conducted including multiple predictors of APO, accounting for clustering by site.

Results: Among 1225 HIV-positive pregnant women of median age 30.5 years (IQR 26.2 – 34.2), 440 women (35.9%) experienced an APO, including 333 (27.2%) preterm deliveries, 54 (4.4%) low birthweight infants, and 80 (18.2%) fatal adverse outcomes (including stillbirths, miscarriages, and maternal, neonatal or infant deaths). Women receiving the text message intervention [adjusted odds ratio (aOR) 0.60, 95%CI (0.45-0.80)] and those who received both text messages and the CMM intervention [aOR 0.68 (0.55-0.86)] had lower odds of having an APO when compared to the control group. (Table1) Women on non-nucleoside reverse transcriptase inhibitors (NNRTI) based ART were less likely to experience an APO when compared to those on protease inhibitors (aOR 0.43, 95%CI 0.21-0.88). Women receiving Tenofovir were twice as likely to experience an APO when compared to women on Zidovudine (aOR 2.00, 95%CI 1.28-3.10). Other factors associated with increased odds of APO included age (aOR 1.14 per 5 years, 95%CI 1.01-1.29) and time on ART.

Conclusions: This cohort of pregnant women on ART experienced high rates of adverse pregnancy outcomes, which were associated with age, type of ART, and duration on ART. Further understanding of the impact of ART and possible mitigating interventions to reduce adverse pregnancy outcomes in this population are needed.

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Adoption of an HIV-Neutral Approach to Pregnancy Care in San Francisco, California

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Background: As biomedical HIV prevention options become increasingly available, perinatal HIV clinics historically serving exclusively people living with HIV (PLWH) have expanded to include care for HIV-negative individuals vulnerable to HIV. However, there are few data to demonstrate whether patient populations, services, and outcomes change, necessitating modified clinical practices. Preliminary findings from early adopters may help other programs determine how integrated HIV treatment and prevention care during pregnancy can be facilitated and optimized.

HIVE clinic, a multidisciplinary prenatal care clinic at Zuckerberg San Francisco General Hospital in San Francisco, California, began offering pre-exposure prophylaxis to pregnant people in 2010. We conducted a retrospective analysis of the HIVE database, including data from pregnant individuals served from 2010 through 2017 regardless of HIV status. We used descriptive statistics to compare demographics, medical and social histories, pregnancy outcomes, and service utilization between PLWH and those vulnerable to HIV.

Results: One hundred and nine pregnancies were followed over the study period, 76 in PLWH (70%) and 33 in individuals vulnerable to HIV (30%). There were no statistically significant differences by age, race/ethnicity, English as a first language, employment or insurance status. Individuals presented for their first prenatal visit at similar stages in pregnancy with no statistical differences by group: approximately half presented in the first trimester, one third in the second trimester, and one tenth in the third trimester. Individuals vulnerable to HIV were more likely to report ever experiencing homelessness (61 vs. 29%; p=0.008), being unstably housed or homeless during the current pregnancy (61 vs. 46%, p=0.1), and using substances in the current pregnancy (39 vs. 17%) compared to PLWH. There were no differences in history of intimate partner violence (IPV) (36 vs. 34%), current IPV (14 vs. 15%), history of mental illness (58 vs. 57%), admission for grave psychiatric disability (9 vs. 7%), current psychiatric medication use (18 vs. 18%), history of incarceration (15 vs. 16%), and child protective services involvement in prior pregnancies (24 vs. 24%). There was a trend toward PLWH being more likely to receive adequate prenatal care, defined as 4 or more prenatal visits (71 vs. 58%, p=0.2). Although PLWH more often had a prior preterm birth (14% vs. 3%, p=0.08), there were no differences in obstetrical complications (24 vs. 26%) nor preterm births (18 vs. 16%) in the current pregnancy. Finally, PLWH were more likely to attend any postpartum visit within 6 weeks of birth (46 vs 30%, p=0.1).

Conclusions: By expanding services to individuals vulnerable to HIV, HIVE clinic continued to care for people with similar social determinants of health who likely benefited from the wrap-around services HIVE has provided for decades. Notably, individuals vulnerable to HIV trended towards having more housing insecurity, ongoing substance use, inadequate prenatal care, and no postpartum care, highlighting gaps in service provision by sero-status. Future studies are needed to understand how services can be tailored to meet individuals' needs, regardless of HIV status, and how healthcare systems can become HIV neutral in their approaches.

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Early Antenatal Care Visit as it Relates to Prevention of Mother to Child Transmission of HIV in Sub-Saharan Africa

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Background: Antenatal care (ANC) aims mainly at prevention, early detection and management of general medical and pregnancy associated disorders. Early ANC booking before 20 weeks of gestation is recommended for maximum utilization, it is also one of the quick-win strategies for Prevention of Mother-to-Child transmission of HIV (PMTCT) as it helps in early detection of HIV positive pregnant women. Despite significant efforts made at improving ANC enrolment in Sub-Saharan Africa, the enrolment rate is still abysmally low in some countries. To this end, this research was done to evaluate the early ANC visit coverage and determinants in different part of sub-Saharan Africa.

Methods: This research used data from 35 sub-Saharan African Demographic and Health Surveys (DHS). The DHS were nationally representative cross-sectional conducted between 2006 and 2016 and were utilized for various analyses. The respondents were women aged 15-49 years old. This study was based on analysis of existing survey data with all identifier information removed. All study participants gave informed consent before participation and all information was collected confidentially.

Results: Overall, a total of 208,876 respondents took part in the study with only 127,211 respondents (61%) accessing early antenatal care before 20 weeks of gestation. The coverage rate ranged from 33% in Kenya to 85% in Ghana, with 16 of the included countries recording rates that were below 60%. Education played a significant role with respondents having secondary-higher educated women 1.4 times more likely to access early ANC service. The likelihood of first ANC visit before 20weeks is higher among the women who had multiple media exposure (OR: 1.9), highest wealth index (OR: 1.6) and living in the urban area (OR: 1.3). The result also showed that surveys conducted from 2010 onwards had significant effects on utilization of ANC service before 20 weeks. The results revealed that maternal age, employment status and marital status were not significant as determinants of early ANC visit in different parts of Africa.

Conclusion: This study revealed that there are still a lot to be done with respect to first ANC visit before 20 weeks if sub-Saharan African countries are to attain the UNAIDS 90-90-90 goals. Countries with less than optimal performance need to adopt policies and channel resources towards this key aspect of PMTCT. We recommend that emphasis should be placed more on women's education, media exposure, and economic empowerment. In addition, rural residence should also receive more support and have innovative programs regarding the benefit of early ANC as it relates to HIV/AIDS and PMTCT.

KEYWORDS: Sub Saharan Africa;; HIV; Early antenatal care; women;, Prevention of Mother to Child Transmission (PMTCT)

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Efficacy of Two-Drug Regimen of Dolutegravir Plus Lamivudine (DTG+3TC) Versus Dolutegravir Plus Tenofovir/Emtricitabine (DTG+TDF/FTC) at 48 Weeks in Antiretroviral Naïve Women: GEMINI Studies Subgroup Analysis

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Background: Two-drug regimens (2DRs) are being evaluated against standard 3-drug regimens for their potential to reduce cumulative drug exposure during life-long antiretroviral therapy in patients with HIV-1 infection. In the GEMINI studies, the efficacy of the 2DR of DTG+3TC was recently shown to be non-inferior to DTG+TDF/FTC at 48-weeks in treatment-naïve adults [1].

Methods and Materials: GEMINI-1&2 are identical, double-blind, multicentre Phase III studies evaluating efficacy and safety of DTG+3TC once-daily in treatment-naïve HIV-1 infected adults with Screening HIV-1 RNA ≤500,000c/mL (ClinicalTrials.gov: NCT02831673/NCT02831764). Participants were randomised 1:1 to treatment with DTG+3TC or DTG+TDF/FTC. The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50c/mL at Week 48 (Snapshot algorithm). We present a secondary analysis of efficacy and safety in women. For the primary endpoint, estimates and confidence intervals were based on a stratified analysis using Cochran-Mantel-Haenszel weights. The subgroup analysis was unadjusted.

Results: 714 and 719 adults were randomised and treated in GEMINI-1&2, respectively. Based on a 10% non-inferiority margin, DTG+3TC was non-inferior to DTG+TDF/FTC at Week 48 in both GEMINI-1&2. Results were generally consistent regardless of age, gender, race or baseline HIV-1 RNA. A total of 211 women were included and exposed to DTG based regimens, representing 15% of the study population. 113 (16%) women were included in the DTG+3TC arm and 98 (14%) in the DTG+TDF/FTC arm. 100/113 (88%) of women taking DTG+3TC achieved plasma HIV-1 RNA <50c/mL at Week 48, and 89/98 (91%) in the DTG+TDF/FTC. Overall rates of AEs were similar between arms, with low rates of withdrawals due to AEs in both arms [GEMINI-1&2 pooled: DTG+3TC 15/716 (2%) vs. DTG+TDF/FTC 16/717 (2%)]. More drug related AEs were reported with DTG+TDF/FTC [GEMINI-1&2 pooled: DTG+3TC 126/716 (18%) vs. DTG+TDF/FTC 169/717 (24%)]. In women, adverse events frequency was comparable between arms. Results of efficacy and safety subgroup analysis were similar in the individual studies compared with pooled results

Conclusions: In GEMINI-1&2, a 2DR of DTG+3TC demonstrated similar efficacy to DTG+TDF/FTC in treatment-naïve adult women. Both regimens were well tolerated. These results demonstrate that DTG+3TC is an option for initial treatment of HIV-infected patients across a spectrum of disease characteristics and patient populations. The studies are ongoing to explore long-term durability and safety.

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1. Non-inferior efficacy of dolutegravir (DTG) plus lamivudine (3TC) versus DTG plus tenofovir/emtricitabine (TDF/FTC) fixed-dose combination in antiretroviral treatment-naïve adults with HIV-1 infection – 48-week results from the GEMINI studies. P. Cahn, J. Sierra Madero, J. Arribas, et al. 22nd International AIDS Conference, Amsterdam, Netherlands, 23-27 July 2018. Abstract TUAB0106LB.

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Tenofovir Alafenamide vs. Tenofovir DF in Women: Pooled Analysis of 7 Clinical Trials

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Background: Globally, the majority of people living with HIV are cis-women, who are underrepresented in clinical trials. Tenofovir alafenamide (TAF) has demonstrated an improved renal and bone safety profile relative to tenofovir disoproxil fumarate (TDF) in multiple randomized trials with similar efficacy. We pooled 7 studies to evaluate the efficacy and safety of TAF vs. TDF for ART initiation or switch in women.

Materials & Methods: Data from 779 cis-women in 7 randomized, double-blind clinical trials (2 in treatment-naïve adults, 5 in virologically suppressed adults) through W96 were analyzed. All participants who initiated or switched to TAF-based regimens (elvitegravir/cobicistat/emtricitabine [FTC]/TAF, rilpivirine/FTC/TAF, FTC/TAF, or bictegravir/FTC/TAF) were compared with those who initiated or continued TDF-based regimens. Virologic suppression (VS; HIV-1 RNA <50 c/mL) rates at W96 were determined by FDA snapshot analysis. Bone mineral density (BMD) and the renal tubular biomarkers urine beta-2-microglobulin (B2M):creatinine (Cr) ratio and retinol binding protein (RBP):Cr ratio are reported at W96. Differences were compared using Wilcoxon rank sum test.

Results: A total of 779 cis-women were enrolled (n=429 TAF, n=350 TDF). Participants were primarily women of color (67% black or Hispanic/Latina; 45% black and 25% Hispanic/Latina). Treatment-naïve women (WTN) had a median age of 37 years with median HIV-RNA 4.47 log10 c/mL and CD4 365 cells/mm³. Women with VS (WVS) had a median age 47 years with median CD4 711 cells/mm³. Of WTN, 86% (TAF) and 85% (TDF) achieved VS (p=0.71) at W96. VS was maintained in 86% of WVS switching to TAF and 85% continuing TDF (p=0.99). Overall TAF and TDF were well-tolerated. Discontinuation due to adverse event/death was 0% (TAF) vs. 1.6% (TDF) in WTN and 1.3% (TAF) vs. 2.2% (TDF) in WVS. At W96 there was less impact on renal biomarkers in WTN initiating TAF- vs. TDF-based regimens (median % change in RBP:Cr ratio +12.1 vs. +67.5; B2M:Cr ratio -37.4 vs. +13.1; p<0.001 for both), and decreases in BMD were smaller (median % change in spine BMD -0.292 vs. -2.606; hip BMD -1.296 vs. -3.938; p<0.001 for both). Women switching from TDF to TAF experienced decreases in tubular proteinuria (median % change in RBP:Cr ratio +8.0 vs. +50.8; B2M:Cr ratio -9.5 vs. +29.2; p<0.001 for both) and improvements in BMD (median % change in spine BMD +1.703 vs. -1.055; hip BMD +1.699 vs. -0.831; p<0.001 for both) at W96.

Conclusions: Similar to the overall results in pivotal naïve and switch trials of FTC/TAF-based regimens, cis-women who initiated or switched to TAF had significantly improved bone and renal safety parameters compared to TDF, with similar rates of virologic suppression through W96. These pooled data from 7 studies demonstrate a safety advantage for initiating therapy with or switching to TAF compared to TDF in women.

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Week 48 Safety and Efficacy of the HIV-1 Attachment Inhibitor Prodrug Fostemsavir in Heavily Treatment-Experienced Women in the BRIGHTE Study

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Objectives: Fostemsavir (FTR) is an investigational first-in-class attachment inhibitor prodrug that is metabolised to its active moiety, temsavir (TMR) which binds to the viral envelope glycoprotein 120 (gp120), locking it in a conformational state that inhibits initial interaction between the virus and host immune cells. This prevents viral attachment and entry into the host CD4+ T-cells [Langley, Proteins 2015]. BRIGHTE is an ongoing Phase 3 study evaluating FTR in heavily treatment-experienced (HTE) patients infected with multi-drug resistant HIV-1 who are unable to form a viable antiretroviral (ARV) regimen. Women account for about 50% of the people living with HIV worldwide. Herein, we present efficacy results by gender subgroups through Week 48. The primary and secondary efficacy and safety results were presented previously [Lataillade, European AIDS Conference 2017; Ackerman, HIV Glasgow Congress 2018].

Methods: HTE participants failing their current ARV regimen (confirmed HIV-1 RNA >=400 copies/mL) were assigned to the Randomized Cohort (RC) or Non-randomized Cohort (NonRC), depending on if they had 1 to 2 or zero remaining, currently approved, ARV classes, respectively. RC participants were randomized (3:1) to blinded FTR 600mg or placebo twice daily (BID) plus current failing regimen for 8 days, followed by open-label FTR 600mg BID plus optimized background therapy (OBT). NonRC participants started open-label FTR plus OBT on Day 1. Efficacy results are presented by gender, and safety results are presented for the overall population.

Results: Twenty-two percent (82/371) of study participants are women. The adjusted mean decline in HIV-1 RNA at Day 8 for the RC was 0.79 log10 copies/mL for FTR versus 0.17 log10 copies/mL for placebo ($p<0.0001$) with comparable results in women [0.74 log10 copies/mL for FTR versus 0.29 log10 copies/mL for placebo] and men [0.82 log10 copies/mL for FTR versus 0.14 log10 copies/mL for placebo]. At Week 48, rates of virologic suppression (HIV-1 RNA <40 copies/mL, ITT-Snapshot analysis) were 54% (146/272) for the RC and 38% (38/99) for the NonRC, and for women, rates were 61% (44/72, RC) and 40% (4/10, NonRC). The mean increase in baseline CD4+ T-cell counts through 48 weeks for the RC was 139 cells/µL (135.1 SD), and by gender was 159 cells/µL (131.9 SD) for women versus 132 cells/µL (135.8 SD) for men. Through the Week 48 data cut-off, 92% (343/371) of all participants had ≥1 adverse event (AE), 35% had ≥1 serious AE (SAE), 3% had ≥1 drug-related SAE and 7% had an AE that led to discontinuation from the study. Compared to participants in the RC, NonRC participants experienced higher rates of severe safety events, including SAEs, Grade 3-4 AEs and deaths.

Conclusion: Female HTE participants on an FTR-based regimen had comparable rates of virologic response and immunologic improvement to male participants through Week 48 in the ongoing Phase 3 BRIGHTE trial. In HTE participants, FTR-containing regimens were generally well tolerated, with few discontinuations due to AEs. These results support further development of FTR as a therapeutic option for HTE patients with multi-drug resistance and few remaining active therapies.

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Efficacy and Safety of the Once-Daily Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) Single-Tablet Regimen in Antiretroviral Treatment (ART)-Experienced and ART-Naïve Women Living with HIV-1: EMERALD and AMBER Week 96 Results

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Background: D/C/F/TAF 800/150/200/10mg, currently approved in the EU, US and Canada, is being investigated in two Phase 3 trials, EMERALD (virologically suppressed adults; NCT02269917) and AMBER (ART-naïve adults; NCT02431247). We present a cumulative through week 96 gender-based analysis of the D/C/F/TAF arms in each trial.

Materials & Methods: Patients in the D/C/F/TAF and control arms of both trials (study designs described previously) continued on or switched to D/C/F/TAF in an open-label extension phase until week 96 provided they consented and continued to derive benefit. Week 96 efficacy endpoints were % patients with cumulative confirmed viral load (VL) ≥50 copies/mL (protocol-defined virologic rebound [PDVR]) (EMERALD only) and VL<50 copies/mL (virologic response) and VL ≥50 copies/mL (virologic failure [VF]) (FDA snapshot) (EMERALD and AMBER). No week 96 comparisons were made between arms during the open-label phase. This secondary analysis focuses on long-term efficacy and safety over 96 weeks in the D/C/F/TAF arms. However the trials are not powered to show differences across genders.

Results: Of the total randomized and treated patients, 205/1141 (18.0%, EMERALD) and 85/725 (11.7%, AMBER) were women. In the D/C/F/TAF arms, 140 women/623 men (EMERALD) and 44 women/318 men (AMBER) continued on D/C/F/TAF in the extension phase.

In EMERALD, PDVR rates (95% confidence [CI]) cumulative through week 96 in the D/C/F/TAF arm were- women: 2.9% (0.8; 7.2); men: 3.2% (2.0; 4.9); week 96 virologic response rates (95% CI) (snapshot) were 85.7% (78.8; 91.1); 91.8% (89.4; 93.8), respectively, and VF rates (snapshot) were 1.4% (0.2; 5.1); 1.1% (0.5; 2.3). Through week 96, incidences of adverse events (AEs) in women/men were 87.1%; 91.2%; study drug-related grade 3–4 AEs: 1.4%; 1.9%; study drug-related serious AEs: 0%; 0.3% and discontinuations due to AEs: 2.1%; 2.2%. Most common AEs (≥10%) were upper respiratory tract infection (URTI), headache, bronchitis and arthralgia in women; URTI, diarrhea and back pain in men. Median Δhip (women: +1.17%; men: +1.65%) and Δspine (women: +0.42%; men: +1.85%) bone mineral density (BMD) improved through week 96 versus baseline and median ΔeGFRcyst remained stable at week 96 for both genders (-0.5 mL/min/1.73m2; -0.9 mL/min/1.73m2).

In AMBER, week 96 virologic response rates (95% CI) (snapshot) in the D/C/F/TAF arm were- women: 86.4% (72.6; 94.8); men: 84.9% (80.5; 88.7) and VF rates (snapshot) were 6.8% (1.4; 18.7); 5.3% (3.1; 8.4).Through week 96, incidences of AEs in women/men were 93.2%; 92.1%; study drug-related grade 3–4 AEs: 6.8%; 2.5%; study drug-related serious AEs: 0%; 0.3% and discontinuations due to AEs: 6.8%; 2.2%. Most common AEs (≥10%) were nausea, diarrhea, rash and headache in women; diarrhea, nasopharyngitis and headache in men. No clinically relevant changes in hip and spine BMD and eGFRcyst were observed through week 96 for either gender.

No darunavir, primary protease inhibitor or tenofovir resistance-associated mutations were observed through week 96 in either trial.

Conclusions: Through 96 weeks, D/C/F/TAF achieved high response and low VF rates, with few discontinuations due to AEs, favorable bone/renal outcomes and a high genetic barrier to resistance in virologically suppressed ART-experienced and ART-naïve women living with HIV-1.

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Prevalence of Cervical Dysplasia in HIV-Positive Women Versus HIV-Negative Women: The Case of Zambia

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Prevalence of Cervical Dysplasia in HIV-positive Women Versus HIV-negative Women: The Case of Zambia

Background: Zambia has one of the highest human immunodeficiency virus (HIV) prevalence rates in Sub-Saharan Africa at 13%. The prevalence rate among women is 15% compared to men at 11%. Zambia also has the world's fourth highest cervical cancer incidence rate at 58.0 per 100,000. Studies have reported an increased prevalence of human papillomavirus (HPV) disease and cervical cancer dysplasia among HIV-positive women compared to HIV-negative women. In May 2018, the President's Emergency Plan for AIDS Relief (PEPFAR), the George W. Bush Institute, and the Joint United Nations Programme on HIV/AIDS (UNAIDS) announced the partnership and a commitment of $30 million to end AIDS and Cervical Cancer among HIV-positive women in eight sub-Saharan African countries, including Zambia. With the focus on HIV positive women, an argument arises as to whether cervical cancer screening resources should be focused on HIV positive women only or on all women, regardless of their HIV status.

Materials & Methods: Between January 2014 and September 2018, PCI in partnership with the Defence Forces Medical Services (DFMS) implemented an integrated mobile HIV testing/ cervical cancer screening program in 49 sites (25 rural, 24 urban). Women 25 to 59 years of age were primarily targeted while sexually active young women and girls below 25 years of age were incidentally enrolled. HIV Testing Services (HTS) were offered by trained lay counselors, and women testing HIV-positive and HIV- negative were offered opt-out cervical cancer screening services. Trained nurse midwives screened women for cervical cancer using visual inspection with acetic acid (VIA). VIA positive women with small precancerous lesions (cervical dysplasia) were treated in a single visit using cryotherapy. Cryotherapy ineligible clients and those with lesions suspicious for cancer were referred to district hospitals for further management.

Results: A total of 21,868 women were enrolled. Of these; 1,231(5.6%) were aged 10-19 years; 7,096 (32.4%) were 20-29 years; 6,941 (31.7%) were 30-39 years; 4,071 (18.6%) were 40-49 years; and 2,549 (11.7%) were over 50 years. 20.3% (4454/21868) tested HIV-positive; 79.0% (17265/21868) tested HIV-negative; and 0.7% (149/21868) opted out of HTS and were of unknown HIV status. 3.9% (861/21868) were VIA-positive. 1.6% (346/21868) were HIV-positive and VIA positive; 2.3% (504/21868) were HIV-negative and VIA positive; and 0.05% (11/21868) were VIA positive and of unknown HIV positive status. The prevalence of VIA positive result was highest among HIV negative young women, aged 20-29 years, at 0.88% (192/21,868).

Conclusions: The high prevalence of cervical dysplasia in HIV negative women, including HIV negative young women, indicate that HIV negative women in the highest burden sub-Saharan African countries should be targeted just as HIV-positive women for cervical cancer screening and treatment. Cooperating partners in Global health should support integration of routine cervical cancer screening and treatment into routine services for HIV negative and HIV positive women with effective, affordable, and safe screening and treatment methods such as VIA and cryotherapy.

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Reflections on a Specialist HIV Menopause Service

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Background: 1 in 3 women living with HIV (WLWH) in the UK are aged 45-56. HIV and menopause increase the risk of osteoporosis and cardiovascular disease. Data suggest that WLWH may undergo earlier menopause and suffer more associated ill-health than women without HIV. Moreover, the potential for interactions between combination antiretroviral therapy (cART) and hormone replacement therapy (HRT) underscores the need to develop experience in managing this growing cohort of women.

In 2015 we established a monthly HIV menopause service overseen by a gynaecologist and an HIV physician. We describe here the characteristics of WLWH attending the clinic.

Methods: Retrospective case note review of WLWH attending the HIV menopause clinic from 1st January 2015 to 19th July 2018.

Results: 55 WLHIV attended. 50% were Black. Median age at first attendance was 51; 84% were referred by their HIV clinician. Median duration of symptoms before clinic attendance was 18 (IQR 11.5-39) months. Median year of HIV diagnosis was 2002 (IQR 1996-2010); median baseline CD4 count was 279 cells/µL. 20% had a previous AIDS defining illness. 7% had hepatitis C co-infection. All were on cART; median last CD4 count was 678 cells/µL; 84% had viral load <50 copies/mL.

27% had a smoking history; 0 current recreational drug users; 31% had existing/risk factors for cardiovascular disease. 25% had a diagnosed mental health illness. 62% had children; 35% had previous abnormal cervical cytology.

Somatic symptoms (87%), menstrual irregularity (62%), psychological (56%) and urogenital (29%) symptoms were reported. 22% had early menopause (onset < 45 years) or premature ovarian insufficiency (menopause onset <40 years). 10 had POI and 2 had early menopause. Mean age of women diagnosed with menopause was 52 years however; mean duration of symptoms for women diagnosed with menopause was 31 (range 12-84) months.

61% had osteopenia or osteoporosis. 71% were prescribed HRT. 29% declined HRT because of expressed concerns about HRT risk, ongoing medical investigations or no longer symptomatic.

Transdermal oestrogen with oral progesterone was the most frequently used HRT regimen. 81 % of women seen at follow up taking HRT described improvement in symptoms. About half of these women required an increase in HRT dose. Median time on HRT was 10 (IQR 3-19) months. No serious HRT complications were observed (endometrial/breast malignancies, venous thromboembolism, CVS disease). There were 5 instances of cART modification (2 due to drug interactions with cART).

Conclusion: Women were predominantly of Black ethnicity. 20% had a previous AIDS defining illness reflected by the low median nadir CD4 count. A significant proportion had mental health illnesses, cardiovascular disease/risk factors or early menopause. The commonest presentation was vasomotor symptoms. Nearly two-thirds had osteopenia or osteoporosis. The long delay from onset of menopause symptoms to offer of treatment suggests a younger age of onset of menopause than the median age at attendance. HRT uptake was high and most women benefited from symptomatic resolution of symptoms. No serious adverse events were observed during the study period. A minority of patients required a change of cART regimen to help optimise HRT.

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38% of Child Bearing Women with HIV in the UK Would Like to Breastfeed-- Results from PACIFY Study Group

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Background: World Health Organisation (WHO) advice for post-partum women with HIV in resource poor settings, is to breast feed (BF) whilst taking suppressive antiretroviral treatment (ART).PROMISE data reports a transmission rate of <1% at 12months in infants BF by mothers on suppressive ART. In resource rich settings avoidance of breast feeding is still advised. Therefore the question remains: what is the acceptable level of breast feeding transmission risk in resource rich settings? We explored the views, of childbearing women with HIV in the UK around BF.

Methods: The Positive Attitudes Concerning Infant feeding (PACIFY) study group devised an anonymised, questionnaire looking at the attitudes of pregnant women living with HIV which was offered to child bearing HIV positive women, in the third trimester of pregnancy or within 3 months post-partum. Women were recruited from 12 UK clinics from June 2017–June 2018.The study had national ethical approval (IRAS number 221952).Demographic data on age, ethnicity and HIV parameters were also collected.

Results: 94 women responded to our questionnaire. 69% (65/94) of participants were Black African, median age was 36 years (20-44).Median CD4 count was 618 cells/mm3, 1 %(1/94) had a detectable HIV viral load, 92 %(87/94) had an undetectable HIV viral load at < 50 copies/ml and 7 %(7/94) no answer was given. 89 %(84/94) said they would BF their child if they were HIV negative, and 38 %(36/94) stated they would like to BF, despite having HIV. 62 %(58/94) had friends, family or community members question why they were not breast feeding, and 66 %(62/94) had to lie about why they were not intending to BF. When asked if they have ever BF: 72% (68/94) had never, 20 %(19/94) had before HIV diagnosis, 3 %(3/94) had after HIV diagnosis (outside UK), and 2 %(2/94) after HIV diagnosis (in UK). Healthcare workers had discussed breast feeding with 89 %(89/94) of women, but half wanted more information.

Conclusion: Whether "Undetectable = Untransmissable" (U = U) for breast feeding has yet to be fully ascertained, but over a third of respondents to this questionnaire said they would like to BF. Stigma and secrecy remain a concerning issue for the women had to lie about their reasons for not breast feeding. We believe it is time for HIV clinicians, in resource rich settings, to have a more open dialogue with women about the risks / benefits of breastfeeding on ART and to optimize ways to support those who may choose to do so.

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Risk of Hospitalisation According to Gender and Ethnicity Among People Living with HIV in the Modern ART Era

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Background: Little is known about the impact of gender and ethnicity on hospitalisations in HIV-positive people in the modern ART era. We considered this issue in the context of a high income setting (the UK) in which a high proportion of women with HIV originate from sub-Saharan Africa.

Materials and Methods: HIV-diagnosed individuals attending the Royal Free Hospital, London, UK, between 2007-2018 were categorised as follows: black women (B-W), other-ethnicity women (OE-W), black men who have sex with women (B-MSW), other-ethnicity MSW (OE-MSW) and men who have sex with men (MSM). Rates of all-cause hospitalisation in the first year after diagnosis (analysis A) and from year one onwards (analysis B) were calculated according to this classification and adjusted for demographic/clinical factors using Cox, and Poisson regression with generalised estimating equations respectively. People who inject drugs (n=146) and pregnancy-related admissions (n=1 analysis A; n=21 analysis B) were excluded. Repeated hospitalisations were considered in analysis B.

Results: For analysis A, 173 hospitalisations occurred in 1,402 newly-diagnosed individuals (66/384 women, 70/312 MSW, 37/706 MSM). 48%, 56% and 43% of hospitalisations in women, MSW and MSM were AIDS-related. Women and MSW were at higher risk of hospitalisation compared to MSM during the first year post diagnosis (unadjusted hazard ratios (95% CI): 3.9 (2.5-5.9) and 2.8 (1.5-5.1) in B-W and OE-W; 4.4 (2.7-7.2) and 5.2 (3.3-8.1) in B-MSW and OE-MSW). The higher hospitalisation rate in women and MSW compared to MSM was partially explained by age, CD4 count and diagnosis year (adjusted hazard ratios (95% CI): 2.5 (1.6-3.8) in B-W and 2.0 (1.1-3.6) in OE-W; 2.4 (1.5-3.9) and 3.5 (2.2-5.5) in B-MSW and OE-MSW). Lower CD4, older age and earlier diagnosis year were each independently associated with higher hospitalisation rate. There was a trend towards longer median days of hospitalisations in women and MSW compared to MSM (11 in women, 18 in MSW, 9 in MSM;p-value:0.0924).

For analysis B, 4,236 individuals diagnosed for >1 year contributed 787 hospitalisations (557 individuals; overall rate=2.8 per 100 pyrs). 13%, 21% and 8% of hospitalisations in women, MSW and MSM were AIDS-related. Black women and MSW remained at higher risk of hospitalisation than MSM, but the association was weaker than in analysis A (unadjusted rate ratios (95% CI): 1.6 (1.3-2.0) and 1.2 (0.8-1.8) in B-W and OE-W; 1.7 (1.3-2.3) and 2.0 (1.5-2.8) in B-MSW and OE-MSW). Age, current CD4 count, CD4 nadir, current viral non-suppression, time since diagnosis and previous AIDS partially explained the higher rate in women and MSW (adjusted rate ratios (95% CI): 1.3 (1.0-1.7) and 1.1 (0.7-1.7) in B-W and OE-W; 1.1 (0.8-1.5) and 1.7 (1.3-2.3) in B-MSW and OE-MSW). Older age, lower CD4 count, viral non-suppression, and previous AIDS were independently associated with a higher rate of hospitalisations. Length of stay was similar across groups.

Conclusions: Women and MSW have increased rate of hospitalisation in the modern ART era, partially explained by clinical factors. Reasons for variations between gender, sexual orientation and ethnicity groups should be investigated further to establish whether targeted interventions are needed.

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Depression Symptom Trajectories Among Mothers Living with HIV in Rural Uganda

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Background: Severity and chronicity of depressive symptoms in mothers are independently associated with behavior problems among children. However, few longitudinal studies of depression symptom trajectories have been conducted in low and middle-income countries (LMIC) in general, and among women living with HIV in SSA in particular.

Materials and Methods: We aimed to identify latent class trajectories of depression symptoms among mothers of young children (2-5 years old) living with HIV in Uganda. Depression was assessed at four time points using the Hopkins Symptom Checklist among 288 women participating in a randomized controlled trial. Using mixture modeling, we describe the number and nature of distinct classes defined by the trajectories of depressive symptoms over time. We explored maternal and child characteristics as predictors of class membership.

Results: Women in this sample were on average 33.5 years old (range 18-54 years), mostly married (69%), had a primary-level education (69%), and were subsistence farmers (82%). Using the standard cut-off score of >1.75 on the average HSCL-depression score, more than half (61%) of women could be classified as having clinically significant depression at baseline. We identified a 3-class solution that resulted in three distinct trajectories of depression symptoms over time. The two largest classes were characterized by low or moderate subclinical (e.g. HSCL score <1.75) symptoms of depression. Class 1 represented the largest percentage of women (53%, n=152). In this class, symptoms were low and stable across the 24-month period of the study. Class 2 (39%, n=113) was characterized by moderate subclinical symptoms with varying degrees of intensity over time. A small percentage of women (8%, n=23) from Class 3 reported high levels of depression symptoms across the entire 24-month period of the study. Depression score among women in this class increased at the 12-month assessment, and returned to the high level reported at baseline, suggesting that their symptoms were relatively chronic and severe. The probability of being in a particular latent class was not associated with baseline socio-demographic or child characteristics. Higher anxiety levels, less social support, more functionality problems, and more executive behavior problems in children predicted membership in the moderate-subclinical and chronic-high classes.

Conclusions: Identifying patterns of depression trajectories can help target intervention efforts for women who are likely to experience the most chronic and impairing symptomatology. Given the prevailing context of significant under-funding of mental health services and research, integrating mental health screening into existing infrastructure and programs that allow targeting of services to sub-groups of women who most need them is essential.

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Development and Piloting of a Scale to Measure Trauma- and Violence-Aware Principles of HIV Care and Practice for Women Living with HIV in Metro Vancouver, Canada

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Background: Women living with HIV (WLWH) experience disproportionately high levels of trauma and violence throughout their lifetimes. There is increasing recognition of the complex relationships between trauma and violence and health and health care access, including along the HIV care continuum, and the role of HIV care and practice (HIVCP) in addressing these relationships. No scale to evaluate current practice exists. Our study goals therefore included: 1) developing a scale measuring trauma- and violence-aware principles within HIVCP; and 2) evaluating the relationships between higher scores on this scale and key outcomes (self-rated health; emotional/physical well-being; barriers to health care; antiretroviral therapy[ART] use; HIV stigma) hypothesized to be influenced by HIVCP.

Materials and Methods: Data were drawn from three years from a longitudinal community-based open cohort of 325+ cis or trans WLWH who lived and/or accessed care in Metro Vancouver, Canada (2014-present)(Sexual Health and HIV/AIDS: Women's Longitudinal Needs Assessment "SHAWNA"). We used a conceptual approach to develop the 32 items considered for inclusion in the scale, and factor groupings, on the combined input from our Positive Women's Advisory Board, peer researchers, staff and community and clinical collaborators, as well as from the literature. Confirmatory factor analysis was conducted within a structural equation modeling framework, and estimated using weighted least squares with mean and variance adjustment to account for repeated measures among participants(Obj1). Multivariable confounder models were constructed to assess the relationships between the overall scale and outcomes(Obj2), adjusting for key confounders including age, reporting African/Black and other visible minority, sexual minority status, employment and injection and non-injection drug use. Adjusted odds ratios (AOR) and 95% confidence intervals (CIs) are presented.

Results: At baseline, of the 288 women included in this study, the median age and duration since first diagnosed with HIV was 45 years (IQR: 38-52 years) and 14 years (IQR: 8-20 years), respectively. Overall, 36.5% of women identified as sexual minority, while 9.7% identified as trans/gender minority. In total, 55.6% of women were Indigenous, 9.4% reported another ethnic minority and 35.1% as white. Our approach resulted in a five-factor solution: 1) Spatial and low-barrier accessibility; 2) Safety and respect; 3) Empowerment and collaboration; 4) Peer support; 5) Women-specific services. The model fit indices were as follows: CFI=0.908, and RMSEA=0.035. In multivariable regression, a higher score on the scale was statistically significantly associated with multiple outcomes, including: positive associations with self-rated health (AOR:1.07, 95%CIs:1.01-1.12); and negative associations with physical/emotional health being a barrier to accomplishing goals (AOR:0.94, 95%CIs:0.89-0.99); barriers to accessing contraceptives (AOR:0.86, 95%CIs:0.77-0.96) and being unable to access mental health care (AOR:0.92, 95%CIs:0.87-0.97); enacted HIV stigma (AOR:0.93, 95%CIs:0.87-0.98); and missing any ART in the last two weeks (AOR:0.95, 95%CIs:0.90-1.00).

Discussion: Our study provides evidence that HIVCP that incorporates trauma- and violence-aware care principles is associated with a number of positive outcomes for WLWH. Given the high prevalence of historical and ongoing trauma and violence experienced by WLWH in Metro Vancouver and globally, our study suggest an urgent need to incorporate trauma- and violence-aware principles within HIVCP for WLWH.

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Impact of Sex on Cryptococcal Meningitis Mortality in Uganda and South Africa

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Background: The role of biological sex on clinical outcomes in AIDS-related opportunistic infections is unclear. We sought to assess the relationship between Cryptococcus disease phenotype and biological sex among HIV positive Ugandans and South Africans.

Methods: We assessed the differences between 582 men and 403 women in disease presentation and clinical outcomes among four cryptococcal meningitis cohorts in Uganda and South Africa enrolled from 2010-2017. We compared mortality at 10 weeks between men and women using Cox proportional hazards models.

Results: The 10-week mortality among women was 48% (193/403), and 41% (240/582) among men. Women had a higher risk of death due to cryptococcal meningitis compared to men in an unadjusted model (Hazard Ratio (HR)=1.22; 95%CI (1.01, 1.47); p=0.04). Women maintained a higher risk in a model adjusted for quantitative Cryptococcus culture/mL CSF, altered mental status, and CSF pleocytosis (HR=1.26; 95%CI (1.03, 1.53); p=0.02) as well as a model that included those covariates in addition to age and antiretroviral status (HR=1.31; 95%CI (1.07, 1.60); p<0.01). However, after including baseline hemoglobin in both adjusted models the risk of death for women did not differ from the risk for men (Model 1: HR=1.10; 95%CI (0.88, 1.37); p=0.39)(Model 2: HR=1.14; 95%CI (0.91, 1.41); p=0.25). Median hemoglobin concentration was 10.6 g/dL (Interquartile Range (IQR) 8.9, 12.0) for women and 12.0 g/dL (IQR (10.3, 13.3)) for men (p<0.01). Among all the cohorts, 16% (56/350) of women and 10% (54/529) of men presented with severe anemia (Hemoglobin < 8.5 g/dL) at baseline (p=0.02).

Conclusions: We found anemia as a potential modifiable risk factor for cryptococcal meningitis mortality that may be the underlying mechanism for the difference in mortality based on biological sex. We recommend further research to establish the association between anemia, biological sex, and Cryptococcus disease phenotype outcomes.

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Treatment of HIV-Related Cryptococcosis in Pregnancy and the Post-Partum Period

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Background: Cryptococcal meningitis causes 15% of AIDS deaths and has an estimated mortality rate of 70% in sub-Saharan Africa in routine care. Knowledge and outcomes of pregnant women with cryptococcal infection are strictly limited to case reports however, as these patients are largely excluded from clinical research. Amongst pregnant women with asymptomatic cryptococcosis, no treatment guidelines exist.

Methods: We retrospectively identified HIV-infected women who were pregnant or recently pregnant with cryptococcosis screened from a series of clinical research studies in Uganda from 2012-2018. We describe maternal and fetal outcomes, and treatment course for cases of cryptococcal meningitis and antigenemia during pregnancy.

Results: From 2012-2018, 571 women were screened for cryptococcosis. Of these, 19 (3.3%) were pregnant (n=14), breastfeeding (n=2), or recently pregnant (within the prior 14 days) (n=3). Twelve had cryptococcal meningitis (n=8 pregnant), six had cryptococcal antigenemia (n=5 pregnant), and one had a recent diagnosis of cryptococcal meningitis and was on 200mg fluconazole maintenance therapy. This woman was two months pregnant at the time and later reported an ectopic pregnancy.

All women with meningitis received amphotericin B deoxycholate and 5 were exposed to 200-800 mg fluconazole during pregnancy, including one woman in 1st trimester. Three of these five delivered healthy babies with no gross physical abnormalities at birth, while one succumbed to meningitis, and one had unknown outcomes. Maternal meningitis survival rate at hospital discharge was 83% and neonatal/fetal survival rate was 55% for eleven women with known pregnancy outcomes. Of the five pregnant and one breastfeeding women with cryptococcal antigenemia, three had unknown courses of treatment, whereas two received fluconazole, and one received weekly amphotericin B in place of fluconazole. All CrAg+ antigenemia women were reported to have survived either at hospital discharge or at six months and none were known to have progressed to meningitis.

Conclusion: Here we report 19 cases of HIV-related cryptococcosis in pregnancy and the postpartum period. We report good clinical outcomes for pregnant women using amphotericin, avoiding high dose fluconazole in the first trimester, and using weekly amphotericin in place of fluconazole for cryptococcal antigenemia. In one woman that received nine days of high dose fluconazole in 1st trimester, we report no gross neonatal physical abnormalities at time of birth.

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Adherence and Retention in Care Among Female Sex Workers in an HIV Pre-Exposure Prophylaxis (PrEP) Clinic, Kampala, Uganda

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Background: Globally, Sub-Saharan Africa remains most severely affected with highest HIV prevalence rates. In Kampala Uganda, female sex workers (FSWs) have high HIV prevalence (33%), much higher than among the general female population of reproductive age (7.5%). FSWs belong to key populations, being at a very high risk of acquiring and spreading HIV. Oral PrEP is a novel biomedical HIV prevention intervention that offers hope and a locus of control, to decrease HIV incidence in this population. In Uganda, PrEP roll-out for high risk populations including FSWs was started in August, 2017. Adherence to PrEP is critical in the population of FSWs to realize the benefits of PrEP for maximum HIV prevention. However, data on adherence to PrEP among FSWs is limited so this study sought to assess adherence to PrEP.

Methods and findings: This study was conducted between May 2018 and August 2018. This study was a cross-sectional study that targeted FSWs attending the clinic at Mulago Hospital; it was conducted at an outpatient STD clinic offering PrEP to most at risk persons in Kampala. The main outcome was adherence to PrEP. The aims of the study were 1) to determine the level of adherence to PrEP,2) to determine factors associated with PrEP adherence and 3) to explore barriers and facilitators of PrEP adherence and retention in care among FSWs using PrEP.
The sample size for the primary outcome was 100 FSWs who had been initiated on PrEP, these were recruited and interviewed using staff administered questionnaires. Records of clinic attendance were reviewed for clients who initiated PrEP; tracing of participants who dropped out of care was done to study objective 3. In depth interviews were conducted with fifteen FSWs: with 5 who dropped out of care, 5 who ever missed at least one of their scheduled clinic visits for PrEP refill and returned for a PrEP refill at least two weeks later, and 5 interviews with FSWs who had never missed a clinic appointment for PrEP refill.
Quantitative data analysis was done using STATA version 14.0, thematic data analysis was done for the qualitative data. Results were considered significant for P value less than 0.05at 95% confidence interval. Prevalence ratios were used as the measure of association.

Results: Reported adherence to PrEP was 78% (n=70/90) while 22% were categorized as poorly adhering. the prevalence of poor adherence to PrEP is 38.1 times higher among FSWs who do not use condoms with paying sex partners (PR 38, 95% CI: 4.267-34.067) as compared with FSWs who use condoms with clients. Barriers of PrEP adherence include experiencing challenging side effects, lack of financial resources, and travel. Reasons for stopping to take PrEP completely include doubts about PrEP efficacy, side effects of PrEP, and not being contacted by the outreach team for more community PrEP refills.
Interventions to enhance
adherence and retention in PrEP care among FSWs in Kampala will be most effective if they address
the inter-related health-system,social, and behavioral factors that influence PrEP adherence and retention in PrEP care.

33 (withdrawn)

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We Can Do It! Addressing Intimate Partner Violence in HIV Research with Women

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Background: Intimate partner violence (IPV) remains a highly salient issue for women living with and vulnerable to HIV. It has been well documented that IPV is associated with increased susceptibility to HIV infection and negative health outcomes for women living with HIV. Incorporating research questions related to IPV into clinical and behavioral HIV research is a vitally important step in developing effective public health based HIV prevention and treatment interventions for women. However, these kids of questions are complicated by numerous challenges that may include ethical considerations, logistical barriers, research site staff training and capacity, and perceived importance and appropriateness on the part of funders and decision-makers.

Materials & Methods: The WHRC is an advisory group of the Legacy Project comprised of women (cisgender and transgender) who are leaders in women's health and HIV from around the United States. This group authored a 2014 paper in which we called for HIV clinical and behavioral research to address IPV in trial design and implementation. Since that time, the group has continued to critically analyze the ethical and logistic barriers that make such assessments particularly challenging. These activities have included the following: a WHRC-facilitated workshop and discussion at the 2016 United States Conference on AIDS, a series of interviews with staff at the NIH-funded HIV/AIDS clinical trials networks, a focus group at the 2017 AIDS Clinical Trials Group full group meeting, and an extensive literature review to develop a position statement on the issue.

Results: Practitioners, researchers, and community advocates recognize the importance of screening for IPV in HIV research from public health, ethical, basic science, and implementation science frameworks. IPV is largely a gendered epidemic that disproportionately impacts women— both cisgender and transgender. However, there remain numerous challenges to addressing IPV in HIV research protocols. These challenges include: real and perceived risks about participant disclosure of IPV; budgetary and logistic concerns related to staff training and time to address IPV; appropriate survey measures and data collection; lack of standardized procedures for screening for IPV; and a dearth of mechanisms to increase "buy-in" from funders and decision makers.

Conclusions: While accounting for IPV in HIV clinical and behavioral research may raise ethical and logistic questions, adopting public health related practices to account for and address IPV in HIV clinical and behavioral research protocols is critical for several important reasons. First, the clinical research trial can function as a public health entry point for some participants. Second, high prevalence of IPV remains a barrier to optimal health. Third, there are potential quality of life benefits for women when IPV is identified in research settings, including providing resources and referrals to culturally appropriate services. Fourth, asking questions around IPV gives researchers the ability to develop interventions that address a more accurate picture of women's lives.

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Postnatal Growth in Children Exposed or Unexposed to HIV–A Nationwide Cohort Study

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Background: Studies mainly from resource-limited settings have shown impaired growth among HIV-exposed uninfected (HEU) children. We aimed to compare anthropometric outcomes of Danish HEU children to a matched control group of children not exposed to HIV in the first 5 years of life.

Methods: In a nationwide register-based study we included all singleton HEU children born in Denmark, 2000-2016. HEU children were individually matched by parity, maternal ethnicity and child sex to five singleton controls born to HIV uninfected mothers. Weight-for-age (WAZ), length-for-age (LAZ) and BMI-for-age (BMI) z-scores were generated according to the WHO standards and the Fenton growth chart for prematurity for infants born <37 week. Differences in WAZ, LAZ and BMI z-scores were analyzed using linear mixed models, adjusting for maternal smoking and total number of growth measurements.

Results: In total, 493 HEU children and 2.495 controls were included, with a mean of 5 growth measurements in each group (range: 1-23). HIV-infected mothers were more likely to smoke during pregnancy (11% versus 7%) and their infants were more likely to be born preterm (<37 weeks) (11% versus 5%) and to be delivered by Caesarean Section (66% versus 27%). Most HIV-infected mothers were fully suppressed at the time of delivery with HIV RNA levels <50 copies/mL (87%). Overall, anthropometric z-scores of both HEU and control group children were close to or above the average population mean of 0. Compared to controls, HEU children were smaller at birth with a difference in mean WAZ and LAZ scores of -0.26 (95%CI: -0.40:-0.13; p=<0.001) and -0.44 (95%CI: -0.69:-0.29; p=<0.001), respectively. Over time, there was a trend towards increasing WAZ and LAZ in HEU children, and there was no significant difference in WAZ z-scores by age 12 months (-0.10 (95%CI: -0.26:0.06; p=0.22) and no significant difference in LAZ z-scores by age 24 months (-0.13 (95%CI: -0.32:0.04; p=0.15). There was no difference in BMI-for-age between the two groups at any age. A sensitivity analysis limited to children with information on breastfeeding did not change results significantly.

Conclusion: In a high-resource setting, exposure to HIV and/or antiretroviral therapy does not seem to be adversely associated with infant and child growth. Compared to a matched control group, HEU children were smaller at birth, but this difference decreased with time and is not considered to have a negative impact the health and well-being of HEU children.

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Dolutegravir: Absence of Reproductive Toxicity Including NTDs in Animal Studies

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Background: Preliminary analysis in an ongoing birth surveillance study conducted by the Botswana Harvard AIDS Institute Partnership noted potential risk of neural-tube defects (NTDs) associated with exposure to Dolutegravir (DTG) prior to conception. The emerging data triggered a detailed review of nonclinical reproductive and developmental toxicity studies in rats and rabbits that would have detected NTDs. A total of 6 studies were conducted at doses up to 1000 mg/kg/day to evaluate the potential adverse effects of DTG on mating and fertility (rats), early embryonic development (rats), embryo-fetal development (rats and rabbits), and pre- and postnatal development in offspring of treated female rats. In humans, neural tube formation starts around the 18th day of gestation and disruption of this process is expected to produce NTDs. In animal's neural tube development occurs between gestation day 9.5 to 11(rat) and 8 to 10.5 (rabbit).

Methods: Methods followed the guidelines outlined by the International Conference on Harmonization of Technical Requirements for registration of Pharmaceuticals for Human Use.

Results: In the fertility study where exposure to DTG occurred during the period of conception that included a period before mating and up to implantation of the embryo, no effects on reproduction or pre-implantation embryonic development were observed. In the rat and rabbit embryofetal development studies, where exposure occurred from implantation to hard palate closure, a sensitive period for organogenesis, no effects on neural tube development were observed. In the rat pre- and postnatal development study, where embryonic exposure to DTG occurred during organogenesis and continued into the post-natal period via the treated mothers milk to the pups, no effects on neural tube development were observed.

Conclusions: There were no DTG-related malformations observed in rats or rabbits nor were there effects on embryonic survival which would be reflective of early embryonic damage due to a NTD. No DTG-related embryo-toxicity was observed in pregnant rats or rabbits exposed during critical periods of pregnancy, where multiples of exposure in animals compared to the maximum recommended human dose were up to 27-fold in rats and equivalent to the human dose in rabbits.

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Prescribing Practices for Women Initiating ART During Pregnancy in the US: 2008-2017

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Background: US guidelines outline recommended antiretroviral treatment (ART) in pregnancy among women living with HIV (WLHIV) based upon efficacy and safety data. We assessed prevalence and predictors of being prescribed a preferred antiretroviral (ARV) regimen among WLHIV initiating ART in pregnancy.

Methods: ART prescribed preconception and antenatally were abstracted from medical records of WLHIV enrolled from 2008-2017 in the PHACS Surveillance Monitoring for ART Toxicities (SMARTT) study, a US multi-site prospective cohort study addressing ARV safety. Among women who were ARV-naïve at conception, we compared first pregnancy regimen with the extant US perinatal guidelines (2006-2015). Regimens were classified as preferred, alternative, special circumstances, insufficient evidence, or not recommended. We used multivariable logistic regression models to assess associations of pre-specified maternal, geographic, and temporal covariates with preferred regimens. For regimens prescribed before 2015 classified as having insufficient evidence, the proportion reclassified as preferred or alternative in subsequent guidelines was quantified.

Results: Of 450 pregnant WLHIV initiating ART antenatally (mean age 27.2 years, 68% Black/African American, 78% with household income <$20k/year), 195 (43%) were prescribed a preferred regimen according to prevailing guidelines. Maternal factors associated with prescribing preferred regimens were earliest pregnancy viral load >1,000 copies/ml (47%; adjusted odds ratio (aOR) 1.69), earliest pregnancy CD4+ count <200 cells/mm3 (57%; aOR 2.12) and household income >$30K/year (59%; aOR 1.92) versus <$20K/year. Hepatitis B co-infection (11%; aOR 0.11) was associated with prescribing non-preferred regimens. Significant geographic variability was observed, with preferred regimens more often prescribed at Midwest and Northeast than Western study sites (Fig 1). Among 66 WLHIV prescribed a regimen classified as insufficient evidence prior to 2015 guidelines, 55 (87%) regimens were reclassified as preferred or alternative in subsequent guidelines.

Conclusions: More advanced HIV disease and higher household income were associated with prescribing preferred regimens, whereas hepatitis B co-infection was associated with prescribing of non-preferred regimens. A high proportion of regimens with insufficient evidence eventually became preferred or alternative. Regional and socioeconomic prescribing pattern differences warrant further investigation.

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Uptake of Postpartum Contraception in Botswana, a High Burden HIV Setting

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Background: In high burden HIV settings, well-functioning sexual and reproductive health programming prevents unplanned pregnancies and HIV transmission. In Botswana, where HIV incidence approaches 1% per 100 person-years and prevalence among adults age 15-49 is > 20%, we sought to quantify pregnancy intention and uptake of contraception among postpartum women living with HIV (WLHIV) and HIV-uninfected (HIV-U) women.

Methods: The Tshilo Dikotla study is prospectively enrolling pregnant WLHIV and HIV-U women ≥ 18 years old in Gaborone, Botswana, and following mother-infant pairs through 3 years postpartum. WLHIV are on a dolutegravir (DTG)- or efavirenz (EFV)-based combination antiretroviral treatment (cART) regimen in pregnancy. Data on contraception use and future pregnancy intention are collected via questionnaire at 6 months postpartum. We compared the proportion of women without plans for pregnancy (ever or within two years), proportions of women reporting use of contraception, and adopted contraception methods by HIV status. In women reporting >1 type of contraception, the most efficacious method was chosen for analysis.

Results: Among 233 participants attending the 6-month postpartum visit, 142 (61%) were WLHIV. WLHIV were older (28.5 vs 24.3 years; p<0.001) and had higher gravidity (3 vs 1; p<0.001) compared to HIV-U women. More WLHIV expressed a desire to prevent future pregnancies or to defer pregnancy for ≥2 years compared to HIV-U women (87% vs 66%; p<0.001). Among women not planning pregnancy in ≤2 years, only 89 (49%) reported using contraception, with similar uptake by WLHIV and HIV-U women (50% vs 47% respectively; p=0.71). Of the 61 WLHIV using contraception, 57% were on a DTG- and 43% on an EFV-based cART, with none using hormonal implant. Only 14% of HIV-U women were using implants. Depot medroxyprogesterone acetate (DMPA) was the most commonly used method for all women. Uptake of condom use was low, yet a higher proportion of WLHIV reported condom use (39% vs 32%). Only 9 women were using more than one method.

Conclusions: Uptake of contraceptives at 6-months postpartum was universally poor among women desiring pregnancy prevention, regardless of HIV status. In addition, dual condom use with more efficacious methods was particularly low, a concerning finding in a high burden HIV setting. Understanding the individual and programmatic impediments to contraception uptake is needed to better match contraception use to pregnancy desires in Botswana and prevent HIV transmission.

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Postpartum Progressive Symptoms in Women Living with HIV in Botswana

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Background: Postpartum depression (PPD) is associated with poor maternal and child health outcomes. Few studies have evaluated PPD in women living with HIV (WLHIV) in Botswana, a high prevalence HIV setting.

Methods: Using the Edinburgh Postnatal Depression Scale (EPDS), we evaluated PPD symptoms at 2, 6, and 12 months (mo) postpartum in WLHIV and HIV-uninfected (HIV-U) women enrolled in the Tshilo Dikotla cohort study in Botswana. Women scoring ≥10 on the EPDS or reporting thoughts of self-harm were defined as at risk for ongoing PPD symptoms. Secondary outcomes included: EPDS score ≥10, EPDS score ≥13, and EPDS score ≥13 or reporting thoughts of self-harm. Generalized estimating equation models were fit to assess the association of maternal HIV infection with risk of PPD symptoms in the first year postpartum. Subgroup analyses in WLHIV were performed to assess factors associated with risk of PPD symptoms.

Results: Of 321 women enrolled, 195 were WLHIV. WLHIV were older (28.9 vs 24.4 years, p<0.01) with higher gravidity, (3 vs 1, p<0.01) and were less likely to complete tertiary education (7% vs 31%, p<0.01) compared to HIV-U women. Among WLHIV, 45% had a CD4 count >500 cells/mm3 and 93% had an HIV RNA level <40 copies/mL at enrolment; median years since HIV diagnosis was 1.6. All WLHIV received a backbone of tenofovir + emtricitabine and either dolutegravir (DTG) or efavirenz (EFV). At 2, 6, and 12 mo postpartum, 301, 233, and 103 women, respectively, completed the EPDS. At 2 mo, 4 WLHIV and 6 HIV-U met the criteria for being at risk for PPD symptoms. At 6 mo and 12 mo, 6 and 4 WLHIV respectively met the criteria for being at risk for PPD symptoms, whereas no HIV-U women met the criteria. After adjusting for age, gravidity, education level, marital status, and employment, WLHIV were at increased risk for PPD symptoms compared to HIV-U women (adjusted Odds Ratio: 3.37, 95% Confidence Interval: 1.14-10.02). Findings were similar in models evaluating secondary outcomes. (Table 1) Among WLHIV, no associations were seen between age, gravidity, employment, CD4, years with HIV, timing of ART initiation, or ART regimen and PPD symptoms.

Conclusions: Despite overall low rates of PPD symptoms in this small Botswana cohort, WLHIV may be at higher risk for experiencing PPD symptoms in their first year postpartum compared to HIV-U women. Screening WLHIV for PPD symptoms and providing support during the postpartum period are an important part of routine postpartum care for this vulnerable population.

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Predictors of Treatment Outcomes Among Adolescent Girls and Young Women Initiated on Antiretroviral Therapy in Faith-Based HIV Programs in Kenya: A Retrospective Cohort Study

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Introduction: Adolescents girls and young women (AGYW) in Kenya are two times more likely to be HIV infected compared to their male counterparts. This population has been disproportionally affected by gender inequality, social, cultural, economic and human rights barriers coupled by anatomical differences that place them at a higher risk of acquiring HIV infection. Given these data our study sought to determine the predictors of treatment outcomes among AGYW living with HIV in order to inform the program on interventions that will optimize clinical and virologic outcomes.

Methodology: This was a retrospective cohort study that used de-identified data from electronic medical records of 54 faith-based facilities within the Christian Health Association of Kenya HIV / AIDS Project database. All AGYW 15-24 years initiating ART in the program between January 2013 and December 2015 were included in the analysis. Descriptive statistics were computed for categorical variables and presented as frequencies. The association between categorical variables was tested using the Chi square test for sufficient samples and McNemar test for small samples. Logistic regression model was used to evaluate the association of treatment outcome with the likelihood of retention at 12 and 24 months after initiation of antiretroviral therapy (ART). Results are presented as ORs and corresponding 95% confidence intervals. All P values were based on two tailed tests, with 5% level of significance. IBM SPSS version 20.0 was used for data analysis.

Results: The study enrolled 860 AGYW among whom 516 (60%) were aged 20-24 years. The baseline median CD4 count for AGYW aged 15-19 and 20-24 years was 344 (IQR 228 - 468) and 335 (IQR 207 - 479) respectively. At baseline, a quarter reported ever being pregnant and a tenth had either lost one or both parents. The prevalence of advanced HIV disease prior to initiation of ART was 12% (106/860) of which 39.6% (42/106) was due to tuberculosis. Majority (69%) initiated ART within 6 months of enrollment. The mean age for starting ART was 18 (95% CI 18.40, 18.17) for those aged 15-19 years and 22.52 (95% CI 22.34, 22.69) for those aged 20-24 years. Viral suppression rate was 84.9% and 85.1% after 12 and 24 months on ART respectively whereas attrition rate was 8% at both 12 and 24 months. Retention in care at 12 months after initiating ART was significantly associated with good adherence to ART at 6 months (OR=1.634 (1.211, 2.023) p=0.033) and early HIV disease (OR=1.554, (1.242, 1.866) p=0.028). AGYW who were virally suppressed at 24 months were more likely to be retained in care (OR=1.818, (1.586,2.052) p=0.001

Conclusion: Early diagnosis of HIV and ART initiation coupled with good adherence among AGYW is key in ensuring favorable treatment outcomes and retention in care.

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Viral Suppression Among the Pediatric and Adolescent Age Groups in Nigeria: A Retrospective Review

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Introduction: Efforts to achieve viral suppression for at least 90% of children and adolescents on ART is ongoing. However, there has been a varied response to ART due to biological, clinical, epidemiological and social factors. With more children and adolescents gaining access to lifesaving ART, having a better understanding of their response is integral to favorable treatment outcomes.

Objectives: This study seeks to characterize the patterns of viral suppression between sexes and sub-populations among children and adolescents on ART in Nigeria.

Methods: This is a retrospective review of program data. Viral load results for 5939 children and adolescents received between April 2017 and March 2018 at health facilities across 13 states in Nigeria were analyzed. All study participants received the standard package of HIV care, support and treatment with viral load samples collected according to the national schedule at 6 and 12 months on ART. Viral load results were dis-aggregated by age and sex bands.

Results: Overall, 51.8% (3076) of the children and adolescents were virally suppressed. Viral suppression was significantly higher among females than males (55.2% vs. 48.0%, p<0.0001). Similarly, viral suppression rates were higher among females in all age groups: under 5 years (52.5% vs. 43.2%, p = 0.009), 5-9 years (57.2% vs. 47.7%, p <0.0001) and adolescent age groups 10 – 19 years (54.9% vs. 49.4%, p = 0.001). Furthermore, viral suppression rates among children under 5 years was significantly lower than children and adolescent age groups (47.6% vs. 52.4% and 52.5%, p=0.04).

Conclusion: Viral suppression was found to be sub-optimal among children and adolescents on ART. Viral Suppression rates was found to be significantly better among females in all the sub – groups; and poorest in the youngest children (< 5 years). Further investigation into factors responsible for observed trends to inform program strategies are therefore required especially for the youngest age groups to attain viral suppression.

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Effect of Gender on Virologic Suppression Among Children and Adolescents on Antiretroviral Therapy

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Introduction: The attainment of viral suppression enables the in the pediatric and adolescent groups is especially critical to live a healthy life, free from most opportunistic infections. This is due to the immature immune systems of these age groups and viral suppression in these age groups will enable a healthy and productive life . With the improvement in access to viral load services, various aspects have affected the ability of the clients to attain viral suppression in the pediatric and adolescent age group.

Objectives: We sought to assess the impact of gender on attaining viral suppression among the different age groups dis-aggregation among the pediatric and adolescent age groups on antiretroviral therapy in a large-scale project.

Methods: We reviewed routinely collected program comparing viral load suppression rates in among 5939 HIV positive clients within the pediatric and adolescent age groups that had viral load investigation done in the 12-month period between April 2017 and March 2018 and July 2017 in a large ART program. All clients were served with the standardized package of care to ensure optimal HIV treatment and care. Viral load results were dis-aggregated by age and sex bands thus: 0 – 4 years,5 – 14 years and 15 – 19 age groups.

Results: Overall, viral suppression was found to be sub-optimal in the pediatric and adolescent age groups at 52% Viral suppression rates were found to be significantly higher among females in the pediatric and adolescent age group at 55% / 48% ($p < 0.0001$). Also, females had a significantly higher viral suppression among the all the age dis-aggregation in the pediatric and adolescent age groups with the female to male proportion as outlined thus: 0 – 4 years: 52% / 43% (n = 800; p = 0.001), 5 – 14 years:54% /49% (n = 3634; p = 0.0026) and 15 – 19 years: 58% /47%(n = 1505 $p < 0.0001$).

Conclusion: Viral suppression in the pediatric and adolescent age groups is sub-optimal and extra effort should be made towards supporting treatment adherence in this age group. The role of gender in conditioning behavioral patterns that predisposes female pediatric and adolescents towards viral suppression needs to be further investigated towards ensuring the optimization of ART treatment outcomes in both sexes across the various age bands.

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Game Changers: A Pilot Intervention to Empower People Living with HIV, Including Women, as Prevention Advocates in Uganda

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Background: "Game Changers," is a 3 phase intervention that aims to empower and mobilize people living with HIV (PLWH) to be agents for HIV prevention and behavioral change in their social networks.
In Phase 1, we conducted separate focus groups of PLWH and members of their social networks (family and friends) to explore barriers to and facilitators of mobilizing patients to advocate for HIV prevention, perceptions of how advocacy can be most effective in motivating behavior change, and how to best structure the intervention and its content. In Phase 2 we used findings from Phase 1, and drew from network-based intervention models to develop the structure and content of an intervention designed to help patients cope with stigma, manage their disease, live positively, and develop motivation and skills for HIV disclosure and prevention advocacy. In Phase 3, we are piloting the group intervention in a controlled trial of 96 patients, with 48 randomly assigned to receive the intervention and 48 to the wait-list control.

The primary objective it to
1. Use qualitative focus group research to empower PLHIV as prevention advocates.

Methodology: The focus groups workshops that we have conducted so far have helped us obtain information about participant opinions about the effectiveness of the intervention in helping them cope with HIV, discuss HIV, and disclose their status, and engage in prevention advocacy.

The groups that have been trained received information on how disclosure to people in their social networks is a key element to being able to engage in effective advocacy we have also discussed stigma as a barrier to disclosure and effective prevention advocacy, how stigma might be overcome, and how self-compassion and empathy are important before starting to do prevention advocacy.
We have discussed disclosure and strategies for deciding whether, how, and when to disclose to someone.
We have exemplary discussed how People Living with HIV can live a normal and healthy life with HIV, and be healthy both emotionally and physically, especially by getting support from people in their social network.
We have also discussed strategies and skills for effectively talking with people in their social network about HIV testing, prevention, treatment, and stigma.

ARCHIEVEMENTS

I. So far 80% of the participants have exhibited confidence and empowerment of doing prevention advocacy.
II. The groups have also identified members in their social networks with whom they are willing to do prevention Advocacy.
III. Over 90% of the study participants have eliminated internal/ self-stigma.

RECOMMENDATION

1. We should embark on using people living with HIV as prevention agents.
2. Prevention for Positives and Treatment as Prevention should be the context in the 90-90-90 efforts.
3. Scaling up prevention advocacy with the social networks of People Living with HIV.

Conclusions: Many people access information through social networks as shown in the results. There is need to address issues hindering prevention advocacy by using people living with HIV and their social networks.
The game changer is an intervention that can be copied and used effectively to accelerate HIV prevention advocacy.

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Low HIV Seroconversion Proportions on Repeat Testing in Maternity in Kayunga Hospital, Uganda, 2018

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Introduction: A previously HIV-negative woman during antenatal care can seroconvert to an HIV-positive status later during pregnancy which necessitates HIV re-testing in maternity. An HIV re-test is done three months after the previous test. Generally, HIV re-tests are hardly done in maternity. We used Quality Improvement (QI) approaches and aimed to increase the proportion of HIV re-testing in maternity in Kayunga hospital to 95% and to determine the proportion of women that seroconverted to HIV positive status on a re-test.

Methods: We established the baseline metric by ascertaining the proportion of women that had had an HIV re-test in maternity in Kayunga hospital from January to June 2018. We trained the maternity staff on the correct eligibility for an HIV re-test and the correct Prevention of Mother to Child Transmission of HIV (PMTCT) codes. We also created a column for eligibility for re-test in the integrated maternity register. We analyzed the proportions of women that had an HIV re-test done in maternity during July to October 2018 and compared with the baseline proportions. We also analyzed the proportions of women that seroconverted on a re-test in maternity.

Results: At baseline, of 447 women attending maternity from January to June, 324 (72%) were eligible for a retest. Of these, 61 (19%) had had a retest done in maternity. The re-testing proportions increased from 31 of the 35 eligible (87.5%) at the start of the intervention to 70 of the 71 eligible (98%) at the end of the intervention. Overall, 206 (93%) of the 221 eligible women had had an HIV re-test in maternity during this period. Of 206 women that re-tested in maternity, two women (1%) seroconverted to an HIV positive status.

Conclusion: The target of 95% of the eligible women having an HIV re-test in maternity was achieved and exceeded. The proportion of women that seroconverted to HIV positive status, and therefore the incidence of HIV was low.

Keywords: HIV, Quality Improvement, PMTCT, HIV-incidence

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Incidence of HIV Infection Among Breastfeeding Women in Botswana

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Background: HIV seroconversion during pregnancy and postpartum increases the risk of mother-to-child transmission of HIV, with consequences to the health of mothers and infants. In this context, Botswana Ministry of Health and Wellness guidelines recommend HIV testing and counseling (HTC) for HIV-uninfected postpartum women every three months if breastfeeding is ongoing. We describe the incidence of HIV in postpartum breastfeeding women in Botswana.

Methods: The Tshilo Dikotla study is a Botswana-based, prospective cohort enrolling pregnant women living with HIV, as well as HIV-uninfected pregnant women and their infants. Data was analyzed on HIV-uninfected women through the first 12 months postpartum. If there was no documentation of HIV testing in the last 3 months, HIV-uninfected women who were still breastfeeding underwent HTC. HIV testing was performed using the Trinity Biotech Uni-Gold™ HIV and Alere Determine™ HIV-1/2 tests. HIV incidence per 100 person-years was calculated with 95% CI (confidence intervals) during the postpartum breastfeeding period.

Results: A total of 141 HIV-uninfected women contributed 71.2 person-years of follow-up. Median age of women was 25 years [Interquartile range (IQR): 21, 29]. Thirty-five percent were married or living with a partner, 30% reported their highest education level as tertiary, and 48% were employed. HIV infection was identified in 2 women during the first year postpartum for an HIV incidence rate of 2.81 per 100 person-years (95% CI: 0.72-11.02). Both women had previously tested negative during pregnancy with documented results in the 3rd trimester at 34 and 38 weeks of gestation, respectively, as per national guidelines. Both women elected to exclusively breastfeed for a period of 60 and 28 days, respectively, after which they switched to formula feeding. DNA PCR testing of both infants showed no HIV infection.

Conclusions: Results from the Botswana Combination Prevention Project (BCPP) reflect an HIV incidence rate of 0.92 per 100 person-years for adults, ages 16-64 years. Our incidence rate in postpartum women ages 19-43 is roughly three times higher than the rate in BCPP, a Botswana population including men and women. While a policy promoting frequent intervals of HTC is important among HIV-uninfected women opting to breastfeed in high burden HIV settings, eliminating mother-to-child transmission of HIV may require more robust prevention interventions.

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Surveillance of HIV-Infected Mothers and Their Newborns as Means to Estimate the Risk of HIV Transmission Among HIV Women Dependant on Social Services in Romania: Data from the National Registry of HIV-Infected Women and Perinatally Exposed Newborns in the National Institute for Infectious Diseases "Prof. Dr. Matei Bals", 2013 – 2017

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Background: A particular category of children perinatally exposed to HIV in Romania is represented by cases assisted by the Social Services. These newborns come from low-income families, from unemployed mothers who are not married or don't have a stable partner, or who take drugs.

Methods: We analyzed the medical and social records of children perinatally exposed to HIV, registered and assisted by the Welfare Services and hospitalized at the National Institute of Infectious Diseases "Prof. Dr. Matei Bals" during 2013 – 2017. The parameters taken into consideration were related to the families of these children, the medical and social status of mothers and children, and the number of hospitalization days and related costs.

Results: From a total of 825 children perinatally exposed to HIV during registered during 4 years of surveillance, 61/825- 7.4%- represented social services dependent cases. All these children came from poor families, 92% from a single-parent families (mothers who are not married, don't have a stable partner or have several partners); 65.5% were mothers without education, 98% of mothers (61/825) were unemployed and 36% (22/61) were i.v. drug users. 34% (20/61) of mothers were detected HIV positive during their pregnancy, 65, 5% (39/61) were non-adherent to ART. As for the children, although all of them (61) benefited from post-partum ARV prophylaxis- 13% (8/61) of those exposed were HIV infected. This is related to the way of delivery- 48% vaginal delivery and breastfeeding- 4%. 70% (43/61) of the welfare dependent cases resulted in child abandonment; these children were placed in institutions or with foster mothers. They required 22 to 272 hospitalization days for various health issues or until their situation was settled.

Conclusion: The perinatal transmission rate of HIV infection in social services dependent mothers is about 3 times higher than the global transmission rate, despite Romania's adoption of clear policies of prevention of mother to child transmission since 1999 and universal access to treatment, irrespective of the CD4 count, in 2001. This rate can be correlated with a risky behavior primarily determined by a poor social background and drug use. Furthermore, this risky behavior leads to decreased adherence to medical care for both mothers and children and even in child abandonment. In this context, a possible solution to curve down the rate of perinatal HIV transmission among women who depend on social services is to readjust Romania's prevention and assistance programmes to their realistic needs and level of understanding.

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Effects of Depression, Stigma and Intimate Partner Violence on Postpartum Women's Adherence and Engagement in HIV Care in Kenya

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Background: Inadequate engagement in care and poor adherence to antiretroviral therapy (ART) among HIV-positive pregnant and postpartum women receiving lifelong ART (Option B+) remain major barriers to achieving optimal prevention of mother-to-child transmission (PMTCT) and maternal health. We explored the association between psychosocial factors and medication and visit adherence in HIV-infected postpartum women receiving lifelong ART in western Kenya.

Methods: In 2017, we verbally administered a cross-sectional survey to HIV-positive women enrolled in the MOTIVATE trial and on ART at 12 months postpartum (N=200). The MOTIVATE parent study is a cluster-randomized trial evaluating the impact of community mentor mothers and text messaging on PMTCT outcomes. Multivariable regression models were used to examine the relationship between medication and visit adherence with psychosocial factors, including internalized and anticipated HIV-related stigma, intimate partner violence (IPV), and depression. Analyses controlled for age, marital status, education, parity and exposure to the MOTIVATE interventions.

Results: Of the 200 women included in the analysis 104(52%) reported depressive symptoms, 106(57%) reported internalized stigma, 84(43%) reported anticipated stigma, and 116(58%) had experienced IPV. Sixty-two women (32%) self-reported that they did not always take medicine as indicated and 17(9%) said they had missed at least one clinic visit in the past year. Women who experienced stigma were more likely to miss clinic visits (internalized stigma aOR 1.3 95%CI 1.03-1.64; anticipated stigma aOR 1.2 95%CI 1.04-1.42) and report difficulty taking ART drugs (internalized stigma aOR 1.32 95%CI 1.10-1.58; anticipated stigma aOR 1.14 95%CI 1.01-1.30). After adjusting for stigma, depression was associated decreased odds of viral load suppression (aOR 0.16 95%CI 0.04-0.76). Experiencing IPV was associated with increased odds of missing clinic visits (aOR 15.71 95%CI 1.47-167.80) and not taking medication (aOR 2.00 95%CI 1.05-3.74).

Conclusion: These cross-sectional results indicate that stigma, depression, and IPV experienced by HIV-infected women may impact their adherence to medication and clinic visits, which are critical for PMTCT and maternal health. These findings represent an opportunity to develop tailored psychosocial interventions to improve mental health and reduce stigma and IPV to improve adherence and engagement in care within the Option B+ setting.

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Application of New American Hypertension Guidelines to a UK Female HIV Cohort and Increased Cardiovascular Risk

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Background: Women living with HIV (WLWH) are at an increased cardiovascular risk with international studies quoting a 1.5-2 fold relative risk compared to peers, controversially this was not validated in the UK by Q-Risk3.
Hypertension (HTN) is the leading risk factor for cardiovascular disease and accounts for 6% of adult deaths worldwide. Estimates state HTN is responsible for 45% and 51% of deaths due to heart disease and stroke respectively.
In 2018 the American College of Cardiology (ACC) updated guidance stating high blood pressure (BP) should be treated at a lower threshold of 130/80mmHg rather than 140/90mmHg. The first reclassification of hypertension in over 20 years and UK guidelines are due to be addressed in 2019.

Methods: This is a prospective study of patients who attend a HIV day centre in a metropolitan city. Exclude were emergency visit as their anxiety levels may have led to an elevated BP. We retrospectively collected data on HTN, HTN medications, diabetes, kidney disease, lipids and smoking.
We were then able to calculate their risk of having a heart attack or stroke within the next 10 years through the Q-Risk 2 calculator.

Results: We collected data on 60 WLWH, avg. age 46.9yrs (± 10.7), and an avg. BP 128/78mmHg. 10(17%) of WLWH were on hypertensive medication but 50% were poorly controlled.
11(18%) of WLWH had a systolic BP>140mmHg which increased to 26(43%) using the ACC guidelines of >130mmHg. However only 7(12%) of patients had a diastolic BP>90mmHg, this increased significantly to 31(52%) when using>80mmHg.
The average calculated 10 year heart attack or stroke risk was 3.5%, for an age and ethnicity matched control the Q-Risk would be 1.5%. This is a relative risk increase of 2.33 for WLWH, which when we compared our male population was only a 1.58 relative risk increment. The higher rates of Q-Risk were driven by high blood pressure and hypercholesterolemia (29 WLWH) as prevalence of diabetes and chronic kidney disease were low 4 and 0 patients respectively.

Conclusion: Hypertension is common in WLWH, with prevalence estimates up to 54.4% in high-income countries. Using the ACC guidelines a significant proportion of our patients 34(57%) will be diagnosed with hypertension. This is significantly higher than the nationally recorded hypertension rates of 13.8%.
Many deaths from stroke, myocardial infarction, kidney and vascular events could be averted by the simple application of basic knowledge about blood pressure for which there has been broad consensus for decades. The ACC guidelines support a lower threshold for BP intervention and targets. By increasing awareness and informing staff we will be able to initiate BP reduction, in this highly vulnerable patient group.
We propose that the ACC Guidelines be applied to WLWH on ART in order to reduce long term cardiovascular risk.

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Waist:Hip Ratio is a Better Predictor of Cardiovascular Risk Than BMI in Women Living with HIV

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Introduction: Antiretroviral therapy (ART) has dramatically reduced morbidity and mortality among women living with HIV (WLWH), including wasting syndrome. Metabolic and cardiovascular diseases are leading causes of death for PLWH in high-income countries.
Obesity is increasing in the HIV population but a lack of data exists in WLWH, and the association with cardiovascular (CV) risk. We aim to determine if central obesity (measured using waist to hip ratio) is a better predictor of CV risk than Body Mass Index (BMI) which does not account for sex and is the current standard to define obesity in WLWH.

Methods: Single centre, prospective study performed in a large metropolitan HIV unit. 30 WLWH had weight, height, waist and hip circumference, and blood pressure (BP) recorded. Data on age, ethnicity, past medical history including CV risk factors and kidney disease, smoking status and postcode was used to calculate waist to hip ratio (W/H), BMI and Q-Risk2.

Results: The study population included 30 women, mean age 46.9 years (SD ± 10.7); 8 (27%) Caucasian, 20 (67%) black African/Caribbean and 2 (6%) another ethnicity. In total, 11 (37%) WLWH were normal, 5 (17%) were overweight and 15 (50%) obese using BMI measurements, there was a significant leftwards shift using WHR with now 13 (43%) WLWH becoming normal, 6 (20%) overweight and only 11 (37%) obese.
Q-Risk2 with a relative risk increment of 2.16 demonstrated that 24 WLWH (64%) had mild risk, 25 (20%) moderate, and 21(16%) were high cardiovascular risk (excluding HIV as a risk factor).
There was significant correlation between WHR and Q-Risk2 ($r=0.44$, $p<0.01$,) but not between BMI and Q-Risk2 ($r = 0.13$, $p = 0.15$). ROC analysis demonstrates that WHR is able to predict Q-Risk2 (AUC 0.74, 95% CI 0.66-0.82, $p<0.01$) with a cut-off of 0.98 having 67% sensitivity and 81% for predicting Q-Risk2 >5%. WHR performed significantly better than BMI (AUC 0.58, 95% CI 0.49-0.67, $p=0.24$) at predicting Q-Risk2 ($p=0.02$ for difference).

Conclusion: Temporal change in waist circumference can indicate change in abdominal fat, with increased abdominal fat being associated with increased CV risk. WHR is superior to BMI at predicting 10 year heart attack or stroke risk (Q-Risk), particularly in women as it accommodates the sex difference in fat and bodyweight distribution. It should be included as part of routine clinical assessment and lifestyle intervention implemented to reduce CV risk in WLWH.

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Patterns in Sexual Behavior, Mental Health, and Intimate Partner Violence Among High-Risk Women in Fishing Communities in Siaya County

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Introduction: Fishing communities (FC) in Kenya/Uganda have an extremely high burden of HIV-1 infection and limited access to health services. We characterized HIV-related behaviors, mental health, and intimate partner violence (IPV) outcomes in high-risk women in Siaya County.

Methods: Data were obtained in an ongoing HIV prevention trial involving HIV self-test (HIVST) provision in FC and hotspots where women exchange sex in Bondo and Rarieda sub-Counties. Following a community census supported by respective beach management units, HIV-negative adult women who reported ≥2 sexual partners were consented and enrolled. Baseline data were analyzed to study sexual behaviors, mental health (MH), and IPV.

Results: 510 women were enrolled in 16 FC clusters, with a mean age of 26. Seventy-five percent were married, 41.2% reported sex work as a source of income, with an average monthly income of 4,730 Shillings (sd=5,535.3). Nearly 80% reported regularly exchanging sex for money/goods/services with a median of 2 transactional sex partners/month. 67.2% of participants perceived a moderate/high chance of acquiring HIV due to their/partner's sexual behaviors. 58.5% reported at least one incidence of physical/psychological/sexual IPV in the past year. 82.9% report having at least one MH issue in the past 2 weeks, with 21.5% of reportable issues lasting >½ that time. 93.8% would test more frequently if HIVST were available.

Conclusions: High-risk women in FC have high rates of transactional sex, IPV, and poor MH outcomes. Collectively, this suggests a need for integrated interventions to reduce HIV risk and provide MH/IPV services in Siaya County.

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Long-Term cART Markedly Mitigates the Potency of CXCR4-Tropic HIV-1 on Mortality and Morbidity: Up to 18 Years Follow-Up in a Women's Cohort

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Background: Emergence of CXCR4(X4)-tropic HIV-1 strains heralded CD4+ cell depletion and accelerated disease progression in infected individuals during pre-cART and early cART eras. To investigate whether long-term cART mitigates X4 strains' deleterious effect, we examined the relationship of HIV-1 tropism to morbidity and mortality in 529 participants followed for up to 18 years in the Women's Interagency HIV Study.

Methods: Tropism of plasma-derived HIV-1 was determined genotypically. Statistical methods are provided below in Results.

Results: We categorized participants into 3 groups according to the reported number of semiannual visits on cART after its initiation: Group 1) ≤3 visits, 74% of whom reported no cART; Group 2) <70% of visits; Group 3) ≥70% of visits. Achievement of viral suppression was strongly correlated with number of visits on cART. The percentage of women in each group who ever achieved complete viral suppression was: 1) 12%; 2) 74%; 3) 92% (P<0.0001 by Fisher's Exact Test). Similarly, the mean number of visits with viral suppression achieved by women in each group was: 1) 1.2; 2) 5.6; 3) 11.9 (P<0.001 by Kruskal Wallis Test).

AIDS mortality rates for participants with detectable X4 strains vs R5 strains exclusively, respectively, were (by group): 1) 62% vs 40% (P=0.0088); 2) 23% vs 22% [Nonsignificant (NS)]; 3) 7% vs 14% (NS)(Fisher's Exact Test). Logistic Regression revealed that HIV-1 suppression for ≥10 semiannual visits (~5 years total) markedly mitigated the effect of X4 tropism on mortality, controlling for viral load and CD4 count. Kaplan-Meier curves depicting time to death due to AIDS or AIDS death and new AIDS-defining illnesses (ADI) showed more rapid clinical progression for participants with ≤3 cART visits and X4 viruses, but no difference in rates of progression stratified by tropism in the other groups (P=0.0002 for AIDS death, P=0.0028 for AIDS death and ADI by Log-rank Test).

Conclusions: This study demonstrated that long-term cART greatly mitigates the deleterious effect of CXCR4(X4)-tropic HIV-1 on morbidity and mortality.

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Maternal Health Indicators in an Era of Perinatal HIV Elimination: What Defines Success?

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Background: Perinatal HIV transmissions in the United States are nearing elimination and the last perinatal HIV transmission in San Francisco occurred in 2005. Getting to and maintaining zero perinatal HIV transmissions requires intensive coordination among multidisciplinary teams and allocation of additional resources to pregnancies that are ultimately near misses. HIVE clinic is a multidisciplinary care team providing specialty perinatal HIV care at Zuckerberg San Francisco General Hospital where the majority of San Francisco's HIV-exposed infants are born. We examined successes and gaps in standards of care across the perinatal HIV care continuum among the HIVE cohort, highlighting areas for improvement and near misses.

Materials & Methods: We developed a perinatal HIV treatment cascade including people living with HIV who had live births and were cared for at HIVE clinic from 2006 - 2017. We chose cascade components based on literature review and expert opinion. We extracted data on pregnant people living with HIV from the HIVE database. We analyzed separately data from 2016-2017 to assess recent trends.

Results: Data for 85 individuals were available for this analysis. Components of the perinatal HIV treatment cascade included: (1) prescribed prenatal antiretroviral therapy (92%); (2) engaged in prenatal care, defined as attending 8 or more visits (60%); (3) virologic suppression by 28 weeks gestation (48%); (4) virologic suppression at birth (71%); (5) infant HIV testing at birth and 2-3 weeks, 1-2 months, and 4-6 months of age (42%); (6) virologic suppression at 6 months postpartum (38%); (7) retention in HIV care postpartum, defined as 2 visits in 12 months (43%); and (8) virologic suppression at 12 months postpartum (27%). In contrast to this aggregate cohort, the 2016-2017 cohort (N=13) had 100% receipt of prenatal antiretroviral therapy and virologic suppression at 28 weeks respectively, 85% engagement in prenatal care, 100% virologic suppression at birth, 85% completion of infant testing, 75% virologic suppression at 6 months postpartum, and 67% retention in HIV care postpartum. Even in the recent cohort, virologic suppression at 12 months postpartum remained low (33%). There were zero perinatal transmissions in the study period. A retrospective chart review of maternal deaths during this same study period identified 9 individuals cared for at HIVE, all of whom died with 10 years of delivering HIV-negative infants.

Conclusions: Despite improvements in cascade indicators over time, these findings suggest opportunities to optimize maternal health, particularly postpartum, and reduce the risk of future perinatal HIV transmissions. The striking successes in perinatal HIV elimination in San Francisco are encouraging, but must be contextualized by continued gaps in maternal health, as demonstrated by the high number of deaths in this reproductive-aged cohort and infrequent maintenance of viral suppression postpartum. While national perinatal HIV prevention interventions necessarily focus on the elimination of perinatal HIV transmission during the antenatal period, perinatal HIV care continuum goals should include heightened attention to postpartum maternal health to characterize unique challenges and opportunities for improvement, highlight near misses, and promote the long-term health of people living with HIV.

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Contraceptive Choice Among Women Living with HIV and HIV-Negative Women in the Children and Women, Antiretroviral and Markers of Aging Cohort (CARMA)

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Background: For women living with HIV (WLWH), preventing unplanned pregnancy supports a woman in making her own decisions regarding childbearing, decreases probability of maternal-child HIV transmission, and prevents pregnancy in the presence of co-morbid illness. A recent retrospective analysis reported 61% of pregnancies in WLWH as being unintended; this greatly exceeds the Canadian average of 27%. Consequently, contraceptive choice is imperative. Hormonal contraceptive use is low among WLWH in Canada compared to HIV-negative women. However, little is known about contraceptive choice in relation to medical comorbidities, drug contraindications, and behavioral factors, specifically how these factors may influence prescribing practices for WLWH. Our objective was to describe and compare the prevalence of overall contraceptive use and use of estrogen-containing methods among WLWH and HIV-negative women.

Methods: Current contraceptive use overall and by estrogen-containing methods, was recorded and compared among 83 WLWH and 62 HIV-negative sexually active women enrolled in the CARMA cohort (Children and women, Antiretroviral and Markers of Aging), between 2012 and 2017. The presence of concomitant drug interactions (antiretrovirals, anticonvulsants etc.), medical comorbidities, and behavioral factors such as smoking that may influence the prescription of estrogen containing contraception was also compared. Participant characteristics were summarized with descriptive statistics and Fisher's exact test was used to compare their distribution stratified by HIV status.

Results: Compared with HIV-negative women, WLWH were older, (median (IQR) 39.2 (34.1- 43.3) vs 31.1 (22.6-40.7) years; p=0.003), less likely to have any post secondary education (37% vs 73%; p=0.0002), and were more likely to have an income ≤ $15,000/year (49% vs 30%; p=0.006). Overall "effective" contraception use (estrogen or progesterone containing contraceptives, tubal ligation, inter uterine device (IUD) and/or male sterilization) was similar between the two groups (46% WLWH vs 35% HIV-negative p=0.2). Use of any hormonal contraceptive (Mirena IUD, progesterone only, estrogen containing) was also similar (30% WLWH vs 32% HIV negative; p=0.9). However, WLWH were more likely to have had a tubal ligation than their HIV-negative peers (16% vs 1%; p=0.02) and were less likely to be on estrogen-containing contraception (4% vs 21%; p=0.002). Additionally, WLWH were more likely to be currently smoking over the age of 35 years (30% vs 6% p=0.0003), precluding the use of estrogen containing contraception, or to have a drug contraindication to estrogen containing contraception (29% vs 0% p=0.0001); all of the latter were antiretroviral-related. Among WLWH, 92% were on antiretroviral therapy and 58% had a contraindication to estrogen containing contraceptives (e.g. drug interaction, medical comorbidity or smoking >35y) compared with 13% for the HIV-negative group, p=0.0001.

Conclusions: Among CARMA participants, most contraceptive methods were similarly used between WLWH and their HIV-negative peers, except estrogen-containing contraceptives, which were less common, and tubal ligation which was more prevalent among WLWH. This could be due to WLWH having more contraindications precluding the use of estrogen-containing contraceptives and may at least partially explain the previous observation of lower hormonal contraceptive use in WLWH. This data supports the need for health care providers to discuss pregnancy wishes and contraceptive options regularly with patients.

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Addressing Unmet Need for Family Planning Among Female Sex Workers on PrEP in Kenya: Findings from Jilinde, a Large Scale Oral PrEP Project

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Background: A systematic review found that HIV prevalence among female sex workers (FSWs) is up to 13.5 times higher than general population women. While FSWs also experience a high risk of unwanted pregnancies, a study conducted in Burkina Faso, Togo and Swaziland found that 25% of FSWs had unmet need for family planning (FP). Since 2016, the Jilinde project in Kenya provides pre-exposure prophylaxis (PrEP) on a large scale to key populations including FSWs in three cluster regions of Kenya (Coast, Lake and Nairobi). Although PrEP provides a highly effective means of HIV prevention, it does not offer protection against pregnancy which condoms, another HIV prevention tool, do. We conducted an analysis of programmatic data to examine the intersection between PrEP and pregnancy prevention among FSWs using PrEP in Kenya.

Materials & Methods: The Jilinde project monitors de-identified client data, which is collected routinely during clinic visits using a nationally sanctioned tool. Records for all FSWs initiated on PrEP from 64 health facilities from February 2017 - June 2018 were examined. Unmet need for FP for women between 15-49 years was defined as not being pregnant, not using FP and not planning to have a child. Associations with the outcome variable were estimated using bivariate logistic regression. Significant variables were entered to a multivariate logistic regression model.

Results: A total of 10,786 FSWs initiated PrEP in the Jilinde project during the analysis period. Virtually all (95.9%) initiated on PrEP were >18 years, 70.3% were not married, 67.1% received PrEP through drop in centres (DICEs) and reported a mean of five partners within 30 days. Unmet need for FP among FSWs was reported for half (50.6%) of FSWs on PrEP. Younger FSWs aged 15-17 years experienced an unmet need for FP more than two times higher, AOR, 2.28(1.57-3.31) than older FSWs. FSWs who reported to be married experienced a higher unmet FP need, AOR 1.34(1.21-1.49). Conversely, FSWs receiving PrEP through DICEs, which are dedicated sites which deliver a package of sexual and reproductive health (SRH) services to key populations using a non-judgmental stance are likely to report lower unmet needs for FP, AOR 0.71(0.64-0.79) compared to those who accessed PrEP through public and private health facilities. Further, FSWs who recently accessed treatment for sexually transmitted infections, AOR 0.57(0.49-0.67) or accessed post-exposure prophylaxis for HIV, AOR 0.71(0.57-0.88) also reported lower unmet need. In addition, FSWs in the Jilinde program sites in the Lake Victoria region, reported a lower unmet need for FP, AOR 0.57(0.51-0.63). All these associations were significant ($p<0.05$) at the multivariate level.

Conclusions: Half of FSWs initiating PrEP reported unmet need for FP at their initial intake visit, highlighting the need for integration of PrEP and FP services. Younger FSWs experience higher unmet need for FP while those already accessing SRH services were less likely. Recommended actions include: training health care providers to identify and address unmet FP need; layering intensified FP messaging alongside demand creation for PrEP services; and programmatic monitoring of risk factors for unmet need for FP.

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Peer and Contextual Characteristics Associated with Retention of Female Sex Workers in Kenyan Key Population Programs

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Introduction: Female sex workers (FSW) are disproportionately affected by HIV with an estimated HIV prevalence of 29.3% compared to the national prevalence of 4.8% among the adult population. Drop in Centers (DICEs), provide comprehensive services including HIV-related services to FSW and aim towards reaching 90:90:90 targets in this key population (KP). We sought to identify the factors that influence retention of FSW in DICEs in Kenya.

Methods: Between February 2016 and May 2017, we conducted a randomized controlled trial in which we purposively selected eight DICEs, two in each of four regions: Kisumu, Migori, Mombasa and Nairobi. The sample consisted of 1,791 FSWs assigned to 56 peer-educators (PEs). We used stratified randomization using a random numbers sampler to assign PEs to two strata of 40-80 or 81-120 FSWs to a PE. Within each stratum, we randomly assigned half of the PEs to maintain their current number of FSWs (Group A), and the other, halving the number of FSWs (Group B). We examined the relationship between retention at 6, 12 and 18 months and selected PE and DICE characteristics using Pearson's chi-square test. Controlling for group, marital status, and HIV status, variables found to be statistically significant ($p < 0.20$) in bivariate analysis were entered into multilevel logistic regression models fitted using STATA 14.0.

Results: The retention rates of FSWs in KP programs were 54%, 36.6% and 24.6% at 6, 12 and 18 months, respectively. Retention at 6, 12 and 18 months was significantly associated with PE: FSW ratio ($p<0.001$). Retention rates at 6 months for PEs with at most 40, 41-60, 61-80, 81-100 and >100 FSWs were 62%, 57%, 42%, 45% and 50%, respectively. Similar trends in retention rates were observed at 12 and 18 months, and lowest in the halved 40-80 strata. The odds of retention were significantly better for Group B compared to A at 12 months [adjusted odds ratios (AOR) 1.28, 95% confidence interval (CI) 1.02-1.61] and 18 months [AOR 1.47, 95% CI 1.14-1.89]. Retention rates among FSW whose PEs were separated was higher than those whose PEs were living together with partners [AOR 1.42, 95% CI 1.01-1.82]. The odds of being retained in HIV care were higher among FSWs in DICEs that had adequate staffing (AOR 3.22; 95% CI 1.65-6.29) and were adequately stocked (AOR=2.07, 95%CI=1.14-3.75).

Conclusion: Retention by FSW at the DICEs is low and wanes with time. Fewer FSWs assigned to PEs improve retention, as do sufficient staffing and supplies. Therefore, KP programs should improve quality of services provided at the DICEs as this may boost FSW retention.

56 (withdrawn)

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Status of Peripartum Women with HIV Lost-to-Follow-Up Within a Cluster-Randomized Trial in Kenya

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Background: Loss-to-follow-up (LFU) from HIV care can dramatically compromise the health of people living with HIV, as well as bias trial findings. Yet, there is currently a poor understanding of actual outcomes amongst those characterized as LFU. The aim of this study is to establish the health outcomes of peripartum female participants who were LFU in the Mother-Infant Visit Adherence and Treatment Engagement (MOTIVATE!) study, as well as identify barriers and facilitators to retention in HIV care and treatment.

Materials & Methods: MOTIVATE! is a cluster randomized trial comparing the individual and combined impact of 2 behavioral interventions (text messaging and community-based mentor mothers) on adherence to ART and retention in care among pregnant and postpartum women living with HIV from 24 clinics in southwestern Kenya. We implemented a sub-study with participants who enrolled between 2015-2018 and were subsequently LFU from MOTIVATE! (defined as no clinic visit >90 days). LFU participants were traced by phone or attempted home visit in August 2018 and completed an in-person questionnaire verbally-administered by local interviewers. If participant was not located, interviewers attempted to establish status (alive, dead, moved) using an informant (spouse, parent, neighbor). Data were collected on tablets using the RedCap Mobile Application. Descriptive analysis was performed in Stata 14.

Results: Of the overall cohort of MOTIVATE! participants (n=1331), 9% (n=124) were LFU at the time of the sub-study, of whom, we collected data on 64% (n=79) – 71 participants and 8 informants. Informants report that 75% (n=6) had moved (50% due to partner conflict) and one was deceased. Of the 71 participants we contacted, 49% (n=35) were currently taking ART and engaged in HIV care; 30% (n=21) were no longer engaged in care nor on ART; 3% (n=2) reported being on ART but not in care; 3% (n=2) were in care but not on ART; and 15% (n=11) declined to answer. Common reasons for not being in care include: work interfered (22%) and fear of status disclosure (17%). Common explanations for not taking ART include: side effects (18%), don't want to (18%), and fear of status disclosure (14%). Of those out of care (n=23), 61% (n=14) report a willingness to return to HIV care. Of those not taking ART (n=22), 45% (n=9) were interested in restarting ART. Participants report the following would be the most helpful in re-starting ART: more flexible appointment times (23%), shorter wait times (18%), and more counseling support (14%). Of the minority of participants with a known viral load (n=24), 42% (n=10) report not being virally suppressed.

Conclusions: These novel findings report on the outcomes of peripartum women LFU from a large behavioral HIV trial. Nearly half of those found reported engagement in HIV care and taking ART, while a substantial proportion (almost one-third) were neither engaged in HIV care nor taking ART at follow-up. Our findings indicate that mischaracterization of women LFU is a significant issue. Addressing noted structural and individual barriers may improve retention and ART use among peripartum women living with HIV.

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How the 4M (My Health, My Child, My Life, My Choice) Peer Mentoring Programme Examines the Challenges Faced by Women Living with HIV

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Background: The number of people living with HIV in the UK is estimated at 101,200 (2017) 69% (n= 69,828) men and 31% (n=31,372) women. The good news story for women in the UK is that the rates of new HIV acquisitions has fallen n = 1125 compared to n= 3236 men (2017).
Treatment for people living with HIV in the UK has surpasses the UNAIDS 90% target (97%). However, there is no platform to address the challenges that are faced by women living with HIV, such as poverty, trauma (including PTSD) and gender based violence.
HIV public messaging has fallen off the national political agenda, leaving this critical work to be facilitated by charitable organisation such as Salamander Trust. By keeping community, knowledge at the core Salamander Trust remains relevant, as their approach to programming & policy interventions are holistic, person centred and inclusive. This is shown clearly in the 4M (My Health, My Child, My Life, and My Choice) model. The model was developed by women living with HIV and seeks to empower their peers, through their journey.

Objective: Examining how the 4M model responses to the 1948, World Health Organisation (WHO) definition of health as being " a state of complete physical mental and social well-being and not merely the absence of disease or infirmity" .

Materials and Methods: A webinar titled "Quality of Life (QoL) for women living with HIV" was delivered by the Principal Scientist –Coordinator of the Positive Voices survey, Public Health England, and a member of the 4M network who is also peer researcher and 4M peer programme evaluator. The duo analysed the results from the Positive Voices Survey (2017), which was a UK wide survey for people living with HIV. The audience of the webinar was a closed group for women living with HIV.

Results: 1,180 (51%) women living with HIV who responded to the positive voices survey. They reported that the most challenging areas affecting quality of life was pain & discomfort and depression & anxiety: 1 in 2 reported some problems. Poverty and lack of access to employment due to undocumented immigration status also remains a challenge. Women also reported that trauma caused by receiving a HIV positive diagnosis remained an issue for them, causing most to be isolated. The risk of re-traumatising also become quite difficult to navigate when discussing Quality of Life, especially where there are limited places to access mental health support if needed.

Conclusions: The 4M model ensure that women within the network are fully supported, from peer to peer support, through supervision and accessing opportunities to improve the contribution to the HIV movement through public speaking, presenting at conferences and further education. However, the HIV Psychosocial Network published in their Austerity Report (2018) that funding stream to holistically address the challenges faced by women living with HIV are being compromised and will lead to server and devastating that will affect the Quality of Life for women who are otherwise bio medically well.

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Understanding the Mental Health of Adolescent Who Acquired HIV Vertically, by Creating a Safe Space to Dialogue with Women Living with HIV Who Self-Identify as Having or Caring for a Child Living with HIV UK

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Background: Data from the Collaborative HIV Paediatric Study (CHIPS) shows that 2,151 children living with HIV were reported to them by the end of March 2018, (91%) were known to have acquired HIV vertically.
HIV treatment is effective in the majority of individuals. It is now important to focus on psychosocial, quality of life & wellbeing issues that significantly affect adolescents as they journey into adulthood. Young women living with HIV need to be able supported in understanding the WHO sexual and reproductive rights guide (2017).
During a session addressing "Quality of life for people living with HIV at the bi-annual People living with HIV Conference (2017) hosted by Positively UK, a UK based charity, a group of adolescents living with HIV highlighted the importance of breaking down the barriers they face in the home environment about meaningfully talking to their parents/caregivers about HIV.
To address the above, Children's HIV Association (CHIVA) incorporated space for women living with HIV who self-identify as having or caring for a child living with HIV, to have open dialogue with adolescents during their annual summer camp (2018).
CHIVA is a UK based charity supporting children and young people living with HIV across the UK and Ireland. CHIVA works to ensure young people have the knowledge, understanding, skills and support needed to live well and achieve their greatest potential. CHIVA acknowledged that addressing mental health issue is a proven way to tackle stigma (including self- stigma)

Materials & Methods: A cycle of two (2) workshops were repeated two times (total 4 sessions) led by two (2) women who self-identify as having a biological child or caring for a child living with HIV. Sessions were in a "lounge" fireplace format to avoid any perceptions of power and barriers. Total number of adolescents that participated was one hundred and two (102)

Results: Qualitative evaluation with young people and the women who led the workshop shows that the intervention is sustainable. It ensured that dialogue in the home environment happens in an inclusive and safe space.
There were some HIV knowledge gaps identified as follows:
a. There as an assumption that all people living with HIV had acquired the virus vertically
b. Another assumption was the HIV was a hereditary condition.

Conclusions: Surveillance study reports show that in the UK adolescents living with HIV are clinically living well. However, during the dialogue at the CHIVA Camp adolescents self -reported experiencing loneliness when it comes to talking about their HV status. It is important that interventions that improve the wellbeing and quality of life be introduced. Provision for more guidelines on how clinicians can incorporate a holistic care package to support adolescents should the need arise.
We conclude that there is a real need for more research on understanding the mental health of adolescents who acquired HIV vertically.

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Communication Between Pregnant Women and Male Partners About HIV Testing

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Background: After implementation of a quality improvement program offering free male partner HIV testing in a low-income urban prenatal clinic, male uptake of testing was poor. Despite high reported desire by pregnant women to know their partners' HIV serostatus, few women achieved this goal. Thus, we performed this follow-up study to understand how pregnant women and their partners communicate about HIV testing and how such communication influences women's knowledge of their male partners' HIV serostatus.

Materials and Methods: This is a qualitative study of non-Hispanic black and Hispanic pregnant women and their partners living in a high HIV prevalence area in the United States. All HIV-negative, English-speaking pregnant women receiving publicly-funded prenatal care at a single tertiary care center and their partners were eligible for in-depth individual interviews. Semi-structured guides were used to investigate couples' interpersonal communication about HIV and HIV testing. Transcripts were analyzed using the constant comparative method to determine themes.

Results: Interviews with 29 pregnant women and 22 male partners yielded a behavioral model of couples' decision-making and actions regarding HIV communication. We identified facilitators and barriers to two aspects of testing communication: 1) pre-test communication (regarding the desire or lack thereof for either partner to undergo HIV testing) and 2) post-test communication (regarding whether testing occurred and the outcome of testing). Facilitators of pre-test communication included: female-initiated conversations, desire to initiate sexual activity with a new partner, presentation of symptoms in either partner, or having a "nothing to hide" attitude (i.e. desire for open attitude about sexual health). In contrast, barriers to pre-test communication included testing not occurring to either partner (perceived low risk status) and trust in the male partner's negative status without desire for confirmation. Subsequently, facilitators of post-test communication (resulting in female knowledge of male test results) included the couple undergoing testing together and the female partner expressing a personal need for confirmation of the partner's negative status. Barriers to post-test communication included partner lack of follow-up, partner non-disclosure of test results, or the couples' assumption that the female's negative prenatal HIV test was assurance of the male partner's negative status. Female initiation of discussion was an overarching facilitator of successfully communicating about HIV testing within the couple.

Conclusions: In this low-income, minority community of pregnant women and their partners, women were commonly the driving force behind couples' communication about HIV testing. However, even when communication regarding testing was initiated, barriers such as male lack of follow-up or failure to disclose results impeded knowledge of partners' HIV serostatus. Consideration of other strategies that foster interpersonal communication, such as couples' testing, should receive further research.

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Uptake of HIV Pre-Exposure Prophylaxis (PrEP) in Clinical Settings in Western Nigeria: Are Healthcare Providers PrEPared for the Key Populations?

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Background: HIV pre-exposure prophylaxis (PrEP) can decrease HIV incidence among several high-risk populations. In order to successfully implement PrEP, healthcare providers will need to have knowledge about counselling, monitoring and drug adherence which are crucial to the success of the intervention. This study was carried out to determine the awareness, practice and preparedness of healthcare professionals to prescribe PrEP in clinical settings especially to key populations in our communities and identify the factors associated with or encouraging its prescription.

Methods: This cross-sectional study was carried out in randomly selected primary, secondary and tertiary level hospitals across four states in Western Nigeria (Ondo, Ekiti, Osun and Lagos). The target population were physicians and nurses largely involved in the antiretroviral clinics in the hospitals. Data was collected by trained volunteers and supervised by appointed supervisors by a face-to-face interview. All data were statistically analysed, using Statistical Package for the Social Sciences (SPSS) and statistical test of significance was performed with Chi-Square test.

Results: A total of 256 consenting respondents participated in the study with a mean age ± SD of 38.52 ± 9.29 years. Gender distribution of the subjects indicated that 130 (51.6%) of them were males while 124 (48.4%) are females. A total of 89.8% of the respondents have heard about PrEP, with 54.3% of them aware of both oral and topical PrEP while only 4.3% have ever prescribed PrEP. The main factor associated with PrEP prescription was work experience (χ^2 = 20.815, df = 1, p = 0.001). Work experience has lower association with PrEP prescription (OR: 0.88, 95% CI: 0.82 – 0.95).

Conclusions: Healthcare professionals in public hospitals in Nigeria are PrEP aware and willing to prescribe, but few have actually ever done the prescription. Regular supply of drugs for pre-exposure prophylaxis purpose and addressing the potential safety issues and medication-related adverse effects will help aid the PrEP implementation effort nationwide especially with focus on the key populations of mem having sex with (MSM) who are in a hostile environment in our own neighbourhood.

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The Stability of the Vaginal Microbiome in Pregnant WLWH: The CARMA-PREG Preterm Birth Study

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Background: The vaginal microbiome in women living with HIV (WLWH) has largely been characterized outside of pregnancy. Dysbiosis is known to influence preterm birth, however universal screening and treatment of dysbiosis has not resulted in decreases in preterm birth in HIV negative women. WLWH have higher rates of dysbiosis and have higher rates of preterm birth. It is unclear if the higher rate of dysbiosis influence the higher rates of preterm birth experienced by WLWH. We sought to characterize for the first time the vaginal microbiome of WLWH who were pregnant and to determine its stability over a pregnancy. In addition, we evaluated the influence of the vaginal microbiome in preterm birth.

Methods: 100 women were recruited from the CARMA-Preg cohort and vaginal microbiome sampling was performed at 16-20, 24-28, 32-36 weeks and at the time of admission for delivery. Cpn60 amplicon sequencing was performed using MiSeq on 262 samples and analyzed via our well established bioinformatics pipeline published elsewhere. (Community State Types (CST) were similar to those established previously. A multi-state Markov model was used to estimate transition probability between CST.

Results: The stability of the vaginal microbiome of pregnant WLWH was dependent on the CST. WLWH with Lactobacillus dominated CST transitioned within Lactobacillus dominated CSTs. WLWH in CST IVD, dominated by Megasphera sp. and Clostridiales sp. did not transition and remained in CST IVD for the duration of their pregnancy. Women in CST IVA/IVC, a heterogenous group containing Gardnerella vaginalis subgroup C and A, Prevotella timonensis (CST IVC) or Prevotella, Dialister, Bacteroides, and Porphyromonas uenonis (CST IVA), stayed the same or transitioned to Lactobacillus dominated CST. Only three WLWH transitioned to CST IVD at any time during pregnancy (Figure 1). There was a trend for Megasphera sp. and a significant association of Clostridiales sp. with unsuppressed VL. We were unable to determine an association between CST and preterm birth. There was a trend for L. iners to have lower abundance in women on PI and Integrase Inhibitor based regimens compared to those not on therapy.

Conclusions: In WLWH the stability of the vaginal microbiome during pregnancy appears to be influenced by the CST. For WLWH who are in CST IVD there is little likelihood that they will transition out of CST IVD. As we begin to understand the role of the vaginal

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Special Populations: Adolescent Girls and Young Women Living with HIV

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Introduction: Gender inequalities frame the epidemic for young people. Adolescent girls and young women (AGYW) are at much greater risk of HIV infection through social norms that make them more vulnerable. Adolescent girls and young women living with HIV face further risk of violence and stigma. The READY to Lead project is being carried out by ATHENA in partnership with the International HIV/AIDS Alliance and Zimbabwe Young Women's Positives (ZY+) and funded by Comic Relief with an aim of addressing these problems so that AGYW will be resilient and empowered, and have the knowledge and agency to make healthier choices, and to support others to do so.

Aim: To realize the challenges and problems faced by AGYW living with HIV and how to mitigate them through mentorship, leadership and advocacy skills and knowledge training.

Methods: The READY to Lead project is being carried out in 4 districts in Zimbabwe which are amongst the HIV hot spots areas. The young women leaders have received leadership, mentorship and advocacy training, using tools such as the 'Step Up, Link Up, Speak Up' guide developed by the Alliance and ATHENA. A survey was administered which was looking at the different data that could define the young women, that is, level of education attained, sex identification , population belonging to (sex workers, LGBTI etc.)

Results: READY to Lead project managed to conducted 5 training workshops that was focusing on leadership, mentorship and advocacy and a second level workshop focusing on National strategic Plans and budget monitoring and allocations. The gaps were identified and they are being advocated for within their respective districts. In total, 92 Young women were trained on leadership, mentorship and advocacy training. The survey results showed that 96% of the young women participants ended their education in primary level whilst 4% have excelled to tertiary level education. 27.6% of the young women trained were sex workers and 63% of them had been in marriage or living together with spouse/cohabit The 92 young women leaders each now mentor an average of 7-10 mentees, having a total of 612 mentees in the project From the 4 training workshops we conducted, we also had an opportunity to interact with the young women leaders with an aim to understand their background, their successes and challenges they are facing and find solutions together as to how these can be tackled. From these one on one interactions, 20% have experience partner violence due to status disclosure.

Although READY to Lead is currently on going, it has provided some insights about the project being a model which can make a difference in the young woman living with HIV lives. It is a sustainable model of young female leadership and the opportunity to connect with other activists for inter-generational learning and mentorship. READY to Lead is able to bring young women into spaces where they can have opportunities to advocate for their issues be it on a local, national, regional and global landscape. T

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Gaps in Viral Load Monitoring in a Cohort of Pregnant Women with HIV in Western Kenya

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Background: According to national guidelines in Kenya, pregnant women living with HIV should receive viral load monitoring at confirmation of pregnancy (if already on ART) or 6 months after ART initiation, and then every 6 months thereafter until the complete cessation of breastfeeding. We examined timing of routine viral load testing at government clinics among pregnant and postpartum women enrolled in the MOTIVATE! Trial, which aims to enhance ART adherence and engagement in HIV care in the Migori, Kisumu, and Homa Bay counties of Kenya.

Methods: In the MOTIVATE Trial, HIV+ women were enrolled at 24 antenatal clinics during pregnancy between 2015-2018 and followed until at least 12 months postpartum. Data on viral load (VL) and other study indicators were routinely abstracted from medical records by study data clerks, with confirmation/supplementation from the national VL database. We examined timing and trends in viral load measurements in terms of stage of pregnancy/postpartum, as well as relative to the date of ART initiation. VL suppression was defined as ≥1,000 copies/ml. Analysis was performed using Stata 15.

Results: Of the 1,331 pregnant women enrolled in the trial, (21.1% newly diagnosed during pregnancy), 182 were discontinued from the study or lost to follow-up. Of 1,149 retained women at the time of analysis, viral load measurements at some point during pregnancy and up to 12 months postpartum (period of observation) were available for 1,121 (97.6%). The mean number of VL measurements during the period of observation was 1.95 (range 0-4, SD±1.08). Among all women with VL measurements (n=1,121), 7.9% of women had one or more non-suppressed VL measurement during the period of observation. Among the 1,149 women retained, 21.0% had a VL measurement during the first trimester of pregnancy, 28.1% during the second trimester, and 32.2% during the third trimester, for a total of 81.3% with any VL measurement during pregnancy. Among women newly diagnosed with HIV during pregnancy (n=222), only 21.6% (n=48) had a VL measurement 6 months after ART initiation (+/- 1 month) and 10.8% (n=24) had a VL measurement 6 months later (12 months +/- 1 month). Overall, 74.3% of newly diagnosed women had a viral load test during pregnancy or up to 12 months postpartum.

Conclusion: Although VL monitoring access has been scaled up in this region of Kenya, significant gaps still remain for pregnant and postpartum women with HIV. Large proportions of women are not getting VL measurements at crucial times during pregnancy and breastfeeding, and did not have VL testing according to current Kenyan guidelines, possibly due to late initiation of antenatal care and delays in ART initiation for women newly diagnosed with HIV. Improved follow up of women with virologic failure during pregnancy or breastfeeding is urgently needed.

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HIV Knowledge, Attitudes and Beliefs Among Rural Pregnant Women in Rural Mysore, India

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Background: According to the UNAIDS report in 2018, India is among the leading countries with the highest HIV epidemic, with approximately 2.1 million people living with HIV. The Karnataka State AIDS Prevention Society (KSAPS) in 2007 reported that only 16% of the estimated 1.2 million pregnant women underwent HIV testing. It remains an increasing concern that HIV testing remains low, yet the prevalence of HIV is high in India. Understanding the knowledge, beliefs and misconceptions of HIV/AIDS is crucial in promoting HIV education and reducing stigma. Inadequate knowledge and risky practices are barriers to prevent HIV transmission. Although HIV knowledge has expanded in recent decades in education, health care and community settings, huge disparities currently exist in rural regions in India and there is limited research done in this community. This study examines the factors that influence the knowledge and attitudes of HIV/AIDS among pregnant women in rural Mysore, India.

Material and Methods: A prospective cohort study was conducted between 2011 and 2014 among 1820 pregnant women. The women were provided an informed consent and answered an interviewer-administered questionnaire on HIV knowledge, perceptions, and disclosure status in the Kannada language. All of the participants underwent routine antenatal care services and were followed up after delivery, at 6 months and 12 months after delivery. Descriptive and chi-square analyses were computed using SPSS 23.

Results: Of the 1820 women surveyed, the mean age of the study population was 21.2±3.2 years, the majority were Hindu (98.6%), more than half (58.8%) had secondary education or higher, and 36.5% were low-income. Almost two-thirds (64.0%) of the pregnant women reported that HIV/AIDS is transmitted from mother to baby through breastfeeding, 71.2% reported the virus could be spread from mother to child, 75.0% indicated HIV can be transmitted through sharing syringes or needles, and 73.1% though unprotected sexual intercourse. Nearly fifty percent (49.3%) of the women indicated that mosquito bites can transmit HIV/AIDS. More than a fifth of the pregnant women reported they did not know or were not sure about the majority of questions concerning HIV transmission and misconceptions. More than half of the women (51.3%) agreed or strongly agreed that someone becomes infected with HIV/AIDS virus often due to a person's own carelessness. 78.2% of the women disagreed or strongly disagreed that during sexual intercourse that they are usually the person who suggested condom use. Increased awareness, knowledge and attitudes of HIV/AIDS was significantly associated with secondary education or higher ($p<0.01$) and older age ($p<0.01$).

Conclusions: Given the existing education and awareness programs by the government, there are still gaps in HIV knowledge among rural pregnant women. The study demonstrates an urgent need to promote comprehensive HIV education among pregnant women in rural regions in India to minimize the incidence and prevalence of HIV/AIDS. It is an utmost priority to ensure culturally appropriate and adequate training for rural communities to increase the knowledge and awareness of HIV/AIDS.

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Disclosure of HIV Results and Knowledge, Attitudes and Beliefs About HIV Among Rural Pregnant Women in India

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Background: Non-disclosure of HIV status is a major barrier to early initiation of antiretroviral therapy, treatment adherence, infant feeding methods and continuum of care for women. This study describes the factors associated with disclosure of HIV status and HIV/AIDS knowledge, attitudes and behaviors (KAP) of rural pregnant women in Mysore, India.

Methods: The study was conducted from January 2009 until January 2011 and consisted of a standardized interviewer-administered questionnaire in Kannada. All women underwent group pretest counseling for HIV testing and individual post-test counseling before receiving their results.

Results: Among 1675 participants, the median age was 20 yrs, 88.4% reported being ever married with single sex partner, 98.7% were Hindus by religion and 13.4% had no education. Approximately two-thirds of the sample had good knowledge about HIV/AIDS. About 12% were quite a bit or extremely (63.8%) worried about getting HIV/AIDS, while only a few were not at all (14.1%) or a little bit (8.4%) worried. If infected with HIV, the majority of women (71.0%) would disclose their status to three or fewer people. Most women would disclose their status to their spouse (90.4%), parents (81.7%), or physician (90.2%). Few reported that they would share their status with religious leaders (1.5%) or community leaders (1.3%). The consequences of disclosure that was most expected include a weakening of the relationship with their partner (49.8%), the breakup of their sexual relationship (58.7%), and estrangement from peers (45.6%). Increased HIV knowledge was associated with higher household income ($p<0.001$) and higher education ($p=0.002$). Increased worrisome attitudes toward acquiring HIV is associated with lower education ($p<0.001$), higher household income ($p=0.033$), increasing disclosure ($p=0.032$), and increasing severity of expected consequences ($p<0.001$). Increased disclosure was associated with higher household income ($p<0.001$), increased worrisome attitudes toward acquiring HIV ($p=0.032$), and increased severity of expected consequences ($p=0.035$). The severity of the expected consequences of acquiring HIV increased with age ($p=0.031$), with increased worry of acquiring HIV ($p<0.001$), and with increasing disclosure ($p=0.033$).

Conclusion: Although HIV knowledge has increased among pregnant women, there are still major barriers such as stigma and fear of consequences of HIV disclosure in rural India. While the government has offered education and awareness campaigns, there needs to be targeted tailored initiatives in reducing stigma while promoting effective messaging about HIV/AIDS.

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Neighborhood Factors Associated with Viral Suppression and Preterm Delivery of Pregnant Women Living with HIV

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Pregnant women living with HIV experience high rates of premature delivery and although prenatal viral suppression has improved over time due to more effective HIV treatment, more needs to be done to improve maternal outcomes of women with HIV. Geographic determinants can negatively impact prenatal viral suppression and preterm birth but these associations have not been well described. The purpose of this study is to evaluate neighborhood- level factors associated with viral suppression near delivery and preterm birth among pregnant women living with HIV.

We performed an analysis of HIV surveillance records of women who had a live delivery in Philadelphia between 2005 and 2015. Outcome variable of interest included viral suppression near delivery, defined as having a viral load (VL) <200 copies/ml using the lab closest to delivery, and preterm birth, defined as having a delivery before the 37th week of pregnancy. Neighborhood variables were measured at the census tract level and included poverty (percentage of individuals below the federal poverty line), median household income, education (<10% of individuals with a bachelor's degree), violent, drug violation and prostitution related crimes. We performed a bivariate analysis to measure the association between the outcomes, individual and neighborhood level factors, followed by the use of multivariable logistic regression models evaluating the association between neighborhood level factors and the outcomes, controlling for individual-level factors.

Of 944 births occurring over the 10-year period, 58.6% were suppressed near delivery and 20.0% had a preterm birth. The majority (>70%) of births from women with HIV occurred in census tracts of high poverty, low median household income and low-education; these neighborhoods also experienced higher rates of drug and prostitution crimes. Viral suppression was low in the early years of the cohort (33% in 2005-2007) and gradually improved to reach 80% in the later years of the cohort (2013-2015). Preterm delivery did not improve overtime: in 2005-2007, 18% of women had a preterm birth compared to 20% in 2013-2015. After controlling for individual level variables, there were no associations between neighborhood factors and the outcomes in the regression models.

Despite having births in neighborhoods of high poverty and crime, viral suppression near delivery significantly improved over time. This success is likely due to progressive clinical policies and more effective antiretroviral therapy, enabling women to overcome social determinants. This success has not been replicated for preterm delivery and interventions are needed to improve preterm births for women living with HIV.

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High STI Prevalence Among HIV-Exposed Women Initiating Safer Conception in Rural Southwestern Uganda

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Background: Sub-Saharan Africa has the world's largest burden of HIV and sexually transmitted infections (STIs). In Uganda and many lower-resourced settings, objective STI screening is not part of public health guidelines. STI syndromic management is often the standard of care, but the majority of STIs are asymptomatic. Since STIs are a known risk factor for HIV transmission and acquisition, undiagnosed STIs pose a risk of significant morbidity and mortality to men, women, and infants.

Materials and Methods: The Healthy Families PrEP study is a longitudinal cohort study enrolling 150 HIV-uninfected women in rural southwestern Uganda with personal or partner plans to have a child within the next year with a partner known or suspected to be living with HIV. At enrollment, women are offered comprehensive safer conception counseling, including TDF/FTC as PrEP, and followed for one year or until pregnancy. Within the Healthy Families PrEP study, we integrated an STI substudy whereby women completed STI testing and interviewer-administered questionnaires at enrollment. Participants provided vaginal swabs for GeneXpert nucleic acid amplification testing (NAAT) for Chlamydia trachomatis (CT), Neisseria gonorrhea (NG), and Trichomonas vaginalis (TV), and blood for Syphilis testing via rapid immunochromatographic testing, confirmed by rapid plasma reagin (RPR) testing with a positive titre of 1:8. These point-of-care tests allow for same-day testing and treatment as well as partner-delivered medication and notification cards for sexual partner(s). We calculated the prevalence of total STIs, each individual STI, and STI co-infection.

Results: Between 06/2018 and 10/2018, 54 participants completed baseline STI testing within this substudy. Median age was 27 (IQR 24 - 30) years, with 37 participants (69%) reporting an HIV sero-positive partner and 17 (31%) reporting an HIV serostatus-unknown partner. Sixteen participants (30%) had prevalent STIs, including 9 (17%) with CT, 2 (4%) with NG, 4 (7%) with TV, and 4 (7%) with Syphilis. Three participants (6%) had STI coinfection with two STIs (two with CT/Syphilis and one with CT/TV). There was no difference in STI prevalence among participants with HIV sero-positive partners compared to HIV status-unknown partners (p=0.98). All women were administered STI treatment at the study-site and were given partner-delivered medication and notification cards for sexual partner(s).

Conclusions: Enthusiasm for safer conception programs is growing, particularly in settings where syndromic screening for STIs is standard of care. This is the first study to describe a high prevalence of curable STIs in a population of HIV-exposed women planning to have a child. A curable STI prevalence of 30% is striking with important implications for the health of women, their partners, and their planned pregnancy. These data highlight the importance of implementing comprehensive reproductive healthcare, including objective STI testing, to support HIV-affected men and women to safely meet reproductive goals.

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HIV Knowledge and Attitudes Among Minority Pregnant Women and Their Male Partners

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Background: HIV seroconversion during pregnancy poses substantial risk to maternal-child health and disproportionately affects urban, minority women. In order to prevent horizontal and vertical HIV transmission, it is essential that at-risk individuals are aware of HIV risk factors and effective transmission prevention strategies. We aimed to examine knowledge about HIV transmission as well as attitudes about HIV among low-income, minority pregnant women and their partners living in a high prevalence community.

Materials & Methods: This is a qualitative study of non-Hispanic black and Hispanic pregnant women and their partners. All women were HIV-negative, English-speaking, and receiving publicly-funded prenatal care in an urban, high HIV prevalence area in the United States. Pregnant women were participants in a clinic quality improvement program offering free HIV testing to their male partners. Semi-structured guides were used to conduct in-depth individual interviews about participant sources of information about HIV, knowledge about horizontal and vertical HIV transmission, and attitudes regarding those living with HIV. Deidentified interview transcripts were analyzed using the constant comparative method to determine themes and subthemes.

Results: Of 51 total participants, 29 were pregnant women and 22 were male partners. Cited sources of information about HIV included television and/or advertisements, community-sourced knowledge, and educational materials (written and web-based). Themes regarding participant knowledge about horizontal and vertical HIV transmission were categorized as accurate, inaccurate, and uninformed (i.e., participant admitted knowledge gaps). Inaccurate knowledge about horizontal and vertical transmission was highly prevalent; for example, one male partner stated, “I think chances are very good passing it to the baby…very high…always most likely…that the baby would come out with HIV.” Lack of knowledge was also common; one woman stated, “I’m just not sure if it’s possible that the mother can have HIV and the child can’t. Maybe I have to do my own research on that.” Both men’s and women’s perceptions of people living with HIV were primarily either agnostic or judgmental. One example of an agnostic view was “They’re just normal people. They just have to keep up with their medications. That’s about it.” Contrasting judgmental or stigmatized views were also common; one participant stated, “Like I wouldn’t say that it’s on them, but that’s your choice. Like you are responsible for letting yourself get like that. You’re responsible for your own actions and you never know what you could come across these days, especially in Chicago.”

Conclusions: Among low-income, minority pregnant women and their male partners in a high HIV prevalence area, inaccuracies and lack of knowledge about horizontal and vertical HIV transmission are common. Enhanced efforts to educate pregnant women and their partners about HIV and horizontal and vertical transmission should address common misconceptions and use popular sources of information. Future research should address the potential benefits of patient-centered education in improving knowledge with the goal of reducing maternal seroconversion in pregnancy.

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African-Born Women Seeking HIV Care in Philadelphia: Qualitative Exploration of a Community of Practice

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Background: In the U.S. both privately and federally funded programs exist to provide targeted HIV care and services. The majority of these programs place emphasis on access to care, especially for programs serving traditionally vulnerable populations. Despite this programmatic availability, African-born, HIV-positive women living in the U.S. continue to experience care disparity. This study's significance derives from the need to redress the injustice of health disparity encountered by this population. The purpose of this qualitative, phenomenological study was to explore and understand the role of a community of practice (COP) among African-born, HIV-positive women seeking and obtaining care in Philadelphia. While preceding research gives evidence to the African-born population's value in community involvement in issues of wellness, little is understood regarding the role a COP can serve in HIV care access.

Material & Methods: The Promise Keepers (PKS) are an existing COP that gathers regularly to share, and create a living repository of their knowledge of living as HIV-positive, African-born women. The participants of this study were purposely sampled by convenience from this existing COP of seven African-born women, representative of five diverse African countries of origin. These seven participants included women ranging in age from 25 to 62 with a mean age of 44 years of age. The methods of this study included one-on-one interviews, group interviews, and participant observation. Through thematic coding of the stories or "Way Makers" of the PKS, this study's three major themes emerged: (a) internal perception of self, (b) external perception of self, and (c) defined relevance of "community".

Results: Apparent through analysis and framed theoretically by Rosenstock's Health Belief Model (HBM) was this study's novel finding of the relevance of education in the restoration of self-efficacy among COP members. As voiced by the PKS, it was the group-mediated education, established trust, and created "safe space" that reduced members' perceived risk of isolation and enhanced their perceived benefit of seeking care and support to achieve wellness. The members of PKS described their lives prior to the group as one of isolation, living in hiding from themselves and others. Conversely, the COP members described their lives within the group as "just being me…not hiding, being my real self." The group richly discussed how gaining encouragement from "people like us" was paramount. Discussed as critical by all COP members was the use of this safe space to tell each other's stories. The COP members equated learning from their sisters as the translational, mediator for "hope" and "encouragement," "hope which means life."

Conclusions: The purpose of this phenomenological study was to explore and understand the role of a community of practice among African-born, HIV-positive women obtaining care. While past literature gives prominence to HIV stigma and loss of one's external community, it was the loss of self and, more importantly, the COP-mediated restoration of self/self-efficacy that was most resonant to this study's participants. It will be the intention of this interactive, conference session to discuss this study's findings, implications for practice and further implication for research.

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Providers Struggle to Discuss Breastfeeding with Patients Living with HIV

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Women living with HIV in the U.S. are discouraged from breastfeeding. Guidelines suggest patient-centered, evidence-based counseling on infant feeding options for women wanting to breastfeed or with questions about breastfeeding, but little is known about how this is implemented in practice.

The National Perinatal HIV Hotline provides 24-hour clinician-to-clinician guidance on HIV diagnosis and management in women and their infants before, during, and after pregnancy. Call data is maintained in a secure database and includes semi-structured case details. We analyzed calls from October 1, 2015, to September 30, 2018, where "Breastfeeding" was identified as a call topic by the consultant. Using narrative case details, we conducted a thematic analysis of calls.

Breastfeeding was a call topic in 202 cases. The majority of cases simply included a consultant recommendation to discuss infant feeding. Forty calls were about HIV-negative women with exposure to HIV. Five calls were new diagnoses during breastfeeding. The remaining 26 calls were specifically related to breastfeeding with HIV – patients wanting to breastfeed or already breastfeeding or provider questions about breastfeeding. Four themes emerged from this last category of calls:

Patient-provider relationships: Providers feel challenged by patients who are firm in their breastfeeding intentions and can view the conversation as a confrontation. One caller asked if this was an indication to refer to child protective services.

"Scripts" to guide dialogue: Providers felt unprepared to talk to their patients about breastfeeding. Many callers were looking for updated risk estimates and recommendations. Some callers were looking for general guidance about how to approach the conversation with patients.

Need for early and open communication: Many calls were about women who were in labor or immediately postpartum. The patients' desires to breastfeed had apparently not been previously shared. Pediatrician callers often had no knowledge of any conversations about breastfeeding that may have occurred during the prenatal period. In four of the five calls where the patient was already breastfeeding, it was without without providers' prior knowledge.

Global differences in recommendations: The vast majority of our calls were related to patients from Africa, many of whom had breastfed previously outside the U.S. Some of these patients were traveling between the U.S. and Africa. Some callers indicated that patients expressed fears about disclosure and stigma, other patients simply viewed breastfeeding as the standard. One caller shared that their patient cited WHO recommendations.

Perinatal HIV Hotline callers often feel unprepared to discuss breastfeeding with patients. Conversations are often happening close to delivery and can lead to tension, especially when patients have a very strong desire to breastfeed. Patients who want to breastfeed are often from countries where women living with HIV are encouraged to breastfeed. Providers should be discuss breastfeeding early and should share their discussions with other prenatal and pediatric providers. National guidelines and professional organizations should continue to provide nuanced guidance for providers on how to discuss breastfeeding with their patients living with HIV, including up to date data on risks and benefits of breastfeeding and explanations of the differences in various guidelines/recommendations.