8th International Workshop on HIV & Women

2 – 3 March 2018, Boston, MA, USA

Abstracts

1

Role of vaginal microbiota on STI/HIV risk among us adolescent girls and young women

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Background: Adolescent and young adult (AYA) women account for half of new sexually transmitted infections (STI) annually in the United States. Host defenses against genital infections include lactobacilli, which produce bactericidal substances like lactic acid and hydrogen peroxide, and cervicovaginal mucus (CVM) that coats the genital tract to serve as a physical barrier. In contrast, altered vaginal flora (AVF) and bacterial vaginosis (BV) impair host defenses, thereby increasing susceptibility to infections. Furthermore, some STIs like Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), and Trichomonas vaginalis (TV) produce mucosal inflammation, which may increase HIV acquisition. The objective of this study was to investigate the impact of altered vaginal flora (AVF) and bacterial vaginosis (BV) on STI prevalence and CVM properties.

Materials & Methods: Sexually active AYAs 13-24 years of age provided self-collected vaginal swabs for CT, NG, and TV nucleic acid amplification tests, microscopy, gram stain, and pH. AVF and BV were diagnosed using Amsel's criteria or Nugent score. A subset of AYAs (n=10) collected CVM. Fluorescently labeled HIV virions were added to CVM to characterize movement using microscopy. Chi-square and logistic regression were performed.

Results: Ninety-three participants enrolled. The median age was 21 (IQR:19-23) and the majority were of black race (N=52, 56%). Twelve (13%) had an STI, 32% had AVF (Nugent ≥ 4), and 19% had BV (Nugent ≥ 7). Black AYAs (p=0.045) and younger participants (19.4 vs. 21.2, p=0.025) were more likely to be STI positive. After adjusting for age and race, the odds of AVF among black AYAs were 4.9 higher (95% confidence interval [CI] 1.58-14.95) than non-black AYAs. There was no difference in the odds of BV for black vs. non-black AYAs (adjusted odds ratio [AOR] 2.75, 95% CI 0.87-8.71). After adjusting for age, race, and AVF or BV, there was no difference in odds of STI for black AYAs (AOR 2.52, 95% CI 0.45-14.14), younger AYAs (AOR 0.82, 95% CI 0.65-1.05), AVF (AOR 2.16 95% CI 0.54-8.75), or BV (AOR 2.16 95% CI 0.54-8.75). HIV virions were highly mobile in CVM with elevated pH vs. complete adhesive immobilization in CVM with lower pH (3.64 vs. 4.32, p=0.014). There was no difference in HIV mobility by menstrual phase (p=0.635), AVF (p=0.389), BV (p=0.389), or STI (p=0.197).

Conclusions: There was no difference in STI prevalence or HIV mobility in AYAs with AVF or BV. Elevated pH predicted HIV mobility in CVM. Vaginal microbiome analyses will further delineate the potential association between vaginal microbiota and STI/HIV acquisition.

2

Uptake of and Retention on HIV Pre-Exposure Prophylaxis (PrEP) among adolescent girls and young women in Kenya

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Background: In 2015, adolescent girls and young women (AGYW) accounted for 450,000 (25%) of all new infections reported among adults in sub-Saharan Africa. Oral pre-exposure prophylaxis (PrEP) has been accepted as a national strategy to prevent HIV acquisition in Kenya. However there is limited information on uptake and retention of PrEP among AGYW. In LVCT health, conducted a demonstration project to assess the deliverability of oral PrEP as part of combination prevention in Kenya.

Methods: This study employed a prospective cohort design and was implemented between September 2015 and December 2017 at three HIV testing facilities. The sites were purposively selected due to their location high HIV prevalence counties (Homa Bay - 26.0% and Nairobi – 6%) and are representative of both urban and rural populations. AGYW aged 15 to 29 years who provided consent to participate were screened for HIV risk using a risk assessment tool. Those found at risk were invited for a PrEP initiation visit after 2 weeks where they received one-month oral PrEP prescription with subsequent monthly follow-up/re-fill visits over a period of one year. Uptake was defined AGYW who received the first one month dose of Truvada™ PrEP. Retention was defined as the proportion of AGYW who came back for the scheduled monthly visits. Data was collected using a structure questionnaire to collect participant's characteristics, clinic charts for follow up visits and focus group discussions with AGYW to understand the factors that influence PrEP uptake. Frequencies were used to describe the respondents' characteristics. Chi-squared for categorical variables and Wilcoxon rank sum test for continuous variables were used to assess evidence of association between uptake of PrEP and other covariates. Qualitative data was coded using NVIVO version 10, and analyzed using the analytical framework method to identify major themes on factors that influence uptake of PrEP.

Results: A total of 693 AGYW found to be at risk for HIV. The median age was 22.5 years. Majority of the study participants were single 442(63.8%), had primary level education 319 (46.2%), living with parents/relatives 291 (42.4 %) and unemployed 542 (78.7%). Most 582 (84.0%) took up the first dose of PrEP. Uptake was significantly associated with age ($p < 0.001$), marital status ($p=0.002$), living alone ($p= 0.001$) and employment status ($p= 0.056$). The most common barriers to uptake mentioned during FGDs included sexual partner / guardian discouragement, belief of misconceptions PrEP use, fear of violence from partner and lack of time due to conflicting priorities like school and work. Retention on PrEP decreased gradually with time. Only 28.4% returned for the 2nd visit and 16.5%, 10.5%, and 5.3% by 4th, 7th, and 10th visits respectively.

Conclusion: Uptake of PrEP among AGYW was high. The decision to take up PrEP by AGYW is not autonomous and is mainly influenced by family and partner consent, fear of partner violence and lack of appropriate information about PrEP. Retention on PrEP was poor. This underscores the need for strategies that eliminate the barriers to uptake and improve retention of PrEP among AGYW.

3

This disease is killing us: Female sex workers' perspectives on pre-exposure prophylaxis (PrEP) in contexts of substance use, violence, and HIV

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Background: Women who engage in sex work experience heightened vulnerability to HIV due to alcohol and drug use, experiences of physical and sexual violence, and limited access to health services. In western Kenya, where sex work is widespread and drug use is a growing public health concern, offering pre-exposure prophylaxis (PrEP) could help prevent HIV acquisition among sex workers. Although Kenya is one of the first African countries to approve PrEP for HIV prevention, its real-world effectiveness will hinge on reaching the highest risk populations. We conducted a qualitative study to identify potential opportunities and barriers to PrEP adoption among women reporting sex work and substance use in Kisumu, Kenya.

Methods: We conducted qualitative interviews with female sex workers reporting recent alcohol or drug use and experiences of violence. In-depth interviews covered social relationships, substance use, sex work, and perspectives on health needs and programming. Content analysis identified themes relating to PrEP knowledge and acceptability in contexts of sex work, substance use, and violence.

Results: Among 45 women, median age was 28 years (range: 18-42). All women reported alcohol use in the past month. Nearly all (93%, n=42) reported lifetime drug use and half had ever injected drugs (49%, n=22). Past-month drug use included bhang (marijuana, 80%, n=36), heroin (56%, n=25), miraa (khat, 27%, n=12) and non-medical use of prescription drugs (18%, n=8). Most women experienced past-year physical (96%) and/or sexual violence (93%), and the majority (91%) reported violence perpetrated by their sex work clients. Fourteen were HIV-infected (self-report, 31%). The majority of women were unaware of PrEP. After interviewers explained PrEP, women expressed strong interest in PrEP for its potential protection against HIV during sex work (e.g., if condoms broke), especially when women were intoxicated and unable to use condoms or in cases of sexual assault. Several women discussed the potential role of PrEP in cases when clients offered significantly higher prices for condomless sex. Women preferred accessing PrEP confidentiality through health centers; several suggested that sex workers could be trained as peer educators to promote PrEP and support uptake among fellow sex workers. Although most women did not perceive significant barriers to taking a daily medication, some expressed concern that alcohol use and frequent migration for sex work could interfere with PrEP adherence. Several women mentioned they would prefer long-acting injectable PrEP (currently undergoing efficacy testing) over daily oral medications.

Conclusions: Sex workers in Kisumu experience high levels of violence and vulnerability to HIV, which is compounded by substance use. Although interest in PrEP was high, our findings suggest that, thus far, this marginalized population is not aware of or benefiting from PrEP. Programs seeking to improve PrEP delivery to sex workers at high risk of HIV acquisition should address issues of substance use and violence and continue to promote condom use with clients. Increasing the acceptability and adoption of PrEP and other biomedical HIV prevention methods will require continued engagement of sex workers in further intervention and implementation research.

4

Sex Differences in Subclinical Coronary Atherosclerotic Plaque Among Individuals with HIV on Antiretroviral Therapy

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Background: In high-resource settings, rates of myocardial infarction are comparable between HIV-infected women and men, and are higher than those observed in the general population. The extent to which unique mechanisms contribute to myocardial infarction risk among women vs. men with HIV is unknown. In this study, we sought to systematically compare subclinical coronary atherosclerotic plaque prevalence, burden, and high-risk morphology features (including positive remodeling and low attenuation) between HIV-infected women and men.

Materials and Methods: Plaque characteristics were compared among 48 HIV-infected women and 97 HIV-infected men on antiretroviral therapy (ART) without known clinical cardiovascular disease who had undergone coronary CT angiography and metabolic/immune phenotyping.

Results: HIV-infected women and men in the cohort had similar age (48 [41, 54] vs. 48 [42, 52] years old, P = 0.75), time since HIV diagnosis (14.6 ± 5.9 vs. 13.8 ± 6.5 years, P = 0.46), duration of ART use (8.9 [3.9, 11.8] vs. 8.0 [4.5, 11.0] years, P = 0.51), CD4 count (535 [411, 759] vs. 462 [303, 744], P = 0.10), and frequency of undetectable virus (84% vs. 85%, P = 0.83). BMI, smoking status, and cocaine use also were similar between groups. Compared with men, women had a lower prevalence of any subclinical coronary atherosclerotic plaque (35% vs. 62%, P = 0.003), a lower prevalence of high-risk positively remodeled plaque (25% vs. 51%, P = 0.003), a lower number of overall plaque segments (1.3 ± 2.3 vs. 2.1 ± 2.5, P = 0.01), and a lower number of positively remodeled plaque segments (0.5 ± 1.1 vs. 1.2 ± 1.5, P = 0.002). Using logistic regression analysis controlling for relevant cardiovascular disease risk factors, male sex was associated with increased odds of any coronary plaque (OR 3.8, 95% CI [1.4, 11.4]) and of positively remodeled plaque (OR 3.7, 95% CI [1.4, 10.9]). Among the subset of HIV-infected individuals with coronary plaque, there was no sex difference in overall plaque burden. In this subset, women had an increased proportion of non-calcified plaque (75% ± 28% vs. 53% ± 38%, P = 0.03), but a reduced proportion of positively remodeled plaque (33% ± 33% vs. 62% ± 37, P = 0.004) compared with men.

Conclusions: We find important differences in subclinical coronary atherosclerotic plaque burden and morphology among HIV-infected women and men on ART. These sex-specific differences suggest that unique pathophysiologic processes may underlie the comparably high rates of myocardial infarction among women and men with HIV. Only by understanding distinct mechanisms of HIV-associated cardiovascular disease in women can we deliver "precision" preventive care to this population of 17 million worldwide.

5

Food insecurity is associated with increased inflammation among HIV-positive women

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Background: Chronic inflammation is associated with worse HIV clinical outcomes including opportunistic infections and non-HIV related comorbidities such as cardiovascular disease (CVD). Limited research has considered how social and structural factors influence chronic inflammation among people living with HIV. Food insecurity, which is associated with HIV-related morbidity and mortality, as well as increased risk of chronic diseases such as diabetes and CVD, may be one such factor. This study assessed whether food insecurity is associated with higher levels of inflammation among a large sample of HIV-infected women in the United States.

Methods: We analyzed cross-sectional data collected from April-September 2015 from participants of the Women's Interagency HIV Study, a multi-site prospective cohort study of women with or at risk for HIV at 9 sites in the United States. Our sample comprised 409 HIV-infected women on antiretroviral therapy, with available fasting blood, and without diagnoses of comorbidities associated with high levels of inflammation (e.g., cancer). The primary predictor was any food insecurity measured using the U.S. Household Food Security Survey. Outcomes were natural log transformations of pro-inflammatory cytokines IL-6 and tumor necrosis factor receptor 1 (TNFR1). We conducted multivariable linear regressions adjusting for age, race/ethnicity, education, income, smoking, and viral load.

Results: Nearly one-third of the women (30.8%) were food insecure. Less than one-quarter (21%) had detectable viral loads and 6% had CD4 less than 200 cells/mm3. In adjusted analysis, any food insecurity was associated with 1.28 times the level of IL-6 (95% CI: 1.09, 1.51) and 1.14 times the level of TNFR1 (95% CI: 1.06, 1.23). In sensitivity analysis restricted to those who were virally suppressed and with CD4 cell counts greater than 500 cells/mm3, findings remained significant.

Conclusions: Food insecurity is associated with elevations in markers of inflammation in HIV-infected women independent of viral load or CD4 cell counts. Prior research shows that both IL-6 and TNFR1 are associated with increased HIV-related morbidity and mortality as well as increased risk of cardiometabolic disease. Longitudinal research to assess whether IL-6 and TNFR1 are on the causal pathway between food insecurity and negative HIV and chronic disease clinical outcomes is needed.

6

LEEP Treatment of Extensive Cervical Intraepithelial Neoplasia in HIV-Infected Women

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Background: WHO guidelines recommend loop electrosurgical excisional procedure (LEEP) in resource-limited settings for histologically confirmed cervical intraepithelial neoplasia 2/3 (CIN2+) regardless of HIV status or extent of lesion. We determined the incidence and correlates of recurrence following LEEP among HIV-infected women with CIN2+.

Methods: From June 2011 to July 2014, HIV-infected women enrolled at the Coptic Hope Center for Infectious Diseases in Nairobi, Kenya underwent cervical cancer screening with Papanicolaou (Pap) smear. Women with high grade squamous intraepithelial lesions (HSIL) and CIN2+ diagnosed by colposcopy-directed biopsy or endocervical curettage (ECC) were treated with LEEP. Recurrence of pre-cancerous cervical disease was defined as HSIL+ on Pap smear taken every 6 months for 2 years. Outcomes were compared between women with biopsy-confirmed CIN2+ lesions limited to the ectocervix (ECL) and ECC-confirmed CIN2+ lesions indicating endocervical involvement (ENL) using Chi-square tests and Cox proportional hazards regression.

Results: Among 275 women who received LEEP at baseline, 186 women with ECL had a median age of 37 years, [interquartile range (IQR), 31-44], 92% were on antiretroviral therapy (ART), 34% had low CD4 (<250 cells/µl) and 69% were treated for CIN3. Eighty-nine women with ENL had a median age of 40 (IQR 36-46), 89% were on ART, 28% had low CD4 and 81% were treated for CIN3. The rate of HSIL+ recurrence was 16.7 per 100 woman-years for ECL and rose to 27.8 for ENL. Women with ENL were significantly more likely to be ≥40 years, compared to women with ECL (53% vs 39%, P=0.034) and report younger age of sexual debut, ≤16 years (39% vs 26%, P=0.059). At the end of follow-up, women with ENL experienced significantly higher recurrence than those with ECL (40% vs 27%; P=0.030). Women treated for ENL were 56% more likely to experience recurrence than women with ECL (Hazard Ratio: 1.56, 95% confidence interval: 1.02-2.39; P=0.039). Recurrence among women with ENL was associated with age ≥40 years (P=0.031) and antecedent pathology of CIN3 (P=0.052), but not with low CD4 <250 cells/µl (P=0.364) or ART use (P=0.975).

Conclusions: Pre-cancerous lesions with endocervical involvement among HIV-infected women were more likely to occur in older women and were 36% less likely to be successfully treated with LEEP compared to lesions limited to the ectocervix. Immune status and ART did not modify recurrence risk after LEEP in HIV-infected women with endocervical involvement.

7

Menopausal symptoms are associated with psychological distress in HIV+ women

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Background: Despite increasing numbers of older women accessing HIV services, there remains a paucity of data on HIV and the menopause. We explore the association of severe menopausal symptoms with psychological distress in women living with HIV (WLWH).

Methods: An analysis of data on 710 women recruited to the PRIME Study; an observational study of WLWH aged 45-60 in England in 2016-17. Psychological distress was measured by PHQ-4 (score≥3 indicating distress). The Menopause Rating Scale was used to capture severe somatic (score≥9) and urogenital (score ≥4) symptoms.

Results: Median age was 49 years (interquartile range: 47-52).The majority were Black African (n=489, 70.9%), with low rates of drug use (n=19, 2.8%). Almost all (n=669, 97.4%) were on antiretroviral therapy; a minority had a CD4 count<200 cells/mm3 (n=49, 8.2%) or detectable HIV viral load (n=70, 10.7%).The majority were either peri- (n=311,44.3%) or post- (n=246, 35.0%) menopausal. Use of systemic and vaginal estrogen was low (n=31, 6.8% and n=28, 4.4% respectively).

Nearly half of WLWH reported psychological distress (n=326, 45.9%); 28.9% scored above the cut-off for anxiety (205/710) and 25.1% (178/710) for anxiety. Women reported high levels of somatic symptoms (n=615, 88.6%) of which 18.7% were severe (115/615). Two thirds had urogenital symptoms (n=463); 42.8% were severe (183/463).

Psychological distress was associated the following demographic factors: unemployment, lower educational status, and lacking money for basic needs (all p<0.001). Psychological distress was also associated with severe somatic and urogenital symptoms (both p<0.001). Women with severe somatic menopausal symptoms were five times more likely than those without to report psychological distress (adjusted odds ratio [AOR] 4.90; 95% confidence interval [CI] 2.71,8.88; p<0.001). Those with severe urogenital symptoms were over twice as likely to report psychological distress (AOR 2.66; 95% CI 1.74,4.01; p<0.001).

Conclusions: In one of the first studies to explore the association of menopausal symptoms with psychological distress in midlife WLWH, we report high levels of somatic and urogenital symptoms. Severe symptoms in both domains were significantly associated with psychological distress, although we cannot assess the direction of this relationship, highlighting the need for longitudinal data. Of note, use of systemic and vaginal estrogen was low in this population. Midlife WLWH with severe menopausal symptoms are a group requiring particular psychosocial support and who may benefit from management of somatic and urogenital symptoms.

8

The Meaningful Engagement of Women Living with HIV in Research, Policy and Programming

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Case study of 4M (My Health, My Choice, My Child, My Life) Train the Trainer (TOT) Perinatal Peer mentoring project and SWIFT (Supporting Women Living with HIV InFormation NeTwork).

Background: HIV treatment is effective in the majority of individuals. The UK is on its way towards reaching the UN 90 90 90 targets, (figures - 87 96 94). It is now important to focus on psychosocial, quality of life & wellbeing issues that significantly affect women's lives. Salamander Trust's programmes and organisation are led by women living with HIV, 33% (n=4) women living with HIV are on the 4M steering group. They conduct Training, Research & Advocacy based on Community Knowledge (RIGHT(S) Track.
SWIFT is a UK & Ireland 'knowledge network' bringing together healthcare providers, (HCP's) researchers, activists, advocates & women living with HIV interested in research on HIV and women highlighting work done, foster collaboration & address current knowledge gaps. The SWIFT steering group includes four (4) women (30 %) openly living with HIV actively contributing to all seminars, projects and presenting data from SWIFT nationally and internationally.

Objective: Responding to sustainable development goals 3 & 5, we explored our experiences of being engaged with SWIFT and 4M.

Material and Methods: A focus group meeting looking at: project evaluation, content development, post training engagement, information dissemination, skills gained, personal satisfaction & empowerment.

Results: Overall, the 4M project had a positive impact on our lives additional increasing personal capacity to provide sustainable peer support, increased confidence, and awareness of upholding human rights through shared experiences and education.
We analysed SWIFT projects on Mental Well Being and living with HIV, involvement in the PRIME study and being a member of the SWIFT steering group. Positive outcomes for SWIFT included being respected as emerging researchers, feeling fully involved with deciding upon and directing projects. Opportunities to collaborate with HCP's , peers and other researchers in engaging and relevant topics, performing literature reviews & sharing research outputs at conferences. Mentorship to women living with HIV (n=2) was provided to expand research knowledge and projects evaluation, again building confidence.

Discussion: As 4M TOT graduates, we were positive of the experience and aspired for 4M to spread across the globe, to ensure project sustainability and create global networks of women who can challenge stigma and discrimination faced by women living with HIV creating opportunities to compliment clinical care. Our involvement with SWIFT encouraged us to be involved in decision making about what mattered most to us and which projects to take forward. Engagement proved meaningful with conference outputs and presentations at seminars to a multidisciplinary audience.

Conclusion: We viewed meaningful involvement as women living with HIV essential for all issues involving us, regarding it as empowering. Involvement is successful when it contains opportunities for personal growth, self sufficiency and self management, demonstrated by 4M and SWIFT projects. The examples shown here demonstrate that when sustainable funding is available programs and projects can be actively and ably led by women living with HIV.

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Changes in brain volume and cognition in mice exposed in utero to ABC/ 3TC-ATV/ RTV

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Background: Combination antiretroviral therapy (cART) has facilitated the radical reduction of perinatal transmission of HIV. However, there are concerns about the effects of cART on fetal development and long-term health outcomes of the offspring. Studies have reported several adverse neurological outcomes in HIV-exposed uninfected children. Our objective was to investigate the impact of in utero exposure to cART on infant brain development and cognitive behavior using advanced imaging techniques and well-validated behavioral testing methods in a mouse pregnancy model.

Methods: Gravid C57BL/6 mice were exposed to human-relevant plasma concentration of Abacavir (ABC)/Lamivudine (3TC)-atazanavir (ATV)/ritonavir (RTV) or water (control) starting from gestational day (GD) 1 to delivery. At GD 16, mice were euthanized; fetal weights were recorded and fetal morphology was assessed using micro-CT. A subset of the pregnant mice was allowed to carry to term and pups were accessed for developmental milestones (motor, tactile, auditory, and olfactory reflexes) from postnatal day 1-21. Postweaning, all mice were subjected to the novel object recognition test to assess non-spatial learning and memory. Alterations in brain regional volumes were assessed by magnetic resonance imaging.

Results: Fetuses exposed to cART were smaller than the controls [mean (SD); 0.32g (0.09) vs. 0.41g (0.06); P=0.007] and continued to remain smaller until sacrifice at 8 months after birth [mean (SD); 27.95g (1.78) vs. 30.95g (1.87) P=0.00025]. Micro-CT imaging showed significant volumetric changes in different regions of the fetal brains including a significant 7% decrease in the volume of the neocortex and amygdala (P<0.05) and a 7% increase in the hypothalamus in the cART-exposed group compared to controls (P<0.05); similar changes were observed in the adult brains by MRI at 8 months. The development of motor skills, tactile and olfactory reflexes were delayed in the cART-exposed offspring compared to controls (P<0.01). The cART-exposed mice had lower memory indices (MI) compared to controls (P<0.0001), and there was a positive correlation between MI vs. hippocampus CA1 and CA2 (r=0.68, P<0.0001), and MI vs. cingulate cortex (r=0.4, P=0.024)

Conclusion: Our data suggest that the in utero exposure to ABC/ 3TC-ATV/ RTV is associated with volumetric changes in key regions of the brain, developmental delays and cognitive deficits in a mouse model of pregnancy.

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Effects of depressive symptoms on HIV suppression at delivery and postpartum in P1025

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Introduction: Women with HIV who have depressive symptoms are at elevated risk for disease progression. Yet, the association between prenatal depressive symptoms and viral suppression during pregnancy, birth, and postpartum (a time when many women fall out of the HIV care continuum) has not been previously examined in a prospective study.

Methods: We assessed the association between prenatal depressive symptoms and viral suppression using data from the multicenter International Maternal Pediatric Adolescent AIDS Clinical Trial P1025, 2002-2013. Prenatal depressive symptoms were evaluated at each visit using the Mental Health Inventory-5 (MHI-5; score range 5-30 with higher scores indicating greater symptoms). Viral suppression (VL<400 copies/ml) at delivery and at 24 weeks postpartum served as the outcome. Covariates included teenage pregnancy, race, education and inconsistent adherence to antiretroviral therapy (ART) measured by any missed doses in the past 1-2, 2-4 and >4 weeks. Multivariable logistic regression models evaluated the association between our outcomes and prenatal depressive symptoms, adjusting for all covariates.

Results: Of 1,409 women (mean age=28, SD=6; 57% black), 23.5% had depressive symptoms scores between 10-19 and 25.2% between 20-30. Examining viral suppression, 71.5% of women were suppressed at delivery compared to 44.3% at 24 weeks postpartum. In our regression models, women in the highest tertile for depressive symptoms were significantly less likely to be suppressed at delivery (AOR=0.6, 95% CI 0.4-0.8) and at 24 weeks postpartum (AOR=0.7, 95% CI 0.4-0.9) compared to women with depressive symptoms scores in the lowest tertile. Other factors negatively associated with viral suppression at delivery and postpartum included teenage pregnancy and inconsistent adherence to ART. Higher education was positively associated with suppression at both time points.

Conclusion: We found that prenatal depressive symptoms were common and that women with high depressive symptoms were less likely to be suppressed at delivery and at 24 weeks postpartum. These findings have tremendous implications for maternal and pediatric health. Depressive symptoms should be adequately assessed and addressed during pregnancy in order to improve perinatal and postnatal outcomes for women with HIV.

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Estradiol levels in HIV-infected pregnant women on dolutegravir-based ART in Botswana

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Background: Estradiol (E2) is an important pregnancy hormone that plays a role in fetal development. E2 is altered with antiretroviral treatment (ART) use in pregnancy and may be associated with poor birth outcomes. Limited data exists on newer antiretrovirals, such as dolutegravir (DTG), and E2. We evaluated associations between DTG use in pregnancy, maternal E2 levels, and infant birth weight (BW) and length (BL).

Materials and Methods: The Tshilo Dikotla study is prospectively enrolling HIV+ and HIV- pregnant women ≥18-years-old in Gaborone, Botswana. All HIV+ women in this analysis were taking combination DTG/tenofovir/emtricitabine. Levels of E2 and sex-hormone binding globulin (SHBG) were measured by ELISA in plasma collected between 24-29 weeks gestation and used to calculate bioavailable E2 (bE2). Infant BW and BL were abstracted from hospital records and converted to z-scores (BWZ, BLZ) using Intergrowth-21 standards. bE2 was log-transformed to normalize the distribution. Maternal-infant characteristics were compared by maternal HIV status using Wilcoxon Rank Sum and Fisher's exact tests. Linear regression models were fit to assess the association between maternal HIV status/DTG use and bE2. Pearson correlation coefficients were derived to quantify associations between log bE2 and BWZ and BLZ.

Results: Specimens from the first 118 pregnant women (47 HIV+ on DTG-based ART) enrolled in the Tshilo Dikotla study were analyzed. HIV+ women were older (27 vs 25 years; p= 0.02) and of higher gravidity (3 vs 1; p<0.01). There was no difference in body mass index between groups (p=0.38). Median time on DTG-based ART at time of blood collection for E2 was 11.7 weeks. Median bE2 was lower in HIV+ vs. HIV- [461 pg/mL, Interquartile Range (IQR):350-778 vs 588 pg/mL, IQR:451-898; p<0.01]. Log bE2 remained lower among HIV+/DTG women after adjusting for maternal age and gravidity (β:-0.10; p=0.03). Log bE2 was positively correlated with BWZ (r= 0.43; p<0.01) and BLZ (r=0.23; p=0.04). Overall, compared with HIV-unexposed infants, BWZ (p=0.64) and BLZ (p=-0.89) of infants exposed to in utero HIV/DTG/TDF/FTC did not differ significantly.

Conclusion: HIV+ women receiving DTG-based ART in pregnancy had lower bE2 compared with HIV- women. Lower maternal bE2 correlated with lower infant BWZ and BLZ. With expanding global use of DTG in pregnancy, further research and national surveillance data are needed to inform the safety of DTG for HIV+ pregnant women and their infants.

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Key achievements in PMTCT program: Rwanda 2006-2016

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Background: PMTCT program in Rwanda was initiated in 1999 with a piloting phase in Kicukiro Health Centre in Kigali City. Subsequently, PMTCT service delivery has been expanded and now over 542 (96%) of total public health facilities are covered in the country. Further, the country aims to maintain mother to child transmission as low as 2% by 2020.
We report on trend analysis of national program data that was carried for the last 10 years.

Methods: we reviewed National PMTCT guidelines and analyzed national data on HIV testing among pregnant women, their partners and children in national PMTCT program from January 2006 to December 2016.

Results: In Rwanda, PMTCT protocol changed over time based on new evidences, it started with single dose Niverapine during labour followed by the use of AZT for the pregnant mother and Nevirapine for exposed child (Option A) to tri-therapy started at 14 weeks of pregnancy up to the weaning period (option B), since 2012 to nowadays the country is implementing option B+ requiring that the pregnant woman receive life-long antiretroviral therapy.

The percentage of pregnant women tested for HIV and got their results increased from 88 to 99 and their prevalence decreased from 5.5% to 0.7% between 2006 and 2016.

The proportion of women who accessed antiretroviral therapy increased from 80% in 2006 to 98.5% in 2016, this resulted into a decrease of HIV transmission among infants aged 18 months from 9.3 % to 1.5%.
Of male partners tested in PMTCT, the percentage increased from 30% in 2006 to 84.9% in 2016, their prevalence decreased from 5.4 to 0.9% in the same period.

Conclusion and Recommendations: These results demonstrate successful scale-up of the national PMTCT program in Rwanda, there is an increase in HIV testing and a decline in HIV prevalence among pregnant women, partners and their children, indicating successful HIV prevention efforts.
The success of PMTCT program in Rwanda result to Political commitment, involvement of stakeholders and the whole community.

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Longitudinal associations between food insecurity and substance use in a cohort of women with or at risk for HIV in the United States

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Background: In cross-sectional studies, food insecurity has been associated with substance use, a risk factor for HIV transmission and poor HIV outcomes. Few longitudinal studies have examined this relationship, particularly among women or by substance class. We hypothesized that current and previous food insecurity would be associated with higher substance use using longitudinal data among women with or at risk for HIV in the United States.

Methods: We analyzed longitudinal data from the Women's Interagency HIV Study (WIHS), a multisite prospective cohort study of women with or at risk for HIV in the US. Data on 2,553 women (11,692 observations) were collected from April 2013-March 2016 at 6-month intervals across nine sites in the US. Food security (FS) was measured using the USDA Household Food Security Survey Module and categorized as high, marginal, low, or very low FS per guidelines. Outcomes were: the use of any illicit substances except cannabis; cannabis use; stimulant use (crack, cocaine, and/or methamphetamines); opiate use (heroin and/or non-prescription methadone); and prescription drug abuse, since the last visit. We used multivariable logistic regression with random effects to examine simultaneous associations of both current and previous FS with the substance use outcomes, adjusting for education, race/ethnicity, income, homelessness/residency, age, insurance status, and physical health status.

Findings: Seventy-one percent of women were living with HIV, 44% were food-insecure, and 13% were using illicit substances (not including cannabis). In adjusted analyses, current low and very low FS were associated with 1.6 (95% CI=1.0, 2.5; p<0.05) and 2.5 (95% CI=1.5, 4.0; p<0.001) higher odds of any illicit substance use, respectively, compared to high FS. Current low and very low FS were also associated with higher odds of cannabis, stimulant, and opiate use (all p<0.05), exhibiting a consistent dose-response relationship. In the same models, marginal, low, and very low FS at the previous visit were associated with 1.7 (95% CI=1.1, 2.5; p<0.05), 1.8 (95% CI=1.1, 2.7; p<0.05), and 2.3 (95% CI=1.4, 3.6; p<0.001) higher odds of any illicit substance use at current visit, respectively. Previous low and very low FS were also associated with higher odds of current cannabis and stimulant use (both p<0.05). HIV seropositivity was negatively associated with most substance use categories (p<0.05).

Conclusions: Food insecurity was longitudinally associated with the use of illicit substances, cannabis, stimulants, and opiates in this cohort of US women. HIV+ status was negatively associated with substance use, which may reflect that women living with HIV are able to access additional healthcare and social services compared with women at risk, or that an HIV diagnosis serves to motivate reductions in risk behaviors and engagement in care. Elucidating the paths underlying these associations could inform efforts to curb substance use and food insecurity in the US, both of which are risk factors for HIV transmission and poor HIV outcomes.

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Physical and Sexual Violence Linked to Increased Incarceration Amongst Women Living with HIV in Metro Vancouver: Urgent Need for Trauma-Informed Care in Prisons and Post-Release

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Background: Despite Women Living with HIV (WLWH) being disproportionately criminalized and overrepresented within correctional facilities in BC and across Canada, there remains limited longitudinal community-based research with WLWH examining factors that make WLWH vulnerable to incarceration.

Materials & Methods: Data is drawn from SHAWNA (Sexual health and HIV/AIDS: Women's Longitudinal Needs Assessment), a community-based longitudinal research cohort with WLWH (cis and trans women), aged 14+ who live or access HIV services in Metro Vancouver, Canada (2010-present). The SHAWNA Project is a partnership with over 20 women's HIV and community service providers guided by two community advisory boards. The SHAWNA Project launched following over 6 months of community-based consultations with WLWH, HIV care providers and policy experts on research priorities and gaps in services. Baseline and semi-annual questionnaires are administered by trained community and Peer Research Associate interviewers, alongside a clinical visit with a sexual health research nurse to support viral load and CD4 monitoring, sexual health education, STI/HCV testing, and linkages to care. SHAWNA interviews focus on lifetime and recent (last 6 months) experiences navigating HIV care, community supports, sexual and reproductive health, and treatment outcomes. In this study, multivariable logistic regression using generalized estimating equations (GEE) and a working correlation matrix was used to prospectively model correlates of recent incarceration exposure over the seven-year period.

Results: Amongst 289 WLWH, the majority (76%) had been incarcerated in their lifetime and 17% of participants had been incarcerated over the follow up period (2010-2017). Participants contributed 1179 observations, with 76 events of incarceration reported during the follow up. Over half of participants (57%) identified as Indigenous, 12% identified as African/Caribbean/Black/other ethnic minority and 31% identified as White. In multivariable GEE analyses, younger age (Adjusted Odds Ratio (AOR): 0.92 per year older, 95% Confidence Interval (CI): 0.89-0.96), recent homelessness (AOR: 2.81, 95% CI: 1.46-5.41), recent physical/ sexual violence (AOR: 2.26, 95% CI: 1.20-4.22) and recent opioid use (AOR: 1.83, 95% CI: 1.00-3.36), were significantly correlated with increased odds of recent incarceration. Lifetime exposure to physical and/or sexual violence by police (OR: 1.97, CI: 0.97-4.02) was marginally correlated with increased odds of recent incarceration.

Conclusions: In this study, younger age, recent homelessness, recent sexual/physical gender- based violence and recent opioid use were significantly correlated with increased odds of recent incarceration. Additionally, lifetime experience of violence from police was marginally associated with increased odds of recent incarceration. This research suggests a critical need for culturally safe trauma-informed interventions and policies for WLWH along their cascade of care, including during periods of incarceration, and following release into communities. Intervention and supports for WLWH post-release from correctional centers must speak to the cyclical nature of violence and incarceration, and must address intersecting women-centered supportive housing and substance use supports.

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High resilience of women living with HIV with psychosocial enabling factors: implications for practice

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Background: Resilience refers to an individual's positive adaptation to challenging situations and is critical to one's health and wellbeing. We aim to assess how sociodemographic and other variables correlate with high resiliency levels among women living with HIV (WLWH).

Methods: We used a cross-sectional approach to assess resiliency of 1,415 WLWH (aged ≥16) enrolled in the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS) from 2013 to 2015 in BC, Ontario and Quebec. Resiliency was measured using the RS10 Resiliency Scale (range=10-70) and dichotomized based on the median (RS10-score ≥64). We conducted univariate analyses and multivariable logistic regression for the outcome, high resilience (RS10-score ≥64).

Results: Women were ethnically diverse (22% Indigenous, 29% African/Caribbean/Black, 41% Caucasian, and 7% other ethnicities). Participants reported a high overall resiliency score with a mean of 62.17 (SD=8.07) and median of 64 (IQR=59-69). Multivariable analysis revealed that sociodemographic variables that correlated with higher resiliency included gender (trans women had higher resiliency than cis women [aOR=1.94; 95% CI=1.04, 3.64]) and place of residence (women in Quebec and BC had higher resiliency than women in Ontario, with those in Quebec having significantly higher levels [aOR=2.15; 95% CI=1.62, 2.86]). Variables enabling higher resilience included food security [aOR=1.70; 95% CI=1.34, 2.16], absence of mental health conditions [aOR=2.38; 95% CI=1.88, 3.02], non-binge drinking compared to binge drinking [aOR=1.54; 95% CI=1.12, 2.12] and no injection drug use (IDU) compared to current IDU [aOR=4.10; 95% CI=2.49, 6.75].

Conclusions: The overall resilience of WLWH was high in this cohort. Trans women reported higher resilience than cis women and this should be celebrated. Care providers could focus on enabling variables that would lead to higher resilience for this population, including supporting women to be food secure, promoting good mental health and assiting women with their substance use, with supportive harm reduction strategies.

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Developing a women-centred HIV care (WCHC) model: using the findings from the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS)

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Background: Worldwide, women are overrepresented in the HIV epidemic with over 50% of people living with HIV being women. Compared to male counterparts, women with HIV experience vast inequities and poorer health outcomes. Women have unique social and health concerns, related to social determinants of health, mental health, sexual, reproductive and women's health. As the main objective of the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS), we aimed to develop an all-encompassing "Women-centred HIV Care" (WCHC) Model to address the unique health needs of women with HIV.

Materials & Methods: We applied Change Management Theory to develop a WCHC model, which included findings from a literature review, focus groups, and baseline survey data from 1,422 women with HIV in British Columbia, Ontario and Quebec. This was followed by assessments from a broad array of stakeholders, incorporation of their feedback, and finally, obtaining buy-in from the key stakeholders.

Results: CHIWOS participants experienced alarmingly high rates of violence and trauma in their lives (79.4% experienced any form of violence and 48.1%, experienced and sexual vioence in adulthood; 47.1% had post-traumatic stress symptoms). Nearly half of participants had depressive symptoms (48.6%). While participants are receiving good HIV care (98.0% were engaged in HIV care and 83.0% were taking antiretroviral therapy), there is a need for improvement in women's health care (only 68.6% had received a Pap test in the past year). Incorporating these findings, the WCHC model has been developed in the shape of a 'house' to represent safety, comfort and trust. Trauma- and violence-aware care is the 'foundation' of the 'house' to help women rebuild a sense of control and empowerment. Person-centred care with attention to social determinants of health and family is on the 'first floor' to ensure that all care needs are addressed in a shared care model. Next, the 'second floor' contains three essential rooms: 1) competent HIV care, 2) competent women's healthcare and 3) competent mental healthcare. Finally, peer support, leadership and capacity building were identified from focus group discussions as vital components to optimize health for women with HIV, and make up the 'roof'. The WCHC model must be flexible in its delivery through various modes (i.e. by a single nurse, nurse practitioner, physician, physician aid, larger clinic with multiple care providers or multiple care clinics working together).

Conclusions: The WCHC model aligns with the World Health Organization's Consolidated Guideline on Sexual and Reproductive Health and Rights of Women Living with HIV, as it takes a woman-centred, holistic approach to HIV care that acknowledges and addresses both the realities and complexities of a woman with HIV's entire life. It not only asserts that women's and mental health should be integrated with HIV care, but also that care be trauma- and violence-aware, person-centred and incorporates peer support. Our next step is to develop a user-friendly toolkit and checklists to allow organizations to implement WCHC for improving the care and outcomes of women with HIV around the world.

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Switching to bictegravir/emtracitabine/tenofovir alafenimide (B/F/TAF) in women

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Background: The unboosted integrase inhibitor containing single-tablet regimen (bictegravir/emtricitabine/tenofovir alafenamide, B/F/TAF) has shown efficacy and safety in HIV-1 infected patients. Bictegravir is a novel, unboosted INSTI that has been coformulated with F/TAF in an STR that has shown high rates of suppression with no resistance in phase 3 studies of treatment naïve patients. We now report Week 24 (W24) safety and efficacy of switching to B/F/TAF versus staying on baseline regimen (SBR) [elvitegravir (E)/cobicistat (C)/F/TAF, E/C/F/tenofovir disoproxil fumarate (TDF) or atazanavir (ATV)+ritonavir (RTV)+F/TDF] in an all-women, international multi-centre, randomized, open-label, phase 3 trial.

Methods: HIV−1 infected, virologically suppressed women on a protease inhibitor or boosted elvitegravir-containing regimen were randomized (1:1) to switch to B/F/TAF or stay on baseline regimen (SBR). The primary efficacy endpoint was the proportion of women with HIV−1 RNA >50 copies (c)/mL at W48 with 4% noninferiority margin (FDA snapshot). A secondary efficacy endpoint of HIV-1 RNA < 50 copies/mL at Week 24 is reported here. Other secondary endpoints include safety (adverse events (AEs), laboratory abnormalities). This interim W24 efficacy and safety analysis was pre-specified.

Results: We randomized and treated 470 women (234 B/F/TAF, 236 SBR (E/C/F/TAF n=125; E/C/F/TDF n=98; ATV+RTV+FTC/TDF n=13). Demographic and baseline characteristics were balanced; overall 37% black, 28.3% white, 21.7% Asian, median age was 39 years and CD4 count was 686 cells/µl. At W24 98.7% in the B/F/TAF group vs. 99.2% in the SBR group achieved HIV-1 RNA <50 c/mL (difference -0.4% (95%CI: 3.0% to 1.9%, p=0.68). Two participants, one in each group, had resistance testing; neither developed resistance to any study drug. No participant discontinued treatment due to an AE; there were no differences between groups in grade 3 or 4 treatment-emergent AEs (3.8% B/F/TAF, 5.5% SBR group). Grade 3 or 4 laboratory abnormalities occurred in 17% of participants on B/F/TAF and 18% on SBR.

Conclusion: At W24 women who switched to B/F/TAF maintained high levels of virologic suppression with comparable efficacy to those who remained on a baseline regimen. B/F/TAF was safe and well tolerated. This analysis supports the efficacy and safety of B/F/TAF in women observed in other B/F/TAF phase 2 and 3 studies.

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Efficacy and safety of darunavir/cobicistat/emtricitabine/tenofovir alafenamide in treatment-experienced and treatment-naïve women with human immunodeficiency virus type 1

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Background: Darunavir 800 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg (D/C/F/TAF) is a once-daily single-tablet regimen for treatment of HIV-1. We report gender-based efficacy and safety findings of D/C/F/TAF from two 48-week randomized non-inferiority studies, EMERALD and AMBER.

Methods: In EMERALD, virologically-suppressed (HIV-1 ribonucleic acid [RNA] <50 copies[c]/mL) patients were randomized 2:1 to switch to D/C/F/TAF or continue current boosted protease inhibitor (bPI) + F/tenofovir disoproxil fumarate (TDF) therapy. In AMBER, treatment-naïve patients with HIV-1 RNA ≥1000 c/mL at screening were randomized 1:1 to blinded D/C/F/TAF or active control (D/C+F/TDF). The primary efficacy endpoints were proportion of patients with: cumulative virologic rebound (confirmed VL ≥50 c/mL or premature discontinuation irrespective of reason with last VL of ≥50 c/mL) through week-48 (EMERALD); and virologic response (VL<50 c/mL; FDA snapshot) at week 48 (AMBER). Safety, including bone- and renal-related, was assessed through week-48.

Results: Of the total patients randomized and treated, 205/1141 (18.0%) and 85/725 (11.7%) were women in EMERALD and AMBER, respectively.
In EMERALD, virologic rebound rates for D/C/F/TAF vs. control were- women: 3.6% vs.1.5%; 2.0 [-5.1, 7.0]; men: 2.2% vs. 2.2%; 0.0 [-2.5; 2.0], and response rates (snapshot) were- women: 93.6% vs.93.8%; -0.3 [-7.1; 9.2]; men: 95.2% vs. 93.6%; 1.6 [-1.5; 5.2]). Safety results for D/C/F/TAF vs. control were- incidence of adverse events (AEs), women: 82.1% vs. 78.5%; men: 81.9% vs. 83.1%; grade 3-4 AEs: women: 7.1% vs. 7.7%; men: 6.7% vs. 8.3%; serious AEs: women: 2.9% vs. 6.2%; men: 5.0% vs. 4.5%; and discontinuations due to AEs: women: 0.7% vs 0.0%; men: 1.6% vs. 1.6%. Most common AEs (≥5% in either arm) were headache, nasopharyngitis and bronchitis in women and upper respiratory tract infection, nasopharyngitis and diarrhea in men. Consistent with the known safety profile of TAF vs TDF, hip and spine bone mineral density (BMD) improved from baseline across genders in D/C/F/TAF group and mean eGFR remained stable across genders in the D/C/F/TAF group (women: -0.2 vs. -1.2 mL/min/1.73m2; men: -0.4 vs.-0.2 mL/min/1.73m2).
In AMBER, virologic response rates for D/C/F/TAF vs. control were- women: 88.6% vs.78.0%; 10.6 [-5.8, 28.0]; men: 91.8% vs. 89.8; 2.1 [-2.5; 6.7]. Safety results for D/C/F/TAF vs. control were- incidences of AEs, women: 90.9% vs. 85.4%; men: 85.5% vs.84.5%; grade 3-4 AEs: women: 9.1% vs. 9.8%; men: 4.7% vs. 5.6%; serious AEs: women: 6.8% vs. 9.8%; men: 4.4% vs. 5.3%; and discontinuations due to AEs: women: 4.5% vs 12.2%; men: 1.6% vs. 3.4%. Most common AEs were nausea, rash and diarrhea in women; diarrhea, headache and nasopharyngitis in men. Consistent with the known safety profile of TAF vs TDF, BMD results were more favourable with D/C/F/TAF in both genders, and mean eGFR increased from baseline across genders in the D/C/F/TAF group (women: 6.1 vs. 1.4 mL/min/1.73m2; men: 5.2 vs. 3.1 mL/min/1.73m2).

Conclusions: Treatment with D/C/F/TAF achieved high virologic response rates with the bone and renal benefits of TAF in suppressed treatment-experienced and treatment-naïve women and men with HIV-1.

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Impact of Duration of Combination Antiretroviral Therapy (cART) on Quality of Life (QofL) in Older Women Living with HIV

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Background: HIV has changed from an acute life threatening illness to a chronic, manageable disease. It is unknown whether older women living with HIV (WLWH) who had longer cART (combination antiretroviral therapy) exposure have different health outcomes compared to women with lesser cART exposure.

Objectives: To compare demographic characteristics, habits and outcomes of QofL measures in an aging female HIV cohort categorized by cART duration.

Methods: Data from OHTN Cohort Study (OCS) survey for WLWH > 50 years of age who completed the Extended Questionnaire in 2014-2015 were studied. Chi-square tests for trend and Kruskal-Wallis tests were used to compare outcomes of the EQ-5D QofL questionnaire by three categories of cART duration: < 10 years, 10-20 years, > 20 years.

Results: 112 WLWH (36, 51, 25 in low to high duration cART categories respectively) were included. The median age was 56 years and BMI was 25. The longest cART duration category had a higher percent of Caucasian (28%, 31%, 72%, p<0.0001) and university educated women (28%, 24%, 44%, p=0.18). The mid-duration cART category had higher HIV endemic (36%, 61%, 20%, p<0.0001) risk factors. Most had VL<50 (92%, 98%, 96%, p=0.36). Frequent alcohol intake and current cannabis use were lower than 20% overall. The longer the cART duration, the lower the percent of current smokers (31%, 18%, 8%, p=0.03). Overall health state (VAR scale) was 70, 75 and 70 (p=0.05) respectively, in the three groups. The outcomes of the five domains of the EQ-5D (mobility, self-care, usual activities, pain, anxiety) were not different in the three groups of older women. More than 40% of women (>80% for self-care) reported no problems, and less than 5% reported significant problems in any category, except for pain where 37% reported no pain, 54% moderate pain and 9% reported extreme pain overall.

Conclusion: WLWH who are >50 years of age report good to excellent QofL which was not different by duration of cART. The frequency of reported pain needs further evaluation.

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Efficacy and Safety of Tenofovir Alafenamide vs Tenofovir DF in HIV-Infected Virologically Suppressed Women at Week 96: Subgroup Analysis of a Randomized Switch Study (GS-US-311-1089)

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Background: Women are under-represented in antiretroviral clinical trials in spite of constituting over half of all HIV-infected individuals globally and one-quarter of people with HIV in the US. In Study-GS-311-1089, a randomized, double blind, active-controlled trial, virologically suppressed participants either remained on an emtricitabine and tenofovir disoproxil fumarate (FTC/TDF) based regimen or were switched to a fixed-dose combination of FTC and tenofovir alafenamide (FTC/TAF), while continuing their various third agent. FTC/TAF had non-inferior efficacy at Week (W) 96 (89% in both arms), plus an improved renal and bone safety profile. This gender sub-analysis describes the safety and efficacy in virologically suppressed women switching to TAF- vs remaining on TDF-based regimens.

Method: We conducted a post-hoc W96 subgroup analysis in women receiving FTC/TDF plus a third agent either switched to FTC/TAF or continued on FTC/TDF while maintaining their third agent.

Results: Of 663 participants, 102 (15%) were women (FTC/TAF n=48, FTC/TDF n=54); median age was 47 years for both arms. Over half of women (FTC/TAF, n=28; FTC/TDF, n=29) were black race vs. to 14% of men. In women, median baseline (BL) CD4 count (cells/mm3) was comparable (735 FTC/TAF vs 727 FTC/TDF) and median BL eGFR (mL/min) was 108.9 vs 102.2, respectively. Virologic success (HIV-1 RNA <50 copies/mL) by FDA Snapshot analysis was maintained in women at W48 [94% FTC/TAF vs 83% FTC/TDF; 95% CI (confidence interval): 10.6% (-2.3% to 23.4%)] and W96 [83% vs 78%, respectively; 95% CI: 5.5% (-10% to 21%)]. One woman on FTC/TAF plus DRV+RTV with reduced adherence, developed resistance (M184V) before W48; no additional participants developed resistance in either treatment arms by W96. At W96, the median changes in CD4 count were similar. A similar proportion of women experienced any adverse events (AEs) between FTC/TAF and FTC/TDF. No women had AEs leading to study drug discontinuation on FTC/TAF vs 2 women on FTC/TDF. Almost twice as many women reported overall Grade 3-4 AEs on FTC/TDF vs those who switched to FTC/TAF (11.1% vs 6.3%). Three deaths were reported, all in men. In women, median change in eGFR (mL/min) at W96 was +10.1 FTC/TAF and +5.5 FTC/TDF. Women who switched to FTC/TAF from FTC/TDF had reductions (median percentage change) in urine protein:creatinine (-7.6% vs +12.8%) and β2-microglobulin:creatinine ratios (-20.1% vs +29.2%), respectively; there were small increases in retinol-binding protein:creatinine (+3.3% vs +37.6%) and urine albumin:creatinine (+11.5% vs +5.7%) ratios in both arms, respectively, but they remained normal in most women. In women who switched to FTC/TAF vs those who continued FTC/TDF, mean percentage change from BL to W96 in spine and hip BMD were +1.4% vs -1.7% and +0.41% vs -0.44%, respectively.

Conclusion: At 96 weeks, women who switched to FTC/TAF had high levels of virologic suppression, reductions in overall tubular proteinuria, and improvements in spine and hip BMD compared to those who remained on FTC/TDF. There were less AEs in women on FTC/TAF vs FTC/TDF and no women discontinued FTC/TAF due to renal AEs. These efficacy and safety results support switching to FTC/TAF for HIV-infected virologically suppressed women among FTC/TDF-based regimens.

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High PrEP uptake among Kenyan pregnant women offered PrEP during routine antenatal care

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Background: Women in high HIV prevalence regions of sub-Saharan Africa have substantial risk of acquiring HIV during pregnancy and postpartum. The PrEP Implementation for Young Women and Adolescents (PrIYA) Project provides real-world evidence on delivering PrEP to pregnant women in Western Kenya.

Methods: We approached HIV-uninfected pregnant women seeking routine antenatal (ANC) services at 10 maternal and child health clinics in Kisumu County, Kenya from June to August 2017. Women were screened for behavioral risk factors and willingness for PrEP counseling according to national PrEP guidelines. Women who wanted to consider PrEP were counseled on PrEP and assessed for medical eligibility. Eligible women willing to initiate PrEP received oral PrEP.

Results: We screened 1,008 pregnant women for willingness to be counseled for PrEP. The median age was 23 years (interquartile range 20-28) and 57% of women were ≤24years. Overall, 347 (34%) women accepted PrEP counseling. Compared to women who declined PrEP counseling, women who accepted more frequently had a partner of unknown HIV status (81% vs 19%, p<0.001), engaged in transactional sex (3% vs 1%, p=0.02), were forced to have sex (2% vs 1%, p=0.02) and were diagnosed with STIs (6% vs 1%, p<0.001) in the last 6 months. Acceptance of PrEP counseling was similar among women ≤24 and >24 years (35% vs 33%, p=0.55). There were no differences in gestational age between women who accepted and declined PrEP counseling (median 28 [IQR 24-32] vs 28 [IQR 23-34] weeks, p=0.26). Of the 347 women counseled for PrEP, one woman (<1%) was medically ineligible, and 252 (73%) wanted to initiate PrEP and were prescribed PrEP the same day. Compared to women who did not choose to initiate PrEP, initiators more frequently had a known HIV-infected partner (9% vs 2%, p<0.001) and >1 sex partner (6% vs 1%, p=0.04). Women in polygamous marriages more frequently initiated PrEP than women in monogamous marriages (88% vs 71%, p=0.05). PrEP initiators less frequently reported any fears about starting PrEP than women who did not initiate (4% vs 59%, p<0.001). Among women who did not initiate PrEP, the most frequently reported fears were pill burden (28%) and stigma (13%).

Conclusions: It was feasible to implement PrEP during ANC in a high HIV prevalence region. A substantial proportion of pregnant women chose to initiate PrEP (25% overall, 73% of those counseled on PrEP). Pregnant women who chose to start PrEP more frequently had risk factors for HIV than those who did not.

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Outcomes of Mother-Infants Pairs Using Dolutegravir for HIV Treatment During Pregnancy

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Introduction: Dolutegravir (DTG), a second-generation HIV integrase-inhibitor is a well-tolerated and effective treatment of HIV infection. However, since it is such a recent drug, safety and efficacy during pregnancy is not well-established. We used a chart extraction to assess maternal and infant outcomes associated with DTG use during pregnancy.

Methods: We performed a retrospective cohort analysis of HIV-positive pregnant women on DTG who received prenatal and HIV care at an urban prenatal clinic in Philadelphia, between 2015 and 2017. Maternal outcomes of interest included tolerability of DTG, undetectable viral load at delivery (≤20 copies/ml), and development of drug resistance. Infant outcomes included birth defects, preterm birth (≤ 37 weeks gestation), small for gestational age (weight <10th percentile for gestational age), Apgar scores, and infant HIV status. Descriptive and trends analyses were performed to assess these outcomes.

Results: A total of 30 women were on DTG and the proportion on DTG increased exponentially each year: in 2015, 17% (2/12) of women were on DTG, versus 29% (7/24) in 2016 and 80% (21/26) in 2017 ($p<0.05$). All women tolerated DTG well during pregnancy. Among women who delivered (n=22), 77% had undetectable viral loads at delivery. In the full cohort (n=30), none of the women developed drug resistance. Infants had a mean APGAR score of 8.1 (SD 0.7) at 1 minute and 8.9 (SD 0.4) at 5 minutes; 27% were born prematurely, 20% were small for gestational age and a total of 2 infants had a birth defect.

Conclusion: An increasing number of women are using DTG in pregnancy and are having successful deliveries. DTG was well-tolerated, achieved adequate levels of suppression, without development of resistance. The few birth defects observed have to be investigated further in larger studies.

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Rapid HIV Testing on Labor and Delivery Should Not Replace Third Trimester HIV Testing

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Rapid HIV testing in labor and delivery (L&D) has a vital role in ensuring that every woman's HIV status is known prior to delivery, but is not a replacement for standard prenatal testing. First and third trimester testing provides the opportunity to treat women prior to delivery. The positive predictive value of rapid HIV testing on L&D can be as low as 43-54%, and unnecessary interventions may be implemented in cases of "false positive" rapid results while awaiting confirmation. To better understand how rapid HIV testing is being used throughout the United States, we sought to describe the nature and context of calls received by the National Perinatal HIV Hotline related to rapid HIV testing on L&D.

The National Perinatal HIV Hotline provides 24-hour clinician-to-clinician advice on HIV diagnosis and management in women and their infants before, during, and after pregnancy. Calls are entered in a centralized database with semi-structured clinical case details. We analyzed calls from November 1, 2013, to December 31, 2016, where "Positive Rapid HIV Test in L&D" was identified as a case category by the consultant. Multiple calls related to the same woman-infant dyad were counted as one case. Using narrative case details, calls were subsequently coded according to the reason for HIV testing on L&D.

The National Perinatal HIV Hotline provided 87 patient-specific consultations related to positive rapid HIV tests on L&D. In 22 cases (25%), testing was done due to lack of prenatal care. In 13 cases (15%), testing was because prenatal results were unavailable. In 21 cases (24%), testing was in addition to 1st and 3rd trimester screening. Reasons for additional testing included "it's protocol", history of false positive test(s) during pregnancy, and concern about HIV risk behavior since third trimester testing. In 21 cases (24%), testing was done because, despite engagement in prenatal care, HIV test was not done in the 3rd trimester. In at least one case without a 3rd trimester test, the patient was confirmed as having HIV and the infant was found to have HIV at birth. In 10 cases (11%), the reason for testing was not documented.

The provision of rapid HIV testing for women who present to L&D with no or inadequate prenatal HIV testing has been a critical public health intervention. Nonetheless, the ideal time to identify HIV is during pregnancy. In our sample, many tests were done despite previously negative results without ongoing risk factors, leading to potentially unnecessary interventions and treatments. At least one true positive HIV result in a patient engaged in prenatal care could have been identified with appropriate 3rd trimester screening, representing an important missed opportunity to begin treating HIV during the antenatal period in order to decrease the risk of perinatal transmission. Prenatal care settings should institute routine third trimester HIV testing per CDC guidelines and have a reliable system of communicating results to the delivering institution, saving rapid HIV testing on L&D for those with no prenatal care or at risk for HIV acquisition since the third trimester test.

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Postpartum mobility and transfer of care among HIV+ women on ART in South Africa

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Background: Women initiating antiretroviral therapy (ART) in pregnancy commonly require transfer of care postpartum. Transfer and mobility present a potential challenge to long-term retention in this vulnerable population.

Methods: Working with a routine primary care cohort, we used electronic health data (HIV-related laboratory tests, ART dispensing and clinic visits from the National Health Laboratory Services and Western Cape Department of Health) to assess HIV care access and mobility in women who initiated ART in an integrated antenatal-ART service in Cape Town, March 2013-June 2014. Transfer out of the integrated clinic was required by all women postpartum. We investigated any linkage to care after leaving the integrated clinic and calculated the number of new clinics attended up to 30m on ART. Among women who did link, we used Poisson regression to explore predictors of i) retention: accessing care at least once at both 6-18m and 18-30m on ART, and ii) viral suppression (VS): HIV viral load ≤1000 copies/ml (>12m on ART).

Results: Among 617 women, HIV care was accessed at 98 different facilities, with 11% of women moving out of Cape Town. Overall, 59% were retained; 21% never linked to care and 20% were lost after linking to a new clinic. Among 485 women who linked to care, 21% attended ≥2 (max 3) clinics. Women ≤25 years old or unemployed were more likely to attend ≥2 clinics (adjusted risk ratio [aRR] 1.10 95% confidence interval [CI] 1.02-1.18 and aRR 1.06 95% CI 0.99-1.12, respectively). Evidence of retention was found for 75% of women who linked (n=363). Those ≤25 years old or reporting unplanned pregnancies were less likely to be retained (aRR 0.87 95% CI 0.76-0.99 and aRR 0.86 95% CI 0.78-0.95, respectively). Among 338 retained women with viral load available, 87% were VS. Being >25 years old, employed or married predicted VS. Although not statistically significant, women who attended ≥2 clinics were slightly less likely to have VS (aRR 0.92 95% CI 0.82-1.03) and the distance they moved after transfer was not associated with VS.

Conclusions: Some women never linked to care after leaving the integrated clinic. Those who did spread to a large number of different facilities and a quarter were not retained in care. Younger age was a shared risk factor for non-retention, raised viral load and mobility. HIV programmes should facilitate clinic transfers when needed and targeted interventions supporting young postpartum women warrant consideration.

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A trauma and violence victimization history associate with immune barrier dysregulation in women

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Psychological challenges can promote immune dysregulation and lead to increased disease risk. In support of this, women with a lifetime trauma and victimization history (LTVH) have an increased risk of acquiring sexually transmitted infections (STI). However, we do not know the relative contributions of riskier sexual behaviors and immune dysregulation in the female reproductive tract (FRT) that may contribute to increased STI risk in women with a LTVH. We examined immune barrier composition at sites of STI exposure and LTVH by performing a characterization of critical cellular immune mediators at the apical lumen of the lower FRT.

Validated scores for LTVH events were compiled among adult STI-negative women (n=42). Participants were grouped according to the median LTVH score (high/repeated: mean 10.15, or low: mean 1.15) and immune barrier measurements were compared among groups. Epithelial and immune cells were collected using an atraumatic vaginal lavage method, enriched using density centrifugation, and characterized using flow cytometry. Statistics calculated by unpaired t test. RNA was extracted from epithelial cells and analyzed by quantitative RT-PCR, results calculated by normalizing to GAPDH and comparing as fold change.

Samples from high compared to low scoring participants presented alterations in barrier homeostasis and cell composition at the FRT lumen. Specifically, samples from high scoring participants exhibited increased detection of MHC class II+ antigen presenting cells (APC) (p=0.04), expressing increased frequencies of CCR5 (p=0.0001) and CD103 (p=0.002) phenotypes relating peripheral tissue trafficking and immune-suppressive function. Corresponding to this observation local T cell populations, which are functionally regulated by APC at the FRT barrier, expressed a reduced frequency of the tissue retention marker CD69 (CD4: p=<0.0001, CD8: p=0.002) and increased frequency of lymphoid trafficking marker CCR7 (CD4: p=0.003, CD8: p=0.01), suggestive of increased trafficking events between the vaginal barrier and circulation. Genes involved in maintaining tight junctions and epithelial barrier integrity were decreased in epithelial cells from women with high LTVH scores. RT-PCR of epithelial cells from high scoring participants exhibited relative to controls a 4.83 fold increase in SPINK7 and a decrease in ALOX12 (-5.06), OCLN (-5.17), and LCE3D (-13.23).

Repeated exposure to trauma and violence victimization was associated with alterations in barrier homeostasis and cell composition at the FRT lumen. While low scoring participant samples expressed characteristics of a healthy immune-restricted barrier, samples from high-scoring participants exhibited immune perturbations that evidence compromised immune defenses to initial pathogen encounter. These data indicate that alterations in immune mediators at the FRT may directly contribute to an increased risk of STIs among women who endure greater trauma and violence victimization.

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HIV diagnoses among women in rural vs. non-rural areas, United States, 2010-2016

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Background: Although most people who receive HIV diagnoses are MSM, women are also at risk of acquiring HIV. Women in rural areas face unique challenges to HIV diagnosis and care, including limited access and transportation to testing and treatment facilities. Although recent U.S. HIV surveillance reports point to substantial declines in HIV diagnosis rates among women (from 7.3/100,000 in 2010 to 5.4/100,000 in 2015), little is known about how demographic and clinical characteristics differ for women with diagnosed HIV by population size of area of residence.

Methods: We examined demographic and clinical characteristics from National HIV Surveillance System data for women aged ≥13 years with HIV diagnosed during 2010–2016. Assessment of trends included 2010–2015. We also used data from 38 jurisdictions with complete laboratory reporting to determine viral suppression during 2014 among women with HIV infection diagnosed by year-end 2013 and alive at year-end 2014. Analyses were stratified by three categories of population size of area of residence: rural (nonmetropolitan area. population <50,000), metropolitan (population 50,000–499,000) and metropolitan statistical areas (MSAs; population ≥500,000), based on residence at diagnosis (for analyses of diagnoses) and current residence (for analyses of viral suppression).

Results: Of 56,941 women with HIV diagnosed during 2010–2016, 2,387 (4.2%) resided in a rural area, this percentage remained stable (4.0% -4.3%) during 2010–2015. The majority of diagnoses were among black/African American women (rural: 57%, metropolitan: 56%, MSAs: 63%). However, rural women were more likely to be white than women in other areas (rural: 30%, metropolitan: 27%, MSAs: 15%). A high percentage of rural women with HIV diagnoses were located in the South (rural: 79%, metropolitan: 70%, MSA: 52%). A slightly higher percentage of rural women had Stage 3 infection (AIDS) at diagnosis (rural: 30%, metropolitan: 28%, MSAs: 25%), and a slightly smaller percentage were virally suppressed (rural: 50%, metropolitan: 54%, MSAs: 56%).

Conclusions: During our study period, most women with an HIV diagnosis resided in urban areas. Women in rural areas had slightly higher levels of late diagnosis and lower levels of viral suppression, which may result from differences in access to testing and treatment services. Efforts to improve access to testing and care, particularly in the South, may benefit from considering access issues for persons in both urban and rural settings.

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Association of HIV status with sexual function in women aged 45-60

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Background: Reproductive aging is associated with decreased sexual function, although there is a paucity of data in women living with HIV (WLWH). Using two national datasets, we explore the association of HIV status with sexual function in women aged 45-60.

Methods: Analyses of cross-sectional data from sexually-active women aged 45-60 resident in England and interviewed for the 3rd National Survey of Sexual Attitudes & Lifestyles (Natsal-3), a national probability sample survey (HIV- women, N=1699), and the PRIME Study, a convenience survey of WLWH (N=366). Self-reported sexual function was captured in both surveys using the validated (Natsal-SF measure in those sexually-active in the past year, with the highest quintile defined as having low sexual function. WLHIV were compared to HIV- women using multivariable logistic regression with adjusted odds ratios (AOR) controlled for age, ethnicity, relationship status, depression and number of chronic conditions.

Results: Median age of HIV- women and WLWH was 51 and 49 years respectively (p<.001); a greater proportion of HIV- women were postmenopausal (56.3% vs 28.3%, p<.001). Almost 90% of HIV- women were White British; 70% of WLWH were Black African (p<0.001). WLWH were more likely to report depression and other chronic conditions, and less likely to be in a relationship (all p<0.05). Amongst WLWH, 71.7% had CD4≥500 cells/mm3 and 90.3% had an undetectable HIV viral load. Relative to HIV- women, WLWH were more likely to: report ≥1 sexual problem(s) lasting ≥3 months in the past year (AOR 2.61 [1.54-4.45]; p<0.001); report almost all of the eight specific sexual problems the surveys asked about (such as lacking interest in sex, physical pain during sex, no orgasm/arousal, and vaginal dryness, all p<0.01); and have low sexual function (AOR 3.87 [2.35-6.38]; p<0.001). Low sexual function seemed more common in postmenopausal WLWH (only), although of borderline statistical significance (AOR:1.78 [0.94-3.38]; p=0.08).

Conclusions: We report an association between HIV status and low sexual function in women aged 45-60 in England. Although we cannot eliminate the possibility of residual confounding and reporting bias, this analysis highlights the burden of sexual problems among midlife WLWH. Further work is required to elucidate potential biological mechanisms underlying low sexual function in women aging with HIV, and we recommend that assessment of sexual function be integrated into routine care for this group.

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A qualitative study of trans women's experiences of living with HIV in the United Kingdom

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Background: Global epidemiological data show that HIV incidence and prevalence are high among trans women. The social, psychological, and physical aspects of living with HIV can be challenging, especially for marginalized groups such as trans women. However there remains a paucity of data from the UK on HIV risk in trans women, and no data to date on trans women's experiences of living with HIV in the UK and how they cope with HIV-related stressors. Our aim was to explore the experiences of living with HIV among trans women in the UK, focusing particularly on factors that may constrain engagement and retention in HIV care.

Methods: The research was driven by a qualitative interview design and tenets of Identity Process Theory, which is a social psychological theory of how social stressors can challenge identity and lead to specific behavioural outcomes. The study investigated the socio-psychological aspects of living with HIV among trans women and how these aspects might impinge on both behavioural and health outcomes. We interviewed seven trans women living with HIV. We analyzed the data using interpretative phenomenological analysis. This analytic approach can enable the analyst to understand how lived experience, that is, the lives and identities of patients, may shape their engagement and retention in HIV care.

Results: We identified the following themes: (1) low rates of HIV testing prior to HIV diagnosis and late diagnosis, (2) situations of vulnerability, (3) multiple layers of stigma, and (4) barriers to HIV care. Interviewees reported low levels of knowledge concerning HIV and low exposure to HIV prevention information prior to infection. They also reported feeling excluded from HIV prevention campaigns, which led to decreased awareness of risk factors and, thus, HIV testing. Complex and intersecting situations of vulnerability, such as substance misuse, poverty and gender-based violence, served both to increase HIV risk and to constrain capacity to engage with HIV care. Moreover, the majority of participants described multiple layers of rejection (or fear of rejection) from family, friends and partners, which led to low rates of HIV disclosure - both to significant others who might provide social support and to sexual partners. This often resulted in the loss of key social support mechanisms, and consequent adverse psychological and physical health outcomes including disengagement with HIV care. The data elucidate experiences of actual and anticipated stigma from healthcare professionals, and concerns around interactions between antiretroviral and hormone replacement therapies, which can also limit engagement in care.

Conclusions: Recommendations for enhancing HIV prevention for HIV-negative trans women and for improving wellbeing in trans women living with HIV are presented. Clinical and policy implications include targeted HIV testing, HIV awareness campaigns targeting trans people, the formulation of clear treatment guidelines for trans patients living with HIV, and the introduction of trans specialist services and holistic care (incorporating wellbeing issues) for trans patients.

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Rwanda's Reduction of HIV Vulnerability Among Women through Integrating Female Empowerment Strategy into National, Cross-Sector Law and Policy

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Background: Due to strong political will and continued efforts to increase availability of HIV prevention, voluntary counseling, testing, treatment and care in Rwanda, the country has led East Africa in controlling the life-threatening infectious disease and kept its prevalence stable at 3% during the last ten years. Today, 96% of these health facilities in Rwanda provide a complete package of HIV services. Yet prevalence rates disaggregated by gender show that women still remain more vulnerable than men, with 3.6% of women testing positive as opposed to 2.2% of men. A complex web of risk factors has produced this female HIV vulnerability, including gender-based violence, high-risk behaviors such as transactional sex, and STI transmission. To combat these risk factors, female empowerment intervention must occur throughout all sectors within society.

Methods: A comprehensive, qualitative desk review was conducted of Rwandan law, gender and health policy, and Demographic and Health Surveys from 2010 to 2015 and the presence of female empowerment strategy was analyzed. Cross-sector female empowerment establishments and their strategies for integrating female empowerment language and policy into practice were also analyzed.

Results: Providing a strong legal foundation and voicing the country's political will to promote and protect the rights of women and girls, the 2003 Rwandan Constitution, revised in 2015, establishes equal rights for all citizens and prohibits discrimination of any kind. A number of national bodies and institutions within Rwanda promote the engagement of women in economic and political life, including: The Ministry of Gender and Family Promotion; the National Women's Council; the National Youth Council; the National Human Rights Commission; and the Forum for Women Parliamentarians. Cross-cutting national policy, including national overarching poverty reduction policies, highlight gender equality a crosscutting area of priority. In both the National HIV Strategic Plans, gender equality has been upheld as a key priority of the national HIV response. In 2010, Rwanda adopted its first gender-based HIV strategy, the 2010-2014National Accelerated Plan for Women, Girls, Gender Equality and HIV. Most recently the 2015-2016 Rwanda National HIV Annual Report established a strong policy, legal and institutional framework to promote gender equality and address and prevent violence against women and children. Looking at Demographic and Health Survey reporting, a correlation can be seen in decreased female HIV prevalence in the years since this dedicated female empowerment integration began, with prevalence in women ages 25-29 decreasing from 4.2% in 2010 to 3.9% in 2015 and from 7.8% in 2010 to 6.1% in 2015 for middle-aged women ages 40-44.

Conclusions: Recognized internationally for its dedication to women empowerment across sectors, from governance to business to health, Rwanda is using its national, cross-sector legal and policy frameworks to diminish this gender bias and ensure that women are empowered to gain the equal access. Though advanced study is needed, there is great promise in the protective impact of legal and policy frameworks that seek to empower women, creating a ripple effect and decreasing their vulnerability to risk factors and increasing their access to HIV prevention, testing, treatment and care.

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No negative impact of prolonged interval for cervical dysplasia screening in HIV positive women

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Background: Considering the high incidence of cervical cancer in the HIV-positive women, early guidelines advised short interval PAP smear screening (e.g. 1 year) in this population. More recent guidelines state that a prolonged interval is permitted in patients with multiple normal smear results. However, the amount of evidence is limited. In this study we analyzed whether prolongation of the screening interval beyond 18 months in women with PAP 1 at baseline is safe.

Methods: This is a retrospective observational monocentric study, performed in the female HIV-postive population under follow-up at the University Medical Center Utrecht between 1989 and 2017. All women with PAP 1 at baseline and at least one follow-up PAP smear were included. After testing for normality of distribution (Shapiro-Wilk-test), the Mann-Whitney-U-test and χ2-test were used to asses significant differences. For the progression rate to cervical dysplasia a Kaplan-Meier curve and a Log Rank test were used. P-values <0.05 were considered statistically significant.

Results: A number of 122 women met the inclusion criteria. The mean age was 32 years (range 17 – 65); mean follow-up time between the first PAP smear and end of follow-up was 108 months (range 15 – 223). In 85 women (69.7%), the PAP result remained normal during the whole follow-up. In 37 patients (30.3%) cervical dysplasia (PAP≥2) was diagnosed at some point during subsequent screening. In the first three years after baseline, an annual cumulative progression rate to PAP≥2 was noted in 1.6%, 9.0% and 12.2% of the patients respectively. Three patients (2.5%) were lost to follow-up in this period. There was no significant difference in dysplasia-free time between patients with a short screening interval (≤18 months) (n=77) and those (n=45) with an interval beyond 18 months (log rank, p=0.18). In addition, there was no significant difference between the number of patients that progressed to PAP 3 in the short-interval screening [n=9 (11.6 %)] versus the prolonged-interval screening [n=5 (11.1%)] (p= 0.9).

Conclusion: In this study, the total progression rate to cervical dysplasia in HIV-infected women with PAP 1 at baseline was relatively low after three years. Short interval screening did not result in better detection of dysplasia than long-interval screening. These data suggest that long-interval screening as advised in the current guidelines is safe, although the results need to be confirmed in a larger prospective study.

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Monitoring Trends in HIV/Hepatitis B Co-infection in 3 Suburban HIV Clinics: Lagos, Nigeria

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Introduction: HBV and HIV are endemic, mainly in sub-Saharan Africa and in the Far East and share their routes of transmission, although HBV is more infectious than HIV. HIV and HBV infections share risk factors and is quite common. More than 80% of HIV-positive patients have some markers of past or current HBV infection. HBV screening is not standard practice in many HIV clinics. There is paucity of data on prevalence of HIV/HBV co-infection at the primary care level which prompted to need to monitor these trends.

Methods: Tapping into already existing structures with community mobilisation, household testing and counselling, identification and referral of HIV clients to health facilities, whilst ensuring quality service and utmost confidentiality, the participants were recruited for the World Hepatitis Day 2017 event where HIV-positive clients in treatment were offered HBV testing to estimate the prevalence in 3 suburban hospitals in Lagos, Nigeria. The study design was a prospective observational report.

Results: Data spanning across the 3 sites showed that 431 participants were screened. The cohort's average age was 34±6 years and most were on TDF/3TC/EFV. 12 (2.8%) were hepatitis B surface antigen positive. Analysis in terms of sex showed HIV/HBV co-infection significantly more in the female: 9 (2.1%) participants than in the male: 3 (0.7%) participants. The risk of hepatitis B co-infection was not significantly different when analysed in terms of viral load or age.

Conclusions: More than half (52%) of the participants showed some evidence of hepatitis B exposure. HIV/HBV co-infection is common in HIV-seropositive and can cause significant mortality and morbidity. However, efforts need to be channelled into advocacy for vaccination programs for HBV especially in non-immune HIV-infected individuals. Women health education, community ownership of these efforts as well as community programs need to be driven, owned by and embedded in the communities.

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Quantifying visit adherence in pregnant women initiating ART in Swaziland

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Introduction: Several studies have reported poor retention among HIV+ pregnant women initiating antiretroviral treatment (ART) under Option B+, particularly at the start of treatment. However, there is limited data on visit attendance patterns among women on ART. We evaluated three measures of ART visit adherence based on the expected follow-up (FU) dates under the Option B+ 'treat-all' approach and Option A, CD4/clinical- eligibility based ART.

Methods: At 12 health facilities in Swaziland, routine patient-level data of all HIV+ pregnant women not on ART making their first an tenatal care (ANC) visit was abstracted as part of an implementation science study comparing maternal retention outcomes under Options A and B+. Among patients who initiated ART and had >=2 FU visits, we performed a descriptive analysis of missed visits (>28 days after expected FU), visit constancy (>=1 visit per each 3-month period) and gaps in care (>6 months without a clinic visit) from ART initiation. Associations between these outcomes and demographic and clinical characteristics at ANC entry were examined using cox proportional hazard models.

Results: We analysed 1417 women; mean age=25.6 years (SD=5.53), median CD4=349 cells/µL (IQR=242-483), median gestation=19 weeks ((IQR=15-24), at first ANC visit; with 11,595 FU visits. Of 1417 women, 84% (n=1190) had >= 2 FU visits, 90 % (n=446) under A vs 81% (n=789) B+, with a median observation time of 14.1 months on ART (IQR=9.1-17.3). More than a half (57%, n=680) had a missed visit, 40% (n=706) did not have a clinic visit in each 3-month period since ART initiation and 29% (n=346) experienced a gap in care >6 months. Among women with a missed visit, 64% did not achieve visit constancy and 48% had >6 month gap in care. In a cox proportional hazard analysis, the risk of experiencing a missed visit was independently associated with age and gestation at ANC entry; each one-year increase in age from 15 years decreased risk by 3% (aHR=0.97; CI=0.96-0.99) and one-week increase in gestation from 4 weeks increased risk by 2% (aHR=1.02, CI=1.01-1.04). Measures of visit adherence did not significantly differ by Option B+.

Conclusion: Given that non-adherence to clinic visit schedules may increase the risk of mother-to-child transmission, this high level of non-adherence to clinic visits is concerning. Younger age groups and late presenters may require targeted retention counselling and support services.

33 *(withdrawn)*

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Early clinical events after ART initiation in pregnancy influence viral load outcomes

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Background: There is growing concern around adherence and virologic outcomes following antiretroviral therapy (ART) initiation in pregnancy. Incident clinical events after ART initiation, including side effects, new symptoms and 'minor' complaints of pregnancy, may influence short-term ART outcomes, but data are few.

Materials & Methods: Consecutive women initiating TDF+FTC+EFV in routine antenatal care in Cape Town, South Africa were followed with viral load (VL) monitoring through 12 months postpartum. Data on clinical events during the antenatal period were abstracted from routine records. For each woman, the first episode of a sign, symptom or diagnosis (including side effects, pregnancy disorders and other illnesses) was included. Poisson methods were used to assess the association between clinical events and VL at delivery and through 12 months postpartum.

Results: In 553 women enrolled (median age 28 years; median CD4 count 349 cells/µL; median pre-ART VL 4.0 log10 copies/ml; median gestation 20 weeks; 258 person-years observation; 1819 clinic visits), 48% (n=263) had at least 1 clinical event (23%, 14% and 11% had 1, 2 and >3 events, respectively). There were 512 clinical events recorded in the cohort, with peak incidence in the first 8 weeks after ART initiation. Clinical events were significantly more likely at CD4 counts <100 and 100-200 than >200 cells/µL (IRR 1.94, 95% CI 1.21–3.13; and 1.38, 95% CI 1.04–1.83, respectively). Overall, 18% of clinical events were dermatologic, 15% neurological, 14% gastrointestinal, 14% genital, and 12% upper respiratory tract. At delivery (median ART duration 120 days) 72% women had viral suppression (VS) (VL<50 copies/mL). Adjusting for age, enrolment VL, and ART duration, delivery VS was marginally less likely in women experiencing a clinical event antenatally (IRR 0.97, 95% CI 0.90–1.04). This association was amplified among women on ART ≥16 weeks at delivery (IRR 0.93, 95% CI 0.86–0.99) and women who experienced >3 clinical events before delivery (IRR 0.93, 95% CI 0.78–1.10). Only 7% of all clinical events resulted in referral to a higher level of care; this was not associated with VS at delivery. There were no associations between clinical events in pregnancy and virologic outcomes during the postpartum period.

Conclusions: Incident clinical events after ART initiation occur commonly during pregnancy and appear associated with viral suppression in the short term; these may warrant specific attention in patient counselling and support interventions.

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HIV resistance in pregnant women on zidovudine-prophylaxis or antiretroviral therapy in the Western Cape, South Africa

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Background: Prior to universal antiretroviral therapy (ART), a substantial proportion of pregnant HIV-infected women in sub-Saharan Africa received zidovudine-prophylaxis (ZDV-P) for vertical transmission prevention. How time-limited ZDV-monotherapy impacts on the prevalence of NRTI drug resistance is uncertain. We aimed to compare the prevalence of nucleoside reverse transcriptase inhibitor (NRTI) and non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance mutations at delivery in pregnant women exposed to >14 days of ZDV-P or on ART.

Methods: This was a cross-sectional analysis of pregnant HIV-infected women, enrolled in a prospective cohort study at a single peri-urban community obstetric unit in Cape Town, South Africa from 2012-2014. According to provincial guidelines at the time, maternally-indicated ART was given for CD4 count <350 cells/µl or ZDV-P if CD4 >350 cells/µl. Delivery CD4 and HIV viral load (VL) were performed and HIV drug resistance genotyping conducted on samples with a detectable VL, using a validated in-house HIV drug resistance assay and the 2009 surveillance drug resistance mutation list (SDRM).

Results: Of 136 HIV-infected pregnant women, 74 (54%) were on ART and 62 (46%) on ZDV-P, for a median [interquartile range (IQR)] of 4.5 [0.5-159.4] and 3.7 [0.4-8.0] months respectively; 67/74 (91%) on ART used first-line NNRTI-based regimens. Women on ZDV-P compared to women on ART had higher median [IQR] CD4 count (402 [275-562] cells/µl vs. 315 [203-431] cells/µl, p=0.005) and median [IQR] log10 VL (3.08 [2.22-4.08] vs. 1.30 [1.30-2.20], p<0.001). VL was <1000 copies/ml in 44% (26/59) on ZDV-P vs. 86% (59/69) on ART. Prevalence of any SDRM NRTI or NNRTI resistance mutations was not different in women on ZDV-P compared to women on ART (4/59 (7%) vs. 5/69 (7%), p=0.93). NRTI mutations occurred in 1/59 women on ZDV-P and 2/69 women on ART; 8 (6%) had >1 NNRTI resistance mutations, no different between women on ZDV-P or ART (3/59 (5%) vs. 5/69 (7%), p=0.72). Of women with resistance mutations, none on ZDV-P received prior ART in pregnancy and 1 on ART had previously received ZDV-P and single-dose nevirapine. No women with resistance mutations transmitted HIV to their infants.

Conclusion: Following ZDV-P for a median of 4.5 months, only 2% of women had NRTI resistance but 5% had NNRTI resistance in the absence of any prior NNRTI exposure. Moderate levels of pre-treatment NNRTI drug resistance in pregnant women may reduce effectiveness of first-line NNRTI-based ART regimen and NNRTI-based infant postnatal prophylaxis.

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Pharmacokinetics of total and unbound darunavir in HIV-1–infected pregnant women receiving a darunavir/cobicistat-based regimen

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Background: Physiologic changes during pregnancy may impact antiretroviral pharmacokinetics in women with HIV-1. A recent study of pregnant women using elvitegravir/cobicistat showed reduced exposure to elvitegravir during pregnancy, as well as to cobicistat, the pharmacokinetic booster that is also used with darunavir. The current phase 3b, open-label study in HIV 1–infected women evaluated the impact of pregnancy on the pharmacokinetics of darunavir/cobicistat.

Methods: Pregnant women living with HIV-1 (18-26 weeks gestation) receiving once-daily darunavir/cobicistat 800/150mg and 2 N(t)RTIs at screening were enrolled. The plasma pharmacokinetics of darunavir (total and unbound [pharmacodynamically active]) and cobicistat were assessed over 24 hours using blood samples obtained at clinic visits during the second and third trimesters (24-28 and 34-38 weeks gestation, respectively) and 6-12 weeks postpartum. Cord blood and maternal plasma samples were taken at the intrapartum visit. Pharmacokinetic parameters (area under the plasma concentration-time curve over 24 hours [AUC24h], maximum [Cmax] and minimum [Cmin] plasma concentrations) for darunavir and cobicistat were derived using noncompartmental analysis and compared using linear mixed effects modeling (pregnancy vs postpartum; WinNonlin). Virologic response (HIV-1 RNA <50 copies/mL), immunologic response, and safety were evaluated at various time points throughout the study.

Results: Of 7 women enrolled, 1 discontinued after the second trimester visit (noncompliance) and 6 completed the study; 7, 6, and 6 women had evaluable pharmacokinetic results for the second trimester, third trimester, and postpartum visits, respectively. Total darunavir exposure was lower during pregnancy than postpartum (50%-56% [AUC24h], 37% 49% [Cmax], 89%-92% [Cmin] lower during second and third trimesters vs postpartum). Unbound darunavir exposure was lower during pregnancy than postpartum (40%-45% [AUC24h], 23%-41% [Cmax], 88% 92% [Cmin] lower). Cobicistat exposure was lower during pregnancy than postpartum (49% 63% [AUC24h], 27%-50% [Cmax], 83% [Cmin] lower). The median cord/maternal plasma ratio was 16.1% (range: 12.3%-31.5%; n=5) and 32.4% (range: 29.1%-62.6%; n=4) for total and unbound darunavir, respectively; a ratio for cobicistat was evaluable for 2 women (10%, 7.7%). Virologic suppression (HIV-1 RNA <50 copies/mL) was maintained in 83.3% (5/6) of women at study completion. There was 1 virologic failure (HIV-1 RNA ≥1,000 copies/mL at visits from the third trimester until the 4-week follow-up; no emerging resistance-associated mutations were observed; woman was noncompliant). Mean CD4+ count increased over time. No HIV-1 was detected at 16 weeks postpartum among the 6 infants born to the 6 women who completed the study. There were no maternal adverse events (AEs) considered possibly related to study drug or leading to study drug discontinuation. Overall, 4 of 6 infants born to women who completed the study experienced ≥1 AEs; serious AEs (SAEs) were reported for 2 infants (omphalitis and transient tachypnea). All infant AEs and SAEs were grade 1 or 2.

Conclusions: Darunavir/cobicistat exposures were substantially lower during pregnancy than postpartum and may require more frequent monitoring. Darunavir/cobicistat was generally well tolerated. Treatment was effective in preventing MTCT and suppressing HIV-1 infection in pregnant women. Based on individualized risk/benefit assessment and/or with viral load monitoring, darunavir/cobicistat may be an appropriate option during pregnancy for HIV-1–infected women.

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Reproductive tract infection risk-based screening for IUD insertion in HIV+ women

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Introduction: Intrauterine devices (IUDs) are safe and effective contraception but IUD use in HIV+ women is limited by concerns about reproductive tract infections (RTI) and possible ascending infection. As RTI testing is a challenge in resource-limited settings, we assessed the performance of an existing screening tool intended to determine RTI risk and guide IUD insertion.

Method: The tool scoring was based on (i) age under 25 years, (ii) cohabitation with partner, (iii) secondary education, (iv) bleeding between periods and (v) the number of sex partners without condom use (minimum score 0, maximum score 5). Women's risk was categorized as low (score=0), moderate (score=1-2) and high (score>=3). In a clinical trial of IUD use among HIV+ women in Cape Town, South Africa (NCT01721798), a nurse administered the screening tool prior to RTI testing for Neisseria gonorrhoea (NG) and Chlamydia trachomatis (CT) via GeneXpert® nucleic acid amplification testing; Trichomonas vaginalis (TV) and bacterial vaginosis (BV) via OSOM® BV Blue and Trichomonas for genital tract specimens; and Treponema pallidum (TP) with Alere® Determine Syphilis rapid diagnostic tests for whole blood. The sensitivity, specificity, and likelihood ratio of both positive and negative results for any RTI, as well as for NG/CT/TV and for NG/CT were calculated. We also explored categorizing the score as 0 vs 1-5, 0-1 vs. 2-5 and 0-2 vs. 3-5.

Results: Of 302 women included, 47% (n=144) were antiretroviral treatment (ART) naïve and the mean age was 31.2 years (range, 18-41). The overall prevalence of any RTI was 37% (NG=8%, CT=10%, TV=11%, BV=16% and TP=2%; 7% of women with multiple infections). RTI prevalence was higher for ART-naïve women compared to women using ART (Table 1). Overall, 4%, 27% and 69% of women had screening tool scores of 0, 1 or 2+, respectively; mean scores did not differ by RTI (infected=1.97 vs uninfected=1.93, p=0.727) but were significantly higher in ART-naïve women vs those on ART (2.17 vs 1.7, p<0.001). At the recommended threshold of 1+, the tool demonstrated high sensitivities (95%-97%) but very low specificities (3%-4%): at a threshold of 2+ and 3+, the tool demonstrated high negative predictive values (60%-89%). The performance of the tool did not differ by ART use or specific type of RTI.

Conclusion: This risk screening tool provided little value in distinguishing women with RTI. Given the high prevalence of RTI in HIV+ women in this setting, there is an urgent need for low-cost diagnostic testing technologies.

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Contraception among women initiating ARV therapy in the ANRS 12313-NAMSAL trial.

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Background: Women of child-bearing age account for more than half of the world's HIV cases. Clinical trials involving antiretroviral drugs demand the use of a reliable form of contraception for these women in order to minimize the risk of exposure of the foetus to trial drugs particularly in a context with limited data suggesting drug safety during pregnancy. Understanding factors that influence contraceptive choice and the side effects of different methods in this population are essential for better oriented counselling on reproductive health choices for HIV positive women.

Methods: The NAMSAL trial is a phase III randomized controlled trial implemented in Yaoundé, Cameroon recruiting ARV naïve adults and initiating them on one of two treatment regimens (DTG+TDF/3TC OR EFV400+TDF/3TC). A gynecological visit for contraception proposal and administration is proposed to all non-menopausal women in the trial after inclusion. We analyze and describe contraceptive preferences and choices in women initiating antiretroviral therapy, compare discontinuation rates and pregnancy incidence per contraceptive type.

Results: In all, 166 non-menopausal women were proposed contraceptives. Median age was 32 years. Contraception acceptance rate was 81.3%. Levonorgestrel subdermal implant (68) and Medroxyprogesterone acetate injectables (Depoprovera) (60) were preferred over Intra Uterine Device (IUD) (2). Pregnancy incidence was 1.5 per 100 women-year recorded in one participant on subdermal implant and the other on injectables. Metrorrhagia was the most common side effect with the majority observed in women with the subdermal implant (80%). Amenorrhea was reported in 13.3% of women receiving injectables. Discontinuation rates due to side effects were higher amongst women on subdermal implant (11.8%); 2 of whom switched to injectables and 1 to IUD. We further analysed a sub population of 90 women who provided data on abortion history. Amongst the 74 women with history of pregnancy, we registered 82 abortions (49 induced and 33 spontaneous) ranging between 1-4 abortions in their lifetime.

Conclusion: Although these findings are preliminary, the high acceptance rate of contraception highlights possible far-reaching benefits of systematic proposal and administration of contraception for women initiating antiretroviral therapy. Systematic proposal of contraception integrated in HIV care can foster uptake, with a positive impact on prevention of vertical transmission and possibly on risky abortion practices quite frequent in this population.

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Relationship Power Imbalance and History of Male Partner Testing for HIV Among Pregnant Women in Central Uganda

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In some societies, a power dynamic is shifted towards greater power and resources given to males over females, and this imbalance can have a negative impact on health, including HIV prevention. This is especially concerning within the context of pregnant couples, where the knowledge of the HIV status of both partners is imperative to prevent mother to child transmission of HIV. We investigated the association between relationship power imbalance and male partner testing for HIV among pregnant women attending antenatal care (ANC) in central Uganda. This analysis uses baseline data from a cluster-randomized HIV self-testing intervention trial in three antenatal clinics in central Uganda. Pregnant women with HIV- male partners were recruited and randomized by day into standard of care or intervention (HIV self-testing kits). Screening and baseline interviews were conducted using REDCap software on electronic tablets. Women were asked about demographics, history of partner testing, characteristics of their relationship, and other factors. Analyses were performed in SAS 9.4, with chi-square tests and $p<0.05$ for significance. 1,514 women were recruited across the three sites between July and November of 2016 (737 in the standard of care arm, 777 in the intervention arm). Overall, the male involvement in pregnancies was very low (only 18.2% of the women's partners had ever accompanied them to their ANC visits. Furthermore, the overall testing for HIV among male partners was also low (only 39.6% of male partners had previously tested for HIV). Among women under 26 years old, contributions to expenses differed by partner testing (overall $p<0.001$), with 47.6% of women whose partners tested made no contribution vs. 63.2% of women whose partners did not test). Relationship status also differed by partner testing (overall $p=0.02$), but 12.4% of women whose partners tested showed a sometimes difficult relationship vs. 5.7% of women whose partners did not test. Among women 26+, decision making for family visits differed by partner testing (overall $p=0.005$), with 52.9% of women made joint decisions with partners who tested vs. 36.5% whose partners did not test. A higher relationship power balance was significantly associated with higher HIV testing among male partners when measured by contribution to expenses and decision making for family visits, but was associated with lower HIV testing as measured by relationship status. Relationship power balance should be considered when counseling women and men to increase HIV testing.

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Estimating HIV Incidence during Pregnancy and Knowledge of Prevention of Mother-to-Child Transmission with an Ad Hoc Analysis of Potential Cofactors

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Background: There is a high rate of MTCT of HIV with seroconversion in pregnancy. Despite this, HIV testing during labour has remained a challenge over the years in Cameroon. In the South West Region, there are no reports regarding the incidence of HIV seroconversion during pregnancy.There is a probability that many cases that seroconvert in pregnancy go without appropriate management, resulting in high rates of MTCT.
The aim of this study was to determine the incidence of HIV seroconversion during the second and third trimesters of pregnancy and ad hoc potential cofactors associated with HIV seroconversion after having an HIV-negative test result in the booking visit.

Methods: This was a hospital based retrospective cohort study of women attending antenatal care (ANC) clinics and labour rooms of the maternity units of seven healthcare facilities in the SouthWest Region, Cameroon, Study participants were pregnant women in their 2nd and 3rd trimesters with a previous negative HIV test at the booking visits obtained from the hospital records. These women were retested for HIV three months after the 1st test. They also filled a questionnaire on their knowledge on HIV and PMTCT as well as questions on their sexual life.
Data collection was done during a period of 12 weeks. HIV seroconversion in pregnancy (HSP) was defined as a woman with a positive HIV 2nd test.
Data analysis was done using Epi info 3.4.5 and Microsoft Excel 2010. Numerical variables like age, parity, and gestational age were classified into groups and their frequencies expressed in percentages. Meanwhile, categorical variables like marital status, educational level, and occupation were expressed as frequencies.
Univariable analysis was done using logistic regression to identify the potential factors associated with seroconversion in pregnancy, and then those with a *P* value less than 0.2 were included in the final model for multivariable logistic regression. *P* values that were considered statistically significant if *P* was less than 0.05.

Results: A total of 477 (27.2%) were enrolled into the study. The incidence of participants who seroconverted was 2.1% (147.25 woman-years), giving an incidence rate of HIV seroconversion during pregnancy of 6.8 per 100 woman-years.
Among the 10 participants who seroconverted in pregnancy, 8 knew about MTCT and PMTCT of HIV including when transmission could occur. All the eight participants also knew it was possible to prevent MTCT (*P* = 0.07). No statistically significant relationship was found between sociodemographic factors and HIV seroconversion in pregnancy.

All the participants who seroconverted were having sexual intercourse during the current pregnancy (*P* =0.37) and 9 (90%) were not users of the condom.
In the multivariate analysis, the odds of HIV seroconversion during pregnancy were 5 times higher among pregnant women who did not know about PMTCT (aOR 5.4; 95%CI 1.06–27.56).

Conclusion: The incidence of HIV seroconversion among pregnant women in the study was 2.1%. The study was underpowered to study associated risk factors for seroconversion. Testing partners of pregnant women and repeat HIV testing during pregnancy could be a major PMTCT strategy in our setting.

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High efficacy contraceptive method use among HIV-positive women in a US urban outpatient clinic

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Introduction: While efficacious contraceptive method use is important for HIV-positive women to meet their fertility goals, prevent unintended pregnancy, and reduce the risk of vertical transmission of HIV, more effective method use is low and understudied among this population.

Methods: Women were recruited from an outpatient HIV care clinic in Atlanta, Georgia between July 2013-November 2014. This cross-sectional analysis evaluated associations between women's demographics; reproductive health knowledge, attitudes, and practices; and clinical characteristics and contraceptive method choice using multivariate logistic regression models. Contraceptive choice was categorized as more effective (Tier 1/2) versus less effective (Tier 3/None) methods, using the United States Medical Eligibility Criteria for contraception use.

Results: In this study of HIV-positive and predominantly African-American women, use of Tier 1/2 efficacy contraceptive methods was relatively uncommon (31%) and was significantly associated with ($p < .05$) with younger age, non-committed relationship status, desire for future pregnancy, longer duration of ART use, and higher most recent CD4 count. A trend was observed for being under 19 at age of diagnosis and being HIV positive during a previous pregnancy. Knowledge of highly effective methods was poor (53% and 31% of women reported having heard of the intrauterine device and implant, respectively), and misconceptions about contraception were common.

Conclusion: Overall knowledge of highly effective methods was low, and older age, poorer clinical HIV status, and beliefs about contraception were associated with choice of less effective methods. Our findings call for improved contraceptive counseling for HIV-positive women so that women can make informed decisions. It may be especially important to tailor and target counseling to women with poorer clinical management of HIV, who may be at increased risk of vertical transmission.

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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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Knowledge of Mother to Child Transmission of HIV and HIV testing during Antenatal Care among Nigerian women

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Background: Prevention of Mother-To-Child Transmission of HIV (PMTCT) is a key step towards the elimination of the global pediatric HIV epidemic. Nigeria is a country with high burden of HIV/AIDS and mother-to-child transmission (MTCT) of HIV. This high burden of MTCT in Nigeria is majorly due to high prevalence of HIV, low PMTCT coverage and prolonged breastfeeding culture. This study was designed to examine the trend and determinants of the knowledge of transmission of HIV infection as it relates to transmission during pregnancy, delivery and breastfeeding periods among Nigerian women. This study also evaluated the level and determinant of HIV testing during Antenatal care (ANC).

Methods: This study was secondary data analyses of the cross-sectional population-based Demographic Health Surveys (DHS) of 2003 and 2013. The participating women were aged between 15-49 years. The data used for this study were obtained from an existing DHS database. All the identifier information were also removed, thereby the data cannot be traced to a particular individual.

Results: The percentage of women who knew that HIV infection could be transmitted via pregnancy, during delivery and via breastfeeding was 98%, 91%, and 92% respectively in 2003 while the same variables were 67%, 70%, and 81% respectively in 2013. The 2013 survey identified respondents who were formally educated as those who were more likely to have the knowledge of transmission of HIV from mothers to their unborn babies during pregnancy; Primary school leavers (OR: 2.1) and secondary/tertiary school graduates (OR: 2.5) when compared to the uneducated women. The findings also showed that the wealthier an individual and exposure to multiple media outlets (OR: 2.8), the more likely she has knowledge about MTCT during pregnancy. Living in urban area (OR: 1.5), living in any of the three Southern regions, those within the age range of 25 – 34 (OR: 1.2) and being employed were determining factors for knowledge of MTCT during pregnancy. These findings follow the same pattern with respect to the determinants for knowledge of MTCT during delivery and breastfeeding periods among this same set of women.
Among the 2013 DHS respondents, only 52% pregnant women were tested for HIV as part of ANC visit. The main determinant for getting tested during ANC was being highly educated (OR: 15.5). Other factors were residence in the urban area and within the age group 35- 49 years.

Conclusion: This study shows that the level of knowledge of MTCT decreased among the newer generation of reproductive age group women in Nigeria. Likewise, the level of women who were tested for HIV was not optimal. It is recommended that innovative public health interventions should be targeted at the groups that are disadvantaged such as rural dweller, those in the Northern regions, unemployed and uneducated. The use of multimedia platforms will also go a long way to increase the knowledge of MTCT and provision of HIV testing services during ANC.

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Mexican experience in the care of HIV-positive pregnant women

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Background: The majority of women HIV infected in Mexico are on reproductive age, a significant proportion of them have a daily sexual activity, often without a safe method of contraception, pregnancy being an expected consequence. We propose as a hypothesis that pregnant women HIV-positive have a high perinatal morbidity, with the additional risk of vertical transmission.

Materials & Methods: A retrospective cohort study was carried out, at the Nacional Institute of Perinatology (INPer), Mexico City, which included 458 pregnant women with HIV/AIDS, that were attended in this Institution during the period from January 2007 to September 2017. The INPer is a government funded, third level healthcare facility that attends low-income patients with high-risk pregnancies, from Mexico City and its suburban areas.
Descriptive statistics was used to characterize the population. A bivariate analysis was performed to identify significant variables associated with an adverse perinatal result, with their relative risk with 95% CI. Finally, confounding variables were controlled by a multivariate analysis using a logistic regression model.

Results: The mean of age of the patients was 26.83 ± 5.8 years, with a beginning of their sexual life at 19.1 ± 7.1 years. The median of sexual partners was 3 (range 1 – 9). The 65.9% had a stable marital status. Only 41 (9%) patients used illegal drugs, mainly marijuana and solvents.
All patients, except six (1.3%), received antiretroviral treatment during their pregnancy, of these, 297 (65%) received treatment since before their pregnancy. Fifty-four (11.7%) were diagnosed through the HIV screening program during pregnancy. In relation to HIV infection, 430 (94%) pregnant women were asymptomatic, 398 (87%) with undetectable viral load and CD4 count greater than 250 cells. The majority received the antiretroviral regimen of zidovudine, lamivudine and lopinavir/ritonavir, followed by the emtricitabine, tenofovir and protease inhibitor scheme. There were three (0.65%) neonatal deaths, two (0.43%) maternal deaths and two (0.43%) cases of congenital infection.
The logistic regression showed that the variables associated with an adverse fetal outcome were the maternal use of drugs (RR 2.54, 95% CI 1.09-5.88, p = 0.03), and the concomitant presence of sexually transmitted infections (RR 3.51, 95% CI 1.93 – 6.36, p = 0.001). The history of a stable partner (RR 0.53, 95% CI 0.29-0.94, p = 0.03) was identified as a protective factor. Concomitant sexually transmitted infections were identified as a variable associated with the presence of premature birth (RR 6.63, 95% CI 3.30-16.55, p = 0.001); while the principal protective factor against this complication was the CD4 value greater than 350 cells (RR 0.27, 95% CI 0.18-0.77, p = 0.01).

Conclusions: The maternal consumption of drugs and the presence of sexually transmitted infections increase the likelihood that HIV positive pregnant women have an adverse perinatal outcome, associated with preterm delivery or the birth of a small fetus for gestational age. Conversely, having a stable marital partner or having CD4 levels greater than 350 can improve perinatal outcomes.

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Healthcare provider trust linked to long-term HIV viral suppression

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Background: Trust in the healthcare system (HS) and health providers (HP) is linked to medication adherence; however, many studies do not link to biological data. We hypothesize that trust differs by HIV status and is associated with longitudinal patterns of viremia.

Methods: A 2006 cross-sectional survey assessed the Healthcare System Distrust Scale (HSDS, 0=trust; 50=distrust), an adapted Patient-Physician Trust Scale (PPTS, 0=distrust; 25=trust), HIV medication distrust and demographics in 1049 HIV+ and 463 high-risk HIV-negative women from the Women's Interagency HIV Study (WIHS). This study identified HIV viral load trajectories in 2440 HIV+ women who contributed ≥ 4 semi-annual visits from 1994-2015. Viral suppression was defined by assay detection limits (<80 to <20 copies/mL). Group-based probability trajectory analyses grouped women based on longitudinal viral load patterns, and identified 3 groups: sustained viremia (SV; n=1,010), intermittent viremia (IV; n=719), and non-viremia (NV; n=711). Ordinal logistic regression models assessed trajectory group and HP/HS trust, controlling for demographics.

Results: Most women were African American (60%), currently insured (89%) non-smokers (56%). HIV+ women were more trusting of HS (HSDS 12.6 vs. 13.8, p=0.02) and HP (PPTS 20.6 vs. 18.8, p<0.0001) compared to HIV- women. HIV+ women with NV had higher HP trust compared to SV women (PPTS: SV 19.9, IV 20.6, NV 21.4, p<0.0001); there was no difference in HS trust between viral trajectory groups. Compared to NV women, SV women were less likely to agree that HIV medicines help people live longer (86% vs. 94%, p<0.0002) or that HIV medicines prevent hospitalizations (73% vs. 87%, p<0.0001). Only 52% of SV women believed HIV medicines work as well for African American/Latina women compared to white women (IV 61%, NV 66%, p=0.0005). In ordinal logistic regression, groups with higher viremia were associated with HP distrust (OR 1.49; 95% CI 1.12, 1.98), HS distrust (OR 1.49; 95% CI 1.12, 1.98), African American race (OR 1.70; 95% CI 1.1.29, 2.24), current smoking (OR 2.42; 95% CI 1.84, 3.19), and current unemployment (OR 1.62; 95% CI 1.23, 2.14).

Discussion: HIV+ women express high levels of HS and HP trust. HIV-negative women's low trust in HS, HP, and HIV medicines may have implications for PrEP use. Trust in HPs and HIV medicines is less common among SV women. Successful long-term HIV management depends on HP and HS trust; current data is needed on healthcare perceptions linked to HIV biological data.

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Dipsticks proteinuria to predict renal dysfunction in HIV-infected pregnant women

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Background: The Zambian national HIV guidelines recommend urinalysis to detect proteinuria as a baseline screening test for renal insufficiency among HIV-infected pregnant women initiating tenofovir-based first-line antiretroviral therapy (ART). To date, few data are available to evaluate the sensitivity of urine dipsticks for renal dysfunction.

Methods: We compared urine dipsticks proteinuria with eGFR among HIV-infected pregnant women starting ART in antenatal care settings in urban Zambia. Analyzing data from a prospective cohort in 3 Lusaka sites, we estimated glomerular filtration rate (eGFR) using the MDRD equation and used the lowest 10th percentile as a proxy for renal dysfunction. We determined the sensitivity and specificity of 2+ proteinuria and 1+ proteinuria for eGFR in the lowest 10th percentile.

Results: From March to August 2017, 215 HIV-infected pregnant women were enrolled and had data for urine dipstick protein and serum creatinine. Median values for age was 27 years (IQR: 24-33), gestational age was 18 weeks (IQR: 15-22), CD4 count was 305 cells/µL (IQR: 191-418), and haemoglobin was 11.0 g/dL (IQR: 10.1-11.8). Elevated blood pressure (i.e., 140/90mmHg) was noted in 12 women (5.6%). Urine dipstick protein 1+ was seen in 16 women (7.4%) and only 5 women (2.3%) had 2+ proteinuria. Having 2+ proteinuria had 0% sensitivity (97.5%CI: 0.0, 16.1) and 97.4% specificty (95%CI: 94.1, 99.2) for detection of reduced eGFR, while having 1+ proteinuria had 9.5% sensitivity (95%CI:11.7, 30.4) and 92.8% specificity (95%CI: 88.2, 96.0).

Conclusions: In contrast to non-pregnant HIV infected adults in similar settings, we found that impaired renal function was rare among HIV+ pregnant Zambian women, and urine dipsticks proteinuria had <10% sensitivity for detecting reduced eGFR making it inappropriate as a screening test for reduced eGFR. This data is the first in our setting to describe renal function in HIV infected pregnant women and has potential to inform guidelines on renal monitoring in women prescribed tenofovir.

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PK, safety, & efficacy of bictegravir/F/TAF single-tablet regimen in HIV-infected female adolescents

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Background: Bictegravir (BIC), a novel, unboosted integrase strand transfer inhibitor (INSTI) with high genetic barrier to resistance, has been coformulated with emtricitabine and tenofovir alafenamide (BIC/FTC/TAF; B/F/TAF) into a once-daily, single-tablet regimen (STR). B/F/TAF (50/200/25 mg) has demonstrated high rates of virologic success with no resistance and was well tolerated in treatment-naïve HIV-infected adults through 48 weeks. Recent data from adolescents treated with B/F/TAF through 24 weeks show similar results to adults. Although approximately half of <18 year-olds living with HIV are females, there are few reports of antiretroviral responses in female adolescents. We now report pharmacokinetics (PK), safety and efficacy data from the first B/F/TAF subgroup analysis in HIV-infected female adolescents.

Materials & Methods: We conducted a post-hoc analysis of female participants enrolled in a prospective, 48-week (W), single-arm, open-label trial of virologically suppressed, HIV-infected adolescents (12 to <18 yrs, ≥35 kg) who received B/F/TAF once daily. Viral suppression (HIV-1 RNA <50 copies/mL) at W24 was determined by FDA snapshot analysis. We assessed adverse events (AEs) and laboratory tests through W24 and acceptability/palatability on day 1 and at W4. Steady-state PK was assessed at week 2 or 4 and compared with PK in adults treated with B/F/TAF.

Results: 24 adolescents from South Africa, Thailand, and the US enrolled, 19 of whom were female. At baseline, median age in the female subset was 15 yrs (range 12-17 yrs), median weight 44.7 kg (range 36.1-88.6 kg), 56% Black, median CD4 count 808 cells/µL, 84% vertically infected. All (100%) had HIV-1 RNA <50 copies/mL at W24; none met criteria for resistance testing. Through a median (Q1, Q3) duration of exposure to study drug of 25.6 (24.7, 27.4) weeks, the most common treatment emergent AE was upper respiratory tract infection (21%, 4 of 19); no other AE occurred in >2 participants. No participant discontinued for an AE. One serious AE was reported (abdominal pain); 1 AE was considered study-drug related (vomiting). Four individuals had grade 3 hematuria due to menses; no other grade 3 or 4 laboratory abnormalities were reported. All participants reported the B/F/TAF tablet size and shape to be acceptable with normal taste, and mean (SD) adherence to study drug was high (97.6% [6.96]). No clinically relevant differences in exposures of BIC, FTC and TAF in female adolescents were observed compared with adults.

Conclusions: The B/F/TAF STR maintained virologic suppression in all female adolescent participants enrolled and was well tolerated through 24 weeks. Similar to adults treated with B/F/TAF, therapeutic plasma concentrations of all components of B/F/TAF were achieved. Efficacy and safety in female adolescents are consistent with that of phase 3 B/F/TAF results in adults, which showed high proportions with viral suppression and no resistance. These data provide a rare sex-specific analysis in a geographically diverse adolescent female cohort given B/F/TAF. This may be an important unboosted INSTI, STR option for HIV-infected female adolescents due to its high barrier to resistance, small tablet size, lack of food requirement, and low potential for drug-drug interactions.

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Awareness of HIV status and factors associated with prior HIV testing among young women in Kumba, Southwest region, Cameroon

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Background: Although young girls and women in Cameroon are vulnerable to HIV/AIDS, their HIV testing practices have not been adequately described. The objective of this study was to investigate HIV status awareness and factors associated with prior HIV testing among young women in Kumba, Southwest region of Cameroon.

Methods: We used data from a population-based survey conducted among young adults aged 21-35 years in the town of Kumba located in the Southwest region of Cameroon. Analyses were restricted to 321 women with complete data on the variables of interest. Awareness of HIV status was defined as having tested for HIV within the past 12 months and receipt of test results. Data were weighted and logistic regression analysis performed to identify the factors associated with prior HIV testing. The level of statistical significance was set at $p<0.05$.

Results: The median age of the 321 women included in the analysis was 25 years (IQR; 23-28). An estimated 80.6% (259/321) of respondents had ever tested for HIV. Of these, 37.4% (97/256) were tested within the past 12 months of the study and 93.8% (91/97) of those tested received their HIV test results. We did not find any significant association between the explanatory variables and awareness of HIV status. In multivariate regression analysis, respondents who were employed (AOR=2.54; 95% CI, 1.09-5.89) and who knew the HIV status of their current sexual partner (AOR=3.85; 95% CI, 2.03-7.31) were significantly more likely to have previously tested for HIV. Respondents who had negative feelings about HIV/AIDS (AOR=0.28; 95% CI, 0.12-0.67) were significantly less likely to have previously tested for HIV.

Conclusion: A significant proportion of young women studied were aware of their HIV status. Nevertheless, strategies to increase and encourage HIV testing among young women should be reinforced at community level.

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Risky sexual behaviour and condom use among the young people in sub Saharan Africa

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Background: Young people are unique and often neglected group in the HIV epidemic intervention. Females aged 15–24 years old often engaged in risky sexual behaviour and are also innately vulnerable biologically and psychosocially. Young people are at higher risk of coercive sex, sexual abuse, have challenges navigating complex decision making processes and are less likely to seek counsel before indulging in any of the risky sexual acts. This study therefore evaluated determinants of risky sexual behaviour and condom usage among late adolescents and young adults aged 15-24 years old in selected Lower and Middle Income Countries (LMICs).

Methods: This research used data from LMICs Demographic and Health Surveys (DHS) conducted between 2010 and 2016. The study evaluated association between different independent variables (age group, educational status, residence, wealth index and marital status and the dependent variables (condom used during last sex with most recent partner and reduce risk of getting HIV: always use condoms during sex condom use during last sexual intercourse) using bivariate logistic regression analysis.

Results: A total of 299,463 participants took part in the study. About three-fifths were sexually active and attained sexual debut before the age of 19 years. Only 16.0% of the female participants used condom during last sexual intercourse with most recent partners. Namibia recorded the highest percent of recent condom usage with 56.2%, while the least usage was in Timor-Leste- 0.1%. The findings showed 69.6% of the respondents always use condoms during sexual intercourse. Rwanda recorded the highest percent of young people who always use condom during sexual intercourse with 91.2%, while the least usage was in Egypt with 69.6% respectively.
Using bivariate analysis, the older respondents (OR =1.09) and educated up to secondary school level (OR =1.27) were more likely to use condom on regular basis. However, rural dwellers were less likely to use condom regularly compared to the urban residents (OR =0.88). There was a trend towards always using condom during sex with increasing wealth index. With respect to the usage of condom during last sex with most recent partner, 20-24 years old respondents were less likely to use condom (OR =0.68) while those who were educated up to primary school level (OR =3.77) and secondary school (OR= 9.56), the richer respondents were more likely to use condom with recent partner during sex.

Conclusions: This study revealed a substantial diversity of condom usage either during regular or with most recent sexual intercourse across various countries. The study confirmed the high prevalence of risky sexual behaviour as shown by various indices such as early sexual debut, low percentage of condom use, multiple sex partners and other findings. This study offers various noteworthy public health policy inferences which could change the status quo for a better outcome. Tackling high prevalence of risky sexual behaviours requires combination of evidence based approaches, targeted service delivery for young people, addressing issues of those at high risk of exposure and use of social and behavioural change models.

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Strengthening the PMTCT of Viruses Programme in Cameroon: Seroprevalence and HIV-1 Drug Resistance in Women in Yaounde

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Background: Mother-to-Child Transmission (MTCT) of HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) constitute a major public health risk to newborns. Inadequate knowledge of the Cameroonian population about their transmission and prevention modes further increases this risk. With the scaling-up of Prevention of Mother-to-Child Transmission (PMTCT) HIV Programme, pregnant women are encouraged during antenatal care (ANC) clinics to get tested for HIV but less so for HBV and HCV. HIV-positive women follow the PMTCT Option B+ Initiative to take antiretroviral therapy (ART). The risk of these women carrying resistant HIV-1 to ART is eminent and therefore the risk of transmitting resistant virus to the baby. We carried out a study to assess the seroprevalence of HIV-1, HBV and HCV, as well as assess the knowledge of the modes of transmission and prevention of HBV, determine HBV vaccination coverage and HIV-1 drug resistance (HIV-DR) level.

Materials & Methods: A cross-sectional analytical study was conducted on two groups of women from September 2011 to April 2014 in three tertiary hospitals in Yaounde, Cameroon, following ethics approval and informed consent obtained from all the subjects. Group 1 constituted of 923 pregnant women with no history of ART exposure, while Group 2 constituted of 50 women on ART (Zidovudine, lamivudine and nevirapine) seen at 6 weeks postpartum. In Group 1, knowledge of HBV modes of transmission and prevention, and HBV vaccination coverage were evaluated using questionnaires, and the seroprevalence of HIV-1, HBV and HCV were determined by serology. In Group 2, HIV drug resistance- associated mutations (RAMs) were identified in the protease and reverse transcriptase genes by nested polymerase chain reaction (PCR) and sequencing. HIV-DR prediction was obtained using the Stanford University Drug Resistance Tool and the International AIDS Society (IAS) Algorithm.

Results: In Group 1, the mean age was 27.49 ± 5.18 years; seroprevalence of HIV, HBV and HCV were 8.67% (80/923), 7.37% (68/923) and 0.98% (9/923), respectively, while HIV/HBV and HIV/HCV co-infections were 0.76% (7/923) and 0.11% (1/923), respectively. Only 47% were aware of the vertical and sexual routes as modes of transmission of HBV. Eighty-three percent were aware about vaccination being a prevention method for HBV infection but only 2% were vaccinated. In Group 2, the mean age was 30±4 years. Eighty percent (40/50) showed virologic failure (viral load ≥1000 copies/ml). The most predominant HIV-1 genotype was CRF02_AG (50%), followed by D (6%). The overall prevalence of RAMs was 22.50% (9/40). Nucleoside reverse transcriptase (NRTI), non-nucleoside reverse transcriptase (NNRTI) and protease (PI) RAMs were at 10% (4/40), 2.5% (1/40) and 2.5% (1/40), respectively.

Conclusions: Amongst these women, knowledge on the modes of HBV transmission and prevention is high although vaccination coverage is low (2%); rate of HIV-1 RAMs is high. These data support the need to scale-up PMTCT Progamme to include routine testing for HBV and HCV, in order to establish an early diagnosis and treatment initiation for the babies.

Key words: HIV, HBV, HCV, vaccination, transmission, prevention, seroprevalence

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Dapivirine vaginal ring use: attitudes and experiences across age groups

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Background: The Ring Study (IPM 027) found that the dapivirine vaginal ring was safe and effective in reducing the risk of HIV-1 infection. Adherence to ring use was lower among young women. Several social and behavioral influencers may underlie varying adherence rates.

Methods: The Ring Study (IPM 027) was a phase III, randomized, double-blind, placebo-controlled trial using the dapivirine vaginal ring, inserted 4-weekly in healthy, sexually active HIV-negative women, 18 to 45 years of age. The study was conducted over 104 weeks at seven centers in sub-Saharan Africa. Data from all participants who took part in individual in-depth interviews (n=55) were included in this analysis of attitudes, concerns and experiences with the dapivirine ring.

Results: In the overall study population (n=1959), reported product adherence was >96%. Fifty-five women were included in this qualitative analysis: 5 were <21 years, 16 were ≥21 to ≤25 years, and 34 were >25 years. Most women ≤25 years felt that the ring was easy to insert, comfortable to wear, and did not impact sex. These women also reported increased condom use during the study, compared to women >25 years who reported no changes with condom use. Women >25 years were more comfortable wearing the ring during menses than younger women. Women >25 years were more likely to participate in the study for altruistic reasons, and reported more partner support, although only after disclosure. In the younger age groups (≤25 years), more than half of women (57%, 11/21) felt that the vaginal ring would empower females against HIV infection. Self-reported ring expulsions and removals were low across all age groups. No social harms were reported in the interviews used for this analysis. Few social harms (5.1%) were reported in The Ring Study population.

Conclusion: Despite the low number of participants under the age of 21 years in this analysis, trends were observed between age groups. Various factors may be responsible, including personal preferences, stage of life, parity and relationship types.

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Self-Reported Risky Sexual Practices among Adolescents and Young Adults in Botswana Differ between Females and Males

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Background: An estimated 1700 adolescent and young adults (15-24) acquire HIV daily, accounting for over a third of new HIV cases. Understanding sexual practices of this high-risk group is critical in designing HIV prevention programming.

Materials & Methods: We sought to examine the sexual practices by gender, regardless of HIV status, of adolescents and young adults aged 16-24 years participating in the Botswana Combination Prevention Project (BCPP), an ongoing pair-matched, cluster-randomised trial of 30 communities. Information on age of sexual debut, and with the last twelve months number of sexual partners, condom and alcohol use during sex, intergenerational sex (intercourse with a partner 10 or more years older), and transactional sex (receiving money, transport, food, drink or other goods in exchange for sex) were collected at enrollment. Modified Poisson estimating equations were used to obtain prevalence ratios comparing engagement in different sexual practices according to gender, adjusting for community-level clustering.

Results: Among the 12,610 BCPP participants, 3,380 were 16-24 years-of-age. Of these 2,311 (68%) reported being sexually active with significantly more females reporting ever being sexually active compared with males (65% vs 35% respectively; p<0.01). Sexually active individuals reported significantly higher levels of poverty, indicated by lack of television (44% vs 38; p<0.01) or refrigeration (56% vs 46%; p<0.01), and reliance on a communal stand pipe for water (26% vs 20%; p<0.01). Compared to males, sexually active females were significantly more likely to report inconsistent condom use (PR:1.61; 95% CI: 1.44-1.80), intergenerational sex (PR: 9.00; 95% CI 5.84-13.88), and transactional sex (PR: 3.46; 95% CI 2.07-5.77). [Table 1] In contrast, women were significantly less likely to engage in sex before age 15 years (PR: 0.59; 95% CI: 0.41-0.85), use alcohol around time of intercourse (PR: 0.59; 95% CI: 0.45-0.76), or have ≥2 partners in the last 12 months (PR: 0.65; 95% CI: 0.57-0.74).

Conclusions: Female self-reported risky sexual practices of adolescents and young adults in Botswana differed significantly from that of males. Economic stress was strongly associated with increased risk behavior in females. Interventions targeting this vulnerability (income transfer, pre-exposure prophylaxis) may represent viable HIV prevention programming tools for adolescent and young adult females in Botswana.

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Vaginal ring acceptability, adherence and social effect: from phase I to phase III

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Background: Three clinical trials in which participants used silicone vaginal rings were conducted in healthy, HIV-negative women in Sub-Saharan Africa. The acceptability and adherence to vaginal ring use in these trials (IPM 011, IPM 015, and IPM 027) are presented.

Methods: IPM 011 was a phase I open-label crossover trial conducted over 24 weeks at five research centres. Women were randomly assigned in a 1:1 ratio to receive either a vaginal ring (containing no active ingredient) or no vaginal ring. IPM 015 was a phase I/II, double-blind trial, conducted over 12.5 months at 10 research centres. Participants were randomly assigned in a 1:1 ratio to receive either a dapivirine ring or a placebo ring. IPM 027 was a phase III, double-blind, trial conducted over 104 weeks at seven research centers. Women were randomized in a 2:1 ratio to receive either dapivirine ring or a placebo ring. Outcomes were assessed through ring diary cards that recorded the participant's sexual activity and ring use, acceptability and adherence questionnaires and reporting of social harms. In-depth interviews were used during phase III. Adherence counseling for vaginal ring use was offered in these trials.

Results: 170, 280 and 1959 participants were enrolled for IPM 011, IPM 015 and IPM 027, respectively. Mean age ranged from 25.4 to 27.0 years. Most participants had a main sex partner. In all three trials, vaginal rings were reported to be highly acceptable, and over 95% of women felt comfortable wearing the ring every day. Most women did not feel the ring during normal activities: 98.7%, 88.8% and 99.0% for IPM 011, IPM 015 and IPM 027, respectively. Most women never felt the ring during sex (>90.6%) and the majority (> 63.3%) reported that their male partners did not feel the ring. Self-reported ring adherence was 98.7%, 92.0% and 99.6% for IPM 011, IPM 015 and IPM 027, respectively. Self-reported ring expulsions were uncommon across trials (22% for IPM 011, < 10.0% for IPM 015, IPM 027). Few social harms (< 5.1%) were reported across phase I to III. Most women (97.0%) in IPM 011 felt that the community would approve of the ring. In IPM 027, men were largely supportive of their female partners participating in the trial and using a vaginal ring.

Conclusions: Acceptability and adherence rates were similarly high in the phase I to III trials. Most women were unaware of the ring during normal activities. The opinion expressed by participants in IPM 011 that the community would approve of the ring was consistent with subsequent phase III IPM 027 findings, where male partners and the community supported ring use. The vaginal ring is a promising future HIV infection prevention option.

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Knowledge and acceptability of HIV pre-exposure prophylaxis (PrEP) in pregnant women

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Background: Washington D.C. (DC) is an epicenter of the HIV epidemic. Despite the high prevalence of HIV and the increased incidence of HIV among women during pregnancy, PrEP research, education, and outreach has infrequently targeted at-risk cis-gender women in the United States. Awareness and acceptability of PrEP in pregnancy is understudied in high-risk resource-rich settings. We hypothesized that there would be low knowledge, but high acceptability of and interest in PrEP among pregnant women in our high prevalence community.

Methods: We conducted an anonymous, validated survey of a convenience sample of pregnant women seeking prenatal care at a tertiary care center in DC to assess knowledge and acceptability of PrEP. The survey instrument consisted of 117 questions, which included demographics, risk-taking behaviors, knowledge of PrEP, a 5 minute CDC PrEP video, and post-video perceptions of/interest in PrEP. Data collection is ongoing. For this preliminary analysis, we used chi-squared and Fisher's exact tests for categorical variables and t-tests for continuous variables.

Results: 130 pregnant, HIV-negative women completed the survey. Average maternal age was 26.5 years (± 5.3 SD) and average gestational age was 6.3 months (± 2.2 SD). The majority were African American (85.4%), single (53.9%), completed at least high school/GED (89.2%), and had incomes below the federal poverty level (83.9%).

84.7% reported having a (negative) HIV test in the last year. 9.2% reported diagnosis with a sexually transmitted infection (STI) within the past year. Despite the prevalence of STIs among participants, the perceived risk of HIV acquisition was lower than the population risk, given the high incidence and prevalence (1.9% among African American women) in DC. 0.8% perceived their risk of HIV acquisition as "moderate" during the pregnancy, 2.3% reported "moderate" or "high risk" in the next 12 months, and 3.9% reported "moderate" or "high" lifetime risk.

Only 14 participants (10.8%) had heard of PrEP before watching the video. No participants had spoken to a healthcare provider about PrEP. Following the video, 68% responded that their perception of PrEP was either "extremely good" or "somewhat good"; over half responded that PrEP was a safe (56.1%) and effective (56.1%) way to prevent HIV infection. Despite low prior knowledge of PrEP and low perceived risk of HIV, 20% of participants reported plans to initiate PrEP in the next year.

Conclusions: Despite low prior knowledge of PrEP and relatively low perceived risk of HIV, pregnant women surveyed in a high-risk community in DC reported high acceptability of PrEP. The survey demonstrates a high need for additional education and education of on HIV prevention and PrEP in this community.

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Implementation strategies to universally screen, educate about, and offer PrEP to pregnant women at two United States medical centers

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Background: The American College of Obstetrics and Gynecology and Centers for Disease Control & Prevention recommend offering HIV pre-exposure prophylaxis (PrEP) to pregnant women. Implementation studies of universal screening, education and offering PrEP to pregnant women in the United States (US) are lacking.

Methods: Using an implementation framework, we report strategies to screen and offer PrEP to pregnant women in 2 urban clinical settings: Bronx Lebanon Hospital Center (BLHC), where the HIV prevalence is 3%, and Zuckerberg San Francisco General Hospital (ZSFG), where the HIV prevalence is 1%.

Results: Prior to implementation, a retrospective chart review identified PrEP provision and missed opportunities in pregnant women at both sites. Data were publicized to motivate stakeholders. At each site, staff from clinics for pregnant women with HIV led multidisciplinary implementation teams. Both teams planned universal screening and offering PrEP to pregnant women using electronic health records (EHR). Key steps included:

1. Developing EHR screening questions: “Are any of your sex partners a man who has HIV, injects drugs, or has sex with men?” (ZSFG); “What is your partner’s HIV status?” (BLHC).

2. Screening and follow-up: ZSFG obstetrical clinic nurses and BLHC community health workers (CHWs) screened women at initial presentation to obstetrical clinics. With affirmative responses, clinicians assessed post-exposure prophylaxis (PEP) eligibility and offered PEP. At ZSFG, those not PEP-eligible were invited to a women’s HIV clinic for care. At BLHC, PEP and PrEP-eligible patients were referred to an HIV clinic with same-day appointments. At both centers, patients with partners of unknown HIV status were offered testing resources. All patients, regardless of response, were offered information about PrEP. Women could continue PrEP care in specialty clinics or obstetrical clinics with consultation. At BLHC, pregnant women were re-screened in the third trimester and on labor and delivery (L&D). Women identified with HIV-positive partners for the first time on L&D were offered expedited viral load testing and perinatal HIV team consultation. Mothers and babies were followed in HIV clinic.

3. Training: The ZSFG team provided one-hour trainings to clinic nurses and physicians. At one year, stakeholders requested refresher trainings and identified additional groups with training needs (medical assistants, midwives, L&D nurses). Academic detailing and video trainings were planned. BLHC CHWs attended off-site, city-sponsored PrEP trainings; nurses and medical providers attended on-site, city-sponsored trainings. BLHC identified additional training needs around acute infection.

4. Identifying missed opportunities: ZSFG stakeholders identified missing women (a) presenting exclusively to L&D, or (b) with biological markers of HIV vulnerability (gonorrhea or syphilis). BLHC identified missed opportunities including (a) PEP provision (b) delay from identification to PrEP initiation (c) underutilization of CHWs as PrEP navigators. Both sites identified challenges with postpartum retention and offering PrEP to women who inject drugs.

Conclusions: Implementation of universal screening, education and offering PrEP to pregnant women is feasible in US urban clinical settings with variable HIV prevalence. Facilitators include pre-existing clinics caring for women with HIV and city-based PrEP programming. Barriers include ongoing training needs and challenges reaching women who infrequently access care.

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From guidelines to implementation: Community consultations to inform oral PrEP roll-out in Zimbabwe

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Background: As Zimbabwe prepares to roll-out oral pre-exposure prophylaxis (PrEP) for HIV prevention, it is critical to understand communities' awareness of oral PrEP across districts and populations. Understanding and designing programs that take into account community perspectives on the benefits of, concerns and misconceptions about, and barriers to uptake of oral PrEP could accelerate PrEP introduction and impact.

Methods: Between August and September 2017, 21 community dialogues were held in 8 out of the 10 provinces of Zimbabwe, among 10 population groups, namely adolescent girls and young women (AGYW), adolescent boys and young men (ABYM), female sex workers (FSWs), adult women and men, internally displaced populations, men who have sex with men (MSM), transgender populations, students in tertiary institutions, and community leaders. Dialogues were conducted by trained moderators using a standardized discussion guide. A reporting tool was used to synthesize information gathered during the dialogues. The syntheses were reviewed by three independent analysts to identify emerging themes regarding PrEP awareness, misconceptions, barriers and benefits.

Results: PrEP awareness was generally low, though some AGYW and FSWs had heard of oral PrEP from past and ongoing research trials and demonstration studies within their localities. Incomplete understanding and misconceptions were apparent. For example, many community health workers and other providers confused oral PrEP with post-exposure prophylaxis, or thought that PrEP works when taken just before a sexual encounter. Concerns were raised primarily by young women about fertility after oral PrEP use, and whether PrEP reduces contraceptive effectiveness. Young men were concerned about whether PrEP reduces libido. In terms of potential benefits, young women viewed oral PrEP as a tool to potentially improve their agency and provide effective options within inequitable relationships to prevent HIV. PrEP was seen as especially empowering when condom use was not acceptable to male partners, as it can be used without a partner's knowledge or consent. Despite communities welcoming oral PrEP as an intervention that was long overdue, they highlighted ongoing fears of HIV testing as a potential barrier, given that an HIV negative test would be required to access PrEP. Communities also expressed concerns about the government's capacity to provide oral PrEP, given exciting challenges in providing consistent access to treatment for all people living with HIV.

Conclusions: Communities are eager for oral PrEP rollout given the perceived benefits. There is need to develop and implement a comprehensive communication strategy that will ensure widespread, correct, and comprehensive knowledge of oral PrEP in communities, along with investments to ensure its consistent availability and delivery. Communication materials, messages and client counseling should address misconceptions and concerns and emphasize benefits of oral PrEP for AGYW and other populations at risk.

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The Power of Social Asset Building Interventions In Promoting HIV Prevention among Adolescent Girls and Young Women

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Background: Through funding from USAID, SAfAIDS is implementing the Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) program in Zimbabwe targeting girls and women aged 15-24 years. The program seeks to reduce new HIV infections among adolescent girls and young women by 40% by 2018 through delivery of clinical HIV prevention and treatment services, social protection, and social asset building services. Key interventions implemented by SAfAIDS are social asset building, condom promotion and distribution, linkages to HTS and post-GBV care, targeting in-school & out of school HIV and GBV prevention. An evidence based HIV and GBV prevention Manual was developed and approved by the Government of Zimbabwe. The manual has 8 sessions including HIV risk assessment, risk mitigation, and risk management and each beneficiary is expected to complete at-least 6 sessions.

Materials & Methods: A cross-sectional survey was conducted with 492 DREAMS beneficiaries and 149 non-DREAMS beneficiaries participating as respondents. 273 had completed all the 8 HIV and GBV prevention sessions, 96 had completed 6-7 sessions, 78 completed 4-5 sessions and 76 had completed 1-3 sessions. More than 50% of the respondents had received other services from other DREAMS partners. The survey focused on assessing the level of determination to protect themselves against HIV and GBV and also uptake of HTS. There were 17 determination indicators assessed using a scale of 1 – 5 where 1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, and 5 = Strongly agree. Overall score per respondent for the 17 indicators was converted into the following five categories; 80-100% = Highly Determined; 70-79% = Satisfactorily Determined; 60-69% = Determined; 50-59% = Fairly Determined; and ≤49% = Lack Determination.

Results: With statistical significant difference (p-value less than 0,005), DREAMS beneficiaries demonstrated more determination compared to non-beneficiaries. 88% of the beneficiaries against 63% non-beneficiaries were highly determined. Conversely, 9% of non-beneficiaries versus none among beneficiaries lacked determination. The level of determination and resilience was also statistically associated with the number of HIV and GBV prevention sessions completed. Respondents who had completed all the 8 sessions (92%); 6-7 sessions (88%); 4-5 sessions (77%); and 1-3 sessions (70%) were highly determined. The level of determination was also positively correlated to the number of DREAMS Core interventions received. It was further noted that 75% DREAMS beneficiaries knew their HIV status against 8.1% of non-beneficiaries. Condom use in the last sexual intercourse was higher DREAMS among beneficiaries (63%) against 5.4% among non-beneficiaries.

Conclusion: Results show that DREAMS interventions are helping girls and women to be determined in protecting themselves against HIV. Although the program was not mature enough for concrete actions to prevent HIV among program beneficiaries, there is good indication that this can be achieved in the few years to come. It was also encouraging to note that the majority of DREAMS beneficiaries had tested and received their HIV results, PEP and PrEP compared to non-beneficiaries. This also is an indication that the program has helped beneficiaries to know sources of such services.

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Assessing the effect of Intimate Partner Violence on the Willingness to Disclose HIV status to sexual partners among women attending Community HIV Testing services in Kenya

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Background: Non-disclosure of HIV status among sexual partners has been identified as a major barrier to uptake HIV testing and life-saving anti-retroviral treatment services. According to the Kenya demographic health survey 2014, women were less likely to disclose their sero-status (60.9%), especially when HIV positive, to their sexual partner when compared to men (75.5%). LVCT health conducted a study to assess the effect to Intimate Partner Violence (IPV) on the willingness to disclose HIV status to sexual partners among women attending HIV testing services in Kenya.

Methods: This study employed a cross-sectional design and was implemented between August and December 2013 at three community based HIV testing sites in Nairobi, Embu and Machakos counties. The sites were selected because of their location in high HIV prevalent regions, having both rural and urban representation and having high inflow of clients per month. Data was collected at baseline using a structure questionnaire for participant's characteristics and IPV screening tool that was adapted from the World Health Organization's Multi-Country Study on Domestic Violence and Women's Health. IPV was defined as having experienced either sexual physical or emotional violence from a sexual partner within the 12 months prior to enrolment into study. Data records from 276 women aged 18 years and older were included into the analysis. Frequencies, means and standard deviations were used to describe the respondents' characteristics. Chi-squared tests were used to assess evidence of association between IPV experience, other covariates and willingness to disclose HIV status and multivariable logistic regression to determine the association between IPV experience and willingness to disclose adjusted for other risk factors.

Results: Majority, 224 (81.2%), of the women reported willingness to disclose their HIV status to their sexual partners. Almost half, 126 (45.7%) reported at least one form of violence. In the bivariate analysis, strong evidence of association was found between knowledge of partners' HIV status (p=0.001), discussion with partner prior to test (P<0.001) and perception of positive partner reaction (p=0.001). Moderate association was found between IPV experience and willingness to disclose HIV status (p=0.012). After controlling for known potential confounders in the multivariable analysis the evidence for association between IPV experience and willingness to disclose HIV status was weaker (OR 2.02 95 percent CI 0.99 – 4.10, p=0.054).

Conclusion: This results show that willingness to disclose HIV status by women is mainly influenced by issues related to the couple's relationship and communication such as knowledge of partners' HIV status, discussion with partner prior to test and perception of positive partner reaction post disclosure. We however found weak evidence supporting the association between IPV and the willingness to disclose HIV status. Nevertheless the findings will increase the body of evidence useful to inform policy and for developing appropriate strategies to promote HIV status disclosure among women to sexual partners within similar contexts.

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Reaching High Risk Women for PrEP: Learning from ARV-based HIV prevention trials

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Background: Programs delivering oral PrEP services in sub-Saharan Africa have requested guidance for reaching women at high risk for HIV. There is little evidence, however, showing how to identify high-risk women and motivate them to initiate PrEP. Clinical trials testing ARV-based prevention products are recruiting high-risk women, as control arms are consistently reaching HIV incidence above 3% (which WHO defines as 'high risk' populations). We conducted a retrospective analysis to derive lessons learned from research experience about effective, practical strategies for attracting women to PrEP services that could be applied in service delivery settings.

Materials & Methods: We conducted a descriptive, mixed methods study examining recruitment methods used in trials (phase IIb, III) testing ARV-based HIV prevention products (collectively referred to as PrEP). Eligible trials were conducted in Africa, included HIV-negative females, started recruitment between January 2007 and January 2017, and had a placebo arm HIV incidence of 3% or higher. We conducted a desk review to compile information about each study. We conducted key informant interviews (KIIs) with study staff responsible for recruitment and eligibility screening to document recruitment strategies and to explore views on which approaches hold promise for real-world service delivery. Questions were guided by the socio-ecological behavioral framework to explore multiple-level factors potentially leveraged by recruiters to encourage PrEP trial participation.

To analyse KII data, the study team developed a codebook corresponding to interview guide themes. Interview notes were coded and sorted in Excel to derive results on the strategies that did and did not work well, the factors influencing success, and the feasibility of transferring strategies to real-world service delivery.

Results: Interviews were completed with 31 study personnel who had worked across 7 clinical trials in 5 countries with urban and rural sites. Community-based approaches were the predominant recruitment mode. Across multiple trials, success factors in community-based recruitment were: engage and seek support from local leaders and service organizations, consult those gatekeepers about venues where high-risk women congregate, use local vernacular to talk about risk, and rely on satisfied PrEP users to serve as product ambassadors. Mass media were viewed as important for raising general community awareness about PrEP. Interview participants advised that groups already providing community-based HIV education and services could be engaged to recruit PrEP users; they cautioned about potential stigma caused by associating PrEP with HIV programming, however. For clinic-based recruitment to succeed, providers must be well trained and enthusiastic about offering the new prevention service. Noted constraints to clinic-based recruitment include providers being busy and the tendency of some women to not frequent health facilities.

Conclusions: Clinical trials provide useful experience to guide recruitment strategies for real-world services. The perceived value of combined recruitment methods with emphasis on community outreach suggests that clinic-based recruitment, while essential, is insufficient to achieve high PrEP uptake among at-risk women. Although trials' outreach strategies are consistent with standard public health practice, they are intensive. Programmers must select those approaches practical and affordable for their setting, while advocating for required budgetary support.

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The risk of IPV occurrence among women accessing HIV testing services in clinical settings in Nairobi County: A cross-sectional study

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Introduction: Globally, more than half of the people infected by HIV are women. Evidence suggests that the risk/and experience of Intimate Partner Violence (IPV) against women is linked to increased HIV risk and a key barrier to uptake of HIV prevention and treatment services. However, there's limited data on the risk of IPV occurrence among women accessing HIV testing services in Kenya. In 2017, we investigated the prevalence of IPV risk among women accessing HIV Testing and Counselling services in within public health facilities in Nairobi, Kenya.

Materials and methods: A cross sectional study design was utilized. Consecutive sampling was used to recruit women aged 18 years and above who presented for HIV testing services (HTS) at three public health facilities located in Nairobi. A total of 675 women participated in the survey. A self-administered structured questionnaire was used to collect data on socio demographics characteristics, HIV risk, IPV risk and IPV occurrence. IPV risk was defined as presenting with any of the following characteristics: a) HIV positive status b) History of experiencing physical/sexual abuse as a child c) History of experiencing abuse by sexual partner. We defined IPV occurrence as experiencing physical, sexual or psychological abuse from a partner six months prior to the survey. Descriptive statistics were employed and data analyzed using SPSS version 22. Ethical clearance to conduct the study was obtained from a local ethics review committee.

Results: Most of the participants were aged between 25-34 years old (47%), were married (76 %), had children (67%), earned an average income of KES 10,000 per month (24%) had attained secondary education (45%). Majority, 365 (54%) presented with one or more risk factors for IPV. Sixty one (9%) were HIV positive, 55 (8%) had experienced physical/sexual abuse as children and 271 (40%) had ever been abused by a partner. 223 (33%) of the respondents reported IPV experience within six months prior to the survey.

Conclusion: IPV risk and experience is common among women who seek HIV testing services in public health facilities in Kenya. There is need to develop interventions that integrate IPV services into HIV setting. Policy makers should consider integration of routine screening for IPV within HTS service delivery points as a strategy to find and link women to appropriate prevention and response services.

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Moving towards Answers: What we know and don't know about adolescent girls and young women in sub-Saharan Africa as users of HIV prevention products

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Background: To address the disproportionate number of new infections in adolescent girls and young women (AGYW) globally, a variety of HIV prevention products need to be introduced to the market in a manner that supports use. The HIV Prevention Market Manager built upon an analysis of completed, ongoing, and planned work on AGYW in sub-Saharan Africa as the end users of HIV prevention products, tracking the studies against key questions for prevention product introduction and marketing efforts.

Materials & Methods: The analysis centers on AGYW ages 15-28 in sub-Saharan Africa and builds off of the HIV Prevention Market Manager's systematic review and landscape mapping. The analysis focused on questions under investigation, tracking along a framework of identifying, reaching and encouraging uptake, and adherence to prevention products and behaviors. Existing data and gaps in knowledge were mapped along stages of product adoption: awareness, evaluation, uptake, adherence, and championing.

Results: Of the 56 end-user projects, primarily in South Africa, Kenya and Zimbabwe, the majority focus on questions relating to acceptability and adherence with oral PrEP the primary product under study. Available literature shows that levels of awareness about HIV and prevention are generally high among AGYW, but does not assess whether that awareness translates to relevance. There is a gap in understanding why awareness and intention around HIV prevention does not translate into action. Little is understood about motivators of intention to use. More is known about the barriers to uptake of different products, but less is known about the tradeoffs in an AGYW's decision to practice prevention. Additionally, existing knowledge of the roles played by different influencers in an AGYW's life when it comes to HIV prevention is rudimentary.

Conclusions: While AGYW research is a crowded landscape, there are significant gaps in research that informs how AGYWs think, act and are influenced along the HIV prevention journey. Research is needed to understand not just acceptability and functional attributes, but desirability and the emotional benefits of HIV prevention products. Research is also needed to understand the full journey and decision-making context of AGYW and HIV prevention—how all the channels, influencers, barriers and drivers interact with each other. The HIV Prevention Market Manager will continue to track all ongoing and planned work.

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Clinical characteristic of HIV-infection and factors associated with staying in care among HIV-positive women who injected drugs in Ukraine

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Background: There is morbidity indices increase of HIV-infection and AIDS with the women-patients of reproductive and able-bodied age prevalence in Ukraine. The negative tendency of the recent years is the increase of sexual transmission significance and the growth of persons beyond the risk groups among the firstly diagnosed HIV cases. However, Ukraine's distribution epidemic is seen to be fueled by women who injected drugs and cases of HIV among this category making up nearly 60% of new HIV infections.

Materials & Methods: Retrospective observational study was conducted to analyze the clinical finding, immune state and factors associated with retention in care in 180 HIV-infected women who were observed in Poltava regional AIDS Center in 2016-2017. Potential risk factors associated with dropout were identified by using multivariate logistic regression models. Patients who missed two or more HIV clinic appointments over the past year or non-attendance for 6 months were considered as unengaged in care. SPSS version 22.0 was used for statistical analysis.

Results: Late HIV-infection diagnostics has been established to occur in the region. Opportunistic diseases have been diagnosed in 90 % of primary medical care recourse: tuberculosis (45,0%), fungal (47,8%), viral (30,0%), bacterial (29,4%) and parasitic infections (11,7%), which develop with CD-4 lymphocytes level > 350 cells/µl in 18,7 % of examined persons. The risk for discontinuing in care was significantly higher in women who inject drugs and those who diagnosed during the pregnancy (OR=1.6, 95% CI 1.1- 1.8; OR=1.9, 95% CI 1.5-2.3). Retention in care among women who inject drugs was best predicted by involving patients in opioid replacement therapy (OR=1.1, 95% CI 1.0- 1.1), social support (OR=1.4, 95%CI 1.0- 2.1) and evidence of severe opportunistic infections including tuberculosis (OR=1.2, 95% CI 1.1- 2.8), herpes zoster (OR=0.5, 95% CI 0.3- 0.8).

Conclusions: The main factors associated with staying in care among HIV-positive women in Ukraine were good access to opioid replacement therapy, social support, appearance of HIV clinical complications including tuberculosis and herpes zoster.

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Heroin use among women who exchange sex in Kenya: Implications for global HIV prevention

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Background: Injection drug use is increasingly contributing to HIV infection across sub-Saharan Africa, where new heroin markets are emerging and evidence-based treatment programs are scarce. In Kenya, efforts are underway to expand medication-assisted treatment (MAT) as a form of drug treatment and HIV prevention. However, women who use heroin, who often engage in sex work and experience heightened vulnerability to HIV, are particularly difficult to recruit into services.

Methods: To inform appropriate MAT and HIV services, we conducted participant observation and qualitative interviews with 45 female sex workers in Kisumu, Kenya, 32 of whom reported lifetime heroin use and comprise the focus of the current analysis. In-depth interviews covered social relationships, substance use, sex work, and health programming needs. We conducted a content analysis and organized the data into higher-order analytical themes.

Results: Among 32 women reporting lifetime heroin use, median age was 28 (range: 18-37). All women used alcohol, and past-month use of other drugs was prevalent. Regarding heroin use, 23 women reported ever injecting (72%) and 25 reported current heroin use (78%), 19 of whom smoked and 7 of whom also injected. We identified three analytical themes around women's heroin use: (1) the importance of social contexts surrounding drug use, (2) women's embodied experience of drug use, and (3) how these factors interact to produce risk management strategies in the context of sex work. First, women were typically introduced to drugs by other sex workers or male friends, and attributed their drug use initiation to social influences, curiosity, stress, boredom, and wanting to know "how it feels." Second, their embodied experience of drug use, or the physical effects and subjective feelings produced by drugs, played a critical role in their drug use trajectories. Importantly, as a third theme, women strategized their heroin use in the context of sex work: the majority of women used heroin before sex work for "morale" to engage in a stigmatized and often unpleasant job, for "courage" to negotiate for condom use and fair prices, and to able to "fight" back against abusive clients. Others did not use heroin until after sex work, as they perceived that heroin rendered them too high to operate safely in their work. In all cases, women kept their heroin use secret to protect themselves from legal risks and the double stigma of being labeled as a woman who does sex work and uses drugs.

Conclusions: Sex workers in Kisumu report smoking and injecting heroin in a rapidly developing drug market where HIV prevalence is already among the highest in Kenya. While we cannot conclude that women's strategies around heroin use made them objectively "safer" in their sex work, subjective perceptions of risk matter because they shape tangible behaviors, including accessing healthcare services. Our findings have implications for drug treatment and HIV prevention, including the new MAT clinic in Kisumu. To appropriately address HIV risk, programs must consider women's own risk perceptions and provide services that address dual sexual and drug-related risks in hidden, stigmatized populations of women.

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Predictors for retention in medical care for HIV-infected women who inject drugs in Ukraine

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Background: PWIDs (people who inject drugs) represent approximately 1% of Ukrainian population, 75000 are women. Twenty thousand female PWIDS live with HIV. In 2016 nearly 60% of new hiv infections in female PWIDs were diagnosed late with a CD4 counts below 350. Retention in medical care remains a big challenge for this population in Ukraine. For a better understanding of the factors causing loss to care we analyzed socio-demographic data, behavioral factors, clinical and quality of life data.

Materials & Methods: A pilot cross sectional study was performed with 24 respondents of whom 10 were in care versus 14 not in care. Participants were recruited through NGOs and health care institutions from central, eastern and western regions. To assess quality of life we used (SF36) questionnaire and the hospital Anxiety Depression factors (HADS).

Results: Socio-demographic characteristic of the patients were as follows: a mean age of 37,0 years, first drug use at 19,8 years, 30% were unemployed and 70% lived in a city. `Time since HIV diagnosis was six years and mean nadir CD4 numbers were 317.
No significant differences between the two groups were observed for disclosure of HIV status, employment rate, living with a partner, receiving opioid substitution therapy, rate of coinfection (TB, Toxoplasmose, Candidiasis) and distance to a medical center. No significant differences were observed for the HADS score, nor for the SF36 mental and physical health components. Although there was trend towards a lower “role physical” (33 vs 65) and mental component summary (31,4 vs 38,2) in patients not engaged in care. Patients not in care were more likely to have a history of incarceration (65 vs 10%), have a HIV positive partner (58 vs 20%) and of being older (40,5 vs 31,8 years).

Conclusions: Factors associated with loss to HIV care among HIV positive women who inject drugs in Ukraine are older age, experience of incarceration and living with a HIV positive partner. HADS (Anxiety and Depression) and SF36 analysis showed a trend towards poorer general health for the group not in care. Larger, prospective studies are needed to better understand the factors and their interplay that determine why and when female PWID enter care, the effects of staying in care and HIV therapy on general health and quality of life.

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Personal Profile and Health Seeking Behaviors of the injecting Drug users in Lomé-TOGO

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Background: Injecting drug users are amongst the most vulnerable people in TOGO to acquire HIV/AIDS. HIV prevalence has dramatically risen from 1.9% in 2013 to 7% in 2016 among IDUs in Lomé city possessing a concentrated HIV/AIDS epidemic.

Methods: A cross sectional study was undertaken to understand the various socio-demographic and personal profile of the IDUs and their health seeking behavior. 218 IDUs were selected purposely from 2 drug rehabilitation clinics and streets in Lomé city. The study tools included in-depth interviews and structured questionnaire.

Results: Most of the IDUs were middle-aged men with no education and average monthly incomes of USD 50. Both intramuscular and intravenous route of drug administration were common. Sharing of needles during the last 3 months among the clinic based IDUs were 18% and 65% among the street group (96%). Knowledge about the diseases transmitted by injection was high among the clinic based IDUs (85%) compared to the street group (16%). 87% first started drugs with cannabis. Median age of starting drug intake was 21 years with 15 being the youngest and 46 the eldest. Median duration of injecting drug was 5 years among the clinic group and 3.5 year among the street group. 63% IDUs prefers mixed injection while 36% chooses buprenorphine alone. Cost of availing health care services was a discouraging factor. Condom uses among the IDUs were only 9%. The effectiveness of exchange programmed in reducing sharing incidences was visible. The street IDUs have limited knowledge about the diseases and thus are greater risk.

Conclusion: Knowledge about HIV transmission and prevention should be improved. Education and interventions specifically aimed at IDUs are needed, because education targeted at the general population may not reach IDUs or influence their behavior.

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Effect of peer education and provision of on-site HCT services on the uptake of HCT among public secondary school students in Abakaliki Ebonyi state

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Background: HIV/AIDS is a source of health economic and social burden. Sub-Saharan Africa has about 10% of the world's population but accounts for 60% of all people living with HIV/AIDS. Less than 10% of these people are aware of their status, majorly because of low uptake of HCT. HIV prevalence among adolescents is aggravated mainly by inadequate sexual health education, and inadequate HIV counselling and testing. This study was undertaken to determine the effect of peer education and provision of onsite HCT services on the uptake of HCT, awareness level of HCT, preferred HCT model, sexual behaviour of adolescents and factors influencing the up-take of HCT among secondary school adolescents.

Methods: This was a school-based quasi-experimental study. Triangulating quantitative and qualitative data collection methods were used. Multistage sampling technique was used to select 466 students from two schools. A pre-tested semi structured self-administered questionnaire was administered and data was analysed using IBM SPSS version 21. Tests of statistical significance were done at p value of less than 0.05.

Results: At baseline 56 (12%) in study and 61(13.1%) in the control group had ever screened for HIV. At 3 months post-intervention, uptake of HCT increased significantly in the study group by 61.6% than in the control group (1.5%); $P < 0.01$. Logistic regression revealed that being female, sexual exposure and condom use were predictors of HCT uptake. Focused group discussion revealed fear of needle prick, sight of blood, fear of blood being used for rituals and confidentiality in the process as reasons for not screening.

Conclusion and recommendation: Peer health education and the provision of on-site HCT services significantly improved adolescents' up-take of HCT. We therefore recommend integrating peer education and HCT into school health programme as a strategy for increasing the up-take of HCT among 'In-School' adolescents.

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Violence and HIV vulnerability among female sex workers in Kisumu, Kenya

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Background: Violence heightens HIV risk. Violence creates barriers to negotiation for safer sex and accessing information and services. Sexworkers may easily be violated, exploited or abused by clients, steady partners and law enforcement officials due to their work environment, disempowerment and lack of legal protection for their human rights. We describe the perpetrators and the context of physical and sexual violence experienced by female sex workers, and discuss implications for interventions in Kisumu, Kenya.

Methods: We conducted qualitative interviews with female sex workers (n=45) who engaged in problematic alcohol and/or drug use and experienced violence. Interviews explored early life history, social relationships, sex work, alcohol and drug use, experiences of violence, HIV risk behaviors, health needs and service utilization. We analyzed transcripts to identify emergent themes focusing on experiences of violence.

Results: Most female sex workers reported experiencing multiple forms of violence from various perpetrators throughout their lives. In addition to intimate partner violence, sex work exposed them to violent clients and police who sexually coerced and beat them. Physical violence was most prevalent from clients, followed by intimate partners, and police. Sexual violence was commonly perpetrated by clients and police including cases of gang rape. Reasons for client-perpetrated violence included client's failure to pay for sex, client refusal to use condoms, alcohol use, and theft by sex workers. Issues including alcohol use by either one or both intimate partners, husband's knowledge of their wife's sex work, and male partner infidelity were factors in intimate partner violence. Police violence was largely an exploitation of power for coerced sex and beatings, including arresting sex workers if they did not comply with their sexual demands.

Conclusion: Our study suggests that female sex workers experience multiple forms of physical and sexual violence that could heighten vulnerability for HIV acquisition and other health harms. Excessive alcohol use was a factor in violence subjected by all perpetrators, suggesting that programs should address alcohol use. Women also suggested that training for alternative jobs could help them avoid exposure to violence in sex work environments. Finally, women reported that police and clients should be sensitized and legal protections of sex worker rights should be reinforced.

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Part-time Continued Education (PTCE): embracing a second chance for Adolescent Girls and Young Women (AGYW) in Mutare District, Manicaland Province, Zimbabwe

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Issues: Adolescent Girls and Young Women (AGYW) 15 to 24 years are mostly affected by HIV and AIDS, accounting for 74% of new HIV infections in sub-Saharan Africa. Lack of education and low socio-economic status forces AGYW to engage in high risk sexual behaviors. Research demonstrates that education significantly improves the lives of AGYW and their families as those educated are most likely to make informed choices on safer sexual practices and family planning. Family AIDS Caring Trust (FACT) through the PEPFAR-funded DREAMS Initiative is providing Part Time Continued Education (PTCE) to AGYW in Mutare District, Zimbabwe to address the HIV risk factors and vulnerabilities AGYW face.

Description / Method: Twenty AGYW were enrolled at Chitakatira Secondary School for PTCE from July 2017 to December 2017. Recruitment targeted AGYW who sell sex, from Apostolic sects, adolescent mothers, living with HIV, in early marriages, single/double orphaned and in ultra-poor families. Eligibility assessment for placement was conducted by 6 community cadres trained on HIV-sensitive case management, adolescent girls' empowerment and the PTCE model. Of the 20 AGYW selected, 95% were enrolled in Form 3 and 5% in Form 5. Among them three were selling sex, 1 a double orphan, 2 Apostolic, 8 single orphaned and 6 from ultra-poor families. Enrollment was hinged on each AG/YW's last level of education versus expected academic competencies. Teachers taught AGYW in selected subjects, providing remedial lessons where required. Case files were opened for each AGYW as part of comprehensive case management. Assessment was then done to analyse how PTCE improved the lives of AGYW from inception to December 2017.

Results: Median age of AGYW was 20 years. AGYW appreciated the second chance to education. School became a strategy that kept them away from HIV risk environments. School became another platform for psychosocial support provision, effective guidance and counselling and a safe space for AGYW to interact with their peers with the same experience. AGYW set themselves personal and professional ambitions as they took charge of their purposes in life. SRH and family planning education was also delivered. 30% AGYW and 5 children who had not been HIV tested were referred for testing and received their results. Reusable sanitary ware production training was provided which improved AGYW's school attendance. Those with children benefitted from parenting input. Training on healthy and sustainable income generation was provided resulting in AGYW who sell sex abandoning their "trade" and engaging in buying and selling goods. Loss of concentration in studies was reported by some AGYW mothers who worried about the welfare of their children left with friends while they attended school. Thus, in 2018, FACT will support AGYW mothers with Early Childhood Stimulation (ECS) program for children below 5 years under the care of trained ECS facilitators for ECS, feeding, care and support.

Conclusion: Beyond lack of education, PTCE was an effective strategy for addressing other HIV risks facing AGYW. It also reduced stigma and discrimination. Trained community cadres supported the AGYW by responding to their needs and helping them overcome stigma.

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Prevalence and correlates of HIV Disclosure Worries among Women Living with HIV in Canada

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Background: For women, HIV disclosure can be challenging in part due to gendered power dynamics, increased risk of violence, potential social rejection, and reduced access to treatment and care services. We examined HIV disclosure worry (HIV-DW) among women with HIV in the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS) and assessed associations with sociodemographic and clinical variables.

Methods: CHIWOS is a community-based, multi-provincial (Ontario, British Columbia, and Quebec), longitudinal study where participants complete a peer-administered questionnaire. We used baseline CHIWOS data of women who answered >50% of the HIV-DW scale (n=1419). The HIV-DW scale consists of 5 items (α=.83) measured on a Likert scale with answers ranging from 'strongly agree' (4) to 'strongly disagree' (0) and final scores were computed for a value out of 100. Multivariable logistic regression was used to determine independent correlates of higher HIV-DW (defined as HIV-DW score ≥75). The model was developed using backward stepwise selection.

Results: Median age was 43 (IQR: 35-50) and median length of time living with HIV was 11 years (IQR: 6-17); 83% were on ART and 79% reported an undetectable viral load. Participants were ethnically diverse (22% Indigenous, 30% African/Caribbean/Black, 41% Caucasian/White, and 7% other ethnicities). The overall HIV-DW mean was 58.8 (SD=24.9); 34% had higher HIV-DW. In multivariable analysis, higher HIV-DW was associated with province of residence (adjusted odds ratio (aOR)=1.93; 95% confidence interval [CI]=1.28-2.92 for QC and similar for ON compared to BC); ethnicity (aOR=2.22; 95%CI=1.61-3.19 for African/Caribbean/Black women and aOR=1.45; 95%CI=1.01-2.10 for Indigenous women compared to Caucasian/White women); unstable housing [aOR=2.70; 95%CI=1.78-4.09]; and food insecurity [aOR=1.42; 95%CI=1.08-1.86].

Conclusions: Over one-third of women with HIV in Canada express substantial worry about HIV disclosure. Disclosure worry varies by markers of socio-demographic vulnerability, including ethnicity, province of residence, housing stability, and food security, and requires further evaluation.

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Retention in care of HIV/HBV co-infected pregnant women in Nigeria and pharmacovigilance: considerations for the national PMTCT programme.

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Background: The HIV prevention, treatment and care of HIV infections uses a broad range of interventions to ensure access and retention of HIV patients, including HIV/HBV co-infected pregnant women. As launch pad for the attainment of the UNAIDS 90-90-90 targets, the initiation of ART, regardless of clinical and immunological stages of the disease, retesting of patients prior to initiation of ART, adoption of PrEP of women at high risk of acquiring the infection and addition of Dolutegravir, Efavirenz 400 mg and Darunavir/Ritonavir to the pool of approved antiretroviral drugs among others are services provided. However, challenges in retention among HIV/HBV co-infected pregnant women are emerging, though pharmacovigilance provides information on 1) drug therapy problems, including ADRs and medication errors among women in the PMTCT program and, 2) issues that could inform modifications of health systems and community interventions.

Materials and Methods: Qualitative- in-depth interviews with 35 prospective HIV/HBV co-infected, pregnant re-initiates to the PMTCT program to know bottlenecks to retention in treatment. Questions asked covered: a) knowledge and perception of HIV, HBV and coinfection; b) perception of treatment education, including adverse effects of drugs administered; c) barriers and motivation for staying in care and d) willingness to continue in care. Participants' responses were reviewed, analyzed and categorized thematically.

Results: None of the women knew they were HBV infected. Most women sought more information about HBV and HIV/HBV coinfection. There was a general expression of relief that the same medications treated both infections. Suspected bridge of confidentiality by providers and poor follow-up were the major reasons for dropping out of care. Major motivations were: fear of effects of co-infection, simplicity of treatment, efficacy of medication and protection of unborn baby from acquiring HIV and HBV. All the women expressed instant willingness to return to care.

Conclusions: Proactive and timely communication of risks and the risk factors so that harm can be avoided or minimized could address retention and related issues. If followed up with a client-centered pharmacovigilance communication strategy, more evidence can be generated to inform improved levels of efficiency for managing co-infected patients especially with the increasing prevalence of HIV/HBV/HBE co-infections.

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Risk factors involved in the late detection of HIV mother-to-child transmission, as identified in National Registry of HIV pregnant women and perinatally exposed children in Romania

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Background: Romania is the only country from the Central and Eastern European area with a particular HIV epidemic. At the end of 2016, a total of 22,095 cases of HIV and AIDS infection were registered and 14,349 persons were living with HIV/AIDS. Most patients were diagnosed during the early infant period (<14) and experienced multiple treatment schemes. From the overall PLWHA, 5971 (41,61%) were women, of whom the age group 25-29 accounted for 49,5%, the 20-24 age group claimed 4% and 13-19 years- 1,8%.

Methodology: In 2013 Romania implemented the National Registry of HIV pregnant women and perinatally exposed children, an electronic system that stores data on HIV infected mothers and their children from the nine Regional HIV Centers in the country. The Registry collects: personal data on both mothers and children, the child's medical history (physiological and pathology data), initial investigation, early detection, investigation at 6 and 18 months of surveillance; the mothers' personal data: time of HIV diagnosis, risk factors, disease and therapeutic history, peripartum immunological and virological investigation, information about the father and siblings.

Results: During January 2013-31 December 2016, we registered 732 mother-child items, 40% of mothers belonging to the Romanian Cohort (infected in the late 1980s and early 1990s) while 28% represent new cases of women with HIV and IDUs. 72% of mothers knew their HIV status prior to their pregnancy while 15% learned about it during pregnancy. 6% of women were confirmed HIV positive during delivery. 78% of mothers were under ART during their pregnancy period, 82% underwent C-section and 49% had undetectable viral load. In what concerns the children, 98% of the overall number benefited from post-partum prophylaxis, 94% of them underwent virological assay during the first 72 hours of life and 96% received feeding formula. Early infant diagnosis revealed that 5% of the assessed children had detectable viral load.

Conclusion: Although in Romania HIV testing is universal, with pre and post test counselling, access to ART treatment is also free and non-discriminatory since the late 1990s, logistical regression showed that under the simultaneous influence of the above-mentioned risk factors, the only one that bears a significant impact on the child's HIV status at birth is "late diagnosis of the mother", namely at delivery (p-stat = 0.012).

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Psychosocial factors affecting infant feeding choices amongst HIV positive Mothers in Lagos State University Teaching Hospital Idi-araba Lagos

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Several research had revealed that transmission of HIV from mother to child is reportedly higher among the mixed fed infants than exclusively breast fed infants. It is estimated that, with Exclusive Breastfeeding (EBF), 13% to 15% deaths of children under 5 years could be averted in low and middle income countries. World Health Organization (WHO) therefore recommends EBF to both HIV exposed and non- expose infants for the first six months of life, however EBF rates remain low throughout the world. In the absence of interventions, World Health Organization estimates that 150,000 babies around the world are infected with HIV via breast milk each year. Hence, this study sets out to examine the psychosocial factors affecting infants feeding choices among HIV positive mothers. The study sample involved 105 HIV positive nursing mothers attending the APIN LUTH Clinic who were randomly selected.

The descriptive cross-sectional research design was adopted for the study.Research findings revealed that majority of the respondent were within the age group 35-44years (50,47.6%) the most represented ethnic group was Ibo (57, 54.3%). Research findings revealed that the respondents prefer bottle feeding ahead of breastfeeding due to the fear of infecting their babies. However, medical intervention for mothers' health coupled with counseling made majority of the respondents (99, 94.3%) to make informed decision on breastfeeding Tested hypotheses revealed that social stigma significantly influenced the choice of infant feeding of HIV positive mothers, and that regular clinic. attendance significantly affect their choice of feeding their babies since the clinic serve as knowledge base for mothers to understand the need to make informed choices. Based on research findings, it was concluded that stigmatization, negative attitude of health workers and lack of adequate information were the leading psychosocial factors identified with the respondents.

It was recommended that there is a need for public sensitization of the proper breast feeding methods for nursing mothers living with HIV and that Health care programmes and Providers need to better understand mothers' social circumstances, their beliefs, motivations and behaviours, and be better prepared to intervene in ways that permit mothers to 'hear' and respond.

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Assessing the Acceptability of a Mentor Mother Intervention to Improve the Continuum of Care of Postpartum Women Living with HIV

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Background: Many women living with HIV fall out of the care continuum after delivery. Existing evidence-based interventions aimed at increasing retention of women have been developed and tested outside the perinatal period but none, in the United States (US), focus on improving retention in HIV care postpartum. There is evidence from low-resource settings show that women who receive peer mentoring benefit from increased retention and viral suppression postpartum. Peer mentor mothers are women who experienced pregnancy while HIV positive and in turn, provide education and psychosocial support to other women with HIV during pregnancy and the postpartum period. Here, we report results of qualitative interviews assessing the acceptability of a peer mentoring intervention for women with HIV in an urban US context.

Methods: In depth interviews were conducted with eight pregnant and seven postpartum women receiving HIV care in a Philadelphia clinic to assess participants' perceived acceptability of the program. We also assessed barriers and facilitators to engagement in HIV care during pregnancy and retention in HIV care postpartum with the goal of tailoring the intervention to patients' needs. Interviews were audio-taped, transcribed and analyzed. Codes were developed and applied to all transcripts and matrices were used to facilitate comparisons across different types of participants.

Results: Participants included low-income Black and Hispanic women with a mean age of 31 (range 22-42). Regardless of their stage in the care continuum, women felt peer mentoring would be an acceptable intervention to help sustain engagement in care after delivery and discussed ways to tailor the program to fit their needs. Participants reported experiencing trauma related to interpersonal violence and conflicts, stigma from HIV or HIV disclosure, and struggles with substance use. Many experienced depression or had a history of suicidal ideation or attempt. An overarching finding was that women's strongest motivator for staying in care was to protect the health and well-being of their baby. In addition, the majority of women found that family support, especially from their mothers, enhanced their coping skills, and in turn, facilitated their retention in care.

Conclusion: A peer mentor mother program is a promising intervention with the potential to improve the care continuum of pregnant and postpartum women living with HIV. The program will be adapted to address women's psychosocial needs and mentor mothers will need to be trained to address a diverse range of issues specific to women during the pregnant and postpartum periods. Messaging that maximize maternal support and women's motivation to keep their infant healthy may leverage retention in care postpartum.

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Quality of life assessment among HIV-positive patients: Significant gender differences in the mental component score (MCS)

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Background: HIV has become a treatable chronic disease and it is assumed that people living with HIV (PLWH) can achieve a normal quality of life (QOL). However there is still a need for real life data on QOL of HIV-positive patients, especially with respect to possible gender related differences.

Methods: We used the Short Form-12 version 2 (SF-12v2) questionnaire to assess the QOL in patients routinely visiting the HIVCENTER Frankfurt between September 2016 and May 2017. Additional information on the personal situation was collected using a specifically-designed questionnaire. The primary study objective was to determine the SF-12v2 mental component score (MCS) in men and women and factors that might have an impact on the outcome. All statistical analyses were bilateral and used a level of significance of alpha=5%.

Results: 286 patients (pts) were enrolled in the study. 11 pts were excluded because of missing data; 2 transgender women were not further analysed. Characteristics of the 150 men and 123 women:
Mean age: men 47.5y; women 43.9y
Non-Western-European origin (%): men 10,7; women 37,4
CDC-stage C (%): men 24.2; women 24.0
Mean CD4 cell count: men 722; women 790
Viral load < 20 copies/mL (%): men 87.8; women 78.5
Unemployment (%): men 66,9; women 63.1
Financial problems (%):men 4.1; women 12.3
High sexual satisfaction level (%): men 43,9; women 41,9
MCS values of 50 are classified as average for the U.S. population with a standard deviation of 10. Several studies found that normative data of the U.S. reference population are applicable to other countries, including Germany. In the overall analysis, mean MCS in the study population was 44.6 for women and 47.7 for men (p=0.02). Several factors had a significant impact on MCS: African versus Western European origin (40.8 vs 47.2), being unemployed versus employed (43.7 vs 47.4), having financial problems versus no problems (37.5 vs 50.9), low sexual satisfaction level versus high satisfaction level (41.7 vs 48.5) and experience of discrimination versus no discrimination (43.3 vs 48.0). There were significant gender differences in the MCS regarding country of origin, unemployment and sexual satisfaction. African heritage was only correlated with a lower MCS in women (41.3 vs 46.1) and unemployment had a significant difference in men (44.3 vs 49.6), not in women (44.1 vs 44.8). In terms of sexual satisfaction levels men who experienced a negative change following HIV diagnosis achieved a significantly lower MCS than men who did not (47.3 vs 52.9). In women, we found the opposite effect: A positive change in sex life correlated with a lower MCS compared to no change (39.7 vs 48.6).

Conclusions: Despite successful antiretroviral treatment PLWH still experience reduced QOL compared to the reference population. Factors contributing to the mental component score (MCS), assessed by SF-12v2 QOL-questionnaire, include country of origin, employment status, financial situation, changes in sex life and discrimination due to HIV. Overall, women living with HIV showed a lower MCS compared to men. Additionally, there were also significant gender differences concerning the factors which have an impact on the MCS.

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Response to Initial Combined Antiretroviral Therapy (cART) Amongst Older Women Living with HIV in the Canadian Observational Cohort (CANOC)

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Background: An increasing number of older people are being diagnosed with HIV and controversies exist as to whether their response to cART is as robust as their younger counterparts. Some studies have shown a reduced CD4 response in older patients initiating cART, although men are disproportionately represented. We compared response to initial cART in women ranging from 18 to 79 years of age, hypothesizing that older women experience a lower CD4 response.

Materials and Methods: We conducted retrospective analyses of CANOC data, an interprovincial cohort of HIV-positive adults, from January 1 2000 to December 31 2014 comparing CD4 cell count and virologic response to cART across age. Participants were 18 years and over, cART naïve, and had ≥ 1 viral load and CD4 count within 1 year prior to cART initiation. Primary outcomes were CD4 change from baseline and absolute CD4 response using linear mixed models. Secondary outcomes included time to viral suppression and viral rebound using Fine and Gray models with death as a competing risk. We reported hazard ratios (HR) with 95% confidence intervals (CI) adjusted for demographic and clinical factors.

Results: We included 1,865 females, of which 225 were ≥50 years of age with a median (IQR) age of 55 (52, 59) years at cART initiation. Older women were more frequently Caucasian (25.3% vs. 19.7%, p<.001), and initiated boosted PIs (43.1% vs. 42.7%), integrase inhibitors (8.4% vs. 2.7%) or NNRTIs (41.3% vs. 39.3%, p<.0001), while less commonly co-infected with Hepatitis C (31.1% vs. 38.8%, p=0.05) and IDU (26.7% vs. 35.7%, p=0.02). Older women had a lower baseline CD4 (200 vs. 220 cells/mm3, p=0.03) and higher baseline viral load (4.90 vs. 4.60 log10 copies/mL, p<0.0001). After adjusting for baseline CD4 and other important covariates (including demographics, calendar start year, and initial cART regimen), older age (per 10 years) was associated with a CD4 change from baseline of -6.5 cells/mm³ (95% CI: -11.8, -1.17 cells/mm³). Older age (per 10 years) was also associated with a lower absolute CD4 response (β=-7.95 cells/mm³, 95% CI: -13.8, -2.08 cells/mm³).

Viral suppression was achieved in 1,542 (84.1%) participants, with 427 (27.7%) subsequently experiencing rebound. The median time to viral suppression was shorter in older women (0.38 vs. 0.45 years, p < 0.01). In adjusted Fine and Gray models, older age (per 10 years) was associated with increased likelihood of suppression (HR=1.08, 95% CI: 1.03, 1.14) and decreased likelihood of rebound (HR=0.80, 95% CI: 0.72, 0.89).

Conclusions: Older age (per 10 years) was associated with a blunted CD4 change from baseline and absolute CD4 response following first line cART, despite the finding that older participants were more likely to achieve and maintain virologic suppression.

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Comparison of the Safety, Efficacy, and Pharmacokinetics (PK) of Bictegravir in its Clinical Development Program for Treatment of HIV

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Objectives: Bictegravir (BIC; B) is a potent, once-daily, unboosted HIV integrase strand transfer inhibitor (INSTI) with a high barrier to resistance. BIC is coformulated with the NRTI backbone of emtricitabine/tenofovir alafenamide (F/TAF) in the single-tablet regimen (STR), B/F/TAF for treatment of HIV-1 infection. This analysis assessed the potential gender differences in pharmacokinetics (PK), safety, or efficacy across the clinical development program of BIC.

Materials & Methods: The safety and efficacy of BIC as a component of the B/F/TAF STR for the treatment of HIV-1 infection in adults was evaluated across 4 Phase 3 clinical studies, which included 2 randomized, double-blinded, active-controlled Phase 3 studies in antiretroviral therapy naïve adults, 1 double-blinded, Phase 3 switch study in virologically suppressed adults, and 1 open-label, Phase 3 switch study in virologically suppressed adults.
The PK and drug drug interaction (DDI) profile of BIC was comprehensively characterized in healthy adult subjects (≥ 18 years of age) across 16 Phase 1 clinical studies following administration of BIC either as a single agent or as a component of the B/F/TAF STR. Population PK modeling for BIC was conducted using pooled intensive and sparse plasma concentration data in healthy and HIV-1 infected adults. The effect of covariates, including but not limited to sex, on the PK of BIC were assessed. Also, the PK/pharmacodynamic (PD) relationships between BIC exposure parameters and efficacy/safety endpoints were evaluated for HIV 1 infected adults who received the B/F/TAF STR in the 2 randomized, double-blinded, treatment naïve Phase 3 studies.

Results: There were no differences in the safety or efficacy profile of BIC as a component of the B/F/TAF STR between females and males across the 4 Phase 3 clinical studies. Of the 1193 HIV-1 infected adults with available PK data, 148 (12.4%) were female. In the BIC Phase 1 clinical program, 598 healthy adult volunteers were administered at least one dose of BIC. Of these 598 adults in the Phase 1 studies, 243 (40.6%) were female. Based on the population PK modeling, there were no differences in BIC PK between females and males in the clinical development program of BIC. In HIV-infected subjects that were administered B/F/TAF in Phase 3 studies, the mean (%CV) BIC AUCtau and Ctrough in females was 107,000 (27) ng*h/mL and 2750 (36) ng/mL, respectively. In comparison, BIC AUCtau and Ctrough in males was 101,000 (27) ng*h/mL and 2590 (35) ng/mL, respectively.

Conclusions: In support of the initial filing of B/F/TAF for treatment of HIV-1 infection, the clinical development program of BIC included 391 females. There were no clinically relevant differences in PK, safety, or efficacy of BIC between females and males. Additionally, FTC and TAF containing antiretroviral regimens for treatment of HIV have been previously well characterized in women. As such, B/F/TAF is expected to be effective and well tolerated in women living with HIV.

8th International Workshop on HIV & Women

2 – 3 March 2018, Boston, MA, USA

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Abstracts # 33 was withdrawn from publication after the abstract review