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1

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Abstracts

1

Sex-specific analyses in oral abstracts from CROI 2019

Short W1, Smeaton L², Bares S³, Cohn S⁴, Dalla Piazza M⁵, Badal-Faesen S⁶, Gianella S⁷, Mngqibisa R⁸, Opollo V⁹, Sheth A¹⁰, Van Schalkwyk M¹¹, Poongulali S¹², Vernon C¹³, Connick E¹⁴, Gandhi M¹⁵

¹University of Pennsylvania, Philadelphia, USA, ²Harvard T. H. Chan School of Public Health, Boston, USA, ³University of Nebraska Medical Center, Omaha, USA, ⁴Northwestern University, Chicago, USA, ⁵Rutgers New Jersey Medical School, Newark, USA, ⁶Clinical HIV Research Unit, Johannesburg, South Africa, ⁷University of California San Diego, La Jolla, USA, ⁸Enhancing Care Foundation, Durban, South Africa, ⁹Kenya Medical Research Research Institute, Kisumu, Kenya, ¹⁰Emory University, Atlanta, USA, ¹¹Stellenbosch University, Cape Town, South Africa, ¹²CART CRS, VHS Infectious Diseases Medical Center, Chennai, India, ¹³Social and Scientific Systems, Silver Springs, USA, ¹⁴University of Arizona, Tucson, USA, ¹⁵University of California San Francisco, San Francisco, USA

Globally, women account for more than half of persons living with HIV (PLWH), yet remain underrepresented in research. Starting in 2018, CROI guidelines specifically recommended reporting of sex distribution and sex-adjusted analyses, but formal review showed rates of such reporting among CROI 2018 oral abstracts were low. Members of the Women's Health Inter-Network Scientific Committee (WHISC) of the ACTG and IMPAACT networks reviewed adherence to these guidelines among oral presentations from CROI 2019. Each CROI 2019 webcast of oral abstract presentations was reviewed by at least 2 WHISC members. For presentations of research relevant to both sexes, reviewers assessed whether sex distribution and sex-adjusted analyses were presented.

Overall, 85 oral abstracts (79 clinical studies and 6 pre-clinical studies) addressed a scientific question relevant to both sexes. 85% (67 of 79) of clinical studies included sex distribution compared to 76% at CROI 2018. In 10% of these (7 out of 67), sex was incorrectly referred to as gender, which was similar to CROI 2018. 51% (34 of 67) of clinical studies included $\leq 25\%$ women; 7 included no women and 3 included no men, but only 5 of these 10 communicated this restriction in the abstract title. Reporting of sex of animals in pre-clinical studies remained low (0 of 6 in 2019 and 1 of 13 in 2018). Finally, 49% (39 of 79) of clinical studies at CROI 2019 included sex-adjusted results, which was slightly higher than the 30% reporting at CROI 2018. Sex-adjusted analyses were higher among observational studies (64%, 29 of 45) than in clinical trials (29%, 10 of 34); While there was some improvement in reporting sex-specific analyses among oral presentations at CROI 2019 compared to 2018, there is still much room for

improvement. Consistent failure to report sex distribution in pre-clinical studies needs to be addressed. Reporting of sex distribution in clinical studies needs more emphasis since 15% of oral presentations failed to include this. Education regarding the difference between sex and gender is necessary and titles should indicate whether findings are restricted to one sex. Finally, enrolling adequate numbers of women to perform meaningful sex-stratified analyses and performing such analyses require additional guidance and even mandates given that over half of PLWH worldwide are women.

2

Outcomes following prenatal exposure to Dolutegravir: the Dolomite-EPPICC Study

Thorne C¹, Rasi V¹, Aebi-Popp K², Ene L³, Florida M⁴, Mendoza Palomar N⁵, Prieto L⁶, Ragone L⁷, Sconza R¹, Giaquinto C⁸, Vannappagari V⁷

¹University College London, London, United Kingdom, ²Bern University Hospital, Bern, Switzerland, ³Victor Babes Hospital, Bucharest, Romania, ⁴Istituto Superiore di Sanità, Rome, Italy, ⁵Hospital Universitari Vall d'Hebron, Barcelona, Spain, ⁶Hospital Universitario 12 de Octubre, Madrid, Spain, ⁷ViiV Healthcare, United States, ⁸University of Padua, Padua, Italy

Background: Dolutegravir (DTG) was approved for treating HIV in adults and adolescents in 2013. In 2018, the Tsepamo Study reported a significantly increased neural tube defect (NTD) risk in women conceiving on DTG (0.94%), leading to a safety alert. In July 2019, additional data showed NTD prevalence with periconception DTG to be lower than in the initial analysis, but still greater than seen for other antiretroviral exposures (0.3% vs 0.1%). We aimed to assess birth outcomes following prenatal DTG use using real-world data.

Methods: Dolomite-EPPICC is a multi-cohort European observational study of DTG use in pregnant women living with HIV and their infants. Analysis of prospectively collected individual patient data on all pregnancies with any prenatal DTG exposure and with birth outcomes reported by Feb 2019 was conducted. Periconception exposure was defined as being within the first 6 weeks of gestation (WG).

Results: A total of 453 pregnancies in 428 women from 6 cohorts were included. Women were mainly of black African (229, 54%) and white (129, 30%) ethnicity. Most (326/428, 76%) women had heterosexual HIV acquisition, 42 women were vertically infected and 11 had injecting drug use history. Of 443 singleton pregnancies, 16 were terminated (1 for birth defects, at 29 WG for neuronal migration disorder and severe microcephaly, with periconception DTG exposure) and 22 ended in spontaneous abortion; of 10 twin pregnancies, 1 was terminated and in 1, a fetus miscarried. There were 417 live-born infants (229 male, 185 female, 3 missing), born at median 39 WG (IQR 38, 40). Five infants were stillborn, all exposed to periconception DTG, none with birth defects. The Table shows birth outcomes for the 400 live-born singleton infants (no twins had birth defects); 266 (67%) had periconception DTG exposure. One neonate died at 2

days (born at 23 GW) with periconception DTG exposure. Among the 417 live-born infants there were 17 with reported birth defects (4.1%, 95% CI 2.4, 6.5); one infant had 2 defects. The 18 defects were in the following systems: genitourinary (7), heart (3), limb addition (polydactyly, 3), gastrointestinal (2), other (3); no CNS defects were reported. There were no vertical transmissions (106 infants still indeterminate).

Conclusions: The birth defect rate and pattern add further support to the current evidence base on safety of periconception DTG use. This study is ongoing, in order to provide robust pharmacovigilance data from European settings.

3

Vitamin D status in pregnant women living with HIV in Denmark and association with birth outcomes - A nationwide cohort study

Berglöv A¹, Moseholm E¹, L. Katzenstein T^{2,6}, S. Johansen I³, Storgaard M⁴, Pedersen G⁵, Weis N^{1,6}

¹Department of Infectious Diseases, Copenhagen University Hospital, Hvidovre, Hvidovre, Denmark, ²Department of Infectious Diseases, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark, ³Department of Infectious Diseases, Odense University Hospital, Odense, Denmark, ⁴Department of Infectious Diseases, Aarhus University Hospital, Skejby, Aarhus, Denmark, ⁵Department of Infectious Diseases, Aalborg University Hospital, Aalborg, Denmark, ⁶Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark

Background: Women living with HIV (WLWH) have an increased risk of low vitamin D levels during pregnancy, which may influence the risk of prematurity and birth size. The aim of this study is to evaluate the prevalence of low vitamin D level in pregnant WLWH receiving combination antiretroviral therapy (cART) in Denmark, to identify risk factors of low vitamin D level, and to assess the association between vitamin D levels and birth outcomes.

Methods: From the Danish HIV Birth Cohort (DHBC), all WLWH giving birth to one or more singleton children in Denmark in the period 2000-2018 with a vitamin D measurement during pregnancy were identified. Data was retrieved from medical records. Vitamin D deficiency was defined as 25(OH)D concentrations <25 nmol/L, insufficiency 25-50 nmol/L, and sufficiency as >50 nmol/L. Risk factors for low vitamin D (deficiency or insufficiency) was assessed using log-binomial regression models, both univariate and adjusted for maternal and HIV factors. The association between vitamin D status and birth outcomes was assessed using linear regression models for continuous outcomes (birth weight and gestational age) and log-binomial models for binary outcomes (preterm and small-for-gestational age (SGA)). Multivariate models were adjusted for maternal age, maternal country of birth, HIV RNA level prior to delivery, smoking and child sex. All models were also adjusted for intragroup correlations in children born to the same mother.

Results: Vitamin D was measured in pregnancy in 208 WLWH during the study period. The prevalence of vitamin D deficiency was 14% (n=28), insufficiency 34%

(n=71) and sufficiency 52% (n=109). All WLWH were on cART, with the majority having undetectable viral load at the time of delivery (93%). There was no difference in maternal age at delivery, pre-pregnancy BMI, season for vitamin D measurement, CD4 count prior to delivery and cART treatment regimens between WLWH with low vitamin D (deficiency or insufficiency) and WLWH with sufficient vitamin D level. Being of African origin (RR 2.68 (95% CI 1.23 : 5.98), p=0.01), Asian origin (RR 3.38 (95% CI 1.49 : 7.69), p<0.01), and HIV RNA levels \geq 50 copies/mL (RR 1.43 (95% CI 1.01 : 2.03), p=0.04) was associated with an increased risk of low vitamin D level in the multivariable models. WLWH with vitamin D deficiency had an increased risk of preterm birth (RR 2.66 (95% CI 1.10 : 6.44), p=0.03) and SGA (RR 6.83 (95% CI 1.35 : 34.70), p=0.02), compared to WLWH with sufficient Vitamin D level, after adjusting for maternal and HIV factors. A sensitivity analyses limited to WLWH of African and Asian origin did not change results significantly.

Conclusion: Low vitamin D level was prevalent among well-treated pregnant WLWH in Denmark, especially among women of African or Asian origin, and in women with detectable viral loads. Vitamin D deficiency was associated with an increased risk of preterm birth and SGA. Studies of vitamin D supplement in pregnancy among WLWH are warranted.

4

Impact of Dolutegravir based ART among Indian women

Poongulali S¹, Ezhilarasi C¹, Pooja S¹, Bhuvana A¹, Kumarasamy N¹

¹CART CRS /infectious Diseases Medical Center, Chennai, India

Background: LMICs are moving to DTG as preferred ART over EFV600/400. There is little data on treatment outcomes from LMICs especially in women who are around 50% of PLHA. Hence we undertook this study to understand the impact of DTG based ART among Indian women.

Methods: Prospective longitudinal clinic based cohort study in Chennai, India in ART naive women initiated on DTG/EFV600/EFV400 and comparing outcomes at month 12.

Descriptive statistics were calculated with mean and SD for normally distributed variables and median and IQR were calculated for variables influenced by extreme variables. Mann-Whitney U test was used to obtain the median difference. Z-test for proportions were used to compare the two proportions. Statistical analyses were performed with IBM SPSS STATISTICS software (version 24.0; SPSS, Chicago, IL). A p value less than 0.05 was considered statistically significant.

Results:

Between 2017 to 2019, 898 women initiated on (N=124) or switched to DTG based ART (N=774).

In DTG initiators, median age was 43.5yrs, CD4 495 cells/uL, weight -58.1kg.

75% initiated on TDF/XTC/DTG and 11.5% on TAF/FTC/DTG.

124, 231 and 41 women initiated on DTG, EFV600 and EFV400 based ART respectively.

Age at initiation was similar (40, 38, 36yrs).

The EFV600 initiators had lower CD4 (325, 231, 404 cells/uL). DTG initiators were most viremic (161500, 24400, 3453 copies/mL) and heaviest at baseline than EFV600/400 initiators (68, 56.8, 55.8kg).

Comparing at 12 months in DTG vs EFV600 initiators, no significant differences in immunological and virological outcomes (CD4 469 vs 427 cells/uL p= 0.171 and PVL

p=0.597) but significant number of CNS adverse events in EFV600 (2.4 vs 19% p=<0.0001). ART modification for adverse events and treatment failure were significantly higher for EFV600 (2.4 vs 19.4% p=<0.0001).

Between DTG and EFV400 initiators at 12 months, no significant differences in CD4 (469 vs 629 cells/uL p= 0.071), virological suppression (p= 0.235) but CNS adverse events was higher even for dose modified EFV400mg (2.4 vs 17% p=0.0006). Modification of ART due to adverse events and treatment failures significantly higher (2.4 vs 24.4% p=<0.0001).

There was significant weight gain across all 3 groups at month 6 and 12 but became insignificant after month 18, 24. Median weights at month 6, 12, 18, 24 are as follows

DTG – 68.7, 70.6, 62.6, 64.2, 65kg (p values = 0.015, 0.027, 0.155, 0.568),

EFV600 – 56.8, 58.4, 57.9, 59.2, 63.3kg (p values = 0.0008, 0.001, 0.631, 0.432),

EFV400 55.8, 57.6, 52.5, 54.2, 58.2kg (p values = <0.0001, <0.0001, 0.492, 0.631).

BMI changes however, were significant only in DTG initiators at month 6 (23.2, 25.2) p=0.013.

Conclusion:

1. DTG based ART is more efficacious and better tolerated compared to EFV 600 /400 in Indian women initiating ART.

2. Weight gain seems to occur in first 6 months across ART initiation in EFV and DTG based regimens. Larger, longer followup studies are needed to confirm if this initial weight gain is sustained and has any impact on occurrence of NCDs.

5

Maternal and cord plasma bioactive eicosanoid profiles differ in pregnant women living with HIV compared to HIV-negative pregnant women

Balogun K¹, Balmert L, Jao J, Sun S, Bazinet R, [Serghides L](#)

¹University Health Network, Toronto, Canada, ²Northwestern University, Chicago, United States, ³University of Toronto, Toronto, Canada

Background: Pregnant women with HIV (WHIV) are more likely to experience adverse birth outcomes, through mechanisms not fully understood. Eicosanoids play important roles in the maintenance of pregnancy and the growth and development of the fetus, but data are lacking in the context of pregnancy, HIV, and antiretroviral therapy (ART). We examined levels of bioactive eicosanoids (cell-signaling molecules derived from polyunsaturated fatty acids) in maternal and cord plasma from a Canadian cohort of WHIV and HIV negative (HIV-) pregnant women.

Methods: 76 maternal samples at gestational week 33-38 (39 WHIV, 37 HIV-) and 55 cord samples (31 WHIV, 24 HIV-) were included. All WHIV received protease inhibitor (PI)-based ART. Levels of 139 eicosanoids were measured using liquid chromatography-mass spectrometry and quantified against standard curves with a lower limit of 0.025ng. Differences between groups for each eicosanoid were assessed using Mann-Whitney test and corrected for multiple comparisons using a false discovery rate of 0.05. Orthogonal partial least squares discriminant analysis (OPLS-DA) was used to differentiate groups by maternal HIV status. Correlations between eicosanoids in maternal and cord plasma were examined by Spearman r .

Findings: A total of 53 eicosanoids were detected in maternal and 58 in cord plasma. Cord and maternal eicosanoid profiles differed, with only 3 correlating between compartments among HIV- women and none among WHIV. Compared to the HIV- group, maternal plasma in WHIV had higher levels of circulating arachidonic acid (AA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA), and elevated levels of lipoxygenase pathway metabolites including several hydroxyeicosatetraenoic acids (HETEs), which have been associated with inflammatory and vasoconstrictive properties. In cord plasma, only 3 eicosanoids differed significantly between groups. All

were vasodilating and pro-angiogenic dihydroxyeicosatrienoic acids (DHETs) (CYP/epoxygenase/soluble epoxide hydrolase metabolites of AA), and were lower in WHIV. OPLS-DA analysis showed group separation by eicosanoids with maternal and cord specimens (see figure).

Conclusion: Bioactive eicosanoid profiles differ in maternal and cord plasma, and are altered in pregnant WHIV. Elevated maternal levels of inflammatory lipoxygenase metabolites and lower cord levels of DHETs in the context of HIV and PI exposure may be indicators of, or contributors to, poor placenta function. Our findings also indicate an altered in utero environment that could contribute to fetal programming.

6

Adolescent girls and young women: should they be formally recognized as a key population for HIV?

Nash M¹

¹AIDS-Free World, Montreal, Canada

Background: Adolescent girls and young women (AGYW) are uniquely vulnerable to HIV and continue to experience much higher rates of infection compared to their male peers. Yet, they are not formally recognized as a key population for HIV. Currently, the internationally recognized key populations for HIV are sex workers, people who inject drugs, men who have sex with men, transgendered people and prisoners. In this paper, we explore whether or not AGYW meet the definition of a 'key population' for HIV.

Materials & Methods: We reviewed the definition of 'adolescents', 'youth', 'young people' and 'key populations' as defined by World Health Organization (WHO). We used publicly available data from the 2019 UNAIDS AIDSinfo database to estimate what percentage of all new HIV infections occurred among AGYW aged 15-24. We calculated the global proportion of new infections which occurred among this population as well as region-specific proportions.

Results: The WHO defines 'adolescents' as individuals in the 10-19 years age group and 'youth' as individuals in the 15-24 years age group, while 'young people' covers the age range of 10-24 years. UNAIDS provides disaggregated data for the age categories 'adolescents' and 'youth' but because of the overlap in these two categories, data on the specific population of AGYW aged 10-24 is not available. Therefore, for the purposes of this analysis, we considered the restricted age group of 15-24 to represent the population of AGYW.

The WHO defines key populations as "populations who are at higher risk for HIV irrespective of the epidemic type or local context and who face social and legal challenges that increase their vulnerability". In 2018, 17% of new infections globally occurred among men who have sex with men, 12% among people who inject drugs and 6% among sex workers. Comparatively, 18% of new HIV infections globally occurred among AGYW ages 15-24.

The region-specific proportions of new infections among this group ranged from 4% to 26%. Regionally,

AGYW accounted for the following proportion of new infections: Eastern and Southern Africa (26%), Western and Central Africa (21%), Caribbean (15%), Asia and Pacific (10%), Middle East and North Africa (9%), Latin America (7%), Eastern Europe and Central Asia (4%), and Western and Central Europe and North America (4%). AGYW accounted for more infections than any other currently recognized key population in both African regions and accounted for the second greatest number of infections in the Caribbean and Latin America regions.

Conclusions: Our simple analysis based on publicly available data suggests that AGYW likely meet the definition of a key population as defined by the WHO and therefore should be recognized as one. At a minimum, UNAIDS should publish disaggregated data for the age range representing AGYW (10-24). Too often AGYW remain invisible to decision-makers. Their designation as a key population will demand improved surveillance and accountability and, ultimately, enable the implementation of more effective HIV responses for AGYW.

7

Women on anti-retroviral therapy (ART) are less likely to achieve HIV RNA <50 copies/ml compared to men – Real World Data from the National Swedish InfCareHIV Cohort

Mellgren Å^{1,2}, Lindh M³, Brännström J^{4,5}, Reepalu A⁶, Svedhem V^{7,8}

¹Department of Infectious Diseases, Sahlgrenska University Hospital, Göteborg, Sweden, ² Department of Infectious Diseases, Institute of Biomedicine, University of Gothenburg, Gothenburg, Sweden, ³Clinic of Infectious Diseases, Södra Älvsborg Hospital, Borås, Sweden, ⁴Division of Infection and Dermatology, Department of Medicine Huddinge, Karolinska Institute, Stockholm, Sweden, ⁵Department of Infectious Diseases/Venhälsan, South Hospital, Stockholm, Sweden, ⁶Clinical infection medicine, Department of Translational Medicine, Lund University, Lund, Sweden, ⁷Department of Infectious Diseases, Karolinska University Hospital, Stockholm, Sweden, ⁸Unit of Infectious Diseases, Department of Medicine Huddinge, Karolinska Institutet, Sweden

Background: Women are underrepresented in prospective randomized clinical trials assessing ART outcome and few studies have found gender differences. Only two randomized prospective all-female ART studies have been performed, although about 20 million girls and women are living with HIV. Real World Data in unselected cohorts are needed to assess the validity of ART outcomes in different populations. The Swedish national quality registry InfCareHIV is following all diagnosed people living with HIV (PLWH) in Sweden since 1999 including sociodemographic data, CD4-cell count, ART prescriptions and HIV RNA levels. In 2011, a validated health questionnaire was added. The aim of this study was to investigate gender differences in HIV RNA levels in PLWH on ART for at least 6 months and to assess the results in relation to clinical parameters, sociodemographic data and patient-related outcomes (PROM) including adherence.

Material and Methods: PLWH (≥18 years) with a date of first ART and being on ART for ≥6 months during 2011-2017 were included. All HIV RNA measures were used. The association between viral load ≥50 cop/ml and demographic characteristics and clinical data was investigated using binomial regression with log-link function, adjusting for within individual correlation, providing relative risks (RR) with 95% CI as effect size.

Results: 8798 PLWH were followed in the InfCareHIV registry during 2011-2017. 902 (10,2% of the men,

10,3% of the women) were excluded, the majority due to not on ART ≥6 months or being <18 years. The remaining study population (n=7896) consisted of 4915 men and 2981 women. Median number of HIV RNA measures in each subject were 13 (range 1-66), including a total of 98105 HIV RNA samples. Median ART duration was 3,2 years (range 0,5-23,6), with no gender difference. Women on ART were more likely to have viral load ≥50 cop/ml compared to men with a RR of 1.20 (95%CI 1.10-1.31) p<0.001. Overall, in men 89% (52482/59001) of all HIV RNA samples were <50 cop/ml compared to 86,6% (33868/39104) of all female HIV RNA samples. 1871 (38.1%) of men and 1285 (43.1%) of the women had had a HIV RNA ≥ 50 at any time p<0.0001 (Fisher's exact test). Women had lower median nadir CD4-cell count 370 (range 0-1660) cells/uL compared to men 390 (range 0-2664) cells/uL. However, women had a numerically higher CD4-cell count on ART, median 545 (range 0-4080) cells/ul, compared to the men 540 (range 0-3660) cells/uL. Women were younger at first registry visit, median 39.1 years (range 18-81) compared to men 43 years (range 18-86,7) p<0.001. 47,1% of the overall study population had performed one or more health questionnaires, 49,7% of the men and 42,7% of the women. In this subcohort, self-reported data regarding adherence showed that 89,6% of the men and 80,5% of the women reported optimal adherence.

Conclusions: Although ART is believed to have the same efficacy in both genders, this national Swedish Real World Data demonstrate a significant difference in ART outcome between women and men. ART adherence may be one explanatory factor. It is important to include sufficient number of women in prospective clinical trials to perform gender analyses regarding ART outcome.

8

Not recommended, but done: Breastfeeding with HIV in Germany

Haberl L¹, Audebert F², Feiterna-Sperling C³, Gillor D⁴, Jonsson-Oldenbüttel C⁵, Khaykin P⁶, Kiener R⁷, Reitter A⁸, Rodríguez E⁹, Rößler S¹⁰, Schüttfort G¹, Stephan C¹, Ulmer A¹¹, von Braun A¹², von Weizsäcker K³, Haberl A¹

¹HIVCENTER, University Hospital, Goethe University Frankfurt, Frankfurt, Germany, ²Praxiszentrum Alte Mälzerei, Regensburg, Germany, ³Charité, Universitätsmedizin Berlin, Berlin, Germany, ⁴MVZ Innere Medizin Köln, Cologne, Germany, ⁵MVZ Karlsplatz, Munich, Germany, ⁶MainFachArzt, Frankfurt, Germany, ⁷University of Cologne, Cologne, Germany, ⁸Krankenhaus Sachsenhausen, Frankfurt, Germany, ⁹Praxis Dr. Cordes, Berlin, Germany, ¹⁰Klinikum Chemnitz, Chemnitz, Germany, ¹¹Gemeinschaftspraxis Schwabstraße 26, Stuttgart, Germany, ¹²University of Leipzig, Leipzig, Germany

Background: Breastfeeding (BF) in mothers living with HIV is still discussed controversially at least in resource rich countries. In Germany, HIV pregnancy guidelines strongly recommend formula feeding. Nevertheless, single cases of BF with HIV have been reported in Germany, but no systematic data collection had been performed so far. This study, titled HELENE, aims to fill this data gap.

Methods: Pre-study, we looked for German HIV treatment centers with experience in BF women. Information on HELENE was distributed via HIV organizations, e.g. German AIDS Society (DAIG), German Association of Physicians specialized in HIV care (DAGNÄ) as well as community organizations. A questionnaire covering the course of BF (e.g. duration of BF, maternal ART, VL) was distributed by a graduate student visiting each study site. Information was collected from patient files. Primary study objectives were the duration of breastfeeding and the ART of the breastfeeding mothers.

Results: Twelve German centers contributed to a total of 35 BF cases so far. Data from 3 centers are still pending. Mean age of BF women was 31.8 years (y) [18-45]. 21 women (60%) were born outside of Western Europe. BF mothers had been tested HIV positive for a mean of 7.1 years. When starting BF the mean time on ART had been 49.3 months [1-24]. 93.5% of the BF women had an HIV infection classified stage A; 6.5% stage B. The first BF case was documented in 2009. Since then the number of BF cases per year increased to 11 in 2017 and 13 in 2018. 22 (62.9%) of the BF mothers were multipara. 9/19 (47.4%) already had BF experience. The majority of the women addressed the

issue of BF already during pregnancy. At delivery all women had an undetectable viral load (<50 copies/mL). During the BF period 2 women experienced a viral rebound: 76 and 867 copies/mL, respectively. The mean duration of BF was 23.8 weeks varying from single BF of colostrum to more than 2 years. All women, except for one elite controller were treated with a NRT backbone (TDF/FTC: 32, ABC/3TC: 1, 3TC:1). 44.1% of BF mothers received NNRTI-, 32.4% INSTI-, 26.5% PI- and 2.9% an entry inhibitor containing regimen. - Mode of delivery: 66.7% vaginal delivery, 15.2% elective c-section and 18.2% emergency c-section.

Conclusions: Although breastfeeding is not recommended for mothers living with HIV in Germany, we were able to identify and analyze 35 cases retrospectively. All women had openly communicated their intention to breastfeed. Facing the small but increasing number of breastfeeding mothers living with HIV in resource rich countries like Germany, health care providers should actively address breastfeeding to pregnant women living with HIV. Guidelines are obliged to implement more detailed recommendations for a standardized management of breastfeeding women. In addition there is a need for prospective national as well as international data collection on breastfeeding with HIV to further improve PMTCT in this specific context.

9

Determinants of PrEP initiation in women at high risk for HIV

Scott R¹, Hull S², Huang J¹, Visconti A³, Coleman M⁴, Ye P¹, Lotke P¹, Balaji D¹, Ward A¹, Beverly J³, Holiday J¹, Elion R³

¹MedStar Health Research Institute / MedStar Washington Hospital Center, Washington D.C., USA, ²George Washington University, Washington, USA, ³DC Health, Washington, USA, ⁴Whitman Walker Health, Washington, USA

Background: Determinants of PrEP initiation are poorly understood in US women at risk for HIV. We sought to identify barriers and facilitators of PrEP initiation among women at risk for HIV in a high HIV prevalence community. We hypothesized that there would be significant demographic, behavioral, and psychosocial barriers to PrEP initiation.

Methods: We offered an anonymous, validated survey to women presenting for care in a hospital-based family planning clinic and a government sexual health clinic in Washington DC. We measured socio-demographics, HIV behavioral risk factors, knowledge, attitudes, norms, and self-efficacy regarding PrEP uptake. Among women at high risk for HIV acquisition (i.e. ≥ 3 reported behavioral risk factors), we performed bivariate analyses to determine associations between the above characteristics and intention to initiate PrEP, using Chi-squared tests, Fisher's exact tests, t-tests, and Mann-Whitney U tests where appropriate.

Results: 1118 women completed the survey; 32.4% (N = 362) were categorized as high risk for HIV acquisition. Among women at high risk, mean age was 27; 8.7% of respondents perceived moderate-high risk of HIV acquisition in the next 12 months and 15.7% moderate-high lifetime risk. The majority were Black (71.6%), single (88.5%), completed \geq high school/GED (94.6%), and reported household incomes $<$ \$25,000 (51.5%). 13.4% (n=48) were committed to starting PrEP in the next 12 months. Although specific behavioral risk factors for HIV were not associated with uptake intention, total number of reported risk factors for HIV (median=4, range: 3-7) was positively associated (Spearman correlation coefficient=0.11, p=0.04). Perceived risk was not associated with intention to initiate PrEP. Age, race, marital status, income, distance from clinics, insurance status, transportation, housing, illicit drug use, prior knowledge of PrEP and perceived HIV risk were not associated with uptake intention.

Prior discussion about PrEP with a medical provider was positively associated with uptake intentions (p=0.02). Positive attitudes toward PrEP were also associated with intention to initiate PrEP (p<0.01), specifically that PrEP was both "safe" (p<0.01) and "effective" (p<0.01) and would "make (women) feel in control of (their) health" (p<0.01). Perceived injunctive norms, namely support from medical providers and social networks (partner, mother, best friend, and sister) were also positively associated with intention to uptake (p<0.01). Conversely, perceived descriptive norms, specifically fear of stigma in relation to PrEP, were negatively associated with uptake intention (p<0.01). Lastly, self-efficacy, in particular, women's confidence that they could take PrEP daily, even if it gave them a stomachache or if their partner did not want them to, was positively associated with uptake intention (p<0.01).

Conclusions: Demographic factors, behavioral risks, and perceived risk were not associated with intention to initiate PrEP among women at high risk for HIV. Psychosocial factors and healthcare provider support, however, were positively associated with intention to initiate PrEP. Our findings have important implications for interventions designed to increase PrEP uptake in underserved populations; particularly, development of interventions that center on the role of providers and social networks in the destigmatization and provision of PrEP.

10

Validating incident pregnancies among women using contraceptives and antiretrovirals

Patel R¹, Jakait B², Amarin G³, Sheperd B³, Bernard C⁴, Mocello A⁵, Musick B⁴, Onono M⁶, Cohen C⁵, Bukusi E⁶, Wools-Kaloustian K⁴, Yiannoutsos C⁴

¹University of Washington, Seattle, United States, ²MTRH/AMPATH, Eldoret, Kenya, ³Vanderbilt University, , USA, ⁴Indiana University, , USA, ⁵UCSF, , USA, ⁶KEMRI, , Kenya

Background: A prior cohort study from Kenya demonstrated reduced effectiveness of contraceptive implants when used in combination with efavirenz-containing antiretroviral therapy (ART). To further validate this finding, we conducted two-phase random sampling with an expanded cohort of women living with HIV (WLHIV) using data from the East Africa International Epidemiology Databases to Evaluate AIDS.

Methods: We conducted a random sampling study of WLHIV, from 15 to 45 years of age enrolled in HIV care in western Kenya between January 2011 and December 2015, to validate the exposure of a combination of contraceptive method and ART regimen and primary outcome of incident pregnancy. We generated a cohort of WLHIV utilizing electronic medical records, and then conducted detailed file reviews for a stratified random subset of the women. We used multivariate Poisson models to compare pregnancy rates among women using different contraceptive and ART combinations, accounting for the second phase sampling with generalized raking inverse probability weighted methods. Lastly, we conducted phone interviews with a further subset of women sampled for the file reviews to compare self-reports against medical records.

Results: 85,819 women contributed 172,378 person-years (p-y) to this analysis. We conducted file reviews for 4,987 women (contributing 16,991 p-y) and phone interviews for 1,275 women (contributing 5,775 p-y). Based on data from the file review, among women using implants in the overall cohort, the pregnancy incidence was 1.1 and 3.3 per 100 p-y for nevirapine- and efavirenz-containing ART users, respectively (incidence rate ratio [IRR] 3.1, 95% CI 2.1-4.5; Table). Among the subset of women using implants with whom we conducted phone interviews, the pregnancy incidence was 2.4 and 9.0 per 100 p-y for nevirapine- and efavirenz-containing ART users, respectively (IRR 3.8, 95% CI 2.0-7.2).

Conclusions: Using probabilistic subsampling, we confirm the prior finding that contraceptive implant effectiveness is reduced with concomitant efavirenz use. Dolutegravir-containing ART, which is not anticipated to reduce implant effectiveness, should be considered for WLHIV already using or interested in contraceptive implants. Self-reports largely corroborated medical records, though the higher rates may be due to recall bias. Our robust and novel validation methodology also highlights a way forward for other studies conducted with electronic medical records.

11

Post-Exposure Prophylaxis in victims of sexual violence. Experience at the Condesa Specialized Clinic (CSC)

Cabrera López T¹, Ramos Alamillo U¹, Langarica Naves E¹, Almaraz Boyzo A¹, Nava Campos C¹, González Rodríguez A¹

¹*Clinica Especializada Condesa, Ciudad de México, Mexico*

Background: Since its implementation in 2008, the CSC's program for treating victims of sexual violence has used post-exposure prophylaxis (PEP) as an effective preventive mechanism. The majority of patients are referred for treatment by the Sex Crimes Department of the Mexico City Attorney General's Office. All patients undergo a rapid HIV test, Agp24, HBsAg, Ab VHC and T. Pallidum. Clinical risk assessment and, in the case of sexual violence having occurred within 72 hours with signs of vaginal and/or anal violence, post-exposure prophylaxis (PEP) is begun for HIV (TDF/FTC/EFV or RAL+TDF/FTC) along with prophylaxes for other STIs including Azithromycin, metronidazole and ceftriaxone; emergency anti-contraceptives are also offered. If the patient has not been vaccinated for the human papilloma virus (HPV), then the vaccine is administered while candidate patients are screened for HPV through a Pap smear and colposcopy. Weekly follow-ups are scheduled in order to monitor for adverse effects from the antiretroviral medications as well as for the detection of Agp24 in week 4. Detection of Agp24, HBsAg, AbVHC and T. Pallidum is performed at the start and week 16. The objective of the study is to demonstrate the effectiveness of post-exposure prophylaxis in victims of sexual violence.

Methods: Transversal study, including victims of sexual violence referred to the CSC's postexposure prophylaxis program during the period spanning December 1, 2008 to October 31, 2019. A description of continuous and categorical variables was undertaken.

Results: 11,139 victims of sexual violence were treated, 93.2% (n=10,383) women and 7.3% (n=816) men. Median age of 20.3 and 17.9 years, respectively. 57.7% (n=6,433) were younger than 19 years old, of which 16.2% (n=1,811) were younger than 12 years old, 22.4% (n=2,506) were between 12 and 15 years old and 18.9% (n=2,116) were between 16 and 19 years old. The postexposure prophylaxis for HIV and STIs was given to 35% (n=3,910) of patients, including 3,621 women and

289 men who showed up within the first 72 hours of sexual violence. Pregnancy resulting from sexual violence occurred in less than 1.07% (n=111) of cases, of which 109 solicited the legal termination of their pregnancy. Of the patients who were victims of sexual violence, 37.6% (n=4,192) had not initiated their sex life at the time of the event. No case of HIV resulting from sexual violence has been detected among the patients in treatment. 94.8% (n=10,567) of the patients were sent from the Sex Crimes Department of the Mexico City Attorney General's Office. The majority of patients live in the Iztapalapa, Gustavo A. Madero and Cuauhtémoc delegations of the city.

Conclusions: Post-exposure prophylaxis is effective for preventing HIV and other STIs in victims of sexual violence, as well as for early diagnosis of unwanted pregnancies resulting from sexual violence, which consequently offers the opportunity to legally terminate the pregnancy. The period following the event is critical for beginning PEP and is the cause of lost opportunities. During follow-up, no cases of HIV transmission resulting from sexual violence were observed.

12

Examining differences in syndemic factors by gender and sexual orientation among women, straight men, and gay, bisexual, and other men who have sex with men living with HIV in British Columbia, Canada

Closson K^{1,2}, Nicholson V², Lee M², Card K³, Cassidy-Matthews C^{1,2}, McLinden T², Marziali M^{2,4}, Trigg J², Wong C², Parashar S², Montaner J², Gibbs A⁵, Hart T⁶, Kaida A⁷, Hogg R^{2,7}

¹University of British Columbia, Vancouver, Canada, ²British Columbia Centre for Excellence in HIV/AIDS, Vancouver, Canada, ³Canadian Institutes of Substance Use Research, School of Public Health and Social Policy, University of Victoria, Victoria, Canada, ⁴Columbia University, New York, United States, ⁵South African Medical Research Council, Pretoria, South Africa, ⁶Department of Psychology, Ryerson University, Toronto, Canada, ⁷Faculty of Health Sciences, Simon Fraser University, Burnaby, Canada

Introduction: Co-occurring syndemic experiences of violence, substance use, and mental health disorders have been strongly linked to increased HIV-risk among key populations globally. However, little is known about how multiple, co-occurring syndemic experiences differ by gender and sexual orientation among people living with HIV (PLHIV). To advance gendered understandings of syndemic experiences of violence, substance use and mental health we calculated a syndemic index and constructed a latent syndemic model between three groups of PLHIV: women (cis and trans inclusive); heterosexual men; and gay, bisexual, and other men who have sex with men (gbMSM).

Methods: The Longitudinal Investigations into Supportive Ancillary health services (LISA) study was a cross-sectional survey conducted among 1,000 PLHIV ≥19 years of age accessing HIV treatment from 2007-2010 in British Columbia, Canada. Using LISA survey data, we assessed the prevalence of syndemic factors: violence (never, ever, in the last 6 months [recent]), depressive symptoms in the past week (10-item Centre for Epidemiological Studies Depression scale [≥10 indicating probable depression]), current street drug use (current heroin, crack, crystal meth or speedball use), and history of excessive drinking (≥2 CAGE score). We examined differences in syndemic factors, by gender and sexual orientation using two methods: (1) an additive syndemic index, and (2) a syndemic latent factor model built separately for trans-inclusive women, heterosexual men and gbMSM. Bivariate socio-

demographic and syndemic factor differences were assessed by gender and sexual orientation using chi-square and Fisher's Exact test for categorical and Kruskal-Wallis tests for continuous variables. Correlation matrices assessed crude associations between syndemic factors and a confirmatory factor analysis was conducted to assess a latent syndemic factor by gender and sexuality.

Results: Of the 999 LISA participants who had complete survey data, 264 (26.4%) were self-identified women, 382 (38.2%) were heterosexual men, and 353 (35.3%) were gbMSM. At the time of interview, over half of the women living with HIV (WLHIV) in our study hadn't completed high school, were unemployed, and had recent depressive symptoms and excessive drinking. Significant differences ($p < 0.05$) in current street drug use (49% among women, 55% among heterosexual men, and 20% among gbMSM), probable depression symptoms (67% among women, 57% among heterosexual men, and 49% among gbMSM), recent violence (17% among women, 18% among heterosexual men and 10% among gbMSM), and excessive drinking (52% among women, 64% among heterosexual men, and 35% among gbMSM) were observed. The median syndemic index count for both women and heterosexual men was 3 (quartile 1-quartile 3 [Q1-Q3]=2-4) and 2 for gbMSM (Q1-Q3=1-3). Overall, correlations between syndemic factors were positive and statistically significant. For women, correlations between excessive alcohol and current street drug use, and depressive symptoms were not statistically significant. For all groups, the strongest correlation was between current street drug use and depressive symptoms. Fit indices for latent syndemic models indicated good model fit for gbMSM and heterosexual men, however not for women.

Discussion: We examined whether there were significant differences in experiences of syndemic factors among PLHIV in BC by gender and sexual orientation. WLHIV in our sample experienced high levels of violence, substance use, and depressive symptoms; however, together these items may not fully capture a latent syndemic factor for WLHIV. In order to improve women-centered and trauma-aware care for WLHIV, future research needs to examine additional factors which may be contributing to the unique syndemic experiences of WLHIV.

13

CD4:CD8 ratio normalization among treatment naïve women

Zhabokritsky A¹, Szadkowski L¹, McClean A², Hogg R², Cooper C³, Walmsley S¹, on behalf of the CANOC collaboration

¹University Of Toronto, Toronto, Canada, ²British Columbia Centre for Excellence in HIV/AIDS, Vancouver, Canada, ³Ottawa Hospital Research Institute, Ottawa, Canada

Background: HIV infection leads to selective depletion of CD4+ T cells and an increase in CD8+ T cells resulting in an inverted CD4:CD8 ratio, which often persists despite antiretroviral therapy (ART). A large cohort study in 2015 reported 14% CD4:CD8 ratio normalization among their participants. A low CD4:CD8 ratio is associated with AIDS and non-AIDS related morbidities. Several studies have observed a trend towards higher rate of CD4:CD8 ratio normalization among women. Current treatment guidelines emphasize early initiation of ART, and there is better availability of more tolerable drugs and single tablet regimens, which improve treatment adherence. We hypothesize that treatment naïve patients starting ART in the modern era have shorter time to CD4:CD8 normalization relative to historical values, with higher rate of normalization among women.

Methods: Retrospective analysis of the Canadian Observational Cohort (CANOC), a collaboration of HIV-infected individuals initiating combination ART between 2000 and 2016. Participants starting on 2 Nucleoside Reverse Transcriptase Inhibitors (NRTIs) with either an Integrase Strand Transfer Inhibitor (INSTI), non-NRTI (NNRTI) or a Protease Inhibitor (PI) on or after January 1, 2011 with a pre-treatment CD4:CD8 ratio <1.0 and ≥2 follow-up ratios within 6 months of treatment initiation were included. Kaplan Meier estimates were used to describe time to CD4:CD8 ratio normalization (CD4:CD8 ratio ≥1.0 on 2 consecutive measures ≥ 30 days apart). Multivariable proportional hazards models were used to estimate the association between gender and time to CD4:CD8 normalization.

Results: 2650 participants (344 women and 2306 men) were included and followed for a median [IQR] 2.8 [1.5, 4.4] years. Median [IQR] age was 39 [31, 48]. In the cohort, 28.7% of women identified as Caucasian, 31.6% as Black and 39.7% as other. 34.2% of women were co-infected with Hepatitis C and 37.9% reported injection drug use. At the start of ART, average baseline CD4 count among women was 306 [159, 440] with a baseline

CD4:CD8 ratio of 0.39 [0.22, 0.60]. 113 (33%) women normalized their CD4:CD8 ratio with a 0.29 (95%CI 0.24, 0.35) probability of achieving normalization within 2 years. 700 (30%) men normalized with a 0.28 (95%CI 0.26, 0.30) probability of achieving so within 2 years (p=0.15). After adjusting for province, initial regimen, pre-treatment CD4 count, viral load, risk factor, hepatitis B and C, women were more likely to achieve normalization (HR=1.32, 95%CI 0.97, 1.81).

Conclusions: Our results show that treatment naïve subjects starting ART in the modern antiretroviral era have high rate of normalization of the CD4:CD8 ratio. In this large Canadian cohort, 33% of women normalized their CD4:CD8 ratio and women were more likely to normalize their ratio compared to men. Whether this is associated with lower rates of comorbidity or improved survival requires further study.

14a

Attitudes towards health, sexual intimacy, and child-bearing among women living with HIV in 24 countries

Okoli C¹, De los Rios P², Muchenje M³, Young B²

¹ViiV Healthcare, Brentford, United Kingdom, ²ViiV Healthcare, Research Triangle Park, US, ³Womens Health In Womens Hands, 2 Carlton St, Canada

Background: Women's sexual and reproductive health are integral elements of their fundamental human rights. Concerns about inadvertently passing HIV to sexual partners/unborn children, or worries about untoward effects of ART on health, may however be sources of worry among women living with HIV (WLHIV). We empirically investigated these concerns among an international sample of WLHIV.

Methods: Data were from the 2019 Positive Perspectives Study, a survey of 18-84-year-old male and female adults under HIV treatment from 24 countries. Our analytical sample comprised n=571 WLHIV. Descriptive analyses were performed to evaluate evolution of preferences in care and perceived treatment needs; statistical significance was set at p<0.05.

Results: Of the 571 women, 64.6% (n=369) were heterosexual, 10.2% (n=58) were women who have sex with women; the remainder identified as "other". Of the four domains of health assessed, sexual health had the lowest percentage of WLHIV reporting optimal status (46.4%), compared to physical (51.1%), mental (54.6%), and overall health (50.1%). 1 in 3 (33%) WLHIV did not report their provider telling them about "undetectable = untransmittable" (U=U) and did not believe their anti-retroviral therapy (ART) prevented transmission, many still worried about the effect of HIV medications on their body/shape (65.0%), or other unknown side effects (62.5%). Concerns about having children was the topic women felt least comfortable discussing with their provider (44.1%); the topic they were most comfortable discussing was side effects of their medication (57.8%). A shift in perceived treatment priorities was observed among WLHIV who had been on ART for ≥one year (n=562). At ART initiation, their topmost priorities had been managing symptoms or illnesses caused by HIV (49.0%), reducing side effects (47.9%), and minimizing potential long-term adverse impacts of HIV treatment (38.8%). At the

time of the survey however, the most important factors ranked by this same cohort were reducing side effects (58.7%), minimizing potential long-term impacts of HIV treatment (53.6%), and preventing transmission to a partner (50.4%).

Conclusion: WLHIV still have unmet treatment needs and are worried about broader issues outside their HIV care. A holistic consideration of psychosocial and emotional outcomes, beyond virologic control, may improve quality of life as espoused in the fourth "90" target of the Joint United Nations Programme on HIV/AIDS.

14b

Differences by gender and sexual orientation in treatment satisfaction and aspirations among persons living with HIV

Okoli C¹, De los Rios, P², Muchenje M³, Young B²

¹ViiV Healthcare, Brentford, United Kingdom, ²ViiV Healthcare, Research Triangle Park, USA, ³Womens Health In Womens Hands, 2 Carlton St, Canada

Background: Fifty two percent of people living with HIV worldwide are women. Additionally, men who have sex with women (MSW) are the third largest population living with HIV globally. Little is known about how perceived needs in antiretroviral therapy (ART) vary by gender/sexual orientation. We compared treatment-related attitudes and perceptions among women, MSW, and men who have sex with men (MSM) in 24 countries.

Methods: We analyzed pooled data for n=2,112 adults aged 18-84 years on ART who participated in the 2019 Positive Perspectives Study. Within-group differences were analyzed with Chi-square tests at p<0.05.

Results: Of participants, 86.8% (n=1,834) were from high-income countries, the remainder were from middle-income countries. Distributions of women, MSW, and MSM in high-income-countries were 28.2% (n=490); 20.7% (n=352), and 50.5% (n=858); corresponding distributions in middle-income-countries were 33.2% (n=81), 27.9% (n=68), and 38.9% (n=95), respectively. Overall, the percentage with >high school education was 71.8%, 75.5%, and 79.3% among women, MSW, and MSM respectively (p=0.003). Prevalence of various health-related outcomes were as follows among women, MSW, and MSM, respectively: self-reported viral suppression (58.8%, 53.1%, 89.1%), treatment satisfaction (62.9%, 60.0%, and 78.4%), optimal mental health (54.6%, 43.8%, and 61.7%), optimal physical health (51.1%, 48.8%, and 66.3%), optimal overall health (50.1%, 50.7%, and 62.4%), and informed by their provider about "U=U" (i.e., Undetectable=Untransmittable, 65.7%, 55.2%, and 71.7%) (all p<0.01). A higher proportion of women were optimistic that advances in HIV care would improve their overall wellbeing (66.5%, 58.3%, 57.6%, women, MSW, and MSM respectively, p=0.002). Furthermore, 65.3% of women felt their healthcare provider met their needs/priorities, vs. 60.5% MSW and

74.9% MSM (p<0.01). Significant differences in ART-related concerns were noted among women, MSW, and MSM, respectively, including worry about: impact on body/shape (65.0%, 55.5%, and 68.5%; p<0.001); risk of drug-drug interactions (52.5%, 47.9%, and 45.2%, p=0.022); and long-term impacts (67.4%, 61.0%, and 68.3%, p=0.024).

Conclusion: Women had poorer health-related outcomes compared with MSM and greater concerns regarding potential longer-term negative impacts of ART than MSW; they were also most concerned about risks of drug-drug interactions. Consideration should be given to these concerns and their impact on health-related quality of life.

14c

Gender, equality, and empowered decision making in HIV care

Okoli C¹, De los Rios P², Muchenje M³, Young B²

¹ViiV Healthcare, Brentford, United Kingdom, ²ViiV Healthcare, Research Triangle Park, US, ³Womens Health In Womens Hands, 2 Carlton St., Canada

Background: Gender inequality has contributed immensely to the spread of the HIV epidemic globally. We investigated gender inequalities in patient-reported receipt of care among persons living with HIV in 24 countries.

Methods: We used data from the 2019 Positive Perspectives Survey of 18-84-year-old adults under HIV treatment (n=2,112); virologic failure and patient-provider communication were self-reported. Country-specific Gender Inequality Index (a composite measure across three domains: reproductive health, empowerment, and labor market participation) were obtained from the United Nations Development program. Descriptive and multivariable analytical approaches were used (p<0.05).

Results: Overall, 70.4% (n=1,486) were male, 27.0% (n=571) were female, and 2.6% (n=55) identified as "other". Females were more interested in greater involvement in their treatment than males (69.4% vs. 61.0%, p<0.001). Yet, a higher proportion of females than males were uncomfortable raising concerns with their providers because of lack of confidence (22.4% vs. 17.2%, p=0.007), fear of being labelled a "difficult patient" (29.9% vs. 25.0%, p=0.022), belief that little could be done (26.1% vs. 20.5%, p=0.006), or belief that the doctor's priorities were different from theirs (23.5% vs. 19.0%, p=0.025). Stratified analyses revealed greater gender gaps in patient involvement among older adults. Among ≥50-year-olds (n=200) who had ever wanted a new regimen for their anti-retroviral treatment, 13.0% of males vs. 25.5% of females reported never asking their provider; 41.5% of males vs. 41.8% of females reported ever asking their provider but never received the medication, while 45.5% (n=91) of males vs. 32.7% (n=32) of females received the medication on asking (p=0.013); no significant gender differences existed among those aged <50 years. After adjusting for age, every unit increase in gender inequality across countries was associated with elevated odds of virologic failure (AOR=4.50, p=0.005).

Conclusions: PLHIV in countries with wider gender inequalities had poorer self-reported clinical outcomes. Despite desiring greater involvement in their care, women were less inclined to discuss with their providers. More so, fewer older females who wished to switch regimens asked their provider, or were prescribed the medication on asking, compared to their male counterparts. Providers should seek opportunities for shared decision making with all patients.

15

Impact of microbial exposures on HPV immune titers and infection among HPV-vaccinated women living with HIV

McClymont E¹, Walmsley S

¹University of British Columbia, , Canada

Background: Several co-factors may play important roles in HPV infection and immune protection following vaccination including natural exposures to HPV, vaginal microbiota, and HSV-2 co-infection. We assessed the relationship between these co-factors and HPV-related outcomes in a cohort of quadrivalent HPV-vaccinated women living with HIV (WLWH).

Materials & Methods: In this multi-site qHPV vaccine study in WLWH, three doses of vaccine were offered. Visits were at months -3, 0, 2, 6, 7, 12, 18, 24, and annually thereafter. Participants provided clinical data including surrogates of HPV exposure; serum for HPV antibody levels (cLIA); cervico-vaginal swabs for HPV DNA detection (Linear array assay) and for microbiota sequencing (cpn60 amplicon); baseline serum was tested for HSV-2 type-specific serology (Focus EIA). We used non-parametric statistics to compare HPV-related outcomes according to HSV-2 serostatus. Mixed-effects logistic regressions were used to assess factors associated with increases of ≥ 0.4 log in antibody titer.

Results: 322 participants were eligible for assessment of immune boosting due to natural HPV exposure (≥ 1 dose of vaccine, ≥ 2 serology results ≥ 2 months post-last dose). Mean age: 34 years (± 12.6). 18.9%, 12.7%, 8.7%, and 7.1% participants had a boosting event of ≥ 0.4 log units for HPV6, HPV18, HPV16, and HPV11, respectively. There was a relationship between having new sexual partners (≥ 1 vs. 0) since last visit and odds of immune boosting (for HPV16: $p=0.02$, OR=4.51, 95%CI=1.25-16.38; for HPV18: $p=0.02$, OR=2.64, 95% CI: 1.17-5.96). 283 cervico-vaginal microbiota samples from 186 women were sequenced. Samples taken at time of incident HPV detection ($n=44$) displayed significantly higher relative abundance of *Gardnerella vaginalis* A than samples without incident HPV. Samples from women with persistent oncogenic HPV infection ($n=41$) had greater relative abundances of *Porphyromonas uenonis* and *Prevotella timonensis* than samples without persistent HPV. 151 women provided baseline

serum samples for HSV-2 testing and seroprevalence was 76.2%. HSV-2 seropositive and seronegative participants had similar frequencies of HPV persistence ($p=1$), clearance of incident HPV infections ($p=0.8$), number of HPV types detected during the study ($p=0.1$), HSIL cytology during the study ($p=0.7$), and CIN2+ histology ever ($p=1$).

Conclusions: The association between an immune boosting event and having new sexual partners since the previous study visit supports natural boosting occurring as a result of sexual exposure to HPV. Our microbiome data support previous reports of association between *Gardnerella vaginalis* subtype A and HPV incidence. *Porphyromonas uenonis* and *Prevotella timonensis* should be further explored as potential co-factors in HPV persistence. HSV-2 seropositivity was not associated with multiple measures of HPV incidence, persistence, and precancerous lesions. Co-factors of natural HPV exposures and vaginal microbiota appear to play an important role in HPV immune protection and infection.

16

Women race, age and regional US & non-US subgroup analysis of dolutegravir (DTG) and non-integrase inhibitor treatment (non-INSTI) regimens in naïve randomized clinical trials at Week 48.

Quercia R¹, Rawlings K², Mole T³, Van Wyk J¹, DeMasi R², Grove R³

¹ViiV Healthcare, GSK House, Brentford, United Kingdom, ²ViiV Healthcare, Research Triangle Park, North Carolina, USA, ³GlaxoSmithKline, Stockley Park, United Kingdom

Objectives and Background: Throughout the Highly Active Antiretroviral Therapy (HAART) era there has been a difference observed in the rate of viral suppression (VS) by gender and race, probably influenced by socio-cultural and economic impact. This analysis aims to evaluate the efficacy of DTG regimens in treatment naïve women at birth by race, age and region of origin

Methods: A pooled analysis of 3 Multicentre RCTs in 20 countries, in treatment naïve subjects [Aria, Flamingo & Single] comparing DTG to non-INSTI regimens was performed. The primary endpoint was VS at W48. Efficacy and safety endpoints were assessed per original study reporting. Unadjusted VS rates were estimated using a fixed effects meta-analysis inverse-variance weighted combination of individual study estimates. Baseline covariate adjusted treatment regimen odds ratios (ORs, DTG: non-INSTI) were estimated using a fixed effects meta-analysis logistic regression of VS.

Results: 1812 ART-naïve subjects were included. DTG and non-INSTI arms were balanced on baseline factors. Median age was 36 years, 29% identified as Black and 38% were women. Virologic success (HIV-1RNA<50c/mL) at W48 for the DTG and non-INSTI arms were 83% and 72%, respectively for women (OR= 1.862, 95% CI=1.287,2.695 p= 0.0010); 78% and 69% for black women (OR = 1.489, 95% CI = 0.873,2.539 p=0.1438) and 87% and 75% for non-black women, respectively (OR= 2.281, 95% CI=1.365,3.809 p= 0.0016). There was no statistical evidence (p>0.10) that the treatment regimen OR (DTG: non-INSTI) differs between black and non-black women. The treatment regimen Odds Ratio in black women relative to non-black women was 0.653 with 95% CI of 0.311 to 1.369 p=0.2590.

The women population was also evaluated by region of origin (US vs non-US). Women in the US reached 79% vs 74% undetectability (OR=1.273, 95% CI 0.667, 2.431 p=0.4647) while women in non-US shown 85% vs 72% (OR=2.226 95%CI=1.417, 3.497 p=0.0005) for DTG vs. non-INSTI based regimens respectively

VS rates were high in women taking DTG based regimens, regardless of age stratification, < or >= 40 years old, showing numerically higher levels of VS of DTG regimens vs. non-INSTI options, <40 years old, 79% vs. 68% [OR=1.695, 95% CI=1.071,2.683 p=0.0244], respectively; >=40 years old women shown 88% vs 79% [OR=2.143, 95% CI= 1.138,4.033 p=0.0182]. No DTG regimen safety concerns were noted.

Conclusions: VS rates were numerically higher for DTG compared to non-INSTIs at W48 in women and all analysed subgroups. The explanation for US vs non-US differences are not clear, may be linked to unobserved reasons probably beyond biological diversity. The data supports higher VS in treatment naïve women on a DTG regimen compared to a non-INSTI regimen at week 48

17

ATLAS and FLAIR: efficacy, pharmacokinetics and reasons for satisfaction in women with cabotegravir & rilpivirine long acting regimen at week 48

Quercia R¹, D'Amico R², Ford S³, Patel P², Wu S⁴, Cutrell A², Chow K⁵, Polli J², Margolis D², van Solingen R⁶, Crauwels H⁶, Chounta V¹, Smith K², Spreen W²

¹ViiV Healthcare, GSK House, London, United Kingdom, ²ViiV Healthcare, Research Triangle Park, North Carolina, USA, ³GlaxoSmithKline, Research Triangle Park, North Carolina, USA, ⁴GlaxoSmithKline, Collegeville, USA, ⁵GlaxoSmithKline, Mississauga, Canada, ⁶Janssen Research & Development, Beerse, Belgium

Background: Monthly cabotegravir (CAB) + rilpivirine (RPV) long acting (LA) was noninferior to daily oral three-drug continued anti-retroviral regimens (CAR). Here, we describe the efficacy, pharmacokinetics (PK) and patient satisfaction in female participants

Methods: Using pooled data from the ATLAS and FLAIR studies, we assess HIV-1 RNA ≥ 50 c/mL at W48 (FDA Snapshot; primary endpoint), HIV-1 RNA < 50 c/mL at W48, and treatment satisfaction (HIV-Treatment Satisfaction Questionnaire) results in women. This subgroup analysis by sex at birth was pre-planned. CAB and RPV PK were descriptively summarized for the pooled population and categorized by select baseline demographics associated with PK variability.

Results: Women comprised 27.4% (162/591, LA) and 28.4% (168/591, CAR) of the participants enrolled in the pooled study population with a mean age of 41 (LA) and 43 (CAR) years. At baseline, 27.2% (44/162, LA) and 28.6% (48/168, CAR) of women had a BMI ≥ 30 kg/m² compared to 13% of men in each of the LA and CAR arms. By W48, 5/162 (3.1%) and 1/168 (0.6%) of women in LA and CAR arms had HIV-1 RNA ≥ 50 c/mL (difference in proportions [95% CI] 2.49 [-0.64, 6.54]), and 150/162 (92.6%) and 159/168 (94.6%) had HIV-1 RNA < 50 c/mL (difference in proportions [95% CI] -2.05 [-7.87, 3.46]). Efficacy rates in women were similar to those observed in men.

Following the initial injection, median plasma CAB trough concentrations were 40% lower in women than men and were 46% lower in individuals with body mass index (BMI) ≥ 30 kg/m² compared to lower BMI. These early PK differences are due to slower absorption of

CAB in women and participants with BMI ≥ 30 kg/m². At W48, greater accumulation in those with slower absorption resulted in no difference in CAB trough concentrations by sex or BMI category. PK differences early in treatment in women and individuals with BMI ≥ 30 kg/m² did not appear to be clinically significant. RPV PK did not differ with sex or BMI.

Women reported a statistically significant increase from baseline in total HIVTSQs score in the CAB + RPV LA arm compared with CAR arm (Adjusted mean difference in HIVTSQs total score [95%CI]: 4.3 [2.6, 6.1] post hoc comparison, pooled ATLAS/FLAIR, Week 44). The highest scored reasons for increased satisfaction among women taking the LA regimen were flexibility, convenience and willingness to continue with treatment.

Conclusions: In women, monthly CAB+RPV LA was non-inferior to daily oral three-drug ART regimens and demonstrated high satisfaction rates. PK differences after initial injections for CAB observed in women and participants with BMI > 30 kg/m² waned by week 48 and were not clinically significant. These results support the therapeutic potential of once-monthly CAB+RPV LA in women.

18

Dolutegravir-containing ART does not reduce etonogestrel implant concentrations

Patel R¹, Stalter R¹, Onono M², Brown E³, Adejo L⁴, Kidiga C⁵, Scarsi K⁶

¹University of Washington, Seattle, United States, ²Kenya Medical Research Institute (KEMRI), Nairobi, Kenya, ³UW-Kenya, Nairobi, Kenya, ⁴NIH, Bethesda, USA, ⁵Jaramogi Oginga Odinga Teaching & Referral Hospital (JOOTRH), Kisumu, Kenya, ⁶University of Nebraska Medical Center, Omaha, USA

Background: Concomitant use of efavirenz-containing antiretroviral therapy (ART) is known to reduce etonogestrel (ENG) concentrations, leading to reduced contraceptive effectiveness of subdermal implants. Dolutegravir (DTG)-containing ART is now the preferred first-line regimen for women of reproductive potential. However, DTG's drug-drug interactions with hormonal contraceptives have been narrowly evaluated thus far, and understanding any potential for interactions between subdermal implants and DTG is important as countries pursue national rollout of DTG-containing ART.

Methods: We conducted a prospective, open-label pharmacokinetic study among women of reproductive potential in Kisumu, Kenya. Women were either HIV-positive, virologically suppressed, and receiving DTG-containing ART for at least 30 days prior to enrollment, or HIV-negative and not receiving any antiretrovirals (control group). An ENG 68mg subdermal implant was placed as part of routine clinical care and women were enrolled in this study within 2 weeks of implant placement. Blood samples were drawn at 2, 4, 8, 12, 16, 20, and 24 weeks after study entry. We analyzed plasma ENG concentrations using a validated LC-MS/MS assay (range 25-30,000 pg/mL). We describe per visit ENG concentrations using median (range) and compare the concentrations per visit between DTG-containing ART and the control groups using geometric mean ratio (GMR; 90% confidence interval) and the Wilcoxon rank sum test.

Results: All women were black African. The median age was 35 and 25 years, and weight was 62.5 and 59.0 kg in the DTG-containing ART and control groups, respectively. Women in the DTG-containing ART group were on this ART for a median of 6.7 (range 4.3-8.3) months prior to study enrollment. ENG plasma concentrations for the DTG and control groups were 692 (470-989) and 588 (277-1050) pg/mL at week 2,

respectively, and decreased to 456 (250-720) and 268 (136-496) pg/mL by week 24, respectively (Table). ENG exposure in the DTG-containing ART group was 19-54% higher compared to controls (all $p \leq 0.05$).

Conclusions: In the first of its kind study, we observed modestly higher ENG concentrations among women using DTG-containing ART vs. HIV-negative women. Our findings suggest that no detrimental drug-drug interactions exist with concomitant use of ENG implants and DTG. DTG-containing ART represents a preferable alternative to efavirenz-containing ART for women already using or desiring an ENG implant.

19

Cabotegravir: Assessment of reproductive and developmental toxicity in animal studies¹

Ziejewski M, Stanislaus D, Romach B¹

¹ViiV Healthcare, , United Kingdom

Background: As part of pharmaceutical development of cabotegravir, an integrase inhibitor for treatment and prevention of HIV, a series of standard regulatory and investigative animal reproduction studies were conducted in rats and rabbits to evaluate potential effects on fertility, pregnancy and postnatal development of their offspring.

Materials and Methods: Cabotegravir at systemic exposures (AUC) >28 times the exposure associated with oral recommended human dose (RHD) of 30 mg was given to rats during critical phases of their reproductive lifecycles in three different studies, more specifically, prior to conception through early embryonic implantation; from implantation through organogenesis until closure of the hard palate; and from implantation throughout gestation, parturition and lactation. Cabotegravir at systemic exposures similar to the human exposure at the RHD were given to pregnant rabbits during the organogenesis period.

Results: At exposures of >28 times the RHD, cabotegravir delayed the onset of parturition in rats (majority of females delivered 1 day later than control), and in some females, this delay was associated with an increased number of stillbirths and early postnatal neonatal mortalities within the same litter; however, there was no effect on the postnatal growth and development of the surviving offspring. In an investigative study, when rat pups born to cabotegravir-treated dams were cross-fostered at birth and nursed by mothers that were not given cabotegravir, similar incidences of neonatal mortalities were observed. Conversely, there was no effect on neonatal survival of pups that were not exposed to cabotegravir during pregnancy but then nursed from birth by cabotegravir-treated mothers; indicating that lactational exposure did not contribute to neonatal deaths, but gestational exposure did. Rat systemic exposures up to 15 times the oral RHD were not associated with delayed parturition or neonatal mortality. For cesarean delivered fetuses, no adverse effects on embryo-fetal development, survival, or any effects that would explain

the delayed parturition or neonatal deaths, were observed in rats or rabbits at maternal systemic exposures that were either >28 times or similar to exposure in humans at the oral RHD, respectively. Studies in pregnant rats also showed that cabotegravir crosses the placenta and can be detected in fetal tissue.

Conclusion: Collectively, cabotegravir given to rats and rabbits at systemic exposures of ≥ 28 times or similar to the exposure in human at oral RHD, respectively, did not cause any toxicity on reproduction including spermatogenesis, ovulation, mating, fertility, implantation, embryonic survival and development, or the postnatal growth and development of offspring. However, exposures of ≥ 28 times the exposure in humans at the RHD, showed adverse effects on onset of parturition in rats which was associated with increased perinatal and neonatal deaths.

1 All studies were conducted in accordance with the GSK Policy on the Care, Welfare and Treatment of Laboratory Animals and were reviewed the Institutional Animal Care and Use Committee either at GSK or by the ethical review process at the institution where the work was performed.

20

Cabotegravir pharmacokinetic tail in pregnancy and neonatal outcomes

Spreen W¹, Patel P¹, Thiagarajah S², Ford S³, Margolis D¹, Romach B¹, Baker M⁴, Harington C¹, Schaefer M¹, Smith K¹, Vannappagari V¹

¹ViiV Healthcare, , United States, ²GlaxoSmithKline, , United Kingdom, ³GlaxoSmithKline, , United States, ⁴ViiV Healthcare, , Switzerland

Background: Cabotegravir (CAB) is a long-acting (LA) HIV integrase inhibitor in Phase 3 development for HIV treatment in combination with rilpivirine LA, and as monotherapy for HIV prevention. Injectable CAB LA, given monthly or every 2 months, maintains plasma concentrations that may persist for a year or longer following discontinuation. Nonclinical reproductive toxicology studies of CAB have not identified a birth defect risk at suprathreshold exposures. We evaluated CAB pharmacokinetics (PK) in HIV-infected women becoming pregnant and neonatal outcomes to date in ViiV-Sponsored trials.

Methods: As of December 7, 2018, ≥ 594 HIV-infected or un-infected females of reproductive potential have been exposed to ≥1 dose of CAB (oral/LA) through Phase 3 in ViiV-sponsored clinical trials. Per protocol, CAB troughs were obtained pre-injection with dosing discontinued upon pregnancy detection, however PK sampling continued quarterly for 52 weeks after last injection. Available CAB PK collected pre-pregnancy and during long term follow-up to evaluate the PK tail during pregnancy, delivery, and post-partum were summarized with birth outcomes.

Results: Thirteen pregnancies were reported during CAB dosing (4 oral CAB; 9 CAB LA), 4 resulting in live births (1 in DAIDS HPTN077 study; conception post CAB LA discontinuation), 5 terminated electively, and 4 with miscarriage in first 9 weeks of gestation. No cases of birth defects have been reported. Three HIV-infected women receiving CAB LA 400mg IM monthly injections (range: 16-176 weeks on therapy) became pregnant with subsequent live birth outcomes. All were virologically suppressed with pre-dose CAB concentrations of 2.41-4.63 µg/mL just prior to pregnancy and 2.10-5.04 µg/mL at time of pregnancy confirmation. Following CAB LA discontinuation, residual CAB concentrations remained measurable throughout pregnancy with a predicted concentration of ~0.5 µg/mL(3x PA-IC90 [0.166 µg/mL]) at delivery and remaining detectable post-partum (range: 2-23 weeks) in 2/3 women. These data are consistent with absorption-rate limited PK.

Conclusions: Pre-pregnancy CAB trough concentrations were consistent with population estimates for monthly dosing and declined slowly following drug discontinuation in pregnancy with predicted concentration 3x PA-IC90 at time of delivery in 2 of 3 HIV-infected women with live birth outcomes. CAB PK tail in pregnancy was within the expected range for non-pregnant women. Pregnancy surveillance in the treatment and prevention program continues.

Maternal CAB Concentration (µg/mL) Profile Pre-Pregnancy and During PK Tail in Pregnancy and Post-Partum			
Event	Subject No. (# weeks relative to gestational week or delivery date)		
	Subject #1	Subject #2	Subject #3
Duration of CAB LA exposure prior to pregnancy (weeks)	16	176	32
Last available pre-pregnancy CAB trough concentration	4.63	2.41	2.95
PK at pregnancy confirmation visit	4.83 (7 weeks)	2.10 (5 weeks)	5.04 (4 weeks)
Residual PK 1	2.7 (15 weeks)	1.13 (14 weeks)	0.295 (13 weeks)
Residual PK 2	1.13 (28 weeks)	0.439 (30 weeks)	Non-quantifiable (NQ) (28 weeks)
Predicted PK at delivery*	0.5 (39 weeks, healthy infant, birth weight 2800g)	0.5 (37 weeks, healthy infant, birth weight 2666g)	NQ (measured value) (38 weeks, healthy infant, birth weight unknown)
Residual PK 3	0.82 (5 weeks post-partum)	0.578 (2 weeks post-partum)	NQ (6 weeks post-partum)
Residual PK 4	0.054 (23 weeks post-partum)	0.353 (15 weeks post-partum)	NA

*Prediction based on median half-life derived from population PK model

21

Achieving the third 95: Keeping adolescents living with HIV virally suppressed in rural Nigeria in test and treat era using Continuous Quality Improvement Model of Peer Counseling & Support Group

Usman S¹

¹APIN Public Health Initiatives, Akure, Nigeria

Background: In 2016, Nigeria transitioned to “Test & Treat”, a policy where all people living with HIV (PLHIV) are treated with lifelong antiretroviral therapy (ART). There are unique challenges achieving viral suppression in ALHIV mainly due to increased stigma, discrimination & lack of social support. Hypothesis tested was antiretroviral therapy adherence effect on viral load outcome. We examined viral suppression among adolescents living with HIV in rural Western Nigeria.

Methods: This study was an observational study of adolescents living with HIV (ALHIV) already initiated on antiretroviral therapy for at least six months, enrolled in health facilities in rural parts of Western Nigeria, during a 12-month observation period starting October 2018 till September 2019. Quantitative viral load analysis was done using Polymerase Chain Reaction, Roche Cobas Taqman 96 Analyzer. All data were statistically analyzed, using Statistical Package for the Social Sciences (SPSS), with multiple comparisons done using Post Hoc Bonferonni test.

Results: A total of 316 (151 males & 165 females) subjects eligible for the study were recruited. Most of them are in the age range of 10 – 19 years, with a mean age of 13.51 ± 2.86 years. 222 (70.3%) & 52 (16.5%) of the subjects had viral suppression of <1000 RNA copies per ml and <20 RNA copies per ml respectively. The 94 subjects went through peer counseling by trained ALHIV and enhanced adherence counseling (EAC) for three months and viral load test repeated thereafter. 22 patients who had completed the three sessions of EAC and repeated viral load increased the entire suppression numbers to 244 (77.2%) & 60 (19.0%) <1000 RNA copies per ml and <20 RNA copies per ml respectively during the period of observation. The ALHIVs in the process joined the institutionalized social-media driven support group & adolescent decentralized care model ensuring they achieve the third 95 at

undetectable viral load level. ART adherence has significant effect on viral load outcome ($\chi^2 = 20.902$, $df = 1$, $P = 0.001$).

Conclusion: Antiretroviral therapy (ARV) treatment adherence counseling is key to the achieving viral suppression and determine infection prognosis, thus, developing robust continuous quality improvement (CQI) plans to address issues across the cascade ultimately helping in the monitoring of HIV/AIDS disease progression and decrease treatment failure tendencies.

22

Timing of HIV diagnosis in HIV-positive pregnant women giving birth in a high prevalence Russian region

Sconza R¹, Plotnikova Y², Plynsky A², Rozenberg V², Thorne C¹

¹UCL Great Ormond Street Institute of Child Health, London, United Kingdom, ²Irkutsk Regional Center on Prevention and Control of AIDS and Infection, Irkutsk, Russian Federation

Background: Women of childbearing age account for an increasing proportion of new HIV diagnoses in the Irkutsk oblast in the Eastern Siberian region, where 1.8% of the population is registered as HIV-positive. Antenatal HIV testing is an important pathway to HIV diagnosis, and repeat HIV testing in the third trimester is national policy. We aimed to describe the characteristics of HIV-positive women giving birth in Irkutsk and explore factors associated with timing of HIV diagnosis in relation to pregnancy and delivery.

Materials & Methods: All HIV-positive women registered to receive care at the Irkutsk Regional Centre of Prevention and Control of HIV/AIDS and Infection who gave birth to a live-born infant between May 2013 and April 2015 and had an HIV diagnosis established before/at delivery or within seven days post-partum were included. Diagnosis in pregnancy was defined as HIV diagnosis dated after the estimated conception date; 'late' diagnosis in pregnancy was defined as HIV diagnosis at >27 gestational weeks (third trimester) and included those diagnosed post-partum. Multivariable logistic regression was used to identify maternal factors associated with having a diagnosis in pregnancy (versus before pregnancy) and a 'late' diagnosis in pregnancy among those diagnosed in pregnancy. Delivery year was included in the models a priori. The final models were restricted to women with complete data on characteristics of interest (age, mode of HIV acquisition, timing of diagnosis, and gravidity) and included 978 and 492 women, respectively.

Results: There were 1018 live-birth pregnancies, all among women born in Russia. Median age at delivery was 29 years (IQR 25-32). Most (86.2%) women were primigravida. Mode of HIV acquisition was available for 978/1018 (96.1%) women; of these, 856 (87.5%) had acquired HIV through heterosexual contact and 122 (12.5%) through injecting drug use (IDU). Nearly one-tenth (96/1018, 9.4%) had documented illegal drug use during pregnancy. Overall, 514 (50.5%) women had an

established HIV diagnosis before pregnancy. Among the 504 women diagnosed in pregnancy, median gestational age at diagnosis was 23.5 weeks (IQR 15.0-31.0), and 204 (40.5%) were diagnosed 'late'. Fifty-four women were diagnosed at delivery and 13 post-partum. Most (96.8%) women received antenatal antiretroviral therapy (ART) and 21.4% (110/514) of women diagnosed before pregnancy conceived on ART. In adjusted analysis, the following factors were associated with diagnosis in pregnancy: maternal age ≤ 24 years at delivery (aOR 2.73 [95%CI 1.87,3.98] vs 30-34 years), heterosexual acquisition (aOR 1.76 [1.16,2.67] vs IDU), and primigravida (aOR 3.59 [2.35,5.48] vs multigravida). Among women who were diagnosed with HIV in pregnancy, those with IDU history were more likely to have a 'late' diagnosis than those with heterosexual acquisition (aOR 2.47; 95%CI 1.26,4.84).

Conclusion: Prevention of vertical transmission requires timely identification of undiagnosed women (including those seroconverting in pregnancy) and prompt initiation of ART for all women not on treatment at conception. Future research will further investigate factors associated with timely access to antenatal care and HIV testing and treatment, alongside pregnancy outcomes including vertical transmission.

23

Mode of birth among women living with HIV: A population-based retrospective cohort study

Shoemaker E^{1,2,3,4,5}, Saiyin T³, Smith S¹, Loutfy M^{2,6,7}, Darling L^{2,8}, Hawken S^{2,4}, Walker M^{3,9}, Fraleigh A¹, Bertozzi B¹, Johnson K¹, Kwaramba G¹, Cousineau A¹, Kendall C^{1,2,3,4,10}

¹Bruyère Research Institute, Ottawa, Canada, ²ICES, Ottawa, Canada, ³University of Ottawa, Ottawa, Canada, ⁴Ottawa Hospital Research Institute, Ottawa, Canada, ⁵University of Manitoba, Centre for Global Public Health, Winnipeg, Canada, ⁶Women's College Research Institute, Toronto, Canada, ⁷University of Toronto, Toronto, Canada, ⁸McMaster University, Hamilton, Canada, ⁹The Ottawa Hospital, Ottawa, Canada, ¹⁰Li Ka Shing Knowledge Institute of St. Michael's Hospital, Toronto, Canada

Background: Globally, women of childbearing age are among the fastest growing demographic of persons living with HIV. The incidence of HIV infections among women of reproductive age is also increasing in Canada. Continuous treatment with combination antiretroviral therapy (cART) enables women living with HIV to become pregnant without mother-to-child transmission and they are increasingly planning to become pregnant. Since 2014, guidelines no longer recommend routine elective Caesarean section for women who are virally suppressed and receiving cART. Little is known about their current maternity care service use. Our objective was to describe and assess the maternity care service use for women living with HIV in Ontario, the Canadian province with more than 14 million residents and the highest number of people living with HIV.

Materials & Methods: Our research is co-led and co-designed with women with lived experience. We conducted a retrospective population-level cohort study using linked health administrative databases at ICES. Participants are all women living with HIV who gave birth in Ontario, Canada, between 2006/07 and 2017/18. We assessed their intrapartum characteristics and used multivariable regression to determine an association between HIV status and Caesarean section birth, controlling for sociodemographic and clinical variables. The research was approved by the Research Ethics Boards of Sunnybrook Health Sciences Centre, Toronto, the University of Ottawa and the Bruyère Research Institute, Ottawa, Ontario, Canada.

Results: Since 2014, women living with HIV were significantly more likely to have a Caesarean section birth than other women (39.9% vs. 29.0%, $p < 0.001$).

The overall proportion of Caesarean sections among women living with HIV remained stable over the study period, but the proportion of primary Caesarean sections decreased between 2006-10 and 2014-18 (28.5%-19.3%), while the proportion of repeat Caesarean sections increased (13.1%-20.5%, $p = 0.013$).

Conclusions: Since 2014, proportions of primary Caesarean section have decreased among women living with HIV and are now comparable to the general population while proportions of repeat Caesarean section have significantly increased among women living with HIV over time. HIV specific knowledge is limited in the broader healthcare system and leads to an overuse of maternity care services and clinical interventions.

24

Prevalence of polypharmacy and medication use contraindicated during pregnancy among a cohort of women living with HIV who are of childbearing age, 2016-2017.

Short W¹, Nambiar P², Parker A², Mohammad E², Abernethy J¹, Cimino C¹, Koenig H¹, Momplaisir F¹, Binkley A¹

¹University of Pennsylvania, Philadelphia, USA, ²Louisiana State University, Shreveport, Shreveport, USA

Background: The risk of birth defects is influenced by timing of prenatal exposure to medications. Many women seek prenatal care after critical steps of embryonic development have already taken place, hence the importance of evaluating prescription patterns for women of childbearing age at risk for pregnancy. Additionally, the majority of women living with HIV report having greater than one unplanned pregnancy. Therefore, preconception counseling is considered an integral part of care for all women of reproductive age. Reviewing medications and their safety profile for use during pregnancy is essential. This evaluation was conducted to describe the proportion of women living with HIV who are of childbearing age on medications that are contraindicated during pregnancy due to their safety profile as well as to evaluate the incidence of polypharmacy in this patient population.

Materials & Methods: Women living with HIV aged 18-45 who presented to the outpatient HIV clinics at the University of Pennsylvania Health System (UPHS) or Louisiana State University, Shreveport (LSU) between January 2016 and December 2017 were included in this analysis. Patients were excluded if they were prescribed any form of contraception, received permanent sterilization, or were post-menopausal. The number of individual medications prescribed in the electronic medical record during the study period was documented. Chronic medications, defined as those prescribed for longer than 3 months, were analyzed. Patients were reported as experiencing polypharmacy if prescribed 5 or more medications at one time. In addition, medication that are considered contraindicated during pregnancy were reviewed and documented.

Results: A total of 340 patients met inclusion criteria for review, 212 from UPHS and 128 from LSU. Of these individuals, 266 (78%) and 116 (34%) patients experienced polypharmacy when including and excluding antiretrovirals, respectively. When antiretrovirals were included, the median number of medications prescribed was 6 (IQR 5-9) at UPHS and 6 (IQR 4.75-9) at LSU. Of the 340 patients included, 121 (36%) were prescribed at least one medication that would be considered contraindicated during pregnancy. The majority of contraindicated medications were angiotensin-converting enzyme inhibitors or angiotensin receptor blocking agents. In this cohort of women of child bearing potential only 25% had been prescribed prenatal vitamins with folic acid.

Conclusions: In our cohort of women of childbearing potential living with HIV, polypharmacy was observed in the majority of women. Thirty-six percent of women were prescribed medication that would be contraindicated if a pregnancy occurred. Given the potential risk of these medications when used at the time of conception and during pregnancy, in addition to the high incidence of unplanned pregnancies in this population, preconception counseling and contraceptive awareness must be discussed during routine clinic visits.

25

Clinical trial simulation to improve HIV pre-exposure prophylaxis dosing in pregnancy

Scott R¹, [Chaturvedula A](#)², Fossler M³, Baeten J⁴, Pyra M⁴, Mugo N⁴, Mugwanya K⁴, Hendrix C⁵

¹MedStar Health Research Institute / MedStar Washington Hospital Center, Washington, USA, ²University of North Texas, , USA, ³Trevena, , USA, ⁴University of Washington, Seattle, USA, ⁵Johns Hopkins, Baltimore, USA

Background: Several studies of pregnant women on TDF/FTC report lower TFV exposures in the 2nd and 3rd trimesters due to pregnancy-related increased volume of distribution and renal clearance. The Partners Demonstration Project showed the largest decline during pregnancy compared to non-pregnant women – 45% to 58% in TFV and active TFV diphosphate concentrations, respectively. We hypothesized that doubling the PrEP dose in pregnancy maintains the target plasma, PBMC, and tissue concentrations of TDF/FTC associated with high levels of HIV protection.

Methods: To estimate the TDF/FTC exposure associated with a 2-fold dose increase, we began with a prior population PK model of plasma TFV based on data from MTN-001, updated the model based on Partners Demonstration Project pregnancy cohort PK data, and performed an in silico simulation. We updated our prior model (NONMEM with FOCEI method for parameter estimation) by replacing creatinine clearance with trimester of pregnancy as a time-dependent covariate on clearance as the optimized final model. As the revised model fit the data well, we used it for further simulation. We simulated 1,000 women starting with a “standard” oral 300 mg daily oral TDF dose prior to pregnancy. Upon becoming pregnant, the simulated patients were split into 2 study arms through the 3 trimesters of pregnancy: 1 arm continuing on a “standard” dose and the other arm receiving “double” the standard dose. The estimated protective trough TFV concentration benchmark (35.5 ng/mL) was based on 90% sensitivity threshold for daily dosing in non-pregnant women in HPTN 066.

Results: In the non-pregnant population, our simulation showed 3.7% of women on a standard regimen would have trough levels below the protective threshold. In contrast, we found that 31.5%, 47.2%, and 62.6% of trough concentrations in the 1st, 2nd, and 3rd trimesters, respectively, were below the protective

threshold. By comparison, in the simulated double dose group, only 4.4%, 7.9%, and 14.4% of troughs fell below protective levels in the 1st, 2nd, and 3rd trimesters, respectively.

Conclusions: Our simulation shows >50% of research participants on standard dosing will have 3rd trimester trough plasma TFV concentrations below levels associated with protection. The double dose arm median TFV concentration in pregnancy is very similar to non-pregnant standard dose median TFV. The simulation provides the quantitative basis for a prospective study to evaluate a double dose to adjust for TFV PK changes in pregnancy.

26

Social media influence on the sexual behaviours of undergraduate students of the university of Buea, Cameroon.

Theckla Efeti I¹

¹Pan-african University Of Life And Earth Sciences, Ibadan, Nigeria

Background: Global use of social media and internet among youths has increased over the years. The influence of social media on social behaviour is a call for concern in Cameroon as little has been done on this phenomenon. Therefore, this study examined the influence of social media on sexual behaviour of youths in the University of Buea, Cameroon

Methodology: A descriptive cross-sectional study was conducted among 404 undergraduate students in the University of Buea, Cameroon. A multistage random sampling was used to select the respondents. A self-administered semi-structured questionnaire was used to obtain information on frequency of use and activities on social media. It also captured the usage and peer influence on social media in relation to the four measures of sexual behaviours; condom use, contraceptive use, multiple sexual partners and early sexual initiation. Data were analysed using descriptive statistics, chi square test and multiple logistic regression. All analyses were conducted at 5% level of significance.

Results: The mean age of the respondents was 21.01years \pm 2.28 and 234(57.9%) females. A total of 392 (97%) used social media and most commonly used networking site was WhatsApp (92.8%). The sexual behaviours of interest engaged in after exposure to social media was condom use (115 {28.5%}), use of other contraceptive methods (88{21.8}), early sexual initiation 32(7.9%) and multiple sexual partner practice 27(6.7%). A total of 311(77%) participants used social media daily while 204 (50.5%) used it more than three times daily. Use of other contraceptive methods increased with increase in age ($\chi^2=10.099$, $p=0.001$). A higher proportion of the males 15(8.8%) reported having multiple sexual partners as compared to 12(5.1%) female participants ($\chi^2=2.156$, $p=0.142$). Respondents who accessed social media 2 to 3 times daily were 3 times more likely to start using condoms after exposure to it as compared to those who accessed social media once daily (aOR: 2.57, CI: 1.05-6.28). Males were 2.33 times less likely to use condoms after

exposure to social media as compared females (CI=0.27-0.68, aOR=0.43). Students at higher levels (levels 300 and above) were 2 times more likely to use contraception after exposure to social media than students 100 level. (CI=1.04-3.67, aOR= 1.96)

Conclusion: The frequency of use of social media and influenced condom use and contraceptive use. However, social media use was not associated with having multiple sexual partners and early sexual initiation. The Ministry of health in Cameroon should target social media for projects geared towards youths to influence their behaviour change.

Keywords; Social media, Sexual behaviour

Word count:410

27

Why Sex make a difference in HIV clinical course? A bioinformatics analysis of differential expressed gene in male and female with HIV disease

Suwanwongse K¹, Shabark N¹

¹Lincoln Medical And Mental Health Center, New York, United States

Introduction: Human immunodeficiency virus (HIV) remains one of the most common infectious diseases that hugely decrease quality of patients' life. It is well established that there are significant gender differences in HIV disease progression and outcomes. Women with HIV disease tend to have lower viral load and favourable clinical markers in early infection but progress to AIDS faster than men. We conducted bioinformatics analysis of differential expressed gene (DEGs) in male and female with HIV disease to better understand the sex-based differences in HIV pathogenesis.

Method: The gene expression profiling datasets (GSE 140713) were obtained from the Gene Expression Omnibus database at www.ncbi.nlm.nih.gov/geo. The dataset were analyzed using GEO2R platform. The t-test was done for comparison of DEGs between females and males with HIV diseases and adjusted P-value of 0.03 by Benjamini & Hochberg method was used as a threshold for statistically significant up-regulated and down-regulated genes.

Result: A total of DEGs 21 were obtained. 14 genes were found to down-regulated in female compare to male with HIV disease, all of them locate on Y chromosome. 7 genes were found to up-regulated in female, 4 located on X chromosome. We identified one interesting gene, which most likely play a vital role in gender inequalities of HIV infection: DDX3X (t 5.3, p 0.0037). DDX3X encoded ATP-dependent RNA helicase regulating RNA metabolism and gene expression including innate immune respond to HIV and stimulation of interferon type I production. DDX3X is concomitantly needed in translation initiation of HIV mRNA. Several studies confirmed critical role of DDX3X in pathogenesis of HIV infection. Thus, different in DDX3X expression may explained a sex-bias of HIV disease prognosis.

Conclusion: The study identified DEGs in females and males with HIV disease. Different DDX3X gene expression may play a role in sex-based differences of HIV disease prognosis and drugs modifying DDX3X gene expression might help in management of HIV disease.

28

HIV transmission patterns among people who inject drugs in the United States

Sami S¹, Paneer N¹, Oster A¹, Lyss S¹, Saduvala N¹, France A¹

¹Centers For Disease Control And Prevention, Atlanta, United States

Background: HIV genetic sequence data can be used to understand patterns of HIV transmission among subpopulations. In recent years, HIV diagnoses among persons who inject drugs (PWID) have begun to rise in some demographic groups, and large outbreaks have occurred. We assessed differences in patterns of recent HIV transmission among PWID in the United States in outbreak and non-outbreak settings.

Methods: We analyzed HIV-1 polymerase sequences reported to the National HIV Surveillance System (NHSS) for persons with HIV diagnosed during 2015–2017. We used HIV-TRACE to identify closely related pairs of sequences (genetic distance $\leq 1.5\%$) that involved PWID (i.e., male PWID, female PWID, and men who have sex with men and inject drugs [MSM who inject drugs]). We assessed transmission patterns by identifying transmission categories of closely related (linked) pairs. Weighting was applied to account for persons with multiple links. Transmission patterns in eight counties in which CDC provided response support for large HIV outbreaks among PWID that occurred during 2015–2017 were compared to those in non-outbreak counties.

Results: In total, 52,977 persons with HIV diagnosed during 2015–2017 had sequences reported to NHSS, including 3,818 PWID. Of these, 2,036 (53.3%) had sequences that linked to ≥ 1 other sequence; 224 (11.0%) resided in an outbreak county at diagnosis. A higher proportion of female and male PWID in outbreak counties linked with other PWID (97.2% and 95.3%, respectively), than did female and male PWID in non-outbreak counties (40.0% and 26.0%, respectively). MSM who inject drugs also more commonly linked with other PWID in outbreak counties (59.3%) than did their counterparts in non-outbreak counties (14.8%). Linkages with MSM, heterosexuals, and other or unreported transmission categories accounted for a majority of transmissions in non-outbreak counties.

Conclusions: Our data suggest transmission patterns among PWID differ in the context of HIV outbreaks:

transmission associated with injection account for a larger portion of transmissions and sexual transmission is less predominant in outbreak compared with non-outbreak settings. Interventions to reduce HIV transmission through injection, such as access to sterile injection equipment, could reduce infections in large HIV outbreaks involving PWID; proactive implementation could reduce the occurrence of such outbreaks.

29

Disparities in PrEP uptake and adherence: implementation of routine adherence monitoring in Philadelphia PrEP clinic

Daughtridge G¹, Hebel S¹, Kahn-woods E¹, Larabee L¹, Lalley-Chareczko L², Van Buskirk G², Shaw H², Culler J², Wallace J², Koenig H^{1,2}

¹Ursure, Inc., Boston, United States, ²Philadelphia FIGHT Community Health Centers, Philadelphia, United States

Background: Pre-exposure prophylaxis (PrEP) is 99% effective at preventing new HIV infections if taken daily. In 2016, women accounted for 19% of new HIV infections in the US but comprised only 7% of all PrEP users. In addition to uptake, adherence is a critical determinant of PrEP efficacy. Multiple studies have demonstrated poor adherence to PrEP amongst women, with rates as low as 12% in the FEM-PrEP clinical trials. Still, there is a paucity of real-world clinical data describing PrEP adherence among individuals who self-identify as female.

We developed a urine-based test that measures the presence of tenofovir (TFV) – one of the components of PrEP – using a liquid chromatography mass spectrometry (LC-MS/MS) method. This test is currently used to provide enhanced adherence support for people taking daily PrEP at a health center in Philadelphia and is sent for patients who endorse daily PrEP use (i.e. not on-demand). Adherence data were analyzed to identify early trends in adherence by sub-population.

Methods: Urine samples were collected during routine appointments and analyzed using the LC-MS/MS TFV adherence test. Providers received results indicating if the patient was recently non-adherent (no dose in at least the past 48 hours) or recently adherent (at least one dose in the past 6 days). Patients with results suggesting nonadherence or suboptimal adherence received enhanced adherence counseling, per standard clinic operating procedures. Adherence test results were paired with gender and sex assigned at birth (SAAB), aggregated, and analyzed to determine adherence rates across sub-population.

Results: 185 samples were tested over a 10-month span. Across self-identified genders, 157 (85%) samples tested were from cisgender males, 8 (4%) samples were from cisgender females, 6 (3%) samples were from

people assigned male at birth who identify as females (transgender women), 4 (2%) samples were from people assigned female at birth who identify as males (transgender men), 5 (3%) samples were from people who self-identified as “other”, and 1 (1%) sample was from an individual who preferred not to disclose their gender. Across SAAB, 173 (94%) samples were tested for men and 12 (6%) samples were tested for women.

Overall, 86% of samples demonstrated recent adherence to PrEP. Adherence rates by gender were 89% for cisgender males, 50% for cisgender females, 50% for transgender women, 100% for transgender men, 80% for those self-identified as “other”, and 100% from the individual who preferred not to disclose their gender. Adherence rates by SAAB were 87% for male and 67% for female.

Conclusions: Preliminary, observational, real-world data from PrEP adherence testing at a large urban health center demonstrate early trends in adherence to PrEP across gender and SAAB. The majority of patients receiving urine adherence testing self-identified as male, aligning with the nationwide trend of low PrEP uptake among females. These data can help better target HIV prevention efforts to the patients who may most benefit from additional adherence support.

30

HIV/AIDS prevention interventions for black women in the US: A systematic review

Sophus A¹, Mitchell J¹

¹University of Hawai'i at Mānoa, Honolulu, United States

Background: Among all women in 2017, Black women represented 59% of new HIV infections. A systematic review of HIV prevention interventions for Black women in the US, which includes newer biomedical HIV prevention strategies, has not been conducted.

Materials & Methods: Electronic databases PubMed, Web of Science, Psych Info, Ebscohost, Health Source, CINAHL, and Academic Search Complete were searched. Interventions published between 2012 and 2017 were included to account for newer biomedical prevention strategies (e.g., pre-exposure prophylaxis (PrEP), treatment as prevention (TasP)) not prominent prior to 2012. Interventions specifically intended for heterosexual Black women and those that had sample populations of 50% or more Black women were included for review.

Results: 1,954 articles were identified, and 24 interventions met the inclusion criteria. Most interventions were conducted in the Southern region of the U.S. (n=16); targeted adult women (over age 18; n = 21); with no intervention being couples-based. Most interventions were also evaluated using an RCT (n=14); used a group-based approach for delivery (n=16); and were behaviorally-focused (n=24). Twenty different theoretical frameworks were identified across the 24 interventions. Nine interventions applied Social Cognitive Theory, 7 applied the Theory of Gender and Power, and 14 incorporated two or more theories. Intervention effects were stratified and described based on the serostatus of each intervention's target population. Among interventions for HIV-negative Black women (n=13), most decreased women's engagement in unprotected sex (n=10), and 6 resulted in an increase in HIV/STI knowledge. Among interventions for HIV-positive Black women (n=11), five decreased women's engagement in unprotected sex (n=5) and five increased their sample's communication skills (i.e., sexual communication, disclosure of HIV status, or communication with healthcare providers). No intervention, whether created for HIV-negative or HIV-positive Black women, was found to have increased

knowledge or use of biomedical strategies for HIV prevention (e.g., PrEP, TasP).

Conclusion: Based on our findings, improvements in HIV prevention efforts for Black women may be needed in three areas. First, few interventions targeted these subgroups: adolescent females (n = 3) and aging Black women (n = 2). Adolescents living with HIV worldwide are increasing worldwide. Moreover, U.S. HIV surveillance reports indicate individuals aged between 40 to 54 have high HIV incidence rates, with older women being more prone to having late HIV diagnoses. Increasing prevention efforts that target these age groups may prove beneficial to further reduce new HIV infections. Second, none of the interventions targeted or included couples, though many HIV-related sexual risk behaviors (e.g., condomless intercourse) are dyadic. Couples-based approaches may help address specific vulnerability and exposure women face regarding gender roles, culturally and biologically. Third, none of the interventions included information about biomedical strategies for HIV prevention. Leveraging and integrating biomedical strategies into current and future behavioral interventions may help decrease HIV incidence rates among Black women and improve the health of Black women living with HIV.

31

Gender based barriers affecting partner notification among HIV positive clients assessing care and treatment services in South East, Nigeria

Eze A¹, Aniwada E², Ifeorah J³, Agada G⁴, Nyamuda L⁵

¹Excellence Community Education Welfare Scheme (ECEWS), Umuahia, Nigeria, ²Department of Community Medicine, College of Medicine, University of Nigeria, Enugu, , Nigeria, ³Excellence Community Education Welfare Scheme (ECEWS), Owerri, Nigeria, ⁴Department of Prevention Care and Treatment, Global Fund HIV/AIDS Project, Achieving Health Nigeria Initiative. , Garki, Nigeria, ⁵Programme Management Department, Integrated Humanitarian Assistance to Northeast Nigeria Project, Family Health International (FHI 360), Maiduguri, Nigeria

Introduction: Effective approaches to HIV testing are needed to reach undiagnosed people and link them to HIV care and treatment. Partner notification helps in early diagnosis and treatment for the partners of infected individuals thereby reducing onward transmission, preventing consequences of undiagnosed infections. This study was to ascertain Gender based barriers affecting partner notification among HIV positive clients assessing care and treatment services in Imo State, Nigeria

Methods: The study was a facility based cross-sectional design. The study was conducted for about 6 weeks among HIV positive clients aged 18 years and above. Questionnaires were used in collecting information on variables studied. Chi square was used for association of experience and barriers with characteristics of clients at $p < 0.05$.

Results: Majority of participants were females 139(62.1%). counselled on partner notification 461(89.3%) agreed to partner notification 347(67.2%), elicited at least a partner before 286(59.3%) and preferred passive or self method of partner notification 213(41.3%). Most, 263(51.0%) have their partner(s) tested before, 145(28.1%) partners tested positive out of which 141(97.2%) have been linked to HIV care and treatment. Higher proportion 489(94.8%) have negative experience/perception on Gender-based Barriers on HIV Partner Notification.

Discussion: This study shows that a very high proportion of participants have been counselled on partner notification and/or sexual network testing as

well as agreed to partner notification. Also, over two third of participants have elicited at least one partner and preferred passive or self-method of partner notification. This is good and encouraging bearing in mind the aim of Partner notification which is to find and treat undiagnosed, often asymptomatic HIV infection. This study showed that majority were positive on overall perception (about 95%) as well as component of Gender-based Barriers to HIV (>75%). Some of them include; fear of violence, fear of stigmatization, fear of loss of relationship or income and cultural norms that frown on having multiple sexual partners. This current study documented that there were no statistically significant associations of age, Sex, educational level, Religion, Occupation, marital status, spouse educational level and spouse Occupation with perception/experience of gender-based barriers on HIV. Nonetheless, in this study there is no obvious gender disparity as similar proportion reported perception/experience of gender-based barriers on HIV.

Conclusion: Partner notification and/or sexual network testing was encouraging however almost all were negative on overall perception/experience on Gender-based Barriers to HIV. More dedicated attention is needed to augment current efforts in order to meet the desired success.

32

Relation between disease knowledge, antiretroviral adherence and viral outcomes in women with HIV in Chile.

Cortes C¹, Estay C²

¹Universidad de Chile, School of Medicine, Santiago, Chile, ²Universidad de Santiago de Chile, Faculty of Chemistry and Biology, Santiago, Chile

Background: Treatment compliance is essential to obtain viral undetectability. Educational interventions have shown to improve adherence. One of the most relevant factors is patient knowledge about their condition. Our study analyzes the relation between the level of knowledge about HIV/AIDS, the degree of ART adherence and virologic success.

Materials & Methods: The study was performed at Fundación Arriaran, the main HIV center in Chile. We conducted a descriptive cross-sectional cohort study. Adherence was estimated through pharmacy dispensing registries. Adherence was estimated by the number of days the patient was late in their monthly ARV pick up during 1 year. We assessed HIV/AIDS knowledge through a 25 true/false question survey developed by our group. Patients were grouped by the number of correct answers in: good [25-21], regular [20-16] and poor [≤ 15] knowledge. The survey included questions on transmission, myths about HIV, current treatment and drug interactions. It was previously validated through an expert panel. If the patients had received pharmaceutical counseling by the clinical pharmacist was registered. Viral load (VL) at the moment of the survey was included in the analysis. For statistical analyzes STATA V15.0 was used.

Results: A total of 244 patients were included. 16% (39) were women living with HIV. Median age was 42 for women and 36 years for men respectively (p 0.001). Women had significantly less years of schooling (p 0.0001). 82% of women and 88% of men belonged to the lowest two quintiles of income boroughs (p NS). Pharmaceutical counseling was received by 71,8% of women and 62,9% of men (p NS). ARV Adherence greater than 95% was reported in 42.9% of women and 52.4% of men (p 0.001). Regarding VL, 82,9% of women and 85,4% of men had <50 copies/mL. The level of HIV/AIDS knowledge measured by the survey showed that only a 15.4% of women and 19.5% has a good level (p NS). There was statistical difference among sex on the following questions: It is safe to breastfeed in

women with HIV?, Do women with HIV must receive ARV during pregnancy? (favors women correct answers p 0.0002 and p 0.001 respectively). In these two questions, it is noteworthy that 12% of women and 39% of men respond that they do not know the answer. On the question: Does HIV affects the immunological system, 96.6% of men and 87.2% of women answered correctly (p 0.04). Among the patients who received pharmaceutical counseling there was statistical difference that favors men in questions about ARV-food interactions and drug-drug interactions knowledge. (p 0.014 and p 0.05 respectively)

Conclusions: This study shows that women treated in the main HIV center in Chile have significantly less education and ARV compliance than men. They have low knowledge about their disease, but in matters related to their sex (breastfeeding and pregnancy) they perform better than men. The high rate of wrong answers in men in these same issues can lead to force their partners to take actions that are detrimental for woman health.

It is necessary to significantly improve the levels of knowledge of the disease, which will make it possible to improve adherence and therapeutic outcomes.

33

U=U among women – are we there yet?

Wroblewka A¹, Skrzat-Klapaczyńska A^{1,2}, Kowalska J^{1,2}

¹Hospital for Infectious Diseases, Warsaw, Poland, ²Medical University of Warsaw, , Warsaw, Poland

Objectives: Women living with HIV (WLWH) are particularly exposed to gynecological infections as well as sexually transmitted diseases (STD). STDs increase the risk of HIV transmission. At the same time female gender is a risk factor for suboptimal adherence. All these factors need to be incorporated in U=U counseling.

Methods: A questionnaire investigating sexual behavioral patterns, history of STDs, and partner status was carried out during routine gynecological visits in a HIV Out-Patient Clinic in Warsaw. Data on ARV treatment and the most recent laboratory values were exported from an electronic database. A statistical analyses compared the characteristics of women with detectable (HIV RNA>50 copies/ml) and women with an undetectable viral load (VL).

Result: We included 97 WLWH: 82 (84.5%) were infected through heterosexual contacts, and 13 (12.6%) through IDU. Medians: age was 39 (IQR: 35 - 45) years, time in care 10 (IQR: 3-15) years, CD4 count 598 (IQR: 404-760) cells/ μ l.

All women claimed to be on ARV treatment but 15 had detectable VL with a median of 23,931 (IQR: 4013-83587) copies/ml. Six of these (40%) had suboptimal adherence due to depression and alcohol problems. One of them took cART only during pregnancies. The main line of treatment was boosted protease inhibitors 45(46.3%) and integrase inhibitors 39(40.2%).

Ten (10.4%) who were sexually active did not know the HIV status of their partner.

Only one of the WLWH had an active chlamydia and gonorrhoea infection.

In the table we compared patients on cART who differed in the detection of viral load.

Conclusions: WLWH lead an active sex life with HIV-negative partners. The lack of adherence to ARV and the rare use of condoms can pose a risk of HIV transmission. The results of this study indicate that counseling about U=U is an important component of gynecological care for WLWH.

34

Gender-based vulnerability in women who inject drugs

Valencia J¹, Ryan P², Troya J², Gutierrez J³, Alvaro-Meca A⁴

¹Harm reduction Unit SMASD; Subdirección General de Adicciones, Madrid, Spain, ²Hospital Universitario Infanta Leonor, Madrid, Spain, ³NGO Madrid Positivo, MADRID, Spain, ⁴Rey Juan carlos University, Madrid, Spain

Background: In comparison with men, women who use drugs (WWUD) have considerably more frequent and intense experiences with interpersonal violence, sexual abuse and trauma. The aim of this study was to evaluate the prevalence of gender-based violence in a group of WWUD attended in a harm reduction setting in Madrid, Spain.

Material and methods: A cross-sectional study was conducted during a screening of blood borne infections. We included WWUD (smoked or injected heroin/cocaine) who were actively screened for HIV, HBV and HCV in a harm reduction setting in Madrid (Spain) from January to December 2017. WWUD were interviewed for gender-based abuse or violence using a face-to-face questionnaire by a trained interviewer. Aspects related to their social-epidemiological condition and gender-based vulnerability were collected.

Results: We included 109 women who were actively using drugs. The median age was 39 (IQR 35-47) years, 84.4% were Spanish born, 22.9% were homeless, 43 (41.7%) had ever used injected drugs, 29 (26.6%) were currently using injected drugs, 6 (5.8%) had HIV diagnostic, and 27.1% had mental health disorders. Aspects related to gender-based vulnerability were collected. Among those surveyed, they reported having ever suffered emotional or psychological damage (88%), having experienced at least one incident of serious physical injury by a male partner (71%), and having ever suffered sexual abuse (49%). In addition, 28% had ever exchanged sex for money/drugs, when compared to women that did not use injecting drugs, those who injected drugs had more frequently exchanged sex for money/drugs (55% vs 21%, $p=0.003$). No differences were found between positive HIV WWUD and negative HIV WWUD

Conclusions: A high proportion of WWUD suffer psychological or physical violence by partners denoting gender-based vulnerability regardless of their HIV

diagnostic. Social resources and interventions in harm reduction settings with multidisciplinary and gender-based approach should be implemented.

35

Characteristics associated with gender among older black people living with HIV

Loo T¹, Adeyemi O², Mazonson P¹, Berko J¹, Spinelli F³, Zolopa A^{3,4}

¹Mazonson & Santas Inc., Larkspur, United States, ²Cook County Health, Chicago, United States, ³ViiV Healthcare, Raleigh, United States, ⁴Stanford University, Stanford, United States

Background: The population of people living with HIV (PLWH) is aging, and black people continue to face a severe burden of HIV compared to other racial/ethnic groups. Within the black PLWH community, men and women face different challenges. This analysis uses data from an online registry called Aging with Dignity, Health, Optimism and Community (ADHOC) to describe gender differences in sociodemographic characteristics and number of comorbidities among older black PLWH.

Methods: A cross-sectional analysis of ADHOC was performed on 207 older black PLWH (age 50+) to determine associations between self-reported gender and sociodemographic, health status, and clinical indicators. These included: quality of life (PozQoL), loneliness (3-Item Loneliness Scale), anxiety and depression (Patient Health Questionnaire), stigma (Internalized AIDS-Related Stigma Scale), and resilience (Connor-Davidson Resilience Scale). Student's t-tests, Chi-square tests, and Pearson's correlations were used as appropriate.

Results: The median age of participants was 58 years (IQR: 55 - 62). Fifty percent (n=103) were women and 50% (n=104) were men. Compared to black men (BM), black women (BW) were less likely to have a college degree (12% vs 34%, $p = .0001$) and less likely to have household income greater than \$25k (11% vs 28%, $p = .0033$). There was no difference in the proportion of participants with health insurance, however BW were less likely to have private health insurance through a group (10% vs 28%, $p = .002$) and more likely to have Ryan White (26% vs 10%, $p = .0033$). BW reported having more comorbid conditions than BM (9.7 vs 6.7, $p = .0004$). Self-reported viral suppression was higher among BW than BM (95% vs 87%, $p = .046$). Additionally, BW had fewer sex partners in the past year than BM ($p < .0001$). Quality of life, loneliness, anxiety, depression, stigma, and resilience were not significantly different between BW and BM in ADHOC.

Conclusions: We found substantial gender differences in the burden of illness in older black PLWH. In these bivariate analyses, BW had more issues compared to BM with regard to education, income, health insurance quality, and comorbid conditions. Despite these challenges, BW were more likely to have undetectable viral loads and had similar psychosocial outcomes. Programs designed to improve health outcomes for older black PLWH must take into consideration the unique strengths and the unique challenges faced by black women versus black men with HIV.

36

The burden of serious non-AIDS-defining events among admitted cART-naive HIV/AIDS patients in China: An observational cohort study

Wang Y¹

¹Clinical And Research Center Of Infectious Diseases, Beijing Ditan Hospital, Capital Medical University, China, Beijing, China

Objective: The objective for this study was to elucidate the burden, risk factors and prognosis of serious non-AIDS-defining events (NADEs) among admitted cART-naive HIV/AIDS patients in China.

Methods: The evaluation of the burden, risk factors and prognosis of serious NADEs was carried out among 1309 cART-naive HIV/AIDS patients admitted in Beijing Ditan Hospital between January 2009 to December 2018.

Results. Among 1309 patients, 143 patients (10.9%) had at least one serious NADEs, including 49 (3.8%) with cerebrovascular diseases, 37 (2.8%) with non-AIDS-defining cancers, 28(2.1%) with chronic kidney diseases, 26 (2.0%) with cardiovascular diseases and 18(1.4%) with liver cirrhosis. Serious NADEs distributed in different age and CD4 levels, especially with age \geq 50 years and CD4 \leq 350cells/ul. Other traditional risk factors, including exposure to cigarette smoking(OR=1.872, CI=1.271-2.757, p=0.002), hypertension (OR=2.473, CI=1.659-3.684, p<0.001), chronic HCV infection (OR=2.765, CI=1.375-5.562, p=0.004) and hypercholesterolemia (OR=4.084, CI=1.184-14.084, p=0.026), were also associated with serious NADEs, 17 cases (1.3%) with serious NADEs were died among cART-naive HIV/AIDS patients when hospitalized, severe pneumonia (HR=6.322, CI=2.186-18.280, p=0.001) and AIDS-defining cancers (HR=5.562, CI=1.549-19.975, p=0.009) as risk factors were associated with an increased hazard of mortality among these patients with serious NADEs.

Conclusions: Serious NADEs also occurred in cART-naive HIV/AIDS patients in China with low prevalence. Our results reminded physicians that earlier screening serious NADEs, timely intervention of their risk factors and management of severe AIDS-defining events, multi-disciplinary cooperation and earlier initiation of cART was essential to reduce the burden of serious NADEs.

37

Male partners' expectations in PMTCT services in Chiradzulu district, Malawi

M'baya Kansinjiro B¹, Nyondo - Mipando A²

¹Department of Public Health, School of Public Health and Family Medicine, College of Medicine, Blantyre, Malawi, ²Department of Health Systems and Policy, School of Public Health and Family Medicine, College of Medicine, Blantyre, Malawi

Introduction: HIV and AIDS is a leading cause of morbidity and mortality among women and children worldwide. Prevention of mother to child transmission of HIV (PMTCT) is the main preventative measure for HIV infection in children. Its uptake and adherence depend on male involvement (MI). Male Involvement levels are low in Sub Saharan Africa, Malawi and Chiradzulu in particular. Lack of well stipulated roles and expectations for men in PMTCT is one of the main barriers. Studies on MI have focused on women and HCW, thereby making men silent partners.

Objectives: The main aim of the study was to explore the expectations of male partners in PMTCT services in Chiradzulu district, Malawi.

Methodology: This was a qualitative study, which involved men whose partners were pregnant or breastfeeding a child of up to 24 months, health care workers who have worked in PMTCT services for over six months and traditional leaders. Nine in-depth interviews and 12 key informant interviews were conducted using a semi-structured interview guide. Data collection was done from January to March, 2018. This study was guided by the theory of reasoned action model and generated data through in-depth interviews and from key informants. All the interviews were audio-recorded, transcribed and translated. Thematic analysis was employed to analyze data.

Results: Male partners play supportive roles, health behaviour roles for HIV prevention and decision-making roles in PMTCT. Health assessment services and health promotion activities are the major male specific services required in PMTCT services and these should be delivered at both health facility and community levels.

Conclusion: Male partners in PMTCT have expectations that need to be met at both health facility and community levels. There is need to have specific related health services that are directly provided to men along with PMTCT services at different levels in order to promote MI.

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38

Determinants of contraceptive choices among HIV- positive women of reproductive age attending for contraceptive service: - the case of Adama FGAE model clinic

Deressa B¹

¹Family Guidance Association of Ethiopia (FGAE), Adama, Ethiopia

Background: Sub-Saharan Africa is the region most severely affected by HIV [1]. Women of productive age account for 58% of the people living with HIV [2] and 53% of all adult deaths [3]. In Ethiopia, more women (2.9%) than men (1.9%) are living with HIV [4]. Most of these women are particularly vulnerable to HIV due to complex burden they have [5] including physiological, social vulnerability and gender inequalities [3]. Research questions:- what is the level of knowledge on modern contraception and types of contraceptives used and what are the factors influencing contraceptive choices among the HIV infected women of 15-49 years'

Methods:- The study was conducted at FGAE model clinic found in Adama cities Ethiopia. The study employed quantitative data to analyses. To this effect, secondary data generated by the clinic was consulted. These sources include quarter statistical report of year 2018.

Key findings:- A total of 88 (98.3%) participants participated in the study. Majority of the respondents 87 (98.8%) had heard about contraception of which 56 (64.3%) heard it from the media. The methods that were mostly used by the women were Depo-Provera 42 (47.7%), implants 21 (23.8%) and pills 3 (3.4%). Male condom was widely used at 25% due to health care providers advice. Dual method was only used by about 12 (13.6%) of the respondents. Out of 88 HIV positive respondents, only 52(59.0%) spouse know their HIV status, among them, 51(86.4%) were positive while 9(13.5%) were discordant result. Out of 51 HIV positive spouses, 32(62.7%) were started ART.

Only 21(40.3%) use condom for HIV prevention. The higher percentage 71 (80.6%) used the method of contraceptive to avoid pregnancy, 2 (2.2%) to prevent spread of HIV/AIDS and 15 (17.0%) used it to avoid pregnancy and prevent spread of HIV/AIDS at the same time. The culture of 6 (6.8%) of the women prohibit use

of contraception though they are keep in using the method secretly. 68 (77.2%) woman was a joint decision between them and their husband while 20 (22.7%) was by their own choice.

21(23.8%) agreed with the statements that there is no need of using contraceptives when one is aware of her HIV status and that use of modern contraception by a HIV positive woman increases her chance of dying earlier due to its side effects. 15(17.0%) of respondents had heard from friends that modern contraceptives are the cause of many sexually transmitted infections including HIV.

Conclusion:- Dual method was only used by a small percentage of the study participants. The high rates of unmet need for family planning among the HIV positive women in studied area, suggests that the WHO'S strategy of preventing unintended pregnancies amongst the HIV positive women to minimize vertical transmission of HIV must be reinforced. Long acting and permanent methods of contraception could fill an important gap in family planning services among this group in Adama.

39

HBV infections among HIV-infected mothers on ART and their exposed infants in a tertiary hospital, Nairobi Kenya

Kangethe J¹, Komu J², Gachuno O³

¹*Kenyatta National Hospital/ University Of Nairobi, Nairobi, Kenya,*

²*Jomo Kenyatta University of Agriculture and Technology, , Kenya,*

³*University of Nairobi, , Kenya*

Mother-to-child transmission (MTCT) of Hepatitis B virus (HBV) is responsible for more than one third of chronic HBV infections worldwide. We determined the prevalence and predisposing factors of HBV infections among HIV infected mothers and their exposed infants. A structured questionnaire was used to capture socio-demographic data and factors associated with HBV infections. 4ml of paired whole blood obtained from HIV positive mothers and their exposed infants was analyzed for Hepatitis B surface antigen (HBsAg) using both rapid and Enzyme linked immune-absorbent assay (ELISA) tests. HBsAg positive samples were further screened for HBV envelope antigen (HBeAg) using ELISA. HBsAg positive samples with both ELISA and rapid tests were subjected to a nested Polymerized chain reaction (PCR) targeting the preS1 region. A total of 534 HIV infected mothers were recruited. Mean age of mothers was 31.2 years (SD 5.4 years) and infants' median age of 6 months (IQR 3-10 months). A total of 502 (94%) of the mothers were taking TDF/3TC/NVP and 32(6%) were on AZT/3TC/NVP or EFV. 19 of 534 (3.6%) mothers were HBV positive by both HBsAg rapid and ELISA tests. All 19 HBsAg positive samples tested HBeAg negative. Of the 19 HBsAg positive samples, 12 also tested positive on PCR targeting the preS1 gene. All infants' samples tested HBV negative with all tests. History of dental surgery was associated with increased rate of HBV infection (OR 3.3 (95% CI 1.1-9.6)). HIV HAART among infected pregnant mothers prevents vertical transmission of HBV infections from mothers to exposed infants.

40

Evolution of the transmission rate of HIV-1 from mother to child in Mali from 2009 to 2018.

Sanogo A¹, Guindo I¹, Koita D¹, Guindo M¹, Kone N², Sylla A², Siby F³, Thiero T¹, Bougoudogo F¹

¹National Institute for Public Health, Bamako, Mali, ²National HIV coordination program, Bamako, Mali, ³UNICEF-Mali, Bamako, Mali

Background: The goal of eliminating mother-to-child transmission of HIV by 2020 remains somewhat remote in some sub-Saharan African countries such as Mali. Our objective is to evaluate the evolution of the transmission rate of HIV-1 from mother to child through early diagnosis by PCR for 10 years in Mali before the introduction of Points of Care in early detection.

Materials & Methods: A cross-sectional study was conducted from 2009 to 2018 to evaluate ten years of Early Inatants Diagnosis activity from 6 weeks to 18 months of age, born to HIV-1 infected mothers, and supported in the reference health centers (CSRef) of 6 health regions in Mali (Kayes, Koulikoro, Sikasso, Segou, Mopti and Bamako district). The DBS samples taken from these children were all sent to the reference laboratory located in Bamako. The DNA proviral extraction from DBS (Dried Blood Spot) was the object according to the extraction protocols of the successor kits: AMPLICOR HIV-1 DNA Test version 1.5; Cobas AmpliPrep / Taqman DNA Test version 2.0 and that of m2000rt / sp. Molecular diagnosis was performed using the same kits according to an algorithm of three identical PCRs: 1st PCR for all DBS, 2nd PCR for positives and re-application cases and a 3rd PCR in order to separate the cases of discrepancies. Epi7 was used for data entry and analysis.

Results: A total of 11,553 infants and children born to HIV-positive mothers were screened by PCR. About 80% of mothers and newborns received ARV prophylaxis, (AZT + 3TC + NVP) for mothers and AZT + NVP for newborns.

A total of 11553 HIV-1 PCRs were performed in the children enrolled in the study. According to the algorithm used in force, approximately 1025 children had a positive PCR on 11553, ie an overall transmission rate of (8.87%) and a rate ranging between 8.66% and 11.41% in 2011 and 2016. The transmission rate was relatively lower among children who received

prophylaxis, ie 5.11%. On the other hand, the rate remains high for children who have received mixed, maternal and artificial breastfeeding, ie 15.96%; 10.1% and 7.52%.

Conclusion: The rate of transmission is all the higher because of "out-protocol" cases during the study, thus writing the inadequacies in PMTCT; the Points of Care recently introduced in the EID program has boosted this activity, which remains to be improved. PCR remains a safe and effective means for the early diagnosis of HIV-1 infection in the country by 2020.

Keywords: Early diagnosis, PCR, DNA, HIV-1.

41

Factors affecting the utilization of PMTCT service among pregnant woman attending for ANC service:- the case of Adama FGAE model clinic

Deressa B¹

¹Family Guidance Association of Ethiopia (FGAE), Adama, Ethiopia

Background: Ethiopia is one of the countries in the sub-Saharan Africa that have a generalized HIV epidemic with about one million people living with HIV/AIDS. In 2010/11, the HIV incidence was estimated at 0.29% with an adult prevalence rate of 2.4% (1.9% among males and 2.9% among females) [5]. Women account for the larger proportion (59%) of people living with HIV/AIDS.

Mother-to-child transmission (MTCT) is an important source of HIV infection among Ethiopian children. To achieve the goal of reducing the number of infants with HIV, there has been a rapid scale-up of ARV therapy and HCT services in the country since 2005 [6]

Main question: Mother-to-child transmission (MTCT) of HIV remains a major public health problem and continues to account for a substantial proportion of new HIV infections among pregnant women. This study try to answer 1, what are the factors affecting the utilization of HCT?, 2. What factors affecting the utilization of ART service among HIV positive pregnant woman and their partners?

Methods:- The study was conducted at FGAE model clinic found in Adama cities Ethiopia. The study employed quantitative data to analyses the outcomes of the intervention. To this effect, secondary data generated by the clinic was consulted. These sources include, quarter statistical report and annual performance reports (year 2018).

Key findings/Results:- A total of 2664 pregnant mothers were attended the clinic for ANC service for year 2018, all pregnant mothers were received HIV pretest counseling. Out of them, only 2475 (92.9%) of them were tested for HIV. Among those refused testing (189), 34.5% were due to fear of test result. Among those tested, only 2393 (96.7%) were received their test result. Among pregnant woman who received their test

result, 26 (1.09%) was found HIV positive. Among HIV positive woman only 22(84.6%) were started ART and the remaining 15.4% didn't due to denying of the result and wanted to get retesting. Only 20 (76.9%) of HIV positive woman notify their partners, the remaining 23% didn't disclosed their result by fear of losing their marriage. Among notified partners, only 18 (69.2%) were attended the clinic and received HIV testing.

Among partners tested for HIV, 17 (94.4%) were positive and 1 partner found discordant. Among HIV positive partners, only 13 (76.4%) were started ART and the remaining didn't due to denying of the result, wanted to stay in pre ART and wanted to be healed by prayer and holy water. Regarding on number of HIV exposed infants receiving HIV confirmatory (antibody test) by 18 months" 24(92.3%) infant became HIV negative and discharged and 2 HIV Positive infant were linked to ART. linked to ART,

Conclusion:-Among 2664 ANC clients, only (92.9%) of them were tested for HIV which still shows the challenge PMTCT service. Those 15.4% HIV positive woman and 23.5% their partners, didn't take ARV therapy due to deny of the result, wanted to stay in pre ART and wanted to be healed by prayer and holy water. This made the prevention of HIV transmission very difficult.

42

Evaluation of the strategy accelerating the elimination of mother-to-child transmission of HIV by using a community-based tool "Pregnant women's tracking book" and sponsorship of seropositive pregnant women in Goudomp Health District (Sedhiou/Senegal).

Keita I¹¹Ministry Of Health And Social Action, Dakar, Senegal

Background: Border to the Republic of Guinea Bissau, the Goudomp Health District (GHD) is located in southern Senegal in the Sédhiou Region, which covers 23.9% of its surface area. It consisted of 14 Service Delivery Points (SDPs) covering 03 boroughs, 15 town halls and 270 villages/neighbourhoods. There is more than 550 staff, 90% of whom are represented by the community fabric. In 2016 GHD had 41,700 women of reproductive age, including 6,134 expected pregnancies. The HIV screening rate at the end of 2015 was 81% for pregnant women (PW) at antenatal consultations (ANCs) with a completion rate of 22%. This screening rate was 08.5% for new-borns from seropositive pregnant women (SPW). Thus the overall objective was to accelerate the elimination of mother-to-child transmission (e-MCT) of HIV by using a community-based tool "Pregnant women's tracking book" and sponsorship of SPW in GHD by the end of 2016.

Methods: The strategy consisted in the creation of a community-based tool "Pregnant women's tracking book" available in all villages/neighbourhoods, which is updated by a Community Leader in collaboration with the sponsoring midwife (SM). She is responsible for monitoring the mother-child relationship from conception to final serology in order to provide communities with equitable HIV testing and care services with a comprehensive package of care and follow-up for SPW and their children. Thus it was an observational study of an evaluative (analytical: before and after) and descriptive (retrospective cross-sectional) type of the contribution of the strategy in the area of responsibility of the GHD in 2016. Data were collected by household survey from 429 women who gave birth between 01/09/2015 and 31/08/2016 in the

district area of responsibility with a multistage cluster survey. In addition, there is a document review using the national platform for routine data management: District Health Information System 2 (DHIS2). Data entry, analysis and interpretation required Epi Info, Excel and DHIS2 software. Finally, the results are presented in the form of tables, graphs and images ; and the ethical considerations were effective.

Results: The community-based tool was available in each village/neighbourhood of the GHD, 93% of which were sponsored by the midwife sponsors of the SPW of these areas. Only the Binako Health Facility where the Head Nurse was the SPW's godmother. This strategy first boosted the use of ANC services from 71% (2015) to 89% (2016). It also increased from 8% (2015) to 49.5% (2016) upon completion of ANC. The strategy then improved from 81% to at least 87.5% the proportion of PW who were screened during ANC and received post-test counselling. The strategy has also improved the enrolment and monitoring of women and their children. Indeed, the proportion of infants born from SPW who received early diagnosis by Dried Blood Spot (DBS) during the first two months of life increased from 8% (2015) to 30% (2016). However, only 63% of SPW were on antiretroviral treatment (ART) in 2016 compared to 100% in 2015.

Conclusion: Experienced in 2016 in GHD, it was a great success in HIV care, particularly in the prevention of vertical transmission, without forgetting its positive externalities on the use and completion of ANC services.

43

Evaluation of a health improvement strategy by creating a Mobile HIV Care Team (MHIVCT) in collaboration with Community Actors (excluding mediators) in the Goudomp Health District (Sedhiou/Senegal).

Keital¹¹Ministry Of Health And Social Action, Dakar, Senegal

Background: Border to the Republic of Guinea Bissau, the Goudomp Health District (GHD) is located in southern Senegal in the Sédhiou Region, which covers 23.9% of its surface area. It consisted of 14 Service Delivery Points (SDPs) covering 03 boroughs, 15 town halls and 270 villages/neighbourhoods. There is more than 550 staff, 90% of whom are represented by the community fabric. Concerned about the accessibility of care, especially HIV-related care, the GHD created a MHIVCT in 2017 to improve the health of communities with the collaboration of this community fabric. The exit from the MHIVCT was always guided by the mapping of the prevalent cases of HIV in the district and especially based on a prioritization of multidisciplinary MHIVCT intervention areas. Thus, the overall objective of the strategy was to strengthen HIV care through the use of an MHIVCT in collaboration with Community Actors (excluding mediators) in the GHD by the end of 2017.

Methods: The strategy was to move the MHIVCT (Physician, Social Worker, HIV Data Manager, Laboratory Technician, etc.) to disadvantaged and hard-to-reach areas in order to provide communities with equitable HIV testing and care services with a comprehensive package of care and support for person living with HIV (PLWHIV). Thus, it was an observational study of an evaluative (analytical: before and after) and descriptive (retrospective cross-sectional) type of the contribution of MHIVCT in GHD area of responsibility in 2017. The data were collected by document reviews using the national platform for routine data management: District Health Information System 2 (DHIS2). Data entry, analysis and interpretation required Excel and DHIS2 software. Finally, the results are presented in the form of tables, graphs and images ; and the ethical considerations were effective.

Results: The strategy boosted HIV testing by 10% in GHD by the end of 2017. Thus the number of newly

recruited PLWHIV increased by 27.2% in 2017, including 15.2% of HIV2 and 4.5% of dual profiles. The share of voluntary screening campaign increased from 42.7% (2016) to 79.5% (2017) including vulnerable groups. Indeed, 210 Men having Sex with Men (MSM) and 60 Sex Workers (SW) were screened in 2017 compared to only 110 MSM and 485 people living with a disability in 2016. In addition, MHIVCT has also improved the enrolment and follow-up of new recruits in the active cohorte. In fact, the proportion of PLWHIV (newly screened) placed on antiretroviral treatment (ART) has increased from 73% (2016) to 94% (2017). The number of PLWHIV on ART and lost to follow-up in the area of responsibility of this district (excluding non-zones) decreased by 62.5%. Also in the follow-up of PLWHIV on ART, the proportion who received viral load increased from 37% (2016) to 46% (2017). For children born to HIV-Positive mothers, the proportion who received definitive serology increased by 62.5% in 2017. Screening for TB-HIV co-infection was boosted by 46.2% in 2017. Finally, the proportion of PLWHIV with ART who died decreased from 31% (2016) to 18% (2017).

Conclusion: Created in 2017 by GHD, the multidisciplinary MHIVCT was a great success in HIV care without forgetting its positive externalities in health.

45

Perceptions of HIV Risk among Women in Southern West Virginia

Whanger S^{1,7}, Bryan N², Bernstein M², Tolley B⁶, El-Bassell N⁵, Robinson C³, Crist A³, Boyd J^{4,7}, Wen S², Hodder S^{1,2}

¹West Virginia Clinical And Translational Science Institute, Morgantown, United States, ²West Virginia University, Morgantown, United States, ³Cabin Creek Health Systems, Dawes, United States, ⁴New River Health Association, Scarbro, United States, ⁵Columbia University, New York City, United States, ⁶FHI 360, Durham, United States, ⁷West Virginia Practice-Based Research Network, Morgantown, United States

Background: Among white persons in rural America who inject drugs, HIV diagnoses increased 25% from 2012-2016, while HIV diagnoses among other races and ethnicities have declined over the same time period. Emergence of Human Immunodeficiency Virus (HIV) among people who inject drugs in the rural United States threatens HIV elimination efforts, yet few published studies have focused on rural women's attitudes toward HIV prevention and harm reduction services. In the midst of West Virginia's (WV) first HIV outbreak related to injection drug use, 40% of identified HIV-infected persons are women. Given that southern WV counties are at the epicenter of the current opioid epidemic, we assessed attitudes toward HIV risk and prevention among women of child-bearing age for purposes of informing future HIV prevention efforts.

Methods: We conducted a mixed-methods, cross-sectional study among women (ages 18-44 years) in rural southern WV (Fayette and Kanawha Counties). Quantitative data were collected through use of audio assisted computer self-interview (ACASI). The qualitative component included a semi-structured interview comprised of open-ended questions, complemented by questions derived from existing literature relating to urban and international rural areas affected by drug addiction.

Results: Eighty-eight women participated in the study; >95% white and 30% with annual household income < \$20,000. The majority of participants, 72%, reported being tested for HIV in the past. Although 81% of the sample reported current or past illicit drug use, only 15% stated that they worried about risk of HIV infection, and of those, only 3% reported always or often worrying about becoming HIV infected. Twenty-three percent of participants reported having sex with a partner who is or has engaged in injection drug use. One participant reported having a sexual partner who

had been diagnosed with HIV. Preliminary review of the interviews found emergent themes of isolation, intergenerational drug use, and considerable community stigma surrounding illicit drug use.

Conclusions: Most southern WV women in this study did not perceive that they were at risk for HIV acquisition, suggesting that effective education on HIV risk is sorely needed. Successful implementation of HIV prevention services must address isolation among rural women at-risk for HIV acquisition and community stigma that negatively impacts availability of harm reduction services such as syringe services and pre-exposure prophylaxis to prevent HIV acquisition.

46

Black Women on PrEP in Maryland vs Alabama

Spencer G¹

¹NMAC, Washington, United States

Background: Black women account for 60% of HIV incidence among women, but only make up 13.7% of the United States population. A retrospective review of Maryland and Alabama women has been conducted. Both states are located in the U.S. South which accounts for 51% of HIV incidence in the United States and its territories. The review examines the impact of Medicaid expansion on PrEP utilization for Black women in those states. Maryland has expanded Medicaid under the provisions of the Patients Affordability and Care Act while Alabama has not expanded Medicaid. This review will look at how insurance access has affected Black women and their usage of PrEP.

Materials and methods: This is a retrospective comparative analysis of HIV-negative Black women on PrEP in Maryland versus Alabama. A thorough literature review was conducted on this topic. A general Internet search was utilized to find and decipher the need for Black women to be on PrEP based on risk criteria. Then a search for how Medicaid expansion affected Black women's usage of PrEP based on publicly available data on insurance coverage between the two states. The research was synthesized to find the conclusion.

Results: It is estimated that every 35 minutes a Black woman in the United States will test positive for HIV. In Maryland 2016, Black women living with HIV were 17.7 times more than White women to acquire HIV. In Alabama 2016, Black women living with HIV was 10.7 times more likely to acquire HIV than White women. In 2017, Black women accounted for 4.5% of PrEP users. In the same year, Maryland had a total of 1438 PrEP users and Alabama had 629 PrEP users. In Alabama, it is estimated that 44 Black women were using PrEP that year. Based off of the national level of Black women using PrEP, it can be assumed that Maryland had 65 black women using PrEP in that year. The PrEP to needs ratio was 2.4 in states with Medicaid expansion (Maryland) and 1.1 in states without Medicaid expansion (Alabama).

Conclusion: Research found that Maryland has more Black women on PrEP than Alabama due to Medicaid expansion allowing more people to have access to PrEP. It can be inferred that Medicaid expansion impacts PrEP utilization for Black women. Expanded data analysis will be needed to explore the impact of physician offer of PrEP; internalized and externalized stigma of PrEP utilization; and availability of culturally-responsive community education tailored for Black women.

47

The role of female sex partners of people who inject drugs in better uptake of retention in HIV Services

Gogia M¹, Jikia G

¹Georgian harm reduction network, Tbilisi, Georgia

Background: PWIDs remain one of the most vulnerable population to HIV in Georgia. Heterosexual transmission rate of HIV is increasing continuously during recent years and became the dominant 63% among new HIV registered cases, while IDU associated transmission decreased from 43% (2012) till 15% in 2017. 14 Harm reduction sites have been providing comprehensive services to 30,000 PWIDs annually within the GFATM program since 2006. From 2016 the program covers sex partners of PWIDs with HIV prevention services to support safer behavior. Majority of sex partners of PWIDs (90-92%) are women.

Methods: The qualitative research methods (in-depth interviews and focus group discussions) were applied to identify 1)attitudes, motivations and needs of sex partners of PWIDs, 2)barriers and facilitators for involvement in HIV prevention programs 3)services needed for sex partners. The convenience sampling method was used to recruit PWIDs, sex partners and harm reduction service providers. The study was provided in 5 cities of Georgia.

Results: The following barriers were revealed for female sex partners of PWIDs: fear of HIV testing and associated stigma; Low awareness of HIV transmission risks and the importance of testing; PWIDs don't allow their sex partners to be tested on HIV; Low awareness about anonymous free HIV testing services; Feeling of shame to do HIV testing, especially in small cities; Lack of women oriented services at harm reduction sites; Negative approach towards PWIDs from society and criminalization of drug consumption in the country. The needed services for them were free HIV and HCV testing; medical consultations and referral to free treatment (HIV, HCV, Syphilis, TB, reproductive healthcare) programs.

Conclusions: More efforts are needed to address the barriers revealed by this study. Harm reduction program personnel should increase motivation of sex partners to do HIV and other testing; Risk counseling of couples should be enhanced for decreasing HIV associated risks and better utilization of harm reduction services; Besides, women oriented services should be developed and adjusted to the needs of sex partners for better uptake of retention in HIV Services of PWIDs.

48

Women who inject drugs and harm reduction in Georgia

Gogia M¹, Kutateladze K¹

¹Georgian harm reduction network, Tbilisi, Georgia

Background: PWIDs remain one of the most vulnerable population to HIV in Georgia. Heterosexual transmission rate of HIV is increasing continuously during recent years and became the dominant 63% among new HIV registered cases, while IDU associated transmission decreased from 43% (2012) till 15% in 2017. 16 Harm reduction sites have been providing comprehensive services to 30,000 PWIDs annually within the GFATM program since 2006.

Women represent the minority of program beneficiaries 5-7% in 2017-2019. Peer-Driven Intervention (PDI) is periodically used to attract new women IDUs in harm reduction program. The purpose of the study is to assess risky behavior of PWIDs, among them women recruited by PDI.

Methods: Cross-sectional study with chain referral model was applied to recruit hidden population. Direct questioning was performed in 11 cities of Georgia during 5 month in 2019. Monetary incentives were used to attract new PWID in PDI. 3 coupons were distributed per one PWID, additional incentive was given to recruit women PWIDs. Risk Assessment Battery (RAB index) was applied to assess sex and injecting behavior.

Results: In total 5.998 coupons distributed, 1990 PWIDs (33%) had returned to program, among them 225 were women. The average age of the women respondents is 35. Their main source of income is money from various support (friend/relatives, borrowed money, social). They mostly live on rent or in shelter. Women's injection Drug Use Practice is 6.83 years (man 9.18) Men (on average 14 days) more frequently use drugs during a month compared to women (on average 10 days) ($p=0.000$), however, also, men mention injection use in larger groups compared to women ($p=0.000$). Besides, men (12%) have more experience in OST treatment compared to women (2% $p=0.014$). RAB index for women (0.24) slightly exceeds the one for men (0.26).

Conclusions: low enrollment of women in the study and low enrollment in OST program may be conditioned by high degree of self-stigma. Women PWIDs mostly have problem regarding of housing, economic dependence on relatives and partners. Special programs should be elaborated that

should address women's basic health and social needs. Women friendly services should be developed for PWID at needle and OST programs.

49

Barriers to vaginal microbicide trials in Nigeria

Onigbogi O¹, Onigbogi M

¹College Of Medicine, University Of Lagos, Lagos, Nigeria

Background: There has been some unsuccessful clinical trials for vaginal microbicide in Nigeria. Many of these trials had limited community acceptability. This study therefore was conducted to assess the willingness to participate as subjects in future vaginal microbicide trials in Lagos, Nigeria.

Materials and methods: Self administered questionnaires in English language were completed by 283 respondents. SPSS version 15 data editor was used to analyze data. Univariate Odds Ratios and 95% Confidence Intervals (95 % CI) were used to determine the correlates of willingness to participate (WTP) in the trials.

Results: A total of 118 (41.6%) of the respondents reported that they will be willing to participate in future vaginal microbicide trials. Decreased WTP was associated with concerns about physical harm (OR = 0.62, 95% CI: 0.21–0.54), social stigmatization (OR = 0.71, 95% CI: 0.42–0.68) and coloring of sample microbicides (OR = 0.81, 95% CI: 0.46–0.63). Increased WTP was associated with involvement in high risk sexual behavior (OR = 1.25, 95% CI: 1.10–1.49), higher levels of awareness about HIV/AIDS (OR = 1.87, 95% CI: 1.34–1.93) and monetary incentives (OR = 1.12, 95% CI: 1.03–1.32).

Conclusions: The low level of willingness recorded indicates that much work still needs to be done in educating subjects in future microbicide trials about their safety. Incentives should also be considered for subjects as a part of the planning to encourage greater participation.

50

Achieving the third 95: Keeping pregnant women living with HIV virally suppressed in rural HIV clinics in Western Nigeria

Usman S¹, Adebajo A¹, Akinbinu B¹, Udechukwu C¹, Ale J¹, Ogboghodo E¹, Emeh A¹, Chiedozi A¹, Fatunsi E¹, Ariyo A¹, Suraju A¹, Anugba E¹, Owolagba F¹, Akande P¹, Jolayemi T¹, Okonkwo P¹

¹APIN Public Health Initiatives, Akure, Nigeria

Background: In resource-limited settings, where genotypic drug resistance testing is rarely performed and unsuppressed viral load outcome is a function of poor drug adherence, programmatic approaches in scaling up optimal adherence is essential. This has associated concerns for linkage to ART & subsequently viral suppression, with particular concern for these patients living with HIV. Hypothesis tested was antiretroviral therapy adherence effect on viral load outcome. We examined viral suppression among pregnant women living with HIV in rural Western Nigeria.

Methods: This study was an observational study of pregnant & breast living with HIV already initiated on antiretroviral therapy for at least six months, enrolled in health facilities across supported facilities in rural parts of Western Nigeria, during a 12-month observation period starting October 2018 till September 2019. Quantitative viral load analysis was done using Polymerase Chain Reaction, Roche Cobas Taqman 96 Analyzer. All data were collected using Epidata & statistically analyzed using Statistical Package for the Social Sciences (SPSS) version 23.0, with multiple comparisons done using Post Hoc Bonferonni test.

Results: A total of 120 pregnant women eligible for the study were recruited. Most of them are in the age range of 25 – 34 years, with a mean age of 28.78 ± 5.13 years. 103 (85.8%) & 24 (20.0%) of the women had viral suppression of <1000 RNA copies per ml and <20 RNA copies per ml respectively during the period of observation. 82 (68.3%) of pregnant women commenced on tenofovir, lamivudine & efavirenz (TLE) combination, from which 40 (48.7%) transitioned to tenofovir, lamivudine & dolutegravir (TLD) in the course of the pregnancy. ART adherence has significant effect on viral load ($\chi^2 = 5.86$, $df = 1$, $P = 0.001$).

Conclusion: Antiretroviral therapy (ARV) treatment adherence counseling is key to the achieving viral

suppression and determine infection prognosis, thus, developing robust continuous quality improvement (CQI) plans to address issues across the cascade ultimately helping in the monitoring of HIV/AIDS disease progression and decrease treatment failure tendencies. This will help more patients stay on first line regimen and prolong their life expectancy, indicating that the UNAIDS last 95 target is achievable among pregnant and breastfeeding women.

51

Pre-exposure prophylaxis (PrEP) in clinical settings in South-Western Nigeria: Implications for country-wide implementation

Usman S¹, Usman I²

¹APIN Public Health Initiatives, Akure, Nigeria, ²Ladoke Akintola University of Technology, Ogbomoso, Nigeria

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

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

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

Conclusion: Healthcare professionals in public hospitals in Nigeria are PrEP aware and willing to prescribe, but few have actually ever done the prescription. Regular supply of drugs for pre-exposure prophylaxis purpose and addressing the potential safety issues and medication-related adverse effects will help aid the PrEP implementation effort nationwide.

52

Patterns and correlates of Gender Based Violence in rural and urban South African communities

Usman S¹, Tshuma N¹, Nubi P¹

¹Best Health Solutions, Johannesburg, South Africa

Background: Violence is the intentional use of physical force or power, threatened or actual, against oneself, another person, a group or community that either results in or has a high likelihood of resulting in injury, psychological harm or death. The objective of the study was to determine the incidents & risk factors for gender based violence in South Africa.

Methods: This study was a cross sectional study. Data was collected by trained volunteers and supervised by appointed supervisors and investigators, by a face-to-face interview using a pre-tested structured questionnaire on GBV. Frequency count was generated for all variables and statistical test of significance was performed with Chi-Square test.

Results: A total of 145 consenting respondents participated with a mean age \pm SD of 31.93 \pm 11.26 years. 73 (50.3%) have experienced physical violence with 47 (32.4%) beaten, slapped and stabbed & 29 (20.0%) of the incidents occurring within the last 6 months. 34 (23.4%) have experienced sexual violence mostly sexual touch (breast/buttock), attempted rape & rape. 21 (14.5%) have had an unwanted pregnancy with 6 (4.1%) aborted. 86 (59.3%) have experienced emotional violence either verbal insult or threat. Partner alcohol consumption is associated with experiencing physical violence ($\chi^2 = 4.32$, $df = 1$, $P = 0.001$) with higher odds (OR: 2.01, 95% CI: 1.04 – 3.89).

Conclusion: Gender-based violence is common in South Africa with alcoholism being a serious risk factor for this violence in the society thus alcohol control law implementation is key to halting this trend.

53

Accelerated HIV case finding & bridging enrolment gap for key populations in Western Nigeria: A breakeven in achieving UNAIDS fast track 95-95-95 targets

Usman S¹

¹Apin Public Health Initiatives, Akure, Nigeria

Background: The clock is steadily ticking towards 2020 when the UNAIDS 95-95-95 global target in the fight against HIV/AIDS is hoped to be achieved. The hypothesis tested is the significant association between youthful age and HIV test outcome. The aim of the study was to engage in an accelerated HIV case finding and ensure enrolment into care among key populations in Western Nigeria fulfilling the first & second 90 of the UNAIDS targets.

Materials/methods: Lay Adhoc Staff/volunteers were purposely selected and trained. Consenting prison inmates had their blood samples taken and tested following the country's HIV serology National testing algorithm, using the recommended HIV testing kits. Those who tested positive went through a retesting process in the laboratory and confirmed positive. Post-test counselling was then conducted.

Results: A total of 771 prison inmates were tested across the four prisons (Male 765, Female 6) with a mean age \pm SD is 31.25 \pm 9.47 years. Ten of them (Male 9, Female 1) were confirmed new positives with a mean age \pm SD is 31.40 \pm 6.24 years, yielding a positivity rate of 1.3%. Eight of the ten positives are in their youthful age (<35 years). Odd's ratio shows that youthful age have higher association with HIV test outcome (OR: 2.81, CI: 0.80 – 9.79). The linkage rate for the positives is 100% with good escort service while adherence is \geq 95%. The patients after six months on tenofovir, lamivudine & dolutegravir achieved viral suppression.

Conclusions: This mode of HIV testing service (HTS) has proved to reach a key population yielding more positives in much fewer numbers of people tested and in a short period of time with 100% linkage with better resource/health financing outlook. Community ART Differentiated Service Delivery (DSD) Model is in line for the patients to sustain the gains in the effort to achieve the 95-95-95 fast track UNAIDS targets.

54

Characteristic features of the course of HIV and the response to ART in a cohort of women compared with a cohort of men during a 5-year follow-up

Shostakovych-Koretskaya L¹, Sheveleva O¹

¹Dnipropetrovsk Medical Academy, Dnipro, Ukraine

Background: One of the factors that can influence the subsequent course of HIV infection is gender. Understanding the role of gender is very important for understanding the evolution of the epidemic, as it makes it possible to influence the trends of the epidemic process and implement effective methods of prevention HIV and management of HIV patients.

Materials & Methods: We conducted a prospective study and comparative analysis between a cohort of women 256 and men 194 with HIV-infection who were prescribed ART with 5 years follow up. Clinical, Immunological and virological data analysis of HIV-infected persons was made based on gender. Statistical analysis was carried out using STATISTICA 6.1 software protection (StatSoft, USA) and Microsoft Excel 2010. We use Cox proportional hazards regression model and ROC analysis to study the factors affecting the survival time of patients, with the risk ratio (HR) and their 95% confidence interval (95% CI). Statistically significant differences considered when $P < 0,05$. In both groups, the majority of patients were diagnosed stage IV of HIV disease.

Results: When comparing the age of patients (36 years in the group of men, 32 years in the group of women; $p < 0.001$). Regarding the way of HIV transmission, a more frequent parenteral infection pathway (67%) was observed in men, in comparison to women 69.9% of whom were infected through the sexual contacts. Injecting drug use among men was observed in 69.6% of patients. Among women, one-third of patients were injecting drug users - 30.9%, respectively. It has also been also associated with a statistically significant prevalence of HIV / HCV / HBVco-infection in the male group ($p = 0.001$). Among co-infection, HIV / tuberculosis among co-infections, tuberculosis was 2 times less common in women than in men. ($p = 0.001$). The absolute and relative level of CD4 + - lymphocytes was slightly higher in women (206.56 [119.5 - 267.0]

cells / μl vs 153.0 [71.0 - 250.0], ($p = 0.001$) . The viral load of HIV RNA in the group of men exceeded the viral load in the group of women almost 2 times (130237 [27789,0 - 419093,0] copies / ml in men, and 48698,5 [13021, 5 - 222596,5] copies / ml - in women. In both groups, a statistically significant ($p = 0.001$) increase in the absolute number of CD4 + lymphocytes was observed during the observation period and receiving ART. However, the rate of growth in absolute CD4 + lymphocyte count among women is greater than among men ($p = 0.09$). During the observation, 63 patients died (37 male and 26 female), with 17.4% dying in the first year of ART, 72% of them were men. According the ROC analysis the risk of death in women's group was 2.4 times lower than in group of men (CI: 1.33-4.24).

Conclusions: The study showed the presence of certain gender differences in group of women and men with a predominance of the sexual route of HIV transmission, less deep immunosuppression and HIV viral load, which determines a more favorable HIV course, response to ART, and a lower risk of fatal events.

55

Fostemsavir and Ethinyl Estradiol Drug Interaction; Clinical Application for Co-Administration

Nwokolo N¹, Post E², Magee M³, Ackerman P⁴, Llamoso C⁴, Moore K²

¹ViiV Healthcare, Brentford, London, United Kingdom, ²ViiV Healthcare, Research Triangle Park, USA, ³Glaxo SmithKline, Upper Providence, USA, ⁴ViiV Healthcare, Branford, USA

Background: Fostemsavir (FTR) is a first-in-class Phase 3 investigational attachment inhibitor in development specifically for heavily treatment-experienced (HTE) patients infected with human immunodeficiency virus-1 (HIV-1). FTR is a prodrug of temsavir (TMR), which binds to viral gp-120 and prevents viral attachment and entry into host CD4+ T-cells. FTR is intended to be used with other antiretrovirals (ARVs) in patients failing their current treatment with limited remaining options due to resistance, intolerance, or safety concerns. For individuals on FTR receiving hormonal therapy, including contraceptives, menopause hormones, and gender-affirming hormone therapy (GAHT), understanding drug-drug interactions (DDIs) is important. Based on data from the FTR-oral contraceptive (OC) DDI study (Study 206279), TMR increased ethinyl estradiol (EE) concentrations but not norethindrone (NE). Applying the results of the FTR-OC DDI study, proposals for co-administering hormones with FTR are provided.

Materials & Methods: Study 206279 and relevant ARV-contraceptive studies were reviewed, and data applied to other contraceptive methods and hormone-based therapies to predict the impact of FTR co-administration. Proposals were based on minimizing risk of thromboembolic events associated with higher estrogen exposure, ensuring adequate hormonal concentrations to maintain targeted effect, and review of relevant treatment guidelines.

Results: In the FTR-OC DDI study, FTR had no effect on NE pharmacokinetics (PK) but increased EE C_{max} and AUC ~40%. Consequently, EE dose should not exceed 30 µg when given with FTR. FTR is not expected to impact progestin-only contraceptives. PK of hormonal contraception with FTR and boosted PIs has not been studied, therefore, alternative or additional contraceptive methods, guided by protease inhibitor (PI) prescribing recommendations, should be considered. Non-oral contraceptives have not been

studied with FTR. A study of lopinavir/ritonavir (LPV/r) co-administration with oral and transdermal contraceptives found changes in EE concentrations were similar with both, therefore an FTR-EE drug interaction may be expected regardless of delivery mechanism, and caution is advised. Additionally, appropriate education on condom use for HIV and sexually transmitted infection (STI) prevention should be ensured, regardless of contraceptive method.

Feminizing GAHT involves use of 17-beta estradiol or conjugated estrogens transdermally, orally, sublingually or by injection, to achieve serum estradiol concentrations in the physiologic cisgender female range of 100 - 200 pg/mL. FTR and estradiol for GAHT can be co-administered with routine monitoring of hormone concentrations and clinical effects, titrating estradiol dose in line with guidelines.

Menopause hormone therapy (MHT) for treatment of vasomotor symptoms and prevention/treatment of osteoporosis should utilize individualized risk-benefit assessment using the lowest effective dose of systemic estrogen consistent with treatment goals, with or without vaginal estrogen for genitourinary symptoms. For co-administering FTR and MHT, estrogen dose should start low and be titrated according to clinical effect.

Conclusions: FTR co-administration with hormone therapy is not expected to impact hormone treatment efficacy. When FTR is co-administered with oral estrogen-based therapies, the EE dose should be ≤ 30µg/day to minimize risk. Estrogen-containing GAHT and MHT can be co-administered with FTR, with monitoring of estrogen concentrations and dose adjustments as needed.

56

Which strategy is more effective - Community Targeted HIV Testing or Community Based Outreach HIV Testing? A Pilot Program in Mangochi District.

Ng'ambi A¹

¹Baylor College Of Medicine Childrens Foundation Malawi Tingathe Outreach Project, Mangochi Office , Malawi

A. Ng'ambi^{1*}, S. Kawonga 1, C. Pfaff 1, E. Chester¹,
1Baylor College of Medicine Abbott Fund Children's
Clinical Center of Excellence Lilongwe, Malawi

Background: Targeted Community HIV Testing (TCT) and Community Based Outreach HIV Testing (OUT) are initiatives to increase identification of new HIV infections, thus accelerating progress towards attainment of the 1st 90 of UNAIDS 90:90:90 goals. TCT involves training committee members of identified high-risk groups with the aim of them inviting their social contacts to the private place prepared for HIV testing. The target population influence decisions of the testing location, hours and time. OUT involves offering HIV testing alongside other routine mobile outreach health care services. The study compared the effectiveness of TCT and OUT testing strategies in Mangochi district.

Methodology: Testing strategies were evaluated from January to March 2019. In the TCT strategy, committees were formed comprising the following high risk social groups - fisher folks, sex-workers, youth aged 15-24, construction workers, estate workers and patients consulting traditional healers. These committees were trained on the importance of HIV testing and linkage to care and then asked their fellow social contacts to come for HIV testing. Testing was done by HDAs and was conducted in the tents and private rooms provided by the community members to ensure confidentiality. In OUT, HIV Diagnostic Assistants (HDAs) accompanied nurses from the District Health office on routine mobile under-5 and antenatal outreach clinics that were conducted monthly in a regular basis in hard to reach communities. For both strategies, HIV testing was performed according to Ministry of Health guidelines.

Results: 49 TCTs were done and 1145 people were tested. Testing venues included tents on fishing

beaches, rooms on a farm estate, rest house, construction site and traditional healers' residences. Through TCT 1,145 people were tested with the following yields in the various groups. Sex-workers – 127 (61 Male) yield 9.4%; fisher folks 790 (543 males) yield 6.7%; youths 15-25 years 145 (17 Males) 0% yield; football players 38 (all male) 9% yield; 10 business people 10 (6 men) 10% yield; 35 construction workers 35 (25 men) 2.8% yield. 67 people tested positive were linked to treatment. Twelve OUT activities were done in various locations on different days of the week. Through OUT, 948 people tested, (259 males) yield 0.9%. Of 9 clients tested HIV positive. All were linked to treatment.

Conclusion: TCT has a higher yield than OUT and shown to be more effective in mobilizing men to be tested. Testing of sex workers and fisher folk had particularly high yield.

57

Sexual Health, HIV Prevention and Violence Among Female Sex Workers

Perera U^{1,2}, Manathunge A³

¹Harvard University, Boston, United States, ²Drexel University, Philadelphia, United States, ³Ministry of Health, Colombo, Sri Lanka

Female sex workers (FSWs) are a highly stigmatized population in Sri Lanka that often lack access to health care. Previous studies have found that knowledge of the transmission of HIV/AIDS and sexually transmitted infections (STIs) among FSWs is limited, leading to an increased risk for infection. This study explored the knowledge, attitudes, and practices surrounding HIV/AIDS and STI prevention among FSWs in Colombo, Sri Lanka, as well as violence against these women. Semi-structured interviews were conducted using open-ended questions with 15 FSWs. Interviews were conducted in Sinhala and translated into English. Inductive content analysis was used to identify emerging themes in the data. Participants described entry into sex work as the result of economic hardships and vulnerable social positions. Most participants were connected to a local sex workers' non-governmental organization (NGO) and reported general use of condoms with clients and awareness of the modes of transmission of HIV/AIDS and STIs. 80% of FSWs reported condom use during their last sex act and 87% received regular HIV and STI testing through governmental free clinics. However, participants indicated that many clients did not want to use condoms and they sometimes lacked the power to negotiate condom use. Violence from clients as a result of FSW suggestion of condom use was reported among 33% of participants. Further, violence perpetrated by police for the carrying of condoms was reported by 60% of participants. These findings can be used to formulate practice, policy and research implications regarding the need for prevention and intervention efforts among FSWs in Sri Lanka. Intervention targets include empowering FSWs with knowledge and self-efficacy to negotiate condom use and study the effect of multi-level violence on sexual health. Moreover, there is a need for better training of the police force to handle the carrying of condoms among FSWs. Further education can be provided through the expansion of the efforts of the sex workers' rights NGO to areas outside of Colombo.

58

“I’ll change his sexual orientation, I don’t think about HIV”: a qualitative study to explore attitudes, behaviors, and experiences among female partners of men who have sex with men in China

Li X¹, Shi C², Zhang Y¹, Zhang B³, Wang H¹, Yan F¹, Chen J¹, Williams A⁴

¹Central South University, Xiangya Nursing School, Changsha, China, ²Yale School Of Public Health, New Haven, United States, ³The Affiliated Hospital of Qingdao University, Qingdao, China, ⁴New York University, Rory Meyers College of Nursing, New York, United States

Background: In China, many men who have sex with men (MSM) marry women because of homophobia and intense family pressure to have children. Studies have found that 17-35% of MSM are currently married to women, and the proportion of Chinese MSM who have female sexual partners is high, ranging from 26-40% in the past 6 months. HIV prevalence among Chinese MSM has risen sharply in the past decade, reaching as high as 10-30% in some regions. However, few HIV studies have directly addressed their female spouses and sexual partners, known as tongqi—a portmanteau of tongxinglian (gay person) and qizi (wife). An estimated 10-16 million women in China are thought to be tongqi. We conducted this exploratory study with tongqi to highlight elements of their sexual attitudes, HIV knowledge, and safe sex practices. A clearer understanding of HIV risk for tongqi can inform future HIV/STI prevention strategies in China.

Methods: From October 2015 to September 2016, we used purposive and snowball sampling to recruit adult women who reported that their male sexual partners (husbands, ex-husbands, fiancés) had a history of same-sex sexual contact. Recruitment was conducted online through QQ (a social media platform) and in-person through a LGBT-friendly community-based organization. Participants completed 50-90 minute semi-structured interviews to discuss their sexual history, HIV/STI risk, sexual agency, and relationship dynamics. Transcripts and field notes were coded and analyzed using thematic analysis.

Results: We enrolled 19 women from QQ, 3 through community-based organization referral, and 2 via word-of-mouth. Among the 24 total participants, 11 had male sexual partners who had been diagnosed with HIV. The

participants’ median age was 33.5 years (range: 26-66), and the median duration of marriage was 7.5 years (range: 0-41). At the time of the interview, sixteen of the participants were married, six were divorced, one was engaged, and one was widowed. Fourteen had ever received HIV testing, and 4 were HIV-positive. Common themes were low HIV/STI knowledge, desire for children, belief that sexual orientation can be changed, and unhappiness within the marriage. Most tongqi reported a low perception of HIV/STI risk and rarely used condoms or sought testing. After learning that their husbands had male sexual partners, most tongqi continued to have condom-less sex with their husbands in order to conceive. There was high variation in intramarital sexual frequency; one-third of tongqi (including the 4 HIV-positive participants) self-reported “normal” sexual frequency. Among couples who rarely had sex, some tongqi felt relieved or pursued sex outside of the marriage.

Conclusions: In the context of an intensifying HIV epidemic among MSM, tongqi also experience elevated HIV risk. To reduce HIV risk and to increase testing uptake, a multi-faceted approach should be taken to increase safe sex practices between MSM and their male and female partners. Our study also suggests that social media may be an effective way to reach out to this hidden population. Any interventions designed for tongqi and their husbands must be implemented with utmost sensitivity and caution to avoid exacerbating high societal levels of homophobia.

59

Female voices are not noises: the progress in promoting PrEP uptake and adherence among female sex workers in Thika, Kenya.

Ndungu A¹, Mbugua P¹

¹National Organization Of Peer Educators (NOPE), Nairobi, Kenya,

²University of Nairobi, Nairobi, Kenya

Background: Pre-exposure prophylaxis (PrEP) is a daily course of antiretroviral drugs (ARVs) taken by HIV-negative people to protect themselves from infection. Evidence shows that, when taken consistently and correctly, PrEP reduces the chances of HIV infection to near-zero. PrEP is cost effective, and there is growing demand for it from people at higher risk of HIV infection, but the scale and coverage currently remains limited. Since 2010 National organization of peer educators has engaged M.O.H and stakeholders on health services for key populations as defined by Kenya AIDS strategic plan (2009/10-2012/13) leading to roll out of PrEP implementation in 2016. According to a report released by (UNAIDS, 2018) On average, sex workers are 13 times more likely to become infected with HIV than adults in the general population. However, there is significant variation between regions and countries. Although sex workers are one of the groups most affected by HIV, they are also one of the groups most likely to respond well to HIV prevention programs. We share the progress on prep implementation among female sex workers in Thika, Kenya.

Material/methods: While rolling out PrEP implementation, NOPE provided training to 37 peer educators mandated to coordinating health service uptake among approximated 3000 FSWs in the region. From July 2019, a sample of 43 FSWs was drawn from 426 FSWs enrolled for PrEP in the past 12 months at the Drop in Center were interviewed. Purposive sampling was used to select FSWs who adhered to the drug use for more than 3 months without stop and those that stopped sooner than 3 months of uptake. The purpose was to identify major factors influencing adherence of prep uptake among FSWs. A hypothesis was formulated and inferential statistics obtained as described in the findings section below.

Findings: Adherence was noted to be high (87%) among FSWs who were not involved in drugs and substance

use. On the hand continuation rate (22%) was lowest among alcohol and other drug users. The study also established that the uptake was lower among FSWs who were involved in gender based violence in the past 12 months. Other factors that was considered to influence uptake of PrEP included, access to key population specific health services, stigma %and discrimination as well as peer influence. The F ratio was significant with $F(1,181) = 34.273$, $P=0.0005 < 0.05$ guiding to rejection of null hypothesis formulated which stated that “Drugs and substance abuse have no significant influence on uptake of prep among female sex workers”.

Conclusions: HIV prevention projects should incorporate interventions targeting to reduce drugs and substance abuse and gender based violence among female sex workers to complement the efforts of implementing PrEP for this group. Effectiveness of this projects will be greatly enhanced when the highlighted constraints are addressed

60

Is teenage pregnancy associated with experiencing intimate partner violence among young South African women disproportionately impacted by the global HIV epidemic?

Closson K¹, Dietrich J², Gibbs A³, Bekinska M⁴, Smit J⁴, Brockman M⁵, Gray G^{2,3}, Kaida A⁵

¹University of British Columbia, Vancouver, Canada, ²Perinatal HIV Research Unit, Soweto, South Africa, ³South African Medical Research Council, Pretoria, South Africa, ⁴Maternal Adolescent and Child Health Research Unit, Durban, South Africa, ⁵Faculty of Health Sciences, Simon Fraser University, Burnaby, Canada

Introduction: Intimate partner violence (IPV) affects millions of women globally. In 2016, 26% of ever partnered South African women reported ever experiencing physical, emotional, or sexual violence by a partner and 16% of women had a teenage pregnancy (aged 15-19). IPV and teenage pregnancy have both directly and indirectly (through mental health, substance use and reduced agency in HIV prevention practices pathways) been associated with increased HIV-risk. However, the link between teenage pregnancy and IPV is not well established. We estimated the association between teenage pregnancy and experiences of physical and/or verbal IPV among young women aged 16-24 in Soweto and Durban, South Africa.

Methods: This analysis uses data from young sexually active women aged 16-24 enrolled in a youth-engaged cohort study (2014-2016) and living in either Soweto or Durban, South Africa. Using cross-sectional baseline survey data, we assessed the independent relationship between reporting at least one teenage pregnancy (pregnancy between 15-19 years of age) and ever experiencing verbal or physical IPV determined by responding yes to "Have you ever been threatened or physically hurt by a partner?". Multivariable logistic regression assessed the independent association between teenage pregnancy and non-teenage pregnancy (vs. never pregnant) and ever IPV adjusting for potential confounders (age [teen vs. ≥20 years], site, income, housing, history of transactional sex, and age disparate [≥5 years older] partner).

Results: Of the 254 young women who completed the baseline survey, 207 (81.8%), median age=19 (Q1, Q3=18-21) reported ever having sex and were included in

this study. One-third of young women reported a teenage pregnancy (33.8%), 17.4% reported ever experiencing IPV, and 6.8% reported experiencing recent IPV (in the 6 months prior to the survey). Young women with a history of IPV were more likely (p -value<0.05) to be older (69.4% ≥20 years of age vs. 42.9%), to have medium/high (vs. no/low) perceived HIV risk (61.1% vs. 42.4%), to have ≥2 sexual partners in the last 6 months (44.4% vs. 16.7%), to have an age-disparate (≥5 years older) partner (57.6% vs. 35.0%), and to have ever engaged in transactional sex (16.7% vs. 5.3%).

Of those who had a teenage pregnancy, 27.1% reported ever experiencing IPV and 11.3% reported recent IPV, of those who were pregnant after 19 years 25.9% experienced lifetime IPV with 3.9% experiencing recent IPV, and of those who have never been pregnant 9.2% experienced lifetime IPV with 3.2% reporting recent IPV ($p=0.004$ for lifetime IPV and $p<0.001$ for recent IPV). After adjusting for confounders, young women who have had a teenage pregnancy (vs. no pregnancy) experienced 2.69 greater odds of ever experiencing lifetime IPV (95%CI=1.10-6.58). While those who reported a pregnancy after the age of 19 (vs. no pregnancy) had 2.18 greater odds of experiencing IPV, although this was not statistically significant ($p=0.21$).

Discussion: Results highlight that a third of young women in our study fell pregnant before the age of 19 and compared to those who have never been pregnant were significantly more likely to have experienced IPV. In order to reduce the disproportionate burden of HIV among young South African women, critical efforts are needed to address pervasive and interacting experiences of teenage pregnancy and IPV that increase young women's risk of acquiring HIV. This includes youth-centered family planning initiatives and violence support for young pregnant women.

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Author index

Name	Paper Title	Abstract #	Page #
Adeyemi, Oluwatoyin	Characteristics associated with gender among older black people living with HIV	35	39
Cabrera López, Teresita de Jesús	Post-Exposure Prophylaxis in Victims of Sexual Violence. Experience at the Condesa Specialized Clinic (CSC)	11	13
Chaturvedula, Ayyappa	Clinical trial simulation to improve HIV pre-exposure prophylaxis dosing in pregnancy	25	29
Closson, Kalysha	Examining differences in syndemic factors by gender and sexual orientation among women, straight men, and gay, bisexual, and other men who have sex with men living with HIV in British Columbia, Canada	12	14
Closson, Kalysha	Is teenage pregnancy associated with experiencing intimate partner violence among young South African women disproportionately impacted by the global HIV epidemic?	60	60
Cortes, Claudia	Relation between disease knowledge, antiretroviral adherence and viral outcomes in women with HIV in Chile.	32	36
Daughtridge, Giffin	Disparities in PrEP uptake and adherence: implementation of routine adherence monitoring in Philadelphia PrEP clinic	29	33
Deressa, Berehanu	Determinants of contraceptive choices among HIV-positive women of reproductive age attending for contraceptive service: - the case of Adama FGAE model clinic	38	42
Deressa, Berehanu	Factors affecting the utilization of PMTCT service among pregnant woman attending for ANC service:- the case of Adama FGAE model clinic	41	45
Eze, Angela	Gender based barriers affecting partner notification among HIV positive clients assessing care and treatment services in South East, Nigeria	31	35
Gogia, Marine	The role of female Sex partners of People Who Inject Drugs in better uptake of retention in HIV Services	47	50
Gogia, Marine	Women who inject drugs and harm reduction in Georgia	48	51
Haberl, Lila	Not recommended, but done: Breastfeeding with HIV in Germany	8	10
Kangethe, James	HBV infections among HIV-infected Mothers on ART and their Exposed Infants in a tertiary hospital, Nairobi Kenya	39	43

Keita, Ibrahima Mamby	Evaluation of the strategy accelerating the elimination of mother-to-child transmission of HIV by using a community-based tool "Pregnant women's tracking book" and sponsorship of seropositive pregnant women in Goudomp Health District (Sedhiou/Senegal).	42	46
Keita, Ibrahima Mamby	Evaluation of a health improvement strategy by creating a Mobile HIV Care Team (MHIVCT) in collaboration with Community Actors (excluding mediators) in the Goudomp Health District (Sedhiou/Senegal).	43	47
M'baya Kansinjiro, Beatrice	Male partners' expectations in PMTCT services in Chiradzulu district, Malawi	37	41
McClymont, Elisabeth	Impact of Microbial Exposures on HPV Immune Titers and Infection Among HPV-Vaccinated Women Living with HIV	15	19
Mellgren, Åsa	Women on anti-retroviral therapy (ART) are less likely to achieve HIV RNA <50 copies/ml compared to men – Real World Data from the National Swedish InfCareHIV Cohort	7	12
Moseholm, Ellen	Vitamin D status in pregnant women living with HIV in Denmark and association with birth outcomes - A nationwide cohort study	3	5
Nash, Madlen	Adolescent girls and young women: should they be formally recognized as a key population for HIV?	6	8
Ndungu, Anthony	Female voices are not noises: the progress in promoting PrEP uptake and adherence among female sex workers in Thika, Kenya.	59	59
Ng'ambi, Advemaas	Which strategy is more effective - Community Targeted HIV Testing or Community Based Outreach HIV Testing? A Pilot Program in Mangochi District.	56	56
Nwokolo, Nneka	Fostemsavir and Ethinyl Estradiol Drug Interaction; Clinical Application for Co-Administration	55	55
Okoli, Chinyere	Attitudes towards health, sexual intimacy, and child-bearing among women living with HIV in 24 countries	14a	16
Okoli, Chinyere	Differences by gender and sexual orientation in treatment satisfaction and aspirations among persons living with HIV	14b	17
Okoli, Chinyere	Gender, equality, and empowered decision making in HIV care	14c	18
Onigbogi, Olanrewaju	Barriers to vaginal microbicide trials in Nigeria	49	51
Patel, Rena	Validating incident pregnancies among women using contraceptives and antiretrovirals	10	9

<i>Abstracts</i>			65
Patel, Rena	Dolutegravir-containing ART does not reduce etonogestrel implant concentrations	18	22
Perera, Udara	Sexual Health, HIV Prevention and Violence Among Female Sex Workers	57	57
Quercia, Romina	Women Race, Age and Regional US & Non-US Subgroup Analysis of Dolutegravir (DTG) and Non-integrase inhibitor treatment (non-INSTI) regimens in naïve randomized clinical trials at Week 48.	16	20
Quercia, Romina	ATLAS and FLAIR: efficacy, pharmacokinetics and reasons for satisfaction in women with cabotegravir & rilpivirine long acting regimen at week 48	17	21
Sami, Samira	HIV transmission patterns among people who inject drugs in the United States	28	32
Sanogo, Alou	Evolution of the transmission rate of HIV-1 from mother to child in Mali from 2009 to 2018.	40	44
Sconza, Rebecca	Timing of HIV diagnosis in HIV-positive pregnant women giving birth in a high prevalence Russian region	22	26
Scott, Rachel	Determinants of PrEP initiation in women at high risk for HIV	9	11
Selvamuthu, Poongulali	Impact of Dolutegravir based ART among Indian women	4	6
Serghides, Lena	Maternal and cord plasma bioactive eicosanoid profiles differ in pregnant women living with HIV compared to HIV-negative pregnant women	5	7
Shi, Cynthia	“I’ll change his sexual orientation, I don’t think about HIV”: a qualitative study to explore attitudes, behaviors, and experiences among female partners of men who have sex with men in China	58	58
Shoemaker, Esther	Mode of birth among women living with HIV: A population-based retrospective cohort study	23	27
Short, William	Sex-specific analyses in oral abstracts from CROI 2019	1	3
Short, William	Prevalence of polypharmacy and medication use contraindicated during pregnancy among a cohort of women living with HIV who are of childbearing age, 2016-2017.	24	28
Shostakovych-Koretskaya, Liudmyla	Characteristic features of the course of HIV and the response to ART in a cohort of women compared with a cohort of men during a 5-year follow-up	54	54
Sophus, Amber	HIV/AIDS Prevention Interventions for Black Women in the U.S.: A Systematic Review	30	34
Spencer, Gabriella	Black Women on PrEP in Maryland vs Alabama	46	49

<i>Abstracts</i>			66
Spreen, William	Cabotegravir pharmacokinetic tail in pregnancy and neonatal outcomes	20	24
Suwanwongse, Kulachanya	Why Sex make a difference in HIV clinical course? A bioinformatics analysis of differential expressed gene in male and female with HIV disease	27	31
Theckla Efeti, Ikome	Social media influence on the sexual behaviours of undergraduate students of the university of Buea,Cameroon.	26	30
Thorne, Claire	Outcomes following prenatal exposure to Dolutegravir: the Dolomite-EPPICC Study	2	4
Usman, Saheed	Achieving the third 95: Keeping adolescents living with HIV virally suppressed in rural Nigeria in test and treat era using Continuous Quality Improvement Model of Peer Counseling & Support Group	21	25
Usman, Saheed	Achieving the third 95: Keeping pregnant women living with HIV virally suppressed in rural HIV clinics in Western Nigeria	50	52
Usman, Saheed	Pre-exposure prophylaxis (PrEP) in clinical settings in South-Western Nigeria: Implications for country-wide implementation	51	52
Usman, Saheed	Patterns and correlates of Gender Based Violence in rural and urban South African communities	52	53
Usman, Saheed	Accelerated HIV case finding & bridging enrolment gap for key populations in Western Nigeria: A breakeven in achieving UNAIDS fast tract 95-95-95 targets	53	53
Valencia, Jorge	Gender-based vulnerability in women who inject drugs	34	38
Wang, Yu	The burden of serious non-AIDS-defining events among admitted cART-naive HIV/AIDS patients in China: An observational cohort study	36	40
Whanger, Stacey	Perceptions of HIV Risk among Women in Southern West Virginia	45	48
Wroblewka, Agnieszka	U=U among women – are we there yet?	33	37
Zhabokritsky, Alice	CD4:CD8 ratio normalization among treatment naive women	13	15
Ziejewski, Mary	Cabotegravir: Assessment of reproductive and developmental toxicity in animal studies ¹	19	23



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