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The Representative Studies Rubric: 12 Steps to Enhance the Representation of Women and Minorities in HIV Research

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Background: Science is incomplete without the inclusion of cisgender and transgender women, who in turn suffer the consequences of their exclusion from research. Failure to prioritize women and minorities in HIV research results in compromised generalizability, gendered disparities in PrEP regulation and coverage, safety and efficacy uncertainties of ARV use in pregnancy and breastfeeding, undermined efforts to address health disparities, and misclassification of study populations. The underrepresentation of women and minorities in HIV research occurs as a constellation of systemic processes, many of which are institutionalized within the field of clinical research.

Materials & Methods: We developed a tool, the Representative Studies Rubric (RSR), consisting of a 12-item questionnaire that can be applied to study protocols to facilitate enhanced inclusion of women and other underrepresented populations. We pilot tested the RSR in a retrospective analysis of 100% of study protocols (47) conducted by the NIH-funded HIV/AIDS clinical trials networks that were actively enrolling study participants in September

2021: AIDS Clinical Trials Group (21 studies); COVID-19 Prevention Network (1 study); HIV Prevention Trials Network (5 studies); HIV Vaccine Trials Network (5 studies); HPTN/HVTN (3 studies); International Maternal Pediatric Adolescent AIDS Clinical Trials (10 studies); and Microbicide Trials Network (2 studies). Findings were presented to research leadership to activate process improvement.

Results: A significant number of study protocols excluded women and gender minorities with no justification for exclusion provided: cisgender women (1 study), transgender women (13 studies), transgender men (23 studies), and gender non-binary people (29 studies). Exclusion most often occurred passively through ambiguous and exclusionary definitions of study populations. Only 11 studies (23%) correctly defined the study population in terms of sex assigned at birth and gender identity. Less than a third of the studies allowed the participation of pregnant individuals, and nearly half of the studies required participants to actively avoid becoming pregnant, citing non-specific safety uncertainty. Recruitment plans largely failed to prioritize women and other underrepresented populations, and stigmatizing language was ubiquitous. After being presented with these findings, research leadership endorsed our recommendation to ameliorate protocol development using the RSR proactively.

Conclusions: Institutionalized barriers in HIV research perpetuate the exclusion of women and other underrepresented populations. The RSR should be implemented proactively in the development of study protocols to help correct these institutionalized barriers, advance scientific integrity, and facilitate equitable representation of study populations.

2

An Analysis of Utilization of Post Gender-Based Violence Care Among Women Between Pre and COVID-19 Timeframes Across Select African Countries

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Background: Globally, one in three women has experienced gender-based violence (GBV). COVID-19-related restrictions exacerbated the risks of GBV. The Elizabeth Glaser Pediatric AIDS Foundations provides GBV care integrated within HIV, FP/SRH and TB service delivery platforms across countries. We analyzed available program data to examine trends in utilization of post-GBV care services, including post violence care by comparing pre- and mid-COVID-19 periods.

Methods: Routinely reported PEPFAR-program data were analyzed across nine EGPAF-supported countries (Cameroon, CDI, DRC, Eswatini, Kenya, Lesotho, Malawi Mozambique, Tanzania). GBV indicators included the number of individuals receiving post-GBV clinical care based on the minimum package, type of violence (physical/emotional and sexual), and post-exposure prophylaxis (PEP) uptake and were evaluated and compared across timeframes. October 2019 to September 2020 was used to reflect the pre-COVID-19 period with October 2020 to March September 2021 representing the COVID-19 timeframe. Data were disaggregated by country, sex, and age.

Results: There was a 47% increase in individuals utilizing post-GBV care when comparing pre- and mid-COVID-19 timeframes; 40,858 individuals sought post-GBV care between October 2020 and

September 2021 compared to 27,843 who sought services between October 2019 and September 2020. There was a 20% increase in care sought for physical/emotional violence from 20,900 to 32,869 when comparing timeframes. The proportions of females seeking post-GBV from physical/emotional violence increased from 71% (n=14,879) to 76% (n=25,076). The proportion of young women (20-24 years) seeking post-GBV care for physical/emotional violence increased from 14% (n=2,891) to 16% (n=5,208). A 15% increase in use of post-violence care (PVC) services as a result of sexual violence occurred with 6,943 individuals seeking care pre-COVID-19 and 7,989 individuals during the COVID-19 period. The proportions of women seeking PVC from sexual violence increased from 88% (n=6,117) pre-COVID to 93% (n=7,423) during COVID-19. The proportion of adolescent girls (15-19 years) who sought PVC increased from 35% (n=2,453) to 39% (n=3,131) between pre- and COVID-19 periods. Among young women (20-24 years), this proportion increased from 8% (n=571) to 10% (n=832), respectively. The proportion of 10-24-year olds consistently made up the majority of those seeking PVC with 65% (n=4,540) pre-COVID-19 and 67% (n=5,362) during the COVID-19 timeframe. Tanzania had the highest number of reported PVC utilization with 4,302 receiving PVC pre-COVID-19 and 4,311 in the COVID-19 era. Among all survivors of sexual violence seeking care, PEP uptake decreased between time periods with 45% (n=3,114) of survivors completing PEP during pre-COVID-19 compared to 40% (n=3,201) during the COVID-19 period. During pre-COVID-19, the proportion of those who received and completed PEP between 10-24 years was 23% (n=1,618); that proportion increased to 29% (n=2,052) during COVID-19.

Conclusion: The number of individuals receiving post-GBV clinical care as a result of both physical, emotional and sexual violence increased when comparing pre- and COVID-19 time periods. The increase in the proportion of women seeking post-GBV care in particular is alarming and warrants further inquiry and response. The decrease in the already low PEP uptake among survivors of sexual violence is a concern.

3

Modeling HIV Infections Averted by Treating Urban, Adult Zambian Women at High-Risk for HIV for Female Genital Schistosomiasis

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Background: Female genital schistosomiasis (FGS) is one of the most common neglected tropical diseases. The World Health Organization (WHO) estimates that 56 million women and girls are living with FGS in sub-Saharan Africa. FGS causes infertility, pregnancy complications, lost productivity, extreme stigma, and is associated with a doubling in HIV risk. Despite an urgent call by WHO for treatment of FGS in adults, adult praziquantel coverage is currently low at 14% and most healthcare professions still view FGS as a disease affecting children in rural areas. FGS prevalence in adult women in urban areas of Africa, where HIV risk is highest, is largely unknown, including in Zambia where schistosomiasis is endemic.

Methods: From March 2020 - September 2021, we recruited adult HIV-negative female sex workers and single mothers from a standing cohort of

women at high risk of HIV to complete a survey assessing FGS risk factors and to undergo colposcopy for gold standard diagnosis of FGS. This cohort was recruited in the two largest cities in Zambia: Lusaka and Ndola. We used findings from a recent meta-analysis on the effect of FGS on HIV risk along with the HIV seroincidence rate observed in our cohort to build a compartmental model outputting the number of HIV infections prevented by treating women for FGS as well as the cost to prevent these infections using current drug prices for praziquantel in Zambia.

Results: Among 400 urban adult women, we found an unexpectedly high prevalence of FGS (25%). HIV seroincidence in this cohort was also high at 2.7/100 person-years. From our compartmental model, we estimated that treating women for FGS with praziquantel in this cohort would prevent 13% of new HIV infections at a cost ranging from roughly \$100 USD (if treating only those diagnosed with FGS) to \$400 (if providing mass drug administration to all women in the cohort).

Discussion: This is one of the first studies to report that the prevalence of FGS in adult women living in urban areas in Zambia is concerningly high. Given that this high FGS prevalence was observed concurrently in a high-HIV risk population, it is urgent that FGS diagnosis and praziquantel coverage, which is an inexpensive drug with few side-effects and no known resistance, increase among urban adult populations in schistosomiasis endemic countries.

5

A Comparison of the Factors Associated with Depression Among Older Black Women and Men Living with HIV

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Background: The population of older adults (age 50+) living with HIV (OALWH) is growing. Within this group, Black people continue to face a heavy HIV burden, and depression is prevalent. Little data exists on the factors associated with depression among Black OALWH and on whether these factors differ for Black women versus men. This analysis uses data from an online registry called Aging with Dignity, Health, Optimism and Community (ADHOC) to describe these differences.

Methods: Self-reported data were collected from 209 Black OALWH between November, 2017 and May, 2019. Depression was assessed using the Patient Health Questionnaire-2; a brief, validated instrument that provides a total score ranging from 0 to 6. A score of 3 or higher is considered a positive screen for depression. Separately for women and men, cross-sectional bivariate analyses were performed to determine associations between depression and self-reported sociodemographic, health status, and clinical indicators. Then, separately for women and men, factors associated with depression at $p < 0.20$ were included in linear regression models, which were reduced through backward selection.

Results: Of 101 Black women, the mean age was 59.7 years (SD=6.5) and 25% screened positive for depression. Of 108 Black men, the mean age was 60.1 years (SD=6.2) and 19% screened positive for

depression. In bivariate analyses among the women, greater depression was associated with anxiety, lower quality of life, not feeling close to friends, loneliness, internalized stigma, low social wellbeing, low resilience, having been diagnosed with HIV less than 20 years ago, and having 6 or more comorbid conditions (all $p < 0.05$). Being younger than 60 years old, having a four-year college degree, poor ART medication adherence, having lost a partner to HIV, and living alone were marginally associated with greater depression (all $p < 0.20$). In bivariate analyses among the men, greater depression was associated with anxiety, lower quality of life, not feeling close to friends, loneliness, internalized stigma, poor ART medication adherence, having a detectable viral load, being single, and living alone (all $p < 0.05$). Low social wellbeing, low resilience, and having lost a partner to HIV were marginally associated with greater depression (all $p < 0.20$).

After backward selection, the multivariable regression model for women showed that the odds of depression were higher among women with anxiety (OR=31.68, 95%CI 6.91–145.15) or poor ART adherence (OR=0.08, 95%CI 0.01–0.45), but lower in women with high resilience (OR=0.08, 95%CI 0.02–0.41), or who were diagnosed with HIV 20+ years ago (OR=0.20, 95%CI 0.05–0.75). For men, like women, the odds of depression were higher among those with anxiety (OR=17.95, 95%CI 3.56–90.69) or poor ART adherence (OR=0.13, 95%CI 0.03–0.71). However, unlike for women, the odds of depression were higher among those who lived alone (OR=5.52, 95%CI 1.22–24.93) or were lonely (OR=8.60, 95%CI 1.50–49.41).

Conclusions: In addition to treating their depression, interventions to address depression among all Black OALWH should address anxiety and medication adherence. Moreover, for Black depressed women OALWH, interventions may be more effective if they foster resilience, whereas in Black depressed men OALWH, interventions may be more effective if they include techniques to combat loneliness. Tailoring interventions to the specific needs of older Black women and men living with HIV should help combat depression more effectively in this important population.

6

Pregnancy Characteristics and Outcomes of Women with Vertically-acquired HIV in the UK, 2006-2021

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Background: As a result of improving health strategies, the number of reproductive-aged women with vertically-acquired HIV (WVHIV) has been increasing globally. However, knowledge gaps on their characteristics and pregnancy outcomes exist. We present UK population-level pregnancy outcome data for this emerging cohort.

Materials & Methods: In the UK, surveillance of all pregnancies to women living with HIV, their infants and any children diagnosed with HIV is carried out by the Integrated Screening Outcomes Surveillance Service (ISOSS), part of the NHS Infectious Diseases in Pregnancy Screening Programme. Data have been collected for over 30 years, and concurrent paediatric and maternity reporting streams offer a unique opportunity to link historical paediatric reports of women diagnosed as children and seen for paediatric care in the UK to pregnancy reports. We present descriptive analyses of pregnancies in WVHIV diagnosed at <14years, reported to ISOSS by 31/12/2021.

Results: 202 pregnancies to 131 WVHIV (37% UK-born, 54% African-born) were reported since 2006 (none prior to 2006): 81 women had one pregnancy, 34 had two, 16 had ≥three. The proportion of pregnancies in WVHIV increased ~12-fold over the period from 0.3% (15/5011) in 2006-09 to 3.5% (83/2403) in 2018-21, $p<0.001$. Median age at diagnosis was 6 years (Q1:2,Q3:11). Most

women (81/131) were diagnosed in the UK, and 112/131 were reported in childhood.

Median age at expected date of delivery was 24 years (Q1:20,Q3:27) for pregnancies to WVHIV and 33 (Q1:29, Q3:37) for women with heterosexually-acquired HIV (WHHIV). 77% of WVHIV initiated antenatal care at <13wk compared to 64% of WHHIV, $p<0.01$. WVHIV conceived on ART in 81% of pregnancies, reaching 88% 2015-21 (vs 77% for WHHIV). WVHIV had significantly lower first pregnancy CD4 count than WHHIV (≥ 500 cells/ μ L in 35% vs 42%, $p<0.001$). Fewer WVHIV had undetectable (<50copies/ml) delivery viral load (dVL): 79% vs 84% for WHHIV ($p=0.127$), increasing to 85% vs 93% in 2015-2021 ($p<0.001$). Among pregnancies conceived on ART, 82% in WVHIV had undetectable dVL vs 94% in WHHIV ($p<0.001$).

Pregnancy outcomes for WVHIV were: 170 livebirths (84%), 10 miscarriages (5%), 18 terminations (9%) and 4 stillbirths (2%). 17% of livebirths were preterm (<37wk) compared to 13% for WHHIV ($p=0.003$). Median birthweight was 3.0kg (Q1:2.5,Q3:2.8) versus 3.1kg (Q1:2.7,Q3:3.4) for WHHIV; 6% of infants had a congenital anomaly reported, comparable with WHHIV, $p=0.6$. Of infants born to WVHIV with known infection status, one infant was diagnosed HIV-positive (1/150, 0.66%) compared to 0.88% (148/16771) over the period to WHHIV.

Conclusions: In this growing sub-population of women living with HIV in the UK, HIV-related markers have improved over time, with one known case of second-generation vertical transmission. The antenatal screening programme is key to supporting engagement in the antenatal period, and successes reflect the strength of existing clinical pathways and specialist paediatric services. Further work is needed to explore why WVHIV may not be on ART at conception and more likely to have detectable dVL. As numbers increase, ongoing surveillance of this population enables monitoring of emerging trends and exploration of related areas such as sequential pregnancies and longer-term outcomes in children born to WVHIV.

7

Understanding the Factors that Influence Infant-Feeding Decisions Among Women Living with HIV in the UK

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Background: There are just over 800 pregnancies in women living with HIV in the UK each year.

Up until 2012, the national British HIV Association (BHIVA) infant-feeding guidelines advised exclusive formula feeding; breastfeeding was viewed as a child protection issue. In 2018, the guidelines evolved to state that while exclusive formula feeding is still recommended, women should be supported to breastfeed if they are virologically suppressed, breastfeed exclusively and have monthly clinical reviews. In the UK, complex discourses surround infant-feeding within the context of HIV, which are in contrast to the wider 'breast is best' messaging in general antenatal care. Using a qualitative approach, we investigated infant-feeding decisions among women and birthing parents with HIV who were pregnant or had given birth within 12-months.

Methods: Between April 2021 – January 2022, we conducted remote semi-structured interviews (online or via telephone) with individuals with HIV who were either pregnant or had given birth within 12 months. Participants were recruited via UK HIV clinics and charities. Interview data were analysed thematically.

Results: Study participants were 31 cis-gender women (18 Black African, 2 Black British African, 1 Black Caribbean, 5 White British, 3 White other, 2 Asian); 23 were born outside the UK. Six were pregnant; 24 were postpartum; one was pregnant and postpartum. Five participants were diagnosed during their current pregnancy, the rest had known beforehand. All reported being virologically

suppressed. Half reported not having enough money to cover their basic needs 'all or most of the time'.

The majority of participants had or intended to formula feed. Their main motivation was to prevent HIV transmission, two women also commented that it facilitated shared feeding duties with their partner. The majority of this group had received free formula milk for up to 12-months postpartum and many remarked that this had eased financial concerns. One participant reported she would have considered breastfeeding in the absence of this provision.

A third of participants intended to or had breastfed. They identified bonding, health benefits, cultural expectations, and a means to avoid revealing their HIV status as motivating factors. Of the five women who had breastfed, two stopped within days due to cracked nipples or lactation issues, while the others had successfully breastfed for their desired length of time.

The majority (n=23) of participants were in long-term relationships. Many discussed the importance of supportive partners – regardless of the feeding decision. Only one reported that she had breastfed because her partner was unaware of her status.

Participants described receiving inconsistent infant-feeding information from healthcare providers (HCPs), and many had limited awareness of the updated infant-feeding guidelines. Half reported not feeling supported to breastfeed by their HIV HCPs, with two recalling their HCP had actively discouraged them from breastfeeding, even though they had wished to breastfeed and met the necessary criteria.

Conclusion: The changes in the UK infant-feeding guidelines are currently not reflected in the experiences of the women interviewed in this study. There is a significant informational need among women with HIV around their infant feeding options. It is clear that some HCPs are either unaware of updated guidelines or are unwilling to implement them in practice. Specific training regarding BHIVA's infant-feeding guidance for all HCPs who support new mothers with HIV will help to empower women to make better informed and supported choices regarding infant feeding.

8

“It Was the Best Decision!” - Experiences of Breastfeeding Mothers Living with HIV in Germany (SISTER Study)

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Background: For mothers living with HIV (MLWH) in resource rich countries breastfeeding (BF) is still not recommended. However, at a low level the number of breastfeeding MLWH is increasing in these countries. The SISTER study aims to analyze experiences of breastfeeding MLWH in Germany.

Methods: An interdisciplinary study group including HIV community representatives designed a questionnaire to capture experiences of breastfeeding MLWH. Study materials were distributed by community networks, HIV specialists, maternity hospitals, pediatricians and other German HIV organizations. Completed questionnaires were sent back anonymously to the study center. The SISTER study was launched in April 2019.

Results: To date, 29 MLWH were included in the study. Median age: 34 (18-43); 17 (59%) women born abroad; 23 (79%) completed education; 20 (69%) worked prior to pregnancy. All MLWH had a viral load <50 copies/ml at start of BF; no reported

comorbidity or history of AIDS. Maternal ART: 55% NNRTI, 38% INSTI, 7% PI.

13 (45%) women already had BF experience. 9 (31%) women decided to breastfeed prior to pregnancy; 20 (69%) during pregnancy. Main reasons for BF were bonding (76%) and/or conviction that breast milk was the optimal nutrition for the baby (73%). Information on BF came from HIV specialists (79%), internet (38%) and/or gynecologists (31%). MLWH were asked to rate reactions to BF decision from 1 to 5 (1 = most negative; 5 = most positive reaction). Ranking: HIV specialists 4.5; gynecologists 4.3; midwives 4.1; lactation consultants 3.9; pediatricians 3.0; nursing staff 2.8.

55% MLWH did not disclose HIV diagnosis to midwives and/or lactation consultants, 28% not to nursing staff and 3 (10%) not even to their partner. 10% each did not inform gynecologists or pediatricians about BF; 2 women (7%) did not inform HIV specialists. 12 (41%) women reported adverse events: 7 (24%) sore nipples, 5 (17%) milk stasis and 2 (7%) cases of mastitis. Median duration of BF: 24 weeks (2-104). Main reasons to stop: BF duration achieved (31%), fear of HIV transmission (17%), lack of milk (14%) and two cases (7%) of viral load rebound.

83% MLWH would breastfeed again, 14% were still undecided and 1 woman (3%) would not breastfeed again. 86% would recommend breastfeeding to other MLWH.

Several women gave a positive feedback because the study enabled them to actively contribute to research.

Conclusions: The SISTER study included 29 breastfeeding women living with HIV in Germany and revealed predominantly positive BF experiences. MLWH were healthy, well educated, on effective ART and almost half of them already had BF experience. In terms of decision making on BF HIV specialists were the most important source of information. Some women decided not to disclose their HIV status to health care professionals. As a consequence of HIV disclosure breastfeeding MLWH reported negative reactions within the medical care system. This could be due to missing or outdated information. An increasing number of HIV pregnancy guidelines in resource rich countries are now more open minded towards BF. Obviously these changes have not yet been sufficiently implemented in clinical practice.

9

Using a Universal PrEP Provision Approach in Pre- and Postnatal Care Services Increases Uptake of PrEP Among Pregnant and Breastfeeding Women (PBFW) in Eswatini

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Background: With HIV incidence among pregnant women estimated at 4.2/100 person years (Justman, 2017), maternal seroconversion continues to be a major contributor to ongoing mother-to-child HIV transmission (MTCT) in Eswatini. HIV prevention, including PrEP, among pregnant and breastfeeding women (PBFW) is a key intervention in elimination of MTCT. Daily oral PrEP has been shown to be very effective in reducing HIV acquisition and is also safe among PBFW. Eswatini has been scaling up PrEP since mid-2019, with PBFW as a priority group.

Material and Methods: EGPAF-Eswatini has supported PrEP scale-up in 63 health facilities across Hhohho and Shiselweni regions, including within PMTCT services. In late 2020, universal PrEP provision, using an opt-out approach was recommended as part of the national EMTCT strategy. EGPAF thereafter began implementing a universal (as opposed to risk-based) PrEP provision strategy through training and mentorship of MNCH

staff, to increase PrEP access among HIV-negative PBFW. We used descriptive data to compare PrEP initiations during early (January-March 2021) and late (July-September 2021) implementation phases of the universal PrEP policy.

Results: Among PBFW receiving PrEP in the early and late implementation periods, 78% (523/671) and 79% (650/821), respectively, were pregnant and 22% (148/671) and 21% (171/821), respectively, were breastfeeding. Among HIV-negative women starting ANC in the early implementation period, only 5% (183/3358) were already on PrEP. However, in the late implementation period, 17% (760/4344) of HIV-negative PBFW were already on PrEP. Overall, PrEP initiations among all the remaining HIV-negative PBFW (not already on PrEP) increased from 21% (671/3175) in the early implementation period to 23% (821/3584) in the late implementation period. In these periods the contribution of PBFW among all new PrEP enrolments increased from 60% (671/1110) to 73% (821/1115).

Conclusions: Routine universal provision of PrEP within PMTCT services can be effective in increasing uptake among HIV-negative PBFW. However, despite Eswatini MOH policies recommending a universal approach, PrEP offer is not routinely implemented for all HIV-negative PBFW and many women offered PrEP choose to opt-out. A greater focus on mentoring staff to reinforce the opt-out universal provision approach, as well as tailored HIV risk and prevention messages for PBFW and their partners is necessary to reduce missed opportunities for HIV prevention in PBFW at high risk of HIV. M&E tools also need to be adapted to enable improved documentation of PrEP offer and acceptance as well as faster identification and monitoring of HIV negative PBFW not on PrEP, throughout the pregnancy and breastfeeding periods.

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Subclinical Atherosclerosis and Immune Activation Among US Females vs. Males with HIV

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Background: Among people with HIV (PWH), sex-differences in presentations of atherosclerotic cardiovascular disease (ASCVD) may be influenced by underlying differences in coronary plaque parameters, immune indices, or relationships therein.

Methods: REPRIEVE, a primary ASCVD prevention trial, enrolled ART-treated PWH globally. At study entry, a subset of US REPRIEVE participants underwent coronary CT angiography (CCTA) ± immune phenotyping (N=755 CCTA; N= 725 CCTA + immune). We characterized sex-differences in coronary plaque (log binomial regression for a relative prevalence rate (RR)) and immune indices (linear regression) and compared immune-plaque relationships by sex. Unless noted otherwise, analyses adjust for ASCVD risk score.

Results: The primary analysis cohort included 631 males with HIV and 124 females with HIV (median age 51 years). ASCVD risk was higher among males (median 4.9% vs. 2.1%) while obesity rates were higher among females (48% vs. 21%). Prevalence of any plaque and of plaque with either visible noncalcified portions and/or vulnerable features (NC/V-P) was lower among females vs. males overall and controlling for ASCVD risk [RR (95% CI) for any plaque 0.67 (0.50, 0.92) and RR for NC/V-P 0.71 (0.51, 1.00) (adjusted for ASCVD risk and BMI)]. Among those with any plaque, prevalence of NC/V-P did not differ by sex (P=0.33). Females vs. males showed: 1) higher levels of IL-6, hsCRP, and d-dimer and lower levels of Lp-PLA-2 (P<0.001 for all); 2) a lower percentage of total monocytes and a shift toward a higher percentage of inflammatory/intermediate (CD14+CD16+) and patrolling/non-classical (CD14-CD16+) vs. classical (CD14+CD16-) monocyte subsets (P<0.001 for all). Higher levels of Lp-PLA-2, MCP-1, and oxLDL were associated with higher plaque (P<0.02) and NC/V-P prevalence, with no differences by sex (interaction P>0.25). Among females but not males, d-dimer was associated with higher prevalence of NC/V-P.

Conclusions: Females vs. males with HIV had a lower prevalence of subclinical coronary atherosclerotic plaque and plaque with visible noncalcified portion and/or vulnerable features, as well as key differences in immune parameters. Immune-plaque relationships differed by sex for d-dimer, but not for other tested parameters. Understanding sex-specific immune drivers of subclinical coronary pathology will be key to tailoring ASCVD preventive therapies to PWH.

11

Reduced Cardiac Strain Among Women with HIV Relates to Inflammatory Monocyte Activation

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Background: Women with HIV (WWH), as compared to women without HIV, have an increased risk of heart failure (HF) and worse HF outcomes. Heightened immune activation among WWH on anti-retroviral therapy (ART) is felt to contribute to this increased HF risk and to adversely affect HF outcomes. General-population based studies have shown that cardiac strain, quantified on cardiovascular imaging as global longitudinal strain (GLS), has superior prognostic value with respect to the progression of subclinical cardiac dysfunction to HF and adverse HF outcomes. We hypothesized that WWH (versus women without HIV) without a prior history of cardiovascular disease (CVD) would have reduced cardiac strain in relation to heightened immune activation.

Methods: In a prospective, cross-sectional study, 20 WWH on ART and 14 women without HIV, group-matched on age and BMI, were enrolled and underwent cardiovascular MRI and systemic immune phenotyping. Women aged 40 to 75 years and without a history of diabetes or CVD were eligible. Cardiac strain was compared in women with versus without HIV and relationships between cardiac strain and other cardio-immune parameters were interrogated. Multivariable regression modeling was performed among the whole group, with cardiac strain, as the dependent variable and with HIV status, age, and ASCVD risk score as

independent variables. Multivariable regression modeling was also performed among the subgroup of WWH, with cardiac strain as the dependent variable and immune/HIV-specific parameters as independent variables.

Results: Women with versus without HIV were similar in age (52±4 vs 53±6 years, P=0.61) and BMI (32±7 kg/m² for both groups, P=0.73). WWH had reduced cardiac strain compared to women without HIV (GLS in WWH versus women without HIV: -19.4±3.0 vs -23.1±1.9%, P<0.0001). In modeling among the whole group, HIV status remained an independent predictor of cardiac strain (Overall Model: R=0.62, P=0.003; HIV status: P=0.0003). Among the whole group (but not in subgroup analyses), cardiac strain related to left ventricular ejection fraction (LVEF), left atrial passive EF, and LV mass index (data not shown). Among the whole group and among WWH (but not among women without HIV), GLS related to an increased density of expression of HLA-DR on the surface of CD14+CD16+ monocytes, reflective of monocyte activation (Whole Group: ρ =0.53, P=0.001; WWH: ρ =0.45, P=0.0475). Among WWH, the density of expression of HLA-DR on the surface of CD14+CD16+ monocytes remained an independent predictor of GLS even after controlling for CD4+ T-cell count and HIV viral load (Whole Model: R=0.63, P=0.0499; CD14+CD16+ MFI of HLA-DR: P=0.02).

Conclusions: WWH versus women without HIV have reduced cardiac strain, which is of relevance to heightened HF risk and adverse HF outcomes. In our cohort, HIV status remained a predictor of cardiac strain controlling for other relevant parameters. Among WWH, increased expression of HLA-DR by inflammatory monocytes was associated with cardiac strain, even after controlling for HIV-specific parameters. Future studies among WWH are needed to examine the role of activated inflammatory monocytes in the development of reduced cardiac strain and to determine whether targeting this immune pathway may reduce risks of HF and/or adverse HF outcomes.

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Increasing Prevalence of Gestational Diabetes in Women Living with HIV in the UK and Ireland

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Background: The risk of gestational diabetes (GD) is increasing proportionally to that of type 2 diabetes globally. Selective screening of pregnant women based on risk factors such as BMI (>30 kg/m²) and ethnicity are recommended by guidelines in the UK however, questions remain regarding population-specific risk factors for women living with HIV (WLWHIV) and trends over calendar time.

Methods: We used data on pregnancies in women diagnosed with HIV prior to delivery reported to the Integrated Screening Outcomes Surveillance Service, part of the NHS Infectious Diseases in Pregnancy Screening Programme. All pregnancies ending in a delivery ≥ 24 gestational weeks with an estimated date of delivery from 1st January 2010 to 31st December 2020 reported by 30 September 2021 were included, with reports from England only in 2020. Every report of GD was considered a case. Our aim was to understand the characteristics of WLWHIV who had reported GD and key birth outcomes. To investigate risk factors for GD, a multivariable logistic regression model (complete case analysis), adjusted for multiparous women using generalised estimating equations (GEE) to account for sequential pregnancies per woman, assessed the effect of independent risk factors. Sensitivity analyses were conducted to evaluate the effect of universal antiretroviral therapy (ART) from 2015 on risk factors for GD.

Results: There were 10,553 pregnancies in 7,916 women, of whom 9,753 had gestational diabetes status available. GD was reported in 460 (4.7%) pregnancies. Overall, median maternal age was 33 years (Q1:29 - Q3:37), and 73% of pregnancies were in Black African women. Women with GD were older (61% vs 41% aged ≥ 35 years, $p < 0.001$) and more likely to be on ART at conception (74% vs 64%, $p < 0.001$) than women without GD. Women with GD had higher risk of adverse birth outcomes than those without GD: stillbirth (1.3% vs 0.6%, $p = 0.038$), emergency caesarean delivery (33.5% vs 23.8%, $p < 0.001$), preterm delivery (15.7% vs 10.9%, $p = 0.001$) and fetal macrosomia (8.2% vs 4.8%, $p = 0.001$).

Multivariable analysis (8,914 pregnancies) identified the following risk factors for GD: year of delivery (GEE-aOR: 1.12, 95% CI: 1.08-1.16, per calendar year); maternal age ≥ 35 years (GEE-aOR: 3.28, 95%CI: 1.80-5.97, vs < 25 years), Asian (GEE-aOR: 2.60, 95%CI: 1.46-4.63) and Black African (GEE-aOR: 1.55, 95%CI: 1.13-2.12) ethnicity, vs white ethnicity. Women with CD4 < 350 cells/ μ L were 26% less likely to have GD than women with higher counts (GEE-aOR: 0.74, 95%CI: 0.57-0.96). ART timing and type had no relationship with GD. Sensitivity analyses yielded similar results with respect to treatment.

Conclusion: The odds of developing GD significantly increased by 12% per calendar year of delivery over the study period, even after adjusting for our aging population of pregnant women. ART was not associated with GD but ethnicity, advanced maternal age and CD4 count were important risk factors. A limitation was that weight indices and diagnostic thresholds for classifying GD cases could not be accounted for. Further studies in large cohorts are required to build upon these results to improve understanding of population-level risk for WLWHIV and inform measures to mitigate risk.

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Age at Menopause in Women Living with and without HIV in the Children and Women: AntiRetrovirals and Markers of Aging (CARMA) and the British Columbia CARMA-CHIWO Collaboration (BCC3) Studies

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Background: Studies report that women living with HIV reach menopause earlier than HIV-negative women, with menopause typically defined as self-reported amenorrhea for ≥ 12 months. However, women may experience prolonged amenorrhea for reasons other than menopause, including hypothalamic amenorrhea from low weight or substance use. As women living with HIV experience more hypothalamic amenorrhea than HIV-negative women (21% vs. 9%), this may confound estimates of menopause age. Hypothalamic amenorrhea can be distinguished from menopause using follicle stimulating hormone (FSH) levels. Herein, we compare age at menopause in women living with and without HIV by self-report versus biochemical confirmation (FSH).

Methods: Cross-sectional data were obtained for a subset of women enrolled in CARMA and BCC3. Participants aged ≥ 35 years and sex-assigned female at birth were included. Women with hysterectomy, bilateral oophorectomy, or hormone

use were excluded. Menopause status was determined by 1) self-report and 2) age at last menstrual period plus serum FSH levels. Women aged ≥ 55 years with body mass index ≥ 35 and amenorrhea for ≥ 12 months were considered menopausal regardless of FSH levels, as estrone production by adipose tissue may lower FSH. Age at menopause was calculated as one year after the final menstrual period. Continuous and categorical data were compared using either Student's t-test or the Chi2 test, respectively. Power calculations indicate a need to include 84 menopausal women in each group to demonstrate a difference in age of menopause; therefore, analyses are preliminary.

Results: In total, 139 women living with HIV and 108 HIV-negative women were included in this interim analysis, of whom 54 (38.8%) and 53 (49.1%) were menopausal based on FSH levels. In univariate analysis, women living with HIV were more likely to have an income less than \$20,000 CAD/year (51.8% vs. 24.1%, $p < 0.01$), less than high school education (48.2% vs. 13.9%, $p < 0.01$), higher parity (2 [2] vs. 1 [2], $p < 0.01$), and previous or current hepatitis C infection (43.2% vs. 7.41%, $p < 0.01$) than women without HIV. Participants were similar with respect to age, ethnicity, current or previous substance use history, age at menarche, and body mass index ($p > 0.05$). Among women living with HIV, 81.0% had a viral load < 40 copies/ml. Self-reported reproductive phase was concordant with biochemical data in 86.8% of women living with HIV and 97.2% of HIV-negative women ($p = 0.003$). By self-report, women living with HIV reached menopause two years earlier than HIV-negative women (48.4 ± 6.0 vs. 50.4 ± 4.8 years; $p = 0.049$). However, when FSH measurements were considered, menopause age was no longer different (49.7 ± 4.4 vs. 50.3 ± 4.7 years; $p = 0.53$).

Conclusion: These interim data suggest that there is no difference in menopause age between women living with and without HIV using biochemical confirmation, compared to self-report alone where women living with HIV appeared to reach menopause earlier. Demographic differences were observed. These results call to question whether women living with HIV truly experience earlier menopause as opposed to more frequent hypothalamic amenorrhea and suggest that biochemical confirmation could be an important tool for evaluating menopause age for women living with HIV.

14

Understanding the Effects of Repeat-Motherhood Among Young Women Living with HIV and Their Children: Evidence from a South African Sample

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Background: Previous evidence suggests compounded negative effects of adolescent pregnancy and HIV on maternal and child outcomes. It is not yet known how having multiple children, in particular while still a teen, could affect maternal well-being and child development in this context.

Method: Data presented are from N = 1017 young mothers (287 (28.2%) ALHIV, 730 (71.8%) not living with HIV) and their children living in South Africa's Eastern Cape Province in communities affected by HIV. Effects of having multiple versus single children on maternal mental health (depression, anxiety, suicidality), as well as child cognitive outcomes on the Mullen Scales of Early learning (MSEL) were explored using χ^2 and t-tests and hierarchical regression as appropriate. We also investigated effects of repeat teen motherhood (as compared to single teen and repeat teen-adult motherhood) on child cognitive outcomes using

hierarchical linear regression, controlling for maternal HIV status.

Results: 92.7% (943/1017) of mothers had a single child and 7.3% (74/1017) had two or more. 4.8% (49/1017) were double-teen mothers, having given birth to two children at or under age 19. Mothers with two or more children were more likely HIV positive (54.1% versus 26.7%, $p < .001$). Maternal mental health was found to be poorer in the group with two or more children, alongside higher parental stress and lower social support ($p = .002-.038$). Child cognitive development scores were higher in children with a sibling; younger age and creche attendance were also positive predictors ($F = 11.81$, $p < .001$, adjusted $R^2 = .10$). In a second model focusing on effects of teen motherhood, first children of repeat-teen mothers appeared to perform equally well to children without siblings, while children of repeat teen-adult mothers seemed to benefit strongly from having siblings ($F = 14.20$, $p < .001$, adjusted $R^2 = .11$). Lower child age and creche attendance were positive predictors, while maternal HIV status did not have a significant influence.

Conclusion: We found that mothers with several children were more likely to be living with HIV. Furthermore, having two or more children was associated with poorer maternal well-being. Delaying second pregnancy until the adult years had benefits – and sibling effects on children were positive. Our data also suggests that the provision of childcare support was a predictor of positive outcomes. Overall, the findings highlight the need to improve social, psychological and family planning support in mothers living with and without HIV.

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15 - Bone Health in Aging Women (BEING) Study: Impact of Switching Antiretroviral Agents on Bone Mineral Density

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Background: Menopause is a high-risk period for the development of osteoporosis, which may be exacerbated by HIV and/or its therapies.

Objective: To study the impact of switching from tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF) on bone mineral density (BMD) in HIV-infected women during the peri-menopausal period.

Methods: A randomized, international, multicenter study of an early vs delayed (48-week) switch. BMD was determined by DEXA scan.

Results: Thirty-four women were enrolled, 19 in the immediate and 15 in the delayed switch arm between Sept 2017 and April 2019; 30 completed the 96-week protocol. The study was prematurely closed because of the COVID pandemic. The median (IQR) age was 51 years (47, 53). 70% participants were enrolled from Canada and 30% from Italy. There was a median (IQR) of 16.5 years (14, 23) since HIV diagnosis and a median (IQR) of 14 years (11, 20) of antiretroviral (ARV) therapy, median 9 years TDF. At enrollment, TDF was used in combination with a boosted protease inhibitor (n=7), an NNRTI (n=13), an integrase inhibitor (n=11) or more than one ARV class (n=3). The median (95% CI) % change in BMD from 0 to 48 weeks in the immediate switch group at the lumbar spine was 1.97% (-1.15, 5.49) compared to a median (95% CI) decrease of -2.32% (-5.11, 0.19) in the delayed arm. Corresponding values for % BMD change at the femoral neck are 1.46% (-2.95, 3.18) compared to 0.22 (-2.83, 3.64) in the immediate and delayed switch arms. The median (95% CI) % change in BMD from 0-96 weeks was 2.80% (0, 4.51) in the immediate arm compared to 1.05% (-3.19, 2.26) in the delayed arm. Respective values at the femoral neck are 0.94% (-1.93, 2.19) in the immediate and 0.12% (-7.13, 2.27) in the delayed arm.

Conclusion: There was a trend to an increase in BMD at the lumbar spine and femoral neck following a switch from TDF to TAF in peri-menopausal HIV-infected women.

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HIV Treatment in Pregnancy Over Time: Gaps Between Guidelines and Clinical Practice

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Background: Effective maternal antiretroviral treatment (ART) can reduce HIV vertical transmission to less than one percent. However, for newly approved antiretroviral drugs, sufficient pregnancy data are lacking. Consequently, these drugs are recommended by pregnancy guidelines with a delay compared to treatment recommendations for non-pregnant adults. Our study PREVENT analyzes trends in ART during pregnancy over the last twenty years and aligns the results with the corresponding national treatment guidelines.

Methods: The PREVENT study was conducted at the HIVCENTER in 2021 to retrospectively analyze the data of the pregnant women of the Frankfurt HIV cohort (HIVCENTER and specialized practices) from January 2002 to July 2021. Primary study objectives were ART during pregnancy, maternal viral load (VL) at delivery and rate of vertical HIV transmissions. Digital and paper based patient files were used for data collection.

The statistical analysis was carried out with SPSS. Two-sided tests with a significance level of $\alpha = 5\%$ were used for statistical tests (t-test, ANOVA, Wilcoxon-Mann-Whitney U-test, Kruskal-Wallis-test, Fisher's exact test. In addition, the correlations between the target values potential influencing factors were calculated (Pearson- or Spearman-correlation).

Results: During the observational period 535 pregnancies resulted in 548 infants (11 twins; 1 triplets). Overall, 31.6% pregnant women already had a viral load (VL) <50 copies/mL at the time of conception and 75.2% achieved a VL <50 copies/mL at delivery, respectively. Three vertical HIV transmissions were observed: In 2003, 2004 and 2010; corresponding to an overall HIV-MTCT rate of 0.6%.

There was a significant increase of virologic suppression over time ($p < 0.01$), especially from 2010 to date ($p < 0.01$). An earlier start of maternal treatment resulting in longer neonatal exposure to ART is observed over time and is also correlated to suppressed VL at delivery ($p < 0.01$). Use of integrase inhibitors (INSTI) started 2008, significantly increased since then ($p < 0.01$) and is linked to a significant better virological outcome at delivery (no use INSTI: average VL <50 copies/mL = 74.5%; use INSTI: average VL <50 copies/mL = 87.5%; $p = 0.022$). In 2021 27.8% of all pregnant women received INSTI containing ART. At the same time (since 2008) as INSTI use increased, the use of protease inhibitors decreased ($p = 0.01$). NNRTI containing ART increased slightly over time on average ($p < 0.026$). In Germany INSTI use during pregnancy was recommended in national guidelines for the first time in 2020.

Conclusions: In this retrospective analysis of 535 pregnancies earlier onset of ART along with an increased use of integrase inhibitors resulted in a significantly higher proportion suppressed viral load at delivery over time (2002-2021).

Notably, our results demonstrate a discrepancy between clinical management of pregnant women and HIV pregnancy guidelines. INSTI based ART for example was used twelve years before it was recommended by the corresponding national guidelines. This time span should be shortened through faster data acquisition from clinical trials which should finally also allow to include pregnant women.

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Age-Specific Human Papillomavirus Vaccine Coverage Among Women Living with HIV in Ontario, Canada

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Background: Women living with HIV are at higher risk for human papillomavirus (HPV)-related dysplasia and cancers and thus are prioritized for HPV vaccination. Canadian immunization guidelines recommend three doses of HPV vaccine for people living with HIV up to 27 years of age but can be considered for those at ongoing risk of exposure up to age 45. We measured HPV vaccine coverage among women attending HIV care in Ontario, Canada, and identified socio-demographic, behavioural, and clinical characteristics associated with HPV vaccination.

Materials & Methods: The Ontario HIV Treatment Network Cohort Study is a multi-site clinical cohort. It is one of the largest community-governed clinical HIV cohorts in North America with over 4,000 active participants, of whom 20% are women. During annual interviews from July 2007 to January 2020, participants who self-identified as a cis- or trans-woman completed a one-time questionnaire on

HPV vaccination. We used logistic regression to derive age-adjusted odds ratios and 95% confidence intervals for factors associated with self-reported vaccine uptake (≥ 1 dose).

Results: Among 591 self-identified women, the median age was 48 years (range=20-84 years) and 13 (2.2%) were biological male at birth. Over half were immigrants from countries with generalized HIV epidemics (58.4%) or identified as Black/African/Caribbean (54.6%); 33.0% were White, 4.6% Indigenous, and 7.7% mixed/other ethnicities. Overall, 78 women (13.2%, 95%CI=10.5-15.9%) received ≥ 1 dose of HPV vaccine, of whom 64.6% were fully vaccinated with three doses. We observed slightly higher coverage among 269 women aged ≤ 45 years for whom HPV vaccine is authorized in Canada (15.6%, 95%CI=11.2-20.0%) and among 38 women aged ≤ 26 years for whom it is nationally recommended (26.3%, 95%CI=11.6-41.0%). After adjusting for age, vaccine uptake was significantly associated with being employed (aOR=3.44, 95%CI=1.29-9.19), higher income (\$40,000-\$59,999 vs. $< \$20,000$; aOR=3.08, 95%CI=1.41-6.73), being married or common-law (aOR=1.96, 95%CI=1.09-3.52), living with children (aOR=2.39, 95%CI=1.37-4.16), immigrating to Canada > 5 years ago (vs. immigrating ≤ 5 years ago; aOR=3.13, 95%CI=1.35-7.25), never smoking (aOR=2.10, 95%CI=1.02-4.35), and being in HIV care longer (per 10 years; aOR=1.86, 95%CI=1.27-2.71).

Conclusions: HPV vaccine coverage was below World Health Organization targets of 90% among women engaged in HIV care in Ontario, Canada, even among younger women most likely to benefit from vaccination. Socioeconomic factors and healthcare access facilitators were identified as key variables influencing uptake. Recommendations for improving uptake include education of healthcare providers and public funding of HPV vaccine for women living with HIV.

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Use of Antiretroviral Therapy in Pregnancy and Association with Birth Outcome Among Women with HIV in Denmark: A Nationwide, Population-Based Cohort Study

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Background: Antiretroviral therapy (ART) is recommended worldwide for all persons with Human Immunodeficiency Virus (HIV), including pregnant women. No single ART regimen has consistently been considered first-line for pregnant women and exposure to HIV and/or different ART drugs during pregnancy may be associated with an increased risk of adverse birth outcomes. The objective of this nationwide study is to describe ART regimens during pregnancy among women living with HIV (WWH) in Denmark, including regimen changes during pregnancy, and to examine the association between ART use in pregnancy and other risk factors, and different adverse birth outcomes.

Materials and Methods: A Danish population-based cohort study including all pregnancies among WWH in Denmark between 2000 and 2019. Data was collected through national registries. Temporal trends of ART use in pregnancy were evaluated. Logistic regression models were used to examine the association between ART use in pregnancy (regimen, use of Protease Inhibitors (PI), and time of ART initiation in pregnancy) and other risk

factors, and different adverse birth outcomes (preterm birth, small for gestational age, intrauterine growth restriction, and low birth weight).

Results: In total, 589 pregnancies were included. The mean age at delivery was 33 years (95% CI 32.2-33.1). Most women were born abroad, with more than half of the women originating from an African country (58%), and most were diagnosed with HIV prior to conception (83%) and were well-treated with an HIV RNA <50 copies/mL at delivery (86%). In total, 67% (n=395) of the WWH were on ART at conception, which increased over time from 33% (n=3) in year 2000 to 88% (n=22) in 2019.

Combination treatment with a Nucleoside Reverse Transcriptase Inhibitor (NRTI) and a PI was the most common regimen (96%). Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) and Integrase Inhibitor (InSTI) were the least commonly used drug classes (26% and 6%, respectively). However, an increase in InSTI based regimen in pregnancy, especially Dolutegravir (DTG) use, was seen in recent years. In total, 118 (20%) women changed their ART regimen during pregnancy. Change was more common in women, who were diagnosed with HIV prior to conception (n=102 (86%)) than among women diagnosed with HIV in pregnancy (n=16 (14%)). ART regimen, PI use in pregnancy, or timing of ART initiation in pregnancy was not significantly associated with risk of preterm birth, small for gestational age, or low birth weight. Initiation of ART in the first trimester and PI use in the first trimester were significantly associated with an increased risk of intrauterine growth restriction in the univariate analysis (OR 3.24 (95% CI: 1.13 ; 9.30) and OR 3.39 (95% CI: 1.34 ; 8.58), respectively), but not in the multivariate analysis adjusting for maternal factors. Smoking and maternal HIV RNA \geq 50 copies/mL were independently associated with an increased risk of adverse birth outcome.

Conclusions: WWH living in Denmark are generally well-treated during pregnancy with NRTI+PI as the most common ART regimen used in pregnancy. The association between ART use in pregnancy and adverse birth outcomes may be explained by maternal risk factors.

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Prevalence, Correlates, and Outcomes of Major or Persistent Pain Among Women Living with HIV in Metro Vancouver, Canada

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Background: Chronic pain is a major cause of morbidity in people living with HIV. While women living with HIV and AIDS (WLWHA) may be twice as likely to report severe or undertreated pain compared to men with HIV and AIDS, there has been limited research on pain among WLWHA. This study therefore assessed the prevalence, correlates, and key outcomes of major or persistent pain among WLWHA in Metro Vancouver.

Methods: Our analysis draws from 5 years (September 2014-August 2019) of data collected through the Sexual Health and HIV/AIDS Women's Longitudinal Needs Assessment (SHAWNA), a community-based open longitudinal study of cis and trans WLWHA who live in and/or accessed HIV care in Metro Vancouver, Canada. Bivariate and multivariable logistic regression with generalized estimating equations for repeated measures were performed to identify associations between social-demographic, psycho-social and social-structural correlates and self-reported major or persistent pain (last 6 months). Multivariable logistic regression analysis was also performed to identify associations between major or persistent pain and three outcome variables (self-rated health, interference of health with social activities, interference of health with goals), with all models adjusted for the same confounders (e.g., age, depression, substance use, food and housing insecurity). Adjusted odds ratios (aORs) and 95% confidence intervals are reported.

Results: The study sample included 1632 observations among 335 participants. At baseline, 55.5% of participants reported being Indigenous, 34.3% White, 6.0% African, Caribbean and/or Black, and 4.2% otherwise racialized persons. Overall, 6.6% were trans women. Throughout the study, 77.3% reported major or persistent pain at least once in the last 6 months, with 46.3% experiencing any undiagnosed pain and 53.1% managing pain with criminalized drugs. Major or persistent pain was associated with age (aOR 1.04 [1.02-1.06] per year older), food and housing insecurity (aOR 1.54 [1.08-2.19] versus no food or housing insecurity), depression (aOR 1.34 [1.03-1.75]), and suicidal ideation (aOR 1.71 [1.21-2.42]). Odds of major or persistent pain were higher for those who used non-injection opioids less than daily (aOR 1.53 [1.07-2.17] versus no opioid use) but lower for those who used non-injection opioids daily (aOR 0.46 [0.22-0.96] versus no opioid use) and those who had access to health services (aOR 0.63 [0.44-0.91]). There was no significant association between pain and viral load, injection opioid use, unintentional overdose, sexual/physical violence, HIV stigma, or discrimination. Compared to other participants, those with major or persistent pain were less likely to report good self-rated health (aOR 0.61 [0.47-0.79]) and more likely to report that their health interfered with social activities (aOR 2.49 [1.90-3.26]) and goals (aOR 3.48 [2.74-4.41]).

Conclusion: More than three-quarters of WLWHA in our study reported major or persistent pain, which was associated with poor self-rated health and functional impairment. Approximately half of participants reported undiagnosed pain and pain self-management with criminalized drugs. This is deeply concerning as contamination of the drug supply in British Columbia has led to an opioid crisis culminating in a record number of overdose deaths over the last two years, with overdose implicated as a major driver of mortality in people living with HIV and AIDS in British Columbia. We have identified social-demographic, social-structural, and psychosocial risk factors for pain in WLWHA that emphasize the need for low-barrier and trauma-informed chronic pain programs and interventions that are embedded within a harm reduction framework.

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Substance Use Treatment Utilization Among Women with and at Risk for HIV in the Southern United States

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Background: Substance use (SU) contributes to poor health outcomes among individuals with HIV and increases risk for HIV acquisition. The extent to which evidence-based interventions for SU management are utilized among women with HIV (WWH) and at risk for HIV (HIV-) is unknown. We sought to describe SU treatment utilization among WWH and HIV- women enrolled in the Southern sites of the Women's Interagency HIV Study (WIHS) in the United States.

Methods: WWH and HIV- women who enrolled and followed in the WIHS in Atlanta, Birmingham/Jackson, Chapel Hill, and Miami with last observed visits from 2014-2020 were included. Current SU was defined as any non-medical use of drugs in the past year at last follow-up visit. SU treatment utilization was determined by self-

reported use of medication replacement therapy or drug treatment program among women who reported current SU. Demographic, clinical, and sociobehavioral characteristics, including healthcare engagement, from the last visit were compared between women who did and did not report SU treatment.

Results: Among 870 women (625 WWH, 245 HIV-), 69% (n=603) reported SU in their lifetime (67% WWH, 75% HIV-), and 36% (n=309) reported current SU (35% WWH, 37% HIV-). Among women endorsing current SU, 82% reported marijuana use, 39% crack/cocaine, 2% opioids, 2% intravenous drugs, and 1% methamphetamine; the median age was 49 years, 81% identified as Non-Hispanic Black, 69% were unemployed, 87% had health insurance, 65% smoked cigarettes, 22% reported heavy drinking, 44% endorsed depressive symptoms, and 24% reported polysubstance use. Only 11% (n=35) reported SU treatment in the last year (12% WWH, 9% HIV-).

Only 10% (n=32) reported SU treatment in the last year (11% WWH, 9% HIV-). Among those reporting current SU, treatment utilization was endorsed among 50% reporting methamphetamine use, 17% intravenous drugs, 29% opioids, 10% crack/cocaine, and 7% marijuana. Among WWH with current SU, retention in HIV care, viral suppression, and ART use did not significantly differ by SU treatment.

Conclusions: Despite high prevalence of current SU among women enrolled in the Southern WIHS sites, there was a substantial gap in SU treatment utilization across substance types, with only 1 in 10 overall reporting SU treatment. Further investigation of treatment underutilization is urgently needed to develop tailored implementation strategies for this population.

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Adolescent Mothers Affected by HIV in South Africa: An Exploration of Risk and Protective Factors for Maternal Mental Health

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Background: Adolescent pregnancy and HIV are prominent global health and, both -independently and combined- may compound mental health difficulties for adolescents. There is an absence of knowledge regarding risk and protective factors for mental health difficulties among adolescent mothers within the context of HIV in sub-Saharan Africa. Existing research has focused on broader populations. This study aims to identify the prevalence of common mental disorder among adolescent mothers (both living with and not living with HIV) and explores hypothesised risk and protective factors for likely common mental disorder.

Materials & methods: Analyses utilise data from 1002 adolescent mothers (10-19 years) from a prospective cohort study of young mothers (10-24 years n=1046) and their children residing in the Eastern Cape Province, South Africa. All mothers completed a detailed questionnaire consisting of standardised measures of sociodemographic characteristics, health (inclusive of management of HIV, if appropriate), mental health and, hypothesised risk and protective factors. Logistic

regression models were utilised to explore associations between hypothesised risk, protective factors and common mental disorder. Risk and protective factors were clustered within a hypothesised socioecological framework and entered into models using a stepwise sequential approach. Interaction effects with maternal HIV status were additionally explored and, marginal effects models were utilised to investigate the cumulative impact of identified protective factors on the probability of likely common mental disorder.

Results: 27.1% (272/1002) of adolescent mothers were living with HIV. Prevalence of common mental disorder among adolescent mothers was 12.6%. Adolescent mothers living with HIV were more likely report likely common mental disorder compared to adolescent mothers not living with HIV (16.2%vs.11.2%, $X^2=4.41$, $p=0.04$). Factors associated with common mental disorder were any abuse exposure (OR=2.90 [95%CI:1.42-5.90], $p=0.003$), perceived social support (OR=0.24 [95%CI:0.15-0.38], $p<0.0001$) and, exposure to community violence (OR=2.10 [95% CI:1.37-3.22], $p=0.001$). There was limited evidence of interaction effects between risk and protective factors and, maternal HIV status. A cumulative impact of protective factors was identified in which an increased number of protective factors experienced was found to reduce the probability of common mental disorder among this group.

Conclusions: These analyses address a critical evidence gap relating to risk and protective factors associated with the mental health of adolescent mothers. Identified risk and protective factors span individual, interpersonal and community levels have the potential to impact adolescent maternal mental health within South Africa. Adolescent mothers living with HIV were more likely to report probable common mental disorder. Programmes need to understand the clustering of challenges for adolescent mothers living with HIV.

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Mental and Sexual Health in Women Living with HIV Aged 40-60 in Denmark: A Cross-Sectional Study

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Introduction: Significant improvements in the treatment of human immunodeficiency virus (HIV) have increased life expectancy of individuals living with HIV to resemble that of the general population. Consequently, issues pertinent to aging in the context of HIV necessitate clinical consideration. Data suggests that women living with HIV (WWH) are at increased risk of mental health problems, sexual dysfunction, and severe menopausal symptoms during midlife when compared to women living without HIV (WWOH). However, the evidence is sparse for this age-group of WWH, and no previous studies have been conducted in Denmark.

Aim: To investigate the mental and sexual health of WWH aged 40-60 in comparison to WWOH in Denmark. Secondly, to examine the severity of menopausal symptoms in WWH.

Methods: Preliminary data was retrieved from the Perception of psychosocial, sexual, and reproductive health among people living with and without HIV in Denmark- the SHARE study; an ongoing nationwide cross-sectional study examining psychosocial, sexual, and reproductive health in people living with HIV in Denmark. WWH were recruited during routine clinical care from five centers in Denmark. A control group of Danish WWOH, matched 1:10 on specific age, was included

from the population-based cohort study Project SEXUS. Data was collected from March to September 2021 by an electronic questionnaire consisting of several standardized and validated Patient Reported Outcome Measures (PROMs); including the Patient Health Questionnaire – 2-item scale (PHQ-2), the Generalized Anxiety Disorder – 7-item scale (GAD-7), and The Female Sexual Function Index – 6 items scale (FSFI-6), as well as individual items covering multiple areas of sexual, psychosocial, and reproductive health. The main analyses applied logistic regression models to compare mental and sexual health data from WWH to WWOH including univariate and multivariable models adjusted for ethnicity, relationship status, financial situation, substance use, BMI, physical health, mental health, smoking, and menopausal status. The sub-analysis explored severity of menopausal symptoms in WWH compared to published reference norms based on a European population of WWOH.

Results: In total, 73 WWH and 730 WWOH, with a median age of 49 years [IQR 45-54] in both groups, were included. WWH were more likely to be single (34% vs. 19%), to live alone (23% vs. 14), and more likely to be born to parents born and raised outside Denmark (52% vs. 2%). The main analyses demonstrated no associations between mental health and HIV status. The prevalence of depression, measured by the PHQ-2, was 21% among WWH vs. 14.6% among WWOH (OR 1.57 [95% CI: 0.82-2.97]), while the prevalence of anxiety, measured by the GAD-7, was 7.0% for WWH compared to 6.7% for WWOH (OR 1.05 [95% CI: 0.39-2.85]). When examining sexual health outcomes, several significant associations with HIV status were found. WWH had significantly increased odds of lower sexual desire levels (aOR 3.19 [95% CI: 1.51-6.73]), lubrication dysfunction (aOR 8.26 [95% CI: 2.59-26.41]), and genital pain dysfunction (aOR 4.98 [95% CI: 1.31-8.90]) when compared to WWOH. The sub-analysis revealed no significant differences in severity of menopausal symptoms in WWH compared to WWOH.

Conclusion: Preliminary results from the SHARE study demonstrated that WWH, aged 40-60, suffered more sexual problems and dysfunctions when compared to WWOH of the same age in Denmark. No difference was seen in mental health outcomes or in the severity of menopausal symptoms.

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Missed Opportunities to Support Pregnant Women Living with HIV in Zambia: Why Are So Many Women Ineligible for a Couples-Based Intervention?

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Background: In settings of high HIV prevalence and low resources in sub-Saharan Africa, couples-based counseling is a promising approach to promote women's engagement in HIV care and treatment during and after pregnancy. However, couples-based approaches require male partners who are available and willing to participate – excluding certain women living with HIV (WLWH) based on underlying relationship dynamics.

Materials & Methods: We sought to understand the reach of a couples-based behavioral intervention (Happy Homes, Healthy Families) targeting WLWH and their male partners in Lusaka, Zambia, during and after pregnancy. We are currently enrolling couples into a randomized controlled trial, testing the effect of a multi-session psychoeducational counseling intervention to improve pregnant and postpartum WLWH's adherence to antiretroviral therapy (ART) and

engagement in HIV care through hypothesized intra- and interpersonal mediating factors. The eligibility criteria include: pregnant female partner living with HIV; both partners 18 years of age or older and willing to participate; the couple is in a stable relationship (married or cohabitating and sleep under the same roof at least once per week) that has existed for ≥ 6 months; and no severe IPV reported in the past 6 months. We reviewed recruitment logs to describe the proportion of women who were ineligible for the study, overall and by specific exclusion criteria.

Results: From December 2020 to January 2022, 266 pregnant women were screened for study participation during routine antenatal care at a large public health center in Lusaka. Almost one-half (48%; n=128) were ineligible to participate. The most common reason for ineligibility was that the male partner/husband was not available (43%; n=55), typically because he was too busy or worked out of town. Fourteen women (11%) reported either being separated (n=12) or widowed (n=2); 8 women (6%) reported their male partner would not consent, including 2 women who stated that the reason he would not consent is because he has another wife. One woman (1%) was ineligible due to severe IPV reported.

Conclusions: In this couples-based intervention trial, a large segment of pregnant WLWH were ineligible for enrollment because they did not have a male partner who was available or willing to participate. Alternative approaches are needed to ensure that WLWH who are ineligible for couples-based approaches get the necessary support for HIV-related health behaviors. Additional research should examine whether other relationships beyond male partners (e.g., siblings, parents, friends) can successfully be targeted to support HIV care and ART adherence among WLWH during and after pregnancy.

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Pregnancy Outcomes and Pharmacokinetics in Pregnant Women Living with HIV Exposed to Long-Acting Cabotegravir and Rilpivirine in Clinical Trials

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Background: Limited data exist among women living with HIV who become pregnant while exposed to long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV). We report outcomes in pregnant participants and LA pharmacokinetic (PK) tail data in pregnant women exposed to CAB+RPV with live births.

Methods: Women of reproductive potential exposed to ≥ 1 dose of CAB+RPV (oral/LA) from ViiV-sponsored Phase 2/3/3b clinical treatment studies and the compassionate use program were included in this analysis and pregnancies identified. Per protocol, upon identification of pregnancy, CAB+RPV was discontinued and an alternative

regimen initiated, with continued quarterly PK sampling for 52 weeks post last injection during long-term safety follow-up (LTFU). Descriptive characteristics of pregnant women and birth outcomes and available CAB and RPV PK during pregnancy for those with live births are summarized.

Results: As of March 31, 2021, 26/325 women of reproductive potential (age 18–49 years) became pregnant while exposed to CAB+RPV (5 oral, 21 LA [including 3 following LA discontinuation]). There were 11 live births (1 oral, 10 LA), of which 10 had no reported congenital abnormalities and 1 had reported congenital ptosis, in a pre-term infant with intrauterine growth restriction. There were 9 elective terminations and 6 miscarriages (5 in first 9 weeks of gestation). Ten women exposed to intramuscular CAB+RPV LA became pregnant with subsequent live birth outcomes, including 3 infants conceived during the PK tail in LTFU. All women were virologically suppressed at time of pregnancy identification. In women becoming pregnant on LA dosing, plasma CAB and RPV concentrations during pregnancy were within the range of expected concentrations in non-pregnant women. Two of 10 women with live births exposed to CAB+RPV LA continued LA therapy during pregnancy (compassionate use program participants).

Conclusions: Pregnancy outcomes in women exposed to CAB+RPV at conception are consistent with earlier findings. There was 1 reported congenital anomaly among 11 live births. CAB and RPV PK tail in pregnancy was within the expected range for non-pregnant women. Ongoing monitoring of birth defects within the antiretroviral pregnancy registry and pregnancy surveillance within the treatment program continues.

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Reproductive Feto-Toxicity Studies to Evaluate Dolutegravir in Combination With Emtricitabine and Tenofovir in Pregnant Mice on a Folate Deficient Diet

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Background: Dolutegravir (DTG), an integrase strand transfer inhibitor (INSTI), is a WHO-alternative first-line regimen. Initial findings from an observational study in Botswana showed an elevated incidence of neural tube defects (NTDs) with peri-conceptual exposure to DTG. We have previously shown that DTG exposure yielding therapeutic levels in pregnant mice on a folate sufficient diet was associated with higher rates of fetal anomalies compared to control-treated mice. Here we explore potential DTG reproductive toxicities in a folate-deficient pregnancy mouse model.

Methods: Female C57BL/6 mice fed a folic acid-deficient diet for a minimum of 2 weeks, were mated and randomly allocated to either control (water) or 1x-DTG (2.5mg/kg DTG+50mg/kg tenofovir 33.3mg/kg emtricitabine). Drug/water was administered once daily by oral gavage from the day of plug detection to sacrifice at E15.5. Fetuses were assessed for anomalies by two independent reviewers who were blinded to treatment allocation. Mixed-effects logistic regression was used to assess differences between treatment groups accounting for litter effects.

Results: A total of 1533 fetuses from 209 litters were assessed (control n=103 litters, 756 fetuses; 1x-DTG n=106 litters, 777 fetuses). Percent viability, placental weight, fetal weight, fetal/placenta weight ratio, and maternal weight gain did not differ between groups. Crown-rump length was lower and head width was higher in the 1x-DTG vs. control groups. Seven NTDs (exencephaly, n=2; encephalocele, n=3; spinal bifida, n=2) were observed in the 1x-DTG group (7/777=0.9%), with no NTDs in controls. Fetuses exposed to 1x-DTG also had higher rates of severe turning defects (2.2% vs. 0.4%, p=0.04), abdominal wall defects (3.5% vs. 0.4%, p=0.04), limb defects (3.9% vs. 0.5%, p=0.001), cranial/spinal bleeds (15.7% vs. 5.4%, p<0.001), and severe edema (7.0% vs. 1.3%, p<0.001).

Conclusion: DTG treatment was associated with higher rates of fetal anomalies compared to controls in pregnant mice on a folate-deficient diet

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Infant Feeding Options for People Living with HIV - 'The Optimal Scenario & Context of Care': Guidance for Healthcare Providers and PLHIV

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Background: This document offers guidance for a shared decision-making process between a person living with HIV and their healthcare providers to ensure that informed choices are made concerning infant feeding options.

Materials & Methods: The construction of this guidance was considered through numerous reviews with both specialist HIV clinicians, healthcare providers representing a range of practices in perinatal care and with a diversity of people living with HIV. It takes into consideration the rapidly changing context of research and knowledge development in this area and has been developed in parallel with a resource developed by the National Association of People with HIV Australia and Positive Women Victoria. In developing this guidance, ASHM evaluated the risks of HIV transmission via breastmilk feeding for mother-to-child transmission (MTCT) in light of accessible combination antiretroviral treatment (cART), weighed against the benefits of breastfeeding. The authors reviewed the latest research relating to the transmission of HIV from parent to child through breastfeeding where the person was on effective cART and fulfilled several

essential criteria and have found no evidence of transmission of HIV.

Results: In recent years, there has been a growing recognition among healthcare providers, researchers and clinicians that breastfeeding* can be a viable choice for people living with HIV if they follow several criteria and are willing to engage in strategies to reduce the risk of HIV transmission. This situation is described as the 'Optimal Scenario' and summarised in an important discussion paper published in July 2018 in the Swiss Medical Weekly. This guidance is based on the underlying evidence for the 'Optimal Scenario' and adds to this scenario what ASHM calls the 'Optimal Context of Care' required to support people living with HIV who may decide to breastfeed.

Both USA and UK guidance provides the following support for this context of care

- People who have questions about breastfeeding have the right to receive patient-centred and evidence-based counselling.
- When people living with HIV choose to breastfeed, they need to be supported with information about risk reduction measures to minimise the risk.
- People who are virologically suppressed on cART with good adherence and who choose to breastfeed should be supported to do so, and should be informed about the risk of transmission of HIV through breastfeeding in this situation and the requirement for extra patient and infant clinical monitoring.

Conclusions: ASHM maintains that the safest choice for a person living with HIV and their infant is formula feeding to ensure that HIV transmission is minimised. However, this guidance recognises that clinicians and healthcare workers providing care and support for people living with HIV will have the experience, or can anticipate the experience, of people who live with HIV expressing a wish, preference or intention to breastfeed.

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Exploring Maternal Mental Health and Child Cognitive Development among Adolescent Mothers and Their Children Affected by HIV in South Africa

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Background: Both adolescent motherhood and HIV are associated with mental health burden and child development challenges. This study explores the relationship between the mental health of adolescent mothers (comparing those living with and not living with HIV) and the cognitive development scores of their children. Factors potentially associated with child development are additionally explored to identify those children born to adolescent mothers who may be at the greatest risk.

Materials & methods: Cross-sectional data utilised within the analyses was drawn from a large cohort of adolescent mothers, both living with and not living with HIV, and their children residing in South Africa. Detailed study questionnaires were completed by adolescent mothers relating to their self (inclusive of health and management of HIV, if appropriate) and their child and, standardised cognitive assessments were completed by trained researchers for all children using in the Mullen Scales of Early Learning. Chi-square, t-tests (Kruskal Wallis tests, where appropriate), and ANOVA were used to explore sample characteristics and child cognitive development scores by maternal mental health status (operationalised as likely common

mental disorder) and, combined maternal mental health and maternal HIV status. Multivariable linear regression models were used to explore the relationship between possible risk factors (including poor maternal mental health and HIV) and, child cognitive development scores.

Results: The study included 954 adolescent mothers; 24.1% (230/954) were living with HIV, 12.6% (120/954) were classified as experiencing likely common mental disorder. After adjusting for covariates, maternal HIV was found to be associated with reduced child gross motor scores (B=-2.90 [95%CI: -5.35, -0.44], p=0.02), however, no other associations were identified between maternal likely common mental disorder, or maternal HIV status (inclusive of interaction terms), and child cognitive development scores. Sensitivity analyses exploring individual maternal mental health scales identified posttraumatic stress symptomology scores as being associated with lower child cognitive development scores. Sensitivity analyses exploring potential risk and protective factors for child cognitive development also identified increased maternal educational attainment as being protective of child development scores and, increased child age as a risk factor for lower development scores.

Conclusions: This study addresses a critical evidence gap relating to the understanding of the complexity of multiple parenting factors affecting child development, including teenage motherhood, HIV and environmental pressures. This group of mothers experience a complex combination of risk factors, including HIV, likely common mental disorder and, structural challenges such as educational interruption. Targeting interventions to support the cognitive development of children of adolescent mothers most at risk may be of benefit. Clearly a basket of interventions needs to be considered, such as the integration of mental health provision within existing services, identifying multiple syndemics of risk, and addressing educational and structural challenges, all of which may boost positive outcomes for this group.

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SHE in Germany: Empowering Women Living with HIV in Peer-to-peer Workshops

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Background: According to the recently published data on people living with HIV (PLWH) in Germany (RKI: HIV/AIDS in Deutschland - Epidemiologische Kurzinformation 2021) women remain a minority (>20%) who live especially isolated (GSSG: Projekte/SHE). The recent stigma index on PLWH in Germany (DAH and IDZ: positive stimmen 2.0) shows: more than two-thirds of the people interviewed cannot talk openly about their infection in many areas of their lives. The persistent stigma around an HIV infection can prevent many women from speaking openly about their infection and/or reaching out. Additionally, HIV-support programs are often primarily aimed at an MSM target group. Therefore, HIV-positive women in particular suffer from this isolation. This lack of community support can have a significant impact on their (mental) health.

Methods: To counteract the isolation, the SHE-program offers peer-to-peer workshops for women living with HIV (WLWH). The name of the program is an acronym for Strong HIV-positive Empowered women, which already hints to the aim of the project. At the center of SHE is a team of currently 11 women, who have been living openly with HIV for at least two years. They are specifically informed and trained on a regular basis to offer peer-support. The trainers organize regular workshops all over

Germany where topics such as partnership, employment and traveling are discussed in relation to HIV. Additionally, they inform each other about empowering tools such as self-care and resilience. SHE offers a safe-space for sharing information, exchanging experiences and the opportunity to network. Thus, SHE provides an opportunity to finally talk openly about living with HIV.

The SHE workshops are often organized in cooperation with counseling centers, HIV practices and ambulances. Thanks to the financial support of partnering pharmaceutical companies, the SHE trainers are compensated for their commitment, while the workshops remain free of charge for the attendees. Moreover, women can attend most workshops anonymously. These conditions facilitate a low-threshold access to the meetings. To allow workshops even during the Cov19-pandemic two new formats have been developed: outdoor and online workshops were added to the classic face-to-face meetings.

Results: In 2021, a total of 15 SHE workshops were held despite the difficult conditions caused by the pandemic. In addition to 7 face-to-face meetings, 3 online and 5 outdoor workshops were offered. 80 WLWH attended this wide range of workshops. All participants were encouraged to provide anonymous feedback and these comments confirm: community support and the opportunity for networking in a peer-to-peer setting is well received. Thus, the SHE program contributes to the empowerment and well-being of WLWH in Germany.

Conclusion: The SHE program is an important project addressing isolation, still a great challenge in the lives of WLWH. SHE is especially meaningful for women because most other HIV programs are targeted at MSM. While the current pandemic has made in-person meetings difficult, the additional formats "online" and "outdoor" have helped many women with HIV in Germany.

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Mental Health Impact of Intersecting Stigmas of HIV, Domestic Violence and Other Marginalized Identities among Women Living with HIV

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Background: Since the start of the epidemic, people living with HIV have experienced stigma and discrimination due to fears of contagion and moral judgement, resulting in violence and social isolation. Women living with HIV have carried a disproportionate burden of this stigma, especially in India, where gender discrimination is still rampant. The result is widespread violence against women, mainly domestic violence from husbands and in-laws, which is itself stigmatized. These intersecting stigmas of HIV, domestic violence, gender and other marginalized identities affect women's mental and physical health.

Materials and Methods: We conducted 47 semi-structured interviews with women living with HIV and key service providers in Kolkata, India, to understand the impact of intersecting stigmas on women's mental health. Eight women also participated in a photovoice project to show how they coped with the negative mental health impact

of stigma and violence. Data from the semi-structured interviews and photovoice were coded in Nvivo qualitative software and analyzed using thematic network analysis. Separate thematic maps were generated to examine the mental health effects of stigma and violence and the external and internal resources used by women to cope.

Results: The chronic stress of stigma and violence pulled women into a spiral of poor health. Violence compounds the mental health effects of stigma and vice versa through depression, stress related to stigma experiences, suicidal ideation and anxieties surrounding non-disclosure and anticipated stigma, finances, and poor health or impending death. Poor mental health led to worsening physical health through a number of different pathways, including poor adherence and non-linkage to care and poor appetite and sleep, as well as reports of low CD4 counts associated with stress. In order to cope, women require and use a variety of internal and external resources. Social resources such as emotional, instrumental, economic, belonging and informational support from a variety of sources bolster women's internal psychological resources, such as positive reframing, self-motivation, relaxation, and faith, that help women cope.

Conclusions: The compounded effect of stigma and resulting violence worsens women's mental health and leads to poor physical health. Women living with HIV who are survivors of violence need or utilize a variety of specialized social and psychological resources to cope with their experiences. Stigma reduction training for counselors and others involved in the care of women living with HIV is critical to reduce violence against them.

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Supporting Resilience of AGYW to COVID-19 Outcomes

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Background: The World Health Organization declared the COVID-19 a global pandemic on March 11, 2020. AGYW in their diversity are facing unprecedented challenges and catastrophic changes that are affecting not only their incomes, but their health as well, including access to HIV and SRH services. The age group most affected is between 15-40 which encompasses the target population of HER Voice Fund. COVID-19 has generally increased the strain on the already existing inequalities among the communities we work with.

HER Voice fund team carried out a short survey with the grantees to understand the challenges faced by the young women in the 13 priority countries. 70 responses were received from all the 13 countries. PMU analysed the results and identified 5 of the most affected countries namely: Uganda, Zimbabwe, South Africa, Namibia and Eswatini which also have very high numbers of COVID-19 community infections and very stringent lockdown measures.

Methods: A survey was sent to the 13 priority countries of the global fund to 63 community based organisations. 60 organisations from Cameroon, Uganda, Kenya, Malawi, Tanzania, Zambia,

Zimbabwe, Namibia, South Africa, Eswatini, Mozambique, Botswana and Lesotho.

Results: The survey found that AGYW faced increased sexual and gender based violence reported and perpetrators being family members and relatives due to COVID 19 restrictions were AGYW are spending most of the time at home. Limited access to treatment (HIV, TB), GBV and SRHR services and issues of AGYW in relation to health and rights have continuously fallen through the cracks as all responses are focusing on the pandemic . for example: reduced access to HIV testing, hindered timely access to HIV prevention and SRHR services, disrupted ART and adherence and a lack of proper nutrition and essential services due to lockdown and largely fear of contracting the virus.. AGYW living with HIV in 5 countries mostly affected by COVID-19 are in a disadvantaged position when it comes to reaching out to their doctors or local clinics to access Antiretroviral (ARV) medication and appropriate care and support. The huge challenge indicated was lack of transport fares to the clinic due to COVID-19 hike of prices and limited access to accurate information on COVID-19 and vaccines

Conclusions/ next steps: With the support provided under the HVF, AGYW improved access to information on the latest news, updates, and resources about the virus and its effect on the public. The safe spaces or other platforms for AGYW to communicate were created and supported, the number of Number of AGYW Supported with transport fares to go and access treatment (HIV, TB), GBV and SRHR services increased. AGYW need continued support to engage and be part of processes that affect them.

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PADAYON: A Phenomenological Study of Women Living with HIV

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This study explores the experiences of women living with HIV by using interpretative phenomenological analysis. Four women consented to participate in the study. Two were ciswomen while two were transgender women, aged 30-54 years.

Semi-structured interviews yielded three superordinate themes with respective sub-themes: (1) The traumatic adversities of HIV diagnosis: *bagsak ang mundo* (ruined life), *pinandirihan kami* (experiences of stigma), and *nanghihina ang katawan* (physical health decline); (2) A quest for wellness and longer life: *nakiusap sa Diyos* (prayer of fortitude), *nakanap ng lunas* (medical intervention), and *nakatagpo ng kakampi* (finding an ally); and (3) Resiliency and meaningful life:

natanggap ang sarili (self-acceptance), *may dahilan* (recognizing life's purpose), and *padayon ang buhay* (surviving with positivity).

The phenomenology of participants in this study provides information that they survived the traumatic physical, psychological and social adversities of HIV diagnosis and achieved wellness and longer life as WLWH by availing the medical treatment of the newer antiretroviral therapy, finding refuge with HIV support groups, and enhancing their religious faith and spirituality which likewise allowed them for self-acceptance, discover their life's purpose, and strengthening their resiliency with meaningfulness of "padayon" (continue, go on, sustain).

The participants' phenomenological meaning of "padayon" illustrates their journey of positivity having a prevailing conviction to continue, go on and sustain with life as they continuously maximize their inner strength, accomplish meaningful tasks and achieve a fulfilling life.

Recommendations include intensifying the quality health care management in the current structure of HIV treatment hubs that must be PLWH-friendly, safe, empathic, compassionate, and gender-sensitive, to build acceptance and resilience among PLWH.

Keywords: lived experiences, women living with HIV, interpretative phenomenological analysis

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Characteristics of Women Living with HIV in the RESPOND Cohort

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Background: We describe women living with HIV in the RESPOND consortium, a large multinational observational cohort of people living with HIV from Europe and Australia.

Materials and Methods: Characteristics of women recruited to RESPOND are compared to men, and presented at RESPOND baseline: the date of starting an integrase inhibitor (INSTI) after 01-Jan-2012, or for those who did not start an INSTI at enrolment, the latest of 01-Jan-2012 or enrolment into the local cohort. Viral load (VL), CD4 count and antiretroviral (ART) regimens are presented for the treatment naïve at first ART initiation ≥01-Jan-2012. Probabilities for cardiovascular disease (CVD) and chronic kidney disease (CKD) were calculated using D:A:D (Data-collection on Adverse Effects of Anti-HIV Drugs) risk models.

Results: Of 33,087 enrolled, 8348 (25%) are women, most are white (59.5% [CI: 58.4, 60.6]) or black ethnicity (25.4% [CI: 24.4, 26.4]) compared with 83.6% [CI: 83.1, 84.1] and 6% [CI:5.7, 6.3] of men, respectively. The median [IQR] age was 43-years [36, 51] for women and 46-years [35, 53] for men. Prior AIDS diagnosis was reported in 20.6% of

women and 19.9% of men. Hepatitis C and B co-infection was reported in 23.9% [CI:22.9, 24.8] and 20.0% [CI:19.5, 20.5] of women and 5.9% [CI:5.4, 6.5] and 7.5% [CI:7.2, 7.8] of men. Current smoking was reported in 18.6% [17.7, 19.4] of women and 24.9% [CI:24.3, 25.4] of men. 23.9% of women and 31.9% of men initiated first ART ≥01-Jan-2012 (P<0.001); of whom, 74.7% [CI: 72.8, 76.6] of women and 81.5% [CI: 80.7, 82.4] of men had VL>200 copies/mL. Among the Tx naïve, 24.6% [CI: 22.7, 26.6] of women and 21.1% [CI: 20.1, 22.0] of men had CD4 counts <200 cells/μL. Women were more likely to initiate a protease inhibitor-based regimen, 21.8% [CI: 20.0, 23.6] vs 16.5 [CI: 16.0, 17.0] among men. Among Tx naïve aged <40 years, 26.4% [CI: 24.0, 29.1] of women and 35.8% [CI: 34.4, 37.3] of men initiated an INSTI. At baseline, 6.7% [CI: 6.2, 7.3] of women and 8.1% [CI: 7.7, 8.4] of men reported ≥3 comorbidities. Common comorbidities among women were dyslipidaemia (51.7% [CI:40.6, 52.8]) and hypertension (28.4 [CI:27.4, 29.4]), but less prevalent than in men, 62.3% [CI:61.7, 62.95] and 36.3% [CI:35.7, 36.9]. At baseline, 55.4% [CI: 53.7, 57.1] of women and 29.1% [CI: 28.2, 30.0] of men had low CVD risk scores; 44.8% [CI: 43.5, 46.2] and 46.4% [CI: 45.7, 47.2] respectively had low CKD risk scores.

Conclusion: Women in RESPOND are diverse in age, treatment stage and clinical history. Compared to men, women were more likely to be black, less likely to smoke and were more treatment-experienced at baseline. Women differed in terms of ART regimen initiated, CD4 and viral load at first ART initiation. There is a need for more sex-stratified analyses on comorbidities and ageing. Further investigation of sex differences in RESPOND may help inform screening and management approaches specific for women of all ages with HIV.

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Prolonged Amenorrhea and Liver Fibrosis in Women Living with HIV Enrolled in the Children and Women: AntiRetrovirals and Markers of Aging (CARMA) Study

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Background: Prolonged amenorrhea occurs twice as often in women living with HIV (WLWH) and can be associated with hypothalamic dysfunction leading to lower levels of estrogen and progesterone. Through their endogenous antioxidant properties, these sex hormones can slow hepatic fibrosis by suppressing reactive oxygen species. Hence, their loss is associated with liver fibrosis progression, but it remains unknown if the same is true in the context of amenorrhea. Our objective was to examine the relationship between amenorrhea and the Aspartate transaminase to Platelet Ratio Index (APRI) score, a validated indicator of liver fibrosis, in WLWH and HIV-negative controls.

Materials and Methods: WLWH and controls ≥ 16 y were enrolled in the CARMA-Endo study between

January 2013 and August 2017. Amenorrhea was defined as past/present amenorrhea for ≥ 1 year unrelated to pregnancy, contraceptives, surgery, or menopause. Degree of liver fibrosis was assessed via APRI score. Demographic and clinical variables were compared using Wilcoxon rank sum and Fisher's exact tests. Linear multivariable models determined relationship between amenorrhea and APRI score, adjusting for potential confounders identified by univariable analysis ($p < 0.05$); interaction between HIV-status and amenorrhea on APRI score was examined.

Results: WLWH (n=181) were similar to controls (n=130) in age and body mass index (BMI). More WLWH had Hepatitis C virus (HCV) antibodies (39.2% vs. 6.9%, $p < 0.001$), while amenorrhea and mean APRI scores were higher in WLWH versus controls (23.2% vs 10.0%, $p = 0.003$; 0.6 vs 0.4, $p < 0.0001$). After adjusting for BMI, HCV, HIV status, smoking, drug use, alcohol use, telomere length and employment, participants with amenorrhea still had 0.21 (0.03-0.38; $p = 0.018$) higher APRI scores than participants without. No interaction was found between HIV and amenorrhea on APRI ($p = 0.07$). Amongst WLWH, suppressed viral load and higher CD4 were associated with lower APRI (-0.37 [-0.61 to -0.14], $p = 0.002$; -0.043 [-0.072 to -0.014], $p = 0.004$ /100 units CD4 increase). Participants with longer non-nucleoside reverse transcriptase inhibitors (NNRTI) exposure had higher APRI scores (0.008 [0.001 – 0.016], $p = 0.034$ per year of NNRTI).

Conclusions: In this evaluation, participants with prolonged amenorrhea history had higher APRI scores than those without amenorrhea, independent of HIV status, indicating that amenorrhea is a potential additional risk factor for hepatic fibrosis. Further study of sex hormones and measures of hepatic fibrosis are needed to corroborate these findings.

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Bone Health of Aging HIV Infected Women

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Background: Bone health can be impacted by aging, HIV and antiretroviral therapy (ART). Little is established of the bone health of elderly treated HIV infected women

Methods: A cross sectional analysis of baseline bone health of women participating in a switch study of tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF).

Results: Data was collected from 34 participants, 24 Canadian and 10 Italian women enrolled in the peri- (48%) or early post- menopausal (52%) period. The median age 51 years, 58.8% black, 38.2% Caucasian. 12% current and 18% former smokers,

median 16.5 years HIV diagnosis and median 14 years ART and median 9 years TDF. The median CD4 cell count 570/mm³ (nadir 168) and viral load suppressed in all cases. 17.6% had a prior HCV diagnosis. The median BMI was 26. 15% were using calcium and 59% vitamin D supplements. No participant had ever received therapy for osteoporosis. 8.8% received hormonal replacement therapy. 21% reported a prior fracture. 20% reported having one or more falls in the previous 6 months. The baseline median score on the short performance physical battery test was 11, with 23% in the intermediate and 77% in the high performance level. The median baseline grip strength was 27.3 (normal). Based on DEXA scan the median (IQR) bone mineral density (BMD) at the lumbar spine was 0.916 (0.804, 1.053) and at the femoral neck was 0.741 (.692, .845) both below normal. At baseline the median FRAX fracture risk score for 10-year probability for a major osteoporotic fracture was 4.4 (2.7, 5.0). The median (IQR) 10 year probability for hip fracture was based on DEXA was 0.2 (0.1, 0.5).

Conclusions: Low BMD was identified in the majority of our older HIV cohort of women on TDF. Although performance measures were in the intermediate to high range, falls were common. Hip fracture risk estimate varied with the calculator. Aging HIV infected women should have regular BMD scans to determine the need for anti-resorptive therapy.

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Characterising Obstructive Sleep Apnoea, Obesity, and Cardiometabolic Health in People with HIV: A Case for OSA Screening in Africa

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Background: Antiretroviral therapy has dramatically improved the life expectancy of people with HIV (PWH), and non-communicable diseases are increasingly important causes of morbidity and mortality in this population. Obstructive sleep apnea (OSA), the most common respiratory sleep disorder, is a known proinflammatory factor associated with increased risk for cardiometabolic disease, though there is limited data from Africa. Understanding the extent of the problem is a critical first step towards developing appropriate interventions for less-resourced high HIV burden settings.

Methods: This is a cross-sectional, observational study of a well-characterised cohort of patients enrolled in the ongoing ADVANCE trial in South Africa. Between September 2021-January 2022, OSA risk was evaluated using the Berlin questionnaire (BQ), a screening tool with high specificity to detect OSA and comprised of 10

questions in three categories. Category one, high-risk was defined as persistent symptoms related to snoring; category two, high-risk was defined as persistent daytime sleepiness, drowsy driving, or both and category three, high-risk was defined as a history of hypertension or a body mass index (BMI) >30 kg/m². Overall OSA risk was defined as high-risk in at least two out of three categories. Demographic and known cardiometabolic risk (CMR) markers were compared between participants at low-risk versus high-risk for OSA and a CMR risk score was calculated using BMI, waist circumference (WC), fasting glucose, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), triglycerides, and mean arterial blood pressure.

Results: Of the 55 individuals included in this analysis, the overall mean age was 39.3 years, 63% were female, 31% had hypertension and 16.3% were high-risk for OSA. High-risk OSA participants had a higher BMI (P = 0.002), higher WC (P = 0.007), higher hip circumference (P = 0.033), and lower HDL-C (P = 0.008) than low-risk OSA participants. There were no notable differences in CMR score between the two groups.

Conclusions: Preliminary findings in a relatively young cohort of PWH comprised of mainly women, obesity, hypertension, and high-risk for OSA were high. Our results highlight the need for screening of OSA to prevent future cardiovascular morbidity in low- to middle-income countries such as South Africa

Keywords: antiretroviral treatment; obstructive sleep apnoea; obesity, cardiometabolic risk, HIV

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The Experience of Pregnancy Among Women Living with HIV in Nordic Countries: Qualitative Results from the 2BMOM Study

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Background: The success of antiretroviral therapy has resulted in the normalization of pregnancy among women living with HIV and a very low risk of perinatal transmission of HIV. Despite these advances, women living with HIV still face complex medical and psychosocial issues during pregnancy. Using qualitative data from the 2BMOM Study, the purpose of this study is to describe experiences of pregnancy and the relevance of social support among women living with HIV in Nordic countries.

Materials & Methods: Pregnant women living with HIV were included from sites in Denmark, Sweden,

and Finland from 2019 to 2020. Data were collected in the third trimester via individual interviews using a hybrid, narrative/semistructured format. The transcribed interviews were analysed using narrative thematic analysis.

Results: In total, 31 women living with HIV were enrolled, of whom 61% originated from an African country and 29% from a Nordic country. The analysis generated four primary narrative themes highlighting the ways that women living with HIV narrate their pregnancy experience: Just a normal pregnancy, unique considerations and concerns, interactions with healthcare, and social support. Women living with HIV have a strong desire to experience normal pregnancies and to be treated like any other pregnant woman. However, this sense of normality is fragile, and being pregnant whilst living with HIV does come with unique considerations and concerns, such as fear of transmission, antiretroviral therapy, and the need for specialized care, that are fundamental to the women's experiences. Interactions with health care providers and social support influence their experiences in both positive and negative ways.

Conclusions: The findings emphasize the desire for a sense of normality in pregnancy among women living with HIV. However, pregnancy does come with unique considerations and concerns, which highly influence the women's experience of pregnancy. Health care providers should focus on person-centred care, ensuring continuity and that women living with HIV do not feel discriminated against throughout their pregnancy.

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Induced Abortions of Women Living with HIV in Finland 1987–2019

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Background: Although most women living with HIV (WLWH) are fertile-aged, little is known about the rates and risk factors of induced abortions among them. Most data come from limited questionnaire studies with varying rates of non-response.

Materials & Methods: A retrospective nationwide register study comprising all WLWH and their abortions both before and after HIV diagnosis in Finland between 1987–2019. The rate of induced abortions was calculated for women aged 15–49 years with death, sterilization or emigration as additional cut-off points for time in follow-up. Risk factors for terminating a pregnancy were assessed with multi-effect logistic regression models examining all pregnancies ending in induced abortion or delivery. A maximum prevalence for undiagnosed HIV at induced abortions was estimated by identifying all induced abortions of WLWH 0–5 years before HIV diagnosis 1987–2014 and comparing them to the total number of induced abortions in Finland.

Results: A total of 1017 women with 15 807 years of follow-up had 396 induced abortions. The rate of abortions decreased from 42.8 to 14.7 abortions/1000 years of follow-up from 1987–1997 to 2009–2019 with the decrease more pronounced in induced abortions after HIV diagnosis. HIV diagnosed before or during pregnancy was associated with a decreased risk of induced abortion after 1997 when compared to 1987–1997, and the decrease was more pronounced in Finnish-born women (2009–2019 vs. 1987–1997 OR 0.16, 95% CI 0.06–0.49). In pregnancies starting after HIV diagnosis in 1998–2018, having previous induced abortions or deliveries was associated with an increased risk for terminating a pregnancy, with the risk increasing until 3–4 previous abortions and 2–3 previous deliveries. Other risk factors were country of birth other than Finland (OR 3.06, 95% CI 1.49–6.26) and younger age (OR 0.95 per year, 95% CI 0.90–1.00). The estimated maximum prevalence of undiagnosed HIV at the time of abortions was 0.22/1000 abortions.

Conclusions: During these 33 years the rate of induced abortions decreased markedly and is approaching the background population, and in the last two decades being diagnosed with HIV has not been associated with an increased risk of terminating a pregnancy. These changes possibly reflect the trust in diminishing risk of MTCT of the women and their caregivers but the rate still is higher than in the background population. The reproductive plans and contraception should be discussed at every appointment. Screening all women at the time of abortion does not seem to be cost-effective in a low-prevalence setting.

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HIV and Pregnancy: Prevention of Vertical Transmission Condesa Specialized Clinics, Mexico City

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Purpose: Describe the characteristics of pregnant women with HIV and the attention to prevent vertical transmission in two Specialized Clinics of Public Health Service of Mexico City.

Methods: Cross-sectional, descriptive study with a cohort of pregnant women with HIV/aids at two Specialized Clinics, from August 2013 through January 2021. Patients were referred from clinics located in every district of Mexico City, they send patients to Condesa Clinics for HIV confirmation and, detection of HBV, HCV, Syphilis, viral load (VL) and, CD4 count was performed. Pregnant patients with the reactive test are immediately evaluated by OB/GYN, internal medicine/infectology mental health, social workers, nurses. Antiretroviral therapy (ART) initiated the same day of HIV diagnosis. VL was performed at 4 weeks of initiated ART, every 3 months, and at 36 gestational weeks. Medical consultation is every 4 weeks or less. In the 37th week, they are referred to a hospital for the determination of the birthing technique.

Results: We have 255 pregnant women in Condesa's Pregnancy Cohort. This analysis included 165 patients, who have more than 6 months in follow-up after born her baby and continue in ART. Group 1 (G1) Chronic HIV women that know HIV diagnosis before the pregnancy (n=73), group 2 (G2) HIV diagnosis for the screening test in pregnancy (n=92). Group 1 (G1): Age at diagnosis of HIV 24 years (SD 8.8), years living with HIV 8 (SD 5.5). Age actually 32 years (SD 6.1). Education: Illiteracy 5.4%, primary 23.2%, secondary 43.8%, high school 15%, university 10.9%. Occupation: Unpaid employment 65.7%, employed 31.5%, student 1.3%, other 1.3%. Marital status: Common-law union 72.6%, single 27.3%. Drug use (during

pregnancy): No 80.8%, legal 9.5%, illegal 9.5%. Partner HIV status: Serodiscordant 67.1%, concordant 26%, unknown 6.8%. Sexual onset: 18 years (SD 2.7), sexual partners 1-3, 68.4%; 4-6 20.5%. Number of pregnancies 1-2, 57.5%; 3-4, 32.8%. Group 2 (G2): Age at diagnosis of HIV 25 years (SD 5.9), years living with HIV 4 (DE 2.9). Age actually 29 years (SD 6). Education: Illiteracy 7.6%, primary 20.6%, secondary 45.6%, high school 20.6%, university 5.4%. Occupation: Unpaid employment 73.9%, employed 19.5%, student 3.2%. Marital status: Common-law union 79.3%, single 20.6%. Drug use (during pregnancy): No 78.2%, legal 10.8%, illegal 3.2%. Partner HIV status: Serodiscordant 36.9%, concordant 50%, unknown 13%. Sexual onset: 17 years (SD 2.8), sexual partners 1-3, 57.6%; 4-6, 32.6%. Number of pregnancies 1-2, 61.9%; 3-4, 31.5%. Pregnancy weeks at the time of the first medical consultation. G1: 10 weeks (SD 9). G2: 25 weeks (SD 8.8). VL and CD4: G1 First in pregnancy 61.6% with VL < 40 copies/ml, finally to the pregnancy 94.5% VL < 40 c/ml. At 6 months after pregnancy 76.5% VL < 40 c/ml and at 12 months after the pregnancy 83.5% VL < 40 c/ml. G2: First viral load in pregnancy 9946 c/ml (SD 143112), finally to pregnancy 80.4% VL < 40 c/ml, at 6 months after pregnancy 80.4% with VL < 40 c/ml, at 12 months after pregnancy 89.1% with VL < 40 c/ml. ART in pregnancy: G1: 39.7% protease inhibitor, 34.2% NNTRI. G2: 72.8% integrase, 22.8% protease inhibitor. ART actually: G1 Integrase 39.7%/G2 76% integrase. Resolution of pregnancy. C-section birth G1: 78%/G2: 90.2%, natural births G1: 8.2%/G2: 7.6%, legal interruption G1: 5.4%/G2: 1%, spontaneous abortion G1: 8.2%/G2: 1%. Baby birth weight G1: 2750g (SD 456) /G2: 2800g (SD 387). Birth control method: Definitive family planning method G1: 58.9%/G2: 58.6%, temporary method G1: 19%/G2: 33.6%. Obstetric complications: G1: Preeclampsia 2.7%. G2: Preterm delivery 1%, placental abruption and covid 1%. Psychiatric comorbidity G1: 12%/G2: 13%. Actually in virologic failure G1: 9%/G2: 7%. No cases of vertical transmission.

Conclusion: The diagnosis of HIV during pregnancy in G2 was at 25 gestational weeks (SD 8.8) therefore it was late. In patients with Chronic HIV only 61% with VL < 40 c/ml in the first consultation for pregnancy, but with ART 94.5% achieved VL < 40 c/ml at finally to the pregnancy. In both groups with ART, prenatal control, and multidisciplinary treatment we achieved prevent vertical transmission.

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Patterns and Correlates of Receiving Counseling and Testing for Sexually Transmitted Infections before Pregnancy and during Prenatal Care in Virginia Women: Results from 2016 – 2020 Pregnancy Risk Assessment Monitoring System Data

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Introduction: Current CDC guidelines recommend counseling and screening for sexually transmitted infections (STI) among all pregnant patients, using a routine panel of prenatal tests to prevent maternal-to-child transmission. Limited research has been conducted to explore the extent of prenatal STI counseling and testing performed in health care settings and the potential disparities across subpopulations of patients. This study examined the patterns and correlates of discussing STI and HIV testing with health care workers (HCW) before pregnancy and during prenatal care in Virginia women, using data from the 2016-2020 Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS) data.

Methods: Data came from a sample of 4,843 women who participated in 2016-2020 VA PRAMS. The survey collected information about mothers' experiences before, during and after recent pregnancies. Discussion about STI and HIV testing with HCW were defined as 1) talked about STI; 2) tested for HIV in the 12 months before pregnancy; and 3) asked if wanted to be tested for HIV during any prenatal care visit. Multivariable logistic regression was used to examine factors related to discussion about STI and HIV testing before

pregnancy and during prenatal care, using STATA16 to adjust for sampling weights. A sub-set analysis was conducted to examine the effect of COVID-19 pandemic, using March 2020 as the cut-off point.

Results: Among women who had a health care visit (62%, 3244/4843) in the 12 months before pregnancy, 25% (748/3244) discussed STI with HCW, and 31% (920/3244) were tested for HIV. Over half (58%) of women reported communication with HCW about HIV testing during prenatal care.

During the 12 months before pregnancy, the odds of receiving HIV testing from HCW were significantly higher among women who were African American (AOR, 2.89; 95% CI, 2.01-4.16), Hispanic (AOR, 2.30; 95% CI, 1.50-3.50), unmarried (AOR, 1.84; 95% CI, 1.27-2.65), having low household income (AOR, 1.57; 95% CI, 1.01-2.42) and receiving military insurance and Tricare (AOR, 1.85; 95% CI, 1.22-2.81). The odds of discussing STI with HCW were significantly higher among women who were African American (AOR, 1.60; 95% CI, 1.10-2.33), Hispanic (AOR, 1.89; 95% CI, 1.20-2.95), unmarried (AOR, 1.99; 95% CI, 1.38-2.86), having low household income (AOR, 1.58; 95% CI, 1.01-2.48) and receiving public insurance (AOR, 1.79; 95% CI, 1.19-2.70).

The odds of having prenatal discussion about HIV testing with HCW were significantly higher among women who were Hispanic (AOR, 1.41; 95% CI, 1.05-1.89), unmarried (AOR, 1.32; 95% CI, 1.01-1.72), having low household income (AOR, 1.41; 95% CI, 1.04-1.92) and receiving public insurance (AOR, 1.79; 95% CI, 1.19-2.70). A decrease in the odds of prenatal discussion about HIV testing was found after the outbreak of COVID-19 (AOR, 0.78; 95% CI, 0.60-1.01, marginally significant).

Conclusions: Findings revealed low levels of STI counseling and HIV testing for pregnant women in Virginia, falling far short of the CDC recommendation. Although women who were socially and economically disadvantaged reported higher odds of having prenatal discussion about HIV testing with HCW, the COVID-19 pandemic compromised these preventive services essential for maternal and child health.

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Experience with Rapid Initiation of ART in Pregnant Women: Longstanding Success

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Background: Elimination of Mother-to-child (MTC) HIV transmission has been attained by many countries including Puerto Rico. Strategies include universal HIV screening and access to ART, Cesarean delivery, infant formula and infant ART. In order to control the epidemic rapid initiation of ART has been proposed for newly diagnosed individuals. This is a strategy that has been in place among prenatal clinics caring for women living with HIV for almost 3 decades. We are documenting our experience with rapid initiation of ART during pregnancy. Pregnancy is a strong motivator for women's desire to accept ART and to improve adherence.

Description: Chart reviews and pharmacy dispensing data were obtained for 106 pregnant women living with HIV presenting for prenatal care (from 2015-2021) at the Maternal-Infant Studies Center in San Juan, PR to determine the timing of initiation of ART from first clinic visit.

Lessons: Of 106 pregnant women, 80 (75%) had a prior diagnosis and 26 (25%) were diagnosed during

prenatal care. Of those who were not on treatment, 92% access ART in less than 3 weeks (45/49); 67% less than 2 weeks (33/49), 65% in 1 week (32/49), 57% tree days or less. Same day treatment was achieved in 33% of women.

Almost one third (29%) of the women with prior diagnosis were not on ART due to lack of care engagement or serious adherence issues. Viral suppression was achieved by 83% of all women at the end of the pregnancy. Viral suppression improved significantly among the women with prior diagnosis (from 63% to 85%) and to 80% for those diagnosed during prenatal care. Mother-to-infant transmission was Zero for all the women in this cohort, as has been consistently for the women receiving care at the clinic for the past 16 years. Three women had serious adherence issues and took longer than 1 month to start their ART. Five women with multiple drug exposure started ART at 1 month due to genotype testing needs.

Conclusions: Rapid initiation of ART (< 3 weeks) was achieved among 92% of the women presenting for prenatal care with either a new diagnosis of a prior diagnosis not engaged in care/not on ART. The majority achieved viral suppression at the end of the pregnancy and none transmitted HIV to the infant. Nevertheless, 3 were on ART after three weeks due to providers waiting for genotype results of patients' adherence issues. Policy changes were made to start ART prior to genotype results, and modify later if needed. A sub-group of women not engaged in care or with serious adherence issues will need closer and more intense monitoring to achieve ART at an earlier stage. Rapid initiation of ART requires access to care and ART and strong clinic commitment with support personnel.

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The Sero-prevalence of HIV among Women who Give Birth Outside the Formal Health Institutions in Chitungwiza, Zimbabwe

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Background: Home delivery is still a problem in most low-income countries. Giving birth outside the formal health institutions is associated with more adverse maternal and neonatal outcomes and hinders efforts for the prevention of mother to child transmission of HIV (PMTCT). The prevalence of HIV in pregnant women accessing antenatal care (ANC) is well documented but there is paucity of data on the prevalence of HIV among women who deliver outside the formal health system. This study aimed at determining the proportion of women who delivered outside the formal health sector and among them, the proportion of women who are living with HIV and to identify some factors associated with home delivery, in Chitungwiza city Zimbabwe,

Methods: This was a cross-sectional study involving a retrospective review of clinic records for women who received postnatal care at all 4 maternity clinics in Chitungwiza city between 01 January 2017 and 31 December 2017. The Chi-square test was used to determine association between participants' place of delivery and socio-demographic variables. Multiple logistic regression was used to determine risk factors associated with

home delivery while adjusting for other study variables. All statistics tests' decisions were concluded at 95% level of significance. All data analysis was performed using STATA (version 13) statistical package.

Results: A total of 4400 women received postnatal care at the 4 maternity clinics in 2017. Of the 4400 women, 3999 (91%) delivered at the clinics whilst 401 (9.1%) delivered at home. Among women who delivered at home, 20.4 % were HIV positive and among those who delivered at the clinics only 9.7% were HIV positive.

There was an association between HIV status and place of delivery after adjusting for other study variables, the odds of delivering at home among those who are HIV positive are 2.1 times that of HIV negative participants ($p < 0.001$). There was an association between age and place of delivery after adjusting for other study variables, the odds of delivering at home among those aged 20 to 34 years and above 34 years, are 0.6 times ($p = 0.018$) and 1.4 times (0.063), respectively, that of participants aged less than 20 years. There was an association between ANC booking status and place of delivery after adjusting for other study variables, the odds of delivering at home among those who were booked are 0.2 times that of participants who were not booked ($p < 0.001$).

Conclusion: Delivery outside formal health institutions is a problem in Chitungwiza city and is associated with a higher risk for HIV infection, no access to ANC and ages of below 20 and above 34 years. The results from this study illustrate the need to identify and reduce barriers of access to antenatal and delivery care in Chitungwiza in order to eliminate intra-uterine pediatric HIV infections. More research is needed to determine the prevalence of pediatric HIV infections among this population of women who give birth outside the formal health system.

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Pharmacokinetics (PK) of Dolutegravir (DTG) and Safety of Dolutegravir/abacavir/lamivudine Fixed Dose Combination (DTG/ABC/3TC FDC) in Pregnant Women with HIV in Study 200336 (ARIA Pregnancy Study)

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Background: At the time of study initiation in 2014, limited data were available on the PK of DTG in pregnant women. We report the results of, and enrollment challenges in, Study 200336, an open-label study to evaluate PK of DTG and safety of DTG/ABC/3TC FDC in pregnant women living with HIV. (NCT02075593).

Materials & Methods: Eligible adult women randomized to DTG/ABC/3TC in the ARIA Study (ING117172; efficacy and safety of DTG/ABC/3TC in ART-naïve women; NCT01910402) were enrolled following withdrawal due to pregnancy. Target enrollment in 200336 was 12 participants. Participants received DTG/ABC/3TC once daily throughout pregnancy and postpartum, and could continue on DTG/ABC/3TC until available locally. Primary endpoint was PK of DTG in trimesters 2 (T2) and 3 (T3), and at 8-12 weeks postpartum (PP), and safety of DTG/ABC/3TC. Samples for intensive PK were collected up to 24 hours post-dosing. Enrollment challenges were encountered. In ARIA, 495 women were treated (248 with DTG/ABC/3TC) from 86 sites in 12 countries, while 11 sites in 4 countries participated in 200336, and 3 sites in 2

countries enrolled participants. Main reasons for low site participation/participant enrollment were: Site declined participation; lack of resources for PK sampling; separate protocols for 200336 and ARIA; short enrollment window from long regulatory/Ethics Committee approval timelines and short duration of ARIA study (48 weeks in most countries); enrollment hold in 2018 due to the potential safety issue related to neural tube defects.

Results: 4 pregnant women were enrolled in Study 200336 between 2014 and 2018. Enrollment was terminated early in 2020. All women had live singleton births, with weight appropriate for gestational age and no congenital abnormalities. Three infants were delivered at ≥ 37 weeks, and one at 36 weeks following rupture of membranes, with premature birth reported as an SAE. No other SAEs were reported during the study.

DTG exposure in pregnancy was consistent with previous data in nonpregnant adults, but was higher in postpartum testing. In T2, T3 and PP, respectively, steady state geometric mean (GM) AUC_{0-24h} h* $\mu\text{g/mL}$ (%Coefficient of Variation [%CVb]) were: 55.0 (24), 42.5 (28), 78.9 (25); C_{max} $\mu\text{g/mL}$ (%CVb) were: 4.42 (27), 3.42 (34), 5.58 (23). C_{24h} concentrations during pregnancy were lower compared to postpartum values: GM C_{24h} ng/mL (%CVb) were: 930 (33), 658 (62), 2155 (59) in T2, T3 and PP, respectively. Cord blood levels (408 to 2880ng/mL) were generally similar to matched maternal levels (529 to 2650ng/mL) collected at the same time during delivery (n=3). All women had HIV-1 RNA <50c/mL throughout the study. Two infants were reported as HIV-negative, one had indeterminate status and one had unknown status (information available at 8-12 weeks postpartum only).

Conclusions: Study enrollment was low due to a variety of factors. Based on limited data from 4 participants, DTG exposure was lower during pregnancy compared with postpartum in the same individual, but was consistent with previous data in non-pregnant individuals. C_{24h} concentrations in all individual participants were above in vivo EC₉₀ (300 ng/mL) during pregnancy and postpartum. Safety was consistent with the label.

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"Women Know Best, Work with Us": Decision Making about Infant Feeding while Living with HIV

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Objectives: UK HIV pregnancy guidelines recommend formula feeding as preferable, but women wishing to breastfeed should be supported. We explore infant feeding decision-making with (i) women living with HIV (4M Mentor Mothers UK-based Network, 4MNet); and(ii) HIV clinicians.

Methods: Qualitative study using peer-led participatory action approach. Six case studies conducted July-August 2020 by phone and email (four Mentor Mothers, two clinicians). Data analysed thematically by women living with HIV, with respondent validation from Mentor Mothers; emergent findings discussed with 4MNet Advisory Group p.

Results: Participants described infant-feeding decisions as fraught with difficulties and others' judgements, made within a complex physiological, psycho-social and emotional matrix. High levels of routine blood tests of mothers and babies can be disincentives to choose breastfeeding, with women feeling judged and blamed. Decisions were influenced by multilevel factors in the following domains: individual (resources), interpersonal (family relationships), community (sociocultural attitudes towards infant feeding) and societal(policies, laws, financial resources). The complexity was amplified by apparently conflicting guidance in different countries. Healthcare professionals in high-income countries can have difficulty supporting breastfeeding; some appear reluctant through fears about vertical transmission. Support from peers facilitated positive experiences of infant feeding.

Conclusions: Women living with HIV have agency and can make informed choices about infant feeding. Value-free, up-to-date, comprehensive information aids decision-making. Respect and non-judgmental support for however a woman chooses to feed her baby is central in building trusted collaborative relationships with professionals, enables infant-feeding experiences to be positive and life-enriching , and upholds women' s sexual and reproductive health and rights.

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Family Planning Use & Fertility Intention of Female Sex Workers Living with HIV/AIDS At Reproductive Health Uganda (RHU) – Iganga Center

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Evidence shows that HIV prevalence among sex workers in Uganda is at 37%. It was also estimated that sex workers and their clients accounted for 18% of new HIV infections in the country, on the same note between 33% and 55% of sex workers in Uganda reported inconsistent condom use driven by the fact that clients will often pay more for sex without a condom (AVERT 2015/16).

On top of that WHO, In 2011 estimated that the extent of sex work varies considerably and is generally higher in urban areas, port cities, and on major highways. In addition, in a number of African countries, the rate of unintended pregnancy among females living with HIV ranges from 51 to 84%, and access to family planning has a major impact on improving the overall health of a woman as well as that of her children by delaying first birth. Despite these benefits, in sub-Saharan Africa, family planning in PLWAH is not widely used.

The study was conducted at Reproductive Health Uganda (RHU) - Iganga District Center. RHU is a volunteer-owned and led organization that started work in Uganda in 1957. Currently, RHU operates 17 branches spread in all the sub-regions of Uganda including the Busoga Region (Iganga District). RHU has made a significant contribution in the area of Sexual Reproductive Health and Rights (SRHR). Many of these efforts have redefined the SRHR landscape including Safe motherhood, family

planning, HIV/AIDS, and adolescents' interventions. Since its establishment in Iganga District, more than 6000 sex workers have visited the center and it is proving integrated SRH service for these special groups.

The study employed was cross-sectional institution-based and the data was collected from February 16th to April 16th, 2019, and 234 female sex workers who came for ART services during the study period were included in the study. Data entry and analysis were done by SPSS version 21. Descriptive statistics: frequencies, percentages, cross-tabulation, graphs, and tables were performed. Then factors that affecting family planning intention were assessed by the Chi-square test. Results were considered statistically significant for $p < 0.05$.

A total of 234 female sex workers who are taking ART were included in the study. The majority 71.2% had the intention to use FP services with 66% among them prefer injectable followed by 30% permanent method and the rest condom and about 21% of them want to have additional children of whom 36.5% of them want more than two (2) children. Only 20.2% of them were using family planning methods previously. Out of these women who were using at least one method of contraception, 72% of them were using injectables followed by the implant (15%), and least was 4% condom besides majority (64%) of them didn't know about emergency contraceptives. The major factors contributing to family planning intention was the no of children respondents have (chi-square) = 10.84(4) $p < 0.036$, educational status (chi Square = 10.47(2) $p < 0.005$)

The family planning and ART service utilization intention was high (72.1%) at RHU center and the most preferred method was injectable, followed by permanent and least preferred was condoms, and the family planning intention variable associated were educational status and no of children respondents have during the study period. Therefore, to achieve Universal Health Coverage, integration of family planning services in HIV/AIDS innovations is key.

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Long-Acting Cabotegravir & Rilpivirine: Pooled Phase 3/3b Week 96 Outcomes for Women

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Background: Cabotegravir (CAB) + rilpivirine (RPV) is a complete long-acting (LA) regimen for the maintenance of HIV-1 virologic suppression. In the Phase 3 development program, CAB+RPV LA dosed every 4 weeks (Q4W) was noninferior to oral therapy and CAB+RPV LA dosed every 8 weeks (Q8W) was noninferior to Q4W at Week (W) 96, including in individual subgroup analyses among female participants at W48. Here, we present the longer-term efficacy and safety outcomes for women across the combined ATLAS-2M and FLAIR studies through W96.

Methods: Data from ATLAS-2M and FLAIR were pooled and stratified by sex at birth. Participants in ATLAS-2M who transitioned from the ATLAS CAB+RPV arm were excluded to ensure only participants with no prior exposure to CAB+RPV were included. Key W96 efficacy endpoints were the proportion of participants with plasma HIV-1 RNA ≥ 50 copies/mL and < 50 copies/mL (FDA Snapshot, intention-to-treat exposed). Incidence of confirmed virologic failure (CVF; two consecutive measurements of ≥ 200 copies/mL), safety, and adherence were also assessed.

Results: In total, 275 cis-women were randomized to receive CAB+RPV LA (Q8W: n=73; Q4W: n=138) or continue oral antiretroviral therapy (n=64; FLAIR study only), representing 23% of the total CAB+RPV naive population in both studies. In women receiving CAB+RPV LA, the median (IQR) age was 43 (34–51) years, 65% (n=137) were White, and 27% had a body mass index ≥ 30 kg/m² (n=57). At W96, 85% (n=180) of women maintained virologic suppression with CAB+RPV LA compared with 89% (n=647) of men. Rates of virologic non-response with CAB+RPV LA in women were low (3%, n=7) and comparable to men (2%, n=15). CVF occurred in 6 (3%) women and 6 (<1%) men receiving CAB+RPV LA, with no new CVFs seen in women between W48 and W96 and only 1 in men. Safety profiles (excluding injection site reactions [ISRs]) were similar between men and women. Adverse events (AEs), excluding ISRs, occurred in 82% (n=172) of women and 92% (n=668) of men; drug-related AEs occurred in 23% (n=48) of women and 33% (n=237) of men. AEs led to withdrawal in 4% of both women (n=9) and men (n=28); 3% (n=6) and 2% (n=15) were drug related, respectively. Drug-related serious AEs were uncommon, occurring in <1% of women (n=2) and men (n=3). Most injections (women: 99%, n=3564/3612; men: 98%, n=12,647/12,955) were received within the ± 7 -day dosing window. ISR events were mostly mild to moderate in severity in both women (99%, n=1831/1840) and men (99%, n=6526/6613), with no Grade 4 or 5 events, and rarely led to withdrawal (women: <1%, n=2/211; men: 3%, n=18/726).

Conclusions: CAB+RPV LA demonstrated high efficacy, safety, and tolerability in women, similar to male participants, through W96, with few treatment-related discontinuations. These data support CAB+RPV LA as a complete regimen for the maintenance of HIV-1 virologic suppression regardless of sex at birth.

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Efficacy and Safety of Dolutegravir/Lamivudine in Virologically Suppressed Female vs Male Participants From TANGO and SALSA: Pooled 48-Week Data

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Background: International guidelines recommend the 2-drug regimen dolutegravir/lamivudine (DTG/3TC) in switch settings. Globally, women represent a large proportion of people with HIV; as such, it is important to evaluate treatment outcomes in the female population. Here, we present efficacy and safety from pooled TANGO and SALSA data, analyzed by sex.

Materials & Methods: This pooled analysis includes 48-week data from the open-label phase 3 TANGO and SALSA trials evaluating efficacy and safety of switching to DTG/3TC fixed-dose combination or continuing current antiretroviral regimen (CAR), which were TAF-based regimens in TANGO and NNRTI-/bPI-/INSTI-based regimens in SALSA. We assessed efficacy (primary and key secondary endpoints: proportion of participants with HIV-1 RNA ≥ 50 c/mL and < 50 c/mL; Snapshot, intention-to-treat–exposed population) and safety by sex assigned at birth. Mixed-models repeated-measures analysis was used for adjusted mean change from baseline in CD4+ cell count and CD4+/CD8+ ratio.

Results: Of 1234 participants in the pooled analysis (DTG/3TC, n=615; CAR, n=619), 250 (20%) were female. Among female participants, proportion with HIV-1 RNA ≥ 50 c/mL at Week 48 was 0.8% (1/133) in the DTG/3TC group vs 1.7% (2/117) in the CAR group (adjusted difference, -0.9%; 95% CI, -3.7, 1.9); results were similar among male participants and consistent with overall findings. Proportion of participants with HIV-1 RNA < 50 c/mL was high in female participants (DTG/3TC, 91.0% vs CAR, 88.9%; adjusted difference, 1.7%; 95% CI, -5.8, 9.2); high proportions of male participants also maintained virologic suppression. No female participants in either group met confirmed virologic withdrawal (CVW) criteria; 1 male participant met CVW criteria (CAR group), and no resistance was detected. Among female participants, adjusted mean change (SE) from baseline to Week 48 in CD4+ cell count was 74 (16) vs -19 (16) cells/mm³ in the DTG/3TC vs CAR groups, respectively; minimal changes were observed in male participants (9 [8] vs 1 [8] cells/mm³) and the overall analysis (22 [7] vs -2.0 [7] cells/mm³). Adjusted mean change (SE) from baseline to Week 48 in CD4+/CD8+ ratio was comparable between treatment groups in female participants (DTG/3TC, 0.067 [0.019] vs CAR, 0.068 [0.021]), with similar results in male participants. Adverse events (AEs) occurred in 74% of female participants in the DTG/3TC group vs 71% in the CAR group, with few AEs leading to withdrawal (DTG/3TC, 2% vs CAR, 3%) and more drug-related AEs with DTG/3TC (19%) vs CAR (5%). Safety results were similar among female and male participants.

Conclusions: One year after switch, DTG/3TC resulted in similarly high rates of maintained virologic suppression, no reported resistance, and improvements in CD4+ cell counts in female and male participants vs CAR. Adverse events leading to withdrawal, which in historical studies have been higher in female participants, were low and consistent between sexes. These results demonstrate that DTG/3TC is a robust switch option with high efficacy, good safety and tolerability, and a high barrier to resistance in women living with HIV.

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HIV Testing During Pregnancy: 7 US States, 2016–2019

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Background: Reducing perinatal human immunodeficiency virus (HIV) transmission is a well-established and shared goal in the field of public health. HIV screening during pregnancy is a key component to prevent perinatally acquired HIV infections. Failure to screen all pregnant women for HIV as recommended by the CDC can lead to unfavorable outcomes. We describe patterns of HIV testing among women with a recent live birth in 7 states by maternal characteristics.

Methods: We used 2016-2019 data from the Pregnancy Risk Assessment Monitoring System (PRAMS), a large, population-based survey in 7 study sites (Alabama, Alaska, Arkansas, Maryland, Massachusetts, Mississippi, and Nebraska) that added an optional question on receipt of prenatal HIV testing on their survey and achieved a weighted annual response rate of at least 55% in 2016 or 2017, or at least 50% in 2018 or 2019.

Results: Among 21,075 women with a recent live birth in the seven states, (66.1%) reported having a test for HIV during their recent pregnancy. A higher percentage of black women reported having a test compared with women from all other racial and ethnic groups (80.7%). A higher percentage of women aged 25 and older were less likely to report having a test for HIV; 25-34 (64.1) and ≥ 35 (66.1) than women under 20 and 20-24 (70.9 and 72.5). A higher percentage of women who had more than 12 years of education (37%), women who were married (40.5%), and women who did not report experiencing intimate partner violence (IPV) (39.5%) were less likely to report having an HIV test compared with their counterparts. A higher percentage of women with private insurance (39.1%), women not enrolled in WIC (39.5%), and women who entered prenatal care in the first trimester (39.5%) were less likely to report having an HIV test during pregnancy compared with their counterparts.

Conclusion: Prevalence of HIV testing during pregnancy varied by demographic and other selected characteristics. Findings illustrate the need for consistent implementation of CDC HIV screening guidelines and the need to increase equitable universal HIV testing during pregnancy in the United States.

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Sex Differences in Children and Adolescents Living with HIV in Germany: Data from the GEPIC Cohort

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Background: The GEPIC cohort was established as a national, multicenter-cohort study and currently includes 191 HIV-positive children and young people from Frankfurt, Berlin, Hamburg and Mannheim. GEPIC collects medical and social data as data on pediatric HIV infection in Germany are scarce.

Methods: The ‘German Cohort of Children and Adolescents exposed or infected with HIV - GEPIC’ collects clinical, immunological and virological data from HIV-positive children and adolescents living in Germany. In this analysis, female patients were compared to male patients with regards to virological and immunological parameters, body weight and antiretroviral regimens.

Results: Out of 191 patients documented, there are 101 female and 90 male patients in GEPIC. The cohort shows in median an effective viral suppression since 1998 – also in comparison with

other cohorts internationally as in almost all age groups over 90% of positive children had viral loads in median below the limit of detection. Overall, the female GEPIC participants show a trend to more efficient viral suppression: viral loads below the detection limit were found in 95% of the girls, while the proportion in the boys was 88%.

In terms of age-specific numbers of CD4-positive cells, data in the cohort are within normal limits at each measured point in absolute numbers and in relation to total helper number as to CD8-positive cells indicating immunological competence in median. No significant gender-specific difference in the absolute level of the CD4 cell count could be determined across the various age groups, although boys in the 3-18-year age group have slightly higher levels of CD4 cells compared to girls in the same age group.

In comparison to a group of healthy children (German KIGG's study of healthy children and adolescents) HIV-positive children and adolescents – and especially girls – tend to be smaller and prone to being overweight. In the total cohort 23% of the females and 16% of the males were overweight (healthy controls: 15%). 5% of the female and 7% of the male participants were underweight with BMI-percentile <10. The duration of first-line therapy was similar, but slightly longer in girls in median (35.1 vs 33.4 months).

Conclusion: For the female participants in the cohort, the response to antiretroviral therapy was slightly better than the response for males and they remained longer on their first line therapy (not significant). In addition, female participants in GEPIC have a significant higher tendency for being overweight than male patients.

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The Relationship Between Genital Inflammation, the Vaginal Microbiome and Antiretroviral Genital Concentrations in Women

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Background: Genital inflammation and vaginal dysbiosis may reduce efficacy of topical tenofovir; thus, there is a need to determine the effects of inflammation and the vaginal microbiome on drug exposure in the female genital tract (FGT). We previously reported interactions between the vaginal microbiome, hormonal contraception, and tenofovir (TFV) and lamivudine (3TC) disposition in the FGT. Here we analyzed cervicovaginal cytokines in the same cohort to elucidate the role of these factors on FGT drug disposition.

Methods: Modifiers of Tenofovir in the Female Genital Tract (NCT03377608) was a single visit pharmacokinetic study examining TFV and 3TC disposition in cervical tissues following oral administration. Cervicovaginal swabs and cervical biopsies were collected from Ugandan women with HIV treated with TFV/3TC regimens. Cytokines were measured in cervicovaginal fluid using the Bio-Rad 27-plex Human Cytokine Assay. Cervical concentrations of TFVdp and 3TCtp (active

metabolites of TFV and 3TC) were measured using LC-MS. Relative abundances of vaginal bacteria were measured using 16S rRNA gene sequencing. Spearman correlations were used to investigate relationships between TFVdp, 3TCtp, cytokines, and relative bacterial abundances. Wilcoxon rank sum tests were performed to compare cytokine concentrations between depot medroxyprogesterone acetate (DMPA) users and non-users.

Results: Ugandan women with HIV (n=50) were enrolled with a mean age of 26 (range 24-30). Of cytokines measured, IL-7 (R2 = 0.35, p = 0.016), IL-10 (R2 = 0.36, p = 0.016), and IL-17 (R2 = 0.48, p = <0.001), were positively correlated with TFVdp concentrations in cervicovaginal swabs. No cytokines were significantly associated with 3TCtp. There were no significant differences in cytokine concentrations between DMPA users and non-users. No cytokines were correlated with age. The genus *Lactobacillus* was negatively correlated with IL-1 beta (R2 = -0.39, p = 0.008) and TNF alpha (R2 = -0.36, p = 0.036). *Sneathia* was positively correlated with IL-8 (R2 = 0.38, p = 0.0088), TNF alpha (R2 = 0.35, p = 0.018), IL-17 (R2 = 0.33, p = 0.024), and IL-1 beta (R2 = 0.31, p = 0.037). *Gardnerella*, *Prevotella*, *Dialister*, and *Megasphaera* were not correlated with any cytokines.

Conclusions: TFVdp was associated with pro-inflammatory cytokines, which could be a result of influx of immune cells in this tissue. Consistent with prior knowledge, *Lactobacillus* is not associated with increased inflammation, in contrast to *Sneathia*, a genus associated with bacterial vaginosis. The clinical significance of these findings is unknown. Currently, work is being done to quantify immune cells in frozen tissue biopsies to further understand the positive correlation between TFVdp and cytokines, specifically IL-7, IL-17, and IL-10. Further work to address the roles of bacteria/cytokines in drug exposure will provide insights for improving drug efficacy.

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Programs to Increase PrEP Knowledge, Adoption, & Adherence among Black & Latina Cisgender Women

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Background: Black and Latina cisgender women (BLCW) are disproportionately affected by HIV, particularly in the US South. In Austin, Texas, HIV incidence among Black and Latina women is 18.4 times and 2.6 times that of White women, respectively. Pre-exposure prophylaxis (PrEP) is a medication that one can take to prevent oneself from contracting HIV; however, PrEP adoption among women, especially in the South, is quite low. Few interventions exist to increase PrEP knowledge, adoption, and adherence among BLCW. This qualitative study sought to determine programs to increase PrEP engagement among BLCW.

Methods: Data collection occurred from May 2018 – November 2019 in Austin, TX. Eighteen PrEP-eligible BLCW were enrolled in the study. Participants completed 3 semi-structured interviews across 3 months. Interviews were transcribed verbatim, coded in NVivo, and analyzed using thematic content analysis. All interviews (n = 47) with information regarding PrEP were systematically analyzed line by line to identify primary themes.

Results: Participants proposed different ideas for interventions to increase PrEP awareness and use

among women susceptible to HIV acquisition including sexual health education, one-on-one sessions, support groups, community-level programs, and structural interventions. Regarding sexual health education sessions on PrEP, participants suggested covering other topics related to HIV risks such as healthy relationship communication, intimate partner violence (IPV), substance use, housing, and economic stability. All participants who perceived themselves as moderate- to high-risk for HIV reported a preference for educational programs. With respect to program logistics, a majority of participants stated that interventions should be held in community spaces and facilitated by individuals from the community being served, particularly by a woman taking PrEP.

Conclusions: Future interventions should consider the multidimensional needs and interests of BLCW who could benefit from taking PrEP. In addition to sexual health education, participants mentioned that PrEP interventions should include mitigation strategies for issues that increase HIV risk and decrease access to PrEP, such as unhealthy intimate partner communication, IPV, substance use, unstable housing, and economic instability. Participants indicated an interest in a range of intervention formats including one-on-one meetings, group sessions, collaborative efforts with organizations and health care providers, and structural changes to PrEP availability. Suggested locations of where to host interventions varied between participants, however, an overwhelming majority stated that interventions should take place in community spaces that are most accessible and safe to participants, with special considerations for those with children and who experience IPV. Many participants also shared how interventions should be led and facilitated by those the intervention intends to serve and perhaps an individual who is taking PrEP, highlighting the importance of trust and community regarding PrEP and HIV prevention for Black and Latina women.

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HIV Surveillance in Romania Assessed by Optima Report

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Purpose: As HIV infection has affected the globe for more than 30 years, various programmes supporting people living with HIV have been implemented. These national efforts have been evaluated in 2019 under the exercise known as Resource optimization to maximize the HIV response. Romania was a part of this exercise, whose purpose was to forecast the benefits of maintaining the HIV response in Eastern Europe and Central Asia.

Methods: Romania's country team consisting of specialized staff from "Matei Bals" Institute, "Romanian Angel Appeal Foundation", "National Public Health Institute" provided HIV epidemiological and program data to Burnet Institute, The Global Fund and UNAIDS in order to conduct an allocative efficiency modeling analysis and to make an assessment whether the national

HIV programme can reach UNAIDS 90-90-90 targets.

Results: The country's national financial efforts between 2015 and 2017 helped avoid 180% new HIV infections and approximately 210% HIV-related deaths. Around 98% of the total HIV budget was spent on HIV treatment, leaving around 1% increase necessary to fully optimize the national antiretroviral programme.

In terms of HIV cascade of care and targets it was estimated that by the end of 2020, 79% of persons with HIV should have been diagnosed, 87% of those diagnosed should have received treatment and 90% of those on treatment should have achieved viral suppression. Although there is a clear tendency to reach the UNAIDS targets, these were not met, the exercise predicting an achievement of the 95-95-95 targets for 2030.

Conclusion: All scenarios recommend maintaining the treatment funding at a high percentage, as this turned out to be the most beneficial intervention, at national level. Prioritization of specific interventions especially HIV testing services mainly intended for the general population could help avoid new infections and retain in care those diagnosed late. However, given the new COVID-19 context, all interventions and measures recommended had to be re-assessed as they suffered a delay due to the sanitary protection measures.

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A GIFT (Genital Inflammation Test) for Identifying Women with Asymptomatic Sexually Transmitted Infections and Bacterial Vaginosis Who Are at Risk of HIV Acquisition

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Inflammation in the female reproductive tract is associated with increased risk of HIV acquisition and adverse reproductive outcomes. In resource-limited populations where HIV is prevalent, this inflammation is primarily caused by discharge-causing sexually transmitted infections (STIs) and bacterial vaginosis (BV). In these settings, etiological tests for STIs and BV are currently too expensive for implementation and are managed syndromically, where women are only treated if they present with clinical signs or symptoms. However, asymptomatic women have equivalent levels of genital inflammation and HIV risk as symptomatic women. We have identified inflammatory cytokines IL-1 α , IL-1 β and IP-10 as biomarkers for detecting asymptomatic STIs and

vaginal dysbiosis (BV or intermediate microbiota), which have been patented in South Africa and Europe.

The Genital Inflammation Test (GIFT) is a rapid point-of-care lateral flow test using these biomarkers and has been developed to help identify women who have asymptomatic STIs, BV or are colonised by inflammatory bacteria. If offered to women attending family planning, primary healthcare and antenatal clinics in resource-limited settings, GIFT may provide a cost-effective method to increase STI and BV case-finding and potentially contribute to efforts to reduce the risk of HIV and adverse reproductive outcomes.

The first iteration GIFT prototypes, which detect IL-1 α and IL-1 β separately, have been developed and were evaluated in women (n=35) from Cape Town, South Africa to determine the optimal sample processing methods. Here, the impact of different volumes and types of running buffer and sample vortexing versus agitation by hand on cytokine concentrations, were evaluated. Compared to absolute cytokine measurements by ELISA, both devices were highly sensitive (92% and 94% for IL-1 α and IL-1 β , respectively), however they lacked specificity (55 and 58% for IL-1 α and IL-1 β , respectively) and will require further optimization. Addition of a surfactant (Tween-20) significantly reduced cytokine detection by ELISA (p=0.0117). Cytokine concentration measurements were significantly lower if samples were eluted by agitation rather than vortexing (p=0.0108) and elution buffer volume did not significantly influence cytokine concentrations (p=0.6165).

These results highlight the significant impact of processing methods on biomarker concentrations. Overall, the GIFT prototypes show promise by identifying the majority of women with elevated IL-1 α and IL-1 β concentrations, but require further optimization, which may include the addition of reference lines, to improve specificity

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PrEP Uptake and Adherence among Females 15-24 as a Way to Curb the Increasing HIV Prevalence within that Population: A Case of AIDS Information Centre - Kampala

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Background: More than 15 trials of oral Pre-Exposure Prophylaxis (PrEP) have shown that, when taken consistently and correctly, PrEP is very effective and reduces the chances of HIV infection to near-zero. This has led some to describe PrEP as a 'game changer' for HIV prevention. AIDS Information Centre (AIC) could not agree less. With 25% contribution to Positivity yield among females aged 15-24 years between January 2021 –

December 2021 compared to other individual age categories, AIC compared data of clients on PrEP within the same age category to assess the impact of PrEP uptake on HIV Prevention.

Materials and methods: Following the increased number of positives within the 15-24 years female age bracket, data of all women tested in the period January 2021 to December 2021 at AIDS Information centre was analysed and comparison of all corresponding women on PrEP and those not on PrEP was done.

Results: Of the 5,872 clients tested for HIV, 1014(17%) were females aged 15-24years. 254 of 5,872 tested HIV positive and 63(25%) were females 15-24 years. Through targeted PrEP outreaches, 2182 clients were tested (1450 being new testers and 732 being PrEP refills). Of the 1450 new testers, 387 were females aged 15-24 and 35 tested positive however of the 732 refills, 110 were females 15-24 but non tested positive.

Conclusions: Awareness of PrEP service and knowledge of high-risk sexual behaviour females in the 15-24 age group could reduce the prevalence of HIV among the population category.

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Perinatal Care and HIV Virologic Control During the COVID-19 Pandemic in the United States

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Background: Changes in perinatal HIV care and virologic control during the coronavirus 2019 (COVID-19) pandemic remain unclear. We aimed to evaluate the association of the pandemic with two metrics of HIV care: perinatal health services utilization and virologic control of pregnant persons living with HIV (PLHIV) in a single tertiary care center in the United States.

Methods: This retrospective cohort study included all pregnant PLHIV seeking care at a multidisciplinary obstetric infectious disease clinic from 2016-2021. The primary outcomes were perinatal health services utilization (prenatal and postpartum visit attendance, telehealth use, antepartum admissions, directly observed therapy [DOT], postpartum contraception) and antenatal virologic control (antiretroviral [ARV] adherence, time to achieve viral suppression, viral rebound, viremia at delivery). We compared outcomes of pregnant PLHIV who delivered during the pre-pandemic (prior to March 12, 2020) and pandemic (April 2020-May 2021) epochs in multivariable regression models.

Results: Among 76 eligible pregnant PLHIV, 20 (26%) delivered during the pandemic epoch. Median overall number of prenatal visits during the pre-pandemic (11, interquartile range [IQR] 7-13)

and pandemic (11, IQR 9-13; $p=0.97$) epochs were similar. DOT utilization (15% vs. 25%; adjusted odds ratio [OR] 2.0, 95% confidence interval [CI] 0.6-7.0) was similar in the pre-pandemic and pandemic epochs, respectively, after adjusting for educational attainment and employment. In the pandemic epoch, 35% and 40% of pregnant PLHIV utilized telehealth for prenatal and postpartum visits, respectively, whereas telehealth was never employed prior to the pandemic. We did not identify differences in other markers of health services utilization in the pandemic and pre-pandemic epochs, respectively, including antepartum admissions (16% vs. 35%; OR 1.8 [95% CI 0.2-13.1]), those with fewer than 10 prenatal visits (38% vs. 30%; OR 0.2 [95% CI 0.02-1.3]), and postpartum visit attendance (91% vs. 95%; OR 1.9 [95% CI 0.20-17.00]). During the pandemic, a greater proportion of pregnant PLHIV achieved viral suppression at time of delivery than pre-pandemic (100% vs. 84%; $p=0.04$). We did not identify differences in other markers of virologic control, including ARV adherence as defined by ≤ 5 missed doses (68% vs. 85%; OR 2.7 [95% CI 0.7-10.4]) or viral rebound after initial viral suppression (12% vs. 10%; OR 0.8 [95% CI 0.2-4.8]). In those who initiated prenatal care with viremia, median time to sustained viral suppression (defined as two consecutive suppressed viral loads) was similar during the pandemic (11 weeks, IQR 7-17) compared to pre-pandemic (12 weeks, IQR 6-18; OR 0.4 [95% CI 0.01-148.5]). Finally, obtainment of contraception postpartum decreased during the pandemic (80%) compared to pre-pandemic (100%; $p<0.01$).

Conclusion: During the pandemic, pregnant PLHIV were more likely to achieve viral suppression prior to delivery, but along with the uptake of telehealth they were less likely to obtain contraception postpartum. How telehealth may have impacted these outcomes warrants further evaluation to optimize perinatal health services utilization for pregnant PLHIV.

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Prevalence and Management of Pain among People Living with HIV in Ontario Prior to and During the First Year of the COVID-19 Pandemic

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Background: People living with HIV (PLWH) are disproportionately affected by high rates of pain. Significant gaps in pain management have been reported among PLWH and the COVID-19 pandemic has further amplified these challenges. Public health restrictions have led to limited access to service providers, substance use treatment and harm reduction services, amid increased psychosocial stresses and financial burdens. We set out to characterize the prevalence, severity, functional impact, and treatment of pain among PLWH in Ontario, Canada, prior to and during the first year of the COVID-19 pandemic.

Methods: The Ontario HIV Treatment Network Cohort Study (OCS) is an observational, open dynamic cohort of PLWH receiving medical care in Ontario, Canada. Interviews using a standardized questionnaire are administered on a yearly basis. All individuals who completed the OCS questionnaire in 2019 (pre-pandemic period) or 2020 (pandemic period) were included in the analysis. Pain prevalence in the preceding 3 months, severity (measured as mild, moderate, and severe), functional impact in the preceding week (measured as a mean of 7 interference items, each

scored on a 0 to 10 scale) and treatment were evaluated in each study period and compared by sex. Chi-square, McNemar's, Wilcoxon rank-sum test and Cochran-Armitage test for trend were used for analyses.

Results: A total of 4040 responses across the two study periods from 2874 participants (23% women) with a median (interquartile range) age of 53 years (43, 60) were included in the analysis. Prevalence of pain was 66% in 2019 (40% reporting mild, 42% moderate and 18% severe pain) and 74% in 2020 (38% reporting mild, 43% moderate and 18% severe pain). Among 1165 participants who completed the questionnaire in both study periods the prevalence of pain increased from 68% to 72% ($p < 0.001$). Women had greater prevalence of pain compared to men both in 2019 (72% vs 65%, $p < 0.001$) and 2020 (79% vs 73%, $p < 0.001$) and reported greater severity of pain in both study periods ($p < 0.001$). Functional impact of pain was higher during the pandemic with 91% of those experiencing pain reporting some degree of interference with daily activities (vs 85% pre-pandemic) with a mean (standard deviation) interference score of 3.6 (1.6), compared to 3.0 (1.6) in 2019. Women reported greater interference with daily activities than men both prior to and during the pandemic ($p < 0.001$). A total of 54% of individuals in 2019 and 62% in 2020 reported receiving any formal treatment for their pain, which was similar between women and men in both study periods. In the first year of the pandemic, utilization of prescription analgesics increased (33% vs 25% in 2019) along with use of over-the-counter agents (55% vs 27% in 2019) and recreational substances (18% vs 10% in 2019), while use of non-pharmacological methods remained stable (21% during both periods).

Conclusions: Prevalence of pain among PLWH in the OCS has increased during the COVID-19 pandemic. Women continue to experience higher prevalence and more severe pain symptoms compared to men. Addressing barriers to pain management among PLWH requires sex-specific strategies.

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Management of HIV Exposed Newborns in Romania 2020, in COVID-19 Context

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Purpose: As HIV mother to child transmission continues to pose problems in certain areas, Romania monitors and releases relevant data, on annual basis, on this phenomenon through the National Registry of HIV Pregnant Women and of HIV exposed newborns.

Methods: In 2020, the National Institute for Infectious Diseases "Prof. Dr. Matei Bals", Bucharest registered 100 mothers and 101 children, one of the mothers having twins. Several data were registered: the time of diagnosis, risk factors, history of disease and therapeutic timeline, antepartum investigations, virological and immunological data, baseline values.

Results: 13% (13/100) of mothers came from the Romanian cohort of children infected between 1989 and 1990. 57% (57/100) of mothers were HIV diagnosed prior to pregnancy; 26% (26/100) registered CD4 values ranging between 200-500 cell/mm³, 25% had no medical assessment at the time of delivery while 33% of them had detectable values of HIV-RNA. 55% of them didn't have a CDC stage upon delivery. 3,97% (4/101) of children had detectable HIV-RNA values at baseline, 6,93% (7/101) were delivered naturally, 23,76% (24/101) were born pre-term, and only 23,76% (24/101) were imagistically investigated.

Conclusion: 2020 was marked by COVID-19 pandemic which led to a decrease in the capacity of surveillance of HIV pregnant women and perinatally exposed newborns, at the level of the general practitioners' network as well as the Infectious Diseases one. Compared to the previous year, more than half of the mothers monitored in 2020 didn't have an HIV stage which led to lack of proper treatment during pregnancy posing more risks for their children. Confronted with new epidemic threats Romania, as many other countries in the area and in Europe should reevaluate its interventions and programmes for pregnant women with HIV so as to take and keep them into care consequently reducing the disease burden for HIV exposed newborns.

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The Lighting Side of the Moon: The Rise of Adherence and Compliance of ARV Therapy in the COVID Era

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Introduction: The new coronavirus had significantly impacted the entire world. The healthcare system suffered the most changes; the medical staff had to adapt to the new restrictions, protocols, and safety regulations. People with underlying medical conditions were at greater risk of infection and its complications.

Material and methods: We evaluated the patients with HIV/AIDS from the Regional Center of HIV/AIDS, Iasi, Romania, during the COVID-19 pandemic.

Results: In March 2020, the Clinical Hospital of Infectious Diseases "Sf. Parascheva" Iasi, had to become a first-line COVID-19 Hospital. We had to

rethink the management of the HIV/AIDS patients to make them feel safe to come for reevaluation and their antiretroviral (ARV) therapy. In the HIV/AIDS Regional Center Iasi, we actively monitor 1617 patients, 1025 (63.38%) male, 592 (36.62%) female. Most of them, 759 (46.93%) are from the pediatric cohort, born between 1988-1990. On the 31st of December 2021, 1521 (94%) were in ARV therapy (TARV). During the pandemic, 103 (6.77%) dropped the TARV, 118 (7.75%) were naive patients that started the TARV, and 410 (27%) were counseled pre and post-testing and also for the ARV therapy initiation. The public health care measures limited the possibility to all support groups. All these restrictions made the HIV-positive patient keep closer contact through telemedicine with their physician and with a team of psychologists. In the past two years, we've noticed an increase of 2.8 times of the number of counseling requests, with the predominance of females (58%). This may be due to the fact that HIV-infected patients acknowledge that a good health can shield them from an unknown enemy. During the COVID-19 pandemic, other services for the prevention and treatment of opportunistic infection and sexually transmitted diseases were limited.

Conclusion: Despite the COVID-19 pressure, we've noticed an increased adherence and compliance of the antiretroviral therapy. To maintain this level, we need a multidisciplinary approach between the infectious diseases specialist and the psychologist.

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Effect of Dolutegravir on Glucose Homeostasis in Female Mice

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Background: Dolutegravir (DTG) has a favourable safety and tolerability profile but has been associated with a small increased risk of neural tube defects (NTDs) as well as weight gain and hyperglycemia. We evaluated the impact of DTG on glucose homeostasis using a mouse model.

Methods: Healthy euglycemic female C57BL/6 mice were assigned to daily gavage treatments for 8 weeks of either control (water, N=15), 1xDTG (2.5mg/kg DTG+33.3/50mg/kg emtricitabine (E)/tenofovir disoproxil fumarate (T), N=13), yielding therapeutic levels of DTG, or 5xDTG (12.5mg/kg+33.3/50mg/kg E/T, N=15). Overnight fasted glucose, body weight, and oral glucose tolerance test (OGTT) were measured at 2, 4, 6 and 8 weeks. Fasting hyperglycemia was defined as fasting glucose >10 mmol/L. Secondary outcomes included severe fasting hyperglycemia defined as >13.3 mmol/L and area under the curve (AUC) glucose concentrations through the OGTT. Mice

were sacrificed at 9 weeks, and tissues were collected for gene expression of factors in glucose homeostasis pathways. ANOVA and chi-squared tests were used for statistical comparisons at each time point.

Results: No differences were observed in weight gain between groups. By week 6, animals in the 1xDTG group displayed a significant increase in overnight fasted glucose. 16 of 28 animals treated with DTG (8 in 1x-DTG, 8 in 5x-DTG) had fasting hyperglycemia at least once. Of these 16, 3 had severe fasting hyperglycemia, 11 had fasting hyperglycemia at 6 weeks, and 10 had resolution by week 8. One animal in the control group experienced mild hyperglycemia. Mice developing fasting hyperglycemia also showed higher glucose AUC levels compared to control. DTG-treated animals that remained euglycemic had a modest downregulation of hepatic genes associated with gluconeogenesis and lipid utilization compared to controls, including glucose-6-phosphatase (% change from control (95%CI): -35% (-59%, -12%), phosphoenolpyruvate carboxykinase (-26% (-49%, -2.5%), and PPAR- α (-23% (-42%, -5.2%).

Conclusions: DTG treatment was associated with transient fasting hyperglycemia in a portion of female mice. Gluconeogenic pathways were moderately downregulated in DTG-treated mice remaining euglycemic, suggesting a potential compensatory mechanism. If further research shows DTG is associated with transient hyperglycemia in humans, this may partially explain the increase in NTDs seen after the rollout of DTG in Botswana, as hyperglycemia is a known risk factor for NTDs.

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Attitudes toward Menstrual Suppression among Women Using Cyclic vs. Continuous Contraceptive Vaginal Ring

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Background: Multipurpose prevention technologies (MPTs) are products that aim to prevent HIV acquisition, as well as other STIs and unintended pregnancy. Many products in development use current contraceptives as models, such as the contraceptive vaginal ring (CVR). The standard cyclic regimen for the CVR NuvaRing[®] is 21-days of ring use followed by a 7-day ring free period; however, it can also be used continuously for 28-days without a ring-free interval. Continuous use typically causes menstrual suppression. We aimed to understand women's attitudes towards menstrual suppression, specifically by investigating their relationship with intravaginal practices (IVP) and sexual risk behaviors.

Methods: We analyzed data from a prospective cohort study conducted in Thika, Kenya from 2016 to 2018 in which 121 women between ages 18-40 years with a history of bacterial vaginosis were randomized to cyclic or continuous CVR use. Participants attended follow-up visits once a month for 6 months. At each visit a new CVR was administered per group regimen, and sexual behaviors and clinical outcomes recorded. Menstrual suppression was defined as reduction or absence of menses. A questionnaire was

administered to assess attitudes toward menstrual suppression, a typical outcome with continuous CVR use, at the month 6 follow-up visit. Bivariate analyses were used to compare responses between cyclic and continuous CVR groups. Responses used a 5-point Likert-scale from "Strongly Agree" to "Strongly Disagree", which were summed to create a total menstrual suppression attitude score. Linear regression models were used to further define factors related to positive or negative attitudes toward menstrual suppression.

Results: The menstrual suppression questionnaire data was collected from subset of participants, 22 women in the continuous CVR use group and 23 in the cyclic CVR use group. There were no statistical differences in age, partner status, or HIV status between the two groups. Women in both groups had similar number of sexual partners and encounters monthly, and condom usage was reported for 34% of encounters. Overall, 46.7% of participants were living with HIV and 79.5% reported intravaginal washing every day. Only 16% of all women experienced complete menstrual suppression throughout the study period. In total, 66.7% of women agreed that safely stopping women from having menses would result in women doing better in school or at work. 81.8% of continuous CVR users believed that one was less likely to get pregnant after using hormonal medication to suppress menses, compared to 47.8% of cyclic CVR users ($P=0.02$), and were more worried that it would cause long-term health effects (86.4% vs 60.9%, $p = 0.05$).

Conclusions: Our participants reported mixed attitudes toward menstrual suppression. Women in the continuous CVR group were more likely to agree that menstrual suppression can negatively affect future pregnancies and long-term health. Menstrual suppression education will be an important part of implementing MPTs.

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Gender Differences in HIV Knowledge among Adolescents in Low- and Middle-income Countries: A Systematic Review

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Background: Adolescence is a critical period of biological, psychological and socioemotional development, usually including increasing autonomy, sexual debut and other transitions. Adolescents have the highest risk of HIV acquisition among all age groups, particularly girls and young women who represent a growing population of new infections. Investigating gender differences in adolescent HIV literacy provides an opportunity to assess gaps in knowledge that lead to risk-taking behavior and to characterize varying social roles for adolescent boys and girls in different communities. This systematic review seeks to compile and critically analyze studies assessing gender differences in HIV-related knowledge among adolescents in low- and middle-income countries.

Materials and methods: We used the Preferred Reporting Items for Systematic Reviews guidelines and searched online databases PubMed, Scopus, HIV/AIDS Clearing House, USAID Development Experience Clearinghouse, UNESCO HIV, AIDS Education Clearinghouse, WHO and UNAIDS. The search strategy combined search keywords with Boolean operators: (HIV OR AIDS) AND (knowledge) AND (gender) AND (adolescents). Two authors (AC and EG) conducted the search and independently reviewed all articles; conflicts were resolved by a third reviewer (GC) to reach consensus. Articles that quantitatively assessed HIV knowledge among

boys and girls ages 10-24 in low and middle-income countries were included.

Results: The search yielded 5,845 titles, of which 15 met selection criteria. Studies included four study designs: randomized control trial, cross-sectional one-time survey, cross-sectional pre-posttest, and prospective cohort study; only two studies included an intervention. Twelve included studies evaluated differences in HIV knowledge in school settings, particularly among secondary and college-aged students; three studies evaluated participants in the clinic setting. Twelve of the included studies utilized their own, self-developed HIV knowledge outcome measures; three studies used adapted UNAIDS or WHO tools. Ten of the included studies reported overall HIV knowledge scores; nearly all (N=9) demonstrated significantly higher knowledge among boys as compared to girls. Eight studies assessed differences in HIV prevention and transmission knowledge; six of those studies reported varied differences in knowledge and two reported no differences. Regarding attitudes and behaviors related to HIV, four studies highlighted concerning findings among girls; girls were less likely to perceive their risk of contracting HIV, less careful in avoiding relationships with people living with HIV, perceived sexual contact with a familiar person as risk-free and were less likely to view condom use as a prevention strategy.

Conclusion: Many previous studies have assessed HIV-related knowledge in adolescents, but few have evaluated findings by gender. We found that boys were consistently more knowledgeable than girls when evaluated through a composite score. Our findings represent a discrepancy between perception of risk and HIV prevalence among girls globally, as women and girls remain at higher risk of infection and are more likely to have exposure to infected partners than their male counterparts. When assessed by topic, gender-based findings varied, making it challenging to draw conclusions. Future studies should consider HIV education and risk assessment programs tailored specifically to girls and young women. No studies meeting inclusion criteria evaluated HIV-related knowledge among gender and sexual minority groups—a notable limitation of this review.

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Gender Differences in Healthy Aging Scores among Canadian HIV-positive Older Adults in the CHANGE HIV Cohort

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Background: Life expectancy among people living with HIV (PLWH) is approaching that of the general population with a growing proportion of individuals who are now over the age 65. Despite this, PLWH continue to experience greater burden and earlier onset of medical comorbidities, especially among those who initiated treatment at lower CD4 counts. Important differences in clinical outcomes and quality of life persist, including gender-based disparities among PLWH. Examining healthy aging as a multidimensional state can guide development of preventative and management strategies that are appropriate for the complex social and healthcare needs of people aging with HIV.

Methods: The CHANGE HIV (Correlates of Healthy Aging in Geriatric HIV) study is a Canadian cohort of PLWH age 65 and older. In this cohort, healthy aging is assessed using the Rotterdam Healthy Aging Score (HAS). Scores are calculated across 7 domains of health (chronic disease, mental health, pain, social support, quality of life, cognitive and physical function). We report on the overall and 7 domains of the HAS for the first 227 participants in the

cohort and determine the proportion of those with healthy (scores 13-14), intermediate (scores 11-12), and poor aging (scores 0-10) scores. Scores were compared according to gender and other sociodemographic and HIV-related factors using Kruskal-Wallis and Fisher's exact tests for comparisons.

Results: Median [IQR] age was 70 [68,74], 203 (89%) were men, 21 (9%) women and 3 (1%) transgender. Majority of participants were white (77%), born in Canada (66%) and retired (77%). A total of 137 individuals (60%) were enrolled in the cohort prior to the COVID-19 pandemic. Median [IQR] HAS was 12 [10,13] with 77 participants (34%) achieving healthy, 89 (39%) intermediate and 61 (27%) poor aging scores. Women and transgender participants had lower median [IQR] HAS (10.5 [9,13] compared to 12 [11,13] among men) and higher proportion of poor aging scores (50% compared to 24% among men, $p=0.015$). Women had fewer comorbidities compared to men ($p=0.024$), but worse cognitive function scores ($p=0.002$) and more pain ($p<0.001$). HAS scores were lower among retired individuals compared to those employed or engaged in volunteer activities ($p=0.013$) but did not differ by age ($p=0.641$), race ($p=0.698$), country of birth ($p=0.887$), CD4 count nadir ($p=0.510$), or duration of HIV infection ($p=0.066$). HAS scores did not differ among those enrolled in the cohort prior to and since the start of the COVID-19 pandemic ($p=0.934$).

Conclusions: Gender seems to have an important impact on the aging experience of PLWH, especially across comorbidity, cognitive function and pain domains of health. Using a multidimensional score like the HAS can identify individuals at risk of poor clinical outcomes and direct interventions that support their healthy aging.

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Cervical Screening and HPV Testing in Young Women Living with Perinatally Acquired HIV: An Interim Assessment of the SHiP Study

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Background: HIV increases the risk of HPV related cervical intraepithelial neoplasia (CIN) and cancer, and potentially women living with perinatally acquired HIV (WLPaHIV) may be at greater risk from an earlier age. Women living with HIV are eligible for annual screening by primary HPV testing aged 25-65, and the prevalence of high-risk HPV (hrHPV) in the general UK population is 16%. The SHiP study aims to explore the prevalence of hrHPV and abnormal cervical cytology in WLPaHIV.

Methods: Eligible WLPaHIV are aged 18+, sexually active and able to give informed consent. Participants complete a short questionnaire for

sexual, HPV vaccination and cervical screening history. A cervical sample is tested for hrHPV using the Cepheid GeneXpert and analysed for cytology by NHS Cytology Screening London. Women positive for hrHPV and/or abnormal cytology are referred to colposcopy.

Results: 38 women have been recruited; 28/38 were of black ethnicity (75%), 16/38 had an ex or current smoking history and 35/38 (92%) had a viral load <200 copies/ml at the last follow up. The median CD4 count at recruitment was 703 cells/ μ l (range 248-1600). Of the 38 recruited, 28 (74%) have had a cervical sample taken. The remaining 10/38 declined or deferred speculum examination but completed the questionnaire. The median age was 27 (range 19-34) with 13 (34%) below NHS screening age. Of those aged \geq 25, 7/25 (28%) had never had a smear before, and of those who did, 6/17 (35%) were known to be abnormal. 23/38 reported prior HPV vaccination. 7/28 (25%) tested positive for hrHPV (2 HPV-16, 0 HPV-18/-45, 7 other hr-HPV) and 2 tested negative for HPV but had abnormal cytology. Of these 9 women, 4 were under screening age. On referral to colposcopy 5/9 attended, none had CIN2+ and 5/5 had CIN1 or other HPV related changes.

Conclusion: In this cohort of young WLPaHIV the prevalence of hrHPV was 25% as measured by Cepheid GeneXpert and of those hrHPV positive 43% were under 25 years.

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Viral Voices. Digital Storytelling, Women and HIV in Podcast Positivos: Mujeres VIHvas Project

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Purpose: Four decades after the first diagnoses women maintain a secondary role in HIV infection and continue to be neglected in HIV policies and strategies. At the same time, society perpetuates stigma and discrimination.

There is a need to constantly explore new tools to address this phenomenon. We aimed to explore the potential of digital storytelling as a tool to challenge the hegemonic herstory around HIV-positive women by analysing the project Podcast Positivos: Mujeres VIHvas.

Method: Interpretative study through virtual ethnography, conducted between September 2020 and June 2021, analysing the narrative of 8 podcast episodes published openly in Spain in 2019 by CESIDA and made by HIV-positive women. Semantic axes, metaphors, forbidden words and explicit and

implicit discourse acts were identified and grouped into different categories of study.

In relation to feminist theories of intersectionality, performativity and cyborg, the use of language, voice and the role of listening were discussed.

Results:

Categories identified:

- HIV as a partial secret, in tension between public knowledge and acceptance according to place, time or life experience.
- Intersections that enable the categorisation of external stigma (social discrimination and violence) and internal stigma (fear and lack of power).
- Embodiment of the virus and the potential for transformation through the protagonists' voice on a digital platform.

Conclusions: Researching the voices and experiences of HIV-positive women allows us to get at the constructed categories, the symbolic burdens imposed on the body, the main stigmas surrounding HIV and the use of storytelling as a therapeutic and visibilisation strategy.

Empowering people living with HIV to improve their emotional well-being has become an important public health priority and e-Health tools such as digital storytelling and podcasting could become an accessible approach option.

This work is based in part on the MSc Thesis in Gender Studies at Linköping University 2020 available at:

<http://www.diva-portal.org/smash/record.jsf?pid=diva2%3A1518400&dswid=5357>

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HIV Uptake in Underserved Clinics During the Pandemic

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Background: The COVID-19 pandemic has affected millions of people and halted daily life. Since the pandemic started, some theorize there was a drop in patient numbers in hospitals and clinics. At Midway Specialty Care Center (MSCC) in Fort Pierce and Port Saint Lucie, Florida, we currently see about 1300 patients with HIV. Based on observational findings at our clinic, there has been a decline in our male population but not our female population. Further observations plan to identify trends in females with HIV entry to care during the pandemic compared to before to identify why females entered our care.

Materials and Methods: Female patients who were newly seen at MSCC in Fort Pierce and Port Saint Lucie, Florida, from March 2020 till October 2021 were evaluated for their reason to care and date of entry. First, patients were separated into three groups based on their appointment date to break the reviewed dates into three time periods (P1, P2, P3) of seven months, seven months, and six months. Then, in each of these three groups, each patient's time from the point of contact to visit, the reason for entry into care, baseline CD4+ count, and HIV RNA levels were extracted through an

electronic medical record. In all, the three patient groups were then compared to a control group (C1) that consisted of patients seen in the same amount of time before the pandemic (seven months). Finally, comparisons were analyzed to find a trend in the collected information for new female patients seen before and during the pandemic.

Results: The control cohort consisted of 15 patients, and the following three cohorts consisted of 18, 20, and 27 patients, respectively. At the end of October 2021, there was an 80% increase in patients seen in P3 compared to C1. In C1, patients on average waited 10 days (SD 12.9) to see a medical provider; in P1, P2, and P3, patients were seen on average of 6 days (SD 5.1), 9 days (SD 9.2), and 9.5 days (SD 6.5) respectively. Before the pandemic, the most common reason for a patient's entry into care was the transfer of care from another clinic(40%), followed by relocation (33%). At the end of P3, relocation was the leading cause of entry into care (41%), followed by transfer of care (30%). During C1, 66.7% (10/15, 1 unknown) of patients entering care were virally suppressed. During P1, P2, and P3, 61.1% (10/18, 2 unknown), 75% (15/20, 3 unknown), and 70.4% (19/27, 3 unknown) of patients entered care virally suppressed.

Conclusions: There was a trending increase in the number of new female patients with HIV seen at MSCC when comparing before and during the pandemic. Relocation is the most common reason for entering care in the observed area throughout the pandemic. COVID has created challenges in providing care. With the increase in new patients seeking care, healthcare facilities need to be prepared through increased staffing and resources.

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Factors Associated with the Performance of Health Facilities in the Prevention and Control of COVID-19 Infection in the West Region of Cameroon

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Background: Since March 2020, Cameroon has been facing the Covid-19 pandemic and recorded 116,718 confirmed cases as of January 26, 2022 with a high infection rate among health personnel. In health facilities (HF), compliance with Infection Prevention and Control (IPC) recommendations is the key to protecting healthcare personnel, patients and users from COVID-19. Despite the multiple sensitizations made at the national level on the IPC, its implementation remained incomplete. The objective of this study was to identify the factors associated with the performance of HF in the West region in Covid-19 IPC.

Methodology: This was an analytical cross-sectional study carried out in 117 health facilities in the West Region of Cameroon. We included in the study all functional HF recognized by the Regional Public Health Delegation of the West, after obtaining informed consent from the manager and any non-functional HF before the occurrence of the COVID-19 pandemic was excluded. Performance was assessed using the World Health Organization COVID-19/IPC scorecard. Data were analyzed using Statistics for Social Sciences software and tables were generated using Microsoft Excel 2016 software. Factors associated with performance were determined by logistic regression using Fisher's test and P value less than 0.05 was considered statistically significant.

Results: Of the 117 health facilities assessed, 62 (53%) were public and 73 (62.4%) were integrated health centers and 35 (30%) respondents had been trained in IPC. The overall score varied between 4.8% and 88.1% with a median of 35.7% and more than two thirds of health facilities (69%) had poor performance (score<50%) in IPC. The factors associated with good performance in IPC were district medical centers (OR=10.1 [1.32; 76.87]; P=0.026), reception of funding dedicated to IPC in the HF (OR =12.2 [1.39; 107.90]; P=0.024) and the existence of an epidemiological surveillance team (OR=9.96 [2.01; 49.40]; P<0.001).

Conclusion: The low performance of HF in COVID-19 IPC seriously exposes health personnel and patients to COVID-19 infection. It is therefore essential to create a national IPC program, appoint IPC regional focal points, create IPC committees in HF and train/retrain health personnel in IPC.

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