INTERNATIONAL WORKSHOP ON **HIV & PEDIATRICS** 2023

ABSTRACT BOOK

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International Workshop on HIV & Pediatrics 2023

21 – 22 July 2023
Hybrid Meeting
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Abstracts
Oral Presentations

1

Increasing Second-Line ART Options for Children With HIV in Africa: Week-96 Efficacy and Safety Results of the CHAPAS-4 Randomised Trial

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Background: There are limited options and formulations for second-line antiretroviral therapy (ART) for children living with HIV. CHAPAS-4(ISRCTN22964075) evaluated long-term outcomes for children starting second-line ART.

Methods: In this 2X4 factorial trial, children from Uganda, Zambia and Zimbabwe were randomised to second-line tenofovir alafenamide/emtricitabine (TAF/FTC) or standard-of-care (SOC) backbone (abacavir(ABC) or zidovudine(AZT) with lamivudine(3TC)) (randomisation 1) and to one of four anchor drug options: dolutegravir(DTG), ritonavir-boosted darunavir(DRV/r), ritonavir-boosted atazanavir(ATZ/r) or ritonavir-boosted lopinavir(LPV/r) (randomisation 2), dosed according to WHO weight-bands. The primary endpoint was viral load(VL)<400copies/mL at week-96. We hypothesised that TAF/FTC would be non-inferior to SOC (10% margin); ATV/r non-inferior to LPV/r(12% margin); both DRV/r and DTG superior to LPV/r and ATV/r arms combined (superiority threshold p≤0.03; as multiple comparisons). Analysis was intention-to-treat, based on logistic regression.

Results: 919 children aged 3-15years (54%male, median [IQR] viral load 17,573copies/mL[5549, 55,700]; CD4 count 669[413, 971]) switching from NNRTI-based ART, were randomised and spent 98% of time on allocated regimen. At week-96, 406/454(89.4%) on TAF/FTC vs 378/454(83.3%) on SOC had VL<400copies/mL, with no evidence of difference between ABC or ZDV. For randomisation 2, 208/226(92.0%) on DTG, 203/230(88.3%) on DRV/r, 193/229(84.3%) on ATV/r, 180/223(80.7%) on LPV/r had VL<400c/ml. TAF/FTC was superior to SOC backbone (difference[95%CI]: 6.3%[2.0, 10.6],p=0.004). DTG was superior to LPV/r and ATV/r (9.7[4.8, 14.5], p<0.0001); DRV/r showed a trend to superiority to LPV/r and ATV/r (5.6%[0.3, 11.0],p=0.04); ATV/r was non-inferior to LPV/r (3.4%[-3.4, 10.2],p=0.33). Results were similar for VL<60copies/mL and <1000copies/mL and at weeks 48 and 144. CD4 count improved in all arms. More grade 3/4 adverse events (AE), predominantly hyperbilirubinemia, occurred for ATV/r vs LPV/r(p<0.0001); DTG had fewer AE vs. LPV/r(p=0.02). There was no evidence of excess weight-gain with DTG±TAF. Improvement in growth parameters were greater with TAF vs. SOC; and with DTG, DRV/r and ATV/r vs. LPV/r. Renal and bone health was similar between arms. One child died (treatment-unrelated); 3% had serious adverse events.

Conclusions: TAF/FTC and DTG were virologically superior to SOC backbone and comparators (ATV/r, LPV/r) respectively, with excellent safety profiles. Child-friendly fixed-dose combinations of TAF/FTC (±DTG or boosted DRV or ATV/r) would increase access to safe, effective second-line ART options for children.

2

Improving Antiretroviral Treatment Continuation Among Children Living With HIV in Nampula, Mozambique

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Background: Mozambique faces challenges with timely HIV treatment initiation and continuation for children living with HIV (CLHIV), essential for prevention of disease progression and mortality. In 2021, treatment continuation at 3 months among CLHIV was 47% in Nampula Province. The aim of this abstract is to describe treatment continuation for CLHIV in Nampula province between October 2019 to September 2022 implementation.

Methods: ICAP University of Columbia supports 59 health facilities (HF) in Nampula province and implements a set of targeted interventions to improve treatment continuation, including 1) linking CLHIV initiating antiretroviral therapy (ART) with peers and mentor mothers; 2) phone reminders one and three days before appointments and immediate outreach for those missing appointments; 3) expansion of HIV services to the community level; 4) roll out of optimized ART regimens; and 5) intensive monitoring with weekly review, feedback and discussion of treatment continuation data with HF teams.
We used routinely reported, aggregate, retrospective data to assess treatment continuation at 3 months and treatment interruption among CLHIV. Treatment continuation at 3 months was defined as the proportion of children newly enrolled on ART 5 months prior to the reporting period end date, who have a clinical consultation or ART pick-up between 61 and 120 days after ART initiation. Treatment interruption was defined proportion of CLHIV who have not returned within 60 days of their expected clinical consultation or ART pick-up, which includes those who were reported as dead by end of reporting period. We report data from the 59 HF for the period from October to December 2019 (pre-intervention) and July to September 2022 (post-intervention).

Results: Pediatric treatment continuation at 3 months increased from 57% (130/228) in the pre-intervention period to 90% (276/308) in the post-intervention period. During the same period, treatment interruption reduced from 27% (61/208) to 2% (6/308), and death reduced from 4% (8/228) to 2% (5/308).

Conclusions: Implementation of targeted interventions, combined with intensive monitoring and data use, led to improvement in treatment continuation outcomes among CLHIV. ICAP will continue to assess gaps and design contextualized interventions to address remaining challenges for treatment continuation in this vulnerable group.

3

Low-Level Viremia as a Risk Factor for Virologic Failure in Children and Adolescents Living with HIV

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Background: Current guidelines in the majority of developing countries use a viral load (VL) cutoff of 1000 copies/mL to define virologic failure (VF). However, research increasingly demonstrates that VL from 50-999 copies/mL or "low-level viremia" (LLV) is a risk factor for future VF.

Material and Methods: A retrospective chart review was performed using the health records from the Baylor College of Medicine Children's Foundation - Tanzania sites in Mbeya and Mwanza. CALHIV up to the age of 19 years who had been on antiretroviral therapy (ART) for ≥6 months (by July 2021) were included in the analysis. Participants were followed longitudinally for at least two subsequent VLs after an initial undetectable VL (<50 copies/mL). VF was defined as ≥1000 copies/mL.

Results: A total of 670 CALHIV were included in the outcome analysis. LLV occurred in 47.5% (318/670) and of those, 52.5% (167/318) had VL 50-199 copies/mL, 27.4% (87/318) had 200-399 copies/mL, and 20.1% (64/318) had 400-999 copies/mL. Kaplan-Meier analysis showed a higher risk of failure with higher LLV category (p<0.0001). When looking at predictors of VF, a Cox proportional hazard model showed that there was an increased risk of VF with higher LLV when compared to <50 copies/mL: adjusted hazard ratio (AHR) 1.73 with 50-199 copies/mL (p=0.01), AHR 2.19 with 200-399 copies/mL (p=0.001), and AHR 3.34 with 400-999 copies/mL (p<0.0001). On multivariable analysis, age of 10-14 years (p=0.03) and immunosuppression, moderate (p=0.008) or severe (p=0.009), were associated with VF.

Conclusions: LLV was associated with increased risk of VF - higher levels of LLV corresponding to higher risk. Age 10-14 years and immunosuppression were also associated with increased risk of VF.

4

Intensive Monitoring Improve Access to Pediatric Dolutegravir and Viral Suppression Among Younger Children Living with HIV in Nampula province, Mozambique

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Background: Pediatric treatment optimization has improved HIV outcomes for children worldwide. However, for children living with HIV (CLHIV) below 20kg, poor palatability of the pediatric formulation of lopinavir and ritonavir (LPV/r) can lead to poor health outcomes, and by the end of 2021, only 68% of CLHIV aged 0-4 years had viral load (VL) suppression in Nampula Province in Mozambique. The introduction of pediatric formulation of dolutegravir (pDTG) by the Mozambique Ministry of Health (MOH) in late February 2022 presented an opportunity to overcome this challenge.

Methods: ICAP at Columbia University worked in collaboration with MOH at national and subnational level to support pDTG roll-out to CLHIV below 20kg at 59 health facilities (HF) in Nampula Province, including data review to inform the provincial distribution plan, training and mentoring of providers, weekly monitoring of transition among CLHIV attending each HF and monthly monitoring of pediatric formulations and regimen consumption per HF. Intensive monitoring enabled timely feedback to HF teams on missed opportunities, to readjust stocks and provide targeted technical assistance for HF with slow transition. We present VL data for the pre- and post-implementation periods to assess preliminary results among CLHIV age 0 to 4 years.

Results: By March 2022, 64% of CLHIV had already transitioned to pDTG and by May 2022 virtually all CLHIV (99.2%) were on a pDTG-based regimen. Data from the pre-implementation phase (Dec 2021-Jan 2022) showed that of the 5,179 CLHIV with a VL result, 3,547 (68%) had VL suppression, while post-implementation data (Oct-Nov 2022) indicated 83% (4,922/5,937) had VL suppression, an increase of 22.1%.

Conclusions: Close monitoring, timely support for supply chain issues and technical assistance enabled rapid transition to optimized regimens among this vulnerable population, leading to early changes in viral suppression among young CLHIV.

5

Characterization of HIV-1 Reservoirs in Children and Adolescents: A Systematic Review and Meta-Analysis Toward Pediatric HIV Cure

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Background: The virostatic effect of antiretroviral therapies (ART) infers viral persistence in sanctuaries, with a high likelihood of reactivation off-treatment. This systematic review and meta-analysis aimed at estimating the global burden of archived drug resistance mutations (ADRMs), the size of reservoirs and their determinants in pediatrics.

Methods: Were included, randomized and non-randomized trials, cohorts and cross-sectional studies of HIV reservoirs in vertically-infected participants, published in English/French between 2002-2022. As primary outcomes, we evaluated the prevalence of ADRMs and estimated the size of reservoirs (HIV-1 DNA copies/10 6 cells) in pediatrics. Subgroup analysis were performed to further characterize the data and the meta-analysis was done through random effect models.

Results: Overall, 50 studies from 17 countries worldwide were included encompassing 2569 vertically infected participants (aged 2-days to 19-years; 52.81% females). There were limited data on the quantitative characterization of viral reservoirs in SSA, and sensitive tool as ddPCR for characterizing viral reservoirs were not implemented in the most sub-Saharan Africa (SSA) countries. Overall prevalence of ADRMs was 37.80% [95%CI: 13.89–65.17], with 48.79% [95%CI: 0–100] in Africa, 42.08% [6.68-82.71] in America, 23.88% [95%CI: 14.34–34.90] in Asia, and 20.00% [95%CI: 10.72–31.17] in Europe; without any difference between infants and adolescents (p=0.656). Starting ART before 2 months of age limited the size of HIV-1 DNA (p=0.054). Participants with long suppressed viremia (>5years) had lower rates of HIV-1 DNA (p=0.027) whereas pre-/post-ART CD4 ≤29% and pre-/post-ART viremia ≥5Log were all found associated with higher rates of HIV-1 DNA (p=0.038, p=0.047, p=0.041 and 0.035 respectively).

Conclusion: Our findings underscore high levels of ADRMs in pediatrics worldwide, with a higher reservoir driven by delayed ART initiation, shorter period of viral suppression and immuno-virological failures. Thus, strategies for pediatric HIV functional cure should target adolescents/children with very early ART initiation, high immunity and long-term viral suppression.

6

Is the Recommended Valganciclovir Dosing for Treatment of Cytomegalovirus in Infants Adequate for Treatment of Cytomegalovirus Pneumonia in HIV-Positive Infants in sub-Saharan Africa? A Pharmacokinetic Sub-Study in the EMPIRICAL Trial

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Background: Cytomegalovirus (CMV) is a cause of severe pneumonia in children with advanced HIV. Valganciclovir, the oral prodrug of ganciclovir, is used to treat CMV in immunocompromised hosts. No pharmacokinetic data is available to support valganciclovir dosing in infants living with HIV. This study aimed to determine adequacy of dosing and sources of pharmacokinetic variability of ganciclovir in infants living with HIV with severe pneumonia.

Methods: The study was conducted within EMPIRICAL trial (#NCT03915366) for the treatment of severe pneumonia in infants living with HIV. Participants randomized to receive valganciclovir for empirical CMV treatment were recruited from hospitals in Zimbabwe, Zambia, Mozambique and Uganda between August 2020-August 2022. Valganciclovir reconstituted syrup was given at 16mg/kg/dose every 12 hours. Pharmacokinetic sampling was done 2 and 5 hours post-administration on day 3 of enrolment after at least 3 doses. Ganciclovir area-under-curve for a 12-hour dosing interval (AUC) was estimated using a limited sampling equation (AUC0-24h = 2*2.7*AUC2-5h +6) [Villeneuve 2013]. The geometric mean AUC and number of subjects within pharmacokinetic target for CMV treatment (AUC0-24h = 80-120 h*mg/L) were determined. Spearman's rank test was applied to test the extent to which baseline parameters (age, weight, weight-for-age, eGFR and BSA) correlated with ganciclovir AUC

Results: Geometric mean AUC0-24h (%CV) was 77.7 (54.4) h*mg/L. Of 85 participants, 30 (35%) had AUC within the pre-defined efficacy target for CMV treatment. The remaining subjects were either below (40 (47%)) or above (15 (18%)) the target. There was a positive correlation between AUC and weight-for-height z-score (r(83)=.22, p=.042). A negative correlation was observed between AUC and age (r(83)=-.41, p<.001), eGFR (r(83)=-.36, p=.001) and BSA (r(83)=-.25, p=.021).

Conclusions: A significant number of participants did not achieve the PK target for CMV treatment when receiving valganciclovir at 16mg/kg/dose twice daily. This could result in decreased treatment response or failure. Exposure to valganciclovir decreased with increasing age, BSA, eGFR, and poorer nutritional status. Future studies should investigate the clinical significance of these findings and if higher dosing or alternative dosing strategies are required. This project is part of EDCTP2 programme supported by the European Union (grant number RIA RIA2017MC-2013)

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CMV Co-infection and Immunological Outcomes Among Children Living With HIV in Canada

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Background: While CMV co-infection among adults living with HIV has been associated with chronic inflammation and HIV disease progression, data in pediatrics is limited. The objective of this study was to determine the association between CMV co-infection and immunological outcomes among children living with HIV (CLWH).

Methods: Sub-study of the prospective, multicenter Early Pediatric Initiation Canada Child Cure Cohort study (EPIC4). CLWH were followed every 3-6 months from 2014–2018. CMV serostatus (IgG) was determined at baseline (Architect™ CMIA and CMV IgG avidity) and end of study for those seronegative at baseline. HIV and CMV viral loads (VL) and lymphocyte subsets were quantified at every visit.

Results: 225 CLWH were enrolled in the study; at baseline, median age was 13.9 years (IQR, 9.3-17.0 years), 98.9% of children were receiving combination antiretroviral therapy, and 81% had suppressed HIV VL. Overall, 192 (85.3%) children had evidence of CMV co-infection at baseline (IgG positive) with 96.8% demonstrating high avidity; this included 5 children with documented congenital CMV infection. Those who were CMV co-infected had significantly lower CD4/CD8 ratios at baseline (0.99 vs. 1.42, p<0.01) and study nadir (0.82 vs. 1.15, p<0.01), and lower CD4% at baseline (33% vs 38%, p<0.01) and study nadir (30% vs. 35%, p<0.01), differences which all remained significant after adjusting for age, age at treatment initiation, the presence of concurrent HIV viremia, and occurrence of any treatment interruption during the study. Thirty-four (17.7%) of the CMV co-infected children were viremic for CMV at least once during follow-up (CMV VL range 85-1991 IU/mL). While children with CMV viremia were more likely to have at least one episode of detectable HIV VL during the study (64.7% vs 33.5%, p< 0.001), the presence of CMV viremia was not associated with any significant differences in lymphocyte subsets in the adjusted models.

Conclusions: Among CLWH in Canada, CMV co-infection is common, and associated with lower CD4/CD8 ratios and CD4% among children with well-controlled HIV infection. Further work is necessary to understand the dynamics of viral co-infection, and if targeted CMV treatments could improve immunological outcomes among CLWH.

8

Immune Responses to Respiratory Syncytial Virus among HIV-Exposed Uninfected Infants from the United States Correlate with Maternal Inflammation during Pregnancy

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Background: Respiratory syncytial virus (RSV) is a major contributor to morbidity and mortality among HIV-exposed, uninfected infants (HEU). We hypothesized that in utero exposure to maternal HIV-associated inflammation impacts HEU immune responses to RSV infection.

Methods: We enrolled pregnant women with and without HIV and collected maternal blood during pregnancy and cord blood at delivery. We measured concentrations of 16 inflammatory markers in maternal and cord plasma and identified differences between women with vs. without HIV, and between HEU vs. HIV-unexposed infants (HUU). We used a novel in vitro model of human respiratory infection to measure cord blood mononuclear cell responses to RSV. We compared 7 indicators of RSV response among innate immune cells from HEU vs. HUU infants, and identified correlations between RSV responses and plasma inflammatory markers.

Results: Samples were collected from 23 women with HIV, 61 women without HIV, and their infants. Among women with HIV, the median (IQR) viral load at delivery was 0 copies/mL (0-15) and CD4 was 655 cells/mm3 (322-814). There were no differences between HEU and HUU in regard to maternal age, mechanism of delivery, infant gestational age, sex, or birthweight. Twelve inflammatory markers were higher in plasma from women with vs. without HIV. Interleukin (IL)-1β was higher in cord plasma from HEU vs. HUU. In the respiratory infection model, HEU dendritic cells (DC) expressed less IL-12 and more CD83 in response to RSV, compared to HUU DC. Killing of RSV-infected respiratory epithelium was associated with higher cord plasma concentrations of IL-1β in both HEU and HUU. Maternal plasma concentrations of IL-6 and tumor necrosis factor-α, as well as two markers of monocyte and macrophage activation (soluble CD14 and CD163) were inversely correlated with several innate immune cell responses to RSV in HEU and/or HUU.

Conclusions: Innate immune responses to an in vitro model of RSV infection are altered in HEU vs. HUU and inversely correlate with the degree of maternal plasma inflammation. HIV-associated maternal inflammation may be a driver of immune dysregulation in HEU infants and predispose to increased susceptibility to morbidity and mortality upon exposure to RSV.

9

Increase in Ambient Air Pollution Is Associated With Cardiovascular Disease Risk in Youth With and Without HIV in Urban Uganda

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Background: Ambient air pollution is a major public health concern, particularly in Sub-Saharan Africa (SSA). Both air pollution and HIV are associated with increased cardiovascular disease (CVD) risk in adults, however, longitudinal data evaluating these associations in youth in SSA are limited.

Methods: A prospective observational cohort study was performed from 2017-2021 at the Joint Clinical Research Center in Uganda. Children with perinatally acquired HIV (PHIV) and children without HIV (HIV-) between 10-18 years of age with no known active infections and who lived in and around Kampala were included. PHIVs were on ART with HIV-1 RNA level ≤400 copies/mL. Ambient concentrations of PM2.5 were measured with a continuous central site monitoring using a Beta Attenuation Monitor or E-Samplers from the GeoHealth Hub at baseline and 96 weeks later. Carotid intima media thickness (IMT) and pulse wave velocity (PWV) were evaluated at baseline and 96 weeks. Groups were compared using unpaired t test and potential predictors of IMT and PWV were assessed using linear regression.

Results: Sixty-nine participants were evaluated at both timepoints (38 PHIV & 31 HIV-). At baseline, median (IQR) age was 13 years (11,14) and 46% were female. The median yearly PM2.5 exposure increased from 26 (25, 38) µg/m3 at baseline to 37 (37, 39, p = <0.001) µg/m3 at week 96. Change in yearly PM2.5 was significantly associated with increase in IMT over 96 weeks (β:0.007, 95%CI: [0.002, 0.01], p = 0.004), after adjusting for HIV status, age, socioeconomic status (p≥0.4 for all) and sex (p=0.03). There was no association between PM2.5 and PWV (p>0.05).

Conclusion: In urban Uganda, adolescents are exposed to PM well over the WHO recommendation of 5 µg/m3 or less per year. The levels of air pollution in the Kampala region increased by 1.4 times over a 2 year period, highlighting an urgent need to rapidly scale up air quality control measures. This is further supported by our observation that increasing PM2.5 exposure over 2 years was associated with elevated CVD risk, irrespective of HIV status, suggesting air pollution may be a prominent driver of CVD risk in SSA.

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Longitudinal Immune Correlates of Cognition at 7 and 9 Years in Early Treated and Long-Term Suppressed Perinatally HIV-1 Infected Children in Cape Town, South Africa

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Background: Many children living with perinatally acquired HIV (CPHIV) show impaired cognitive function, possibly secondary to neuroinflammation. Our objective was to identify immune biomarkers of HIV-1-associated cognitive outcomes among school-aged CPHIV from the Children with HIV Early antiRetroviral (CHER) trial.

Methods: We investigated associations between clinical, immunological, and cognitive outcomes longitudinally and cross-sectionally (N=74). Forty immunological plasma biomarkers were measured by Luminex®Multiplex Assays and ELISA in samples obtained within 6 weeks of birth (baseline), 2–3 years following antiretroviral therapy (ART) initiation, and at 8 years of age. Cognitive performance was assessed at ages 7 and 9 years. Statistical analyses included timepoint-specific Spearman and Pearson correlations.

Results: We observed several significant relations between baseline pro-inflammatory immune markers and cognitive outcomes at both 7 and 9 years of age. For instance, IL-1RA and MIP-1α was significantly associated with psychomotor functioning at age 7 respectively (r=-0.47; p<0.01; (r=-0.44;p=0.01), and IL-2, IL-18, sCD163 and IFN-γ was significantly associated with attention at age 7 respectively, (r=-0.46; p<0.01; r=-0.48;p<0.01; r=-0.39;p=0.03; r=-0.38;p=0.03). IL-4 and hsCRP was significantly associated with mental processing (i.e., overall cognitive performance) (r=-0.42;p=0.02; r=-0.43;p=0.01) at 9 years of age.

After 2–3 years on ART, these relations persisted with further association. For instance, RANTES was significantly associated with reaction time scores at 7 years (r=-0.38;p=0.01) and CD40L was significantly associated with impulsivity at 9 years.

At 8 years, following long-term viral suppression and reconstituted CD4 counts, the immune biomarkers: IL-18 and CD40L was significantly associated with learning and memory (r=-0.42; p<0.01; r=-0.31; p=0.02). IL-1α was significantly associated with executive functioning (r=-0.39; p<0.01). IL-2; IFN-γ and FGF was significantly associated with mental processing (r=-0.27; p=0.04; r=-0.27; p=0.04; r=-0.33; p<0.01) at 9 years. IL-18, IL-2 and IFN-γ persisted longitudinally as correlates for cognitive outcomes.

Gestation time and longitudinal CD4% were significantly associated with attention at 7 years respectively, (r=-0.41; p=0.02; r=-0.40;p=0.02) and longitudinal CD4% were strongly associated with impulsivity at 9 years (r= -0.55,p <0.01).

Conclusion: Despite early ART and viral suppression, inflammatory insults affected later cognitive performance. Early immunological and clinical parameters may predict cognitive outcomes at 7 and 9 years of age in CPHIV.

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Factors Associated With Breastfeeding Transmission of HIV in the Era of Universal Maternal Antiretroviral Therapy

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Background: Understanding the role of breastfeeding in vertical transmission (VT) of HIV is critical to achieving elimination of VT.

Methods: We used routinely-collected data to identify infants with HIV exposure, born May 2018 to April 2021 to mothers known with HIV by delivery (Western Cape, South Africa), with follow-up through mid-August 2022. We assessed HIV status in infants who had an HIV test/diagnosis at age >14 weeks and had a previous negative HIV-PCR test between age 8 days and 14 weeks, as a proxy for breastfeeding transmission. We used mixed-effects Poisson regression to assess factors associated with breastfeeding transmission.

Results: We identified 50,461 infants with HIV exposure, born to 48,166 mothers known with HIV by delivery (89% of whom received any ART during pregnancy). Of those infants diagnosed with HIV, 41% (n=366/894) were diagnosed at age >14 weeks. In multivariable analysis, we included 17,820 HIV-exposed infants with HIV testing/diagnosis at age >14 weeks and a previous negative test, 205 of whom were diagnosed with HIV. Maternal ART use patterns prior to delivery were associated with breastfeeding transmission. Both receiving no antenatal ART and restarting ART during pregnancy >8 weeks before delivery were associated with transmission rates 7 times higher, compared to starting ART before pregnancy with no antenatal ART gaps. Starting/restarting ART within 8 weeks of delivery, starting earlier in pregnancy or before pregnancy but with ART gaps (of >2 weeks) thereafter during pregnancy were associated with rates 6, 4 and 2 times higher, respectively. Breastfeeding transmission was strongly associated with unknown or elevated most recent (within 6 months) maternal viral load (VL), with VL>100,000 copies/ml associated with rates 23 times higher (95% CI 12-44) than VL<100 copies/ml. CD4 200-349/unknown and CD4<200 were associated with transmission rates 3 and 5 times higher, respectively, vs CD4≥500 cells/µl. Younger maternal age (<20 vs ≥30 years) and higher parity (≥3 vs 1) were also associated with rates 2 times higher.

Conclusions: Despite high maternal ART coverage, ongoing VT attributable to breastfeeding transmission is a concern. Interventions to ensure retention on ART and sustained viral suppression throughout BF are needed to minimise postpartum VT.

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Modeling the Impact of Viral Load Testing and Mentor Mother Programs on Vertical Transmission in a High HIV Prevalence African Setting

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Background: Prevention of vertical transmission (PVT) programs have significantly decreased infant HIV acquisition by expanding ART coverage and increasing viral suppression (VS) among mothers living with HIV. Vertical transmission could be further reduced by addressing gaps in maternal viral load (VL) testing, as well as through "mentor mother" (MM) peer support strategies that improve retention and VS. The aim of this study was to model the impact of implementing VL testing and MM programs on vertical transmission in a high HIV prevalence African setting.

Methods: We developed a microsimulation model of HIV progression and PVT care for a hypothetical cohort of 100,000 pregnant women living with recently acquired HIV in Africa, who present to antenatal care and initiate ART at 5 months gestation. We simulated six combinations of VL testing and MM implementation: 1) No VL testing or MM (NT); 2) VL testing with 50% switching regimens after two unsuppressed VL results (VL+S50%); 3) VL testing with 100% switching (VL+S100%); 4) MM without VL testing (MM-NT); 5) MM plus scenario 2 (MM/VL+S50%); 6) MM plus scenario 3 (MM/VL+S100%). We determined maternal VS and percent reduction in vertical transmission compared to NT over pregnancy + 18 months breastfeeding.

Results: Under NT, maternal VS was 73% at 9 months postpartum, and 11.3% of infants acquired HIV by 18 months. Compared to NT, the two VL testing scenarios increased VS to 77-80% and reduced vertical transmission by 1.9-2.2%, whereas MM implementation (MM-NT) increased VS to 87% and reduced vertical transmission by 16.8%. Adding VL testing to MM implementation further improved VS to 90-91% and reduced perinatal transmission by 17.0-17.8%.

Conclusions: Among pregnant women living with recently acquired HIV, MM strategies may lead to better VS and PVT than improving the VL testing cascade alone. Concurrent implementation of both interventions has the greatest potential to improve outcomes. Further research should evaluate PVT when women initiate ART prior to conception.

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Association Between In-Utero PrEP Exposure and Bone Mineral Density at 36 Months of Age Among Mother-Infant Pairs in Kenya

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Background: Previous studies found that tenofovir-based ART use during pregnancy among women living with HIV is associated with lower bone mineral density (BMD) in neonates. It is unknown whether these differences persist beyond the neonatal period or exist among women without HIV who used tenofovir-based PrEP during pregnancy.

Methods: We utilized data from an ongoing evaluation of perinatal PrEP use in Kenya. In the parent study (NCT03070600), HIV-negative women were enrolled and offered tenofovir-based PrEP during pregnancy at 20 public clinics and followed through 9 months postpartum regardless of PrEP status. An extension cohort to evaluate safety outcomes enrolled mother-child pairs at 4 sites to be followed until the child's 5th birthday. A subset of singleton children aged 36 months with in-utero PrEP exposure was randomly selected and matched to children without in-utero PrEP exposure on maternal age, education level, and child sex and age. Whole-body bone mineral density was measured by dual-energy x-ray absorptiometry (DEXA) at Aga Khan University Hospital in Nairobi, Kenya. Linear regression adjusting for matching characteristics was performed to evaluate the relationship between BMD and PrEP exposure.

Results: From December 2021 to December 2022, 40 children with in-utero PrEP exposure and 71 without PrEP exposure had whole-body BMD measurements. The median age at DEXA scanning was 36.7 months (IQR: 36.2-38.0), 40% of children were female, and the median maternal age at delivery was 27.6 years (IQR: 22.1-32.6). The median height for children at DEXA scanning was similar between those with and without PrEP exposure (94.3 cm vs. 94.0 cm, p=0.455). The median whole-body BMD for children with and without in-utero PrEP exposure was 418.5 mg/cm2 (IQR 399.2-440.0) and 423.0 mg/cm2 (IQR 395.5.0-457.5.0), respectively. There was no difference between mean whole-body BMD among children with and without in-utero PrEP exposure (adjusted mean difference -21.6 mg/cm2, 95% CI -60.1-17.0, p=0.270).

Conclusions: PrEP exposure was not associated with BMD or height at 36 months among children with mothers who used PrEP during pregnancy. Our findings suggest that in-utero PrEP exposure may not impact BMD into early childhood.

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Neonatal Hospitalization and Mortality in Infants HIV-Exposed Uninfected and HIV-Unexposed Uninfected in the Western Cape, South Africa

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Introduction: In a province-wide cohort of 2018/2019 Western Cape public-sector births we previously observed an elevated prevalence of low birth weight (LBW; <2500g) in infants born to pregnant people with HIV, regardless of antiretroviral therapy (ART) status, compared to those without HIV. In this cohort we evaluated neonatal (0-28 days) mortality or hospitalization and impact of LBW by HIV exposure (HIV-exposed uninfected [HEU]; HIV-unexposed uninfected [HUU]).

Methods: This retrospective cohort study included all live-born infants in 2018/2019 from the Western Cape Provincial Health Data Centre (WCPHDC) without evidence of HIV acquisition. The WCPHDC integrates individual-level data from multiple electronic platforms using unique identifiers with routine maternal-infant linkage. We extracted maternal obstetric and HIV-related characteristics, infant birth weight, maternal and infant HIV-testing, hospitalization, and mortality data. The primary outcome, neonatal mortality/hospitalization, was compared by maternal HIV/ART status (HUU; HEU-no-maternal-ART (mART); HEU-preconception-mART (first ART >294 days before delivery); HEU-pregnancy-initiated-mART (first ART ≤294 days before delivery)). We calculated prevalence ratios (PR) [95% confidence intervals] using log-binomial regression.

Results: Among 166,288 infants included, 135,938 (81.8%) were infants HUU and 30,050 (18.2%) were HEU (HEU-no-mART 11.1%; HEU-preconception-mART 59.9%; HEU-pregnancy-initiated-mART 29.0%). Infants HEU were more often LBW (18.9% vs 13.6%). Neonatal hospitalizations occurred in 18,487 (13.6%) vs 4,696 (15.5%) and mortality in 974 (7.2/1000) vs 257 (8.5/1000) infants HUU and HEU respectively. Unadjusted PRs (uPR) for neonatal mortality/hospitalization were higher in all groups of infants HEU than HUU (HEU-no-mART 1.23 [1.14-1.33], HEU-preconception-mART 1.11 [1.07-1.15], HEU-pregnancy-initiated-mART 1.15 [1.09-1.21]). Adjusting for maternal age, multiparity, hypertension, early maternal mortality/hospitalization, and infant sex attenuated the aPRs slightly (HEU-no-mART 1.19 [1.09-1.29], HEU-preconception-mART 1.13 [1.08-1.17], HEU-pregnancy-initiated-mART 1.13 [1.07-1.19]). Further adjusting for LBW attenuated 46-67% of the association between maternal HIV/ART and neonatal mortality/hospitalization, yet associations persisted (HEU-no-mART 1.09 [1.03-1.15], HEU-preconception-mART 1.04 [1.01-1.07], HEU-pregnancy-initiated-mART 1.07 [1.05-1.11]). Restricted to non-LBW infants (N=142,989), aPRs for neonatal mortality/hospitalization remained associated with maternal HIV/ART (HEU-no-mART 1.20 [1.08-1.39], HEU-preconception-mART 1.14 [1.08-1.20], HEU-pregnancy-initiated-mART 1.17 [1.10-1.25]).

Conclusion: Neonatal mortality/hospitalization was elevated in all infants HEU, irrespective of maternal ART. LBW may be an important contributor to excess hospitalization/mortality in neonates HEU, yet hospitalization/mortality also remained elevated in non-LBW neonates HEU.

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Child Neurodevelopment Among Children Who Are HIV-Exposed Uninfected in Kenya

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Background: Studies suggest increased risk of neurodevelopmental delay among children who are HIV-exposed uninfected (CHEU) compared to their HIV-unexposed uninfected peers (CHUU), but predictors of neurodevelopment among CHEU remain poorly understood.

Methods: Mothers with and without HIV and their children were enrolled during 6-week routine postnatal care visits across six sites in Kenya. Infant neurodevelopment was assessed using the Malawi Developmental Assessment Tool, including social, language, fine motor, and gross motor domains. This exploratory analysis used multivariate linear mixed effects models to identify associations between neurodevelopment scores, HIV and ART exposure, and maternal factors, adjusting for confounders selected a priori and clustering by site.

Results: At 1-year evaluation, CHUU (N=715) and CHEU (N=416) had comparable median age (52 weeks) and sex distribution (52% vs. 51% female). Mothers with HIV were older (31 vs. 28 years), had lower education (49% vs. 27% primary), were more likely to be unmarried (14% vs. 12%) or in a polygamous marriage (14% vs. 4%), and report moderate-to-severe food insecurity (19% vs. 9%) ($p<0.01$ for all). CHEU and CHUU had comparable neurodevelopment scores across all four domains ($p>0.1$ for all). Among all children, maternal report of intimate partner violence (IPV) was significantly associated with lower gross motor scores (adjusted coefficient: -1.34, 95% CI: -2.18, -0.48). Maternal marital status, and having a deceased or absent father, were significantly associated with lower child neurodevelopment, across multiple domains. Among CHEU, lower gross motor scores were associated with in utero efavirenz exposure during pregnancy compared to dolutegravir (DTG) exposure (adjusted coeff: -0.55, 95% CI: -1.06, -0.05) and longer maternal ART duration. Maternal mental health measures were not associated with child neurodevelopment.

Conclusion: Biologic and social factors were associated with child neurodevelopment, and despite several sociodemographic differences between CHEU and CHUU, 1-year neurodevelopment was similar. Addressing IPV may provide benefits for both mother and child, regardless of maternal HIV status. DTG use was associated with higher neurodevelopmental scores in CHEU, compared to EFV-based regimens, potentially contributing to a lack of neurodevelopmental difference observed between CHEU and CHUU.

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A Baseline Analysis of the Physical, Social, and Mental Health of a Prospective, Global Cohort of Adolescents and Young Adults Living With HIV, the Adolescent and Young Adult Network of IeDEA (AYANI)

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Background: We sought to better understand the physical, mental, and social issues influencing the health of adolescents and young adults living with HIV (AYA-HIV).

Methods: We enrolled AYA-HIV aged 15-24 and on antiretroviral therapy (ART) into a global, prospective cohort study at 14 sites in six geographic regions of IeDEA (Asia-Pacific, AP=3; Central and South America, CSA=2; Central Africa, CA=2, East Africa, EA=4; Southern Africa, SA=2, West Africa, WA=1). Biospecimens were collected and AYA-HIV completed culturally adapted, standardized questionnaires, including the Short-Form Household Food Security Scale; IeDEA Comprehensive Adherence Measure for Pediatrics; Adapted WHO Sexual Health Survey; Patient Health Questionnaire-9; Generalized Anxiety Disorder-7; Child PTSD Symptom Scale or PTSD Checklist; Alcohol Use Disorders Identification Test; and WHO Alcohol, Smoking, and Substance Involvement Screening Test. We describe baseline characteristics.

Results: Between 09/2021 and 04/2023, we enrolled 565 AYA-HIV (AP=75; CSA=60; CA=125, EA=123, SA=100, WA=82); 51% were female. Median age was 19.8 years (interquartile range 17.8-22.1; 74% >18), and 84% had perinatally acquired HIV. The majority were in school (61%) and lived with immediate family (76%); 19% were employed. Low and very low food security were reported by 18% and 32%, respectively. Half reported missing >1 ART dose in the past month. Among 313 (55%) with viral load measurements, 79% were undetectable (<60 copies/mL). Of the 40% (n=226) reporting ever being sexually active, 43% of females reported ever being pregnant and 10% of males reported pregnancies among sexual partners. Among the 26% of AYA-HIV screening positive for moderate to severe symptoms of mental health disorders, 9% reported moderate to severe depression, 12% had suicidal ideation, 8% reported moderate to severe anxiety, and 10% had probable PTSD. Hazardous or harmful alcohol use was reported by 10%; in the past 90 days, 12% reported using tobacco, 7% marijuana, and 4% other drugs.

Conclusions: Comprehensive baseline data collected for this global cohort of AYA-HIV reveals substantial challenges beyond HIV care, including food insecurity, mental health disorders, and early pregnancy. Missed ART doses and treatment failure also were common. These findings support advancing more comprehensive models of AYA-HIV care.

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Vitamin D and Calcium Intake Are Associated With Bone Deficits Among Adolescents Living With HIV in Zambia and Zimbabwe

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Background: Adolescents living with HIV (ALWH) have lower bone density despite antiretroviral therapy (ART), and the aetiology may be multifactorial. We investigated whether dietary vitamin D and calcium intake were associated with bone density at baseline in peripubertal ALWH in Zambia and Zimbabwe, enrolled in a trial of Vitamin D and calcium supplementation.

Methods: ALWH aged 11-19 years, established on ART for ≥6 months were enrolled from five HIV clinics in Lusaka and Harare. A clinical history and examination was undertaken and HIV viral load was measured. Dual-energy X-ray absorptiometry was used to measure total body-less head bone mineral density (TBLH-BMD) Z-score. The association between vitamin D/calcium daily dietary intake (calculated from a validated diet questionnaire) and TBLH-BMD Z-score was investigated using multivariable linear regression. A vitamin D dietary intake of <4mcg/day was defined as low. Height- and weight- for-age z-scores of <-2 using UK reference standards were defined as stunting and wasting respectively.

Results: 842 ALWH (420 from Zambia and 422 from Zimbabwe, 448 (53.2%) female, mean age 15.0 years) were enrolled between February and November 2021. Unsuppressed HIV viral load (>1000 copies/ml) was observed in 11.7%; 29.9% were stunted and 30.3% were wasted. A low vitamin D intake was reported by 31.2%. Among 818 participants who had a DXA scan, lower dietary vitamin D was associated with lower TBLH-BMD Z-score; 0.07 (95%CI 0.01-0.13, p=0.025) lower for each 1mcg vitamin D, after adjusting for sex, Tanner stage, socioeconomic status and country. Similarly, lower dietary calcium intake was associated with lower TBLH-BMD Z-score; 0.10 (95%CI 0.02-0.17, p=0.015) for each 100mg calcium, adjusting for the same covariates. Mean TBLH-BMD Z-score was 0.26 lower in participants with unsuppressed HIV viral load.

Conclusions: ALWH in Zimbabwe and Zambia have low vitamin D and calcium dietary intake, and may benefit from supplementation to improve bone health.

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Efficacy and Safety of Dolutegravir/Lamivudine (DTG/3TC) in Antiretroviral Therapy (ART)-Naive Adolescents Living With HIV-1: DANCE Study Week 96 Results

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Background: DTG/3TC is an effective, well-tolerated initial ART regimen globally recommended for adults with HIV-1, but data in adolescents are scarce. We present efficacy and safety of DTG/3TC in ART-naive adolescents with HIV-1 through Week (W) 96.

Material and Methods: DANCE is an ongoing phase 3b, single-arm, multi-center, open-label study evaluating once-daily, fixed-dose combination DTG/3TC (50 mg/300 mg) as initial ART for adolescents aged ≥12 to <18 years and weighing ≥25 kg, with HIV-1 RNA 1000 to ≤500,000 c/mL. The previously reported primary endpoint assessed proportions achieving HIV-1 RNA <50 c/mL (Snapshot, ITT-E) at W48. Secondary endpoints assessed proportions with HIV-1 RNA <50 c/mL (Snapshot, ITT-E), safety, and tolerability at W96. Participants meeting confirmed virologic withdrawal (CVW) criteria (consecutive HIV-1 RNA measurements ≥200 c/mL) underwent viral resistance testing.

Results: Of 32 enrolled participants, 66% were male, 59% were Asian, and 41% were Black; median age was 17 years. At W96, 22/32 (69%; 95% CI, 50%-84%) participants had HIV-1 RNA <50 c/mL (Snapshot, ITT-E). W96 virology data were absent for 7 participants due to GCP-related site closure and imputed as treatment failures (Snapshot, ITT-E). In W96 sensitivity analyses excluding data from these 7 participants, 22/25 (88%; 95% CI, 69%-97%) achieved HIV-1 RNA <50 c/mL. Median (Q1-Q3) CD4+ cell count increased from baseline (371.5 [270.0-507.5] cells/mm³) to W96 (682.0 [499.0-863.0] cells/mm³). One participant had CVW at W72; no findings of treatment-emergent mutations were observed through W96. Overall, 29/32 (91%) participants experienced AEs through W96, with 27/32 (84%) participants having a maximum grade 1 or 2 AE. AEs leading to withdrawal were grade 2 depression and suicidal ideation (n=1) and grade 3 glomerular filtration rate decrease (the only drug-related AE; n=1). Four SAEs were reported in 3/32 (9%) participants (anal abscess, orchitis, and post-operative complication after vulvovaginal wart removal in participant with vulvovaginal warts SAE); none were drug-related.

Conclusions: DTG/3TC was well tolerated, demonstrated high efficacy, and had a high barrier to resistance in ART-naive adolescents with HIV-1 through W96. These results and well-established data in adults support DTG/3TC as a first-line ART treatment option in adolescents to achieve and maintain virologic suppression.

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Weight and BMI-for-age Evolution Before and After the Initiation of Dolutegravir-Based Regimen Among Adolescents Enrolled in the IeDEA West African Pediatric Cohort (pWADA)

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Background: We described the weight and body-mass-index (BMI) for age evolution following the transition to DTG-based antiretroviral therapy (ART) regimens among adolescents living with HIV (ALHIV), enrolled in the IeDEA West African Pediatric cohort (pWADA).

Methods: ALHIV aged 10 to 19 years who initiated or transitioned to DTG-based regimens, with at least one available data on weight six months after initiating DTG were eligible. Mean weight and mean BMI-for-age Z-score (BAZ) (WHO Child Growth Standards) were described every 6 months, within a time window between 24 months prior and 24 months after DTG initiation. Weight and BAZ evolution were estimated using individual linear mixed models, with a spline term at the time of DTG initiation to estimate the weight and BAZ slope trajectory prior and after DTG initiation.

Results: Since 2019, 1467 ALHIV initiated or transitioned to DTG-based regimens, of whom 148 (9%) were eligible for this analysis, followed-up in three university hospitals in Côte d'Ivoire, Burkina Faso and Nigeria. Among them, 41% were female and 67% were from Nigeria. At DTG initiation, median age was 13.3 years (Interquartile Range [IQR] 11.7-14.8), only two participants were ART-naïve, and the median duration on ART prior DTG initiation was 9.7 years (IQR 6.9-11.4). Median time on DTG-based regimen was 2.8 years (IQR 1.2-3.1). Mean weight and BAZ at DTG initiation were 39.0kg (SD 9.8) and -0.84 SD (SD 1.17) respectively. There was no significant difference in the estimated weight gain, (0.17 kg/month (95% Confidence Interval [95%CI] 0.05,0.31) in the 24 months prior versus 0.13 kg/month (95%CI 0.08;0.18) after DTG initiation), or in the estimated BAZ evolution (0.012 SD/month (95%CI -0.008;0.033) prior versus 0.002 SD/month (95%CI -0.005;0.010) after DTG initiation). No patient became overweight (BAZ>+2SD) after DTG initiation.

Conclusions: This first descriptive analysis did not highlight any excessive weight gain in the 24 months after DTG initiation among West-African ALHIV. Close monitoring of the transition towards DTG-based regimens, with improvements of anthropometric data availability, must remain a priority. As the transition scales up, the impact of DTG-based ART regimens among ALHIV deserves further explorations, focusing also on virologic response and metabolic disorders.

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Long-Acting HIV Pre-exposure Prophylaxis (PrEP) among Adolescent Girls and Young Women (AGYW) in South Africa: Cost-Effective at What Cost?

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Background: HIV Prevention Trials Network 084 demonstrated the superior efficacy of long-acting, injectable cabotegravir (CAB-LA) compared to daily oral tenofovir/emtricitabine (TDF-FTC) for HIV PrEP in cisgender women in sub-Saharan Africa. We projected the drug cost at which CAB-LA would provide good value compared to TDF-FTC among adolescent girls and young women (AGYW) in South Africa.

Methods: Using microsimulation modeling, we examined two PrEP strategies over 10 years among AGYW (ages 15-30y; scaled to n=10,000): TDF-FTC and CAB-LA. For each strategy, we modeled two cohorts: an AGYW cohort and an all-male partner cohort that engages in sexual activity with the AGYW cohort. Published data informed model inputs, including: HIV incidence (TDF-FTC: 1.85/100 person-years, CAB-LA: 0.2/100 person-years); HIV transmissions off-PrEP from 10,000 AGYW to partners (161/year); and 2-year retention (TDF-FTC: 88%, CAB-LA: 85%). We assumed constant incidence and transmission risk over time. Annual costs included: PrEP drug+program (TDF-FTC: $40+$12, CAB-LA: $80+$21), ART ($50 to $740), and HIV-related care ($230 to $1,800). Model-projected outcomes include incident infections among and transmissions from AGYW, life-years (LYs), costs, incremental cost-effectiveness ratios (ICER=$/LY, discounted 3%/year), and CAB-LA's maximum price premium (MPP: the highest drug price at which CAB-LA would have an ICER below a willingness-to-pay [WTP] of 50% of South Africa's per-capita GDP [$3,500/LY]).

Results: Per 10,000 AGYW in South Africa, projected infections and transmissions were higher and LYs lower in TDF-FTC (2,043 infections / 658 transmissions / 89,705 LYs), compared to CAB-LA (1,150 / 342 / 89,992). HIV infections avoided among male partners resulted in 143 LYs gained in CAB-LA over TDF-FTC. At $80/year drug cost, CAB-LA would be cost-effective (ICER=$600/LY). The projected MPP for CAB-LA to be cost-effective and cost-saving would be $94/year and $77/year, respectively. Accounting only for the benefits accruing to AGYW, the MPP to be cost-effective would be lower, $79/year. Varying transmissions from 20/year to 403/year would yield an MPP of $81-116/year to remain cost-effective.

Conclusions: Among AGYW in South Africa, CAB-LA could reduce transmissions and increase life-years compared to TDF-FTC. CAB-LA should be priced around twice the cost of TDF-FTC to be cost-effective in South Africa.

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High Prevalence of Unconfirmed Positive HIV PCR Test Results among African Infants with Perinatal HIV Exposure in the International epidemiology Databases to Evaluate AIDS (IeDEA) Consortium

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Background: Scale-up of vertical transmission prevention services has reduced incident infections among infants with perinatal HIV exposure (IPHE). However, as vertical transmission declines, the positive predictive value of HIV testing decreases and the probability of false-positive results increases, highlighting the importance of confirmatory testing. This study aimed to determine the prevalence of unconfirmed positive HIV PCR test results among African IPHE in the International epidemiology Databases to Evaluate AIDS (IeDEA) consortium.

Methods: This retrospective analysis utilized data from clinical sites in four IeDEA regions: Central Africa (CA), East Africa (EA), Southern Africa (SA), and West Africa (WA). IPHE born 2004-2021 were included. IPHE with only one positive virologic test (qualitative or quantitative DNA and/or RNA PCRs) at <18 months and no additional positive virologic or antibody test at ≥18 months were considered "unconfirmed positives." Among unconfirmed positives, virologic testing (or lack thereof) performed at any time after the initial positive result was described.

Results: This analysis included 72,618 IPHE (10,520 in CA; 47,015 in EA; 8,600 in SA; and 6,483 in WA). Overall, 3,652 (5% [range: 2% in WA to 6% in EA]) had at least one positive virologic test at <18 months, and 1,610 (44% [range: 13% in SA to 91% in WA]) of these lacked a confirmatory positive test. Among these unconfirmed positives, 1,393 (87% [range: 80% in CA to 95% in SA]) lacked additional virologic testing at any time after the initial positive result. There were 217 (13% [range: 5% in SA to 20% in CA]) unconfirmed positives with additional non-positive virologic testing after the initial positive result; 166 (10%) had ≥1 DNA PCR that was negative or indeterminate, 50 (3%) had ≥1 RNA PCR that was undetectable, and 1 (<1%) had both a DNA PCR that was negative and an RNA PCR that was undetectable.

Conclusions: Unconfirmed positive HIV test results were highly prevalent among African IPHE in this cohort. Additional efforts are needed to ensure implementation of confirmatory testing to reduce the risk of potentially false-positive results.

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Change in HIV-Related Characteristics of Children Hospitalised With Infectious Diseases in Western Cape, South Africa, 2008 – 2021: A Time Trend Analysis

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Introduction:
HIV prevalence among hospitalised children has been used as an indicator of the HIV epidemic's effects on child health services. With scaling up of vertical HIV transmission prevention programmes, the HIV-related population profile of children in South Africa has shifted. We described temporal changes in HIV-related characteristics of children, aged ≤3 years (up to third birthday), with infectious disease hospitalisations across the Western Cape province.

Methods: We used routinely collected electronic data to identify children born in the Western Cape with infectious disease hospital records for lower respiratory tract infections, diarrhoea, meningitis and tuberculous meningitis, from 2008-2021. Linked maternal and child unique identifiers were used to extract pregnancy, HIV-related, laboratory, pharmacy and hospitalisation data. We described temporal changes in child HIV exposure and infection status, timing of maternal HIV diagnosis and antiretroviral therapy (ART) start, infant exposure to maternal ART and timing thereof, and maternal CD4 and HIV viral load at pregnancy start. We used logistic and multinomial regression to assess changes in characteristics between the Pre-Option B+ (2008-2013), Option B+ (2013-2016) and Universal ART periods (2016-2021).

Results: Among 52,825 children aged ≤3 years with hospitalisations, the proportion HIV exposed uninfected increased from 14.0% (2008) to ~18.0% (2014–2017), while those with HIV infection decreased from 7.5% (2009) to 1.1% (2021). Among mothers with HIV (N=9,883), the proportion diagnosed with HIV and starting ART before pregnancy increased from 20.2% to 75.2% and 5.8% to 62.0%, respectively, between 2008 and 2020. Children hospitalised during the Universal ART period had eight times higher odds (Odds Ratio: 8.41; 95%CI: 7.37–9.62) of exposure to maternal ART versus children admitted Pre-Option B+. Among mothers of children HIV exposed uninfected with CD4 records during pregnancy (N=7,523), the proportion with CD4 <350 cells/µl decreased from 90.6% (2008) to 27.8% (2021).

Conclusions: In recent years, among children hospitalised with infectious diseases, fewer have HIV, while an increased proportion have maternal HIV and ART exposure but without HIV infection. We need to look beyond child HIV prevalence and consider child HIV and ART exposure among children without HIV, when assessing the HIV epidemic's impact on child health services.

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Improving Access to HIV Prevention and Care and Treatment for Adolescent and Youth Through Community-Based Service Delivery Models in Nampula, Mozambique

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Background: Adolescent and young people (AYP) in sub-Saharan Africa (SSA) are disproportionally affected by the HIV epidemic. Among 1.75 million adolescents living with HIV worldwide, 88% (1.5 million) are in SSA. In Mozambique, 98,000 individuals were newly infected with HIV in 2020 and 17% (17,000) were adolescents. ICAP worked with Nampula's Provincial Health Authorities (DPS/SPS), community-based organizations (CBO) and the private sector to design and implement a community service delivery model to reach AYP and engage them in health services in Nampula Province.

Methods: In June 2022, AYP-targeted mobile brigades (MB) were launched, in collaboration with provincial and facility leadership. The MB offered comprehensive HIV prevention, care and treatment (C&T) at the community level, integrated into general health services (e.g. maternal and child health services, outpatient consultation). Preferred locations were identified with AYP, focusing on AYP congregation areas, universities and technical schools. Recreational activities, such as music, sports and theatre competition, complemented clinical services to promote demand for services and to strengthen HIV and health literacy.

Results: Between June and November 2022, 31 MB were implemented, reaching 1,043 AYP (615 females and 428 males). Of these, 730 tested for HIV, with 28 (4%) testing positive and all initiating antiretroviral therapy. Of the 702 who tested negative for HIV, 259 (141 females and 118 males) were eligible for pre-exposure prophylaxis (PrEP) and 98% (138/141) of females and 95% of males (112/118) accepted and initiated PrEP.

Conclusions: Contextualized interventions to reach AYP are essential, as targeted demand creation and health literacy strategies using peers, coupled with decentralization of services to communities, resulted in high uptake of health services. A relatively high percentage of males were reached, and demand and acceptance of PrEP was high among adolescent females and males. These initial results reinforce that service delivery models should be reviewed to ensure they respond to AYP needs and interests.

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Effectiveness of Caregiver Mentor Directly Observed Treatment and Support Model on Viral Load Suppression in Uganda

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Background: Viral load non-suppression remains a challenge among children and adolescents. Those with detectable viral load receive intensive adherence counseling (IAC) but with non-compliance and a low re-suppression rate (23%). Caregivers sometimes fail to attend these sessions due to personal, psychological, financial, and child-related challenges. Directly observed therapy (DOT) has shown great improvement in treatment outcomes through improving literacy and supporting drug administration challenges using a peer-to-peer approach. We assessed the effectiveness of the caregiver DOTs model on viral load suppression in Uganda.

Methods: We conducted a mixed methods implementation effectiveness Type 2 study among caregivers at Kasaala HCIII, Kiganda HCIV, Kiboga, Mityana, and Mubende Hospital in Central Uganda from June to December 2022. We identified caregivers of unsuppressed children and adolescents (2-15years) and paired them with caregivers of those suppressed from the same area within a radius of 2 kilometers on a ratio of 1:5-7. We trained those with suppressed children and adolescents as mentors in providing treatment literacy, and directly observing daily treatment. They conducted DOTs for a period of 60-90 days and provided linkage to livelihood support. We analyzed the viral load results after the third IAC and those who were still unsuppressed were checked for Drug resistance.

Results: A total of 30 caregivers of 49 unsuppressed children were enrolled on the study. The average age of the children was 8.8(±3.8) Years 20 males and 29 females. Of which 77.1% were on 1st Line, 20.8% were on 2nd Line, and 77.6% were on DTG-based regimen. The mentors identified lack of information, negligence, low treatment literacy, and lack of a supportive environment at home as the major factors for non-suppression. After DOTs intervention, 28(57.1%) had non-detectable viral load, 18 (36.7%) suppressed with viral load < 200 copies, 1 lost to follow-up, and 2 had unsuppressed viral load and confirmed having Drug-resistant.
Conclusion Caregiver DOTs can effectively support caregivers of non-suppressing children and adolescents to improve treatment outcomes through improving literacy and supporting drug administration. Therefore, there is need to support caregiver mentors to provide peer-to-peer support at household level which reduces the burden on the overloaded health facilities.

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Prevalence of HIV among Pregnant Women Tested at Labour and Delivery at a High-Volume Facility in Kampala, Uganda

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Introduction: Undiagnosed HIV Infection among pregnant and breastfeeding women are key barriers to achieving elimination of mother-to-child transmission of HIV. To improve outcomes, we determined HIV positivity rate, average time to a re-test and predictors of a positive test at labor and delivery.

Methods: We conducted a cross-sectional review of electronic medical records of pregnant women tested for HIV at labor and delivery at Kawempe National Referral Hospital from August 2020 to June 2022. All women with an unknown HIV status (first time testers) and those who tested HIV negative more than 3 months prior to admission (re-testers) were offered an HIV test. We analyzed the HIV positivity rate in both groups and time to retest for women who were re-tested. Logistic regression was used to determine predictors of a positive test.

Results: A total of 28,748 women were tested for HIV at labor and delivery during the study period; 1,757 (6%) were first time testers of whom 4.5% (79/1,757) were HIV positive, while 26,991 (94%) were re-testers and 0.3% (84/26,991) were HIV positive. The mean age for all first-time testers was 25.5 years (standard deviation [SD]:5.9) while that for re-testers was 25.4 years (SD=5.6). Neither age >25 years (OR=2.2, CI: 0.6 – 7.6, p = 0.205) nor marriage/cohabitation (OR =0.3, CI: 0.1 – 1.2, p = 0.086) were associated with HIV positive status. Fifty-one percent (13,763/26,991) of re-testers had documented dates of the previous test and of these, 13% (1,753/13,763) had results that were >6 months old. The mean time to a retest for women who tested positive was 4.2 months (SD: 1.7).

Conclusion: First time and repeat testing at delivery identified new pregnant women living with HIV. HIV testing at labor and delivery is critical to identify women at high risk of mother-to-child HIV transmission. Interventions are required to establish the HIV status for all pregnant women, to provide timely repeat tests prenatally and to provide PREP for women at risk of HIV acquisition.

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Low Coverage of Antenatal and Peripartum HIV Screening Tests in a Tertiary Center in the Philippines

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Background: WHO initiated a campaign on triple elimination of neonatal HBV, syphilis and HIV to expand their capacity to address vertical transmission of these infection. The Philippines provides antenatal screening tests for HBV, syphilis and HIV free of charge at government-funded health facilities. However, HIV testing policy is performed thru provider-initiated counseling and testing, rather than opt-out policy as HBV and Syphilis tests. Data from the Department of Health revealed that only 173,737 pregnant women had HIV testing out of the 2.4 million births in year 2021. This study aims to describe coverage of HIV testing at antenatal and peripartum care (ANC) service during 2016-2002 in a tertiary care center.

Material and Methods: A retrospective aggregate data on coverage of HIV, HBV and syphilis tests among women who gave birth at Jose B. Lingad Memorial General Hospital in Pampanga, Philippines was reviewed. These tests were offered at the first ANC visit or at the time delivery or immediately postpartum if without ANC. Prevalence of infection was reported as percentage and 95% confidence interval. Early infant diagnosis was performed by HIV RNA PCR at 4-6 weeks and 4-6 months.

Results: From 2016 to 2022, there were 44,062 pregnant women who delivered baby in this hospital. The uptake rates of HIV, Syphilis, and HBV were 10.5%,100% and 100%, respectively.

Corresponding prevalence rate of HBV infection was 0.54%(95%CI 0.47-0.62) and for Syphilis 0.07%(95%CI 0.05-0.11). Among 4754 women who received HIV test, prevalence rate was 1.03%(95%CI 0.76-1.36). Mode of delivery were 30(61%) vaginal delivery and 19(39%) cesarean section. All except one infant received neonatal post exposure prophylaxis antiretroviral drugs. HIV early infant diagnosis was 36(74%) completed, 9(18%) only one HIV PCR test, 3(6%) not done due to lost to follow up, 1(2%) died at 7 months presumed HIV infection.

Conclusion: With rising HIV incidence among adults in the Philippines, there is an urgent need to increase uptake of HIV testing during antenatal care service using opt-out strategy as part of triple elimination initiative. Missed opportunities in preventing vertical transmission of HIV should be addressed with a collaborative integrated effort in maternal child health service.

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HIV Prevalence and Barriers to Testing among 0-14 year-old Children in Nigeria: A Population-Based Survey

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Introduction: Early initiation of antiretroviral therapy in infants and children living with HIV is life-saving and mitigates long-term adverse outcomes. Thus, it is important to continuously evaluate the prevalence of HIV and barriers to timely testing in this population.

Methods: This study utilized population-based cross-sectional data from the 2018 Nigeria National HIV/AIDS Indicator and Impact Survey, which was conducted across all 6 geopolitical regions. Weighted frequency and percentages were employed to describe HIV prevalence and barriers to testing among 0–14-year-olds. Bivariate and multivariable analysis was performed with statistical significance set at 5%.

Results: Overall HIV prevalence among children was 0.1%. Disaggregation showed that prevalence among children under 5, 5-10 and 10-14 years was 0.1%, 0.2% and 0.2% respectively. Pediatric HIV prevalence was highest in the South-South and North-Central regions (0.2% respectively). A total of 139,138 (96.4% of children surveyed) had never been HIV-tested for HIV prior to the survey.
The most reported barrier to HIV testing among never-tested children was “mother’s belief that they were at low risk/test was unnecessary” (43.6%). Other reasons included “distance to health facility” (5.5%), “high test costs” (4.9%), high transportation costs (3.9%), and religious objection (1.8%). Among previously never-tested children found to be HIV-positive, the most reported barrier to testing was “low risk/the feeling that the test was unnecessary” (39.1%), and “unsure of test location” (20.2%). We also found that 1.5% of surveyed women were HIV-positive, and 6.4% of HIV-positive mothers had HIV-positive children; the odds of having an HIV-positive child was higher among HIV-positive mothers as opposed to HIV-negative mothers ($\chi^2=843.28$; $p<0.001$).

Conclusion: HIV prevalence among Nigeria children is relatively low, however, this and the vertical transmission rate needs to approach zero to achieve the WHO target of an AIDS-free generation. Given that the vast majority (~97%) of children had never been tested, there are potential missed opportunities for early detection and treatment of HIV. Addressing the testing barriers and misconceptions through community health education, awareness campaigns and affordable/free/more accessible tests could increase uptake of HIV testing and overcome these barriers.

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Factors Associated with Early Interruption in Treatment among Pregnant and Breastfeeding Women on Antiretroviral Therapy in South Sudan

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Background: Antiretroviral therapy (ART) coverage and retention among pregnant and breastfeeding women (PBFW) are challenges in South Sudan, with an estimated 9,600 pregnant women in need of ART, and approximately 45% of those on ART with interruptions in treatment (IIT). PBFW in South Sudan receive HIV treatment in ART clinic separately from antenatal care (ANC) and postnatal care. Understanding factors associated with IIT among PBFW is necessary to improve care.

Methods: A retrospective analysis of records of PBFW on ART in twenty health facilities (5 urban, 7 peri-urban and 8 rural) was conducted. A random selection method was used to select facilities and PBFW on ART from October 2019 to February 2022. Demographic, obstetric and HIV information was abstracted from facility-based registers and patient files, including age, marital status, employment, facility or home delivery, gravidity, HIV status, and treatment status and gestational age at ANC enrollment. Logistic regression was used to measure associations of early IIT, defined as missing the first ART follow-up visit by greater than 28 days. Data analysis was conducted using STATA version 17.

Results: A total of 1,478 PBFW were identified and approximately one third (33.8%, 33.6% and 32.6%) resided in urban, peri-urban, and rural areas, respectively. More than half (59%) were aged 20-29 years and the majority were married (84%) and unemployed (80%). Among the PBFW, 9% were primigravida, 24% delivered at home, 31.8% enrolled prior to 16 weeks gestational age, 54% had known HIV positive status prior to ANC enrollment and 29.5% had early IIT. Residing in rural area (adjusted odds ratio (aOR)=1.5, 95% confidence interval (CI): 1.1–1.9) and attending only one ANC visit (aOR=1.6, 95% CI: 1.1–2.2) were associated with early IIT, after adjusting for age, delivery location, HIV status and treatment status at ANC enrollment.

Conclusions: Strengthening community-based care and expanding use of community outreach volunteers and mentor mothers may improve IIT by promoting access to HIV care in rural areas and ANC attendance to improve retention in HIV treatment. Further studies are warranted to understand optimal approaches to reduce IIT among PBFW.

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Evaluation of Adoption, Implementation, and Effectiveness Of of PMTCT Retention Activities in Uganda, 2015-2020.

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Introduction: Despite its progress towards the elimination of mother-to-child transmission of HIV, Uganda has not been able to meet 2020 UNAIDS targets to end pediatric AIDS. This is mainly attributed to the poor retention of mother-baby pairs. To curb this loss, the Ministry of Health (MoH) developed several interventions: appointment tracking systems (ATS), “bring back mother-baby pair” (BBMB) initiatives, birth cohort monitoring (BCM), and the use of color-coded stickers (CCS). We evaluated the degree of adoption, implementation, and effectiveness of these national PMTCT interventions.

Methods: The evaluation was cross-sectional across 123 proportionately sampled health facilities, using both qualitative and quantitative approaches. We defined adoption as the uptake of PMTCT interventions, implementation to fidelity as the degree to which MoH guidelines were followed, and effectiveness as the proportion of mother-baby pairs retained. Qualitative data were collected through focus group discussions and key informant interviews. Data on effectiveness were abstracted from the DHIS2 at 6, 12, and 24 months.

Results: The most adopted interventions were ATS (98%) and BCM (81%). 86% of the health facilities implemented the retention interventions to fidelity. Factors influencing the adoption and implementation of PMTCT interventions included: simplicity of implementation, adequate knowledge, availability of data collection tools, availability of resources to facilitate follow-up activities, the complexity of collating data from different sources, and perceived duplication with other interventions. From 2015 to 2020, retention increased from 69% to 81% at six months, 64% to 84% at 12 months, and 68% to 73% at 24 months.

Conclusion: Retention of pregnant and lactating women LHIV and their infants improved between 2015 and 2020. During this period, appointment tracking and birth cohort monitoring were the most adopted and implemented interventions. MoH should work with regional partners to promote the adoption of these two interventions as the basic package of retention interventions. These packages should be adapted to strengthen male partner involvement in the PMTCT cascade as well as intensify psychosocial support for mothers LHIV to optimize retention efforts.

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Impact of a Stakeholder Selected Implementation Strategy Package – Fast Tracking, Provider Re-Training, and Co-location – on PrEP Implementation for Pregnant Women in Antenatal Care Clinics in Western Kenya

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Background: Pregnancy and postpartum are high risk periods for HIV acquisition. Pre-exposure prophylaxis (PrEP) is recommended for this population by the World Health Organization and Kenyan Ministry of Health. In resource-limited settings, gaps exist in delivering PrEP integrated into maternal and child health clinics (MCH).

Methods: We conducted a difference-in-differences study (3 months pre- and 3 months post) between January-July 2022 in 8 facilities (4 intervention and 4 comparison) in western Kenya. During the 6-month period, we tested a combination of 3 stakeholder selected implementation strategies to improve PrEP delivery: retraining health providers, fast tracking PrEP clients, and dispensing PrEP in the MCH. We assessed absolute changes in PrEP penetration (proportion screened), PrEP fidelity (proportion receiving HIV testing, risk screening, and PrEP counseling), client and provider satisfaction, client PrEP knowledge, and waiting time & service time (a priori outcomes). We compared post hoc PrEP offer and HIV testing among women seeking MCH services. We assessed acceptability and appropriateness of the implementation strategies by providers.

Results: During the intervention period, there were widespread shortages of HIV testing kits during which PrEP delivery decreased in comparison sites but remained relatively stable in intervention sites. We observed either improvements or no change in indicators assessed. PrEP penetration increased 5 percent points (p=0.002); PrEP offer increased 5 percentage points (p=0.002); and client PrEP knowledge increased 0.44 out of 7 total points (p<0.001). We observed non-significant changes in PrEP fidelity (+4 percentage points; p=0.185), no changes in service time (+0.14 minutes; p=0.212) or waiting time (0.00 minutes; p=0.988), client satisfaction (+0.1/24 total points; p=0.559), HIV testing at first antenatal care visit (13 percentage point decrease, p=0.230), in intervention vs comparison facilities. The implementation strategy bundle was deemed appropriate and acceptable by providers (median: appropriateness: 18.5/20; acceptance 18.5/20).

Conclusions: The implementation strategy bundle – retraining healthcare workers, fast tracking PrEP clients, and PrEP dispensing in MCH – was associated with maintaining or improving integrated PrEP implementation and service delivery despite commodity shortages.

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Neonatal Outcomes of Children who are HIV Exposed and Uninfected Compared with HIV Unexposed in Western Kenya

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Background: Nearly 16 million children are born to mothers with HIV globally and emerging literature suggests that those who are HIV-exposed and uninfected (HEU) are at an increased risk for adverse neonatal outcomes compared to their HIV unexposed, uninfected (HUU) peers. This study is among the first to further investigate whether maternal HIV exposure is associated with newborn unit (NBU) admission in Kenya.

Methods: This is an interim analysis of a longitudinal cohort study of infants born to women living with HIV who are maternally age-matched to those born unexposed to HIV in western Kenya within the Academic Model for Providing Access to Healthcare (AMPATH) Partnership. Both maternal and infant characteristics were prospectively collected, and infants were followed for the first 28 days of life. Multivariable logistic regression was used to determine the associations between HIV exposure and NBU admission, adjusting for birth weight.

Results: A total of 511 infants and their mothers were included for analysis, including 253 infants who are HEU and 258 unexposed infants. Eleven infants died prior to 28 days of life (n=7 HIV-exposed, n=4 HIV-unexposed; p=0.521). Maternal anemia and other maternal chronic disease (non-HIV) were significantly higher in the HEU cohort (24.5% vs. 8.1%, p<0.001; 4.0% vs 8.5%, p=0.047). Infants who are HEU had a significantly higher rate of NBU admission compared to HUU peers (13.0% vs. 2.7%, p<0.001), as well as higher rates of low birth weight (<2500 g), preterm birth (<37 weeks gestation), supportive care in 24 hours, and respiratory distress (21.3% vs. 10.9%, p=0.002; 23.7% vs. 13.2%, p<0.001; 10.3% vs. 3.9%, p<0.001; 6.7% vs. 1.2%, p=0.003.) When adjusting for birth weight, odds of NBU admission remained higher for infants who are HEU (aOR=4.55, 95% CI 2.06-11.5, p<0.001).

Conclusion: Infants who are HEU had increased odds of NBU admission, even after adjusting for birth weight. They also had higher rates of preterm birth, NBU admission, low birth weight, supportive care in 24 hours, and respiratory distress compared to unexposed infants. Close follow-up and medical management of pregnant women living with HIV is critical for improving care for infants exposed to HIV in Kenya.

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Low Levels of Self-Efficacy and Indicators of Depression Predict Non-viral Suppression Using the AIDS Clinical Trials Group Adherence Questionnaire Among Women Living With HIV in Kampala, Uganda

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Background: Studies indicate that a substantial proportion 53-74% of women living with HIV face challenges with adherence to ART postpartum. Annual viral load test results are often a lagging indicator. Thus there is a need for reliable culturally-appropriate screening tools to identify women at heightened risk of poor adherence in order to provide timely intervention. We sought to determine the association of non-Viral Suppression with the constructs within the AIDS Clinical Trial Group (ACTG) adherence questionnaire in an urban Uganda setting.

Methods: The ACTG questionnaire was cross culturally adapted to Uganda. Consenting postpartum women were assigned to Audio Computerized self –Assisted (ACASI) and Provider Assisted Interviews (PAIs) in a nested study within the PROMOTE Cohort Study in Uganda. Questionnaire construct scores for self-efficacy, social support, anxiety and depression plus viral load, patient demographics and clinical predictors of ART adherence were modelled using a mixed effects logistic model, with repeated measures over a period of one year.

Results: Of 166 women, 21 had the questionnaire administered via ACASI while 145 via PAIs. 4.2% (7/166) were not virally suppressed at baseline and their level of non-suppression was consistent throughout one year of follow up. High self-efficacy scores were associated with 27% lower odds of viral non-suppression (Odds Ratio [OR] 0.73;95% CI:0.54 - 0.98). High depression scores were associated with 22% higher odds of non-suppression (OR 1.22;95% CI:1.01- 1.49) by 22%. Other variables like Age, Body Mass Index, Duration on ART, Marital status, Employment, Education level, Electricity in premises, Tap water and Travel time to clinic from home were not associated with viral suppression in the covariate-adjusted analyses. Median Self efficacy and depression scores were 8 (IQR 1-9) and 1.2 (IQR 0-16) respectively. Focussed group discussion data showed high acceptability and feasibility of using the ACTG questionnaire in Ugandan settings.

Conclusion: Lower Self efficacy and higher depression scores on the ACTG adherence questionnaire could be used to identify Ugandan women at risk of viral non-suppression in HIV program settings.

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Growth and Neurodevelopmental Outcomes of 18-Month-Old Children With Exposure to Maternal HIV and Placental Insufficiency in a Peri-Urban Area of South Africa

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Background: Children who are HIV-exposed-and-uninfected (CHEU) and those who are growth restricted in utero due to placental insufficiency are both regarded as high risk populations, which can impact growth and neurodevelopment as well as short- and long-term complications in terms of morbidity and mortality. However, the growth and neurodevelopmental outcomes of CHEU who have also experienced growth restriction in utero have not been researched. We therefore compared the growth and neurodevelopment outcomes of children aged 18 months with in utero HIV exposure and abnormal umbilical artery resistance indices (UmA-RI), indicating placental insufficiency.

Methods: The cross-sectional study investigated 264 mother-child pairs, who were grouped into four subgroups based on HIV exposure and history of normal/abnormal UmA-RI, using available pregnancy and birth information. The World Health Organization standard procedures were used for anthropometric measurements and z-score calculations, and Bayley III to test child development.

Results: CHEU with abnormal UmA-RI (n=14) had lower length-for-age z-scores (-1.40 ± 1.40 vs -0.04 ± 1.31; p=0.001), weight-for-age z-scores (-0.60 ± 0.96 vs 0.04 ± 1.16; p=0.02) and head-circumference-for-age z-scores (0.42 ± 0.66 vs 0.90 ± 1.15; p=0.04) compared to children who are HIV-unexposed-and-uninfected (CHUU) with normal UmA-RI (n=181). Nearly a quarter (21.4%) of CHEU

with abnormal UmA-RIs had a mild delay in cognitive development, 7.1% had a moderate delay in language and 7.1% had a moderate delay in motor development compared to CHUU with normal UmA-RI: 2.2%, 2.8% and 0.0%, respectively.

Conclusion: Exposure to both maternal HIV infection and placental insufficiency is associated with stunting, underweight and cognitive developmental delay.

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Exploring the Roles of the Pharmaceutical Industry in Supporting Research on Novel Biomarkers for the Early Identification of Adverse Health Outcomes Among HIV-Exposed Uninfected Children in Africa: A Systematic Review

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Background: Globally, there are over 15 million HIV-exposed uninfected (HEU) children, with 90% (13.5 million) residing in Africa. HEU children in Africa face increased morbidity and mortality risks, hence, require improved clinical management to improve adverse health outcomes (AHO). The early identification of AHO via biomarkers could aid in developing targeted interventions and improving their clinical management. This systematic review explored the roles of the pharmaceutical industry in supporting research on novel biomarkers for HEU children in Africa.

Method: A comprehensive systematic review was conducted to identify relevant studies on biomarkers for HEU children in Africa. Electronic databases including Google Scholar, PubMed, and Embase were searched, with a restriction to studies published in English from January 2013 to January 2023. Data on study design, sample size, type of biomarkers investigated, and outcomes were extracted, and a qualitative analysis was performed to synthesize findings on the opportunities for the pharmaceutical industry to develop and implement biomarker research for HEU children in Africa. The results were interpreted and presented using a narrative approach.

Result: Of 354 papers identified, 25 met our inclusion criteria. The studies identified were cross-sectional (n=21), longitudinal (n=4), and focused specifically on HEU in Africa. The studies investigated various biomarkers, such as immune markers (n=18), cytokines (n=10), viral load (n=6), and metabolites (n=3), to assess AHO such as growth, morbidity, mortality, and neurodevelopment. Findings indicate limited research on biomarkers for early identification of AHO in HEU children in Africa. However, interleukin-7 and chemokine CXCL10 were identified as promising biomarkers to identify and improve AHO for HEU children in Africa, although grossly under-investigated and under-researched.

Conclusion: Despite the increased morbidity and mortality risks faced by HEU children in Africa, there is still limited research on promising biomarkers for early identification of their AHO. There is a need for more rigorous research in biomarkers, and the pharmaceutical industry can play a critical role in supporting this effort. Practical steps that the industry can take include forming partnerships with academic institutions, providing significant funding for research institutes in Africa towards biomarker research, and facilitating the translation of research findings into clinical practice.

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Similar Early Hearing Outcomes in Infants With and Without HIV Exposure

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Introduction: Data are limited and mixed for risk of congenital and early-onset hearing loss in infants with HIV exposure (HEU). Among Kenyan infants aged 6 weeks, we examined the association between HIV exposure and hearing outcomes.
Methods: Mother-infant pairs were recruited at infant age 6 weeks as part of a multi-site study of neurodevelopmental outcomes and HIV exposure

in Nairobi and in Kisumu, Kenya. Infants received hearing screening using otoacoustic emissions (OAE) devices. Infants meeting criteria for referral were offered services for diagnostic evaluation. Logistic regression was used to compare both hearing outcomes and return for diagnostic evaluation among referred infants between HIV exposure groups.

Results: Among 959 infants screened, 30 did not pass in one ear (3.1%), 32 (3.3%) did not pass in both ears, 7 (0.7%) did not pass in one ear and had an incomplete screen for the other ear. Among 69 infants with a refer result for at least one ear, only 24 (34.8%) accessed diagnostic evaluation, of whom 6 (8.7%) had hearing loss in one ear, and 1 (1.4%) had hearing loss in both ears, and 17 (24.6%) had normal hearing in both ears. Five (7.2%) infants declined diagnostic evaluation or were unreachable, and 40 (58.0%) had a missed visit. Two infants (5.6%) with HIV exposure had hearing loss (one unilateral and one bilateral) and 5 (15.2%) HIV unexposed uninfected (HUU) infants had hearing loss (all unilateral); odds ratio (OR), 0.35 (95% confidence intervals 0.04, 1.83); P=0.2. The rate of hearing loss was 6.3 per 1000 overall and 10.2 per 1000 for HUU and 4.1 per 1000 for HEU. Uptake of diagnostic testing was similar and poor in both groups with 23 of HEU (63.9%) and 17 (51.5%) of HUU missing diagnostic evaluation (OR, 1.65 (95% CI, 0.63, 4.43); P = 0.3).

Conclusion: Rates of hearing loss were high in Kenyan infants. Age 6 week hearing outcomes were similar for HEU and HUU; however, it remains important to monitor infants with HIV exposure for hearing outcomes in infancy and early childhood. Studies to identify and address barriers to uptake of diagnostic evaluation are urgently needed.

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Lessons from Parents Living with HIV on How to Promote Advocacy for Their Children Who Are HIV-Exposed Uninfected to Achieve Their Fullest Potential

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Background: Nearly 16 million children globally have been perinatally exposed to HIV but do not acquire HIV perinatally. This population is at higher risk of worse health outcomes, including neurodevelopmental delays, compared to children born HIV-unexposed uninfected (HUU).

Description: Three listening sessions were conducted with parents living with HIV (PLHIV), one with parents from the Pediatric HIV/AIDS Cohort Study network parents in the United States (n=4) and two with groups of mothers2mothers Mentor Mothers in Kenya (n=10) and South Africa (n=10) These sessions explored parents' understanding of typical child development and assessed their preferences of how and when to communicate research findings about health disparities among children who are HIV-exposed uninfected (HEU). Based on a semi-structured interview guide featuring vignette narratives, parents described their level of comfort and knowledge around assessing child development, challenges encountered in engaging healthcare providers to evaluate their child when developmental concerns existed, and perspectives on how to share research differences noted between HEU and HUU children when clinical significance is not yet established. Cutting edge research demonstrating differences in

brain volume and structure between young children HEU and those who are HUU using brain imaging was also presented to elucidate parental perspectives on research dissemination.

Lessons Learned: Parents reported observing impaired speech/language; delayed walking; poor memory; poor learning ability/school performance and behavioural issues as markers of developmental delay. Not all parents felt that health providers adequately listened to or took action when they expressed development concerns about their child. There were mixed preferences about when and how to share research data for which the clinical significance of findings was not yet understood. Parents also shared preferred language for describing findings about cognition in sensitive and non-stigmatizing ways.

Conclusion/Next steps: Understanding parental perspectives provides a meaningful foundation to guide approaches for disseminating research findings to families without creating unnecessary anxiety or stigma. This foundation also represents a critical step guiding development of materials to equip and empower caregivers with knowledge needed to seek evaluation and interventions for their children affected by HIV, in particular where they may need extra support.

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Differences in Weight Trajectory in Breastfed Hiv-Exposed Uninfected and HIV-Unexposed Infants in Kenya

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Background: There are limited data comparing growth trajectories of breastfed HIV-exposed uninfected (HEU) infants exposed to maternal dolutegravir (DTG)-based ART and HIV-unexposed uninfected (HUU) infants.

Methods: Prospective cohort of 350 pregnant women enrolled in two antenatal clinics in Migori, Kenya and followed with their infants to age 12-months. Anthropometry was measured within 7 days of birth, at 3 and 6 weeks, and months 3, 6, 9 and 12. Length-for-age (LAZ), weight-for-age (WAZ), weight-for-length (WLZ) Z-scores, and stunting (LAZ<-2), underweight (WAZ<-2), and wasting (WLZ<-2) were compared between HEU and HUU using linear mixed effects and logistic regression models.

Results: Of 336 (96%) mother-infant pairs with infant follow up data, 330 (HEU=168; HUU=162) were included in the analysis with a mean of 7 follow up visits. Mothers of HEU were older, multiparous, more anemic in pregnancy, and had lower education and more food insecurity than mothers of HUU. All mothers of HEU were on ART during pregnancy with 90% on dolutegravir/lamivudine/tenofovir, 77% initiating ART pre-pregnancy, and 98% virally suppressed. Birth characteristics were similar in both groups (preterm:10% HEU, 9% HUU; low birth weight:5% HEU, 6% HUU). Most HEU (70%) and HUU (81%) infants were breastfeeding at 12 months. In multivariable analysis adjusting for maternal age, body mass index, breastfeeding duration, education, depression, anemia, wealth index, food insecurity, and parity, HEU had a more negative WLZ trajectory than HUU (adjusted $p<0.001$), and higher odds of underweight at 12 months (12% HEU vs 4% HUU, adjusted Odds Ratio [aOR] 4.62, 95% CI 1.42-18.8). There was no difference in LAZ and WAZ trajectories between two groups. At 12 months, stunting (13% vs 13%), wasting (4% vs 1%), and overweight (3% vs 5%) were similar in HEU and HUU, respectively. Among HEU, maternal ART initiation before vs during pregnancy, and longer maternal ART duration (>2 vs ≤2 years) were associated with faster WAZ increase (both adjusted $p<0.01$).

Conclusion: Despite optimal maternal ART and breastfeeding, HEU had poorer weight gain growth than HUU. Pre-pregnancy ART was associated with greater WAZ gain in HEU infants, underscoring the importance of management of maternal HIV infection on growth.

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Evaluation of the Prevention of Mother-To-Child Transmission of HIV Programs at the Second Immunization Visit in Burkina Faso and Zambia, Two Countries With Different HIV Epidemics

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Introduction: Monitoring indicators for prevention of mother-to-child transmission of HIV programs (PMTCT) is key to assessing the progress toward elimination of mother-to-child transmission of HIV (MTCT). Using a patient-orientated innovative strategy based on the second visit in the expanded program on immunization (EPI-2) visit at 6-8 weeks, we assessed PMTCT indicators in Burkina Faso and Zambia.

Methods: From December 2019 to September 2021, the PROMISE-EPI study (Clinical Trial : NCT03870438) assessed women attending EPI-2 at primary health care facilities in Burkina Faso and Zambia with their children about their exposure to PMTCT interventions in. Women living with HIV (WLHIV) viral load was measured using GeneXpert® HIV RNA, and their children were tested for HIV using GeneXpert® HIV Qual.

Results: Overall, 25093 and 8961 women attending EPI-2 visit were enrolled from Burkina Faso and Zambia, respectively. Almost, all women attended at least one antenatal care (ANC) visit, the median number of visits was 4 (IQR: 3-5) in both countries. Among women (n=22939 in Burkina Faso and n=7426 in Zambia) who tested for HIV during pregnancy, only 42.5% and 52.5% have been tested in the last three months in Burkina Faso and Zambia, respectively. Among Women diagnosed with HIV at EPI-2, 4.5% and 1.7% were not aware of their HIV status, in Burkina Faso and Zambia, respectively. Among those aware of their HIV positive status, 95.8% and 99.2% were on ART in Burkina Faso and Zambia respectively. Among WLHIV on ART, 75% and 79.2% achieved a viral load suppression (Viral load < 1000 copies/mL) in Burkina Faso and Zambia respectively. Infant post-natal prophylaxis (PNP) was administered from birth until EPI-2 to 60.9% and 89.7% of HIV exposed children in Burkina Faso and Zambia, respectively. In Burkina Faso, only 60/192 (31.3%) of HIV exposed children were sampled for early infant diagnosis (EID) after delivery and 3 (1.6%) received a result by EPI-2. In Zambia, these figures were 879/1465 (64.0%) and 9.9% (145/1465) respectively.

Conclusion: This evaluation strategy could strengthen program monitoring and help identifying programmatic gaps to be addressed on the last mile towards elimination of mother to child transmission of HIV.

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On the Path to Elimination of Vertical Transmission of HIV: Maternal Retesting Uptake Across 15 Districts in South Africa

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Background: Longstanding programming in South Africa resulted in the reduction of vertical transmission from 15.3% (2010) to 2.9% (2022) according to UNAIDS.(1) Despite this success, an estimated 10,000 new infections occurred in children in 2021, 27% of these attributable to incident maternal infections after a negative HIV test in ANC1.(2) Preventing, identifying, and treating maternal HIV infections is vital to eliminate vertical transmission. National guidelines include retesting of pregnant persons at each ANC visit, labor and delivery, and every three months while breastfeeding.(3) Our abstract describes maternal retesting uptake in 15 USAID-supported districts in South Africa.

Material and Methods: Data reported for ANC1 and post-ANC1 testing from health facilities in 15 USAID-supported districts through PEPFAR's Monitoring, Evaluation, and Reporting system was reviewed from fiscal year (FY) 2019 to 2022 (October 2018 - September 2022).

Results: Despite declines in ANC1 testing volume and positivity from FY19 to FY22 (Number tested: 365,257 to 311,946; positivity: 10% to 6%), ANC1 testing coverage remained at or above 98% and the proportion of pregnant persons living with HIV presenting to ANC1 already on treatment increased from 62% to 73%. From FY19 to FY22, post-ANC1 testing increased by 56% from 418,759 to 651,823; positivity decreased from 0.9% to 0.3%; and positive tests decreased from 3,741 to 1,793. The ANC1 to post-ANC1 testing ratio was 1:1.1 in FY19 and 1:2.1 in FY22, indicating rapid scale-up of post-ANC1 testing services. Infections among infants decreased from 1,493 to 1,176 from FY19 to FY22. Infant proxy positivity at two months remained 0.6%, while at 12 months there was a slight increase from 0.8% to 0.9% from FY19 to FY22.

Conclusions: Tremendous progress has been made in scaling maternal retesting in South Africa. These results point to the need to sustain maternal retesting to identify incident infections and scale up pre-exposure prophylaxis among highest risk mothers to curb new child infections towards elimination of vertical transmission of HIV.

1) UNAIDS, 2010 - 2022
2) UNAIDS stacked bar, 2022 estimates for 2021
3) National Department of Health. National HIV Testing Services: Policy. Republic of South Africa: Department of Health; 2016.

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Programmatic Data Audit of New HIV Infections Diagnosed Among HIV Exposed Infants in Mwanza, Tanzania

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Background: In Tanzania, mother to child transmission (MTCT) of HIV is 11% despite significant progress in maternal ART coverage and the prevention of MTCT (PMTCT). With funding from U.S. Center for Disease Control and Prevention, ICAP supported the Government of Tanzania with PMTCT interventions in Mwanza region. Between October 2021 and September 2022, 57 HIV-exposed infants were confirmed to have acquired HIV infection through MTCT. This abstract describes a programmatic audit done for 57 infants to understand the potential MTCT root causes.

Methods: Following the HIV positive diagnosis of the 57 infants, we performed a programmatic audit using routinely collected information from these infants' mothers. Healthcare workers retrieved and reviewed relevant information extracted from care and treatment client files, and registers from antenatal care (ANC), labor and delivery, and postnatal care.

Results: Among 57 HIV positive identified infants, 29 (51%) were diagnosed below 2 months of age, and 28(49%) at 2 months and beyond. Infants born to women diagnosed for the first time during labor and delivery were 14(25%). Ten (18%) of the HIV diagnosed infants were delivered at home, 7(12%) were born to HIV positive mothers who had refused ART up until delivery, and 7(12%) infants were on exclusive breastfeeding for less than 6 months. Five (9%) infants were born to mothers with poor ART adherence, while 4 (7%) had mothers who experienced treatment interruption. In addition, although to a lesser extent, some infants were born to women who had late ANC booking (n=2), HVL >50c/ml (n=3), late diagnosis >32 weeks (n=2), and diagnosis during the postnatal period (n=3).

Conclusions: Mothers' varying clinical and behavioral characteristics contributed to vertical HIV transmission to their infants. Getting tested for the first time at the point of delivery and home delivery were the most common attributes identified in the audit. The findings informed the prioritization of strategies to address frequently occurring root causes linked to MTCT in Mwanza, Tanzania. Our audit-based approach can be adapted to understand better, predict, and prevent the occurrence of MTCT elsewhere in Tanzania and other similar settings.

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Closing Pediatric HIV Case-Finding Gaps Through Safe and Ethical Index Testing Services in South Africa

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Background: South Africa has made tremendous progress in addressing its HIV epidemic. However, results for children (< 15 years of age) significantly lag achievements among adults, and recent modeling estimated that in 2018, 44% of children living with HIV (CLHIV) were undiagnosed at 2 years of age (JIAS). The USAID/South Africa program is committed to supporting the national HIV program and supports approximately one-third of CLHIV on antiretroviral therapy (ART). The program's pediatric HIV testing services (HTS) are focused on closing 1st 95 gaps across all age groups and geographies. Additionally, the program is committed to supporting timely, family-friendly, child-centered linkages to appropriate prevention and treatment services.

Description: USAID/South Africa district support partners (DSPs) collaborated with the Department of Health to support facility- and community-based pediatric HTS. From 1 October 2021 - 30 September 2022 (fiscal year [FY] 22), DSPs increased efforts to ensure safe and ethical index testing services were universally offered to biological children of adults living with HIV. HTS demand creation and treatment literacy were decentralized through close collaboration between clinical and OVC implementing partners. Quality assurance was supported through routine meetings with clinical and community cadres, monitoring and evaluation meetings with DSPs, and site visits.

Lessons learned: Analyzing FY22 program data, DSPs provided pediatric HTS across nine testing modalities, spanning facility and community service delivery points. Most CLHIV were identified through provider-initiated testing and counseling (PITC) and index testing (55% and 28%,respectively). Over the course of FY22, through increased efforts to improve pediatric contact elicitation, the proxy ratio of pediatric contacts tested:women index cases improved from approximately 1:3 (10,188:26,809) in the first quarter to approximately 1:1 (19,950:25,369:) in the fourth quarter, and the contribution of index testing also increased from the first to fourth quarters (22% to 30%) in FY22. Index testing positivity among pediatric contacts was consistently 1-2%.

Conclusion/next steps: South Africa continues to address the glaring case-finding gaps for children through scaling and decentralizing pediatric HTS. Re-aligned efforts to accelerate scale up of index testing has the potential to close case finding gaps in an equitable manner.

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Improving the Diagnosis of HIV in Hospitalized Infants: Lessons Learned From The EMPIRICAL trial

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Background: WHO recommendations for infant HIV diagnosis in high-burden settings include routine provider-initiated testing and counseling (PITC) for breastfeeding mothers, and early infant diagnosis (EID) virologic testing for newly-identified HIV-exposed infants (HEI) or those with findings suggestive of HIV. On inpatient wards, HIV diagnosis is urgent given advanced disease presentation, yet many African hospitals have implementation shortfalls due to limited resources for PITC, delays in receiving EID results, and underuse of presumptive diagnosis. The EMPIRICAL trial (#NCT03915366), which is enrolling infants with severe pneumonia and confirmed HIV, has worked to strengthen diagnostic practices at 22 recruiting hospitals across six African countries, with implementation experience that addresses these PITC/EID challenges.

Methods: HIV testing results for infants hospitalized with pneumonia and their mothers were extracted from screening logs and the trial database. Operational information detailing PITC/EID practices was collected via questionnaire.

Results: Interim data after implementation of a revised, more detailed screening log (Nov.2021-Dec.2022) reveal that 2,673 mothers had rapid antibody tests performed, of whom 193 (7.2%) were newly HIV-positive, and 95 (49.2%) of their infants subsequently tested HIV-positive. From recruitment onset in March 2020 through December 2022, 390 HIV-positive infants were recruited, of whom 276 (70.8%) were newly diagnosed with point-of-care EID (PoC-EID) during hospitalization. In questionnaire feedback from 19 hospitals, 18 (94.7%) reported needing counselors, often employed by partners, for timely testing of all admissions. Six sites in Mozambique (31.6%) routinely repeat PITC for breastfeeding women who tested negative in the preceding three months, diagnosing three new cases with this approach in 2022. All sites stressed the importance of PoC-EID, as turn-around-times for conventional DNA-PCRs frequently exceed 4 weeks.

Conclusions: In settings with medium-high HIV prevalence and high rates of seroconversion during breastfeeding, PITC for mothers of hospitalized infants is crucial, and dedicated counselors help improve testing coverage. Repeat PITC should be considered regardless of the time since last maternal test in the context of severe infant illness. PoC-EID expansion plans should prioritize access for pediatric wards either with on-site machines or sample referral networks to facilitate rapid diagnoses, timely opportunistic infection treatment, and prompt linkage to antiretroviral therapy.

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HIV Rapid Testing as a Screening Test for HIV-Exposed Children on the OPPTIM Study in South Africa

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Background: HIV rapid testing (HRT) in children <18 months may reduce the number of polymerase chain reaction (PCR) tests required, if limited to children screening HRT positive. Persistence of maternal HIV antibodies in children beyond 18-months limits use of HRT for diagnosis. We describe sero-reversion at various time points in HIV-exposed, uninfected children.

Methods: Mother-child pairs were enrolled in the OPPTIM study at the child's 6, 10, or 14-week clinic visit between July 2018 and April 2019. At enrolment, 6-, 9-, 12-, 18-, 21- and 24 months, children were tested using three HRTs (Trinity Biotech Uni-GoldTM, INSTI® and Abbott DetermineTM) and had a POC EID (Cepheid GeneXpert) test conducted using whole blood, by trained study staff. Abbott ArchitectTM HIV ELISA assays were performed at 18-, 21-, and 24-months. HRT seropositivity is presented at each visit per test. Interrater agreement between tests was calculated using the Kappa (κ) statistic.

Results: In the study, 404 children were enrolled, 143 (35.4%), 201 (49.8%) and 60 (14.9%) at 6, 10 and 14 weeks, respectively. 216 (53.5%) male, 234 (57.9%) exclusively breastfeeding, 149 (36.9%) exclusively formula feeding, and the remainder mixed feeding. The Determine test remained positive in 50% of children at 12-months. For the INSTI and Uni-Gold tests, only 23% and 28% (respectively) remained positive at 6-months and <7% by 9-months (Figure). None of the children tested PCR positive at any time point. Agreement between the INSTI and Uni-Gold HRTs was 93.7% (κ=0.84, p<0.001), across all time periods. At 18-months, 3/24 children who tested positive on any HRT, were HIV ELISA positive; 18/21 HIV ELISA positives were HRT negative (κ=0.04, p<0.247). At 21- and 24-months, all HIV ELISA assays were negative among 8 HRT-positive children while 19 were HIV ELISA positive but HRT negative (κ=-0.04, p<0.681 and κ=-0.03, p<0.683, respectively). Attrition was high, only 59% in study at 18-months, 34% at 21-months, and 56% at 24-months.

Conclusions: Delayed seroreversion for HRT beyond 18 months is minimal using HRT, but HRT and HIV ELISA may result in false positive diagnoses and an HIV PCR should be conducted to confirm the diagnosis and avoid unnecessary treatment.

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Undiagnosed HIV Infection in Children: Identification Using an Entry Point in Adult HIV Care Facilities in Burkina Faso, a Low HIV Prevalence Setting in Western Africa

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Objective: To estimate the feasibility and yield of an HIV testing strategy in children by offering child testing to HIV-infected women of childbearing age in outpatient clinics (OPC) in Burkina Faso.

Methods: From September 2021 to June 2022, mothers living with HIV followed at nine OPC in Burkina Faso were offered facility-based rapid serological testing of their children aged 18 months to 5 years. Intervention uptake and yield were calculated, and implantation challenges from the health workers' perspectives were reported.

Results: Of the 799 eligible children, 663 were effectively tested, representing an uptake of 83%. Sixteen new paediatric HIV infections were identified for a yield of 2.5% (95% confidence interval, 1.5–4.1%). Compared to non-infected children, children living with HIV (CWHIV) tended to be weaned after 12 months (93.3% versus 54.4%, p=0.003) and not be tested before or at 12 months (93.7% versus 57.7%, p=0.003), while their mothers had not been informed about the 18-month testing

(62.5% versus 14.5%, p<0.001) and more recently became aware of their HIV status (median, 1.5 [interquartile range, 1–6.5] versus 7 years [interquartile range, 3–11], p=0.005). Implementation obstacles against the index-testing strategy included HIV rapid test shortage, increased health care workers' workload, and difficulty accessing children not living with their mothers.

Conclusion: Testing HIV-exposed children through their mothers followed in OPC is feasible and effective in a low-prevalence HIV setting such as Burkina Faso. The implementation of this strategy to detect undiagnosed CWHIV and the need for antiretroviral therapy is recommended.

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Acceptability of Point-Of-Care Viral Load Testing and Early Infant Diagnosis in Papua New Guinea

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Background: Point-of-care (POC) testing technology has the capacity to radically change the landscape of HIV in Papua New Guinea (PNG), through access to same-day results of HIV viral load (VL) testing and early infant diagnosis (EID), the latter being critical to timely initiation of life-saving ART for infants. Prior to ACTUP-PNG, PNG had a centralised model of HIV VL and EID testing in the national capital, followed by a decentralised VL program limited to provincial laboratories. With this model, <5% HIV VL coverage was achieved. With ACTUP-PNG, clinic-based POC testing was provided (increasing VL coverage to between 80 and 90% for different clinics) with 90-96% of VL/EID results returned on the same day. This paper assesses the acceptability of ACTUP-PNG's POC VL testing programme.

Material and Methods: This paper derives from qualitative interviews with key informants including PLHIV, guardians of HIV-exposed infants and children, health workers including clinicians, nurses and POC laboratory staff, HIV positive peer counsellors, and administrative staff. Data collection occurred between November 2022 and April 2023, with 70 individuals. Interviews were conducted in English and/or Tok Pisin and digitally recorded, transcribed and translated into English for analysis using the Theoretical Framework for Acceptability (TFA).

Results: Findings indicate strong support for clinic-based viral load testing. Overall, participants felt that same-day VL results allowed them to better monitor treatment progress and reduced the time and monetary costs of additional clinic visits (perceived effectiveness), despite the additional effort required by service providers to learn about and implement the programme (burden, self-efficacy). Service-users and caregivers felt strongly motivated to adhere to treatment, and healthcare workers and patient experts (peer counsellors) reported stronger job satisfaction and feeling more confident about how they should proceed with client treatment plans (ethicality and affective attitude).

Conclusions: Our findings strongly suggest that point-of-care interventions in resource-limited settings can significantly advance progress against UNAIDS 95-95-95 targets through informing the management of routine clinical care and supporting the knowledge and motivation of end-users regarding viral suppression and treatment uptake/adherence, thereby reducing treatment attrition (including lost to follow-up), drug resistance, and HIV transmission.

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Addressing HIV Testing and Case Identification Inequalities Among Children of Women Working in the Sex Industry Through a Peer-Led Door to Door Approach - A Case of Aids Information Centre (AIC)

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Background: As countries strive to eliminate vertical transmission of HIV, women in the sex industry (FSW) still face barriers to accessing HIV services. Data on FSW uptake of HIV and reproductive health services before, during and after pregnancy reveal inadequate service utilization. The stigma and discrimination they face prevents them from seeking healthcare services for themselves and their children exacerbating the risk of vertical transmission. The nature of their work, which often involves multiple sexual partners, inconsistent condom use, and high rates of sexually transmitted infections, increases the risk of vertical transmission yet, there is low demand for testing among their children. It is on this note that AIC embarked on a peer-led door to door approach to conduct HIV testing to biological children of FSW for early diagnosis and provision of prevention, care and treatment interventions.

Methods: In January-2022, AIC recruited three peer mothers of FSW and trained them with basics of HIV/AIDS. They continuously identified, mobilized and sensitized FSW mothers with their children in the different hotspots within the targeted areas of Kampala. They created line lists of identified FSW mothers and their children and provided it to the community counselors who contacted the FSW to arrange for a convenient time for their children to get tested in their respective homes. After consent, a team of two AIC health workers including a counselor and a laboratory technician, led by the FSW peers, visited the respective homes of the FSW mothers to conduct HIV testing on their children.

Results: Between January-December 2022, 45 FSW were identified. 21 had children and these elicited 85 children. Out of the 85 children, 72 were tested. 3 turned HIV positive and were linked to care. Further tests were conducted on the mothers of the children who also turned HIV positive however, they had registered a negative HIV test after birth of the children.

Conclusion: FSW need continuous provision of HIV services, including testing, treatment, and care, even after the birth of their children. community-based approaches, such as peer-led interventions proved effective in reaching this population thus providing early treatment interventions.

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Introduction of Near Point of Care Testing Platform for Early Infant HIV Diagnosis in Nigeria

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Background: In Nigeria, only 27% of HIV-exposed infants (HEI) received early infant diagnosis (EID) by 2 months of age in 2021. The median turnaround time (TAT) of laboratory results ranged from 28-60 days. Multi-disease testing using a polyvalent near point-of-care (POC) testing platform provides new opportunities for reducing the TAT for EID. This analysis describes the use of GeneXpert platform to improve the efficiency of EID in Akwa Ibom and Taraba States, Nigeria.

Materials & Methods: The USAID-funded Reaching Impact Saturation and Epidemic Control (RISE) project used GeneXpert machines (previously only used for TB diagnosis) for EID. In collaboration with relevant stakeholders, we selected 8 GeneXpert sites across Akwa Ibom (2), and Taraba (6) States, and networked 83 other facilities using the hub and spoke approach. RISE trained and mentored laboratory personnel to test dried blood spot (DBS) specimens using GeneXpert at sites, and monitored TAT and return of results weekly. We analyzed data from 83 spokes health facilities and 8 GeneXpert hub sites before (July to September 2022) and after (October to December 2022) the intervention.

Results: Before the intervention 165 DBS samples [(51%(84/165) (<2 months), 49%(81/165) (2-12 months)] were received at 2 molecular laboratories with 64% results returned, and a median TAT of 40 days. Post-intervention, 506 DBS samples [(60%(305/506) (<2 months), 40%(201/506) (2-12 months)] were received at 8 GeneXpert sites with 88%(446/506) results returned; median TAT of 2 days. There was a 24% increase in the proportion of results returned and a 95.2% reduction in TAT. EID uptake increased by 21.9% at <2 months (67.9%(57/84) before and 89.8%(274/305) post-intervention). All results were returned to the caregivers (100%); the positivity was 5.3% (3/57) for <2 months and 2.1% (1/48) for 2-12 months before the intervention and 2.9% (8/274) for <2 months and 5.8% (10/172) for 2-12 months after the intervention. The linkage to treatment was 100% before (n=4) and after the intervention (n=18).

Conclusion: The implementation of near POC EID using the GeneXpert increased access to EID, improved early case identification, and reduced TAT.

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Adherence to the Early Infant Diagnosis Algorithm and Associated Factors Among HIV-Exposed Infants in Uganda, 2017-2019

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Background: Early infant diagnosis (EID) among HIV-exposed infants is crucial to HIV diagnosis and initiation to care and treatment. Uganda has however faced challenges in its implementation majorly due to the loss of mother-infant pairs. In 2017, the ministry of health developed several interventions to curb this loss. We assessed the adherence to the EID algorithm and associated factors for HIV-exposed infants following the introduction of these interventions.

Methods: We used data from the 'Impact of the National Program for Prevention of Mother-to-Child Transmission of HIV in Uganda' study. We determined the mean number of HIV tests done per child. We also determined the proportion of children that had appropriate tests at the recommended time points (within 6 weeks after birth, at 9 months, 6 weeks after cessation of breastfeeding, and at 18 months). We used generalized linear models to assess the association between infant and maternal predictors and adherence to the EID algorithm.

Results: Of the 1,804 HIV-exposed infants, 912 (51%) were male and 530 (29%) were 6 weeks old or less. A mean of 4 SD (±1.4) tests was done per infant. At baseline, 1605 were HIV negative, 37 were positive and 162 had indeterminate results. Of those negative at baseline, 1212 were negative, 1 was positive and 392 were not tested at 9 months. Of those negative at 9 months, 946 were negative, 2 were positive and 264 were not tested at 15 months. At 18 months, 854 were negative and 92 were not tested. Overall 803 (45%) of infants adhered to the EID algorithm. The factors independently associated were: feeling discriminated against after HIV status was known [RR=0.80, 95%CI (0.66-0.97)], number of pregnancies [RR=1.07, 95%CI (1.03-1.10)], and reporting sexual violence [RR=1.38, 95%CI (1.21-1.58)].

Conclusion: Adherence to the EID algorithm remains low. Findings indicate that discrimination is an important barrier while reporting sexual violence improves adherence to the EID algorithm. Interventions to promote reporting of sexual violence, and screen for and address stigma may be important in improving EID.

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Coverage and Facilitators of HIV Testing among Children in Rural Nigerian Communities: Implications for Reaching the UNAIDS First 95 Target

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Introduction: Children are falling far short of the UNAIDS 95-(testing) 95-(treatment) 95-(viral suppression) targets. Target achievement has been particularly difficult in rural areas which historically have low testing coverage. We investigated the coverage and facilitators of pediatric HIV testing in rural communities across Nigeria.

Methods: We conducted a secondary analysis for children 0-14 years using data from the nationally representative 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS), which was conducted across all 6 geopolitical zones in the country. Descriptive, bivariate, and multivariate analysis were conducted. Significance was set at 5%.

Results: Overall, 86719/89004 (97.5%) surveyed rural children had never been previously HIV-tested and HIV prevalence was 1.4%. Among ever-tested rural children, 20.3% were HIV-positive. Maternal HIV testing history and status were associated with HIV testing among children (p<0.001 for both). Specifically, children with HIV-positive mothers (OR: 9.19; 95%CI: 4.15, 20.34) and mothers/guardians who had ever been tested for HIV (OR: 9.27; 95%CI: 7.66, 11.22) had higher odds of HIV testing. The odds of HIV testing increased with mother/guardian and child's age. Mothers/Guardians who had ever attended school (OR: 4.47; 95% CI: 3.29,6.08) and had received antenatal care during pregnancy with the surveyed child (OR: 7.66; 95% CI: 14.50) were more likely to consent to HIV testing for the child. Also, children delivered at a healthcare facility (OR: 3.68; 95% CI: 2.23,6.08) were more likely to be tested. The odds of HIV testing were highest in the South-South zone (OR: 16.97, 95%CI: 10.52,27.39) and significantly higher among children of unmarried mothers (OR: 1.85; 95%CI: 1.51,2.28).

Conclusion: There was a high HIV positivity among children who had ever been tested, however the pediatric testing rate in rural Nigeria was very low. This undermines the first 95 agenda for children in rural areas and nationally. Furthermore, we find that several facilitators of HIV testing among children in our study are tightly linked to modifiable maternal factors. Our findings provide evidence to guide pediatric first 95 scale-up strategies in rural Nigeria, including considerations for children of mothers/guardians who are young, have low literacy, and have low utilization of healthcare services, especially antenatal care.

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Young Adults who Acquired HIV Perinatally Have Poorer Viral Suppression than Those who Acquired HIV Later in Life: a Population Survey in Zimbabwe

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Introduction: Young adults (aged 18-24 years) in Zimbabwe may have acquired HIV perinatally or horizontally. Perinatally acquired HIV is often diagnosed late and may lead to worse health outcomes compared to later acquisition. We aimed to compare the demographic and clinical characteristics of young people who were diagnosed with HIV in childhood and adulthood, as a proxy for route of HIV acquisition (perinatal vs horizontal).

Methods: A cross-sectional representative population-based survey of young people aged 18-24 years was conducted in 3 provinces in Zimbabwe. Participants were asked their HIV status, the date of their HIV diagnosis if positive, and whether they had been diagnosed as a child. A dried blood spot was taken to measure HIV viral load. Multilevel mixed-effects generalized linear modelling was used to estimated the association between HIV acquisition time and viral non-suppression, defined as ≥1000 copies/ml.

Results: 17,682 participants (60.8% female) were enrolled of whom 12,003 (67.9%) knew their HIV status; 435 (3.6%) reported being HIV positive and 90.0% were taking ART. All but 6 reported their age at diagnosis: 196/429 (45.7%) were diagnosed as children (median age of diagnosis 7 years (IQR 1-12)) and median diagnosis age in the remaining 233 participants was 21 years (IQR 19-24). 54/429 (12.6%) of those with HIV were underweight (BMI z-score <-2) with no difference by acquisition route. A higher proportion of adult-diagnosed than child-diagnosed participants were female (91.4% vs 76.5%), had ever had sex (93.6% vs 61.5%), ever been married (60.1% vs 19.4%) and ever been pregnant (80.3% of women vs 40.0%). Over half (54.8%) of participants diagnosed in childhood had viral non-suppression compared to 45.2% of those diagnosed as adults. After adjusting for sex, age, marital status and education, those diagnosed as children had higher odds of viral non-suppression (adjusted odds ratio=1.92, 95%CI 1.19-3.09, p=0.008).

Conclusion: Young adults who acquired HIV perinatally are at greater risk of viral non-suppression compared to their peers who acquired HIV in adulthood. Extending into adulthood, those with perinatally acquired HIV continue to have additional needs and worse outcomes.

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Suicidal Behaviors among Thai Adolescents and Young Adults Living with HIV

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Background: We aimed to describe suicidality among Thai adolescents and young adults living with HIV(AYA-HIV).

Methods: A cross-sectional study was conducted among Thai AYA-HIV aged 15-24years in Chiang Mai. Participants were interviewed about lifetime and recent suicidal ideation and behaviors, using a cross-culturally validated Thai version of the Columbia-Suicide Severity Rating Scale (C-SSRS). The questions are divided into 4 subscales: (1) suicidal ideation; (2) intensity of ideation; (3) suicidal behaviors; (4) lethality of suicide attempts.

Results: Of 150 AYA-HIV, 90 (60%) had perinatally acquired HIV, 101 (67%) were male, and median age was 21 (IQR:19-23) years. All were on combination antiretroviral treatment. The median CD4 count was 547 (IQR:378-747) cells/mm³, 79% had viral load <50copies/mL. Overall, 44 (29%) AYA-HIV reported lifetime suicidal ideation, 8 of whom (18%) reported symptoms within the past month. Among these 44 participants, 35 (80%) ever had non-specific active suicidal thoughts, 23 (52%) ever had active suicidal thoughts without intent to act, 12 (27%) ever had active suicidal thoughts with intent to act, and 8 (18%) ever had active suicidal thoughts with specific plan and intent. Forty-six percent had suicidal ideation <1time/week, and 66% had symptoms lasting <1hour. Reasons for suicidal thoughts included (1) completely to end/stop pain (n=7; 16%); (2) mostly to end/stop pain (n=12; 27%); (3) equally to get attention/revenge/reaction from others and to end/stop pain (n=8; 18%); (4) mostly to get attention/revenge/reaction from others (n=2; 5%); (5) completely to get attention/revenge/reaction from others (n=3; 7%); (6) non-specific reasons (n=12; 27%). Additionally, 16 (11%) AYA-HIV reported lifetime suicidal behaviors, 2 (13%) within the previous 3months. Among these 16 participants, 2 (13%) ever prepared for suicidal act/behavior, 9 (56%) ever had an aborted/self-interrupted attempt, 8 (50%) ever had an interrupted attempt, and 12 (75%) ever had an actual suicide attempt. Among AYA-HIV with actual attempts, 2 (17%) sustained no/very minor physical injury, whereas 6 (50%) had minor, 3 (25%) had moderate, and 1 (8%) experienced severe physical damages.

Conclusions: Suicidal ideation and behaviors were prevalent among Thai AYA-HIV. Screening for suicidality in primary HIV clinics could help with earlier detection and linkage to appropriate management.

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The Role of Peer Support in Linkages for Mental Health Services Among Adolescents and Young People Living with HIV: Experiences from Zimbabwe

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Adolescents and Young People Living with HIV (AYPLWHIV) are at substantial risk of common mental disorders (CMDs), which have been correlated with poor adherence to antiretroviral therapy(ART). Zvandiri, a peer support program for AYPLWHIV, trained Community Adolescent Treatment Supporters (CATS), to screen all beneficiaries ages 10 – 24 for CMDs and refer those identified as being at risk to healthcare workers (HCWs). We implemented a quality improvement (QI) project with the goal of improving the mental health of beneficiaries through identification of risk and the provision of support. We examined the effect of the QI initiative on screening coverage, risk identification, support, and referrals.

Description: The QI initiative was conducted October 2021 to March 2022. 58 CATS and 18 HCWs participated in a one-day training on mental health screening using the Shona Symptom Questionnaire (SSQ), support and referrals of those at risk of CMDs to HCWs. CATS received weekly supervision. Weekly targets were set with the CATS for screenings and the number expected to be found at risk based on known prevalence of CMDs (20-30% of AYPLHIV in Zimbabwe). After three months, CATS who did not achieve their targets received a follow-up half-day training to improve screening and counselling skills. HCWs were provided an additional 1-day training on CMDs and intervention strategies to strengthen referral pathways.

Results: Compared with 41% (667/1,665) of beneficiaries having been screened in the year prior to the QI initiative, with 7% (49/667) identified as at risk of a CMD, outcome measures improved to screening reach of 85% (990/1,160), with an average risk identification rate of 14% (143/990) at endline. Of those at risk of CMDs, 97% (139/143) were assisted with additional support by the CATS, and 92% (128/139) were referred to HCWs for in-depth evaluation and management. After three months 89.5% (128/143) of those at risk were rescreened. 82% (117/143) were no longer at risk.

Conclusion: Providing mental health training and supervision to HIV peer counsellors, along with capacity building to strengthen referral pathways, is a promising way to improve the integration of mental health and HIV services, and the mental health of AYPLWHIV utilizing.

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High Pregnancy Incidence Rate Among HIV-Infected Adolescents in Urban West Africa

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Background: Sexual and reproductive health issues in adolescents living with HIV (ALHIV) are overlooked in HIV care programs. Female ALHIV are at risk of unwanted pregnancy which can jeopardize their future, HIV-care and exposes their newborn to HIV transmission. We estimated the 18-month pregnancy incidence rate and their outcomes

among female ALHIV enrolled in the OPTIMISE-AO project in West Africa.

Methods: The OPTIMISE-AO-ANRS-12390 project is a stepped-wedge trial aimed to improve HIV-disclosure and treatment adherence in ALHIV aged 10-17 years, nested in six pediatric clinics of the IeDEA West African cohorts. We estimated the 18-month pregnancy incidence per 100 person-years (PY) among female ALHIV aged 14 to 17 years enrolled in Abidjan, Cote d'Ivoire and Ouagadougou, Burkina Faso. Data on incident pregnancies were obtained through medical visits and interviews with health professionals. ALHIV lost-to-follow up, transferred out or deceased were censored at either the date of last follow-up or date of death.

Results: From February to December 2021, 224 female ALHIV were enrolled. Among them, 111 aged ≥14 years were included in this analysis. At baseline, 97% were schooled, 57% orphaned of one or both parents, 62% fully HIV-disclosed (defined when the adolescent names his/her illness as HIV/AIDS), 82% received a dolutegravir-based regimen, and 72% were virologically suppressed (viral load<50cp/mL). At 18-month, 12 pregnancies were reported after 153 PY of follow-up. Overall, the pregnancy incidence rate was 7.8/100 PY (95% confidence interval [95%CI]: 4.4-13.7). Stratified by age at enrolment, the pregnancy rate was 2.19 (95%CI: 0.3-15.5), 7.6 (95%CI: 2.8-20.3), 13.1 (95%CI:5.4-31.4), 11.5 (95%CI: 2.8-45.8) per 100 PY in those aged 14, 15, 16, and 17, respectively. All pregnancies were reported as unwanted. The median age of their partners was 21.5 years (interquartile range: 20.0-25.5). Six ALHIV out of 12 gave birth; the remaining pregnancies are ongoing. All children received a prevention of HIV mother-to-child transmission. Three of the six babies were eligible and had a 6-week early infant HIV diagnosis, all were HIV-negative.

Conclusion: In these West-African settings, incidence of unwanted pregnancy was high among ALHIV. Interventions to meet the sexual and reproductive health needs of ALHIV are urgently needed.

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Transforming U=U Into a Youth Friendly Concept: The Development of a U=U Tool by Young People for Young People

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Background: U=U (Undetectable=Untransmittable) is acknowledged as an important element in the comprehensive care of adolescents and youth living with HIV (AYLHIV) when the approach is cognizant their needs. There is a dearth of tailored messaging tools and know-how in communicating U=U with AYLHIV. Alongside the University of Cape Town (UCT), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) Committee of African Youth Advisors (CAYA) sought to create an adolescent-friendly tool to address this gap.

Description: Over a 12-month period, CAYA members, EGPAF staff, and UCT researchers met to discuss, explore, and develop key focus areas and action items in the development of a tool. CAYA consists of youth 15-29 years from 11 sub-Saharan African countries. An initial gap analysis on the formal and grey literature was conducted, followed by several surveys and design workshops with CAYA. The first version of the tool was used in psychosocial support (PSS) groups led by CAYA members in Uganda, Malawi, and Kenya to gather additional insight from broader adolescents and youth outside of the CAYA group. A standardized questionnaire to gather insights and feedback was used.

Lessons: The literature review revealed gaps in messaging and content in U=U materials, particularly for adolescents and youth in African settings. Through an iterative process focused on understanding misconceptions and complexities of U=U from the perspective of young people, CAYA members created relevant graphic stories featuring diverse youth in situations to address and explain common areas of confusion including condom use and U=U and U=U in pregnancy. The 187 youth 15-25 years who participated in PSS groups provided

overwhelming positive feedback on the types of stories, characters portrayed and content, along with practical edits for characters, language, and settings in the initial version. These edits were incorporated into the final tool.

Conclusions: There is a critical gap in the literature and a lack of knowledge on how to message and use U=U to empower AYLHIV across Sub-Saharan Africa to live full, healthy lives. The development of a U=U tool in partnership with young people was feasible and effective in creating a comprehensive tool that is being integrated into programming.

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Prevalence and Associated Factors of Anxiety Among Thai Adolescents and Young Adults Living With HIV

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Background: Adolescents and young adults living with HIV(AYA-HIV) have been shown to be at risk for mental health co-morbidities. This study aimed to determine prevalence and associated factors of anxiety among Thai AYA-HIV.

Methods: A cross-sectional study was conducted among AYA-HIV (15-24years) who attended an HIV clinic in Chiang Mai, Thailand. A cross-culturally validated Thai version of the Generalized Anxiety Disorder 7-item tool (GAD-7) was used to assess anxiety symptoms. Additional evaluations were conducted assessing lifetime suicidal ideation and behaviors (Columbia-Suicide Severity Rating Scale), alcohol use disorders (Alcohol Use Disorders Identification Test; AUDIT), resilience (Ego resilience scale; ER89), and HIV-related stigma (HSS; Youth-HSS for AYA-HIV aged<18years; Berger-HSS for AYA-HIV aged ≥18years). Logistic regression analysis was performed identifying factors associated with screening positive for anxiety (GAD-7 score ≥10 out of 21).

Results: Among 150 AYA-HIV, median age was 21 (IQR:19-23) years, 49 (33%) were female, and 48 (32%) lived independently from parents/guardians. Sixty (40%) had behaviorally-acquired HIV, and median age at HIV disclosure was 15 (IQR:10-20) years. At enrollment, all AYA-HIV were on combination antiretroviral treatment, of which 70% were non-nucleoside reverse transcriptase inhibitors-based regimens, and median self-reported adherence was 95% (IQR:90-100%). Median CD4 count was 547 (IQR:378-747) cells/mm^3, and 79% had viral load <50copies/mL.

Overall, 17 AYA-HIV (11%; 95%CI: 7-18%) had GAD-7 scores ≥10. Additionally, 44 (29%) reported having lifetime suicidal ideation/behaviors; 12 (8%) had moderate to severe alcohol use (AUDIT ≥16 out of 40); 86 (57%) had moderate (HSS score 81-120) and 8 (5%) had high levels of perceived HIV stigma (HSS score 121-160); and 108 (72%) had high/very high resiliency scores (ER89 score ≥35 out of 56). In multivariable logistic regression analysis, living independently from parents/guardians (adjusted odds ratio[aOR]: 6.4; 95%CI: 1.1-38.6 vs. living with biological parents), older age at HIV disclosure (aOR: 1.2; 95%CI: 1.1-1.4, per one year increased in age), and reporting lifetime suicidal ideation/behaviors (aOR: 14.7; 95%CI: 3.3-66.1) were significantly associated with GAD-7 scores ≥10.

Conclusions: Screening positive for anxiety were prevalent among our Thai AYA-HIV. As noted in other contexts, routine screening and subsequent managements of this co-morbidities are critically important for this population.

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High Prevalence of Suicidal Ideation Among Adolescents and Young Adults Attending HIV Care Services in Bangkok, Thailand

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Background: Studies of adolescents and young adults (AYA) with or at HIV risk suggest high rates of suicidal ideation (SI) and significant underlying mental health problems. This study aimed to investigate prevalence of SI and suicidal attempts among AYA attending HIV services in Bangkok.

Methods: AYA aged 15-24 years attending HIV care services were administered the PHQ-9, a depression screening tool with a specific question on SI in the past two weeks routinely at every 3 monthly visit. Depressive symptoms were categorized as moderate (PHQ-9 score 9-15) and severe (score >15). AYA with PHQ-9 scores >9 and/or endorsing SI were provided care by a clinical psychologist and/or psychiatrist.

Results: Between November 2020 and October 2021, 376 AYA were screened (146 AYA living with HIV; 230 AYA at HIV risk with a median age of 20 years (IQR 18-22). Sixty-one AYA reported SI; a prevalence of 16.2% (95% CI 12.5-20.2). Overall, 5.3% attempted suicide, by physical self-harm (n=11) or overdoses (n=9,). SI was commoner in AYA living with HIV (24%) versus AYA at HIV risk (11%). Of those reporting SI, 56% were subsequently diagnosed with a mental health disorder: major depressive (n=27), bipolar (n=2), ADHD (n=2), social anxiety (n=2), post-traumatic stress (n=1), disorders, with AYA living with HIV having higher rates of mental disorders (80%) versus AYA at HIV risk (23%). At 1-year follow-up, 56 of 61 of those reporting SI at baseline were retained, of which 25 (45%) had persistent SI. Of the 315 with no SI at baseline, 275 were retained at 1 year, of which 22 reported new SI, an incidence rate of 8.0 (95% CI 4.8-11.2).

Conclusions: Suicidal ideation is common in Thai AYA receiving HIV services. Mental health screening should be implemented routinely in AYA-centered services for early detection and intervention.

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Bridging a Gap for Young Adults with Perinatal HIV During the HIV Care Transition

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Background: Studies reported high virologic failure, attrition rates, and morbidities among young adults with perinatal HIV (YAPHIV) after transitioning from pediatric to adult services. We identified the challenges and assessed their HIV service satisfaction and mental health (MH) while trying to bridge the service gaps.

Methods: The prospective study was conducted in Chiang Mai, Thailand, from November 2021 until the present. We enrolled YAPHIV aged ≥20 years who transitioned to adult HIV services within the past 12 months or beyond 12 months but remained struggling in transition. Participants were contacted trimonthly for a brief interview to report their challenges after transitioning. We used 5-point Likert scale questions for the HIV service satisfaction and the patient health questionnaire-9 (PHQ-9) for MH assessment.

Results: We followed 36 YAPHIV, mean age of 23.0±3.1 years, 18(50%) females. Sixteen (44%) had VL >1,000 copies/mL. Their current HIV clinics were in private (n=21, 58%), tertiary care (n=8, 22%), and community (n=7, 19%) hospitals.

YAPHIV identified 62 challenges during the 168 contacts before offering advice/counseling. The common challenges included:
-Unpleasant services (n=16, 26%) -multiple stops, lengthy waiting time, and frequent visits.

-Suffering from comorbidities (n=15, 24%) -tuberculosis, opportunistic infections, neuropsychiatric symptoms.
-Antiretroviral (ARV)-related issues (n=11, 18%) -pill burden, dosing time, and side effects.
-HIV-related stigma/disclosure (n=9, 15%).

Approximately half of YAPHIV were very satisfied/satisfied with each component of HIV services which included commuting (51%), clinic setting (49%), doctors (49%), other healthcare providers (48%), visit flexibility (51%), and ARV-related issues (54%). Some participants were dissatisfied with the doctors (8.9%) and the inflexible clinic operations (8.9%).

Eleven (31%) had depressive symptoms (PHQ-9 score ≥10). Psychiatrists followed two, and we linked the other two. Seven YAPHIV had explainable depressed moods and were advised/supported in the clinic.

At week 48, one-third of YAPHIV (6/16) with VL >1,000 copies/mL at entry became virologic suppressed, and all except one (10/11) with depressive symptoms at entry had PHQ-9 <10.

Conclusions: YAPHIV might benefit from a post-transition follow-up to determine if they could fit in with the services and ensure they could overcome challenges and did not struggle with any manageable logistic or health problems.

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Consenting and Re-Consenting Kenyan Children and Adolescents Living With HIV in Research Involving Biological Sampling and Bio-Banking

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Background: Research that involves collection, storage, and bio-banking of biological samples for future analyses requires answering questions such as when and how to re-contact and re-consent participants, and what constitutes an adequate re-consenting process. These concerns are amplified when engaging vulnerable populations, like children and adolescents (youth) living with HIV (YLWH) – for whom these questions have rarely been examined. We sought to investigate the views of Kenyan YLWH, their caregivers, and Subject Matter Experts (SMEs) on re-consenting requirements for biospecimen collection and storage, confidentiality considerations related to stored specimens, receipt of research-related test results, and perspectives on sharing samples with outside researchers.

Method: We conducted semi-structured interviews with 99 participants; 20 YLWH enrolled in an ongoing study, 20 research-naïve YLWH, 20 caregivers of adolescents enrolled in the parent study and 39 SMEs (5 community advisory board members, 10 health care providers, 10 community leaders, 5 IRB experts, 5 clinical researchers, 3 social science researchers, and 1 laboratory lead). All YLWH were aware of their HIV status.

Results: Among the 99 participants (53% male), YLWH were median age 17.5, (11-24), 50% female; caregivers were 70% female, and SMEs were 33% female. All participant groups identified that re-contacting and re-consenting is both needed and an important legal consideration, as it ensures participants understand the purpose of storing samples, methods to maintain confidentiality, and when samples may be shared with outside researchers. YLWH participants thought that the original consent should indicate what test results will be provided through the study and when and where to access them. Caregiver participants highlighted the benefit and sufficiency of using broad consent at study enrollment, and that re-consenting is not required for additional, future use of the specimens; caregivers expressed trusting researchers, the regulatory and institutional processes.

Conclusion: Researchers should provide comprehensive information on the purpose of biospecimen storage, when samples will be shared with other researchers, confidentiality measures and procedures for accessing study results; re-consenting should be initiated when broad consent was not used. Additional work is needed to ensure that research participants clearly understood

comprehensive information included in consent forms.

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The Role of Researcher-Participant Relationships and Trust in Children and Adolescents Living With HIV Participating in Research

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Introduction: Health research with children and adolescents living with HIV (CALWH) is critical to improving clinical outcomes, particularly in high burden countries. Unique vulnerabilities of this group, including their age, HIV status, and social contexts, raise bioethical questions, including their interactions with and confidence in the researchers, which might impact their experience. We evaluated perspectives on the role of researcher-participant relationships and trust in CALWH research participation.

Methods: In-depth, semi-structured interviews were conducted with CALWH (ages 10-24 years, enrolled in HIV care at Academic Model Providing Access to Healthcare (AMPATH) in western Kenya), caregivers of CALWH, and other subject matter experts (SMEs). Thematic analyses were conducted to identify preliminary codes and themes.

Results: Interviews were conducted with 99 participants (53% male): 40 CALWH (median age 17.5 years, (range 11-24), 50% female), 20 caregivers (70% female), and 39 SMEs (33% female; 46% community leaders, 26% health care providers, 15% clinical researchers, 8% social scientists, 3% international research experts, 2% laboratory experts). All groups highlighted the importance of relationships and trust-building between researchers and CALWH participants. Caregivers and SMEs discussed the implied trust associated with researchers due to the beliefs that there are inherent benefits of research participation and that researchers have the individuals' best interests in mind. SMEs and CALWH stressed the importance of researchers demonstrating and proving their ability to maintain confidentiality, noting that confidentiality facilitates trust. Similarly, SMEs held the perspective that CALWH may be more willing to share vulnerable HIV-related information when trust is built with the researcher. All groups indicated that CALWH and caregivers are more likely to consent to future contact and participation in research if trust has been established. Caregivers reported being more comfortable with research biospecimens leaving Kenya for analyses or sharing data with other researchers if there was an established relationship and trust built with the original investigator.

Conclusion: Researcher-participant trust is integral in conducting studies among CALWH. This trust influences what is shared during the study, as well as future decisions about research participation. Efforts should be devoted to maximizing researcher-participant relationships and trust.

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Cardiometabolic Risk Profiles of Adolescents living with Perinatally Acquired HIV in South Africa.

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Background: The current generation of adolescents living with perinatally acquired HIV may be at increased risk of cardiovascular disease (CVD) compared to those HIV-negative.

Materials and Methods: Coronary artery (CA) and abdominal aorta (AA) Pathological Determinants of Atherosclerosis (PDAY) scores were calculated for 56 participants over 15 years of age, using a weighted combination of dyslipdaemia, cigarette smoking, hypertension, obesity, and hyperglycaemia. Qualitative cytomegalovirus (CMV) specific-IgG and CMV viral load was recorded in addition to HIV viral load (VL), CD4 count, antiretroviral regimen, and highly sensitive CRP (hs

CRP). A PDAY score ≥1 is associated with early atherosclerosis.

Results: Fifty-six participants, 30 (53.7%) females, were enrolled, 46 (83.6%) were on a single tablet regimen of tenofovir, emtricitabine, and dolutegravir and 47 (83.9%) had a VL <50 HIV RNA copies/ml with a median CD4 count of 695 cells/µL [Interquartile range (IQR) 499 – 861]. The median time on antiretroviral therapy (ART) was 16.2 years (IQR 15.8 – 16.5). Fasting median HDL was 20.1mg/dL (IQR 16.0 – 23.7) and median non-HDL 38.3mg/dL (IQR 30.8 – 44.3). Only 1 (1.8%) participant smoked cigarettes, but 5 (8.9%) smoked hookah pipe and 26 (46.4%) smoked cannabis. The median systolic blood pressure was 115 mmHg (IQR 107 - 121). Median BMI was 21.3 kg/m2 (IQR 19.5 – 24.7) and median fasted serum glucose was 82.0mg/dL (IQR 75.7 – 87.3). Seven (12.5%) and 8 (14.3%) participants had PDAY scores of ≥1 and mean CA and AA PDAY scores were 1 (IQR 0 - 1) and 1 (IQR 0 - 1) respectively. HIV VL > 50 copies/ml was associated with a CA PDAY (p = 0.039) and AA PDAY (p=0.005) ≥1. Median hs CRP was 0.5 (IQR 0.2 – 2.8) and was not associated with a high HIV VL (p=0.93) nor with increased CA (p=0.83) or AA (p=0.73) PDAY scores. All participants tested were CMV specific-IgG positive with undetectable CMV viral load.

Conclusions: Adolescents with perinatally acquired HIV and VL > 50 HIV RNA copies/ml appear at higher risk for CVD. Specific tools for monitoring this risk are needed so that appropriate preventive interventions can be instituted.

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Change in Size-Adjusted Bone Density Outcomes by HIV Status Among Peripubertal Children in Zimbabwe: A Prospective Cohort Study

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Background: HIV infection is associated with lower bone density, increasing the risk of fracture. Puberty is a key growth period where substantial bone mass is accrued (measured by bone mineral content and density). We investigated how bone outcomes change over one year in peripubertal children living with HIV (CWH) compared to HIV-uninfected children (CWOH) in Zimbabwe.

Methods: From 2018 to 2020, CWH from public sector HIV clinics aged 8 to 16 years on antiretroviral therapy (ART) for at least two years, and CWOH of similar ages from nearby schools were recruited in Harare. Dual X-ray absorptiometry was performed at baseline and 12 months and Z-scores calculated against a reference population. Bone measures included height-adjusted total-body less-head bone mineral content for lean mass (TBLH-BMC) Z-score and size-adjusted lumbar spine bone mineral apparent density (LSBMAD) Z-score. Separate linear regression models for boys and girls compared longitudinal changes in bone outcomes by HIV status adjusting for age, pubertal stage, baseline bone measurements and time since first visit. Age and bone mass datapoints were plotted to observe the association of HIV with bone outcomes.

Results: There were 244 CWH (mean age 13.0 years old (SD 2.3), 199 (48.8%) girls) and 248 CWOH (mean age 12.9 years old (SD 2.4), 126 (50.8%) girls). Among CWH, 82% were virally suppressed (<1000 copies/ml). The prevalence of stunting (height-for-age Z-score <-2) at follow-up among CWH was 28.1% compared to 8.7% among CWOH (p<0.001). Among girls, bone density gains over a median 35 months were similar between CWH and CWOH: adjusted mean differences in LSBMAD (0.05 [95%CI -0.06,0.16], p=0.35) and TBLH-BMC (0.11 [-0.02,0.25], p=0.11). Male CWH gained less TBLH-BMC (-0.15 [-0.31,-0.09], p<0.001) compared to CWOH, whilst LSBMAD gains were similar (0.06 [-0.44,0.55], p=0.85). HIV was associated with delayed bone mass gains, particularly among older boys who appeared to be still gaining bone at the end of study follow-up.

Conclusion: Unlike girls, boys living with HIV experience reduced bone mass gain over one year. Despite ART, bone growth is perturbed during adolescence which has implications for future fracture risk. Strategies to address this are warranted.

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Cognitive Functioning Using a Mobile-Based Tool in Adolescents and Youth Living With HIV in Kenya

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Background: Adolescents and youth who acquired HIV perinatally have increased risk for neurocognitive compromise. Neurocognitive impairment is an important consideration for adolescents and youth living with HIV (AYLHIV) as they age into young adulthood. Access to neurocognitive tests is limited in lower- and middle-income countries (LMIC) with few neuropsychologists and lack of normative data. Simpler scalable tools may provide opportunities to identify AYLHIV in HIV programs in LMIC who may benefit from focused support. Our objective was to pilot the use of a tablet-based assessment tool among AYLHIV and determine correlates of cognitive scores.

Methods: Cognitive assessment was performed using the NeuroScreen tool, a short, validated tablet-based application on AYLHIV aged 13-24 years attending a large HIV treatment program in Nairobi, Kenya. Sociodemographic and clinical characteristics were abstracted using structured questionnaires and medical records respectively and summarized as proportions for categorical and medians (interquartile range [IQR]) for continuous variables. The outcome measure was cognitive test scores in AYLHIV. Scores for each domain were summed, generating a composite score. Linear regression analysis was conducted to determine the correlates of cognitive test performance.

Results: Among 146 participants, median age was 18 years, median age at ART start was 10 years, 53% were male and 75% were enrolled in school. Many AYLHIV (46%) had early-stage disease (WHO stage I/II) at HIV diagnosis and 23% had detectable viral load at last measurement. Male sex and education level were associated with significantly higher cognitive scores on univariable analysis. Adjusted for sex and level of education, school grade correlated with measured cognitive function. Adolescents with above-average and average school grades had better scores compared to those with below-average grades (mean difference 5.31 (95%CI 1.93, 8.68) p=0.002, 4.09 (95%CI 1.44, 7.92) p=0.012 respectively.

Conclusion: Lower scores for executive functions, processing speed, verbal learning, verbal recall/memory, and motor speed using NeuroScreen correlated with poorer school performance, suggesting that the test reflects functional performance. Gender differences may reflect physiologic, social or educational differences. Studies to further evaluate NeuroScreen as a potential tool to identify ALHIV with cognitive impairment are warranted.

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High Prevalence and Low Awareness of Chronic Hepatitis in Adolescents Living with HIV in Thailand

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Background: Hepatitis C is an asymptomatic infection with high prevalence amongst men who have sex with men (MSM) and people who use drugs (PWUD). Direct acting antivirals are widely available, however many individuals living with HCV remain undiagnosed. This study aims to determine the prevalence of chronic HCV and assess awareness of HCV among youth attending HIV/STI services.

Methods: A cross-sectional study was conducted in MSM youth aged 15-24 years attending an HIV/STI clinic in Bangkok. Hepatitis C antibody rapid diagnostic tests using whole blood from finger pricks were performed using the STANDARD Q HCV Ab Test (SD Biosensor, Korea). HCV quantitative nucleic-acid tests were used to confirm HCV viremia. Self-reported questionnaires were

collected to assess knowledge and attitudes regarding HCV transmission and management. The primary endpoint was chronic HCV infection prevalence.

Results: From March to April 2023, 107 AYAs with a mean age of 21.5 (SD2.1) years were enrolled, including 42 living with HIV (LHIV) and 65 taking HIV pre-exposure prophylaxis. Nineteen were PWUD (13 used crystal amphetamine, 6 other drugs). Only 3 people LHIV (7.1%) previously screened for anti-HCV. Mean age at sexual debut was 16.7 (SD 2.5) years. Median lifetime partners was 10 (IQR:4-23). Self-reported condom use >50% of sex acts was 72.9%.

Six participants had positive HCV antibody tests, 4 had confirmed HCV viremia with elevated ALT. Overall prevalence of chronic HCV was 3.7% (95%CI:1.0-9.3). Prevalence amongst PWUD was 21.0% (95%CI:6.1-45.6). Prevalence of HCV was higher among MSM LHIV; 7.1% (95%CI:1.5-19.5) than HIV seronegative MSM; 1.5% (95%CI:0.04-8.3).

Mean score for HCV knowledge was 7.9 (SD1.5) out of 11. However, 29.1% of participants were unaware that HCV could be spread through shared needles, 71.8% misunderstood that HCV was transmitted via oral sex. Barriers to HCV screening included the lack of tests offered at clinics (43.9%). Three-quarters (72.7%) of participants believed that HCV was preventable by vaccination, and 77.7% that HCV is a treatable disease.

Conclusions: One-fifth of youth with a history of drug use had chronic hepatitis C. Misconceptions about HCV transmission and prevention exist. Health education and screening of HCV should be considered in HIV/STI clinics.

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Key Influences on the Sustainability of an Adolescent Transition Package for Youth Living with HIV in Kenya

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Background: Improving HIV treatment outcomes among youth living with HIV (YLH) requires sustaining evidence-based interventions (EBIs) into routine care. The ATTACH study developed and evaluated an Adolescent Transition Package (ATP) which improved youth's readiness to transition from pediatric to adult care. We aimed to identify factors influencing implementation of the ATP post-trial.

Material and Methods: One year post-trial, we surveyed 147 healthcare workers (HCWs) supporting YLH at the 20 ATTACH clinics and interviewed a purposive subset of HCWs from each site (2-3 per site). We conducted descriptive analyses of survey data to understand implementation outcomes influencing sustainability. Informed by the Consolidated Framework for Implementation Research (CFIR) and Structural Readiness for Change, we conducted thematic analyses of debrief reports and a subset of transcripts to explore themes on sustainability.

Results: HCWs had implemented the ATP for a mean of 1.7 years, and most (90%) were trained by the ATTACH team. Almost all (94%) HCWs agreed they would like to continue using the ATP. Long-term implementation was influenced by strong clinic support, ease of integrating the ATP into clinic operations, and supportive HIV clinic leadership. Barriers to sustained use included lack of ownership among new staff who did not participate in the ATTACH study and high workload. HCWs felt strongly that the ATP was an appropriate tool to improve adherence, retention, and viral suppression among YLH. When evaluating long-

term fidelity to intervention tools, HCWs used the disclosure and transition booklets most frequently. However, some clinics adapted booklet use to focus only on YLH experiencing care challenges. When considering future scale-up, HCWs highlighted the need for adolescent champions to support intervention delivery, integration into electronic medical records, strategies to increase HCW motivation, and Ministry of Health engagement.

Conclusions: We observed high rates of continued ATP use across sites one year post-trial, likely attributed to the high acceptability, appropriateness, and feasibility of the ATP. Given variations in implementation fidelity, strategies promoting inclusive training and reduced HCW workload such as refresher courses and simplified tools, may support sustainability. Understanding the factors which influence sustainability outside of research settings can inform future scale-up of the ATP.

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Increased Expression of CD57+CD56dimCD16dim Natural Killer Cells in Ugandan Adolescents with Perinatally Acquired HIV: a Possible Role in Atherogenesis

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Introduction: Perinatally acquired HIV (PHIV) and lifelong antiretroviral therapy (ART) may alter the development and function of the immune system. Our preliminary data and published literature suggest reprogramming innate immune cells may accelerate aging and increase the risk for future end-organ complications, including cardiovascular disease (CVD). Natural killer (NK) cells are a highly heterogeneous population with divergent immune functions and play a critical role in preventing HIV transmission and contributing to disease progression and CVD in adults. However, little is known about the role of NK cells in HIV-associated cardiovascular risk. Here, we studied NK cell subsets and their potential role in atherogenesis in adolescents with and without HIV.

Methods: In this cross-sectional study, using high dimensional flow cytometry, plasma biomarker profiling, and transcriptomics, we compared immune signatures in cryopreserved peripheral blood mononuclear cells and plasma from Ugandan adolescents with PHIV on ART and virally suppressed (HIV-RNA<400copies/mL) (n=18) and HIV unexposed and uninfected adolescents, n=20). The median age was 14 years, and 50% were females.

Results: In the PHIV cohort, we found elevated activation (CD69, HLA-DR, NKp44) markers in most NK subsets compared to HIV- ($p<0.05$). CD57, a marker of NK maturation and memory, was significantly elevated in this CD56dimCD16dim NK subset. CXCR3, which mediates NK cell migration to vascular endothelium, was significantly elevated in the CD57+CD56dimCD16dim subset in PHIVs. Oxidized LDL (ox-LDL) (taken up by vessel wall macrophages) levels were significantly lower in the plasma of PHIVs. Further, a negative correlation was found between the CD57+CD56dimCD16dim subset and plasma oxLDL among PHIVs. This was confirmed by in vitro studies which revealed increased uptake of oxLDL by macrophages in the presence of activated NK cells ($p<0.05$). Bulk-RNA sequencing data confirmed the activation of multiple innate immune pathways in the PHIV group.

Conclusion: Our data demonstrate, for the first time, increased expression of an activated, mature CD57+CD56dimCD16dim NK subset with the potential to homing to the vascular tissue and influence the increased uptake of plasma oxLDL into vessel wall macrophages and initiate atherogenesis in the adolescent with PHIV. We are currently performing mechanistic and longitudinal studies to confirm these findings.

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Burden and Associated Factors of Depression and Anxiety Among Young Thai Men Who Have Sex With Men at Risk for and Living With HIV

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Background: We aimed to assess prevalence and associated factors of depression and anxiety among Thai young men who have sex with men (YMSM) at risk for and living with HIV.

Methods: A cross-sectional study was conducted among YMSM (18-25years) who were at risk for or living with HIV, and attended HIV clinic at a community clinic or tertiary hospital in Chiang Mai, Thailand. Patient Health Questionnaire 9-item (PHQ-9) and Generalized Anxiety Disorder 7-item scales(GAD-7) were used to screen for depression and anxiety, whereas post-traumatic stress disorder(PTSD) CheckList-Civilian Version(PCL-C) and Multidimensional Scale of Perceived Social Support(MSPSS) were performed to screen for PTSD and social support (low-to-medium support: score 1.0-5.0; high support: score 5.1-7.0), respectively. Logistic regression analysis was conducted to identify factors associated with significant depressive symptoms (PHQ-9≥10 of 27) and anxiety symptoms (GAD-7≥10 of 21) among these populations.

Results: We enrolled 100 YMSM at risk for HIV (median age: 20years) and 50 YMSM living with HIV (median age: 22years). Among at-risk YMSM, 28% had moderate-to-high self-evaluated risk of HIV infection, and 24% were on pre-exposure prophylaxis. Of YMSM living with HIV, all were clinically stable on cART, and 78% had viral load <20 copies/mL. The prevalence of significant depressive symptoms were 27% (95%CI: 19-37%) and 32% (95%CI: 20-47%) (P=0.81), and significant anxiety symptoms were 15% (95%CI: 9-24%) and 16% (95%CI: 7-29%) (P=0.97) for YMSM at risk for and living with HIV, respectively. In multivariable logistic regressions, having significant anxiety symptoms (adjusted odds ratio[aOR]: 1.6; 95%CI: 1.2-2.2), and low-to-medium social support (aOR: 7.3; 95%CI: 1.1-50.4) were associated with significant depressive symptoms for at-risk YMSM, whereas higher PCL-C scores (aOR: 1.3; 95%CI: 1.1-1.6, per one score increased) was an associated factor for YMSM living with HIV. Regarding significant anxiety symptoms, having significant depressive symptoms was the only associated factor for at-risk YMSM (aOR: 1.7; 95%CI: 1.2-2.4), and this factor showed a trend toward statistical significance for YMSM living with HIV (aOR: 1.6; 95%CI: 0.9-2.7).

Conclusion: Significant depressive and anxiety symptoms were prevalent among our Thai YMSM, both at risk for and living with HIV. An integrated mental health services are critically needed for these populations.

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Elevated Plasma Galectin-9 among Vertically Infected Youth with HIV on ART is Associated with Inflammation and Cognitive Performance

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Background: Perinatally infected adolescents with HIV are distinct from adults living with HIV in terms of rapid disease progression, increased viral burden and depletion of CD4 T cells. We previously showed that plasma and CSF Galectin-9 (Gal-9) levels, a lectin immunomodulator, are elevated during adult HIV infection and this was compounded by age and HIV viremia. Here we investigated the influence of

Gal-9 in HIV disease progression among adolescents with perinatal HIV infection and sought to determine links to cognitive performance.

Methods: Blood was obtained from two independent cohorts of perinatally infected adolescents in the southern region in Asia. Cohort I included adolescents with HIV (AWH) on suppressive ART (n=15), ART-naïve (n=15), and adolescents without HIV (AWOH; n=10) from India with median age of 10yrs. Cohort II from Myanmar included AWH on ART (n=54) and AWOH (n=22) with median age of 12yrs. Cohort II also completed standardized cognitive tests adapted for cultural relevance. We measured plasma Gal-9 by immunoassay, inflammatory mediators by Luminex and T-cell activation based on HLA-DR and CD38 co-expression by flow cytometry. Data were analysed using Mann Whitney t-tests and Spearman correlations.

Results: Gal-9 levels were found to be elevated in ART-treated AWH on ART when compared to AWOH in both cohorts (all $p<0.05$). Higher Gal-9 levels correlated with increased levels of sCD14, IP-10, TNFα, MCP-1, IL-10 and measures of CD8 T cell activation (HLA-DR CD38). In Cohort 2 it was notable that in AWH higher Gal-9 levels correlated with higher TNFα and MCP-1 (all $p<0.05$) and with lower cognitive performance on visual learning and memory test ($r=-0.31;p<0.05$).

Conclusions: Similar to adults, Gal-9 remains elevated among vertically infected youth with HIV receiving ART and correlated with persistent inflammation. The association with cognition suggests that Gal-9 may serve as a marker of neuroinflammation and brain injury in AWH.

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Pediatrics HIV and Asymptomatic Malaria Parasitemia (AMP) Co-Infection

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Background: Pediatrics HIV viral suppression remain a major challenge across Africa. In this study, we sought to establish the relationship between AMP and a sustained plasma HIV viremia among a population of pediatrics clients on Antiretroviral Therapy (ART). We also seek to determine the prevalence of AMP among the study population.

Methods: 180 pediatrics clients on ART at four (4) Comprehensive Hospitals in Jos, Nigeria, participated in this study between the months of October to December 2022. The mean age of the study participants was 13 years. Venous blood was drawn from the participants after consent were sought, and ethical approval obtained from the Plateau State Specialist Hospital (PSSH) Research and Ethics Committee. All samples were screened for AMP using the CareStart® HRP2 Malaria kit. The Absolute and % CD4 values of the clients were obtained using the BD Presto® CD4 Analyzer. The separated plasma samples were assayed for HIV viral load using the Roche Cobas C4800® system. Obtained data were analyzed using simple descriptive statistics.

Results: From the 180 participants in this study, 12.8% (23) have AMP. 90.6% (163) were virally suppressed (<1000 copies/ml), while 9.4% (17) were virally unsuppressed (>1000 copies/ml). 11.7% (19/163) of the virally suppressed population have AMP, with a mean absolute and % CD4 values of 648 and 31%. The virally suppressed population without AMP have a mean absolute and % CD4 values of 719 and 32% respectively. 24% (4/17) of the virally unsuppressed population have AMP, with a mean absolute and % CD4 values of 514 and 26%. The virally unsuppressed population without AMP have a mean absolute and % CD4 values of 292 and 16% respectively.

Conclusion: Our study shows that there is a high prevalence of AMP among the study populations (11.7% and 24% respectively). This high prevalence of AMP among the virally unsuppressed with a mean absolute and % CD4 values of 514 and 26% alludes to the fact that malaria co-infection with HIV fosters a dysregulated immune complex response which favors a sustained increase HIV plasma viremia. We thus recommend the routine use of Malaria IPT in pediatrics HIV clients.

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Pediatrics Regimen Optimization: Strategies Used and Effect on Viral Suppression Among Children Living With HIV Less Than 15 Years in 5 States in Nigeria

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Background: Children have been reported to have poor viral suppression partly linked to use of non-optimal regimens including non-nucleoside reverse transcriptase (NNRTI) based regimen. In 2021, Nigeria adopted the WHO recommendations and successfully began transitioning children living with HIV (CLHIV) less than 10 kg to dolutegravir (DTG) based regimen. This analysis describes the strategies implemented by the USAID-funded Reaching Impact Saturation and Epidemic Control (RISE) project to rapidly transition CLHIV to optimal regimens and impact on viral suppression

Description: The strategies implemented to transition CLHIV to DTG-based regimens included; Patients level interventions such as Caregivers and client's sensitization, active call back of CLHIV for refill with optimal regimen even when they have old regimen, home-based support for adherence by case managers; capacity building for prescribers and development of Job Aids; efficient commodity management process like accurate quantification of the unmet need, use of unmet need for drug requisition rather than consumption, agreement with donors and government to quarantine all NNRTI, establishment of commodity supply mechanism to ensure "Last Mile Distribution" rather than dumping at central stores; and progress monitoring through regular clinical and supply chain meeting to review consumption in line with supply and effective intra-program commodity redistribution

Lessons learned: At October 2019, 318/1256 (25%) of CLHIV< 10 years and 547/688(80%) of 10 – 14 years were on optimal regimen. This improved to 1523/1544 (99%) and 869/874(99%) for all < 10 and 10-14 years respectively by September 2020. Transition to pediatric DTG for CLHIV < 20kg began in October 2021and by December 2021, 1532/1605(95%) were transitioned.
Overall rates of viral suppression improved from 88/175(50%), 271/535(51%) and 319/513(62%) at October 2019 to 635/688(92%), 1512/1674(90%) and 1750/1952(90%) for age bands 1 -4, 5 -9 1nd 10 -14 years respectively by December 2022.

Conclusions: The strategies used in RISE project including caregivers' education, active call back of eligible patients and efficient commodity management were effective in achieving rapid transitioning of CLHIV to optimal regimen with subsequent improvement in viral suppression.

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Virological Suppression and Weight Gain in Children in Europe on Dolutegravir Compared to Protease Inhibitors: A Propensity Score Analysis

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Background: Dolutegravir (DTG)-based ART is recommended for treating HIV-1 in children. Excess weight gain on DTG has been reported in adults but paediatric data are limited.

Materials and methods: Children aged 6-<18 years receiving 2NRTIs+DTG or 2NRTIs+protease-inhibitors (PI) from 2010-2020 in 12 cohorts in the European Pregnancy and Paediatric Cohort Collaboration were included. First, percentage with viral suppression (VS, viral load (VL)<50c/ml) and change in BMI-for-age z-score (zBMI) were estimated at 48 and 96 weeks across three groups

based on treatment experience and VL status at DTG/PI start: "ART-naïve", "ART-experienced/suppressed" (VL<50c/ml) and "ART-experienced/unsuppressed" (VL≥50c/ml). Second, differences in VS, zBMI and weight change on DTG and PI were estimated using propensity score (PS, derived using characteristics at DTG/PI start) matching among those ART-experienced (insufficient numbers ART-naïve).

Results: Overall 1582 were included (46% male, 68% black ethnicity); 644 on DTG (73(11%) ART-naïve, 402(62%) ART-experienced/suppressed, 112(17%) ART-experienced/unsuppressed, 57(9%) ART-experienced with unknown VL) and 938 on PIs (173(18%) ART-naïve, 318(34%) ART-experienced/suppressed, 304(32%) ART-experienced/unsuppressed, 143(15%) unknown VL). Median age was 14.0[IQR 11.8,15.9] years at DTG start and 13.7[10.9,15.8] years at PI start.

Among ART-naïve, ART-experienced/suppressed and ART-experienced/unsuppressed, VS at 48/96 weeks was 92%/93%, 94%/94% and 71%/73% on DTG and 74%/77%, 89%/89% and 58%/63% on PI, respectively. After PS-matching, VS among children ART-experienced/unsuppressed was 10.2%(95%CI -4.7,25.3) and 12.6%(-6.7,32.0) higher on DTG than PI at 48 and 96 weeks, respectively, and among ART-experienced/suppressed the difference was 4.0%(-1.8,9.8) and 1.8%(-4.7,8.2).

Mean zBMI change on DTG was highest among ART-experienced/unsuppressed (0.11(-0.01,0.24)(n=27) at 48 weeks and 0.33(0.00,0.66)(n=24) at 96 weeks and <0.1 for ART-naïve and ART-experienced/suppressed). After PS-matching, among children ART-experienced/unsuppressed, zBMI change at 48 and 96 weeks was 0.14(-0.01,0.29) and 0.43(0.04,0.82) higher on DTG than PI, and weight gain was 1.4kg(-0.3,3.1) and 2.3kg(-0.6,5.0) higher on DTG. Among ART-experienced/suppressed corresponding zBMI changes (-0.05(-0.16,0.06) and -0.14(-0.31,0.03)) and weight change (-1.0kg(-2.2,0.2) and -1.2kg(-3.0,0.6)) were lower on DTG than PI.

Conclusions: Overall viral suppression was higher on DTG- than PI-based regimens but the differences in the PS-matched analysis were not statistically significant. Greater gains in zBMI on DTG compared to PI were only observed among children ART-experienced and viremic at DTG/PI.

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Uptake and Outcomes of Tenofovir Alafenamide Fumarate (TAF) – Based Therapy in Children and Young People Living With HIV in the European Pregnancy and Paediatric Infections Cohort Collaboration

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Background: TAF was originally approved in Europe for children and young people living with HIV (CLWHIV) aged ≥6 years in 2016, initially as part of fixed-dose combinations (some approvals were extended to age ≥2 years in 2022). Data are limited on TAF uptake and outcomes in this population.

Materials and Methods: CLWHIV aged<18 years at HIV diagnosis and followed in 11 cohorts across Europe were included. Uptake of TAF, characteristics at TAF start and viral suppression (VS) (viral load (VL)<50c/ml) at 6, 12 and 18 months on TAF were described by treatment and VL status at TAF start.

Results: Of 3318 in follow-up since 2016, 670(20%) ever received TAF; 56% were female; 95% perinatally acquired HIV or aged<10 years at entry to HIV care; 36% from the UK, 26% Spain, 24% Italy, 15% elsewhere in Europe. Median age at ART initiation was 3.5[IQR 0.6,8.8] years.
At TAF start 11% were aged 5-11, 24% 12-17, 27% 18-23 and 20% ≥24 years. Half (48%) were on INSTI-based regimens, 31% PI, 13% NNRTI, 7% other/multiple classes: 66% previously used TDF. Twenty-one (3%) were treatment naïve and 649 (97%) treatment-experienced, of whom 51% were supressed (VL<50), 24% were viremic (VL≥50) and 25% had unknown VL at TAF start. Median age at TAF start was 14.8[14.2,16.4] for naïve,

17.1[13.8,22.1] for those treatment-experienced and supressed and 17.7[15.0,22.0] for treatment-experienced and viremic. CD4 count at TAF start was 373[211,660], 720[575,951] and 482[299,670] cells/mm3, respectively. Median duration on TAF was 1.2[0.6,2.0] years.
At 6, 12 and 18-months on TAF, overall VS was >80% but was lower (60-70%) in those treatment-experienced and viremic at TAF start. At 12 months after TAF start, VS was 100% (95%CI 72%-100%)(n=11) in those naïve, 86% (80-91%)(n=169) in those treatment-experienced and suppressed and 70% (56%-81%)(n=59) in treatment-experienced and viremic at TAF start.

Conclusions: One-fifth of CLWHIV in our pan-European cohort had received TAF, most were adolescents and young adults. Those virally suppressed at TAF start maintained good levels of suppression over follow-up, while two-thirds of those treatment-experienced and viremic at TAF start achieved viral suppression. Longer-term follow-up data are needed, particularly in younger children.

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Adverse Pregnancy Outcomes Following Dolutegravir Transition Among Women Delivering at Surveillance Sites in Eswatini

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Background: Preconception dolutegravir (DTG) was initially associated with neural tube defects (NTD) in the Botswana Tsepamo study, becoming nonsignificant with increased exposures. We conducted similar surveillance in Eswatini and describe overall birth outcomes by maternal HIV/antiretroviral therapy (ART) status.

Methods: Deliveries in five hospitals (73% births nationally) were surveilled September 2021-September 2022. Routine data on HIV/ART status and pregnancy outcomes for all deliveries were abstracted from clinic records. Women delivering live/stillborn infants with birth defects were consented for interviews and birth defect photographs; a medical geneticist conducted blinded review. We used Chi-square tests for infant outcome comparisons by maternal HIV/ART status; denominator was singleton live births for low birthweight (LBW) and preterm delivery (PTD) and all pregnancies (including miscarriages) for stillbirths.

Results: Among 24,830 deliveries, 7,554 (30%) were HIV-positive women, 6,220 (82%) receiving DTG-based ART: 4,832 DTG preconception, 1,027 new DTG initiation during pregnancy, and 367 unknown regimen at conception but on DTG at delivery; 1,328 women were on non-DTG-based ART preconception. 106 major surface birth defects were identified in live/stillbirths: 0.4% of 17,270 HIV-negative women (n=74), 0.4% of 4,832 women on DTG preconception (n=20), 0.6% of 1,328 on non-DTG ART preconception (n=8) and 0.3% of 1,084 newly diagnosed with HIV during pregnancy and no preconception ART (n=3). Nineteen (17.9%) major birth defects were NTDs, with no difference by HIV-negative status (13, 0.08%), HIV-positive status (6, 0.08%) and women on DTG preconception (4, 0.08%). There were 591 stillbirths. Compared to HIV-negative women, women with HIV were more likely to have a stillbirth (2.0% vs. 2.7%, p<0.001) and slightly higher rates of LBW (11.8% vs. 13.2%, p=0.004) and PTD (10.3% vs. 11.7%, p=0.001). There were no significant differences between DTG and non-DTG preconception groups for NTD (0.08% vs. 0.16%, p=0.62), stillbirth (2.6% vs. 3.2%, p=0.19), LBW (12.7% vs. 13.7%, p=0.35), or PTD (11.4% vs. 11.8%, p=0.65).

Conclusions: With 80% of HIV-positive women receiving DTG-based ART at conception, HIV-positive women had slightly higher adverse pregnancy outcomes than HIV-negative women. There was no evidence that DTG preconception increased rate of any adverse outcome compared to non-DTG preconception.

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Estimated Prevalence and Trends in Viral Load Non-suppression Among Antiretroviral Treatment-Experienced Pre-adolescent Children in Kenya, 2015–2021: A Nationwide Population-Based Cohort Study

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Background: Virological non-suppression (VLNS) in children is a major public health concern because uncontrolled viremia increases the risk of mortality and morbidity. We aimed to estimate the VLNS trend and factors associated with it in Kenyan pre-adolescent (0–12 years old) children between 2015 and 2021.

Methods: Participants were eligible if they were enrolled in any of the country's HIV point-of-care clinics, had an HIV-positive test, were on ART treatment, and were <12 years old during the study period. The viral load data for the study came from the Kenya National AIDS & STI Control Program's (NASCOP) VL/EID database. The Mann-Kendall trend test was used to estimate the VLNS trends while multivariable logistic regression model was used to identify the factors associated with VLNS.

Results: Between 2015 and 2021, 508 743 viral load assays on pre-adolescent children were conducted. The prevalence of VLNS in 2015 was 22.9% [22.4–23.3] which declined to 12.5% [12.1–12.9] in 2021. A Mann-Kendall trend test revealed a significant decreasing trend (τ = -0.333, $p < 0.001$). In the multivariable analysis, factors positively associated with VLNS were: sex-male (aOR 1.17, 95% CI 1.15–1.19; $p < 0.001$); and NVP based first-line ART regimen specifically ABC+3TC+NVP (aOR 1.37, 95% CI 1.34–1.41; $p < 0.001$). The factors negatively associated with VLNS were: DTG-based regimen specifically TDF+3TC+DTG (aOR 0.36, 95% CI 0.34–0.38; $p < 0.001$); and year of the test (aOR 0.86, 95% CI 0.85–0.87; $p < 0{\cdot}001$) after adjustment for all the model covariates

Conclusions: The Mann-Kendall trend test shows a significant decreasing trend from 2015 to 2021. To sustain the decreasing trend, accelerating the switch from the suboptimal NVP first-line regimen to the DTG regimen is warranted. However, a focus on arid and semi-arid counties that have lagged in creating geographical VLNS hotspots is needed.

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Uptake of New Pharmacovigilance Tool to Assess Acceptability and Tolerability of Pediatric Antiretroviral Drugs in Kenya

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Introduction: Pharmacovigilance enables detection of intolerance and adverse drug reactions (ADR). We developed an acceptability/tolerability (AT) assessment tool for children starting or switching to pediatric dolutegravir (pDTG) and evaluated its uptake in Homa Bay County, Kenya.

Methods: From February-June 2022, we rolled out a paper-based AT assessment tool at 35 healthcare facilities. We conducted a retrospective review of medical records with completed AT tools in children initiating pDTG from March-July 2022. From October-November 2022, we surveyed 42 healthcare workers (HCWs) who administered the AT tool and assessed their use of the tool.

Results: We collected data from 502 follow-up visits for 248 children (124 males, median age 5 years, median weight 16 kg) initiating a pDTG-based regimen. Among all visits within three months of pDTG initiation, 16 ADRs were reported (3%): appetite change (4), vomiting (4), skin rash (1),

pallor/dizziness (1), lack of weight gain (1), and weight gain (5). None were life threatening or required regimen change. Follow-up visit attendance decreased from 198 children (80%) at two-week follow-up to 67 (27%) at three months, affecting ability to monitor ADRs. HCWs completed the AT tool for 502/590 (85%) of follow-up visits, with use declining from 93% of children at the two-week visit to 63% at three months. Most HCWs found the tool useful (98%), easy to fill in (100%), and would recommend it to colleagues (100%), but would prefer the tool in electronic format (98%). The majority of AT tools were filled by clinical officers (62%), followed by adherence counsellors (22%), but adherence counsellors were more likely than clinical officers to fully complete tools, 88% versus 73% respectively.

Conclusion: Our results indicate that pDTG-based ARV regimens for children 3 kg – 20 kg in Kenya were well tolerated, with 3% of patient visits reporting mild ADRs. Limitations to pharmacovigilance were decreased adherence to follow-up visits over time, and the short three-month period of monitoring. Next steps to advance active pharmacovigilance of pediatric ARVs include integrating the AT assessment tool into electronic medical records with links to the Pharmacy and Poisons Board reporting system, and ongoing training and mentorship of HCWs.

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Follow-up Outcomes of Children, Adolescents and Young People on Darunavir-Based Third-line Antiretroviral Therapy – Observational Cohort from Nine African Countries

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Background: Ritonavir-boosted darunavir, combined with a nucleoside reverse transcriptase inhibitors backbone, with or without dolutegravir is recommended for third-line antiretroviral therapy in children living with HIV. We assessed clinical outcomes among children, adolescents and young people (<25 years) on darunavir-based antiretroviral therapy (ART) in nine sub-Saharan African countries.

Methods: From January 2019 to December 2022, we collected data from an observational cohort of children, adolescents and young people receiving third-line ART from HIV treatment centers in Cameroon, Eswatini, Kenya, Lesotho, Nigeria, Rwanda, Uganda, Zambia and Zimbabwe. Data on treatment continuity, viral suppression, death and clinic transfers were extracted from patient medical records, at baseline and every 6 months during follow-up. Data were summarized as frequencies and proportions; Kaplan Meier estimates were used to describe retention in care and time to death; and multivariable Cox proportional hazards model were used to identify factors independently associated with retention in care.

Results: Of 871 participants enrolled, 488 (56.0%) were female, median age 14.8 (range: 0.2 – 24.7) years; 694 (79.7%) had previously been on lopinavir or atazanavir-based ART; 72 (8.3%) on efavirenz or nevirapine-based ART, 57 (6.5%) on dolutegravir and 48 (5.5%) on other regimens. Of 820 (94.1%) participants with final outcomes after initiating darunavir-based third-line ART; [median duration of follow-up: 28.3 months (IQR:17.5 – 45.2)], 720 (87.8%) were alive and in care at the end of study follow-up, 29 (3.5%) died, 30 (3.7%) transferred to other facilities, and 41 (5.0%) were lost to follow-up. Altogether, 98.4%, 97.4% and 86.6% of participants remained in care at 6, 12 months, and 5 years, respectively. Retention in care was less likely among males compared to females (aHR: 0.85, 95%CI 0.72-1.0), and in 10-14-year-olds compared to younger children. Adolescents 15-19 years had higher mortality compared to children under 10 years of age (aSHR: 4.20, 95% CI 1.37-12.87). Viral suppression was seen in 345/433 (79.7%), 249/320 (77.8%), and 546/674 (81.0%) patients with results at 6, 12 months and end of follow-up, respectively.

Conclusion: A high proportion of children and young people receiving darunavir-based third-line ART in Sub-Saharan Africa, remain in care, and attain viral suppression during follow-up.

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Preexisting and Postbaseline Resistance Analyses in Pooled Pediatric Studies of Emtricitabine/Tenofovir Alafenamide (F/TAF)-based Antiretroviral Therapy (ART)

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Background: We present pooled analyses of baseline resistance and after long-term follow-up from four studies evaluating F/TAF-based ART in pediatric populations.

Material and Methods: Treatment-naïve (TN) or virologically suppressed (VS) participants, aged 2 to <18 years, received bictegravir/F/TAF (B/F/TAF), elvitegravir/cobicistat/F/TAF (E/C/F/TAF) or F/TAF+third agent. Baseline resistance was assessed by RNA or DNA HIV-1 genotyping and/or historical genotype. Postbaseline HIV-1 genotyping/phenotyping was performed for participants with HIV-1 RNA >200 (B/F/TAF) or >400 copies/mL (E/C/F/TAF, F/TAF+third agent) at confirmed virologic failure or last visit. Outcomes were determined by HIV-1 RNA at last on-treatment visit.

Results: 341 participants were enrolled and treated: 122 B/F/TAF, 179 E/C/F/TAF, 40 F/TAF+third agent. Median age was 12 years. Baseline genotypic data were available for 100% (50/50) of TN and 28% (82/291) of VS participants; 39% (132/341) had protease/reverse transcriptase data and 35% (121/341) had integrase data. At least one preexisting primary resistance substitution was identified in 30% (39/132; 31 B/F/TAF, 8 E/C/F/TAF). NNRTI resistance was most commonly reported (20%; 27/132), followed by NRTI resistance (15%; 20/132). Protease inhibitor (PI) resistance occurred in 7% (9/132), and integrase strand transfer inhibitor (INSTI) resistance in 4% (5/121). At least one thymidine analog mutation (TAM) was identified in 10% (13/132), and M184V/I in 9% (12/132). Median treatment duration was 157 weeks; 95% (323/341) had virologic suppression at last visit, including 92% (36/39) with and 95% (88/93) without preexisting resistance. Of participants with NNRTI, NRTI, PI, or INSTI resistance, ≥1 TAM or M184V/I, 93% (25/27), 90% (18/20), 100% (9/9), 80% (4/5), 92% (12/13) and 83% (10/12), respectively, had HIV-1 RNA <50 copies/mL at last visit. Overall, 9% (32/341) met the criteria for postbaseline testing (9 B/F/TAF, 19 E/C/F/TAF, 4 F/TAF+third agent). No treatment-emergent resistance to B/F/TAF or E/C/F/TAF was found. Study drug resistance was detected in four participants without baseline data receiving F/TAF+efavirenz: all had NNRTI resistance and two had K65R, one with M184V. All four switched third agents; three achieved virologic resuppression (including two with K65R+/-M184V).

Conclusions: High levels of virologic suppression through 157 weeks of follow-up, regardless of preexisting resistance, demonstrate the efficacy of F/TAF-based ART in children.

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Integrase Inhibitor Use in Children Living With HIV the European Pregnancy and Paediatric Infections Cohort Collaboration (EPPICC) Over the Last Decade: Uptake and Virological Response

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Background: Integrase inhibitors (INSTIs) were first approved for paediatrics from 2013 and are preferred anchor drugs for children living with HIV (CLWHIV). We assessed INSTI uptake and virological response in CLWHIV across Europe and Thailand between 2010-2020.

Materials and Methods: CLWHIV in paediatric HIV cohorts in EPPICC, aged<18 years at start of each calendar year, were included in repeated cross-sectional analyses to describe trends in INSTI use over time. Characteristics at INSTI start, and proportion virally suppressed (VS)<50copies/mL at 12 and 24-months were described by treatment and viral load status at INSTI start.

Results: Of 7,835 CLWHIV included, the proportion taking INSTI increased from 0% in 2010 and 1% in 2015 to 22% in 2020. Uptake was highest in Western Europe, with 50% on INSTI by 2020, compared to ≤11% in other regions (Eastern/Central Europe, Russia).
Among 1,674 ever taking INSTI, 65%(1,085) received dolutegravir(DTG), 32%(532) raltegravir(RAL), 11%(176) elvitegravir(EVG) and 1%(18) bictegravir(BIC). 53% were female, median age at INSTI start was 13 years [IQR 10,15]. 23% were aged<6 years at start of RAL compared to ≤2% on other INSTIs. At drug start, the proportion naïve, treatment-experienced and VS, treatment-experienced and viremic (≥50copies/mL) were: 9%, 50% and 22% for DTG, 8%, 26%, 39% for RAL, 3%, 63% and 18% for EVG and 11%, 39% and 22% for BIC, respectively; the remainder were treatment-experienced with missing viral load.
At 12 and 24-months after INSTI start, the proportion VS was highest among those naïve (83%(95% CI 71-92) and 85%(71-94) on DTG, 77%(55-92) and 72%(47-90) on RAL, respectively) (insufficient numbers on EVG and BIC) or treatment-experienced and VS at drug start (93%(90-95) and 93%(89-96) on DTG, 89%(81-95) and 95%(87-99) on RAL, 91%(83-96) and 95%(85-99) on EVG, respectively). VS at 12 and 24-months was lowest among those treatment-experienced and viremic at drug start: 65%(57-73) and 64%(54-73) on DTG, 58%(50-66) and 60%(51-68) on RAL, 57%(34-78) and 50%(19-81) on EVG, respectively).

Conclusion: Half of CLWHIV in Western Europe were on INSTIs by 2020 but there was much less access in Eastern/Central Europe and Russia. Viral suppression was markedly lower (<70%) among children treatment-experienced and viremic at INSTI start.

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Weight Change and Metabolic Assessment of Virologically Suppressed Children With HIV Aged ≥2 Years and Weighing 14 to <25 KG Who Received a TAF-containing Regimen

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Background: Antiretrovirals have differing effects on weight and metabolic parameters. The impact of tenofovir alafenamide (TAF) on weight has not been reported in children aged <6 years. This analysis explored the effect of switching to a TAF-based regimen on weight, height and lipid metabolism in children aged ≥2 years with virologic suppression of HIV.

Material and Methods: Children aged ≥2 years and weighing 14 to <25 kg from two ongoing, open-label studies received bictegravir/emtricitabine/TAF (B/F/TAF; NCT02881320) or elvitegravir/cobicistat/F/TAF (E/C/F/TAF; NCT01854775) for ≥48 weeks. Demographics and changes in weight, height, body mass index (BMI) and lipid metabolism were analyzed in the pooled population.

Results: Overall, 49 participants were included in the analysis (B/F/TAF: n=22; E/C/F/TAF: n=27). Median age was 6 years, 42.9% were male and 81.6% were Black. At Week 48, increases (median [interquartile range; IQR]) from baseline were observed in weight Z-score (0.26 [0.00, 0.51]), height Z-score (0.06 [-0.26, 0.37]), BMI Z-score (0.31 [-0.32, 0.85]) and BMI-for-age percentile (4.1 [-4.8, 17.3]). The proportion of participants who were underweight decreased (20.4% [baseline] to 14.3% [Week 48]), normal weight increased (67.3% to 73.5%), and overweight/obese remained at 12.2%. Baseline lipid metabolism parameters (median [IQR]) were as follows (mg/dL): total cholesterol, 167 (155, 183), low-density lipoprotein, 107 (93,

128), high-density lipoprotein, 54 (47, 67), and triglycerides, 86 (62, 116); all decreased from baseline to Week 48 (-11 [-30, 7], -14 [-28, 1], -4 [-9, 4], and -11 [-45, 16], respectively). Assessment categories for lipid metabolism parameters generally improved: acceptable levels of total cholesterol and low-density lipoprotein both increased from 52.2% to 69.6% of participants, while acceptable levels of triglycerides increased from 45.7% to 60.9%. Low levels of high-density lipoprotein increased from 4.3% to 15.2% of participants.

Conclusions: At Week 48, the proportion of participants who were underweight decreased and the proportion who were normal weight increased, while the proportion who were overweight or obese remained stable. Overall, lipid metabolism parameters improved during 48 weeks of treatment. These changes are consistent with normal child development during this timeframe and support the use of TAF in this population.

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Antiretroviral Therapy Regimens and Viral Suppression Among Adolescents on HIV Treatment in Kenya

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Introduction: There are approximately 99,159 adolescents living with human immunodeficiency virus in Kenya, with a viral suppression rate of 67%, according to the Joint United Nations Program on HIV/AIDS(UNAIDS) in 2021 [1]. There are limited studies in Kenya on the types of regimens associated with viral load suppression among adolescent. This study aimed to determine the Antiretroviral therapy regimens and the viral suppression outcome among adolescents on antiretroviral therapy.

Methods: A retrospective cross-sectional analysis of 38,503 HIV-infected adolescents (10-19 years) receiving antiretroviral therapy for at least 6 months with a documented viral load was conducted. The data analyzed was HIV program data in Kenya from electronic medical records stored at the National Aids and STI Control Program (NASCOP) for the period of January 2018–December 2022.

Results: The viral suppression was at 81.2%, distinctly higher than the 2021 UNAIDS estimate of 67%.and the national suppression rate of 75% from the Kenya health information system report of 2022. Virologic suppression with ABC and TDF was 81.6% and 86.4%, respectively. The suppression with protease inhibitors-based regimens was 70% (highest) and 56.4% (Lowest). 3TC+DTG+TDF showed the highest viral suppression rate at 86.4% while 3TC+ABC+DTG showed a viral suppression rate of 81.6%. (AOR 0.57, 95% CI -1.65). The 3TC+ATV/r +TDF had a viral suppression rate of 70.1%, (AOR 0.4, 95% CI -0.34-0.45) relatively lower but significant. The other ART regimens showed lower viral suppression rates among adolescents in Kenya, with 3TC+ATV/r +AZT at 62.7%, (AOR 0.28, 95% CI -0.24-0.32), 3TC+AZT+LPV/r at 62.2%, (AOR 0.23, 95% CI -0.21-0.26), 3TC+AZT+DTG at 58.7%, (AOR 0.2, 95% CI -0.17-0.22) and 3TC+ABC+LPV/r at 56.4%. (AOR 0.18, 95% CI -0.16-0.20).

Conclusion: There was better viral suppression for adolescents who were on Integrase Strand Transfer Inhibitor (INSTI) based regimens compared to those on protease inhibitors either as first line or second line regimens. There is a need to interrogate the viral suppression, for the adolescents on protease inhibitors-based regimens and consider switching to optimal regimens in order to realize better treatment outcomes.

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Adherence to Antiretroviral Therapy (ART), Drug Resistance, and Their Impact on Evolving Viral Suppression Among a Long-Term Cohort of Youth Living With Perinatal HIV Infection in Western Kenya

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Background: In African settings, youth living with HIV (YLWH) rarely have comprehensive antiretroviral therapy (ART) adherence monitoring or drug resistance (DR) testing. We longitudinally assessed ART adherence and its impact on viral outcomes among Kenyan YLWH.

Methods: YLWH ≤15 years on NNRTI-based 1st line ART were enrolled at the Academic Model Providing Access To Healthcare (AMPATH) in western Kenya. Adherence was monitored prospectively by caregiver-reported questionnaires, electronic dose monitors (MEMS) and NNRTI plasma drug levels at months 1 (M1) and 4 (M4), defined as: (1) number of missed/late doses, (2) % MEMS openings, (3) MEMS interruptions ³48 hours, (4) duration of maximum interruption, and (5) low/therapeutic/high plasma NNRTI levels. DR was evaluated upon treatment failure (TF; viral load (VL) >1,000 copies/mL). TF was modeled with logistic regression (odds ratio (OR) and 95% confidence interval (CI) for each adherence measure, adjusted for age, CD4%, ART duration and sex). DR mutations (DRMs) were modeled with Poisson regression (rate ratio (RR) and CI). Interaction terms were examined if adherence effect on M4 TF differed by M1 TF status.

Results: At enrollment, 692 participants (51% female; median age 8.4 years) had median 2.6 years on ART. All were on nevirapine/efavirenz-based regimens, most combined with abacavir/lamivudine. Of 464 with M1 VLs, 143 (31%) had TF. Among those with M1 TF, 43% had TF at M4. Lower percent MEMS adherence was associated with TF (OR=0.69 per 1 unit z-score higher MEMS adherence, 95% CI=0.50-0.95), as was more enrollment non-adherence (OR=1.25 per 1 higher non-adherence, 95% CI=1.05-1.48). DRMs were detected in 93% of the 120/143 available M1 genotypes. The M1 DRM number was greater for those with shorter maximum treatment interruptions (log-10 transformed (RR)=0.63, CI=0.42-0.94)), more ART years (Log-10 transformed RR=1.47, CI=1.15-1.89)), and higher M1 log-10 VL (RR=1.21, CI=1.06-1.37)). Percent adherence by MEMS® had a significant, U-shaped relationship, with most DRMs at lower (<50%) adherence. Having therapeutic (RR=2.11, CI=1.45-3.08) or supra-therapeutic (RR=1.58, CI=1.11-2.27) vs. sub-therapeutic drug levels was associated with more DRMs.

Conclusions: Extensive non-adherence, associated with high TF and DR were seen in Kenyan youth with HIV, outcomes assumed - but seldom documented in this setting.

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Change in Body Mass Composition (BMC) in Adolescents and Children With HIV Starting Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF)

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Background: Antiretrovirals may impact weight, but the relationship of E/C/F/TAF with weight and

BMC in children has not been fully assessed. We evaluated changes in BMC from baseline to Week (W) 48 in children/adolescents aged 2–<18 years weighing ≥14 kg who initiated E/C/F/TAF.

Material and Methods: GS-US-292-0106 (NCT01854775) is a Phase 2/3, open-label study evaluating E/C/F/TAF in treatment-naïve adolescents aged ≥12 years weighing ≥35 kg (Cohort 1 [C1]), and children with virologic suppression aged 6–<12 years weighing ≥25 kg (C2) or aged ≥2 years and weighing ≥14 kg (C3). We evaluated changes in anthropometric measures alongside fat mass (FM) and lean mass (LM).

Results: 129 participants were included (C1: n=50; C2: n=52; C3: n=27), with median ages per cohort of 15, 10 and 6 years, respectively. Percentages of female and Black participants were 56% and 88% in C1; 58% and 71% in C2; and 63% and 89% in C3, respectively. Median baseline CD4 counts were 456, 926 and 1,061 cells/µL, respectively. There were increases from baseline in median (Q1, Q3) total FM and LM at W48 across all cohorts (C1: by 1.6 [0.4–3.8] kg and 2.6 [0.7–4.3] kg, C2 by 2.3 [0.9–3.7] kg and 1.5 [-0.5–2.9] kg and C3 by 0.8 [0.4–1.4] kg and 1.6 [1.1–2.1] kg). Percentage total FM increased from baseline in C1 and C2 and remained stable in C3. Increasing body mass index (BMI)-for-age positively correlated with accretion of total FM in C1 and C2, and with accretion of total LM in C1 and C3 (p<0.05 for all). According to stepwise multivariate linear regression analysis, being in C2 (6–<12 years) was associated with a larger increase in BMI-for-age versus C1 (≥12 years) at W48 (p<0.15).

Conclusions: In children and adolescents receiving E/C/T/TAF, total FM and LM increased between baseline and W48. Increases in total FM directly correlated with increases in BMI-for-age, particularly in children aged 6–<12 years. This is consistent with expected physiological changes in this age group, where faster growth is associated with faster FM accretion and pubarche. Overall, BMC changes after initiating E/C/F/TAF were consistent with growth dynamics in general pediatric populations.

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Virological Outcomes and Associated Factors Among Children Living With HIV Initiating or Switching to Pediatric Dolutegravir in the Democratic Republic of Congo

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Per World Health Organization recommendations, dolutegravir (DTG) is the standard of care for antiretroviral therapy (ART) for children living with HIV (CLHIV). We assessed ART switching rates and viral load suppression (VLS) among children initiating or switching to DTG in the Democratic Republic of the Congo (DRC) following the introduction of 50mg DTG for children ≥20kg in June 2019 and 10mg pediatric DTG (pDTG) for children <20kg in January 2022. Before December 2021, children <20 kg were initiated on ritonavir-boosted lopinavir (LPV/r)-ART

CLHIV ages 0-14 years newly/currently enrolled in HIV services at 20 health facilities in Kinshasa in June 2019-July 2022 were included in this retrospective cohort. Data were extracted in June-December 2022 from electronic clinical records. We assessed the number of anchor drug switches, viral load (VL) coverage per guidelines (six months after initiation/switch) and VLS rates (<1000 copies/mL).

Of 801 children enrolled in HIV services (median age 7.7 years [5.2-10.4], 51.7% female), 699 (87.3%) started on/switched to DTG-ART. 546/801 (68.2%) children newly initiated ART; 316 (57.9%) were started on DTG-ART 50mg (n=307) or 10mg (n=9). Over half of children (426/801, 53.2%) maintained the same antiretroviral anchor drug throughout follow-up; 307 children (38.3%) had one anchor drug switch; and 68 (8.5%) had 2-5 switches. Most switches (220/375, 58.7%) were from LPV/r to DTG-ART. Of 681 children who received DTG-ART >6 months before study end, VL was measured in 392 (56.6%), despite 668 (98.1%) remaining active in care (4 lost-to-care, 6 transferred, 3 died). Of those ever on DTG, 499 received continuous DTG for ≥6

months; of these, 301 (60.3%) had VL ≥6 months after starting DTG, with a 90.0% VLS rate. Of the 301 with VL measured, 159 (52.8%) had newly initiated ART and achieved greater VLS compared to 142 ART-experienced children (94.3% vs. 85.2%, p-value=0.008).

Most children transitioned to DTG-based regimens; among those receiving VL testing, >85% achieved VLS after ≥6 months DTG-ART. Better virological outcomes were found for newly-initiated compared to ART-experienced children. However, VL monitoring was not performed for 43% of children after switching to or starting DTG, despite most of them remaining in clinical care.

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Pharmacokinetics and Virological Efficacy of Dolutegravir Dispersible Tablets in Thai Children Weighing Less Than 20 KG

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Background: Dolutegravir (DTG) dispersible tablet (DTG-DT) is a pediatric-friendly formulation recommended for young children living with HIV. We aimed to describe the pharmacokinetics (PK) and virological responses of generic DTG-DT as part of antiretroviral therapy in young children weighing 6 to <20 kg.

Methods: Children living with HIV-1, treatment-experienced, aged 3 months to 7 years, weighing 6 to <20 kg were eligible. A generic 10-mg scored DTG-DT formulation (Viatris Ltd) was used. Participants were divided into three weight bands(WB): WB1 (6 to <10 kg), WB2 (10 to <14 kg), and WB3 (14 to <20 kg)and received DTG-DT 20 mg, 20 mg, and 25 mg, respectively. Doses follow WHO recommendations, except for a higher dose for children 6 to <10 kg (20 mg vs. 15 mg). Abacavir/lamivudine DT (120/60 mg) was administered as the NRTI backbone. Steady-state PK was assessed with blood drawn pre-dose and 1, 2, 3, 4, 6, and 24 hrs post-dose. A non-compartmental PK analysis was performed using Phoenix-WinNonlin(v.8.3). DTG trough concentrations (Ctrough) and 24-h area under the curve (AUC0-24h) were calculated. HIV viral suppression was defined as plasma HIV RNA<200 copies/mL and assessed at weeks-24 and 48.

Results: From August 2021 to March 2023, 29 children with a median (IQR) age of 3.2(1.5-5.8) years were enrolled; 8 in WB1, 9 in WB2, and 12 in WB3. Before DTG-DT initiation, 12 had HIV viremia [median (IQR) HIV RNA 4.3 (3.7-5.0) log10 copies/mL], and 17 had plasma HIV RNA<200 copies/mL. PK sampling was performed at median (IQR) 12 (9-12) days after DTG initiation. Geometric mean (coefficient of variation percentage,CV%) DTG Ctrough was 1.02 (46%) mg/L [WB1, 0.93(53%); WB2, 0.89(27%); WB3, 1.20(51%)] and geometric mean (CV%) DTG AUC0-24h was 83.23 (24%) h×mg/L [WB1, 84.34(31%); WB2, 76.85(16%); WB3, 87.58(25%)]. HIV viral suppression rates at weeks-24 and 48 were 89% and 92%, respectively. One participant in WB3 had grade-2 impaired GFR (declined from 63 to 55 mL/min).

Conclusions: Generic scored 10-mg DTG dispersible tablets provided adequate drug exposure in Thai children weighing 6 to<20 kg. A higher DTG-DT dose of 20 mg in children weighing 6 to<10 kg improved DTG exposure without serious adverse effects.

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High Acceptability and Preference for Pediatric Dolutegravir 10mg among Patients in Nigeria at 1- and 6-month Follow Up, an Abservational Study

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Background: Nigeria is an early adopter country of the generic formulation of pediatric dolutegravir 10mg (pDTG) that became accessible in December 2020. This study aims to assess the acceptability and preference of pDTG among patients newly initiated or transitioned to the drug. Findings from the study was used to guide national scale-up.

Methods: Pediatric patients weighing >3kg and <20kg were enrolled between September and December 2021 in 7 sites across 7 state (Akwa-Ibom, Benue, Cross river, Lagos, Plateau, Rivers and Sokoto). Acceptability and experiences were assessed through surveys conducted with patients and their caregivers as respondents at 1 and 6 months following pDTG initiation using a structured questionnaire. Participants were asked about side effects, ease of administration, and regimen preferences. Data from 1- and 6-month follow-ups were analyzed for frequencies and trends.

Results: The study enrolled 180 patients and the mean age was 4.7 years, with 98% being treatment experienced. At month 1, 99% of the treatment experienced respondents prefer the pDTG-based regimen to their previous regimen, this increased to 100% at month 6. On ease of administration, at month 6, 99% and 100% of respondents respectively reported that pDTG tastes better and was easier to administer than previous regimen, compared to 99% and 96% respectively at month 1. 99% of respondents at both months 1 and 6 were satisfied or very satisfied with their pDTG regimen.

The most common side-effect reported at months 1 and 6 was increased appetite (25% and 43% respectively). 97% and 94% of respondents at months 1 and 6 respectively reported that the patient either gained weight appropriately or had no change in weight. Hyperactivity was reported by 29% of participants at month 6.

Conclusion: There is a high acceptability and preference for pDTG compared to legacy regimens such as LPV/r, with improved taste and ease of administration. Increased appetite was the most common side-effect reported. With the favorable findings from the study to date, national HIV program has commenced scale-up of pDTG with emphasis on pharmacovigilance. Further follow-up at 12 months will provide more evidence of pDTG's impact.

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Improved Viral Load Suppression With Transition to Pediatric Dolutegravir Among ART-experienced children in Kenya and Cote d'Ivoire

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Background: Access to safer and more efficacious and tolerable antiretroviral therapy (ART) is recommended for children and adolescents living with HIV (CALHIV). We evaluated viral load (VL) suppression at baseline and subsequent VL outcomes in a cohort of ART-experienced children who transitioned to dolutegravir (DTG)-based ART in Kenya and Cote d'Ivoire (CDI).

Method: This was an observational prospective cohort study of ART-experienced CALHIV who

transitioned to DTG-based regimens. CALHIV 0-14 years, weighing 3-20 kilograms, were enrolled in 12 randomly selected facilities in CDI and Kenya, November 2021-May 2022 and followed for 12 months. Study facilities were randomly selected using probability proportional to size. Demographic data were collected, and VL testing were completed at baseline, 6 and 12 months. The national guidelines on use of antiretroviral drugs for treating and preventing HIV recommend VL monitoring at baseline, 6 and 12 months for CALHIV who are optimized on DTG-based regimen. Data were summarized using frequencies and proportions, as well as median and interquartile ranges.

Results: Overall, 676 CALHIV initiated pediatric DTG with a median age of 9 (IQR: 6-12) years were enrolled into the study. A total of 355 (52.5%) were female, and 639 (83.3%) were living with biological parents. About three quarters (73.2%, 494/676) of the CALHIV were on a protease inhibitor-based regimen prior to DTG initiation. Median duration on ART regimen prior to DTG transition was 59 (IQR: 32, 84) months. Baseline VL uptake was 494/676 (83.3%). The uptake dropped to, 50% at 6 months and 74% at 12 months. Compared to a VL suppression of 80.6% [95% Confidence Interval (CI): 77.4%, 83.9%] at baseline, overall suppression was 87.7% [95% CI: 83.6%, 91.7%] at 6 months (p=0.013), and 89.6% [95% CI: 85.8%, 93.5%] at 12 months (p=0.002) post-DTG transition. There was no statistically significant difference in the viral load suppression at 6 and 12 months post-DTG transition (p=0.486).

Conclusions: While there remain challenges with viral load uptake and testing at time of transition to optimized regimen and follow up for CALHIV, there is improved VL suppression with DTG transition.

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Lessons Learned on the Successes and Barriers of Uganda's pDTG Implementation

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Background: In 2021, an estimated 88,000 children aged less than 15 years were living with HIV in Uganda, and an estimated 4,000 children died from AIDS-related causes. In late 2021, Uganda utilized a phased implementation plan to begin transitioning children to pDTG due to its improved efficacy and tolerability relative to existing regimens.

Description: Uganda was one of the first countries in the region to introduce pDTG for eligible children in October 2021. The transition process required stakeholder coordination, the development of a phased implementation plan, adaptation of educational materials and job aids, community engagement, routine monitoring and reporting efforts, and national target-setting. As of September 2022, 87% of eligible children have been transitioned to pDTG.

Lessons Learned: Stakeholder engagement was an important first step for the introduction of pDTG in Uganda, as buy-in from the Ministry of Health and donors was critical. To mitigate concerns regarding legacy stock wastage, a phased implementation plan was developed to first transition newly initiating and virally unsuppressed clients to pDTG, before transitioning stable clients on existing regimens. Global pDTG educational materials and job aides were adapted to fit the Uganda context before being used to supplement virtual facility trainings. In parallel, treatment literacy information was disseminated to and via communities of people living with HIV to support demand generation. Monitoring and reporting was also prioritized to track uptake of pDTG, which encompassed efforts to include pDTG in existing national tools. As implementation unfolded, MOH set targets for transition, and conducted data calls and supervisory visits to select low-performing facilities

to ensure targets could be met. By September 2022, 87% of eligible children were transitioned to pDTG, falling just short of the 95% transition target. Barriers identified that prevented an even more accelerated transition were initial healthcare worker concerns over legacy stock wastage and the national requirement for a pre-transition viral load. Steps are being undertaken to analyze and then address gaps in uptake at specific facilities.

Conclusion: Success factors and barriers to transition that arose in the pDTG introduction and scale-up in Uganda provides a roadmap for other countries optimizing pediatric ART regimens.

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Barriers to ART Adherence in Neonates and Infants from the LIFE Study in Mozambique

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Background: In 2021, only 65% of Mozambican children on antiretroviral therapy (ART) were virologically suppressed. Poor adherence is the principal driver of ART failure, and a deeper understanding of underlying causes is needed for improved treatment support, particularly for infants who have even lower suppression rates. Data from intensified adherence support visits for HIV-positive neonates and infants enrolled in the LIFE study in Mozambique were analyzed to address this knowledge gap.

Methods: Infants with positive point-of-care virologic tests at birth or post-natal visits initiated ART and were followed up to 18 months of age, with routine viral load monitoring. Information from adherence interventions was extracted from narrative reports and merged with clinical data.
Results: A total of 117 recruited infants tested HIV-positive. DTG-based ART was initiated in 2 (1.7%) infants and 39 (33.3%) transitioned from LPVr to DTG-based ART. At 6, 12, and 18-month study visits, 70.3%, 72.7%, and 63.6% of caregivers reported no ART interruptions in the past week. Virologic suppression rates for the same study visits were 31.1%, 47.0%, and 50.9%. Qualitative adherence data was available for 62.4% (73/117) of participants. The percentage of infants with reported barriers by category were: 1) paternal-related, 72.6% (53/73); 2) maternal-related, 60.3% (44/73); 3) socioeconomic, 42.5%(31/73); 4) medication-related, 32.9% (24/73); and 5) provider-related, 5.5%(4/73). Non-disclosure to the father was a noted adherence barrier for 28.8% (21/73). Excluding infants with missing data, 33.7%(28/83) of mothers had not disclosed their serostatus to the father by the first adherence intervention, and 75.0%(21/28) of them lived with the father. Fear of abandonment was the most common reason for non-disclosure to fathers, reported for 67.9%(19/28) of mothers.

Conclusions: Medication-related adherence barriers were common, and most children received LPVr-based ART. It was not possible to quantify in this analysis, but the recent introduction of dispersible DTG tablets, allowing for once-daily dosing, has the potential to improve the unacceptably low virologic suppression rates observed. However, the impact of optimized pediatric ART will be minimized without intensified and proactive efforts to identify and address family-specific barriers that adversely impact adherence, with particular attention to paternal factors and serostatus disclosure.

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Early Virological Response to Dolutegravir in Children and Adolescents Living with HIV in Ugandan UP-ART Cohort Study

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Background: Dolutegravir (DTG) is the preferred anchor drug for first and subsequent-line treatment

of children and adolescents living with HIV (CALHIV). We assessed early virological response to DTG in CLWHIV in routine HIV care in Uganda.

Materials and Methods: Children and adolescent aged ≤19 years at diagnosis of HIV and attending HIV care at three participating centres were enrolled in the UP-ART observational cohort study. Individual level data on clinical and treatment history were extracted from electronic medical records (data cut-off February 2023). We describe DTG uptake, demographic and clinical characteristics at DTG start and proportion with viral suppression (VS) (viral load (VL)<1000copies/mL) at 6, 12, 16 and 24-months of DTG overall, by treatment and VL status at DTG start.

Results: Of 1,364 CALHIV in UP-ART, 1,306(95.6%) ever received DTG and included in further analysis. Just over half (52.8%) were female, median age at HIV diagnosis/entry to HIV care was 4.5[IQR 1.84,8.36] years. At DTG start, the median age was 12[9.1,16.1] years, 9.5% were ART naïve, 58.2% treatment-experienced and VS, 5.1% treatment-experienced and viraemic (≥1000copies/mL) and 27.2% were treatment-experienced with no VL available within 6-months prior to DTG start. The most common treatment combination was TDF/3TC/DTG (57.4%) and ABC+3TC+DTG (31.9%).
The median duration on DTG was 15.4[0.9,26.2] months. Overall, 2 participants died, 1 withdrew, 14 transferred out. Among CALHIV on DTG at 6, 12, 18 and 24-months after DTG start, 602/809(74.4%), 483/657(73.5%) and 418/556(75.2%) and 267/397(67.3%) had a viral load measurement available, respectively.
Overall VS was >90% at 6, 12, 18 and 24 months. Suppression was highest among those treatment-experienced and VS at DTG start (94%(95%CI 91-96), 93%(89-96), 95%(91-97) and 98%(94-99), followed by treatment-experienced with unknown VL at DTG start (94%(88-97), 93%(88-96), 93%(88-96) and 96%(89-99) and those ART naïve (93%(81-99), 93%(78-99), 93%(70-99), and 81%(48-98), respectively. VS was lowest among those treatment-experienced and viraemic at DTG start: 63%(40-81), 82%(56-96) and 90%(55-99) (insufficient numbers at 24-months).

Conclusion: In our Ugandan cohort, over 90% of children/adolescents on DTG were virally suppressed through to 24-months. However, there were lower rates of early suppression among those treatment-experienced and viraemic at DTG start which warrants further monitoring.

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The CHERISH (Children HIV-Exposed Research to Inform Survival and Health) Dynamic Cohort

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Introduction: The Children HIV-Exposed Research to Inform Survival and Health (CHERISH) study is designed to sustainably measure fetal and postnatal exposures, and compare survival, hospitalization, growth, and neurodevelopment in children HIV-exposed uninfected (HEU) and HIV-unexposed to age 3-years. CHERISH employs a complementary multi-level cohort approach (province-wide, sentinel site and detailed prospective dynamic cohort) in the Western Cape, South Africa.

Methods: Since 2022, the CHERISH Dynamic Cohort has been enrolling pregnant people with (PPHIV) and without HIV between 24-36-weeks gestation from one urban and one rural community, following mother-child pairs, including children HEU (target N=1000) and HIV-unexposed (target N=500) to age 3 years. In-person visits occur at enrolment, delivery, 12-, 24- and 36-months with intervening 3-monthly telephone data collection. Children and mothers without HIV undergo HIV testing at all in-person visits. Data on exposures and outcomes are collected from routine standardised healthcare

documentation, maternal interview, measurement (growth and neurodevelopment) at in-person visits, and linkage to the Western Cape Provincial Health Data Centre (hospitalization and survival). We describe characteristics of pregnant people enrolled to date, compared by HIV status.

Results: By 03/31/2023, 510 pregnant people were enrolled, 290 (57%) with and 220 (43%) without HIV, 273 (54%) from the urban and 237 (46%) from the rural site. PPHIV are older (median [IQR] 30.8 [27.0-36.0] vs 26.7 [23.0-32.4] years), have more often experienced a previous stillbirth or neonatal loss (7.2% vs 4.1%), food insecurity (17.9% vs 7.7%) and any pregnancy alcohol use (13.8% vs 7.3%). While any pregnancy tobacco use (4.8% vs 6.8%) and possible depression (11.4% vs 10.0%) were similar and median [IQR] enrolment gestation did not differ (28.5 [25.6-32.0] vs 29.2 [26.2-33.1]). Amongst PPHIV, 222 (76.6%) were diagnosed with HIV and 214 (73.8%) had started antiretroviral therapy before this pregnancy, 254 (87.5%) were on tenofovir-emtricitabine-dolutegravir, and amongst those already delivered 207/216 (95.8%) had a delivery HIV viral load recorded with 168/207 (77.8%) <50 copies/ml.

Conclusion: The CHERISH Dynamic Cohort is well poised to interrogate maternal factors associated with outcomes in children HEU in the current era of high antiretroviral therapy exposure at conception.

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Viral Load Suppression and Acquired HIV Drug Resistance Among Adolescents Living With HIV Routinely Followed Up at One of the Largest HIV Treatment Centre in Cameroon

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Background: HIV drug resistance (HIVDR) has become a growing challenge, particularly among adolescents living with HIV (ALHIV), often associated with high rates of virological failure (VF). We prospectively assessed the virological suppression (VS) rate and acquisition of HIVDR among ALHIV in Cameroon.

Methods: A prospective cross-sectional assessment was carried out at the Laquintinie hospital of Douala (LHD), where adolescents (10-19 years) receiving treatment for at least 6 months were included between February and September 2021. Socio-demographic and clinical data were collected and a first viral load (VL) test was measured using the ABBOTT Platform. For adolescents with VL ≥1000 copies/ml, a second VL was measured after 3 months. Adolescents were considered in VS if they had a single VL <1000 copies/ml. Genotypic resistance testing (GRT) using an in-house method was performed for participants with VL2 ≥1000 copies/ml, confirming VF. HIVDR mutations were analyzed and a genotypic susceptibility score (GSS) estimating the number of fully active drugs was calculated using the Stanford HIVdbv9.4 algorithm.

Results: A total of 280 adolescents were enrolled. The median age was 16.0 (IQR: 13.0-18.0) years, the median duration on treatment was 9.8 (IQR: 5.1-12.8) years, and 52.5% (147/280) of them were on a first-line regimen (Efavirenz-based). Of the 279 available VL results, 246 had a VL <1000 copies/ml, i.e. a VS rate of 88.2% (CI: 83.8%-91.7%). GRT was successfully performed for 28/31 ALHIV declared in VF. Overall HIVDR was 75.0% (21/28), with 64.3% (18/28) to NNRTI, 57.1% (16/28) to NRTI and 7.1% (2/28) to PI. For INSTI, only accessory mutations were found in 3/28 participants (10.7%). Regarding the newly introduced Tenofovir-Lamivudine-Dolutegravir combination, cumulative GSS predicted fully active drugs among 50% (14/28) of the participants (GSS=3), but a reduced susceptibility to lamivudine and tenofovir/lamivudine in 32.1% (GSS<3) and 17.8% (GSS<2) participants respectively.

Conclusion: The high rate of VS (88.2%) found in this study is encouraging but the high level of HIVDR mutations among those in VF is threatening the progress made. The presence of only accessory mutations on INSTI supports their use among adolescents but highlights the need for close monitoring of HIVDR to ensure their efficacy.

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Bone Mineral Density Changes in Postpartum Mothers Living With HIV on ART [76/85]

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Background:
In the IMPAACT PROMISE 1077BF study, we found that postpartum declines in bone mineral density (BMD) during breastfeeding were greater in African women living with HIV (WLWH) receiving TDF-based ART compared to those not on ART. We describe postpartum BMD changes in breastfeeding African women in the PROMISE trial who then enrolled in the PROMOTE observational cohort.

Method: In four African countries, former PROMISE participants were enrolled in the PROMOTE study. Total hip and lumbar spine (LS) BMD were assessed by Dual Energy X-ray Absorptiometry (DXA) after delivery (week 0) and at postpartum week 74 in PROMISE, then at PROMOTE entry. Country-specific Z-scores were created by internal standardization to the PROMISE DXA result at delivery. Linear mixed models adjusted for country were used to estimate the average 5-year change in hip and LS BMD Z-scores after postpartum week 74.

Results: At PROMOTE entry, 459 women had available DXA data from PROMISE. Median (IQR) age was 32 (29-36), BMI 24.6kg/m2 (22.0-29.3), parity 3 (2-4), months on ART in PROMISE 24.8 (14.2-34.7). HIV-1 viral load was <1000 copies/mL in 93%, 92% were on TDF-ART. In the median 3.3 (2.2-3.7) years since postpartum week 74, 19% had a new pregnancy and 13% were still lactating at PROMOTE entry. At entry, mean (SD) BMD was 0.96 (0.12) for LS and 0.95 (0.12) g/cm2 for hip. LS BMD Z-scores increased by 31% per 5 years (95%CI: 22%, 40%) and hip by 8% per 5 years (1%, 16%), adjusted for country. Compared to women without, women with new pregnancies had lower annualized rate of change in BMD: mean difference (95%CI) LS = -0.057 (-0.078,-0.035) and hip = -0.032 (0.053,-0.011).

Conclusion: Compared to women who had new pregnancies, WLWH who had no new pregnancies had greater LS BMD recovery, but not hip, in the 3 years after week 74 postpartum.

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Pharmacokinetics, Safety and Efficacy of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Virologically Suppressed Pregnant Women with HIV

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Background: Safe, effective and convenient treatment options are needed for pregnant women with HIV. Bictegravir (BIC) is highly protein bound and metabolized by uridine diphosphate glucuronosyltransferase 1A1 (UGT1A1) and cytochrome P450-3A4 (CYP3A4). Physiological changes during pregnancy, including increased CYP3A4 and UGT1A1 activities, have been reported; however, limited data exist on B/F/TAF pharmacokinetics, safety and efficacy during pregnancy.

Material and Methods: An open-label study (NCT03960645) of B/F/TAF was conducted in 33 pregnant women in second and/or third trimester with virologic suppression of HIV-1. Steady-state plasma samples were collected over 24 hours following oral administration of B/F/TAF during pregnancy, and 6 and 12 weeks postpartum. For BIC and TAF, protein binding was measured and serial sparse samples were collected in neonates. Pharmacokinetic comparisons were made between the pregnancy and postpartum samples using percent geometric least-squares mean (%GLSM) ratios. Plasma HIV-1 RNA and trough peripheral

blood mononuclear cell (PBMC) tenofovir diphosphate (TFV-DP) levels were also measured, and the proportion of participants with HIV-1 RNA <50 copies/mL (missing=excluded) at delivery was calculated.

Results: Plasma B/F/TAF exposures were lower during pregnancy than at 6 and 12 weeks postpartum; %GLSM ratios for AUCtau ranged from 40.57%–44.65% for BIC, 56.52%–77.62% for TAF and 64.26%–69.19% for emtricitabine. For BIC and TAF, %GLSM ratios for AUCtau were higher when adjusted for protein binding, although they remained <100% for pregnancy versus postpartum, ranging from 58.84%–62.40% for BIC and 83.61%–89.27% for TAF. Trough PBMC TFV-DP levels were generally similar during pregnancy and postpartum. Virologic suppression was maintained by all pregnant women, with HIV-1 RNA <50 copies/mL at delivery (n=32 [100%]). In neonates, median (interquartile range) BIC half-life was 43 (38–58) hours, and TAF level was below the quantitation limit in all neonates. No adverse events (AEs) led to premature discontinuation, and no drug-related AEs were reported in pregnant women or neonates.

Conclusions: Despite the comparatively lower exposure to BIC, emtricitabine and TAF during pregnancy versus postpartum, as expected, given physiological changes during pregnancy, all participants maintained virologic suppression, and B/F/TAF was generally well tolerated, suggesting B/F/TAF is appropriate for use during pregnancy, without the need for dose adjustment.

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Systemic Inflammation in Pregnant Women With HIV: Relationship With Preterm Delivery and HIV Treatment Regimen

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Background: HIV treatment regimen during pregnancy was associated with preterm delivery (PTD) in the PROMISE trial. Systemic inflammation among pregnant women with HIV could be linked to PTD, and could help explain differences in PTD by treatment regimens.

Materials and Methods: A nested 1:1 case-control study (N=362) was conducted within PROMISE 1077BF, a randomized trial comparing three HIV antiretroviral regimens in pregnant women from 6 countries in Africa, and India: zidovudine-alone, or combination antiretroviral therapy (ART) with lopinavir/ritonavir and either zidovudine or tenofovir. Cases were women with PTD (<37 weeks of gestational age) and controls were those with a term delivery. We assessed the relationship of second trimester plasma biomarkers, measured before (13-23 weeks of gestational age) and 4 weeks after ART initiation, with PTD using logistic regression models. We also studied the associations between treatment regimen and biomarkers, and assessed whether inflammation was a mediator in the relationship between ART regimens and PTD. The following soluble markers were assessed by immunoassays: interleukin-6 (IL-6), interferon-γ (IFNγ), tumor necrosis factor α (TNFα), soluble CD14 (sCD14), sCD163 and intestinal fatty-acid binding protein (I-FABP). Concentrations in the highest quartile at both time points were considered persistently high. Concentrations in the lower three quartiles at both times were considered persistently low.

Results: Persistently high IL-6, but not other markers, was associated with increased PTD (adjusted odds ratio [persistently high versus persistently low]: 2.47, 95% confidence interval: 1.16-5.29). Compared to the zidovudine-alone, the average within-person difference in concentration between week 0 and week 4 was significantly higher ($p<0.05$) for both combination PI-based arms: IL-6 (only zidovudine ART arm), IFNγ (both ART arms), TNFα (only tenofovir ART arm), sCD14 (both ART arms) and I-FABP (both ART arms). The estimated proportion of the ART effect on increased PTD mediated by persistently high biomarker levels was 5% or lower for all biomarkers.

Conclusions: Persistently high IL-6 during pregnancy was associated with PTD. While PI-based ART were associated with increases in inflammation, our results suggest that factors other than inflammation explain the increased PTD observed in women taking ART-based regimens compared to zidovudine alone in the 1077BF PROMISE trial.

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Information Packaging at First Contact, the Key to the Improvement of Health-Seeking Behaviors and Better Health Outcomes Among Adolescent Girls and Young Women in Homa Bay, Kenya

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Background: The sexual and reproductive health decision-making done by adolescent girls and young women (AGYW) is greatly influenced by their knowledge. With support from ELMA Philanthropies, the Elizabeth Glazer Pediatric AIDS Foundation designed a multi-faceted peer-centered case management initiative, G-POWER, aimed to mitigate these gaps and ensure better health outcomes for AGYW.

Methodology: The G-POWER initiative is implemented in 27 facilities in Homa Bay County and led by 30 capacitated AGYW peer mentors. Parallel provision of screening, testing, linkage, and navigation for gender-based violence (GBV), pregnancy, and HIV is conducted by peer mentors for all AGYW presenting to the facility. Once identified, pregnant and breastfeeding (PBF) AGYW are enrolled in G-Power, regardless of HIV status. They then complete an individualized case contact form with a peer mentor, informing their individualized care plan with messaging, mentorship, and social needs throughout their pregnancy, delivery, post-partum, and early motherhood periods. All PBF AGYW receive tailored prevention, adherence, antenatal care (ANC), post-natal care (PNC), nutrition, GBV, and early childhood development information, support and services throughout the PBF cascade.

Results: From January- March 2022, 6,575 AGYW were screened for pregnancy, with 40% (2,630) being suspected of pregnancy. In this cohort, 93% (2,437) were tested for pregnancy and 865 (35%) tested positive. Of those, 97% (838) were linked to ANC services and 100% were tested for HIV at the first ANC, with a 1.3% positivity rate and 100% transition to ART services. Zero seroconversions occurred after HIV testing of this cohort in the third trimester and at labor and delivery. All 1,765 PBF AGYW within this cohort who were not pregnant received family planning counseling. We screened 1,049 (59%) AGYW for PrEP; 35% (372) were eligible, and 363 (98%) were initiated on PrEP.

Conclusions: The provision of appropriate health information from a trusted and relatable individual plays a significant role in PBF AGYW taking ownership and responsibility for their health. Tailored and continuous prevention messages from AGYW peer mentors support low seroconversion through the pregnancy and breastfeeding period as well as linkage to treatment and prevention options.

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How Many Children and Adolescents Are Reaching Undetectable? An Analysis of Viral Load Outcomes Among Children and Adolescents Living With HIV in the Democratic Republic of the Congo

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Background: Evaluating attainment of reaching suppression and undetectable viral load (VL) levels across age cohorts is important to inform programming. EGPAF in the Democratic Republic of the Congo (DRC) implements tailored programming to improve VL coverage and suppression among children and adolescents living HIV via skills building among caregivers, adherence workshops, disclosure and psychosocial support, and ongoing counselling.

Methods: We analyzed routinely-reported PEPFAR program data from five health zones in Kinshasa, DRC [Bandalungwa, Binza Météo, Kikimi, Kingasani, Masina-2]. Data covers 12-months from October 2021 to September 2022. Indicators assessed

include VL coverage and VL outcome. VL coverage refers to individuals with a documented VL test who received their results in the last 12 months. VL outcomes include unsuppressed (>1,000 copies/ml), suppressed (50-<1,000 copies/ml), and undetectable (<50 copies/ml) VL levels. Data were disaggregated by age: 0-9 years (children); 10-14 (young adolescents); 15-19 (older adolescents); 20-24 (young adults); and 25+ (adults). The proportion reaching undetectable, suppressed, and unsuppressed VL outcomes was calculated stratified by age.

Results: Over the 12-month period, 25,735 individuals had a documented VL test, signifying 73% (25,735/33,792) VL coverage. Across all population groups, 83.4% (21,475/25,735) achieved undetectable status; 10.6% (2,728/25,735) attained detectable-suppressed levels; and 5.95% (1,532/25,735) were non-suppressed. Adolescents had the lowest rate of achieving undetectable (78.8% for older and 79% for younger adolescents). Children had undetectable rates similar to young adults (85.2% and 85.1%, respectively). Undetectable rates in adults was slightly lower, 83.4%. A similar trend was seen concerning non-suppressed levels. Younger and older adolescents had the highest proportions at 7.7% and 7.6%, respectively. Children had the lowest level of non-suppression at 4.5% compared to adults at 5.9% and young adults at 6.1%. Among the five health zones, Kikimi consistently achieved one of the highest undetectable proportions across quarters, ranging from a high of 96.1% (1,494/1,555) in January-March 2022 to a low of 87.8% (707/8,050) July-September 2022.

Conclusions: Younger and older adolescents had the lowest proportions of reaching undetectable levels and the highest levels of non-suppression; children <10 years had rates similar to young adults. Variability among ages and health zones highlights the need for tailored interventions.

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Integrating Orphans and Vulnerable Children (OVC) services in HIV care: An opportunity to optimize viral load outcomes among children and adolescents living with HIV on ART in Southern province of Zambia

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Background: Attaining optimal viral load coverage (VLC) >95% and suppression (VLS) >95% among children and adolescents living with HIV(C/ALHIV) is a concerning gap in HIV programs. One strategy to improve VLC and VLS among C/ALHIV is integrating OVC services among eligible C/ALHIV receiving standard ART services. OVC programs offer direct community support and bi-directional referrals between OVC service providers and health facilities We describe the access to and effect of OVC services on VLC and VLS among C/ALHIV in Southern Province, Zambia.

Material and Methods: We reviewed retrospective program data from the PEPFAR Zambia December 2022 monthly ART monitoring report for Southern province. The data included counts of C/ALHIV 0-19 years which were categorized into two subgroups: those enrolled in OVC services and those not enrolled. Chi-square test was employed to assess differences in viral load coverage and suppression rates between the two subgroups.

Results: A total of 10,793 C/ALHIV, with 55% girls were in care at 380 health facilities in December 2022. Median age was within the 10-14 years age band. Among these, 2,596 (24%) were enrolled in OVC services, 8,197 (76%) were not. Among 2,261 OVCs in care were eligible for VL testing, 2,144 (95%) had a valid VL, of which 96% (2,065) had <1000 viral copies/ml. Among 7,704 C/ALHIV not enrolled in OVC services eligible for VL testing, 6,589 (86%) had a valid VL, and 93% (6,160) had VL <1000 copies/ml. VL coverage was significantly

higher among C/ALHIV in OVC services compared to those not in OVC services (p<0.001), and VL suppression was significantly higher among C/ALHIV in OVC services (p<0.001).

Conclusions: Though only 24% of C/ALHIV on ART in OVC services, these children and adolescents attained high viral load coverage and suppression, while suboptimal viral load outcomes persisted among those receiving ART standard of care. These findings underscore the critical role of OVC services in complementing other interventions to optimize viral load outcomes among C/ALHIV. Increased investment in and scale-up of OVC programs is needed to increase access to OVC services and to close concerning gaps in VLC and VLS among this sub-population in resource-limited settings.

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Advancing Equity: Improving HIV and Well-Being Outcomes Among Children and Young Adolescents Living With HIV Through Integrated OVC and Clinical Support in South Africa

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Background: South Africa has nearly one million orphans as a result of HIV/AIDS and 270,000 children and young adolescents (<15y) living with HIV (C/YALHIV)(UNAIDS). Progress against UNAIDS 95/95/95 targets continues to lag among children and adolescents. USAID/South Africa supports approximately one-third of the country's C/YALHIV on antiretroviral therapy (ART). Clinical and Orphans and Vulnerable Children (OVC) programs closely collaborate to deliver family-friendly differentiated care and linkage to testing, prevention, treatment, and socioeconomic services.

Description: USAID/South Africa clinical and OVC partners collaborated with the Departments of Health and Social Development to support facility and community services for children, adolescents, and their families. From 1 October 2021 - 30 September 2022 (fiscal year [FY] 22), USAID/South Africa partners increased C/YALHIV enrollment into the OVC comprehensive program. This effort was supported through intentional collaboration between clinical and OVC partners to provide comprehensive, family-centered case management.

Lessons learned: In FY22 275,593 children and youth (<18y) were enrolled in the OVC comprehensive program and received a differentiated package of services based on their risks, vulnerability, and assets. Adolescents 15-17y comprised the greatest proportion of program participants (40%). In FY22, 97% of OVC comprehensive program participants <18y reported a known HIV status, with young children (1-4y) having the highest (97%) and older adolescents (15-17y) having the lowest (89%) reported HIV status. By the end of FY22, 78,149 (28%) of OVC comprehensive program participants <18y were known to be living with HIV, of whom 99% were reported to be receiving ART. Viral load suppression was higher among those <18y in the OVC program (92%) compared with VLS among USAID-supported individuals <19y overall (81%) which includes those in the OVC program and those not enrolled in the OVC program.

Conclusion/next steps: South Africa continues to strengthen the clinical cascade for C/YALHIV through robust facility and community OVC programs. To advance equity, it is vital to: ensure all program participants are offered appropriate HIV testing services; expand differentiated service delivery for treatment continuity; and, deliver socioeconomic support to improve HIV outcomes and overall well-being among C/YALHIV.

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Optimised Differentiated Service Delivery Model for Children Living with HIV: Experience from Mwanza, Tanzania

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Background: Achieving optimal treatment outcome among children living with HIV (CLHIV) is a complex challenge. Optimised services to address the needs of CLHIV are necessary to reach the last mile in achieving and sustaining viral load suppression (VLS). ICAP through the FIKIA+ project in Mwanza Tanzania, supported delivery of differentiated services for CLHIV attending paediatric Saturday clinics. We aim to describe changes in appointment adherence, viral load coverage (VLC) and viral load suppression (VLS) among CLHIV in Mwanza.

Methods: Preparations for clinics were made by expert clients who listed of CLHIV due for appointments and made reminder phone calls 1-3 days prior to appointment date. CLHIV files were sorted according to eligibility for various intervention including HVL test, adherence counselling, disclosure, Antiretroviral therapy (ART)refills, and treatment optimisation. On clinic days, clinical consultations were preceded by psychosocial sessions provided by health care workers and trained peer educators focusing on disclosure and adherence, followed by HVL sample collection for eligible CLHIV. During clinical consultations CLHIV were screened for opportunistic infection, offered appropriate management or prophylaxis and optimal ARV regimen. Saturday clinics were equipped to provide edutainment materials and children's games. We analysed programmatic data to show changes in the proportion of CLHIV with appointment adherence, viral load (VL) test results, and VLS as the final outcomes of interest between the first quarter of fiscal year 2022 (October to December 2021) and the last quarter (July to September 2022).

Results: CLHIV adherence to clinic appointments increased from 95% to 99%. The proportion of CLHIV with documented viral load test increased from 89% to 96%. Viral load suppression among CLHIV increased from 93% to 96% by the end of the last quarter.

Conclusions: Differentiated service delivery models targeting the specific needs of CLHIV contributed to improved appointment adherence, coverage for viral load testing, and viral load suppression exceeded the targets of 95%.

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Investigating Attrition of Children and Adolescents Living With HIV From Care, Uganda, 2017 – 2021: Implications for Robust Estimates

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Background: Lack of robust estimates of children and adolescents living with HIV (CALHIV) impedes effective epidemic control and HIV resource planning. We investigated the contribution of aging out, loss from care and death on the number of CALHIV in care, enabling more accurate projections for HIV programming.

Methods: Our study utilized secondary data from electronic medical records (EMR) in selected high-volume health facilities nationwide. We included all CALHIV who were active in care during each of the years from 2017 to 2021 and we collected data on: age, gender, date of enrolment in care and status in care as of August 2022. This data was collected in excel and analysed using STATA. Descriptive analyses were made and trends of proportions of CALHIV were determined and analysed.

Results: The number of CALHIV ranged from 39,227 in 2017 to 49,835 in 2021, with more females than males (1.3:1, P=0.001). The average annual increase in CALHIV during 2017-2020 was 2% (P=0.001).

There was an average attrition of 16,073 from care CALHIV most due to loss to follow up (56%) with the least contributor being death (5%) during the study period but on average, attrition due to loss to follow up or transfer out decreased by 1% during 2017 – 2021 (P<0.05) while the average mortality stagnated at 2% each year. On average, 7% of adolescents aged out each year. The median survival time for CALHIV in care during the study period was 4 years and was similar for males and females (P=0.170). Children aged 6 – 9 years and adolescents 10-14 years had longer median survival time in care compared to CALHIV of other age bands (P=0.05).

Conclusions and recommendations: The consistent proportions of loss to follow up from care, mortality and aging out of the adolescent subgroup suggest that these proportions can be used to confidently determine the estimates of CALHIV in care at any given time point.

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Chart Audits Improve Viral Load Results Returned and Coverage Among Pregnant and Breastfeeding Women Living With HIV in Wakiso District, Uganda

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Introduction: Effective antiretroviral therapy (ART) among pregnant and breastfeeding women (PBFW) living with HIV prevents mother-to-child-transmission (MTCT). Regular Viral load (VL) testing helps monitor for poor ART outcomes. An assessment conducted in July–September 2021 showed that only 27% PBFW on ART had VL test results returned per MOH guidelines at 44 health facilities. VL quality-improvement activities were conducted to improve VL coverage to >90 by July-September 2022. We analyzed data to understand the impact of quality-improvement activities on VL results returned.

Methods: We analyzed quarterly program reports for July-September 2021–July-September 2022 from 44 facilities. VL coverage rate was calculated as the number of PBFW on ART with samples collected over those eligible for VL in given period. VL results returned rate was calculated as those with results returned to the facility over those with samples collected. The quality-improvement activities included monthly chart audits to generate a line-list of PBFW on ART with prior missing VL results at the facility or most recent VL last conducted 6-months prior. Line-lists were forwarded to peer-mothers for follow-up of PBFWs by phone and/or home visits. We also improved VL data reporting templates; oriented staff on VL client flow, lay testers in venipuncture and activated two VL point-of-care testing facilities.

Results: The proportion of returned results increased to 64% (95%CI: 62-66; p-value<0.001) from 27% (1091/4025) in the first quarter. In each quarter, on average, of 4,526 eligible PBFW, 4,063 (90%) samples were collected, and of these, 2,779 (68%) were returned. Generally, there was an upward trend in the proportion of PBFW with collected samples and returned samples over all the quarters (p-value<0.001). Overall, results returned improved from 27% to 91% in one year. The VL coverage rate increased from 87% (4025/4651), (95% CI: 80-94) to 95% (4,081/4,302), (95% CI: 91-99). (Figure).

Conclusion: Comprehensive quality-improvement activities improved VL coverage and timely results reporting among PBFW on ART at the facility.

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Evaluation Pediatric HIV Outpatient Policy: How Deviation of Implementation in LMIC Could Impact Treatment Adherence and Outcome

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Background: In Indonesia, a target to eliminate HIV/AIDS by the end of 2030 has been established. Since 2018, the Ministry of Health has prioritised methods to achieve this goal, including early and routine antiretroviral (ARV) treatment alongside required clinical monitoring every 3 months. However, challenges in the implementation of this policy have emerged, as many children with HIV/AIDS are lost to follow-up within the Indonesian healthcare setting.

Objective: This study aimed to evaluate the implementation of an HIV paediatric outpatient clinic which was established in accordance with Indonesian policy at a large tertiary referral hospital in Bandung, Indonesia,
Method. A cross-sectional study was conducted to review attendance of all children with HIV/AIDS referred to the clinic over a three-month period (27 December 2022 to 3 March 2023). Qualitative research methods were used to evaluate reasons for missed clinic appointments.

Result: Of 202 children with HIV/AIDS referred to the outpatient clinic (median age: 11 years; range 1 to 17), less than half (100/202, 49.5%) attended their scheduled appointment. Most of the patients who attended were clinically well (91/100, 91%). By contrast, of the children who did not attend, the majority were HIV stage 3 (29/102, 29%) or stage 4 (33/102, 33%). Most children are prescribed AZT+3TC+NVP, although nine patients (4%) required second-line regimens (TDF and LPV/r); all of these patients were within the group that do not routinely attend clinic.

Conclusion: More than half of the children registered to attend scheduled HIV review clinics missed appointments, and children with Stage 3 and 4 were most likely not to attend. Strategies to reduce non-attendance in clinically and socioeconomically vulnerable patients and their families will be important to address, to enhance treatment adherence and improve clinical outcomes for children living in Indonesia with HIV/AIDS.

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Health-Related Quality of Life among Children Living with HIV in North-Central Nigeria

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Introduction: With the availability of effective ART, HIV is now considered a chronic condition. While necessary, conventional outcome indicators like viral load are insufficient to assess long-term outcomes for children living with HIV (CLHIV). Pediatric quality of life is recommended as an important additional health outcome measure among children with chronic disease. This study assessed health-related quality of life of CLHIV in Nigeria.

Methods: Ninety-six primary caregivers of CLHIV and their 96 wards were enrolled into the ongoing Caregiver Peer Support (CaPS) study. CaPS is being implemented at six health facilities in two states in North-Central Nigeria: Federal Capital Territory and Nasarawa. CaPS is measuring the impact of caregiver peer support on ART adherence and viral suppression (VL <1000 copies/mL) among CLHIV aged 6 months-10 years. Baseline pediatric quality of life was assessed using the 23-item Peds QL 4.0 questionnaire administered to the caregivers. Scores below the mean score of 80 (0 to 79) were categorized as "poor quality of life". Descriptive analyses and binary logistics regression were done using Stata MP16, and a significance was set at a $p < 0.05$.

Results: Mean age of CLHIV and their caregivers was 5.7 (S.D 3.2) years and 36.9 (S.D 8.3) years respectively. Approximately 80% (n=77) of caregivers and 51% of CLHIV were female. Baseline CLHIV viral suppression rate was 56.3%. The overall mean quality of life score of CLHIV was 79.9 (S.D 13.2), ranging from 34-92, with 63.5% of CLHIV having a "good" quality of life (score 80 to 92).
Having a male caregiver (aOR = 5.59, 95%CI=1.18-26.47) and disclosure of child's HIV status to partner by caregivers (aOR = 8.16, 95%CI=1.24-53.79) were more likely to positively influence the children's quality of life.

Conclusion: 1) Disclosure of CLHIV status by caregivers to partners of the caregivers and 2) primary involvement of male caregivers in CLHIV care were found to play an important role in the quality of life of our Nigerian CLHIV cohort. This adds evidence to advocacy for disclosure support in HIV programs, and for context-specific interventions to facilitate disclosure and male caregiver involvement to improve quality of life for CLHIV.

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Consistency of Multi-Month Dispensing of Antiretroviral Therapy and Association With Viral Load Coverage and Suppression Among Pediatric Clients in Mozambique and Eswatini

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Background: Multi-month dispensing (MMD) of antiretroviral therapy (ART) has increased dramatically among children in recent years. However, little is known about consistency of MMD receipt over time and its association with virological outcomes.

Methods: We conducted a secondary analysis of individual-level data from routine HIV services at 16 facilities in Mozambique and 31 facilities in Eswatini. Children ≤14 years living with HIV who visited clinics between September 2019-August 2020 (Mozambique) and July 2020-December 2020 (Eswatini) were enrolled. Data were abstracted from clinic visits, ART pickups, and viral load (VL) monitoring for ≥12 months after enrollment. We analyzed proportions of children ever receiving three-month MMD and receiving consistent MMD (three-month supply at all pickups the following year), and VL coverage and suppression (<1,000 copies/mL) after MMD transition.

Results: Overall, 82% of children in Mozambique (3,594/4,383) and 67% in Eswatini (1,041/1,559) ever received MMD during the study period. In both countries, older children were more likely to receive MMD (p<0.001). In Eswatini, MMD transition varied from 11%-98% of children by site. Among children ever receiving MMD, 40% in Mozambique and 31% in Eswatini received consistent MMD, primarily children 10-14 years (48% and 41% respectively). In Mozambique, 40% of children on MMD had a VL within 12 months of starting MMD, and consistent MMD was significantly associated with lower odds of having a VL (0.8, 95% CI: 0.6-0.9, model adjusted for age and sex). VL coverage was higher in Eswatini (87%) and not associated with MMD consistency. Of children with VL result ≥ six months after first MMD, 185/881 (21%) in Mozambique and 32/436 (7%) in Eswatini were unsuppressed, most commonly among children 0-4 years. Children with unsuppressed VL were significantly less likely to receive consistent MMD in both countries.

Conclusion: While most children received MMD, fewer than half received MMD consistently. More information is needed on drivers of dispensing practices, including service implementation gaps (e.g., stockouts), client/provider preferences, and clinical contraindications for MMD. In settings like Mozambique, with lower overall VL coverage particularly among children with consistent MMD, attention is needed to ensure children with fewer visits still receive timely VL monitoring.

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Trends in HIV Differentiated Service Delivery Model Utilization among Children and Adolescents in Uganda, 2020-2022

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Background: HIV programs struggle to provide care to children and adolescents living with HIV (CALHIV). Differentiated service delivery models (DSDM) aim to make HIV care more client-centered and improve diagnosis, retention, and viral load suppression. DSDM in Uganda comprise two community-based models [community-client-led ART distribution (CCLAD) and community drug distribution points (CDDP)] and three facility-based models [facility-based individual management (FBIM), facility-based group management (FBGM), and fast-track drug refill (FTDR)]. They are also classified by level of follow-up as 'intensive' (FBGM and FBIM) or 'less intensive' (community-based models and FTDR). All CALHIV in Uganda were initially assigned to intensive DSDM. Recently, less intensive DSDM have been expanded to include CALHIV. We assessed DSDM utilization by CALHIV in Uganda from January 2020 to December 2022.

Methods: We extracted data from District Health Information System for DSDM used by CALHIV (aged 0-19 years) during the study period. We calculated the proportion of CALHIV enrolled on ART by DSDM each quarter and assessed trend significance using the chi-square test for trends.

Results: Among 89,409 CALHIV on ART with data during the last quarter of 2022, 69% were <15 years and 31% were 15-19 years; 53% were female. Of those with data (74-99% by quarter), almost all (96-100%) enrolled in facility-based models. Utilization of the less intensive facility-based model (FTDR) ranged from 15-28% by quarter; utilization of intensive facility-based models ranged from 72-85%. FTDR utilization over the 12 quarters increased from 0% to 12% among children aged <10 years, 14% to 29% among ages 10-14 years, and 19% to 32% among ages 15-19 years (p<0.001).

Conclusion: Expansion of DSDM options for CALHIV led to an increase in CALHIV utilization of less intensive models. However, community DSDM enrolments remained low. Studies to address this gap may enable improved enrolment in and continuity of HIV care and treatment for CALHIV.

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Adherence Above All: Lessons from the First Year of a Pediatric Viremia Clinic in Tanzania

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Background: Virologic suppression rates in children and adolescents living with HIV (CALHIV) continue to lag behind their adult counterparts and meeting the last UNAIDS 95-95-95 goal (virologic suppression) will be a major challenge for most low and middle-income (LMIC) countries. The establishment of a viremia clinic (VC) may help to elucidate the issues keeping CALHIV from attaining virologic suppression.

Methods: An interdepartmental VC was established at the Baylor College of Medicine Children's Foundation - Tanzania clinic in Mbeya in February 2022 enrolling CALHIV who had been on antiretroviral therapy (ART) for ≥6 months and had virologic failure (VF) (≥1000 copies/mL). The main precepts of the clinic were as follows: consolidating services for CALHIV with high viral load (VL), emphasizing continuity of care, ensuring delivery of a package of services, maintaining a schedule for service delivery, providing peer support (both for client and caregiver), and aggressively following up missed appointments.
For this study, medical records were examined between January and December of 2022.

Results: Over the study period, the number of CALHIV with VF ranged from a nadir of 99(February 2022) to a high of 142(August 2022). Suppression rates fell to 89.0%(1153/1295) in August 2022 before rising to 92.3%(1238/1352) by the end of the study. No ART changes were made due to

resistance concerns and only one CALHIV had a protease inhibitor presumptively added to her regimen for caution/salvage due to sustained viremia. Two CALHIV had genotypes taken which demonstrated likely potency of their current regimens, thus no changes were made. The participants with VF on 2nd line ART were 17.6% (18/102) at the beginning of the study and 14.4% (15/104) by the end. Overall, the transition from unsuppressed to suppressed rose from 80.8% (139/172) to 89.6% (121/135) over the study period.

Conclusions: Most VC services were aimed at increasing adherence to ART, through educational, social, or emotional means. This strategy proved successful, demonstrated by the large increase in VS after initial failure rates among participants. Moreover, neither genotypes - which are costly and time-consuming in most LIMC settings - nor ART switching proved to be essential for achieving suppression in the majority of cases.

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Impact of COVID-19 Pandemic on HIV Viral Load Testing in Paediatric HIV Clinics in the European Pregnancy and Paediatric Infections Cohort Collaboration (EPPICC)

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Background: The COVID-19 pandemic impacted HIV services globally, with in-person clinics visits often limited to priority patients. In children and young people living with HIV (CLHIV) we explored trends in viral load (VL) monitoring and associated factors from 2015 to September 2020.

Materials and Methods: Data from 12 paediatric HIV cohorts in Europe were included. First, generalised estimating equations (GEE) were used to estimate VL testing rates and the proportion of tests with unsuppressed VL (VL≥200c/ml). Models assessed trends by calendar year for 2015-2020, and by month for 2019-September 2020. Second, using logistic regression we explored factors associated with having ≥1 VL test in the first quarter of the pandemic (April–June 2020).

Results: Between 2015-2020, 4,659 CLHIV were in follow-up; 35% in Ukraine, 24% United Kingdom, 25% Russia, 16% elsewhere in Europe. Overall, VL test rates were stable from 2015-2019 (p=0.250) at a mean 0.182(95% CI 0.179,0.185) tests per patient per month before declining to 0.122 (0.116, 0.129) in 2020, with lowest rates in April 2020 (0.050(0.034,0.065)). The percentage of unsuppressed VL tests decreased from 27.9% (26.7%,29.1%) in 2015 to 17.4% (15.9%,18.8%) in 2020 with no evidence of change in this declining trend (p=0.135).
Among 1,784 CLHIV in care during April-June 2020, 54% were female, median age 12.3[IQR 8.1,15.5] years. CLHIV who may be considered priority included those: treatment naïve (0.8%), initiated ART within previous 12-months (6.9%), interrupted treatment (2.5%), recent viremia (≥1 VL≥200c/ml in previous 12-months) (25.6%) or severely immunosuppressed (CD4<200 c/mm3) at last visit (1.4%). Overall, 22.3% had ≥1 VL test between April-June 2020. In multivariable models, adjusting for cohort, age and sex, recent viremia (aOR=2.1(1.5,2.8)), initiated ART in previous 12-months or ART naive (aOR=2.1(1.3,3.4), vs. on ART ≥3 years) were associated with increased odds of having a VL, while treatment interruptions had lower odds (aOR=0.3(0.1,1.0)).

Conclusions: The pandemic had considerable impact on VL testing with evidence of prioritisation of some CLWHIV based on treatment and VL status. The proportion of tests unsuppressed was declining pre-pandemic and appears unchanged during 2020. Further data are needed to assess any knock-on effects of the decline in visits on virological outcomes.

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Acceptability of CAB-LA in Cisgender Female Adolescents in South Africa, Uganda, and Zimbabwe (HPTN 084-01)

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Initiation of and adherence to daily oral HIV pre-exposure prophylaxis (PrEP) has been low among African adolescent girls and young women (AGYW). Along with other sociocultural factors, PrEP uptake and adherence are a function of product acceptability. Understanding the acceptability barriers and facilitators faced by AGYW in regard to long-acting HIV prevention products is critical for successful implementation. This qualitative analysis explored acceptability of long-acting injectable cabotegravir (CAB-LA) among cisgender adolescent females in South Africa, Uganda, and Zimbabwe.
The HPTN 084-01 study, which examined safety, tolerability and acceptability of CAB-LA among 55 adolescent cisgender females, included a qualitative component to better understand the participants' experiences with CAB-LA. In-depth qualitative interviews were conducted near the end of the product exposure period (Week 34 – after 5 injections) with 15 participants (5 per site) to explore issues of acceptability of CAB-LA injections, including negatives and positives associated with CAB-LA, as well as qualities of the injection itself. Participant interviews were deductively coded by five team members using NVivo 12 and representative memos were created via thematic analysis.
Several major themes emerged regarding acceptability of CAB-LA injections. The needle size (1½ inch) and site of administration (gluteal muscle) were generally deemed acceptable by participants. Injection pain was the most reported barrier to acceptability, followed by injection site reactions and fear of the injection. Despite this, positive overall experiences with injections were reported because of the lack of adherence challenges with bi-monthly injections as well as the discretion offered by CAB-LA in comparison to daily oral tablets. In addition, familiarity with the mode of administration of CAB-LA emerged as a theme around CAB-LA and injectable contraceptives.
In regard to HIV prevention products, the importance of choices is evident in the HPTN 084-01 data. While many participants reported a preference for CAB LA, and most (92%) chose to stay on CAB-LA during the open label extension (HPTN 084), some participants still preferred oral tablets for various reasons, including pain and fear of the injection. These barriers and facilitators should be discussed with future clients as part of the decision-making process around HIV prevention product choice.

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Adolescent PrEP Initiation at Clinics Participating in a Randomized Trial of a Standardized Client Actor Training Intervention in Kisumu, Kenya

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Background: Adolescent girls and young women (AGYW) in Kenya experience high risk of HIV acquisition. AGYW have low PrEP initiation rates due, in part, to stigmatizing interactions with healthcare providers. Our recent randomized trial of a standardized client actor (SC) training intervention for AGYW providers found higher quality of PrEP service delivery at intervention sites. However, it was unknown whether higher quality care improved AGYW PrEP initiation.

Methods: This secondary analysis of the Priya-SP cluster randomized trial used routine clinic data from 12 control and 12 intervention health facilities in western Kenya. The intervention aimed to improve health provider adherence to Kenyan national guidelines and communication skills when offering PrEP to AGYW. Record sources included the MoH 731 Plus tool (and its older iterations) and facility-level PrEP registers from May 2019-June

2021. Mirroring trial timelines, we defined May-December 2019 as the baseline period and December 2020-June 2021 as the post-intervention outcome assessment period. We analyzed data at the facility level and used linear regression with percent initiating as the outcome, intervention and baseline initiation rates as covariates, and the number eligible during post-intervention at each facility as frequency weights.

Results: In total, 1,375 PrEP-eligible AGYW presented to PrIYA-SP sites and were included in this analysis (baseline: n=706, post-intervention: n=669). Among 706 PrEP-eligible AGYW in the baseline period, 441 were at intervention sites and 265 at control sites. Overall, 410 (58.3%) initiated PrEP at baseline: n=203 (46.0%) at intervention sites and n=207 (78.1%) at control sites. Among 669 PrEP-eligible AGYW in the post-intervention period, 360 were at intervention sites and 309 at control sites. Overall, 591 AGYW (88.3%) initiated PrEP at post-intervention: n=335 (93.9%) at intervention sites and n=256 (82.8%) at control sites. Adjusted for baseline initiation proportions, there was 12.1% higher PrEP initiation among AGYW presenting to intervention sites compared to control sites (p<0.001, 95% Confidence Interval: 0.09-0.15).

Conclusions: Our study found a significant improvement in PrEP initiation among AGYW who presented to facilities that had been randomized to SC training. SC training interventions that improve quality of service delivery could lead to enhanced PrEP coverage.

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Youth and Young Adult Preferences for PrEP Service Delivery Models and Formulations in Colorado, USA

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Background: Youth and young adults (YYA) continue to represent a large proportion of new HIV infections; however, uptake and utilization of PrEP by YYA remains low. As new strategies for providing PrEP, including telehealth and injectable PrEP, are implemented, understanding the preferences of YYA remains vital.

Methods: We explored the experiences and perceptions of YYA ages 18-24 years at risk for HIV in Colorado via an electronic survey, conducted between Feb-March 2023. Participants were recruited through youth and LGBTQ+ serving organizations, social media, and word of mouth. PrEP model comfort was analyzed using Fisher's exact test.

Results: Participants included 137 YYA (35% 18-24 years, 85% 20-24 years); 85% identified as male, 14% as transgender females, and 2% as non-binary or other gender. Almost a third (28%) were Black, 10% Hispanic/Latino and 49% White. Nearly half (46%) had never been on PrEP while 27% were currently on, and 27% previously on (27%) PrEP. Demographics did not differ between groups. Those on PrEP reported higher level of comfort with TelePrEP (95%) compared to those previously on PrEP (59%) or never on PrEP (33%; p=0.00). Higher proportions of both those on PrEP or previously on PrEP reported being very comfortable with mail delivery of PrEP (57% and 43%, respectively) versus those never on PrEP (25%; p=0.005). Comfort with HIV self-testing was high in all groups, and (85% overall) as was delivery of PrEP by school-based clinics (75% overall). Overall, 74% of respondents preferred long-acting injectable PrEP compared to oral PrEP which was most pronounced in those YYA never on PrEP (81% compared to 68% in other groups; p=0.17).

Conclusion: YYA at risk for HIV in Colorado have differential preferences for PrEP service delivery depending on PrEP utilization. There was a high level of comfort with PrEP offered at school-based clinics and with HIV self-testing. Injectable PrEP was preferred by all groups but highly preferred in YYA not yet using PrEP.

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Considerations for the Inclusion of Adolescents in HIV Prevention Clinical Trials: Experiences From Two Registrational Trials Assessing Lenacapavir as a Long-Acting PrEP Option

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Introduction: Despite the high incidence of HIV in adolescents globally, they are often excluded from registrational HIV prevention clinical trials due to ethical and regulatory guidance designed to protect children, delaying access to effective PrEP products for years. Adherence to daily medications, including PrEP among adolescents, is often lower than in adults. We sought to demonstrate that older adolescents (16- and 17-year-olds) can be safely enrolled in Phase 3 pivotal trials.

Methods: PURPOSE-1 (NCT04994509) is a Phase 3 study evaluating lenacapavir (LEN, subcutaneous injection every six months) and emtricitabine/ tenofovir alafenamide (daily pill) for PrEP in cisgender adolescent girls and young women. PURPOSE-2 (NCT04925752) is a Phase 3 study of LEN for PrEP in cisgender men, transgender women, transgender men, and gender non-binary individuals who have sex with men. We reviewed scientific literature and advocacy calls to include adolescents in adult clinical trials to reduce medication access delays. We consulted with key stakeholders including regulators, trial investigators, ethics review boards, and community advocates before and during trial execution, and identified priority actions to facilitate inclusion of adolescents.

Lessons Learned: Specific actions that promote the inclusion of adolescents include: 1) early engagement with community stakeholders and investigators who have experience enrolling this age group, 2) sharing best practices on recruiting and enrolling adolescents into clinical trials with investigators to improve confidence, 3) engaging with regulatory authorities and implementing a protocol requirement for an early review of unblinded safety data by an independent committee before opening adolescent enrolments, 4) navigating and adapting to local regulations and ethics requirements, 5) consulting young adults to advise how best to engage adolescents in our consultations and our community advisory group, and 6) adapting to specific participant needs such as flexible study visit schedules for those attending school.

Conclusion: Early and robust stakeholder engagement can facilitate the inclusion of adolescents in HIV prevention research. The PURPOSE program evaluating twice yearly subcutaneous LEN for PrEP (www.purposestudies) is the first registrational PrEP clinical trial program to include adolescents upfront and will hopefully provide early access to a very long-acting prevention option for this disproportionately affected age group.

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"If You Want to Reach the New Generation… TikTok:" Querying Adolescent and Young Adult Views on HIV Pre-exposure Prophylaxis Education

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Background: Adolescents and young adults (AYA) account for nearly one quarter of new HIV diagnoses in the US, but pre-exposure prophylaxis (PrEP) use is limited in this population, in part due

to their lack of knowledge about PrEP. Our objectives were to assess where AYA prefer to receive youth-tailored PrEP messaging, and how framing of messaging using behavioral economics concepts would be received.

Methods: AYA aged 13-25 years were recruited from clinical settings in Boston and Los Angeles and online postings to participate in virtual focus groups. Participants completed surveys about their demographics and sexual health histories. Focus group discussion topics included participants' knowledge of HIV and PrEP, their preferences for receiving education about PrEP, and feedback on phrasing of messaging using gain-frame or loss-frame messaging. Interviews were transcribed verbatim and analyzed using rapid qualitative methods.

Results: Six focus groups were held from September 2022-November 2022 with a total of 24 participants; the mean age was 22 years (range 17-25 years). The majority of participants identified as white (58.3%) and not Hispanic/Latinx (95.8%); over half identified as women (58.3%) and half as straight/heterosexual (50.5%). Many youth (79.2%) had heard of PrEP and 12.5% had taken PrEP. Major emergent themes included: 1) AYA had limited knowledge about HIV, much of which was learned in school settings; 2) Despite AYA being familiar with PrEP, their knowledge was basic (e.g., it prevents HIV) and lacking in details around efficacy and practical issues in accessing PrEP (e.g. coverage by insurance); 3) AYA preferred to learn about PrEP through social media platforms, and several had learned about PrEP through dating apps; 4) AYA preferred to receive messages about PrEP from specific sources, including age-appropriate peers, social media influencers, and health professionals; and 5) Loss-framed messaging was poorly received.

Conclusions: AYA in the US have only basic knowledge about PrEP, even when familiar with the medication. Expanding educational outreach beyond print and websites to include social media platforms and peer influencers could improve knowledge and access to PrEP for youth, in particular if messaging is tailored for AYA and uses gain-frame as opposed to loss-frame messaging.

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Progress in Offering PrEP to Adolescent Girls and Young Women (AGYW) through DREAMS in Nampula, Mozambique

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Summary: Mozambique continues to have a high HIV prevalence (12.5%), with women being hardest hit by the epidemic. HIV prevalence among women aged 20 to 24 in Mozambique is 11.8% but 3.8% among their male counterparts (INSIDA 2021). ICAP works in collaboration with the provincial health and education ministries to implement PEPFAR's DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) strategy, to reduce adolescent girls and young women (AGYW) vulnerability to HIV, including increasing pre-exposure prophylaxis (PrEP) literacy and demand. Nationwide, less than 10% of men and women have heard of PrEP. `

Description: ICAP has worked in close collaboration with Nampula provincial leadership to implement DREAMS in Nampula City and Erati district across 16 health facilities (HFs). ICAP DREAMS supervisors were trained on PrEP key messaging, counseling and clinical follow-up. They provided health talks about PrEP literacy and created demand at secondary schools, universities, and technical schools, as well as in waiting areas at the supported HF in coordination with ICAP-supported peers. Community partners' DREAMS mentors received initial training on PrEP and weekly support from ICAP DREAMS supervisors on how to manage misinformation and myths related to PrEP at the community level.

Lessons Learned: The DREAMS Mentors' training and the subsequent demand creation resulted in greater service provision of PrEP for AGYW. Prior to DREAMS implementation (Oct 2019- Sept 2020), 840 AGYW between 15-24 years of age, initiated PrEP across the 16 HFs. During the first year of DREAMS implementation (Oct 2020-Sept 2021), PrEP initiation increased over eightfold to 6,872 at the same HFs, with sustained high-enrollment

levels the following year (8,459), an increase of 23.1%.

Conclusion: DREAMS implementation contributed significantly to the initiation of PrEP among AGYW, efforts to increase literacy and demand creation among AGYW before contact with HF, addressing fear, stigma and disinformation were essential to increase demand for PrEP, while the involvement of community actors was crucial in supporting PrEP initiation among AGYW, a group at particularly high risk for HIV.

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High Number of Long Term HIV Infections among Adolescents; Implications for Uganda

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Background: Despite the efforts that have been committed by PEPFAR through the Ministry of Health of Uganda to fight HIV, Uganda still registers a high number of new HIV infections especially among the young people. Research has shown that approximately 570 young women aged 15 to 24 get infected with HIV every week in Uganda. The major reason young people engage in sexual activities at an early age in Uganda is money and unfortunately, they take long to identify the infection.

Materials and Methods: We conducted a study in eight districts in the north central region of Uganda to find out the HIV infections newly identified among the young people aged 15-24 and the recency status. Review of secondary data was done at district level from the reports submitted by the health facilities on a quarterly and monthly basis into the reporting system. We reviewed data for the period between January and December 2022 and this was disaggregated by age and sex.

Results: In the eight districts, 2,731 new infections were registered between January and December 2022 for children and adolescents below 24 years. Of the 2,217 new infections registered for adolescents between 15-24, 1,903 (85.8%) were females while 314 (14.2%) were males. 1410 females between 15-24 were subjected to a recency test and 1256 (89%) had a long term infection while 154 (11%) had a recent infection. This means that 1256 out of 1410 girls had spent 12 months or more with unidentified infection.

Conclusions: The implication of this is that Uganda will not be able to meet the UNAIDS strategy of ending HIV by 2030 if this does not change. This is because, the rate of transmitting HIV is higher among people not on treatment than those on treatment. Early diagnosis and treatment of HIV among adolescents could help reduce further the HIV epidemic prevalence rate in Uganda.

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Large-Scale Community Based PrEP Implementation targeting AGYW Through DREAMS in South Africa: Lessons Learnt

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Background: Pre-Exposure Prophylaxis (PrEP) has been available in South Africa (SA) since 2016 with progressive roll-out; the country has the largest PrEP programme in the world. Wits RHI through USAID funding for DREAMS, implements community-based Sexual Reproductive Health (SRH) and HIV prevention programme targeting adolescent girls and young women (AGYW) across 14 SA priority districts. This abstract highlights key lessons learnt from scaling-up community-based PrEP programme targeting vulnerable AGYW.

Materials and methods: Secondary analysis of routinely collected programme data from PrEP and SRH service delivery, monitored uptake of services and evaluated implementation strategies.

Results: Since November 2019, the Wits RHI's PrEP programme had exponential growth in-support of SA National Department of Health's PrEP scale-up plans targeting people at-risk. By December 2022 a total 112 946 beneficiaries were initiated on PrEP, significant scale-up was between October 2021-September 2022 (64 973 beneficiaries initiated) achieved through the following strategies:
- Target-driven planning that informed resources allocation, quantified implementing staff recruitment and ongoing adaptive programming.

- Differentiated PrEP service delivery model at selected community high-volume AGYW sites. 63% of beneficiaries reached through community-based sites while co-locating and layering services with other DREAMS implementing partners, 24% in DREAMS-priority secondary schools, and 13% in institutions of higher learning targeting AGYW.
- 74% of beneficiaries reached reported partners' HIV status unknown, 65% had condomless sex and 14% had sex under influence of alcohol, therefore the programme was reaching the most at-risk AGYW.
- Social mobilisation and community-entry dialogues facilitated normalization of PrEP and addressing misconceptions that potentially hinders the uptake of PrEP. 179 dialogues with community gatekeepers supported by 53 Community-Based Organisations were done.
- Providing PrEP as part of integrated services is key: 18% of beneficiaries reached were also offered contraception services and screening for STIs. All beneficiaries were screened for GBV and 3% reported GBV exposure.

Conclusion: Scaling community-based PrEP requires multitude of strategies for optimal reach and targeting at-risk beneficiaries as a differentiated PrEP service delivery model. The lessons highlighted enabled Wits RHI to successfully scale community-based service delivery.

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Relationship of Reported Adherence to Blood Drug Levels in Youth Aged 13-24 Years Taking Oral Pre-Exposure Prophylaxis for HIV.

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Background: Youth have a disproportionately high risk of acquiring HIV and may have difficulty remaining adherent to Pre-Exposure Prophylaxis (PrEP). It would be helpful to observe how closely youth self-reports of adherence reflect tenofovir-diphosphate (TFV-DP) and emtricitabine-triphosphate (FTC-TP) drug concentrations in dried blood spots (DBS).

Material and Methods: An evaluation study followed 42 youth for 1 year after initiating oral PrEP. Investigator developed adherence questionnaires and Dried Blood Spot (DBS) specimens were collected at 3, 6, 9, and 12 months. Results from DBS analysis yielded absolute drug concentrations and a color-coded scale describing adequate (> 800), questionable (400-799), or inadequate (<400) fmol/punch concentrations to prevent HIV infection based upon benchmarks established in the Iprex OLE analysis. Percentage of youth meeting each drug level were described with frequencies. Differences between youth < 18 and youth ≥18 and the relationship between youth reports of adherence and the color scale blood concentration results were analyzed with the Kruskal Wallis test.

Results: Youth with adequate drug concentrations to prevent HIV infection varied from 91.7% at 3 months to 66.7% at 12 months. For Truvada, mean TFP-DP concentrations per visit ranged from 1295.5 to 1861.5, while emtricitabine-triphosphate concentrations ranged from 0.256 to .373. For Descovy, mean TAF TFV-DP concentrations ranged from 980.0 to 1928, with emtricitabine-triphosphate levels ranging from 1.69 to 3.27. There were no significant differences between younger and older youth. Mean days missed in the last week was 1.4 (SD=2.2). The relationship between the color scale and self-reported number of days missed in the last week was significantly correlated at 3 (p=.01), 6 (p=.03) and 12 months (p=.02). There was no significant relationship between color scale and time since last missed dose. There were no time trends detected in drug concentrations or adherence.

Conclusions: Youth were relatively honest and accurate in reporting adherence. Reports of doses missed in the last week correlated well with blood drug concentrations. Teens who remained in care maintained consistent blood concentrations of PrEP over time. This study showed excellent drug concentrations in young persons who persisted in taking PrEP, a population with historical challenges adhering to PrEP.

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Prevalence and Correlates of Violence among HIV Positive Adolescents living with HIV in Western Kenya

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Background: Violence against adolescents is often under-reported due to stigma and fear of retribution. Violence has been associated with increased risk of acquiring HIV. We aimed to determine the prevalence and correlates of violence among the adolescents and young adults living with HIV (AYALHIV) in western Kenya and to determine potential impact of the COVID-19 epidemic.

Methods: This was a cross-sectional analysis using data from Data informed Stepped Care (DiSC) study. AYALHIV aged 10-24 years attending 9 HIV care facilities in Homabay and Kisumu counties in Kenya, were enrolled. Behavioral survey data was collected at baseline after routine healthcare appointments and follow up at month 6.

Findings: Between April 2019 and July 2020, 1384 AYALHIV were enrolled, of whom 66% were female; males were significantly younger than females enrolled (mean age 16 vs. 18, p<0.001). Prevalence of lifetime violence increased with age, with 24% and 25% (under 20-years) and 48% and 42% (20+ year old), prevalence of violence in females and males, respectively. Among females under 20, violence was significantly associated with depression, internal stigma, orphan status, and transactional sex. Prevalence of reported recent violence (past 6 months) was 12% among females and 6.1% among males. In males, recent violence declined from 13.0% to 6.1% (p=0.002) and in females from 15.0% to 12.0% (p=0.053) with lower rates in the post-COVID-19 period than the period pre-COVID-19. Females had declines in physical (10.0% to 7.2%, p=0.051), emotional (8.0% to 4.5%, p=0.014) and main partner violence (12.0% to 6.2%, p=0.018). Among males, physical violence declined significantly post-COVID (11% to 3.1%, p=0.001), while emotional and main partner did not significantly change.

Conclusion: Prevalence of violence among ALHIV was higher during the pre- COVID-19 than post-COVID period. This may reflect lower exposure to violence in school or external relationships that were not present during the COVID-19 lockdowns. Our findings differ from other studies which found increased violence, particularly among women during this period.

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Strengthening Provision of Sexual and Reproductive Health Knowledge and Services to Adolescent Girls and Young Women Through DREAMS in Nyamagana, Mwanza Region

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Background: Adolescent girls and young women (AGYW) are disproportionately impacted by HIV. UNAIDS 2021 data indicate that 6 of 7 new infections among adolescents in the region are in girls (15-24 years). In Mwanza region, FIKIA+ project experienced low uptake of sexual and reproductive health services among AGYW, due to low knowledge, awareness, and access. This resulted in inadequate biomedical services coverage including HIV testing services (HTS), HIV self-test (HIVST) distribution, Pre-exposure prophylaxis (PrEP), and condom distribution. Through implementation of DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored and Safe) in Nyamagana district, DREAMS peers were capacitated to provide of sexual reproductive health knowledge to participants with expansion of bio-medical services.

Description: ICAP engaged and trained 12 health-care workers (HCWs) from 11 health facilities (HF) to provide person-centered sexual and reproductive health education and services (SRHS) to AGYW in DREAMS community safe-spaces and health facilities. HCWs provided HTS, HIVST, immediate linkage to antiretroviral treatment

services for those identified as HIV-positive, PrEP and condoms to DREAMS participants. ICAP recruited and trained 44 AGYW peers to sensitize s and create demand for DREAMS services and uptake of bio-medical services across all 18 supported wards in Nyamagana. In addition, ICAP established adolescent and youth friendly services corners in mapped HFs to provide SRHS to AGYW during extended working hours including weekends, and public holidays for DREAMS participants.

Lessons learned: Enrollment into ICAP's DREAMS initiative increased from 1,371 in FY21 to 9,579 in FY22 with expanded uptake of sexual reproductive health and bio-medical services.

Conclusions/Next steps: Capacitated DREAMS peers and HCWs have potential to address gaps in knowledge, awareness, and access to sexual and reproductive health services through people centered services approach especially when coupled with layered primary and secondary services.

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Paediatric Dolutegravir - Why Are We Not There Yet?

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Background: Progress has been made with the rapid introduction of pDTG in ensuring that children living with HIV (CLHIV) receive optimal first- and secondline treatment as stipulated by the WHO guidelines. However, in 2021, CHAI estimated that only 36% of children from 20 LMICs were on DTG-based regimens.

Methodology: PATA provides a collaborative linking and learning platform for frontline health providers (HPs) in sub-Saharan Africa through quarterly virtual case presentations (PATA REAL Webinar) and convening (PATA annual summit). In 2022, two different online surveys were conducted with HPs,the first at PATA REAL in Aug 2022 with 60 HPs from 31 countries, and the second, at the PATA annual Summit in Nov 2022 with 234 HPs from 18 countries. The objectives of these surveys were to establish HPs perspectives on and experiences of pDTG implementation.

Results: On the webinar and summit platform, 75% and 59% of HPs respectively reported that pDTG had been rolled out in their country. Less than half (48%) of webinar participants reported they received training on when and how to transition CLHIV to pDTG (not asked at summit). Challenges associated with poor transition include reluctance of uptake by caregivers (summit 14%; webinar 42%), health systems issues (summit 20%; webinar 12%) these include procurement, and lack of resources to monitor viral load. More than half, (summit 55%; webinar 52%), perceived inadequate training as the most significant implementation barrier. Training gaps identified included lack of clarity on when to transition, dosage and weight bands, and dispensing given the 90 tablet bottles.

Conclusion: With only 52% of CLHIV accessing treatment globally, we cannot allow simple, addressable barriers to prevent access to optimal and quality treatment. Addressing these barriers requires 1) frontline HPs being able to voice their experiences in terms of barriers and enablers to inform service improvements; 2) ongoing mentorship and facilitation of peer-to-peer case-based learning; and 3) access to key information through context appropriate mediums. Only when frontline HPs feel equipped with the right knowledge and tools can the mortality and morbidity of children be reduced, and ending AIDS for this population by 2030 become a reality.

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Longitudinal Lymphocyte Dynamics in Virologically Suppressed Children With HIV Initiating Single-Tablet Elvitegravir, Cobicistat, Emtricitabine and Tenofovir Alafenamide (E/C/F/TAF)

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Background: Lymphocyte counts are known to fluctuate in young children, and several antiretroviral therapies have been associated with hematologic effects. We assessed lymphocyte dynamics in children (age 2–<12 years) with virologic suppression of HIV receiving E/C/F/TAF for 48 weeks.

Material and Methods: Children with virologic suppression of HIV were assessed from two cohorts of a Phase 2/3 open-label study (NCT01854775); Cohort [C] 2: age 6–<12 years, weight ≥25 kg; C3: age ≥2 years, weight 14–<25 kg. E/C/F/TAF was administered once daily for ≥48 weeks. Lymphocyte populations were analyzed by flow cytometry of whole blood using a panel of anti-CD3, CD4, CD8, CD16, CD19 and CD56 antibodies.

Results: Of 52 and 27 participants enrolled in C2 and C3, respectively, median ages were 10 and 6 years, 42% and 37% were male, and 71% and 89% were Black. Median (interquartile range [IQR]) absolute lymphocyte counts (×10³/µL) at baseline were 2.31 (1.92, 2.78) and 2.96 (2.39, 3.82) in C2 and C3, respectively, and these decreased during treatment; changes at Week 48 were -0.04 (-0.67, 0.29) and -0.52 (-1.16, -0.05). Small decreases were also observed in median (IQR) absolute CD4 T-cell counts (cells/µL) at Week 48, with changes of -33 (-194, 80) and -187 (-370, 44) in C2 and C3, respectively. The relative proportion of CD4 T cells and the CD4/CD8 ratio remained stable during treatment. Changes from baseline to Week 48 in CD8 T-cell count (cells/µL) were similar in C2 (-55 [-232, 67]) and C3 (-76 [-293, 98]), but changes in B-cell count (cells/µL) differed between cohorts: 29 (-48, 116) in C2 and -162 (-389, 37) in C3. Respective changes in natural killer cell counts (cells/µL) were 32 (-38, 99) and 1 (-52, 155).

Conclusions: Minor fluctuations in absolute lymphocyte subpopulation counts were observed over 48 weeks of treatment with E/C/F/TAF. The decline in absolute CD4 T-cell counts mirrors known physiological fluctuations in young children, mainly observed in those aged <6 years. No clinically relevant effects of E/C/F/TAF on lymphocytes were identified in this population.

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Generic Dispersible Dolutegravir (DTG) formulation for children: Formulation for Children: A Randomized, Balanced, Two-Treatment, Four-Period, Two-Sequence, Single-Dose, Crossover Oral Bioequivalence Study of VIATRIS's DTG Dispersible Scored Tablets 10 mg with GSK1349572, 5.0 mg in Normal Healthy Adults Under Fasting and Fed Conditions

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Background: To address the needs of children living with HIV (CLWH), the development of and access to age- and weight-appropriate dosing of antiretrovirals (ARVs) play a key role. Through the

Medicines Patent Pool, Viatris holds a voluntary sub-license from ViiV Healthcare to develop and provide access to generic pediatric scored dispersible DTG tablets. The primary objective of this study was to investigate the bioequivalence of Viatris's DTG dispersible tablets (test product, T) 10 mg with GSK1349572 5 mg, (reference product, R) manufactured by GSK R&D Limited UK. The secondary objective was to monitor safety and tolerability.

Material and Methods: This was a randomized, balanced, two-treatment, four-period, two-sequence, single-dose, crossover oral bioequivalence study under fasting and fed conditions. 40 healthy adults were included, aged 18-45 years, weighing ≥50 kg. Bioequivalence of T with that of R were concluded if the 90% confidence intervals (CI) of geometric least square mean ratio (GLSMR) of T and R product fell within the acceptance range of 80% – 125% for ln-transformed pharmacokinetic parameters of Cmax, AUC0-t and AUC0-inf for DTG. Statistical analysis was performed using Phoenix® WinNonlin® Software Version 8.0. Each subject received either one DTG tablet for oral suspension (10mg) of Viatris or two tablets of GSK1349572 (2x5mg).
A minimum 7-day washout separated the periods. During each period, pre-dose (2h before dosing) and post-dose blood-samples (at 26 timepoints over 72h) were collected.

Results: The GLSMRs of T and R product in fasting condition (n=38) for Cmax was 98.95% (90% CI 95.74-102.27), AUC0-t 98.82% (90% CI 96.23-101.49) and AUC0-inf 98.32% (90% CI 95.65-101.05), and in fed condition (n=36) for Cmax was 101.5% (90% CI 98.82-104.33), AUC0-t 95.2 % (90% CI 91.67-98.88) and AUC0-inf 97.7% (90% CI 95.59-99.90). No adverse events (AEs) or serious AEs were reported.

Conclusions: The test product DTG tablets for oral suspension when compared to GSK1349572 met the bioequivalence criteria regarding rate and extent of absorption under fasting and fed conditions. T was as safe as R. The availability of this pediatric formulation is an important step to reach CLWH in Low- and Middle-Income countries.

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'Inhliziyo Iyagxumagxuma (My Heart Is Skipping a Beat)': Global Consultations With Adolescents Living With HIV on the Acceptability and Accessibility of Long-Acting Injectable ART

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Long-acting injectable (LAI) ART is seen as a solution to poor adherence in adolescents living with HIV (ALHIV), but to date, no-one has formally engaged this group to explore how acceptable and accessibly this medication is to them.

Penta, with the support of ViiV Healthcare, ran the Long Acting Injectables Advisory Group Project (LAAG). This engaged NGO partners in five different countries: Argentina, South Africa, Thailand, Uganda, UK. Each hosted a consultation workshop for a minimum of 8 ALHIV (horizontal and vertically infected), then supported two representatives to attend a global advisory group.

Partners were located through the Penta network and advertising. Workshops ran April-May 2023 using youth-participation theories and youth-friendly activities. Country workshop representatives presented at a global advisory group meeting, using interpreters to ensure full participation.

The provisional findings include the following areas:
- Unawareness of LAI development.
- Excitement as hiding medicine no-longer necessary.
- 'Freedom' from pill burden, reminders, and alarms.
- Better adherence and health outcome.
- A way to 'forget' about HIV.
- Perinatal ALHIV questioned if they could 'trust' injections and worried about viral rebound, sickness, and death.

- Fear of perceived pain from the injections and injection site.

Solutions offered to support their community included:

- Education and demonstrations on LAIs to address fear.
- Pain relief.
- Exploring other injection sites (other parts of body, self-injection, less frequent injections).
- Administrating injections in the community.

Learning to-date included:
Locating NGO partners varied enormously. Either there are limited NGO's offering ALHIV support in some countries, or they have limited on-line presence. This led to having to work in alternative countries to those originally planned.

The workshops offered additional therapeutic and educational opportunities for those attending.

LAI's may support burying HIV self-stigma deeper in this cohort, which could lead to unaddressed mental-health issues. Those supporting ALHIV must actively address this as part of adolescent's care package.

To conclude, engaging ALHIV in discussion on LAI's offered important insights on how they need to be engaged, educated, and supported, as well as offering community-led ideas of ways to administer LAIs and future ART development.

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Assessing the Impact of Non-disclosure of HIV-Positive Status on Adherence in Children Aged 8-14 Years

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Background: Over the years, there has been an increase in poor adherence and viral load non-suppression among children on ART despite all the interventions in place. W.H.O recommends partial disclosure at 6 years and full disclosure by 12years. However, this has not been done by some parents due to fear of its consequences. AIDS Information Centre-Uganda (AIC) carried out a survey on 20 children in care with poor adherence and their parents to ascertain if non-disclosure affects adherence

Materials and Methods: We got a line list of the 20 children with poor adherence and their parents. These were invited for a support group meeting where parents were interviewed on how they addressed questions about daily medication from the children and how the children felt about taking daily medication. Two different questionnaires were used in interviewing the children and parents.

Results: Out of 20 parents interviewed, 4 told their children they were on Tuberculosis medication, 5 told them the daily medication was for strength, 4 told them it boosts class performance, 2 told them to take medication because they were also taking daily medication, 4 reported that their children found out from school and took drug holidays, 1 parent confessed giving 2 of her negative children painkillers to encourage the positive one to take ART.
On assessing the impact of the above findings on adherence; 2 became non-suppressed and were switched to second line, 9 children randomly stopped taking medication for 2-4 weeks as reported by their parents, 3 children stopped due to side effects, and 6 children had a detectable viral load.
One on one counselling revealed that these children indeed had interrupted treatment because of non-disclosure. However, when health- workers supported parents to disclose, all the children are now adhering well because they understand its benefits.

Conclusion: The findings above confirm that non-disclosure indeed affects adherence. Children have a right to know why they are taking daily medication, therefore parents should be supported by health workers on the onset of curiosity about their health and disclose their HIV status to them.

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Cambodia's People-Centered Approach to pDTG Introduction: A Model for the Region

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In Cambodia, an estimated 2,300 children were living with HIV (CLHIV) in 2021; 56% knew their status, 56% were on treatment, and 49% were virally suppressed. In mid-2021, paediatric DTG (pDTG) was included in Cambodia's national treatment guidelines, in line with WHO guidelines, due to its clinical superiority and improved tolerability, which strengthens adherence.

Cambodia is one of the first countries in Southeast Asia to include pDTG in HIV treatment guidelines and transition eligible CLHIV to pDTG-based regimens. The smooth transition required a series of policy and data analyses, national target-setting, clinical consultations, operational guidance amendments, training/IEC materials, monitoring of suboptimal ARV stock, wastage analysis, and site-level trainings. To date, all 71 ART sites have been trained on pDTG clinical management and operational guidelines. As of November 2022, after its introduction in January 2022, 42% of eligible CLHIV on treatment were on pDTG.

Setting the national target for pDTG transition and communicating it to relevant stakeholders, including national and frontline staff, has been key in pDTG introduction and scale-up. The National HIV Program, donors, and UN agencies play a critical role in establishing buy-in, supporting development of an early adoption strategy, and building a business case by calculating risks and benefits, including via cost-effectiveness analyses. Confidence and leadership of the National HIV Program with support from WHO and other global HIV innovators were the main drivers of this initiative. Evidence-based policies were drawn by collecting empirical data on client adherence and clinicians' experiences dealing with caregivers' frustrations with regimen switches, while policy makers were helpful in sharing global practices and market intelligence. A people-centered approach 'Patient, Policy Maker, and Provider - 3Ps' was core throughout the implementation process. Although the transition is encouraging, there were barriers to a more accelerated uptake, including widespread resistance to wastage of legacy products, a pre-transition viral load requirement, and miscommunication on the transition timeline at the site level.

The pDTG rollout in Cambodia provides important building blocks that can be emulated by other countries interested in optimising ARV regimens and illuminates potential barriers that should be addressed to ensure smooth uptake.

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Integrating Ovc Services in HIV Service Delivery to Achieve the 95.95.95 for Children and Adolescents

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Introduction: In Uganda, despite the interventions delivered by the Ministry of Health, ART initiation is still below 90%, viral suppression rates among children remain low, at 77%, way below the UNAIDS target of 95%. Moreover, viral suppression among children <5 years is even much lower at 60%, retention for children in care is 80%. the Ministry of Health coordinated with the PEPFAR's OVC program to deliver child-focused, family-centered interventions that seek to improve well being and mitigate the impact of HIV and AIDS on children and families. This effort involved working in partnership with health facilities to identify, plan, and complete a series of actions in an effort to achieve the 95-95-95.
The study explored areas of focus in strengthening OVC integration in HIV service delivery in Uganda.

Methods: This was a rapid assessment and was both qualitative and quantitative in districts across Uganda for a period of 8 months intended to pick early learning in strengthening OVC integration in HIV services. Qualitative data collected was through coordination meetings at national and regional level while quantitative data was collected through

health facility supervision and assessment reports which were analyzed to inform the results.

Results: Quantitative data collected from 27 districts and 603 health facilities showed that only 41% children are screened for OVC services and 66% enrolled on the OVC programs. Regular coordination meetings at national level by line ministries Ministry of Health and Ministry of Gender, Labour and Social Development, PEPFAR, OVC and Clinical partners, joint supervision, performance review and data sharing between the OVC and clinical partners strengthened coordination among the different parties.
The areas of improvement noted included: training of social workers and OVC officers in HIV services, strengthen documentation at health facility level for services provided to children by OVC partners.

Conclusion: There are major barriers to strengthening integration of OVC services in HIV especially the limited capacity of OVC workers in understanding the HIV cascade. There is need to improve linkages between OVC and health facilities, documentation, timeliness of OVC service delivery especially to the non-suppressed clients to improve retention, viral load coverage and suppression.

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Engaging Orphans and Vulnerable Children (OVC) Programs to Improve Pediatric Viral Load Coverage and Suppression in Burundi

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Background: Although Burundi is home to 64,000 orphans as a result of HIV and 7,800 children and young adolescents (<15y) living with HIV (C/YALHIV) (UNAIDS), pediatric viral load achievements continue to lag adult achievements. The PEPFAR/Burundi clinical and Orphan and Vulnerable Children (OVC) programs are committed to supporting C/YALHIV to achieve and maintain viral suppression.

Description: PEPFAR/Burundi clinical and OVC local partners collaborated with the national HIV program to support facility and community pediatric HIV services. From 1 October 2021 - 30 September 2022 (fiscal year [FY] 22), PEPFAR/Burundi expanded OVC programming from five to six provinces. Clinical and OVC partners increased deliberate collaboration to ensure C/YALHIV were offered enrollment in OVC services and conducted joint case conferencing meetings. Clinical partners supported optimization of treatment regimens. The OVC program offered peer support groups for C/YALHIV to enhance adherence to treatment and leveraged peer networks to provide testing referrals to at-risk youth. The OVC program also provided family-centered case management to deliver services including access to other health services, education support, and economic strengthening. A key effort in the program has been to transition funding and allocate program targets to local partners to address case-finding and treatment gaps among C/YALHIV.

Lessons learned: Based on routine FY22 data, viral load coverage (VLC) among C/YALHIV improved from 75% to 90% and overall viral load suppression (VLS) remained ~90% throughout FY22. However, VLC and VLS varied between provinces, with an estimated VLC range of 75% - 117%, and VLS range of 85% -100%. As a testament to the Government of Burundi's and PEPFAR's commitment, OVC programs have received a 47% increase in funding over the past five years, which has allowed the OVC program to expand geographic coverage and offer a robust package of services to support C/YALHIV.

Conclusion/next steps: Burundi continues to strengthen C/YALHIV viral load achievements through clinical and OVC programmatic collaboration. To address equity gaps, there is an ongoing need to ensure all C/YALHIV enrollees are offered person-centered facility and community support that fosters timely case identification, treatment initiation, treatment continuity, and long-term viral suppression.

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Oral Health Status and Its Association with CD4+ Cell Count In Paediatric Living With HIV

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Background: HIV positive children are at higher risk of oral mucosal lesions. The association with a reduced CD4+ count is not fully explained in the literature. This study examined the association between the decayed, missing and filled teeth (DMFT) score and CD4+ cell counts in paediatric children living with HIV. Further other parameters like debris index, salivary flow, salivary pH and oral health-related quality of life are also examined.

Methods: Hospital data was assessed to evaluate the patients. The study population had 63 HIV positive patients. The DMFT index was retrieved and viral load data was matched. Multiple logistic regression analysis was performed to corelate dental caries with viral load.The cut-off point for undetectable viral load was set at < 40 copies/mL.

Results: DMFT scores and debris score were negatively associated with the CD4+ cell count in paediatric children. A positive association were observed between salivary pH and CD4+ count and between salivary flow.

Conclusions: Children living with HIV have a higher DMFT score and poorer salivary pH level. Preventive interventions need to be performed to align to have a good oral quality of life.

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Analyzing HIV Pediatric Deaths In USAID Afya Yangu Southern Program - FY22

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Analyzing HIV Pediatric Deaths In USAID Afya Yangu Southern Program - FY22

Problem Statement: The USAID Afya Yangu Southern program undertook deaths analysis on its pediatric clients aged <5 and 5-14 years across program regions as part of its data quality and reporting improvement strategy to inform program performance. The analyzed data covered Oct 2021-Sep 2022.

Methods: The annual pediatric analysis followed up on the dead clients' duration on treatment, latest CD4 Ranges before death, regimens at death, last HVL status, reasons for death (verbal autopsy), adherence and IPT status using CTC Analytics and MS Excel.

Results: The analyzed data showed 140 total deaths. For children under 5 deaths were dominant among high (>500) CD4, Lopinavir first-line users, those with > 6 months in treatment, not initiated on TPT, poor adherence and unknown reasons for deaths constituting 56% while for those aged 5-14 the death toll was among DTG3 users (Not Lupinavine), HVL suppressed, those who were on treatment > 1 year and those who did not complete IPT at 44%. Similarities existed between the groups on high death casualties attributed to poor adherence and high (>500) CD4 indicating significant statistical association between these factors and death among the two groups.

Discussion and Conclusion: The analyzed data indicated more deaths for children under 5 compared to those above 5. Most of these died while under regimen for > 6 months, most of them were not routinely checked for HVL as required which calls for close monitoring on the area. As for those aged > 5, the situation is similar with exception that most of those who died under this age group had suppressed HVL status.
The significant number of deaths attributed to poor treatment adherence and IPT non completion

which could infer services improvement need and/or data quality and completeness issues is an eye opener to the program which needs addressing.

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Electronic Monitoring Devices Feasible and Acceptable for Adolescents Living With HIV in Zimbabwe

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Introduction: Adherence to antiretroviral therapy (ART) among adolescents living with HIV (ALWH) is lower than other age-groups, which leads to viral non-suppression. Electronic monitoring devices (EMDs) can improve adherence. EMDs provide detailed daily information about medication intake which can be used to identify those at risk of treatment failure. The use of EMDs by ALWH has been limited in both research and clinical practice. We conducted a mixed methods study to assess the field operationalisation and acceptability of EMDs among ALWH in Zimbabwe.

Methods: ALWH enrolled in a clinical trial investigating the effect of weekly vitamin D supplementation on bone health in Harare were randomly selected to use the EMD for 24 weeks to take the trial drug. No feedback on vitamin D adherence recorded by the EMD was given to participants. 16 participants were purposively selected for qualitative interviews to explore acceptability of using the EMD.

Results: Of the 97 participants enrolled, 50 (52%) were female and age range was 11–20 years. All participants used the EMD to store and take vitamin D. One EMD was destroyed in a housefire, 5 recorded low battery (after a median 19 weeks) and were brought back in time for recharging, and 36 (37%) EMDs lost connectivity with the server for ≥ 14 days during the study, of which 8 spontaneously restored connectivity. The 28 participants whose EMDs lost connectivity were recalled for manual data upload. No data was lost as the EMD can record and save pillbox events even when offline. In 10 cases loss of connectivity was caused by the participant visiting a rural area. Participants found the EMD easy to use. Older adolescents (16-20 years) expressed that the EMD was better than traditional ART pillboxes because it was discreet and prevented inadvertent HIV disclosure. Most participants felt that the device would be beneficial in improving ART adherence as a result of knowing that they were being monitored.

Conclusion: EMDS are feasible and acceptable for ALWH in Zimbabwe. This study has informed a clinical trial investigating effectiveness of EMDs paired with text message reminders for ART adherence.

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Prevalence and Associated Factors of Suicidality Among Young Thai Men Who Have Sex With Men at Risk for and Living With HIV

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Background: To demonstrate prevalence and associated factors of suicidality among Thai young men who have sex with men (YMSM) who are at risk for and living with HIV.

Methods: A cross-sectional study was conducted among YMSM (15-25years) who were either at risk for or living with HIV, and received medical services at a community clinic or tertiary hospital in Chiang Mai, Thailand. Suicidality was evaluated using a self-report questionnaire which asks about lifetime and recent (within 1month) suicidal ideations and behaviors, and a suicidal plan in the next 3months. The severity of suicidality was defined as very low (never having suicidal ideation/behavior), low (ever having lifetime suicidal ideation), moderate (ever having recent suicidal ideation and/or lifetime

suicidal behavior), and high risk (ever having recent suicidal behavior and/or future suicidal plan). Additional evaluations included Patient Health Questionnaire 9-item (PHQ-9), Generalized Anxiety Disorder 7-item scales (GAD-7), Post-traumatic stress disorder (PTSD) CheckList-Civilian version (PCL-C), and Alcohol Use Disorders Identification Test (AUDIT) for screening depression, anxiety, PTSD, and alcohol use disorders, respectively. Logistic regression analyses were performed to determine factors associated with moderate-to-high suicide risk.

Results: We enrolled 100 at-risk YMSM (median age: 20years; 24% on pre-exposure prophylaxis), and 50 YMSM living with HIV (median age: 22years; all on cART; 78% had viral load <20copies/mL). Overall, moderate-to-high suicide risk was identified in 10 at-risk YMSM (10%; 95%CI: 5-18%), and 4 YMSM living with HIV (8%; 95%CI: 2-19%) (P=0.90). Additionally, significant depressive symptoms (PHQ-9≥10 out of 27), anxiety symptoms (GAD-7≥10 out of 21), and PTSD (PCL-C≥45 out of 85) were identified in 27% versus 32% (P=0.81), 15% versus 16% (P=0.97), and 10% versus 24% (P=0.02), and the median AUDIT scores were 5 versus 4 out of 40 (P=0.07) among at-risk YMSM versus YMSM living with HIV, respectively. In multivariable logistic regressions, significant depressive symptoms (adjusted odds ratio[aOR]: 5.3; 95%CI: 1.1-25.4) was associated with moderate-to-high suicide risk among at-risk YMSM, whereas higher AUDIT score (aOR: 1.6; 95%CI: 1.1-2.3, per one score increased) was an associated factor for YMSM living with HIV.

Conclusions: Suicidality was relatively prevalent in our Thai YMSM. Early assessment of suicidal ideation and behaviors in primary HIV services is important.

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"I Did Not Want Them Seeing Me": Factors Influencing Antiretroviral Treatment Adherence During the Adolescent Period of Young People With Perinatal HIV in Thailand: A Qualitative Study

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Background: The varying rates of antiretroviral treatment adherence between 19-99% in adolescents living with HIV were reported globally. Young people with perinatal HIV (YPHIV) who survived and grew up into adulthood experienced adherence challenges that led to unsustainable but resumable virologic suppression. We explored factors influencing treatment adherence during adolescent years from real-life experiences of YPHIV.

Methods: A qualitative study was conducted in Chiang Mai, Thailand, from June to November 2022. Twenty YPHIV (8 females /12 males, aged 21-29) were invited to share their adolescent experiences through in-depth interviews. Audio transcripts were analyzed using content analysis to identify the barriers and facilitators influencing their treatment adherence.

Results: The study divided barriers and facilitators to treatment adherence in their adolescent period into the personal, community, and healthcare system levels.

At the personal level, barriers to treatment adherence included hanging out with friends, sticking in the middle of work or entertainment, uncertain working hours, belief in their strength/ invincibility, unfavorable personal life situations, mental health difficulties, pill burden, and annoying side effects of medications. The facilitators were perceiving their health deterioration and revisiting opportunistic infections during virologic failure, being afraid of hospitalization and medical procedure-related sufferance, and the wish to be healthy and move on.

The most common barrier reported at the family, friends, and community level was fears of HIV disclosure when taking medications. While the facilitators included perceiving family support, the desire to prevent mother-to-child transmission, their responsibility for kids, and their determination to complete family without HIV transmission.

At the healthcare system level, extra medical care payment and transportation costs to the clinic were identified as barriers to adherence. YPHIV described the negative service behaviors of healthcare providers as a part of their HIV care experiences which could be considered barriers or facilitators in different circumstances.

Conclusions: The main factors influencing adolescents' treatment adherence concentrate on various personal factors and fears of HIV disclosure. Understanding those existing factors would enable mindful health service delivery. Our study supported the need to allocate more time for tailored individual counseling to maximize adherence self-efficacy during the transitional period of young people's life.

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Association Between Mental Disorders With Detectable Viral Load and Poor Adherence to Antiretroviral Therapy Among Adolescents Infected With Human Immunodeficiency Virus on Follow-up at Chantal Biya Foundation, Cameroon

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Adolescents living with Human Immunodeficiency Virus (ALHIV) are more likely to experience mental health challenges. In resource-limited countries, co-morbid mental health trouble in ALHIV is the most neglected condition in the HIV care package. The vast majority of Antiretroviral Therapy (ART) patients affected by mental health problems remain undiagnosed and untreated. Mental health disorders may lead to poor HIV treatment outcomes. This study aimed at identifying mental health conditions associated with detectable viral load or poor ART adherence among 10-19-years old Cameroonian adolescents.

This was a cross-sectional study which enrolled adolescents perinatally infected with HIV, aged 10-19 years, on follow-up in a referral hospital in Cameroon. Structured questionnaires were administered to the study participants. The primary outcome was detectable viral load, defined as elevated viral load > 40 copies/mL in plasma in a person with HIV who has been on ART for at least six months. The secondary outcome was poor ART adherence, defined as > 1 missed dose of ART drugs within the last three days before screening.

In total, 302 adolescents were recruited in the study at a median age of 15.2 years old, including 159 (52.7%) girls. Out of 302 adolescents who were enrolled in this study, 53 (35.0%) were poorly adherent to ART. Among the 247 adolescents with available viral load, detectable viral load was recorded in 33 (26.7%) of them. Low self-esteem was strongly associated with higher risk of poor adherence to ART (p=0.022). However, poor ART adherence was slightly less frequent when the adolescent was living with the father (p=0.085) or the household was equipped with a televisor(p=0.069). Having both parents alive (p=0.031) or receiving efavirenz or dolutegravir-based ART regimen (p=0.047) were strongly associated with a lower likelihood of detectable viral load. Moreover, detectable viral load was slightly less frequent in adolescents whose household was equipped with a televisor (p=0.084) or who were completely disclosed for HIV status (p=0.070).

This study found that co-morbid low self-esteem had higher odds of poor ART adherence in ALWHIV. Moreover, both poor ART adherence, and

detectable viral load were associated with impaired life conditions in ALHIV.

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Implementation of a Collaborative Care Model for Mental Healthcare among Adolescents and Young Adults Seeking HIV Services in Bangkok: A Qualitative Study

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Background: Adolescents and young adults (AYA) living with and at risk for HIV have high depression rates, which are associated with delayed HIV care access and poor medication adherence. An integrated collaborative care model to screen and treat depression in AYA by HIV providers could address limited availability of mental health services (MHS) in Thailand.

Materials and Methods: From November 2021-February 2022, we conducted in-depth interviews with 16 AYA (8 with HIV, 8 using pre-exposure prophylaxis) and 16 healthcare providers at an adolescent clinic in Bangkok. Interviews explored attitudes towards mental illness and MHS, feasibility, acceptability, facilitators, and barriers to care integration. Interview guides and analyses were guided by the Consolidated Framework for Implementation Research. Interviews were transcribed, uploaded to Dedoose, and analyzed using a content analysis approach.

Results: Median AYA age was 20 years (range 16-24); 82% identified as men who have sex with men. Providers were 75% female, and included 4 pediatricians, 4 psychiatrists, 2 nurses, 2 psychologists, 2 peer educators, and 2 health advisors. Providers described increased societal awareness of mental illness over the past decade. Most AYA saw mental health issues as stigmatized and wanted improved access to and provision of MHS. Providers commented that feasibility of integrated care could be improved through staff training, ongoing specialist support, and depression and suicidality care protocols. AYA suggested that increased clinic hours, "one-stop" comprehensive services, holistic care, online contact, and friendly staff were important to successful care integration. Staff described integrated care as acceptable because it improved treatment adherence, whereas acceptability from AYA was through its improvement of MHS accessibility. However, some AYA worried integrated care would limit access to psychiatrists to manage severe mental health issues. Facilitators of care integration for AYA included MHS visibility in mainstream media and educational institutions, and use of self-screening tools with service linkage information. Care integration barriers for AYA included stigma, inaccessibility, inconvenience, cost, lack of MHS availability, and judgmental/aggressive staff.

Conclusions: Staff and AYA viewed the collaborative care model as a feasible and acceptable solution for implementing integrated HIV and mental healthcare in a high mental healthcare needs context.

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Optimization of a Stepped Care Intervention for Adolescents and Youth Living With HIV in Kenya Using Continuous Quality Improvement

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Background: The Data-informed Stepped Care study is a cluster randomized controlled trial testing provision of a differentiated care program (Stepped Care) across 24 HIV care clinics in Kenya, aimed at improving retention in care for youth living with HIV (YLH). We describe adaptations to Stepped Care

implementation made by health providers to optimize uptake and delivery.

Methods: Between May and December 2022, we conducted continuous quality improvement (CQI) meetings with providers to adapt Stepped Care delivery at 12 intervention sites in 3 counties (Kisumu, Homabay, and Migori). Guided by plan-do-study-act (PDSA) processes, providers identified challenges and proposed targeted adaptations to improve intervention reach, adoption, acceptability, feasibility, and fidelity. Providers also completed surveys to quantify implementation perceptions. CQI meetings were audio recorded and analyzed using the Framework for Reporting Adaptations and Modifications-Expanded (FRAME) to categorize the level, context, and content of planned adaptations and determine if adaptations were fidelity consistent or inconsistent.

Results: Providers, including nurses (N=14) and clinical officers (N=35), participated in 96 CQI meetings. Providers were a median age of 34 years (IQR: 30 – 38) and mostly female (53%). A total of 65 adaptations were made (23 unique). The majority of adaptations were context-specific, related to implementation, and consisted of improving documentation addressing scheduling challenges (election climate or reaching in-school YLH), or clinic workflow. Primary reasons for adaptation were to increase reach among YLH who did not attend clinic with caregivers, lacked updated contact numbers or phones, or were unreachable because they were in school. Adaptations to addressing challenges with reach included reminder calls to caregivers to attend visits with YLH, collaborating with schools to ensure in-school YLH attend their appointments, and addressing transportation challenges. Providers also adapted to mobile delivery to improve adoption and feasibility of counseling sessions, and improved fidelity by adapting processes for assessing levels of care and ensure YLH received correct services.

Conclusions: Adaptations identified by providers targeted availability of resources and aimed to reduce barriers to service access unique to YLH. Adaptations that optimize implementation and promote integration into routine practice can inform future scale-up and scale-out of Stepped Care to other settings.

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Preservation of Postural Control in Kenyan Adolescents Living With HIV

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Impaired motor function has been reported in children and adolescents with vertically transmitted HIV. Correspondingly, cortical and subcortical brain regions involved in motor behaviour show structural abnormalities in this population. Recent evidence suggests that postural control may be impaired in adolescents living with HIV (ALHIV). We measured postural sway in Kenyan ALHIV and community controls to test the hypothesis that alterations in postural control would be evident in ALHIV. Participants were 32 ALHIV who were 14-17 years old and had been recruited directly from an existing NIH-funded cohort enrolled in a longitudinal adherence study of children who perinatally acquired HIV in Kenya. Thirty-two community controls also participated. Participants stood as still as possible on an AMTI Accusway (Watertown, MA) force platform for 120 seconds in 4 conditions that varied according to visual input (eyes open vs. closed) and base of support (feet shoulder width apart vs. feet together). Center-of-pressure (COP) path length and area were calculated, and COP time series fluctuations were decomposed into centrally and peripherally mediated components using 2 conceptually related by distinct approaches: rambling-trembling analysis and frequency-specific fractal analysis (FsFA). Group differences were determined using repeated measures ANOVAs. Similar analyses were conducted within the ALHIV group using an independent, binary categorical variable for viral suppression for which ALHIV with viral load > 1,000 copies/mL at any point during clinical care were defined as virally non-suppressed. Sway path and area did not differ between groups, nor were there differences in rambling-trembling or FsFA measures. Within the HIV group, viral suppression status did not significantly differentiate between groups, nor did it not interact with key sway outcomes. Contrary to previous recent reports and

to our hypotheses, ALHIV in this study showed no evidence of postural control deficits and were remarkably similar in sway performance to community controls. This group of ALHIV is differentiated from previous studies by a high rate of medical engagement over multiple years resulting from their participation in an NIH-funded longitudinal adherence study. The high level of engagement necessitated by study participation may have may have provided neuroprotective benefits resulting in preservation of postural control.

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Emergence of Pediatric Advanced HIV Disease in a Tertiary Center in the Philippines: A Case Series

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Background: The Philippines has a low HIV prevalence, 0.2% in general adult and Central Luzon ranks 3rd as the region with the highest number of cases in the country. HIV testing in antenatal care is voluntary, and only <1% of pregnant women know their HIV status. According to the Department of Health, there were <1000 pediatric cases reported from 2010-2022, yet majority of children brought in were the index case in the family, and already in advanced stage. The study aims to present case series of children living with HIV seen in a tertiary referral center in Pampanga, Philippines during 2016-2022.

Method: Retrospective case series of children diagnosed with HIV at Jose B. Lingad Memorial General Hospital (150 pediatric beds) in Pampanga, Philippines. Clinical presentations and antiretroviral treatment outcomes were described.

Result: There were 14 children living with HIV with median (range) age of 34 months (10-154), ten of them diagnosed as index case in the family. Seven patients were diagnosed in 2015-2021 and another seven in 2022 alone. Nine children (64%) already in WHO stage 3 or 4. Median CD4 at baseline was 285 (0-1036) cell/mm3. Opportunistic infections noted were tuberculosis (n=6), oral Candidiasis (n=5), Pneumocystis jiroveci pneumonia (n=3), CMV retinitis (n=1). Antiretrovirals initiated were Nevirapine (7), Dolutegravir (3), Efavirenz (2), Lopinavir/ritonavir (1), Abacavir (1)-based regimen. Currently, all except one used crushed adult antiretroviral treatment due to lack of access to pediatric formulation. For the outcome: 2 died, 2 lost to follow-up, 2 transferred hubs. Among those who continue to follow up, only 2 out 5 patients (40%) achieved plasma HIV RNA viral suppression < 40 copies/mL

Conclusion: This study described the emerging pediatric HIV/AIDS situation in Philippines. With low coverage of HIV antenatal screening and limited supply of pediatric antiretroviral drug formulation, the outcome of children living with HIV is poor. The policy on voluntary HIV screening pregnant women and the supply of pediatric formulation of antiretroviral drugs need urgent scrutinization to immediately address this alarming crisis in the Philippines.

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Generalized Mycobacterium Avium Complex (MAC) in Children Living With HIV in Ukraine

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Mycobacterium avium complex (MAC) include multiple related species of nontuberculous mycobacteria (NTM). With the implementation of antiretroviral therapy (ART) the MAC incidence as an opportunistic infection in people living with HIV dramatically decreased (1). However, the risk of disseminated MAC infection in children living with HIV is still remains and increases with age and decreasing CD4 T lymphocyte (CD4) cell count.

Aims: To estimate incidence of MAC in pediatric HIV cohort in the Infectious Disease Centre "Clinic for treatment children with HIV/AIDS" (Clinic), immunologic characteristics of patients, clinical features and severity of process, MAC -immune reconstitution inflammatory syndrome (MAC-IRIS) characteristics, challenges in diagnostic and

treatment MAC-IRIS in pediatric HIV cohort in Ukraine.

Methods: The retrospective analysis of the medical records of children 0-18 years old with HIV, who received treatment in Clinic from 01 January 2022 to 01 January 2023 was made. Three patients with disseminated MAC were found.

Results: The average age of patients who were diagnosed with MAC was 9 y.o., 100% female. The average CD4 percentage and absolute cells count before the MAC diagnostic were 2,7% and 10 cells /ml, respectively. All patients had a fever, abdominal pain, anemia at the presence. In 2 cases MAC were diagnosed in bronchoalveolar lavage (BAL), in 1 case BAL was negative, but nontuberculous bacteria were found in bone marrow. In 66% ART was started before MAC treatment, however, with azitromycin preventive treatment on the background. The average time from start ART till presents of MAC-IRIS was in range 4-34 days.

Discussion: Despite the wide coverage of ART in Ukraine in recent years, the situation with late diagnosis of perinatal HIV infection still persists, moreover, it worsens in war conditions. As the experience of our clinic shows, the number of disseminated MAC infections increased with a high frequency of IRIS development.
The current tendentious «test and treat» works effectively, however, for those, who have severe immunosuppression this strategy can lead to IRIS developing. The patients who diagnosed with HIV should be carefully examined for OI before ART, although, on the extremely low CD4 cells it is an enormous challenge.

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The Situation of Adolescents in New HIV Infections in the Key Population Group in the Health District of Richard-Toll, Senegal in 2022

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Background: Richard-Toll is located in the north of Senegal, about 400km from the capital. It has a population of 200698 and covers an area of 2912km2. The district follows a cohort of 284 patients living with HIV. Over the past 5 years, an increase in new infections among young people has been noted. The objective of the study was to analyze the cohort of patients followed and to identify the causes of this new wave of contamination.ague de contamination.

Methods and Materials: Survey forms on the socio-demographic characteristics of patients, contacts, profession, lifestyle, environment, level of knowledge on HIV, clinical and paraclinical characteristics of patients, level of education, sexual orientation and practices were distributed according to the study protocol. Screening activities were also conducted during the study. Individual and focus group interviews were held. The statistical software R studio was used.

Results: Thus 79% of the patients in the cohort were considered to be in key populations (sex workers 27%), (injecting drug users 12%), (6% were young children who had experienced mostly gender-based violence such as rape in childhood, often unpunished and kept secret in a poor family with an income of less than 1 euro per family member per day). 55% of the patients were in the age group of 15-25 years and were pupils, students in the majority and others were engaged in art activities or were unemployed. The analysis of the survey forms showed that nearly 75% of these young people had same-sex sexual orientations and stated that they could not live their sexuality fully because of society's homophobic reticence and did not find the reception satisfactory to be able to attend health structures in order to benefit from care in case of illnesses and to obtain the available prevention methods. The majority of these young people said they needed proctology consultations but did not have access to them and feared gender-based violence.

Conclusion: The results of this study identified an urgent need to develop strategies for these key populations to provide better access to screening, treatment, and prevention.

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Results Among HIV-Positive Women Hospitalized With COVID-19 at Moi Teaching and Referral Hospital, Eldoret, Kenya

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Background: COVID 19 continues to cause high mortality rate in Kenya among HIV+ expectant women diagnosed with COVID 19. Preliminary data on COVID 19 infection shows that some immune compromised hosts experience worse outcomes. We performed a cohort study to characterize outcomes in HIV-positive women with COVID 19 infections.

Methods: Primary Data was collected from medical records for HIV+ expectant women diagnosed with COVID 19 hospitalized at Moi Teaching and referral hospital between April 1, 2020 to May 30, 2020, we matched 25 HIV+ expectant women diagnosed with COVID 19 with 50 HIV negative patients using a greedy nearest-neighbour algorithm. Admission symptoms and laboratory test results were recorded and compared among the two set groups.

Results: Although there was a trend toward increased rates of intensive care unit admission, mechanical ventilation, and mortality in HIV-positive patients, these differences were not statistically significant. Rates for these outcomes in our cohort are similar to those previously published for all patients hospitalized with COVID-19. HIV-positive patients had significantly higher admission. Other inflammatory markers did not differ significantly between groups, although HIV-positive patients tended to have higher peak values during their clinical course. Three HIV-positive patients had superimposed bacterial pneumonia with positive sputum cultures, and all 3 patients died during hospitalization. There was no difference in frequency of thrombotic events or myocardial infarction between these groups.

Conclusions: This study provides evidence that HIV coinfection does not significantly impact presentation, or outcomes of HIV+ expectant women diagnosed with COVID 19, when compared with matched non-HIV patients. A broader and detail study is required to determine whether the trends we observed apply to all HIV+ expectant women diagnosed with COVID 19.

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Prevalence and Factors Associated With Risky Sexual Behaviors Among Female Adolescents in Zambia

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Introduction: In sub-Saharan Africa, female adolescents are four times more likely to get HIV than boys; Zambia reports an HIV seroprevalence of 13.9% among women VS 8% among men. Adolescents are vulnerable for various adverse health outcomes due to lower perceptions of consequences of risky sexual behaviors (RSB). HIV/AIDS and unintended pregnancies continue to be major causes of mortality among adolescents in Zambia, necessitating public health action. This study aims to explore the prevalence and factors associated with RSB among Zambian female adolescents.

Methods: RSB is defined as sexual activities which expose people to the risk of HIV, STIs and/or unintended pregnancies, this includes early sexual initiation, sex with multiple partners, having sexual intercourse while intoxicated, transactional sex, and unprotected sex.
Data on adolescent females, aged 15-19 (n= 3000), were obtained from the 2018 Zambia Demographic and Health Survey, an interviewer-administered, nationally representative survey that used multistage sampling. The study conducted multivariable logistic regression to explore the correlates of RSB.

Results: Of respondents, 49.7% reported ever having sexual intercourse and 35.3% (71.1% of sexually active respondents) reported engaging in RSB. The following RSB percentages were reported: intercourse before age 16 (25.1%), not using condoms at last intercourse (18.8%), engaging in transactional sex (3.1%), alcohol use at last intercourse (2.3%) and multiple sexual partners

(0.9%). Educational attainment and household wealth showed strong inverse trends with RSB and there were notably large geographic differences in RSB within Zambia (22.1% in Lusaka region versus 62.4% in Western province). The multivariable results revealed that those who were older, employed, less educated, less wealthy, residing in Southern, Western and Northwestern provinces and those with no exposure to print media were significantly more likely to have engaged in RSB (AOR: 1.28-4.11, p<0.05). Among sexually active females, similar trends were noted except that younger, non-married adolescents without internet access were at higher risk of RSB.

Conclusion: This study has shown that over a third of Zambian female adolescents and over 70% of the sexually active females are at high risk of adverse reproductive health outcomes. Therefore, there is a need for more adolescent health programs targeting SRB.

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Assessment of the Effectiveness of Prevention of Mother-to-Child Transmission (PMTCT) of HIV Program in a Tertiary Health Institution in South East, Nigeria

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Background: Effective prevention of mother-to-child transmission (PMTCT) of HIV requires women–infant pairs to access all relevant interventions such as antiretroviral treatment (ART) for the mother, a short course of ARV drugs, and appropriate feeding practices for the baby. We set out to explore the effectiveness of PMTCT in the HIV program in NAUTH Nnewi, southeastern Nigeria.

Methods: We conducted a retrospective secondary data analysis of 181 mother-infant pair data sets from 2020 to 2022. Data were extracted from the Monitoring and Evaluation (M&E) LAMIS software and the PCR Laboratory's LIMS and analyzed. Mother/infant antiretroviral (ARV), viral load, feeding practices, and outcomes were reviewed to assess the effectiveness of the PMTCT Program in the center.

Results: Of the 181 recruited HEIs, 93.4% (169/181) received ARV prophylaxis (six weeks AZT/NVP), while 6.6% (12/181) received nothing. The prevalence of HIV among HIV Exposed Infants (HEI) was 4.4%. About 77.9 % (141/181) of children received breast milk while 22.1% (40/181) did not. Approximately 5.0% (7/141) and 2.5% (1/40) of infants who received, and did not receive breast milk tested positive for HIV, respectively. The prevalence of positive infant PCR tests was lower among mothers who received HAART before pregnancy (1; 0.6%) and during pregnancy (3; 1.6%) compared with HAART naïve mothers (4; 2.2%). The percentage of mothers with viral suppression was 86.7% (157/181). The frequency of MTCT was lower among mothers with viral suppression (1.3%; 2/157) compared with their unsuppressed counterparts 25% (6/24).

Conclusion: This study suggests that PMTCT services help reduce the prevalence of HIV among HEI. Hence, women living with HIV should receive HAART before pregnancy and during delivery while HEI should receive a timely ARV chemoprophylaxis.

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Adolescents Paediatric+HIV Progress on Prevention, Treatment and Care

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Background: Adolescents living with HIV (ALHIV) in Malawi experience multiple challenges associated with their illness and various social, environmental, economic and cultural factors. In exploring their various medical concerns and social vulnerabilities, we consider the role of multiple services in creating a pathway for resilience.

Methods: Multiple methods and case studies allowed for triangulation of evidence and provided a holistic understanding of resilience among adolescents with complex needs. The research methods included: (1) a survey to identify examples of adolescents with complex needs, (2) qualitative interviews and field notes to further explore these needs, (3) patient files and health passports to identify clinical challenges, and (4) ecomapping exercises to personalize cases and identify resilience-enabling resources and supports. We present four case studies to highlight the complex experiences and access to services of ALHIV, and to illustrate their growing power and decision-making capacity over time.

Results: Adversity experienced by ALHIV varied by gender, family situation, years of schooling, and use of teen-clubs for support. The two female adolescents emphasised their need to be accepted and how this impacted sexuality and reproduction. The two males illustrated how ideas of masculinity influenced their sexual practice and involvement with health services and the correctional justice system. Multiple risks (alcohol use, sexual activities) and complex needs (belonging, having a purpose in life/productive activities, autonomy, desire for offspring) influence pathways to resilience. ALHIV were able to strengthen their own wellbeing by resisting negative behaviours and peer pressure and caregiver interactions through 'strategic silence'.

Conclusion: ALHIV experienced self-transformation as a result of taking ART, with fewer severe episodes of illness and distressing skin conditions. Continuous engagement at the teen-club clinic transformed both productive activities and social relationships among ALHIV as they set life goals, gained a sense of empowerment, requested SRH services, and formed intimate relationships. These transformative opportunities allowed them to learn ways of minimizing risk of reinfection and violence, and of navigating health worker–caregiver–adolescent interactions.

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Nigeria HIV/AIDS Indicator and Impact Survey

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The Nigeria HIV/AIDS indicator and impact survey (NAIIS) is the largest human virus population-based survey conducted globally with a sample size of 83,909 households and 383,574 individuals and coverage across 36 States (and the Federal Capital Territory). NAIIS determined the HIV incidence, HIV prevalence, viral load suppression and risk behaviours. For the first time, we have estimated national HIV incidence and viral load suppression and the prevalence of hepatitis B and C virus infections. NAIIS also enabled determination of the effectiveness and population-level impact of HIV related prevention,care and treatment interventions implemented in the country, and our progress achievement of the UNAIDS 95-95-95 targets.

The findings show steady improvements in reducing HIV prevalence especially among women and children when compared to previous survey estimates. However, gaps remain in awareness of HIV status. The results also show varied HIV prevalence across States and highlights the need for more, responsive approaches that take into consideration the situation of the epidemic in each State. The findings in relation to new HIV infections point us towards the need to increase our efforts in targeted testing of community-level especially in areas with high HIV prevalence and low testing coverage.

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Lessons Learned From Community Contact Tracing of Women Disengaged From an Urban PMTCT Program in Uganda.

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Background: Though the modest benefits of community tracing for clients with HIV who have disengaged from care has been documented, few of these studies discuss the processes and challenges of physical tracing of disengaged clients much less address these challenges in the unique population of women receiving PMTCT services. In addition, there are no standard guidelines that outline evidence-based approaches to effectively trace disengaged pregnant and post-partum women in the community. We share our experiences of tracing activities from an urban Prevention of Mother to Child Transmission (PMTCT) program

Methods: The parent study was a prospective case-control cohort. The study was carried in Uganda at six Kampala Capital City Authority (KCCA) clinics. Prior to study tracing activities, we integrated study nurse counsellors into the program's outreach team. Once study tracing activities began, a team of outreach workers, which included the study nurse counsellors, traced the disengaged woman through telephone calls and home visits.

Lessons Learnt: During this period the nurse counsellors learned 1) how to trace women in the community; 2) about the prevailing religious and cultural beliefs that impact women's perspectives about HIV treatment and disclosure, as well as their stigma experience; and 3) how to maintain confidentiality during outreach.

Recommendations: We acknowledge that outreach teams need to adapt their approach to community entry based on the understanding of local societal norms including social-economic dynamics, cultural traditions, and the ambient risk of gender-based violence. However, we posit that there are common approaches and challenges to community outreach to disengaged pregnant and post-partum women with HIV (PPWH) and that sharing these experiences between programs will ultimately improve program effectiveness.

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Review of Four Unusual Cases of HIV-Positive Infants; Cryptic Pregnancy Scam and Mother–To-Child-Transmission (MTCT) of HIV in Nigeria

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Background: Cryptic pregnancy is defined as lack of awareness of pregnancy until the last weeks of gestation or during labour and delivery. However, the term cryptic pregnancy has been wrongly interpreted and falsely used to mislead and take advantage of women in Nigeria. In Nigeria, cryptic pregnancy is a situation where a woman in need of a child is made to believe that she is pregnant when she is actually not. These women are then subjected to hormonal injections to induce abdominal swelling; however, there is absence of gravid uterus both on clinical palpation and ultrasonography. These women are later presented with babies whom they are made to believe are theirs but the true biological mothers are not known to them. The victims are usually women who have problem of infertility. These case reports were therefore, aimed at providing information on the emerging concept of the Nigerian cryptic pregnancy scam and its relevance to mother-to-child transmission of HIV.

Result: In this case series, we reported four children who have discordant HIV tests with their supposedly biological parents. All the mothers were above 40 years of age with a range of 9 to 18 years of infertility in marriage. They had vague details of pregnancy and delivery. Their infants had mixed feeding as mothers claimed that their breast milk wasn't flowing well. Diagnosis of HIV infection was made at infancy following positive rapid test and HIV antigen test.

Conclusion: The menace of cryptic pregnancy scam in Nigeria is setting aback the gains of HIV prevention and control. This report revealed an important contributory factor to rising cases of HIV in children in Nigeria through a rare, unique and novel route of MTCT of HIV infection. Awareness creation and a step-up widespread campaign

against Cryptic pregnancy scam and spread of HIV/AIDS especially in children. is recommended.

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Three Decades of Success: Zero Perinatal Transmission of HIV in Mongolia

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Background: Mongolia, a World Bank classified lower-middle-income country, has made remarkable gains in reducing and maintaining low levels of perinatal HIV transmission, mirroring the country's small population. The major risk factor for HIV transmission in Mongolia is men who have sex with men. However, heterosexual transmission has risen since 2016. Subsequently, in 2020, a Health Ministerial policy was established to screen all pregnant women for HIV antibody in all primary and secondary public and private clinics, both within the capital cities and in rural settings.

Methods: We report on three decades of practice to describe the strategies which enabled Mongolia to attain and maintain significant progress in preventing perinatal transmission of HIV.

Results: Between 1992 to 2022, 641 HIV cases have been diagnosed in Mongolia. In total, 31 babies have been born to 17 HIV positive mothers. Women who are found to be HIV-1/HIV-2 lateral flow test positive on routine screening are referred to the infectious disease specialty hospital for further confirmatory testing and commence anti-retroviral treatment (TDF+3TC+EFV) immediately regardless of the CD4 count. Subsequently, delivery occurs at a regular maternity hospital via a recommended elective Caesarean-section and bromocriptine is prescribed to prevent HIV transmission via breastfeeding. Upon birth, babies are prescribed either daily NVP or twice daily AZT for 4-6 weeks and followed up for HIV testing.

Conclusion: Routine screening of pregnant women for HIV in Mongolia has contributed to enhanced detection of HIV and eliminated perinatal transmission, via a conservative yet effective Health Ministerial policy. This surveillance strategy accompanied by clinical practices to prevents perinatal transmission of HIV has enabled Mongolia to eliminate vertically-acquired pediatric HIV infections within the country.

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Elimination of Mother-To-Child Transmission of HIV: Early Experiences From the Maloa HIV Centre in Timor-Leste

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Background: Timor-Leste is an independent country in the Asia Pacific region with a population of 1.3 million. The Maloa HIV Centre in Dili is a joint initiative between the Ministry of Health and NGO Maluk-Timor. This review describes experiences implementing elimination of mother-to-child HIV transmission services since the program began in 2018.

Methods: This analysis was performed using routinely collected data held in the Maloa HIV Centre registration and monitoring database.

Results: Data collection was from 23/11/2018-31/12/2022. 249 people living with HIV were registered at the Maloa HIV Centre, of whom 81 were women. At least one pregnancy was recorded for 33 women. Of these, 45% (15/33) had late HIV disease at presentation (CD4 count <350 cells/µL and/or with an AIDS-defining event). 39 pregnancies and 40 live infants were recorded. 50% of mother-baby pairs lived in Dili while 50% lived remotely.
Appropriate ART was initiated pre-delivery in 95% of pregnancies (37/39). 89% of mother-baby pairs were retained in care (33/37, excluding 2 deaths, 1 transfer-out). Viral load testing during pregnancy was performed for 77% (30/39). Of these, 83% (25/30) were virologically suppressed (<400 copies/mL). Infant antiviral prophylaxis was commenced within 4 hours of delivery for 76% (25/33, excluding 1 infant death, 2 women lost to follow up, 4 missing data). Maternal viral load testing during breastfeeding was performed for

39% (12/31, excluding 4 lost to follow up, 1 transfer-out, 3 formula-fed only, 1 death), and of these 50% (6/12) showed viral suppression. 83% (5/6) of those with high viral loads during breastfeeding were referred late in pregnancy or post-delivery. HIV diagnostic testing was performed within 3 months of birth for 44% of infants (16/36, excluding 1 death, 3 missing data).

Conclusions: Living remotely is a key factor that impacts on HIV care during the perinatal period. Further challenges include availability of appropriate perinatal and neonatal testing and medications.