IAS 2023 & Pediatric HIV Workshop
Selected PMTCT, Pediatric, Adolescent, and Maternal/Adult Abstracts

Lynne M. Mofenson MD
Update on Epidemiology of Pediatric HIV

2023
Over 3 Million New Infections Averted in Children With ART and PMTCT Programs Since 2000

Cumulative 3.4 million new infections averted in children due to maternal ART

Source: UNAIDS epidemiological estimates 2023: aidsinfo.unaids.org
However, ART Coverage in Pregnant/Breastfeeding Women Has Remained Stalled Since 2018

Coverage of pregnant women who receive ARV for PMTCT

No real change in maternal ART coverage since 2018!

Source: UNAIDS epidemiological estimates 2023: aidsinfo.unaids.org
ART Coverage in Pregnant/Breastfeeding Women Varies Considerably by Geographic Region

Source: UNAIDS epidemiological estimates 2023: aidsinfo.unaids.org
New Child Infections Have Only Slightly Decreased

130,000 new pediatric HIV infections estimated in 2022

Although 58% decline from 2010, since 2015, ↓ new infections is only 10,000/year

At this pace, to reach 2020 target of 20,000 new infections/year will take more than a decade!

Source: UNAIDS epidemiological estimates 2022: aidsinfo.unaids.org
Causes of New Child Infections Globally 2022 Varies by Region

- Globally 65,000 new child infections – nearly 50% - still occur because pregnant women are not diagnosed and started on ART

- Significant regional differences:
  - In West/Central Africa, 67% of new infections are due to lack of maternal ART and only 12% due to incident infection
  - In East/South Africa, only 29% are due to lack of maternal ART and incident infections account for 29% of new vertical infections

Source: UNAIDS epidemiological estimates 2022: aidsinfo.unaids.org
Early Infant Diagnosis (EID) Globally
Increased from 62% in 2021 to 68% in 2022

→ Globally, 68% of infants had EID by age 8 weeks in 2022, a slight increase from 62% in 2021.

→ EID in west/central Africa (generally lower HIV prevalence countries) decreased between 2019 and 2022, currently coverage is only 23%.

→ EID in east/southern Africa (most high HIV prevalence) continues to increase in 2022, currently coverage is 83%.

UNICEF 2022 DATA data.unicef.org/topic/hivaids/paediatric-treatment-and-care/
ART Coverage in Children Remains Significantly Lower than ART Coverage in Adults

Coverage of people receiving ART - by age

→ 62% of children living with HIV who are not on ART are estimated to be age 5-14 years – so HIV testing outside of EID is critical, such as home or self-testing

Source: UNAIDS epidemiological estimates 2022: aidsinfo.unaids.org
Children lag behind adults in knowing HIV status (63% vs 87%), being on ART (57% vs 77%), and viral suppression (46% vs 72%)
Significant Regional Differences: In Western/Central Africa
Nearly 2 of Every 3 Children Living with HIV Are Not Receiving ART
In Contrast, 3 of Every 4 Adults with HIV Are Receiving ART

Source: UNAIDS epidemiological estimates 2022: aidsinfo.unaids.org
Although the annual rate of new infections in adolescents/young people has ↓ ~65% from peak in 1997, the decline has slowed to ~10-20,000/year in last 10 years (2012-2022)

Adolescent girls and young women continue to have 1.5-fold higher rate of new infections than adolescent boys and young men
Pediatric Treatment: ARV Drugs, ARV Effects, Viral Efficacy
Managing Pediatric/Adolescent Treatment Failure in Seven Sub-Saharan Countries, New Horizon Study

*Spencer M et al. AIDS 2023, Brisbane Australia July 2023, Abs. TUPEE09*

- New Horizon Collaborative is focused on drug donation of DRV/r and ETV by J&J for treatment of children with viral failure on ART and building country health capacity for management of children with treatment failure.

- Data from 7 New Horizon Collaborative countries – Cameroon, Eswatini, Kenya, Lesotho, Nigeria, Uganda and Zambia – on treatment failure management cascade obtained from country programs.

- 6,245 children were failing PI or DTG-based regimen: 2,380 in Uganda (38%), 2,259 in Kenya (36%), 575 in Nigeria (10%), 507 in Zambia (9%), 217 in Eswatini (3%), 155 Lesotho (2%), 152 Cameroon (2%)

- Most received enhanced adherence counseling (EAC) and had viral resuppression, varied between countries (42-88%).

- Children with continued viremia were referred to technical working groups for review and drug resistance test (DRT) approval; **Uganda** had highest rates of DRT approval but <60% of approved tests were collected, and only 50% received test results.

- Challenges to DRT included patient fees, lab capacity, and long turnaround time for results.

- EAC is strong tool to achieve resuppression

- Variability in management btn countries & challenges with access DRT observed
919 HIV+ children ages 3-15 years failing 1st line ART

**Virologic Response (VL <400 c/mL), Stratified by Randomization**

<table>
<thead>
<tr>
<th></th>
<th>% Wk 96 VL &lt; 400/ % Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAF vs ABC or ZDV (TAF superior)</td>
<td>89.4% vs 83.3%/ 6.3% (1.0, 10.6)</td>
<td>0.004</td>
</tr>
<tr>
<td>DTG vs LPV/r or ATV/r (DTG superior)</td>
<td>92.0% vs 82.5%/ 9.7% (4.8, 14.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>DRV/r vs LPV/r or ATV/r (DRV/r trend to superior)</td>
<td>88.3% vs 82.5%/ 5.6% (0.3, 11.0)</td>
<td>0.04</td>
</tr>
<tr>
<td>ATV/r vs LPV/r (non-inferior)</td>
<td>84.3% vs 80.7%/ 3.4% (-3.4, 10.2)</td>
<td>0.33</td>
</tr>
</tbody>
</table>

- No difference CD4 response either randomization
- No difference AE for NRTI
- More grade 3/4 (mostly bilirubin) for ATV/r vs LPV/r
- DTG fewer grade 3/4 AE vs LPV/r
- DEXA: Greater ↑ BMD total body with TAF (p=0.04), no difference z score
- Increase total cholesterol and LDL with LPV/r vs ATV/r, DRV/r or DTG
NRTI: ↑ weight to wk 96: +7.0 kg TAF vs +6.2 kg ABC or ZDV

Anchor drug: ↑ weight in all arms except LPVr

Change in weight to wk 96: +5.6 kg LPV/r vs +6.7 kg ATV/r vs +6.7 kg DRV/r vs +7.2 kg DTG

Non-significant ↑ weight with DTG/TAF (interaction=0.51)

→ TAF superior to SOC ABC or ZDV
→ DTG superior to SOC 2nd line PI ART
→ ATV/r was as good as LPV/r
→ DRV/r trend to being superior to other PI regimens
→ LPV/r had poorest weight gain and least favorable lipid profiles
→ Suggest need for child-friendly formulation TAF/FTC + DTG, DRV/r or ATV/r for 2nd line ART
Low-Level Viremia (LLV) as a Risk Factor for Viral Failure (VF) in Children and Adolescents with HIV

McKenzie KP et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs. 3

- Chart review, 2 Tanzania BIAPI sites, of 1,042 CALHIV <19 yr on ART for ≥6 mos; FU for those with ≥2 VL after initial undetectable VL (<50)
  - 51% ♀, mean age 10 yr; age ART start 48.1 mo; 66% on DTG, 26.8% PI

- 318 (47.5%) had LLV: 51-199 c/mL:167 (52.5%); 200-399 c/mL: 87 (27.4%); 400-999 c/mL: 64 (20.1%)

<table>
<thead>
<tr>
<th>Adjusted Hazard Ratio for Factors Associated with VF</th>
<th>aHR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VL no LLV</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>51-199</td>
<td>1.7 (1.1-2.6)</td>
<td>0.01</td>
</tr>
<tr>
<td>200-399</td>
<td>2.2 (1.4-3.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>400-999</td>
<td>3.3 (2.1-5.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Age (yr) &lt;5 yr</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5-9</td>
<td>0.7 (0.4-1.2)</td>
<td>0.18</td>
</tr>
<tr>
<td>10-14</td>
<td>0.5 (0.3-0.95)</td>
<td>0.03</td>
</tr>
<tr>
<td>15-18</td>
<td>0.6 (0.3-1.3)</td>
<td>0.22</td>
</tr>
<tr>
<td>Nutrition Normal</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>SAM/MMM</td>
<td>6.6 (1.03-42.7)</td>
<td>0.05</td>
</tr>
<tr>
<td>CD4 Normal</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>2.2 (1.2-3.9)</td>
<td>0.008</td>
</tr>
<tr>
<td>Moderate</td>
<td>8.3 (1.7-40.0)</td>
<td>0.009</td>
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</tbody>
</table>

→ LLV was associated with ↑ risk VF, with higher LLV levels associated with higher risk

→ Age, malnutrition, CD4 count also associated
HIV Drug Resistance (DR) in Adult Clients Experiencing ART Failure After Switch to DTG-Based 1st Line ART in Mozambique

Bhatt N et al. AIDS 2023, Brisbane Australia July 2023, Abs. LBEPB16

- Cross-sectional study, 7 clinics Gaza Province, Mozambique Aug 2021-Feb 2022, of DR post-ART failure; genotype conducted on samples from 716 patients (although study in adults, expect similar results children):
  - age ≥18 yr on 1st line ART for ≥12 mos before switch to DTG ART and unsuppressed VL (≥1,000) ≥ 6 mos post-DTG and 2nd unsuppressed VL after completing at least 3 enhanced adherence counseling visits (EAC)
- 216 (30%) with VF; genotyping for 172 (80%), 167 (90%) successful; 130 (78%) of these had pre-DTG VL available.

- Intermediate-high DTG resistance in 35/167 (21%).
- 10/25 (27%) with DTG resistance had resistance to all 3 drugs in TLD; if 2-drug resistance, none had combined DTG-TDF resistance.
- Pt with ART failure and DTG resistance more likely to have unsuppressed (19%) or no (40%) VL than suppressed (11%) VL prior to DTG switch.

In pt with confirmed VF on DTG, 21% had DTG resistance
Pt with unsuppressed or no VL prior to DTG switch higher risk of DTG resistance
HIV Drug Resistance Trends Among 251 ART-Experienced Children and Young Adults Ages 0-24 Years with Viral Failure, Eswatini

Zyambo KD et al. AIDS 2023, Brisbane Austraia July 2023, Abs. EPB0108

- Retrospective review EMR and genotype results (National Reference Lab South Africa, using DBS, performed btn Jan 2014-Jan 2023) from BIPAI-Eswatini from 251 ART-experienced clients aged 0-24 years, with ≥2 detectable VL on PI or DTG-based ART

- NRTI: ~50% had high level resistance to 3TC from M184V mutation

- NNRTI: Despite none on NNRTI at time of genotype and many had not ever received, ~50% had high level resistance to NNRTI, ~1/3 had high level resistance to RPV

- PI: ~20% had intermediate-high resistance to PI needing change ARV; DRV resistance less common

- InSTI: Of 13 pt on DTG, 2 (15%) had intermediate-high DTG resistance

→Shows importance of pediatric ARV drug resistance surveillance to inform/optimize future effective ART regimens
InSTI Use in Children with HIV in EPPICC in Europe/Thailand 2010-2020: Uptake and Viral Response

Scott K et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPB0253

- 7,835 children age <18 yrs in FU from Jan 1, 2010; proportion on InSTI increased from 1% in 2015 to 22% in 2020; highest in Western Europe (50% by 2020 vs ≤11% other regions)

- Of the 1,811 children ever receiving InSTI, 1085 (60%) received DTG, 532 RAL (29%), 176 EVG (10%), 18 BIC (1%)

- Median age at InSTI start 13 yr with variability across drug with RAL largest proportion <6 yr

- Median 6-10 yrs on ART when start InSTI

- Proportion ART-experienced and virally suppressed at InSTI start varied from 26% of those on RAL to 50% on DTG and 63% EVG

- Among all those on InSTI at 12 and 24 months, >80% were virally suppressed on DTG and EVG compared to 69-71% on RAL

- Children who were ART-experienced and viremic at InSTI start had lower levels of suppression (50-66%) than those ART-naïve or ART-experienced and virally suppressed at InSTI start

→Overall, 1 in 4 CLHIV were on InSTI, with variation by region

→>80% viral suppression on DTG/EVG, 70% RAL

→Suppression lower among those ART-experienced and viremic at time InSTI switch
Caution - DTG Resistance Can Occur in ART-Experienced Children Switched to DTG

  - While none of the patients on 1st line DTG ART with VF had DTG resistance, 4/22 (18%) patients with VF on 2nd line DTG-based ART had DTG resistance

  - 8/36 (22%) participants with VF on DTG developed resistance to DTG.
  - All with resistance had viremia at the time of DTG initiation (range 594 to >1 million c/mL); 6/8 had initial viral response to DTG

- While risk of resistance when switch to DTG in children with VF remains relatively low (~20%), as in Mozambique study in adults, children who are viremic at the time of DTG switch may be at greater risk of developing DTG resistance.
Used routine EMR records from 155 health facilities in Akwa Ibom and Cross River states, Nigeria, to evaluate viral response in 2,358 children age ≤9 years transitioned to DTG regimen as of Dec 2021

- Median age 6 yr (IQR 4-7 yr); 51% ♀
- At baseline
  - 81.6% (n=1,924) were undetectable (<40)
  - 14.6% (n=345) had low level viremia (41-999)
  - 3.8% (n=89) were unsuppressed (≥1000)

Of 2,148 (91.1%) children who remained on ART after 12 months, 90.6% were undetectable, 7.0% had low-level viremia, and 2.4% were unsuppressed.

- No difference in viral response by sex
- Improved viral response observed in CLHIV post-DTG transition
Weight- and BMI-For-Age in Adolescents Transitioning to DTG

Jesson J et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs.19

- Evaluated weight and BMI-for-age evolution following DTG transition in adolescents with HIV in IeDEA West African Pediatric prospective cohort with at least 1 available weight within 24 mo before and 3 mo after DTG start through Sept 2022

1467 adolescents 10-19 yr initiated or transitioned to DTG

1159 (79%) available weight data 24 mo before/at DTG

178 (15%) with available weight data >3 mo after DTG

146 (82%) in clinical centers with at least 10 eligible pt

- 58% ♂
- Median age ART start 3.2 yr
- Median duration ART prior to DTG 9.6 yr
- Median age DTG start 13.2 yr

→ No excessive weight or BMI gain in after DTG transition in West African adolescents, but sample size small and FU post DTG short

→ Will continue to monitor
Efficacy and Safety of DTG/3TC in ART-Naïve Adolescents, DANCE Study Week 96 Results

Puthanakit T et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs.18; AIDS 2023 Abs. EPB0250

- Ongoing single-arm study evaluating dual DTG/3TC (50/300mg) in 32 ART naïve adolescents (median age 17 yr, median RNA 4.96, 83% horizontal tx) from 9 centers in Thailand, Kenya and South Africa (1 site closed due to GCP non-compliance so sensitivity analysis excluded these 7 pt)

Viral Response <50 Through Week 96
Overall ITT-E and Excluding 1 site ITT-E sensitivity analysis

Comparison Virologic DANCE to Adult GEMINI Study

- Most AE were grade 1 or 2; 1 pt grade 3 TB (achieved and maintained viral suppression)
- 4 SAE, none related to study drug, no deaths

→DTG/3TC well tolerated, high efficacy and no resistance observed (1 VF) in ART-naïve adolescents through week 96; small numbers but support use DTG/3TC in adolescents as 1st line option
→PENTA-21 study is evaluating DTG/3TC in children 2-15 yr
Survival analysis 63,421 adults starting ART 2004-2019, S Africa IeDEA cohort
- Median age 33 yr; 68% ♀; 33% started 2012-2015, 44% started 2016-2019

Care interruption: 180 d no contact, then return care (for 1st interruption: early <6 mo post ART start vs late ≥6 mo)

**Mortality by ART Interruption Status**

<table>
<thead>
<tr>
<th></th>
<th># ALHIV (63,421)</th>
<th>Person-yrs (188,358)</th>
<th>Deaths (3,585)</th>
<th>Adjusted*HR</th>
</tr>
</thead>
<tbody>
<tr>
<td>No interruption</td>
<td>40,828</td>
<td>132,594</td>
<td>2,587</td>
<td>1</td>
</tr>
<tr>
<td>Early interruption</td>
<td>8,845</td>
<td>18,429</td>
<td>427</td>
<td>2.32 (2.1-2.6)</td>
</tr>
<tr>
<td>Late interruption</td>
<td>13,748</td>
<td>37,334</td>
<td>571</td>
<td>1.90 (1.7-2.2)</td>
</tr>
</tbody>
</table>

*Adjusted for other significant factors: sex, baseline age and CD4

**Survival Curve by ART Interruption Status**

- Care interruption doubled risk of mortality; even late interruption ↑ mortality
- Mortality ↑ as duration of care interruption increases
- Although in adults, expect might see same in children
Trends in ART Continuity in Children/Adolescents with HIV in 14 Districts in South Africa 2019-2022

Mugisa B et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPC0482

Retrospective review of pediatric ART data from PEPFAR DATIM system, 5-year period Jan 2018-Sept 2022, 14 districts South Africa

→ 57% ↑ in ART initiation Mar 2018-Mar 2020 (from 66,780 to peak of 105,107), but 21% ↓ to Sept 2022 (to 83,287), despite 31,223 new ART initiations in same period

→ Mortality accounted for only 0.9-2.4% of loss between Oct 2019-Sept 2022 (1,148 deaths)

→ Changing definitions complicate interpretation

→ Some programs losses could also account for decrease, with an expected >20% decrease new infections and by aging-out of child/adolescent HIV care
Results highlight the complexities in program retention for children with HIV and underscore the need for enhanced program data to improve accountability for continuity of care and need to standardize reporting systems to ensure precision and accuracy.

→ Mobility of the population may also play a part - ART interruptions were marked by seasonality, with 6-8% interruption during holiday months around Dec (Q4-Q1), compared to 3-5% during non-holiday months.
Children/Adolescents with HIV Who Are Active in OVC Program More Likely to Be Virally Suppressed Than Those Not in OVC Program in Ethiopia

Meheretu W et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPC0491

- Routine clinical data collected for 364 OVC and 429 non-OVC children from same clinic/hospital, all receiving ART, mean age 12.3 years; viral suppression endpoint.

- OVC program pt likely to have **viral suppression** than pt not in OVC program (98% vs 90%)

- Non-OVC program pt 7-fold greater risk of **not having VL measurement** past 12 mo

- OVC program pt 23% ↓ risk of missing clinic appt past 6 mos than pt not in OVC program

- OVC program pt 23% ↓ risk of missing ART pick up on time than those not in OVC program

- Compared to children in clinical care alone, children in both the clinical care and OVC program in Ethiopia had better viral suppression, clinic and ART pick-up adherence and ↑ VL measurement.
Advantages of Being in OVC Program in Ethiopia
Meheretu W et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPC0491

→ Additional services provided by OVC program in addition to that provided by clinic program at same site

→ Top 5 services provided: support with HIV treatment and adherence, school assistance (financial, with homework), hygiene/WASH, insurance and ITN
Perinatally-Infected Young Adults Have Poorer Viral Suppression Than Those Who Acquire HIV Later in Life, Zimbabwe

Dzavakwa N et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPB0248

- Population based cross-sectional survey of 17,682 randomly selected young people aged 18-24 years resident in 24 communities in 3 provinces of Zimbabwe; DBS taken for HIV antibodies and VL.
- 435 self-reported they were HIV positive: 196 perinatal infection, 239 behavioral acquisition

- Overall, 61% female, mean age 20 years
- Youth with behavioral HIV were more likely female, age 21-24 years, diagnosed at older age and lower SES.
- Youth with perinatal HIV were more likely to be stunted, less likely to have had sexual debut, be married or be pregnant, and had higher TB prevalence.
- Youth with perinatal HIV were almost 2-times as likely to have unsuppressed VL

Young people with perinatal HIV have worse health outcomes and greater risk of viral non-suppression.
Characteristics and Causes of HIV-Related In-Patient Pediatric Deaths, Two Tertiary Hospitals Zambia Jan-Dec 2021
Zyambo KD et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPB0108

- Describe characteristics associated with 148 HIV-related in-patient deaths in children occurring in the only 2 children’s hospitals in Zambia between Jan-Dec 2021

- Of 148 deaths, 88 (60%) in HIV-exposed infants, 53% not receiving ARV for PMTCT.
- HIV confirmed in 60 (41%) with 28% never started on ART
- 53% had moderate-severe malnutrition
- Mixed breastfeeding noted in 34%, no breastfeeding in 16%
- Median age at admission was 10 mos (IQR 17)
- Median duration admission-death was 7 days

- Primary cause of death was respiratory diseases in 58%, followed by infectious/parasitic disease in 10%

- Most HIV in-hospital related deaths occurred in children age <24 mos and almost 50% had not received either ART or PMTCT. Most deaths due to respiratory diseases.
PMTCT Cascade
Factors Associated with Breast Milk Transmission in ART Era
Anderson K et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs. 11

- Retrospective study of 50,461 infants of 48,166 mothers in Western Cape born May 2018-Aug 2021 (3-yr cohort), FU to Aug 2022 (15-51 mos)
  - ART: 51% before and 27% during pregnancy (83% NNRTI, 11% InSTI, 5% PI), 6% no ART
  - At delivery, 78% mothers VL <1000, 62% CD4 >350
  - MTCT 1.8% (n=894): 0.9% IU, 0.4% IP, 1.5% BF (dx age >3 mos)

- Evaluated risk factors for BF MTCT in mother known HIV+ at delivery and infant dx age >3 mos:
  - Younger maternal age (1.5 ↑ risk if 20-<30, 2.2 ↑ risk if <20 vs ≥30 years)
  - Higher parity (1.6 ↑ risk if parity ≥3)
  - Inconsistent ART during pregnancy ↑ risk
  - Lower CD4 ↑ risk
  - Higher VL ↑ risk
Evaluated data reported for ANC1 and post-ANC1 HIV testing in PEPFAR MERS from FY19 (10/18) - FY 22 (9/22) in 15 USAID-supported districts.

- Maternal HIV Re-Testing Uptake Across 15 Districts South Africa

Mabasa H et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs 39

- Annual # Pregnant Women Receiving HIV testing At ANC-1 and Test Positivity

- Despite ↓ in ANC1 testing volume/HIV+ (356,257 tested/9%+ to 311,946/6%+) FY19 to FY22, ANC1 testing coverage remained >98% & those already on ART at ANC1 ↑ from 62% to 73%

- Post-ANC1 testing ↑ FY19 to FY22 by 56% from 418,759 to 651,823; positivity ↓ from 0.9% to 0.3%, and positive tests ↓ from 3741 to 1793

- ANC1/post-ANC1 testing ratio ↑ from 1:1.1 to 1:2.1, but incomplete adherence BF period (repeated BF testing should result in higher ratio for post-ANC1 tests)

- Infant HIV+ at 2 mos stable at 0.6%; HIV+ at 12 mo slight ↑ HIV+ from 0.8% FY19 to 0.9% FY22

→ Progress in post-ANC1 testing, but need to closely monitor retesting in BF period
Microsimulation model to estimate impact of VL testing and MM on MTCT in high HIV prevalence setting; describes hypothetical cohort women with recent HIV starting ART in pregnancy through pregnancy/BF and risk MTCT

No VL Testing or MM
(Assume: DTG ART start 5 mo GA, Risk VF 9%, risk LTFU 25%)

VL Testing (50 or 100% adherence guidelines)
(Assume: VL 3 mo after ART start then q6 mo during BF (Kenya); 50% resuppress counseling, no switch to 2nd line if repeat VL unsuppressed)

MM
(Assume MM program ↓ LTFU from 25% to 10%)

Evaluated 6 strategies, including combination MM/VL testing
Modeling the Impact VL Testing and Mentor Mothers on MTCT in High HIV Prevalence Setting

Duarte H et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs.12

→ Limited impact of VL testing (0.1-0.5% reduction)
→ MM has greater impact than VL testing (11.7% reduction)
→ Concurrent implementation of both has greatest impact (11.9-12.2% reduction)

Why limited impact of VL testing – VL testing can only improve outcomes for mothers who are:
- Retained in care
- Have unsuppressed VL – only small proportion of women (9%) have unsuppressed VL – if rate VF is higher, impact↑

Why greater impact of MM relative to VL testing
- MM programs intervene further upstream in the cascade of care, preventing LTFU
- Have the potential to impact a larger proportion of mothers than VL testing

Greatest impact is with combination MM and VL testing

Note: did not account for potential enhanced infant prophylaxis if mom viremic (but only 9% viremic in pregnancy)
Factors Associated with Acceptance Partner HIV Self-Testing and PrEP in Pregnant High-Risk Women Kenya

Ngumbau N et al. AIDS 2023, Brisbane Australia July 2023, Abs. OAC0403

To evaluate acceptance of PrEP, HIVST or combined PrEP/HIVST, used data from PRIMA study: 911 high-risk women (score >6 on assessment tool) offered HIVST for male partner with unknown HIV status, and PrEP

- Awareness of ♂ partner HIV status guides ♀ HIV prevention decisions
- Low HIV risk perception may hinder acceptance of HIVST and PrEP
- Women unable or unwilling to negotiate HIVST prefer PrEP alone
In 2022, USAID DISCOVER rolled out KYCS to all 173 project-supported sites
- Obtain line-list of all women with HIV on ART from each facility to pull biologic and non-biologic children (contacts) aged <19 years
- Project provided resources (registers, test kits, transport) to facilitate HIV testing

- 30,830 (85%) of women with HIV accepted line-listing, of which 56,521 contacts elicited (average 1.8 child per woman)
- Only 24,513 (43%) of contacts had known HIV status; 90% (28,926) contacts with unknown status tested.
- ID 903 children with HIV ≤19 yrs (1.46% yield), all linked to ART
- Median age of identified children with HIV was 15.2 years
- Female contacts 1.5 times more likely to test positive than males; female adolescents 15-19 yr were ~3-times more likely to test positive than male counterparts

→ KYCS requires large volume of HIV testing to find HIV+ pediatric patients but is a crucial and successful strategy to ensue no child/adolescent is left behind
As vertical transmission declines with maternal ART, predictive value of single infant positive PCR decreases, with probability of false positive result increasing.

Therefore, all + tests should have confirmatory testing to avoid misdiagnosis and unnecessarily started on ART.

Evaluated prevalence unconfirmed tests in African IeDEA infants born 2004-2011:

- Unconfirmed positive: infant with only 1 + viral test at age <18 mos and no additional + tests at age >18 mos.

Of 72,616 perinatally exposed infants, 3,652 (5%) had ≥1 + test. 44% lacked a confirmatory test at <18 mos, most (87%) never repeat test.

Unconfirmed + Tests by Africa Region:

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Central 2004-06</th>
<th>East 2004-21</th>
<th>South 2014-17</th>
<th>West 2004-18</th>
</tr>
</thead>
<tbody>
<tr>
<td># exposed</td>
<td>72,616</td>
<td>10620</td>
<td>47015</td>
<td>8600</td>
<td>6463</td>
</tr>
<tr>
<td>% any + test</td>
<td>5%</td>
<td>4%</td>
<td>6%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>unconfirmed + &lt;18 mo</td>
<td>44%</td>
<td>58%</td>
<td>42%</td>
<td>13%</td>
<td>91%</td>
</tr>
<tr>
<td>Unconfirmed and no test at &gt;18 mo</td>
<td>87%</td>
<td>80%</td>
<td>87%</td>
<td>95%</td>
<td>93%</td>
</tr>
</tbody>
</table>

Unconfirmed Prevalence Decreased Over Time:

Unconfirmed + test highly prevalent, but less common in more recent years.

Additional efforts needed to ensure confirmatory testing to reduce risk false + results.
Birth defect surveillance, similar to Botswana Tsepamo Study, Sept 2021-March 2023 at 5 highest-volume maternity sites, in all 4 regions Eswatini (73% all births).

- 35,799 pregnant women; 30% HIV+
- 88.8% HIV+ (9,583/10,806) received DTG ART: 7,413 preconception; 1,514 during pregnancy; 639 non-DTG at conception but DTG at delivery; 27 unknown ART at conception but DTG at delivery; 1,697 on non-DTG ART at conception (94.2% on EFV)

### Birth Outcomes (Birth Defects/NTD, Stillbirth, LBW, PTD) by HIV and ART Status

<table>
<thead>
<tr>
<th>Women's HIV Status* and ART Regimen if HIV-Positive</th>
<th>Women delivering (live/stillbirth)</th>
<th>Single live births</th>
<th>Major birth defects (among all women delivering)</th>
<th>NTD (among all women delivering)</th>
<th>Stillbirths (among all pregnancies)*</th>
<th>LBW (&lt;2500g among single live births)</th>
<th>PTD (&lt;37 weeks gestation among single live births)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>35,779</td>
<td>35,375</td>
<td>141 (0.4)</td>
<td>32 (0.9)</td>
<td>868 (2.2)</td>
<td>3,215 (9.1)</td>
<td>3,555 (10.0)</td>
</tr>
<tr>
<td>HIV-negative</td>
<td>24,965</td>
<td>24,084</td>
<td>94 (0.4)</td>
<td>20 (0.8)</td>
<td>329 (1.9)</td>
<td>2,195 (9.1)</td>
<td>2,388 (9.9)</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>10,806</td>
<td>10,285</td>
<td>47 (0.4)</td>
<td>12 (0.1)</td>
<td>937 (2.9)</td>
<td>1,020 (9.9)</td>
<td>1,167 (11.3)</td>
</tr>
<tr>
<td>DTG ART at conception</td>
<td>7,413</td>
<td>7,050</td>
<td>34 (0.5)</td>
<td>6 (0.8)</td>
<td>231 (3.0)</td>
<td>666 (9.7)</td>
<td>777 (11.0)</td>
</tr>
<tr>
<td>Non-DTG ART at conception</td>
<td>1,697</td>
<td>1,619</td>
<td>10 (0.6)</td>
<td>5 (0.3)</td>
<td>51 (2.9)</td>
<td>166 (10.3)</td>
<td>193 (11.9)</td>
</tr>
<tr>
<td>New on ART during pregnancy</td>
<td>1,524</td>
<td>1,453</td>
<td>3 (0.2)</td>
<td>1 (0.07)</td>
<td>51 (3.1)</td>
<td>157 (10.8)</td>
<td>185 (12.7)</td>
</tr>
<tr>
<td>Unknown ART at conception</td>
<td>172</td>
<td>163</td>
<td>0</td>
<td>4 (0.9)</td>
<td>117 (6.6)</td>
<td>12 (7.4)</td>
<td></td>
</tr>
<tr>
<td>Unknown HIV status</td>
<td>8</td>
<td>6</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Data available for 3,150 (83.9%) of 3,753 miscarriages: 869 (27.6%) HIV-positive, 2,228 (70.7%) HIV-negative, and 53 (1.7%) had an unknown HIV status.

- Most HIV+ women in Eswatini are receiving DTG ART
- Despite ART, HIV+ women slightly higher adverse pregnancy outcomes; no evidence DTG vs non-DTG preconception ↑ risk
- No sig diff major BD prevalence by HIV status (0.4% both)
- NTD non-significantly higher HIV+>HIV- (0.11 vs 0.08%, p=0.37)
- Compared to HIV-, HIV+ ↑ stillbirth (1.9 vs 2.9%, p<0.001), LBW (9.1 vs 9.9%, p=0.02), and PTD (9.9 vs 11.3%, p<0.001)
- Among HIV+, no sig differ DTG vs non-DTG at conception for major BD (p=0.48), stillbirth (p=0.84), LBW (p=0.52) or PTD (p=0.03)
- NTD higher in non-DTG vs DTG at conception (p=0.04) (# exposures smaller)
Surface birth outcomes surveillance by hospital midwives at sentinel sites Botswana (70% all births in country).
- Between Aug 2014-Aug 2022, 235,286 (99.8%) deliveries with evaluable infant surface examination.
  - 11,110 DTG from conception
  - 24,368 non-DTG ART from conception (14,587 to EFV)
  - 6,925 DTG during pregnancy
  - 179,890 women without HIV

1,455 deliveries with major defects (0.62%, 95% CI 0.59-0.62%); no significant difference by exposure.

162 neural tube defects (0.07%; 95% CI 0.06-0.08)

**NTD Prevalence & Age-Adjusted Prevalence Difference by ARV/HIV Exposure**

No significant difference in NTD by exposure category

NTD prevalence higher when conception in May–June (early/dry) then Aug–Oct (late/dry) period

Differed by calendar year, highest in 2014, 2015, 2017

Most common: club foot (0.18%), hydrocephalus (0.09%), NTD (0.07%), postaxial polydactyly (0.04%), abdominal wall defect (0.04%) and cleft lip (0.04%)
For DTG-conception exposures, NTD prevalence among pregnancies conceived in 2017 (1st yr DTG rollout) was 0.53%, significantly higher than all subsequent years, when remained in expected range (0.09%, range 0.06-0.10%)

- Factors associated with NTD (maternal age, diabetes, weight >90 kg, anti-epileptic med, folic acid at conception) was similar in 2017 and all other years, and no association with temperature or rainfall

Prevalence (95% CI) of NTD with DTG at Conception Over time

- Possible explanations: statistical chance (most likely?); interaction between DTG and an environmental exposure that may have occurred in 2017 such as low population folate; or increased risk NTD related to unmeasured demographic difference in first group women started on DTG in Botswana

→ No detectable ↑ in NTD or major structural defects in >11,000 exposures to DTG at conception in Tsepamo study 2014-2022.
HIV-Exposed Uninfected Infants

16 million

>20% of children born in multiple countries including South Africa are HEU

80% of brain growth happens by 3 years
In Utero Oral PrEP Exposure and Bone Mineral Density (BMD) in Exposed Infants at Age 36 Mos

Wu L t al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs.13; AIDS 2023 Abs OAC0402

- Conducted whole-body BMC by DXA, Nairobi, Kenya in 111 infants followed up from the PrIMA and PrIMA-X (extended FU) oral TDF/FTC PrEP vs placebo at infant age 36 mos (all DXA done in duplicate, read by certified technologist, with 15% QA external reviewer)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=111</th>
</tr>
</thead>
<tbody>
<tr>
<td>In utero PrEP: exposed</td>
<td></td>
</tr>
<tr>
<td>unexposed</td>
<td></td>
</tr>
<tr>
<td>36%</td>
<td>64%</td>
</tr>
<tr>
<td>Median age at DEXA</td>
<td>37 mos (36-38)</td>
</tr>
<tr>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>40%</td>
<td></td>
</tr>
<tr>
<td>Median GA at birth</td>
<td>38 wk (38-40)</td>
</tr>
<tr>
<td>Median PrEP duration pregnancy</td>
<td>12 wk (7-17)</td>
</tr>
<tr>
<td>Trimester PrEP start:</td>
<td></td>
</tr>
<tr>
<td>1st</td>
<td></td>
</tr>
<tr>
<td>2nd</td>
<td>5%</td>
</tr>
<tr>
<td>3rd</td>
<td>52%</td>
</tr>
<tr>
<td>3rd</td>
<td>43%</td>
</tr>
</tbody>
</table>

- No Significant Difference Height
- No Significant Difference BMD

→ In utero PrEP exposure was not associated with BMD or height at 36 months

→ Plan quantify PrEP exposure in pregnancy (drug levels in hair/DBS) for further analyses and plan DXA in infants at age 52 mo and mothers at 36 and 52 mos PP
Neonatal Hospitalization and Mortality in HIV-Exposed Uninfected (HEU) and HIV-Unexposed (HUU) Infants, South Africa

Bovu A t al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs.14

- Western Cape Province cohort of 166,288 births in 2018/2019; previously observed elevated prevalence LBW in infants of women with HIV regardless of ART compared to those without HIV.
- Evaluated neonatal (0-28 d) mortality or hospitalization in this same cohort HEU/HUU infants, comparing rate in HUU; HEU no maternal ART; HEU preconception ART; HEU pregnancy start ART

<table>
<thead>
<tr>
<th></th>
<th>HUU</th>
<th>HEU</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (total 166,288)</td>
<td>135,938 (81.8%)</td>
<td>30,350 (18.2%)</td>
</tr>
<tr>
<td>HEU: no mART</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART preconception</td>
<td>0</td>
<td>3,371 (11.1%)</td>
</tr>
<tr>
<td>ART start pregnancy</td>
<td>0</td>
<td>18,179 (56.9%)</td>
</tr>
<tr>
<td>LBW</td>
<td>18,421 (13.5%)</td>
<td>4,515 (18.9%)</td>
</tr>
<tr>
<td>Neonatal hospitalization</td>
<td>18,427 (13.6%)</td>
<td>4,696 (15.5%)</td>
</tr>
<tr>
<td>Neonatal mortality (/1000)</td>
<td>974 (7.2%)</td>
<td>257 (8.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adjusted Prevalence Ratio (PR) (95% CI)</th>
<th>Adjusted PR (Adjusted for LBW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUU</td>
<td>1.0</td>
</tr>
<tr>
<td>HEU no mART</td>
<td>1.24 (1.1, 1.4)</td>
</tr>
<tr>
<td>HEU ART preconception</td>
<td>1.16 (1.1, 1.2)</td>
</tr>
<tr>
<td>HEU ART pregnancy start</td>
<td>1.20 (1.1, 1.3)</td>
</tr>
</tbody>
</table>

- HEU, regardless mART, had 15-22% ↑ prevalence neonatal hospitalization/death compared to HUU
- Adjusting further for LBW, LBW accounted for 25-36% of this association

<table>
<thead>
<tr>
<th>Adjusted PR Stratified by Non-LBW and LBW</th>
</tr>
</thead>
<tbody>
<tr>
<td>NON-LBW ONLY</td>
</tr>
<tr>
<td>HUU</td>
</tr>
<tr>
<td>1.0</td>
</tr>
<tr>
<td>HEU no mART</td>
</tr>
<tr>
<td>HEU ART preconception</td>
</tr>
<tr>
<td>HEU ART pregnancy start</td>
</tr>
</tbody>
</table>

- Among LBW infants, no difference HEU vs HUU
- Among non-LBW infants, HEU had 16-24% ↑ prevalence neonatal hospitalization/death
- Indicates factors besides LBW drive adverse outcomes in this group
Multisite prospective HOPE cohort of 1000 mothers living with and 1000 without HIV and their infants in Kenya

Reporting on neurodevelopment at 12 mos, using Malawi Developmental Assessment Tool (MDAT), covering Social, Language, Fine Motor and Gross Motor domains

Compared HEU (n=712) and HUU (n=715), cofactors for neurodevelopment, and HIV/ART cofactors in HEU

Overall HEU-HUU had comparable neurodevelopment

→ CHEU had better language scores (were more likely to have siblings)
→ Male children lower social and language scores
→ PTD associated with lower gross motor scores
→ Lower social support associated with lower gross motor scores
→ Food insecurity associated with lower social scores
→ Although uncommon, IPV associated with lower fine and gross motor scores
Child Neurodevelopment: Focused on HIV-Exposed Uninfected Infants (HEU) Infants in Kenya

Bultery's M et al. International Pediatric HIV Workshop, Brisbane Australia July 2023, Abs.15

HIV-Exposed Uninfected Infants (All Mothers Receiving ART)

- Male children lower social scores
- PTD associated with lower gross motor scores
- Deceased/absent father associated with lower gross motor scores
- Single/widowed mother associated with lower fine motor scores
- Most recent ART EFV associated with lower gross motor scores
- Only received EFV (vs DTG) associated with lower gross motor scores

- Biologic and social factors influence neurodevelopment
- HEU/HUU comparable 1-yr neurodevelopment
- Addressing IPV and supporting single mothers essential, especially for those with HIV
- DTG exposure was associated with higher neurodevelopmental scores than EFV
PrEP: Oral, Vaginal Ring, and Long-Acting CAB

Wara NJ et al. AIDS 2023, Brisbane Australia July 2023, Abs. EPC0436


**Participant Characteristics**

- More interest in community delivery in South Africa

**Importance of offering choice community and clinic options for PrEP pick-up**

**Need for context specific strategies as varied by country**
Kenya is evaluating using private pharmacies for differentiated PrEP delivery; ongoing pilot study in Kisumu and Kiambu

Surveyed 496 PrEP clients at Month One FU regarding preference for oral PrEP, injectable PrEP, or vaginal ring if ♀; ~50% ♀ and <25 yrs; ~75% unmarried, ~85% PrEP-naïve

Factors Associated with Preferring Injectable

→ Most – but not all - clients indicated preference for injectable PrEP; varied among subgroups, indicating importance of offering both oral PrEP as well as injectable PrEP
Acceptability of CAB-LA in Female Adolescents South Africa, Uganda and Zimbabwe

Hamilton E et al. Int. Ped Workshop, Abs 107; AIDS 2023, Brisbane Australia July 2023, Abs. OALBC0603

- Single-arm study in 55 adolescent ♀ age <18 yrs, 3 countries
- Step 1: oral CAB; Step 2: IM CAB; Step 3: IM CAB or oral TDF/FTC
- Included qualitative in-depth interviews 15 pt & 15 parents wk 34

Emergent Themes - Facilitators
- Lack of adherence challenges
- Discretion (vs. daily oral tablets)
- Knowledge of efficacy
- Administration mode
  - Needle size (1½ inch)
  - Site of administration (gluteal muscle)
  - Familiarity due to use of injectable contraceptives
- Parent/guardian buy-in

Emergent Themes - Barriers
- ISRs (injection site reactions)
  - Injection pain
  - Fear of the injection
  - Some experienced side effects

→CAB-LA acceptable to AGYW, with 92% choosing to stay on CAB-LA; most felt benefits outweighed the pain of the injection

→However, choice matters – some pt still preferred oral tablets for various reasons

→Discuss barriers and facilitators with future clients as part of decision-making

48-week choice:
- 92% CAB-LA
- 8% oral TDF/FTC
Assessed PrEP choice (CAB-LA vs oral TDF/FTC), reasons for choice and factors associated with choice among HPTN 084 pt in open-label extension, when could choose PrEP modality

2,472 participated in open-label and product choice

78% overall chose to receive CAB-LA (varied by arm)

→ Majority chose CAB, only 15% with oral lead-in

→ Product choice influenced by personal preference for product attributes, risk behavior, and social/geographic context

→ Importance of having choice of products available
Long-Acting HIV PrEP in AGYW in South Africa: Cost-Effective at What Cost?

Neilan AM et al. Int. Ped Workshop, Abs 20; AIDS 2023, Brisbane Australia July 2023, Abs. OAE0302

- Used CEPAC model to evaluate cost-effectiveness of TDF/FTC vs injectable CAB-LA in AGYW age 15-30 yr in South Africa over 10 yr period
- Evaluated highest annual drug price (maximal price premium) where CAB-LA has incremental cost-effectiveness ratio (ICER) <$3,500 (50% S Africa’s per-capital annual GDP)

<table>
<thead>
<tr>
<th>Input parameter</th>
<th>Value</th>
<th>Derivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>26</td>
<td>Modeled population</td>
</tr>
<tr>
<td># tx/10,000 AGYW over 10 yr</td>
<td>600</td>
<td>SA data</td>
</tr>
<tr>
<td>HIV incidence: No PrEP TDF/FTC CAB-LA</td>
<td>3.2/100 p-y 1.9/100 p-y 0.2/100 p-y</td>
<td>Delany-Moretiwe Lancet 2022, Palanee-Phillips PLoSOne 2022</td>
</tr>
<tr>
<td>2-yr retention TDF/FTC CAB-LA</td>
<td>88% 85%</td>
<td>Delany-Moretiwe Lancet 2022</td>
</tr>
<tr>
<td>PrEP drug + program $/yr: TDF/FTC CAB-LA</td>
<td>$40 / $12  $80 / $21</td>
<td></td>
</tr>
<tr>
<td>HIV care cost/yr</td>
<td>$230-$1,8000</td>
<td>Clarly Cost Eff Resource Alloc 2008</td>
</tr>
<tr>
<td>ART cost./yr</td>
<td>$50-$890</td>
<td>CHAI 2022</td>
</tr>
</tbody>
</table>

For CAB-LA to be CE for AGYW in S Africa, needs to be priced at no more than twice TDF/FTC
Mixed methods study in HIV-negative high risk AGYW age 18-25 years in 8 districts in Zimbabwe offered either DPV ring or oral PrEP (n=1206 took DVR, n=390 oral PrEP), FU monthly.

- High DPV ring acceptability, rural>urban

HIV incidence DPV ring vs Oral PrEP

- HIV incidence not significantly different than oral PrEP, similar to HOPE (2.7/100PY)/DREAM (1.8/100PY) studies

- Most seroconversions observed in 1st mo; after 1st mo, pt reported removing the ring and having unprotected sex at some point.

→ High acceptability of DPV ring by AGYW; higher continuation rates than oral PrEP; comparable HIV seroconversion with oral PrEP cohort with most in 1st mo
Adolescents and HIV
Prevalence Intimate Partner Violence in AGYW Enrolled in DREAMS Project, Zimbabwe 2022

Mudzengerere F et al. AIDS 2023, Brisbane Australia July 2023, Abs. OALBX0202

- IPV: physical, sexual, psychologic harm from intimate partner; reported by 43% AGYW in 2019 Zimbabwe (Mukahanana 2022)

- Qualitative study, 282 sexually active AGYW 9-19 yr enrolled in DREAMS in 9 districts, Zimbabwe Aug 2022-Jan 2023

   - 14.9% (42/282) reported experienced IPV

   - Lower prevalence IPV in DREAMS district than prior reports from Zimbabwe, possibly attributable to community interventions to address harmful social norms and practices

   - IPV most common in married women in rural setting

- Predictors IPV in AGYW

<table>
<thead>
<tr>
<th>Variable</th>
<th>Prevalence of IPV</th>
<th>Adjusted Odds Ratio (AOR)</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>26% (13/50)</td>
<td>2.99</td>
<td>(1.36-6.57)</td>
<td>0.01</td>
</tr>
<tr>
<td>Primary school</td>
<td>26.5% (9/34)</td>
<td>1.58</td>
<td>(0.15-30.17)</td>
<td>0.70</td>
</tr>
<tr>
<td>Less than 15 years old</td>
<td>1 out of 8</td>
<td>2.14</td>
<td>(0.15-30.17)</td>
<td>0.57</td>
</tr>
<tr>
<td>Urban and peri-urban</td>
<td>15% (41/274)</td>
<td>0.37</td>
<td>(0.18-0.78)</td>
<td>0.01</td>
</tr>
<tr>
<td>Completed primary pack</td>
<td>16.2% (18/111)</td>
<td>0.98</td>
<td>(0.50-2.01)</td>
<td>0.98</td>
</tr>
</tbody>
</table>

Actions taken by Community Leaders and Men to protect AGYW from Violence
Evaluated new infections and teen pregnancies over 5 years (FY 2017 Q2 to FY 2022 Q3) in PEPFAR data in AGYW age 15-19 years, comparing 3 districts participating in DREAMS (n=117,47) to 3 non-DREAMS districts (n=140,000) in Malawi.

→ DREAMS districts had 77.8% ↓ in new HIV diagnoses (from 2.8% at baseline to 0.6% at endline) in AGYW compared to 58.1% ↓ (from 1.6% to 0.7%) in AGYW in non-DREAMS districts

→ Significant difference in % change in new HIV infections between DREAMS and non-DREAMS districts (p=0.003)

→ DREAMS districts had 12.2% ↓ in teen pregnancies (from 25.4% to 22.3%) compared to 6.5% ↓ (from 24.7% to 23.1%) in non-DREAMS districts (difference in % change not significantly different)
Empowering Adolescent School Girls with SKILLZ – 6 Month FU From Cluster Randomized Trial, Zambia

Musonda M et al. AIDS 2023, Brisbane Australia July 2023, Abs. TUPEC18

- Cluster-randomized trial to assess impact of sports-based demand-generating program (SKILLZ) on uptake of HIV testing and contraception by girls; randomized 46 schools in Zambia; randomly sampled Grade 11 girls with self-administered survey at baseline (Mar-Dec 2021), 6 and 12 months.

Baseline Characteristics of Participants at Control vs Treatment Schools

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=1,917)</th>
<th>Control (N=964)</th>
<th>Treatment (N=953)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Employed/earns income</td>
<td></td>
<td>17.79</td>
<td>1.35</td>
</tr>
<tr>
<td>Food insecurity</td>
<td></td>
<td>486</td>
<td>25.9%</td>
</tr>
<tr>
<td>HIV Knowledge (Correct)</td>
<td></td>
<td>579</td>
<td>31.9%</td>
</tr>
<tr>
<td>Ever had sex</td>
<td></td>
<td>5.33</td>
<td>1.14</td>
</tr>
<tr>
<td>Total number of sexual</td>
<td></td>
<td>461</td>
<td>25%</td>
</tr>
<tr>
<td>partners</td>
<td></td>
<td>0.72</td>
<td>0.65</td>
</tr>
<tr>
<td>Received money/support</td>
<td></td>
<td>524</td>
<td>42%</td>
</tr>
<tr>
<td>from sexual partner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent contraception</td>
<td></td>
<td>34%</td>
<td>20%</td>
</tr>
<tr>
<td>Ever pregnant</td>
<td></td>
<td>75</td>
<td>4%</td>
</tr>
<tr>
<td>Tested for pregnancy</td>
<td></td>
<td>292</td>
<td>15%</td>
</tr>
<tr>
<td>Friend ever pregnant</td>
<td></td>
<td>1,533</td>
<td>84%</td>
</tr>
<tr>
<td>- Friend ever abortion</td>
<td></td>
<td>749</td>
<td>60%</td>
</tr>
<tr>
<td>Ever STI symptoms</td>
<td></td>
<td>222</td>
<td>12%</td>
</tr>
<tr>
<td>Ever tested for HIV</td>
<td></td>
<td>1,103</td>
<td>58%</td>
</tr>
<tr>
<td>Tested within last 12</td>
<td></td>
<td>687</td>
<td>37%</td>
</tr>
<tr>
<td>months</td>
<td></td>
<td>31</td>
<td>3%</td>
</tr>
<tr>
<td>Shreya Empowerment score (*/10)</td>
<td>76.43</td>
<td>17.67</td>
<td>77.77</td>
</tr>
</tbody>
</table>

Impact on HIV Testing and Contraception Uptake

- Increase in HIV testing and contraception with SKILLZ program compared to control.
Empowering Adolescent School Girls with SKILLZ – Process Evaluation of Intervention Engagement

Chiu C et al. AIDS 2023, Brisbane Australia July 2023, Abs. MOPEE06

- Process evaluation at 23 intervention SKILLZ schools to characterize attendance, changes in HIV and SRH knowledge from pre/post test.
- Of 1,135 girls at intervention sites: 79% attended at least one session, of which 90% attended at least 8 of 12 sessions to “graduate”; mean attendance varied by school (50-100%) and by coach but not correlated with prior HIV testing.

Program was well-attended and led to large knowledge gains in HIV and SRH (and HIV testing and contraception, prior presentation).
Cluster randomized trial of community-based integrated HIV and sexual/reproductive health services for youth 15-24 yr in 3 provinces in Zimbabwe - intervention CHIDZA

- High attendance and uptake of multiple services

- HIV testing highly accepted by both ♀ and ♂; likely driven by provision and acceptance of other services
Leveraging Community and Private-Sector HIV Self-Testing Distribution to Improve Testing and ART for AGYW Uganda

Tumusiime J et al. AIDS 2023, Brisbane Australia July 2023, Abs. OALBA0505

- Introduced HIVST in different distribution models across 3 urban districts Uganda

**Multiple options for HIVST services:** Directly assisted versus unassisted HIVST; oral or blood-based HIVST kits; HIVST use videos available online and through social media for those preferring anonymous access and HIVST options.

**Peer-driven demand generation and follow-up:** Peers from target population groups (such as AGYW) were identified and trained to lead demand generation and outreach, offer HIVST services, follow-up (via WhatsApp/SMS; telephone call; or home visit) to confirm HIVST results, and link clients to health facilities for confirmatory diagnosis and linkage to ART or prevention services.

**Various cadres of health care workers trained to provide HIVST services:** In addition to peers, health care personnel at public-sector outpatient and maternal/child health wards; pharmacists; and physicians, nurses, and midwives running specialty clinics were trained and equipped to offer HIVST services and coordinate with peer workers to ensure follow-on confirmatory diagnosis and/or linkage to care or prevention services.

- 203,377 people received HIVST kits >29% distributed to females between 15-24 years of age (AGYW).

- Similar rates for HIVST reactivity, positivity, AR linkage, and ART initiation rates among all individuals who received self-tests and AGYW:
  - **Reactivity:** 0.95% (overall) versus 0.97% (AGYW)
  - **Testing positivity:** 0.8% versus 0.78%
  - **ART linkage:** 99%
  - **ART initiation:** 81% versus 82%

*Includes people who received invalid HIVST results and were tested for HIV.*
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- About 2/3 of HIVST kits were distributed to young women aged 20-24; 67% preferred unassisted HIVST; 50% of AGYW who received an HIVST had not tested in past 12 mo, 0.2% never tested before
- Community models had the greatest volume of AGYW with HIV (door-door, 43%, targeted 32%); private sector had highest testing positivity rate (83% of all HIV+ persons were tested at pharmacy)
- Among AGYW who had never tested, 86% were reached through community and private sector models (hotspots, nurse-led clinics)

Community (particularly peer-driven) and private sector models were most effective at reaching AGYW with testing services and ID HIV-positive AGYW; peers to lead FU key to high linkage rates
Thank You For Your Attention!

Questions?