# FY 2024 Technical Considerations

PEPFAR

20 YEARS OF IMPACT

**Disclaimer:**

This PDF file shows red-line edits to the *FY 2023 Technical Considerations*, which were originally Section 6 of the 2022 COP/ROP Guidance. **For quick reference, the Appendix has a table-style summary of all edits. That said, the red-line edits and section edit summaries clarify precisely what was changed for fiscal year 2024 (FY24) as compared to technical considerations within *PEPFAR 2022 Country and Regional Operational Plan (COP/ROP) Guidance for all PEPFAR-Supported Countries*.**

In 2 instances (**Section 6.6.8**—Impact-Driven Information Systems and Data Management Investments and **Section 6.6.9** Sustainability of the HIV Response) the technical considerations were necessarily redrafted to align with PEPFAR's new strategic direction and policy changes. **Section 6.6.10** (Local Partners Definition) and the last 2 technical considerations in this document (**Section 6.8**—Surveys-Surveillance, Research, and Evaluation (SRE) Technical Considerations and **Section 6.9** Addressing Barriers to Health Equity: Stigma, Discrimination, and Human Rights) are new. Outside of these 5 sections, changes were only made to align wording with policy, to remove content that is no longer fit for purpose, or to correct errors.

**Other Notes:**

1. **Section Numbering:** Technical Considerations section numbering was carried over from the 2022 COP/ROP Guidance. Consequently, the 2023 COP/ROP Guidance references to Technical Considerations content appear as "FY24 Technical Considerations Section 6.X.X."
2. **Data Preface:** The data throughout the Technical Considerations was not updated. However, recognizing that PEPFAR embraces data-driven approaches, this year there are "Status of the Epidemic" and "Status of the Response" updates that serve as the FY24 Technical Considerations introduction. The latest PEPFAR program data are available at PEPFAR Panorama Spotlight.
3. **The Future of Technical Considerations:** This year's light-touch editing is not reflective of the future of PEPFAR's Technical Considerations management. Rather, this measure was applied to help S/GAC teams, in-country programs, and other stakeholders focus on implementing PEPFAR's 5-Year Strategy. In calendar year 2023 (FY24), PEPFAR will convene stakeholders to discuss the future of PEPFAR's Technical Considerations to

ensure these recommendations remain agile and appropriately responsive to policy changes and updates in best practices.

4. **Comment Period:** Because most of the wording for FY 2024 Technical Consideration is carried over from the prior year, the comment period will only collect feedback on *new content (i.e., only on content in red font).*

# TABLE OF CONTENTS

**STATUS OF THE EPIDEMIC** 1

**STATUS OF THE RESPONSE** 20

**SECTION 6: TECHNICAL CONSIDERATIONS** 40

**6.1 CONTINUITY OF TREATMENT AND ENSURING PROGRAMS WORK FOR PEOPLE LIVING WITH HIV** 41

6.1.1 LINKAGE TO ART, EARLY ENGAGEMENT, AND TREATMENT LITERACY 45

6.1.2 DIFFERENTIATED SERVICE DELIVERY 51

6.1.2.1 Differentiated Service Delivery for Children 56

6.1.2.2 Differentiated Service Delivery for Adolescents and Youth 60

6.1.2.3 Differentiated Service Delivery Support for Men and Women, Including Pregnant and Breastfeeding Women 65

6.1.3 CONTINUITY OF TREATMENT 69

6.1.3.1 Multi-Month Dispensing and Decentralized Drug Delivery 73

6.1.3.2 Interruptions and Re-engagement in Treatment 77

**6.2 PRIMARY PREVENTION** 79

6.2.1 PRE-EXPOSURE PROPHYLAXIS (PREP) 81

6.2.2 PREVENTION FOR ADOLESCENT GIRLS AND YOUNG WOMEN 92

6.2.2.1 Pre-Exposure Prophylaxis for Adolescent Girls and Young Women 93

6.2.2.2 The DREAMS Partnership 96

6.2.2.3 AGYW Prevention in Non-DREAMS Countries 106

6.2.3 PRIMARY PREVENTION OF HIV AND SEXUAL VIOLENCE FOR VULNERABLE 10-14 YEAR OLDS 107

6.2.4 PREVENTION FOR WOMEN AND PMTCT 110

6.2.4.1 Prevention in ANC and PMTCT 111

6.2.4.2 PrEP for Women 116

6.2.5 PREVENTION FOR MEN 121

6.2.5.1 Voluntary Medical Male Circumcision 122

6.2.5.2 PrEP for Men 130

6.2.6 CONDOMS AND LUBRICANTS 132

**6.3 HIV Testing Services Strategies: Reaching & Maintaining Global 95-95-95 Goals** **137**
6.3.1 HIV Testing Strategies for Case Finding 146
6.3.1.1 HIV Rapid Testing Continuous Quality Improvement 149
6.3.1.2 Retesting for Verification 151
6.3.1.3 Infant Diagnosis: Birth Testing, Integrating POC for Early Infant Diagnosis (EID) 152
6.3.1.4 Best Practices to Close Remaining Gaps in EID 157
6.3.1.5 Index Testing 160
6.3.1.6 HIV Self-Testing 161
6.3.1.7 Optimized Provider-Initiated Testing and Counseling (PITC) 167
6.3.1.8 Targeted Community-Based Testing Services 174
6.3.1.9 Community Engagement and Ensuring Quality of HIV Testing Services 177
6.3.2 Case Finding for Pediatrics 179
6.3.2.1 Pediatric Index Testing Considerations 185
6.3.2.2 Case Finding and OVC Programs 188
6.3.3 Case Finding for Adolescents and Youth 189
6.3.4 Retesting in Pregnant and Breastfeeding Women (PBFW) 192
6.3.5 HIV Testing within Prevention Services 196
**6.4 Optimizing HIV Care and Treatment** **199**
6.4.1 ART Optimization Best Practices, Drug Interactions, and Regimen Sequencing 202
6.4.1.1 Newborn HIV Prophylaxis for HIV-exposed Infants 204
6.4.1.2 Pediatric ART Optimization 205
6.4.1.3 Adolescent and Adult ART Optimization 211
6.4.2 Identification and Treatment of Advanced HIV Disease 214
6.4.2.1 Approach to CD4 Testing 219
6.4.2.2 Identification and Treatment of Pediatric Advanced Disease 221
6.4.2.3 Reducing Mortality and the Aging Cohort 225
6.4.3 TB/HIV 227
6.4.3.1 TB Case-Finding Among People Living with HIV 229
6.4.3.2 Optimizing Treatment for People with TB and HIV 240
6.4.3.3 TB Prevention 243
6.4.4 Cervical Cancer Screening and Treatment 252
6.4.5 Approach to Viral Load Testing 259

6.4.5.1 Use of Point-of-Care Platforms for VL Testing in Pregnant and Breastfeeding Women, Infants, and Children 262
6.4.5.2 Best Practices to Close Remaining Gaps in Viral Load Testing Coverage and Suppression 264
6.4.6 Approach to Virological Non-Suppression 269
6.4.6.1 Virologic Non-suppression Among Adults and Adolescents 270
6.4.6.2 Virologic Non-Suppression Among Children 272
6.4.6.3 Use of Point-of-Care Platforms for Viral Load Testing in Virally Non-suppressed Patients 274
6.4.7 Monitoring for HIV Drug Resistance (HIVDR) 275
6.4.8 Integrated Women's Health 278
**6.5 PEPFAR's Key Populations Approach and Strategy 281**
6.5.1 Providing Quality, Person-Centered HIV Services with Key Populations in Prevention, Diagnosis, Treatment, and Care 284
6.5.1.1 Prevention for Key Populations 289
6.5.1.2 Key Populations: Optimizing Testing and Case-Finding Strategies 299
6.5.1.3 Continuity of Treatment for Key Populations: Initiation to Undetectable 307
6.5.1.4 Structural Interventions for Key Populations 315
6.5.2 Sustainability of KP Programming 322
6.5.2.1 Key Population-Led Civil Society Organizations Financing 323
6.5.3 Considerations for Monitoring Key Populations Programs 326
6.5.3.1 KP Surveys and Surveillance 326
6.5.3.2 Unique Identifier Codes & Special Considerations for KP 329
6.5.3.3 Monitoring of Key Populations Programs 331
6.5.4 Considerations for Children of Key Populations, Adolescent and Young Key Populations 333
6.5.4.1 Children of Key Populations 333
6.5.4.2 Adolescent and Young Key Populations (AYKP) 337
**6.6 Cross-Cutting 340**
6.6.1 Laboratory 341
6.6.1.1 Diagnostic Network Optimization (DNO) 341
6.6.1.2 Laboratory Global Purchasing and Service Level Agreements to Streamline Supply Chain 345
6.6.1.3 Laboratory Continuous Quality Improvement and Accreditation 346
6.6.1.4 Multi-disease use of Diagnostic Testing Platforms for HIV, TB, COVID-19, and HPV 348
6.6.1.5 Biosafety and Waste Management 350

6.6.2 GENDER EQUALITY 351
6.6.2.1 Gender-Based Violence and Violence Against Children 355
6.6.3 ORPHANS AND VULNERABLE CHILDREN: EVOLVING THE OVC PORTFOLIO IN A CHANGING EPIDEMIC 361
6.6.4 FAITH AND COMMUNITY ENGAGEMENT 372
6.6.5 BEHAVIORAL HEALTH 379
6.6.5.1 Addressing Mental Illness in HIV Prevention and Treatment Services 379
6.6.5.2 Psychosocial Support 386
6.6.6 EMERGENCY COMMODITY FUND 395
6.6.7 OPTIMIZING HRH STAFFING FOR MAXIMUM IMPACT AND SUSTAINABILITY 395
6.6.8 IMPACT-DRIVEN INFORMATION SYSTEMS AND DATA MANAGEMENT INVESTMENTS 402
6.6.8.1 Advancing National Unified Health Information Ecosystems 403
6.6.8.2 Supporting National, Integrated, Longitudinal Person-Level Data 405
6.6.8.3 Operationalizing National Unified Health Data Ecosystems 409
6.6.8.4 Recent Infection Surveillance Among Newly Diagnosed PLHIV 415
6.6.8.5 HIV Recency Surveillance and Response Among Newly Diagnosed PLHIV 420
6.6.9 SUSTAINABILITY OF THE HIV RESPONSE 424
6.6.9.1 HIV Response Sustainability Framework 425
6.6.9.2 Convening Sustainability Stakeholders 431
6.6.9.3 Finding Efficiencies to Enable Investing in Sustaining the Response 433
6.6.9.4 Identifying Priority Systems Gaps for Investment 435
6.6.10 LOCAL PARTNER DEFINITION 436
**6.7 SITE SAFETY 438**
6.7.1 INFECTION PREVENTION AND CONTROL 439
6.7.2 OCCUPATIONAL HEALTH 446
6.7.3 WASTE MANAGEMENT 448
6.7.4 CLEANING, DISINFECTION, AND STERILIZATION 449
**6.8 SURVEYS-SURVEILLANCE, RESEARCH, AND EVALUATION (SRE) TECHNICAL CONSIDERATIONS 453**
**6.9 TECHNICAL CONSIDERATIONS FOR ADDRESSING BARRIERS TO HEALTH EQUITY: STIGMA, DISCRIMINATION, AND HUMAN RIGHTS 462**

**APPENDIX 1: SUMMARY OF EDITS 468**

# Status of the Epidemic

To allocate resources in the most efficient and effective manner, we must lead with data and understand where the HIV/AIDS pandemic is now—globally, nationally, and subnationally—by population. HIV treatment and prevention services have significantly decreased new infections and all-cause mortality among people living with HIV. More countries are now at a point in which the number of people requiring HIV treatment services is not annually increasing—HIV prevalence is decreasing, and over the past decade, incidence and mortality have been halved.

The COVID-19 pandemic and other infectious disease outbreaks continue to test PEPFAR program durability. Communities have adapted their behaviors, and PEPFAR has adapted and leveraged its platforms to protect HIV gains while also aiding the COVID-19 response.

Population-Based HIV Impact Assessment (PHIA) surveys continue to provide insight into the HIV response as well as information on gaps in routine health information data. Routine health data inform day-to-day patient and program management. As treatment and prevention programs have effectively scaled, data systems have also scaled—though they need to be brought together across sites at the individual level and institutionalized for accurate, routine use.

Data out of Botswana, Malawi, Zimbabwe, Uganda, Lesotho, Namibia, Eswatini, and Rwanda demonstrate that reaching more than 73% community viral suppression across age/sex bands is achievable and leads to stabilized—and even decreasing HIV disease burden. Botswana and Eswatini released PHIA results in 2022; these surveys were conducted during COVID-19 and assessed the resilience of people living with HIV staying on life-saving antiretroviral therapy (ART). Botswana reached 95-98-98 among those 15 years of age and older, and Eswatini achieved 94-97-96 These countries are well on their way to eliminating HIV/AIDS as a public health threat by 2030 (See **Figures 1 and 2**).

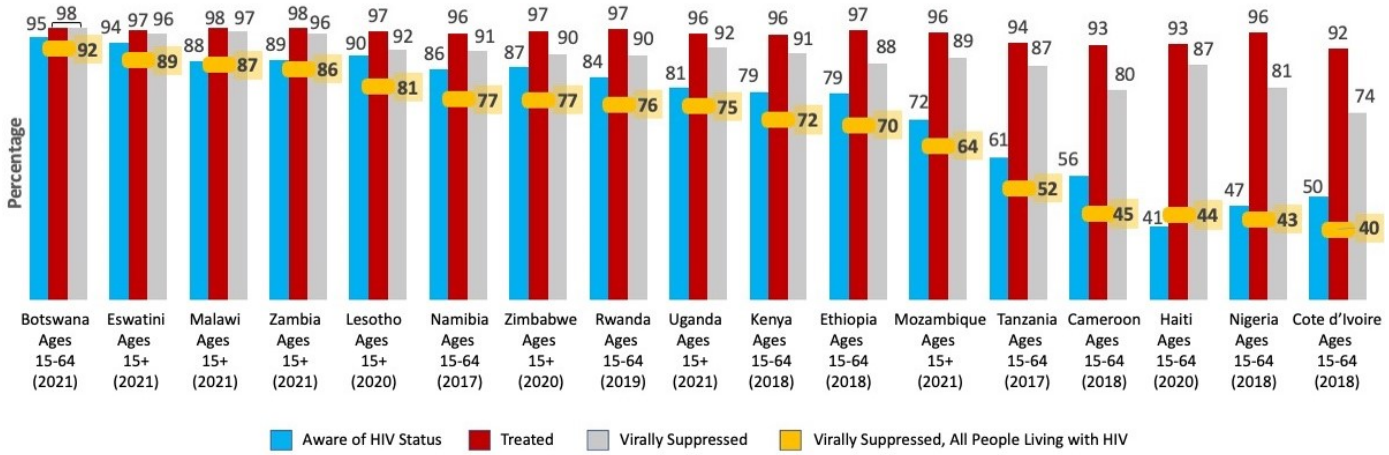



**Figure 1 Progress toward Equitable Services UNAIDS 95-95-95 Targets among Adults (15 Years of Age and Older) across Select Countries in Southern, Eastern, and Western Africa:** Of the 17 countries depicted in this graph, Botswana is the only one that has reached all three UNAIDS 95-95-95 targets and has an estimated 92% viral suppression among all people living with HIV. Eswatini, Malawi, and Zambia have achieved the second and third 95 for treatment and viral suppression and are nearing the first 95 target. Tanzania, Cameroon, Haiti, Nigeria, and Cote d'Ivoire are lagging far behind other countries, with significant gaps to reaching the first 95 and low population viral suppression. *Source: PHIA surveys (2016–2021)*

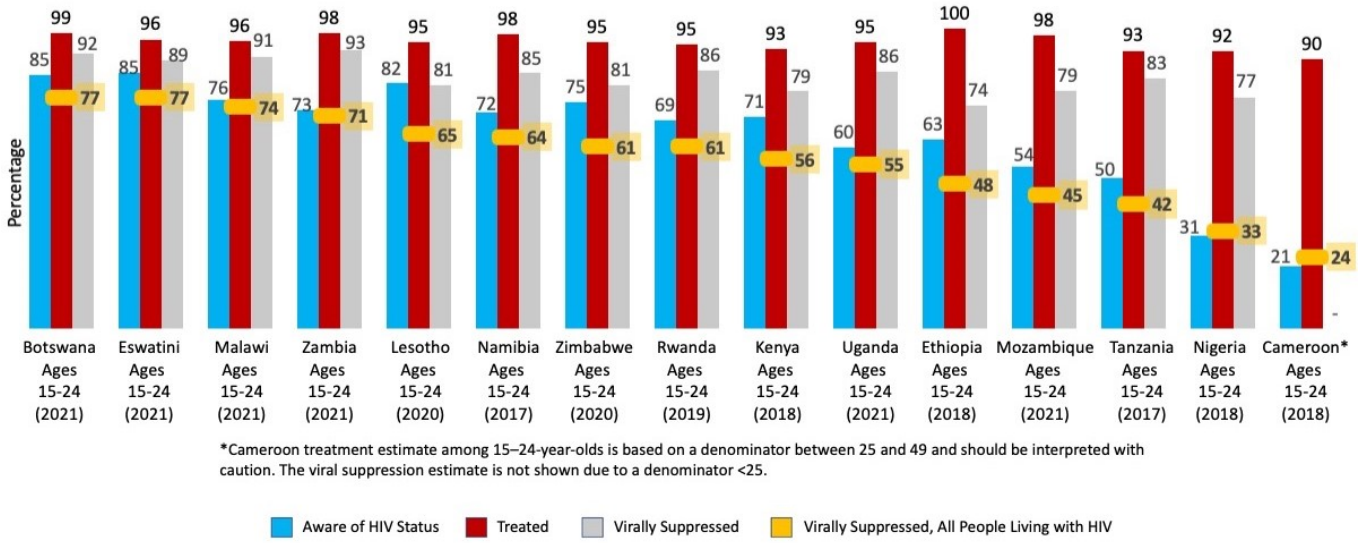


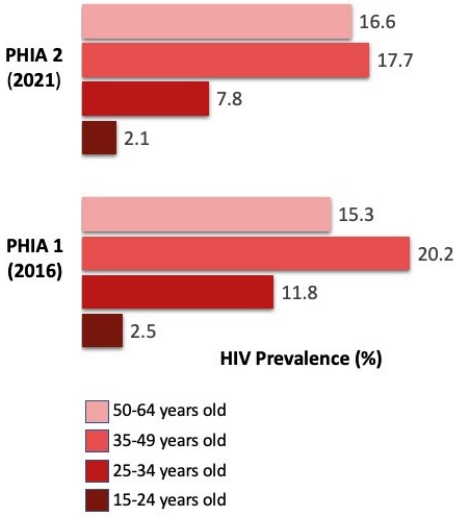

**Figure 2 Progress toward Equitable Services Reaching UNAIDS 95-95-95 Targets among 15- to 24-Year-Olds across Select Countries in Southern, Eastern, and Western Africa:** Achievement of the 95 targets and viral suppression among all people living with HIV aged 15 to 24 years old is lower for all countries compared to that of adults aged 15 years and older. Botswana has the highest achievement at

85-99-92 and 77% population VLS, while Nigeria has the lowest achievement (31-92-77, 33% population viral load suppression [PopVLS][1]). There is no cascade viral suppression estimate for Cameroon due to a denominator of less than 25. *Source: PHIA surveys (2016–2021)*

Upon comparing recent, second-round PHIA results to first-round results, we see progress toward health equity and reaching 95-95-95 targets for all.[2] Data for Zimbabwe, Lesotho, Malawi, Uganda, and Eswatini reveal that prevention and treatment programming that targeted specific gaps and previously unmet needs in younger populations is paying off—there are now fewer new infections in younger populations (15- to 24- and 25- to 34-year-olds). Of course, as people living with HIV age, HIV prevalence has shifted toward older adults. This expected outcome should not be ignored as we continue our work against HIV/AIDS.

Follow-up PHIA results for Malawi, Zimbabwe, Lesotho, Eswatini, Uganda, and Zambia show significant gains in reaching the 95-95-95 goals for every age (15 and older) and sex group since the prior PHIA (See **Figures 3–8**). MPHIA 2021 data show that Malawi has achieved 95-95-95 among females 35 to 39 years of age—following a 7% increase in the number of people living with HIV who know their HIV status and a 6% increase in the number of people who are on ART achieving viral suppression since 2016 round-one PHIA (See **Figure 3**). Comparing 2017 to 2020 PHIAs, Lesotho shows similar achievement among males 50 years of age and older (See **Figure 5**). In each of these countries, iterative programming helped fill gaps and improve clients' health outcomes.

[1] Population viral load suppression (PopVLS) is the estimated percentage of all people living with HIV who have a suppressed viral load.
[2] Third-round PHIA in Eswatini

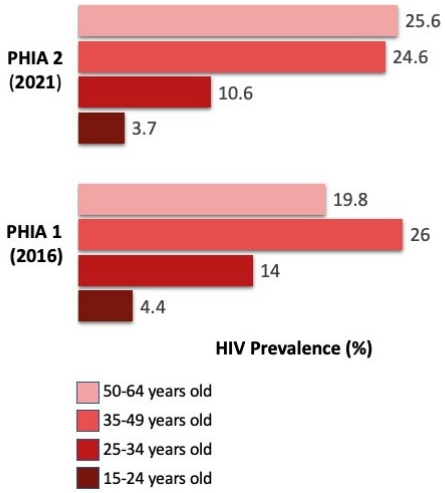



| PHIA 2 (2021) | | |
|---|---|---|
| Age | Male | Female |
| 50+ | 90-98-97 | 93-99-98 |
| 35-49 | 89-98-98 | 95-99-98 |
| 25-34 | 70-95-95 | 86-97-96 |
| 15-24 | 77-(95)-(91) | 76-96-91 |

| PHIA 1 (2016) | | |
|---|---|---|
| Age | Male | Female |
| 50-64 | | |
| 35-49 | 77-91-89 | 88-94-92 |
| 25-34 | 61-78-93 | 77-92-94 |
| 15-24 | * | 58-88-81 |

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.
*Results suppressed due to very small denominator (<25)

**Figure 3 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Malawi:** The prevalence of HIV has shifted to the older population from the first PHIA (PHIA1) in 2016 to PHIA2 in 2021, with prevalence among 50- to 64-year-olds increasing from 15.3% to 16.6%, and prevalence decreasing among the younger age groups (people aged 15 to 24 and 25 to 34 years). Females 35 to 49 years old have reached the UNAIDS 95-95-95 targets; however, despite improvements since the first PHIA, males still show equity gaps compared to their female counterparts in all age groups. *Source: PHIA1 and PHIA2, Malawi*



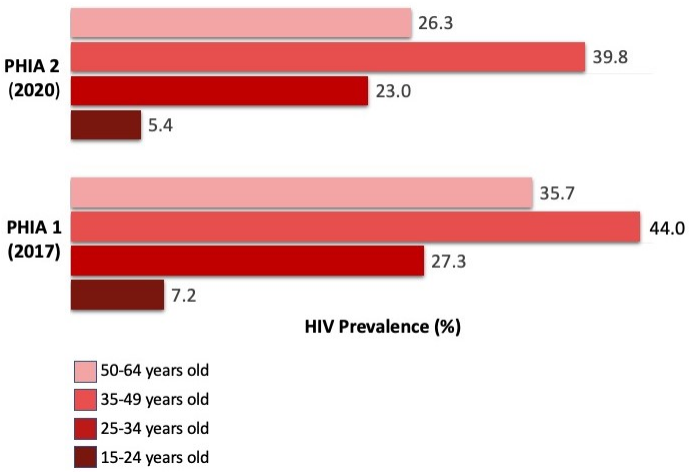

| PHIA 2 (2020) | | |
|---|---|---|
| Age | Male | Female |
| 50+ | 93-97-93 | 93-100-97 |
| 35-49 | 87-97-90 | 92-97-91 |
| 25-34 | 64-90-86 | 82-97-86 |
| 15-24 | 72-(96)-(72) | 77-95-85 |

| PHIA 1 (2016) | | |
|---|---|---|
| Age | Male | Female |
| 50-64 | | |
| 35-49 | 76-87-81 | 88-90-87 |
| 25-34 | 57-81-77 | 76-83-83 |
| 15-24 | 65-83-75 | 58-89-86 |

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.

**Figure 4 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Zimbabwe:** Zimbabwe had a significant shift in HIV prevalence from the younger age groups to the older population between PHIA1 in 2016 and PHIA2 in 2021. Though all age groups under 50 showed a reduced burden of

HIV, the prevalence among those 50 to 64 years old increased from 19.8% to 25.6%. The second Zimbabwe PHIA highlights remaining inequities among males and the younger age groups, with lower achievement of the UNAIDS 95-95-95 targets compared to females and older people living with HIV. *Source: PHIA1 and PHIA2, Zimbabwe*

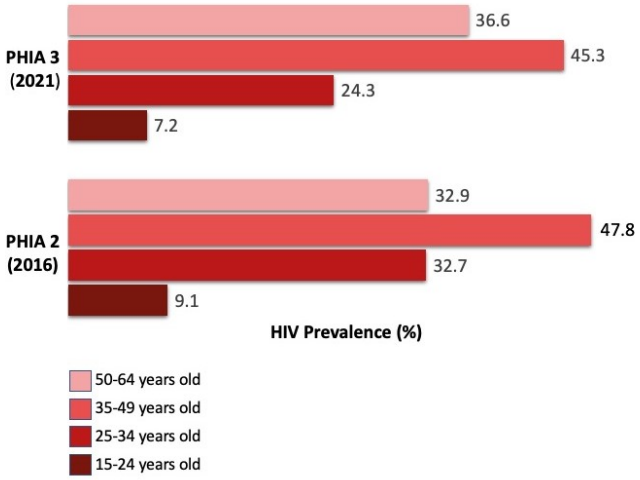



| PHIA 2 (2020) | | |
|---|---|---|
| Age | Male | Female |
| 50+ | 96-99-95 | 94-99-96 |
| 35-49 | 89-96-91 | 95-98-94 |
| 25-34 | 77-91-82 | 88-97-89 |
| 15-24 | (84-94-75) | 82-96-83 |

| PHIA 1 (2017) | | |
|---|---|---|
| Age | Male | Female |
| 50-59 | 92-97-93 | 87-96-94 |
| 35-49 | 82-92-88 | 90-93-91 |
| 25-34 | 59-88-84 | 83-89-84 |
| 15-24 | 71-(84)-(78) | 66-93-77 |

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.

**Figure 5 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Lesotho:** People who are 35 to 49 years old have the greatest burden of HIV (39.8%), followed by those who are 50- to 64 years old (26.3%) in PHIA2 (2020)—although, prevalence has lowered for all age groups since PHIA1 (2017). PHIA2 found that males 50 and older and females from 35 to 49 years old have achieved the 95-95-95 targets, though inequities still exist between ages and sexes, with younger age groups showing the greatest gaps in achieving their targets. *Source: PHIA1 and PHIA2, Lesotho*



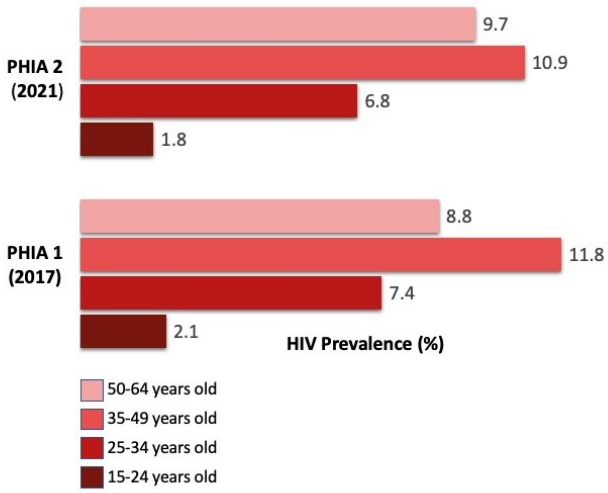

| PHIA 3 (2021) | | |
|---|---|---|
| Age | Male | Female |
| 50+ | 97-98-99 | 97-100-99 |
| 35-49 | 93-97-97 | 98-98-97 |
| 25-34 | 75-87-96 | 93-97-95 |
| 15-24 | 93-96-(87) | 84-97-91 |

| PHIA 2 (2016) | | |
|---|---|---|
| Age | Male | Female |
| 50-64 | | |
| 35-49 | 85-90-92 | 95-90-94 |
| 25-34 | 69-84-85 | 91-86-91 |
| 15-24 | 60-(92)-(58) | 76-84-81 |

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.

**Figure 6 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Eswatini:** HIV prevalence decreased for most age groups from PHIA2 (2016) to PHIA3 (2021); the prevalence among 50- to 64-year-olds increased from 32.9% to 36.6%. This shift is primarily due to successful HIV-treatment

programming that has led to an aging population of people living with HIV. Though the estimated 95s are higher for all age and sex groups from PHIA2 to PHIA3, PHIA3 revealed that the greatest inequity in reaching UNAIDS's 95-95-95 targets is among males 25 to 34 years old. At an estimated achievement of 75-87-96, males 25 to 34 years old lag behind younger and older male age groups and behind all female age groups. *Source: PHIA2 and PHIA3, Eswatini*

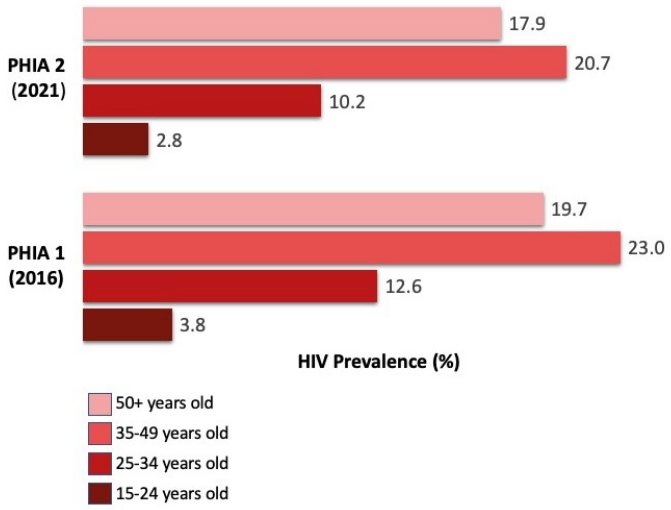



| PHIA 2 (2021) | | |
|---|---|---|
| Age | Male | Female |
| 50+ | 89-96-94 | 92-98-97 |
| 35-49 | 83-94-92 | 90-96-95 |
| 25-34 | 59-93-(87) | 82-97-90 |
| 15-24 | * | 64-95-87 |

| PHIA 1 (2017) | | |
|---|---|---|
| Age | Male | Female |
| 50-64 | | |
| 35-49 | 75-89-84 | 86-91-87 |
| 25-34 | 55-77-74 | 73-91-84 |
| 15-24 | * | 53-94-77 |

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.
*Results suppressed due to very small denominator (<25)

**Figure 7 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Uganda:** Results from the 2021 PHIA2 in Uganda show HIV prevalence shifting to older age groups, with the greatest burden among those aged 35 to 49 years (10.9%). Females in all age groups show the highest attainment of UNAIDS 95-95-95 targets—particularly, among those 35 to 49 years old and 50 years old and older. Males are still lagging along the cascade as compared to their female counterparts; however, achievement has improved since their PHIA1 in 2017. *Source: PHIA1 and PHIA2, Uganda*




| PHIA 2 (2021) | | |
|---|---|---|
| Age | Male | Female |
| 50+ | 92-99-99 | 94-99-98 |
| 35-49 | 91-98-97 | 94-98-97 |
| 25-34 | 70-95-97 | 83-97-95 |
| 15-24 | 73-(99)-(92) | 73-98-93 |

| PHIA 1 (2016) | | |
|---|---|---|
| Age | Male | Female |
| 50-59 | | |
| 35-49 | 77-88-87 | 81-90-92 |
| 25-34 | 47-76-91 | 73-81-89 |
| 15-24 | 48-(89)- * | 45-81-77 |

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.
*Results suppressed due to very small denominator (<25)

**Figure 8 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Zambia:** All age groups saw a reduction in estimated HIV prevalence from PHIA1 (2016) to PHIA2 (2021); the highest prevalence remains in the 35- to 49-year-old group, followed by the 50-years-old and older age groups (20.7% and 17.9%, respectively). All age and sex groups have made great progress toward achieving 95-95-95 targets, though males—particularly, those aged 15 to 24 and 25 to 34—still lag far behind. *Source: PHIA1 and PHIA2, Zambia*

While we celebrate nearing and achieving 95-95-95 in many countries, there is still work to do—especially when it comes to keeping new infections low in the face of the youth bulge. PHIA 2 results reveal gaps in equitable services. In all countries with a recent follow-up PHIA, males in all age groups are further from the 95 targets than females in similar age bands. In Lesotho, females 35 to 49 years old have achieved all three 95s (95-98-94), whereas their male counterparts are lagging (89-96-91). And though males 50 years old and older have reached their targets (96-99-95), younger males (25 to 34 years old) are further behind at 77-91-82 (See **Figure 5**). Uganda's second PHIA in 2021 shows that females who are 50 years old and older are at 92-98-97; however, females who are 15 to 24 years old are only at 64-95-87—a 28% difference in the number of younger females living with HIV who know their status as compared to older females (See **Figure 7**). Identifying programs that effectively serve each age/sex population is critical to decreasing incidence and mortality. Data such as these remind us that a sustained response against HIV/AIDS requires youth programming that is adaptive to changing cultural and social norms.

As we implement PEPFAR's 5-Year Strategy, we emphasize that equitable treatment of all populations we serve is essential to ending HIV/AIDS as a public health threat. The data reveal that we must consider the different level of services that aging populations need and implement effective and sustainable programs that reach men and younger age groups.

**Progress on New Infections**

In PEPFAR partner countries in sub-Saharan Africa, trends in new infections have been declining since 2010; however, new infections among women continue to be higher than in male counterparts (See **Figure 9**). Among people 15 to 24 years old and 25 to 34 years old, new infections among females are double that seen for males of the same age group. Across all age/sex populations, males had the steepest decline in new infections since 2010—a 65% reduction in new cases in males 15 to 24 years old and a 59% reduction in new cases among 24- to 34-year-old males. Among females, the same age groups had 50% and 41% decreases respectively. Voluntary medical male circumcision (VMMC) and HIV treatment services had the most impact among males during this period.

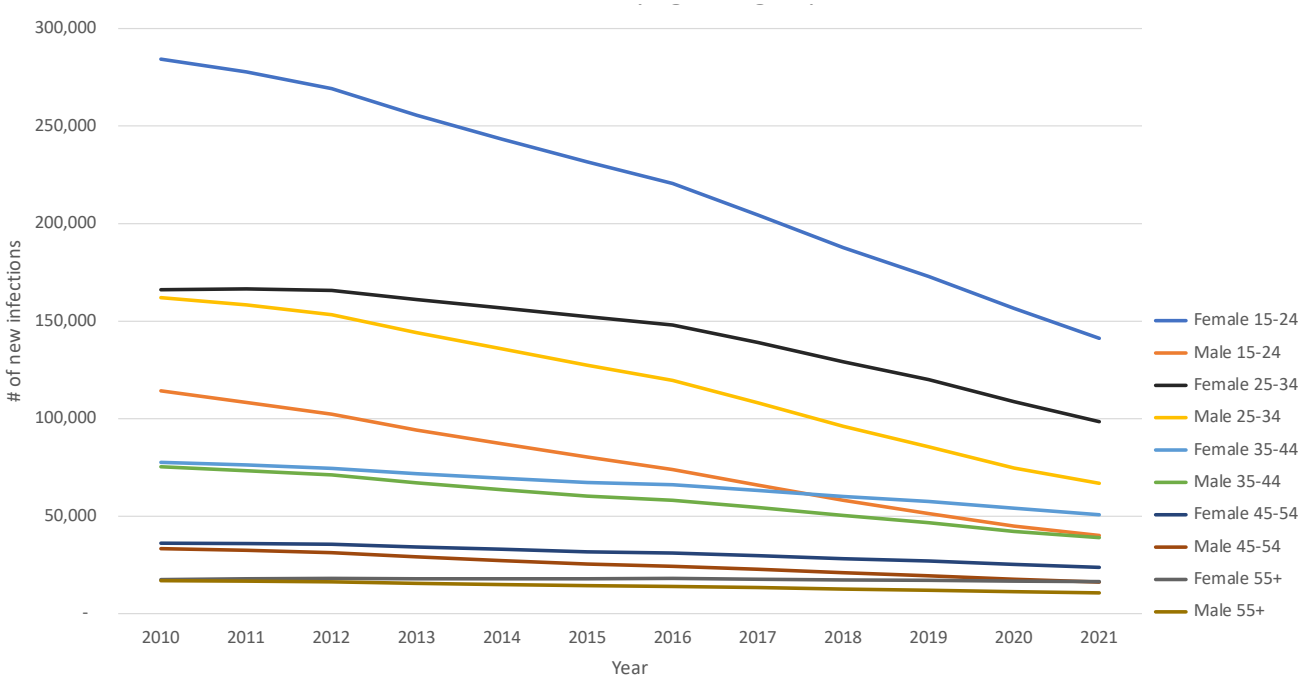



**Figure 9 Trends in New Infections by Age Group in PEPFAR Partner Countries in Sub-Saharan Africa:** Nearly all age and sex groups for those aged 15 years and older have seen a decline in the number of new HIV infections from 2010–2021. In every year, females 15 to 24 years old had the greatest

number of estimated new infections but also saw the greatest reduction in number of new infections over time. *Source: UNAIDS 2021 Estimates*

We need to increase the reach of PEPFAR HIV-prevention programs. One way to better target our services is to reflect on demographic data in combination with epidemiological data. For example, as shown in **Figure 10**, crossing demographic data with epidemiological data shows where high-risk adolescent girls and young women in Uganda remain underserved. This mapping can proactively inform where clinical and prevention services need to be bolstered for a more equitable response.

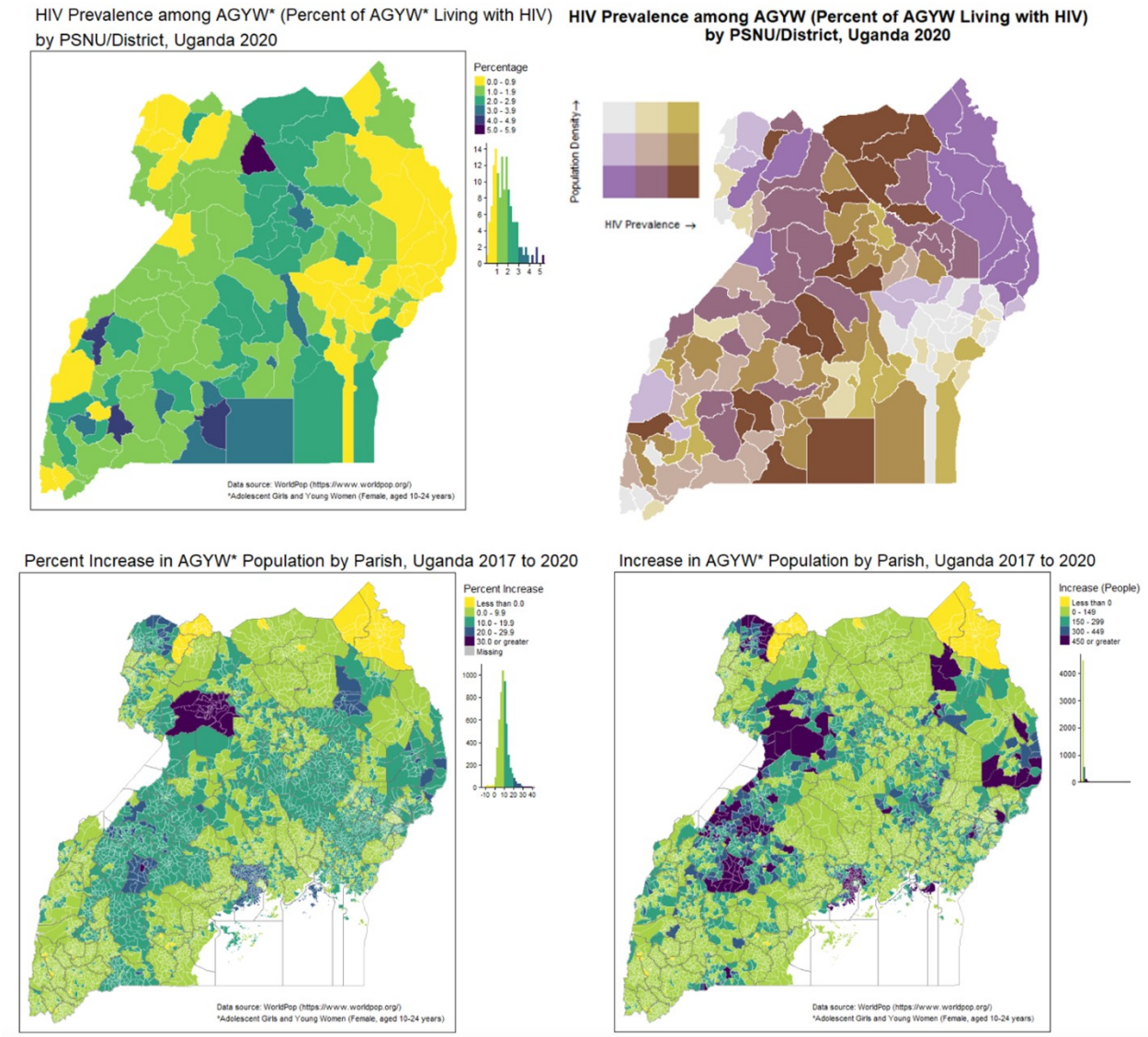



**Figure 10 Triangulating HIV Prevalence, Population Density, and Increases in the AGYW Population in Uganda:** (Top Left) National HIV prevalence among adolescent girls and young women by priority sub-

national unit (PSNU) / district in 2020; (Top Right) National HIV prevalence among adolescent girls and young women crossed with population density in each district; (Bottom Left) Percentage increase in adolescent girls and young women by parish from 2017–2020; (Bottom Right) The count increase in the number of adolescent girls and young women, 2017–2020.

### Progress among Children

Shifting to pediatric data, new infections among children have dramatically decreased since 2010 (See **Figure 11**). PEPFAR-funded comprehensive programming, including treatment and prevention, has resulted in more than 5.5 million babies being born HIV-free—prevention of mother-to-child transmission of HIV (PMTCT) services alone saved 3 million babies from being born with HIV (See **Figure 12**). Babies who have born HIV-free have cut new infections in most PEPFAR partner countries by more than 60%. While celebrating this accomplishment, we can't ignore the gaps that remain to reach 95-95-95 targets among children. While ART coverage has increased for all since 2010 and, on average, 81% of pregnant women are on treatment, children only have an average of 52% coverage. Understanding the unique service-delivery needs for children is essential to address this inequity.

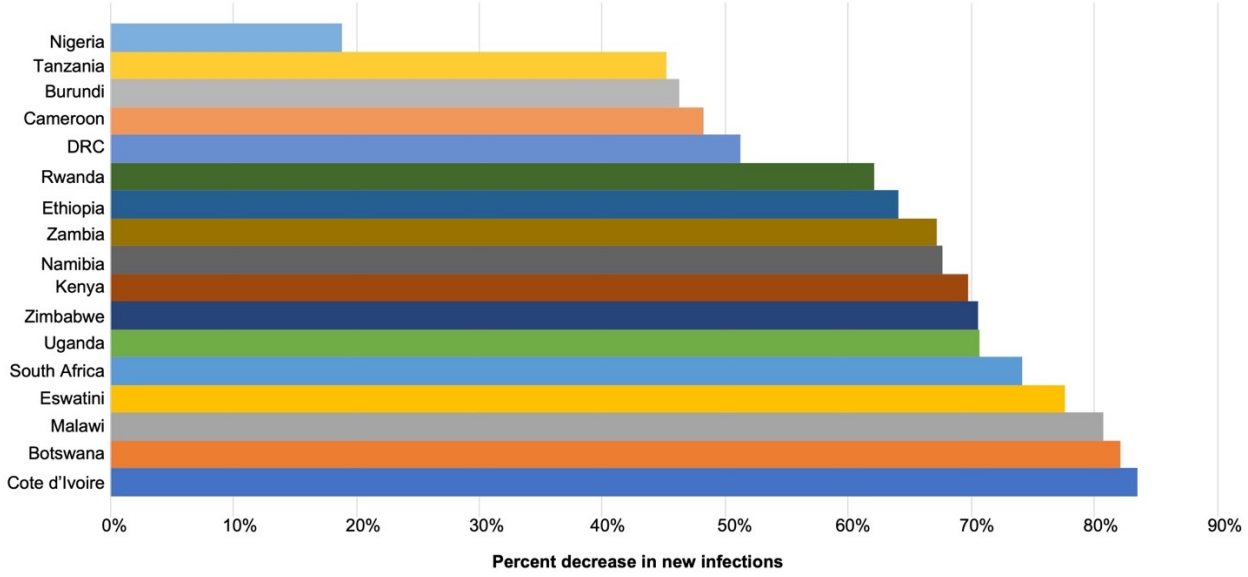
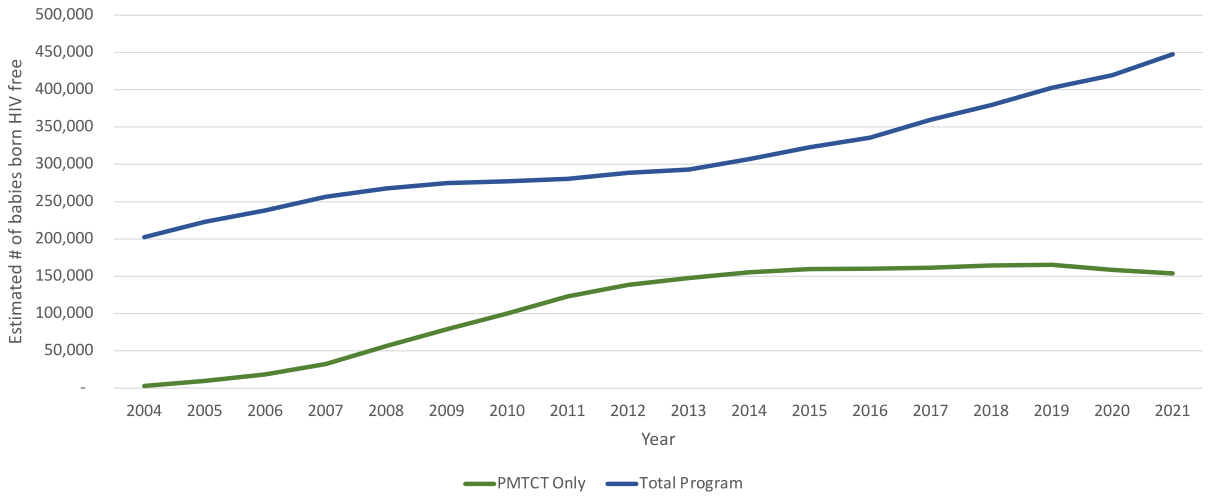



**Figure 11 Reduction in New Infections among Children (2010–2021):** Since 2010, Nigeria has had a nearly 20% reduction in new infections among children. Malawi, Botswana, and Cote d'Ivoire reduced the number of new infections among children by more than an estimated 80% between 2010–2021. *Source: UNAIDS 2021 Estimates*




*These results reflect implementation in PEPFAR supported countries from 2004 to 2021. Estimated babies born HIV free due to PMTCT only refers to prophylaxis or HIV treatment to HIV positive mothers to prevent mother to child transmission. Total program impact to prevent babies born with HIV includes HIV prevention and clinical services.

**Figure 12 Babies Born HIV-Free through PEPFAR Support (2004–2021):** In 2021, the PEPFAR PMTCT program in each country resulted in an estimated 150,000 babies being born without HIV through prophylaxis or HIV treatment to mothers living with HIV to prevent mother-to-child transmission. When including general HIV prevention and treatment services, the total PEPFAR program has prevented an estimated 450,000 babies from being born with HIV, an increase from an estimated 200,000 babies born HIV-free in 2004.

## Progress among Orphans

As communities reach 90-90-90 targets and beyond, vulnerable communities are stabilized, quality of life improves, and overall fewer children are being orphaned due to AIDS. Though the absolute number of orphans due to AIDS has increased since the start of PEPFAR, the rate of orphaning has decreased (See **Figure 13**). UNAIDS estimated 13.6 million orphans in 2003 at PEPFAR's inception, an estimated 18 million in 2012, and an estimated 14.9 million in 2021.[3] The age distribution of orphans has also shifted: more than half of orphans are older than 12. Children 6 to 11 years old make up the next largest groups of orphans due to AIDS.

[3] UNAIDS AIDSinfo – AIDS orphans (0–17) Estimates. Accessed December 8, 2022. https://aidsinfo.unaids.org/

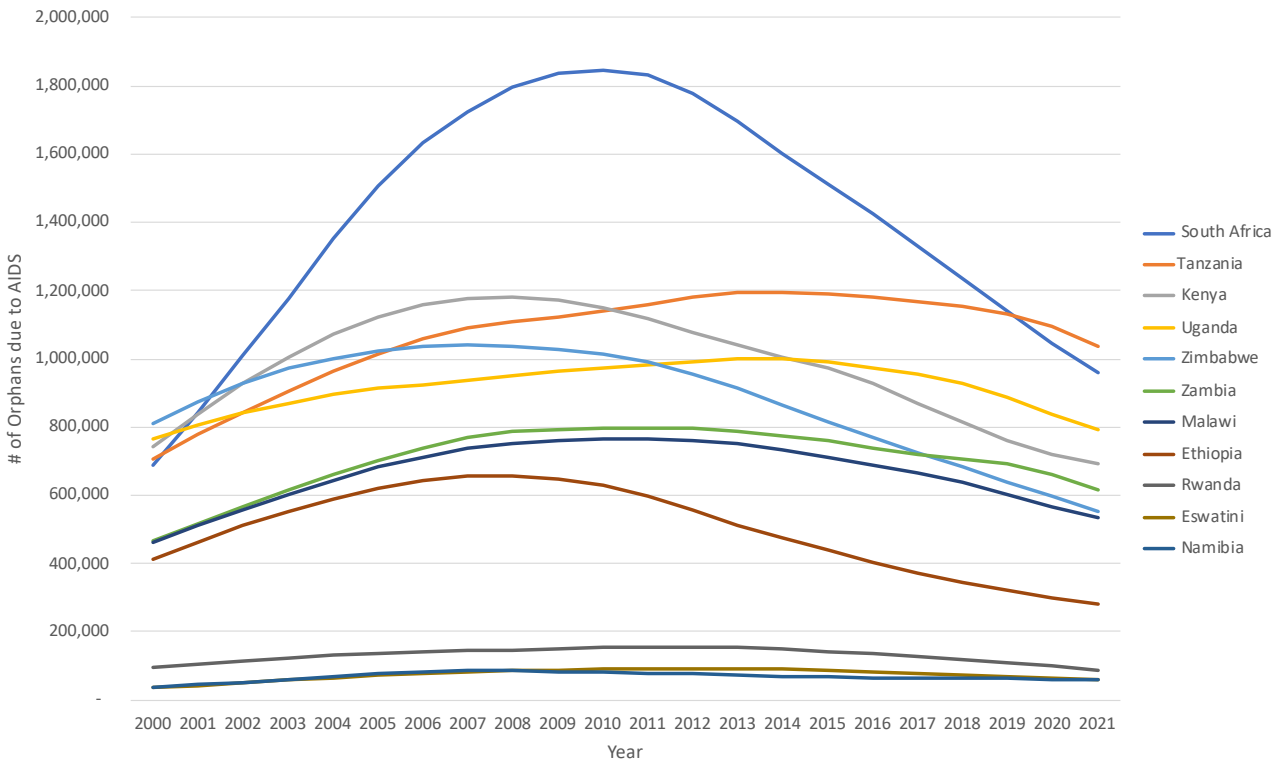



**Figure 13 Number of Orphans Due to HIV/AIDS (2000–2021):** South Africa shows the greatest number of orphans due to AIDS from 2000–2021, with a peak around 2010 of just over 1.8 million and then decreasing to just under 1 million in 2021. Namibia, Eswatini, and Rwanda had the smallest number of orphans due to AIDS each year, with their estimates remaining relatively flat from 2000–2021. *Source: UNAIDS 2021 Estimates*

## Progress among Key Populations

Though key populations (KPs) make up less than 5% of the population worldwide, the 2022 UNAIDS Global AIDS Update estimated that 70% of new, global HIV infections were among key populations and their sexual partners.[4] Impact of the response and progress toward 95-95-95 among key populations is varied; more routine data and surveillance data are needed to fully address HIV prevention and treatment inequities. Quality estimates require quality data inputs, but large gaps remain in epidemiological and KP surveillance data. Representative survey and surveillance data are critical to improve estimates and inform efficient, effective programs for key

[4] IN DANGER: UNAIDS Global AIDS Update 2022. Geneva: Joint United Nations Programme on HIV/ AIDS; 2022. Licence: CC BY-NC-SA 3.0 IGO

populations. KP surveillance surveys must use representative sampling approaches like respondent-driven sampling and time-location sampling alongside empirical population-size estimation methods to ensure that resources are used to produce high-quality data.

Risk, availability of services, stigma, violence, and discrimination concerns differ by key population—both between and within countries—and must be understood to address remaining inequities that slow progress. Examples from a couple of countries demonstrate these differences. Further technical guidance for key populations can be found in **FY24 Technical Considerations Section 6.9**.

**Sex Workers**

Results from the Crane Survey of Female Sex Workers in Uganda demonstrate similar UNAIDS 95-95-95 findings as seen for the general population (See **Figure 14**). PEPFAR Uganda has implemented services for female sex workers since the beginning of the program; the Crane Survey has provided routine data to direct and refine the program over the years to close 95-95-95 gaps.

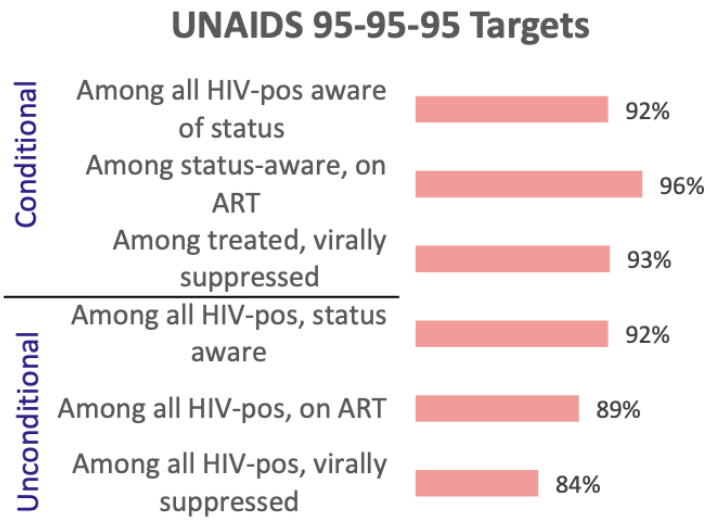



**Figure 14 Status of UNAIDS 95-95-95 Goals among Female Sex Workers in Kampala, Uganda:** Unconditional percentages show that out of all female sex workers living with HIV in Kampala, 92% know their status, 89% are on ART, and 84% are virally suppressed. Conditional cascade percentages show that 92% of HIV-positive female sex workers in Kampala know their status, 96% of those who know their status are on treatment, and 93% of those who are on treatment are virally suppressed.

## Men Who Have Sex with Men

The 2021 bio-behavior survey among men who have sex with men (MSM) in the Kyrgyz Republic found that only 41% of MSM living with HIV knew their status (See **Figure 15**). This represents a significant gap in achieving the first 95 target and indicates that MSM at increased risk may not be accessing HIV testing services. Addressing policies at national level and site level to remove barriers for same day initiation, multimonth dispensing and timing of services must be addressed for equitable services.

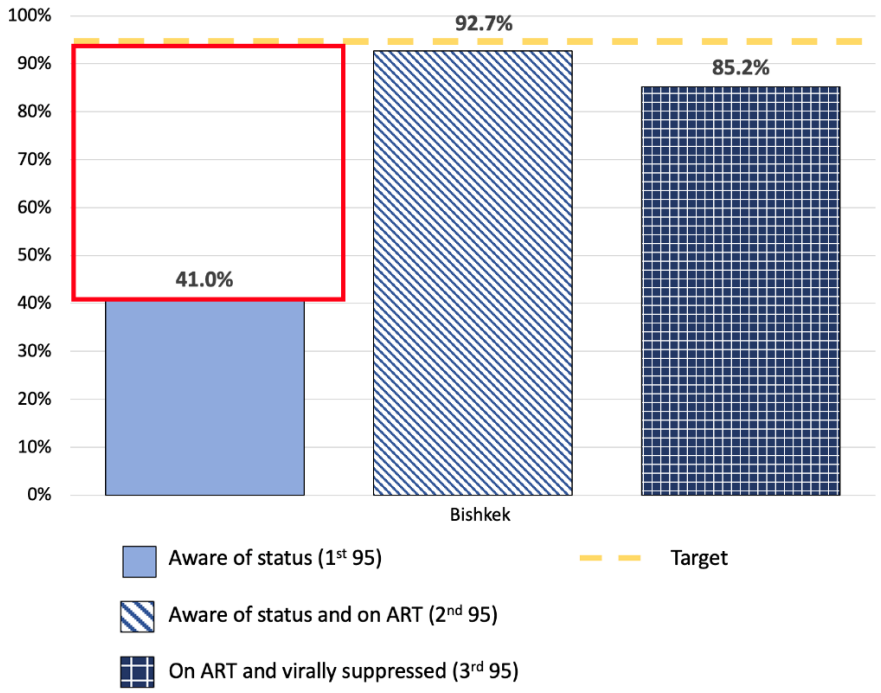



**Figure 15 Achievement of UNAIDS 95-95-95 Goals among MSM in Bishkek, Kyrgyz Republic:** Though the percentage of MSM who know their status and are on treatment is nearing the second 95 target at 92.7%, there is a significant gap in the percentage of MSM living with HIV who know their status (41.0%). *Source: 2021 Bio-Behavior Survey*

## Summary

Many people living with HIV are successfully receiving prevention and treatment services; however, inequities that jeopardize the entire HIV pandemic response remain. To maintain gains and simultaneously address remaining inequities, we need more granular data to focus our attention on where inequalities and gaps still exist. We need to collect and use person-centered data to continuously refine prevention and clinical services for youth and for aging populations.

Flexible prevention programming for youth including VMMC, Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS), and pre-exposure prophylaxis (PrEP) is vital. It's also important to learn from prevention programs that are successful in reaching youth to adapt clinical services for the younger population.

As people living with HIV age, programs need to responsively scale efficient and effective clinical services that address the total health of people over the age of 50 who are living with HIV—particularly those with other chronic conditions. Aligning case-finding approaches to rapidly identify people with new and undiagnosed long-term infections is essential; therefore, active public health response approaches—including safe and ethical index testing—remain critical. Of course, inequities in children must also be addressed. Some of the barriers we need to overcome to succeed in closing gaps for children are specific to child services (e.g., well-tolerated treatment regimens); others exist in the general health system.

We also need to overcome the data gap for key populations; we need to know where clinical and prevention services for key populations need bolstering. Countries have made extensive use of PHIA data; we should similarly use bio-behavioral study (BBS) and population size estimate (PSE) data to inform services and triangulate with program data. Results from KP surveys should be shared with all stakeholders within 2 months of the end of data collection to quickly discover gaps and ensure continuous program quality improvement and equitable resource allocation. PEPFAR has a track record of identifying gaps and addressing these inequities, and together we can once again rise to the challenge to close remaining inequities.

**Figures 16–18** demonstrate where countries stand in achieving UNAIDS 95-95-95 goals, new infections, mortality, and stabilization of the HIV/AIDS epidemic.

**Figure 16 (Panels A–F) Countries That Have a Stabilized HIV/AIDS Epidemic and Have Reached the 73% Population Viral Load Suppression Target:** Botswana, Zimbabwe, Lesotho, Kenya, Ethiopia, and Eswatini have stabilized HIV/AIDS epidemics, as shown by a trend of decreasing HIV incidence (new infections) and total all-cause mortality among the HIV-positive population. They also have an estimated viral load suppression of at least 73% among all people living with HIV. *Source: UNAIDS 2021 Estimates*

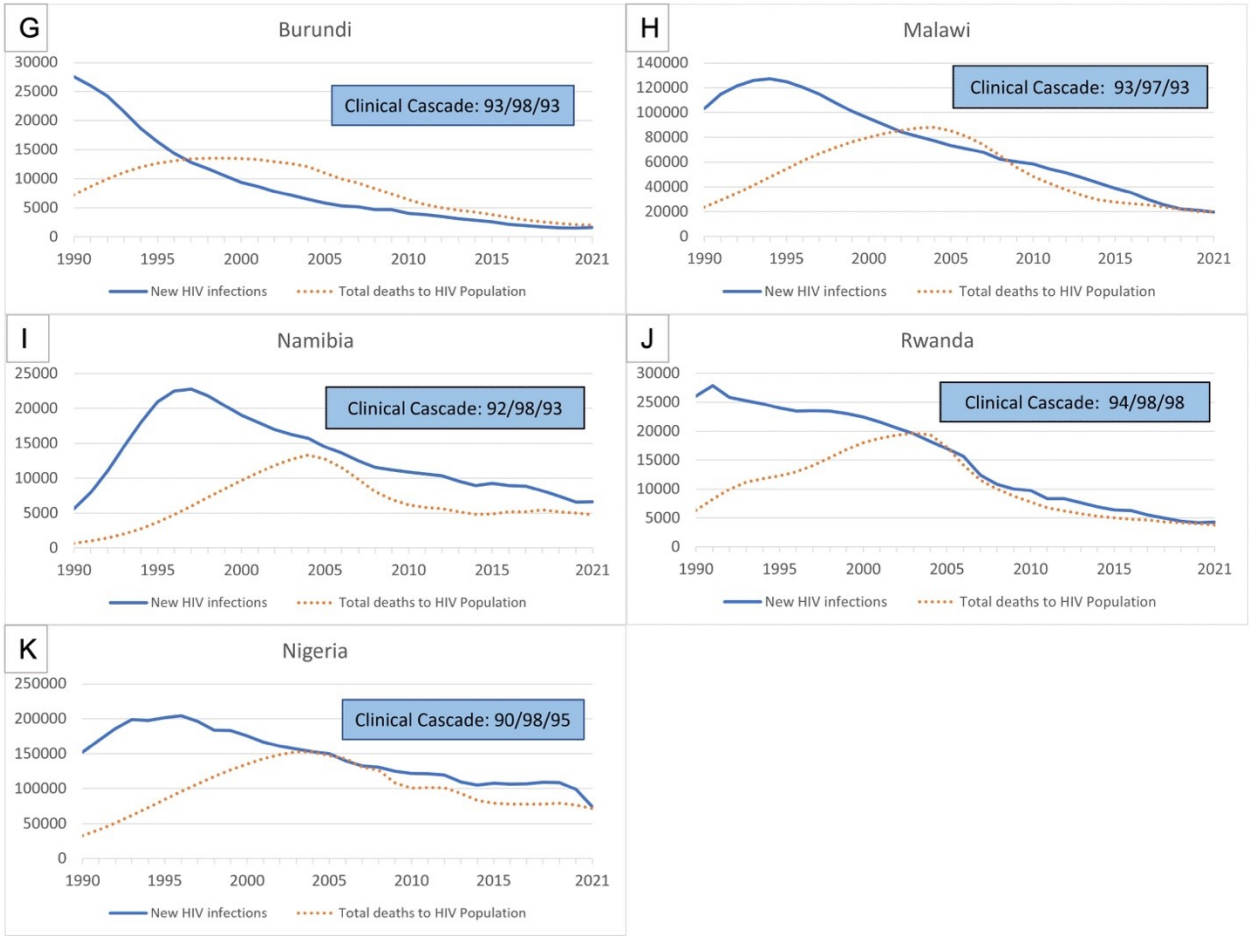



**Figure 16 (Panels G–K) Countries That Have a Stabilized HIV/AIDS Epidemic and Have Reached the 73% Population Viral Load Suppression Target:** Burundi, Malawi, Namibia, Rwanda, and Nigeria have stabilized HIV/AIDS epidemics, as shown by a trend of decreasing HIV incidence (new infections) and total all-cause mortality among the HIV-positive population. They also have an estimated viral load suppression of at least 73% among all people living with HIV. *Source: UNAIDS 2021 Estimates*

**Figure 17 Countries in Which the HIV/AIDS Epidemic Has Been Stabilized but the 73% Population Viral Load Suppression Target Has Not Yet Been Reached:** Cameroon, Cote d'Ivoire, the Democratic Republic of the Congo (DRC), Mali, Togo, and Sierra Leone have stabilized HIV/AIDS epidemics, as shown by a trend of decreasing rates of HIV incidence (new infections) and total all-cause mortality among people living with HIV However, these countries have not yet achieved a viral load suppression rate of at least 73% among all people living with HIV. *Source: UNAIDS 2021 Estimates*

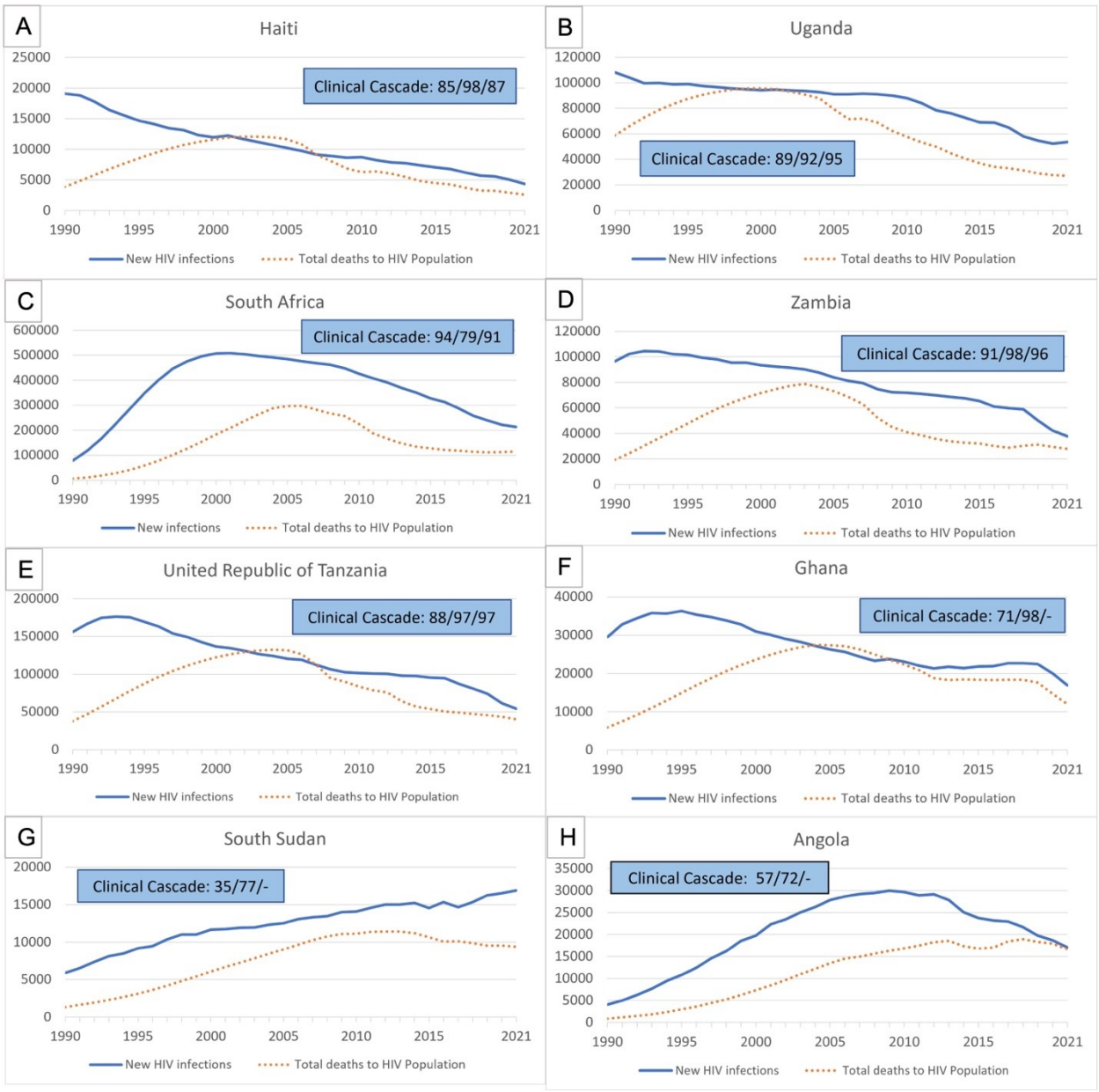



**Figure 18 Countries That Have Increasing HIV/AIDS Epidemics:** Haiti, Uganda, South Africa, Zambia, Tanzania, Ghana, South Sudan, and Angola do not have stabilized HIV/AIDS epidemics. These countries display a trend of increasing or flat rates of HIV incidence (new infections) and/or total all-cause mortality among people living with HIV and have not yet achieved a viral load suppression rate of at least 73% among all people living with HIV. *Source: UNAIDS 2021 Estimates*

# Status of the Response

Along with COVID-19, other public health threats have emerged—including monkeypox and a resurgence of Ebola—albeit these threats haven't had the same global impact as COVID-19. Nevertheless, these threats test PEPFAR program resilience. The same health systems PEPFAR established to respond to HIV are now being used to combat other emerging and existing public health threats as they continue to protect our gains in the HIV response. OU teams have worked with partner-country governments and other stakeholders to scale HIV services, such that over 20 million people living with HIV are now sustained on lifesaving, continuous ART. Of those on ART, 17.7 million clients have a documented viral load test result, and 94% of those tested (nearly 16.8 million) are confirmed to have achieved viral suppression. PEPFAR programs continue to demonstrate that controlling the HIV/AIDS epidemic is achievable through focusing and prioritizing the most impactful programs. The priority is to reach 95-95-95 targets by 2025 for people of all ages and sexes living with HIV— including children, adolescents, and key populations—and to ensure public health systems can operate in a routine manner to maintain this level of programmatic success.

To ensure that at least 90% of people living with HIV are linked to ART (95-95-95) by 2025, we need to further improve person-centered services for continuity of treatment and case finding. **Figure 19** depicts country graphs that show the age/sex gaps remaining at the end of COP22 which need to be addressed in COP23 to reach global 95-95-95 goals. In countries that have attained over 80% ART coverage, the age distribution of people living with HIV left to find is different than in countries that have not reached this goal. We must examine ART continuity by age and sex and adapt programs to sustain impact and prevent an increase in new infections and AIDS related mortality.

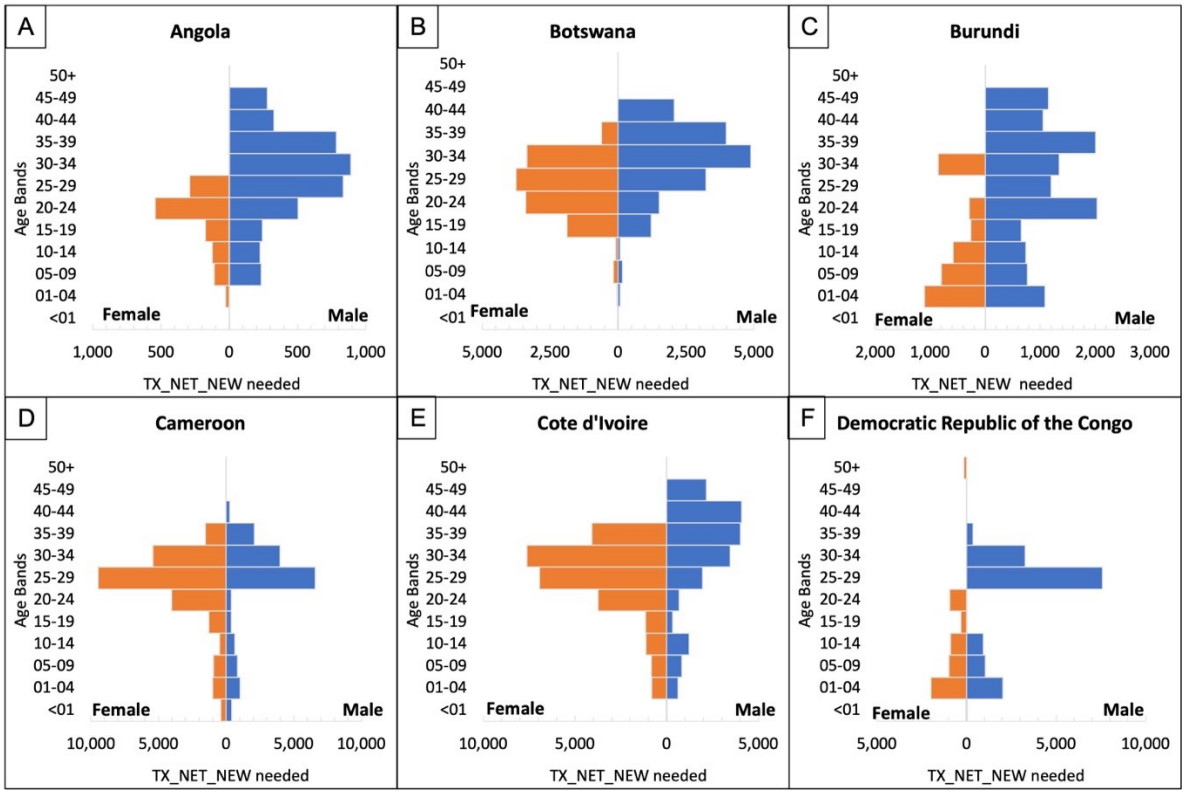



**Figure 19 (Panels A–F) Adaptive Services to Address Continuity on ART, Fourth Quarter (Q4) of FY22:** By the end of FY22: (A) In Angola, all groups of females older than age 30 met their treatment targets, while males still showed TX_NET_NEW needed for all age groups. (B) Botswana reached its treatment targets for females age 40 and older, but males age 35 to 44 still represent a gap in TX_NET_NEW; individuals 15 to 34 years of age made up the majority of TX_NET_NEW needed for both sexes.C) Burundi met its treatment targets for females aged 25 to 29 years and 35 years and older; all male age groups show TX_NET_NEW needed to reach treatment targets. (D) Cameroon met treatment targets for females who were 40 years old or older and males who were 45 years old or older, with large gaps for both sexes aged 25 to 29 and 30 to 34 years. (E) Cote d'Ivoire shows many more females needing to meet their treatment targets compared to males, especially in the 20-to-39 age bands. (F) DRC shows a large gap in TX_NET_NEW needed of nearly 9,000 for males aged 25 to 29 years and close to 5,000 for males aged 30 to 34 years. Smaller gaps are seen for females, mostly in the 1- to 4-year-old age group.

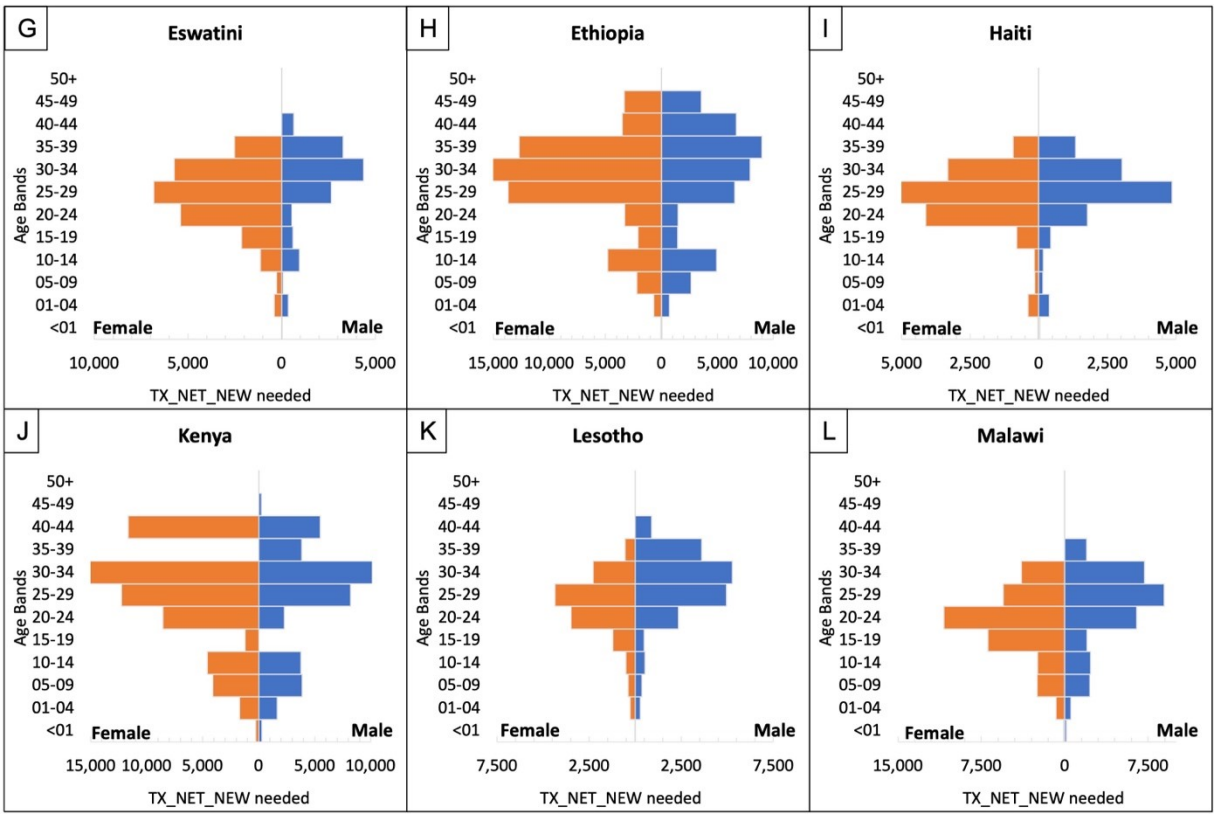



**Figure 19 (Panels G–L) Adaptive Services to Address Continuity on ART, FY22 Q4:** (G) In Eswatini, the TX_NET_NEW needed to reach treatment targets for females was double that of males in nearly every age band, and there was a bulge among the 20- to 24-year-old and 35- to 39-year-old age groups for both sexes. (H) Though Ethiopia met TX_CURR targets for both males and females 50 years old and older, significant gaps remain among those 25 to 39 years old, especially for females. Males have more TX_NET_NEW needed in the older age groups. (I) Haiti has reached treatment targets for both males and females older than the age of 40 but has large gaps remaining for those who are 20 to 24, 25 to 29, and 30 to 34 years old, with similar distributions of TX_NET_NEW needed by sex. (J) In Kenya, TX_CURR targets were met for males and females 50 years old and older; however, both sexes have bulges in TX_NET_NEW needed for those 5 to 14 years old and 20 to 44 years old, with larger gaps for females. Nearly 15,000 females aged 30 to 34 years are needed to meet their treatment target, while close to 10,000 males are needed in the same age group. (K) Lesotho has more males needed to reach their treatment targets for most age bands—particularly, among those 25 to 39 years old, with 3,000–5,000 TX_NET_NEW needed in each age band. (L) Malawi has a similar distribution and total number of males and females needed to reach their TX_CURR targets, though females have the largest gaps at 15 to 19 and 20 to 24 years old, while males have the largest gaps at 20 to 24, 25 to 29, and 30 to 34 years old.

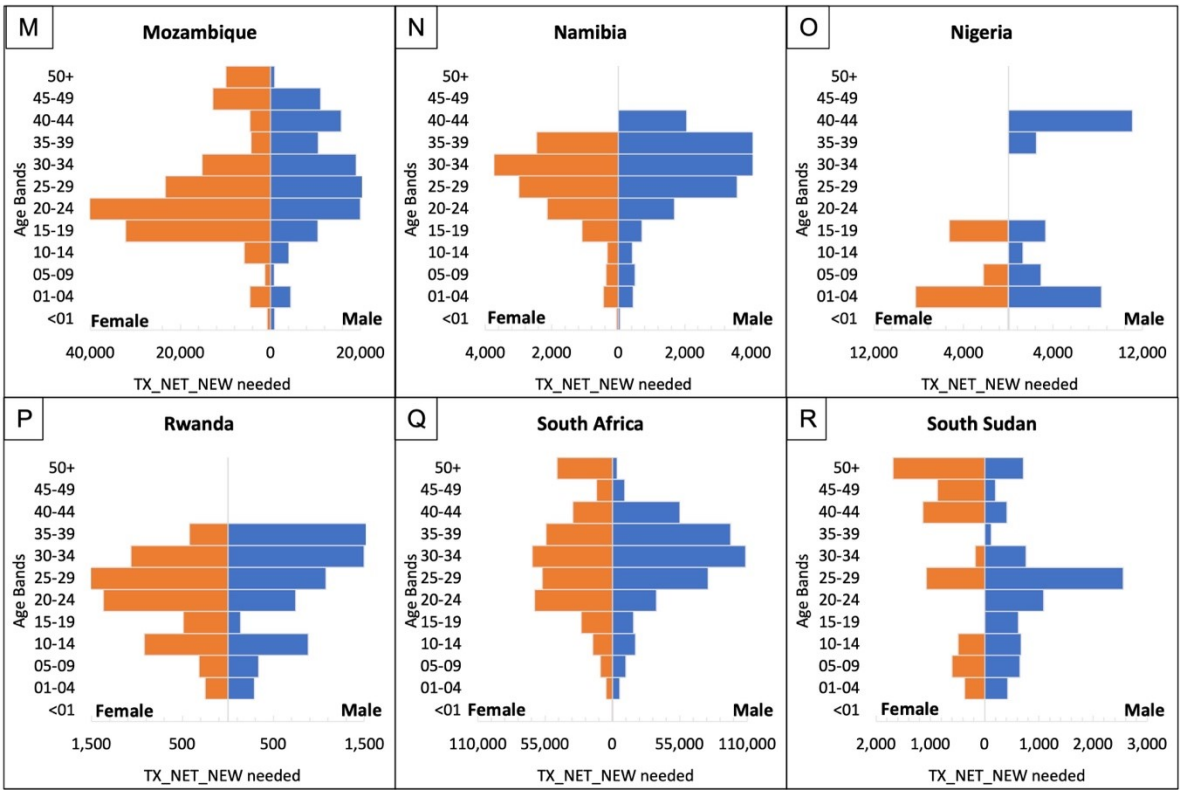



**Figure 19 (Panels M–R) Adaptive Services to Address Continuity on ART, FY22 Q4:** (M) Mozambique has not reached treatment targets for any age/sex population. Over twice as many females are needed compared to males, with the largest gaps in 15- to 19-year-old and 20- to 24-year-old females (30,000–40,000 TX_NET_NEW needed). Nearly 20,000 males aged 20 to 24, 25 to 29, and 30 to 34 years are needed to reach targets in those age groups. (N) Namibia has reached treatment targets for females aged 40 years and older and males aged 45 years and older but has similar sex gaps among those 20 to 39 years old. (O) Nigeria has reached treatment targets for females aged 10 to 14 years and 20 years and older and males aged 20 to 34 years and older than 45 years. The largest gaps remain for males and females 1 to 4 years old and males 40 to 44 years old, at nearly 12,000 TX_NET_NEW needed in this older age group. (P) Rwanda has reached treatment targets for females and males aged 40 years and older. The remaining gaps are skewed slightly younger for women 20 to 34 years old and for men 25 to 39 years old. (S) Significant treatment coverage and continuity gaps are seen across all age and sex groups in South Africa, though the gaps are larger for men, with nearly 110,000 males 30 to 34 years of age needed and similar TX_CURR gaps for males aged 25 to 29 and 35 to 39 years. Nearly 55,000 females are needed for each 5-year age group between 20 to 39 years old. (T) South Sudan has more

TX_NET_NEW needed among females aged 40 years and older and for younger males, with a large treatment gap of nearly 3,000 among males 25 to 29 years old.

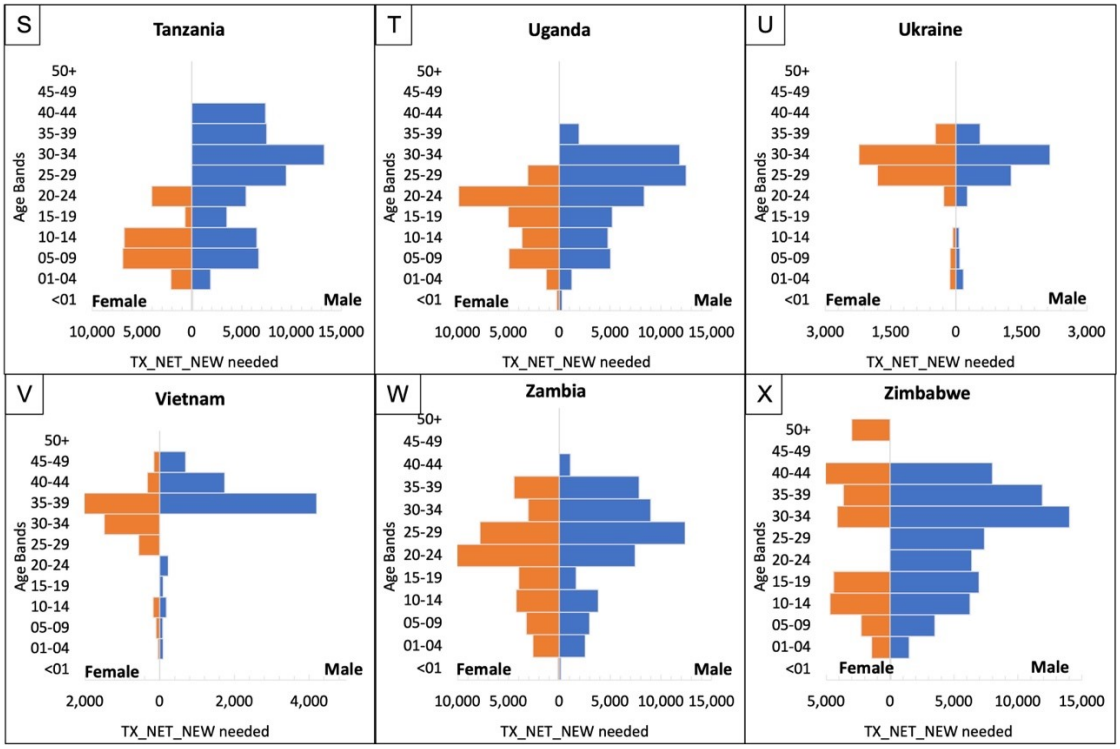



**Figure 19 (Panels S–X) Adaptive Services to Address Continuity on ART, FY22 Q4:** (S) Tanzania has met its treatment targets for females aged 25 years and older, though it needs close to 5,000 girls in the 5- to 9-year-old and 10- to 14-year-old age groups. Many more males are needed across all age bands, with the largest gaps at 25 to 29 and 30 to 34 years old. (T) In Uganda, significant treatment gaps remain among males 20 to 24, 25 to 29, and 30 to 34 years old as well as females who are 20 to 24 years old. More than twice as many males are needed to reach treatment targets than females. (U) Ukraine has met most of its TX_CURR targets by 5-year age band for both sexes, though work still needs to be done to improve ART coverage and continuity among males and females 25 to 29 and 30 to 34 years old. (V) While Vietnam has largely met its treatment targets for males younger than 35 years old, nearly 4,000 TX_NET_NEW is needed for males 35 to 39 years old and 2,000 for males 40 to 44 years old. Females have the largest gaps among the 30- to 34-year-old and 35- to 39-year-old age bands, with 1,500–2,000 TX_NET_NEW needed for each group. (W) Similar age distributions for TX_NET_NEW needed to meet treatment targets in Zambia are seen for both sexes, though there are many more men needed to close ART coverage and continuity gaps. Females have the largest gaps in the 20- to 24-year-old and 25- to 29-year-old age bands, while males have the largest gaps in the 25- to 39-year-old age groups. (X) In

Zimbabwe, nearly three times as many males are needed to reach their treatment targets than females across all age bands, with the largest gaps being among males 30 to 44 years old.

While striving to reach the 95-95-95 target by 2025, we must also ensure that clients presently on ART are receiving services that address their current needs and health systems must be able to maintain people living with HIV on ART as they age. With the aging HIV population, more than 22% of people living with HIV are older than 50 (See **Figure 20**), and other health conditions, such as hypertension, are emerging that need to be treated through an integrated service delivery platform.

Case finding to reach 95-95-95 requires continuous adaptation to find undiagnosed individuals for treatment services to promote healthy living. Using active public health testing such as safe and ethical index testing has proven to be effective for finding previously undiagnosed individuals. **Figure 21** showsdistribution by modality of positive HIV test results in FY22. For efficient use of limited human resources and test kits commodities, as countries are reporting a shortage of test kits, allocating these finite resources where case finding can be most effective and efficient for reduction in incidence and mortality is important.

Health equity and functional health systems are intertwined, and barriers to equitable services often signal that the health system is not adaptable or functional for certain populations. Progress toward establishing person-centered prevention and treatment services needs to be examined by age and sex groups to ensure the system is meeting the needs of all people living with HIV.

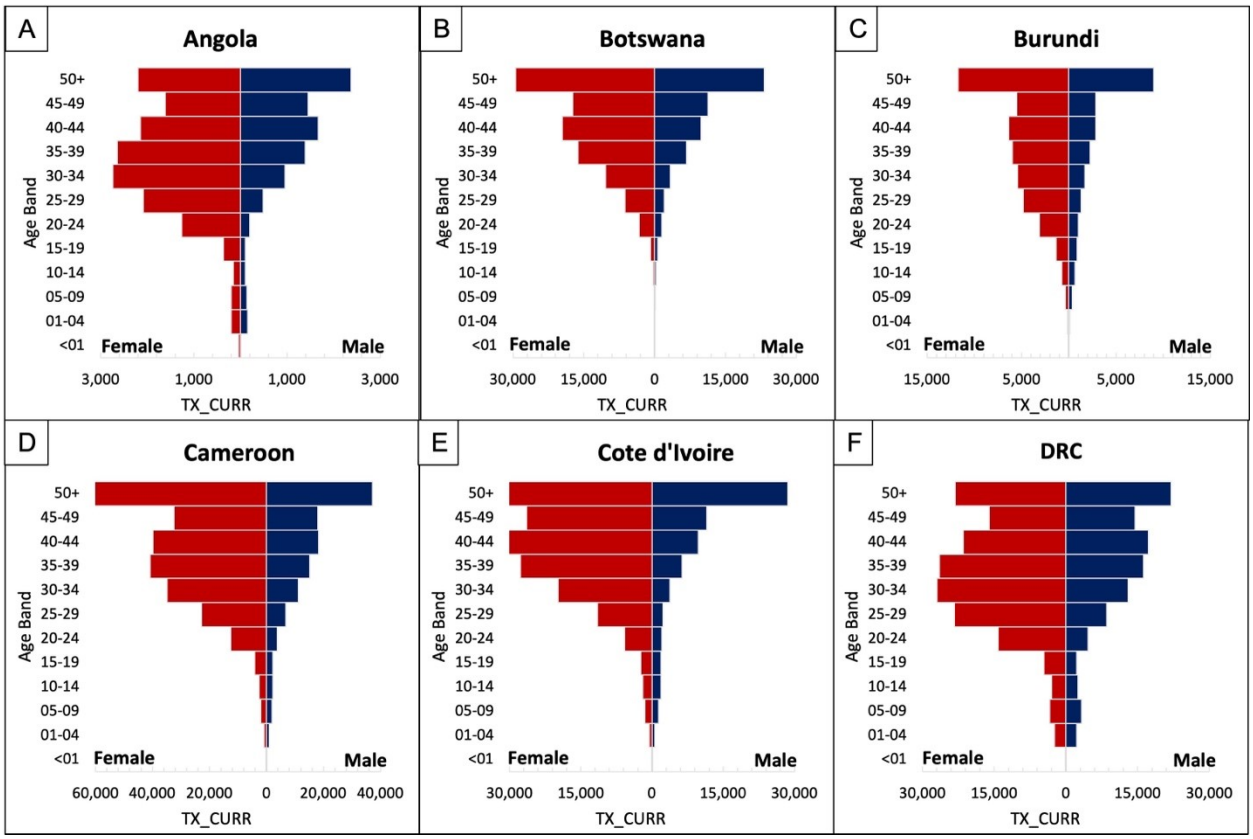



**Figure 20 (Panels A–F) Age Distribution among Those on ART, FY22 Q4:** (A) In Angola, more women are on treatment than men. For women, the age groups with the most people on treatment are 30 to 34 and 35 to 39 years old; for men, it is those who are at least 50 years old. (B) In Botswana, most individuals on treatment are at least 35 years old. The largest TX_CURR is nearly 30,000 at 50 years old and older for both men and women; more women are on ART than men for all ages. (C) In Burundi, more women are on treatment than men, with the largest age group being those 50 years old and older. (D) In Cameroon, many more women are on treatment than men, with the largest age group being those 50 years old and older, with increasing treatment cohort size in the older age groups. (E) A similar pattern is seen in Cote d'Ivoire, where more women were on treatment than men, the largest age group being those 50 years old and older. (F) In DRC, more women were on treatment than men. Among women, the 30- to 34-year-old and 35- to 39-year-old age groups had the most people living with HIV on treatment, at around 30,000 TX_CURR, while, for men, it was 50 years old and older.

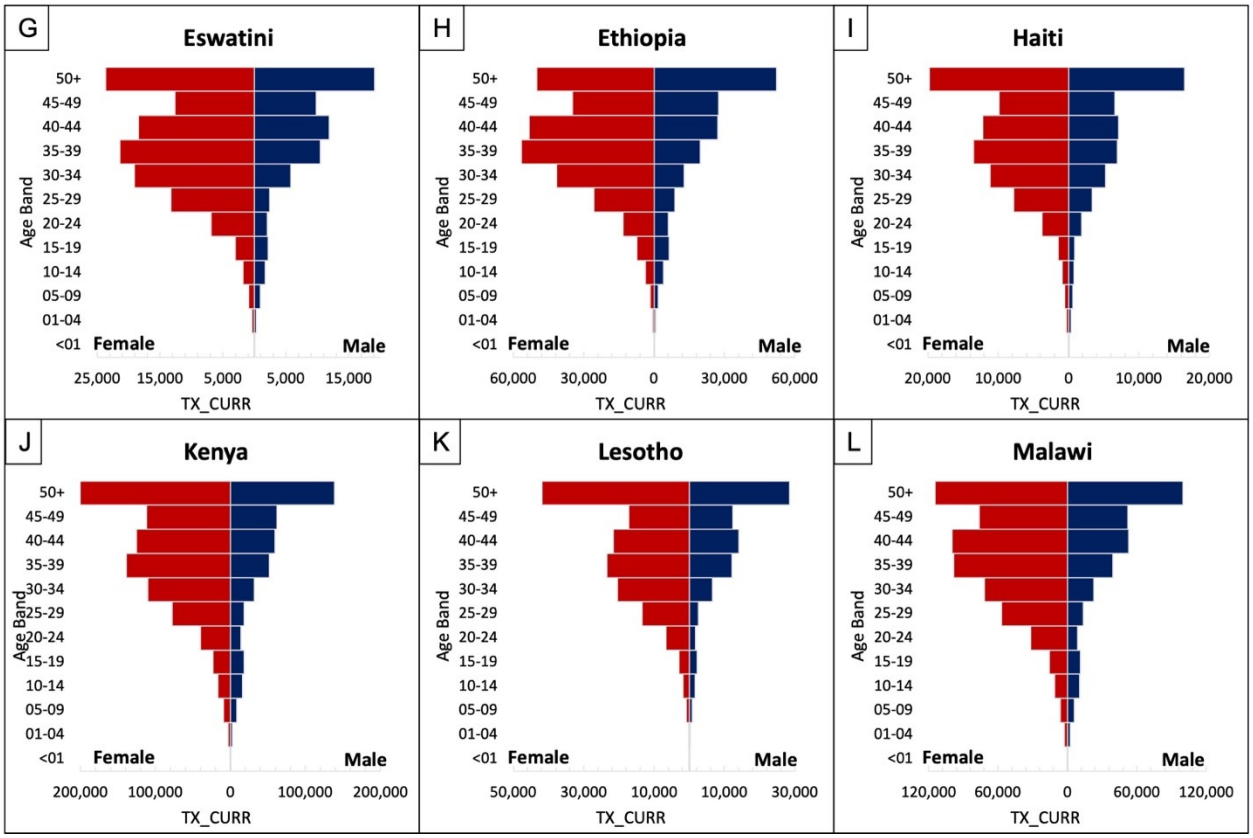



**Figure 20 (Panels G–L) Age Distribution among Those on ART, FY22 Q4:** (G) In Eswatini, nearly twice as many women were on treatment than men, with the largest age group on treatment being those 50 years old and older for both sexes. There were many women aged 30 to 44 years on treatment as well. (H) In Ethiopia, more women were on treatment than men. For women, the age groups with the most people on treatment were 35 to 39, 40 to 44, and 50 years old and older; for men, the age group with the most people on treatment was 50 years old and older, with steadily decreasing TX_CURR as the age groups got younger. (I) In Haiti, more women were on treatment than men—particularly, in the 25- to 49-year-old age groups. The largest age group on treatment for both sexes was those 50 years old and older, with 20,000 TX_CURR for women and 17,000 for men. (J) In Kenya, more women were on treatment than men in all age groups, with the largest age group on treatment being those 50 years old and older for both sexes. There were also many women on treatment between the ages of 30 and 49. (K) Lesotho shows a similar trend, with many more women on treatment than men across all age bands, with the largest TX_CURR age group for both sexes being 50 years old and older and a large cohort of women 30 to 49 years old. (L) Malawi has approximately twice as many women on treatment than men; many women on treatment are in the 30- to 49-year-old age band. The largest age group on treatment for both sexes was 50 years old and older, with around 115,000 TX_CURR for women and 100,000 for men.

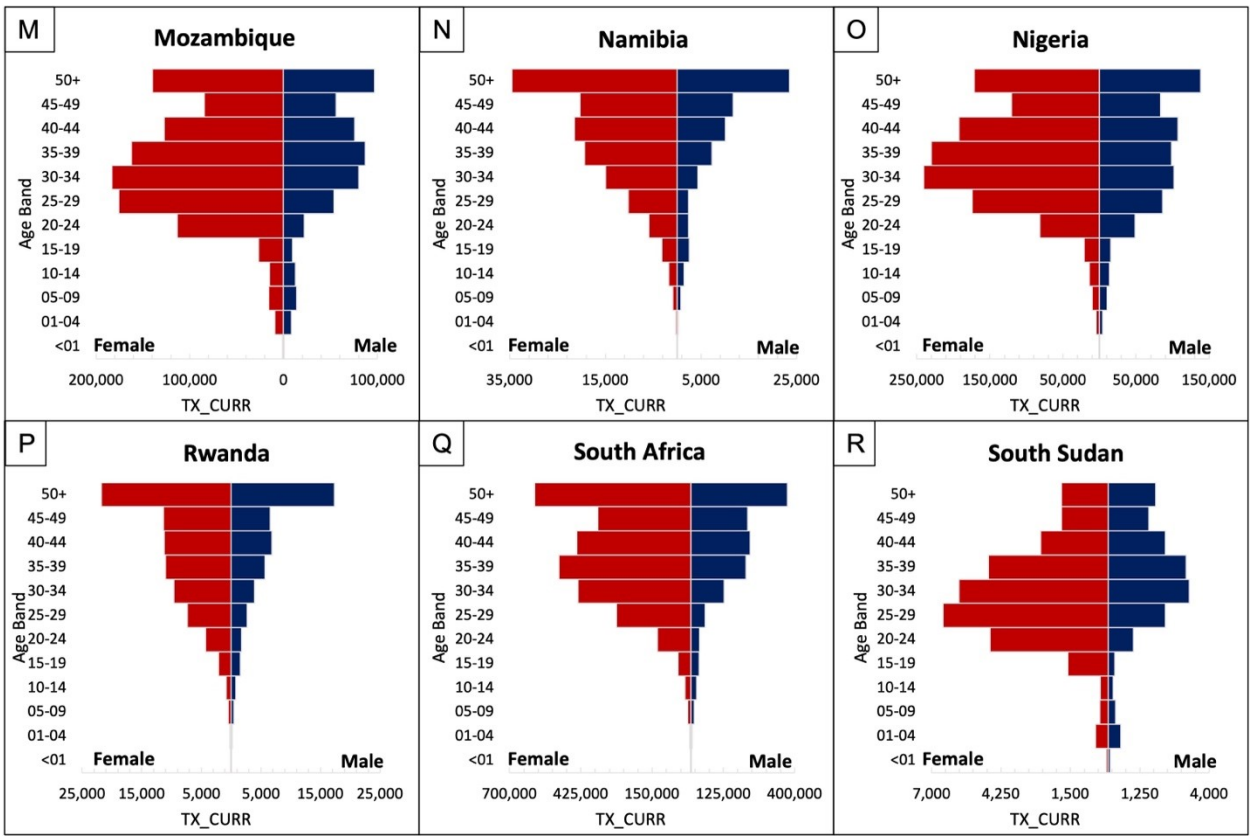



**Figure 20 (Panels M–R) Age Distribution among Those on ART, FY22 Q4:** (M) In Mozambique, 3 times as many women were on treatment than men in nearly every 5-year age band. For women, the 30- to 34-year-old age group had the most people on treatment, with 176,000 TX_CURR, closely followed by 25- to 29-year-olds and 35- to 39-year-olds. From there, treatment coverage decreases until the age group of 50 years old and older. In contrast, the male age group of 50 years old and older had the most men on ART, with 97,000 TX_CURR, followed by men in the 30- to 44-year-old age band. (N) Namibia had at least twice as many women on treatment than men, with the largest age group on treatment being those 50 years old and older for both sexes. The greatest sex differences start at the 20- to 24-year-old age band and are especially stark among those 30 to 49 years old. (O) In Nigeria, many more women are on treatment than men. The largest TX_CURR age group for women is 30 to 34 years old at 241,000, closely followed by 35- to 39-year-olds, while, for men, it is 50 years old and older, with 138,000 TX_CURR. (P) More women are on treatment than men in Rwanda, with increasing TX_CURR in each progressively older age group. The largest age group on treatment for both sexes is 50 years old and older. (Q) In South Africa, 2 to 3 times more women are on treatment than men, with the largest age group on treatment being those 50 years old and older at 603,000 women and 373,000 men. There is a bulge in the female treatment cohort for those 30 to 44 years old. (R) South Sudan has more women on treatment than men. Most women on treatment are in the 25- to 29-year-old and 30- to 34-year-old age groups, while, for men, it is the 30- to 34-year-old and 35- to 39-year-old age groups.

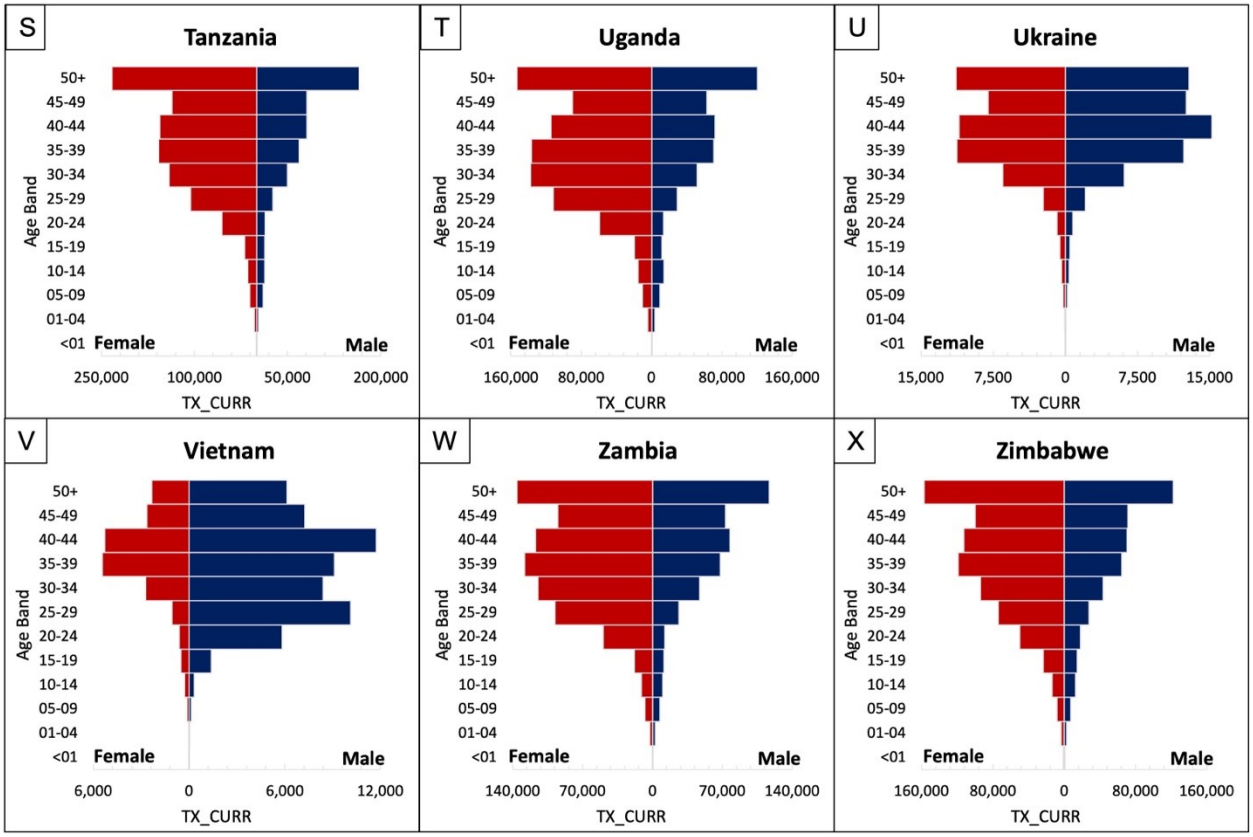



**Figure 20 (Panels S–X) Age Distribution among Those on ART, FY22 Q4:** (S) In Tanzania, many more women were on treatment than men, with the largest age group on treatment being those 50 years old and older. There were also many women on treatment between the ages of 20 and 49 years old. (T) Uganda saw a similar pattern in its treatment cohort, with many more women on treatment than men. In addition, the largest age group on treatment was those 50 years old and older for both sexes, and there was a large female TX_CURR bulge between the 25- to 29-year-old and 40- to 44-year-old age groups. (U) In Ukraine, more men were on treatment than women, with most people living with HIV on treatment for both sexes in the 35- to 39-year-old and older age groups. The treatment cohorts for females 35 to 39, 40 to 44, and 50 years old and older were nearly the same. The largest was around 11,000 TX_CURR; for men, the largest treatment group was 40 to 44 years old, with 16,000 TX_CURR. Males 35 to 39, 45 to 49, and 50 years old and older had similar numbers on treatment: around 12,500. (V) In Vietnam, 3 to 4 times more men were on treatment than women in all age groups. Among females, the 35- to 39-year-old age band had the most females on treatment, while, for men, it was 40 to 44 years old, closely followed by 25 to 29 and 35 to 39 years old. (W) Zambia had more women on treatment than men, with the largest age group on treatment being those 50 years old and older. Many women 25 to 44 years old were also on treatment. (X) In Zimbabwe, more women were on treatment than men, with the largest age group on treatment being those 50 years old and older, with 158,000 TX_CURR for women and 122,000 for men.

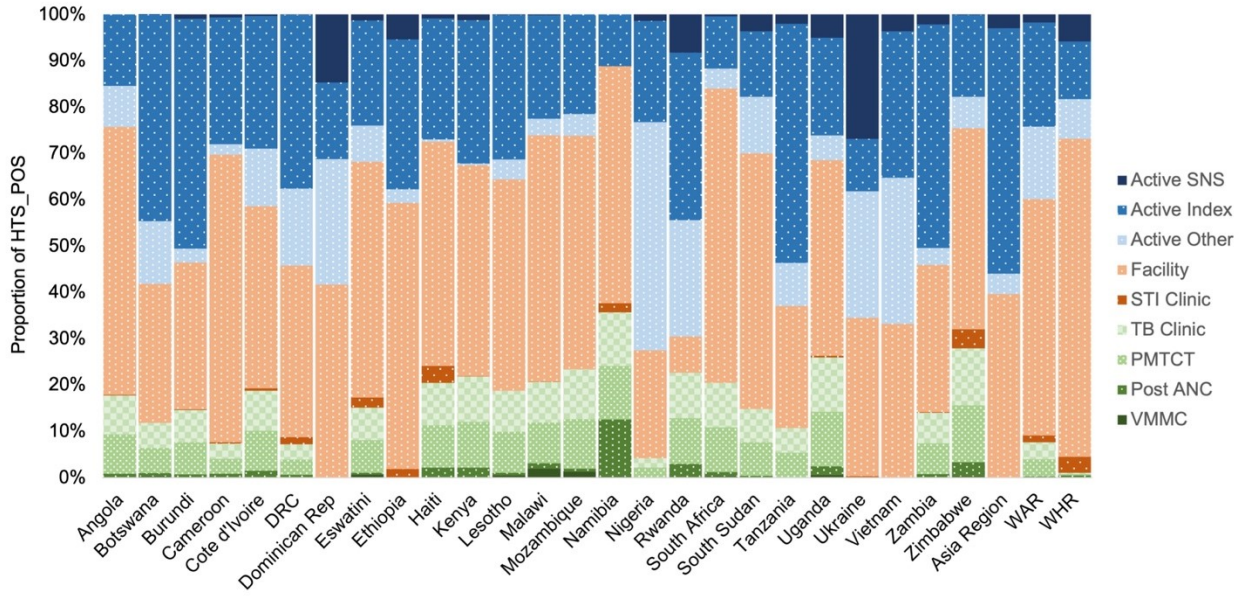



**Figure 21 Proportion of PEPFAR Case Finding through Active Public Health Response, Facility Testing, and Standard of Care Modalities, FY22:** Across all OUs, the greatest proportion of positive test results were found through the Facility and Active Index testing modalities in FY22. Nigeria had a significant proportion of positive test results through the Active Other modality, which is an outlier and warrants further questions. The Dominican Republican and Ukraine found at least 10% of their positives through Active social network strategies (SNS) testing.

VMMC has been successful in reducing new infections among men, and PEPFAR has been circumcising the 15- to 29-year-old age group for maximum prevention impact. Many countries are now recovering from the pause in VMMC during COVID lockdowns (See **Figure 22**). Countries have begun saturating the 15- to 29-year-old age group and are adjusting strategies to reach the next highest age group or geography for prevention impact. Further reducing incidence among men through impactful VMMC services is a core component to reach the 2030 UNAIDS goal to end HIV/AIDS as a public health threat.

Pre-exposure prophylaxis (PrEP) is another effective HIV prevention method and has scaled exponentially since FY19, from 160,000 HIV-negative individuals initiated on PrEP in FY19 to nearly 1.5 million people new PrEP enrollments at the end of FY22. In **Figures 23 and 24**, we can see the scale up of PrEP initiation among key populations and females. Innovation is needed to successfully get PrEP into populations with the greatest need through person-centered models.

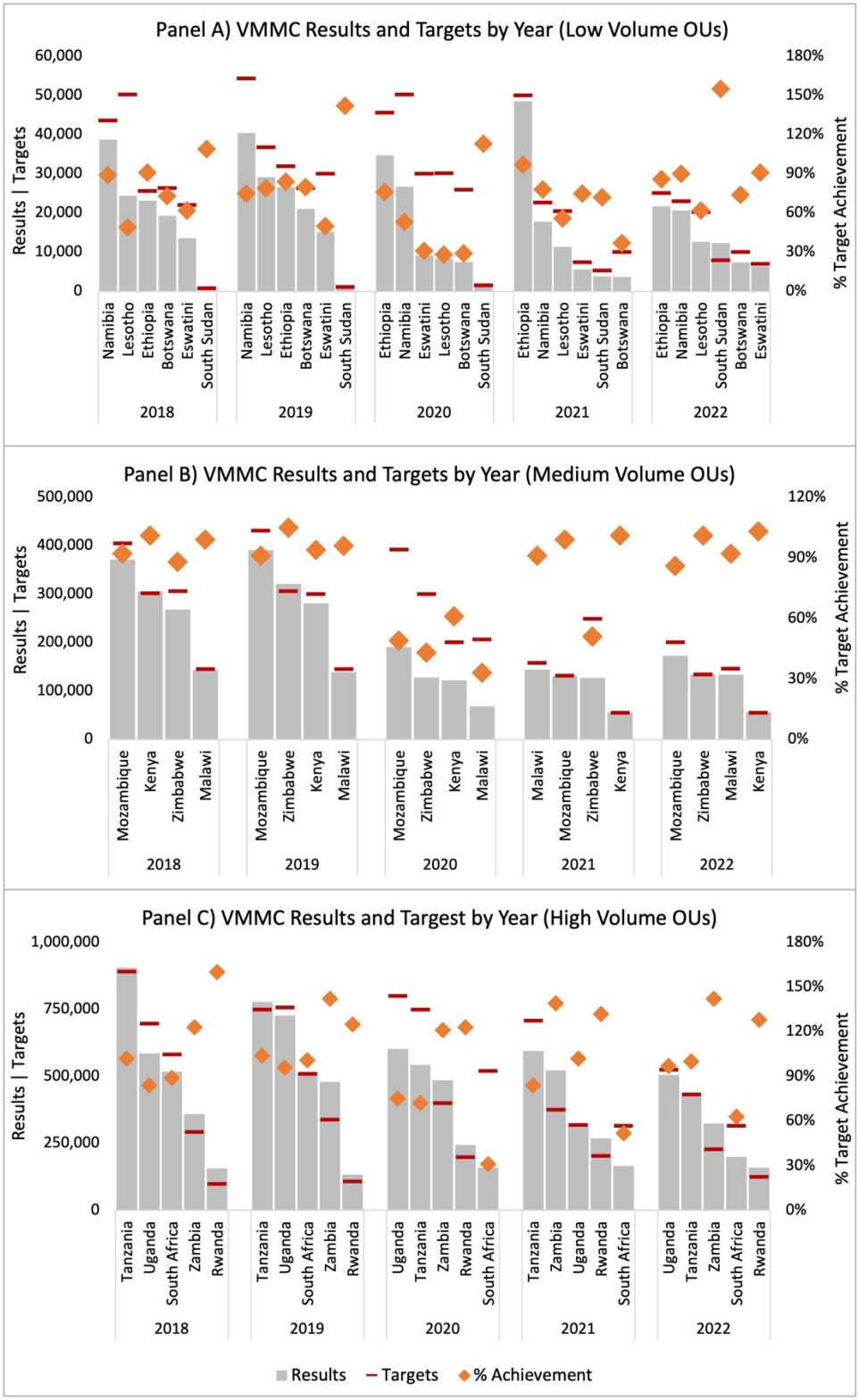



**Figure 22 Trends in Prevention for Men, Voluntary Medical Male Circumcision, 2018–2022:** Panel (A) groups OUs with low VMMC volume and shows fewer VMMCs performed in FY22 compared to FY18 for each country and between 60–120% target achievement. Panel (B) groups OUs with medium VMMC

volume and shows a decreasing trend in volume of VMMCs performed and targets from FY18–FY22. Kenya and Zimbabwe both reach their targets, at 103% and 101% respectively. Panel (C) groups OUs with high VMMC volume, showing a similar trend of lower targets and number of VMMCs performed from FY18–FY22. South Africa had the lowest target achievement in FY22 of 63%, while Zambia had the highest at 142%.

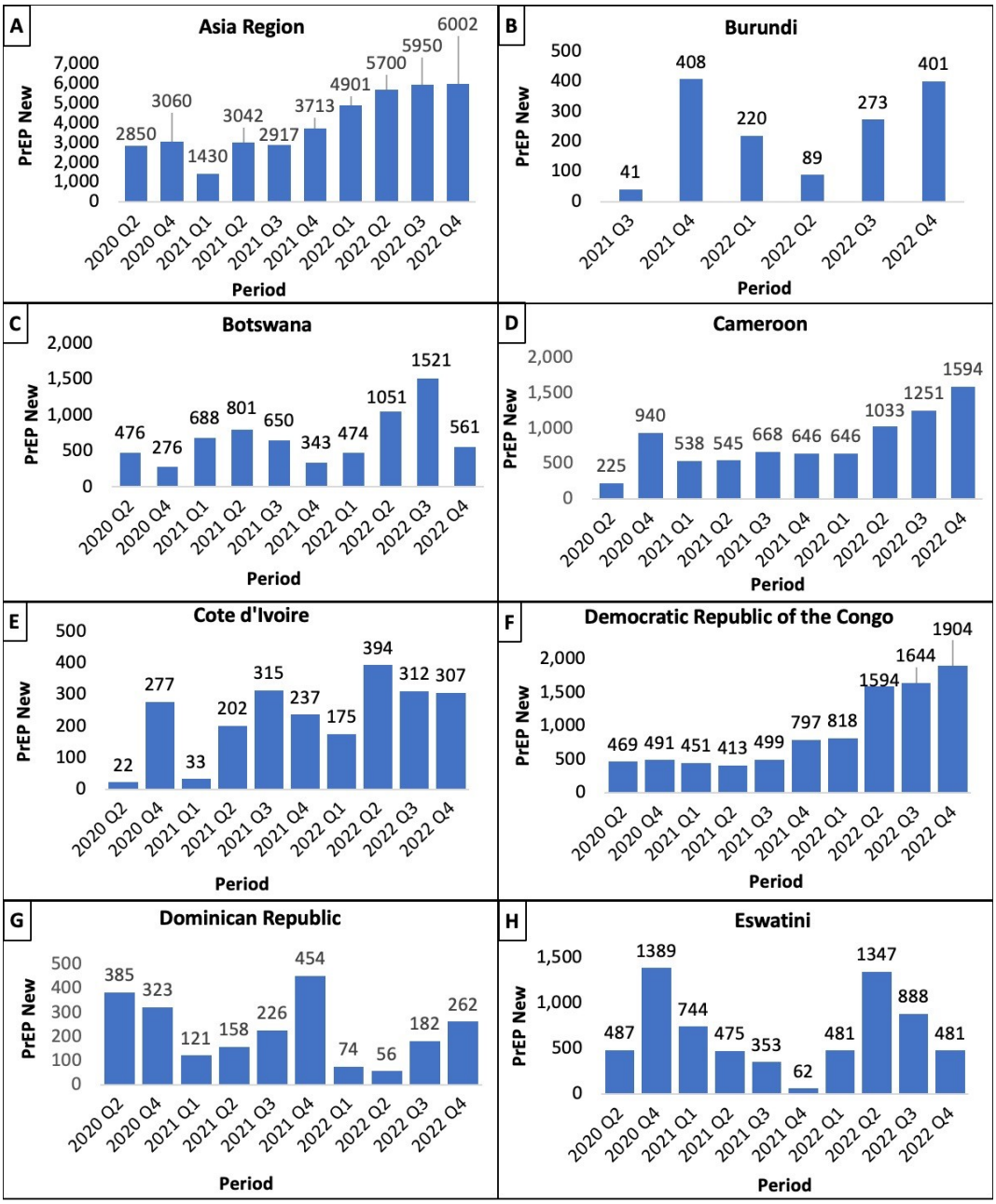



**Figure 23 (Panels A–H) Trends in Key Populations Receiving PrEP:** (A) For Asia Region, the number of KP clients newly on PrEP has consistently increased since FY21 Q3—with 6,002 people on PrEP in FY22 Q4. (B) Burundi tends to connect more KP clients with PrEP in Q4 of a given year; 401 KP clients

were newly on PrEP in FY22 Q4. (C) Botswana enrolled 1,521 more KP clients on PrEP in FY22 Q3; there was a decrease in PrEP initiation at FY22 Q4. (D) Cameroon has increased the number of KP clients newly on PrEP since FY22 Q2—with 1,594 KP clients on PrEP in Q4. (E) Cote d'Ivoire saw an increase in the number of KP clients initiated on PrEP with 394 PrEP_NEW in FY22 Q2, but there's a decline in FY22 Q4 with 307 KP PrEP_NEW. (F) DRC has consistently increased the number of KP clients newly on PrEP since FY21 Q3—with 1,904 KP clients on PrEP in FY22 Q4. (G) For the Dominican Republic, the number of KP clients initiating PrEP was highest in FY21 Q4 with 454 PrEP_NEW. Declines occurred during FY22 Q1 and Q2, with an increase in FY22 Q4 to 262 KP clients initiated on PrEP. (H) Eswatini connected more KP clients to PrEP in FY20 Q4 with 1,389 initiated on PrEP; FY22 Q4 experienced a decrease to 481 PrEP_NEW among key populations.

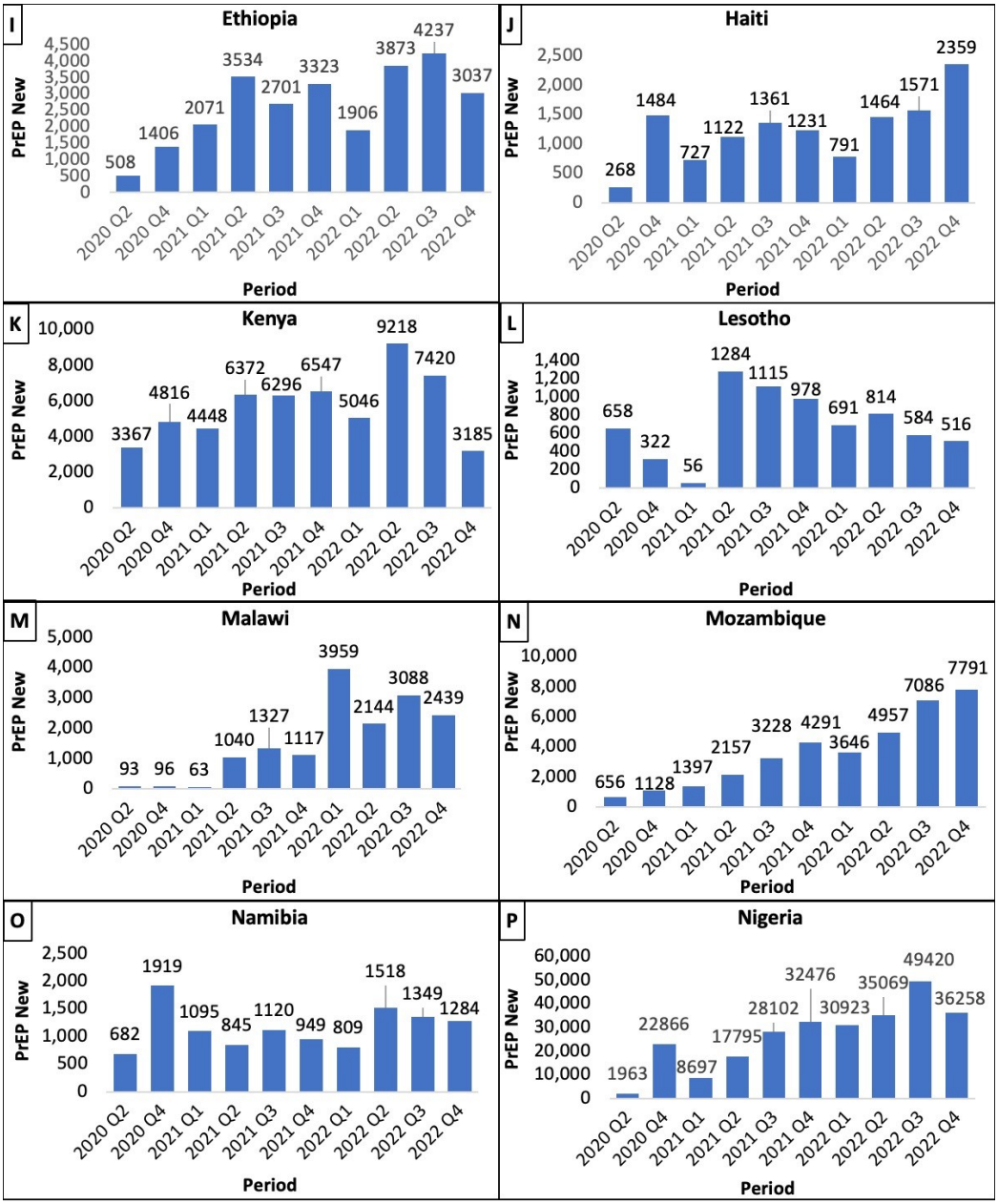


**Figure 23 (Panels I–P) Trends in Key Populations Receiving PrEP:** (I) Ethiopia initiated more KP clients on PrEP during Q2 of FY21 and FY22. (J) Haiti sustained an increase of KP clients newly on PrEP since FY22 Q1. (K) Kenya's highest KP PrEP_NEW was in FY22 Q2 with 9,218; a noticeable decrease is evident in FY22 Q4. (L) Lesotho initiated 1,284 new KP clients on PrEP in FY21 Q2; fewer KP clients initiated PrEP in FY22 Q3 and Q4. (M) Malawi experienced greatest KP PrEP_NEW in FY22 Q1 at 3,959, with a decrease in subsequent periods. (N) Mozambique has experienced a steady increase in PrEP initiation since FY20 Q2. (O) Namibia tends to connect more KP clients with PrEP during Q2 and Q4 of a given year. (P) Nigeria enrolled the greatest number of KP clients on PrEP among all countries in a single quarter, with 49,420 KP PrEP_NEW in FY22 Q3.

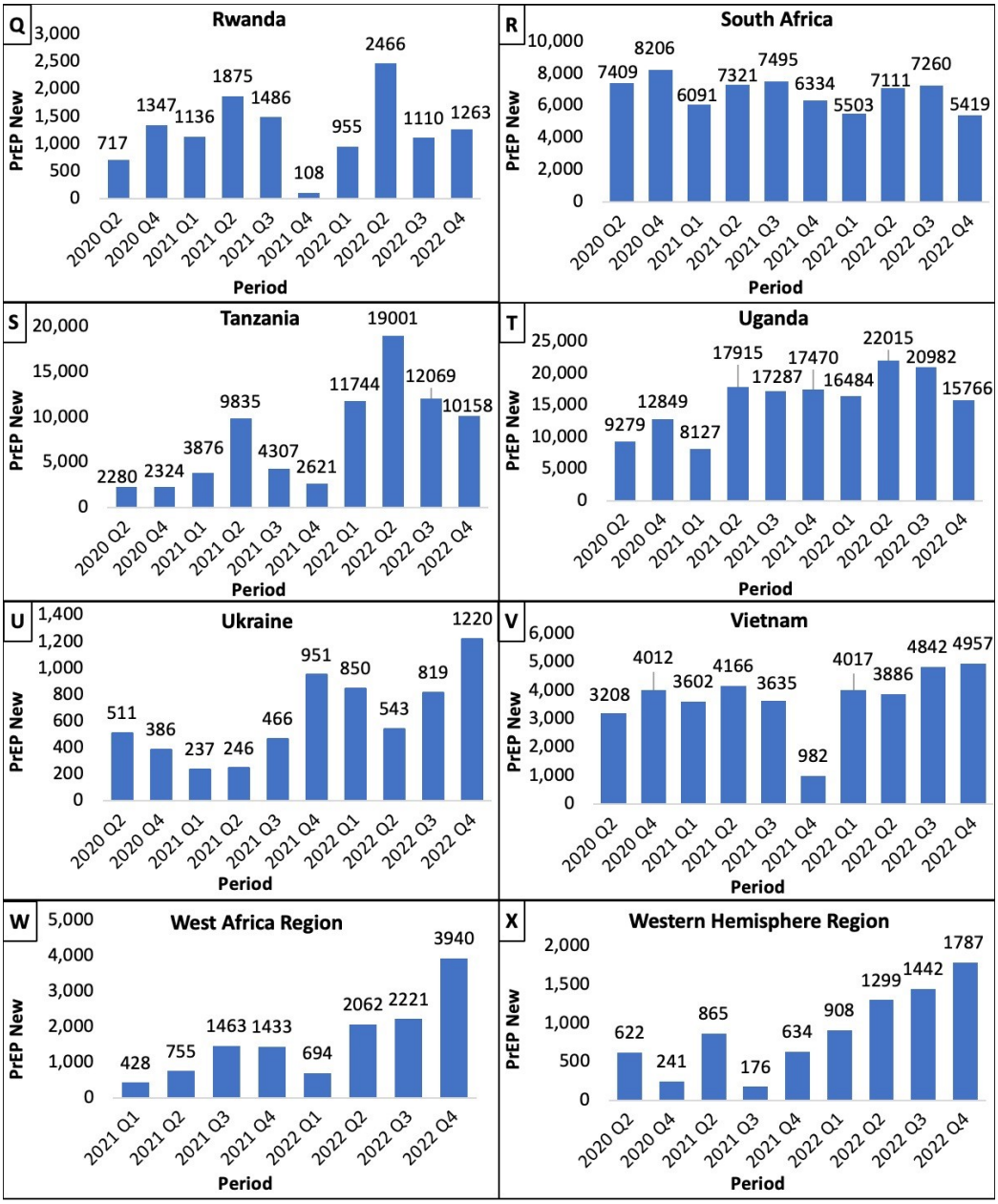


**Figure 23 (Panels Q-X) Trends in Key Populations Receiving PrEP:** (Q) For Rwanda, the number of KP clients newly on PrEP was lowest in FY21 Q4 (108) and highest in FY22 Q2 (2,466). (R) South Africa consistently enrolled more than 5,000 new KP clients on PrEP every quarter. (S) Tanzania initiated the greatest KP clients on PrEP in FY22 Q2 but experienced a decrease of nearly half in FY22 Q4. (T) Uganda saw a large increase in KP PrEP_NEW starting in FY21 Q1, jumping from 8,127 in the prior quarter to 17,915 in FY21 Q1. (U) Ukraine enrolled an impressive 1,220 KP clients on PrEP in FY22 Q4, their highest PrEP_NEW of any quarter. (V) Vietnam had consistent trends in KP PrEP_NEW between 3,200-4,900—except for FY21 Q4 with only 982 PrEP_NEW. (W) and (X) West Africa Region and Western Hemisphere Region both show consistent, increasing trends in KP clients newly enrolled on PrEP over time.

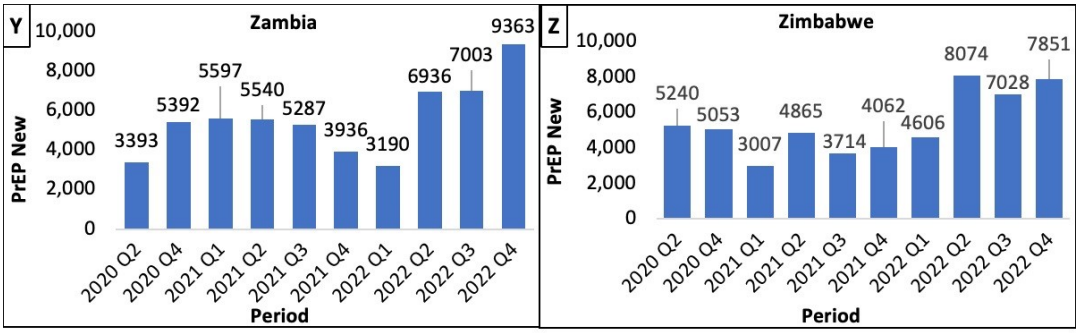



**Figure 23 (Panels Y–Z) Trends in Key Populations Receiving PrEP:** (Y) Zambia initiated the most KP clients on PrEP in FY22 Q4 with more than 9,000 PrEP_NEW. (Z) Zimbabwe tends to initiate more KP clients on PrEP during Q2 and Q4 of a given fiscal year.

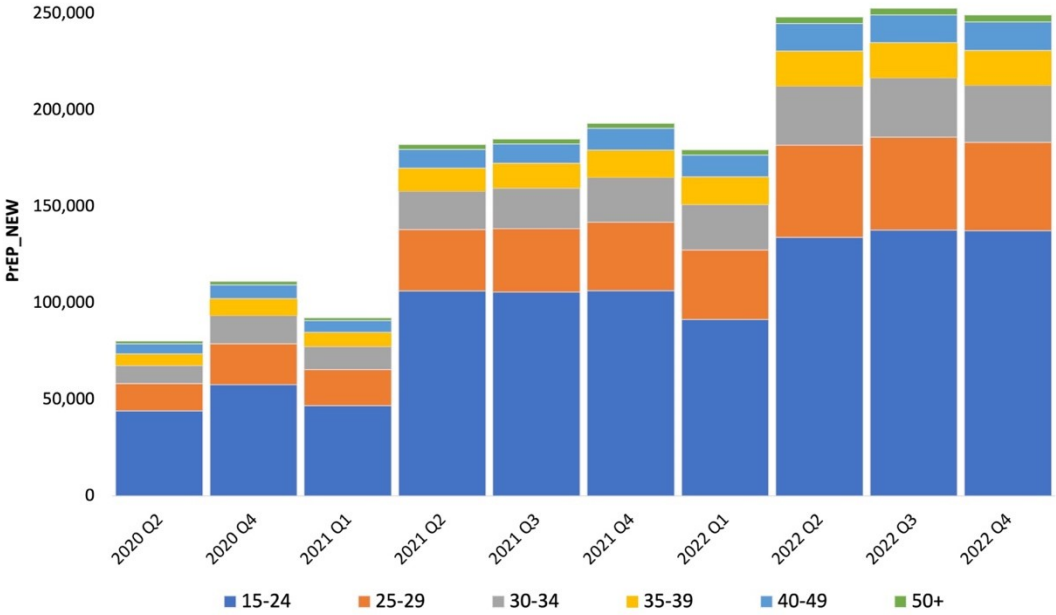



**Figure 24 Trends for Women Receiving PrEP, all PEPFAR OUs:** The total number of women starting PrEP services each quarter has increased since FY22 Q2. A total of 249,379 women across all age groups

initiated PrEP in FY22 Q4, up from 80,309 in FY20 Q2. Roughly half of all female PrEP users are 15 to 24 years old; women 25 to 29 years old are the next highest volume age group for PrEP_NEW.

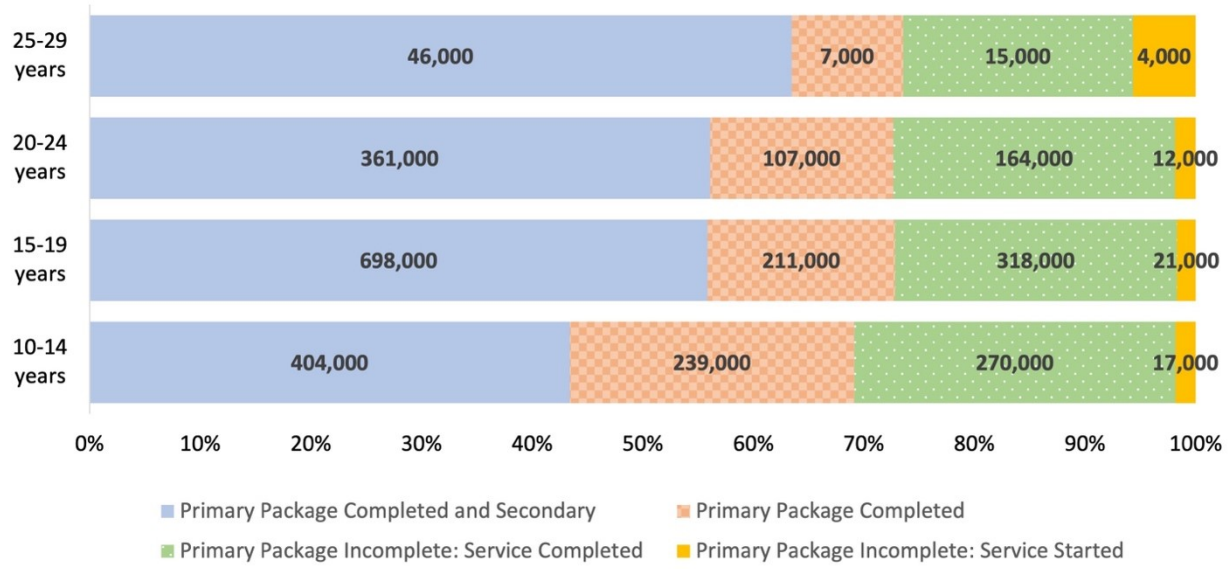



**Figure 25 DREAMS Completion by Age Group in FY22 Q4.** 70-75% of all DREAMS participants in all age groups completed a primary or primary and secondary DREAMS package. Approximately 30% of participants 10 to 14 years old are active or newly enrolled and around 45% (404,000) completed both the primary and secondary packages.

A rapid scale-up of tuberculosis (TB) preventative therapy (TPT) has been observed since PEPFAR committed to scaling up TPT among individuals on ART; however, gaps persist in TB screening, preventive therapy, and treatment. The COVID-19 pandemic was a setback for the TB program, and it's crucial that programs recover lost ground to prevent mortality among HIV-positive individuals. **Figure 26** shows TPT completion rates for those newly initiating ART by country. Many countries' TPT completion rates are more than 90% for this population; however, many high HIV-burden countries that haven't reached this threshold still exist. To achieve person-centered HIV services, TB screening, prevention, and treatment are essential to reduce morbidity and mortality.

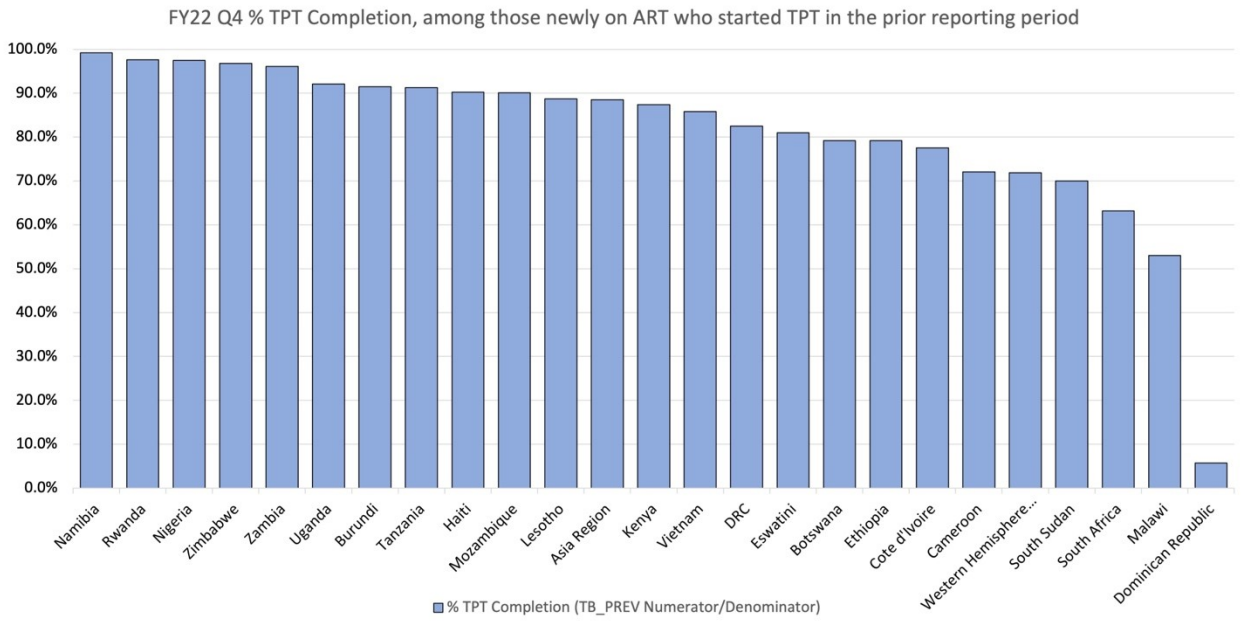



**Figure 26 Completion of TPT among Individuals on ART Who Started TPT in the Prior Quarter, Cumulative for All individuals on TPT and in FY22 Q4 among Those Newly Enrolled on ART, by Operating Unit (OU):** Rwanda, Namibia, Nigeria, Zimbabwe, Zambia, Uganda, Burundi, Tanzania, Haiti, and Mozambique have TPT completion of 90% or higher among those newly on ART who started TPT in the prior reporting period. All other countries have less than 90%. South Africa, Malawi, and the Dominican Republic have the lowest TPT completion rates, at 63.2%, 53.0%, and 5.7%, respectively.

Person-centered HIV multimonth antiretroviral (ARV) dispensing (MMD) continues to expand (See **Figure 27**). Country policies continue to adapt to enable patients to receive their medication more easily. As MMD continues to grow, it is important to link patient and pharmacy systems, so it's known which patients are and are not receiving ARVs for patient management and accountability. Clinical visits should also be aligned based on the individual's status, leading to most HIV-positive, healthy individuals coming only once a year for clinical care.

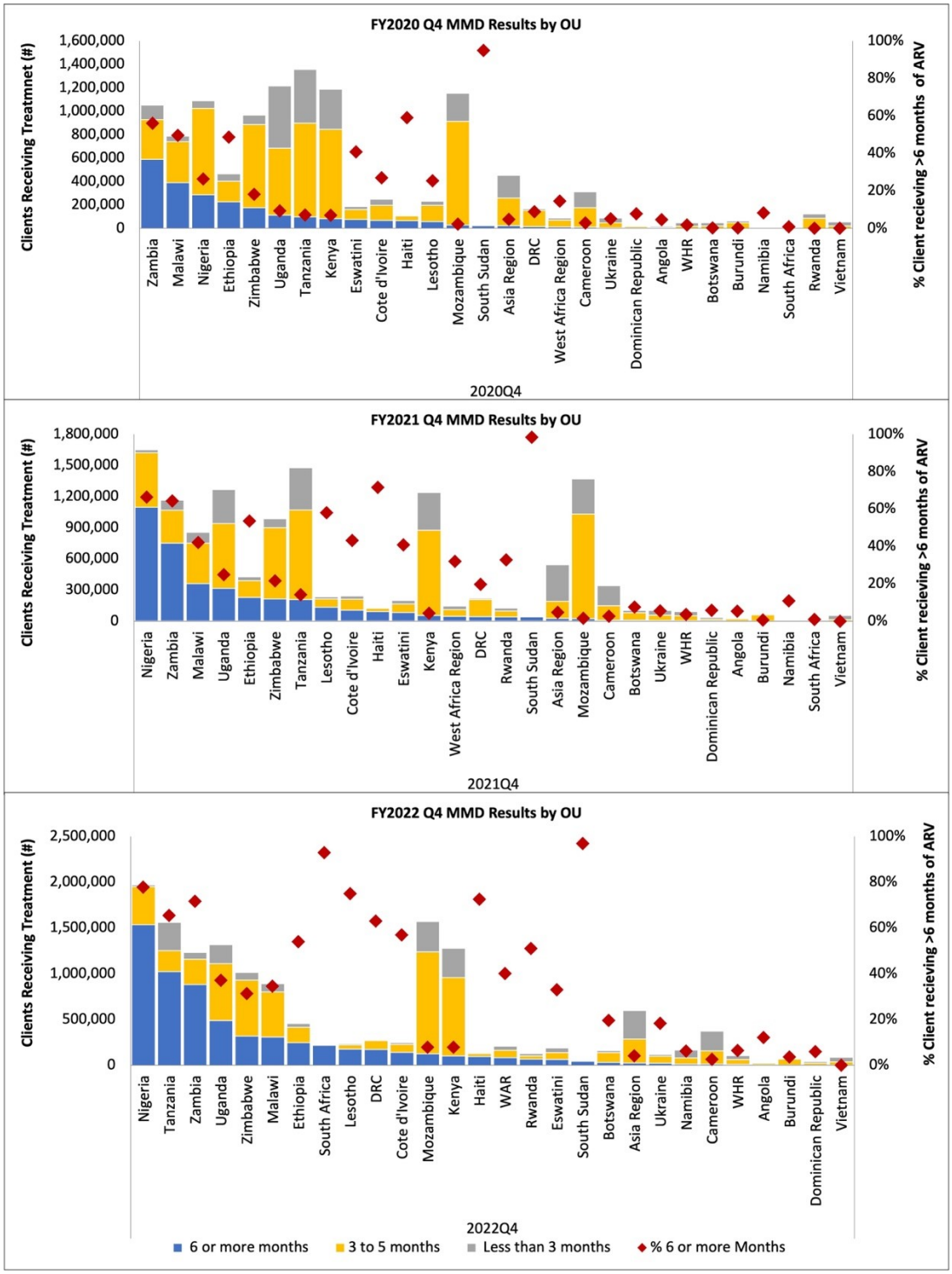



**Figure 27 MMD Implementation Changes FY20–FY22:** Every country has a greater number and proportion of their treatment cohort receiving at least 3 months MMD from FY20-FY22. Eleven countries have at least 90% of individuals on ART receiving more than 3 months MMD; more than 90% of individuals on ART are on 6 or more MMD in South Africa and South Sudan. Nigeria, Tanzania, and Zambia were

able to successfully transfer a large number and percentage of individuals on treatment to 6-MMD by FY22 Q4.

Routine viral load coverage has improved in most countries since last year, though some setbacks have presented (See **Figure 28**). While viral load testing is increasing in clinical programs, not all people in treatment are being tested for viral suppression. This is a multifactor issue and needs to be assessed by subnational unit (SNU)—separating operational issues (including sample transport and timely return of results back to the clinical record) and procurement issues (including purchasing sufficient reagents/kits for HIV viral load testing).

Some countries have had setbacks in viral load testing of individuals living with HIV on ART. Addressing barriers leading to fewer patients receiving standard of care—including viral load testing—is linked with health systems, sustainability, and reaching 95-95-95 for all. To ensure health equity for all people living with HIV, we must identify and address viral- load testing gaps and barriers by subpopulation, age, sex, and key population.

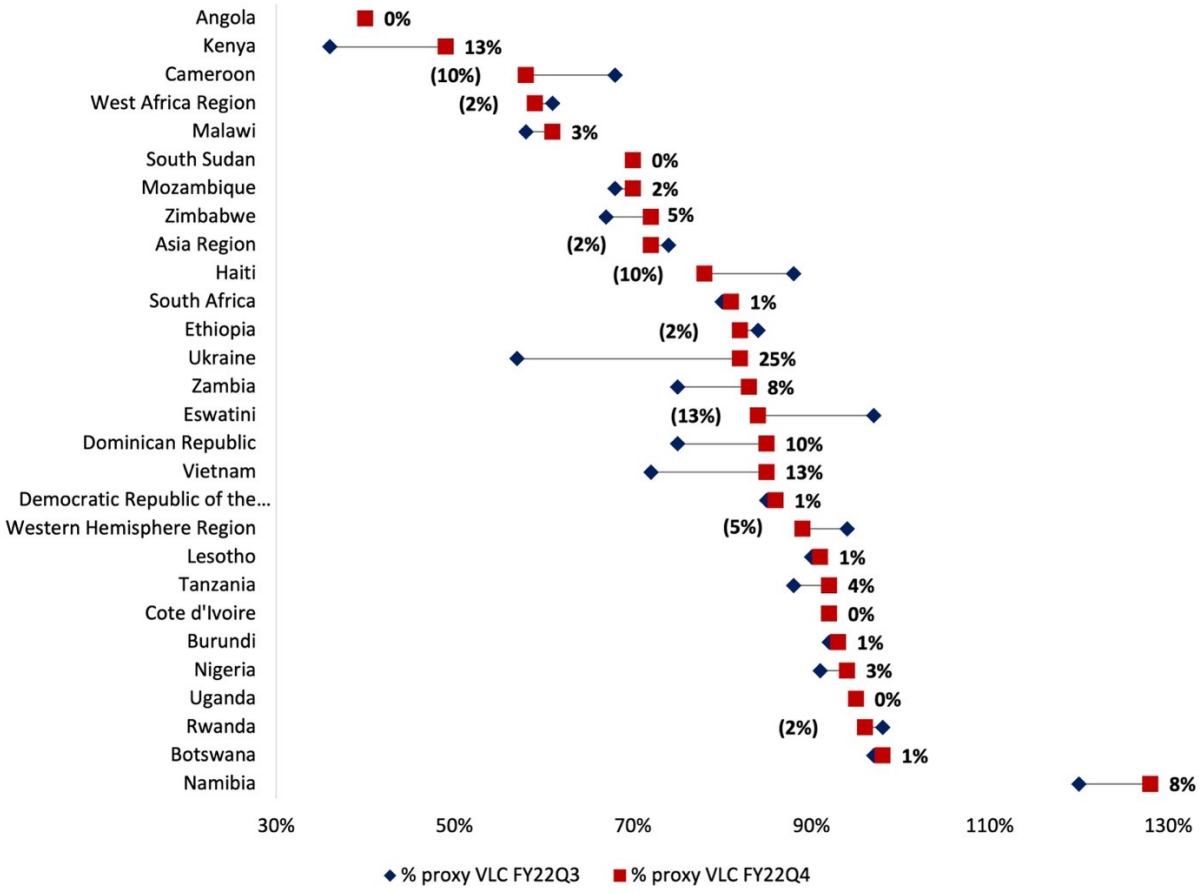



**Figure 28 Viral Load Testing *Coverage* Changes *from FY22 Q3–Q4*:.** Most OUs show an increase in proxy VLC from FY22 Q3–FY22 Q4;, however 8 OUs had a decrease in viral load coverage ranging from 2%-–13% and 4 OUs had no change in VLC. Namibia had the highest proxy VLC in FY22 Q4 at 128% with an 8% increase from FY22 Q3. Angola had the lowest proxy VLC at 40% and a 0% change.

# Section 6: Technical Considerations

**A Note on Section Numbering:**

Section numbering was carried over from the COP/ROP22 Guidance, in which technical considerations comprised all of Section 6. As such, there are not sections 1–5 for the FY24 Technical Considerations. When COP/ROP23 Guidance references a section within the Technical Considerations, notations appear as “FY24 Technical Considerations Section 6.X.”

# 6.1 Continuity of Treatment and Ensuring Programs Work for People Living with HIV

**What's New in 6.1 Continuity of Treatment and Ensuring Programs Work for People Living with HIV for COP22:**

- Consolidating linkage guidance that is evidence-based and data-driven with a focus on at-risk sub-populations such as children, OVC, youth and men (Section 6.1.1)
- Reinforcing the importance of a coordinated linkage and entry into treatment to reduce early interruptions for people newly diagnosed with HIV (Section 6.1.1)
- Defining HIV treatment literacy to support policy progress against MPR number 11 and utilize data collected by CLM to empower people and communities (Section 6.1.1)
- New examples of pediatric Differentiated Service Delivery models that are associated with improvement in VLS rates in children (Section 6.1.3.1)
- Stressed the importance that youth engagement should be a central tenet in the development, implementation, and monitoring and evaluation of interventions geared towards Adolescents and youth living with HIV. (Section 6.1.3.2)
- Recognizing that cycles of engagement and re-engagement in care are not uncommon (6.1.3.2)

The goal of treatment for all people living with HIV is durable viral suppression, which reduces morbidity and mortality and prevents HIV transmission. Continuity of treatment is critical to maintaining health and achieving epidemic control. Steps taken at treatment initiation may have a profound effect on treatment continuity. Specifically identifying treatment challenges for each individual and addressing them in a thoughtful and caring way may go a long way to individual treatment success. Treatment approaches must acknowledge gender norms and inequities in gender relations and seek to develop actions that adjust to and compensate for them. Continuity of treatment requires a positive therapeutic alliance between the recipient of care, the health care provider, and the health care system, and all efforts should be made to support that alliance. 'Retention' and 'adherence' are terms used to describe the clinic and client elements of ongoing engagement in treatment. In COP21, those terms were replaced by 'continuity of treatment' and 'interruption in treatment' to emphasize the therapeutic alliance that is important for successful treatment of all people living with HIV. Treatment literacy at initiation or re-initiation of therapy

should include non-judgmental information about the importance of re-engagement should an interruption in treatment occur.

The following interventions form the core package of PEPFAR's approach to durable and effective treatment.

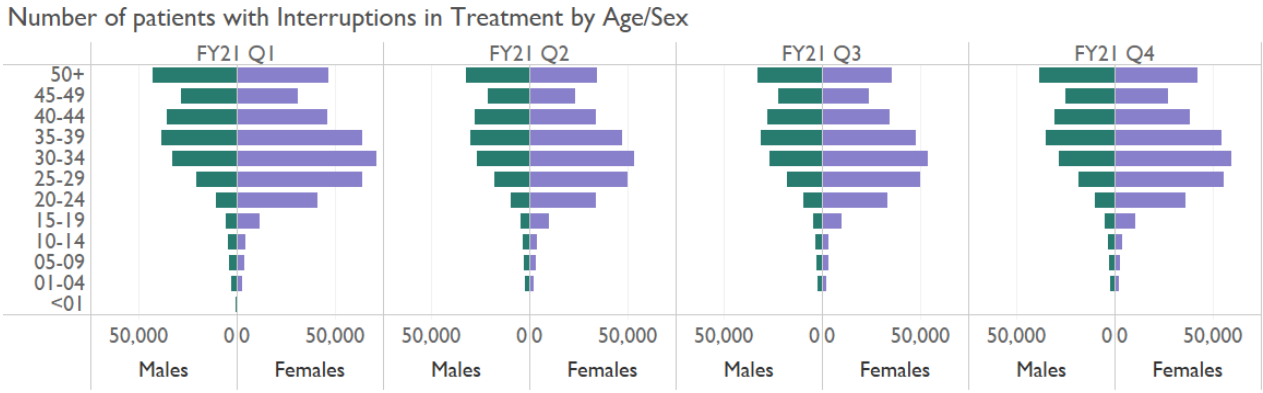
- The complete scale-up of the fixed-dose combination of tenofovir, lamivudine and dolutegravir (TLD) for all eligible people living with HIV, including women of child-bearing age. TLD is well-tolerated, and PEPFAR supports the use of this fixed dose combination for PLHIV ≥30 kg. For children (<30 kg) unable to take tenofovir disoproxil fumarate (TDF), DTG should be given with backbones that do not contain TDF (see Section 6.4.1.1 of ART optimization).
- The foundation to empowering people in their treatment journey is treatment literacy. Providers should describe new treatment paradigms using hopeful language that includes the benefits of viral suppression (including the science of U=U) achieved by consistently taking ARVs. See Section 6.1.1.
- Differentiated service delivery models tailor HIV treatment by location, health worker cadre, frequency of visits, and package of services and can be adapted to subpopulations that have specific needs. See Section 6.1.2.
- Multi-month dispensing (MMD), and decentralized drug distribution are interventions that have been accelerated during COVID-19, and this should continue (see Section 6.1.3.1).
- The focus of person-centered services in COP22 requires providers to minimize the burden of treatment on clients. Programs are strongly encouraged to coordinate timing of clinical appointments, drug pick-ups, and viral load monitoring, when possible, at facility or community levels for all members of a family/household on ART. Programs are encouraged to actively use CLM feedback to improve services and to be responsive to the specific needs of each sub-population. Existing qualitative research may help clarify challenges and enablers that help providers to tailor interventions for the specific context. Integration of services such as family planning, child wellness, tuberculosis preventive therapy, non-communicable disease, GBV care, and psychosocial support and mental health services into ART can help mitigate some of the gender-specific barriers to sustained engagement with health services. Accessible, person-centered quality treatment does not start at the facility door, evidenced-based efforts must extend where appropriate into the communities and households of clients and potential clients.

- User fees are a barrier to treatment and enforce gender disparities related to economic decision-making and control. Formal and informal user fees must be eliminated for HIV testing, clinical visits, provision of ART, laboratory testing, and medications required for prophylaxis against opportunistic infections or for treatment of advanced HIV disease complications at all PEPFAR-supported clinics. User fees for any health service that may serve as a barrier to access to HIV services should be addressed.

The TX_ML indicator is helpful in identifying specific populations with challenges in treatment continuity. There may be wide variability in the reasons for disengagement from treatment, which may be patient, clinic, or structurally based and will differ by age, sex and by sexual orientation and gender identity and expression. It is now recognized that individuals sometimes disengage from care and later reengage, often cycling in and out of care. Measures of TX_ML and TX_RTT show that disengagement and engagement occurs for a significant proportion of clients. For example, in the final quarter of 2020, 1.1 million clients disengaged or reengaged in care. Planning for and normalizing this phenomenon is a harm-reduction activity.

Analysis of TX_ML disaggregated by time on ART (<3 months vs >3 months) suggests that interruptions are much more likely early in treatment compared to later in treatment. Interruption for people newly initiating treatment represents a failure to fully link the patient to treatment and programs should work to identify specific populations that may need attention. Overall increases in treatment interruption were seen in Q3 of 2020, including a large number of treatment interruptions among the over-50 age group. This was a time when many countries were implementing COVID-19 mitigation measures and highlighted the need for specific attention to re-engage older clients who interrupted treatment and better support treatment access through COVID-19. These indicators can help identify action points for intervention in specific groups or geographic regions.

*Figure 6.1.1 Number of Interruptions Treatment by Age and Sex in FY21 by Quarter*

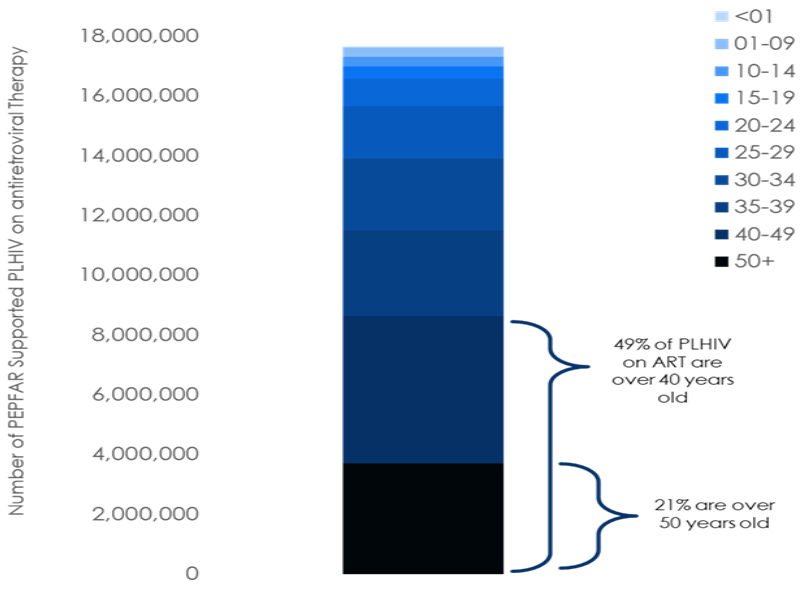



**Adolescents/Youth:** This group has special challenges with successful therapy that include diminishing caregiver oversight, lack of youth-friendly services, and inadequate preparation for the transition to adult HIV treatment. Approaches must be tailored to age and developmental stage and gender-sensitive (see Section 6.6.2 on Gender Equality). Section 6.1.3.2 details the PEPFAR approach to this group.

**Older patients.** In 2021, approximately 20% of the individuals supported by PEPFAR on ART were over 50. There is wide variability in the number and proportion of older individuals on ART across countries, ranging from 7% in South Sudan to 30% in Botswana and the Dominican Republic. This proportion will almost certainly grow over time, as the cohort currently in care ages with diminished mortality, and the number of newly infected younger patients drops. Data on the age structure of people living with HIV should inform program planning and design.

The needs of older adults may be different from those of younger adults, and this group has a higher all-cause mortality. Data from AFRICOS suggest that the burden of comorbidities in this population is significant. In accordance with national guidelines and supported by Ministries of Health, other recommended screenings and linkage to appropriate services may be performed in this population. Older age, especially with other comorbidities, is a significant risk factor for severe and fatal COVID-19. Provision of other needed medications in a fast track or with ART may protect these vulnerable clients and may be lifesaving. See Section 6.4.2.3 for a broader discussion.

*Figure 6.1.2 Number of PEPFAR Clients on Treatment by Fine Age Band in Q4 2021*




## 6.1.1 Linkage to ART, Early Engagement, and Treatment Literacy

Summary of section edits:

- Section updated to identify that longitudinal person-centered data is preferred.

In COP22, PEPFAR emphasizes linkage to care and early engagement in treatment. This section addresses linkage for those who are re-testing (i.e., non-treatment naïve people), early engagement in care, and the importance of treatment literacy.

New in COP22:

- Consolidating linkage guidance that is evidence-based and data-driven, with a focus on the additional linkage needs for HIV self-testing and for at-risk subpopulations such as children, OVC, youth and men
- Reinforcing the importance of a coordinated linkage and entry into treatment to reduce early interruptions for people newly diagnosed with HIV
- Defining HIV treatment literacy to support policy progress and utilize data collected by CLM to empower people and communities to drive long-term epidemic control

Successful linkage is the first step in a lifelong therapeutic partnership between the person and the health care system. How this is accomplished is critical to sustained treatment success. The

primary responsibility for linkage to HIV treatment rests with the testing partner regardless of where the testing was done. Coordination between testing and treatment services is critical to success.

PEPFAR recommends use of WHO guidance on effective linkage packages to ensure that clients arrive at services.[5] Different HIV testing modalities: (e.g., clinic-based, community-based, index testing and self-testing) may require tailored linkage strategies that lead to the successful start and engagement in treatment. A range of evidence-based program approaches to improve linkage to treatment are on the PEPFAR Solutions portal[6] and across agencies[7]

HIV self-testing is an important tool in case identification. See Section 6.3.1.6 for more information about HIV self-testing. However, linkage can be a challenge using this mode of testing. To mitigate this, PEPFAR recommends continued engagement with national stakeholders supporting HIVST policy implementation and attention to data around distribution and linkage to treatment. Programs should aim for >95% linkage rates for all individuals who are diagnosed with HIV, including those who were diagnosed with a confirmatory test after a positive HIVST.

To sustain optimal linkage rates across testing modalities, PEPFAR recommends using linkage strategies that best serve clients newly diagnosed with HIV. The following is a consolidated list of common components of successful linkage programming:

- Availability of immediate ART offered as multi-month starter pack.
- Escorted linkage and navigation that is discrete and empathetic, including a male for male clients, or a peer for an adolescents or youth, or other expert clients who are living with HIV and are successfully on treatment.
- Friendly clinic services, operated by experienced staff that have been mentored, trained, or oriented to the needs of the people they serve. Friendly clinics provide services for like populations (days/time or with dedicated space), expedited services (fast-tracking) for those working, or in school, including after-hours, weekends, and convenient community services or decentralized drug delivery.

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[5] Consolidated Guidelines for Testing in a Changing Epidemic, WHO (2019). https://www.who.int/publications/i/item/WHO-CDS-HIV-19.31

[6] https://www.pepfarsolutions.org/solutions/tag/linkage+to+care

[7] https://www.cdc.gov/hiv/research/interventionresearch/compendium/lrc/index.html https://www.hiv.gov/topics/linkagetocare

- Access to in person counseling and remote psychosocial support (PSS) (SMS, phone calls, or community workers), with agreed upon contact methods before the next clinic appointment.
- An accountable staff member designated to confirm successful linkage and early engagement, such as a case manager, clinic coach, or expert client to explain the treatment schedule, options for care, support decision-making for people's treatment needs, including safe disclosure, particularly for early treatment support from family and partners.

Please find additional guidance in Figure 6.1.1.1 to attain equity across for sub-populations that have historically suffered for lower linkage to treatment here.

*Figure 6.1.1.1 Additional Linkage Guidance by Population*

| **Population** | **Additional linkage guidance** |
|---|---|
| Infants and young children | Linkage programming should be family-centered with a focus on mothers and caregivers. The use of information and communication technology (ICT) and mHealth platforms, such as automated texts and provision of rapid results by SMS, has been shown to increase ART initiation rates when used in a confidential, sensitive, and safe manner. Point-of-care EID services may increase linkage to care and shorten time to treatment initiation and should be made available as appropriate. |
| Children and adolescents | Clinic spaces should be made welcoming to families and children (5-18 years), and psychosocial support, including peer groups and age-appropriate disclosure support available for both caregivers and children. Clinics and Clinical IPs should also establish formal relationships (via memorandums of understanding or agreement) with OVC IPs to coordinate bi-directional linkages to assess C/ALHIV for enrollment into the OVC program for socioeconomic, adherence and engagement support. Successful linkage interventions work seamlessly with treatment services. See Section 6.1.2.1 for details. |
| OVC | Clinics should also establish formal relationships (via memorandums of understanding or agreement) with OVC IPs to coordinate bi-directional linkages to assess C/ALHIV for enrollment into the OVC program for socioeconomic, adherence and retention support. Please see OVC 6.6.3 |

| | |
|---|---|
| Adolescents and youth | Linkage services that are friendly, peer-delivered, and integrated.[8] Pre-and post-test counseling remain vitally important to ensure that HIV diagnosis delivery is age and developmentally appropriate, non-threatening, non-judgmental, and clear. If parents/guardians are involved or legally required in treatment decisions, careful attention to confidentiality and consent to treatment laws and policies for adolescents/youth, including age of consent and client-assent, are needed. Connecting this population to peer community support groups at time of linkage can increase engagement.<br>In addition to comprehensive treatment services, referrals and services that address mental health, substance use, and sexual and reproductive health services are a priority for this population. See Differentiated Service Delivery for Adolescents and Youth 6.1.2.2. |
| Pregnant and Breastfeeding Women (PBFW) | Linkage for the mother-baby pairs is needed, especially through the breastfeeding period. There are many places along the care journey for a pregnant woman to be engaged in PMTCT through to family care, or adult differentiated service delivery models, along with tracking each HEI and if confirmed children living with HIV services. Peer supporters, such as mentor mothers or experienced clients, can facilitate treatment navigation, partner services, and disclosure. It is especially critical for AGYW mothers, newly diagnosed mothers, and women with an unsuppressed viral load in their pregnancy. See Section 6.1.2.3 for details on integrated services for PBFW. |
| Men | Services should address common and client-identified barriers to successful linkage. Males often perceive that HIV will lead to diminished career success, having less fun, with reduced social status due to stigma and discrimination that can lead to denial of HIV diagnosis. Messages should confirm male treatment benefits, including a return to normalcy with a suppressed viral load in intimate relationships, simplified ARV regimens, and ease of treatment access around life/employment schedules. Private sector consumer marketing approaches and faith-based programming work |

[8] WHO, 2019. https://www.who.int/publications/i/item/adolescent-friendly-health-services-for-adolescents-living-with-hiv

| | |
|---|---|
| | well to link men to treatment. See Section 6.1.2.3 on MenStar and Section 6.6.4 on Faith and Community Engagement for details. |
| Older adults | Older adults who are newly diagnosed with HIV or are re-engaging in care after an interruption may benefit from services tailored to their needs including the evaluation for advanced disease and screening for and providing or linking to comorbidity services. Psychosocial support of the older adult is covered in 6.6.5.2. |
| Key populations | See Section 6.5.1.3 for details. |

**Early Engagement**

The treatment implementing partner/service provider is responsible for ensuring successful early engagement (<3 months) and reducing events reported as interruptions in treatment (TX_IIT). They should work harmoniously with the testing partner to create synergies, so that no one is left behind, especially individuals who did not expect to test HIV positive, or are reluctant to start ART, or have been avoiding testing.[9] PEPFAR data may identify who is at highest risk of treatment interruptions and where interruptions are most frequent, using disaggregated age, sex, and location data. However, use of cross-site integrated person-centered longitudinal data (e.g., where available data from emergency medical record (EMR) in national data repositories may be used) is preferred for monitoring, measuring and mitigating treatment interruptions and deaths.

All eligible individuals with newly diagnosed HIV should be offered same-day or rapid (within 7 days) start of optimized treatment, regardless of how and where they are diagnosed. Those clients, or parents/guardians of children, who are unable or unwilling to start therapy on the same day should be offered the opportunity again within 7 days of diagnosis and be actively but sensitively tracked and supported to prevent interruptions in care, particularly within the first three months after treatment initiation or re-initiation. All efforts should be made to coordinate timing of early clinical appointments, drug pick-ups and viral load monitoring, when possible, at the same facility for all members of a family or household on ART. Programs are encouraged to actively use CLM feedback to be responsive to the needs of each sub-population.

[9] Grimsrud, A., Wilkinson, L., Eshun-Wilson, I. *et al.* Understanding Engagement in HIV Programmes: How Health Services Can Adapt to Ensure No One Is Left Behind. *Curr HIV/AIDS Rep* 17, 458–466 (2020). https://doi.org/10.1007/s11904-020-00522-1

The only medical contraindication to rapid ART start is central nervous system infection. A pending TB workup should not delay ART initiation. See Section 6.4.2 on advanced HIV disease for additional guidance.

Early engagement remains a challenge across PEPFAR programs. OUs should use data to understand the trends and tailor the response as necessary to achieve targets and contribute to epidemic control. At epidemic control, and when possible, OUs should expand use of people-centered data (via EMR and with unique IDs) to better predict subgroups at higher risk for early interruption.

If engagement challenges persist, a data quality assessment (DQA), Root Cause Analysis (RCA), and site support are recommended to understand and address the factors driving higher early IIT. This includes more detailed information around above-site and site-level variables such as ARV supply and access to MMD, clients who access care at multiple locations, or emergency refill clients affected by COVID-19 supply shifts, the client experience navigating treatment, the friendliness of the clinic, wait times, staff coordination, and any available client feedback. Implementation of national unique identifiers (with proper controls for privacy) should be a key above-site priority.

**Treatment Literacy**

In COP22, PEPFAR is emphasizing the importance of treatment literacy to attain and sustain epidemic control of HIV.

PEPFAR defines treatment literacy as the degree to which individuals have the capacity to obtain, process, and understand HIV information and available treatment services needed to make appropriate health decisions.[10] Literacy includes the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain treatment success. By improving people's access to HIV information and their capacity to use it effectively, treatment literacy is critical to empowerment.

PEPFAR acknowledges for efficient, sustained epidemic control, HIV service providers must reliably transfer user-friendly knowledge that aligns with their lived realities and provides

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[10] Parker, R. G., Perez-Brumer, A., Garcia, J., Gavigan, K., Ramirez, A., Milnor, J., & Terto, V. (2016). Prevention literacy: community-based advocacy for access and ownership of the HIV prevention toolkit. *Journal of the International AIDS Society*, *19*(1), 21092. https://onlinelibrary.wiley.com/doi/full/10.7448/IAS.19.1.21092

motivation for their continued engagement to people and communities to support their informed HIV treatment and prevention decision making. Lived realities across PEPFAR supported OUs are diverse, so localized plans must make treatment information accessible and accurate for clients to achieve and sustain treatment success. Literacy efforts should equip people with information about the benefits of treatment, to prepare clients to persevere along their treatment journey, and to help them understand new clinical guidance as treatment improves over time. They should aim at providing information that is relevant and appropriate to the life-stage of the client and those for whom they care.

Research from Malawi, South Africa, and Zimbabwe suggests that what people living with HIV are learning about ART is not motivating many of them to stay on treatment. This motivation gap is partly due to a knowledge and confidence gap among providers, who often leave out information about the benefits of treatment, including its role in preventing transmission (U=U) when talking to patients. The significance of viral suppression with respect to health, sexual "normalcy" and preventing viral transmission should be emphasized. In addition, information about lower intensity differentiated service delivery models may be helpful in outlining the treatment journey. Hearing treatment literacy information once may not be enough, and strategies designed to reinforce important messages may be important.

In COP22, programs should continue to implement activities utilizing existing treatment literacy and consumer marketing materials developed in partnership with the private sector. These should be adapted or improved as needed and delivered using communication channels appropriate to the intended audience. Initiatives such as Flip the Script in Malawi and Zimbabwe, Coach Mpilo in South Africa, Furaya Yangu in Tanzania, and B-OK bottles for men are examples of tailoring of materials and messages to increase treatment literacy, especially for men.[11]

## 6.1.2 Differentiated Service Delivery

Continuity of care requires a positive therapeutic alliance between people, the health care provider, and the health care system, and all efforts should be made to support that alliance. Access to convenient, patient centered care, case management and attention to client concerns around confidentiality are critical elements of this process. In contrast, mistrust of the health care

[11] Resources at: https://www.coachmpilo.co.za/

system or health care providers, and stigma, including perceived, anticipated, and internalized, and discrimination are threats.

Patient needs often go beyond HIV care. Some patients will require coordinated care for other conditions, including TB, STIs, non-communicable diseases, or family planning services. Close attention to coordination/harmonization of service location, service provider and schedules for clinical appointments, medication dispensing, and laboratory testing are important to continuity of treatment. Client factors such as harmful substance use, experiences of violence, and mental health concerns can also undermine successful HIV therapy. Untangling the specific issues for each client and addressing them directly improves patient outcomes and allows the opportunity to provide additional client-specific services but doing so requires a diverse, well trained health workforce that can respond to these needs.

Differentiated service delivery is a person-centered approach to HIV care and treatment that tailors services to different groups of people living with HIV depending on their evolving needs while maintaining the basis of the public health approach: simple, standardized and evidence based. When multiple differentiated service delivery models are available, health care workers (clinical and non-clinical) should work with clients to ensure awareness of service options and continuously support their client's decision to successfully attend. Differentiated service delivery models represent an important response to barriers threatening the therapeutic alliance as it aims to address the diverse needs of clients. The move to more universal access to differentiated service delivery models has been accelerated in response to COVID-19 and should continue even as COVID-19 related disruption of services ends. COVID-19-related differentiated service delivery adaptation include the expansion of multi-month dispensing (MMD), community-based drug delivery, and other decentralized drug distribution (DDD) models. These interventions have accelerated decongestion of health facilities, reduced transmission of COVID-19, and allowed greater attention to those requiring more intensive services. The WHO has recently released guidance on differentiated service delivery: https://www.who.int/publications/i/item/9789240023581

COVID-19-related differentiated service delivery adaptations include the expansion of multi-month dispensing (MMD), less frequent clinical consultations, community-based drug delivery, and other decentralized drug distribution (DDD) models. In addition, countries expanded eligibility for differentiated service delivery to additional populations such as children, pregnant and breastfeeding women, men, individuals with advanced disease, those who have not yet

achieved viral suppression or whose viral suppression is yet undetermined,[12] as well as people with co-morbidities along with HIV infection. These recommended policy changes have been enacted in multiple OUs expanding MMD to a broader array of individuals. Individuals without a viral load result should be prioritized for viral load testing but should still be offered MMD. Similarly, individuals starting ART should receive multiple months of treatment. See Section 6.1.3.1 for a discussion of MMD.

Differentiated service delivery models have been categorized into four categories, all of which should include a component of multi-month dispensing (MMD):

1. Client-managed groups[13,14,15,16]

   Clients in these groups receive ART refills as a group (i.e., a single member of the group will visit the facility to pick up medications for the entire group and distribute; this role is rotated among group members). The group is managed by the clients themselves, who are usually from the same community. The groups generally meet in a community location away from health facilities and provide adherence support to each other as needed or desired. MMD should still be provided in this context, there is no need for a member of the group to attend the health facility each month to collect ART refills for monthly community group distribution. Where the group wants to increase peer-to-peer support through more regular group meetings this can be done separately from ART refill collection. Data from Zimbabwe and Lesotho demonstrate that 3-month Community Adherence Groups are non-inferior to 3-month clinical care with respect to retention in care (Zimbabwe and Lesotho) or VL suppression (Lesotho).

2. Facility-based individual models[17]

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[12] https://www.differentiatedservicedelivery.org/Resources/Resource-Library/DSD_Policy_Dashboards

[13] PEPFAR solutions (paper 1, PEPFAR solutions write up), CIDRZ CAGs in Zambia, CAGs in Zimbabwe, CAGs in Lesotho

[14] Fatti G, Ngorima-Mabhena N, Mothibi E, et al. Outcomes of Three- Versus Six-Monthly Dispensing of Antiretroviral Treatment (ART) for Stable HIV Patients in Community ART Refill Groups: A Cluster-Randomized Trial in Zimbabwe. *J Acquir Immune Defic Syndr*. 2020;84(2):162-172. doi:10.1097/QAI.0000000000002333

[15] Tukei B, Fatti G, Chasela C. et al Twelve-month outcomes of community-based differentiated models of multi-month dispensing of antiretroviral treatment among stable HIV-infected adults in Lesotho: a cluster randomized non-inferiority trial. JAIDS Journal of Acquired Immune Deficiency Syndromes Publish Ahead of Print DOI: 10.1097/QAI.0000000000002439

[16] Pepfar solutions: Data from Adherence Clubs in the Western Cape, South Africa (paper 1, paper 2, paper 3, PEPFAR solutions)

[17] https://www.pepfarsolutions.org/women/2018/1/13/improving-access-to-hiv-treatment-services-through-community-art-distribution-points-in-uganda

Under this model, ART refills are separated from clinical visits, both of which are scheduled at longer intervals. When clients come to the facility for a refill visit, they proceed directly to the pharmacy or fast track or one-stop room for medication refills. These models are among the least intensive and least expensive and are among the easiest to implement and scale. There are examples of this facility-based fast track model in both Ethiopia and Malawi.

3. Out-of-facility, community, and individual models:

   ART refills are provided to clients outside of health care facilities with clinical consultations usually provided at longer intervals at the health facility. Examples include external pick-up points (private pharmacies, community venues and lockers) in South Africa (e.g., Dablap), and community pharmacies in Nigeria.

   Some countries have also moved the clinical consultations into communities by developing facility extensions in the community, which often operate out of minimal spaces in residential or commercial communities. They serve as clinical checkpoints for adverse events, dispensaries, and in some cases testing facilities.[18] Outreach services and home delivery of treatment and other services may be provided in this model. In some OUs, the COVID-19 pandemic has led to the expansion of home visits for medication delivery and the inclusion of other services such as VL blood draw and enrollment into MMD. This model maximizes convenience, and further assessment of effectiveness and cost is warranted.

4. Health worker-managed groups[19,20]
   Clients receive their ART refills in a group managed by a lay health worker. These groups can meet within or on the grounds of a health care facility or at a community venue or at a member's home. Multi-month ART refills should be provided with longer intervals between clinical consultations. Examples include facility and community adherence clubs in South Africa, and urban adherence groups in Zambia.

Special Populations

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[18] https://www.pepfarsolutions.org/women/2018/1/13/improving-access-to-hiv-treatment-services-through-community-art-distribution-points-in-uganda

[19] Data from Adherence Clubs in the Western Cape, South Africa (paper 1, paper 2, paper 3, PEPFAR solutions write up)

[20] Finci I, Flores A, Gutierrez Zamudio AG, Matsinhe A, de Abreu E, Issufo S, Gaspar I, Ciglenecki I, Molfino L. Outcomes of patients on second- and third-line ART enrolled in ART adherence clubs in Maputo, Mozambique. Trop Med Int Health. 2020 Sep 22. doi: 10.1111/tmi.13490. Epub ahead of print. PMID: 32959934.

Health care worker groups, both in and out of facility models, are adaptable to support clients with different types of needs including those who may require more intensive monitoring or support. These include:

- Newly initiated
- Those returning to care after an interruption
- Those not virally suppressed
- Individuals with advanced disease (see Section 6.4.2)
- Families with several individuals living with HIV: Family-centered models are described in Section 6.1.2.1
- Adolescent and youth: See Section 6.1.2.2.
- Pregnant and breast-feeding women, including mentor mother groups and post-natal clubs
- Older adults: as described in 6.4.2.3
- Key populations (see Section 6.5 for details).
- Migrant populations, including those displaced by civil unrest, severe weather (flood, drought, extreme storms), or economic instability

All these models require monitoring for adverse events and pill taking.

See Section 6.1.3.2 for a discussion of documentation of successful treatment.

**Support for successful treatment**

Approaches are detailed in Sections 6.1, 6.1.3, and 6.1.3.2. In brief, it may be that particular populations require nuanced interventions tailored to their needs. Treatment literacy efforts are critical to successful treatment. Peer mentors/HIV champions/coaches/case managers have been used successfully in South Africa where data suggest that 96% of men return or link to care with the support of a man living with HIV serving as a coach or linkage facilitator, and 95% retain on treatment.[21]

Additional contact with health care providers and regular check-in with lay health workers, including home visits, staggered at different times, if they can be adapted to the COVID-19 realities. The use of virtual platforms for communication may be helpful.

- The use of community support personnel to work with clients facing other issues, such as mental health conditions, GBV, relationship problems or financial limitations.

[21] https://www.coachmpilo.co.za/

- Patient support tools to help navigate the treatment experience, including support for disclosure (especially partner disclosure).
- OVC wrap around services and case management to help address barriers to HIV testing, linkage to treatment, continuity of treatment, and viral suppression among children and adolescents, and among key populations who have children.

### 6.1.2.1 Differentiated Service Delivery for Children

Summary of section edits:

- Wording was updated to align with policy that all children irrespective of age should be eligible for multi-month dispensing (MMD) of ART.

Continuity of treatment is essential for averting morbidity and mortality among children living with HIV (CLHIV). In addition to barriers to continuity of treatment relevant for both adults and children, there are additional barriers for CLHIV, including dependence on caregivers, conflicts with school schedules, malnutrition, lack of disclosure, limited implementation of family-centered service delivery models, and health policies that exclude children. To create optimal clinical environments for CLHIV that promote continuity of treatment, programs should ensure that children are included in differentiated service delivery models within a family-centered framework. For instance, children can receive community-based ART delivery and be included in other family-centered differentiated service delivery models.

All CLHIV, irrespective of age, should be eligible for MMD of ART. Weight increases requiring dosing changes occur infrequently and thus should not preclude providing MMD to CLHIV. For the average child, only six weight-based ART dosing changes are anticipated to occur before ten years of age.[22] As described in Section 6.1.3.1, one of the critical adaptations to COVID-19 has been the expansion of MMD for CLHIV and the importance of separating clinical services from drug delivery services. ART refills can be delinked from clinical consultation visits, provided

[22] World Health Organization, CDC, USAID, PEPFAR, IAS. Key considerations for differentiated antiretroviral therapy delivery for specific populations: children, adolescents, pregnant and breastfeeding women and key populations. Geneva, Switzerland: World Health Organization; 2017.

outside of health facilities, and managed by trained lay providers (including OVC workers in cases where children face challenges in accessing ART).

Programs should make every effort to supply all CLHIV with a 3-month supply (3MMD) at initiation of treatment. Children 5 years of age and older who are already on treatment should be supplied with a 6-month supply. The caregiver should be allowed to pick up the child's medication without bringing the child unless the child is due for a clinical visit. For children requiring co-trimoxazole and/or TPT these drugs should be provided to children at the same place and interval as their ARVs. Since pDTG 10mg comes in a 90-count bottle, it is permissible to dispense children <2 years of age with more than a month supply of their complete antiretroviral therapy regimen. Proper follow-up and outreach are important to ensure children return to clinic for their scheduled visits regardless of number of months dispensed.

For children (especially those who are younger) starting a new medication, administration of the first dose should be done before the child and caregiver leave the ART site. While children aged two years and older should receive at least a 3-month supply of ARVs, clinical follow-up should still occur (within 2-4 weeks) by phone, electronically, or in-person and include assessment of medication dosing and administration of the new or changed regimen. Limited stock of pediatric ARVs can hinder a program's ability to implement pediatric MMD; therefore, national supply chain planning must consider MMD for CLHIV. In COP22, programs should complete optimization of pediatric ARV regimens and ensure full uptake of DTG 10 mg dispersible tablets, simplifying the implementation of 3MMD for children 2-<5 years of age. In Malawi, use of a virtual pediatric optimization toolkit (V-POT) geared toward healthcare workers and caregivers and family ART clinics, resulted in timely regimen transition for children despite limited in person support related to COVID-19.

Alignment of children's clinical visits with their caregiver's appointments, including the location and date of visit, is strongly encouraged, as implementing a family-based differentiated service delivery model can foster continuity of treatment for both caregivers and children. Consideration should also be given to selecting times and dates that suit children attending day school or boarding school, such as scheduling visits during school holidays, weekend days, etc. Caregivers should be counseled and oriented on age-appropriate disclosure processes as disclosure is associated with better clinical outcomes. However, disclosure should not be a requirement for MMD.

While optimized differentiated service delivery for children will improve CoT, treatment interruptions may still occur. Re-engagement of children and their caregivers requires a

welcoming and non-judgmental service delivery approach. Clinical and OVC cadres should be trained and mentored on age-appropriate and supportive communication with caregivers and children, regarding the importance of disclosure and continuity of treatment. In addition, providers in facilities that serve HIV exposed and HIV-positive children of key populations (KP) should be trained to provide safe, family-centered, and non-judgmental services to key populations and their children, should KP prefer to bring their children to the site. Disclosure support should be offered to all caregivers who take care of a child. After children are fully disclosed to, they should be linked to peer support at the facility or community (See Section 6.1.2.3 on Adolescent Differentiated Service Delivery) and healthcare workers should continue to support caregiver engagement in the child's care and treatment services.

Re-engagement service delivery algorithms for adults should also be applied, and tailored as necessary, to children to ensure family-centered approach including immediate or shortened timeline access to MMD and differentiated service delivery models upon re-engagement. In Kenya, participation in a family-centered model that included: family/caregiver treatment literacy sessions, engagement with peer educators, participation in psychosocial support groups, ART optimization, and linking patients to OVC programs led to a two-fold increase in VLS for children 2-9 years of age.[23] There are also opportunities to provide differentiated service delivery models for VL testing services for families as shown by RISE-Nigeria who utilized VL champions to provide VL and EID testing in the community, home, or facility depending on a family's preference. This model resulted in increases in both VLC and VLS for participants.[24]

**Orphans and vulnerable children and adolescents**

Formal relationships should be established between clinical partners, health facilities, and surrounding OVC and KP implementing partners (IPs) and the CBOs with which they work to address the psychosocial and economic needs of children and caregivers who are high-risk clients. OVC IPs support adherence by providing child and family in-depth assessments to

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[23] D. Ogiti , E. Amadi, R. Oyuga, V. Ousso, D. Onea, L. Nyabiage, C. Ng'eno, E. Koech, N. Blanco, M. Lavoie Impact of a family-centered care model on viral suppression among HIV-infected children in Migori, Kenya. Geneva, Switzerland: International AIDS Society; 2021

[24] T.N. Yakubu M. Syowai, B.M. Okeowo F. Emerenini , C. Immanuel , A.-u. Attah , B. Dare , F. Abbah , O. Ejoh , E.M. Shabi, J. Dung , O. Fadare, U. Omo-Emmanuel , C. Obanubi, E. Oliveras, M. Strachan, R. Fayorsey. Differentiated service delivery (DSD) model to increase access to HIV ' 1 RNA viral load testing in four states in Nigeria. Geneva, Switzerland: International AIDS Society, 2021

determine needed support and utilize case management to link and track patient access to clinical and socio-economic services.

Starting in COP20, Clinical OVC and KP IPs, health facilities and CBOs should have developed formal relationships, such as a memorandum of understanding (MOU), outlining the roles and responsibilities of each member of the multi-disciplinary team (e.g., local community service organizations and health facility) and addressing key issues such as bi-directional referral protocols, case conferencing, shared confidentiality, index and other testing support joint case identification, and data sharing. In high volume clinics within high burden SNUs, at least 90% of children and adolescents (<19 years of age) in PEPFAR supported treatment sites should be offered enrollment in OVC programs. In COP22, emphasis should be on scaling systems and processes to improve the implementation of these relationships. PEPFAR-supported Clinical IPs play a key role in training community (OVC) case workers to build their knowledge in areas such as adherence, CoT, disclosure, ARV transitions and drug administration, viral load testing and suppression, and making referrals for presumed TB. Likewise, OVC IPs can help train clinic staff to understand the broader factors (e.g., socioeconomic, and cultural) that impact health seeking behaviors (such as EID, HTS, keeping clinic appointments, adhering to medication, returning for viral load test and results), and to help facility-based staff recognize which families and children/ adolescents would benefit from OVC program support and other community-based services.

**Solutions**

Additional solutions to mitigate treatment interruptions and improve treatment continuity include:

- Clinical cadres should be trained and mentored on age-appropriate and supportive communication with caregivers and children, regarding disclosure issues, adherence, prevention and living positively with HIV.
- Counseling and structured PSS for CLHIV and caregivers are key to improving CoT. Psychosocial support can occur more frequently than every three months, does not need to be linked to medication dispensing or clinical consultations, and can be provided virtually or in-person. Please see Section 6.6.5.2 on psychosocial support. Structured counseling and support should be provided to parents/caregivers of perinatally infected children around disclosure. Both caregivers and children starting to approach pre-adolescence benefit from peer support groups. Familial support interventions are also pertinent, such as the *Families Matter!* Program and *Parenting for Lifelong Health*.
- Linking community-based interventions with healthcare facilities, including patient navigators and home-based visits. Case support and management approaches should be

emphasized as a best practice for children who need enhanced support. Children at high risk for treatment interruptions after treatment initiation (see Section 6.1.1) and families experiencing challenges with continuity of treatment and ART adherence should be prioritized for enrollment into OVC programs.

- Adaptation of a quality score measurement system to improve treatment continuity with consistent documentation of most recent weight, ART regimen/doses/formulation, adherence counseling, VL testing, TB screenings/TPT (prescription/refills), TB treatment, and co-trimoxazole (prescription/refills).
- Facilities should establish standard operating procedures to support a transition process for C/ALHIV moving from pediatric/adolescent service delivery points to adult care and treatment. The standard operating procedures can specify a decision framework for differentiated care for children and adolescents.
- Identifying and responding to violence against children, including referrals to child protection services and the provision of age-appropriate clinical care.

Programs should routinely review continuity of treatment indicators by disaggregated sex and fine age bands to further identify challenges unique to specific sub-populations. Given the potential for aging into and out of age bands to impact assessments, programs are encouraged to evaluate EHRs and person-based registries to assess the actual experience of cohorts of children. This approach can foster targeted interventions for these priority populations.

### 6.1.2.2 Differentiated Service Delivery for Adolescents and Youth

Adolescents (ages 10-19 years) and youth (ages 15-24 years) living with HIV (A/YLHIV) struggle with continuity of treatment, ART adherence, and viral suppression. These poor outcomes are due to a number of barriers faced by adolescents and youth, including developmental changes occurring during adolescence, lack of adolescent- and youth-friendly services, limited scale of peer support, inadequate psychosocial support, mental health challenges that often arise in adolescence[25] (see Section 6.6.5.1 and 6.6.5.2 on Mental Health and Psychosocial support), experiences of violence, and food and financial insecurity. Inadequate preparation for the transition from pediatric/adolescent to adult HIV care and treatment is also a critical barrier to continuity of treatment for adolescents. Training/mentoring programs for healthcare workers

[25] World Health Organization. Adolescent mental health Geneva, Switzerland: World Health Organization; 2020

(e.g., clinicians, cadres that provide PSS, etc.) positioned at pediatric/adolescent and adult treatment sites can help foster continuity of treatment from the start of ART and a smooth transition of adolescents into adult care.

When tailoring services for youth, the heterogeneity of young people must be considered. Adolescents will face unique barriers based on their sex, gender, and sexual orientation. For example, adolescent girls and young women, as well as young key populations, are at increased risk of having experienced gender-based violence as a cause and consequence of HIV infection. Men and boys may be less likely to access health services in many communities; these cultural influencers of service uptake should be assessed and incorporated into services in collaboration with young people as active participants.

Adolescents may no longer receive constant caregiver oversight and attend to their duties and appointments with increasing independence. Normal developmental changes during adolescence often make it difficult for adolescents to understand and accept an HIV diagnosis, to self-determine rational and wise health behaviors and understand the health implications of risky behaviors. A/YLHIV should be involved in decision making about their own health and empowered to take charge of their own health through health literacy and mentorship and support from peers and trusted adult figures in addition to their parents/guardians. Healthcare workers should foster relationships with A/YLHIV by creating a balance between appropriate health supervision and listening to A/YLHIV's voices regarding their health. Healthcare workers must ensure personal beliefs do not preclude or interfere with providing A/YLHIV non-judgmental person-centered care. It is also important for healthcare workers to openly discuss the involvement of caregivers with adolescents when caregivers could be helpful in providing emotional and tangible support, while respecting adolescents' confidentiality if they chose not to have certain personal information shared with caregivers. Caregiver skills building can be an important component of services provided, as caregivers can play a critical role in supporting continuity of treatment for adolescents.

In addition to ensuring programs work to address barriers faced by A/YLHIV, it is important that A/YLHIV have access to facility- (e.g., fast track) and community-based differentiated service delivery models and MMD that meet their needs. Similar clinical criteria to those used for adults in determining MMD eligibility may be applied to adolescents, with the addition of the availability of enhanced psychosocial support, particularly from peer A/YLHIV, both in facility and community settings. ART refill collection and clinical consultation frequency can be reduced through the separation from psychosocial support if adequate psychosocial support services can be provided

more frequently in the community or virtually. To optimize HIV outcomes and ensure differentiated service delivery models meet the needs of A/YLHIV, youth engagement should be a central tenet in the development, implementation, and monitoring and evaluation of interventions to strengthen programs and ensure the needs and experiences of youth inform current activities. Programs should recognize the specific needs of youth cohorts, including young pregnant and/or breastfeeding mothers, young key populations, and other youth populations when linking youth to relevant support services.

Countries should routinely review adolescent and youth fine age bands and specific youth cohort (i.e., young pregnant/breastfeeding mothers, young KPs, etc.) data to identify ongoing gaps in continuity of treatment and viral load suppression in these populations. Normal aging in youth cohorts, with transition of patients between age bands, can make interpretation of aggregate MER indicators challenging. It is important to assess the treatment experience of defined cohorts of youth using person-based data to better assess progress and inform program planning. To do this, programs should use EMR and other locally available clinical data sources to analyze continuity of treatment outcomes by age band.

Noting that youth are the most technologically connected age group, with 71% of the worldwide population online compared with 48% of the total population, adherence activities and differentiated service delivery models targeted to youth should include new opportunities to leverage technological resources and innovations.[26] Such technology approaches provide an excellent way to engage with A/YLHIV both during and following COVID-19, such as web-based applications for peer support groups, improving youth-provider communications, and identifying local youth-friendly services.

**Solutions** unique to this population include:

*At both Health Facility and Community levels:*

- Promptly link A/YLHIV to peer-led service delivery models to provide peer support and motivation, build resilience, strengthen problem-solving skills, and overcome adherence challenges (e.g., quality A/YLHIV support programs such as Positive Connections, Teen Clubs, Operation Triple Zero, and Zvandiri). Where feasible link them to services within

[26] World Health Organization. Children in a Digital World. Geneva, Switzerland: World Health Organization; 2017

their community or comfort and safety zones where they will feel like they belong and are welcomed.

- Utilize targeted interventions to improve continuity of treatment amongst A/YLHIV, including fast tracking (e.g., EGPAF's Red Carpet program), case management, mental health screening and referrals, and referrals to broader psychosocial and economic/employment support resources.
- Ensure **all** human resources are comprehensively trained and mentored on client-centered and -friendly care, including male-friendly, AGYW, KP, and A/YLHIV services. Trainings should allow opportunities for all staff to practice these skills (i.e., role-play) and partake in open discussions about possible biases that may arise when caring for A/YLHIV. This is an ideal opportunity to include youth as co-facilitators, thus grounding the training in youth experience as well as providing a useful professional development opportunity for youth.
- Provide training on first-line support for disclosures of trauma, including violence, referrals to services and the provision of post-GBV care, and work to enhance the safety of A/YLHIV for treatment continuity.
- Ensure partner government and/or facility- and community-based implementing partners have policies, SOPs, transition guidelines, and procedures in place related to patient-centered and friendly care, specific for adolescents and youth.
- Provide psychosocial support and education related to transition to adult HIV care and treatment services including transition readiness assessments for A/YLHIV, age and developmentally appropriate disclosure (in line with partner country disclosure guidelines), and self-care support services for A/YLHIV that includes enhanced treatment literacy and incorporates agency and choice of young people. Implementation of an adolescent transition package is recommended to provide healthcare workers with the experience and tools to prepare ALHIV for transitioning to adult care.[27]
- Coordinate tracking of A/YLHIV for appointment reminders/missed appointments using A/YLHIV peer navigators.

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[27] D. Mangale, I. Njuguna, C. Mugo, A. Price, C. Mburu, H. Moraa, J. Itindi, D. Wamalwa, G. John-Stewart, K. Beima-Sofie. Influences on healthcare worker acceptability, feasibility and sustainability of an Adolescent Transition Package in Kenya. Geneva, Switzerland: International AIDS Society, 2021

- Support implementation of or linkage to programs that provide improved parenting skills for caregivers of ALHIV.
- Ensure linkages from facilities to OVC programs and vice versa are seamless to ensure ALHIV are provided optimal support to meet their needs. And that, ALHIV are offered enrollment into OVC programs that can provide more intensive support including case management, parenting skills building, and access to socio-economic services.

*At the Health Facility level:*

- Incorporate adolescent- and youth-friendly services, e.g., adolescent and youth hours and/or days of operation.
- Provide facility-based A/YLHIV psychological and peer support, including both individual and group peer support, which can be provided in-person or virtually. Please see Section 6.6.5.2 on psychosocial support.
- Use tools to implement and monitor provision of youth-friendly services and interventions, including demand creation, youth-oriented educational materials, integration of HIV and sexual and reproductive health services, feedback boxes, A/YLHIV community-led monitoring activities i.e., “mystery shoppers,” and facility checklists to track the youth-friendly components of a facility, and making sure these services are advertised appropriately.
- Include youth representatives on facility advisory committees.

*At the Community Level:*

- Provide community-based peer support (groups, buddy systems, community adherence groups (CAGs) and health literacy
- Provide (peer) accompaniment to clinics
- Conduct home-based visits in coordination with the OVC program (where applicable) after obtaining consent
- Through coordination with the OVC program, link A/YLHIV to economic strengthening activities
- OUs should work with OVC programs, Ministry of Education, schools, and other community platforms to decrease stigma and discrimination, and to prevent violence against A/YLHIV (from school staff members and peers)
- Deliver gender norms change messaging and programming that challenge norms that serve as barriers to service uptake

### 6.1.2.3 Differentiated Service Delivery Support for Men and Women, Including Pregnant and Breastfeeding Women

Sex differences in treatment outcomes are well described and there are different challenges for men and women across the treatment cascade. Research suggests that women with HIV are more likely than men to engage successfully with the health care system and earlier during HIV disease[119] Engagement with family planning and antenatal services provides early access points.

Partners in the MenStar Coalition have conducted qualitative research to understand these differences, and that research highlights specific emotional and psychological issues and behavioral patterns that may impact health-seeking behavior at different stages of the cascade. Inconvenience, stigma, and negative attitudes from health care providers are commonly reported. Men tend to report an unbalanced cost/benefit ratio, i.e., it is not clear that the reward of being on treatment outweighs the negative experience of the clinic and the medicine on their lives. A framework has been developed that may be helpful and is designed to spur the development of specific interventions adapted to the local context. Proactive interventions are needed, including gender-equitable approaches that account for gender expectations, stereotypes, and power relationships that affect the participation of men (see Section 6.6.2, Gender Equality). These efforts should create awareness of new medicines, as well as the convenient services, and must also address clients' emotional barriers to treating their disease.

The following strategies and interventions can be deployed to reach men and engage them more effectively in continuous ART and adherence outcomes:

**Rapid optimization of TLD**

- See 6.4 Optimizing HIV Care and Treatment

**Strengthen the service delivery experience to be more convenient and welcoming**

The Service Delivery Experience, including the physical space and the providers, should meet the functional and emotional needs of the clients. Client satisfaction should be monitored regularly and used for ongoing improvements in areas of convenience, hospitality, responsiveness, and effective support / rapid feedback loops. Implementation of the recommendations below should never negatively impact the services to children, adolescents, or women at the same sites.

For example, through MINA, a national campaign launched in South Africa aiming to promote treatment initiation and retention for men living with HIV, insights-driven messaging based on consumer marketing practices led to an increase in men testing for HIV and starting/staying on treatment. The brand look and feel, messaging and approach was tailored specifically to resonate with men and MINA clinics were branded and designed to meet the needs of men at different touchpoints in their HIV journey.

**Welcome back messaging** as described in Section 6.1.3.2 with tailored messages

**Treatment support mechanisms**

- Includes escorted linkage, peer navigation, case managers, adherence clubs
- Digital or virtual aids to support treatment continuity

See Section 6.1.2 Differentiated Service Delivery.

**Build coping potential with messages on the benefits of therapy**

Treatment literacy which focuses on the benefits of viral suppression (see Section 6.1.1)

U=U messaging. The message that viral suppression means that HIV cannot be transmitted to sexual partners is a powerful motivator for many individuals, and counselling and messaging should emphasize this information. Reframing the treatment narrative with aspirational and achievable goals, allowing individual clients agency in these goals may go a long way to achieving therapeutic success and viral suppression. Messaging to men can focus on the positive roles of men (e.g., provider, husband, father, friend, coach) challenge negative or violent behaviors, and champion treatment adherence in their communities.

**Women, including Pregnant and Breastfeeding Women**

With the implementation of test and start for pregnant and breastfeeding women with HIV infection, rates of ART initiation in PMTCT programs are very high. However, multiple countries have reported treatment interruptions in women initiating ART during pregnancy and especially during breastfeeding. At particular risk are younger women and those who are newly diagnosed with HIV.[120] Poverty, experiences of gender-based violence (specifically intimate partner violence, domestic violence, or violence against children), and low educational levels are important contributors.[121,122]

Continuity of treatment and viral suppression are critical for mothers in ART programs. Viral load suppression to undetectable levels has a substantial impact on improved maternal health and prevention of vertical transmission. When HIV is diagnosed, ART is initiated, and viral

suppression (to <50 copies/mL) is achieved prior to conception and maintained over the course of pregnancy and breastfeeding, the risk of vertical transmission is extremely low. To attain this near zero risk of vertical transmission for WLHIV, programs should provide client education and service delivery that focus on: (1) testing and starting WLHIV on ART prior to conception, (2) supporting pregnancy planning for WLHIV on ART, and (3) ensuring viral suppression throughout pregnancy and breastfeeding. Measuring viral loads before and during pregnancy is critical to the success. These educational and service interventions are needed at both PMTCT service delivery points as well as in the community and general ART clinics to ensure that women know their status, start ART and are virally suppressed prior to conception."

Viral suppression for women during and beyond the breastfeeding period also reduces the risk of perinatal transmission in future pregnancies.[123]

Stigma and discrimination are important barriers to care for these women, but they face other unique challenges. Cultural norms that limit a woman's autonomy to make independent health care decisions, such as unsupportive male partners[124,125] intimate partner violence and fear of disclosure,[126] are often features in the lives of these women. Structural issues such as movement across many different service delivery points (ART clinic, ANC, L&D, postpartum, immunization, etc.), long wait times at ANC, low quality of care, and negative perceptions by staff and transport distance and costs complicate the care of pregnant and breastfeeding women.

Strategies that can improve continuity of care among PBFW:

- Integrated services during pregnancy and postpartum[127] "one stop shop" for maternal and infant care including dispensing medications in clinic.
- MMD to align with ANC/MCH schedule as well as with contraceptive/family planning commodity refills post-delivery.
- Access to differentiated service delivery, WHO 2021 guidelines highlight eligibility criteria specific to PBFW for accessing differentiated ART delivery models (included below)
    - Women who are receiving HIV treatment within a less-intensive differentiated service delivery model should be screened regularly for pregnancy and family planning needs and preferences. If women become pregnant, it is essential that they have access to antenatal care services and viral load testing, but this does not require referral out of their differentiated service delivery model unless they have a viral load >1000 c/ml, are at high risk for ART nonadherence, or choose to return to a more-intensive model. Women who were not in a differentiated service delivery model prior to pregnancy should also be enabled to qualify for

differentiated service delivery postnatally provided that an HIV-negative test result for the infant with a nucleic acid test (NAT) at 6 weeks has been received, and evidence of accessing infant follow up care. Where culturally women travel away from their usual home to give birth and in the immediate post-natal period, MMD should be considered to align with their return date.

- Ensuring full access to TLD
- Engaging community health workers[128]
- Structured peer mentors
- Mentor Mothers,[129] M2M, or other structured peer mentoring such as community focal mothers. See the PEPFAR Solutions Platform and Section 6.6.5.2 Psychosocial Support.
- Pregnant and breastfeeding adolescent girls and young women may require additional support and group antenatal care with the provision of ART may be helpful.
- Male involvement[130]
- Family centered care
- Point-of-care viral load testing, with education and counseling
- Ante-natal and Post-natal clubs[131]
- Family centered services with integrated maternal newborn and child health HIV care:
- Identification of intimate partner violence and provision of client centered care
- Conduct clinical enquiry for violence, provide first-line support (LIVES) to those who disclose experience of violence, and provide or refer survivors to local clinical and/or non-clinical GBV response services (see GBV Section 6.6.2.1 for additional information).
- Ensure care is trauma-informed and client centered.

Adolescent girls and young women are at particular risk for treatment interruption and require special efforts to promote and encourage continuity of care such as peer support and home-based care and support. Improved tracking of women across services (including through the expansion and use of electronic medical records in ANC/PMTCT settings, with linked identifiers for mothers and infants), the use of technology driven reminders, and assistance with transportation are local solutions that may help retain these women in care. Importantly, pregnant women who are receiving their HIV care within a differentiated service delivery model should not be referred out of this model when they become pregnant, but rather supported to have their ANC care provided within the same differentiated service delivery model.

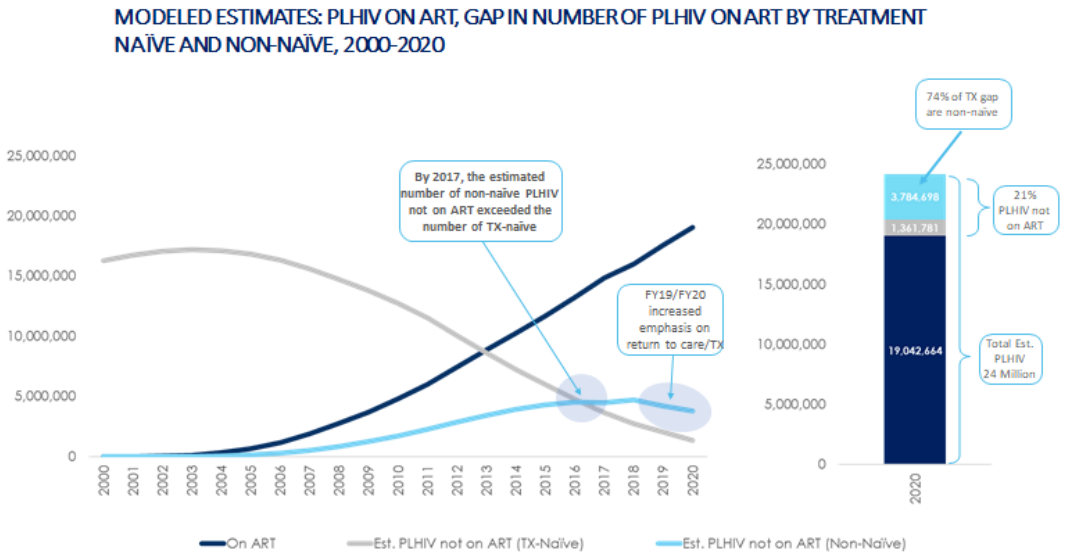
## 6.1.3 Continuity of Treatment

Program efforts in COP22 will investigate reasons for treatment interruption and seek to advance practices that facilitate continuous treatment. High quality programs will seek to prevent interruptions and rapidly identify, locate, and support people living with HIV who do not initiate ART, who miss appointments early in treatment (<3 months), or who disengage from services (3 months or more), and document outcomes. More attention will be given to support client's adherence, while recognizing that context-specific challenges will require resilient health treatment systems and rapid modifications, especially related to COVID-19[28] After any break, clients should be warmly welcomed to re-engage in client-centered services including access to immediate or shortened-timeline differentiated service delivery to achieve the best possible treatment outcomes. Testing and treatment implementing partners must coordinate resources and efforts to support individuals seeking to re-engage in care and treatment services. The development of re-engagement service delivery algorithms may facilitate this process.

Spectrum analysis using modeled data from PEPFAR supported countries from 2000 to 2020 has indicated that investments that seek to re-engage people on treatment will be critical for OUs to sustain and improve TX_NET_NEW targets in FY2023. This modelled data from Botswana, Cameroon, CDI, DRC, Eswatini, Ethiopia, Haiti, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe indicate that Test and Treat efforts have successfully identified and started people on treatment, but the number of treatment-experienced clients not receiving ART is now greater than treatment-naïve people living with HIV who are not on ART as indicated in figure 6.1.3.1; data include Spectrum estimates, which vary by country and differ from PEPFAR program data. Countries included in the analysis are Botswana, Cameroon, CDI, DRC, Eswatini, Ethiopia, Haiti, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe.

*Figure 6.1.3.1 Spectrum Modelled Estimated: Trends in Number of Treatment Naïve and Non-Naïve People on ART from 2000 to 2020*

[28] Jewell B. et. al. (2020) "Potential effects of disruption to HIV programmes in sub-Saharan Africa caused by COVID-19: Results from multiple mathematical models." Lancet, Vol. 7 (9) E629-630.




Caveats/Assumptions: Modeled estimates from SPECTRUM courtesy John Stover. IIT rates are assumed and vary by country IIT rates may be over or underestimated. Countries included in this analysis: Botswana, Cameroon, Cote d'Ivoire, DRC, Eswatini, Ethiopia, Haiti, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe

To ensure equity, sub-populations of people living with HIV may require modified or supplemental treatment interventions to ensure optimal health outcomes. These include men, children and adolescents, pregnant and breastfeeding women (including their HIV exposed infants), older adults, especially those with comorbidities, key populations, and individuals with advanced disease. These detailed intervention components are described in previous sections for linkage and differentiated service delivery, attention to the client's needs and quality of the services delivered is essential.

During COVID-19 disruptions, OUs adopted a range of rapid and flexible service delivery model that ensured continuity of treatment in difficult times. Key factors were:

- Collaboration with the Ministry of Health to ensure that the HIV clients who were displaced when from facilities were assigned as COVID-19 centers could be traced and supported at the nearest sites.
- Proactive communication, including virtual methods, to ensure clients were directed to access rapid ARV refills at the nearest clinic, and received remote adherence and PSS for clients on treatment.
- Rapid supply chain support and distribution of multi-month dispensation of ARVs with more discreet 3-month supply bottles, that reduce the chance of accidental disclosure
- Extended policy allowances for MMD for all clients, no matter their clinical status. Of note, that patients with unsuppressed viral load and in EAC were less likely to resuppress and did need specialized care.

- Decentralized delivery of ARVs at the community level to reduce transport burden and costs for clients, often delivered in collaboration with non-PEFPAR food security for adults living with HIV, or as coordinated with PEPFAR OVC programming for C/ALHIV enrolled.

Clinical partners are responsible for ensuring that clients receive continuous treatment. Where relevant and available, they should ensure that functional non-clinical support is provided in an ongoing manner within the community space to support adherence[29] and sustained continuity of treatment. Collaborative partnerships with community partners that include people living with HIV, networks of expert patients, and support groups should be optimized to address social and structural challenges with a direct impact on adherence and engagement, especially misinformation, stigma, and discrimination.

At epidemic control, OUs will need more precise people-centered data and systems work to identify and predict who, when, and where IIT is most likely to occur and recover any clients that disengaged in treatment before and through COVID-19 disruptions. More targeted return activities and welcome back efforts for all non-treatment naïve clients who ever disengaged in care will be critical. Careful attention will be needed to set a program threshold for treatment interruptions (even lower than 2%) to be able to sustain the cohort at 95-95-95 across all ages.

Assessments of PEPFAR performance revealed that continuity challenges can easily be underestimated or overestimated by incompleteness of data, site shifts, normal aging reflected in age band shifts, and reliance on proxy indicators. FY2023 plans should include an evaluation of TX_ML disaggregates to identify which populations and clinics are experiencing the highest volume of treatment interruptions and develop targeted interventions that may help address these issues. In OUs with access to electronic medical records for unique clients, more precise data around TX_ML (and time to return to treatment should be used as factors influencing adherence are likely to differ over time).

Data quality and completeness are central to efficient and responsive activities. Systematic tracking and tracing activities for missed visits should be performed in as close to real time as possible. COVID-19 adaptations have increased virtual or telephonic contact, which should streamline efforts to counsel clients and reschedule for their priority clinical needs, namely ARV

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[29] Whiteley, L.B., Olsen, E.M., Haubrick, K.K. et al. A Review of Interventions to Enhance HIV Medication Adherence. Curr HIV/AIDS Rep (2021). https://doi.org/10.1007/s11904-021-00568-

refills, preventing and treating comorbidities, and viral load monitoring. These remote encounters should be counted as clinical contact.

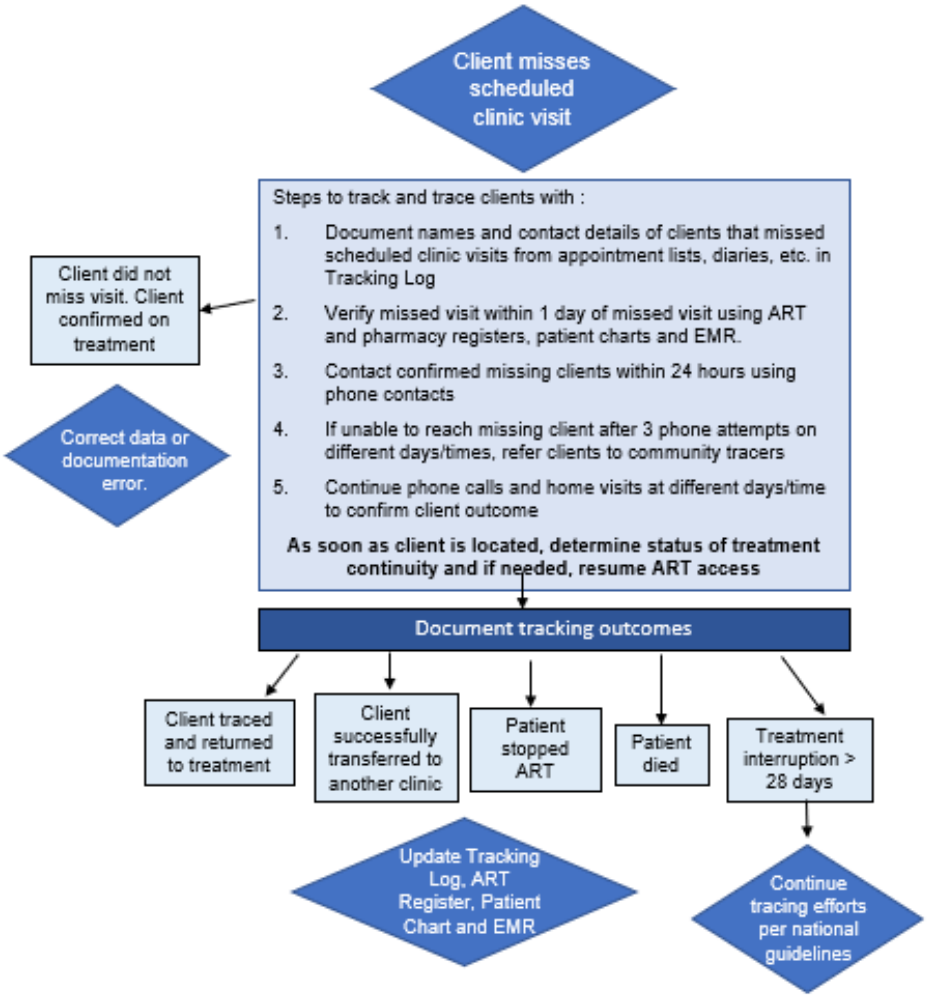
Tracking and tracing efforts have benefited from coordination with community health workers, CSOs and government food security efforts especially when mitigation efforts for COVID-19 are in place. Coordination with OVC programming to improve household food security and provide short-term emergency food or cash support for C/ALHIV in destitute situations alongside ARV refills is recommended. For non-OVC clients, collaboration with local government and use of COVID-19 funds to ensure continual access to ARVs.

Of particular importance are preventing and addressing treatment interruptions among pregnant and breastfeeding women as mother and baby receive the full package of services, and transfer between adult treatment and PMTCT and HEI services.

Some programs have found that a substantial proportion of patients initially identified as having interrupted treatment were in fact active on ART but had transferred or enrolled in a differentiated service delivery program. Programs must work to strengthen record keeping, advance national unique identifiers, and harmonize documentation and data management systems to capture silent transfers more effectively, differentiated service delivery patients, and pharmacy pickups.

See Figure 6.1.3.2 for a sample tracking log.

*Figure 6.1.3.2 Sample Tracking Log*




## 6.1.3.1 Multi-Month Dispensing and Decentralized Drug Delivery

**Multi-Month Dispensing**

COVID-19 has accelerated MMD scale-up and initiation in the majority of PEPFAR OUs. Thirty countries have changed guidelines, and there has been a 78% increase in 6MMD since the beginning of the COVID-19.

Multi-Month Scripting is a prerequisite for MMD but does not replace MMD and should not be equated with MMD. Similarly, MMD is an important part of differentiated service delivery but should not be equated with differentiated service delivery. The critical intervention is separation of drug delivery from clinical care. This innovation reduces the burden at clinical sites and allows more attention to the patients who need clinical evaluation and allows for less frequent clinical

evaluations for individuals who are well. Six-month dispensing is preferred, but there may be circumstances where three-month dispensing is necessary. Requirements such as a minimum time on ART or a documented suppressed viral load are barriers to the successful scale-up of this intervention. At a minimum, most clients at ART treatment sites including adults, children, adolescents/youth, pregnant and breastfeeding women, members of key populations, and foreign nationals should be offered prescriptions for six months of ART. Individuals newly on ART and those re-engaging in treatment should be offered MMD. For children initiating and refilling ART, every effort should be made to supply them with a 3-month supply of ARVs for children 2-<5 years old and a 6-month supply for children age 5+ years. Additionally, programs should provide storage instructions for patients on multi-month 90-count and 180-count ARV bottles. Countries should continue to scale up programs for 6-month MMD for adults and a minimum of 3-month MMD for children. See Section 6.1.2.1 for details of MMD in children. In brief, CLHIV initiating and refilling ART should be provided with a 3-month supply of ARVs for children 2-<5 years old and a 6-month supply for children over age 5 years. Task Sharing, as recommended by WHO, is essential for both Multi-Month Scripting and Dispensing.

The MER disaggregate of the TX_CURR indicator for MMD improves accountability regarding MMD for programs and partners. Facility-level partners are also required to report two supply chain indicators (SC_CURR and SC_ARVDISP) biannually for COP22 and beyond, underscoring the importance of implementing MMD and commodity availability.

The logistics of MMD implementation must be planned carefully, identifying the number of patients that will receive MMD in close coordination with clinical and country's supply chain staff to accurately forecast and quantify volumes for COP22, especially for bottles of ART which provide treatment for greater than one month. A monitoring and evaluation system should be in place to track these patients and oversee inventory management. In addition, decentralized drug distribution plans should be incorporated to ensure that patients receive their medications through a timely method that is convenient for them to avoid treatment disruption.

- MMD must be part of the annual quantification, forecasting, and supply planning exercise and this will be expected in COP22.
- Ensure that ARV quantity sizes (e.g., 90-, or 180-count) are accurately identified within the commodity section of the FAST. No 30-count bottles of first line ARVs have been purchased after January 1, 2020. All new clients should be given a minimum of 3 months' worth of drug supply even if a follow-up visit is needed in less than 3 months.

- Other drugs that the person requires, such as TPT, CTX, family planning commodities and drugs for other conditions should be provided whenever possible for the same duration of dispensing as ARVs. Supply chain support and forecasting should be adjusted accordingly for these medicines as well.
- Allocating the appropriate drug supply is required for client adherence.
- National formulary documents in-country should be revised to include larger pack sizes.
- Safe storage conditions as well as appropriate shelf life must be considered to ensure patients receive good-quality ARVs. Product expiry should be carefully monitored for larger bottles ensuring that patients receive bottles with more shelf life than months of treatment enclosed.

The Ministry of Heath, Customs Agency, Central Medical Store, the Regulatory Authority, other relevant government agencies and Global Fund (where applicable) must recognize larger pack-sizes of ARVs. Countries should treat these new pack sizes as a separate line-item product when forecasting, updating supply plans, and generating future orders. Ministries of Health should also issue circulars, policy briefs or guidance through the health system encouraging MMD for all HIV positive patients.

In addition to confirming sufficient stock is available to supply all patients with 3 and preferably 6MMD, health facilities must ensure systems are in place to routinely identify, enroll and keep patients on MMD. Key considerations include:

- Creating demand for MMD by counseling clients on benefits of MMD and encouraging peers to share their experiences in clinic education and support activities.
- Providing coaching, training sessions, and supportive supervision site visits for facility. staff on country specific MMD policy, implementation, and monitoring.
- Establishing facility MMD focal person to manage patient file reviews, develop line-lists. of clients not currently enrolled on MMD or needing to transition from 3 to 6MMD and oversee implementation of MMD for clients newly initiating treatment.
- Assessing (and routinely re-assessing) client preference to ensure clients receive the dispensing interval and pill packaging (e.g., 90 or 180-count pill bottles)
- Involving community health workers, patient navigators, psychologists, and lay workers to support clients enrolled on MMD through in-person or virtual engagement between

extended ART pickups to ensure treatment adherence and satisfaction in the MMD model.

- Promoting family-centered approach to MMD by synchronizing MMD schedules and drug pick-ups for caregiver-child pairs, and caregiver- grandparent/auntie/uncle pairs.
- Where possible, integrating other medicines into MMD of ART including TPT, TB treatment, family planning and or non-communicable disease medicines.
- Ensuring that appropriate monitoring and evaluation occurs including monitoring for adverse events, continued viral load monitoring, adequate clinical follow-up, and person-centered referrals.

**Decentralized Drug Distribution:**

The core principle for differentiated care is to provide ART delivery in a way that acknowledges specific barriers identified by clients and empowers them to manage their viral load with the support of the health system. Common DDD models include distribution through private hospitals or pharmacies, postal or courier services, ATMs, alternative community pick-up points automated lockers, home delivery, community-based organizations, or community-based distribution through peer groups or fixed sites (e.g., churches, mosques, schools, etc.). DDD models can also be used for decentralized PrEP distribution to improve uptake and continuation. Private sector expertise and approaches can be leveraged to support the implementation of DDD models. See Section 6.1.2 for a further description of differentiated service delivery models of care.

Because DDD programs may move existing clients from one point of dispensation to another point (which may be satellite to a parent facility, community-based, or other) the supply chain implications of a DDD program are primarily related to logistics, transportation, quality control, and reporting. Depending on the model, logistics and transportation may be managed by the private sector, governments, implementing partners, or clients (for peer-led models). Key supply chain considerations are as follows:

- As DDD programs achieve scale, programs can achieve greater efficiency, increase convenience for clients, and reduce stigma by integrating a wide array of non-HIV commodities into decentralized sites (e.g., condoms and other family planning commodities, TPT).
- Commodities which are dispensed in smaller units than the original packaging must go through a labor-intensive repacking process (e.g., if a 180-pill bottle is distributed

to two different patients receiving 3MMD). Breaking bigger packs into smaller packs should be avoided.

- The addition of new satellite sites which are relationally tied to 'parent' dispensing facilities, or the expansion of DDD through private hospitals, clinics, and pharmacies, will increase the need for supportive supervision visits to ensure quality drug distribution practices.
- Commodity ordering and reporting tools must be able to collect patient consumption data (whether in the public or private sector) and ensure that this data is entered back into existing logistics management information systems (LMIS/eLMIS) and linked with reporting systems at the hub/parent facilities.

PEPFAR supports the elimination of user fees in public sector sites. Where DDD services in the private sector are fee-based for improved sustainability of services, fees must be voluntary, and a pre-implementation assessment must determine an appropriate fee that does not cause undue barriers to clients. If DDD sites require additional transportation resources or modifications to existing transportation routes for commodities, this must be considered considering the available budget, vehicles, and human resource capacity.

### 6.1.3.2 Interruptions and Re-engagement in Treatment

Summary of section edits:

- Updated to include recommendations for clinical management of individuals returning to care and the use of longitudinal data for understanding interruptions.

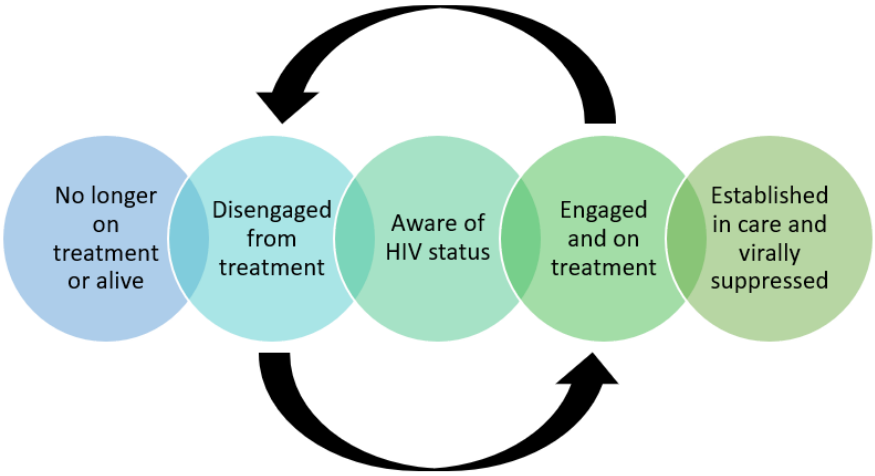
There is a growing recognition that the continuum of care is cyclical with periods of engagement and disengagement.30 This movement in and out of treatment has been described by some as 'churn.'31 Planning for these interruptions is an integral part of chronic disease management. In COP22 PEPFAR supports a "welcome back to care" approach which is personalized and attempts to understand the reason for disengagement, is

[30] Ehrenkranz, P., Rosen, S., Boulle, A., Eaton, J. W., Ford, N., Fox, M. P., Grimsrud, A., Rice, B. D., Sikazwe, I., & Holmes, C. B. (2021). The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals. *PLoS medicine*, *18*(5), e1003651. https://doi.org/10.1371/journal.pmed.1003651

[31] Hartmut B Krentz, Quang Vu, M John Gill, The Impact of "Churn" on Plasma HIV Burden Within a Population Under Care, *Open Forum Infectious Diseases*, Volume 6, Issue 6, June 2019, ofz203, https://doi.org/10.1093/ofid/ofz203

empowering, and is actively supported by both services and providers (both clinical and non-clinical).[32] Clinical management of individuals who have been out of care differs between those who re-engage quickly and those who have been out of care for some time. Individuals who re-engage after being out of care for one year or more require an evaluation for advanced HIV disease with a measurement of CD4 as part of that initial evaluation, although evaluations for advanced disease should occur whenever clinically indicated. Individuals re-engaging after 3-6 months should be offered differentiated service delivery models including multi-month dispensing, based on clinical considerations and country policies.

*Figure 6.1.3.2.1 Model of Engagement and Reengagement in Treatment*




Various strategies to measure interruptions have been used in both interventional and observational studies. Self-report and clinic-based pill counts are commonly used, but both measures are imprecise. Pharmacy refill data is a useful source of data and missed refills have been associated with virological failure and mortality. Importantly, these data may be available

[32] Blanco, N., Lavoie, MC.C., Koech, E. *et al.* Re-Engagement into HIV Care: A Systematic Review. *AIDS Behav* (2021). https://doi.org/10.1007/s10461-021-03365-y

electronically.[33] A smart phone app for use by pharmacists was demonstrated in Botswana, and other digital solutions may be helpful.[34]

The COVID-19 pandemic has amplified the difficulty of identifying individuals who may have experienced treatment interruption because many individuals have fewer clinical contacts. This means that every missed contact or missed pharmacy refill must be identified quickly and efforts made to contact the individual. Pharmacy data, electronic medical records and telephone logs may all be useful. The PEPFAR COVID-19 guidance[35] has emphasized the need to keep accurate clinic lists, these will be helpful in the setting of lockdowns and clinic closures. Routine clinical data may underestimate the level of treatment interruptions,[36] however, several MER indicators may be helpful in tracking interruptions in treatment at a population level and identify individuals at risk for interruption. See Section 7 for a full discussion of these indicators. The TX_ML indicator, with disaggregates may identify specific challenges in particular populations. Identifying and evaluating interruptions and returns using the TX_ML and TX_RTT indicators may identify important gaps. Where applicable the use of cross-site integrated person-centered longitudinal data (e.g., where available data from EMR in national data repositories may be used) is preferred.

## 6.2 Primary Prevention

As countries approach epidemic control, the reduction in community viral load will have a strong prevention effect since people living with HIV with undetectable viral load cannot sexually transmit HIV. Primary prevention program impact will hinge upon developing systems to consistently find and engage individuals most vulnerable to acquiring and transmitting HIV. Just as for other interventions, realizing the full impact of primary prevention interventions requires

[33] Orrell, C., Cohen, K., Leisegang, R., Bangsberg, D. R., Wood, R., & Maartens, G. (2017). Comparison of six methods to estimate adherence in an ART-naïve cohort in a resource-poor setting: which best predicts virological and resistance outcomes?. *AIDS research and therapy*, *14*(1), 20. https://doi.org/10.1186/s12981-017-0138-y

[34] Coppock, D., Zambo, D., Moyo, D., Tanthuma, G., Chapman, J., Re, V. L., 3rd, Graziani, A., Lowenthal, E., Hanrahan, N., Littman-Quinn, R., Kovarik, C., Albarracin, D., Holmes, J. H., & Gross, R. (2017). Development and Usability of a Smartphone Application for Tracking Antiretroviral Medication Refill Data for Human Immunodeficiency Virus. *Methods of information in medicine*, *56*(5), 351–359. https://doi.org/10.3414/ME17-01-0045

[35] https://www.state.gov/pepfar/coronavirus/

[36] Phillips, T. K., Orrell, C., Brittain, K., Zerbe, A., Abrams, E. J., & Myer, L. (2020). Measuring retention in HIV care: the impact of data sources and definitions using routine data. *AIDS (London, England)*, *34*(5), 749–759. https://doi.org/10.1097/QAD.0000000000002478

countries to understand the specifics of their epidemics at a sub-national level, leverage partnerships and community strengths to develop strategies that identify those at highest risk, support continuous client-centered ART for those living with HIV, and engage and support peer-led, peer-designed prevention services that center on the needs of clients and are tailored to the client's situation. It is important to remember that those most vulnerable to acquiring HIV are often the ones who face the greatest barriers to accessing the services that they need to protect themselves, leading to inequities in service coverage. Engaging these individuals with prevention services requires something other than business as usual. This Guidance promotes a people-centered approach to the delivery of services that empowers people to make choices among an expanding array of HIV prevention options. It recognizes that this can only be achieved by addressing critical inequalities that underpin the epidemic and dealing with persistent inequities in the provision of services.

Comprehensive HIV prevention services including HIV and risk reduction education, condoms, and lubricants, VMMC referral, harm reduction interventions, and HIV post-exposure and pre-exposure prophylaxis (PEP and PrEP) along with counselling, should be incorporated into all existing services such as antenatal and postnatal/MNCH services, family planning and sexual and reproductive health services, STI testing and treatment services, key population and AGYW venues and spaces, and provided in the community. Prevention services should be integrated and accessible across existing medical services and also de-medicalized when possible, making them simpler for people to navigate and access, and centering them on people's needs and lives. Prevention and PrEP programs are well positioned learn from differentiated service delivery approaches (DSD) for HIV treatment. It is imperative that prevention programs adopt DSD to ensure a quicker evolution to scaled implementation. DSD for PrEP includes multi-month dispensing of PrEP refills, spacing of clinical consultations, PrEP maintenance visits that are conducted by peers, lay providers and community health workers and community-based PrEP distribution models. Delivery of HIV prevention services has been adapted to enable safe and efficient service delivery in the setting of COVID-19 as an essential service for HIV epidemic control. Programs are encouraged to continue to leverage lessons learned and adapt prevention interventions at both the facility and community levels. In cases where COVID-19 adaptations have enhanced the reach of prevention services, they should be continued independent of the COVID-19 pandemic's course.

**What's New in 6.2 Primary Prevention for COP22:**

- Expanded section on new PrEP products and preparing for product introduction (6.2.1)

- Updates to the WHO guidelines for creatinine testing for PrEP (6.2.1)
- STI testing and treatment added to DREAMS core package as part of youth friendly SRH component (Section 6.2.2.2)
- Permission for OUs to spend some of DREAMS funds to implement and assess solutions to fill programming gaps (Section 6.2.2.2)
- Added guidance that men known to be living with HIV be compliant on ART for at least three months before being circumcised; guidance on follow-ups on "virtual" platforms; summary of the cost-effectiveness modelling (6.2.5.1)

## 6.2.1 Pre-Exposure Prophylaxis (PrEP)

Summary of section edits:

- New product information was updated.
- Updated to align with new WHO guidance on differentiated and simplified pre-exposure prophylaxis for HIV prevention (https://www.who.int/publications/i/item/9789240053694).
- Updated to align with status-neutral service delivery considerations.

Substantial risk of acquiring HIV continues to be seen among populations in concentrated and general epidemics such as serodifferent couples with inconsistent condom use when the partner living with HIV is not virally suppressed, adolescent girls and young women in many parts of sub-Saharan Africa, pregnant and breastfeeding women (PBFW), key populations (e.g., men who have sex with men, transgender persons, sex workers, people who inject drugs, and people in prisons and other enclosed settings), highly mobile populations and other epidemic-specific high-incidence populations (e.g., people in fishing communities, migrant workers, long distance truck drivers, etc.). A growing evidence base establishes that oral pre-exposure prophylaxis (PrEP) with tenofovir or tenofovir-containing regimens reduces the risk of HIV acquisition among

numerous populations.[37,38,39,40] WHO guidelines recommend offering oral PrEP to those at substantial risk of HIV infection.[41] Oral PrEP is a proven, safe, scalable intervention that can drastically reduce new HIV infections.[42] In 2020, WHO guidelines recommended the PrEP ring as an additional prevention choice for women. In 2022, the WHO recommended CAB-LA be offered as an additional prevention choice for people at substantial risk of HIV infection. The use of PrEP is an important part of a package of comprehensive primary prevention services that includes condom and lubricant promotion, post-exposure prophylaxis (PEP), VMMC, risk reduction education, harm reduction, and other structural interventions to reduce vulnerability to HIV infection. In COP20, PEPFAR made oral PrEP a core programmatic requirement and set and met an overall goal of newly initiating over one million people on PrEP in FY 2021. With countries successfully adapting programs to continue prevention service delivery in the time of COVID-19, the global scale up of PrEP continues in COP22.

Adoption of equitable national policies that ensure broad access to and availability of PrEP are the foundation of quality PrEP program implementation. PrEP services require, at a minimum: trained providers capable of providing person-centered consistent and accurate information and messaging, quality guidelines and SOPs, HIV testing services, planning and M&E systems, available and sufficient stocks of PrEP, and routine inquiry for gender-based violence (GBV), including intimate partner violence (IPV) and referral for GBV services. These components are essential to avoiding confusion and empowering eligible individuals to initiate PrEP. Importantly, to prevent negative consequences and improve effective use of PrEP, new or suspected cases of GBV, including IPV, must be identified and provided necessary GBV response services per WHO clinical guidelines (see Section 6.2.2.1 Pre-Exposure Prophylaxis for Adolescent Girls and

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[37] iPrEX: Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men N Engl J Med 2010;363(27):2587-99
[38] TDF2: Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. N Engl J Med 2012;367(5):423-34
[39] Partners PrEP: Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women N Enel J Med 2012;367(5):399-410
[40] Bangkok Tenofovir Study: Company K, Martin M, Sundararajan P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial . Lancet 2013;381(9883):2083-90
[41] World Health Organization. WHO expands recommendation on oral preexposure prophylaxis for HIV infection. Accessed on 8/24/2020. Available at: https://www.who.int/hiv/pub/prep/policy-brief-prep-2015/en/
[42] Koss, C et al. (2021). HIV incidence after pre-exposure prophylaxis initiation among women and men at elevated HIV risk: A population-based study in rural Kenya and Uganda. PLoS Med. 18(2): e1003492. https://doi.org/10.1371/journal.pmed.1003492 .

Young Women). Screening for GBV including IPV should be happening at PrEP initiation and PrEP continuation visits, and, of note, the experience of violence does not make one ineligible for PrEP. Providers should be appropriately trained to offer clients first-line support (e.g., LIVES) and referrals for clients who disclose experiences of violence. Resources have been developed to support the integration of IPV inquiry and referral into PrEP services.[43] PrEP can also be integrated into GBV services.

Countries that have been implementing oral PrEP for a few years should be working towards normalization of PrEP in addition to PrEP saturation in highest risk populations. Prioritization of risk groups for scaling up PrEP must be evidence-based and, in addition to HIV incidence rates, can be informed by coverage estimates, recency testing, PHIAs, and/or other survey data (see Targeting for PrEP section below). Scaling up PrEP should include demand creation efforts and usage continuation efforts tailored to priority groups and may have unique population-specific requirements. However, all those who report more than one sexual partner, inconsistent condom use, and/or share drug use injection equipment, may benefit from PrEP. Therefore, the pairing of targeted communications with more general PrEP normalization efforts that look to decrease stigma, increase awareness, health literacy, uptake, and continued use generally among all people who may benefit from PrEP should also be considered. Programs should tailor their messaging to address the needs of different populations and service delivery points, for example, within DREAMS programs, family planning services, post-violence clinics, and maternal and newborn child health (MNCH) settings where services can also be extended to male sexual partners. Private sector partnerships can be leveraged to support demand creation efforts and to ensure a people-centered approach, particularly for priority risk groups. Country programs can look to MenStar an example of how private sector partnerships apply a people-centered approach and innovative demand creation to improve healthcare for men at each stage of the HIV treatment cascade.[44] The quality of services will also depend on appropriate provider education and consistent messaging and information. These are essential to avoid creating confusion, mistrust, and misuse of PrEP in communities. Among other topics, consistent information on eligibility, use, lead-in times for effectiveness and dosage, and interaction with hormones and family planning, is critical.

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[43] https://www.prepwatch.org/resource/sop-job-aid-ipv-prep-services.
[44] https://www.menstarcoalition.org/

In 2022, WHO released updated implementation guidelines that emphasize integrated, differentiated, and simplified PrEP services.[45] Country teams should work to align national policies with the updated WHO guidelines to streamline PrEP services and decrease barriers to PrEP use. In COP22, PrEP should be available in all HIV service delivery points (including HTS, ART clinics, ANC/PMTCT clinics, DREAMS settings, STI testing and treatment, and KP services) and in a client-centered manner that considers DSD approaches such as decentralized dispensing, MMD, and task shifting of PrEP maintenance visits to lay providers and other community and facility-based models. WHO guidance also stresses that routine STI control is an essential component of prevention services. Client-centered approaches should also include the event driven PrEP (ED-PrEP) option for people who are assigned male at birth who do not use exogenous estradiol-based gender affirming hormones (See Section 6.5 PEPFAR's Key Populations Approach and Strategy) and include stigma reduction education for PrEP providers. PrEP should continue to be linked to HIV testing services and OUs should ensure that all HIV-negative contacts of index clients are immediately linked to the full package of comprehensive prevention interventions including PrEP. All individuals testing negative for HIV should be linked to appropriate prevention interventions, including PrEP, using an informed choice and gain-framed counseling to support individuals in selecting the best combination prevention modalities that fit their life, understanding that their preferences and needs may change over their life course. Importantly, anyone who directly requests PrEP should be offered PrEP, even if they do not wish to disclose the reason for their request or risk context.

Some clients presenting for HIV testing and/or PrEP may have had a recent exposure that has potential for HIV transmission. In alignment with WHO guidelines, these individuals should be offered and initiated on post-exposure prophylaxis (PEP) as early as possible, ideally within 72 hours of potential exposure.[46,47,48] PEP is the use of ARV drugs by people without HIV, who may have been exposed to HIV, to prevent acquisition. WHO recommends that in emergency situations where HIV testing and counseling is not readily available but the potential for HIV acquisition is high or when the exposed person refuses initial testing, PEP should be initiated, and HIV testing, and counseling undertaken as soon as possible.

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[45] https://www.who.int/publications/i/item/9789240053694
[46] https://www.who.int/hiv/pub/prophylaxis/en/
[47] https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf?ua=1
[48] https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1

WHO guidelines for PEP cover all types of potential exposures to HIV, in all population groups, including adults, adolescents and children. PEP is an additional HIV prevention tool and a key component of both the comprehensive HIV prevention package and the minimum package of post-violence clinical care services. Like PrEP policies and programs, country teams should ensure that PEP policies and programs that align with WHO guidance and that support its access and use for all potential exposures to HIV are in place. PEP should NOT be restricted to healthcare providers or others with potential occupational exposure and should never require anyone, including survivors of sexual assault, to file reports with law enforcement to access PEP.

Information about PEP and how to access and use PEP should be included in PEPFAR programs across prevention and treatment programs and include a component to increase public awareness as well as a plan to streamline/fast track the process for a client to receive this service. Use of PEP in the past six months is an indication that a client might benefit from PrEP to prevent HIV acquisition. Clients completing PEP and testing negative for HIV should be linked to prevention interventions including PrEP and can start PrEP, ideally without a gap between PEP and PrEP, if the client is willing and it is otherwise indicated, in alignment with PrEP guidelines. Clients starting PrEP who then have an exposure to HIV before full protection from PrEP has been achieved should be considered for PEP.[49]

Additional guidance on and references to PEP can be found in Sections 6.6.2.1 (Gender-Based Violence and Violence Against Children), and 6.7.1 (Infection Prevention and Control).

**New Biomedical Prevention Modalities**

Biomedical HIV prevention is an active area of new product research and advanced development. New ARV-based prevention products such as the vaginal PrEP ring, long-acting injectable ARVs, long-acting oral PrEP, multi-purpose technologies, patches, and implants are quickly progressing through regulatory approvals or late phase clinical trials. To facilitate the introduction of new biomedical prevention options and therefore realize the potential for new products to reduce HIV incidence in vulnerable populations, a proactive approach to national policy and guideline development for new products will be required. Once introduced into the market, partnerships with private sector can be utilized to address potential barriers in uptake and continued use of these biomedical interventions.

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[49] https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1

The vaginal PrEP ring is a woman-controlled prevention product that has been approved and is available as an alternative option.[50] The European Medicines Agency issued a positive scientific opinion on the ring in July 2020, with the full product indication for the ring as: "To reduce the risk of HIV-1 infection via vaginal intercourse in HIV-uninfected women 18 years and older in combination with safer sex practices when oral PrEP is not or cannot be used or is not available." The ring is now on the WHO prequalification list and has been approved for use in several countries, with additional national registrations occurring on a rolling basis. PEPFAR is currently only procuring the PrEP ring for PEPFAR-funded implementation science studies. PEPFAR will actively work with countries and other donors who can procure the PrEP Ring and will fully support programmatic implementation when procured by these other parties (e.g., the Global Fund).

Long-acting injectable cabotegravir (CAB-LA) for PrEP has been approved for use by the U.S. FDA as well as the Australia Therapeutic Goods Association, the Zimbabwe National Medicines Registry, and the South African Health Products Regulatory Authority with additional regulatory submissions underway in several other countries. CAB-LA is a long-acting injection, delivered intramuscularly every two months, providing a potentially discrete, powerful new option for HIV prevention. In July 2022, WHO published normative guidance on the use of CAB-LA for PrEP and implementation is in various planning stages. PEPFAR leadership has been engaging directly with the manufacturer of CAB-LA (ViiV) and other critical stakeholders (donors, multilateral agencies, global CSOs) to help facilitate an effective rollout of CAB-LA as part of our broader approach to enable choice in prevention. In the first 2- to 3 years of formal implementation, we expect a relatively small number of doses to be available (relative to the size of the oral PrEP portfolio). Given the relative scarcity of product, a continued priority is to scale up PrEP as a whole in alignment with promoting a broader prevention strategy. PEPFAR intends to work with countries and other donors on roll-out strategies to substantially impact programmatic outcomes and ensure a successful product integration into the portfolio of prevention services.

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[57] https://www.ema.europa.eu/en/news/vaginal-ring-reduce-risk-hiv-infection-women-non-eu-countries-high-disease-burden

Studies on islatravir (formerly MK-8591), an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) formulated as a once-monthly oral pill, were recently discontinued by the innovators, and this drug is no longer being studied as a prevention option.

Lenacapavir is an investigational long-acting HIV capsid inhibitor recently approved for HIV treatment and in development for the prevention of HIV infection. It is currently being investigated in a phase 3, double blind trial as a subcutaneous injectable PrEP option administered every 6 months. Taken together these products and others could represent additional options for biomedical prevention in the not-too-distant future.

In COP22, preparatory work is encouraged to support an enabling environment for and identify implementation needs related to new product regulatory approval, supportive policies, service provider education, service delivery channels, demand generation, and procurement. As new products are introduced to the marketplace, they should be presented with thorough information on all available HIV prevention options, including each method's relative efficacy and safety, and with counseling and adherence support, allowing for an informed choice regarding biomedical HIV prevention options. Lessons learned from oral PrEP service delivery programs, and monitoring and evaluation of oral PrEP programs, will provide important information for the introduction of new biomedical prevention interventions, and aid in maximizing the impact new products may have for reducing new infections in vulnerable populations.[51] Those who prefer an alternative to daily oral PrEP or for whom ED-PrEP is not indicated or are unable to adhere to daily dosing, may soon have multiple new options and formulations to consider as part of a comprehensive biomedical prevention program.

**Budgeting for PrEP**

As PrEP products and services are scaled up and/or expanded in an OU, the costs of demand creation, rolling out and disseminating new PrEP guidelines/SOPs and training staff in screening, initiation, and maintenance of effective PrEP use should be accounted for in the budget and must be focused. However, once implemented, PrEP activities including staffing should be covered within the budget of the service onto which it has been added, such as HTS, ANC/PMTCT, DREAMS settings, VMMC, and key population services. PrEP services should leverage and promote differentiated service delivery models across the full continuum of care. Prevention, like

[51] https://www.avac.org/infographic/years-ahead-hiv-prevention-research

all HIV services, should be designed to meet the needs of clients. Clients should be engaged across the life of development of services and programs. Models will vary by venue and population and may include a range of facility- and community- based innovations depending on country context and prevention product type. Integrating PrEP into existing prevention or treatment services maximizes efficiency and broadens access. Budgets and targets must be fully consistent with a program's focus–in other words, no one should be reached without a full evaluation of prevention and treatment needs; thus, all reached individuals need to be offered HIV testing as a component of prevention and treatment services. It is expected that most of these elements (e.g., staff time) may already be budgeted for under other existing PEPFAR program elements or supported by non-PEPFAR funding (e.g., partner governments, other donors).

With PrEP budgets only incorporating what is new or additional to existing HIV or other services, the primary drivers of the OUs PrEP budget are the cost of commodities (including new products) and the increased volume of patients receiving PrEP services. PrEP budgets may include commodities such as ARVs, rings, laboratory tests, HIV testing, and condoms/lubricants, as well as costs for demand creation. It is important to consider both the incremental cost to PEPFAR of scaling up PrEP (specific resources provided by the PEPFAR implementing partner) and to the national program and that each partner in the effort is aware of and committed to providing the budgeted resources. OUs should consider the key stakeholders they should engage with on PrEP, including community organizations, partner governments, prevention or PrEP technical working groups in country, and other donors supporting PrEP implementation. Attention should be paid to leveraging domestic financing and/or other funding sources (e.g., the Global Fund) for PrEP to support scale up and enhance sustainability.

More detailed examples of budget considerations are listed below:

a) Communication, Social and Behavior Change for PrEP Demand Creation

PrEP demand creation messaging can be integrated into existing prevention and treatment program communications materials, strategies, and platforms (including virtual platforms), whenever possible. For instance, information on PrEP can be incorporated into sexual and reproductive health curricula being developed for and budgeted under HIV prevention activities for AGYW or the finding-men-initiatives. To reach specific populations such as women of reproductive age and their partners, social and behavioral change approaches that address

PrEP as part of a package of healthy behaviors should be integrated into existing programs such as FP, ANC, HIV Testing, and when screening for STIs.

b) Laboratory Testing

A negative HIV test is required to initiate PrEP. The WHO recommends, and PEPFAR supports, the initiation of PrEP without kidney function testing. In July 2021, WHO updated guidance on creatinine testing to be optional for individuals less than 30 years of age with no kidney-related comorbidities. Individuals 30 years or older and those younger than 30 years old with comorbidities can be screened once within 1-3 months after oral PrEP initiation. More frequent screening than once is only recommended for individuals of any age with a history of comorbidities such as diabetes or hypertension, those 50 years or older, and those who have had a previous creatinine clearance result of <90 ml/mn. For these oral PrEP users, a screening every 6-12 months thereafter can be considered. Waiting for creatinine screening results should not delay starting PrEP.

After PrEP initiation, HIV testing should be offered every 3 months to monitor for seroconversion. During the COVID-19 pandemic, some OUs experienced disruption to HIV testing services and began using HIV self-tests to maintain essential services, including for initiating and monitoring ongoing PrEP use. Given the recent WHO guidance updates,[52] PEPFAR supports the use of HIV self-testing to facilitate easier access to and effective use of PrEP for prevention. OU teams may incorporate HIVST to support PrEP use as applicable to their programs. Expected testing volumes for the PrEP program should be shared with the appropriate laboratory and commodity procurement planning units (see commodities below). In addition, programs should refer to the updated WHO recommendations on hepatitis B and hepatitis C testing (particularly for key populations), which is not required before initiating PrEP, but is similarly good practice to test new PrEP users especially in areas with high prevalence.

c) Personnel

As discussed above, in most settings, PrEP will be added to existing services, and the number of additional staff depends on the scale-up and size of PrEP targets and capacity of current staff. HIV testing and oral PrEP drug refills are recommended every three months. The personnel that will be involved in PrEP administration include clinical and non-clinical staff: clinicians, laboratory

[52] https://www.who.int/publications/i/item/9789240053694

technicians, community educators, community health workers, advocates, counselors, and others. Task sharing is recommended for successful implementation. De-medicalization of PrEP services should also be considered where possible and like service integration, may take different form in different countries. For example, implementing task shifting away from requiring doctor-driven delivery of PrEP and decentralizing services as much as feasible may allow for multiple access pathways for clients. Programs are encouraged adapt prevention interventions at both the facility and community levels to expand equitable access and use. To facilitate up-take and scale-up of PrEP, PEPFAR partners can consider budgeting for the costs of peer educators/navigators or other community support for effective use of PrEP.

d) Commodities

Tenofovir, tenofovir/emtricitabine, or tenofovir/lamivudine for oral PrEP and the vaginal PrEP ring are all acceptable regimens according to WHO guidelines. OU teams should select PrEP regimens based on regulatory approvals and availability in-country. Monthly expected numbers of patients requiring PrEP products, HIV rapid test and HIV self-test kits to be used, condoms/lubricant, and laboratory monitoring test volumes for the PrEP program should be estimated in conjunction with the appropriate laboratory and commodity procurement planning units within the national program. Forecasting should include considerations for duration of PrEP use, product mix, multi-month dispensing, buffer stock, expiry, warehousing and distribution, lead time for delivery to country and delivery to point of service, stock-outs, and influence on the ART supply chain. Teams should consult commodities experts at HQ for any technical assistance needed with commodity forecasting, product mix, confirming whether their country is eligible for subsidized ARV procurement, or any other PrEP commodities-related questions.

**Target Setting for PrEP**

Part of ensuring that PrEP is reaching the people who need it is engaging in a thoughtful, evidence-based national target-setting process to ensure that adequate coverage can be achieved with the resources available. Countries newly implementing PrEP, in consultation with partner governments, should begin by determining which populations are appropriate to offer PrEP. Various sources of information—including HIV testing yield data, recent survey, or surveillance data, and/or other study data that applies to the sub-population—can be used to determine whether these populations are at substantial risk for HIV acquisition as defined by WHO guidelines. PrEP rollout has gained traction and support globally over recent years and can be targeted for vulnerable or key populations, as well as for those that have challenges with

using other prevention interventions and/or in PEPFAR priority sub-national units. Once the populations have been prioritized, several resources have been developed to help identify individuals within these groups that may be at higher risk of HIV acquisition and can be found on http://www.prepwatch.org.

Focusing on risk groups will help to prioritize services and develop tailored demand creation materials, however, it should be acknowledged that risk groups often overlap, and steps must be taken to ensure the PrEP intervention is not stigmatized by association with only one group nor a certain group further stigmatized using PrEP. Moreover, risk alone should not determine use or be used to restrict access to PrEP. All people who report more than one sexual partner and inconsistent condom use may benefit from PrEP.

To understand the scope and impact of PrEP scale-up, OUs should look at PrEP coverage (# individuals initiating (and continuing)/people at risk) in a priority population and considering saturation in highest risk populations. The coverage numerator is a combination of both people newly initiating PrEP and people who continue to use PrEP over time. PrEP use is most often not lifelong and can be started and stopped based on a person's risk of acquiring HIV. Each OU should look at strategies to communicate risk and to promote and measure continued PrEP use where substantial risk of HIV acquisition persists. Surveillance studies such as PHIAs can provide an avenue for measuring PrEP coverage and HIV incidence at the population level.

Tools to facilitate target setting for PrEP have been developed. PrEP-it 2.0 may be a useful tool in developing country targets, costs, and commodity forecasts, estimating capacity to deliver PrEP services, and tracking the PrEP initiation cascade.[53] In countries where population sizes are poorly specified, teams should support efforts to get accurate estimates of key and vulnerable populations with reasonable upper and lower bounds. However, imprecise population size estimates should not limit efforts to provide PrEP. Program data and recency testing, if being implemented in the country, can also inform PrEP estimates.

For countries not currently implementing PrEP, funding allocated in this area must have a definitive start date for the launch of PrEP services established with the partner government before any investment is made. Teams should factor in the anticipated start date in determining

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[53] https://prepitweb.org/

targets and budgets. Teams should develop a process for target-setting in consultation with the partner government. Note that some assumption of rates of uptake and continuation, which consider willingness and ability to use and continue PrEP, should be made according to the most recent data found in the literature.

Additional PrEP resources can be found at the following links: PrEP service delivery is a particularly active area of investigation and new information is available regularly. Teams are encouraged to consult implementation subject matter experts (ISMEs) and vet information to ensure programs are up-to-date with the latest recommendations and WHO Guidance.

- Readiness materials, training materials, monitoring and evaluation (M&E) materials, advocacy materials, and demand creation materials including communications tools: www.prepwatch.org (landing page for multiple tools and resources) and www.accelerator.prepwatch.org Some of these materials are specifically for AGYW.
- Implementation tools: https://www.prepwatch.org/options-tools-resources/; and www.conrad.org/launchingV
- WHO PrEP implementation and M&E tool: https://apps.who.int/iris/bitstream/handle/10665/279834/WHO-CDS-HIV-18.10-eng.pdf?ua=1
- WHO PrEP implementation tool for adolescents and young people: https://apps.who.int/iris/bitstream/handle/10665/273172/WHO-CDS-HIV-18.13-eng.pdf?ua=1
- Guideline templates for daily oral PrEP, event-driven PrEP, and the ring: https://www.prepwatch.org/promise-choice-tools-resources/
- HIV Prevention Ambassador Training Package and Toolkit: https://www.prepwatch.org/resource/ambassador-training-package/
- Oral PrEP eLearning Resource Package: https://hivoralprep.org/
- Addressing IPV in PrEP Services: https://www.prepwatch.org/resource/sop-job-aid-ipv-prep-services/

## 6.2.2 Prevention for Adolescent Girls and Young Women

Despite substantial declines in the number of new HIV infections, the epidemic among **females aged 15-24** in sub-Saharan African countries remains significant. In 2020, adolescent girls and young women accounted for 78% of new infections in young people aged 15-24 years in Eastern

and Southern Africa.[54] In 2020, around 4,200 AGYW aged 15-24 acquired HIV every week, despite the dramatic increase in 15-24-year-olds due to the youth bulge in sub-Saharan Africa.[55] AGYW in Eastern and Southern Africa remain up to 14 times more likely to be infected with HIV than their male peers.[56] The 2019 ECHO trial, enrolling women requesting contraception in Eswatini, Kenya, South Africa, and Zambia, demonstrated incidence rates over 3/100 women despite inclusion of prevention education at each visit.[57] Incidence rates over 5/100 women were seen in several South African sites, with the highest rate being 6.8/100 women.[58] The COVID-19 pandemic and associated control measures have resulted in the disruption of critical health services globally and threaten to reverse gains in HIV epidemic control. Evidence suggests that the impact of COVID-19 may be more acute for AGYW, an already disadvantaged population. COVID-19 has contributed to compounding physical and SRH risks, including increased incidents of violence, unplanned pregnancies, and transactional sex—further increasing their risk factors for HIV acquisition and creating even more urgency to reduce HIV among this population.[59] For many countries, comprehensive prevention and treatment programs are needed to break the cycle of transmission that continues to disproportionately impact AGYW.

### 6.2.2.1 Pre-Exposure Prophylaxis for Adolescent Girls and Young Women

***PrEP and DREAMS***. Pre-exposure prophylaxis (PrEP) is an essential part of the DREAMS core package as it directly reduces the risk of HIV acquisition for AGYW. In COP22, all DREAMS OUs should be aggressively scaling up PrEP as part of their core package. If PrEP is not available,

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[54] UNAIDS http://aidsinfo.unaids.org/

[55] UNAIDS. (2021). Fact Sheet 2021: Global HIV Statistics. https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

[56] PHIA Project Resources. https://phia.icap.columbia.edu/resources/. ICAP. 2020.

[57] Evidence for Contraceptive Options and HIV Outcomes (ECLHO) Trial Consortium. (2019). *HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomized, multicentre, open-label trial*. Lancet. Jul 27;394(10195):303-313. doi: 10.1016/S0140-6736(19)31288-7. Epub 2019 Jun 13. https://www.ncbi.nlm.nih.gov/pubmed/?term=Evidence%20for%20Contraceptive%20Options%20and%20HIV%20Outcomes%20(ECHO)%20Trial%20Consortium%5BCorporate%20Author%5D

[58] ECHO Trial Consortium. (2019). *High HIV incidence among young women in South Africa: data from the ECHO trial*. Abstract LBPEC23, International AIDS Society Conference, Mexico City, July 2019.

[59] Oulo, B., Sidle, A.A., Kintzi, K., Mwangi, M., Akello, I. (2021). *Understanding the Barriers to Girls' School Return: Girls' Voices from the Frontline of the COVID-19 Pandemic in East Africa*. AMPLIFY COVID-19 Research Brief. Nairobi, Kenya.

OUs should have a detailed plan for how they will work with their ISMEs, Chairs, and PPMs to remove policy, supply chain and structural barriers to providing PrEP for vulnerable AGYW within COP22.

- OUs who are currently implementing PrEP for AGYW should continue to expand PrEP targets for AGYW (where saturation has not yet been reached) and also support effective use and demand creation as necessary, in beneficiaries already using PrEP.
- PrEP targets for AGYW should be set based on need estimates and coverage estimates for the population of AGYW at highest risk, rather than simply the results/targets from COP21 (see Section 6.2.1 on PrEP tools). A justification of proposed targets compared to needs should be included in the COP22 proposal. Targets will be closely reviewed by AGYW ISMEs and S/GAC DREAMS country contact to determine that scale-up is fully underway. Biomedical prevention is an active area of research and advanced development. New ARV-based products such as long-acting injectable ARVs, implants, vaginal rings, and patches are rapidly progressing through regulatory approvals. OUs should have an active group tracking which of these methods will become available in the OU and begin planning for rollout to increase prevention choices for AGYW. Teams should not wait until products are available to start planning for rollout of new technologies. For more details, see Section 6.2.1.

All DREAMS OUs are required to include PrEP information and education within their primary package of services for AGYW ages 15-24 (including information about helping AGYW understand their individual risk for HIV), and all should include PrEP services (initiation/refills and continuation counseling/support) as part of their secondary package for vulnerable AGYW who meet the criteria for being offered PrEP. PrEP information and education will assist AGYW in identifying seasons of risk during which they should be using additional protection and can be integrated into existing activities across the DREAMS Core Package (i.e., PrEP user clubs in Safe Spaces, PrEP ambassadors, etc.). PrEP should be prioritized for young women at the greatest risk of HIV acquisition, including those who are pregnant or breastfeeding or who may be having transactional sex. Please refer to Section 6.2.1 for more information about at-risk groups. All AGYW who seek out PrEP and are determined to use it, whether or not they disclose their reasons for doing so, should receive PrEP services as well. Risk alone must not determine AGYW access to PrEP. AGYW receiving PrEP should also be offered condoms and lubricants and access to other contraceptive services to reduce risk of STI acquisition and unplanned pregnancy, in conjunction with client-centered counseling.

Governments and cross-sectoral ministries must be engaged in PrEP delivery for AGYW (e.g., Ministries of Health, Education, Youth). OUs should continue to advocate for PrEP-friendly national policies, especially for adolescents, and regulations that include access for AGYW in all high-burden geographic areas and are not limited only to female sex workers or AGYW in serodifferent couples. AGYW, including DREAMS and PrEP ambassadors, should be meaningfully engaged in advocacy and sensitization efforts. In countries where PrEP is not available beyond those populations, OUs must create detailed plans to seek policy solutions with local governments for expanding access to all vulnerable AGYW. Country teams should also continue to advocate with local governments around lowering the age of consent for PrEP, ideally, to be aligned with age of consent for contraceptive use to facilitate delivery of HIV prevention and SRH services together as part of PEPFAR's integration efforts.

In addition to providing PrEP in facility-based settings, it should also be offered to DREAMS participants through community delivery in line with client-centered approaches (e.g., DREAMS on Wheels mobile units and DREAMS Safe Spaces). Regardless of location, PrEP initiation for DREAMS beneficiaries should follow the same IPV screening requirements and provision of first-line support (e.g., LIVES) for identified cases of GBV (see Section 6.2.1). Due to the COVID-19 pandemic, DREAMS programs quickly adapted PrEP service delivery innovations (e.g., virtual demand creation; small, physically distanced support groups; virtual support for PrEP continuation through SMS and WhatsApp groups or other technology; multi-month dispensing of PrEP; alternate testing modalities) in order to continue to provide the product to clients. DREAMS OUs should identify those strategies that were most successful and work to strengthen and scale these up in COP22, as appropriate within national and local regulations.

***PrEP and non-DREAMS AGYW.*** Sexually active non-DREAMS AGYW in high-incidence areas should also be prioritized for PrEP introduction. All AGYW who seek out PrEP and are determined to use it, whether or not they disclose their reasons for doing so, should receive PrEP services as well. In geographic areas of high HIV risk, all service delivery points, e.g., ANC, PNC, HTS, FP, GBV response, and KP drop-in centers, should offer AGYW HIV testing, and referrals or provision of PrEP as indicated. Hotspot or incidence mapping can also support identification of locations of high risk for AGYW. PrEP services for AGYW should follow the DREAMS approaches explained in the previous section as well as the general PrEP and PEP guidance (see Sections 6.2.1 and 6.2.4.2).

***Routine or Clinical Enquiry for Intimate Partner Violence in PrEP Service Delivery***. To prevent negative consequences and improve effective use of PrEP among AGYW and adult

women, routine enquiry to screen for intimate partner violence (IPV) should be conducted as part of PrEP initiation counseling. Clients who disclose experiencing violence or fear of violence must be provided first-line support (e.g., LIVES) and counseled on safety issues and how to use PrEP safely in the context of their relationship. Because IPV is a barrier to PrEP initiation and adherence, strategies to mitigate the effects of IPV on PrEP outcomes should be discussed. Experience of IPV should not disqualify a potential user from PrEP access. Any service providers counseling and prescribing PrEP to AGYW and adult women should follow the guidance provided in Section 6.6.2.1 on GBV and Section 6.6.2 on Gender Equality.

## 6.2.2.2 The DREAMS Partnership

Summary of section edits:

- The "DREAMS Maintenance" section was changed to "DREAMS programming in saturated SNUs" and wording was updated to remove the maintenance plan requirement.
- "GeneXpert" and replace with "multi-disease testing platforms" so as not favor one manufacturer or instrument given there are many options on the market.

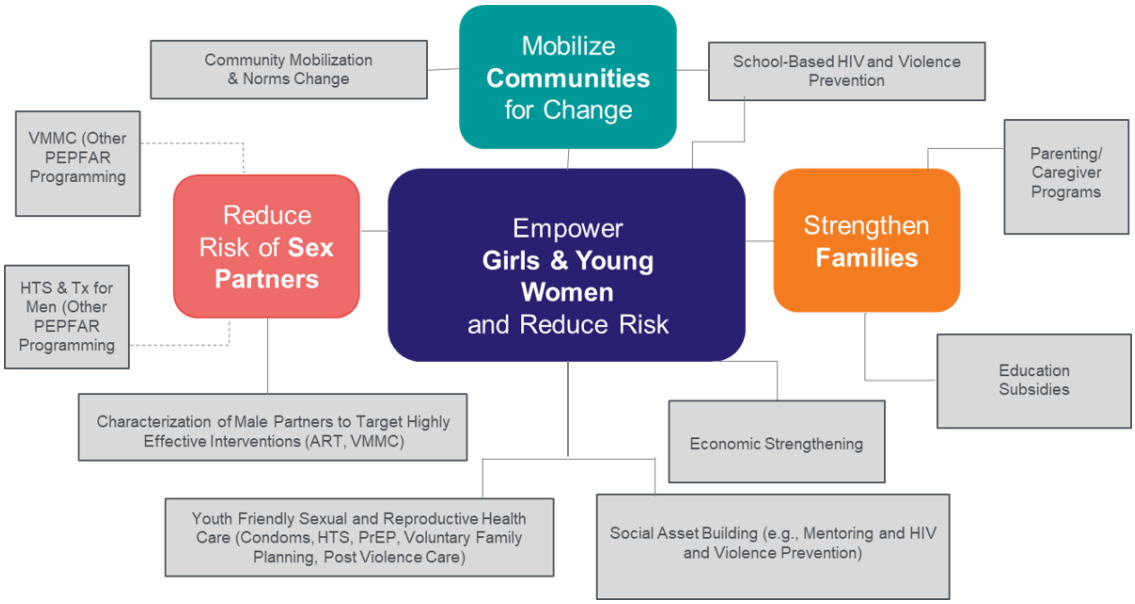
Launched on World AIDS Day 2014, the DREAMS Partnership focuses on reducing HIV incidence in AGYW through a multi-sectoral, comprehensive package of evidence-based interventions. The DREAMS core package, illustrated in Figure 6.2.2.2.1, layers interventions that address individual, community, and structural factors that increase AGYW's HIV risk, including gender inequality, gender-based violence, and limited access to education and economic opportunities. DREAMS has now been implemented for over five full years and has expanded to a total of 15 countries.

Modeling data of new HIV diagnoses in ANC among AGYW since 2015 continue to show impressive declines in DREAMS geographic areas in the 10 original countries. As of Worlds AIDS Day 2020, all DREAMS geographic areas showed a decline of new HIV diagnoses among AGYW, and the majority (62%) showed a decline of greater than 40%. PEPFAR continues to assess best practices that should be scaled, and conversely what should be course corrected for COP22 implementation. Figure 2.1.2.21 in Section 2.1.2 shows the average percent decline of new HIV diagnoses in ANC in DREAMS geographic areas.

## DREAMS IMPLEMENTATION

In COP22, all 15 DREAMS countries should follow the updated DREAMS Guidance,[60] as well as the COP22 specific guidance in this section to refine their programming. (See Section 6.6.2 and 6.6.2.1 for additional information on gender equality, GBV, and violence against children)

*Figure 6.2.2.2.1: DREAMS Core Package*




***Meaningful Engagement of* AGYW.** Country teams must establish or work with existing mechanisms to enable meaningful AGYW participation in DREAMS. For example, DREAMS mentors and ambassadors, AGYW-led organizations and/or an AGYW-led advisory council should participate in the design, implementation, and monitoring of DREAMS. Furthermore,

[60] PEPFAR. (2021). *PEPFAR DREAMS Guidance* (revised). https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf

AGYW should receive training and support that will prepare them for their roles, including opportunities for professional growth where possible.[61]

***Finding and Engaging the Most Vulnerable AGYW.*** DREAMS programs should use targeted entry points and eligibility criteria that are based on scientific literature and consistent across partners and SNUs to reach AGYW who are the most vulnerable to HIV For specific criteria see DREAMS Guidance[62], but note that HIV status should not be used as a criterion for inclusion or exclusion in DREAMS.

AGYW should be actively consulted in the identification and mapping of entry points. All OUs must actively identify and engage out-of-school AGYW 10-19 years and collaborate with PMTCT platforms, ANC clinics and GBV service delivery points, as well as HTS, STI and FP settings, to create strong referral networks and enroll AGYW the most vulnerable to HIV who meet the DREAMS eligibility criteria.

Specific sub-groups of AGYW may experience more risk and vulnerability factors as outlined in the DREAMS guidance.[63] OUs should make a concerted effort to find and screen the following sub-groups of AGYW for DREAMS eligibility: Pregnant, breastfeeding and/or parenting AGYW, out-of-school AGYW 10-19 years old; AGYW living with disabilities; survivors of sexual violence; and AGYW engaged in transactional sex/selling sex and gender and sexual minorities (in collaboration with the key populations team). OUs may also need to target highly vulnerable AGYW sub-groups specific to the OU context (e.g., migrant AGYW, AGYW on or near military installations) if data show increased vulnerability to HIV for that group.

***Layering & Linkage.*** Layering, or the provision of multiple evidence-based interventions/services from the DREAMS core package to each active DREAMS beneficiary, is a core principle of DREAMS. Rather than depending on passive referrals, layering should take place by actively linking AGYW to services and tracking completed services/interventions, similar to what is done in the clinical cascade. See DREAMS Guidance[64] for details and promising practices on layering and linkage. In COP22, all DREAMS OUs should budget for reliable

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[61] UNICEF, 2020. Engaged and heard! guidelines on adolescent and civic engagement, https://www.unicef.org/media/73296/file/ADAP-Guidelines-for-Participation.pdf

[62] PEPFAR, 2021. *PEPFAR DREAMS Guidance* (revised). https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf

[63] Ibid.

[64] Ibid.

electronic databases that use unique identifiers for each AGYW to track the completion of services/interventions in line with their layering tables. Please refer to the MER 2.6 AGYW_PREV indicator reference sheet for more information.[65] As part of COP22 development, all DREAMS OUs should submit updated DREAMS Layering and Intervention Completion Tables to OGAC and their AGYW ISMEs, detailing the primary, secondary, and contextual package of services for each DREAMS age band (10-14, 15-19, 20-24).

***Finding Efficiencies.*** In COP22, OUs currently implementing DREAMS should continue to assess the efficiency of their core package using the DREAMS Efficiency Questions.[66] This becomes especially critical as OUs reach saturation and/or propose to expand into new geographic areas or in SNUs where OVC and DREAMS overlap.

***DREAMS Expansion.*** In COP22, some countries may want to consider broadening geographic coverage beyond the current DREAMS SNUs to other prioritized SNUs. Consideration of DREAMS geographic expansion should be made by each OU team in consultation with their Chair, PEFPAR Program Manager, AGYW ISMEs, and the S/GAC DREAMS team. Expansion decisions will be approved based on epidemiological need, not solely on the existence of saturated current DREAMS SNUs. OUs should use recent data from UNAIDS estimates, PHIAs, recency-based surveillance, demographic and health surveys, VACS, implementing partner data, and other current sources to determine areas for expansion. DREAMS geographic expansion should also take into consideration alignment with key partner programs (e.g., partner country government, Global Fund).

OUs must meet the following criteria to propose geographic expansion in COP22:

- Saturation in at least one age group in an existing DREAMS SNU
- Development of a maintenance plan for saturated SNUs (see section below)
- Capacity for expansion based on current DREAMS portfolio, including implementation of all primary, secondary, and contextual interventions in any agreed upon COP21 expansion SNUs

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[65] PEPFAR MER 2.6 https://datim.zendesk.com/hc/article_attachments/4407645101588/FY22_MER_2.6_Indicator_Reference_Guide.pdf

[66] PEPFAR SharePoint. (2020). *DREAMS efficiency questions*. DREAMS - 2018-02-01 DREAMS Efficiency Questions.pdf - All Documents (sharepoint.com).

- Epidemiological data suggesting the need for DREAMS expansion with a focus on the total burden of HIV among all age groups and HIV incidence in AGYW of at least 1% at the SNU level. OUs should also consider current gaps or potential duplication in AGYW prevention programming by local governments or other donors.

***DREAMS Saturation.*** All DREAMS countries should analyze DREAMS saturation on an annual basis to inform programming and planning processes. Saturation in DREAMS is achieved when at least 75% of AGYW most vulnerable to HIV in a DREAMS SNU have completed the appropriate package of DREAMS interventions for their age group. Specific guidance on estimating DREAMS saturation is detailed in the *Program Completion and Saturation* section of the DREAMS Guidance[67] and Process Resources[68] on PEPFAR SharePoint.

**DREAMS Programming in Saturated SNUs (formerly Maintenance)**

As DREAMS SNUs reach saturation, PEPFAR should continue DREAMS contributions to prevention and epidemic control. Decisions regarding continued programming in saturated SNUs may balance potential cost savings of reduced reach of adolescent girls and young women (targets) post-saturation, and the needs of other SNU and OU-level DREAMS investments (such as geographic expansion, secondary service provision for a greater proportion of enrolled adolescent girls and young women, or increased implementation of contextual interventions). This is intended to be a fluid, country-led process.

When implementing DREAMS in saturated SNUs, PEPFAR OU teams should follow the below guiding principles:

- Reach and maintain saturation levels (defined as at least 75%) by age band and SNU.
  - Phased Approach: When one or more age bands in a DREAMS SNU is saturated, but at least one age-band is still progressing toward saturation.
  - Full saturation: When all age bands are saturated.

[67] PEPFAR DREAMS Guidance (revised). https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf
[68] PEPFAR SharePoint – Process Resources. DREAMS - Tools and Guiding Documents - All Documents (sharepoint.com)

- Continue offering services as indicated in the layering table of primary and secondary interventions by age group and individual needs.
- Adjust target setting processes; consider that the remaining adolescent girls and young women who have yet to complete the DREAMS program may be among the hardest to reach (e.g., out of school adolescent girls and young women, young women who sell sex or engage in transactional sex), require a broader set of interventions (primary plus secondary services), and include those who "age-in" to DREAMS and "age-up" between DREAMS age bands in saturated SNUs. In a phased approach, targets might increase for the age band(s) not yet saturated.
- Continue to update saturation calculations to inform target setting.

***DREAMS/OVC Collaboration.*** Programming using DREAMS and OVC funds should be closely coordinated to maximize AGYW-focused prevention activities in all DREAMS SNUs for AGYW 10-17 and young women 18-20 finishing secondary school. DREAMS AGYW aged 10-17 who receive an eligible OVC service (per MER Appendix D[69]) should be reported under OVC_SERV (as well as under AGYW_PREV). This requires co-planning and tracking of targets, budgets, and services between DREAMS and OVC PEPFAR staff and implementing partners to ensure that the complex prevention needs of AGYW are met, regardless of the platform in which they are initially enrolled. Based on epidemiological context and program enrollment criteria, teams should work to quantify the number of AGYW the most vulnerable to HIV in each SNU that should be enrolled in DREAMS, AGYW who qualify to be enrolled in the OVC comprehensive program as part of a household, AGYW who do not qualify for DREAMS or OVC comprehensive program but might participate in the OVC preventative program, or AGYW enrolled in both the OVC comprehensive program and DREAMS. For example, DREAMS participants who would benefit from family-based case management with home visits or who need more intensive child protection support should be referred to the OVC comprehensive program for enrollment screening for her family. Any minor (girls aged 10-17 in DREAMS) who discloses an experience of sexual violence should be offered support to access post-violence medical, psychosocial, and/or legal services, as well as local child welfare and protection authorities. They should also be referred to an OVC program and once enrolled supported by OVC case management. The

[69] PEPFAR. (2021). Monitoring, Evaluation, and Reporting Indicator Reference Guide (Version 2.6). https://datim.zendesk.com/hc/article_attachments/4407645101588/FY22_MER_2.6_Indicator_Reference_Guide.pdf

support should be holistic ensuring that the child can navigate multiple systems of care and support. AGYW ages 10-20 in the OVC program who need more intensive HIV prevention support should be referred to the DREAMS program for enrollment screening.

***SRHR Adolescent Friendly Services.*** One component of the DREAMS Core Package is the provision of adolescent and youth friendly services (AYFS). While these services are funded and provided through the clinical platform and budget, DREAMS may need to complement efforts for SRH services in DREAMS SNUs. In these cases, there should be a mapping and denoting of sites that have already completed this training/offer AYFS. DREAMS partners should train service providers on the provision of adolescent-friendly service delivery and emphasize the importance of empathetic, non-judgmental language. Partners should seek to establish, regularly assess and improve the quality of adolescent friendly-health services in DREAMS SNUs (see WHO[70] and UNAIDS Global Standards for Adolescents[71] for additional information).

***Partner Management.*** Partner management is critical to DREAMS performance and achievements, just as it is within the clinical cascade, therefore, DREAMS OUs should apply partner management strategies outlined throughout COP22 guidance. Specific examples of partner management for DREAMS include: 1) align DREAMS activities with DREAMS Guidance recommendations (e.g., work with ISMEs to review curricula used by partners and to establish implementation plans for delivering interventions to ensure fidelity); 2) ensure coverage, collaboration, coordination, and direct interaction between partners for planning and actively linking AGYW to services to verify layering takes place; 3) ensure that all DREAMS IPs report to the DREAMS layering database; and 4) establish routine communication with SNU-level DREAMS coordination committees and DREAMS ambassadors and mentors supporting coordination and data collection. Partners should ensure they deliver on all components of planned services and commitments to program participants. If challenges arise, partners should immediately notify the appropriate agency management to discuss challenges and mitigation strategies.

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[70] World Health Organization. (2012). Making health services adolescent friendly: developing national quality standards for adolescent friendly health services. World Health Organization. https://www.who.int/reproductivehealth/publications/adolescence/9789241503594/en/

[71] World Health Organization & UNAIDS. (2015). Global standards for quality health-care services for adolescents: a guide to implement a standards-driven approach to improve the quality of health care services for adolescents. World Health Organization. https://apps.who.int/iris/handle/10665/183935

***Responsive Programming.*** PEPFAR has sought to provide ongoing services and safe spaces for DREAMS participants in responsive and innovative ways while navigating the safety considerations of the COVID-19 pandemic. Given evolving restrictions in many countries on holding in-person, group-based activities, DREAMS partners are engaging with program participants via virtual platforms to maintain contact and provide support where feasible. Partners should refer to the Virtual Delivery of Group-Based DREAMS and Orphan and Vulnerable Children Content During COVID-19 Guidance[72] and PEPFAR Technical Guidance in the Context of the COVID-19 Pandemic[73] for the latest information and considerations.

***Identifying New Solutions to Fill Programming Gaps.*** As DREAMS matures, specific gaps and areas for program innovations and improvements have been suggested by internal and external stakeholders. The areas identified include retaining 20–24-year-olds; psychosocial support for emotional wellness, resilience, and coping skills; and reaching highly HIV-vulnerable and hard-to-reach sub-populations such as pregnant, breastfeeding, and parenting AGYW, AGYW with disabilities, and young women engaging in transactional sex or selling sex. These areas are not addressed in detail in the DREAMS guidance and therefore solutions are needed that hold potential for increasing the reach and impact of DREAMS. OUs may spend a small portion of their DREAMS funding envelope on short-term projects with rapid assessment focused on specific defined gaps. These short-term program adaptations should be small in scale (i.e., not across the entire DREAMS footprint until the concept is proven), and last no longer than one year. Recognizing the shortened timeline, OUs and partners should actively manage intervention implementation to ensure commitments to participants are kept and the full intervention is implemented. OUs should report interim observations to S/GAC and their AGYW ISMEs on at least a quarterly basis to inform future programming and guidance. These should not be formal research projects. Examples of similar projects in the past that OUs can look to as examples include Uganda's use of a QA/QI project to determine the root causes of treatment interruptions with 20–24-year-olds in DREAMS and subsequent program adaptations, and adaptations in

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[72] PEPFAR SharePoint. (2020). *Virtual delivery of group-based DREAMS and orphan and vulnerable children content during COVID-19 guidance*. https://pepfar.sharepoint.com/sites/DREAMS/Shared Documents/Forms/AllItems.aspx?id=%2Fsites%2FDREAMS%2FShared Documents%2FTools and Guiding Documents%2FCOVID-19 Guidance%2F2020-06-05_Virtual Delivery of DREAMS Content during COVID-19%2Epdf&parent=%2Fsites%2FDREAMS%2FShared Documents%2FTools and Guiding Documents%2FCOVID-19 Guidance

[73] *PEPFAR technical guidance in the context of the COVID-19 pandemic,* 08.18.21-PEPFAR-Technical-Guidance-During-COVID.pdf (state.gov)

several countries to create men's corners and hours in clinics to increase the engagement of men in HIV services.

**COP22 GUIDANCE ON SPECIFIC DREAMS COMPONENTS**[74]

***Mentoring.*** In COP22, DREAMS OUs should continue enhancing existing processes, specifically around mentor training, supportive supervision, and compensation, to ensure that mentors are supported and capacitated to provide DREAMS participants with the most effective, evidence-informed mentoring available.

1. **Training**: OUs should have a clearly defined comprehensive onset and refresher training plan for mentors that includes technical information, facilitation & mentorship skills, and first-line support to strengthen mentors' capacity to respond to disclosures of violence. This should include information on supporting children and young adolescents (including evidence-informed guidance specific to minors, curricula facilitation and delivery, information on gender expression and sexual orientation (e.g., Gender & Sexual Diversity Training[75]), and other relevant training as needed. For example, since mentors encounter trauma disclosures and may be survivors themselves, mentors should receive training in psychosocial support and communication skills to better equip them to navigate these circumstances. See Section 6.6.5.2 for additional information on psychosocial support interventions. Trainings provided to mentors should be tailored to empower mentors with supplementary resources (e.g., linkage and referral tools).
2. **Supportive Supervision and Peer Support**: Routine supportive supervision both to oversee the conduct of specific responsibilities as well as ensure the well-being of mentors must be prioritized. Roles, responsibilities and expectations of supervisors, mentors and mentees should be explicitly outlined (e.g., scope of work) and shared with mentors during onboarding and reviewed regularly to ensure alignment. Mentors should receive ongoing evidence-informed supportive supervision and be provided with standardized tools/SOPs, refresher trainings and opportunities for shared learning and peer support. IPs should also have a cadre of counselors and social workers for mentors to link AGYW to or access themselves for support. IP staff should also be trained in first-

[74] PEPFAR. (2021). PEPFAR DREAMS Guidance (revised). https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf

[75] Health Policy Project. (2014). *Gender and sexual diversity training: A facilitator's guide for public health and HIV programs*. 398_GSDGuide.pdf (healthpolicyproject.com)

line support (e.g., LIVES) as they may receive disclosures of violence from mentors and can actively support mentor's secondary trauma. See Supervision in Mentor Section of DREAMS Guidance for more information.

3. **Compensation**: Mentors should receive remuneration and resources (i.e., wages, transport stipend, airtime allowances) representative of the level of engagement with and service delivery to DREAMS AGYW. (See Compensation in Mentoring Section of DREAMS Guidance for more information.)

Please see the DREAMS Mentoring section of the DREAMS Guidance for more information.

***Economic Strengthening.*** Economic disparity related to gender inequality is an ongoing and complex driver of HIV. Scaling implementation and strengthening economic interventions continues to be a priority in COP22 with the goal of decreasing AGYW's reliance on transactional sex and strengthening AGYW's self-efficacy and decision-making power in relationships. Detailed information on implementation, required components by age band, and evidence-based comprehensive interventions can be found in the 2021 DREAMS Guidance on PEPFAR Solutions. All DREAMS participants should receive tailored financial literacy education regardless of age. Emphasis should continue to be placed on developing strong partnerships, including with the private sector, to support entrepreneurship or transition to wage employment for older and out-of-school AGYW. PEPFAR is dedicated to cultivating a resilient, inclusive, and equitable health workforce. Eligible DREAMS participants should be considered and trained for health and social service systems positions within PEPFAR, MOH and other ministries, and broader health and development organizations, such as community health workers, community led monitoring, M&E personnel, lab systems, survey data collectors, and other health systems work. Ideally, we should work to support preparing and positioning eligible DREAMS participants to enter into the health care workforce if they desire, as community health workers, nurses, clinicians, etc. OUs should also coordinate with other U.S. Embassy interagency led women's empowerment and educational programming opportunities to determine if they would be appropriate and beneficial for DREAMS participants.

***STI Testing and Treatment.*** Sexual and reproductive health services often include testing and treatment for sexually transmitted infections (STIs) as part of integrated preventative services. Recent findings from multiple studies, like the ECHO Trials and POWER, demonstrated significantly elevated rates of STIs—particularly chlamydia and gonorrhea—among women <25

in Eastern and Southern Africa, which may independently increase risk of HIV acquisition.[76,77] Although there is variation across countries, up to 42% of AGYW ages 15-24 in some of the highest HIV burdened communities present with STIs, while only roughly 9% report symptoms.[78] Strengthening STI management may decrease HIV acquisition and improve overall health benefits (e.g., decrease progression of PID, ectopic pregnancy and other sequela of STIs). In COP22, STI testing, and treatment is a permissible activity for DREAMS funding, but is not required. DREAMS teams should work collaboratively with partner country governments and clinical and laboratory partners to prioritize STI screening, testing and treatment beyond syndromic management for AGYW. OUs should leverage the use of multi-disease testing platforms beyond HIV and TB to include STIs when feasible. In countries where national guidelines reflect a syndromic approach, teams should intensify advocacy for creating an enabling policy environment. DREAMS should support creating and strengthening in-country technical capacity to implement more accurate STI screening and testing approaches.

### 6.2.2.3 AGYW Prevention in Non-DREAMS Countries

Countries without DREAMS funding should examine HIV incidence and prevalence in AGYW ages 10-24 years before dedicating significant resources to prevention in AGYW. Countries should examine which geographic areas have the highest HIV prevalence/incidence and other indicators of HIV risk such as median age of first sex, rates of adolescent pregnancy, rates of sexually transmitted infections, rates of GBV, and number of girls not in school. If data indicate that AGYW should be a priority population, the OU should base activities for this population on

[76] Ahmed, K., Baeten, J. M., Beksinska, M., Bekker, L.-G., Bukusi, E. A., Donnell, D., Gichangi, P. B., Heller, K. B., Hofmeyr, G. J., Justman, J., Kasaro, M. P., Kiarie, J., Louw, C., Mastro, T. D., Morrison, C. S., Mugo, N. R., Nair, G., Nanda, K., Nhlabatsi, Z., … Welch, J. D. (2019). HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: A randomised, multicentre, open-label trial. The Lancet, 394(10195), 303–313. https://doi.org/10.1016/s0140-6736(19)31288-7

[77] Laga, M., Manoka, A., Kivuvu, M., Malele, B., Tuliza, M., Nzila, N., Goeman, J., Behets, F., Batter, V., & Alary, M. (1993). Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: results from a cohort study. AIDS (London, England), 7(1), 95–102. https://doi.org/10.1097/00002030-199301000-00015

[78] Celum, C. L., Delany-Moretlwe, S., Baeten, J. M., van der Straten, A., Hosek, S., Bukusi, E. A., McConnell, M., Barnabas, R. V., & Bekker, L. G. (2019). HIV pre-exposure prophylaxis for adolescent girls and young women in Africa: from efficacy trials to delivery. Journal of the International AIDS Society, 22 Suppl 4(Suppl 4), e25298. https://doi.org/10.1002/jia2.25298

the current DREAMS Guidance[79] to the extent possible based on budget, with a focus on interventions most proximally related to incidence reduction such as condoms and PrEP. If data do not indicate a focus on comprehensive programming for AGYW, countries could also focus efforts on preventing HIV and sexual violence among 10-14-year-old boys and girls using evidence-based interventions (see Section 6.2.3 for more detail). If your OU does not receive DREAMS funding and is considering AGYW prevention programming in COP22 planning, please reach out to the co-leads of the AGYW Prevention COOP so that technical assistance can be provided if needed.

### 6.2.3 Primary Prevention of HIV and Sexual Violence for Vulnerable 10-14 Year Olds[80]

Adolescents face complex risks that can negatively impact their lives well into adulthood. According to nationally representative data from the Violence Against Children Surveys (VACS), HIV risks start young, given that both sexual violence and early sexual debut (occurring at the age of 15 or younger) persist at high rates. The VACS data show that 7-24% of girls and 6-46% of boys report that their sexual debut occurs at or before the age of 15, and it is often not by choice. In DREAMS countries, the VACS show that 12-54% of female respondents report their first sexual experience as forced or coerced. Furthermore, sexual violence is not limited to sexual debut, but often follows young people through adolescence and young adulthood.

Sexual violence against children (SVAC) places children on a trajectory of negative health outcomes. Short- and long-term consequences of childhood sexual violence can include physical injury, mental health challenges (e.g., depression and suicidal ideation), substance misuse, and risk for HIV and other sexually transmitted infections. PEPFAR has responded to these data by increasing its focus on the primary prevention of sexual violence and HIV among 10-14-year-olds, to try and prevent these vulnerabilities from ever occurring. These primary prevention and response interventions are implemented within the broader PEPFAR program, including comprehensive services for children, families, and community-level mobilization and social norms changes through OVC (see Section 6.6.3) and DREAMS programming (see Section

[79] *PEPFAR DREAMS Guidance* (revised), 2021. https://www.pepfarsolutions.org/resourcesandtools-2/2021/8/19/pepfar-dreams-guidance

[80] The age range for primary prevention will be aligned with DREAMS target beneficiaries beginning in FY22. Programs should begin to transition their targeting in the interim.

6.2.2.2 and Figure 6.2.2.2.1) For information regarding preventing violence against younger children including the role of parenting interventions, please see sections: 6.6.2.1 Gender-Based Violence and Violence Against Children and 6.6.3 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic.

***Approved Programming.*** In COP22, OUs should continue using the evidence-informed modules[81] developed consultatively by S/GAC to deliver primary prevention of HIV and sexual violence programming. These modules address three topics – healthy relationships, making healthy decisions about sex, and sexual consent. OUs should work with their AGYW and OVC ISMEs to add the primary prevention modules to HIV and violence prevention curricula implemented through DREAMS and OVC programming if they have not already done so. All OUs must use approved curricula for program delivery. The following curricula have been approved for all OUs:

- Families Matter! Program (FMP),
- Parenting for Lifelong Health (also known as Sinovuyo),
- Coaching Boys Into Men (CBIM),
- No Means No (formerly called IMPower).

Please work with AGYW/OVC ISMEs to ensure implementation and adaptation guidelines of approved curricula are met. Any other curricula must incorporate the three evidence-informed modules referenced above and must be approved by S/GAC and the relevant agency HQ representatives (i.e., AGYW/OVC ISMEs) prior to implementation. This includes approved curricula listed above that the OU team has adapted significantly.
S/GAC also developed an SVAC 101 tool to support providing community leaders with a standardized, basic level of education about SVAC so those leaders can support SVAC prevention and response in their communities. If an OU would like to conduct community leader workshops with SVAC 101, please contact S/GAC Gender or OVC leads.

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[81] PEPFAR. (2019). *Primary Prevention of Sexual Violence and HIV among 10-14 year olds.* https://pepfar.sharepoint.com/:b:/r/sites/DREAMS/Shared%20Documents/9-14%20Year%20Old%20Prevention%20Modules/2019-01-16_PEPFAR%209to14%20Prevention_COMPLETE%20DOCUMENT_Modules%201%20-%203_FINAL.pdf?csf=1&web=1&e=Orc9uX

***Implementation Considerations.*** Implementation should occur in school and/or community settings (e.g., including faith networks, youth sports clubs, community centers). These interventions should be implemented in DREAMS SNUs, as well as other PEPFAR SNUs with high incidence and/or prevalence of HIV and SVAC. In SNUs with both OVC and DREAMS programs, USG staff and implementing partners should work together to coordinate implementation of primary prevention interventions across the OVC and DREAMS platforms. In general, primary prevention interventions for 10-14-year-old girls that are active DREAMS beneficiaries should be targeted and budgeted for within the DREAMS program while all others (e.g., 10-14-year-old girls not in DREAMS and 10-14-year-old boys) should be targeted and budgeted by a mix of DREAMS and OVC programs with consideration given to existing partner presence in targeted schools and communities in order to gain efficiencies (e.g., if the DREAMS program is already providing an approved primary prevention intervention in schools to boys and girls, OVC beneficiaries in those schools should be included as well).

Given that primary prevention of sexual violence and HIV interventions discuss sensitive topics, facilitators must be trained in first-line support for children and young adolescents (employing evidence-infirmed guidance specific to minors) to better respond to disclosures of HIV status or experience of sexual violence including country-specific legislation and policies, current protocols of how and where to refer children for appropriate services, and information on mandatory reporting and SOPs for reporting. For example, if a child discloses an experience of sexual violence during a session, the child should receive adequate first-line response and be referred to appropriate post-violence medical, psychosocial, and/or legal services and to local child welfare and protection authorities. They should also be referred to an OVC program and once enrolled supported by OVC case management. Children should also be referred to the OVC program for enrollment screening if they disclose that they are living with HIV, are living in a household with HIV, or require family-based case management and/or more intensive child protection support. Female adolescents should also be referred to the DREAMS program for enrollment screening.

***Targeting Considerations.*** For DREAMS, all active DREAMS beneficiaries aged 10-14 years should receive primary prevention of HIV and sexual violence as part of their primary package. OVC programs should complement DREAMS by targeting 10-14-year-old boys (and10-14-year-old girls not participating in DREAMS) in impoverished areas of SNUs with high incidence and/or prevalence of HIV. For further discussion of OVC IP's role in prevention for 10-14-year-olds

please see Section 6.6.3. All primary prevention of sexual violence and HIV interventions for 10-14-year-olds should be reported under the OVC_SERV indicator, under the prevention disaggregate (MER 2.6 guidance).

***Budgeting Considerations.*** COP22 funding for primary prevention interventions should be budgeted under the *Prevention: Primary Prevention of HIV and Sexual Violence* financial classification.

## 6.2.4 Prevention for Women and PMTCT

Women are uniquely vulnerable to HIV acquisition at different times in their life cycles, and as a result, PEPFAR programs must ensure that the most evidence-based interventions are available during times when the intervention can provide the most impact. From the expansive reach of PEPFAR PMTCT programs to the successes seen through DREAMS, HIV prevention investments have been a focus of PEPFAR since its inception. As these adolescent girls and young women continue to age, the continuum of prevention and treatment services must remain intact so that they can maintain their health, and that of their families, over time.

Women represent the majority of the clients tested and started on treatment within the PEPFAR platform and maintaining their engagement is critical. Providers should continue to offer gender-sensitive primary prevention services across the lifespan for women that include evidence-based information and counseling, HIV and violence risk assessments, condoms and lubricants, and pre-exposure prophylaxis (PrEP) at every visit (particularly in the pregnancy and breastfeeding period). See Section 6.6.2 on Gender Equality for additional information on gender-transformative approaches. Evidence has shown that gender-based violence (GBV) may act as a barrier to accessing HIV services and adherence for females. Therefore, it is important to integrate and strengthen GBV programming and trauma-informed services across the programs and platforms where women seek healthcare services. See Section 6.6.2.1 on GBV and VAC.

The COVID-19 pandemic has also had a significant impact on HIV testing services for pregnant and breastfeeding women (PBFW) at first antenatal clinic visit. The challenge underscores the need for increased community engagement and case management to provide women and their infants with early accessible testing and prevention services.[82] Essential HIV case-finding

[82] UNAIDS. (2020, October 27). *COVID-19's impact on HIV vertical transmission services reversed*. https://www.unaids.org/en/resources/presscentre/featurestories/2020/october/20201027_covid19-impact-hiv-vertical-transmission

services for PBFW and children should be maintained, including maternal testing and diagnostic testing for HIV-exposed infants (HEI). Additionally, adaptations such as bundling services in the same visit and providing community testing to reduce exposure risk to COVID-19 should be leveraged to reduce the spread of COVID-19.[83]

This section of the COP guidance outlines key elements that will help close the gaps in the delivery of HIV prevention and PMTCT services for women, namely: enhancing and refining PrEP programs (Section 6.2.1 & Section 6.2.4.1), GBV trauma-informed services (Section 6.6.2), cervical cancer screening (Section 6.4.4) within HIV platforms, and optimizing prevention, testing and treatment for PBFW and their infants. Wherever possible we must strengthen the platforms where women seek care to optimize their health, as well as that of their infant and/or family. More specifically, integration and linking of multiple services across platforms and utilizing service delivery sites as entry points for vulnerable populations such as adolescent girls and young women will promote rapid scale-up of key prevention interventions, optimize testing and treatment and provide health education opportunities, all of which, will lead to sustainable progress and achievement of the UNAIDS 95-95-95 goals and elimination of vertical transmission.

## 6.2.4.1 Prevention in ANC and PMTCT

Summary of section edits:

- Added "DREAMS" to the section.
- Wording was updated to state that HIV/dual test procurement and integration into testing programs should be done where treatment for syphilis is readily available and ministries of health should work to ensure treatment availability at time of testing.

The goal of PEPFAR's prevention of mother-to-child transmission of HIV (PMTCT) program is to prevent HIV among PBFW, to keep mothers healthy and alive on ART, and to prevent HIV transmission from the woman living with HIV to her infant. PEPFAR accomplishes this by:

[83] Vrazo, A. C., Golin, R., Fernando, N. B., Killam, W. P., Sharifi, S., Phelps, B. R., Gleason, M. M., Wolf, H. T., Siberry, G. K., & Srivastava, M. (2020b). Adapting HIV services for pregnant and breastfeeding women, infants, children, adolescents and families in resource-constrained settings during the COVID-19 pandemic. *Journal of the International AIDS Society*, *23*(9). https://doi.org/10.1002/jia2.25622

- Preventing incident infections in women of reproductive potential, including pregnant and breastfeeding women (PBFW) (Section 6.2.4.2)
- Prevention of unintended pregnancies among women living with HIV by ensuring access to voluntary family planning counseling and services, including integration into ART services and in the postpartum setting and provision of safer conception counseling for women living with HIV who wish to become pregnant.
- Identifying all PBFW living with HIV as early as possible, including through HTS at ANC1 and intensifying maternal retesting during pregnancy and breastfeeding (as appropriate for a country's context) in maternal newborn and child health (MNCH) settings (Section 6.3.4)
- Providing services to support continuity of treatment for PBFW to help achieve and maintain viral suppression through the end of breastfeeding (BF) and beyond. It's critical to ensure increased access to VL testing and timely results in pregnancy and during BF (Section 6.4.5.1)
- Longitudinal tracking and retention support for women living with HIV (WLHIV) and HIV-exposed infants (HEI)
- Optimizing comprehensive care of HEI, including HIV prophylaxis for HEI (Section 6.4.1.1), increasing timely infant virological testing/early infant diagnosis of infants living with HIV, ensuring rapid linkage to treatment (Section 6.3.1.3), and continuity of care and testing for HEI until final HIV status is ascertained

To prevent new HIV infections among PBFW, who are at substantially increased risk of acquiring HIV if exposed during the late pregnancy, postpartum and breastfeeding periods, priority actions should also focus on: 1) counseling on the heightened risks of HIV acquisition during this period; 2) index case testing, including partner notification and couples-based services to promote scaled-up testing and treatment of male partners [recognizing that not all pregnant women are in a stable "coupled" relationship]; 3) expanded use of self-testing kits for both women and men; 4) greater access to voluntary medical male circumcision; and 5) active promotion of PrEP in PBFW at substantial HIV risk (Section 6.2.4.2).

Pregnant and breastfeeding adolescents and young women living with HIV represent an especially vulnerable group of people. Pregnant and breastfeeding AGYW are less likely to know

their HIV status before pregnancy and less likely to be engaged in PMTCT and ANC.[84, 85] Pregnant and breastfeeding AGYW are also at increased risk of poor outcomes, including mother to child transmission of HIV, maternal mortality, and stillbirth.[86] Age-appropriate interventions are needed to address these ongoing disparities. Services for pregnant and breastfeeding AGYW include: 1) actively screening young mothers for HIV risk-factors and sero-conversion during pregnancy or the breastfeeding period, infant immunization visits, family planning visits, and offering PrEP to women who test negative for HIV; 2) adolescent-friendly PMTCT services including peer led activities specific to young mothers (e.g., age-appropriate mentor mothers for pregnant and breastfeeding and clubs for AGYW and young mothers); 3) flexible ANC schedules; 4) Maternal/Child Health (MCH) staff who are trained to provide adolescent- and youth- friendly services, including psychosocial support and mental health services; and 5) Points of contact/champions for AGYW in ANC. Coordination between key programs including pregnancy crisis counseling, DREAMS, OVC case management and home visiting interventions, and gender-based violence prevention and response can further enhance care for pregnant and breastfeeding AGYW and their infants. Use of age disaggregated PMTCT data can help identify disparities and gaps that require program response. This data can include MER indicators (PMTCT_STAT, PMTCT_STAT_POS, and PMTCT_ART) and other custom in-country data sources. Periodic revision of data collection/reporting tools, development of SOPs and job aides, and routine data quality checks can be used to improve the quality of age-disaggregated data.

To combat low continuity of treatment among PBFW and HEI, priority responses should also include (Section 6.1, Section 6.1.2, and Section 6.1.2.3):

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[84] Ronen, K., McGrath, C. J., Langat, A. C., Kinuthia, J., Omolo, D., Singa, B., Katana, A. K., Ng'Ang'A, L. W., & John-Stewart, G. (2017). Gaps in Adolescent Engagement in Antenatal Care and Prevention of Mother-to-Child HIV Transmission Services in Kenya. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, *74*(1), 30–37. https://doi.org/10.1097/qai.0000000000001176

[85] Woldesenbet, S., Jackson, D., Lombard, C., Dinh, T. H., Puren, A., Sherman, G., Ramokolo, V., Doherty, T., Mogashoa, M., Bhardwaj, S., Chopra, M., Shaffer, N., Pillay, Y., & Goga, A. (2015). Missed Opportunities along the Prevention of Mother-to-Child Transmission Services Cascade in South Africa: Uptake, Determinants, and Attributable Risk (the SAPMTCTE). *PLOS ONE*, *10*(7), e0132425. https://doi.org/10.1371/journal.pone.0132425

[86] Fatti, G., Shaikh, N., Eley, B., Jackson, D., & Grimwood, A. (2014). Adolescent and young pregnant women at increased risk of mother-to-child transmission of HIV and poorer maternal and infant health outcomes: A cohort study at public facilities in the Nelson Mandela Bay Metropolitan district, Eastern Cape, South Africa. *South African Medical Journal*, *104*(12), 874. https://doi.org/10.7196/samj.8207

- Integration of PMTCT services into all antenatal, postpartum, neonatal, and child health services (including OVC programs) to provide one-stop services for mothers and infants.
- Full access to better-tolerated and more robust treatment (e.g., dolutegravir).
- Use of differentiated service delivery models to facilitate access to treatment or continuation of pre-pregnancy care, including assessing eligibility for 3-6 multi-month drug (MMD) dispensing for the mother.
- Mother-to-mother mentoring, counseling, case management (including psychosocial support, active tracing of mother-infant pair (MIPs) who miss appointments) and other community-based and evidence-based interventions to support for PBFW (including discussion and planning for the estimated 18-month to 2-year period of follow-up of MIPs).
- Community mobilization to boost male involvement in partner's PMTCT services, including shifting harmful gender norms. (See Section 6.6.2 on Gender Equality)
- Engagement of communities of women living with HIV.
- Facilitating processes for medical record sharing between PMTCT service delivery points and ART clinics to ensure continuity of care.

Clinically stable women receiving ART through a differentiated service delivery model prior to pregnancy should have the choice to continue receiving their ART through differentiated service delivery or to have their ART delivery integrated within their MCH care while they are pregnant as well as during the postpartum period in accordance with national guidelines.[87] Please refer to (Section 6.1.2.3) for more guidance.

In addition, it is important to expand messaging to PBFW on the substantial impact that viral load suppression to undetectable levels has on improving maternal health and preventing vertical transmission. While the U=U criteria used for sexual transmission do not strictly apply to MTCT, evidence shows that when HIV is diagnosed, ART is initiated, and viral suppression (to <50 copies/mL) is achieved prior to conception and maintained over the course of pregnancy and

[87] Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach, July 2021, WHO

breastfeeding, the risk of vertical transmission is extremely low.[88,89] Expanding the messages in U=U campaigns to emphasize early ART start and viral suppression before and throughout pregnancy and breastfeeding could have an important impact on MTCT.[90,91,92] To attain this near zero risk of vertical transmission for WLHIV, programs should provide client education and service delivery that focus on: (1) testing and starting WLHIV on ART prior to conception, (2) supporting pregnancy planning for WLHIV on ART, and (3) ensuring viral suppression throughout pregnancy and breastfeeding. These educational and service interventions are needed at both PMTCT service delivery points as well as in the community and general ART clinics to ensure that women know their status, start ART, and are virally suppressed prior to conception or as early as possible in the pregnancy.

The WHO has established validation criteria for elimination of vertical transmission of HIV and syphilis as well as the Path to Elimination (PTE) with bronze, silver, and gold tiers to recognize high HIV burden countries who have made significant progress in reducing infant HIV infections but do not yet reach the vertical transmission case rate criterion (HIV MTCT rate of <5%; <50/100,000 new pediatric HIV infections due to MTCT).[93] Many PEPFAR-supported countries have shown interest in the PTE certification process and are in various stages of preparation and application. OUs should work with Ministries of Health and other stakeholders to support national strategies and provide technical input to the elimination of vertical transmission/PTE processes, where relevant.

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[88] Mandelbrot, L., Tubiana, R., le Chenadec, J., Dollfus, C., Faye, A., Pannier, E., Matheron, S., Khuong, M. A., Garrait, V., Reliquet, V., Devidas, A., Berrebi, A., Allisy, C., Elleau, C., Arvieux, C., Rouzioux, C., Warszawski, J., & Blanche, S. (2015). No Perinatal HIV-1 Transmission From Women With Effective Antiretroviral Therapy Starting Before Conception. *Clinical Infectious Diseases*, civ578. https://doi.org/10.1093/cid/civ578

[89] Townsend, C. L., Byrne, L., Cortina-Borja, M., Thorne, C., de Ruiter, A., Lyall, H., Taylor, G. P., Peckham, C. S., & Tookey, P. A. (2014). Earlier initiation of ART and further decline in mother-to-child HIV transmission rates, 2000–2011. *AIDS*, *28*(7), 1049–1057. https://doi.org/10.1097/qad.0000000000000212

[90] Giuliano, M., Andreotti, M., Liotta, G., Jere, H., Sagno, J. B., Maulidi, M., Mancinelli, S., Buonomo, E., Scarcella, P., Pirillo, M. F., Amici, R., Ceffa, S., Vella, S., Palombi, L., & Marazzi, M. C. (2013). Maternal Antiretroviral Therapy for the Prevention of Mother-To-Child Transmission of HIV in Malawi: Maternal and Infant Outcomes Two Years after Delivery. *PLoS ONE*, *8*(7), e68950. https://doi.org/10.1371/journal.pone.0068950

[91] Myer, L., Phillips, T., McIntyre, J., Hsiao, N. Y., Petro, G., Zerbe, A., Ramjith, J., Bekker, L. G., & Abrams, E. (2016). HIV viraemia and mother-to-child transmission risk after antiretroviral therapy initiation in pregnancy in Cape Town, South Africa. *HIV Medicine*, *18*(2), 80–88. https://doi.org/10.1111/hiv.12397

[92] Mofenson, L. Plenary Presentation: Is U=U Applicable to Breastfeeding? International Workshop on HIV Pediatrics, Nov 2020.

[93] WHO global guidance on criteria and processes for validation: Elimination of Mother-to-Child Transmission of HIV and syphilis, 2nd edition, Nov 2017.

PMTCT programs should include services and support related to HIV testing for all pregnant and breastfeeding women and their partner(s), including linkage to treatment. This includes first tests at ANC1 visits, as well as additional tests conducted throughout the pregnancy and breastfeeding window (See Section 6.3.4 Retesting in PBFW). This should also include the procurement and support for implementation of the dual HIV/syphilis rapid tests during ANC for pregnant women in PEPFAR countries. In planning for HIV/Syphilis dual test utilization, ministries of health should work with programs to ensure that the appropriate treatment for syphilis infection is readily available at the point of care.

The gaps that lead to new child infections are variable by country. Countries should review national/subnational, PEPFAR, and other programmatic data to identify factors contributing to new child infections and implement targeted responses.

## 6.2.4.2 PrEP for Women

**Pregnant and Breastfeeding Women (PBFW)**

Pregnant and breastfeeding women (PBFW) in many areas are at substantial risk of acquiring HIV during the antenatal and postnatal period. Behavioral (i.e., less condom use, intimate partner violence [IPV]) and biologic (i.e., altered hormonal levels, untreated reproductive tract infections and STIs) susceptibilities are increased for pregnant and breastfeeding women, which subsequently enhances potential exposure and acquisition of HIV. PBFW have been shown to be at 3-4 times higher risk of incident HIV infections when compared to their non-pregnant counterparts.[94] In addition, women who acquire HIV during pregnancy have a high risk of transmitting the HIV virus to their infants. In 2020, UNAIDS estimated that there were 150,000 new HIV infections in young children and data shows that a large majority of these cases occur among children 0-4 years either through pregnancy, birth, or breastfeeding.[95] Close to one quarter of infant infections globally are estimated to occur because of maternal acquisition of HIV during pregnancy and breastfeeding.[96] It is for this reason that effective strategies for the prevention of mother to child transmission (PMTCT) should include routine HIV testing of PBFW

[94] Thomson, et.al., The Partners in Prevention HSV/HIV Transmission Study and Partners PrEP Study Teams; Increased Risk of HIV Acquisition Among Women Throughout Pregnancy and During the Postpartum Period: A Prospective Per-Coital-Act Analysis Among Women With HIV-Infected Partners, The Journal of Infectious Diseases, jiy113, https://doi.org/10.1093/infdis/jiy113
[95] Global AIDS Update 2021: https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update
[96] Ibid.

in antenatal care (ANC) clinics (at ANC1 and in the third trimester of pregnancy; see Section 6.3.4), and PrEP as an essential component of the PMTCT prevention toolkit for HIV-negative women.

Implementing and continuing to scale up PrEP in MNCH and FP settings is a priority in COP22 as it increases access to PrEP for PBFW as well as their eligible partners. Guidance from the WHO indicates that PrEP should be offered to individuals with substantial risk of acquiring HIV, recognizing that individual risk varies considerably within populations, and that local context and heterogeneity in risk should be considered when determining who might benefit from PrEP.[97] PEPFAR programs are strongly encouraged to incorporate PBFW as a priority population for prevention services including counseling and risk assessment for PrEP. There is evidence that in areas where PBFW are at substantial risk of acquiring HIV, universal PrEP counselling and offer of PrEP for PBFW is an effective approach.[98]

There are multiple identified barriers to implementation of PrEP services for PBFW. Barriers include lack of PBFW inclusion in national PrEP guidelines, insufficient provider training, low client knowledge about and demand for PrEP, low risk perception in PBFW, and stigma in using PrEP. Many providers and clients have concerns about the effects of PrEP during pregnancy on infants, causing a barrier to provision and uptake of services in this population. A recently published study[99] noted that "pregnancy outcomes and early infant growth did not differ by PrEP exposure" thus the safety of PrEP during pregnancy should be emphasized as part of the provider training and demand creation efforts specific to this population.

Strategic planning and ongoing implementation support are needed to ensure that PrEP scale-up is inclusive of PBFW and MNCH and reproductive health settings (i.e., antenatal care, postnatal care, and family planning clinics). Planning and implementation of PrEP for PBFW should include:

- Inclusion of PBFW in national guidelines, strategic plans, and budgets for PrEP

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[97] WHO consolidated guidelines, July 2021: https://www.who.int/publications/i/item/9789240031593

[98] Kinuthia J, Dettinger J, Stern J, et al. Risk-based versus Universal PrEP Delivery During Pregnancy: A Cluster Randomized Trial. In: *VCROI 2021 Abstract Book*. CROI 2021; 2021:280. Accessed June 25, 2021. https://user-degqumh.cld.bz/vCROI-2021-Abstract-eBook/280/

[99] Dettinger JC1, Kinuthia J1,2, Pintye J1, Abuna F3, Begnel E1, Mugwanya K1, Sila J3, Lagat H3, Baeten JM1,4,5, John-Stewart G1,4 Perinatal outcomes following maternal pre-exposure prophylaxis (PrEP) use during pregnancy: results from a large PrEP implementation program in Kenya. J Int AIDS Soc. 2019 Sep;22(9): e25378. doi: 10.1002/jia2.25378.

- Training and ongoing support of MNCH/FP and family planning providers and peer supporters/mentor mothers on PrEP for PBFW and their eligible male partners.
- Community and MCH stakeholder engagement in PrEP planning
- Demand creation for PrEP in PBFW, including addition of PrEP efficacy and safety messaging and adherence support for PBFW, especially adolescent and young mothers
- Development of service delivery models for PrEP in MNCH and family planning settings where PrEP is provided as part of comprehensive package of combination HIV prevention services, including condom use for the prevention of other STIs.
- PrEP service delivery and training tools that include considerations for PBFW including addressing a client's exposure to or risk of gender-based violence and intimate partner violence. Service providers should conduct intimate partner violence (IPV) routine enquiry when counseling for PrEP initiation. Clients found to be experiencing violence must be provided first-line support (LIVES); referred to local clinical and/or non-clinical violence response services; and informed of ways in which they can take PrEP with or without their partner's knowledge (see Section 6.6.2.1 for additional information)
- Active monitoring and evaluation of PBFW receiving PrEP, including incorporation of PrEP in PBFW into relevant M&E tools and adverse events reporting systems for information on the safety and efficacy of PrEP in PBFW
- Implementation science and impact evaluations that include PBFW, particularly in formative research and implementation of newer PrEP products such as the ring.

PBFW should also be included in PrEP programming that is offered in community settings, particularly those geared toward AGYW. PEPFAR programs are encouraged to set targets for PrEP in PBFW and monitor progress with scale-up in this priority population. Last, since many PBFW may also be AGYW, FSW, or both, programs should consider issues unique to this vulnerable population to enhance quality and access to PrEP and other HIV prevention services, including through DREAMS (see Section 6.2.2.2) and key populations (see Section 6.5) platforms. Resources to support PrEP provision to PBFW are available on PrEPWatch.[100]

**PrEP Initiation and Continuation for Contacts of Index Testing Clients**

[100] https://www.prepwatch.org/resource/prep-for-pregnant-and-breastfeeding-women/

In reaching and maintaining epidemic control, HIV testing approaches will be targeted to HIV case finding through optimized testing that is symptom-based or risk-based and index testing. Index testing is indicated for all persons newly testing HIV positive and will identify HIV-negative partners at high risk for HIV acquisition. In addition, testing strategies for individuals whose partners (positive or negative, adolescent or older) are pregnant and breastfeeding should be employed, particularly in areas with high HIV prevalence. In contexts like these, not only will programs likely find high yields for men using index testing (when testing the partners of HIV-infected pregnant women), but given the heightened risk of seroconversion for PBFW, male partner testing of HIV-uninfected PBFW can hopefully identify male infections earlier in this window to prevent transmission.

Serodifferent couples are an important group to reach through this strategy. HIV uninfected partners should be offered PrEP as a bridging strategy until the partner living with HIV infection achieves durable viral suppression. Median time to suppression to less than 50 copies/ml was 60 days for those on integrase strand inhibitors (such as dolutegravir (DTG).[101] In an open-label implementation study in Kenya, approximately 60% of serodifferent couples were found to be at high risk and were offered PrEP. Uptake of PrEP was 97% while uptake of ART for the partner living with HIV was 78%. Based on these limited data, approximately 50-60% of serodifferent couples may be at risk and the HIV-uninfected partner willing to take PrEP ongoing or, if preferred, until the partner living with HIV is suppressed on treatment. Couples may be at risk and willing to take PrEP until the partner living with HIV is suppressed on treatment for greater than six months. If the partner living with HIV has issues with ART adherence or other reasons that inhibit viral suppression such as co-infection with another virus or tuberculosis, the partner should consider PrEP.

During FY20 PEPFAR operating units identified over 2 million HIV-negative people during index testing campaigns. These 2-plus million HIV-negative clients are, by the nature of their connection to an HIV-positive index client, at elevated risk of acquiring HIV. This presents a population who should be screened for and offered prevention services including PrEP as an effective and immediate prevention measure. Index testing not only helps fast-track individuals

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[101]Jacobson K, Ogbuagu O. Integrase inhibitor-based regimens result in more rapid virologic suppression rates among treatment-naive human immunodeficiency virus-infected patients compared to non-nucleoside and protease inhibitor-based regimens in a real-world clinical setting: A retrospective cohort study. Medicine (Baltimore) 2018.

who should be immediately linked to HIV treatment services, but it helps HIV-negative individuals stay negative by matching them with appropriate prevention services (condoms, PrEP, DREAMS, VMMC, etc.). As index testing continues to progress as a case finding strategy, a two-fold opportunity grows to link clients to their next step on prevention or treatment service delivery cascades. Higher risk HIV negative partners of index cases, and especially persons identified with recent HIV exposure, should be offered PrEP as a standard of care in most situations. All partner notification materials and messages should include linkage to prevention services including PrEP. As part of both index testing and PrEP, providers should conduct intimate partner violence (IPV) routine enquiry, and clients found to be experiencing violence must be provided first-line support (LIVES); referred to local clinical and/or non-clinical violence response services; and informed of ways in which they can take PrEP with or without their partner's knowledge (see Section 6.6.2.1 for additional information on GBV). PEPFAR teams should consider how they can utilize differentiated service delivery models for initiating and supporting continuation of PrEP among populations at highest risk of HIV acquisition in the same way that PEPFAR has expanded these options for treatment services. Models will vary and may include a range of facility- and community- based interventions including the use of mobile, pharmacy-based, and tele-health models.

**Opportunities to enhance PrEP access and uptake through existing PEPFAR platforms**

Integrating PrEP into FP services may be a good opportunity to leverage an existing community and facility-based platform that is well utilized by women of reproductive age, especially AGYW. This has been an option for accessing PrEP identified by women from many contexts.[102,103] It is important to note that there are some differences in the approaches and requirements for provision of PrEP and FP services, so field programs should carefully review service delivery protocols and capacity of health providers before initiating a new integrated activity.

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[102] Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial Consortium. HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial. Lancet. 2019 Jul 27;394(10195):303-313. doi: 10.1016/S0140-6736(19)31288-7. Epub 2019 Jun 13. Erratum in: Lancet. 2019 Jul 27;394(10195):302. PMID: 31204114; PMCID: PMC6675739.

[103] Quaife M, Terris-Prestholt F, Eakle R, Cabrera Escobar MA, Kilbourne-Brook M, Mvundura M, Meyer-Rath G, Delany-Moretlwe S, Vickerman P. The cost-effectiveness of multi-purpose HIV and pregnancy prevention technologies in South Africa. J Int AIDS Soc. 2018 Mar;21(3):e25064. doi: 10.1002/jia2.25064. PMID: 29537654; PMCID: PMC5851344.

Experience from the PrEP Implementation for Young Women and Adolescents (PrIYA) project in Kenya found that use of a seconded PrEP provider within the FP service delivery setting was an effective way to provide PrEP as part of the overall services offered to FP seeking clients. Also, important to consider is integrated demand creation for both services. Integration within FP services could also be leveraged for new prevention modalities as they become available. OUs are encouraged to explore inclusion of the new biomedical prevention products as part of a future suite of HIV prevention options available for women through FP and other services.

### 6.2.5 Prevention for Men

Preventing HIV infection in men is essential in disrupting HIV transmission and reaching epidemic control. PEPFAR PHIA results in eight high-burden countries show that men aged 15-49 years lag behind women in terms of their HIV diagnosis rates (the first 95), treatment (the second 95) and viral suppression (the third 95). Given the rates of sexual transmission, men are at increased likelihood of transmitting HIV to their partners, especially women aged 15-24 years. Prevention messages should engage and educate men and address specific barriers that inhibit them from being tested. In addition, testing partners should assume the responsibility of linking men who test negative to prevention partners for comprehensive prevention interventions. All persons concerned about HIV should be referred for testing and prevention services. For men, prevention services include education and self-efficacy training, condom and lubricant distribution, voluntary medical male circumcision (VMMC), and pre-exposure prophylaxis (PrEP). Men who have had a recent exposure that has potential for HIV transmission, should be offered and initiated on post-exposure prophylaxis (PEP) as early as possible (see Section 6.2.1 Pre-Exposure Prophylaxis (PrEP)).

Current communication and messaging around HIV are often not effective at reaching and encouraging men to come for testing and treatment, and testing times and locations are not always conducive for men. In surveys, men often describe their perception that conventional HIV service facilities are oriented toward women and communicate a desire for facility hours and environments that are more convenient and comfortable for them. Regardless of the type of health facility, men (like all other populations) require confidentiality in services, and programs should look for ways to provide this. Peer leadership programs, such as coach or mentor models, may help men who do not see their risk of HIV acquisition as elevated or understand how specific behaviors or actions lead them to be at elevated risk of HIV acquisition. Connecting

opportunities for HIV testing to screening, testing and treatment of STI's or another primary health care service can also help to reach men with HIV services.

### 6.2.5.1 Voluntary Medical Male Circumcision

Summary of section edits:

- Clarified assent and consent language
- Wording on target setting models and testing protocols was updated.

VMMC reduces the risk of HIV acquisition from heterosexual sex for men by about 60 percent and has added benefits such as reduction in STIs and protection against penile cancer in men and cervical cancer in women.[104] PEPFAR has supported over 28 million VMMCs since the program's inception in 2007 across priority countries in Eastern and Southern Africa. Recent technical and programmatic review by WHO reaffirms continued support for VMMC as a critical HIV prevention intervention.[105] PEPFAR worked with the Gates Foundation and the HIV Modeling Consortium to determine the cost-effectiveness of VMMC for HIV prevention across sub-Saharan Africa (publication forthcoming). This modeling aimed to determine if VMMC continues to be a cost-effective intervention in the region in the context of epidemic control and decreasing HIV incidence. Using five existing well-described HIV mathematical models, the work compared the impact of continuation of VMMC for five years in males aged fifteen and older to no further VMMC in this age group in regions across sub-Saharan Africa; findings indicated that VMMC remains a cost-effective prevention intervention and thus PEPFAR recommends continuation towards the male circumcision coverage targets in all of the VMMC priority countries.

Data from recent analyses from the PEPFAR-supported Population-based HIV Impact Assessments (PHIAs) which closely looked at both male circumcision status and HIV incidence, should inform VMMC prioritization to address geographic coverage gaps and maximize the impact of VMMC by targeting men in geographic areas with the lowest VMMC coverage and the

[104] Tobian AA and Gray RH, The medical benefits of male circumcision, JAMA 2011; 306(13):1479-1480 . https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684945/

[105] Preventing HIV through safe voluntary medical male circumcision for adolescent boys and men in generalized HIV epidemics: recommendations and key considerations. WHO August, 2020. https://www.who.int/publications/i/item/978-92-4-000854-0

highest HIV incidence. Additional data sources, such as military SABERS, should also inform prioritization. Countries should validate the inputs to the online VMMC modelling tool, the Decision Makers' Program Planning Toolkit, Version 2 (DMPPT2)[106] against survey and VMMC program data to ensure that the coverage and target estimates are as accurate as possible. The DMPPT2 tool allows country teams to generate coverage estimates, scale-up targets, and impact projection by five-year age bands at the district, provincial, or regional levels. The DMPPT2 tool is now supported by UNAIDS models enabling VMMC coverage estimate outputs from the DMPPT2 to be directly exported into COP planning tools.

VMMC should be performed within a required minimum package of services, including age-appropriate sexual risk reduction counseling, counseling on the need to refrain from sexual activity or masturbation during the healing process, medical history to include bleeding risk, physical examination with STI screening as clinically indicated -and treatment/referral (with deferral of surgical circumcision until treated), HIV testing prior to circumcision for men and their partner as indicated, linkage to care and treatment for those testing positive in HTS. Post-VMMC follow-up, including adverse event assessment and management, and distribution of condoms. Men with ongoing high-risk sexual behavior testing negative for HIV should be offered or referred for PrEP.

**Key Considerations**

**Age Considerations:** Safety is the primary consideration in VMMC programs. The minimum age of eligibility for VMMC remains 15 years old. However, not all 15-year-olds will have reached physical maturity and any client with immature genitalia should not be circumcised. Health care providers should strive to postpone non-emergency invasive and irreversible interventions like VMMC until the adolescent is mature enough to understand the risks and benefits and agree to the procedure (assent for minors, consent for adults). Programs should ensure that adolescents have access to the information that is essential for their health and development and that they have opportunities to participate in decisions affecting their health (notably through informed assent and the right of confidentiality).[107] While confirmation of age can be difficult, it is essential that surgical VMMC not be performed in adolescents under age 15 or with immature genitalia.

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[106] www.vmmcipt.org/

[107] Preventing HIV through safe voluntary medical male circumcision for adolescent boys and men in generalized HIV epidemics: recommendations and key considerations. WHO August, 2020. https://www.who.int/publications/i/item/978-92-4-000854-0

The only exception to this age rule is for programs who have received approval to use the ShangRing device for 13-and-14-year-olds where informed consent or assent of the adolescent can be obtained in addition to the consent of a parent or guardian. Programs wishing to implement ShangRing use in the 13–14-year age group should work to gain approval during the COP process and considerations for use of ShangRing in this age group should be discussed with HQ technical experts. For programs approved to perform ShangRing in 13–14-year-olds, there is an additional monthly reporting requirement[108] of all moderate and severe adverse events. The ShangRing mechanism may protect against risks of glans injury and fistula for immature genitalia, but sufficient volumes of data are not yet available in VMMC settings to rule out other risks of injuries in young adolescents that may be similarly uncommon, especially during the *in situ* period. No infant circumcision activities will be supported. Partner governments interested in circumcising boys <15 are advised to follow WHO guidance on approved VMMC methods, VMMC tools, safety criteria, and consent/assent procedures to prevent adverse events

For those presenting for VMMC services between 10-14 years of age, including where ShangRing is not approved for those 13-14 years old, age appropriate sexual and reproductive health education and tetanus vaccine (if DPT coverage was under 70% in that birth cohort) should be provided using partner country funding along with education on returning for VMMC at age 15.

For districts where at least 80% saturation has been reached among 15–29-year-old males, VMMC services can continue as long as demand remains steady in adolescents aged 15 years or older and adult males. Given the wide confidence bounds for estimates, services should be based on demand. For districts where coverage saturation has been reached or is being approached, the programs should develop plans for sustainable ongoing circumcisions of those reaching age 15 and above so that coverage gains are maintained once saturation is achieved. Domains to be considered for sustainability of services include financing, health work force, strategic information including safety monitoring, supplies and equipment, leadership and governance, and service delivery. Assuring sustainability will require enabling laws and policies,

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[108] Enhanced ShangRing Monitoring https://pepfar.sharepoint.com/:f:/r/sites/VMMC/Shared%20Documents/Enhanced%20ShangRing%20Monitoring?csf=1&web=1&e=1sA4Rr

community engagement, and multisector partnerships. More information is available from the WHO.[109]

**HIV Testing:** Epidemiologically, men often lag behind women with 1st 95 achievements, and offering HTS to men seeking VMMC services is an ideal opportunity to provide HTS to men.

HTS remains option for VMMC clients, i.e., an HIV test is not a requirement to receive VMMC. However, testing should remain available to any VMMC client, particularly those who request it. An HTS package that includes HIV counseling, HIV information, and optional HIV testing should be provided. VMCC sites should establish relationships with ART sites to assure that immediate linkage to treatment is available for those testing positive and men who test negative with ongoing high-risk sexual behavior are referred to PrEP services.

**VMMC in Men Living with HIV (MLWH):** In recent years, severe adverse events have been reported among MLWH who have received VMMC services. Although MLWH are eligible for VMMC, they should be on ART and virally suppressed prior to being circumcised to; 1) optimize immunocompetence for wound healing and decrease risk of infection, and 2) to decrease the risk of HIV transmission especially with a circumcision wound that is not fully healed. The WHO's updated VMMC guidelines[110] state:

> *"Those who test positive for HIV should start treatment for their own health. Those who test positive and wish to be circumcised should delay circumcision until ART has lowered their viral load." (p. 212)*
>
> **and**
>
> *"Because of HIV-positive men's higher risk of passing HIV infection if they have sex before their circumcision wound heals, HIV-positive men who want circumcision should be supported to be on ART and virally suppressed before undergoing circumcision." (p. 225)*

Starting in COP22, at a minimum, all clients known to be living with HIV must be compliant on ART for at least 3 months prior to being circumcised. Additional considerations to improve safety include communicating with the client's HIV provider to address any safety concerns about the client undergoing circumcision and reviewing available laboratory studies which would ideally demonstrate a viral load of <200 copies/ml within the last 12 months. Because HIV testing is voluntary, it's understood that the status of some clients who are living with HIV will remain

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[109] https://www.who.int/publications/i/item/978-92-4-000854-0
[110] Ibid.

unknown to VMMC staff and that they could be circumcised without these safety checks. Programs should continue to ensure all men are counseled on the risks and benefits of circumcision, including a potential increased risk of adverse events in the case of undiagnosed and untreated HIV infection.

**COVID-19 VMMC Service Delivery Considerations:** In settings with ongoing COVID-19 transmission, programs should always prioritize staff and client safety and ensure adherence to all recommended IPC practices and national COVID-19 risk mitigation measures. Additional guidance for site and program level COVID-19 risk reduction activities are included in PEPFAR's Technical Guidance During COVID-19.[111]

**Follow up:** The COVID-19 pandemic has accelerated the use of telemedicine in many settings. To reduce crowding, facilitate physical distancing, and decrease the number of healthcare facility exposures for clients, some VMMC programs have included virtual post-operative follow-up as part of their COVID-19 risk mitigation strategy. A recent narrative review, along with additional studies from low-and-middle-income settings, found comparable safety, lower cost, and high patient acceptability when low risk surgical patients were followed up virtually instead of in-person.[112]

The use of virtual follow-up methods (such as by phone, two-way texting, or video call) is supported as an option for low-risk post-VMMC clients circumcised with surgical methods and should be included in the quarterly reporting of post-surgical follow-up. Clients circumcised with devices must continue in-person follow-up. Virtual follow-ups, even as the COVID-19 situation improves, are supported with the following considerations:

- A virtual follow-up program must be implemented in a planned and deliberate fashion. This means programs should:
    - Develop eligibility criteria based on a client's medical history, test of access to reliable communication method, occurrence of intra-operative adverse events that may increase AE risk, and client health literacy
    - Develop SOPs for staff training and responsibilities
    - Obtain client consent for the selected mode of virtual follow-up

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[111] https://www.state.gov/pepfar/coronavirus/

[112] McMaster, T., Wright, T., Mori, K., Stelmach, W., & To, H. (2021). Current and future use of telemedicine in surgical clinics during and beyond COVID-19: A narrative review. *Annals of medicine and surgery (2012)*, *66*, 102378. https://doi.org/10.1016/j.amsu.2021.102378

    - Standardize communication schedules, questions asked, and decision tree for responses
    - Monitor outcomes for any differences from in-person follow up
- Virtual vs. in-person follow-up must allow client preference; therefore, clients should be given a choice between in-person and another follow-up means
- Ensure virtual follow-up program conforms to national VMMC and patient privacy requirements
- In-person follow-up must be available where and when virtual follow-up is used to examine any potential adverse events quickly
- Ensure clients are educated on the signs and symptoms of adverse events and know how and when to use regular virtual follow up vs. emergency hotline communication

**Safety and Notifiable Adverse Events Monitoring and Reporting:** Patient safety is of the highest priority. Programs should establish policies and procedures to ensure patient safety and appropriate adverse event prevention and management throughout all steps of the VMMC process. Programs should work to integrate patient safety within broader patient safety efforts in countries. Infection prevention standards should be maintained (see Section 6.7.1).

- Sites must have emergency kits including all equipment and supplies on the kit list.
- As severe AEs are rare, facility managers should provide updates and reminder briefings on such events, their identification, prevention, and management. Updated and refresher trainings, including training on anatomy and new age guidelines, are necessary to prevent adverse events, such as urinary fistulas.
- Diathermy should not be used in the frenular area, nor on clients with a small penis.
- When a fistula is identified, the client must be referred to a specialist with experience in fistula management. Repair of the fistula is not urgent; best results are obtained with conservative management and delayed repair. Each country should identify the appropriate experts for peer consultation and referral of fistula cases, which may be outside of the country, and IPs should provide support for referral and follow up care.
- The lot number and batch number of the local anesthetic used should be recorded on every VMMC client record so that in case of adverse events the lots/batches can be tracked.

- Ensure an appropriate preoperative physical assessment is conducted to look for the presence of keloids, which serve as contraindication to VMMC.
- Investigations of NAEs should avoid oversimplifying the events and should be performed in a non-punitive fashion. Investigations should evaluate possible contributing causes from all components of VMMC programming, not just the actions of providers and clients.

PEPFAR programs should continue to support partner government ministries as they implement adverse event reporting recommendations outlined by WHO. **Immediate reporting of notifiable adverse events (NAE) to PEPFAR should continue as previously outlined.** NAE reporting is now conducted in DATIM. More information is available on PEPFAR SharePoint[113] or contact your VMMC agency lead or VMMC_AE@state.gov. Programs are encouraged to work with Ministries of Health to establish quality assurance and improvement systems that include ongoing monitoring of adverse events. These systems should ensure long-term sustainability of high-quality VMMC services (e.g., continuous quality improvement, external quality assurance assessments and other activities to monitor and ensure quality and safety).

Additional measures to minimize VMMC complications and notifiable adverse events include limiting case load per day for providers, ensuring adequate lighting for procedures, and using a 4.0 fast absorbing Vicryl Rapide suture on a 19 mm 3/8 circle reverse cutting needle. VMMC single-use Essential Consumables kit for Dorsal Slit and single-use Convenience Kit for Dorsal Slit now includes this suture/needle combination as standard.

**Additional Considerations**

- Programs should document plans for identifying and increasing VMMC uptake in "higher risk men" - HIV-negative men at high risk for HIV infection from heterosexual transmission - showing consideration for geographic and other demographic factors in addition to age.[114]

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[113] https://pepfar.sharepoint.com/:f:/r/sites/VMMC/Shared%20Documents/NAE%20Reporting%20Resources?csf=1&web=1&e=vibrgX

[114] World Health Organization. Web Annex 5.3, 2021: Update to enhancing uptake of VMMC among adolescent boys and men who are at higher risk for HIV - evidence and case studies. 2021. (Forthcoming.) Update to: World Health Organization. Preventing HIV through safe voluntary medical male circumcision for adolescent boys and men in generalized HIV epidemics: recommendations and key considerations, 2020 .

- Programs should link with ongoing initiatives directed at finding men that are identifying high-risk, HIV-negative men, including those over age 30, and be sure they are linked to VMMC and other prevention services, including PrEP.
- COP21 guidance stated, "*A recent meta-analysis suggests that VMMC may also be effective for MSM, with 23% decreased odds of acquiring HIV, and reduced risk of genital herpes and HPV infections.*[115] *In addition, up to 70% of MSM in Africa also have sex with women."* To clarify, these data are preliminary and the HIV protective effect of VMMC in MSM is uncertain, although if the client also has sex with women, the preventive effect will apply to those heterosexual encounters. MSM who would like to be circumcised in countries where VMMC is being implemented should be counseled about the uncertainty around if, and how much, HIV protection is afforded by VMMC during same-sex male encounters. The intent of this guidance is to make both VMMC and KP staff aware of recent data that can help tailor HIV prevention messaging to MSM clients in VMMC priority countries.
- Programs should provide quantitative evidence of substantial shifts toward reusable instruments in their justification of proposed VMMC commodities budgets. Use of reusable instruments must be accompanied by a detailed and robust plan and budget to ensure proper instrument reprocessing, including monitoring of the instrument sterilization effectiveness.
- The PEPFAR headquarters interagency VMMC technical working group standardized all PEPFAR VMMC kit components to ensure our implementing partners have the necessary instruments to perform a safe medical male circumcision. This standardization of VMMC kits allows our supply chain partner to leverage global quantities and negotiate competitive unit prices from pre-approved vendors. To that end, any deviations from the currently approved VMMC kit component specifications need to be discussed with and approved by SGAC prior to procurement.
- Communication and demand creation interventions should be informed by evidence-based methods (e.g., human-centered design) and include a component of effectiveness

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[115] Tanwei Yuan, Thomas Fitzpatrick, Nai-Ying Ko, et al. Circumcision to prevent HIV and other sexually transmitted infections in men who have sex with men: a systematic review and meta-analysis of global data. Lancet Global Health 2019;7:e436-47.

monitoring and evaluation. Demand creation for VMMC should include interventions geared toward various segments of the male population as well as secondary audiences likely to influence men's decision to get circumcised such as their partners, peers, or religious leaders. Evidence-based interventions should guide demand creation messaging and activities and pay particular attention to barriers and facilitators to VMMC and address cultural norms around masculinity.

- Any incentives given to clients for VMMC uptake should be non-coercive in type and scale, designed to overcome practical barriers to obtaining MC such as transportation or lost wages, and programs should support alternative solutions to financial incentives for out-of-pocket costs such as providing transport. Any use of incentives should include an effectiveness monitoring and evaluation plan. Previous guidance on ensuring that incentives to mobilizers and providers is non-coercive should continue to be followed. Any introduction of incentives into a VMMC program should be carefully considered in the context of sustainability.[116]

### 6.2.5.2 PrEP for Men

A significant proportion of adult men worldwide, especially in sub-Saharan Africa, may be at substantial risk of acquiring HIV. Prevalence in men continues to decline disproportionally to women and thus PrEP for men should be behaviorally based, focused on key and priority populations. Prioritization should be evidence-based and may be guided by PHIA data, Demographic and Health Surveys (DHS), recency, and other programmatic evidence. Prioritization aside, all men who report more than one sexual partner and inconsistent condom use may benefit from PrEP. Failure to disclose risk should not be used to refuse access to PrEP. Scale-up of PrEP for men should be targeted primarily for MSM, other KP men, men with sex partners within higher incidence populations (AGYW, FSWs, PBFW, TGW, PWID), or men with serodifferent partners until their partner is virally suppressed at which point, they can opt to continue or discontinue PrEP. Some epidemic contexts identify other high incidence populations

[116] https://www.usaid.gov/sites/default/files/documents/1864/pepfar_best_practice_for_vmmc_site_operations.pdf

that may warrant prioritization for PrEP such as migrant populations, long distance truck drivers, etc.

Several areas may offer unique opportunities for reaching men with PrEP services.

- ANC services and PMTCT services offer HIV testing for PBFW. Sex partners of PBFW should also be considered for testing, including self-testing. Contacts of the PBFW index client (a client living with HIV and not virally suppressed) with a negative HIV test should be offered PrEP. Studies among serodifferent couples have highlighted the effectiveness of PrEP when the partner without HIV takes PrEP until the partner with HIV has a durable suppressed viral load. In this regard, partner notification services would serve as an important setting for PrEP service provision for men.
- Voluntary medical male circumcision (VMMC) remains a priority HIV prevention service for PEPFAR which reaches hundreds of thousands of men each year. Men targeted through VMMC services who are at substantial risk for HIV acquisition can also benefit from PrEP services as an additional prevention strategy. Males aged 15 years and above with elevated risk should be referred for VMMC where available, and men and sexually active adolescent boys at high risk could also consider using PrEP to prevent HIV acquisition.
- Additional considerations for PrEP in KP men can be found in Section 6.5 PEPFAR's Key Populations Approach and Strategy.
- Opportunities to reach partners, friends, and/or family members who may benefit from PrEP should also be leveraged. In areas where the primary focus is HIV prevention for at risk women, targeting PrEP to the male partners may be an effective supplementary strategy.

PrEP services should leverage and promote differentiated service models across the full continuum of care. Models will vary and may include a range of facility- and community- based innovations including the use of mobile, pharmacy-based, and tele-health models. These services should benefit **anyone** seeking PrEP, aim to alleviate bottlenecks and not disproportionately advantage one person over another.

MSM face specific and particularly daunting stigma and are often marginalized and require extra effort to reach; therefore, efforts to reach MSM for PrEP need to be specific and intentional and require coordination with CSOs and advocacy groups that have experience working with this population. MSM who have infrequent sexual contacts may benefit from event-driven PrEP (ED-PrEP), an additional PrEP dosing regimen currently recommended for MSM only (See Section

6.5 PEPFAR's Key Populations Approach and Strategy). Note that the WHO is currently reviewing and updating guidance on the populations for whom ED-PrEP dosing is indicated. As part of PrEP initiation, providers should screen for IPV and provide first-line support (e.g., LIVES) and referrals for post-violence care services if indicated.

## 6.2.6 Condoms and Lubricants

Condoms, both outer ("male") and inner ("female"), and lubricants play an important role within the context of HIV prevention and sustained HIV epidemic control. As part of a combination prevention approach, condom promotion and distribution are most effective when integrated with other services as part of an "informed choice" and person-centered approach to preventing HIV. Condoms (and lubricants) should be strategically integrated into all service delivery including VMMC, HTS, HIV care and treatment, PrEP, DREAMS, KP-specific interventions, and other community interventions. Condom programs should continue to employ approaches that ensure equitable access to condoms (and lubricants) with medically accurate information among key and priority populations and low-income groups. It is essential that condom programs also identify demand-side barriers to condom use through user-centered research and employ a range of approaches to address these barriers. Condom programs should also consider gender-related factors, including gender norms that give women little control over the nature and timing of sex and little power to negotiate with men over safer sex and use of condoms. For condom programming to be sustainable, it must include technical support to governments to take on greater stewardship, leadership, and oversight of condom programs. OU teams should do a detailed, data-driven analysis of demand, availability, access, use, and sources of funding (including from partner countries and other donors) for condoms and lubricants to determine specific needs for commodities (e.g., color/scent and packaging) and to plan for transition to government ownership.

**Coordination with the Global Fund and other donors:** As in past years, OU teams should coordinate their planning for COP22 condom programming with any condom-related work supported by Global Fund Country Coordinating Mechanisms and/or other donors. The current Global Fund cycle runs 2020 to 2022 and is guided by a document[117] prepared by the Global

[117] https://hivpreventioncoalition.unaids.org/resource/developing-effective-condom-programmes-technical-brief/

Condom Working Group which describes best practices in condom programming in countries with a moderate to high burden of HIV.

Like PEPFAR, the Global Fund continues to prioritize its investment in prevention programming, including for condoms and lubricants, and aims to ensure that the quality of condom programs leads to increased condom availability and use among priority populations. Both agencies also support national and sub-national systems for condom program management with a focus on strengthening partner country coordination, ownership, and market stewardship. Effective and results-oriented condom programming requires an inclusive national planning process that examines the current situation and develops interventions to address specific challenges. To that end, PEPFAR COP22 condom activities should be designed, implemented, and monitored to tackle program gaps, barriers, bottlenecks, and/or market failures that other funders are not currently addressing or to strengthen/expand successful condom efforts that need supplemental support. Feasibility, timelines, complexity, political will, and integration with other prevention interventions should be considered when setting priorities for condom-related activities.

PEPFAR's goal is to ensure high levels of use, equitable access to, and sustained demand for condoms and lubricants. Overall, the vision of success for condom programming in PEPFAR includes:

- Adequate and sustainable supplies of free condoms and lubricants specifically targeting key and priority populations and low-income groups
- Educational and promotional condom programming thoughtfully and effectively integrated into existing prevention, care, and treatment platforms with messages that emphasize the utility of condoms (and lubricants) in HIV/STI and pregnancy prevention and address norms that hinder use
- Gender-sensitive condom programming that addresses how gender affects men and women's vulnerability to HIV and creates obstacles to condom use. Programs can design gender-sensitive messages and strategies, train condom providers on gender issues, increase women's protective options, foster couple communication, and create community dialogue between women and men
- Effective and impactful partner-government stewardship and ownership of condom programs, including national strategies and policies that create a supportive context for condom and lubricant distribution and promotion within the public and private sectors

- A total market approach (TMA) for each country that improves effectiveness and efficiency within the various condom and lubricant markets (e.g., public, social marketing, and commercial) to maximize coverage and health impact and to achieve greater sustainability and equity over time

**Effective and efficient supply solutions:** USG support for procurement and supply of free condoms and lubricants should be based on context-relevant quantifications - forecasts and supply plans based on stock-on-hand, consumption, actual demand, and realistic and comprehensive estimates for projected growth in the supported programs. Supply chain support should also take into consideration the logistics capacity of the public sector and partners that support the last-mile distribution to targeted populations and remote and isolated geographies. Additionally, in the context of COVID-19, including condoms (and lubricants) as part of essential supplies requires dedicated attention. Coordination with other donors, Ministries of Health, supporting agencies (particularly UNFPA and GF), and implementing partners is necessary to align and optimize long-term forecasts and supply plans at both the country and global levels. Tools for forecasting condom needs have recently been developed by UNAIDS and UNFPA.[118]

Procured condoms and lubricants should leverage the partner country's public sector supply chain, to the extent possible, to avoid the creation or support of parallel distribution systems; however, countries may realize the importance of leveraging private sector or civil society organizations to distribute condoms and lubricants to key and priority populations, in cases where that may be more suited. Public sector health facilities are an important point to access free condoms. Community distribution is also critical and should be coordinated with the public sector system with the objective of triggering demand for condoms, attracting new users, communicating the importance of condoms within the context of comprehensive prevention, care and treatment programs, and referring users to access condoms at health facilities, pharmacies, and community sites. Community distribution should target key and priority populations, including young people, and low-income groups, all of whom may face stigma or discrimination in clinical settings.

[118] https://hivpreventioncoalition.unaids.org/resource/condom-needs-and-resource-requirement-estimation-tool/

**Intervention and activity areas:** While each country needs to determine its own set of interventions based on the local context, the following set of interventions should be considered across PEPFAR countries:

- Integrate condom and lubricant programming into other platforms and interventions: USG support should ensure effective integration in the context of other HIV efforts (VMMC, HIV care and treatment, PrEP, DREAMS, ANC, community programs to engage men, and KP-specific interventions), including free condom and lubricant distribution and education/promotion/counseling in clinical and community settings. Effective counseling will help overcome specific barriers related to condom use and should focus on improving skills for proper use, increasing self-efficacy to negotiate use, and creating social and gender norms to support use. Free condoms should be distributed and tracked at health facilities providing prevention, care, and treatment services. Self-reported condom use should be measured periodically in addition to numbers of condoms distributed outside of the health facility setting to improve visibility in this area and gain a more accurate picture of total consumption.
- Support partner country governments to assume increased ownership and financing of condom programming: As the economies of PEPFAR partner countries expand, USG and GF programs should support partner country governments to assume full ownership of condom programming and procurement of condoms, where feasible. This includes forecasting, supply planning, procurement, storage, distribution, and financing of free condoms. Support for government stewardship of condoms may also include funding the gathering, analysis, and dissemination of condom-related data and research and coordination with all sectors including the commercial sector. Where partner country governments are not ready to assume full ownership of condom programming, PEPFAR programs should continue to coordinate with other donors to ensure the adequate availability of stable supplies of free condoms. In OUs where a complete transition of social marketing programs is not immediately possible, an alternative approach could be to include condom social marketing in social contracting models (similar to what is considered for key populations), where national governments start contributing to co-funding condom social marketing. Many countries are expected to continue to need financial assistance to procure condoms throughout COP22 to ensure access, but some should be ready to graduate from this activity.

- Foster an enabling environment for a TMA: USG support should be programmed to leverage the contributions of all market players, including and not limited to social marketing organizations, social enterprises, and the commercial sector. OUs should identify a “market facilitator” to support a TMA that ensures the following: each country has a condom programming vision, strategic framework, and supporting interventions informed by market knowledge; partner-country government and donor priorities, policies, and regulations are well-coordinated and consider the private sector; all relevant market actors are constructively engaged and effectively coordinated; and data-driven decision-making is prioritized. The USG should prioritize demand generation (i.e., education/promotion/counseling) and aim to gradually phase out procurement and supply support for branded social marketing of condoms and ensure that social marketing organizations leverage program income to take ownership of their programming.

  As noted above, OUs should continue to work to graduate all social marketing brands. In recent years, several country programs have demonstrated significant progress – or achievement – of full cost-recovery for condom social marketing brands. PEPFAR programs should aim to phase out procurement and supply support for socially marketed branded condoms, ensuring that the social marketing organizations leverage their program income to assume procurement and distribution of socially marketed condoms in the future. PEPFAR condom programs should avoid investments in “branding” free condoms except where data suggest it would help drive condom use without drawing users away from other, more sustainable options, and a plan should be put in place for the government to sustain the free brand through its own funding and management. At the same time, the expertise of social marketing programs can be applied in supporting free condom distribution with strategic information and demand generation within lower-income segments of the population.

  For graduating programs – either to Ministries of Health or social marketing programs – OU teams must continue to monitor whether programmatic activities and procurement have continued for a minimum of one-year after the end of PEPFAR support. Where programs falter, OU teams should be prepared to offer technical assistance or request such support from headquarters.

The process for estimating COP22 condom needs is outlined below:

- Review the partner country's GF program for condoms and lubricants, demand generation, and stewardship activities.
- Conduct an analysis of condom and lubricant needs and gaps based on the current condom and lubricant national quantification (inclusive of public sector and socially marketed condoms; as well as storage and last mile distribution costs); OUs can use the UNAIDS needs assessment tool or refer to the current annual, national quantification.[119]
- Provide a clear justification for any central condom and lubricant requests that outlines stock-on-hand, quarterly consumption trends, national forecast and supply plans, estimated condom and lubricant funding expected from other donors and the partner country, the amount of condom and lubricant funding covered in the country's base COP22, and the potential gap amount to be filled by central condom and lubricant funding.

## 6.3 HIV Testing Services Strategies: Reaching & Maintaining Global 95-95-95 Goals

Summary of section edits:

- Table 6.3.1 was updated to align with current PEPFAR guidance for HTS within VMMC programs.
- Clarified frequency of retesting for key populations.
- The paragraph on "Sustainability Planning for HTS" was removed because sustainability considerations are covered in COP/ROP23 Guidance.
- Aligned technical considerations with COP/ROP23 guidance on the use of HTS to support re-engagement to HIV treatment services

**What's New in HIV Testing Services Strategies: Reaching and Maintaining Global 95-95-95 Goals for COP22:**

- Expansion of the retesting subsection to include guidance on role of HTS in reengagement in care and treatment Services (Section 6.3)
- Inclusion of WHO's 2019 HTS guidance, recommendations, and good practice statements (Section 6.3)

[119] Condom Needs and Resource Requirement Estimation Tool, UNAIDS 2019 https://hivpreventioncoalition.unaids.org/resource/condom-needs-and-resource-requirement-estimation-tool/

- New guidance: Considerations for transitioning to national governments (Section 6.3)
- Reinforcement that the PEPFAR target for ≤ 2month EID coverage is ≥ 95% (Section 6.3.1.3)
- Reinforcement of the critical role of offering safe and ethical index testing to 100% of eligible individuals (Section 6.3.1.5)
- Expanded guidance on HIV self-testing among adolescents, youth, and high-risk subpopulations (Section 6.3.1.6 and Section 6.3.3)
- Recommended screening approach for optimizing PITC (Section 6.3.1.7)
- Role of community in ensuring quality of HIV testing services (Section 6.3.1.9)
- In SIMS 4.2, CEEs related to monitoring ethical and safe services will be required in any comprehensive assessment. (Section 6.3.1.9)
- Inclusion of new implementation resources for index testing of biological children and adolescents (<19 years) of persons living with HIV through Clinical and OVC Partner Collaboration (Section 6.3.2.1)
- Updated approach to pediatric/adolescent OPD testing strategy to ensure programs right-size OPD testing programs to address either undertesting or over testing and ensure OPD testing program is aligned to the countries' current pediatric ART coverage. (Sections 6.3.2 and 6.3.3)
- Updated approach to recommend routine pediatric inpatient department (IPD) in high HIV burden areas (e.g., prevalence ≥ 5%) (Section 6.3.2).
- Recommendations for demand creation activities for adolescent/youth HIV testing services (Section 6.3.3)
- New guidance: Role of HIV testing in prevention services to maintain epidemic control (Section 6.3.5)

HIV testing services (HTS) are essential for achieving and maintaining HIV epidemic control, and HTS remain a crucial platform to provide up-to-date, evidence-based HIV testing, prevention, and treatment health education. Timely and appropriate HIV testing interventions are critical to ensure focused access to prevention and treatment services for individuals to reduce HIV transmission and HIV-related morbidity and mortality.

Epidemic control is not a static state, and thus a sustainable, strategic combination of HIV testing approaches is critical to maintain and accelerate achievements. As countries approach 95% diagnostic rates among all people living with HIV, HTS programs must increasingly focus efforts on those at elevated risk of HIV acquisition. Within efforts to reduce incident infections, standard

of care HIV testing as part of prevention services serves as a critical marker for monitoring the impact of prevention services. (See Section 2.3.1 for additional guidance on how HTS should evolve as equitable epidemic control is achieved and Section 6.3.5 for additional considerations on HIV testing for prevention services).

To maximize impact, PEPFAR country programs should utilize the most recent epidemiological data at a sub-national level and develop targeted and innovative strategies that address contextualized, data-driven case finding gaps. In almost all countries, gaps in case finding for men and children/adolescents are disproportionately large, and effort should be exerted to implement innovative and efficient ways to swiftly close gaps among subpopulations.

Throughout the planning process, programs must consider the current gap to the first 95 and the anticipated number needed to test and diagnose to hasten achievement and maintenance of the first 95. Deliberate attention should be paid to testing volume, testing positivity, and case finding volume for each testing modality implemented (see Table 6.3.1). While each program's mix of strategic case finding and prevention monitoring HTS modalities may vary, offering safe and ethical index testing should be a core component across programs. (See Section 6.3.1.5 for guidance on implementing safe and ethical index testing.) Outcomes need to be viewed holistically by monitoring changes in both testing positivity and total case finding volume (HTS_TST_POS results).

*Table 6.3.1 Summary of implementation considerations for HIV testing modalities for case finding, prevention monitoring, and quality assurance (on next page)*

| HIV Testing Modality | Primary Purpose of Modality | Complexity/Cost to Implement | Estimated Positivity Based on Literature and/or Prior Program Performance | Priority for Plan & Budget | Comments |
|---|---|---|---|---|---|
| Facility-Based Index Testing for Older Adolescents and Adults (≥15y) | Case finding | Medium | ≥10% | Universal offer required | Emphasis to remain on offering coverage over testing positivity. |
| Community-Based Index Testing for Older Adolescents and Adults (≥15y) | Case finding | High | ≥10% | Universal offer required | Emphasis to remain on offering coverage over testing positivity. |
| Index testing of Biologic Children and Adolescents (<19 years of age) of persons living with HIV | Case finding | High | Low (*no predetermined positivity*) | Universal offer required.<br>Implementation catch-up plan required. | Emphasis to remain on offering coverage over testing positivity. |
| Social Network Testing | Case finding | Low to medium | Similar to targeted testing for key populations | Strategic use for case finding | See Section 6.5.1.2 for additional information on Social Network Testing. |

| | | | | | |
|---|---|---|---|---|---|
| HIV Self-Testing (HIVST) | 1) Case finding<br>2)Prevention Monitoring | Low to medium (dependent on approach and HIV ST kit unit cost) | **For case finding:** While not every HIVST outcome will be tracked, ascertained positivity should reflect treatment-adjusted prevalence populations or at least 1% if used for case finding.<br><br>**For prevention:** No expected positivity as modality is not for case finding | Strategic use for case finding; some prevention applications | HIVST is currently used for screening and not for HIV diagnosis. All positive HIVST results require confirmatory HTS. Comprehensive monitoring requires use of IP-provided program data to complement MER data. Data triangulation is needed to assess relationship between HIVST distribution for case-finding and HTS positivity and number of diagnoses by SNU. Successful implementation should be showing increases in other HTS modalities. |
| OtherPITC for Older Adolescents and Adults (≥ 15 years) | Case finding | Low | Equal to or greater than FY21 OtherPITC positivity. | Based on estimated case finding by subpopulation. | OtherPITC positivity of ≥ 10% may indicate insufficient testing coverage. See Sections 6.3.2 and 6.3.3 for important considerations for PITC for children and adolescents. |
| TB Clinics | Case finding | Low | 5 – 15% | Universal offer required | Emphasis to remain on testing coverage over testing positivity. |
| STI Clinics | Case finding | Low | 2-5% | Universal offer required | Emphasis to remain on testing coverage over testing positivity. |
| Targeted Community | Case finding | High | 5 – 10% | Context-specific, including accessibility to facility-based HTS during COVID-19 | Anticipated minimum community testing positivity for adult general populations is 2%. See Section 6.3.1.8 for additional details. |
| ANC and Post ANC for PMTCT | Prevention monitoring | Low | No expected positivity as HTS is minimum standard of care for PMTCT | Universal required | See Section 6.2.4 for additional guidance on PMTCT. |

| | | | | | |
|---|---|---|---|---|---|
| FP Clinics | Prevention monitoring | Low | No expected positivity as modality is not primarily for case finding | Context-specific, high incidence settings only | Focus on high incidence settings as part of AGYW programming and PrEP. Additional WHO guidance may be found here. |
| PrEP | Prevention monitoring | Low | No expected positivity as modality is not for case finding | Based on PrEP targets | Seroconversion while on PrEP should lead to further investigation. |
| VMMC | Prevention monitoring | Low | No expected positivity as modality is not for case finding | Based on VMMC targets | Though HIV testing is not required (i.e., remains optional) prior to receiving VMMC services, programs are encouraged to systematically offer HTS to individuals (especially men 15 – 35 years of age) seeking VMMC services. All HTS must remain aligned with the WHO's 5 Cs (https://apps.who.int/iris/handle/10665/179870) |
| Testing for Verification Prior to ART Initiation | Quality assurance measure | Low | 99% | | Positive test results should ***not*** be reported under HTS_TST_POS. See Section 6.3.1.2 for important considerations regarding retesting for verification. |

**HTS Operational Guidance**

WHO's 2021 consolidated guidelines for HIV testing, prevention, treatment service delivery and monitoring reiterate WHO's 2019 operational guidance on HTS demand creation and messaging; implementation considerations for priority populations; HIV testing strategies for diagnosis HIV; optimizing the use of dual HIV/syphilis rapid diagnostic tests; and considerations for strategic planning and rationalizing resources such as optimal time points for maternal retesting.[120,121] A summary of recommendations and good practices is shown in Figure 6.3.2.

*Figure 6.3.2 Summary of WHO's HTS guidance, recommendations, and good practice statements*[122]

**Box. 1 Summary of new WHO guidance, recommendations and good practice statements**

1. **Demand creation:** NEW Good practice statement highlighting evidence-based approaches and considerations for the use of incentives for HIV testing services, including linkage.
2. **Counselling message:** Updated messages and guidance on concise communications with emphasis on linkage and latest information on the benefits of treatment and prevention services.
3. **HIV self-testing:** Updated HIV self-testing should be offered as an approach to HIV testing services *(strong recommendation, moderate-quality evidence)*.
4. **Social network-based approaches:** NEW Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention *(conditional recommendation, very low-quality evidence)*.
5. **HIV testing strategies:** Updated. In response to changes in the HIV epidemic, WHO encourages countries to move toward using three consecutive reactive tests to provide an HIV-positive diagnosis.
6. **Western blotting:** NEW Western blotting and line immunoassays should not be used in national HIV testing strategies and algorithms *(strong recommendation, low-quality evidence)*.
7. **Dual HIV/syphilis rapid diagnostic tests:** All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg) at least once and as early as possible *(syphilis testing: strong recommendation, moderate-quality evidence; HBsAg: strong recommendation, low-quality evidence)*.
   NEW Dual HIV/syphilis rapid diagnostic tests (RDTs) can be the first test in HIV testing strategies and algorithms in ANC settings.
8. **Optimal maternal retesting time points:** Updated. In high HIV burden settings, retesting is advised for all pregnant women with an unknown or HIV-negative status during late pregnancy (third trimester). Catch-up testing is needed if the first test or retest is missed or delayed. High HIV burden countries could consider an additional retest in the post-partum period for specific districts or regions with high HIV burden or incidence, women from key populations or who have a partner with HIV who is not virally suppressed.

PEPFAR partners providing HTS must maintain an ethical code of conduct which delineates how to provide HTS in a safe, dignified, non-discriminatory, non-exploitative and supportive way. PEPFAR HIV testing programs must balance target achievement with the safety and security of recipients of services. Importantly, all HTS must be offered in alignment with the WHO 5C minimum standards: consent, confidentiality, counselling, connection to

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[120] WHO. (2021, July 16). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. https://www.who.int/publications/i/item/9789240031593

[121] WHO. (2019, November 27). Consolidated guidelines on HIV testing services for a changing epidemic. https://www.who.int/publications/i/item/WHO-CDS-HIV-19.31

[122] Ibid.

treatment/prevention, correct test results to ensure that (1) all PEPFAR supported sites meet the minimum standards for safe and ethical index testing services, and (2) routine monitoring, and remediation practices are in place for accountability and action. PEPFAR will continue to collaborate with civil society partners, government leaders, and implementing partners to ensure all voices are heard, remediation actions are conducted in a timely manner, and the safety and ethical treatment of clients remains of utmost importance. (See Sections 6.3.1.5 and 6.3.1.9 for additional information on index testing and community engagement and ensuring quality of HTS, respectively.)

All communications around HIV testing (including demand creation, group pre-test information, and post-test counseling) must align with current national and PEPFAR minimum standards, program priorities, and population/individual needs. HTS programs should provide non-judgmental, positive, consistent messaging to all supported persons and communities on the benefits of appropriate testing services, prevention services (including PrEP and VMMC), partner and index testing services, and HIV treatment (including U=U). Additionally, it is imperative for programs to establish and maintain strategic partnerships with community and subpopulation organizations that are a part of the communities and populations PEPFAR serves.

Programs must implement context-specific case finding strategies and promote prevention and treatment services by providing a positive, respectful clinical experience. The positive predictive value of any diagnostic test is dependent on the specific disease prevalence, and therefore it is important to take this into consideration when counseling individuals who reside in a low HIV prevalence area or are part of a low HIV prevalence subgroup (e.g., children) about the possibility of a false positive test. Lay counselors and social service providers should be engaged to work with those who seek HTS to facilitate timely access to and use of appropriate prevention or treatment services.

**Retesting & Reengagement in Care and Treatment Services**

Retesting occurs as a regular function of HTS programming. Examples of standard of care retesting may include:

- Offering at least annual voluntary retesting of key populations; depending on individual risk behaviors and/or national HTS guidance, more frequent voluntary

retesting can be offered,[123]

- Retesting of individuals who are HIV seronegative and in a serodifferent relationship,
- Retesting of individuals recently exposed to HIV and with a recent HIV-negative result,
- Retesting individuals who are taking PrEP in accordance with guidelines,
- Maternal retesting during antenatal, postnatal, and MCH care,
- Retesting individuals with a discrepant result (when the test results for two or more assays do not agree), and
- Verification testing to ensure correct test results for those newly initiating ART.

**Need to minimize unnecessary retesting:** The above examples are expected and indicated retesting practices; however, not all currently implemented retesting practices are necessary, and **unnecessary retesting must be minimized**.

There are intrinsic factors (e.g., limited health literacy, limited understanding of health system process, psychosocial conditions) and extrinsic factors (e.g., promotion of faith healing) influencing retesting behaviors. HTS programs must understand each of these driving factors and develop strategies to reduce unnecessary testing to the greatest extent possible. Strategies to reduce unnecessary testing include the following:

- Use of context-appropriate, validated screening tools,
- Strengthening health information talks that describe who should and should not be tested, inform about the process of retesting for verification as part of ensuring correct test results, and dispel myths about “cures”, and
- Strengthening health information systems at the site level to cross-check individual’s medical history.

HTS programs have an essential role in reengaging individuals who have experienced an interruption in care or treatment. Reengagement is critical for achieving and maintaining HIV epidemic control, and testing and treatment implementing partners must coordinate resources and efforts to support individuals seeking to re-engage in care and treatment services. Health

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[123] Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2022. https://apps.who.int/iris/rest/bitstreams/1453332/retrieve

facilities must provide appropriate services for all individuals living with HIV, including those who seek to resume HIV treatment. Providers must remain empathetic and nonjudgmental to mitigate previously diagnosed individuals feeling pressured to present themselves as unaware of a previous HIV diagnosis. Establishing and implementing standardized transfer and intake procedures, person-centered services, signage, and health talks that speak to this will make it easier for previously diagnosed individuals to reengage in a transparent way. Furthermore, treatment sites should also strengthen risk assessment practices to identify those who may be more likely to experience treatment interruption and proactively support these individuals to remain engaged in treatment services. A critical element to supporting treatment continuity includes implementation of health information systems that allow providers ready access to an individual's medical history to streamline both transfer and reengagement processes.

As PEPFAR continues to support persons-centered health education and service provision through implementation of dignified and effective welcome back service delivery, it is recognized that some individual's past health system experience may contribute to fear of fully disclosing prior or current interruptions in treatment. Judicious retesting may be considered a reengagement tool while continuing to improve other components of re-engagement service delivery.

### 6.3.1 HIV Testing Strategies for Case Finding

Programs should develop a comprehensive portfolio of case finding strategies for communities and facilities that incorporate data-driven, evidence-based, and person-centered approaches; these strategies should also capitalize on new technologies (e.g., HIV self-testing and multiplex testing where appropriate). Implementing person-centered approaches fosters an enabling environment and aligns communication for successful responses through affirming the dignity of persons living with, or vulnerable to, HIV.

Each OU must implement a strategic mix of case finding approaches based on the respective country's first 95 achievements across subpopulations within the clinical cascade. Such contexts will include target populations, ART coverage, and potential or actual innovative adaptations in response to COVID-19. Programs should perform the following actions while developing case finding strategies:

- Review most recent PHIA findings, Spectrum estimates, the WHO HTS Dashboard (https://whohts.web.app/), and other in-country data by geography, sex, and age disaggregates as well as key populations estimates.

- Review current geographic mapping of people living with HIV, target populations, treatment gaps, testing and other services.
- Review feedback obtained through satisfaction surveys, “mystery client” approaches, or community-led monitoring conducted to inform implementation and tailoring of person-centered services.
- Review rates of linkage to and continuity of treatment across subpopulations.
- Closely examine the proportional contributions and testing positivity data with a focus on new cases/diagnoses being identified, by different case finding approaches disaggregated by age, sex, and key population.
- Evaluate the cost and cost-effectiveness of different testing approaches using country data and while assuring sentinel and other surveillance mechanisms are in place to identify potential new cases or outbreaks.
- Intentionally engage with CSOs, traditional leaders, FBOs, youth-specific associations, OVC-supporting organizations, and other community organizations.
- Evaluate and incorporate the critical role of HTS in promptly linking individuals who test HIV negative to prevention services including PrEP, Sexual and Reproductive Health and Rights (including condoms and STI screening), and VMMC, as appropriate.

In response to each partner country’s unique context and evolving needs, PEPFAR is no longer instituting uniform, “one size fits all” positivity targets as each setting’s context is unique. Additionally, the observed extensive variation in OU performance limits the ability to apply uniform positivity target expectations. To guide COP22 HTS_TST and HTS_POS target setting, OUs are expected to utilize available epidemiological and program performance data, including ART coverage, to institute a HTS program that best positions the partner country to swiftly reach and maintain the first 95. This should be accomplished through:

- Providing high coverage of safe and ethical index testing (100% offer of index testing services) among newly diagnosed and virally unsuppressed populations as a minimum standard. This includes both facility and community interventions.
- Focusing PITC in generalized epidemics on the following:
    - Targeted testing (i.e., testing persons with specified risk, and this may include members of subpopulations with recognized gaps to achieving or maintaining the first 95 (e.g., men)) and diagnostic testing (testing persons with signs or symptoms of HIV); and
    - Universal screening (testing everyone) of ANC, TB, STI, malnutrition, and inpatient

populations.

- Focusing PITC in concentrated epidemics on the following:
  - Diagnostic testing (testing persons with signs or symptoms of HIV) that aim to achieve a positivity rate equal to or greater than the undiagnosed prevalence for the OU/SNU; and
  - Universal screening (testing everyone) of ANC, TB, STI, and malnutrition populations.
- Implementing highly targeted, community-based testing aimed at populations with gaps in the first 95 and/or high incident infections (e.g., key populations, adolescent girls and young women, and other priority populations). (See Section 6.3.1.8 for important consideration on targeted community-based testing services.)
- Strategically leveraging HIV self-testing (HIVST) to maintain access to testing across different service delivery points.
- Establishing testing services as part of evidence-based prevention interventions (e.g., PrEP, DREAMS, and VMMC). (See Section 6.3.1.6 for additional HIV self-testing considerations.)

It is imperative that testing protocols follow normative guidance to ensure consent, confidentiality, adequate counseling, correct results (minimizing false negatives and false positives) and connection to prevention and treatment services as applicable (i.e., WHO's 5Cs).[124] Case finding efforts should focus specifically on outstanding gaps. The extent to which programs are able to characterize and understand subpopulations of undiagnosed persons living with HIV is directly proportional to the extent programs can tailor effective and efficient case finding strategies to meet the testing needs of undiagnosed persons living with HIV.

The most obvious and efficient way to find cases, in terms of testing positivity, is to follow transmission dynamics, and all programs are required to consistently implement index testing services in a safe and ethical manner. (See Section 6.3.1.5 for important index testing guidance.) As mentioned in Section 2.3.4, as the COVID-19 pandemic has highlighted, it may be necessary to reduce exposure of individuals within health facilities

[124] WHO. (2015). *Consolidated guidelines on HIV testing services: 5Cs: consent, confidentiality, counselling, correct results and connection 2015*. https://apps.who.int/iris/handle/10665/179870

by offering testing services for contacts of index clients outside of facilities in a consistently safe and ethical manner.

Utilizing the privacy afforded by HIVST and considering the impact from COVID-19 on facility-based HTS, HIVST could extend testing access to individuals who may otherwise be reluctant or unable to seek facility-based services. Programs may consider accelerating plans for scaling HIV self-testing kit distribution in the following settings:

- Reaching priority populations within the community or facilities,
- Providing HIVST to an index client for their partner,
- Providing parents (index clients) with HIVST to screen biological children ≥ 2 years of age,
- Scale-up of HIVST for key populations and clients of female sex workers,
- Providing HIVST for high-risk PBFW, and/or
- Targeted use in OPD settings.

The above mentioned HIVST distribution modalities must be conducted in congruence with WHO's 5Cs and only implemented if appropriate for the local epidemiological context. Individuals who utilize HIVST kits must be informed of what the results mean and the purpose and place for confirmation testing. (See Section 6.3.1.6 for additional HIV self-testing considerations.)

Strategies that are effective at case finding among specific populations, such as social network testing in key populations, may work for other populations after appropriate adaptation.

### 6.3.1.1 HIV Rapid Testing Continuous Quality Improvement

Improving the quality of laboratory and point of care HIV testing to reduce error and ensure efficient delivery of services is a critical, but often neglected aspect of global public health systems strengthening. HIV rapid testing is a critical tool in the PEPFAR response – making HIV testing accessible in areas with limited laboratory facilities, performed by staff without any formal laboratory training and significantly increasing the number of persons who learn their HIV status at the point of testing. Several recently published and unpublished program results indicate that misdiagnosis of HIV status can occur due to poor quality HIV tests, limitations of the national testing algorithm or the HIV testing process. Preliminary data from proficiency testing programs

in selected countries have returned error rates between 5% and 10%.[125] However, the actual magnitude of misdiagnosis is unknown since some of the misdiagnosis is not reported and many countries do not have proper Quality Assurance (QA) procedures in place.

A good example of an innovative approach to ensure sustainable quality assurance practices that lead to accurate, reliable patient results is the WHO/PEPFAR supported HIV Rapid Testing Continuous Quality Improvement (HIV RTCQI).[126] This process brings together different elements of the quality assurance cycle in a holistic manner to ensure full engagement of countries and stakeholders to minimize and eventually eliminate testing errors. Also, to minimize possible misdiagnoses the WHO recommends retesting all persons newly diagnosed as HIV positive before initiation of ART ("verification testing").[127]

PEPFAR teams should consider the following elements of the HIV RTCQI in COP22 planning:

1. Implement the DTS EQA technology to monitor the quality of HIV RT, including the expansion of DTS EQA to all testers at a testing point.
2. Strengthen systems for internal quality control at testing points.
3. Develop and adhere to national testing algorithm(s).
4. Use HIV RT standardized logbooks for data capturing, monitoring, and reporting.
5. Implement tools (i.e., database) to manage and analyze quality data (i.e., HIV EQA program, logbook, site audits, etc.).
6. Develop reporting strategies at the national and sub-national levels to ensure test providers and sites that are performing poorly receive feedback and implement corrective actions in a timely manner.
7. Develop and implement policies to guide testing, particularly policies that endorse the use of point of care (POC) testing and task sharing to use non-laboratorians as testers.
8. Develop policy on competency-based training programs to certify/re-certify testers for HIV RT and creating a network of testers who are trained and certified.
9. Develop human resources through recruitment, training, and certification of in-country. Quality Corp (Q-Corp) volunteers and officers to assist in the implementation of HIV RTCQI.

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[125] Johnson et al. (2017) J Int AIDS Soc. 6:21755.
[126] WHO (2015) https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf
[127] WHO (2019) https://www.who.int/publications-detail/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

10. Improve and certify sites using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklists, as appropriate.
11. Monitor quality and performance of rapid tests in the field after procurement as post-marketing surveillance.
12. The MER Lab_PTCQI annual indicator should be used to monitor and report on participation and performance in EQA and CQI programs.

### 6.3.1.2 Retesting for Verification

Although the existing WHO prequalified HIV rapid diagnostic tests all have sensitivities of >99% and specificity >98%, given the large volume of tests conducted worldwide, it's inevitable that a not insubstantial number of tests will be false negative or false positive. Based on data from a systematic review of 64 studies, an estimated 93,000 people could be misdiagnosed per year.[128]

Several factors may lead to a false-positive misdiagnosis during the initial testing event, including user error, poor recordkeeping, inadequate management and supervision, and over-interpretation of weak reactive results. A false-positive misdiagnosis may lead to grave consequences for individuals (including stigma and discrimination, strains on family relationships and reproductive choices, and unnecessary lifelong use of medication) as well as for a community's trust in public health and HIV testing programs. To assure accurate test results and reduce the likelihood of HIV misdiagnosis, the WHO recommends that national programs follow validated HIV testing algorithms and revised testing recommendations, including retesting for verification of all HIV-positive cases prior to ART initiation.[129]

Retesting for verification of HIV positive status provides an opportunity to reduce HIV misdiagnosis. Retesting for verification should occur prior to or at ART initiation. Retesting for verification should apply only to newly identified HIV positive persons and those not yet initiated on ART. Retesting for verification is not recommended for persons who have been on ART for long time as rapid tests may give false negative results due to waning of antibodies.

Previous reviews of national guidelines have found that there has been slow adoption of the retesting guidance which may be because of a variety of factors including reliance on clinical assessments, lack of data on the frequency of misdiagnosis, concern about delays in ART

[128] Johnson et al. (2017) J Int AIDS Soc. 20.7.22190
[129] WHO (2019) https://www.who.int/publications/i/item/WHO-CDS-HIV-19.31

initiation, or concerns regarding additional costs of verification. Multiple studies have demonstrated that retesting is cost effective in various population groups, including pregnant women and low and high-prevalence settings.[130,131,132,133] In light of this, it is recommended that PEPFAR supported sites should retest all newly identified HIV-positive persons before initiation of ART.

### 6.3.1.3 Infant Diagnosis: Birth Testing, Integrating POC for Early Infant Diagnosis (EID)

Summary of section edits:

- Stringent preconditions for birth testing such as: coverage by 2 months for infant virologic testing is >95%, and availability of immediate treatment regimens for neonates who are identified as HIV+, have been removed because countries are following WHO testing guidance and conducting birth testing without this threshold.

HIV-exposed infants (HEI) face a higher risk of morbidity and mortality than HIV-unexposed infants. To reduce morbidity and mortality among HEI who acquire HIV infection, continuity of care for the mother and infant, including prompt diagnosis and ART initiation and optimization (Section 6.4.1.1) during the breastfeeding period is critical. Programming must be gender responsive to the unique barriers faced by women–for example, experience of IPV has been shown to negatively affect uptake of early infant HIV testing and HIV status disclosure among post-partum women.[134]

Globally, most pediatric infections are due to mother to child transmission (MTCT), with half (51%) occurring after 6 weeks post-delivery. All OUs have struggled with ensuring that HEI receive all the necessary repeat virologic tests (per national testing strategy recommendations) throughout the breastfeeding period, culminating with a 'final outcome test" at 18 months of age or 3 months after the cessation of breastfeeding, whichever is later. It is imperative that all HIV-

[130] WHO (2015) https://www.ncbi.nlm.nih.gov/books/NBK316036/
[131] Hsiao et al. (2017) J Int AIDS Soc. 20(Suppl 6):21758
[132] Eaton et al (2017) Clin Infect Dis. 2017 Aug 1; 65(3):522-525.
[133] Lasry et al (2019) PLoS ONE 14(7): e0218936.
[134] Hampanda et al. (2017) https://doi.org/10.1186/s12981-017-0142-2

infected infants be identified as early as possible, because, up to 50% of untreated HIV-infected infants die by the second year of life, with mortality being high in the first few months of life.[135]

As of FY21Q4, only 1 of the PEPFAR-supported countries has reached the goal of achieving 95% testing coverage of HIV-exposed infants by age 2 months and linking 95% of infants with HIV infection promptly to treatment (Figure 6.3.1.3.1). PEPFAR teams should work with countries and other stakeholders to ensure EID testing is scaled to ensure at least 95% of HEI are tested by age 2 months. The current COVID-19 pandemic may present challenges relating to client safety and access to clinics. To overcome this, mitigation options within the facilities that allow for social distancing should be followed to create a patient-friendly environment and ensure appropriate sample collection testing and timely return of results. In addition, approaches should be used to reach mothers and infants who have missed appointments for EID testing, such as telephone outreach or use of community health workers/peer mothers, ensuring all COVID-19 protocols are followed (See Section 6.3.1.4). Laboratories should continue to prioritize the rapid processing of infant samples, identify positive results as a critical lab value that follows an expedited communication procedure, and communicate immediately on sample rejection as well as sustain close monitoring of sample quality and rejection rates and make improvements as needed, given that diagnosis of HIV infection in an infant can be considered a medical emergency, requiring immediate treatment.

Recommendations from the WHO, published in 2021, include consideration of a nucleic acid test (NAT) at birth ('birth testing') and introduction of point-of-care (POC)/near POC NAT tests.[136] These testing strategies may help address some barriers to achieving high testing coverage and early initiation of ART for HIV-infected infants. Immediate ARV therapy must be available for infants with positive birth or POC testing. Confirmatory testing of initial positive early infant test results is critical due to potential contamination with maternal blood, specimen mislabeling, and laboratory contamination. The WHO recommendation to repeat testing of all indeterminate results[137] to avoid errors in test results classification is currently feasible only with the Roche Cobas Ampliprep/Taqman platform for which the indeterminate range has been established. WHO is currently working with other instrument manufacturers to establish similar

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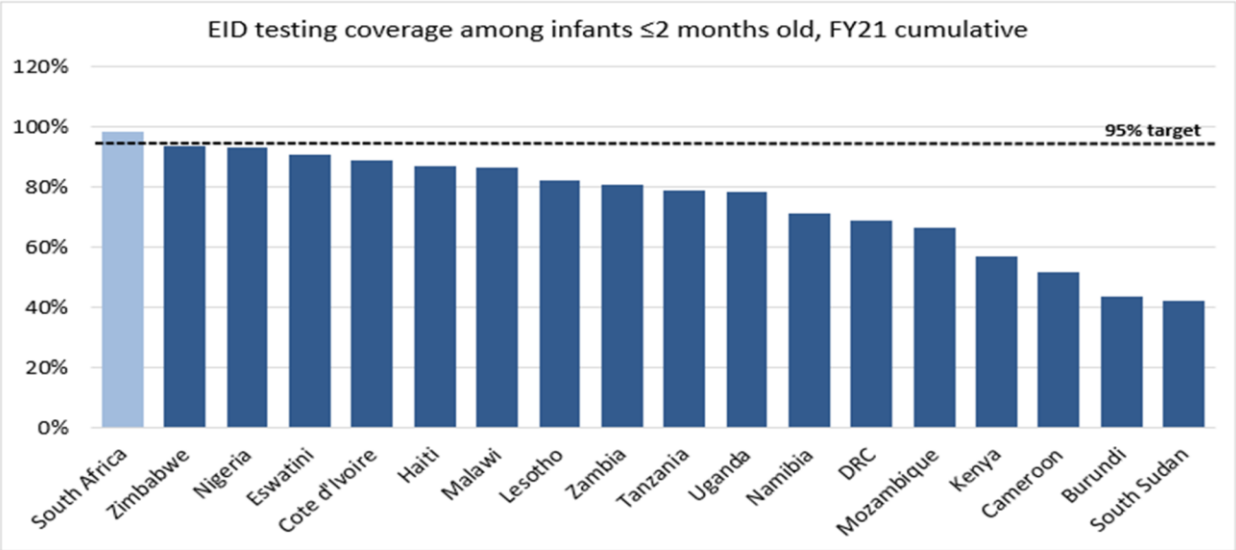
[135] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext#secd1175567e1778
[136] WHO (2021) Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (who.int)
[137] WHO (2018) http://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf

indeterminate ranges. PEPFAR recommends that all samples that initially tested **HIV POSITIVE**, including target detected with low and high signals, should be repeated immediately using remnant spots of the same DBS sample for all conventional instruments.

A follow-up confirmatory test of all initial positive test results should be done using a new sample at the time treatment is initiated or before. Repeat testing of the same sample may not be possible with POC or near POC technologies when the sample is directly applied from the heel to the cartridge; however, in such instances a new sample should be taken and immediately tested to confirm a positive test result.

*Figure 6.3.1.3.1: Only one OU achieved the 95% Coverage Target of EID 2-month Testing in FY21*




When considering how to strengthen the testing program for HIV-exposed infants and whether POC/near POC testing or birth testing may be appropriate in their settings, PEPFAR programs should consider the following:

**Birth Testing**

- PEPFAR programs are recommended to ensure that the following conditions are met to ensure the best outcomes for birth testing of HIV-exposed infants regarding standard 4-6-week NAT testing:
  1) coverage by 2 months for infant virologic testing is ≥95% of infants born to women receiving ART in prevention of mother-to-child (PMTCT) programs,

2) Monitoring and evaluation systems are updated to capture the birth test, the 2mo test, and subsequent infant testing time points, and data are reviewed and use to identify gaps in infant testing at the various time points.

- While birth testing may be conducted using conventional laboratory based or POC virologic tests, emphasis should be made to prioritize POC testing.
- Identification of high-risk infants for selective birth testing can be difficult; universal birth testing of HIV-exposed infants may be easier to operationalize.
- While some countries in resource-limited settings have demonstrated higher overall early testing coverage by adding birth testing to their algorithm, the addition of birth testing may decrease the number of infants returning for follow up HIV testing by age 4-6 weeks. Careful counselling messages will be needed for birth testing to ensure that infants with a negative HIV test at birth return for ongoing care and testing, including a test at 4-6 weeks and ascertainment of final HIV status at the end of breastfeeding.
- Coverage of PMTCT programs is an important consideration. Modeling shows that a greater proportion of perinatal (intrauterine and intrapartum) infections are expected[138] to occur *in utero* in settings with high PMTCT coverage*;* birth testing may be most valuable in these settings. However, high PMTCT coverage should translate to low HIV prevalence among HIV-exposed infants, meaning that more false positive results are anticipated. This risk of false positives highlights the importance of collecting a second specimen for confirmatory testing from all infants with an initial positive virologic result.
- Immediate, same-day linkages to effective pediatric ART services must be in place to ensure all positive test results at birth lead to immediate initiation of appropriate ART for HIV-infected newborns. To prevent loss of newly identified HIV-infected infants not immediately started on ART, active tracking should be in place.
- Existing M&E tools and systems will need to be adapted to comprehensively capture birth testing activities including strengthening of tools to capture confirmatory testing.
- Customized indicators should be developed to capture birth testing numbers and results and to evaluate impact of birth testing on EID services received by two months of age. Potential additional program monitoring indicators may include: the number of infants receiving birth testing (0-7 days of age); the number of birth test results reaching caregiver; the time to ART initiation for infants identified HIV+ through birth testing; the number of HIV-

[138] WHO (2018) https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1

exposed infants receiving EID by 2 months of age (excludes neonates who received birth testing at 0-7 days).

- The addition of birth testing requires additional resources, including the costs associated with the second test, the potential need for more health workers and expanded systems to ensure return of results and linkage to services and initiation on treatment.

**Use of Near Point of Care and Point-of-Care Platforms for EID**

A positive EID result is a recognized program failure, and the priority districts with ≥ 5% incidence in newborns must enhance care and support to pregnant and breastfeeding mothers, including integration of routine maternal retesting during the breastfeeding period (Section 6.3.5). To ensure comprehensive and timely diagnosis in newborns, programs must use POC testing to complement laboratory-based platforms in support of EID and VL testing in pregnant and breastfeeding women. This is especially important in countries with long turnaround time (>7 days) for results to caregivers. Strategic placement of POCs and optimization of the EID testing network is critical; not doing so could impact TAT on conventional platforms that use batch testing if the lab experiences significant drops in samples referred to the lab. WHO has prequalified the use of two platforms (Cepheid GeneXpert® near POC and Abbott m-PIMA POC) for early infant diagnosis and viral load testing.[139] POC testing for EID and VL could make results available for patient management within hours of specimen collection. Data from Unitaid supported studies conducted in both Mozambique[140] and Malawi[141] showed that the use of POC for EID led to reduction in TAT, increase in number of infants tested and placed on ART, and was cost-effective. To ensure continued support to programs on incorporation of POC EID, the PEPFAR VL/EID Community of Practice has put together a solution document[142] to guide this process. PEPFAR programs should work closely with their respective ISMEs to use the solution document and other resources to support scale-up of EID using POC. Implementation and scale-up of POC for EID is an important consideration for country programs that are not on target to reach testing 95% of HIV-exposed infants by 2 months of age.

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[139] WHO (2019) https://www.who.int/diagnostics_laboratory/evaluations/190918_prequalified_product_list.pdf?ua=1

[140] Jani etal. (2018). AIDS. 32(11):1453-1463

[141] Mwenda et al. (2018) Clin Infect Dis. 10.1093/cid/ciy169.

[142] PEPFAR, 2018 https://www.pepfarsolutions.org/solutions/2018/11/6/increasing-access-and-coverage-of-hiv-1-early-infant-diagnosis-through-use-of-point-of-care-testing

Data from Cameroon show that the use of POC EID at entry points outside of the PMTCT program (including ANC, immunization, and maternity), such as emergency, pediatric wards, and outpatient, led to improvements in testing numbers and positivity yield.[143] Programs should consider placing POC platforms outside of PMTCT entry points to increase access to timely infant HIV testing. Priority clinical sites for consideration of placement of POC devices include TB clinics, pediatric inpatient wards, immunization clinics, malnutrition clinics, or in other sites that have a high volume of potentially HIV-infected infants as well as remote sites with adequate volume. Other strategies to reach infants and older children outside of PMTCT programs will rely on index testing, appropriate PITC (see Section 6.3.2 on Pediatric case finding), and risk-based screening in OVC programs and other community-based settings.

Furthermore, breastfeeding, and continued risk of transmission require follow-up and appropriate testing of infants throughout the period of risk until final diagnosis. In concordance with WHO 2018 guidelines.[144] PEPFAR recommend the use of NAT for HIV diagnosis among infants at 9 months of age to ensure more accurate diagnosis.

### 6.3.1.4 Best Practices to Close Remaining Gaps in EID

In an effort to close remaining gaps in 2 months EID testing coverage and linkage of HIV-positive infants to optimized ART regimens (Section 6.5.1.1), the VL/EID ISME Community of Practice has put together some best practices, tools, and guidance that programs should consider adapting to their particular setting. See summary below. Details of these resources can be accessed through this link: https://pepfar.sharepoint.com/sites/VL-EID.

Though significant progress has been made in improving infant diagnosis even within the context of COVID-19, many countries have not yet reached the 95% target for EID coverage by 2 months of age and have lengthy turnaround time and poor linkage to ART (<95%). In addition, global data highlights the extent of new HIV acquisitions among children via breastfeeding among women who are in the PMTCT program, or who never entered it.[145] This highlights the importance of ensuring consistent follow up on not only infant virological testing status for HIV-exposed infants at postpartum entry points (such as MCH, immunization, or family planning) and through to final outcome, but also expanded efforts for maternal HIV retesting at timepoints

[143] Tchendjou et al. (2020). J Acquir Immune Defic Syndr 84 Suppl 1:S34-S40.
[144] WHO (2018) https://apps.who.int/iris/bitstream/handle/10665/273155/WHO-CDS-HIV-18.17-eng.pdf?ua=1
[145] UNICEF (2020) http://www.childrenandaids.org/Last-Mile-to-EMTCT

post-ANC1. As noted elsewhere in COP guidance (Section 6.3.1.3), point-of-care EID testing in selected settings has led to reduced EID turnaround time and improved linkage to ART for HIV-positive infants across multiple countries.[146,147] Several other innovations have demonstrated improvements in infant HIV testing and linkage of HIV-positive infants to ART and may be adapted as best practices in appropriate settings:

(1) *Maternal and infant HIV screening at immunization clinics:* A pilot in Western Kenya implemented systematic screening at immunization clinics, offering maternal re-testing for those eligible, and DBS collection from all HIV-exposed infants (HEI), including those newly identified as exposed on the same day. This well-structured 6-week immunization clinic intervention provided an opportunity for early identification of HEI and linkage to care. Of over 90,000 infants screened for HIV exposure status at immunization clinics, 1,025 new HIV-exposed infants (1%) were identified.[148] A validated pediatric simulation model assessed the cost-effectiveness, MTCT, and life expectancy of implementing universal maternal screening at six-week infant immunization clinics alongside existing EID programs vs. relying solely on existing EID programs in South Africa, Zimbabwe, and Cote d'Ivoire. Three factors influenced cost-effectiveness: screening program cost, infant linkage to nucleic-acid testing after referral from the screening program, and maternal knowledge of HIV status during pregnancy. Inclusion of universal immunization screening decreased total MTCT by 0.2%-0.5% and improved life expectancy by 1.5 years for children with HIV. Inclusion of universal immunization screening[149] increased mean lifetime per-person costs from $17 to $22 per child in all settings but remained below the per-capita GDP per year-of-life saved threshold for all three countries. The study concluded that utilizing screening at immunization clinics in addition to EID programming can be of comparable value to current HIV-related interventions in high maternal HIV prevalence settings like South Africa and Zimbabwe.

(2) *Mother-baby pair tracking by peer mothers:* A household and community-based intervention by AIDSFree in Eswatini addressed interruption in treatment and promoted continuity of care using Community Focal Mothers (CFMs) to visit mother-baby pairs (MBPs) in their home to encourage them to continue visiting the health facility for care prior to any missed appointments.

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[146] https://www.pepfarsolutions.org/solutions/2018/11/6/increasing-access-and-coverage-of-hiv-1-early-infant-diagnosis-through-use-of-point-of-care-testing?rq=kenya
[147] https://www.thelancet.com/pdfs/journals/lanhiv/PIIS2352-3018(19)30033-5.pdf
[148] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6401209/
[149] Lorna et al. (2021) https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25651

This project led to 100% of enrolled infants receiving EID and results at 6-week well child visits.[150] The main components of the interventions included: MBPs enrolled at 6-week postpartum visit, CFM created care plan with mothers during monthly home visits to proactively address challenges in attending visits up to 24 months, Care plan updated in subsequent CFM visits, CFMs issued referral forms to mothers who miss a visit, and CFMs met bimonthly with facility focal person for review of MBP engagement.[151]

(3) *Mobile health platform for mothers:* MomConnect, a mobile phone-based intervention in South Africa, provides standardized health messages and appointment reminders to support pregnant and breastfeeding WLHIV. Once registered, women receive weekly mobile phone messages, including ART reminders, tips on how to manage treatment side effects, breastfeeding guidance, and reminders to return for recommended testing and care for their infants, based on the woman's stage of pregnancy or the child's age. This mHealth initiative enabled women to interact with the health system, providing feedback on the quality of care received to improve service delivery.[152,153]

(4) *EID Quality Improvement initiatives:* An EID quality improvement project in Uganda noted that the use of expert clients to track lost Mother Baby pairs from the communities and link them to facilities resulted in increased DNA PCR testing, because the expert clients were accessible, appropriate, and acceptable to HIV-positive mothers.[154] Similarly, an EID Quality Improvement Collaborative in Cameroon showed improvements in EID coverage and results return with a "change package" of 30 successful interventions identified.[155] Country programs should consider using some of these best practices to improve early infant diagnosis coverage and prompt linkage to treatment as indicated, particularly for infants who are <2 months of age.

(5) *Post-natal Clubs:* Post-natal clubs have been identified as a promising practice from South Africa to improve services for mothers living with HIV and their infants. These clubs can

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[150] https://www.pepfarsolutions.org/solutions/2018/12/19/cfm-improving-mother-baby-pair-retention-in-interated-maternal-and-child-health-and-hiv-services-in-eswatini?rq=eswatini
[151] CFM: Improving mother-baby pair retention in integrated maternal and child health and HIV services in Eswatini — PEPFAR Solutions Platform (BETA)
[152] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5922496/
[153] https://www.praekelt.org/momconnect
[154] https://www.hindawi.com/journals/bmri/2016/5625364/
[155] https://icap.columbia.edu/wp-content/uploads/Cameroon-QICIP-Success-Story.pdf

positively impact early retention, maternal viral suppression, uptake of infant testing services, and integration of maternal and child health services.[156]

## 6.3.1.5 Index Testing

Summary of section edits:

- Removed content that is either obsolete or redundant with material and resources available on PEPFAR Solutions Platform
- Provided links to relevant PEPFAR Solutions Platform pages

Index testing (also referred to as contact tracing, or partner notification, or partner services) is a case-finding approach that focuses on eliciting the sexual or needle sharing partners and biological children of individuals living with HIV and offering them HIV testing services. Partners and children who test HIV positive can then be linked to lifesaving HIV treatment while HIV-negative contacts in a serodifferent relationship with the index client can be linked to effective HIV prevention strategies such as PrEP and VMMC. Index testing can also be used as a re-engagement strategy by identifying partner(s) and children who have been previously diagnosed as HIV seropositive but are not currently receiving antiretroviral treatment. Once identified, these "known (sero)positive" contacts can be linked to or re-engaged in HIV treatment services. WHO guidance supports the scale-up of index testing services as an HIV case finding strategy, stating that "provider assisted referrals should be offered for all people with HIV as part of a voluntary comprehensive package of testing, care, and prevention (strong recommendation, moderate-quality evidence)."[157]

**Minimum Standards for Conducting Safe and Ethical Index Testing Services**

PEPFAR recognizes the importance of providing all HIV testing services (HTS), including index testing services, in accordance with internationally recognized standards to ensure the provision of safe and ethical HTS to all clients. All index testing offered at PEPFAR-supported sites must adhere to PEPFAR's Guidance on Implementing Safe and Ethical Index Testing and WHO's

[156] https://differentiatedservicedelivery.org/Models/PostNatalClubs
[157] WHO. (2019, December 1). *Consolidated guidelines on HIV testing services*. https://www.who.int/publications/i/item/978-92-4-155058-1

5Cs minimum standards (consent, counseling, confidentiality, correct test results, and connection to appropriate HIV prevention and treatment services).[158]

Additional guidance on safe and ethical index testing can be found on PEPFAR Solutions Platform: https://www.pepfarsolutions.org/resourcesandtools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

## 6.3.1.6 HIV Self-Testing

Summary of section edits:

- Updated to align with current WHO and PEPFAR guidance to promote user choice and therefore to encourage countries to have a mix of blood-based and oral fluid HIVST assays
- Updated to align with WHO's and PEPFAR's current guidance for use of HIVST within PrEP programs.
- Updated list of HIVST kits that have been pre-qualified by WHO
- Updated to emphasize that use and disclosure of results should be voluntary and never forced or coerced
- Updated to emphasize the importance of support mechanisms for if and when individuals using HIVST request additional information

HIV self-testing (HIVST) is defined by WHO as a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a simple, rapid HIV test and interprets the result, where and when they want.[159] In November 2019, WHO issued guidance that HIVST should be offered as an approach to HIV testing services.[160]

HIVST is an effective tool for expanding access to individuals at risk who may not otherwise test and individuals at ongoing risk who may need to test more frequently. This may include underreached and underserved individuals, including men and youth. HIVST is particularly valuable in key populations. There is evidence that HIVST increases uptake of HIV testing,

[158] WHO. (2015, July). *Consolidated guidelines on HIV testing services: 5Cs: consent, confidentiality, counselling, correct results and connection 2015*. https://apps.who.int/iris/handle/10665/179870

[159] WHO. (2021). *HIV self-testing*. https://www.who.int/reproductivehealth/self-care-interventions/hiv-self-testing/en/

[160] WHO. (2019, November 27). *WHO recommends HIV self-testing – evidence update and considerations for success*. https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36

compared to standard facility-based HTS and positivity and linkage rates are comparable to facility-based testing.[161] HIVST is acceptable and feasible in a variety of settings and populations, and potential social harms and misuse are rare.[162] There is no evidence that HIVST increases sexual risk behavior.

There is some evidence that HIVST as a screening tool is highly sensitive, has lower HRH requirements, can increase testing uptake, including reaching individuals missed through PITC or risk-based screening, respects the agency of those tested, and decreases perceptions of coercion.[163]

HIVST may be either oral/buccal mucosal or blood-based kits. Country teams should choose the proper kit for their specific context and targeted distribution needs. WHO encourages national HIV programs to promote user preference, and this can be done by ensuring the allowance and availability of both blood-based and oral fluid HIVST kits. Therefore, programs are encouraged to ensure there is a favorable policy and supply chain environment and adequate HRH. Specifically, national guidelines and algorithms should cater to both types of kits and both types of kits should be registered for national procurement. Programs with permissive operational contexts should have year-on-year increases in HIVST investments.

**Distribution and Use of HIVST**

There are two main methods of offering HIVST: directly assisted HIVST and unassisted HIVST. Directly assisted HIVST refers to when individuals who are self-testing for HIV receive tailored, translated or pictorial instructions for use with additional support such as a local telephone hotline, virtual real-time support or supervision through online platforms, an in person or video-based instruction or as part of a large group (e.g., waiting room) from a trained provider or peer

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[161] Eshun-Wilson, I., Jamil, M. S., Witzel, T. C., Glidded, D. V., Johnson, C., Le Trouneau, N., Ford, N., McGee, K., Kemp, C., Baral, S., Schwartz, S., & Geng, E. H. (2021). A Systematic Review and Network Meta-analyses to Assess the Effectiveness of Human Immunodeficiency Virus (HIV) Self-testing Distribution Strategies. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*, *73*(4), e1018–e1028. https://doi.org/10.1093/cid/ciab029

[162] Witzel, T. C., Eshun-Wilson, I., Jamil, M. S., Tilouche, N., Figueroa, C., Johnson, C. C., Reid, D., Baggaley, R., Siegfried, N., Burns, F. M., Rodger, A. J., & Weatherburn, P. (2020). Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis. *BMC medicine*, *18*(1), 381. https://doi.org/10.1186/s12916-020-01835-z

[163] Dovel, K., Shaba, F., Offorjebe, O. A., Balakasi, K., Nyirenda, M., Phiri, K., Gupta, S. K., Wong, V., Tseng, C. H., Nichols, B. E., Cele, R., Lungu, E., Masina, T., Coates, T. J., & Hoffman, R. M. (2020). Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial. *The Lancet. Global health*, *8*(2), e276–e287. https://doi.org/10.1016/S2214-109X(19)30534-0

*before* distribution of the HIVST kit, with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use. Directly assisted HIVST does *not* mean that the test must be performed in the presence of a provider. Unassisted HIVST refers to the distribution of HIVST kits with the manufacturer-supplied instructions, but without additional instruction or assistance.

Importantly, HIVST is a screening test and should not be used to provide a definitive HIV diagnosis. *A reactive (positive) HIVST result is* ***not*** *equivalent to an HIV-positive diagnosis.* Programs may need to develop alternate workflows to ensure that patients can receive further testing per the national testing algorithm, and in-person and/or virtual support should be provided to help individuals promptly receive appropriate further HIV testing, prevention, and treatment services. The positive predictive value of any test is dependent on prevalence, and it is important to take this into consideration when counseling individuals who reside in a low HIV prevalence area or are part of a low HIV prevalence subgroup (e.g., children) about the possibility of a false positive HIVST result and the imperative for further HTS prior to a confirmed HIV diagnosis.

HIVST should be part of the HTS portfolio especially in high-burden settings and should be strategically deployed to screen adolescent girls and young women and their partners, male partners of ANC clients, key populations and their partners, adult men, and other priority populations (e.g., refugees, young at-risk men) that face high levels of stigma and discrimination.

HIVST implementation should be strategic and based on the country's epidemiologic environment. As indicated by the local epidemiological context, programs may consider accelerating plans for scaling HIVST kit distribution in the following settings:

- Reaching priority populations (including at-risk men, adolescent girls and young women) within the community or facilities
- Implementing index testing services, by providing a HIVST kit to an index client to distribute to (a) partner(s) or to screen biological children ≥2 years of age
- Scaling of HIVST for key populations and clients of female sex workers; due diligence is required to ensure that requesting individuals to distribute HIVST kits will not jeopardize the individual's safety
- Augmenting PMTCT services through provision of HIVST for high-risk pregnant and breastfeeding women
- Optimizing OPD-based HTS through targeted use of HIVST

Linkage to HIV testing services by a trained provider to confirm HIV status, starting with the first testing in the national algorithm, is critical following a reactive HIVST screen. In a review of all populations, linkage to treatment has been shown to be comparable to standard HTS, as is linkage to prevention services for those who screen negative; however, when looking at linkage to care among sub populations, there was noted to be a slight decrease in linkage to care compared to standard HTS for sex workers.[164] Linkage rates can be improved when linkage support interventions are included with HIVST kit distribution.[165] Implementing partners may develop and explore emerging linkage support tools (e.g., digital, or community-based) for unassisted self-testing.

Where feasible, messages and materials should be tailored to the barriers and drivers within subpopulations. It is vital to engage community groups to advocate for, design, implement, and analyze the success of HIVST. Programs should anticipate, identify, and address the internal and external barriers and challenges individuals may face in deciding whether to access testing, prevention, and/or treatment services.

Scale-up of HIVST has varied by country, although annual targets increased overall 30% from FY2021 to FY2022. In line with increased HIVST distribution targets, many PEPFAR operating units increased their respective HIVST kit distribution target for FY2022 (COP21) compared to FY2021 (COP20).

Based on positive programmatic outcomes (e.g., linkage and initiation on ART), HIVST should be taken to scale. Innovative distribution channels should be considered including retail pharmacies and stores, alternative pickup points in the community, and other private sector channels, in line with national policies. Additional studies on proven distribution strategies and utilization, as well as innovations with HIVST in shifting contexts can be found in special issues

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[164] Jamil, M. S., Eshun-Wilson, I., Witzel, T. C., Siegfried, N., Figueroa, C., Chitembo, L., Msimanga-Radebe, B., Pasha, M. S., Hatzold, K., Corbett, E., Barr-DiChiara, M., Rodger, A. J., Weatherburn, P., Geng, E., Baggaley, R., & Johnson, C. (2021). Examining the effects of HIV self-testing compared to standard HIV testing services in the general population: A systematic review and meta-analysis. *EClinicalMedicine*, *38*, 100991. https://doi.org/10.1016/j.eclinm.2021.100991

[165] Nguyen, V., Phan, H. T., Kato, M., Nguyen, Q. T., Le Ai, K. A., Vo, S. H., Thanh, D. C., Baggaley, R. C., & Johnson, C. C. (2019). Community-led HIV testing services including HIV self-testing and assisted partner notification services in Vietnam: lessons from a pilot study in a concentrated epidemic setting. *Journal of the International AIDS Society*, *22 Suppl 3*(Suppl Suppl 3), e25301. https://doi.org/10.1002/jia2.25301

of the British Medical Journal[166] and the Journal of the International AIDS Society.[167]

**COVID-19 Adaptations for HIVST**

Within the context of COVID-19, distribution of HIVST kits may help reach individuals who otherwise would be unable or reluctant to go to a facility. Self-test kit distribution should be maximized outside of the clinic setting - including providing self-tests through decentralized distribution approaches such as peer home delivery, private or community pharmacies, etc. - which may help reduce COVID-19 transmission by decongesting facilities and reducing the frequency and/or duration of client-provider interactions. As per the PEPFAR guidance on COVID-19,[168] where feasible and effective, programs should consider distributing HIV self-testing kits to index clients so that partners can screen themselves prior to coming to the facility. This may help ensure that only partners who are most likely to have HIV will come to the facility for confirmatory HIV testing per the national testing algorithm. National policies may limit the feasibility of partner notification through index testing in light of the COVID-19 pandemic and, as such, programs should take this into account. Countries may consider accelerating their plans for scaling HIVST kit distribution for those with increased risk of HIV infection which may include extending COVID-19 adaptations such as providing oral testing kits to index clients to screen biological children ≥2 years of age for HIV.[169]

During COVID-19, some settings experienced disruptions to HIV services and began using HIV self-tests to maintain essential services–including for providing PrEP. In July 2022, WHO published technical guidance on differentiated and simplified PrEP that addresses broader use of HIVST within PrEP programs. Country teams should take into consideration the information available in Section 6.2.1 (PrEP) and WHO's technical guidance to inform how best to appropriately maximize HIVST within PrEP programs.

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[166] BMJ. (2021, June). *Innovating with HIV self-testing in a changing epidemic: Results from the STAR (Self-Testing AfRica) Initiative*. BMJ Global Health. https://gh.bmj.com/content/6/Suppl_4

[167] JIAS. (2019, March). *Realizing the potential of HIV self-testing for Africa: lessons learned from the STAR project*. https://onlinelibrary.wiley.com/toc/17582652/2019/22/S1

[168] PEPFAR. (2021). *PEPFAR Technical Guidance in Context of COVID-19 Pandemic*. PEPFAR's HIV Response in the Context of Coronavirus Disease 2019 (COVID-19). https://www.state.gov/pepfar/coronavirus/

[169] https://www.state.gov/pepfar/coronavirus/

**Procurement of HIVST Kits**

As of September 2022, six HIVST kits have been pre-qualified by WHO (listed in alphabetical order of manufacturer):

1. Abbott's blood-based HIV self-test assay (CheckNOW™)
2. bioLytical Laboratories' blood-based HIV self-test assay (INSTI®)
3. Chembio Diagnostics blood-based HIV self-test assay (SURE CHECK HIV 1 /2 Assay)
4. Mylan's blood-based HIV self-test assay (formerly Atomo HIV self-test)
5. OraSure Technologies' HIV oral/mucosal self-test assay (OraQuick Advance Rapid HIV 1/2 Test)
6. Wondfo's blood-based HIV self-test assay

National policies increasingly support programmatic application of HIVST. Programs should work to ensure appropriate policy development and approvals for HIVST kit importation and utilization across all approved populations to support procurement and policy implementation. PEPFAR supports efforts to reach price parity for WHO pre-qualified HIVST kits to ensure that countries choose the optimal test(s) to address contextual needs.

**Monitoring and Reporting HIVST Kit Distribution**

HIVST means an individual performs a test on themselves in private or under observation of a professional if they so desire. HIVST should be voluntary and never forced or coerced. Equally, individuals who use a self-test should never be forced or coerced to disclose the result to anyone and should only voluntarily disclose results. However, this does not preclude the need for support mechanisms to be in place for when the individual requests additional information, such as seeking advice on the results (particularly reactive results) and/or potential next steps or available services.

PEPFAR's MER includes an HTS_SELF indicator that measures trends in the distribution of HIVST kits within a country at the lowest distribution point and, where possible, measures intended use of HIVST. Disaggregates of HTS_SELF include number of test kits distributed to a person by age/sex, number of test kits distributed to Key Populations and test kit distribution for use (e.g., self, sex partner, and other). *Utilization of self-test kits should not be reported under HTS_TST (or HTS_TST_POS).*

HTS registers can be adapted to include reason for visit, including community and facility HTS sites and treatment sites. Reason for visit can include having a reactive HIV self-test and needing confirmatory testing. This is one way to assess whether individuals with a reactive HIV self-test have received HTS for confirmatory diagnostic testing. HIVST indicators or metrics that indicate downstream clinical impacts (e.g., numbers and proportions linked to further testing by a trained provider to confirm HIV status, both in PEPFAR and non-PEPFAR-supported sites, and subsequently to treatment and/or prevention services) should be developed by programs. Methodologies to track outcomes of HIVST may include activities such as:

- Utilization of QR codes added to kits and other virtual applications (e.g., phone apps, webpages, and instant messaging software),
- Survey questions on HIVST use at testing intake,
- Follow-up surveys or tracking among a sample of HIVST kit recipients (this can be done via phone, SMS, or direct in-person follow-up), and/or
- Drawing inferences from an increase in uptake of testing and treatment within target HIVST population.

Programs should attempt to track and appropriately respond to all adverse events associated with HIVST, including instances of self-harm or intimate partner violence. Adverse events related to related to secondary distribution also require appropriate response.

## 6.3.1.7 Optimized Provider-Initiated Testing and Counseling (PITC)

Summary of section edits:

- Removed Figures 6.3.1.7.1 and 6.3.1.7.2 to strengthen alignment with current HTS program guidance
- Updated guidance on use of HIV risk screening tools within PITC settings to further emphasize need for validated tools and to increase focus on highly sensitive HIV self-testing

Provider-Initiated HIV Testing and Counseling (PITC) remains the leading contributor to HIV case finding in PEPFAR partner countries, despite its relatively low testing positivity. There is inherent tension between HIV testing strategies aiming for high positivity and those seeking to identify the largest absolute number of individuals with HIV, and programs are faced with an ethical imperative to not allow persons living with HIV accessing healthcare services to remain

undiagnosed and untreated. Deciding on which HIV testing approach to prioritize exemplifies the common public health conundrum of whether to focus on rates (positivity) or absolute numbers, and at what cost.

A balanced and informed consideration is required to determine the right mix of HTS strategies required to achieve progress, even amid COVID-19-related constraints. PITC remains one of the least costly case finding strategies available and remains appropriate in many contexts. Careful selection and implementation of PITC approaches should be informed by proportional attribution to case finding and must be driven by the needs of the country and its subpopulations.

**Strategies to Strengthen Case Finding and Address Resource Constraints in Health Facilities**

There are three strategies of selection that may be employed in PITC:

1. **Diagnostic testing** is the testing of individuals who present with signs or symptoms suggestive of HIV, including signs or symptoms of TB. Diagnostic testing should be implemented regardless of ART coverage in a country or SNU.
2. **Targeted testing** is the testing of subpopulations of increased risk as identified by behavioral, clinical, or demographic characteristics, or a combination of these such as MSM, FSW, individuals receiving STI care and treatment, or persons residing in high burden areas.
3. **Universal testing** is the testing of individuals presenting for medical attention regardless of presenting complaint. All people presenting for care in the following settings are considered at risk and should be tested for HIV: Antenatal Care Clinics, TB clinics, STI clinics, malnutrition clinics (for children), MAT clinics, harm reduction sites, and for hospitalized patients, including children in inpatient wards.[170]

A strategic combination of PITC optimization efforts such as HIV self-testing (HIVST), validated HIV screening, and targeted routine testing (such as in antenatal clinics) can accelerate first 95 achievements. This strategic combination is of particular importance for settings experiencing COVID-19 and/or health system constraints.

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[170] Cohn, J., Whitehouse, K., Tuttle, J., Lueck, K., & Tran, T. (2016). Paediatric HIV testing beyond the context of prevention of mother-to-child transmission: a systematic review and meta-analysis. *The lancet. HIV*, *3*(10), e473–e481. https://doi.org/10.1016/S2352-3018(16)30050-9

Evidence is emerging on HIVST as a complementary effort to PITC optimization and as a HIV screening tool. Recent evidence suggests that using HIVST as a highly sensitive screening tool in facilities can increase testing coverage among priority populations and generate significant efficiencies in service delivery.[171] (See Section 6.3.1.6 for additional HIV self-testing guidance and considerations.)

**Considerations on when, how, and where to implement PITC Strategies**

It is important to align HIV case finding and testing policies with data on ART coverage, potential gaps in testing, cost of testing (across all funders), and COVID-19 mitigation efforts. In generalized epidemics, hospital medical wards usually have a high concentration of persons living with HIV who will benefit from diagnosis and treatment. PITC strategies should be targeted toward the unmet needs of geographic areas and specific subpopulations. In areas with high ART coverage and lower gaps, PITC should be highly targeted to ensure people living with HIV continue to be diagnosed at a rate that matches or exceeds new HIV infections to achieve and sustain the first 95.

Monitoring and evaluation are essential to the optimal delivery of PITC and should include an assessment of current HTS coverage to help improve service delivery. For example, the number and proportion of people tested, service delivery point, new cases diagnosed by population, age and sex, and the timing of additional tests for pregnant and breastfeeding women (e.g., pregnancy, labor and delivery, breastfeeding) can determine how well services are covering populations in need. In settings where testing positivity is high and testing coverage is low, programs should consider incorporating HIVST within the facility to increase coverage, improve effectiveness, and decrease the burden on health workers. There is no single strategy that is effective for all settings and careful consideration should be given to local prevalence and population(s) served. For example, in countries where HIV prevalence is low in the general population (<5%), steps should be taken to focus testing on SNUs and subpopulations that have

[171] Dovel, K., Shaba, F., Offorjebe, O. A., Balakasi, K., Nyirenda, M., Phiri, K., Gupta, S. K., Wong, V., Tseng, C. H., Nichols, B. E., Cele, R., Lungu, E., Masina, T., Coates, T. J., & Hoffman, R. M. (2020). Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial. *The Lancet. Global health*, *8*(2), e276–e287. https://doi.org/10.1016/S2214-109X(19)30534-0

not achieved or sustained the first 95. In settings where HIV prevalence is high (≥5%) and HIV testing coverage is low, programs need to take steps to achieve broader coverage. This may involve demand creation within the community or target populations.

An excellent example of optimizing and integrating HIV services comes from a Malawi PEPFAR Solutions program which piloted a program targeting men in three clinics by offering provider-initiated testing and counseling combined with routine screening for STIs, diabetes, and hypertension as well as expanded clinic hours resulting in higher HIV positivity rates than other clinics nationally.[172]

**Implementing Targeted HIV Testing**

Over time, the proportion of outpatient department (OPD) patients testing HIV seropositive has declined in many programs, however diagnostic volumes in this setting, even at lower positivity remain, the largest of any modality and are critical for originating index clients and reaching populations who may not be captured through index testing alone. Testing positivity trends are heterogeneous across countries and within country programs. Programs should review their OPD testing positivity rates by site and focus on targeted and diagnostic testing where testing positivity rates are low. Sites that have large absolute numbers of people living with HIV but low testing positivity rates in OPD must consider how to make OPD testing more strategic without losing case finding volume.

Two primary strategies to reduce unnecessary PITC include:

1. Aligning counseling messages on retesting to include retesting based on exposure and *not* a one-size fits-all 3-month window period, and
2. In general, not retesting persons with a documented previous HIV diagnosis. (There might be infrequent circumstances where retesting is in the best interest of an individual who is requesting HTS as an entry point to reengaging in care and treatment services.) *It is not recommended to retest an individual who is on ART, as being on ART may lead to an incorrect HIV rapid test result*.[173]

In high HIV prevalence areas, pregnant and breastfeeding women who initially test HIV negative should have repeat testing around delivery and during breastfeeding since risk of acquisition

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[172] PEPFAR Solutions, 2018. *Addressing the Blind Spot in Achieving Epidemic Control in Malawi: Implementing "male-friendly" HIV services to increase access and uptake*.

[173] WHO. (2021, July 16). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. https://www.who.int/publications/i/item/9789240031593

may be increased in pregnant and breastfeeding women and new infection during this time is associated with increased risk of vertical transmission. (See Section 6.2.4.1 for additional ANC and PMTCT guidance.) Additionally, for high HIV prevalence areas, individuals engaging in unprotected intercourse who have not been tested in the past six months may also have high rates of HIV infection and should be offered HTS.

In low HIV prevalence and concentrated epidemics, HTS is only recommended for:

- Members of key populations,
- Partners of persons living with HIV,
- People with sexually transmitted infections, TB, or viral hepatitis,
- Individuals who have never been tested or have not recently been tested for HIV,
- Persons who present to health facilities with signs and symptoms suggestive of underlying HIV infection*, including tuberculosis and malnutrition, and
- Children known to have been exposed to HIV perinatally or during breastfeeding.

Although those seeking outpatient services are generally less ill than those admitted to inpatient wards, in generalized epidemic settings, targeted HIV testing, and counselling should also be implemented in medical outpatient department (OPD) facilities utilizing an HIV screening tool. Evidence shows that screen-in tools have proven more effective than screen-out tools and PEPFAR programs should focus on screen-in tools, ensuring that those at risk of infection are offered testing.[174]

**Symptoms that should prompt an HIV test** may include, but are not limited to, the following:

1. Significant and rapid weight loss
2. Cough, especially persistent cough >2 weeks
3. Fever or profuse night sweats
4. Unexplained tiredness and/or fatigue
5. Prolonged swelling of the lymph glands in the armpits, groin, or neck
6. Sores of the mouth, anus, or genitals
7. For children: any child with recurrent skin problems, recurrent infection, swollen abdomen (enlarged liver or spleen), delayed physical and developmental growth, any child that has

[174] Ong, Jason and Coulthard, Katie and Quinn, C and Tang, MJ and Huynh, T. and Jamil, M. and Baggaley, Rachel and Johnson, Cheryl, Risk-Based Screening Tools to Optimise HIV Testing Services: A Systematic Review. Available at SSRN: https://ssrn.com/abstract=3858557 or http://dx.doi.org/10.2139/ssrn.3858557

had poor health in the last 3 months or been hospitalized, swollen lymph nodes, intermittent diarrhea, oral thrush[175] history of TB or TB symptoms, pus coming from ear, discharge, or sores in genital area.[176,177,178,179]

8. For women: any mother of a child born with HIV or with unexplained illness who died before age 2 years.

**Using Validated HIV Risk Screening Tools in PITC Settings**

An HIV risk screening tool is a set of questions (behavioral, demographic, symptom-based, etc.) used to identify individuals who need HIV testing. In accordance with WHO guidance[180], risk screening tools should be validated for the program's setting and should only have a screen-in approach to reduce missed opportunities in critical entry points. Specifically, screen-in tools "identify high-risk individuals for HIV testing who would not otherwise be offered a test."[181] *HIV risk screening tools should not be used to reduce testing volume.*

For programs that are currently utilizing highly sensitive, validated, screen-in tools, efforts should be maximized to support prompt re-engagement for individuals identified as having an interruption in treatment.

Due to 1) the lack of screen-in tools that are validated with appropriate sensitivity, 2) the increased availability of highly sensitive, highly specific, and more affordable HIV self-test

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[175] WHO. Manual on Paediatric HIV Care and Treatment for District Hospitals: Addendum to the Pocket Book of Hospital Care of Children. 2011.

[176] Bandason T, McHugh G, Dauya E, Mungofa S, Munyati SM, Weiss HA, et al. Validation of a screening tool to identify older children living with HIV in primary care facilities in high HIV prevalence settings. AIDS. 2016;30(5):779-85. doi:10.1097/QAD.0000000000000959;

[177] Katureebe, C, et al. (2019, July). *Developing a pediatric and adolescent HIV-screening tool in outpatient setting in Uganda.* [Abstract]. 11th International Workshop on HIV Pediatrics, Mexico City, Mexico. http://regist2.virology-education.com/abstractbook/2019/abstractbook_Pediatrics2019.pdf

[178] Horwood, C., Vermaak, K., Rollins, N., Haskins, L., Nkosi, P., & Qazi, S. (2009). Paediatric HIV management at primary care level: an evaluation of the integrated management of childhood illness (IMCI) guidelines for HIV. *BMC pediatrics*, *9*, 59. https://doi.org/10.1186/1471-2431-9-59

[179] Moucheraud, C., Chasweka, D., Nyirenda, M., Schooley, A., Dovel, K., & Hoffman, R. M. (2018). Simple Screening Tool to Help Identify High-Risk Children for Targeted HIV Testing in Malawian Inpatient Wards. *Journal of acquired immune deficiency syndromes (1999)*, *79*(3), 352–357. https://doi.org/10.1097/QAI.0000000000001804

[180] WHO. (2019, December 1). *Consolidated guidelines on HIV testing services*. https://www.who.int/publications/i/item/978-92-4-155058-1

[181] Ong JJ, Coulthard K, Quinn C, et al. Risk-Based Screening Tools to Optimise HIV Testing Services: a Systematic Review. *Curr HIV/AIDS Rep*. 2022;19(2):154-165. doi:10.1007/s11904-022-00601-5

(HIVST) assays, all programs are encouraged to optimize the use of HIVST within PITC and in other testing sites where staff and HTS coverage may be limited. For populations in settings with very low prevalence and low testing coverage (e.g., children), validated, screen-in risk screening may be considered to help increase testing coverage among these individuals. See Section 6.3.1.6 for additional operational considerations for HIV self-testing.

**HIV Case Finding among Individuals with Presumptive or Diagnosed TB**

While HIV testing coverage among persons with confirmed TB is generally >90%, with high testing positivity, there remains a large gap in identifying and testing individuals with TB symptoms but who have not received a TB disease diagnosis (presumptive TB). All individuals who are either diagnosed with or presenting with pulmonary or extrapulmonary symptoms of tuberculosis should be tested for HIV. Persons with presumptive TB have been shown to have markedly higher prevalence of HIV than the general population. The number of individuals with presumptive TB exceeds the number of those who are diagnosed with TB, and there is a disproportionate number of males with presumptive TB. Given high rates of HIV infection in this population, identification of persons with TB symptoms is a priority for HIV case finding efforts.

*Therefore, HIV testing should be offered to all individuals presenting with TB symptoms, even before diagnosis of TB disease.* In the setting of COVID-19, countries should consider implementing universal screening algorithms for TB and COVID-19, as appropriate to their epidemiological context. All individuals, including children, should be screened for TB symptoms, and linked to TB and HIV testing services if screened positive. This should be considered a dual infection control and case finding strategy.

All individuals presenting with poor weight gain (for children), malnutrition, fever, or cough, should be tested for TB and offered HIV testing. High-yield entry points such as inpatient wards, malnutrition clinics, STI, and TB clinics should have PITC registers to document testing, and HIV testing coverage among people who present with TB symptoms at these entry points should be >90%. Although HIV testing positivity among individuals with presumptive and confirmed TB are high, testing volumes for this group have been far below expected. Programs must scale up identification of presumptive TB as a high-yield HIV case finding strategy. Use of existing presumptive TB registers is an effective way to document and monitor HIV testing among those with presumptive TB and to monitor whether presumptive TB patients are being appropriately referred from all service delivery points of the health facility. Countries should evaluate the fidelity to which individuals with presumptive TB are being identified in both outpatient and inpatient settings and may use an anticipated ratio of 5:1 of presumptive:

confirmed cases as a guide. (See Section 6.4.3 for additional guidance on TB case finding and diagnostic strategies for all ages, including utilizing TB case finding as a high-yield HIV case finding strategy.)

### 6.3.1.8 Targeted Community-Based Testing Services

Community-based testing services are HIV testing services (HTS) offered within a community and outside of a health facility.[182] WHO recommends community-based testing, especially to reach men, key populations and their partners, young people, and other vulnerable populations who may be less likely to be seen or tested in facilities. However, it is important to recognize that these more targeted approaches to community-based testing have the potential to reinforce stigma, as it relates to these populations and HIV risk. Given the potential for unintended reinforcement of stigma, careful planning and implementation of stigma mitigation strategies is a must for all targeted community-based testing services.

As countries progress towards the UNAIDS 95-95-95 targets, it is crucial that programs deploy a mix of community-based targeted testing strategies. All community testing for adult general populations should be as focused as facility-based testing modalities. *Only community-based testing that is coordinated with laboratories to ensure correct results, and that leads to immediate linkage to appropriate HIV prevention, care, and treatment services is allowed for implementation.*

There are several important considerations when designing community based HTS including engagement of the target communities and inclusion of approaches focused on the relevant populations and settings. It is integral that facility and community partners work closely together through sharing data and best practices and through collaborating on strategies to ensure the safe and ethical implementation of index testing. This includes offering all contacts of index clients testing services and support to be promptly linked to prevention or treatment services.

In addition to civil society organizations, PEPFAR recognizes faith-based organizations (FBOs) and other communities of faith as essential partners with a critical role in accelerating and sustaining HIV epidemic control. Programs are encouraged to support strategic engagement with CBOs, FBOs and other faith and traditional communities (including Religious Parent

[182] WHO. (2019, December 1). *Consolidated guidelines on HIV testing services*. WHO. https://www.who.int/publications/i/item/978-92-4-155058-1

Bodies) to scale up evidence-based models in high- and low-burden areas, as appropriate. These organizations and communities are trusted gatekeepers with social capital and ready access to communities. Given the cost-effectiveness of decentralized services,[183] PEPFAR supports the scale-up of data-driven models such as the Circle of Hope Faith-Engaged Community Posts.[184] This model offers decentralized HIV service delivery across the HIV prevention and care continuum for men, women, and children with sustained HIV positivity and linkage rates that compare or exceed facility-based services. Moreover, throughout the COVID-19 pandemic, this model maintained the safe delivery of services which contributed to the decongestion of health care facilities.

To maximize impact, community-based testing should be limited to high-burden geographic areas or non-facility locations (e.g., bars, clubs, places of worship, harm reduction sites, cruising sites, workplaces, or mobile outreach) where selective and targeted community mobile testing or co-location of health clinics/testing sites may be acceptable and produce high positivity or high absolute number of new diagnoses. Furthermore, studies show that community-based testing strategies that integrate health assessments and multi-disease screenings can effectively reduce stigma at the community level by normalizing HIV testing as part of routine health care.[185] Among key populations, HIV testing uptake is highest when combined with testing for TB, STIs, FP, and/or hepatitis but somewhat lower when combined with screening for chronic conditions. In contrast, in Nigeria, the Baby Shower Initiative, a church congregational-based approach that coupled HIV testing with other chronic diseases, facilitated the identification of HIV-positive pregnant women and their male partners, many of whom were not engaged with facility-based care.[186]

Both index testing services and HIV self-testing (HIVST) are key strategies for targeted community-based testing. Index cases are identified in health facilities and within the

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[183] Dave, S., Peter, T., Fogarty, C., Karatzas, N., Belinsky, N., & Pant Pai, N. (2019). Which community-based HIV initiatives are effective in achieving UNAIDS 90-90-90 targets? A systematic review and meta-analysis of evidence (2007-2018). *PloS one*, *14*(7), e0219826. https://doi.org/10.1371/journal.pone.0219826

[184] PEPFAR Solutions. *Circle of Hope: Using faith-based community outreach posts to increase HIV case finding, linkage and retention on treatment in urban and rural settings in Zambia*.

[185] Chamie, G., Napierala, S., Agot, K., & Thirumurthy, H. (2021). HIV testing approaches to reach the first UNAIDS 95% target in sub-Saharan Africa. *The lancet. HIV*, *8*(4), e225–e236. https://doi.org/10.1016/S2352-3018(21)00023-0

[186] Gbadamosi, S. O., Itanyi, I. U., Menson, W., Olawepo, J. O., Bruno, T., Ogidi, A. G., Patel, D. V., Oko, J. O., Onoka, C. A., & Ezeanolue, E. E. (2019). Targeted HIV testing for male partners of HIV-positive pregnant women in a high prevalence setting in Nigeria. *PloS one*, *14*(1), e0211022. https://doi.org/10.1371/journal.pone.0211022

community-based testing programs. During community-based testing, newly diagnosed persons will be identified, in which case partner notification services should be offered to the index client (See Section 6.3.1.5 for additional index testing considerations). To support timely linkage to treatment, counselors should continue to follow-up with consenting individuals newly diagnosed with HIV until they have initiated treatment.

Programs should also consider incorporating HIVST into community-based testing strategies where appropriate. PEPFAR does not support broad community distribution of HIVST kits; instead, HIVST kits should be targeted to high-risk individuals, notably those with risk factors such as being among sexual or social networks of persons living with HIV or key populations with very high risk. (See Section 6.3.1.6 for important HIVST considerations.)

In low burden settings, community-based testing should be limited to targeted testing of key populations, men, and adolescents/young people as appropriate for the local epidemic. Community-based testing strategies targeting female sex workers should also include their clients. All community-based testing strategies should offer and support immediate linkage to prevention services (e.g., PrEP, VMMC) for high-risk individuals who are HIV seronegative.

Implementing partners supporting HIV testing programs are responsible for offering various testing modalities, including HIVST, and for promptly linking to treatment those who are HIV seropositive. Implementing partners supporting HIV testing programs must also provide the option of facilitated linkage (e.g., peer navigation) to treatment facilities and are required to demonstrate successful linkage to treatment. Community-based testing for key populations will continue to be supported in all PEPFAR settings, including high ART coverage areas. However, for all community-based testing, programs should closely monitor the numbers of individuals tested, testing positivity, and case finding volume to inform the continued or refined use of these strategies. If the numbers of individuals tested, number diagnosed, and/or positivity does not support continued efforts/expense, programs should discontinue the specific strategy. Programs providing community HTS must ensure that immediate ART linkage is available, aim to achieve >95% linkage, and establish memorandums of understanding/agreement with treatment and prevention implementing partners to foster timely linkage to treatment and prevention services.

Studies show that community-based testing strategies are most effective when paired with demand generation activities.[187] One of the Faith and Community Initiative hallmarks has been investment in creating materials that capacitate FBOs and faith and traditional communities to disseminate new Messages of Hope across their religious parent body infrastructures.[188] This suite of communication prototypes provides accurate information about HIV and COVID-19, respectively, and affirms messages about testing, prevention, and advances in HIV treatment (e.g., U=U) for dissemination through sermons and across traditional mass media channels and digital and social media platforms to reduce stigma and increase uptake of targeted HIV testing. While created with and for faith communities, these Messages of Hope and the accompanying repository of materials may be adapted for any setting; hence, programs should include these resources, as appropriate, within community-based testing strategies.

### 6.3.1.9 Community Engagement and Ensuring Quality of HIV Testing Services

Summary of section edits:

- Removed obsolete information on SIMS

Many countries that achieved the 90–90–90 targets by 2020 have been leaders in differentiated service delivery, where facility-based services are complemented by community-led services. Collaborative engagement can greatly enrich the HIV Testing Services (HTS) program's understanding of community dynamics and provide valuable feedback to improve HIV testing services, processes, and program quality for populations and persons served. Programs and implementing partners are required to develop and maintain relationships with local communities to ensure that HTS meet the needs for reaching and maintaining epidemic control and remain responsive to community needs and concerns. Key stakeholders for community engagement can include, but are not limited to, local and national civil society organizations,

[187] Chamie, G., Napierala, S., Agot, K., & Thirumurthy, H. (2021). HIV testing approaches to reach the first UNAIDS 95% target in sub-Saharan Africa. *The lancet. HIV*, *8*(4), e225–e236. https://doi.org/10.1016/S2352-3018(21)00023-0

[188] Faith and Community Initiative. (2021). *Faith and Community Initiative Communication Prototypes*. FCI. https://www.faithandcommunityinitiative.org/

community and/or clinic advisory groups, and civic and faith leaders.

Countries should endeavor to implement a strategic and dynamic mix of community engagement methodologies to monitor the impact of HTS programs. A testament to the importance of community engagement is Uganda's Local Capacity Initiative. Through this initiative, the Uganda program was able to demonstrate improvement in facility-based and community-based HIV testing services serving KP.[189]

Coordinated community engagement serves as an important platform to provide and receive early notification of potential challenges, ranging from shifts in population patterns to community perceptions. Examples of population shifts can include changes in favored drug utilization patterns, neighborhoods where PWID acquire or use drugs, locations where sex workers congregate or solicit services, and neighborhoods/venues that serve specific KP groups. Engaging with the community may also reveal public perception challenges that may dissuade persons from seeking or continuing testing, prevention, and treatment services. Examples of such perceptions include lapses in privacy or confidentiality, collaboration between case finding programs and local police services, lack of support or empathy from providers, pressure, or coercion to participate in services, conditional access to services, and/or difficulty in scheduling/accessing services.

Ensuring the quality of HIV case finding services includes routine review of program data, utilization of standardized monitoring and supportive supervision tools (including the Gender-based Violence Quality Assurance Tool), supportive visits, adaptations of the Community Score Card, and Community-Led Monitoring. (See Section 3.2.3 for Community-Led Monitoring guidance.)

HTS programs can utilize data sources to monitor the quality of services provided, and programs must routinely review program data to swiftly identify outcomes outside of program expectations. For example, index testing cascades that demonstrate abnormally high or low acceptance rates may signal of data quality issues, opportunities for skills building or retraining, and/or the potential loss of client and contact's autonomy in deciding their participation in index testing services.

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[189] MEASURE Evaluation. (2020, January). *The PEPFAR Local Capacity Initiative Supports the Community Score Card to Improve HIV Services for Key Populations in Uganda*.

Safe and Ethical Index Testing Site Assessments were initiated during COP20; data from Safe and Ethical Index Testing Site Assessments should be reviewed with implementing partners, partner country MOH, and civil society to identify where PEPFAR-supported programs may not be compliant with minimum standards established for index testing. This data should be used to swiftly develop and implement remediation plans for sites not meeting program standards; alternatively, eligible index clients can be referred for services at a compliant site. Community engagement and collaboration are critical, and programs are encouraged to co-develop response plans based on assessment findings to ensure community trust is maintained. Countries interested in implementing ongoing monitoring of site adherence to safe and ethical index testing standards may incorporate the assessments into their national quality assurance guidelines for case finding programs with routine monitoring activities.

Embedding supportive supervision and mentorship within case finding programs can improve the skillset of front-line staff and assist with the dissemination of innovations.[190] To support optimal outcomes, programs are encouraged to implement Continuous Quality Improvement (CQI) activities. Tools for conducting supportive supervision and mentorship, including interview and field observation forms, are available for adaptation on PEPFAR Solutions.

## 6.3.2 Case Finding for Pediatrics

Summary of section edits:

- Wording was updated to be person-centered.
- Wording was updated to encourage country teams when setting targets to recalibrate historical testing positivity as needed to ensure adequate HTS commodities are procured to close the case finding and treatment gaps for children.

The successful scaling-up of universal HIV testing and ART for pregnant women has reduced the number of new infant infections in recent years; however, progress has stagnated in some countries and renewed efforts are needed (see Section 6.2.4.1). Additionally, over 50% of transmission occurs after six weeks of life, during breastfeeding, resulting in high numbers of

[190] Kassa, G., Dougherty, G., Madevu-Matson, C., Egesimba, G., Sartie, K., Akinjeji, A., Tamba, F., Gleason, B., Toure, M., & Rabkin, M. (2020). Improving inpatient provider-initiated HIV testing and counseling in Sierra Leone. *PloS one*, *15*(7), e0236358. https://doi.org/10.1371/journal.pone.0236358

infants and children/adolescents living with HIV (C/ALHIV) remaining undiagnosed because they are never retested after 2 months or were never tested because mother's HIV infection went unrecognized (either not reached for testing in ANC or incident infection after negative test at ANC1). There have been increasing proportions of newly diagnosed children aged 5 years and older (see Figure 2.1.2.12 in Section 2.1.2), many of whom were missed by PMTCT and EID programs due to mother-infant pairs not remaining in care or treatment services or incident maternal infections during pregnancy or breastfeeding. Without treatment, children living with HIV are at high risk of death, yet, in 2020, only 54% of children and young adolescents (<15 years) living with HIV globally had access to treatment.[191]

Some countries that have reached or are close to reaching epidemic control for adults living with HIV **have not** reached 95/95/95 for children and adolescents (<15 y/o). HTS_POS targets and results for children and young adolescents (<15 y/o) in PEPFAR programs have decreased over the past two years by half,[192] even though the testing gap has remained static. In developing HTS targets, teams need to develop strategies for populations by age and sex specifically, and this is particularly true for CLHIV, who continue to have large treatment gaps. When setting targets for CLHIV (<15 y/o), country teams should recalibrate historical testing positivity (typically set too high, since pediatric HIV prevalence is <1%) as needed to ensure adequate HTS commodities are procured to close the case finding and treatment gaps for children. Figure 2.1.2.12 in Section 2.1.2 highlights the need to refocus case-finding and treatment efforts on school-aged children and adolescents, while also improving early infant diagnosis and identification of children in the 1-4 years age band. Although children infected during breastfeeding may have slower disease progression and live beyond five years of age and into adolescence, early diagnosis is important to prevent morbidity and mortality due to HIV.[193]

Sexual abuse of children–especially in settings with high HIV population burden–also contributes to pediatric HIV infections, though the number of child HIV infections attributable to child sexual abuse is not well characterized. Strategies should ensure that victims of childhood sexual violence are identified, receive appropriate medical care including HIV testing, and

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[191] UNICEF, 2020AIDSinfo I UNAIDS, Coverage of people receiving ART – by age (Global AIDS Monitoring 2020; UNAIDS estimates, 2021.

[192] MER structured database available on PEPFAR Panorama Spotlight, April 2021

[193] Marston M, Becquet R. Net survival of children HIV-infected perinatally and through breastfeeding: a pooled analysis of individual data from resource-constrained settings, December 2010. (Slide from Patel, November 20, 2017, WHO/UNAIDS Consultation: Modelling pediatric HIV and the need for ART).

promptly referred to local child welfare authorities. Psychosocial support services and OVC programs are critical when designing programs that target case finding for children.

Age is an important factor to take into consideration when defining a program's case finding strategy. This section will focus on finding children and adolescents with perinatal HIV exposure. Section 6.3.3 will provide guidance on case-finding in adolescents (10–19 years of age) and youth (15–24 years of age) with sexual HIV exposure. These age ranges overlap given some adolescents may have sexual risk factors prior to age 15 years based on age of sexual debut and some perinatally-infected children may survive to or beyond 19 years of age even in the absence of treatment.

**Early Infant Diagnosis (EID)**

Early infant diagnosis (EID) is a critical approach to test perinatally HIV-exposed infants (HEI) and promptly link infants living with HIV to treatment by 2-months of age. Please see 6.3.1.3 on EID. Untreated infants living with HIV are at high risk for mortality due to HIV. Over 50% of untreated infants living with perinatally transmitted HIV die within the first two years of life, with mortality being especially high in the first few months of life.[194,195,196] Even if we reach high 2-month EID coverage, there is a need to ensure appropriate testing at all recommended time points per national guidelines. FY21 data showed that 21% of HEI had an undocumented final outcome (see Figure 6.3.2.1 below); this is concerning given the above-mentioned high rates of mortality among infants living with HIV who do not receive effective treatment, and the high rates of transmission during breastfeeding.

Mother-to-child transmission of HIV should be dramatically decreasing due to continued investments in PMTCT programs; however, due to continuity of care and treatment barriers

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[194] Marston M, Becquet R, Zaba B, Moulton LH, Gray G, Coovadia H, Essex M, Ekouevi DK, Jackson D, Coutsoudis A, Kilewo C, Leroy V, Wiktor S, Nduati R, Msellati P, Dabis F, Newell ML, Ghys PD. Net survival of perinatally and postnatally HIV-infected children: a pooled analysis of individual data from sub-Saharan Africa. Int J Epidemiol. 2011 Apr;40(2):385-96. doi: 10.1093/ije/dyq255. Epub 2011 Jan 18. PMID: 21247884; PMCID: PMC3140269. https://academic.oup.com/ije/article/40/2/385/733186

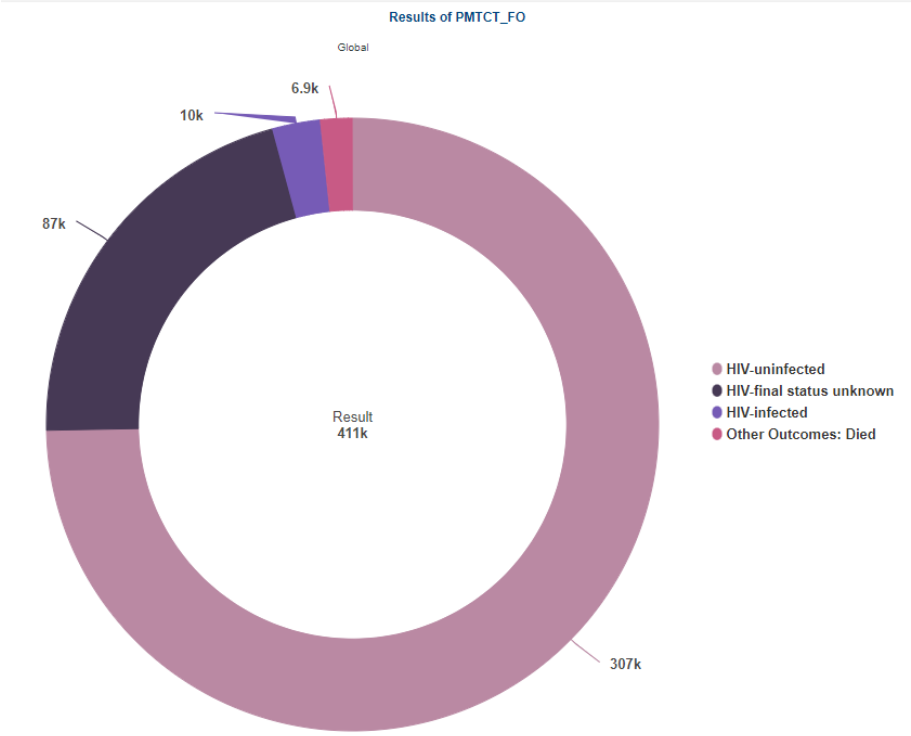
[195] Newell ML, Coovadia H, Cortina-Borja M, Rollins N, Gaillard P, Dabis F; Ghent International AIDS Society (IAS) Working Group on HIV Infection in Women and Children. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. Lancet. 2004 Oct 2-8;364(9441):1236-43. doi: 10.1016/S0140-6736(04)17140-7. PMID: 15464184. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext#articleInformation

[196] Kabue, Mark M et al. "Mortality and clinical outcomes in HIV-infected children on antiretroviral therapy in Malawi, Lesotho, and Swaziland." *Pediatrics* vol. 130,3 (2012): e591-9. doi:10.1542/peds.2011-1187. [Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3962849/

facing mother-infant pairs, there continue to be missed opportunities for diagnosis and prompt linkage to treatment. Country programs must invest human and financial resources in finding older children missed during routine PMTCT services. This can be done by implementing safe and ethical index testing in a systematic manner, and concurrently improving access to and uptake of timely EID services. (Please see Section 6.3.1.3 for guidance on EID.) Mother-infant pairs at risk of not meeting PMTCT benchmarks (e.g., timely return for EID) should also be prioritized for enrollment into the OVC program, especially for adolescent/youth mothers living with HIV. It is critical for programs to ensure that maternal retesting for women in late pregnancy and while breastfeeding occurs judiciously (please see Section 6.3.5), with immediate testing of infants of newly diagnosed women with HIV.

*Figure 6.3.2.1: Proportion of Infants with a PMTCT Final Outcome Status by Type in FY21*

Status includes HIV uninfected, HIV final status unknown, HIV infected, and Other outcomes including death.[197]

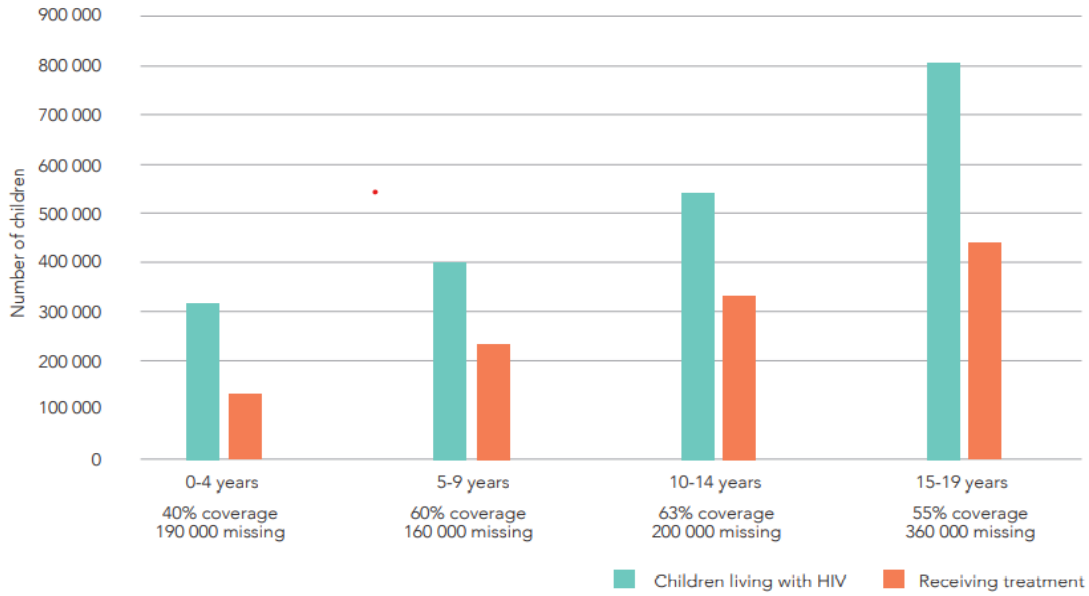



**Children and adolescents (≤19 years old)**

[197] Source: Panorama, *PMTCT-HEI Global* Dossier, *Overall Results of PMTCT_FO*, November 20, 2020 FY20 data

An optimal mix of testing strategies is needed to maximize the identification of C/ALHIV, while ensuring high pediatric index testing coverage, strong outpatient testing, and testing coverage at sick entry points. As shown in figure 6.3.2.2, which summarizes UNAIDS Focus Country results in 2020, large proportions of children and adolescents are missing from treatment. Each program should identify an overall testing strategy that ensures effective pediatric case identification with the goal of increasing the absolute number of CLHIV identified. Re-engagement of C/ALHIV into care is also critical to close the treatment gap and should be supported through coordinated efforts and resources between testing and treatment implementing partners. PEPFAR country teams should utilize analyses that evaluate testing volume, number of newly diagnosed C/ALHIV, number needed to test (NNT) to identify one C/ALHIV, contribution and trends of new diagnoses by testing modality, and fine age and sex band analyses, to understand the context specific HTS landscape. (Note: NNT is the inverse positivity/yield. An NNT of 100 is 1 positive/100 tested, or 1% positivity or yield).

*Figure 6.3.2.2 Number of Children and Adolescents living with HIV Receiving Treatment and Missing from Treatment from UNAIDS Focus Countries in 2020*




Note: The available data were extrapolated to produce estimates for all countries.
Source: special analysis of UNAIDS epidemiological estimates, 2021 and Global AIDS Monitoring data, 2021.

Figure 6.3.2.3 illustrates that Other PITC and Index testing account for the largest volume of newly diagnosed C/ALHIV. While index testing has slowly increased, the lack of scale has led to

missed opportunities in finding undiagnosed CLHIV. Sufficient resources (including human resources) must be allocated to testing so that all children (under 19 years of age) with a biological parent living with HIV are offered HIV testing services. See Section 6.3.2.1 for further details on pediatric index testing.

Countries must right-size OPD testing programs to address either undertesting or over testing and ensure a robust OPD testing program that is aligned to the countries' current pediatric ART coverage. Programs must monitor and analyze the results of OPD testing. Implementing with fidelity the use of validated screen-in risk screening tools in OPD settings to increase the absolute number of CLHIV identified. Risk screening tools should be evaluated to ensure they are appropriate for the setting in which they are being used and accurately predict children at risk for HIV, identify children in need of HIV testing, and minimize number of undiagnosed CLHIV missed.

Offering universal HIV testing to all children (not already known to have HIV infection) at sick-entry points (malnutrition, TB, inpatient, STI clinic) remains an important strategy for pediatric HIV case finding in high-burden settings. However, this approach reaches only a relatively small number of children and only after they are already ill. Household contact investigations of people living with HIV and TB can be effective for diagnosing both HIV and TB among children.

Testing monitoring for these sick entry points should be routinely conducted to ensure that they remain prioritized, effective, and efficient modalities from which to identify CLHIV. Routine inpatient department (IPD) testing is still appropriate in many high HIV burden areas (e.g., prevalence ≥5%). Risk screening in IPD may be considered in low prevalence settings in alignment with WHO guidance.

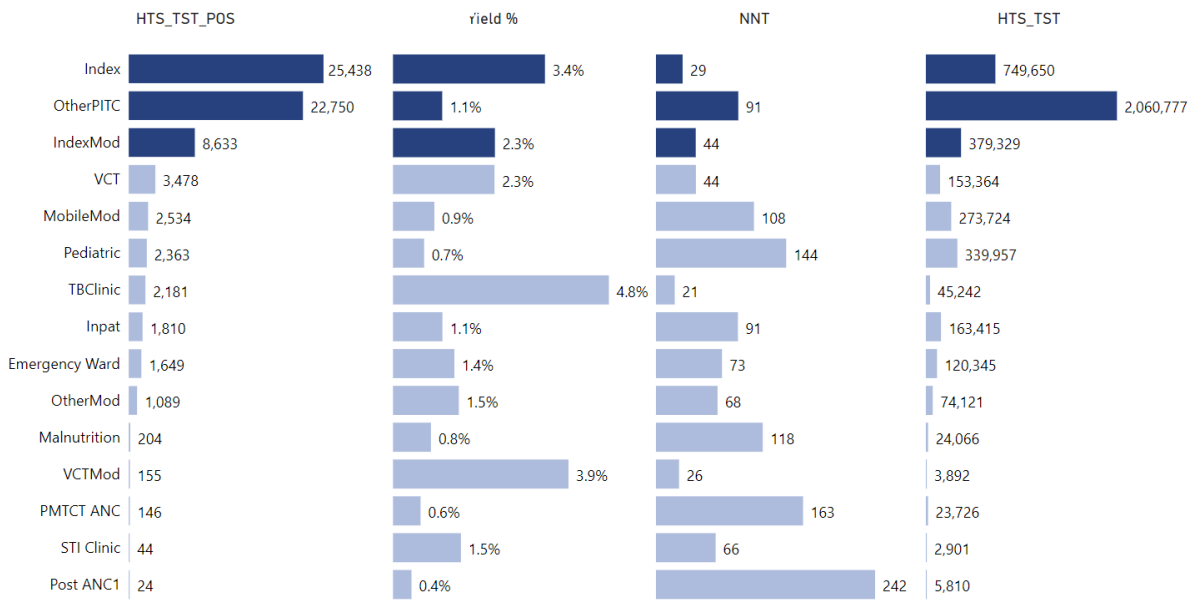
Pediatric testing strategies should include:

1. Pediatric index testing services for all people living with HIV to ensure all biological children know their HIV status, in a manner consistent with PEPFAR Guidance on Implementing Safe and Ethical Index Testing.
2. Assess family tree completion (i.e., documented HIV status for all biological children, biological parents, and biological pediatric and adolescent siblings) on ART files at every clinic visit.
3. OPD testing (Other PITC, MCH/pediatric (<5 years of age) well child clinic) using context-specific validated screen-in risk screening tools (e.g., HIV-infected parent or sibling with HIV, deceased biological parent or sibling, signs/symptoms suggestive of

HIV, factors associated with elevated HIV risk) to ensure the high volume of undiagnosed CLHIV presenting to OPD are identified.

4. Routine HIV testing for sick-entry points (malnutrition, TB, IPD, STI clinic).

*Figure 6.3.2.3: Number of HIV-Infected Test Results for Children (1-14 years) across HIV Testing Modalities by Yield, NNT and Number of HIV Tests, FY21Q1-4*[198]




## 6.3.2.1 Pediatric Index Testing Considerations

Summary of section edits:

- Text related to yield (positivity) was removed because case finding for children should not focus on yield.
- Language was added to allow for KP and OVC community cadres to support caregivers with HIV mucosal screening of children at home.
- Clarification was provided on the use of HIVST as a screening - not diagnostic - test.

The most effective strategy to reach C/ALHIV before they become sick in all settings is through index testing. See Section 6.3.1.5 for more information on index testing.

[198] Source: MER Structured Database, November 20, 2021 FY21 APR data

Countries should mobilize resources, including the requisite human resources, to ensure that **100% of biological children (<19 years of age) of a parent diagnosed with HIV are offered safe and ethical HIV testing services if the biological child/adolescent has not had a documented final HIV test (i.e., known positive or known negative), or has ongoing risk exposure.** It is important for HTS, Clinical and OVC and KP partners and staff to closely work together to ensure all children under the age of 19 years with an HIV positive biological parent are offered necessary, safe and ethical HIV testing services, as per the Case Finding Minimum Program Requirement, while also optimizing testing at all facility and community entry points to identify at-risk children, including biological pediatric and adolescent siblings of C/ALHIV (see Section 6.3.2.2 on OVC case finding). Additional implementation resources, including Index Testing for Biological Children and Adolescents (<19 y/o) of people living with HIV: Clinical and OVC Partner Collaboration to Expand Testing Services, to improve coverage of safe and ethical index testing for children are available on PEPFAR Solutions. Programs must ensure index testing services for all populations adhere to the PEPFAR Guidance on Implementing Safe and Ethical index testing (described in Section 6.3.1.5 and available at https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services). *This includes ensuring that HIV-positive parents, adolescent children, and/or adolescent siblings (depending on* of age of consent for HIV testing) *must never be coerced in any way to receive HIV testing services for their dependents or themselves or denied any relevant services. Adolescent index clients below the legal age of consent, should be asked to provide assent before undergoing HIV testing.*

Programs will be expected to provide data showing that all biological children of women with known HIV-positive status are offered HIV testing services. Biological children of men living with HIV are eligible for index testing services if the biological mothers' HIV status is HIV-positive, unknown, or unable to be obtained. It is important to offer timely HIV testing to children of women with an unknown HIV status (i.e., do not delay the child's HIV test to first reach and test the biological mother). It is also imperative to offer HIV testing to children whose mothers with HIV or unknown status have died. Trainings and messaging on index testing should increase awareness among healthcare workers, OVC case managers and KP site staff, and people living with HIV about the importance of offering index testing to all biological children <19 years of age in a manner compliant with the PEPFAR Guidance on Implementing Safe and Ethical index testing. Programs should report and analyze disaggregated index testing cascade results (as per the MER Guidance on HTS_INDEX) for both pediatric contacts and adult contacts of an index client in order to meaningfully assess percent coverage (number of elicited children per

adult index contact) of elicited children tested, including reporting on those with known HIV-positive status and documented HIV negative status) and yield (as one of the measures of fidelity and impact) for this essential pediatric case-finding strategy. The pediatric index testing cascade, which includes pediatric contacts (<15 or 15+) of adult index clients, should be analyzed separately from the adult index cascade to better assess volume of testing and new C/ALHIV identified, along with positivity. Programs must ensure children with a known HIV-positive status at entry are on treatment, or link them to ART. For children with a previously documented final HIV-negative status, confirm the result was a final outcome test at 18 months of age and at least 3 months following the cessation of breastfeeding with no new exposure risk. If the result cannot be confirmed at entry, the HIV test should be repeated. Children with a documented final negative status or later negative test result do not require retesting, which is a new reporting requirement and HTS_INDEX disaggregate in MER 2.6.

Index testing is a priority strategy to identify biological children of KPs who may be HIV positive, particularly among female sex workers, persons who inject drugs, and MSM living with HIV who have biological children who may require specialized[199] approaches to engage with and reach in a safe and ethical manner, further detailed in Section 6.5.1.2.

A strategy to increase the uptake of index testing of child contacts is to use caregiver-assisted HIV oral self-test kits to screen children at home. Studies have shown that rapid HIV- 1/2 saliva-based antibody tests have high sensitivity and specificity in children ≥2 years of age.[200]KP and OVC and other community cadres can support caregivers with HIV mucosal screening of children at home. *PEPFAR Technical Guidance in Context of COVID-19 Pandemic* recommends programs collaborate with Ministries of Health to consider authorization for adult index clients to receive HIV oral testing kits to screen their biological children (aged ≥2 years) with an unknown HIV status at home to mitigate the decline in HIV testing for children. Ongoing assessments of the acceptability, feasibility, and impact of HIV self-testing are being conducted and the results may help inform OU-specific PEPFAR programming. HIVST are screening tests, and some reactive screening results will be false positives (FPs). This is expected, especially among children (i.e., a low prevalence population), and it is important to include in provider

[199] Office of HIV/AIDS: Children of KP Taskforce. Addressing Children of Key Populations. U.S. Agency for International Development, Global Health Bureau, Washington DC, April 2018.
[200] Chikwari CD, Njuguna IN, Neary J, et al. Diagnostic accuracy of HIV oral rapid tests versus blood based rapid tests among children. CROI 2019. Poster 0782.

trainings and caregiver resources. All reactive screening tests require confirmatory testing to determine the child's HIV status. Clearly defined and close collaboration among HTS, clinical, and community providers (e.g., OVC and KP partners) is recommended. This may include the creation or modification of a memorandum of understanding among all parties.

### 6.3.2.2 Case Finding and OVC Programs

Clinical and OVC programs must formalize their partnership and work together as part of multi-disciplinary teams in order to ensure that 100% of biological children (<19 years old, with unknown HIV status) of current adults and siblings diagnosed with HIV are offered testing (consent from parent or adolescent based on consent policies) consistent with Safe and Ethical Index Testing Guidance. Programs should determine a reasonable time frame (e.g., 2 weeks) for referral and follow-up by OVC partners to ensure that children who are elicited or identified as part of index testing are tested. Clinical and OVC IPs should have developed formal relationships, such as a memorandum of understanding (MOU), outlining the roles and responsibilities of each member of the multi-disciplinary team and addressing key issues such as bi-directional referral protocols, case conferencing, shared confidentiality, index and other testing support, and joint case identification, and data sharing. All women living with HIV with biological children of unknown HIV status should be referred to an OVC case worker to assess barriers to pediatric testing so that the OVC team can, in coordination with HTS providers and other clinic staff, help ensure that these children are tested.

Index testing may miss children, including children of key populations, who are not in the care of their parents, often because their parents are living elsewhere (e.g., for work, being incarcerated, or being excluded and marginalized by their communities) or have died; such children may be in OVC programs or may be in the care of relatives or other community members. OVC programs are uniquely positioned to identify such children and assist their caretakers in accessing testing. OVC programs should systematically screen all beneficiaries for HIV testing needs utilizing HIV risk screening tools. This does not mean that all OVC beneficiaries need HIV testing; however, testing should be facilitated for OVC beneficiaries (who haven't already had adequate testing to establish their HIV status) according to the principles of family testing (mother with HIV; father with HIV and mother's status not known to be negative; sibling with HIV; mother deceased), targeted risk-based testing (e.g., violence survivor, blood transfusion, etc.), and diagnostic testing (i.e., poor growth/nutrition, known or suspected TB, or other illness concerning for HIV). Programs should have documentation for all OVC aged 0-17

years showing HIV status in accordance with the OVC_HIVSTAT MER indicator (i.e., HIV-positive, HIV-negative, or test not required based on risk assessment). Such children will generally need to undergo HTS only once, unless they have ongoing risk of infection (e.g., infant being breastfed by mother living with HIV, exposure to violence, or an emerging adolescent who has become sexually active). A new training module outlining key roles for OVC programs in support of index testing is now available on the PEPFAR solutions website.[201]

## 6.3.3 Case Finding for Adolescents and Youth

This section will provide guidance on case-finding in adolescents (10–19 years of age) and youth (15–24 years of age) with sexual HIV exposure. For guidance on case finding for adolescents with perinatal HIV exposure please see Section 6.3.2.

Adolescents and youth living with HIV (A/YLHIV) are much more likely to be unaware of their HIV status compared to adults because adolescents and youth at high risk of HIV acquisition do not always have access to HIV testing services (HTS) and may not recognize the need for HTS. Reasons for lower uptake of HTS include a low perception of risk, perceived cost of services or lack of transportation to testing facilities, legal and policy barriers that may require parental or guardian permission to test, and not having been previously offered HTS. Additional barriers to HTS among adolescents include the potential need for parental/legal guardian consent, possible HIV stigma and discrimination, and limited access to youth-friendly, non-judgmental health services. As stated in WHO guidance, programs should ensure that all HIV testing services are coupled with linkage to prevention, treatment, and care, for all adolescents 10-19 years old.[202]

While most strategies for case-finding in adults are applicable to adolescents and youth with sexual HIV exposure, certain strategies may be more effective, such as index testing, social network testing, PITC for youth presenting for sexual and reproductive services, and HIV self-testing (HIVST). Young people should be offered a menu of HIV testing modalities and the opportunity to choose their preferred mode of testing. Adolescents and youth engaging in sex work, injecting drugs as well as young MSM and transgender individuals should be prioritized for testing given the increased risk of acquiring HIV (see Section 6.5.4.2) Client-centered,

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[201] https://www.pepfarsolutions.org/resourcesandtools-2/2021/10/5/index-testing-for-biological-children-and-adolescents-lt19yo-of-plhiv-clinical-and-ovc-partner-collaboration-to-expand-testing-services

[202] World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva, Switzerland: World Health Organization; 2021

adolescent-, youth- and KP-friendly modifications are necessary for all strategies, including flexible hours (outside of school hours) and/or walk-in/same-day services. It is of paramount importance to engage youth in developing these services (see Section 6.3.1.9 on community engagement). Those providing HTS should be adequately trained and skilled in delivering services that are non-judgmental and maintain confidentiality, as per the WHO 5Cs of HTS. IPs should ensure that there are defined referral pathways and protocols to link newly identified AGYW from the DREAMS program to treatment and support.

HIVST, has a high acceptance rate among youth, with little to no evidence for unintentional harm.[203] However, as with all testing approaches, it is imperative to ensure that youth are not being coerced to conduct an HIVST.[204,205] Although HIVST holds the potential to increase HTS coverage among adolescents and youth, programs will need to ensure that individuals screening reactive are linked to confirmatory testing, as per the national testing algorithm, and treatment services as indicated. These services should be youth-friendly and KP-competent. As linkage to confirmatory testing and ART after self-testing is lower in A/YLHIV than older adults, national programs and implementing partners should ensure that prior to commencement of HIVST kit distribution to A/YLHIV, procedures, including the use of youth peer cadres to provide in-person and/or virtual support, for follow-up and linkage to appropriate testing and other services are clearly outlined in SOPs and included in staff trainings. Countries should also review national guidance for HIV self-testing to work to align eligibility for HIVST with the age of consent for HIV testing.

Social network testing, in which HIV-positive and high-risk, HIV-negative individuals recruit others from their social, sexual, and drug-using networks for HTS, is an effective case-finding approach among young KPs and should always be conducted in a manner compliant with WHO's 5 Cs of HTS (see Section 6.5.4.2). This strategy may be effective among high-risk

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[203] Ibid.

[204] Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L, Dheda K, Peeling RW. Supervised and unsupervised self-testing for HIV in high- and low-risk populations: a systematic review. PLoS Med, 2013; 10(4):e1001414.

[205] Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, Sambakunsi R, Mdolo A, Makombe SD, Desmond N, Hayes R, Maheswaran H, Corbett EL. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: A community-based prospective study. PLoS Med, 2015; 12(9):e1001873.

groups of adolescents and youth, including young KP, as several studies have shown that encouragement from peers is an important motivation for seeking HTS.

For adolescents and youth presenting to OPD, validated opt-in risk screening tools developed specifically for adolescents and youth can be used. However, there is no one-size-fits-all screening tool. Programs may want to develop a screening tool designed to reach adolescents and youth based on population-specific HIV risk factors and ensure that these tools are validated specifically for the age range they intend to screen. Some examples of adolescent risk factors, which will vary based on context, include but are not limited to: ≥3 sexual partners/year, ≥8 drinks/week or ≥4 drinks/occasion, transactional sex, partner concurrency, AGYW with a partner who is ≥5 years older, no or low school attendance, experiences of GBV/IPV, presentation with signs/symptoms of an STI and diagnosis with an STI. Given the poor treatment coverage of adolescents in high burden settings as shown in figure 6.3.2.2 in Section 6.3.2, providers should utilize OPD as an opportunity to offer sexually active adolescents and youth HTS. Anyone who is identified as at risk for or is the survivor of maltreatment (negligence or abuse, including violence against children or intimate partner violence) should be provided with first-line support aligned with the LIVES framework and referred to the appropriate medical, psychosocial, legal, and in coordination with OVC, child welfare and protection services.

Younger adolescents (10-14 years old) can be screened using validated context-specific pediatric HIV risk screening tools. Pediatric screening tools can include an STI question (e.g., does this child have sores or discharge from the private parts?) to account for childhood sexual abuse and children with early sexual debut. Adolescents whose HIV risk factor screen indicates the need for HTS should be promptly provided HTS, in alignment with the laws of informed consent and consistent with the WHO 5Cs of HTS, and linked to timely HIV prevention or treatment services, as determined by the result of the HIV test.

PEPFAR endorses WHO's recommendation to support demand creation for adolescent/youth HIV testing services.[206] Evidence supports peer-led demand creation, including mobilization, and the use of digital platforms with short videos that encourage HIV testing, advertise specific attributes of HTS, or promote HTS using motivational messages. Countries may consider direct-to-client approaches using social media, or other adolescent platforms, to create demand for

[206] World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva, Switzerland: World Health Organization; 2021.

HTS, or link to assisted HIVST services. Innovative, client-driven strategies (e.g., UberEats model) for HIVST, where peer counselors on motorcycles meet clients, assist with HIVST, and link to appropriate prevention or treatment services.

**Adolescent consent requirements**

Consent requirements can complicate or restrict access to treatment. Research has shown that a lower legal age of consent for independent HTS is associated with an increase in HIV testing uptake among adolescents in high-HIV burden countries.[207] Policymakers should review their existing regulatory frameworks governing adolescent health care to facilitate timely linkage from HIV testing to prevention and life-saving treatment services. For example, an adolescent who possesses the legal right to access HTS should have autonomous access to HIV prevention and treatment services. Additional advocacy is needed to influence age of consent to improve access to HIV services for adolescents. Should a young adolescent or youth be denied treatment due to lack of parental consent, PEPFAR programs should follow client-centered, safe, and ethical protocols to help them access treatment.

## 6.3.4 Retesting in Pregnant and Breastfeeding Women (PBFW)

HIV-positive pregnant and breastfeeding women (PBFW) are at risk of transmitting HIV to their infants during pregnancy, labor, and delivery and throughout the entire breastfeeding period, which may extend to 2 years or beyond. It has been shown that HIV-negative PBFW are at increased risk of HIV acquisition during pregnancy and postpartum. HIV seroconversion during this critical time can result in high maternal viral loads, placing their fetus/infants at extremely high risk for vertical transmission. According to 2020 UNAIDS estimates, there were 150,000 new HIV infections among children aged 0-14 years, with almost all occurring during pregnancy, birth, the breastfeeding period, and ages 0-4 years.[208] Maternal retesting is increasingly important to help reach targets on eliminating vertical transmission and the UNAIDS 95-95-95 goals.[209]

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[207] Ibid.

[208] *Adolescent HIV prevention*. (2021, July). UNICEF. https://data.unicef.org/topic/hivaids/adolescents-young-people/

[209] Drake AL, Thomson KA, Quinn C, et al. Retest and treat: a review of national HIV retesting guidelines to inform elimination of mother-to-child HIV transmission (EMTCT) efforts. J Int AIDS Soc. 2019;22(4):e25271. doi:10.1002/jia2.25271

Many mature PMTCT programs now provide opt-out HIV testing to almost all pregnant women at their first antenatal clinic visit (ANC1) with rapid initiation of lifelong antiretroviral treatment (ART); this has reduced vertical transmission rates at 6 weeks to below 5% in some countries. However, in 2020 UNAIDS estimates, 27% of new infections in children were linked to acute infection in pregnancy and breastfeeding.[210]

Evidence shows that:

1. Pregnancy, itself, may be a risk factor for HIV acquisition.[211]
2. The risk of HIV transmission per sex act steadily increased through pregnancy and was highest in the postpartum period. Even when adjusting for condom use, female age, PrEP, and male HIV RNA, late pregnancy (aRR 2.82, p=0.01) and postpartum periods (aRR 3.97, p=0.01) had higher risk of HIV transmission per sex act compared to non-pregnant time.[212]
3. Acute HIV infection is associated with elevated viral loads that increase risk of transmission.[213] In African cohorts, vertical transmission risk was significantly higher among women with incident versus chronic HIV infection in the postpartum period (odds ratio (OR) 2.9, 95% confidence interval (CI) 2.2-3.9) or in pregnancy/postpartum periods combined (OR 2.3, 95% CI 1.2-4.4).[214]
4. In COP18, PEPFAR introduced additional disaggregates to capture maternal testing after ANC1, in labor and delivery, and in the breastfeeding period, which should be reported in HTS_TST using the disaggregate for Post-ANC1 testing. There were over 2.3 million post-ANC1 tests reported across PEPFAR in FY20 with a trend toward increasing the number of women tested each quarter despite COVID-19 Trends in the data collected and reported in the post ANC1 modality, PMTCT_STAT_POS and

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[210] UNAIDS epidemiological estimates 2020. http://aidsinfo.unaids.org/

[211] Thomson, et.al., The Partners in Prevention HSV/HIV Transmission Study and Partners PrEP Study Teams; Increased Risk of HIV Acquisition Among Women Throughout Pregnancy and During the Postpartum Period: A Prospective Per-Coital-Act Analysis Among Women With HIV-Infected Partners, The Journal of Infectious Diseases, jiy113, https://doi.org/10.1093/infdis/jiy113.

[212] Thomson KA et al. Conference on Retroviruses and Opportunistic Infections (CROI), 2018; Boston; Abs. 45

[213] Lehman DA, Farquhar C. Biological mechanisms of vertical human immunodeficiency virus (HIV-1) transmission. Rev Med Virol. 2007;17(6):381–403T

[214] Drake et.al. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis; PLoS Med. 2014 Feb 25;11(2)

HEI_POS from FY20 and FY21 should be assessed as a proxy for maternal retesting and evaluated to determine if current results reflect strategic testing.

**Considerations on where and how to implement maternal retesting**

WHO recommends maternal retesting in high HIV burden settings for all women in early pregnancy (first ANC visit) and retesting for all women of unknown or HIV-negative status at the third trimester ANC visit/late pregnancy with the option of adding an additional retest at either 14 weeks, six-months, or nine-months post-partum in districts or provinces with high HIV prevalence and among key populations or women at high risk of HIV acquisition from their partner.[215] In 2021, Meisner and Roberts published a cost-effectiveness study that found late pregnancy with 'make-up' testing up to 6 weeks postpartum to be the most cost-effective retesting strategy in areas with high HIV prevalence.[216] Some low HIV prevalence countries with high vertical transmission rates may benefit from retesting in high prevalence SNU's at high volume ANC sites or those offering postnatal care or under-5 visits, particularly among women with high ongoing HIV risk. Countries, regions, and/or facilities with a high number of HIV-positive women or HIV-positive infants should introduce more opportunities to provide repeat HIV tests for PBFW and, if found positive, appropriately, and immediately provide linkage to treatment for the mother and testing for infant.

Maternal retesting can be focused based on geographic considerations such as where high numbers of mothers and infants are present and high HIV incidence. For example, immunization (EPI) clinics are a practical location for infant/pediatric case finding and HIV testing for postpartum mothers who previously tested HIV negative. In addition, it may be efficient to integrate maternal retesting in family planning (FP) settings, since many women routinely access these services during the postpartum period. When implementing maternal retesting, consideration should also be given to the appropriate staffing, physical space, job aids, M&E tools, and inclusion of PrEP services.

Implementation of maternal retesting, especially when trying to expand beyond PMTCT/ANC service delivery areas, should take into consideration:

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[215] Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020.

[216] Meisner, Roberts, et.al. Optimizing HIV retesting during pregnancy and postpartum in four countries: a cost-effectiveness analysis. Journal of the International AIDS Society, 2021, 24:e25686

- Assessing the number of mothers/infants being served in the service delivery locations to project procurement and human resource needs.
- Trained HTS staff placed in the service delivery locations (i.e., MNCH, EPI, FP).
- Examination of the physical space and clinic flow to allow for confidential HTS.
- Ensuring linkage and continuous treatment for newly diagnosed mothers and HEI, for example using mentor mothers.
- Having M&E tools that document longitudinal testing history for an individual mother, eligibility for retesting (based on national retesting policies and ongoing risk), the distinction between initial HIV tests and subsequent HIV tests, the HIV test results, and PCR results for the HIV exposed infants and linkage to care.

Programs should also consider using site-level checklists of requirements for successful retesting to assess the status of retesting and track improvements over time at the facility level.[217] These questions can be assessed alongside SIMS or incorporated into granular site management or used as a stand-alone assessment.

In high HIV prevalence settings, even when the requirements for successful retesting are addressed, there may be limited resources for retesting all mothers at multiple time points. Programs in high-prevalence areas should aim to scale up retesting in late pregnancy as a cost-effective strategy for identifying incident infections and reducing vertical transmission. If mothers are missed in late pregnancy, they can be retested in the early post-partum period. Some women at higher risk (ex. age <30 years old, serodifferent couple, multiple sexual partners, condomless sex with partner with high-risk behaviors, partner with unknown HIV status, history or ongoing intimate partner violence, or history of STI) may require more frequent testing. There is also evidence that HIVST as a screening tool is highly sensitive and can increase testing uptake, including reaching individuals who are missed through risk-based screening. In this context, distribution of HIVST to sexual partners of breastfeeding women who test negative in the early postpartum period to encourage partner testing may be utilized to increase retesting coverage of PBFW and interrupt vertical transmission.

Programs in lower HIV prevalence areas might prioritize retesting women at increased risk of incident HIV infection and should pursue retesting any time that a pregnant or breastfeeding woman presents with potential symptoms of acute HIV infection.

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[217] For facility assessment checklists, see Maternal retesting resource document on PEPFAR SharePoint

In regard to monitoring and reporting, PMTCT programs are encouraged to review trends in MER data to assess the impact of COVID-19 pandemic on the volume of retesting (post-ANC-1 testing modality). Countries with high HIV prevalence should consider targeting women who test HIV-negative at ANC1 for retesting in late ANC with make-up testing up to 6 weeks post-partum. Due to increased vertical transmission risk from postpartum incident infection, pregnant women with a negative ANC1 HIV test should be actively counseled that unprotected sex during pregnancy and post-delivery before the cessation of breastfeeding increases the risk of vertical transmission. Should a mother engage in unprotected sex during this time period, she should request an additional retest. Variability in retesting policies can make it difficult to interpret the HTS post-ANC1 MER indicator. Therefore, programs are encouraged to use the narrative to describe the context for reporting retesting data for their country.

Risk screening tools for maternal retesting are not widely available; however, programs may adapt or use existing PITC/outpatient screening tools already available, particularly when universal retesting is not indicated. Teams may consider drawing from existing risk screening tools that were developed to predict HIV acquisition in women.[218] and target PrEP in high-risk pregnancy and in postpartum/breastfeeding women.[219] Such tools, once adapted and validated, can be incorporated into the comprehensive HIV prevention package during pregnancy and post-partum visits. Risk screening for maternal retesting will also require improved documentation approaches to track women who have previously screened negative and need to be re-screened for eligibility, such as a mother-baby cards and electronic medical records systems.

## 6.3.5 HIV Testing within Prevention Services

Summary of section edits:

- Renamed section to align with WHO's current approach to providing HTS *within* HIV prevention programs and to abate confusion over the purpose of HTS within prevention programs

[218] Balkus, Jennifer E., et al. An Empiric HIV Risk Scoring Tool to Predict HIV-1 Acquisition in African Women, JAIDS Journal of Acquired Immune Deficiency Syndromes: July 1, 2016 - Volume 72 - Issue 3 - p 333-343 doi: 10.1097/QAI.0000000000000974

[219] Pintye J, et al. A Risk Assessment Tool for Identifying Pregnant and Postpartum Women Who May Benefit From Preexposure Prophylaxis. Clin Infect Dis. 2017 Mar 15;64(6):751-758. doi: 10.1093/cid/ciw850. PMID: 28034882; PMCID: PMC6075205.

- Acknowledged KP programming in the introduction; this was an inadvertent omission from COP/ROP22 Guidance
- Revised PrEP bullet to align with current WHO and PEPFAR guidance to promote user choice of blood-based and oral fluid HIVST assays
- Revised PrEP bullet to align with current WHO and PEPFAR PrEP implementation guidance to broader use of HIVST within PrEP programs

UNAIDS call for "95% of people at risk of HIV infection [to] use appropriate, prioritized, person-centered and effective combination prevention options by 2025."[220] HIV testing services (HTS) directly contribute to HIV prevention outcomes when individuals with a seronegative HIV status are offered appropriate HIV prevention services, and linking individuals who test HIV negative to person-centered prevention services is essential. HTS can also be a valuable tool to monitor and refine prevention programming.

WHO has established standards articulating HIV testing services as a critical component of HIV prevention interventions including KP programming (see Section 6.5.1 for additional details), VMMC programming, PrEP programming, ongoing testing services for negative partners of discordant couples, OVC programs, DREAMS programs, ANC, and post-ANC services.[221]

Below are select prevention program areas where HTS remains a pivotal component.

- **VMMC:** Programs should offer HIV testing based on individual's risk behaviors and factors, including age and sexual debut, following national guidelines. HTS in VMMC settings is voluntary and should remain available to any VMMC client upon request. Testing strategies should be informed by data obtained by monitoring testing outcomes (uptake, positivity, etc.). Programs should show a clear track record of or plan for decreasing testing among low risk, low yield males. Planning for testing in VMMC should be included in the overall COP22 planning to improve testing yields across modalities and should follow the positivity standards applied to other testing modalities. VMMC sites should establish relationships with ART sites to assure that immediate linkage to treatment is available for those who test HIV positive. Males who are HIV negative and at

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[220] UNAIDS. (2021). *2025 AIDS TARGETS*. https://aidstargets2025.unaids.org/
[221] WHO. (2019, November 27). *Consolidated guidelines on HIV testing services for a changing epidemic*. https://www.who.int/publications/i/item/WHO-CDS-HIV-19.31

significant risk of acquiring HIV should be linked to other prevention services including PrEP programs.

- **PrEP**: Oral PrEP when taken as prescribed reduces the risk of acquiring HIV in numerous populations whether the transmission risk is via sexual contact or injection. Testing for PrEP enrollment requires standard HTS to ensure HIV negative status. Once enrolled in a PrEP program, clients should be tested every three months for HIV with an assay that meets WHO sensitivity requirements. If HIV seroconversion is detected among an individual taking PrEP, the individual should be immediately linked to treatment services. (See Sections 6.2.1 (PrEP) and 6.3.1.6 (HIV Self-Testing) for considerations on integrating HIV self-testing within PrEP programs.
- **Preventing transmission within serodifferent couples:** Serodifferent couples should be offered a package of services including disclosure support, conception advice, PrEP, and HIV testing. The partner who is HIV negative in a serodifferent couple should be tested at least annually (or more often if warranted by risk assessment) and promptly linked to appropriate prevention or treatment services.
- **OVC:** OVC_HIVSTAT is a self-report of HIV status and is not an indicator of HIV tests conducted. OVC program participants should be routinely assessed for the need for HIV testing, and those with a need for testing should be provided a supportive referral. Testing results for orphans and vulnerable children who are referred for testing should be reported under HTS_TST based on the service delivery point where they are tested. Partners are encouraged to confirm HIV and ART status through clinical record confirmation wherever possible.
- **DREAMS:** The goal of DREAMS programming is to reduce infections among adolescent girls and young women aged 15-24 years. Adolescent friendly HTS services are part of the DREAMS core package of interventions and should be provided in a manner that is responsive to the needs of adolescent girls and young women. HTS services for adolescent girls and young women may include mobile HTS, after-hours services in health facilities, HTS delivered in Safe Spaces/Girls Clubs, and HIV self-testing. HTS should also be offered to the male sex partners of DREAMS participants, when possible, either through DREAMS or broader PEPFAR HTS programming.
- **PMTCT, ANC testing**: HTS within ANC settings is a minimum standard and testing coverage among ANC clients is generally high. With many countries approaching 90% diagnosis rates, overall positivity and case finding volumes are decreasing among ANC clients. Nevertheless, routine HTS continues to be a minimum standard to reduce

vertical transmission, to ensure continuation of prevention services to women with a negative HIV serostatus and to prompt treatment for women who seroconvert. Sex partners of pregnant and breastfeeding women should also be considered for testing, including HIV self-testing, where applicable.

- **PMTCT, Post ANC testing:** WHO recommends maternal retesting in high HIV burden settings in early pregnancy (first ANC visit) and/or the third trimester ANC visit/late pregnancy (if ANC care delayed), with the option of adding an additional retest at either 14 weeks, six-months or nine-months postpartum in SNUs with high HIV prevalence and among key populations or women at high risk of HIV acquisition.[222] (See Section 6.3.4 for important maternal retesting considerations.) It is imperative for the health of the mother and infant that pregnant and breastfeeding mothers have routine access to HTS, prevention and treatment services.

Please refer to Section 6.5 for important prevention programming considerations for key populations.

## 6.4 Optimizing HIV Care and Treatment

What's New in Optimizing HIV Care and Treatment for COP22:

- Discussion of drug-drug interactions; added chart on interactions with contraceptive agents. (6.4.1)
- Strengthened language on rapid initiation of ART making the point that delay of initiation only warranted for CNS disease (6.4.2)
- Approach to CD4 testing revised to allow for the identification of advanced disease (6.4.2.1)
- New recommendation to perform CD4 count for CLHIV ≥ 5 years of age with CD4 testing if they have had an interruption from treatment for 12 months or greater (6.4.2.2)
- Added new mortality data on CLHIV < 5 years of age who have been identified and initiated on treatment in PEPFAR (6.4.2.2)
- Added information about the aging cohort and the burden of co-morbid disease (6.4.2.3)

[222]WHO. (2021, July 16). *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach*. https://www.who.int/publications/i/item/9789240031593

- (Section 6.4.3) – Intensified TB case finding among PLHIV: 2021 WHO updated guidelines on TB screening
- (Section 6.4.3.1) – WHO updated guidelines on TB screening highlighting the four-symptom screen, with addition of Chest X-Ray (CXR), or C-Reactive Protein (CRP), or molecular WHO rapid diagnostic testing (mWRD)
- (Section 6.4.3.1) – PEPFAR partners are encouraged to work with ministries/national programs to assess their screening algorithm and develop feasible plans for improving sensitivity
- (Section 6.4.3.1) – COVID-19 vaccine program can be leveraged to expand TB screening and subsequent TB diagnostic testing for people who may otherwise not access health services
- (Section 6.4.3.1) – Consider expanding TB symptoms screening and linkage to care in health entry points used by children, such as Maternal and child health, OVC and nutrition clinics
- (Section 6.4.3.1) – laboratory technicians trained for processing stool specimen to improve pediatric TB diagnosis
- (Section 6.4.3.1) – Incorporate TB contact investigation and screening among household contact of PLHIV with TB disease
- (Section 6.4.3.1) – Updated information on WHO expanded list of mWRD nucleic acid amplification tests to include those of low complexity
- (Section 6.4.3.1) – the goal is to progressively replace microscopy and increase use of mWRD test as the preferred method for diagnostic evaluation of PLHIV with presumptive TB
- (Section 6.4.3.3) – WHIP3TB study results (patients on 3HP had a higher completion rate than those on INH)
- (Section 6.4.3.3) – Recommendation for a single course of TPT for life (WHIP3TB study showed no additional benefits of a repeated round of TPT
- (Section 6.4.3.3) – Consideration to adopt the “kitting” approach for successful MMD and decentralized drug distribution for TPT expansion in the wake of COVID-19
- (Section 6.4.3.3) - Sustainability for TB/HIV interventions
- Updated cervical cancer screening and treatment guidelines and algorithm (See Section 6.4.4)
- More specificity on DTG weight/age guidelines and dosing for nearly all CLHIV (6.4.5.1)

- Stressed importance that single DTG switch can and should occur irrespective of the availability of a VL test/result or the value of the latest VL result, while maintaining or optimizing children on an ABC/3TC backbone (6.4.5.1)
- Additional guidance provided on administration of pediatric DTG dispersible formulations for healthcare workers and caregivers, including guidance against repackaging of pills in smaller bottles and how to store half pills (6.4.5.1)
- Algorithm and management guide for viral non-suppression streamlined and revised (6.4.6.1)
- Added a new algorithm for ARV optimization, clinical management and viral load monitoring of infants and children on ART (6.4.6.2)
- Expanded recommendation for programs to implement mechanisms to empower PLHIV to receive timely direct communication from laboratories regarding VL results for themselves and their children (6.4.6.1, 6.4.6.2)

Successful antiretroviral therapy reduces or eliminates HIV-related morbidity and mortality at all stages of HIV infection, eliminates sexual transmission and dramatically reduces vertical HIV transmission. The goal of therapy for all people living with HIV should be maximal and durable suppression of plasma viremia. Guided by an overarching objective to lower mortality and improve quality of life for people living with HIV and the communities in which they live, OU teams and implementing partners should develop comprehensive, accessible, gender-sensitive (see Gender Equality Section 6.6.2), and person-centered HIV treatment programs that meet the needs of the populations they serve. This includes services tailored for marginalized populations and integrated services for populations with co-existing clinical needs. Program interventions should aim to reduce the burden on clients as much as possible and facilitate long-term continuity of treatment, including the psycho-social burden. Programs should be developed and implemented to adequately address the needs of individuals presenting with advanced disease, those at both ends of the age spectrum, and patients at risk for HIV-related comorbidities such as cervical cancer and TB. Programs should also deliver services and/or provide referrals to programs that respond to common barriers to continuity of treatment, including psychosocial (Section 6.6.5.2) and mental health services (Section 6.6.5.1), GBV response services (Section 6.6.2.1), and substance use support. Finally, interventions that focus on those at risk of treatment interruption to help them attain and maintain viral load suppression are, critical to ensure community and national-level epidemic control.

## 6.4.1 ART Optimization Best Practices, Drug Interactions, and Regimen Sequencing

All people living with HIV should have access to the most effective, convenient therapy with minimal or no side effects. Optimal antiretroviral therapy (ART) is critical to lifelong continuity of treatment and viral load suppression and is the cornerstone of the PEPFAR program. The WHO released updated normative and derivative guidance documents in July 2021. PEPFAR, based on both RCT and observational cohort data[223] recommends TLD as the preferred option for ART for both first- and second-line treatment (for all persons living with HIV ≥30 kg including adolescents and pregnant and breast-feeding women) and DTG-based regimens as the preferred option for ART for both first- and second-line treatment for all infants, children, and others <30 kg (from age 4 weeks and weight 3 kg). Countries should fully and actively transition people receiving non-DTG based regimen, both first- and second-line regimens, to DTG based regimens. Evidence supports routine DTG transition for individuals currently on PI and NNRTI based treatment. See Section 6.4.1.3 for the approach to individuals whose current non-DTG ART regimen is failing virologically and for the management of individuals who are intolerant of one or more of the components of TLD.

Another advantage of DTG therapy is that drug-drug interactions are minimized, though there are several that are important. Metformin, rifampin, many calcium carbonate-based antacids and iron containing compounds such as prenatal vitamins are significantly affected. To maximize DTG absorption, DTG should not be taken within 2 hours of antacids and prenatal vitamins.[224] When DTG is co-administered with rifampin, 50 mg twice daily is recommended. This adjustment is also recommended for efavirenz and boosted protease inhibitors. Efavirenz and boosted protease inhibitor regimens have important drug interactions as well that may persist after drug discontinuation. Other drugs that individuals on ART may take for co-morbid conditions or coinfections may also interact. Rifamycins and opioid agonists such as methadone have drug-drug interactions. Interactions with methadone are covered in the KP section. Interactions related to rifampicin are covered in the TB section.[225]

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[223] Keene, CM.[a]; Griesel, R[b,c]; Zhao, Y[d]; Gcwabe, Z[d]; Sayed, K[d]; Hill, A[e]; Cassidy, T[a,f]; Ngwenya, O[d]; Jackson, A[d]; van Zyl, G[g]; Schutz, C[c,h]; Goliath, R[d]; Flowers, T[a]; Goemaere, E[a,f]; Wiesner, [b]; Simmons, B[i]; Maartens, G[b,c]; Meintjes, G[c,h] Virologic efficacy of tenofovir, lamivudine and dolutegravir as second-line antiretroviral therapy in adults failing a tenofovir-based first-line regimen, AIDS: July 15, 2021 - Volume 35 - Issue 9 - p 1423-1432

[224] https://clinicalinfo.hiv.gov/en/guidelines/perinatal/dolutegravir-tivicay-dtg

[225] https://www.hiv-druginteractions.org/checker; http://hivinsite.ucsf.edu/interactions

See Figure 6.4.1.1 for drug-drug interactions for ARVs, TB, and MAT treatment that may affect the activity of contraceptive agents.

*Figure 6.4.1.1: Summary of Selected Drug-Drug Interactions with Contraceptive Agents*

| Treatment Drug | Hormonal Contraceptives (pill, patch, ring) | Levonorgestrel emergency contraception | DMPA* | Etonogestrel or Levonorgestrel Subdermal Implants |
|---|---|---|---|---|
| **First line ART** | | | | |
| **EFV** | Consider an alternative method to prevent pregnancy | Consider increasing the dose from 1.5mg to 3mg | No additional contraceptive protection is needed. | Consider an alternative method to prevent pregnancy |
| **DTG** | No additional contraceptive protection is needed. | Standard dose | No additional contraceptive protection is needed. | No additional contraceptive protection is needed. |
| **Boosted protease inhibitor-based ART** | | | | |
| **ATV/ ritonavir** | No additional contraceptive protection is needed. | Standard dose | No additional contraceptive protection is needed. | No additional contraceptive protection is needed. |
| **Darunavir/ ritonavir** | No additional contraceptive protection is needed. | Standard dose | No additional contraceptive protection is needed. | No additional contraceptive protection is needed. |
| **Tuberculosis** | | | | |
| **Rifampicin** | Consider an alternative method to prevent pregnancy | Consider increasing the dose from 1.5mg to 3mg | Consider dosing DMPA every 8-10 weeks during RIF therapy. | Consider an alternative method to prevent pregnancy |
| **Opioid agonists** | | | | |
| **Methadone** | No additional contraceptive protection is needed. | Standard dose | No additional contraceptive protection is needed. | No additional contraceptive protection is needed. |

### 6.4.1.1 Newborn HIV Prophylaxis for HIV-exposed Infants

Identification and appropriately timed testing of HIV-exposed infants (HEI) are essential for rapid diagnosis and initiation of HIV prophylaxis. Without the initiation of HIV anti-retroviral therapy (ART), it is estimated that 35% of HIV infected infants die within the first year of life, with infection being especially high during two to three months of age, and 52% of untreated infants are estimated to die by their second year.[226,227] Implementation of immediate ART for all people living with HIV, including all pregnant and breastfeeding women, has significantly reduced vertical transmission of HIV; however, despite significant improvements in maternal testing and ART initiation prior to delivery, in 2020 there were 150,000 new HIV infections among children aged 0-14 years, with almost all occurring between the ages of 0-4 years during pregnancy, birth, or the breastfeeding period.[228] Shift in the timing of HIV infections in infants from the intrauterine period to the postpartum and breastfeeding periods necessitates an enhanced focus on early infant testing and repeated infant testing until the end of the breastfeeding period in accordance with current WHO guidance and national guidelines, with a final outcome (FO) documented at 18 months of age or 3 months after the cessation of breastfeeding, whichever is later. As of 2020 global coverage of early infant diagnosis (EID) was 67%, which is a slight improvement from 57% in 2018.[229] PEPFAR supported programs have increased proxy <2-month EID coverage from approximately 72% in FY20 to approximately 84% in FY21;[230] however, although these numbers are higher compared to global data, they still fall short of the 95% global EID target. Optimization of newborn HIV prophylaxis for HEI relies on enhanced systems for identifying high-risk infants, implementation of routine infant HIV testing at birth centers (where feasible) or within the first 2 months of life, strengthening laboratory capacity to accurately identify and confirm positive and indeterminate test results, and improved linkage of HEI to HIV prophylaxis (see Section 6.3.1.3).

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[226] Bourne DE, Thompson M, Brody LL, Cotton M, Draper B, Laubscher R et al. Emergence of a peak in early infant mortality due to HIV/AIDS in South Africa. AIDS. 2009;23:101–6.

[227] Violari A, Cotton MF, Gibb DM, Babiker AG, Steyn J, Madhi SA et al. Early antiretroviral therapy and mortality among HIV-infected infants. N Engl J Med. 2008;359:2233–44.

[228] Data source: 2020 UNAIDS Estimates (AIDSinfo | UNAIDS)

[229] UNAIDS. (2021, July). *Start Free, Stay Free, AIDS Free Final report on 2020 targets*. https://www.unaids.org/en/resources/documents/2021/start-free-stay-free-aids-free-final-report-on-2020-targets

[230] Panorama. *PMTCT-HEI Global* Dossier. *PMTCT and HEI Cascade* Chapter. [Accessed 30 November 2020.]

Evidence from a systematic review of randomized clinical trials support the use of a dual regimen of zidovudine (AZT) and nevirapine (NVP) for high-risk infants for the first 6 weeks of life, with extension to 12 weeks depending on assessed risk of on-going vertical transmission during breastfeeding.[231] An infant at high risk of acquiring HIV is one *whose mother* meets any of the following criteria:[232]

- Viral suppression (<1000 copies/mL) was not achieved prior to delivery
- Late initiation of ART in pregnancy (i.e., received less than 4 weeks of ART at time of delivery)
- First identified as infected with HIV in the peripartum or postpartum period
- Newly infected with HIV during pregnancy or breastfeeding.

The WHO 2018 guidance on *HIV Diagnosis and ARV use in HEI*[233] outlines formulations of postnatal prophylaxis medications, including for low-risk and high-risk HIV-exposed infants. Decisions on recommended formulations, administration and duration of treatment, and recommended treatment protocols should be made in accordance with country resources and national guidelines. In addition, given the impact of timing and treatment of maternal infections on the HIV status of the infant, strengthening of maternal (re)testing (See Section 6.3.4) and treatment efforts, higher uptake of PrEP for PBFW (see Section 6.2.4.2), increased achievement of maternal viral suppression at the time of delivery, and improved continuity of care for WLHIV during pregnancy and especially during breastfeeding, are critical components for eliminating vertical transmission and optimizing outcomes for those infants who are infected.

## 6.4.1.2 Pediatric ART Optimization

Summary of section edits:

- As pediatric treatment continues to evolve, PEPFAR is supportive of ABC/3TC/DTG (pALD) use and country teams should plan accordingly for this product. A protease-inhibitor based regimen is recommended for children with intolerability of DTG or with

[231] Beste S, Essajee S, Siberry G, Hannaford A, Dara J, Sugandhi N, et al. Optimal Antiretroviral Prophylaxis in Infants at High Risk of Acquiring HIV: A Systematic Review. Pediatr Infect Dis J. 2018;37(2):169-75.
[232] 2016 Consolidated Guidelines on the Use of ARVs for Treating and Preventing HIV Infection: https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1
[233] *HIV DIAGNOSIS AND ARV USE IN HIV-EXPOSED INFANTS: A PROGRAMMATIC UPDATE*. (2018, July). https://apps.who.int/iris/bitstream/handle/10665/273155/WHO-CDS-HIV-18.17-eng.pdf?ua=1

virological failure one year after first detectable VL on DTG. For infants <3 years of age, the LPVr 40/10 mg granules are the preferred product.

- PEPFAR funds cannot be used to procure the "4-in1" ABC/3TC/LPV/r capsule until it is FDA approved. For children that are at least 3 years of age, the treatment of choice is Darunavir with Ritonavir.

There continues to be robust efforts to make optimal ARV drugs available for infants and children in a timely fashion. The U.S. government (USG), through PEPFAR and together with global partners, continues to work on accelerating the entire product life cycle of pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security and program uptake.[234] Building upon the momentum from meetings convened at the Vatican beginning in 2016,[235] all global partners continue to demonstrate commitment to advance robust, child-friendly pediatric HIV treatment options.

DTG is superior to NNRTIs and PIs as a first-line anchor ARV due to its high barrier to resistance, higher rates of VL suppression, shortened duration to achieve viral suppression, ability to be used in children on TB treatment, cost-effectiveness, palatability, minimal side effect profile, and allowance for once-daily dosing.[236,237,238] In 2021, WHO released updated pediatric DTG dosing guidelines[239] for pediatric DTG 10 mg formulations, an updated optimal formulary for pediatric ARVs,[240] and implementation guidance for transitioning to optimal pediatric HIV

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[234] World Health Organization. Global Accelerator for Paediatric Formulations Network (GAP-f). Geneva, Switzerland: World Health Organization; 2021
[235] Rome Action Plan. Paediatric HIV & TB : Rome Action Plan. 2020
[236] World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed. Geneva, Switzerland: World Health Organization; 2016
[237] World Health Organization. Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV: interim guidelines. Supplement to the 2016 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: Switzerland: World Health Organization; 2018
[238] World Health Organization. Considerations for introducing new antiretroviral drug formulations for children. Geneva, Switzerland: World Health Organization; 2020
[239] World Health Organization. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva, Switzerland: World Health Organization; 2021
[240] World Health Organization. The 2021 optimal formulary and limited-use list for antiretroviral drugs for children. Geneva, Switzerland: World Health Organization; 2021

regimens.[241] This guidance encourages **rapid programmatic transition to DTG-based regimens for ALL children (at least 4 weeks old and 3 kg) new to ART and established on ART (first line or second line) irrespective of their current regimen. As stated in WHO's 2021 guidelines update, this single switch can and should occur irrespective of the availability of a VL test/result or the value of the latest VL result, while maintaining or optimizing children on an ABC/3TC backbone.** (See Figure 6.4.6.2.1 in Section 6.4.6.2)

Rapid policy adoption and procurement of optimal pediatric ART regimens must continue to be a priority for all countries. Programs should be completing transition of all infants (at least 4 weeks old and 3 kg), children and adolescents to DTG-based regimens. Ultimately, by end of December 2022, all infants, children, and adolescents should be on DTG-based regimens, with an anticipated extremely small percentage (less than 10%) to remain on LPV/r-based regimens due to potential intolerance of DTG.

As shown in Figure 6.4.1.2.1, DTG, combined with an ABC/3TC NRTI backbone, is the preferred first line regimen for CLHIV 4 weeks of age or greater and weighing 3.0–29.9 kg; for children weighing 20 kg–29.9 kg, DTG50mg film coated tablets in combination with ABC/3TC (or TAF/FTC if at least 25 kg) backbone is preferred; TLD is preferred beginning at 30 kg. For children on ABC/3TC + LPV/r and who are being optimized to DTG-based regimens, it is appropriate to maintain the optimized ABC/3TC backbone. Early results from the NADIA trial[242] provide assurance that it is not necessary to further modify an optimized NRTI backbone during anchor drug optimization. Additionally, ARV optimization should not be postponed for viral load monitoring to take place.

Careful supply planning must continue in COP22 and should leverage DTG 10 mg transition tools available in COP20 and COP21, including DTG 10 mg Readiness Questionnaires. OUs must continue to collaborate with their respective Ministry of Health to specify concrete implementation plans and timelines to ensure national treatment guidelines are updated with current WHO-recommended treatment regimens and formulations for infants (including neonates), children, and adolescents. Detailed planning will be extremely important to achieve a prompt transition and help ensure the full and prompt uptake of DTG is not hindered by

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[241] World Health Organization. Transitioning to the 2021 optimal formulary for antiretroviral drugs for children: implementation considerations. Geneva, Switzerland: World Health Organization; 2021

[242] Paton N et al. Nucleosides and darunavir/dolutegravir in Africa (NADIA) trial: 48 wks primary outcome. CROI 2021 (virtual). 6–10 March 2021. Oral abstract 94.

concerns over using up remaining supplies of pediatric LPV/r products. Agencies should ensure that all pediatric treatment implementing partners' work plans are aligned with PEPFAR pediatric treatment priorities and include clearly defined activities and timelines to support implementation of pediatric DTG. Programs are encouraged to work with respective stakeholders to ensure context-specific demand creation activities are in place to support ongoing pediatric ART optimization efforts.

Figure 6.4.1.2.2 depicts the current and expected DTG products that are or will be available for PEPFAR countries. Generic manufacturers are currently developing ABC/3TC/DTG (pALD), FDC. pALD is approved for use in children > 10 kg and studies are underway for the use of pediatric pALD in infants weighing <10 kg. Regulatory approval for generic pALD has been submitted to the FDA and a decision is anticipated in FY24 Q1. In anticipation of switching to pALD, avoid overstocking ABC/3TC 120/60 mg. DTG 10 mg may continue to be required for children within the 3.0 kg to 5.9 kg weight band as well as for children being co-treated for TB/HIV.

A protease-inhibitor based regimen is recommended for children with intolerability of DTG or with virological failure one year after first detectable VL on DTG. For children <3 years of age, the LPVr 40/10 mg granules are the preferred product. PEPFAR funds cannot be used to procure the "4-in1" ABC/3TC/LPV/r capsule until it is FDA approved. For children that are at least 3 years of age, DRV/r 120/20 mg should be prioritized once tentative FDA approval is obtained, and country teams should plan accordingly for this product. Programs may consider the use of raltegravir 100 mg granules for suspension in combination with AZT/3TC for treatment of neonates (0 to 4 weeks of age) with HIV infection in programs that are implementing at- or near-birth testing (see Section 6.3.1.3) and should use this regimen for the shortest period possible until the infant can safely be administered pediatric DTG at 4 weeks of age **and** weighing at least 3 kg.

*Figure 6.4.1.2.1:[243] DTG is a component of the preferred first line ARV regimens in WHO guidance.*

[243] World Health Organization. The 2021 optimal formulary and limited-use list for antiretroviral drugs for children. Geneva, Switzerland: World Health Organization; 2021

**Table 1.** Summary of preferred and alternative first-line ART for neonates and children

| | Neonates | Children |
|---|---|---|
| Preferred | AZT+3TC+RAL[a] | ABC + 3TC + DTG |
| Alternatives | AZT+3TC+NVP | ABC + 3TC + LPVr<br>TAF[c] + 3TC (or FTC) + DTG<br>ABC + 3TC + RAL[d] |
| Special circumstances[d] | AZT+3TC+LPVr[b] | ABC + 3TC + EFV[e] (or NVP[f])<br>AZT + 3TC + EFV[e] (or NVP[f])<br>AZT + 3TC + LPVr (or RAL) |

[a] For the shortest time possible, until a solid formulation of LPVr or DTG can be safely administered.
[b] From two weeks of age if oral solution or granule formulations can be used. Although LPVr pellets cannot be used for neonates, they can be used from three months of age.
[c] For age and weight groups with approved TAF dosing (since January 2020, TAF has been approved from 25 kg).
[d] For special circumstances when preferred and alternative regimens are not available or cannot be used.
[e] From three years of age.
[f] Only in cases where no other alternatives are available.

*Figure 6.4.1.2.2: Current and Expected DTG formulations with FDA approval status available for PEPFAR*[244]

| Dolutegravir Product | Formulation | US FDA Status | Global Availability | Characteristics for Eligibility | Can tablet be split? |
|---|---|---|---|---|---|
| DTG | Film Coated Tablet, 50 mg | Tentatively Approved | Widespread | 20 kg and above | No |
| Tenofovir Disoproxil/ lamivudine/ dolutegravir | Fixed Dose Combination Tablet, 300/300/50 mg | Tentatively Approved | Widespread | 30 kg and above | No |
| DTG | Scored Dispersible Tablet, 10 mg | Tentatively Approved | Widespread | Minimum of 3 kg and 4 weeks | Yes |
| Abacavir/ Lamivudine/ Dolutegravir | Dispersible, Fixed Dose Combination Tablet, 60/30/5 mg | Tentative Approval anticipated in 2023/2024 | Anticipated to have widespread availability post FDA tentative approval | Minimum of 6 kg and 4 weeks | No |

The administration of DTG dispersible formulations resembles the administration of ABC/3TC dispersible formulations, and the dispersible formulations are easier for caregivers to administer than LPV/r granules or pellets. Healthcare workers may require ongoing guidance and training on appropriate dosing and administration of pediatric DTG formulations and approaches for counseling and educating caregivers. Please see CHAI's HIV New product Introduction

[244] The majority of PEPFAR-supported countries will be able to access generic DTG. For countries that cannot access generic DTG due to patent, Tivicay® (dolutegravir 50 mg and dolutegravir 5 mg) is available.

Toolkit[245] for HCW and caregiver resources for implementation of pediatric DTG. It is critical that frontline providers receive intensified support to effectively prescribe, dispense, and monitor infants and children on ART. DTG dispersible formulations should be dispensed intact in their stock bottles just as it is expected that all ARVs are dispensed in their original bottles in order to protect the integrity of the medication. Since pDTG 10 mg comes in a 90-count bottle, it is permissible to dispense children <2 years of age with more than a month supply of medication. Proper follow-up and outreach are important to ensure children return to clinic for their scheduled visits regardless of number of months dispensed. **It is imperative to ensure alignment in the number of pills dispensed for ABC/3TC and DTG to reduce the possibility that a child could inadvertently receive mono/dual therapy.** If tablets need to be broken based on dosage, parents and caregivers who are administering medications to children can be instructed that half tablets can be placed back into the stock bottle for safe storage and **do not** have to be prioritized for the next scheduled dose.

Implementing partners in collaboration with district health teams should continuously build the capacity and confidence of healthcare workers and caregivers to successfully provide and administer optimal ART regimens through ongoing supportive mentorship and supervision. Clinical implementing partners should also train OVC frontline teams working in the same catchment areas on the newer pediatric formulations and practical information on pediatric ARV administration, including timepoints for ARV dosing, formulation, and/or drug transition. OVC frontline teams can help reinforce treatment literacy to support the DTG transition, as well as appropriate administration and adherence counseling for ARVs received from the facility. Continuous strategic mentorship and supportive supervision of OVC staff/teams on essential pediatric ART optimization activities need to be clearly outlined in work plans for all relevant implementing partners. Implementing partners are encouraged to use customized indicators to monitor and refine pediatric ART optimization efforts in order to meet minimum program requirements. pDTG sensitization activities among CSOs, especially those who support children and families, are essential to improve demand creation for pDTG in the community and in health facilities to ensure a timely transition to pDTG.

In collaboration with the MOH, country programs must monitor the uptake, scale-up and outcomes of pediatric ART. Programs should report the number of CLHIV on ART in real time, stratified by ART regimen (including specific LPV/r and DTG formulation), WHO dosing weight

[245] https://www.newhivdrugs.org/

bands, and if feasible, PEPFAR finer age bands. M&E tools should be adjusted to capture this required data. PEPFAR partner countries are also encouraged to implement pharmacovigilance as a key facet of pediatric ART optimization activities; however, pharmacovigilance should not become a barrier to rapid introduction and widespread use of pediatric DTG. It is imperative that PEPFAR programs ensure children reach and maintain ≥95% VL coverage as viral load monitoring informs if a child is on an effective treatment regimen. Due to the increased risk of morbidity and mortality among CLHIV who are not virally suppressed, any high viral load must be treated with urgency. Please see Section 6.4.6.2 on recommendations to mitigate and address viral non-suppression in children.

### 6.4.1.3 Adolescent and Adult ART Optimization

Summary of section edits:

- Wording was updated to include children ≥3 kg and ≥4 weeks of age to be transitioned and maintained on a DTG based regimen.

Dolutegravir (DTG)-containing regimens are the preferred first-line and second-line ART for all people living with HIV who are ≥3 kg and ≥4 weeks old. The fixed dose combination (FDC) of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) is the WHO-preferred ART regimen for all adolescents and adults ≥30 kg and other DTG containing regimens are preferred for those <30 kg. COVID-19 caused widespread delays in the transition to DTG-based ART, but countries are expected to complete the transition for children, adolescents, and adults if this has not already been accomplished. TLD should be provided to all adults and adolescents (≥30 kg) as initial ART or as a replacement for their current ART regimen, including for current protease inhibitor (lopinavir/ritonavir or atazanavir/ritonavir or darunavir/ritonavir) regimens. In the rare instances in which a patient cannot take TLD because of failure or intolerance, a regimen with DRVr is preferred, provided DRVr is reliably available at an affordable price. TLE may be considered instead if DRVr is not yet readily available. Consistent with findings from EARNEST and NADIA, data from ACTG 5288 suggest that NRTIS, particularly TDF/FTC and TDF/3TC can be effectively recycled with highly efficacious therapies such as DRV/r or DTG. The approach to non-suppression and virological failure is documented in Section 6.4.6.

TLD should be provided to all adults and adolescents (≥30 kg) as initial ART or as a replacement for their current ART regimen. This includes those who were taking:

- tenofovir/lamivudine/efavirenz (TLE),
- tenofovir/emtricitabine/efavirenz (EFV) (TEE),
- lamivudine/zidovudine/nevirapine (LZN)
- other EFV- and NVP-containing regimens,
- regimens containing lopinavir/ritonavir or atazanavir/ritonavir (as either first- or second-line ART)

Routine viral load monitoring is encouraged, but viral load testing and documentation of a suppressed viral load should not be a requirement for transitioning to TLD. Viral load testing should be given priority after the change in regimen for patients who either have no prior viral load testing or who have non-suppressed viral load results before switching.

Individuals who are in a differentiated service delivery model, should remain in that model of care including for drug dispensation/MMD during and after their transition to a DTG-based regimen. Evidence is reassuring for the use of DTG at standard dosages for pregnant women. Compared to EFV, DTG has been shown to reduce VL faster in pregnant women and to increase the likelihood of VLS by delivery[246] Expanded data sets evaluating the relationship between peri-conceptional dolutegravir exposure and neural tube defects suggest that the risk of this abnormality is extremely low[247] and there is no statistical difference between the risk among women taking DTG and the background risk[248] These data led the WHO to recommend DTG for all populations as first- and second-line therapy including for women of childbearing age and during pregnancy.[249] US Department of Health and Human Services HIV Guidelines were updated in December 2020 and DTG is now a preferred ARV drug throughout pregnancy and for women who are trying to conceive.[250]

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[246] Kintu, K., T. Malaba, J. Nakibuka, C. Papamichael, A. Colbers, K. Seden, V. Watson, H. Reynolds, D. Wang, C. Waitt, C. Orrell, M. Lamorde, L. Myer and S. Khoo (2019). Rct of dolutegravir vs efavirenz-based therapy initiated in late pregnancy: dolphin-2. Abstract 40. Conference on Retroviruses and Opportunistic Infections Seattle, Washington

[247] Zash R et al. Update on neural tube defects with antiretoviral exposure in the Tsepamo study, Botswana, IAS Virtual July 2021 Abs #2562

[248] Reefhuis J, FitzHarris LF, Gray KM, et al. Neural Tube Defects in Pregnancies Among Women With Diagnosed HIV Infection — 15 Jurisdictions, 2013–2017. MMWR Morb Mortal Wkly Rep 2020;69:1–5. DOI: http://dx.doi.org/10.15585/mmwr.mm6901a1external icon

[249] Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (who.int)

[250] https://clinicalinfo.hiv.gov/en/guidelines/perinatal/table-5-situation-specific-recommendations-use-antiretroviral-drugs-pregnant

Programs should therefore actively and routinely include all pregnant and breastfeeding women and women of reproductive potential in their TLD transition plan. Programs are encouraged to follow data on uptake and outcomes of TLD amongst men and women across different age groups closely. Specifically, they should report ARV exposures during pregnancy to "The Antiretroviral Pregnancy Registry" at www.APRegistry.com. This data reporting procedure should be incorporated in a standardized fashion into HCW trainings.

Concerns have been raised that DTG use could be linked to higher weight gain including the development of obesity which is associated with cardiovascular disease, non-AIDS related cancers and metabolic syndrome. Data from the ADVANCE and NAMSAL trials confirm excess weight gain in individuals initiating DTG, women, and individuals on a regimen including TAF were the most affected. Treatment emergent metabolic syndrome was observed in the TAF containing arm of the ADVANCE trial.[251,252] In the AFRICOS cohort a clinically small but statistically significant rise in the weight of individuals switching to dolutegravir was noted, however an excess of metabolic syndromes was not observed. Continued efforts for pharmacovigilance should be made in coordination with national and supranational programs using active monitoring and surveillance including in pregnant women as new ARV drugs are introduced.

Countries should have zero wastage of current legacy TLE600 or TEE after the transition to TLD and TLE400 is complete. PEPFAR no longer supports any NVP-based formulations for treatment of infants, adolescents or adults living with HIV. All children (≥3 kg and ≥4 weeks of age) and adults treated for HIV in PEPFAR-supported programs should have been transitioned to a DTG-based regimen. **Note:** PEPFAR will continue to procure NVP oral solution and NVP dispersible tablets for infant prophylaxis and very limited use for treatment of newborns with HIV

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[251] Venter, W., Sokhela, S., Simmons, B., Moorhouse, M., Fairlie, L., Mashabane, N., Serenata, C., Akpomiemie, G., Masenya, M., Qavi, A., Chandiwana, N., McCann, K., Norris, S., Chersich, M., Maartens, G., Lalla-Edward, S., Vos, A., Clayden, P., Abrams, E., Arulappan, N., … Hill, A. (2020). Dolutegravir with emtricitabine and tenofovir alafenamide or tenofovir disoproxil fumarate versus efavirenz, emtricitabine, and tenofovir disoproxil fumarate for initial treatment of HIV-1 infection (ADVANCE): week 96 results from a randomised, phase 3, non-inferiority trial. *The lancet. HIV*, *7*(10), e666–e676. https://doi.org/10.1016/S2352-3018(20)30241-1

[252] Calmy, A., Tovar Sanchez, T., Kouanfack, C., Mpoudi-Etame, M., Leroy, S., Perrineau, S., Lantche Wandji, M., Tetsa Tata, D., Omgba Bassega, P., Abong Bwenda, T., Varloteaux, M., Tongo, M., Mpoudi-Ngolé, E., Montoyo, A., Mercier, N., LeMoing, V., Peeters, M., Reynes, J., Delaporte, E., & New Antiretroviral and Monitoring Strategies in HIV-infected Adults in Low-Income Countries (NAMSAL) ANRS 12313 Study Group (2020). Dolutegravir-based and low-dose efavirenz-based regimen for the initial treatment of HIV-1 infection (NAMSAL): week 96 results from a two-group, multicentre, randomised, open label, phase 3 non-inferiority trial in Cameroon. *The lancet. HIV*, *7*(10), e677–e687. https://doi.org/10.1016/S2352-3018(20)30238-1

infection in the first 2-4 weeks of life. See section of Pediatric ARV optimization for guidance on optimal ARV regimens for infants and children only

Patients receiving treatment for TB (with rifampin-containing regimens) require an additional DTG 50 mg administered 12 hours after TLD; therefore, TLD planning should include planning for procurement of adequate DTG 50 mg tablets for management of patients above 20 kg with TB coinfection for the duration of rifampin therapy.

PEPFAR currently recommends the use of tenofovir alafenamide fumarate (TAF) containing regimens only in individuals with renal insufficiency or osteoporotic bone disease. Widespread procurement is not recommended. Currently, PEPFAR does not support the procurement or recommend long-acting formulations for treatment.

## 6.4.2 Identification and Treatment of Advanced HIV Disease

Summary of section edits:

- Clarification added regarding TB screening in individuals with advanced HIV disease
- Cryptococcal guidance was updated to align with WHO guidance

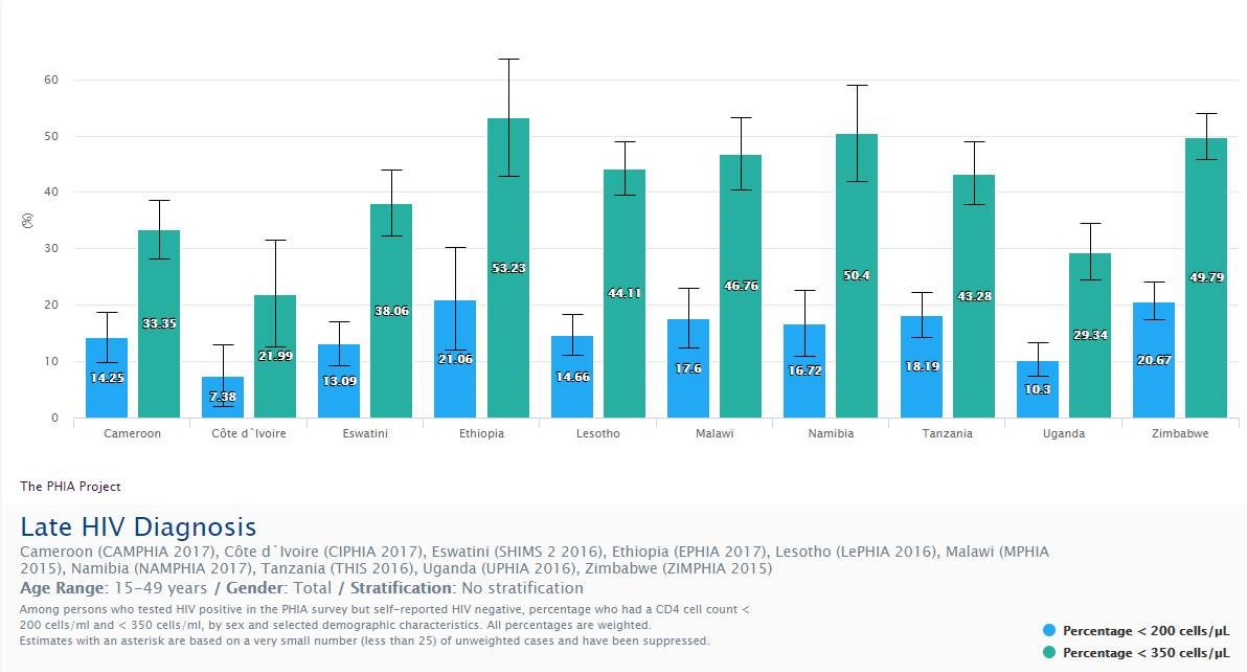
Individuals with advanced HIV disease require a more intensive level of care and experience a greater morbidity and mortality than those without advanced disease. The proportion of people with advanced disease at HIV diagnosis continues to decline with expanded testing efforts and universal ART policies but varies by country and region.

For adults, adolescents, and children five years or older, advanced HIV disease is defined as having a CD4 cell count <200 cells/mm$^3$ or with current WHO clinical stage 3 or 4 findings.[253] All children under 5 who are not on effective ART are considered to have advanced disease because, in the absence of effective treatment, children with HIV have higher viremia and more rapid disease progression with high mortality. PHIA data noted that among persons aged 15-24 years who tested HIV positive but self-reported HIV negative, 7-21% had a CD4<200 cells/mm$^3$ [254] (See Figure 6.4.2.1).

[253] https://www.who.int/publications/i/item/9789240008045
[254] https://phia-data.icap.columbia.edu/visualization.

In the AFRICOS cohort, the proportion of individuals with advanced disease remained near 20% until 2019[255] The IeDEA cohort published data on trends in CD4 testing among adults ≥15 years of age starting ART in Southern Africa (Lesotho, Malawi, Mozambique, South Africa, Zambia, and Zimbabwe) from 2005 to 2018 and noted the percentage starting ART with advanced HIV disease declined from 83.3% in 2005 to 23.5% in 2018; however, the proportion of individuals with a CD4 measured at ART initiation also declined during the study period.[256]

*Figure 6.4.2.1: PHIA Data Showing the Proportion of Clients with Late HIV Diagnosis for Select Countries*




People with advanced HIV disease in PEPFAR programs include those who are initiating ART and those who are treatment experienced (i.e., persons re-initiating ART after a treatment interruption). The Zimbabwe 2016 PHIA showed that 17% of people testing positive for HIV had a CD4 <200, and 35% of those were treatment experienced. In this group of ART-experienced

[255] Oboho et al. Advanced HIV Disease among Adults in the African Cohort Study (AFRICOS) ID Week 2020
[256] Zaniewski E et al, JAIDS, 2020) http://www.ncbi.nlm.nih.gov/pmc/articles/pmc7343336/

individuals, it is likely that treatment interruption was important in the development of advanced disease.

Enhanced screening for and treatment of opportunistic infections has substantially reduced early mortality in individuals in North America and Europe. The WHO has identified a package of interventions[257,258] that reduce morbidity and mortality in individuals with advanced HIV disease, which includes the following:

1. Rapid initiation of ART (a delay is warranted only for central nervous system (CNS) infection)
2. Co-trimoxazole prophylaxis
3. Screening for active TB disease using the algorithm described in Section 6.4.3 with rapid return of results and prompt initiation of anti-TB treatment or TB preventive therapy as indicated. Urinary TB-lipoarabinomannan (LF-LAM) point-of-care testing (in addition to routine molecular WHO-recommended diagnostic and drug susceptibility testing) is strongly recommended for individuals with advanced HIV disease and for additional groups as noted in Section 6.4.3.1 on TB case finding, including individuals who are seriously ill in hospital. These diagnostic interventions should happen in parallel, not sequentially. Initiation of TB treatment in individuals who are presumed to have TB, or have a positive LF-LAM, should not be delayed for further confirmation. Of course, detecting rifampin resistance with mWRD remains important to inform treatment regimen choice. If people with advanced disease do not have TB, then they should be offered tuberculosis preventive therapy as discussed in Section 6.4.3.3.
4. Screening for cryptococcal disease with cryptococcal antigen (CrAg) testing and either preemptive therapy with fluconazole (except for children younger than 10 years) or treatment of meningitis.
5. Intensified support to ensure adherence to the AHD package. In places where histoplasmosis is endemic (e.g., Central and South America), the WHO has additionally recommended urinary screening for histoplasma antigen.

A hub-and-spoke differentiated service delivery approach can help to place key interventions according to the capacity of the health system while maximizing access to these interventions.

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[257] https://apps.who.int/iris/bitstream/handle/10665/255884/9789241550062-eng.pdf

[258] The IeDEA and COHERE in EuroCoord Cohort Collaboration (2020). All-cause mortality after antiretroviral therapy initiation in HIV-positive women from Europe, Sub-Saharan Africa and the Americas. *AIDS (London, England)*, *34*(2), 277–289. https://doi.org/10.1097/QAD.0000000000002399

Use of differentiated service delivery models that distinguish between those who are clinically unwell and admitted to hospital, those who are unwell but able to be managed in the outpatient department, and those who are clinically well but have advanced disease may be particularly helpful to support guidance for up-referral and to allow resources to be deployed where they are most needed. The first three months after ART initiation is a critically important time for individuals with advanced HIV disease and close follow-up with screening for and treatment of opportunistic interventions can dramatically reduce early mortality. See http://www.differentiatedcare.org/Resources/Resource-Library/DSD-for-advanced-HIV-disease-toolkit for more detail and resources for implementation and https://cquin.icap.columbia.edu/news/workshop/ for resources on best practices.

Individuals with advanced HIV disease who have been identified in a hospital setting and are being discharged from a hospital are at high risk of mortality. Linkage to follow-up care is critical to successful therapy. Intensified follow-up approaches appropriate to the local context should be implemented (e.g., phone calls, community follow up, etc.). At hospital discharge, linkage is needed to an agreed OPD or PHC with adequate information and planning so that treatment and prophylaxis for opportunistic infections may be continued. ART should be initiated as an inpatient. Delays in ART initiation should occur only for meningitis (tuberculous or cryptococcal) or other CNS infections (e.g., histoplasmosis). For those with suspected TB, pending evaluations for tuberculosis should not delay ART initiation. Providers should initiate ART while rapidly investigating for TB, with close follow-up within seven days to initiate TB treatment if TB is confirmed and clinical care for Immune Reconstitution Inflammatory Syndrome (IRIS) if there is evidence for that condition. IRIS events are more common in individuals with extremely low CD4 counts (e.g., <50 cells/mm$^3$). Concerns about IRIS should not delay ART start, except as noted in the setting of CNS infections.

Please see Section 6.5.2.1 for the approach to CD4 testing. When CD4 testing is not available, clinical criteria including WHO clinical staging and assessment for severe illness (as defined by WHO or local context) should be used to identify patients who will benefit from the package of care.

Cotrimoxazole prophylaxis for *Pneumocystis jirovecii* pneumonia and bacterial infections and (in endemic areas) malaria, as well as presumptive treatment for TB infection, should be considered in settings where access to diagnostics tests is limited and people present with

typical or possible signs and symptoms.[259] Shorter course TB preventive treatment (TPT) and the use of fixed-dose formulations that contain INH/cotrimoxazole/Vit B6 may facilitate more widespread use of these lifesaving therapies (see Section 6.4.3.3). Cotrimoxazole is recommended for all children and adults with HIV (irrespective of clinical stage or CD4 count) in settings with a high prevalence of malaria and/or severe bacterial infections and for all adults with advanced disease and children with HIV (irrespective of clinical stage or CD4 count).[260] As noted in the minimum program requirements, no person receiving treatment in a PEPFAR program should pay for cotrimoxazole (CTX), TPT, or the diagnostics and medicines required for secondary prophylaxis or pre-emptive treatment of cryptococcal meningitis. PEPFAR funds may be used to purchase CTX.

The diagnostic approach to TB for individuals with advanced disease is outlined in Section 6.4.3 and includes screening for TB at every clinical encounter. For individuals who screen positive for TB symptoms, further workup is needed as outlined in Section 6.4.3. **TB treatment should be initiated immediately if there is clinical suspicion and continued regardless of test result if the clinical symptoms are consistent with TB**. Detailed guidance on TB diagnosis, including the use of LF-LAM for TB diagnosis, may be found in Section 6.4.3.2.

Evaluation for TB disease should not delay the initiation of ART, and TB treatment should be initiated immediately following positive results from rapid point of care LF-LAM testing while awaiting confirmatory rapid molecular tests results. Enhanced linkage and tracking interventions should be in place to follow-up pending TB diagnostic results to ensure appropriate anti-TB treatment.

Pneumocystis pneumonia (PCP) caused by the fungus *Pneumocystis jirovecii* continues to be an important opportunistic pathogen affecting individuals with advanced HIV disease. A recent meta-analysis of African studies estimated that the pooled prevalence of a laboratory confirmed diagnosis among individuals with HIV and respiratory symptoms was 19%.[261] PCP has an estimated case fatality rate of nearly 20%.[262] Prompt recognition, and institution of specific

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[259] https://www.who.int/publications/i/item/9789240031593

[260] https://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_dec2014/en/

[261] Wills NK, Lawrence DS, Botsile E, Tenforde MW, Jarvis JN. The prevalence of laboratory-confirmed Pneumocystis jirovecii in HIV-infected adults in Africa: A systematic review and meta-analysis. Med Mycol. 2021 Jul 14;59(8):802-812. doi: 10.1093/mmy/myab002. PMID: 33578417; PMCID: PMC8331329.

[262] Wasserman S, Engel ME, Griesel R, Mendelson M. Burden of pneumocystis pneumonia in HIV-infected adults in sub-Saharan Africa: a systematic review and meta-analysis. BMC Infect Dis. 2016 Sep 9;16(1):482. doi: 10.1186/s12879-016-1809-3. PMID: 27612639; PMCID: PMC5018169.

therapy, including corticosteroids if indicated, can be lifesaving. COVID-19 adaptations have increased the availability of pulse oximeters in some facilities. Hypoxemia or desaturation with exercise accompanied by the appropriate clinical syndrome in both adults and children warrants immediate therapy while specific investigations are pending. Outpatient clinics should facilitate timely referral to the inpatient setting for further diagnostics and management as appropriate.

PEPFAR recommends cryptococcal antigen testing, preemptive therapy with fluconazole, and management of cryptococcal meningitis according to the WHO guidance. Individuals older than 10 with advanced HIV disease should have a cryptococcal antigen performed. Treatment for cryptococcal meningitis consists of an induction phase followed by a consolidation phase and then maintenance or secondary prophylaxis. The WHO preferred treatment for induction is a single dose of liposomal amphotericin B with 14 days of flucytosine and fluconazole. Conventional amphotericin B deoxycholate given with flucytosine, or fluconazole with flucytosine, are listed as alternatives if liposomal amphotericin is not available.[263] Fluconazole in different doses is recommended for consolidation and maintenance therapy. Repeated lumbar punctures are often required. Other fungal diseases are important regional causes of morbidity and mortality in individuals with advanced HIV disease. These include histoplasmosis in Latin America and talaromycosis in Asia. Rapid diagnostic tests are available for histoplasmosis and are in development for talaromycosis. Treatment of invasive disease consists of amphotericin followed by oral antifungals.

Countries should review existing diagnostic resources and networks to inform network designs and plans and budget for individual commodities (e.g., supplies for lumbar puncture) and network revisions (e.g., policies, algorithms, laboratory and clinical trainings, quality assurance activities) for diagnosis and treatment of advanced disease.

### 6.4.2.1 Approach to CD4 Testing

CD4 testing is supported by PEPFAR to identify individuals with Advanced HIV Disease (AHD). It is **not** to be used for determining eligibility for ART or monitoring response to ART: HIV Viral load (VL) testing remains the primary method used to monitor the effect of therapy. ART initiation should not be delayed by efforts to obtain a CD4 test or because a CD4 test result is

[263] Guidelines for diagnosing, preventing and managing cryptococcal disease among adults, adolescents and children living with HIV. Geneva: World Health Organization; 2022. License: CC BY-NC-SA 3.0 IGO.

not yet available. A CD4 may be obtained anytime within the first weeks of initiating or re-initiating therapy.

CD4 testing is recommended

1. At initiation of therapy for all individuals over 5
2. Upon re-initiation into care for those out of care for more than a year
3. For individuals with documented virologic failure, defined as 2 consecutive VL measurements above 1000 copies/ml taken at least 3 months apart with adherence support following the first viral load test.

All programs should consider using an optimized and quality-assured CD4 testing approaches, whether laboratory-based, near-care, or point-of-care testing (POCT). AHD care must have access to CD4 testing services, whether within a network or at the facility, with the appropriate CD4 technology, which should be of quality, reliable, and low-cost.

Where appropriate, consideration for POCT and near-care CD4 technology should be given highest priority. Many countries now have access to a variety of POCT and near-care CD4 technology, including the WHO-prequalified Omega Diagnostics VISITECT CD4 Advanced Disease test,[264] a rapid, semi-quantitative lateral flow assay that differentiates CD4 values above and below 200 cells/mm$^3$. Where existing instruments are not available or are available and without existing or planned service and maintenance and/ or resource support, but not functional, the VISITECT test is preferred as it does not require any instruments to meet low throughput testing needs.

To achieve optimal CD4 testing,[265] the Ministry of Health should review access of CD4 testing services to support facilities' HIV care and treatment. This review should include: (1) an inventory of facilities providing diagnosis and/or care for AHD patients, (2) an estimate of number of patients and volumes of CD4 testing needed at each facility, (3) determination of each facility's access to existing CD4 testing services, (4) determination of specimen referral and result reporting network linking facilities to CD4 testing services, and (5) if possible, geospatial maps and/or calculations of national and subnational test demand versus existing

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[264] https://www.medicaldevice-network.com/news/omega-who-prequalification-visitect-test/

[265] World Health Organization, WHO Prequalification of In Vitro Diagnostics : PUBLIC REPORT, Product: VISITECT CD4 Advanced Disease. 2020. https://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/200818_pqdx_0384_077_00_vistect_cd4_advanced_disease.pdf?ua=1

and/or projected capacity. This review should be used to provide optimization of existing, CD4 testing services. CD4 testing technology selection should be guided by the health facility capacity to provide reliable and quality CD4 testing and need for CD4 testing services. Resources should not be diverted from viral load activities for CD4 testing. PEPFAR does not envision immediate wide-spread scale up of CD4 testing, rather prioritization of testing in places that provide care for individuals with advanced HIV disease with a view to implementing a hub and spoke model of care. Programs implementing CD4 testing should aggregate and regularly review available data to assess need and monitor delivery of advanced disease interventions.

### 6.4.2.2 Identification and Treatment of Pediatric Advanced Disease

Summary of section edits:

- Text was added to address mortality in CLHIV under 5 years to: (**1**) support mortality surveillance systems and cause of death audits to allow for targeted mortality prevention efforts; (**2**) ensure CLHIV newly initiating ART are provided with intensive case management until viral suppression is achieved; and (**3**) ensure malnutrition is diagnosed and treated early, especially during the first 6 months of ART initiation.

Due to increased risk of mortality among younger children living with HIV (CLHIV), WHO broadly defines all CLHIV <5 years old as having advanced HIV disease (AHD) *at time of diagnosis***. Clinically stable young CLHIV (<5 years of age) on ART are not classified as having advanced HIV disease.** CLHIV ≥5 years of age and adolescents living with HIV (ALHIV) with a CD4 count <200 are considered to have advanced HIV disease irrespective of WHO clinical stage as well as those with WHO stage 3 or 4. C/ALHIV ≥5 years of age who had previously initiated ART and are re-engaging with care after 3 months or greater of ART interruption should be assessed for advanced disease and offered the advanced HIV disease package of care as indicated. Assessment should include CD4 testing if IIT is for 12 months or greater. Additionally, supportive, client-centered counseling and support for both the caregiver and the child should be provided to help improve continuity of treatment, as well as to identify and address any psychosocial or socioeconomic barriers to treatment continuation. Children with advanced HIV disease should be prioritized for enrollment in the OVC program in order to access socioeconomic and home-based support.

When examining MER data, CLHIV <5 years of age who have been identified and initiated on treatment have the highest proportion of reported deaths among all age groups in PEPFAR

programs at 0.68% for FY21 APR. These results underpin the importance of improving EID coverage, linkage, treatment initiation, rapidly adopting pediatric DTG (see Section 6.4.1.2), and implementation of the AHD package of care for all children <5 years of age at time of HIV diagnosis. In addition, for CLHIV under 5 years, it's recommended that OUs: 1) Support mortality surveillance systems and cause of death audits in collaboration with country governments to allow for targeted mortality prevention efforts; 2) Ensure CLHIV newly initiating ART are provided with intensive case management until viral suppression is achieved; and 3) Ensure malnutrition is diagnosed and treated early in CLHIV, especially during the first 6 months of ART initiation.

In July 2020, WHO released a technical brief[266] that outlines a package of interventions to STOP AIDS among C/ALHIV (see Figure 6.4.2.2.1). PEPFAR programs must incorporate this package of AHD interventions into PEPFAR-supported pediatric HIV programs. Although many components of the package addressing pediatric AHD are similar to the package for adults, there are several critical additions for children, including screening for malnutrition and ensuring routine childhood vaccinations. Another key difference is that cryptococcal disease in children is rare; therefore, screening for cryptococcal antigen and pre-emptive therapy is only recommended for individuals ≥10 years of age. PEPFAR should coordinate with other stakeholders to ensure children are receiving all pediatric standard of care interventions that can decrease morbidity and mortality, including treatment for helminthic and parasitic disease (i.e., deworming), malaria prophylaxis, iron and vitamin A supplementation, and linkage to nutritional support for children with malnutrition. Increased focus on TB diagnosis and TB prevention in children is needed, and whenever possible, countries should be reviewing age-disaggregated TB prevention and treatment data to identify gaps in TB services for children (see Section 6.4.3).

Countries should include children in quantification exercises for advanced HIV disease commodities and procure pediatric formulations of medications for prophylaxis and treatment when available. All facilities providing advanced HIV disease services for adolescents and adults should be supported to provide advanced HIV diseases services for children, through mentorship, supervision, and supply chain coordination. Monitoring and evaluation tools for advanced HIV disease should include age-disaggregation to allow for assessment of

[266] World Health Organization. *Package of care for children and adolescents with advanced HIV disease: stop AIDS.* Geneva, Switzerland: World Health Organization; 2020.

implementation and outcomes for children. No family should incur fees for the commodities and medications needed to prevent or treat advanced HIV disease.

*Figure 6.4.2.2.1: WHO Package of Care for Children and Adolescents with Advanced HIV Disease to STOP AIDS*

## Box 1. Screen, Treat, Optimize and Prevent AIDS

### Screen[a]

**TB**

- Screen for TB using a clinical algorithm[b] followed by X-ray when indicated and if available
- Use the following diagnostic tests to confirm TB as applicable:[c]
  - Rapid molecular diagnostic (Xpert® MTB/RIF or Ultra) on (induced) sputum, stool, gastric aspirate or nasopharyngeal aspirate or other extrapulmonary samples if relevant
  - Lateral flow urine lipoarabinomannan (LF-LAM) assay[d]

**Cryptococcal infection among adolescents**

- Serum or plasma or blood cryptococcal antigen screening followed by lumbar puncture if positive or symptomatic

**Malnutrition**

- Weight-for-height
- Height-for-age
- Mid-upper arm circumference among children 2–5 years old

### Treat

**TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis** and **severe acute malnutrition** according to WHO guidelines

### Optimize

**Rapid antiretroviral therapy start** – within seven days with optimal regimens[e]

**Antiretroviral therapy counselling**

### Prevent

**Bacterial infections and *Pneumocystis* pneumonia**

- Co-trimoxazole prophylaxis

**TB**

- TB preventive treatment

**Cryptococcal meningitis among adolescents**

- Fluconazole pre-emptive therapy

**Vaccinations**

- Pneumococcal vaccine
- Human papillomavirus
- Measles
- BCG

[a] Screening refers to screening and diagnostics throughout this publication.
[b] See Fig. 3 in *Guidance for national tuberculosis programmes on the management of tuberculosis in children (9)*.
[c] A negative test result does not exclude TB in children living with HIV in whom there is a strong clinical suspicion of TB.
[d] See Table 2 and the text for recommendations.
[e] Unless TB or cryptococcal disease is diagnosed *(10)*.

## 6.4.2.3 Reducing Mortality and the Aging Cohort

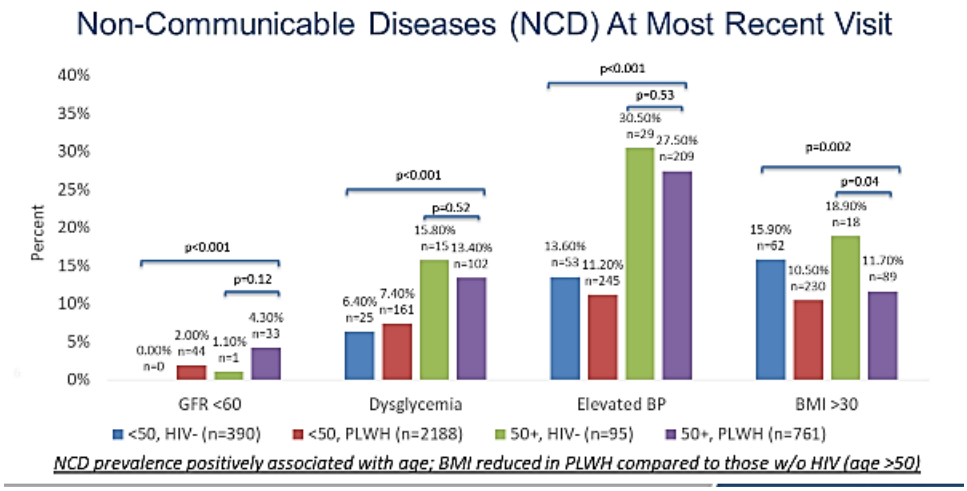
Summary of edits to this section:

New language was added to address integrated care for adults with comorbidities.

Preventable mortality among individuals with HIV remains a persistent issue in the HIV treatment field. Program data suggest that burden of excess mortality is born by three groups: individuals over 50, those with advanced disease, and children, particularly those under 5. Advanced disease, and the excess risk of opportunistic infections and the special needs of the pediatric population are covered in Sections 6.4.2 and 6.4.2.2. As countries reach epidemic control there is a growing population of adults in treatment who are older than 50 years of age, and this population is expected to grow. Starting in FY22, the age bands for TX_CURR will be expanded to 50-54, 55-59, 60-64, and 65+.PEPFAR is committed to improving the quality of life for all people living with HIV, which will translate to better health outcomes for all. Non-infectious chronic diseases, rather than advanced HIV disease, are expected to account for increasing contributions to mortality in this older group. Comorbid conditions are common among people living with HIV and increase with age. The AFRICOS cohort identified a significant burden of non-communicable disease, especially hypertension, obesity, and diabetes, among people with and without HIV.[267] See Figure 6.4.2.3.1 for the frequency of NCD for clients on ART, or not, at their most recent clinic visit.

*Figure 6.4.2.3.1: Summary of NCD Prevalence for People Less Than and Greater Than 50 Years Old*

[267] Chang D, Esber A, Dear N, Iroezindu M, Bahemana E, Kibuuka H, Owuoth J Maswai J, Crowell T, Polyak C, Ake J, Godfrey C: Non-Communicable Diseases in Older Persons Living with and without HIV in Four African Countries; International workshop on HIV and Aging: Reviews in Antiviral Therapy & Infectious Diseases 2021_8.




The COVID-19 pandemic has placed even more emphasis on the healthcare and social needs of older adults with HIV, especially those living with certain non-communicable diseases such as cardiovascular disease, diabetes, and obesity. Even among those with excellent HIV control, older adults with HIV may have a greater prevalence of non-communicable comorbidities that compound their risk for severe COVID-19 and death. Multiple cohorts have demonstrated a significant excess mortality from COVID-19 for people living with HIV.[268,269]

The rollout of MMD and decentralized drug delivery for ART has improved longer-term ART adherence and HIV viral suppression. However, the treatment of many NCDs lags behind. NCDs often require regular blood work, visits, and prescriptions that may not be as accessible due to lack of decentralization or task-shifting. Recognizing the long-term benefits of pairing treatment of HIV and NCDs, and in accordance with national guidelines and supported by ministries of health, person-centered care for older adults should make HIV services and all other recommended screenings and treatment available through an integrated health care model. ART and other needed chronic medications should be provided in a fast track or other client-friendly manner consistent with the model of care in which they are receiving their ART.

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[268] Barbera, L. K., Kamis, K. F., Rowan, S. E., Davis, A. J., Shehata, S., Carlson, J. J., Johnson, S. C., & Erlandson, K. M. (2021). HIV and COVID-19: review of clinical course and outcomes. *HIV research & clinical practice*, 1–17. Advance online publication. https://doi.org/10.1080/25787489.2021.1975608

[269] African COVID-19 Critical Care Outcomes Study (ACCCOS) Investigators (2021). Patient care and clinical outcomes for patients with COVID-19 infection admitted to African high-care or intensive care units (ACCCOS): a multicentre, prospective, observational cohort study. *Lancet (London, England)*, *397*(10288), 1885–1894. https://doi.org/10.1016/S0140-6736(21)00441-4

As programs successfully achieve goals for HIV care and viral suppression, person-centered care must address "living well with HIV". This refers to ability of people living with HIV to have both normal life span (years of life) and health span (years in good health, without disease). Many age-related comorbidities such as cardiometabolic, pulmonary, and liver diseases, cancer, and geriatric conditions (frailty, cognitive impairment) occur both at a greater prevalence and an earlier than anticipated age among people living with HIV, as a direct consequence of HIV, ART, and many sociodemographic and lifestyle factors. PEPFAR recognizes the needs of this population and is evaluating the programmatic data that will allow for appropriate support to maximize both the lifespan and the years of healthy life ('health span') of this vulnerable population.

## 6.4.3 TB/HIV

Summary of section edits:

- Reference to Xpert MTB/RIF Ultra and Truenat MTB Plus with MTB Rif Dx as the currently available mWRDs is outdated and inconsistent with WHO policy. Several other multi-disease testing mWRDs are now available. Wording was updated to reflect these points.

Globally, TB has been the leading cause of death from a single infectious disease. In the wake of COVID-19 pandemic, a shortfall in TB case detection due to the disruptions in access to TB care was observed in 2020 and could result in an excess half a million TB deaths according to a 2020 WHO modelling.[270] TB notifications fell by 18% between 2019 and 2020, from 7.1 million to 5.8 million and number of TB related deaths increased to 1.5 million; an increase of 100,000 deaths which is first time TB deaths have increased in the last ten years. TB remains the most common cause of death among people living with HIV, responsible for an estimated 215,000 deaths in 2020—approximately one-third of all HIV-related deaths.

Implementation of the package of evidence-based TB/HIV interventions is a crucial and high-impact priority for PEPFAR programming. PEPFAR country teams should look for potential synergies and alignment among TB, HIV, and COVID-19 interventions that improve people-

[270] https://www.who.int/publications/m/item/impact-of-the-covid-19-pandemic-on-tb-detection-and-mortality-in-2020

centered care and safety. The PEPFAR TB/HIV strategy is based on three key objectives and designed to reduce morbidity and mortality among all people living with HIV, and is in alignment with the recently adopted UNGA targets for reduction of overall HIV related mortality:[271]

1. **Intensified TB case-finding among all People Living with HIV**
   - *All people living with HIV must be screened at every clinical encounter for TB symptoms.* The new 2021 WHO recommendations on TB screening include symptom screening at each encounter, and given the sub-optimal sensitivity of symptom screening, consideration of adding Chest X-Ray (CXR), C-reactive Protein (CRP), or a molecular WHO-recommended Rapid Diagnostic (mWRD) test to the screening algorithm for PLHIV new or re-engaging in care, and once a year thereafter, depending on local circumstances.[272] WHO-approved rapid diagnostic tests used for screening shorten turnaround time for TB treatment or TPT initiation. If not already done, PEPFAR country teams are encouraged to assess screening performance and evaluate the feasibility of amending their current TB screening algorithms and revise algorithms to maximize screening yield in accordance with updated WHO screening guidelines.
   - TB screening for all age groups, with linkage to prevention services or diagnostic evaluation, should also be conducted within all PEPFAR-supported community settings (e.g., ANC, OVC, KP services, etc.) and in differentiated service delivery models.
   - Linkage to TB testing services should be ensured for those that screen positive in community and/or household settings away from health facilities.
   - All confirmed and presumptive TB patients should be tested for HIV and linked to rapid ART for those who test positive.
2. **Optimized TB/HIV care and treatment**
   - All people living with HIV that screen positive for TB should be referred promptly for clinical evaluation and have quality specimens collected for diagnostic testing, with a mWRD test. Of note, mWRDs are now available from multiple manufacturers (i.e., Cepheid, Molbio, Abbott, Roche, Bruker/Hain, BD, etc.). Program selection or use of mWRD(s) should be done in coordination with government HIV and TB programs; be guided by national, subnational, and site-level factors (see the UN Stop TB Partnership

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[271] https://www.unaids.org/en/resources/documents/2021/2021_political-declaration-on-hiv-and-aids
[272] World Health Organization (WHO) consolidated guidelines on tuberculosis, Module 2: Screening; Systematic screening for tuberculosis disease. 2021. Available at: https://apps.who.int/iris/bitstream/handle/10665/340255/9789240022676-

Global Laboratory Initiative's mWRD Selection Guide); and ensure usage of the most sensitive tests.

- Appropriate TB treatment should be initiated promptly after TB disease diagnosis.
- Completion of TB treatment should be ensured for those who are started through the provision of psychosocial, nutritional, and adherence support.
- Provision of TB/HIV services should be people-centered, and HIV and TB testing, as well as ART and TB treatment need to be optimized and harmonized, including in differentiated service delivery models.

**3. TB Prevention**

- TB preventive treatment (TPT) interventions should be offered to all eligible people living with HIV, including children and adolescents.
- TPT should be integrated into differentiated HIV service delivery models for adults, children, and adolescents.
- All eligible children and adults who are household contacts of people living with HIV and TB disease should be screened for TB disease and provided with TPT.
- Infection Prevention and Control measures should be implemented at all facilities and community settings, including TB screening, testing and treatment (preventive or curative, accordingly) for healthcare workers.
- TB prevention Quality Assurance (QA) and Quality Improvement (CQI) should be implemented across all TB/HIV services at health facilities and in communities.

## 6.4.3.1 TB Case-Finding Among People Living with HIV

Summary of section edits:

Wording was added to clarify that:

- C-Reactive Protein (CRP) blood testing can be done as a point-of-care test or at higher levels of the laboratory network (e.g., centralized laboratory).
- WHO recommends rapid molecular diagnostic tests (mWRDs) universally for people living with HIV new or re-engaging in care.
- Abnormal chest radiography, including by computer-aided detection (CAD) software, can be regarded as a positive TB clinical screening result.
- All people living with HIV who test positive for resistance to rifampicin should be linked to molecular or phenotypic screening methods.

It is essential to detect and treat TB promptly, and to prevent TB morbidity and mortality among people living with HIV, including among children living with HIV, who can progress rapidly to severe TB disease. Regular and high-quality TB screening, followed by prompt diagnostic testing and treatment for TB for people who screened positive, or treatment with TPT if screened negative and otherwise eligible for TPT, are life-saving programmatic interventions. TB screening should be conducted for all people living with HIV at every encounter, with special emphasis for people new to or re-engaging in HIV care, whether they are presenting at a facility, are enrolled in a differentiated service delivery model of care, being seen in the community, or being assessed remotely via innovative digital platforms, by phone, or SMS. In settings with high rates of TB and HIV transmission such as prisons, TB screening should be performed for prisoners who are HIV positive at entry, annually, and at exit.

Four-symptom TB screening has consistently shown suboptimal yield due to low sensitivity of the screening tool, inconsistency of screening, and poor documentation of and follow through on the screening results. In addition, symptom screening misses asymptomatic TB or TB among people presenting with non-specific respiratory symptoms. Following the March 2021 release of the new WHO Guidelines on TB screening, PEPFAR country teams are encouraged to work with national HIV and TB program leadership to determine what can be done to update the screening algorithm to improve on current performance. The new WHO guidelines recommend four approaches for TB screening to improve TB case finding:

1. Symptom-based screening, wherein the client is assessed for symptoms regardless of duration (W4SS: fever, cough, night sweats, or weight loss). This is recommended for all people living with HIV regardless of age at every encounter.
2. Abnormal chest radiography, including by computer-aided detection (CAD) software, can be regarded as a positive clinical screening result.
3. Molecular WHO-recommended rapid diagnostic tests (mWRDs) universally for people living with HIV new or re-engaging in care, those who screen positive, and where feasible, regularly at some interval thereafter.
4. C-Reactive Protein (CRP) blood testing, a low-cost, point-of care test for inflammation, which can be used as a proxy for active TB infection in ART-naïve patients, and for which relatively low-cost and centralized, as well as decentralized (near-POC and POC) options are available.

WHO recommendations should be used as country teams assess relevant data and update screening algorithms to address gaps in quality, coverage, or performance of current TB screening efforts.

Countries should position the W4SS, CRP, CXR and mWRD in combination with diagnostic evaluation using mWRDs and LF-LAM within national TB screening and diagnostic algorithms according to their feasibility, the level of the health facility, resources, and equity. Algorithms exploring the available *WHO Consolidated Guidelines on Tuberculosis: Systematic Screening for Tuberculosis* Disease screening tools are presented in the *WHO operational handbook*, including modelled performance of accuracy and yield.[273] While all of the screening tools presented are recommended for all people living with HIV for ease of programming, evidence showed notable accuracy of CRP for TB screening in people not yet receiving ART and that CXR enhanced the sensitivity of the W4SS among people receiving ART, both of which should be considered when choosing algorithms.

Programs need to ensure that there are no user fees associated with TB screening, diagnosis, or treatment, including molecular diagnostic testing, services for sample collection, and chest X-rays, if they are part of the national algorithm.

TB and COVID-19 symptoms may overlap, and patients may be co-infected. Therefore, it's critical that integrated TB and COVID-19 symptom screening algorithms and IPC procedures be implemented at all PEPFAR supported facilities and other sites. COVID-19 and TB screening algorithms and evaluation pathways should be bi-directional. This implies that people living with HIV should be routinely evaluated for TB and COVID-19 symptoms, even if they are being seen in the community. Those who are screened for COVID-19 should be screened for TB, and those being screened for TB should be screened for COVID-19. To achieve this, in high TB prevalence areas, programs may consider training and installing a designated community health worker responsible for ensuring systematic symptom screening, appropriate triage of patients presenting with respiratory symptoms, and airborne IPC practices.

The proportion of people living with HIV expected to screen positive for TB varies widely by the country's TB epidemiology and clinical characteristics (like average CD4 cell count), but as a general rule, countries should anticipate that at least 15% of newly enrolling, ART-naive patients and approximately 5% of previously enrolled patients would screen positive for TB symptoms. Where

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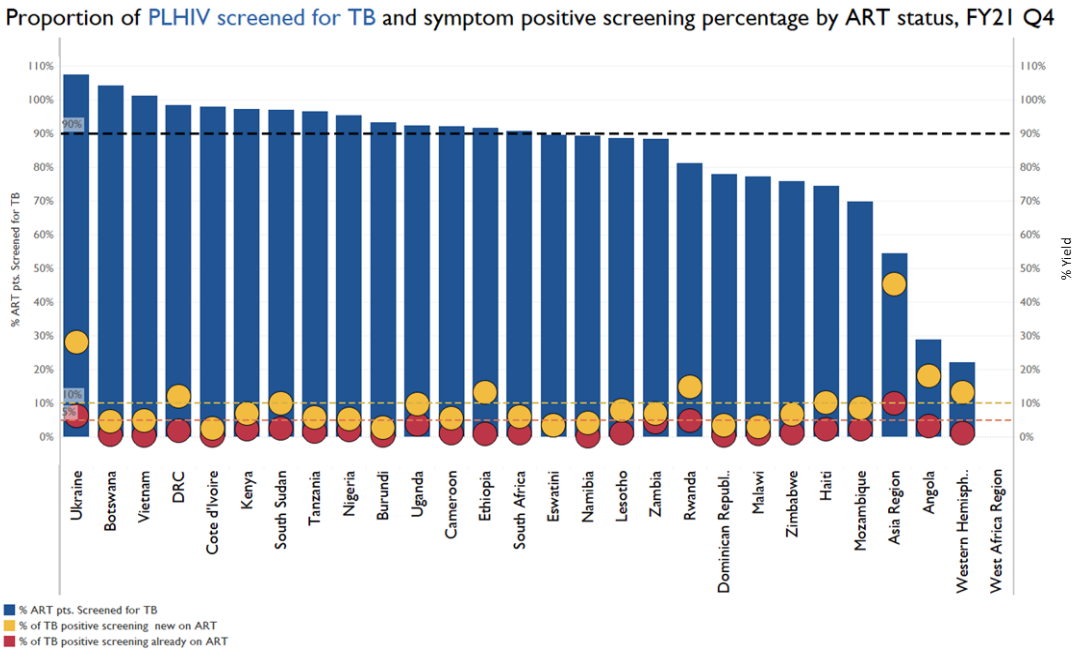
[273] https://www.who.int/publications/i/item/9789240022614

possible, programs should triangulate screening data with local TB prevalence surveys and ART coverage rates to ensure that screening is being done with fidelity. Screening yields that are well below expectations should prompt investigation for screening quality and evaluation of the screening and disease evaluation algorithms. A recent retrospective study in Kenya demonstrated that TB symptom screening was done poorly and resulted in missed opportunities to prevent TB morbidity and mortality.[274] PEPFAR data at FY2021 Q4 are consistent with these findings (see Figure 6.4.3.1.1) which shows Screening Yield for TB by ART status in FY2021 Q4 (PEPFAR programs). The screening yield for TB among PLHIV newly enrolled in care was < 10% for 17 countries, while only four OUs had a yield above 15% (range 3-45%). The screening yield for TB among PLHIV already on ART ranged from 0.1% (suggesting poor screening quality) to 10%.

Another study in Tanzania demonstrated that while there was high yield of TB symptom screening among people living with HIV presenting to clinics, more than 30% of those who screened positive for TB symptoms did not receive further evaluation, suggesting that programs need to improve linkage to diagnostic testing and ensure rigorous implementation and quality assurance along the full TB cascade.[275] A study in Ghana showed that the implementation of a simple audit tool and data feedback to providers resulted in the improvement of screening practices at ART clinics.[276]

*Figure 6.4.3.1.1: Screening Yield for TB by ART status in FY21 Q4 (PEPFAR programs)*

[274] Owiti P, Onyango D, Momanyi R, Harries AD. Screening and testing for tuberculosis among the HIV-infected: outcomes from a large HIV programme in western Kenya. BMC Public Health (2019): 19:29.
[275] Maokola W, Ngowi B, Lawson L, Mahande M, Todd J, Msuya SE. Performance of and Factors Associated with Tuberculosis Screening and Diagnosis Among People Living with HIV: Analysis of 2012-2016 Routine HIV Data in Tanzania. Front. Public Health. 06 Feb 2020.
[276] Bjerrum S., et al. TB screening in patients with HIV: use of audit and feedback to improve quality of care in Ghana; Glob Health Action 2016




**Special considerations for TB screening, testing and diagnosis for infants and children**

Active TB is among the top ten killers of children less than 5 years, however, there are specific challenges related to TB screening and diagnosis among children, especially young children.[277] It is imperative that programs ensure that there is specific training and considerations for TB diagnosis among children living with HIV. National TB, HIV and TB/HIV guidelines should specifically address TB screening, diagnosis, treatment and TPT for these children.

It is critical that children living with HIV, including those enrolled in programs for orphans and vulnerable children (OVC), are screened for TB symptoms at each clinical and community visit/encounter. Programs should consider expanding TB symptoms screening and linkage to care to health entry points more commonly used by children, such as maternal and child health (MCH), OVC, and nutrition clinics. Programs should also ensure that children who are household contacts of a person living with HIV who is diagnosed with TB are screened and evaluated for TB and treated for TB or provided with TPT if TB is ruled out.

Children generally are more likely to present with extrapulmonary TB which can make diagnosis more challenging and emphasizes the importance of a high index of clinical suspicion. There is limited data

[277] The Pneumonia Etiology Research for Child Health (PERCH) Study Group. Causes of severe pneumonia requiring hospital admission in children without HIV infection from Africa and Asia: the PERCH multi-cohort control study. Lancet 2019; 394 (10200): p.757-779.

on the best screening tools for TB among children, who can present with more subtle or vague symptoms than adults. Clinicians and programs should, therefore, maintain a low threshold to make a clinical diagnosis of TB disease in children, as TB diagnostic testing is commonly negative in children even when they have active TB disease.

A recent review of TB symptom screening among children and adolescents in several high burden TB/HIV countries found that this screening tool was specific (88.8%) but not very sensitive for diagnosing TB (61.2%) highlighting the need for more accurate and sensitive screening approaches for identifying TB disease among children living with HIV.[278] Furthermore, there is evidence that the symptom screen has even lower sensitivity (51%) for detecting TB disease among children on ART.[279] Despite the limitations of these tools, these studies highlight the critical importance of consistent child-specific screening tools and strategies, TB contact investigations, and a high index of clinical suspicion to ensure that children living with HIV who have active TB are diagnosed and placed on treatment promptly. All children living with HIV positive for any of these symptoms during routine screening or who have a history of contact with a TB patient should be evaluated for active TB disease immediately. If TB disease is excluded after an appropriate clinical evaluation or according to national guidelines, these children should be offered TPT, regardless of their age.

**TB diagnosis among children living with HIV or OVC service participants**

Special considerations are needed to improve TB diagnosis for children, including evaluation for extrapulmonary TB, and child-friendly specimen collection and processing. Young children are generally unable to produce quality sputum specimens and may have paucibacillary or extrapulmonary disease which can undermine the utility and performance of available laboratory tests for TB diagnosis. Therefore, clinical diagnosis continues to play an important role in the management of childhood TB. Physical examination, clinical history, contact history, radiography, response to treatment, and other assessments together can lead to a confident, empirical diagnosis of TB in young children and should be paired with available laboratory diagnostic testing to support and confirm a TB diagnosis where feasible.

Specific training to empower health care workers to make a clinical diagnosis of TB in children should be considered in PEPFAR supported programs. In addition to clinical diagnosis, implementation of

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[278] Vonasek B, Kay A, Devezin T, et al. Tuberculosis symptom screening for children and adolescents living with HIV in six high HIV/TB burden countries in Africa. AIDS 2020; pre-print. doi: 10.1097/QAD.0000000000002715

[279] Sawry S, Moultrie H, Van Rie A. Evaluation of the intensified tuberculosis case finding guidelines for children living with HIV. Int J Tuberc Lung Dis. 2018 Nov 1;22(11):1322-1328. doi: 10.5588/ijtld.17.0825. PMID: 30355412.

procedures for collection of alternative sample types (i.e., gastric aspirates, nasopharyngeal aspirates, stool) and extrapulmonary TB specimens for molecular diagnostic testing should be supported according to WHO guidance.[280] In addition, urine should be collected for LF-LAM testing, which should be routinely available for diagnostic testing of children presenting with TB symptoms.[281] Where appropriate, programs should ensure mWRDs testing for children is done using both sputum and non-sputum specimen types (including stool) according to the WHO policy guidance for each test type.[282] Reagents and supplies required for testing of non-sputum specimens should be treated as essential commodities and budgeted accordingly. Should standardized stool processing solutions become available and recommended for use, they should be prioritized for procurement in settings conducting stool testing. Procurement quantities should at minimum match the number of eligible children who present to care with TB symptoms. Laboratory technicians should be trained to handle and process stool specimen for TB diagnosis. SOPs for laboratory procedures and standardized training materials should be available at country level. Monitoring and quality assurance activities will help to reinforce stool-based pediatric TB diagnosis and rollout this activity in all TB diagnostic sites.

**Index Testing and TB Contact Investigation have high yields for HIV and active TB**

Tracing and screening contacts of people living with HIV who have TB disease can be effective for HIV and TB case-finding. A recent PEPFAR study in Mozambique further emphasized the role of TB contact investigation in the community as an effective and high yield strategy for HIV case finding in countries or geographies with high TB and HIV prevalence.[283]

In order to expand TB case-finding, partners should work with National HIV and TB Programs to develop the capacity to conduct routine contact investigations for all persons living with HIV who are found to have TB disease and community-based, patient-centered approaches should be prioritized. All contacts of persons living with HIV with active TB should be screened for TB and sexual partners and biological children should be tested for HIV. Contacts with TB symptoms or positive screening tests should be immediately referred for clinical evaluation and specimen

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[280] WHO, Rapid communication on updated guidance on the management of tuberculosis in children and adolescents. Available at: https://www.who.int/publications/i/item/9789240033450

[281] Kay A, Garcia-Prats, AJ, Mandalakas, AM. HIV-associated pediatric tuberculosis prevention, diagnosis and treatment. Current Opinion in HIV and AIDS. November 2018. Vol 13(6): 501-506.

[282] https://www.who.int/publications/i/item/9789240029415

[283] Kerndt et al. TB contact investigations as an active HIV case finding strategy in Mozambique: Lessons for high TB and HIV syndemic countries. IAS OAB0507

collection for TB diagnostic testing with a mWRD test. All contacts who screen negative should be offered TPT, if they have no other contraindication.

There is an opportunity to utilize existing network and infrastructure used for index testing to incorporate TB contact investigation and screening among household contacts (HHC) of people living with HIV with TB disease. This will not only improve TB and HIV case finding and appropriate treatment for TB or HIV among HHC of TB and HIV clients but will also facilitate TPT provision among HHC with active TB disease ruled out. PEPFAR programs should coordinate closely with National TB Programs (NTPs), as in most countries NTPs are in the lead on contact investigations, to ensure effective collaboration and avoid duplication on efforts and waste of precious program resources.

**Testing for TB should be done with sensitive and specific laboratory diagnostic tools**

A holistic network assessment approach should be used by programs, in collaboration with NTPs, to ensure that the instruments/ tests that are selected meet their specific patient demand/ needs and build upon their current infrastructure, lab systems, and geographic variability.

TB specimen collection should adhere to national guidelines. Individuals should be provided with materials and instructions for sample self-collection in an outdoor or well-ventilated space. All persons living with HIV with TB symptoms should be referred promptly for clinical evaluation and have quality specimens collected for initial testing with a mWRD test capable of producing a drug-susceptibility result for rifampicin. In 2021, WHO updated its guidelines and associated Operational Manual for TB Diagnosis, expanding the list of WHO-recommended mWRD nucleic acid amplification tests (NAATs) from Xpert MTB/RIF Ultra and Truenat MTB Plus and the reflexed MTB-Rif Dx to include those NAATs of low complexity (e.g., LC_NAAT, Xpert MTB/XDR, moderate complexity (MC-NAAT, Abbott m2000 RealTime MTB and MTB-RIF/INH, BD MAX MDR TB, Roche cobas MTB and MTB-RIF/INH, Bruker-Hain FluoroType MTB and MTB-DR), and high complexity (HC-NAAT).[284]

The list of newly endorsed NAATs includes instruments used by PEPFAR for HIV viral load and/ or early infant diagnosis testing (e.g., Abbott m2000 and Roche cobas 6800/8800 systems), highlighting an opportunity for multi-disease testing services for persons living with HIV that screen positive for TB, access care within the centralized testing network capture area and

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[284] WHO Consolidated Guidelines on TB, Module 3. Diagnosis July 2021. Available at: https://www.who.int/publications/i/item/9789240029415

would receive TB diagnostic test results according to recommended turnaround times. Multi-disease testing strategies will be most effective when coordinated with MOH, National HIV and TB programs, and should be guided by stakeholder engagement and designed in alignment with national disease and laboratory strategic plans. The selection of mWRDs tests should be guided by national and subnational epidemiology, the capacity and gaps within the current testing network, testing site infrastructure and biosafety, and other practical factors needed to support quality test implementation and service provision. An mWRD selection guide is under development by the Stop TB Partnership Global Laboratory Initiative that may be used, if available, to facilitate mWRD selection during COP planning.

All persons living with HIV that test positive for resistance to rifampicin should be linked to WHO-recommended follow-on molecular or phenotypic testing tests for detection of resistance to Isoniazid (INH), fluoroquinolones, and other second-line anti-TB medicines, including bedaquiline—where used for shorter, oral, regimens. These follow-on tests may be done by leveraging multi-disease platforms, if feasible and beneficial in the context of the national TB testing network. TB culture and drug susceptibility testing services remain essential for the detection of resistance to drugs with no available molecular test and for TB treatment monitoring to ensure the full spectrum of drug resistance is quickly identified, the most effective TB treatment regimen is provided, the efficacy of the regimen is determined, and TB cure can be defined. Sputum smear microscopy for acid-fast bacilli (AFB) is known to have unacceptably low sensitivity regardless of HIV status and should not be used as the initial diagnostic test. In areas where low or no access to approved mWRD testing exists, smear microscopy may be used as a last resort. These areas/sites should be urgently prioritized for support through diagnostic network expansion and/or improved linkage to existing testing services through enhanced specimen referral networks. The goal should be to replace microscopy and use mWRD tests as the preferred method for diagnostic evaluation for people living with HIV who have presumptive TB.

In addition, PEPFAR IPs should procure and utilize the urine LF-LAM assay as a rapid point-of-care diagnostic test according to national guidelines and in line with WHO recommendations. By contributing to early detection and treatment of tuberculosis, for PLHIV with advanced HIV disease, the LF-LAM assay is the only TB diagnostic test currently available that has demonstrated a mortality reduction for persons living with HIV in a randomized controlled trial. The current WHO guidance (2019) on use of LF-LAM recommends LF-LAM for both in-patient

and outpatient diagnosis of TB among people living with HIV.[285] LF-LAM is not intended to replace initial mWRD tests however, and it should be used in combination with these molecular diagnostic tests, for adults, adolescents, and children living with HIV. A positive LF-LAM result is considered as bacteriological confirmation of TB in a person living with HIV, and TB treatment should be initiated immediately while waiting for confirmatory molecular test results per national guidelines. The recommendations for use of LF-LAM are differentiated based on whether a client is presenting to an inpatient or outpatient setting, and are outlined below:

**In inpatient settings, use LF-LAM in the following clinical scenarios:**

- All hospitalized PLHIV/CLHIV with CD4 cell count <200, regardless of signs and symptoms of TB; including children with advanced disease
- Any PLHIV (adult, adolescent, child) presenting with signs and symptoms of pulmonary and/or extrapulmonary TB, regardless of CD4 count
- Adult or Adolescent PLHIV who are seriously ill (defined as ANY of the following symptoms: respiratory rate of ≥30/minute, temperature ≥39 °C, heart rate ≥120/minute, or unable to walk unaided), or have clinically staged advanced disease regardless of CD4 count
- Children with HIV who are seriously ill (defined as having any of the following: temperature ≥ 39 °C, age-defined tachycardia, age-defined tachypnea, lethargy, or unconsciousness; convulsions; unable to drink or breastfeed; or repeated vomiting)

**In outpatient settings, use LF-LAM in the following clinical scenarios:**

- Adults, adolescents, or children with HIV presenting with signs or symptoms of pulmonary and/or extrapulmonary TB
- Adults, adolescents, or children with HIV presenting with serious illness (per above definitions)
- Adults, adolescents, or children with HIV and CD4 count <200, regardless of signs and symptoms of TB. PEPFAR recommends urine LF-LAM testing for anyone with CD4 below 200 cells/mm$^3$ given the relative ease of making this distinction with the Visitect assay.

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[285] Lateral flow urine lipoarabinomannan assay (LF-LAM) for the diagnosis of active tuberculosis in people living with HIV. Policy update 2019. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.1 IGO Available at: https://www.who.int/tb/publications/2019/LAMPolicyUpdate2019/en/

In both inpatient and outpatient settings, it is important to note that LF-LAM is used exclusively as a "rule-in" test. A negative test does NOT rule out TB and providers should all be diligently informed of this and trained to proceed with treatment for TB based on clinical suspicion, local epidemiology, and results from other mWRD tests.

OU teams should make urine LF-LAM tests available in all in-patient settings that admit PLHIV with advanced disease as well as outpatient settings where PLHIV are evaluated for TB symptoms or may present with advanced HIV disease. If clinical suspicion is high, treatment for TB can be initiated, regardless of a negative urine LF-LAM or rapid molecular diagnostic test result per national guidelines.

PEPFAR implementing partners should collaborate with MOHs and other stakeholders to ensure policies, algorithms, standard operating procedures, laboratory and clinical training materials, and quality assurance programs are developed, disseminated, and implemented to support quality-assured LF-LAM testing, as indicated in the Stop TB Partnership Practical Guide on LF-LAM Testing (Initiative, 2020). Roll-out of trainings, including assessment of user competency, on use of LF-LAM for facility personnel should be conducted in coordination with national TB programs and national TB reference laboratories. They should also ensure adequate forecasting and procurement for quantities of LF-LAM commensurate to their needs based on the number of PLHIV, including CLHIV, who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings. The WHO SPI-POCT checklist and CDC HIV RT-CQI program may be adapted for use with LF-LAM as a point-of-care (POC) rapid test.[286] Future LF- LAM assays are likely to require the same testing network support and coordination as the existing test, such that their early establishment should ease introduction of any future lateral-flow based POC TB tests.

Delays in TB diagnostic workup and therefore TB treatment and ART initiation result in significant morbidity and mortality; countries should prioritize implementation and increased access to LF-LAM, mWRD tests, and optimization of specimen transport systems for required TB culture and drug susceptibility testing services and results reporting processes.

**Testing for HIV among individuals with presumptive TB has high yield for HIV**

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[286] WHO Handbook. Improving the quality of HIV-related point of care testing: Ensuring the reliability and accuracy of test results. December 2015 .
https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf?sequence=1

While HIV testing coverage among persons with confirmed TB is generally >90%, with very high testing yields, there remains a large gap in identifying and testing persons with TB symptoms (i.e., "TB presumptive"). Most countries are currently facing gaps in diagnosing and/or reporting of all individuals with TB disease, and this has been particularly exacerbated by the decline in health facility visits in the setting of COVID-19 and may result in significant increases in TB transmission and disease. Given high rates of HIV infection in this population, identification of persons with TB symptoms is a priority for HIV case finding efforts. Therefore, HIV testing should be offered to all patients presenting with TB symptoms even before confirmation of TB disease. HIV testing among TB presumptive patients is also among the highest yield modalities across all OUs.

### 6.4.3.2 Optimizing Treatment for People with TB and HIV

Summary of section edits:

- Wording was added to reflect that in areas with high HIV and TB coinfection, HIV and TB screening, prevention, and care, should be fully integrated with one another.
- A recommendation for TB treatment optimization for C/ALHIV was added.

PEPFAR teams should ensure that all TB patients are tested for HIV, and that all TB patients with HIV are rapidly started on both appropriate TB treatment and ART. Initiation of TB treatment should not delay ART start. (See Section 6.4.2 Identification and Treatment of Advanced Disease). The updated WHO guidelines (March 2021) recommend initiating ART as soon as possible within two weeks of initiating TB treatment, regardless of CD4 count, among persons newly diagnosed with HIV.[287]

Whenever possible, patients should be treated in the same clinic for both TB and HIV (one-stop shop) to minimize the time spent in accessing and receiving care, whether at the health facility or in community settings, to optimize their treatment regimens and minimize potential for drug-drug interactions, streamline monitoring, and avoid confusion for both patients and providers. The need to design and implement TB and HIV innovative service delivery models to bring prevention and care services close to where populations live is crucial. The "One-Stop Shop" service delivery

[287] WHO Guidelines. HIV Prevention, Infant Diagnosis, Antiretroviral Initiation and Monitoring. March 2021. https://www.who.int/publications/i/item/9789240022232

model for TB and HIV should be implemented as much as possible to ensure continuity of quality TB and HIV services for better impact and outcomes.

In settings with high rates of TB and HIV co-infection, patients engaging the healthcare system in any and all settings should be offered combined screening for TB and HIV, and timely linkage to care and treatment, as well as preventive services such as TPT and PrEP for all priority populations (i.e., PMTCT/MCH, OVC and Key Populations programs). TB screening, treatment, and TPT should also be integrated into all available differentiated service delivery models as part of the basic service package being offered to PLHIV on ART. To ensure continuity of TB preventive and treatment services in the context of COVID-19, many countries moved into implementation of multi-month dispensing (MMD) for TPT and TB treatment aligned with ART MMD plans. Country programs should be supported to integrate and sustain such proven innovative and efficient approaches in service provision.

Most commonly, PLHIV with TB are treated in the TB clinics for the duration of TB treatment, after which they are transferred back to the HIV clinic for ongoing care, but programs can adopt whichever protocol best suits their environment.[288] Adherence support should impose no additional burden on patients, and monitoring of adherence to treatment should be conducted at the patient's convenience – either in the home by family, peers or community workers, or by remote telephonic or video communication.[289,290] As above, teams should also ensure access to both HIV and TB diagnostic testing at current HIV service sites for all household contacts of PLHIV with active TB. It is important to remember that the undiagnosed person with TB presents the greatest risk for transmission; once effective treatment is initiated, patients become non-infectious within days. Therefore, effective TB screening and diagnosis, together with prompt treatment, are critical for preventing transmission.

Please see Section 6.4.3.3 below for examples of differentiated service delivery models that integrate HIV care and TPT.

**Optimizing Treatment adherence**

Appropriate care of individuals with TB and HIV aims to support adherence by minimizing the burden placed on the patient. Adherence support may include addressing barriers to treatment

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[288] https://www.pepfarsolutions.org/solutions/2019/1/4/tb-hiv-collaborative-activities

[289] Subbaraman R, de Mondesert L, Musiimenta A, Pai M, Thomas BE, Haberer J. Digital adherence technologies for the management of tuberculosis therapy: mapping the landscape and research priorities. BMJ Glob Health 2018; 3(5): e001018.

[290] https://www.who.int/tb/areas-of-work/digital-health/Digital_health_EndTBstrategy.pdf

adherence through for example, peer or other treatment support, identifying and addressing food insecurity or transportation barriers, using electronic or mobile devices for additional support, and procurement of pediatric-friendly fixed dose combinations for TB disease treatment when available. Close monitoring via community visits or telephone or digital consultation during the intensive phase of TB treatment is especially critical and should focus on screening for signs of deterioration that would warrant a visit to a healthcare facility and on counseling regarding medication adherence.

There is a need to implement adherence counselling sessions for children and adolescents based on their specific needs. The aim for these sessions would be to explore barriers to adherence in these populations and identify strategies to improve sustained engagement in care, to explain viral load results (i.e., un/detectable viral load, suspicion of treatment failure, etc.), to assess patient competency on ART, TB treatment or TPT, and to screen for depression and addictions. These adherence and psychological support sessions will help patients to be involved in their own treatment strategies for better outcomes.

Furthermore, optimizing treatment for C/ALHIV with the shorter treatment regimen (4HRZE) for non-severe disease based on clinician's judgment of predictors of treatment success such as degree of immunosuppression, drug interactions, co-morbidities is recommended.

**TLD Transition**

As countries transition patients from efavirenz-based regimens to TLD, it is important to note that patients with TB being treated with rifampin and TLD should receive an extra dose of dolutegravir (DTG) 50mg per day (taken 12 hours apart instead of 24 hours apart) for the duration of their TB treatment course.[291] There is scant information on drug interactions with rifapentine, but with the weekly dosing it is likely that PLHIV on TLD and the shorter TPT regimen 3HP do not need an extra dose of DTG. Please see below and Section 6.4.1 for additional information on drug-drug interactions.

**Patients Ineligible for TLD transition**

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[291] Kelly E Dooley, Richard Kaplan, Noluthando Mwelase, Beatriz Grinsztejn, Eduardo Ticona, Marcus Lacerda, Omar Sued, Elena Belonosova, Mounir Ait-Khaled, Konstantinos Angelis, Dannae Brown, Rajendra Singh, Christine L Talarico, Allan R Tenorio, Michael R Keegan, Michael Aboud, Dolutegravir-based Antiretroviral Therapy for Patients Coinfected With Tuberculosis and Human Immunodeficiency Virus: A Multicenter, Noncomparative, Open-label, Randomized Trial, Clinical Infectious Diseases, ciz256, https://doi.org/10.1093/cid/ciz256

Although the numbers of patients determined to be ineligible for transition to TLD is anticipated to be minimal, PEPFAR recommends the use of Tenofovir DF/lamivudine/efavirenz (TLE) 300/300/400mg over TLE 300/300/600mg due to its equivalent efficacy, increased tolerability by patients and its competitive cost. Data are extremely limited on the use of TLE400 in TB patients who are receiving treatment with rifampin-containing regimens (i.e., first-line TB treatment that includes rifampin, along with isoniazid, pyrazinamide, and ethambutol). WHO currently endorses the coadministration of EFV400 and RIF; however, larger studies of PLHIV with TB disease who are on TLE400 are needed.

**Drug-Drug interactions**

Several drug-drug interactions are important when treating TB. RIF is a potent inducer of the CYP 450 system. RIF drug interactions have been known for 25 years, and include opioid agonists, contraceptives, and anticoagulants among many other drugs. When initiating TB treatment, it is important to take a patient's full medication history including the use of herbal preparations and make necessary dosing adjustment based on known drug interactions. Please see Section 6.4.1 for further discussion and a table of drug interactions with contraceptive agents.

These websites are helpful in identifying potential drug interactions https://www.hiv-druginteractions.org/checker; http://hivinsite.ucsf.edu/interactions.

## 6.4.3.3 TB Prevention

TB preventive treatment (TPT) has benefits not only for individuals but has been demonstrated to decrease TB infection rates at a population level. TPT can reduce incident TB among PLHIV, including CLHIV, by up to 89% when combined with ART and has been shown to independently reduce mortality. Therefore, completion of TPT for all PLHIV (including eligible household contacts of PLHIV with TB disease) is PEPFAR Minimum Program Requirement. Broader awareness will reduce stigma and discrimination around TB/HIV, increase knowledge about benefits of TPT among health workers and patients, and support demand for services. This can be done by engaging and educating providers, health worker organizations, and civil society organizations including former TB patients, and organizing social marketing campaigns.

PEPFAR has committed to reach and/or maintain full TPT coverage and targets. All PEPFAR-supported care and treatment programs should be implementing TPT at scale with clear timelines to

100% coverage. Countries will need to implement TB "catch-up" plans in order to achieve full TPT coverage in a timely way.

In order to facilitate rapid TPT scale-up, partners and facilities should ensure that clear policies and/or guidelines for the use of TPT are in place, including integration with differentiated service delivery models, and that they have adequate budget and plans for training, patient literacy/education, procurement and supply management, adequate diagnostic capacity (including specimen transportation and laboratory results reporting), and appropriate data collection and data alignment systems. In Global Fund high-impact countries implementing joint TB/HIV grants, PEPFAR teams should also seek opportunities to support effective joint program implementation to ensure rapid scale-up without duplication.

An efficient and effective TPT implementation progress monitoring system (i.e., initiation and adherence, TPT outcomes, including adverse events) should also be established to ensure continuous program quality improvement. Programs should assess and track on an individual level as well as across their OU, who has completed a course of TPT, and if possible, which TPT regimen they received. An assessment of cumulative TPT coverage and gaps should inform a clear surge or mop-up plan with clear targets. Country teams are encouraged to monitor in real time TPT initiation and completion to ensure OUs are on track to achieve results and close identified gaps.

**TPT Regimens**

Previously, the preferred treatment regimen was 6 (6H) or 9 months of isoniazid (9H); however, new shorter regimens now exist. In March, 2020, the WHO released consolidated updated guidance on tuberculosis preventive treatment (Module1: Prevention) and endorsed the use of four shorter regimens: 1) Three months of weekly high-dose isoniazid and rifapentine (3HP); 2) One month of daily rifapentine plus isoniazid (1HP); 3) Three months of daily isoniazid and rifampicin (3HR); and 4) Four months of daily rifampicin (4R).[292] All PEPFAR-supported care and treatment programs should be fully engaged in achieving TPT coverage goals using rifapentine-based regimens. Presently, 3HP is the preferred PEPFAR regimen for TPT for adults and adolescents. There is evidence from the Weekly High dose Isoniazid and Rifapentine (P) Periodic Prophylaxis (WHIP3TB) study that patients on 3HP have higher treatment completion rates and

[292] https://www.who.int/publications/i/item/9789240001503

less treatment interruption due to adverse events.[293] PEPFAR recognizes that supply of rifapentine has been limited due to manufacturing disruptions related to COVID-19, delays in External Review Panel (ERP) approval, as well as nitrosamine related alerts requiring additional quality control measures.[294] In August 2021, the MedAccess CHAI-UNITAID-led consortium announced a package of interventions regarding the Macleods rifapentine/INH fixed dose combination (FDC), including a volume guarantee and extension of the $15 per patient course. PEPFAR OU teams should work closely with Ministries of Health and partners to support this effort and ensure communication and collaboration for this roll-out. It is anticipated that supply capacity will improve in FY2022.

Since EFV induction of enzymes responsible for DTG metabolism can last for 2-4 weeks after EFV is discontinued, it is reasonable to wait 2-4 weeks before starting 3HP in patients who are transitioning from EFV to DTG. Based on the results from the SPRING-1 study and pending results from DOLPHIN TOO, it is reasonable to start 3HP and TLD simultaneously in treatment naïve patients.[295] However, this decision is ultimately determined by country policies. PEPFAR OU teams are encouraged to support Ministries of Health in their plans to scale-up those regimens. During the transition of TPT regimens from INH to newer shorter regimens, OUs may continue procurement of INH, FDC formulations of INH, cotrimoxazole, and B6, and alternative TPT regimens using PEPFAR funds.

**TPT for CLHIV**

It is crucial that CLHIV are screened for TB symptoms routinely (See Section 6.4.3.1) and initiated on TPT if active TB disease is ruled out. While TPT is a lifesaving intervention for children with HIV, there are special considerations for children with regards to the choice of regimen (i.e., ARV drug interactions, pill burden, and availability of child friendly TPT formulations). There is extensive evidence that isoniazid (6H or 9H) is well-tolerated in children and adolescents; therefore, it should

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[293] https://www.acpjournals.org/doi/10.7326/m20-7577

[294] FDA. "FDA works to mitigate shortages of rifampin and rifapentine after manufacturers and nitrosamine impurities." October 29, 2020. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamines-rifampin-and-rifapentine

[295] Dooley KE et al. Safety & PK of weekly rifapentine/isoniazid (3HP) in adults with HIV on dolutegravir. CROI 2019. Seattle. 4–7 March 2019. Oral abstract 80LB.

continue to be used as the regimen of choice for children.[296,297,298] Special attention needs to be given to the forecasting of pediatric formulations of INH (INH 100 mg dispersible formulations). Inaccurate forecasting of pediatric formulations of INH will likely result in commodity shortages and consequently in low TPT initiation or completion among children.

Two other regimens have been demonstrated to be non-inferior to 6 to 9 months of INH (6-9H) for TB prevention, including three months daily isoniazid and rifampin (3HR) and three months weekly isoniazid and rifapentine (3HP) (see Figure 6.4.3.3.1 which shows the Comparison of TPT Regimens for CLHIV and drug-drug interactions with ARVs*)*. However, there are known or anticipated drug-drug interactions between rifampin/rifapentine and different ARV regimens for children. Pending results from the DOLPHIN KIDS Study to assess for drug-drug interactions between 3HP and DTG are anticipated in early 2022.

*Figure 6.4.3.3.1: Comparison of TPT Regimens for CLHIV and drug-drug interactions with ARVs*[299]

| | 3HP | 3HR | 6-9H |
|---|---|---|---|
| **Age** | ≧2 years | All children <5 | All children <5 |
| **Efficacy** | Non-inferior to 9H | Likely Equivalent to 6-9H | comparator |
| **Completion Rates** | 88.1% | 89.5%<br>(63-97%) | 80.9% and 65.5%<br>(20-93%) |
| **Hepatotoxicity** | None | None<br>(2-17%) | None<br>(1.2-1.6%) |
| **Adverse Events** | 0.6% (G3 only) | None<br>(2-64%) | 0.2% (G3 only)<br>(1-24%) |
| **Formulation** | Under study | Dispersible tablet | Dispersible tablet |
| **DDI with DTG** | DOLPHIN Kids | Double dose for children ≧ 6 years | None |
| **DDI with EFV** | None | None | None |
| **DDI with LPV/r and NVP** | Anticipated interaction | Known interaction | None |

For HIV-negative child contacts of PLHIV with TB, the current preferred regimen is three months daily regimen of isoniazid and rifampin (3HR) which is available in child-friendly dispersible formula. Four

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[296] Hsu KH. Isoniazid in the prevention and treatment of tuberculosis. A 20-year study of the effectiveness in children. *JAMA*.1974; 229: 528-533

[297] Marais BJ, Van Zyl S, Schaaf HS, et al. Adherence to isoniazid preventive chemotherapy: a prospective community-based study. *Arch Dis Child*. 2006; 91: 762-5

[298] Nolan CM, Goldberg SV, Buskin SE. Hepatotoxicity associated with isoniazid preventive therapy: a 7-year survey from a public health tuberculosis clinic. *JAMA*. 1999; 281: 1014-8

[299] Table courtesy of Dr. Nicole Salazar-Austin as presented during the International Union for TB and Lung Diseases Meeting. "Moving to Shorter Regimens for TB Preventive Treatment in Children: Current and Future Opportunities." October 2020.

months of daily rifampicin may also be considered for HIV-negative contacts pending availability in a child-friendly formulation.

### TPT in Pregnant and Breastfeeding Women

Women with HIV are at high risk of progression from TB infection to disease. It is imperative that PMTCT programs continue to screen for active TB during clinical encounters and ensure linkage to diagnostic testing, treatment, and household screening.[300] If a pregnant or breastfeeding woman living with HIV is diagnosed with TB disease, treatment for TB disease is recommended immediately in accordance with national guidelines. For those without TB disease, there remain uncertainties around the safety, efficacy, and appropriate timing of TPT in pregnant women with HIV. WHO consolidated guidelines still recommend TPT among pregnant women with HIV.[301] The preferred regimens for pregnant women with HIV are six or nine months of daily isoniazid (6H or 9H) with vitamin B6 supplementation. According to WHO consolidated guidelines, there are limited data on the pharmacokinetics and safety of rifapentine in pregnancy; therefore, the use of 1HP or 3HP in pregnancy is not recommended, pending more data on safety. Country programs should consider the benefits and risks of deferring TPT initiation for pregnant women with HIV based on their ARV history, clinical presentation, and documentation of close contact with a person with active TB disease. The IMPAACT 2001 study demonstrated that the dose of rifapentine in a 3HP regimen does not need to be adjusted in pregnant or post-partum women on efavirenz-based ART and generated preliminary data supporting the safety of 3HP in pregnant women.[302] 6H or 9H remain the preferred regimens in pregnant and breastfeeding women with HIV or contacts of TB patients. Pregnant women should be informed and empowered to decide when and whether to initiate TPT; this may include a review of hepatoxicity risks by ARV regimen based on immediate or deferred TPT.

### Additional considerations

Countries that plan to continue with INH-based TPT should plan to use the fixed-dose combination of INH/cotrimoxazole/Vit B6 for patients who weigh >25 kg who will receive cotrimoxazole and a half

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[300] Mathad JS, Gupta A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. Clin Infect Dis. 2012;55:1532–49

[301] https://apps.who.int/iris/bitstream/handle/10665/331170/9789240001503-eng.pdf p4, p22

[302] IMPAACT 2001. CROI https://apps.who.int/iris/bitstream/handle/10665/331170/9789240001503-eng.pdf p.28)

tablet for CLHIV >14-24.9 kg.[303] At this time, PEPFAR recommends a single course of TPT for life for all eligible PLHIV. The WHIP3TB study results did not show additional benefits (i.e., reducing further TB incidence) of a repeated round of TPT. PLHIV with documentation of a completed course of TPT would be considered ineligible for an additional course of TPT.[311] However, a repeat course of TPT should be considered among PLHIV who previously completed TPT but have been, thereafter, household or close contact of TB patient.[304]

WHO recommends the consideration of vitamin B6 (pyridoxine) coadministration to PLHIV receiving INH to prevent peripheral neuropathy.[305] PEPFAR supports inclusion of vitamin B6 in INH-containing TPT regimens, lack of vitamin B6 has been cited by communities as a major barrier to acceptance of TPT regimens and additional local contributors such as underlying malnutrition and alcohol use should be considered. Forecasting and supply planning for vitamin B6 should mirror that for INH if purchased separately. Lack of availability or delays in procurement of Vit B6 alone is not a reason to discontinue or prevent initiating TPT in otherwise eligible PLHIV.

There are many important considerations in the implementation and scale-up of TPT from commodity planning to clinician education to monitoring for adverse events and reporting (see Figure 6.4.3.3.2 which shows TB preventive Treatment Implementation Roadmap). A full suite of tools to assist with program implementation and scale-up is available on PEPFAR Solutions (see TB Preventive Treatment Implementation Tools).[306] This toolkit has been recently updated to include INH patient information pamphlets and considerations for incorporating TB treatment into differentiated service delivery models.

Commodity agents from GHSC-PSM are available to assist with forecasting and procurement and supply planning. An effective supply chain management technique called “kitting” has been implemented by Nigeria and other OUs to ensure that PLHIV initiated on TPT do not have interruptions in treatment due to supply chain delays. Kitting refers to a mechanism to ensure that a patient has a dedicated complete course of drugs available at the point of care to avoid

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[303] WHO Technical Brief. Package of Care for children and adolescents with Advanced HIV Disease: STOP AIDS. July 2020. https://apps.who.int/iris/bitstream/handle/10665/332907/9789240008045-eng.pdf?sequence=1&isAllowed=y

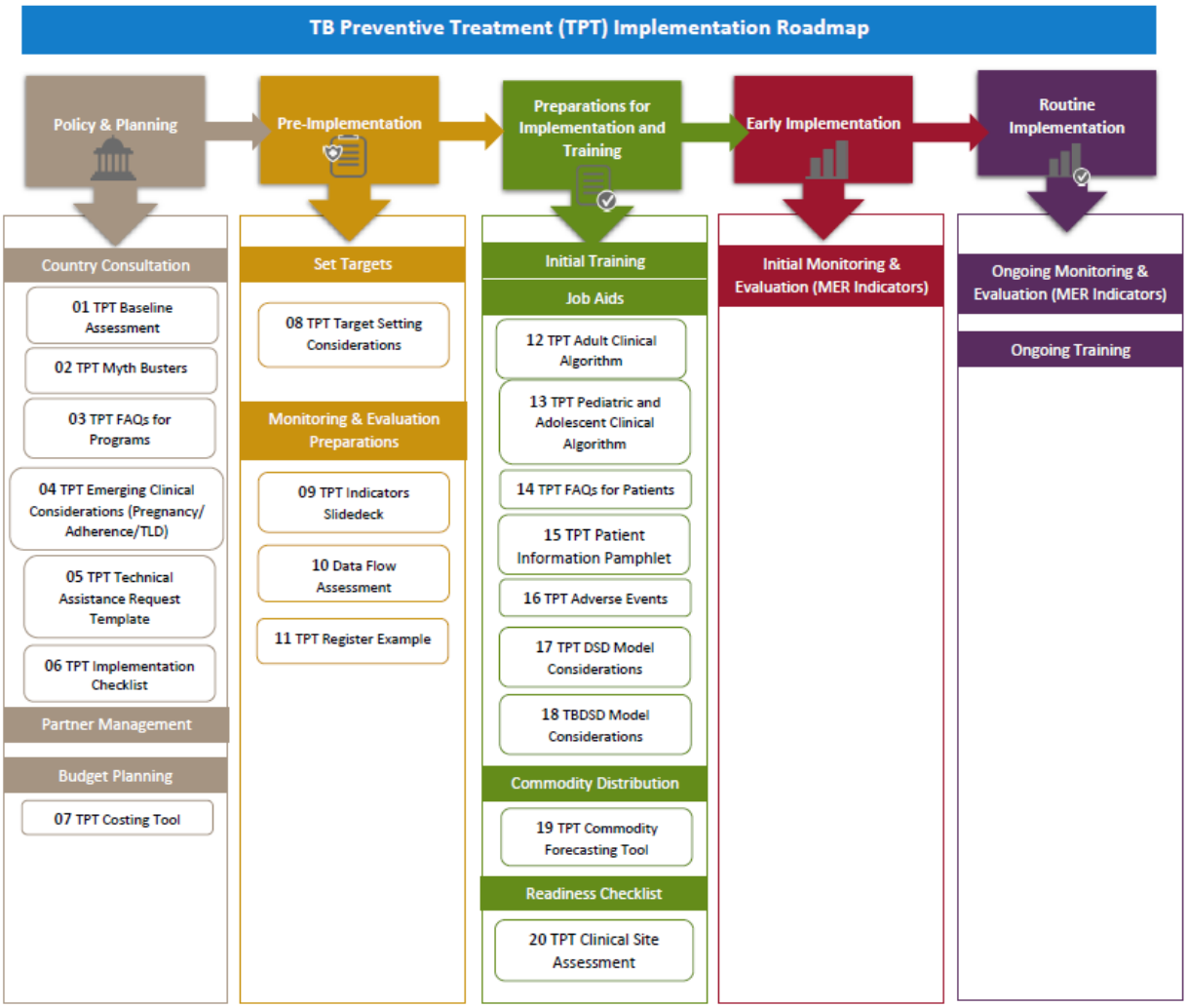
[304] https://www.who.int/publications/i/item/9789240002906

[306] PEPFAR Solutions: TB Preventive Treatment Implementation Tools https://www.pepfarsolutions.org/resourcesandtools-2/2018/9/25/tpt-implementation-tools

treatment interruption. PEPFAR IPs should consider adopting the “kitting” approach during the planning and implementation of MMD and decentralized drug distribution (DDD) for TPT expansion in the wake of COVID-19.

There is a need for quality data on TPT implementation, especially during the transition and introduction of new and shorter TPT regimen. With such a rapid scale-up of activity, it is crucial to rigorously monitor implementation and adverse events. Programs should consider including TPT initiation and completion in existing dashboards that are tracking other key indicators as part of surge initiatives (e.g., index testing, TLD transition, multi-month dispensing). In addition, programs are expected to develop or strengthen pharmacovigilance and adverse event monitoring, regardless of TPT regimen. Programs should also explore ways to monitor adherence to TPT (as well as adherence support tools) as a measure of quality of TPT implementation and TPT completion.

*Figure 6.4.3.3.2: TB Preventive Treatment Implementation Roadmap*




**Differentiated Service Delivery for TB/HIV**

Differentiated service delivery models for PLHIV should include all recommended TB/HIV services, including regular TB screening, case finding with linkages to TB diagnostic, care and treatment, and TPT provision. Differentiated service delivery models for delivery of TB services can be modified to accommodate children and adolescents living with HIV and adapted to the national COVID-19 response. PLHIV with TB disease should be prioritized for differentiated service delivery models adapted specifically to PLHIV with advanced disease.

In considering implementation of TPT scale-up in PEPFAR-supported HIV programs, it is important to consider how to deliver TPT both to newly diagnosed PLHIV and to already enrolled PLHIV on ART in differentiated service delivery models. Differentiated service delivery models have been implemented in all PEPFAR-supported HIV programs and will be required for PEPFAR programs moving forward, with prioritization of MMD, DDD, and visit-spacing.

Stable PLHIV on ART in these programs may receive ART refills and facility-based clinical monitoring once every three to six months, or they may receive ART refills and/or clinical monitoring more frequently but in the community. Thus, for TPT to be delivered to all PLHIV as part of a comprehensive package of HIV care, certain programmatic adaptations such as mop-ups and line listing those remaining eligible, must be considered. This will ensure stable PLHIV on ART already in these differentiated service delivery models complete a course of TPT.

**General programmatic considerations for TPT in differentiated service delivery models**

A critical part of integrating TPT into differentiated service delivery models is ensuring that there is enough investment in client treatment literacy around TB symptoms and TPT safety and side effects to facilitate adherence, seek clinical care when needed, thereby avoiding adverse events and ensure TPT completion. Differentiated service delivery models should not pose additional challenges to completion of TPT, and should allow for seamless integration with HIV care, TPT adherence and monitoring of TPT treatment outcomes.

TPT delivery to PLHIV receiving care in differentiated service delivery models should include programmatic considerations of place, delivery of TPT, clinical management, monitoring for adherence and adverse events, and documentation of TPT completion. Whenever possible and appropriate, changes to the client's chosen service delivery model should be minimized to preserve the intent of differentiated service delivery enrollment and not discourage care-seeking. For each consideration, policymakers and practitioners should consider the applicable elements of providing services through differentiated service delivery models: *what* activity is being done, *when* or how often the activity takes place, *where* is that activity taking place, and *by whom* is the activity completed. Children should be considered for differentiated service delivery for TPT, especially if their parent, guardian, or caregiver is also receiving ARVs and/or TPT through differentiated service delivery (aligning their model to their caregiver). Differentiated service delivery models should account for potential weight changes and needed dose adjustments for young children. Examples of differentiated service delivery models for TPT delivery can be found on the differentiated service delivery website.[307]

**Preventing TB Transmission**

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[307] https://differentiatedservicedelivery.org/Models/Treatment

Preventing TB disease requires focused efforts to reduce transmission as well as efforts to diminish the risk of developing active disease among PLHIV through TB preventive treatment (discussed in more detail in Section 6.4.3.3). All program systems investments should include facility-level and administrative measures for TB infection prevention and control. Please see Section 6.7.1 for further detail.

**Sustainability for TB/HIV interventions**

Sustainability for TB/HIV activities will entail a gradual shift from the current direct service delivery model in defined geographical areas to a national level technical assistance (TA) approach. This national TA should be directed more into policy and technical support for strengthening governance, public policy, enhancing public private partnerships and increasing the level of accountability and transparency from national stakeholders on high-quality TB/HIV programming and service delivery. Increasing domestic funding for TB/HIV response and self-reliance would be a crucial cross-cutting and foundational element of the move to country ownership, paramount for greater sustainability.

## 6.4.4 Cervical Cancer Screening and Treatment

Summary of section edits:

- Removed MER data results from the CXCA-TX in the "Cervical Cancer Screening Approach" paragraph
- Clarified that not all aspects of the benchmark list must be achieved prior to transitioning to HPV testing
- Clarified that while PEPFAR funds cannot be used to procure HPV vaccines, PEPFAR sites may administer HPV vaccines procured through non-PEPFAR funding

Cervical cancer is an important public health problem worldwide. In 2020, an estimated 604,000 women were diagnosed with cervical cancer and about 342,000 died from the disease worldwide.[308] Cervical cancer is the number one cause of cancer mortality in women in sub-Saharan Africa (SSA). Roughly 70,000 women in SSA were diagnosed with cervical cancer in

[308]Global Cancer Observatory: https://gco.iarc.fr

2020, and of these 67% died from the disease.[309] Women living with HIV (WLHIV) are six times[310] more likely to develop persistent precancerous lesions and progress to cervical cancer, often with more aggressive forms and with higher mortality. Recognizing the preventable and curable nature of the disease, WHO and global partners launched the *Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem*[311] in 2020 with the following 2030 targets:

- Vaccinate 90% of eligible girls against HPV;
- Screen 70% of eligible women at least twice in their lifetimes (once by 35 years, once by 45 years) with a high-performance test; and
- Effectively treat 90% of those with a positive cervical cancer screening test or cervical lesion, including palliation when needed.

Starting in FY18, PEPFAR refocused its effort to provide cervical cancer screening and treatment of pre-invasive lesions to WLHIV in areas of high HIV prevalence through the use of ART and other service delivery platforms via the creation of the Go Further partnership. The Go Further Partnership brings together PEPFAR, UNAIDS, the George W. Bush Institute, Merck, and Roche by leveraging strengths of each institution. In COP18/19, PEPFAR committed funding to eight sub-Saharan African countries (Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, Zambia, and Zimbabwe) to accelerate cervical cancer screening and pre-invasive treatment services for WLHIV. In COP20 four additional countries (Tanzania, Uganda, Kenya, and Ethiopia) were added as Go Further countries.

In support of national cervical cancer programs, all PEPFAR supported countries with UNAIDS 2021 HIV prevalence above 5.0% among women in the 15-49-year-old age group are expected to provide at least one life-time cervical cancer screen for WLHIV receiving ART. Support of cervical cancer surveillance beyond the acceleration efforts of the Go Further initiative will rely upon the integration and absorption of cervical cancer screening and treatment services for WLHIV into national cancer programs, and should be incorporated into sustainability plans for PEPFAR OUs.

Programs utilizing PEPFAR resources (regardless of whether or not they are a Go Further country) for cervical cancer services are expected to adhere to PEPFAR Clinical Guidance and report on the

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[309] Ibid.

[310] Stelzle et. al (2021). Estimates of the Global Burden of Cervical Cancer Associated with HIV. *The Lancet Global Health, 9*(2), e161-e169. https://doi.org/10.1016/S2214-109X(20)30459-9

[311] Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization; 2020.

current MER indicators. Funding may be used for screening with VIA and HPV, treatment with cryotherapy, thermal ablation, LEEP, or cold knife conization, histopathology services, and quality assurance activities. Palliative therapy for women with invasive cervical cancer may be supported. HPV vaccine procurement, other treatments for invasive cervical cancer, and funding of screening and pre-invasive treatment of women who are not HIV infected, is not supported.

***Cervical Cancer Screening Approach**:*

Cervical cancer screening for WLHIV should be integrated into routine HIV treatment services in each country program. Current PEPFAR clinical guidance recommends screening to start at age 25 or according to national guidelines, whichever is earlier. PEPFAR programs may also consider earlier screening among women with long-standing HIV infection, e.g., perinatal infection. WLHIV who are between ages 50 and 65 years and have not been screened may be offered a single screening test, and screening should be discontinued if they screen negative.

Since 2018, PEPFAR has recommended a “screen and treat” approach where the cervix is visualized with 5% acetic acid (VIA) in a single ‘point-of-care’ visit followed by “same-day” treatment of identified precancerous lesions with cryotherapy, thermal ablation, or a loop electrosurgical excisional procedure (LEEP) for eligible lesions. In resource constrained settings or in populations where there’s a concern for follow-up, the “screen and treat” approach has demonstrated merit in aiding in the early detection of cervical cancer because of its simplicity, low cost, and ease of implementation. VIA may be performed by well-trained healthcare workers of different cadres (physicians, nurses, midwives, lay health workers), with appropriate quality assurance measures. Despite these benefits, there are noticeable challenges with ensuring consistency amongst providers in screening quality and diagnosis accuracy. VIA has an overall sensitivity ranging between 60-80% and a specificity of 70-90% although these metrics can vary substantially. Data from 12 PEPFAR countries from FY2020- FY21 Q2 show a positive precancerous lesion screen rate ranging from 4.9-22.4% and a suspected cervical cancer rate ranging from approximately 1-44% after previous screening with VIA and precancerous lesion treatment in the prior year. Because of this variability, programs that continue to use a “screen and treat” will be supported to implement continuous quality improvement plans to ensure PEPFAR facilities provide the highest quality care to WLHIV, and, where feasible, should transition to high performance testing.

Released earlier this year, the 2021 *WHO Cervical Cancer Guidelines* recommends a pivot away from “screen and treat” to a “screen, triage, and treat” approach for all women regardless of HIV

status.[312] In this approach, the decision to treat is based on a positive high performance primary test that is confirmed by a positive second (or "triage test") with or without a histologically-confirmed diagnosis. In this "screen, triage, and treat" approach, HPV DNA testing is recommended, with visual inspection with acetic acid (VIA) triage for all WLHIV with a positive HPV test, followed by immediate treatment of precancerous lesions. The rationale for this change takes into consideration the benefit that high performance testing has in reducing both cervical cancer mortality and treatment-related morbidity resulting from non-quality assured VIA screening.

Considering the variability in PEPFAR Program achievement in reaching annual screening and treatment targets, and to better align with international guidance and accelerate progress towards the achievement of 90-70-90 WHO 2030 global strategy goals, PEPFAR programs should begin a phased transition by SNU within each country to the "screen, triage, treat" approach (See Figure 6.4.4.1) depending on resources, health worker force, and should achieve the following before transitioning:

- ≥90% of WLHIV with a positive screen (CXCA_SCRN_POS) on visual inspection with acetic acid within the SNU have received the appropriate treatment with either cryotherapy, thermal ablation, or LEEP (CXCA_TX; treatment interruption rate less than 10%) in the previous reporting period (Q2 or Q4).
- Optimization of laboratory infrastructure within SNU to support an HPV DNA testing turn-around time (TAT) and report of results to providers in 7 days or fewer.
- Finalization and implementation of Standard Operating Procedures (SOPs) for quality assurance procedures for VIA at each service delivery point within SNU, with established systems for the monitoring & evaluation of quality practices including a plan for the timely remediation of identified gaps.
- Reliable systems for providing results to - and tracking clients through - the cervical cancer clinical cascade.

HPV DNA sample collection should be conducted in accordance with national guidelines and SOPs. Given the evidence, acceptability, and the demonstrated effectiveness that HPV DNA self-collection has had in PEPFAR programs to maintain/and or increase the ability for OUs to screen WLHIV for cervical cancer during COVID-19 restrictions, self-collection of samples for HPV self-testing is a feasible option for OUs, in accordance with national guidelines. Systems to

[312] WHO Guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. July 2021.

enhance client tracking, reduce turnaround time, or promote same-day testing, triage, and treatment should be created wherever possible. **PEPFAR does not support prophylactic treatment for women who are HPV-positive but have no lesions seen on VIA.** Where available, HPV DNA testing should be prioritized for the single screen of women aged 50-65 years in whom pelvic exam and visualization of the transformation zone may be difficult.

If platforms and capacity for HPV DNA testing are not available in an SNU or the SNU did not achieve the performance and quality targets described above, a "screen and treat" approach, with quality-assured VIA testing and immediate cryotherapy or thermal ablation treatment for eligible women is recommended. Loop electrosurgical excision procedure (LEEP) must be available at selected high-volume sites for referral of women with cryotherapy/ablation-ineligible lesions (e.g., women with lesions covering >75% of the cervix, lesions extending into the endo-cervical canal, or not completely covered by the largest available cryo-probe or ablation tip).

Screening for cervical cancer should begin at high-volume sites and be scaled to all women receiving ART in PEPFAR-ART sites either on-site or through referral to hub sites within the region. Screening should be available in the ART clinic or in affiliated clinics on-site such as women's health or maternal child health clinics for WLHIV to utilize. We do not recommend screening or treatment services for people during pregnancy or for two months post-partum.

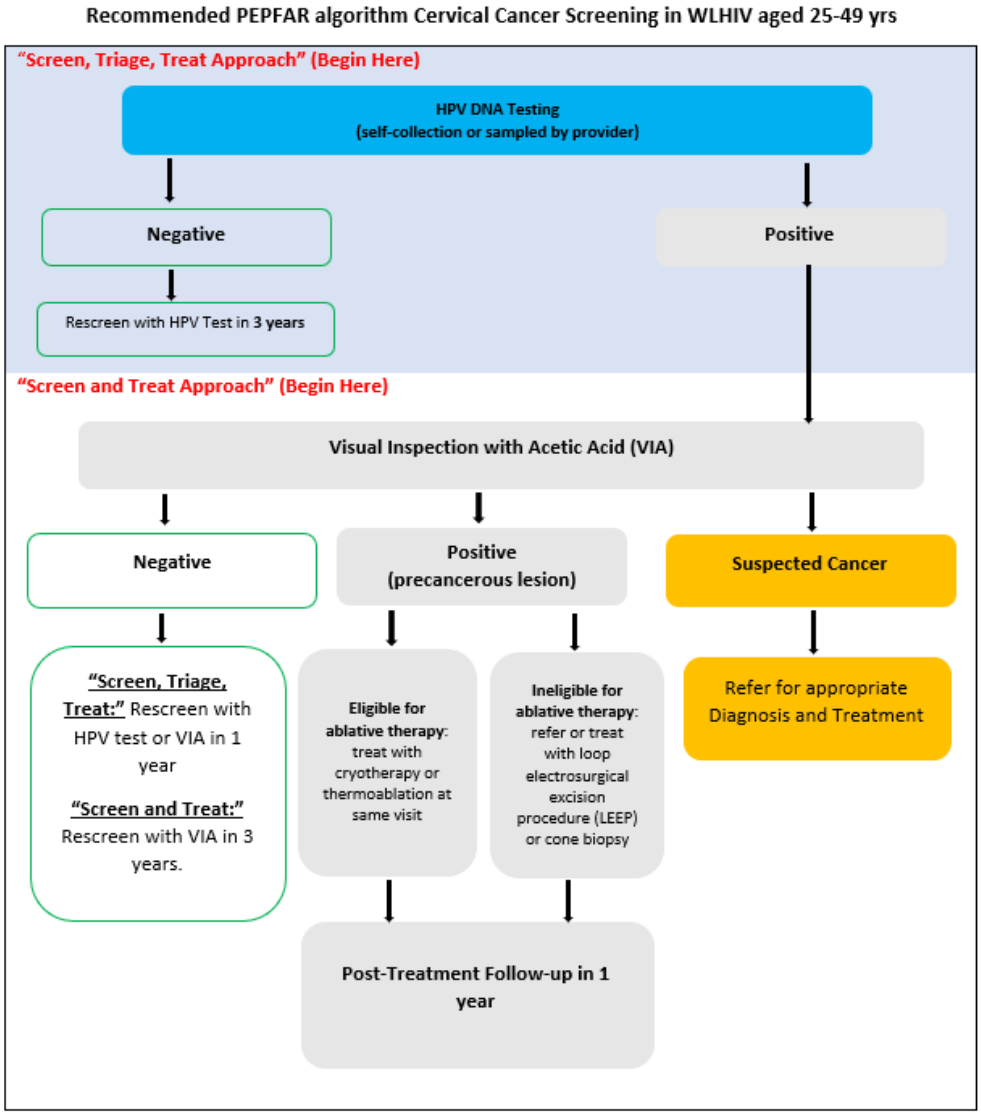
**Management of Precancerous Lesions and Cervical Disease**

The aim of treatment of pre-cancer is to effectively remove lesions suggestive of cervical pre-cancer i.e., cervical intraepithelial neoplasia (CIN) grades 2 or 3, ensuring that post-treatment cervical screening is negative, while minimizing harm to the patient from the treatment. In accordance with the WHO Global Cervical Cancer elimination strategy, PEPFAR programs should ensure that a minimum of 90% of women who screen positive are linked to treatment.[313] Cervical pre-cancer can be treated with ablative treatment approaches such as cryotherapy or thermo-coagulation or with excisional treatment approaches such as LEEP or cold knife conization (for eligible lesions). The PEPFAR program should aim to include provision of cryotherapy or thermal coagulation at all VIA sites and LEEP at a subset of screening sites. PEPFAR funds may be used to establish or expand histopathology services for evaluation of LEEP and cervical cone biopsy specimens. Patients who have received treatment for CIN should undergo post-treatment follow-up at 12 months. Women with

[313]Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization 2020.

suspected invasive cervical cancer should either receive additional evaluation and treatment at the same facility or be referred to established treatment referral sites. All sites providing cervical cancer screening that do not provide cryotherapy or thermal ablation and LEEP should establish a relationship with a site that performs these procedures to allow the referral of women needing treatment, LEEP, or a more definitive diagnosis. Women should be given specific appointments, assisted with logistical planning, provided resources to reach the referral site (including the use of nurses, peer or community navigators), and monitored to assure follow up. Referral sites should also have the capacity to track patients and report on outcomes.

*Figure 6.4.4.1: Cervical Cancer Screening Algorithm*



**Demand Creation**

In order for WLHIV to feel comfortable and confident in navigating through the screen and treat process, clients will need education on HPV and cervical cancer, screening protocols, including HPV DNA testing, and the meaning of screening results. Community education is also needed to dispel myths about a cervical cancer diagnosis and reduce stigma for women who screen positive for pre-invasive cancer lesions.

Opportunities to support these types of discussions include:

- HIV support groups (including CSOs, faith-based organizations, cancer advocacy groups and communities of WLHIV) to communicate cervical cancer messaging and advocate for uptake of services and treatment continuity
- VMMC platforms (where HIV-uninfected men can be encouraged to get circumcised while their female partners living with HIV are getting screened/treated for cervical cancer preinvasive lesions)
- HIV testing facilities, ART clinics, PMTCT service delivery sites, reproductive health (RH) departments and other clinical care units that can also offer and ensure immediate linkages to screen and treat services for eligible WLHIV
- ART clinics where group health talks can include men to be sensitized as supportive partners

**Quality Assurance**

We must ensure that all care provided to women is the highest level of quality care. Best practices include enhanced clinical mentoring for LEEP providers, provider training for provider- and self-collected HPV DNA sampling, digital interventions to improve the quality of screening and treatment services, adequate equipment and sufficient human resources support, rapid detection and immediate adverse event reporting, dedicated healthcare workers at high-volume sites, expedited and robust pathology systems, and interactions with patients on their well-being after their procedures.

The co-location of same-day screening and treatment services has been explicitly requested by women in the Go Further countries and is expected based on the guidance except in rare circumstances such as remote, low-volume facilities. Ensuring treatment availability with cryotherapy, thermal ablation, and LEEP should be a priority in COP22.

For more specific detail on the PEPFAR cervical cancer screening and treatment program, including changes to the screening and follow-up timelines, please see the clinical guidance developed in June 2018 and updated in 2021 (forthcoming), available on PEPFAR SharePoint.

## 6.4.5 Approach to Viral Load Testing

Summary of section edits:

- This section was revised to indicate that PSC (plasma separation card) is another sample collection tool.
- A reminder that point-of-care VL testing requires plasma samples (not DBS or PSC) was added.

The goal of antiretroviral therapy is virological suppression, and this should be achievable by all people living with HIV. A viral load should be assessed with results available at six months after initiating ART, 12 months after initiation of ART, and yearly thereafter if virologically suppressed. Though many PEPFAR supported programs have made significant progress in achieving 95% viral suppression, most of these countries are below 95% viral load testing coverage. Recent efforts to bridge this gap have been impacted by COVID-19 lockdown at country levels that resulted in many patients not coming to the clinic for sample collection and inability to transport samples from rural communities to the central laboratory for testing. For individuals on a less intensive differentiated service delivery model, visits to collect blood should align with medication pickup and clinical consultations. See Section 6.1.3.1. Supply chain challenges associated with border closures, global flight restrictions, and inefficient inter-program coordination further led to reagent stock outs and sample backlogs. Figure 6.4.5.1 did not show any significant change in VLC overall from FY20Q1 to FY21Q4 in all PEPFAR OUs during COVID-19 outbreak. In fact, this remains almost flat for a year between FY20Q3 and FY21Q3, indicating the need for more innovative COVID-19 adaptation approaches. PEPFAR teams should work with countries and other stakeholders to ensure viral load testing is scaled at least 95% national coverage. As MMD is scaled up to 6 months in the context of COVID-19, programs should ensure that medication dispensing coincides with the period for VL sample collection to avoid missed testing periods. COVID-19 mitigation options within the facilities that allow for social distancing such as: reduction in waiting times for sample collection, avoiding crowded waiting rooms, scheduling, and staggering appointments, streamline clinic flow so that patients for sample collection do not interact with multiple clinic providers, and reactivating safe sample transport systems should be implemented to ensure improved sample collection and testing. Another option includes use of DBS for sample collection outside of the facility to improve viral load coverage where plasma is not feasible. Decentralizing VL sample collection to collection

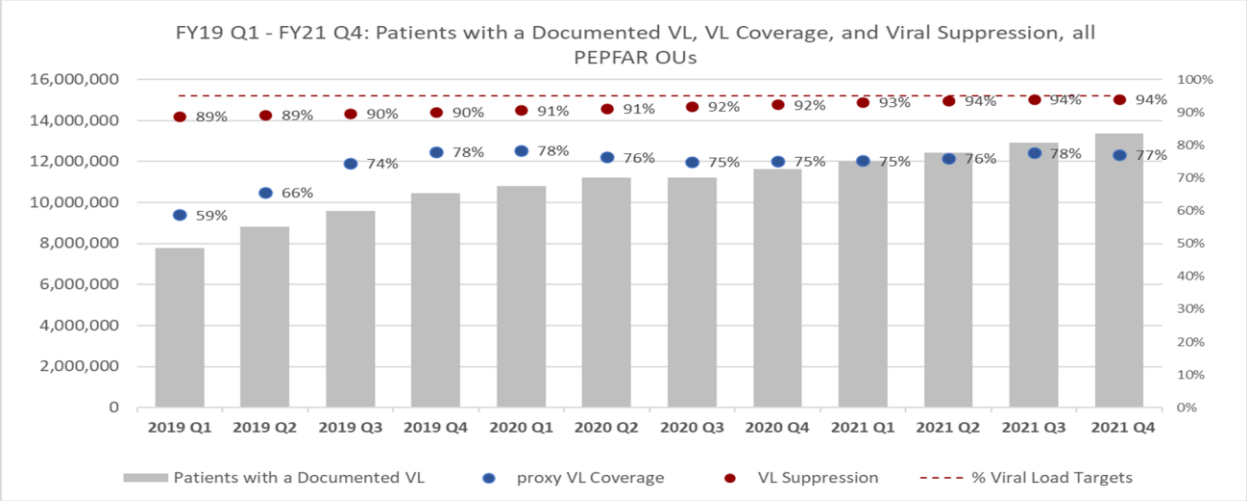
points in the community, especially where DBS is expanded should also be considered to improve access to VL testing for people living with HIV. In the event of shortages of viral load testing commodities, reagents, and clinic supplies which countries may face as a result of the ongoing COVID-19 pandemic, countries are advised to prioritize testing for infants, children, adolescents, pregnant and breastfeeding women in their priority populations for VL testing.

Creating demand for VL remains a challenge in many national HIV programs. The following education points should be widely disseminated by all providers, community health workers and counselors doing HIV testing.

1. A suppressed viral load is critical to ensuring healthy living with HIV.
2. U=U. It is now widely accepted that individuals who are virally suppressed cannot pass HIV to their sexual partners.
3. Effective therapy significantly reduces the risk of vertical transmission and transmission to individuals with whom they may share drug using equipment.

To address this, partners should ensure there is dissemination of information to peer educators and counselors regarding routine VL testing, significance of results, and clinical management. Systems such as SMS could be incorporated to remind people of their VL appointment in line with other efforts to ensure continuity of clinical care. Treatment literacy efforts should include education of healthcare workers on the benefits of treatment to prevent onward transmission (U=U), national HIV treatment guidelines or algorithms, explaining the importance of VL and management of high VL results. Importantly, results should be provided directly to the clients, this is a critical educational effort that enhances client engagement in their care. There should be positive reinforcement if VL has improved since the last test. Engagement of community-based organizations to increase patient demand by promoting awareness and education of VL testing, sample collection and utilization of results for patient management is needed. Treatment literacy should include sharing information on opportunities to participate in less intense model of care, particularly for patients who are virologically suppressed.

*Figure 6.4.5.1: Quarterly Trends in VL Coverage and Suppression Across PEPFAR During COVID-19*




Critical to the goal of virological suppression is the return of results to the clinical staff and patient, and action on a non-suppressed VL. A VL ≥1000copies/ml should be considered a critical lab value and communicated to the clinical staff and the patient in an expedited fashion. Enhanced adherence counseling should follow immediately and VL tests must be repeated in 3-6 months. It is important to ensure that effective laboratory information management systems are in place for the prompt identification of viremic patients. While patient results go to the charts, there should be a method either through SMS or other electronic systems[314] to ensure every client is also immediately alerted of his or her results being available. Country programs should consider leveraging private sector innovations to enhance the effectiveness and efficiency in returning viral load results directly to patients. No viral load result should go to charts without a method to ensure every client is also immediately aware of availability of the result at the facility with proactive counseling at visit to provide viral load literacy and needed follow up based on results.

The PEPFAR VL/EID Community of Practice (COOP) has put together the VL/EID Reference Manual that could be used to guide Implementation Subject Matter Experts (ISME), PEPFAR OU teams, and Implementing Partners to address gaps and accelerate VL and EID scale-up. This manual presents innovative tools, best practices, and proposed solutions to address VL/EID challenges that are common across PEPFAR programs. This manual can be accessed by USG OU teams through this link: https://pepfar.sharepoint.com/sites/VL-EID.

[314] https://www.senaite.com/

**Use of Dried Blood Spot (DBS), Plasma Separation Card (PSC) and other alternatives**

DBS or PSC are easy to collect and store under field conditions (no phlebotomist is required), easy to transport to centralized laboratories, and have reduced costs associated with fewer required collection materials and ease of transportation under ambient temperature. Point-of-care VL testing requires a plasma sample. The use of phlebotomy for blood draw for viral load testing using plasma sample type may be challenging particularly among infants and children and may partly contribute to low testing coverage among this population. If not possible, consider the use of DBS or PSC for sample collection and transportation to the central lab for testing. OUs should be sure to order pediatric VL commodity bundles in the FAST which includes capillary tubes and butterfly needles for younger children sample collection.

## 6.4.5.1 Use of Point-of-Care Platforms for VL Testing in Pregnant and Breastfeeding Women, Infants, and Children

Although the importance of routine VL monitoring for individuals receiving ART for HIV infection is widely recognized, VL testing coverage among pregnant and breastfeeding women (PBFW), infants, children and adolescents has been low in most PEPFAR-supported countries. Data from IAS 2019 characterizing VL burden among HIV-positive pregnant women around the time of delivery in South Africa using POC platforms, showed that 20% of women were virally non-suppressed.[315] According to UNAIDs estimates, 9% of new vertical HIV infections globally in 2020 are attributable to mothers on ART who are virally unsuppressed, and an additional 43% of these new vertical transmissions are among mothers not on ART.[316] Viral non-suppression is a preventable medical urgency among pregnant and breast-feeding women as it represents a clear risk to the child and must be addressed rapidly. With consistent and available viral load monitoring for PBFW, there is the ability to provide intensified adherence counseling, alternate ARV regimens for the mother as needed, and an intensified prophylaxis regimen for exposed infants whose mothers have elevated viral load at delivery.[317] Hence, POC testing could be used to improve the viral load testing coverage gap among PBFW.

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[315] Moyo (2019) https://pubmed.ncbi.nlm.nih.gov/31914002/
[316] UNAIDS (2020) https://www.unaids.org/sites/default/files/media_asset/start-free-stay-free-aids-free-2020-progress-report_en.pdf
[317] WHO (2021) https://www.who.int/publications/i/item/9789240031593

Sub-optimal VL testing coverage among infants and children has been partly associated with the use of venipuncture/phlebotomy for sample collection (using hollow needles and syringes to access a vein to withdraw blood into a tube) for plasma sample type. One previous suggestion to address this has been to use fingerstick or heel stick methods to collect blood directly onto cards to prepare DBS and transport to a centralized. Given the time sensitivity of VL among infants and children, this approach may further compound the challenge of VL coverage and poor pediatric outcomes. The use of fingerstick or heel stick approach for sample collection, centrifuge, and direct transfer to the POC instrument cartridge for immediate testing and release of results should address the above challenges. Also, since POC testing is already being used within the same setting for VL testing among mothers (PBFW), extending this to be used for VL testing among infants and children will enhance family centered testing as well as improve optimization and effective use of these instruments. One example is Lesotho that showed POC VL for PBFW and children was feasible, improved testing coverage, patient satisfaction and reduced median time from sample collection to results return from a range of 13-43 days in FY21Q1 to a median time of 24 hours by the end of FY21Q3. Considering this, it is recommended that in COP22, programs should continue to use POC for VL testing among PBFW and infants and children. It is important for programs to plan appropriately, considering the multiplexing capability of existing POC and near POC instruments for the implementation of POC testing in these populations. Programs should consider the current and future testing demand and how it relates to existing instrument capacity, patient access to POC and conventional testing, POC quality assurance and continuous quality improvement program implementation at all sites, data systems and connectivity, and service and maintenance and supply chain costs and logistics considerations. PEPFAR is no longer procuring instruments so all potential POC network expansions will need to be in the context of “all-inclusive” reagent rental contracts. Diagnostic network optimization (DNO) that can help countries with several of these considerations should be performed prior to placement of POC or near POC devices.[318] Programs should also continue to address other systemic issues affecting VL scale-up and ensure access to VL testing for other populations using conventional or laboratory-based instruments.

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[318] Alemnji et al. (2020) J. Acquir. Immune. Defic. Syndr. 2020, 84, S56–S62.

## 6.4.5.2 Best Practices to Close Remaining Gaps in Viral Load Testing Coverage and Suppression

In an effort to close remaining gaps in VL testing coverage and suppression, the VL/EID ISME Community of Practice has compiled some best practices, tools, and guidance that programs should consider using. See summary below. Details of these resources can be accessed through this link: https://pepfar.sharepoint.com/sites/VL-EID

*1. Patients with virologic non-suppression*: The goal of overall 95% viral load suppression requires that all eligible people get viral loads measured (viral load coverage) and that they are virally suppressed. A comparison of FY18Q4 and FY21Q4 showed tremendous improvement in viral load testing coverage among PEPFAR supported countries, however, this does not correspond to similar increases in viral suppression over the same time (Figure 6.4.5.2.1), implying need for more attention on viral suppression. From a programmatic and laboratory perspective, the use of viral load cascades and high viral load registers may be useful in identifying and addressing virologic non-suppression. Hence, investments to train, mentor and supervise cadres responsible for EAC delivery are needed, with multi-disciplinary community-facility team meetings to discuss clients' management, to share best practices, and identify areas requiring remediation. Also, evaluation of parameters such as age and sex may help identify specific populations with a high prevalence of viral non suppression and appropriate virtual and community based EAC delivery may be deployed.

*2. Low VL suppression among infants, children and adolescents and very low VLC in children <5 years old*: Continued low VL suppression among infants, children and adolescents compared to adults has been an area of concern that warrants targeted innovations (Figure 6.4.5.2.2). Additionally, VL testing coverage among children <5 years old compared to all other populations is staggeringly low. A combination of issues contributes to this inequity, including weak demand creation, inconsistent verification/utilization of VL at clinic level and use of venipuncture/phlebotomy rather than DBS for pediatric sample collection. Low VL suppression is related to use of sub-optimal pediatric formulations, difficulty in dosing and administration of pediatric ART, lack of /or incomplete age-appropriate (and caregiver dependent) EAC, and delayed repeat VL testing after EAC. Some best practices to address these challenges include mapping of infants, children, and adolescents non-suppressed and those with poor VL coverage by areas of residence, home visits and community VL sample collection (as seen in the Nigeria

RISE example),[319] and assigning them to community-based volunteers (CBVs) for quality EAC, repeat VL testing, and enrollment in OVC programs. Additionally, identification of caregivers and adolescents to join support groups on a voluntary basis, monthly support group meetings covering specific topics (e.g., adherence, health literacy and positive living), tailoring clinical services to promote age-appropriate services, and building the capacity of health care workers/case managers to provide stigma free services can be very helpful (https://pepfar.sharepoint.com/sites/VL-EID). The recommendation to use POC platforms for VL testing among infants and children mentioned in Section 6.4.5.1 is also applicable.

*3. Low viral load testing coverage among pregnant women*: Viral load coverage among pregnant women in PEPFAR programs, or the number of viral load tests among pregnant women out of an estimate of the number of pregnant women who were on ART when they entered antenatal care has remained low. Apart from Tanzania and Cote D'Ivoire, pregnant women have had persistently lower VL coverage documented in MER compared to all populations (Figure 6.4.5.2.3). Possible explanations may include the following: 1) the M&E system does not allow for reporting of pregnant or breastfeeding women, 2) misunderstanding of the MER indicator, and 3) program performance is suboptimal among pregnant women.

To address this, it is suggested that country teams, implementing partners, and facility staff investigate both clinical VL practices and VL reporting processes to identify the reasons for this low coverage, and tailor appropriate interventions in the local context. To ensure the HIV-free survival of infants, consistent with updated global recommendations, all pregnant women should have a viral load test near the start of antenatal care and just prior to delivery to inform optimal infant care, with more frequent biannual viral load monitoring throughout the breastfeeding period.[320] In addition, 1) laboratory requisition forms for HIV viral load testing must include information on pregnancy or breastfeeding status, 2) procedures should be in place on how laboratory staff should proceed when forms are incomplete, 3) a data quality review should be done periodically to assess the completeness of the forms. A data quality module for assessing and strengthening the quality of viral load testing data for all categories of PLHIV developed in 2020 by PEPFAR and multilateral partners should be considered.[321] Community/home-based services including obtaining specimens for VL testing and delivering results should be

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[319] https://theprogramme.ias2021.org/Abstract/Abstract/1018
[320] WHO (2021) https://www.who.int/publications/i/item/9789240031593
[321] WHO (2020) https://www.who.int/publications/i/item/978-92-4-001037-6

considered. Also, it is currently not possible to measure VL coverage in breast feeding women because the VLC calculation uses PMTCT_ART in the denominator which is only for pregnant women. These groups still represent priority populations during a critical time to prevent mother-to-child transmission. The recommendation to use POC platforms for VL testing among PBFW as mentioned in Section 6.4.5.1, should applied in this setting as well. Sample laboratory requisition forms and more detailed suggested approaches that programs may use to achieve this goal are in the best practice manual at the following link: https://pepfar.sharepoint.com/sites/VL-EID.

*4. Low viral load testing coverage among key populations (KPs):* KP disaggregates within MER treatment and viral load indicators are a requirement for PEPFAR programs. Global VL coverage is lower among KPs when compared to the general population on a global level. Common challenges behind decreased coverage include: 1) Inability to document KP disaggregates within national lab systems, 2) Lack of capacity of health care workers to properly identify KPs and document within the facility, 3) Fear or experienced stigma and discrimination which impact KP's willingness to access services, 4) Potential inadequate demand creation to ensure KPs are aware of importance of knowing one's viral load, 5) Community KP sites that collect VL samples are often not included in national lab sample transportation systems, 6) and KP programs often don't have access to EMR systems which limits understanding of VL test eligibly for their KP cohort. Ensuring KPs have access to client centered services for VL services including demand creation, community VL test collection and return of results and access to KP competent providers is essential to increasing access. In addition to all the above, more targeted effort should be made to ensure community-based programs in-country have a clear understanding of the viral load protocols and are capacitated to transfer and transmit this information to KPs within the community.

*5. 6-Month (MMD).* PEPFAR recommends 6-month MMD to decrease the burden of medication access on PLHIV, reduce treatment interruptions and ensure VL suppression. In many countries, MMD has been scaled-up rapidly as a means of reducing congestion and foot traffic in facilities especially during the COVID-19 pandemic. To mitigate the potential impact on other important clinical services such as VL testing, additional interventions such as harmonizing medication pick-up appointments with VL testing and enabling VL sample collection in the community are critical to ensure PLHIV maintain access to VL testing. For examples, in Zambia, a phlebotomy station was set up to draw blood at the same station where the client on MMD was picking up ARVs. This resulted in an increase of 20,000 more ARV bottles dispensed from

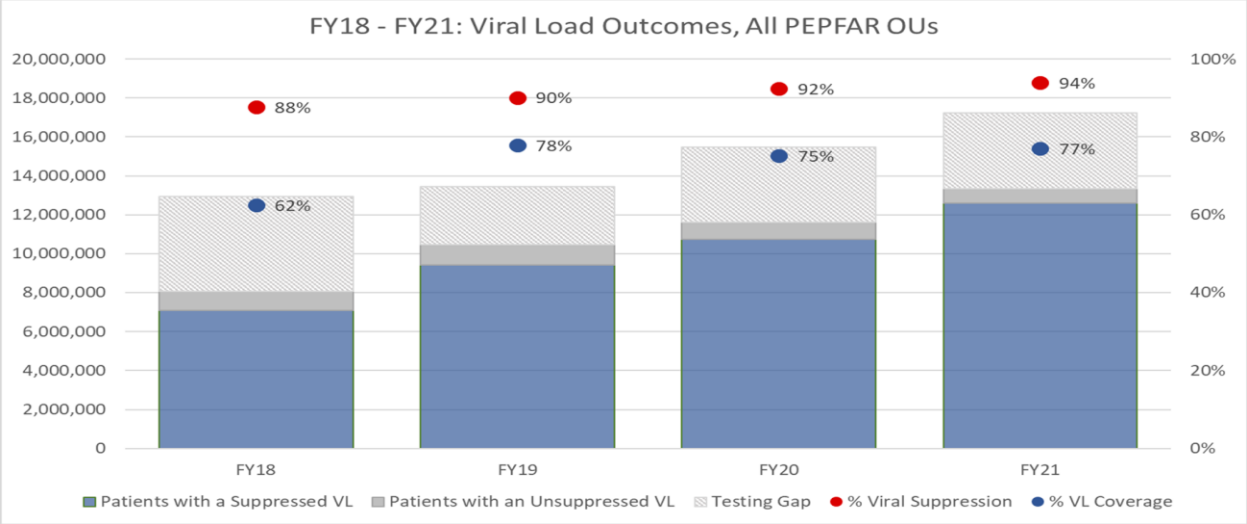
FY20Q1 to Q2, 20% of clients on 6MMD, and 15% more VL tests performed (https://pepfar.sharepoint.com/sites/VL-EID). Also, Nigeria has maintained good VLC while also scaling up 6-month MMD through use of DBS in difficult to reach areas, makeshift sample collection structures and VL collection appointments for clients in the community to increase access to VL testing (https://pepfar.sharepoint.com/sites/VL-EID).

*6. Delivery of test results to patients*: As one of the key client-centered approaches in COP20, there was a recommendation that while patient results continue to be filed in harts, there should be a method to ensure every client is also immediately alerted of his or her results. In addition, proactive counseling at each visit to improve viral load literacy should be included. Achieving this has been problematic because of lack of data systems that will simultaneously deliver complete results to facility and patient; instead, result alert systems to include use of SMS are feasible and possible. For example, Zimbabwe has developed an SMS system that could send notifications to patients when their results are ready. If the VL is suppressed, they will be advised to go to the clinic for the next appointment. If the result is non-suppressed, the clients will be advised to visit their facilities as soon as possible. At the same time, another notification is sent to the Clinician at the facility with an actual result and Patient unique ID. The country is currently using this system for COVID-19 testing, and HIV VL and EID results reporting will be incorporated into this system as well.[322] Similarly, through PEPFAR support in Eswatini, an implementing partner has collaborated with a cell phone company to pilot and roll out an approach for communicating high VL results to patients. Through this VL notification system, the patient receives an SMS alert as soon as a result is authorized in the Laboratory Information System (LIS) while the actual results are transmitted to the clinician. The SMS will advise the patient to visit their health facility to get the results. Country programs must be innovative and consider incorporating patient result alert systems that fit into their local context. In addition, countries should explore the development of remote sample logging (RSL), a module of a national LIMS which allows for decentralized data entry of samples and results receipt by laboratory personnel at health facilities. Such automated systems, when connected to a lab information system, can improve sample tracking, and reduce turnaround time for sample to/from conventional labs (assuming other systems are optimized, including HRH, sample transportation and information systems). One example is as of July 2021, RSL in Nigeria

[322] https://www.senaite.com/

reduced the pre-analytic phase from 15 days to 6 days and time between sample receipt at lab and sample tested and returned from 12 to 9 days.

*Figure 6.4.5.2.1: Trends in Number and Percent Viral Load Coverage and Suppression from FY18 through FY21 Across PEPFAR*




See the next figure that shows lower viral load suppression among infants, children and adolescents and very low VLC in children <5 years.

*Figure 6.4.5.2.2: Viral Load Testing Outcomes by Fine Age Band Across PEPFAR in FY21Q4*

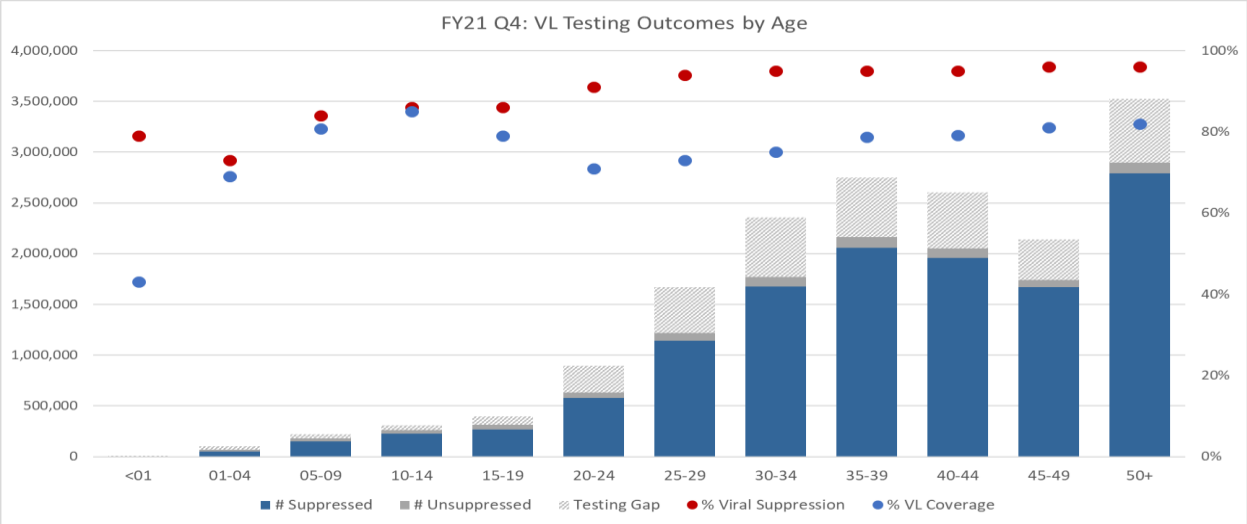
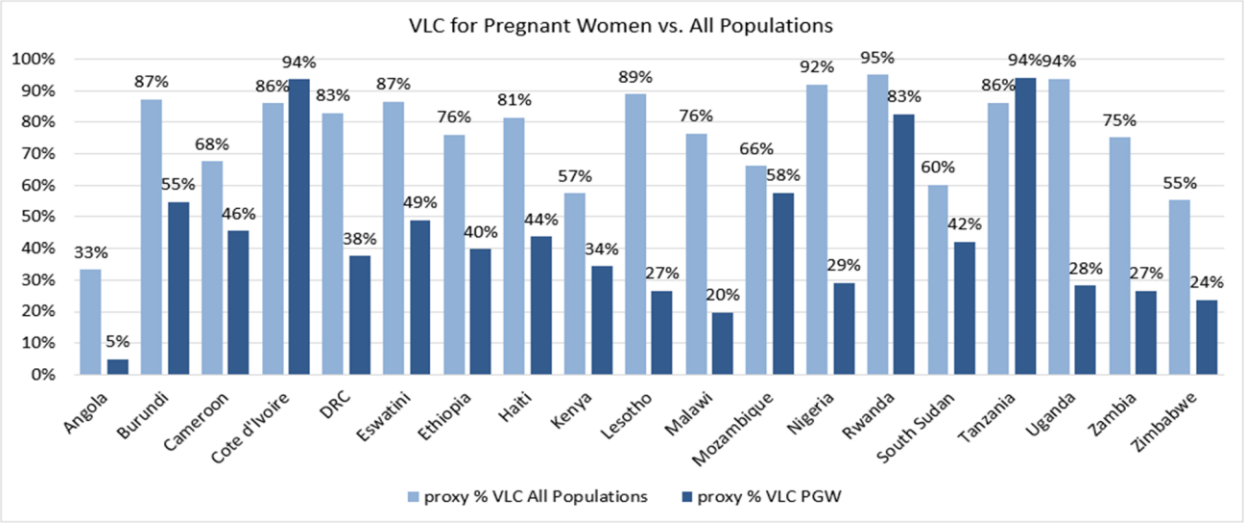



*Figure 6.4.5.2.3: Proportion VLC for All Populations and Pregnant Women by OU (FY21Q4)*




## 6.4.6 Approach to Virological Non-Suppression

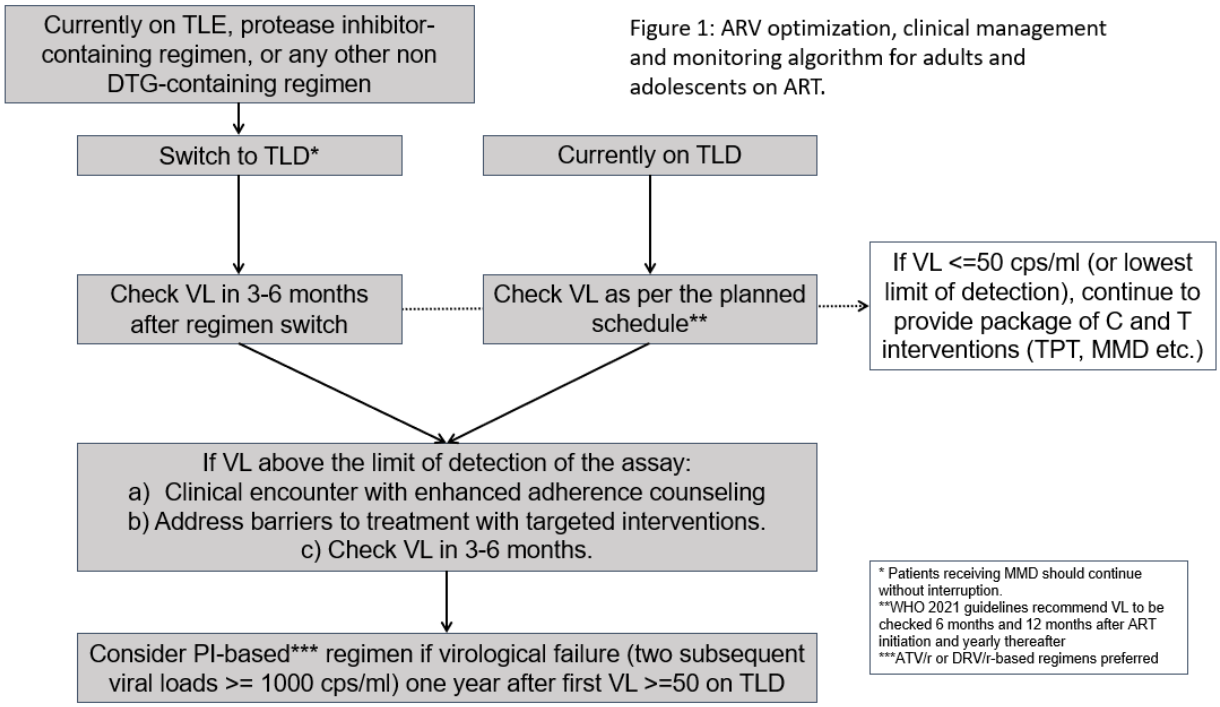
The goal of antiretroviral therapy is virological suppression (VS), which should be achievable by all PLHIV. Virological non-suppression is defined as any detectable VL greater than 50 copies/ml. All individuals on an efavirenz-based regimen, regardless of VL result, should be switched to TLD as soon as possible. A VL ≥1000cps/ml is the threshold for viral failure. It should be noted that for calculating the third 95 (virological suppression) a cutoff of <1000 cps/ml is used. This is not the clinical definition of viral suppression. As detailed in Section 6.4.6.1, any viral load over 50 cps/ml is actionable and should prompt ascertainment of barriers to treatment and provision of support, including individual case management as available,

enhanced adherence counselling, repeat viral load testing, and referral to necessary services such as mental health (Section 6.6.5.1), psychosocial support (Section 6.6.5.2), GBV response (Section 6.6.2), and substance use services. Structural barriers to treatment such as frequency of visits and location of clinics should be addressed with differentiated service delivery models and MMD (Section 6.1.3.1). See Sections 6.1.3 and 6.1.3.2 for the approach to interruptions in treatment and enhanced adherence interventions.

### 6.4.6.1 Virologic Non-suppression Among Adults and Adolescents

Any viral load ≥50 copies/mL is actionable. PEPFAR's approach is detailed in the figure below (Figure 6.4.6.1.1) for any individual with a detectable viral load above 50 cps/ml. Close coordination with the laboratory is needed to quickly identify these individuals. After appropriate interventions, the viral load should be repeated in 3-6 months. Point of care tests, discussed below, may facilitate repeat testing.

*Figure 6.4.6.1.1: Algorithm for ARV Optimization, Clinical Management, and Monitoring of Adults and Adolescents on ART*




There is a body of literature examining the implications of viral loads above the limit of detection, but not reaching the threshold of virologic failure of >1000 cps/mL. Individuals with persistent non-

suppression (more than 1 measurable viral load) are at significant risk for virologic failure,[323] increased all-cause mortality and serious non-AIDS events.[324] Low level viremia (LLV) in the AFRICOS cohort was associated with an increased risk of several NCDs.[325] Definitions of LLV vary in the literature, and the significance of very LLV (50<200 cps/mL) is emerging. Based on data from CNICS, it seems clear that the mortality for individuals increases with the level of LLV.[326]

The suggested management for LLV is outlined above: a quantifiable VL above 50 cps/ml should prompt an evaluation of barriers to treatment, enhanced adherence counseling and a repeat viral load.

Individuals who repeatedly have LLV despite optimized ART regimens and several enhanced adherence interventions may be considered for a regimen switch.

Limits of detection vary by platform and sample type. For example, DBS and PSC sample types and some POC plasma-based platforms have limits of detection ranging between 500 and 900 cps/ml, while plasma samples on most centralized and some POC platforms have limits of detection ranging between <20 to 40 cps/ml. It is expected that the majority of individuals who are undetectable with DBS, PSC, and other higher LOD platforms will also be undetectable using more sensitive assays. PSC, DBS, and POC testing are essential tools for increased access to timely VL testing. If a test result is below the level of detection on a point of care testing platform, repeating the VL test on a different laboratory platform is not recommended. Sections 6.4.5.1 and 6.4.6.3 detail how point of care testing should be used where possible to support VL testing among pregnant and breast-feeding women (PBFW) and virally non-suppressed populations. For PBFW, any measurable viral load requires immediate intervention

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[323] Fleming, J., Mathews, W. C., Rutstein, R. M., Aberg, J., Somboonwit, C., Cheever, L. W., Berry, S. A., Gebo, K. A., Moore, R. D., & HIV Research Network (2019). Low-level viremia and virologic failure in persons with HIV infection treated with antiretroviral therapy. *AIDS (London, England)*, *33*(13), 2005–2012. https://doi.org/10.1097/QAD.0000000000002306

[324] Elvstam, O., Marrone, G., Medstrand, P., Treutiger, C. J., Sönnerborg, A., Gisslén, M., & Björkman, P. (2021). All-Cause Mortality and Serious Non-AIDS Events in Adults With Low-level Human Immunodeficiency Virus Viremia During Combination Antiretroviral Therapy: Results From a Swedish Nationwide Observational Study. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*, *72*(12), 2079–2086. https://doi.org/10.1093/cid/ciaa413

[325] Esber,A et al. CROI 2020 abstract 712 https://www.croiconference.org/abstract/persistent-low-level-viremia-is-associated-with-noninfectious-comorbidities/

[326] Lee, J. S., Cole, S. R., Richardson, D. B., Dittmer, D. P., Miller, W. C., Moore, R. D., Kitahata, M., Mathews, C., Mayer, K., Geng, E., Achenbach, C. J., Eron, J. J., Jr, & Center for AIDS Research Network of Integrated Clinical Systems (2017). Incomplete viral suppression and mortality in HIV patients after antiretroviral therapy initiation. *AIDS (London, England)*, *31*(14), 1989–1997. https://doi.org/10.1097/QAD.0000000000001573

because maximal consistent suppression of maternal VL leads to the lowest risk of vertical transmission.[327,328]

## 6.4.6.2 Virologic Non-Suppression Among Children

Children have lower rates of viral suppression than adults (see Figure 6.4.5.2.2) and any child with known virologic failure requires urgent attention. Programs must immediately ensure all infants and children have access to optimal treatment as well as viral load (VL) monitoring in order to achieve >90% VL coverage, and most importantly for their health and wellbeing, >95% VL suppression. **DTG is the preferred anchor ARV for infants and children ≥4 weeks of age and weighing ≥3 kg,** as recommended by PEPFAR and the July 2021 WHO consolidated guidelines that outlines preferred ART regimens for children (see Figure 6.4.1.2.1 in Section 6.4.1.2).

Programs must ensure that infants and children have access to routine viral load (VL) monitoring services, with appropriate phlebotomy, POC instrument, and/or dried blood sample (DBS) specimen collection materials (Section 6.4.5.2). Programs must also strengthen the management of infants and children with high viral load results, including completion of age-appropriate disclosure and enhanced adherence counselling (EAC) sessions for caregivers and children, repeat viral load testing, and timely switching of ART regimens in accordance with national HIV treatment guidelines. **When a child on first-line ART presents with an elevated VL and is not already on a DTG-based regimen, the child should be immediately switched to a DTG based regimen, before sending the confirmatory VL or starting EAC**. A proportion of children with a detectable VL will become undetectable just by switching them off their NNRTI-based regimen or LPV/r-based regimen. **Children on a DTG-based regimen**

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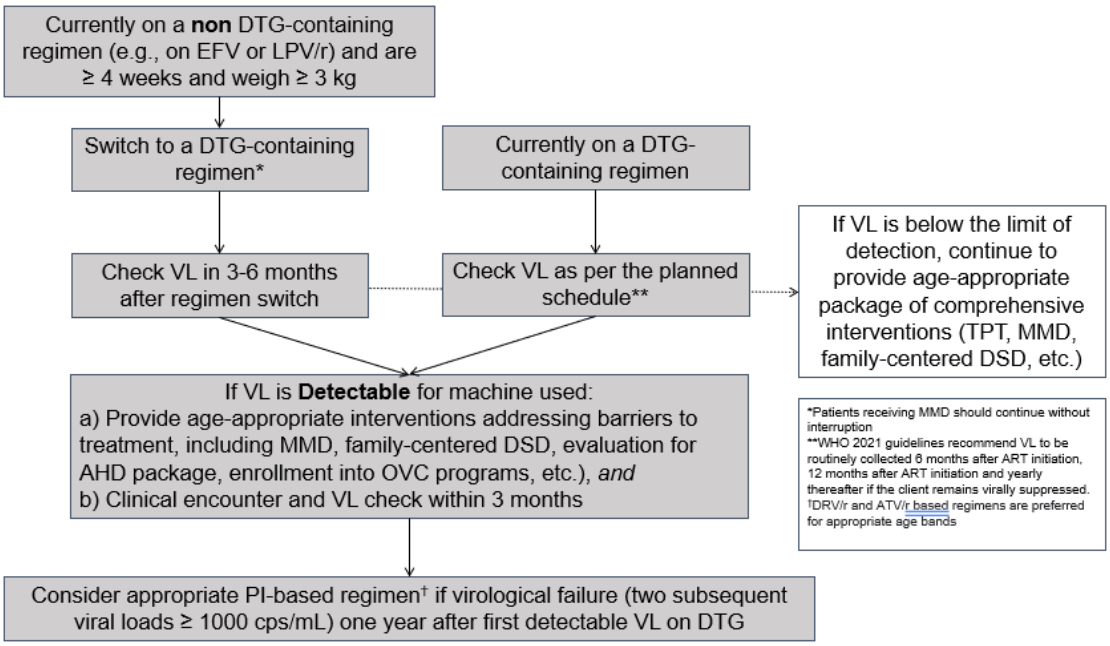
[327] Flynn, P. M., Taha, T. E., Cababasay, M., Fowler, M. G., Mofenson, L. M., Owor, M., Fiscus, S., Stranix-Chibanda, L., Coutsoudis, A., Gnanashanmugam, D., Chakhtoura, N., McCarthy, K., Mukuzunga, C., Makanani, B., Moodley, D., Nematadzira, T., Kusakara, B., Patil, S., Vhembo, T., Bobat, R., … PROMISE Study Team (2018). Prevention of HIV-1 Transmission Through Breastfeeding: Efficacy and Safety of Maternal Antiretroviral Therapy Versus Infant Nevirapine Prophylaxis for Duration of Breastfeeding in HIV-1-Infected Women With High CD4 Cell Count (IMPAACT PROMISE): A Randomized, Open-Label, Clinical Trial. *Journal of acquired immune deficiency syndromes (1999)*, *77*(4), 383–392. https://doi.org/10.1097/QAI.0000000000001612

[328] Flynn, P. M., Taha, T. E., Cababasay, M., Butler, K., Fowler, M. G., Mofenson, L. M., Owor, M., Fiscus, S., Stranix-Chibanda, L., Coutsoudis, A., Gnanashanmugam, D., Chakhtoura, N., McCarthy, K., Frenkel, L., Beck, I., Mukuzunga, C., Makanani, B., Moodley, D., Nematadzira, T., Kusakara, B., … PROMISE Study Team (2021). Association of Maternal Viral Load and CD4 Count With Perinatal HIV-1 Transmission Risk During Breastfeeding in the PROMISE Postpartum Component. *Journal of acquired immune deficiency syndromes (1999)*, *88*(2), 206–213. https://doi.org/10.1097/QAI.0000000000002744

**should have two subsequent VLs ≥1000 cps/mL one year after the first detectable VL on DTG before being switched to a PI-based regimen.** Please see figure 6.4.6.2.1 for further guidance on clinical management and monitoring for infants and children on ART.

*Figure 6.4.6.2.1: ARV optimization, clinical management and monitoring algorithm for infants and children on ART*




Programs should implement mechanisms to empower caregivers to receive timely direct communication from laboratories regarding VL results. Healthcare facilities should continue to use High VL registers that include the age of individuals to tailor client-centered support and management services for infants and children. Programs with EMR capabilities should run high VL queries on a regular basis. Designated clinical staff need to regularly review these registers and provide timely support for all infants and children with high VL results and those at risk for or with previous treatment interruption, delays in repeat VL testing, or requiring a change in treatment regimen.

Additional counseling, support, and treatment literacy should be provided to caregivers when infants or children are initiated on new drugs or formulations, to ensure appropriate administration and adherence. Critical to the care of these infants and children is educating caregivers on the importance of adhering to a correct treatment regimen (including appropriate ART dose and timing), the importance of routine VL testing, and providing anticipatory guidance

on the formulation/dose required as infants and children grow. Continuous QI approaches and site level data audits have been used to identify and ensure VL testing is up to date.

Disclosure support for caregivers and children, linkage to caregiver or child peer support programs, and strong collaboration with OVC programs are important interventions that can help maximize adherence among C/ALHIV (see *Operation Triple* Zero[329] and *Zvandiri*[330] in PEPFAR Solutions[331]). See Section 6.1.3.1 on adherence support for children and families. See EGPAF toolkit[332] on disclosure support for children. Health literacy about viral load is key for caregivers and disclosed children and should be integrated into routine pediatric and adolescent service delivery. Case management approaches utilized by OVC programs have shown promise in improving treatment linkage and viral suppression outcomes among enrolled C/ALHIV 0-17 years of age by providing comprehensive care tailored to families and children to address treatment, adherence, disclosure, and other needs. As countries develop systems and procedures to increase enrollment of C/ALHIV into OVC programs, children, and adolescents with high VL should be prioritized as well as families with parents with unsuppressed VL.

### 6.4.6.3 Use of Point-of-Care Platforms for Viral Load Testing in Virally Non-suppressed Patients

Both programmatic data and information from the published literature suggest that few individuals receive a second viral load. For example, a study by Médecins Sans Frontières on viral load treatment algorithm in six countries and among 149 clinical sites showed that only 52% of the virally non-suppressed patients received a second or follow-up VL.[333] Data gathered from national HIV dashboards of three countries showed that despite high VL coverage and suppression, less than 10% of individuals with non-suppressed VL underwent adherence

[329] PEPFAR Solutions. Operation Triple Zero: Empowering Adolescents and Young People Living with HIV to Take Control of Their Health in Kenya. Washington, DC: PEPFAR Solutions; 2018

[330] PEPFAR Solutions. Zvandiri: Peer Counseling to Improve Adolescent HIV Care and Support. Washington, DC: PEPFAR Solutions; 2018.

[331] PEPFAR Solutions. Applying a Quality Improvement Approach at Scale to Deliver Client - Centered Interventions that Significantly Improved Outcomes of People Living with HIV in Uganda Washington, DC: PEPFAR Solutions; 2018.

[332] Elizabeth Glaser Pediatric AIDS Foundation. Disclosure of HIV Status Toolkit for Pediatric and Adolescent Populations Washington, DC: PEPFAR Solutions; 2018.

[333] MSF (2016) https://msfaccess.org/making-viral-load-routine

counselling and received the recommended follow-up viral load test.[334] Some individuals may be experiencing a prolonged period of viremia with its attendant health challenges.

Point of care (POC) viral load tests or improved transport and communication of results is critical to ensuring access to VL re-testing in non- suppressed individuals or in settings where prompt identification of viremia is critical, such as in pregnant and breastfeeding women. The first randomized, controlled implementation trial of POC HIV viral load testing in South Africa demonstrated an increase in viral suppression and retention in care after a year in those who received the test.[335] Using POC viral load may mitigate logistical difficulties associated with long distances between facilities and testing laboratories and will result in shorter turnaround time for results and shorter time to clinical action when virologic non-suppression is detected. Facilities should continue to take proactive measures in addition to utilizing POC to ensure results are returned to patients promptly. A retrospective analysis across 7 countries (Cameroon, DRC, Kenya, Malawi, Senegal, Tanzania, and Zimbabwe) found that POC viral load was consistently associated with shorter turnaround times both for results receipt at the clinic and by the patient but found that only 48% of patients with an elevated viral load result received a clinical action during the 90-day follow-up period even when nearly half of POC results were available at the clinic on the same day.[336] Programmatic efforts should be prioritized to reduce TAT and ensure timely clinical action in addition to use of POC.

## 6.4.7 Monitoring for HIV Drug Resistance (HIVDR)

Summary of section edits:

- Wording was updated to better reflect current CADRE protocol.

[334] WHO (2019) https://www.who.int/hiv/pub/vct/hiv-molecular-diagnostic/en/
[335] Paul et al. (2019) http://www.croiconference.org/sessions/point-care-viral-load-testing-improves-hiv-viral-suppression-and-retention-care
[336] Boeke et al. (2021) https://onlinelibrary.wiley.com/doi/epdf/10.1002/jia2.25663

Data support transition to TLD regardless of viral load (VL) suppression or the presence of dual NRTI resistance.[337,338,339] Failure with INSTI related drug resistance mutations among patients not virologically suppressed on a DTG-based regimen has been reported but at very low rates in the setting of inadequate dosing of DTG with TB treatment or after exposure to raltegravir.[340]

Given that TLD is used for first- and second-line regimens in PEPFAR-supported countries for individuals >30 kg, and DTG regimens are used for all children older than 4 weeks and 3 kg, the PEPFAR HIVDR monitoring strategy focuses on detecting DTG resistance in adults and children with a high viral load on DTG containing regimens.[341] The goal is to ensure the durability of DTG containing regimens, inform ART regimen switch algorithms, and provide guidance for the clinical management of the anticipated small proportion of patients who may not achieve virologic suppression on these regimens.

HIVDR monitoring activities supported by PEPFAR should include children in all sampling cohorts and:

1) Use VL remnant samples routinely collected for patient care
2) Obtain samples and minimal epidemiologic data from laboratory platforms, where possible, using the Cyclical Acquired Drug Resistance Patient Monitoring approach (CADRE; Figure 6.1). Specifically, the methodology should:
    a. Focus on sampling remnant viral load specimens with ≥1000 c/ml of individuals with two or more high viral load (virological failure) after at least 9 months on TLD or another dolutegravir-based regimen. If viral loads in any individual patient cannot be tracked longitudinally, consider sampling from any viral load >1000 copies/mL after at least 9 months on TLD.

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[337] Paton, N.I., et al., Dolutegravir or Darunavir in Combination with Zidovudine or Tenofovir to Treat HIV. New England Journal of Medicine, 2021. 385(4): p. 330-341.
[338] Keene, C.M., et al., Virologic efficacy of tenofovir, lamivudine and dolutegravir as second-line antiretroviral therapy in adults failing a tenofovir-based first-line regimen. AIDS, 2021. 35(9): p. 1423-1432.
[339] da Silva J, Siberry G, Godfrey C, Phillips A, Raizes E. Dual NRTI resistance expected to have limited impact in overall viral suppression rates post-TLD transition. XXVIII International Workshop on HIV Drug Resistance and Treatment Strategies; Johannesburg, South Africa 2019
[340] Saladini F, Giannini A, Boccuto A, Dragoni F, Appendino A, Albanesi E, et al. Comparable in vitro activity of second-generation HIV-1 integrase strand transfer inhibitors (INSTIs) on HIV-1 clinical isolates with INSTI resistance mutations. Antimicrobial agents and chemotherapy. 2019. Epub 2019/10/16. doi: 10.1128/aac.01717-19. PubMed PMID: 31611362.
[341] da Silva, J., et al., Monitoring Emerging Human Immunodeficiency Virus Drug Resistance in Sub-Saharan Africa in the Era of Dolutegravir. The Journal of Infectious Diseases, 2021

b. Randomly select laboratories from a framework of all laboratories conducting viral load testing in country.

c. Collect a set of minimal epidemiologic data that allow programs to understand who is being affected by emerging drug resistance (age, gender, ARV regimen, time on ARVs).

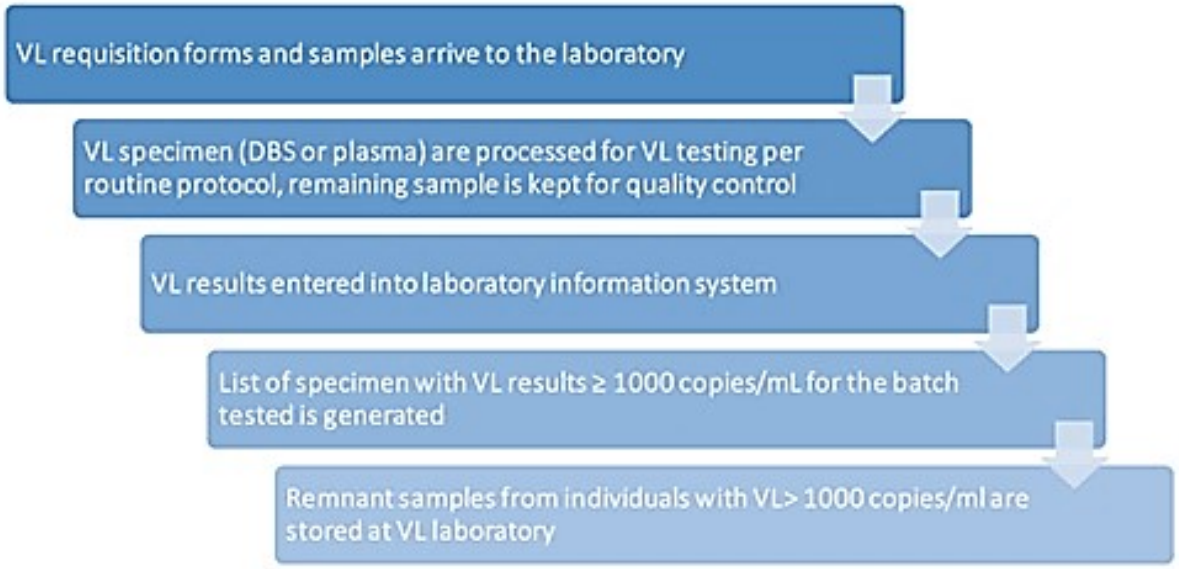
3) Limit monitoring to persons on TLD and other dolutegravir-based regimens as the prevalence and pattern of HIVDR for persons failing NNRTI (i.e., efavirenz and nevirapine) and PI-based regimens has already been established.

4) Prioritize detection of INSTI drug resistance mutations.

5) Incur minimal additional data collection or other burden to programs.

Pre-treatment and transmitted drug resistance (PDR and TDR) surveys are not supported except if utilizing residual specimens from other activities such as the Tracking with Recency Assays to Control the Epidemic (TRACE) initiative or the Population-based HIV Impact Assessments (PHIAs). Broader PDR and TDR surveys may be considered if and when there is emergence of acquired drug resistance to integrase inhibitors (i.e., DTG) in the programmatic setting. Figure 6.4.7.1 describes the PEPFAR CADRE strategy.

*Figure 6.4.7.1: Cyclical Acquired Drug Resistance Patient Monitoring Approach (CADRE)*



## 6.4.8 Integrated Women's Health

Summary of section edits:

- Tenofovir, lamivudine, and dolutegravir (TLD) regimen language was updated.

Women have the right to access the full range of contraceptive options for any reproductive needs they may have throughout their lifetime. Many regions with high HIV burden have high unmet contraceptive need, which can lead to unintended pregnancies, increased rates of maternal morbidity and mortality, and poor sexual and reproductive health outcomes.[342] Comprehensive sexual and reproductive health services for PEPFAR programs should include access to a wide range of contraceptive choices, including protective barrier methods, in addition to immediate access to combination prevention strategies, such as condoms and pre-exposure prophylaxis (PrEP), to prevent the spread of HIV.

Increasing evidence has found integrated family planning and HIV service delivery is critical to both reduce vertical transmission of HIV and prevent unintended pregnancies.[343] The WHO released New Recommendations for Contraception for Women at High Risk of HIV affirming the following principles:[344]

- A woman's risk of HIV does not restrict her contraceptive choice.
- Women at a high risk of HIV infection are eligible to use all hormonal contraceptive methods and intrauterine devices (IUDs) without restriction (MEC Category I).
- Efforts to expand contraceptive method options and ensure full and equitable access to voluntary family planning services must continue.
- Renewed emphasis on HIV and STI prevention services is urgently needed.

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[342] Mayondi GK, Wirth K, Morroni C, Moyo S, Ajibola G, Diseko M, et al. Unintended pregnancy, contraceptive use, and childbearing desires among HIV-infected and HIV-uninfected women in Botswana: across-sectional study. BMC Public Health. 2015 Dec;16(1):44.

[343] Wilcher, Rose; Hoke, Theresa; Adamchak, Susan E.; Cates, Willard Jr Integration of family planning into HIV services, AIDS: October 2013 - Volume 27 - Issue - p S65-S75

[344] WHO. (2019). Contraceptive eligibility for women at high risk of HIV. World Health Organization. https://apps.who.int/iris/bitstream/handle/10665/326653/9789241550574-eng.pdf;jsessionid=F75B2DA4E583E94BE029D931C7FCE755?ua=1

Under the Fast-Track strategy to end the AIDS epidemic by 2030, the newly adopted UNAIDS interim targets for 2025 outline a clear vision for holistic, integrated, client-centered HIV care.[345] Recognizing the critical contribution comprehensive HIV and reproductive health services make to reaching epidemic control, the interim targets explicitly outline a new 95 target: 95% of women access HIV and reproductive health services.[346] To this end, PEPFAR programs should look for innovative approaches for expanding HIV prevention options for women at high risk of acquiring HIV. This should include integration of HIV testing services (HTS) within FP settings and scale up of women's access to FP and HIV prevention services, including PrEP, with a focus on reaching AGYW, in high HIV prevalence settings. FP services should also be coordinated with scheduled ART visits, where feasible. Programs should review (Section 6.6.2) to ensure that a strengthened continuum of response between GBV prevention and clinical post-violence response services is integrated into the HIV cascade, including the provision of post-exposure prophylaxis (PEP) and emergency contraception.

PEPFAR programs need country specific supportive tools and guidance to operationalize standardized national, facility and patient-level HIV and FP messaging. This messaging will be adaptive and address all women living with HIV (WLHIV) who may need access to voluntary contraception, and safer conception education and counseling, when a pregnancy is desired.

Voluntarism and informed choice are key principles for all USG FP and HIV programs, in every health care setting. Denying a client, a benefit, such as refusing to provide ART unless the client uses contraception, may coerce an unwilling client to use contraception. Conditioning any ART provision on contraceptive use (including a particular type of contraceptive method) raises compliance concerns under U.S. government law and policy and violates quality of care standards for FP programs. The WHO 2021 HIV treatment guidelines emphasize the importance of providing women clear information about potential benefits and potential risks of any medication, including ART. According to WHO guidelines, Tenofovir, Lamivudine, and Dolutegravir (TLD) is the preferred first-line regimen for all people living with HIV, including women of childbearing potential because of improved tolerability, greater efficacy and the absence of increased neural tube defects risk associated with dolutegravir use around

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[345] UNAIDS. 2025 AIDS Targets (2021)

[346] Ibid. https://aidstargets2025.unaids.org/#:~:text=The%202025%20targets%20prioritize%20sexual,to%20life%2Dsaving%20treatment%20services.

conception [347,348,349] Women in PEPFAR programs should receive comprehensive counseling and be supported to choose the ART regimen that works best for them. Family planning services should be safe, effective, timely, accessible, and tailored to meet individual client needs.

**Integration of Contraceptive Care/Family Planning into DSD Models**

WLHIV should be eligible to participate in differentiated service delivery models of care, receive multi-month dispensing (MMD) of ART, and visit health care facilities less frequently. WLHIV should also receive a multiple month supply of their family planning method. This is particularly relevant during the ongoing COVID-19 pandemic as lockdowns and other mitigation measures hinder frequent contact with health facilities. For women who have chosen a long-acting reversible contraceptive (LARC), such as an implant or IUD, no further intervention is needed (until such time that removal of the device is requested or required). However, for women who have chosen a short-acting method (such as pills or an injectable) the client-centered goal would ideally be to align their method refills to their ART visits or leverage MMD regimens, where available and feasible in each OU for pregnancy prevention; however, use of condoms is recommended for STI prevention.

**FP/HIV Programming Opportunities**

The following considerations may be useful when considering how to work with country governments to expand access to high quality FP information and services through PEPFAR supported activities, including prevention, care, and treatment interventions.

- HIV service providers should be trained in and receive supportive supervision on FP service delivery, including client-centered counseling and provision/removal of short- and long-acting contraceptive methods, and referrals for methods that may not be available at an HIV service delivery point, such as permanent methods. HIV settings that offer FP services should be equipped to offer them according to global and national standards, including having private spaces for screening, counseling, and method provision as well as having necessary instruments and medical equipment

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[347] Policy brief: update of recommendations on first-and second-line antiretroviral regimens. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/325892, accessed 1 June 2021).
[348] Zash. AIDS 2020. Abstr OAXLB0102.
[349] Zash et al, IAS 2022. Abstract PELBB02

- If HIV providers are not able to offer high quality FP services, they should provide referrals to sites that have trained providers and a range of contraceptive methods available
- HIV providers should have the capacity to track essential FP indicators and contraceptive stock information for national and sub-national data collection
- Contraceptive commodity needs of WLHIV in ART sites should be quantified in national FP forecasting efforts to ensure appropriate ordering and distribution of commodities
- FP integration targets should be set and tracked for all PEPFAR-supported sites through FPINT_SITE and custom FP service delivery indicators.

## 6.5 PEPFAR's Key Populations Approach and Strategy

Summary of section edits:

- Wording was updated to delete the reference to an illustrative table.I

According to the UNAIDS 2021 Global AIDS Update, at the end of 2019, individuals from key populations[350] and their sexual partners were estimated to account for the majority (65%) of new HIV infections globally and are 25-35 times more likely to acquire HIV than non-key populations.[351] The new Global AIDS Strategy and subsequent political declaration by member states emphasize the achievement of 95-95-95 goals in all subpopulations, including and especially key populations.[352] In order to advance epidemic control, PEPFAR teams should reach, provide prevention interventions, test, treat and ensure treatment continuity for key populations to achieve durable, undetectable viral load (VL) among key populations themselves, as well as to strengthen engagement with their partners and other people in their social and sexual networks, and strengthen the access of these individuals to HIV services. Important components of all KP programs include:

[350] "Key populations" throughout this guidance refers to sex workers, gay men and other men who have sex with men, transgender people, people who inject drugs and people in prisons and other enclosed settings.
[351] https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update
[352] https://www.unaids.org/sites/default/files/2025-AIDS-Targets_en.pdf

- Scaling up differentiated, person-centered HIV prevention, diagnosis, and treatment services, utilizing a case management approach, where desired by KP, to ensure each individual receives all needed services.
- Partnering with community and civil society groups to improve the quality of KP programs and service delivery organizations.
- Mentoring, building capacity of, and increasing funding to, nascent KP-led service delivery organizations.
- Addressing the broader enabling, legal and policy environment, including reducing stigma and discrimination present in public and private HIV and other service settings, strengthening the KP-competency of service delivery providers, and ensuring zero-tolerance policies regarding discrimination among PEPFAR-funded staff and partners. This work requires linkage to and strong coordination with other USG agencies whose focus is on strengthening democracy and human rights. The inability to address the above issues will prevent scale up of key populations services. Addressing and preventing violence and various forms of abuse against key populations.

- Ensuring each country in which PEPFAR operates is utilizing confidential, high-quality, accurate and safely collected and securely stored data to understand the size of key populations groups, their risk of HIV acquisition and onward transmission and service delivery coverage along the cascade, in order to inform resource allocation and programming.
- Ensuring strong coordination with other PEPFAR program areas, including DREAMS, OVC, labs and pediatrics and the enabling systems and policies necessary to fund these targeted services and ensure the availability of drugs and commodities to KP differentiated sites such as community-based service points.
- Ensuring strong coordination with other partners and donors to build a high quality, sustainable KP program at the national level.

Teams should also reference 2016 and forthcoming 2022 WHO Consolidated Guidelines on HIV Prevention Diagnosis, Treatment and Care for Key Populations and key population-specific implementation toolkits.[353]

**What's New for Key Populations COP Guidance in COP22**

- Strengthened, practical definition and approach for KP Competency
- Code of conduct and elaboration of a do no harm approach
- Strengthened content related to programming for transgender individuals, people in prisons and other enclosed settings, adolescent and young key populations and structural interventions
- Minimum Requirements of PEPFAR Key Populations Programming. (See list below)

**Minimum Requirements/Expectations of PEPFAR Key Populations Programs**

1. OUs will be expected in COP/ROP22 discussions and SDSs to document the trajectory of KP budget and expenditures over the prior two COP cycles utilizing PEPFAR financial classification system.

2. Greater commitment to regular and safe key populations size estimation exercises as part of PEPFAR's planning cycle in all countries with updates for new data and methods, where PSE are conducted separately from BBS, they should be conducted every 2-5 years. In intervening years, PSE and BBS data should be triangulated with program data. Mathematical and statistical models estimating population size should be updated as needed, as they are for generalized population estimates.

3. Establishment of an independent PEPFAR-funded KP community consortium where/if it does not already exist, in collaboration with diverse stakeholders; emphasis should be on avoiding the creation of duplicative or parallel systems, and on ensuring there is regular engagement with KP communities in the geographies where PEPFAR works and with the national program.

4. PEPFAR remains committed to its affirming 'do no harm' principle that emphasizes voluntary, confidential, non-judgmental, non-coercive, and non-discriminatory services. Additionally, this

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[353] TRANSIT: http://www.who.int/hiv/pub/toolkits/transgender-implementation-tool/en/
IDUIT: http://www.who.int/hiv/pub/idu/hiv-hcv-idu/en/
SWIT: http://www.who.int/hiv/pub/sti/sex_worker_implementation/en/
MSMIT: http://www.who.int/hiv/pub/toolkits/msm-implementation-tool/en/

includes a focus on all activities related to data collection, analysis and use of strategic information and data on key populations. All implementing partners (IPs) and their staff will be required to sign and abide to a code of conduct regarding ethical, non-discriminatory service provision for key populations.

5. OU Community-led Monitoring activities must include provision for distinct participation and leadership of key populations

6. Provision of integrated KP-competent public and private service delivery that provides the opportunity for person-centered prevention, care, and treatment for the multitude of issues affecting key populations. Emphasis is placed on integrated services that facilitate access to and continuity of services.

7. Each OU that serves key populations will submit, as part of its formal COP submission, a table or other visualization that details how the OU's key populations program will ensure a comprehensive, integrated service package, guided by WHO guidelines, for each key population group. The table will indicate:

- Specific key populations sub-groups served including geographic variations
- Specific prevention, testing, treatment, and structural interventions, by implementing partner, and where not financed by PEPFAR, the collaborating organizations
- Clear mapping of intervention, partner, geography and expected indicators to report

8. Development of risk mitigation and continuity plans to ensure the safety and security for KP clients and organizations and related data in the event of political upheaval and/or violence directed at key populations.

9. Articulation of a remuneration standard for peer outreach workers/navigators, to ensure decent work and fair pay is provided. See Section 6.6.7 on Optimizing HRH Staffing for Maximum Impact and Sustainability for more details.

## 6.5.1 Providing Quality, Person-Centered HIV Services with Key Populations in Prevention, Diagnosis, Treatment, and Care

Summary of section edits:

- Language on PEPFAR's opposition to so-called "conversion therapy" was enhanced, in line with the June 2022 White House Executive Order.

PEPFAR's overall approach to key populations HIV service delivery emphasizes people-centered and differentiated service delivery that meets the specific needs and addresses barriers that KP encounter across the entire HIV cascade. Key populations often require differentiated service delivery, with support for public and private health care facilities to deliver KP-competent, KP-led, and community-based models of care which allow them to access services outside of general facilities, if desired.

Current success stories for differentiated models are highlighted in the International AIDS Society's Differentiated Service Delivery: A Decision Framework for Differentiated Antiretroviral Therapy for Key Populations, as well as a recent virtual workshop.[354] These resources feature a number of PEPFAR-supported interventions, and consider the who, what, where, and when of key populations HIV service delivery. Critical components of KP differentiated service delivery models, include targeted prevention and treatment case management teams, peer-led interventions, drop-in centers and other community-based service and commodity pick-up points, and other person-centered approaches described throughout these two specific resources.

PEPFAR requires evidence-based interventions and data-driven decision making. Interventions that are not evidence-based are not permitted. Specifically, there have been allegations of PEPFAR support for so-called "conversion therapy" in several countries. PEPFAR unequivocally opposes this practice. Conversion therapy is not evidence-based, has been discredited, and is not aligned with PEPFAR's vision of person-centered, non-discriminatory services that promote equity and reduce inequality.[355] Additionally, the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals[356] directs agencies to ensure that United States foreign assistance programs do not use foreign assistance funds for so-called conversion therapy. In addition, referral to so-called conversion-therapy programs, even where not financed by PEPFAR, is not an acceptable component of any PEPFAR program. See Section 6.6.2 on Gender Equality for more information on PEPFAR's commitment

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[354] https://differentiatedservicedelivery.org/Portals/0/adam/Content/2a0WxWUHfUKtul1mKWdmGQ/File/Decision%20Framework%20Key%20Population%20Web_Post_Conference_FINAL.pdf

[355] The Human Rights Campaign maintains a listing of policy and position statements from leading medical, pediatric and psychological associations: https://www.hrc.org/resources/policy-and-position-statements-on-conversion-therapy

[356] https://www.whitehouse.gov/briefing-room/presidential-actions/2022/06/15/executive-order-on-advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals/

to advancing gender equality for key populations and gender and sexual minorities within HIV programs and services.

**Working with Community & Civil Society to Strengthen Programs**

UNAIDS recognizes that "when communities organize and people empower each other, oppression can be replaced by rights and access to HIV services can be accelerated. Community leadership in the AIDS response helps to ensure that HIV services are relevant to, and reach, the people who need them the most."[357] For key populations, community leadership is even more impactful. Highly marginalized and often living in criminalized settings, many key populations are challenged to access basic health services for fear of stigma, discrimination, and violence. For this reason, key populations themselves are best positioned to advise PEPFAR programs on how best to provide services appropriate to their communities.

A best practice for PEPFAR teams that has emerged through the Key Populations Investment Fund (KPIF) and previous work is explicit support, financial or otherwise, to establish and maintain fora, consortia or other bodies that convene, on a routine basis, representatives of key populations communities and organizations at the national level to advise PEPFAR teams and the national program on key populations programs, priorities, initiatives, data, and other concerns. PEPFAR should work with KP advocacy communities and other development partners to support such entities, as a means for greater KP leadership in PEPFAR processes.

Meaningful engagement of "KP-led" and "KP-competent" CSOs is vital to the success of any PEPFAR KP program. "KP-competent" organizations have specific aptitudes to serve KP communities and is further defined and discussed in the below section.

**Promoting KP Competency and Leadership in Programs**

PEPFAR is committed to engaging KP-led and KP-competent organizations as the primary implementers of KP programming. This engagement includes support of capacity strengthening activities for existing KP-led organizations to be able to effectively implement these programs, and/or encouraging implementing partners to have more KP leaders in leadership capacities.

A KP-led organization is defined as an organization with which the majority of leadership/ decision-making staff identify as members, or former members, of the KP communities they serve. A KP-led organization is more likely to be KP-competent, although that may not always

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[357] https://www.unaids.org/sites/default/files/media_asset/JC2236_guidance_partnership_civilsociety_en_0.pdf

be the case. PEPFAR has developed, with input from KP community stakeholders from various local contexts, a minimum operating standard for what constitutes a KP-competent organization (see Figure 6.5.1.1 below). Local partners, along with input from CSOs and KP community members, should build upon this minimum operating standard to define KP competency within their local context. It is of utmost importance to engage KP-competent and /or KP-led organizations to assist Ministry of Health-focused health facility and community programs to provide and expand training for KP providers on person-centered services for key populations.

*Figure 6.5.1.1: Competency Minimum Required Standards for all Implementing Partners Serving Key Populations*

**KP-Competency Minimum Required Standards for all Implementing Partners Serving Key Populations**

1. **Organizational Composition**
   1.1. Affirms human rights of KP through their stated organizational mission/vision
   1.2. Demonstrates substantial and increasing leadership involved in policy setting, governance and programmatic decision-making are members, or former members, of the KP community served by the organization. The organization includes and respects the input of KP leaders in organizational and program management.
2. **Prioritization of Privacy and Security**
   2.1. The organization has documented policies that set standards for and emphasize the importance of maintaining confidentiality and privacy of clients
   2.2. All staff, including peers, are trained and required to maintain client confidentiality, safety, and security, as well as risk mitigation*
3. **Commitment to Affirming and Promoting the Dignity and Human Rights of KP**
   3.1. All staff receive relevant KP sensitization training, based on all the key population(s) they serve*
   3.2. The organization provides non-judgmental and non-stigmatizing services to all clients, including key population members, which also assist clients in knowing their rights
   3.3. The organization commits to delivery of services based on harm reduction principles without judgement, coercion, discrimination, or requiring that clients stop related behavior.
   3.4. The organization has formal systems to respond and react to stigma, discrimination and violence that may occur in health and other social service settings – both meeting client's needs and addressing structural barriers (See Section 6.5.1.4 on Structural Interventions and Section 6.6.2 on Gender Based Violence)
4. **Capacity to Meet the Health Needs of KP**
   4.1. The organization provides minimum package of evidence-based services that meet the needs of KP.
   4.2. The organization ensures cultural, geographic, linguistic, financial, and procedural accessibility to KP services – as determined in consultation with local KP communities.
   4.3. The organization has recognized legitimacy as an advocate for key populations and ability to mobilize KP in collaboration with KP CSOs
   4.4. The organization has strong financial management procedures and policies that establish the ability to manage grants
   4.5. The organization's KP peer ratio to KP reached is sufficient and in line with global/national recommendations, peer workers receive fair remuneration, there is an explicit plan for peer progression and professional development, peers influence the implementation of interventions

***Trainings must be recognized/approved by PEPFAR**

As outlined above, KP-competency as an organizational quality is comprised of different organizational characteristics, demonstrated capacities, and priorities and commitments put into practice. The outlined criteria for KP-competency should also be considered for sites funded by private sector donors. Each of these elements can be objectively assessed and if necessary, practical steps taken to cultivate and improve these competencies.

In addition to the minimum operating standard outlined above, the full criteria for what constitutes a KP-competent organization in a particular OU should be context-specific and defined with input from local stakeholders. The elements above are not exhaustive but are meant to serve as a starting point for consideration.

### 6.5.1.1 Prevention for Key Populations

Summary of section edits:

- Language on PEPFAR's opposition to so-called "conversion therapy" was enhanced, in line with the June 2022 White House Executive Order.
- Wording was added to reflect the FDA approval of long-acting injectable cabotegravir.
- Changes were made to reflect recently released WHO consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment, and care for key populations.

HIV programs for key populations should employ combination HIV prevention approaches linked to immediate access to treatment and care, tailoring a package of services to specific needs and context of the target communities and sub-populations in alignment with WHO Consolidated HIV Guidelines for Key Populations. Combination HIV prevention blends behavioral, biomedical, and structural approaches to reduce the number of new HIV infections. Prevention interventions for key populations include HIV testing, PrEP, post exposure prophylaxis (PEP), STI diagnosis and treatment, condoms, both outer ("male") and inner ("female"), and lubricant programming, opioid agonist therapy (OAT), and risk reduction counseling, mental health services, violence prevention and response, and support to address substance use, misuse, and addictive disease. These are targeted to providing improved access to key populations for their HIV-related prevention and treatment to ensure improved health and quality of life outcomes which are further described in this document. PEPFAR teams that serve young adult women at high risk should ensure coordination between KP and DREAMS partners so that these women are able to access the most comprehensive and appropriate services according to their unique needs. Factors to consider include age, type of programming needed to best serve these women, and IP capabilities to handle the special needs of these populations (See Section 6.2.2.2 for The DREAMS Partnership). In addition, essential strategies to support and enabling environment are key to a successful KP prevention program and are outlined in the Structural Interventions Section 6.5.1.4.

2022 WHO KP guidelines[358] note that "policy-makers and providers should be aware that counselling behavioral interventions that aim to change behaviors to reduce risks associated with these infections for key populations have not been shown to have an effect on HIV, viral hepatitis and STI incidence nor on risk behavior such as condom use and needle sharing." However, it was further noted that "counselling and information-sharing, not aimed at changing behaviors, can be a key component of engagement with key populations, and when provided it should be in a non-judgmental manner, alongside other prevention interventions and with involvement of peers." Further, it should be noted that the guideline is focused on behavior change interventions to reduce risk but does not address behavioral interventions to promote uptake of services.

WHO guidance also notes that counselling interventions which promote “rehabilitation” or “conversion” of key populations are not recommended. These interventions are not to be supported by PEPFAR funds. These practices are against human rights and medical ethics principals of consent, freedom from arbitrary arrest, access to quality health, freedom from torture and cruel, inhuman, and degrading treatment.

In addition, PEPFAR recommends funding and implementing structural interventions that mitigate structural and social barriers, and promote the inherent dignity of key populations, as a crucial component of our efforts; these may enable stronger outcomes from behavioral interventions that seek to increase access or uptake of services.

**PrEP for Key Populations**

PEPFAR KP programs have been at the forefront of expanding access to PrEP; however, there is more work needed to ensure PrEP is scaled and made available to every KP who is at continued risk. COP 22 will seek to scale up PrEP. To achieve this differentiated service delivery, models for PrEP initiation, refill and continuation including implementation in more

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[358] Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2022.

localized health facilities, integration into other health services, through community-based organizations and private providers are essential to moving services closer to clients and expanding access to the highest risk communities. Program adjustments catalyzed by COVID-19, such as home PrEP delivery, virtual adherence support, contactless initiation, and multi-month dispensing, are all key innovations that have improved access and continuity of treatment. Community models for the differentiated service delivery of oral PrEP and the dispensing of oral PrEP within the community are a vital component to ensure wider access to oral PrEP and scale uptake and impact. Also important is support for innovations in PrEP administration, such as long-acting injectables. Preliminary work to prepare for the launch and scale-up of additional PrEP tools is critical for key populations.

Adherence to daily oral PrEP can be a challenge for many key populations. Fortunately, several effective alternatives are entering the market. Innovations like the vaginal PrEP ring may be considered as an additional option for cisgender women, including FSW and female PWID, at substantial risk of HIV. Long-acting injectable cabotegravir (CAB-LA) has received FDA approval during COP22 and may further expand potential opportunities for increasing access and continuity of PrEP services for key populations. Event driven (ED)-PrEP is an additional dosing option for MSM which may increase oral PrEP uptake and continuation as well. The regimen consists of the use of a double dose (2 pills, which serves as the loading dose) of a tenofovir-containing regimen (TDF/FTC or TDF/3TC) between 2 and 24 hours **in advance** of sex; then a third pill 24 hours after the first dose of 2 pills was taken and a fourth pill 24 hours after the third pill was taken (i.e., 2+1+1).

At this time, there is evidence on safety and efficacy/effectiveness for ED PrEP only for men who have sex with men (men exposed through receptive or insertive anal sex with other men).[359,360,361] ED-PrEP is not currently considered as a dosing strategy for transgender women and men who have vaginal and/or anal sex with women. Evidence does not support this dosing strategy for cisgender women. PrEP providers should ensure that these populations are offered

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[359] Glidden DV, Anderson PL, Grant RM. PharmacologysupportsonDemandPrEP.LancetHIV.2016;3(9):e405–e6.
[360] Seifert SM, Glidden DV, Meditz AL, Castillo-Mancilla J R, Gardner EM, Predhomme J et al. Dose response for starting and stopping HIV preexposure prophylaxis for men who have sex with men. Clin Infect Dis. 2015;60(5):804–10.
[361] Arcia Lerma JG, Cong ME, Mitchell J, Young Shpairo j AS, Zheng Q, Masciotra S et al. Intermittent prophylaxis with oral truvada protects macaques from rectal SHIV infection. Sci Transl Med. 2010;2(14):14ra4.

daily dosing. ED-PrEP dosing is currently under review by WHO and in all cases, programs should ensure they are aware of the latest WHO guidelines.

Gender affirming care, including gender affirming hormone therapy (GAHT), is an important component of transgender friendly care, and can improve access and uptake of PrEP for transgender (TG) individuals. In Vietnam, for example, the number of transgender women on oral PrEP nearly quadrupled when information on oral PrEP and gender-affirming hormones, hormone testing, and counseling became available at KP-clinics. Meeting the broader health and social needs of transgender individuals is vital to engage these communities as evidence suggests a comprehensive approach is consistent with stronger HIV outcomes. Qualitative research also suggests that provision of GAHT with PrEP services would increase acceptability of PrEP for transgender women.[362,363] Where possible, PEPFAR programs should leverage provision of GAHT services to increase uptake of HIV services, utilizing an approach that coordinates resources from different sources, aligns with country government policies and funder mandates to provide optimal service, and considers the sustainability of these services.

Current information available suggests that there are no significant interactions between oral PrEP medicines and hormone therapy.[364] Some factors that contribute to low continuity and adherence to oral PrEP particularly among FSW, include mobility as well as stigma associated to ARVs in packaging that is almost identical to ARVs used for treatment. To address these challenges, programs are encouraged to provide intensified adherence counseling and quarterly testing for those retained on oral PrEP in addition to expansion of differentiated service delivery models. Alternative oral PrEP packaging including discreet pill cases and messaging on empowerment and protection should also be implemented to avoid confusion with ARVs for HIV treatment and facilitate associations with self-care and prevention. In addition, pregnant and breastfeeding FSW are also a priority sub-population for PrEP services since HIV incident infection in these women puts them at high risk for transmission of HIV to their infants.

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[362] Sevelius, J. M., Keatley, J., Calma, N., & Arnold, E. (2016). 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women. *Global Public Health*, *11*(7–8), 1060–1075.
[363] Sevelius, J. M., Deutsch, M. B., & Grant, R. (2016). The future of PrEP among transgender women: the critical role of gender affirmation in research and clinical practices. *Journal of the International AIDS Society*, *19*, 21105.
[364] Jenna L. Yager & Peter L. Anderson (2020) Pharmacology and drug interactions with HIV PrEP in transgender persons receiving gender affirming hormone therapy, Expert Opinion on Drug Metabolism & Toxicology, 16:6, 463-474, DOI: 10.1080/17425255.2020.1752662

WHO recommends PrEP should also be considered and included as part of a comprehensive prevention package for PWID and people in prisons or enclosed settings who are at substantial risk.[365] Data on the use of PrEP to prevent HIV from parenteral exposure come from the Bangkok study which was a randomized double-blind study of tenofovir alone in 2,413 participants enrolled between 2005 and 2010. That study documented a nearly 50% reduction in HIV incidence.[366] In a separate analysis the authors concluded that adherence improved outcomes, however one of the arms included daily directly observed therapy.[367] Male and female PWIDs are at risk for acquiring and transmitting HIV through high-risk sexual behaviors. Research has documented that concurrent sexual partners are common in the PWID community and dense networks of sexual partners are common. Transactional sex as well as coercive sex and sexual violence are well described particularly among women who inject drugs.[368,369] For these reasons daily PrEP may be an appropriate intervention. The data on the effectiveness of post exposure prophylaxis after parenteral exposure is derived from occupational exposures in the health care environment where there is often a discrete single exposure. PWID may have multiple exposures, so the data may not be precisely analogous. However, there is enough biological plausibility to recommend PEP if requested, and WHO guidelines indicate PEP should be available to all eligible people from key populations on a voluntary basis after possible exposure to HIV.

**PrEP Implementation Resources for Key Populations**

To further assist OUs with scale up of PrEP, WHO has developed a series of modules to support the implementation among a range of populations in different settings. These modules are for oral PrEP users (including key populations), HIV testing providers, clinicians, community

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[365] World Health Organization. (2021, July). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: Recommendations for a public health approach . https://www.who.int/publications/i/item/9789240031593

[366] Choopanya, K., Martin, M., Suntharasamai, P., Sangkum, U., Mock, P. A., Leethochawalit, M., Chiamwongpaet, S., Kitisin, P., Natrujirote, P., Kittimunkong, S., Chuachoowong, R., Gvetadze, R. J., McNicholl, J. M., Paxton, L. A., Curlin, M. E., Hendrix, C. W., Vanichseni, S., & Bangkok Tenofovir Study Group (2013). Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet (London, England)*, *381*(9883), 2083–2090.

[367] Ibid.

[368] Edeza, A., Bazzi, A., Salhaney, P., Biancarelli, D., Childs, E., Mimiaga, M. J., Drainoni, M. L., & Biello, K. (2020). HIV Pre-exposure Prophylaxis for People Who Inject Drugs: The Context of Co-occurring Injection- and Sexual-Related HIV Risk in the U.S. Northeast. *Substance use & misuse*, *55*(4), 525–533.

[369] Kerr, T., Shannon, K., Ti, L., Strathdee, S., Hayashi, K., Nguyen, P., Montaner, J., & Wood, E. (2016). Sex work and HIV incidence among people who inject drugs. *AIDS (London, England)*, *30*(4), 627–634.

educators and advocates, counselors, leaders, monitoring and evaluation staff, pharmacists, regulatory officials, and program planners/managers.[370] Other resources that might be useful for PEPFAR programs include the UNAIDS PrEP target-setting guide which was designed to assist countries with estimating the size of key populations at various levels of exposure to HIV, which may be targeted given the resources available for PrEP in a country setting. PEPFAR also developed a tool called PrEP-IT for oral PrEP implementation planning, monitoring and evaluation, including program monitoring, assessing site-level service delivery capacity, target setting, program cost estimation, and ARV supply forecasting.[371] Programs should also consider tracking HTS_TST specifically conducted for PrEP lab follow-up re-testing as custom indicators, and should disaggregate those lab tests from HTS_TST achievements. By disaggregating PrEP-related testing, there is potential to evaluate testing results more accurately for case finding versus quarterly testing required to rule out seroconversion among PrEP clients. For more information and guidance on PrEP please see Section 6.2.1.

**Opioid Agonist Therapy (OAT) for People who Inject Drugs**

According to WHO Key Populations guidelines, people who inject drugs (PWID) should have access to the same package of interventions as all other key populations, with the specific addition of harm reductions services such as OAT (also known as Medication Assisted Treatment (MAT), and access to needle and syringe programs. Opioid agonist therapy (OAT) is an important therapy for opioid dependence and reduces the risk of HIV acquisition and transmission by reducing unsafe injecting behaviors that put people who inject drugs at risk for HIV, preventing HIV transmission. OAT has been shown to improve continuity of antiretroviral

[370] WHO. (2017). WHO PrEP Implementation Toolkit. https://www.who.int/tools/prep-implementation-tool
[371] *PrEP-it –*. (2021, July 20). PrEPWatch. https://www.prepwatch.org/resource/prep-it/

treatment and antiretroviral outcomes for individuals living with HIV.[372,373] A meta-analysis suggested that OAT was associated with an average reduction in all-cause mortality of 25%.[374]

OAT has been shown to improve linkage to other care including viral hepatitis screening and treatment.[375] OUs should reference Section 2.3.5 for PEPFAR guidance on addressing co-morbidities, including viral hepatitis. OAT services, including methadone, and buprenorphine where available based on national guidelines, can be delivered in primary healthcare settings or in specialized outpatient clinics offering treatment to clients. PEPFAR recommends conducting advocacy at a national level to introduce buprenorphine. According to WHO guidance, PWID should have access to other prevention interventions, with an emphasis on integrated, person-centered service-delivery, such as sterile injecting equipment through needle and syringe programs, condoms, overdose prevention education and PrEP. Availability of these standard harm reduction services should also provide an opportunity for PWID to access OAT, ART, HIV testing, TB prevention, diagnosis and treatment services, and other important health services such as viral hepatitis prevention, screening and treatment and wound care. PWID who are receiving OAT should also have access to co-located HIV prevention and treatment services. HIV testing and ART provision should be integrated into care settings that provide OAT. Per WHO and previous PEPFAR guidance, it is critical to incorporate Naloxone distribution for drug overdose management and training at both facility and community levels and provision of other essential harm reduction approaches.[376]

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[372] Low, A. J., Mburu, G., Welton, N. J., May, M. T., Davies, C. F., French, C., Turner, K. M., Looker, K. J., Christensen, H., McLean, S., Rhodes, T., Platt, L., Hickman, M., Guise, A., & Vickerman, P. (2016). Impact of Opioid Substitution Therapy on Antiretroviral Therapy Outcomes: A Systematic Review and Meta-Analysis. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*, *63*(8), 1094–1104.

[373] Grebely, J., Tran, L., Degenhardt, L., Dowell-Day, A., Santo, T., Larney, S., Hickman, M., Vickerman, P., French, C., Butler, K., Gibbs, D., Valerio, H., Read, P., Dore, G. J., & Hajarizadeh, B. (2021). Association Between Opioid Agonist Therapy and Testing, Treatment Uptake, and Treatment Outcomes for Hepatitis C Infection Among People Who Inject Drugs: A Systematic Review and Meta-analysis. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*, *73*(1), e107–e118.

[374] Sordo, L., Barrio, G., Bravo, M. J., Indave, B. I., Degenhardt, L., Wiessing, L., Ferri, M., & Pastor-Barriuso, R. (2017). Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ (Clinical research ed.)*, *357*, j1550.

[375] Grebely, J., Tran, L., Degenhardt, L., Dowell-Day, A., Santo, T., Larney, S., Hickman, M., Vickerman, P., French, C., Butler, K., Gibbs, D., Valerio, H., Read, P., Dore, G. J., & Hajarizadeh, B. (2021). Association Between Opioid Agonist Therapy and Testing, Treatment Uptake, and Treatment Outcomes for Hepatitis C Infection Among People Who Inject Drugs: A Systematic Review and Meta-analysis. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*, *73*(1), e107–e118.

[376] World Health Organization. (2016). Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations, 2016 update. World Health Organization. https://apps.who.int/iris/handle/10665/246200

For countries that have recognized recent increases in HIV among PWID, or in specific subgroups such as young PWID, it is important to implement OAT service delivery models that are responsive to local conditions. In Kenya, one teaching and referral hospital provides integrated service delivery, including but not limited to TB screening and treatment, condom distribution, overdose management, psychosocial interventions, HIV treatment, HIV testing, wound care, and OAT. All OAT clients accessing ART at the clinic received viral load testing in the previous 12 months and were virally suppressed, suggesting that an integrated service delivery model can facilitate HIV treatment outcomes for PWID.[377] Because OAT programs are slowly expanding, operating units may benefit from observing existing OAT programs in neighboring countries first-hand to learn about implementation of OAT services. Provision of hepatitis and sexually transmitted infection services to PWID can also have a positive influence on demand for OAT and these programs are recommended by WHO global guidance.

Other innovations in OAT delivery, such as take-away doses (TAD) and mobile delivery, are being tested in some PEPFAR settings. TAD involves providing stable OAT clients with extra doses of medication to reduce the need to attend the clinic for daily dispensing. Several countries (e.g., Tanzania, Kenya, India, Kyrgyz Republic) have implemented TAD on a small scale and early results are promising. TAD should be encouraged and explored as an important intervention for differentiated service delivery component of person-centered care for PWID. As one example, PEPFAR India worked closely with state health authorities in NE India to roll out take home dosing of buprenorphine as a means to support continued OAT for PWID during multiple COVID-19 lockdowns. The critical elements that led to this important program and policy advancement were advocacy at national, state and community level; framing take-home dosing as a key principle to improve program quality and ensure low threshold access (and as a critical aspect of larger integrated service delivery programs); and community demand generation and engagement in program service delivery.

**OAT Clinical Considerations**

The most commonly used opioid agonist in PEPFAR supported countries is methadone, a long-acting oral daily medication. Methadone at therapeutic doses may prolong the QTc interval increasing the risk for ventricular tachyarrhythmias especially when given with other drugs that

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[377] Onyango, B. Integrated service delivery for people who inject drugs in Western Kenya: JOOTRH Wellness Centre. ICAP/CQUIN meeting, 30 Aug 2021. https://cquin.icap.columbia.edu/wp-content/uploads/2021/08/Onyango_JOORTH-case-study_Final-24082021.pdf

cause QT prolongation. Methadone's pharmacology is complex, and there is significant interindividual variation. There are well described drug-drug interactions that may require methadone dose adjustment. EFV, LPV/r and DRV/r increase the clearance of methadone and opioid withdrawal syndrome is described with concomitant use of EFV.[378] Other drugs that increase the clearance of methadone include rifampicin and phenytoin. Fluconazole decreases clearance and individuals on that drug may require less methadone.[379] Further information about drug-drug interactions may be found in Section 6.4.1.

**Condoms and Lubricants for Key Populations**

Effective condom and lubricant distribution, counseling and promotion ensures condoms act as a barrier to sexual transmission for key populations. To achieve this, peers and providers must promote skills for key populations to use condoms and lubricants correctly and to build self-efficacy of key populations to negotiate with sexual partners. Free condoms (both internal and external) and lubricants should be distributed through sites where key populations are found, i.e., in drop-in centers, anti-retroviral therapy (ART) and PrEP sites, and hotspot venues including bars and other locations key populations and their sexual partners may gather. Distribution should vary based on need. SOPs outlining the quantities and methods by which condoms and lubricants are distributed and promoted can be informed by existing implementation tools. Lubricant supply and distribution deficits should be monitored and PEPFAR should intervene to ensure reliable supplies for sex workers, MSM, and transgender programs.

**Sexually Transmitted Infections (STI) Services for Key Populations**

Screening, diagnosis, and treatment of STIs are crucial parts of a comprehensive response to HIV; this includes services for key populations. WHO STI Guidelines note that STIs may facilitate the sexual transmission of HIV infection, particularly those involving genital ulcers, increasing susceptibility to HIV infection.[380] Left untreated, multiple negative health outcomes

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[378] Bruce, R. D., Moody, D. E., Altice, F. L., Gourevitch, M. N., & Friedland, G. H. (2013). A review of pharmacological interactions between HIV or hepatitis C virus medications and opioid agonist therapy: implications and management for clinical practice. Expert review of clinical pharmacology, 6(3), 249–269 . https://doi.org/10.1586/ecp.13.18

[379] Fanucchi, L., Springer, S. A., & Korthuis, P. T. (2019). Medications for Treatment of Opioid Use Disorder among Persons Living with HIV. Current HIV/AIDS reports, 16(1), 1–6. https://doi.org/10.1007/s11904-019-00436-7

[380] Guidelines for the management of symptomatic sexually transmitted infections. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO . https://www.who.int/publications/i/item/9789240024168

can occur including infertility, pelvic inflammatory disease, and cervical/anal cancer. Acute STIs are an important marker for condom less sexual behavior and risk of HIV transmission and WHO guidance stresses that routine STI screening is an essential component of prevention services, including PrEP, and HIV treatment. PrEP follow-up visits are a critical opportunity to diagnosis and treat STIs and failing to intervene could lead to increased STI incidence.[381] Not only is it important to address STIs in key populations due to the benefits of HIV prevention and overall improved sexual health, but it also serves as an entry point and increases demand for HIV services particularly for MSM, sex workers and transgender individuals. STI management should be consistent with existing WHO normative guidance which as of 2021 strongly encourage an etiologic diagnosis with nuclei acid amplification tests (NAAT) and syndromic management as the last option for people with symptomatic STIs. Syndromic management leads to overtreatment which is becoming increasingly undesirable due to worsening antimicrobial resistance and limited treatment options. Near point-of-care tests based on molecular technology can be performed during the clinic visit for the same-visit test results for gonorrhea and chlamydial infections and pooling samples from multiple anatomical sites (pharyngeal, anorectal and urethral for MSM and transgender[382] Rapid diagnostic tests for syphilis (treponemal test) are available, cheap and allow for a same-day "screen and treat" approach. Dual HIV and syphilis rapid tests are also available and provide an opportunity for increasing access to HIV and syphilis testing. Amplified molecular detection by PCR of herpes simplex virus (HSV) DNA from swabs of genital lesions is the most sensitive and specific test. STI services should be confidential and free from coercion.

People from key populations commonly have multiple comorbidities and are disproportionately affected by sexually transmitted infections. In order to adequately address these disparities, the WHO KP Consolidated Guidelines stress both targeted and integrated provision of STI services.[383].

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[381] Jenness, S. M., Weiss, K. M., Goodreau, S. M., Gift, T., Chesson, H., Hoover, K. W., Smith, D. K., Liu, A. Y., Sullivan, P. S., & Rosenberg, E. S. (2017). Incidence of gonorrhea and chlamydia following human immunodeficiency virus preexposure prophylaxis among men who have sex with men: A modeling study. Clinical Infectious Diseases, 65(5) . https://doi.org/10.1093/cid/cix439

[382] Almeria J, Pham J, Paris KS, Heskett KM, Romyco I, Bristow CC. Pooled 3-anatomic site testing for Chlamydia trachomatis and Neisseria gonorrhoeae: A systematic review and meta-analysis. Sex Transm Dis. 2021 Sep 16. doi: 10.1097/OLQ.0000000000001558

[383] World Health Organization. (2016). *Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations*. World Health Organization. https://www.who.int/publications/i/item/9789241511124

Provision of STI management and treatment remains one of PEPFAR's SIMS service delivery standards, affirming the importance of such interventions as part of the HIV-related package of quality services. STI services, including STI diagnosis and treatment for key populations (e.g., herpes, syphilis, gonorrhea, chlamydia), and appropriate referral, should be prioritized in a systematic approach that coordinates resources from different sources and aligns with country government policies and funder mandates to provide optimal service.

### 6.5.1.2 Key Populations: Optimizing Testing and Case-Finding Strategies

PEPFAR teams should consider how they can access undiagnosed sub-populations of key populations living with HIV and their partners through a set of optimized testing approaches that includes social network strategy testing, index testing and risk network testing, self-testing, social media and information communication technology (ICT) platforms to complement standard venue-based HTS in community and facility testing settings. Newer approaches that use ICT allow KP programs to book key populations for testing via online methods and to refer interested individuals for community and facility testing. As KP programming becomes more centered, both physical and online methods are needed with seamless linkage mechanisms to confirm results and link to rapid ART.

**Social Media and Information Communication Technology (ICT) Platforms**

KP programs are increasingly utilizing social media and other ICT platforms to reach a broader range of key populations, e.g., key populations who may be reluctant to access services because of stigma, other sub-populations who network online rather than in physical venues, especially popular among younger key populations and those unable to access community platforms due to COVID-19. Programming for Key Populations has rapidly adopted the use of technology to provide virtual services since the onset of the COVID-19. During the pandemic, some interpersonal KP services such as small group interventions and peer education have reconfigured delivery to the virtual space to provide HIV outreach safely for the duration of the pandemic. Social media platforms (e.g., Facebook, WhatsApp, dating apps such as Grindr or Hornet, online reservation apps attached to targeted KP content) provide KP programs with additional strategies to reach and engage key populations to HIV services including risk screening, and general education, and linkages to essential health and HIV services in a way that meets key populations needs in a confidential and person-centered way.

Once key populations are reached through these various platforms, programs must ensure linkage and referral of clients to appropriate services takes place. Virtual activities such as online risk assessments linked to reservations applications or websites, e-referral methods like e-vouchers, or in person through peer worker follow up that bring key populations into appropriate services. In India, for example, a counselor hotline ensured those reached virtually could access a counselor to provide counselling and help bring them in for HIV services.[384]

In addition, virtual approaches and ICT platforms can be utilized by peer workers, case managers and other program and health system personnel to not only continue support through referral follow up, appointment reminders and management, treatment literacy and adherence support, linkage to additional services, and overall case management but also by utilizing these platforms for tracking and reporting services provided. Lastly, KP programs across PEPFAR have also integrated electronic client feedback systems[385] into ICT platforms and data management systems as part of the program's quality assurance efforts so services can be improved and evolved to meet client's needs. For example, in Thailand an electronic client feedback system was integrated into partners' existing program data monitoring system where an automated message is sent to clients who accessed services via SMS message with a link to an electronic survey asking for feedback on the quality of services they received. The results are then visualized via web-based dashboards down to the site level which are used during project performance meetings.

Tracking and reporting services like online outreach, engagement, reach and referral to services and actual linkage and delivery of services is essential to assess impact of these approaches use for decision making, and to ensure key populations reached virtually are linked to a full range of quality HIV services.

For all of these approaches, a strong system and data security measures and precautions must be built in to protect the data of all individuals engaged within any social media or ICT platform to eliminate the risk of identifying information of key populations being exposed. For additional

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[384] FHI 360, LINKAGES Project. 2019. A Vision for Going Online to Accelerate the Impact of HIV Programs. Washington, D.C., U.S.: FHI 360. https://www.fhi360.org/sites/default/files/media/documents/resource-linkages-electronic-client-feedback-systems.pdf

[385] Ibid.

program resources on how various ICT platforms can be utilized for KP programming, please reference PEPFAR supported Going Online tools.[386]

**Index Testing for Key Populations, their Partners, and Children**

Given the criminalization and stigmatization of key populations, and the high levels of violence they face, there are important considerations for providing safe and ethical index testing services to key populations living with HIV and their partners and children to ensure their safety and security. All PEPFAR sites serving key populations living with HIV (KPLHIV) must ensure implementation of safe and ethical index testing, complying with PEPFAR guidance (See Section 6.3.1.5 and PEPFAR Solutions Platform).[387] Providers should be sensitized to the possibility that non-disclosing members of KP groups are seeking services outside of specialized KP provider facilities. If there is any possibility of harm coming to the index client or contacts as a result of provision of index testing services, those services should not be provided.

Some specific considerations and points of emphasis for key populations include:

- An emphasis must be placed on participation in index testing and partner elicitation as voluntary and that establishment of trust between KP clients and service providers is paramount.
- Confidentiality, privacy, informed consent, and their implications for index testing including in country-specific contexts needs to be stressed. Service providers must be aware of the legal and cultural environment where they operate and how KP may be adversely impacted from disclosure of their KP "status."
    - For example, index testing programs must avoid practices that may out gay, bisexual, and other men who have sex with men as they might face the risk of violence, losing their livelihoods or being expelled from their homes, which is a particular concern for youth.
- Personal identity and other information about key populations must be protected and kept confidential. The Minimum Program Requirements (MPRs) require use of unique identifier codes (UICs) with all populations. In particular, programs working with key

[386] FHI360 Going Online to Accelerate the Impact of HIV Programs. https://www.fhi360.org/resource/going-online-accelerate-impact-hiv-programs
[387] https://www.pepfarsolutions.org/resourcesandtools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

populations should utilize UICs in registers and on forms that capture contact information to further protect the identity of the index client.

  - The use of unique IDs and separate registers for listing contacts is another way to ensure confidentiality of index clients, their contacts, and the nature of their relationship.

- Compared to the general population, key populations have an increased risk of experiencing violence, including IPV; therefore, similar to general populations, IPs should train staff to inquire about the risk of IPV during partner elicitation and should establish resources, referrals, and procedures to handle reports or concerns of violence. See Section 6.6.2.1 on Gender Based Violence for minimum requirements for routine IPV screenings.

Training for healthcare workers on index case testing, should be complemented by training on inquiring about and responding to disclosures of violence according to the WHO LIVES approach. See Section 6.6.2.1 on Gender Based Violence for more information on the provision of first-line support using the LIVES approach.

- For every referral (child or partner), key populations may need assurance that providers will do no harm (i.e., not to impact physical custody of children or promote violence from partners)
- A good counsellor or motivational interviewer can impact the number of partners elicited considerably. Investing in training and evaluating counsellor performance is critical.
- Considerations for partner elicitation should be practiced (e.g., prioritize eliciting non-paying partners, “sweethearts” or “special boyfriends” of sex workers of all genders; MSM and transgender individuals must be asked about sex partners of all genders; PWID must be asked about both needle-sharing and sexual partners of all genders).
- Programs should explore social network testing and HIV self-testing options when discussing index testing options with key populations who are reluctant to provide contact names and information and for those who opt out of index testing due to fears of stigma and discrimination.
- To the extent possible, peer-led approaches should be used to deliver safe and ethical index testing services.
- Use of ICT by trained peers and healthcare workers who may obtain consent from index clients to contact partners using anonymous screen names and other web-based approaches.

- Biological children under 19 years of age should be elicited from key populations living with HIV, and a strong referral, treatment linkage, and continuity of treatment support with trusted providers (i.e., coordination with OVC programs) should be in place to ensure services for these children. Maintaining confidentiality of the HIV status of key populations and their children is especially important, as parents may fear that children may be removed from the home due to authorities' perceptions of abuse or neglect due to parenting by adults from a KP group. KP, clinical, and OVC partners should coordinate to ensure that children of key populations are not lost from referral, and that CLHIV of KP are linked to treatment and continue on treatment. (For more guidance on Safe and Ethical Index Testing for children of KP living with HIV, see 6.3.2 Case Finding for Pediatrics).

Stigma and discrimination are significant barriers for key populations to access HIV services. For index testing, where trust is critical to successful partner elicitation, ensuring that all staff are properly trained and sensitized is crucial to the success of index testing outcomes among key populations. Thus, countries should work to ensure health workers, peers, and facility staff across service delivery points, but especially those conducting index testing, are properly trained to effectively serve key populations. In the United States and other global settings, partner notification has been successfully delivered through online platforms, email, and online networks, notifying index partners that they should be tested with integrated booking and counselling services. For additional guidance on addressing stigma and discrimination and building trust within KP communities, see Section 6.5.1.4 Structural Interventions for Key Populations.

**Social Network Testing**

Focused HIV testing through sexual, drug-using, and other social networks of key populations to improve the efficiency of HIV testing efforts has proven to be a very effective case-finding strategy. These strategies have led to improved case identification among key populations and their partners, accelerating overall potential for linking and retaining key populations in HIV services. Examples of effective, social network and risk network HIV case-finding approaches include Social Network Strategy (SNS), Enhanced Peer Outreach Approach (EPOA), and Risk Network Referral (RNR), which have been implemented in most PEPFAR countries.

Social and risk network strategies complement traditional peer outreach by engaging previously unidentified key populations and their contacts for HIV prevention and testing. The goal is to reach hidden, high-risk networks, expand HIV case detection potential, and, as an integrated part of a differentiated service delivery model, rapidly link HIV-positive key populations to ART,

and connect HIV-negative key populations to combination prevention services including PrEP and other services such as STI screening and risk reduction counseling that will help them remain HIV-negative.

These approaches have been used since 2014 to supplement peer-to-peer and venue-based outreach. Key population mobilizers (also known as “seeds”) who are living with or high-risk HIV-negative (depending on the strategy) promote and refer testing among members of their sexual, drug-using, and social networks. In SNS, these KP mobilizers use coupons to begin chains of referral for HIV testing, where those who are referred for testing are also given the opportunity to refer their sexual, drug-using, and social network members for HIV testing. This network referral process facilitates high-yield HIV testing among hidden and hard-to-reach key populations, and specific sub-populations of KP like those who use “party” drugs, such as amphetamine-type stimulants (ATS), during sex, often referred to as ChemSex. Operationally, social network approaches require an integrated information management component to track the effectiveness of KP mobilizers or seeds, the status of key populations tested from their referrals, and follow-up required for individuals referred or tested. It is recommended that these approaches are informed through technical assistance to ensure they are adapted effectively. Monetary and non-monetary incentives for testing can be utilized to encourage testing and referrals, but must be non-coercive and well monitored, in line with ethical testing policies, and part of a sustainable national approach.

Due to COVID-19 mobility restrictions and lockdowns, key population groups may have limited interaction with their network members. One innovation to address this barrier is the use of electronic photo coupons, or vouchers, in addition to paper, to facilitate and track recruitment of network members. This strategy allows KP with cell phones to take a photo of a paper coupon and share it with their network members they want to refer for HIV testing. This strategy has been used effectively to increase or maintain HIV testing referrals in multiple countries.

**Blended Index Testing and Social Network Strategy**

Many OUs have built upon a core foundation of targeted community, facility and complementary index testing and social network strategy (SNS) to expand their case-finding options for key populations at highest risk. Index and SNS can be used together to ensure that all high-risk, direct exposure contacts and social network members are tested, and that testing extends into

harder-to-reach networks of undiagnosed PLHIV, especially among key populations. In addition, index testing and SNS are blended in many strong KP programs to ensure not only increased case-finding of key populations, but also to ensure all potential partners of key populations (e.g., clients of sex workers and wives or partners of MSM) or biological children can be brought into HIV services. See Sections 6.5.1.2 (index testing) and (social network testing) above for specific guidance on these case-finding strategies as it relates to key populations.

Index testing, considered a core public health case-finding strategy, involves the voluntary elicitation of potentially exposed contacts from an individual living with HIV (index client), often one is newly diagnosed once the immediate priority for treatment has been addressed. SNS is an additional case-finding activity that involves the personal referral of at-risk network members (e.g., sexual, social and injection drug-using contacts) by an HIV-positive or HIV-negative KP member using HIV testing services (HTS) referral coupons. SNS referral coupons may be offered to KP clients who are unwilling or unable to provide names or contact information of all direct-transmission partners during index partner elicitation but would be willing, or able, to share the SNS referral coupon directly with a network member. Please refer to PEPFAR MER Guidance on how these data should be reported.

Extending the options for key populations even further, programs have combined the option of HIV self-testing (HIVST) within a blended index and social network testing approach. Providing HIVST kits to index KP for distribution to their partners when they are unwilling or unable to share KP contacts, for example, allows for greater anonymity and safety for key populations and their partners. Integrated HIVST must ensure follow-up steps, however, to ensure linkage to confirmatory testing and treatment as needed. See Section 6.3.1.6 for more information about general self-testing.

**HIV Self-Testing for Key Populations**

HIV self-testing (HIVST) is an evidence-based intervention that increases the accessibility and frequency of testing. HIVST has demonstrated effectiveness in reaching individuals who might not otherwise test and is especially suited to reaching key populations, including young KP, and their risk networks. Properly implemented, it provides opportunities to promote linkage to treatment for those who screen HIV positive.

Primary HIVST kit distribution strategies for key populations include drop-in centers, hotspot distribution, home delivery, online orders, automatic dispensers, community-based mobile units targeted to cover KP community events and venues, and private pharmacies. HIVST can also

be used in cases where routine testing doesn't effectively reach difficult-to-find KP networks, for example, clients of sex workers, men who have sex with men but do not identify as gay or are closeted, or young key populations who will only order a HIVST online or pick one up but who won't visit a testing site. Linkage to HIV testing and treatment services by a trained provider to confirm HIV status is critical following a reactive HIVST screen. Those distributing HIVST kits should provide supportive counseling as well as appropriate linkage interventions to individuals receiving HIVST kits to foster prompt linkage to additional services.[388,389]

Barriers faced by key populations to the uptake of testing (including privacy/confidentiality concerns, fear of stigma and discrimination from health care providers, fear of being outed and limited access to HIV testing services) can be addressed through HIVST kit distribution. Brazil's HIVST kit distribution to MSM overcomes some of these barriers through online orders and automated dispensers installed in generic locations such as transport hubs. Secondary HIVST kit distribution to key populations and their sexual partners in Tanzania made it possible to continue community-based HTS even during COVID-19 restrictions.

The WHO policy brief from November 2019 outlines considerations for HIVST implementation that apply to the KP context.[390] Additionally, Witzel et al. have cataloged successful strategies in their systematic review of HIVST among KP.[391]

### Venue and Mobile Testing

While venue-based and mobile HIV testing opportunities have been a mainstay of key population prevention programming since the early days, not all PEPFAR operating units have implemented or re-imagined their current HTS approach to better diagnose key populations. Current global guidance on comprehensive HIV services and differentiated service delivery for

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[388] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7713313/ BMC Med. 2020; 18: 381. 3. doi: 10.1186/s12916-020-01835-z Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis T. Charles Witzel, et al.

[389] https://pubmed.ncbi.nlm.nih.gov/33503050/ Njau B, Damian DJ, Abdullahi L, Boulle A, Mathews C. The effects of HIV self-testing on the uptake of HIV testing, linkage to antiretroviral treatment and social harms among adults in Africa: A systematic review and meta-analysis. PLoS One. 2021 Jan 27;16(1):e0245498. doi: 10.1371/journal.pone.0245498. PMID: 33503050; PMCID: PMC7840047.

[390] World Health Organization. (2019). *WHO recommends HIV self-testing: evidence update and considerations for success: policy brief* (No. WHO/CDS/HIV/19.36). https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36

[391] Witzel, T. C., Eshun-Wilson, I., Jamil, M. S., Tilouche, N., Figueroa, C., Johnson, C. C., ... & Weatherburn, P. (2020). Comparing the effects of HIV self-testing to standard HIV testing for key populations: a systematic review and meta-analysis. *BMC medicine*, *18*(1), 1-13.

key populations recommends flexible, mobile, and venue-based options to expand the pool of at-risk individuals who have access to testing.[392,393] To ensure the diagnosis and linkage to ART for key populations who comprise a growing proportion of new infections globally, HTS must become more flexible and available to reach key populations and their sexual partners.

To overcome current barriers to HTS—such as perceived or experienced stigma and discrimination in traditional clinical venues and difficulties accessing facilities during COVID-19 restrictions—rapid HIV testing and screening services for key populations can benefit from a wider range of community-based and online options. Current practices to expand facility-based options include moonlight testing where key populations gather and reside, multi-disease screening (e.g., HIV and syphilis), HIV self-testing (HIVST), and online requests for appointments or HIVST kits. Examples of improved HIV case-finding results have been observed in Ukraine where social network testing strategies were combined with mobile testing units among PWID; introduction of syphilis screening for young MSM in Vietnam; and through combining multiple testing approaches (e.g., social network testing and peer distribution of HIVST) for all key population groups on the foundation of backpack nurse cadres and mobile unit testing in Tanzania.[394,395]

## 6.5.1.3 Continuity of Treatment for Key Populations: Initiation to Undetectable

### Comprehensive Case Management from Initiation to Undetectable

Partners implementing KP programs need to ensure that all key populations diagnosed with HIV have immediate access to accessible, stigma-free, and safe facility or community-based care and treatment services. These service delivery points should ensure that all care and treatment standards, from rapid initiation all the way to viral load monitoring, are met, including TB prevention and treatment and cervical cancer screening.

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[392] WHO. (2016, June). *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations.* https://www.who.int/publications/i/item/9789241511124

[393] International AIDS Society. (2018). *A Decision Framework for HIV testing services*.

[394] Maruyama, H., Franks, J., Laki, D., Msumi, O., Makyao, N., Rwabiyago, O. E., Rabkin, M., Kagashe, M. J., & El-Sadr, W. M. (2021). Bringing HIV services to key populations and their communities in Tanzania: from pilot to scale. *Journal of the International AIDS Society*, *24*(S3).

[395] Mahiti, M. (2021, August 26). *Differentiated HIV Testing Services to Reach Key Populations: Tanzania FIKIA Project Experience*. Https://Cquin.Icap.Columbia.Edu/. https://cquin.icap.columbia.edu/wp-content/uploads/2021/08/Mahiti_ICAP_TZ_CQUIN-Key-Populations-Meeting_Slides_FNL.pdf

Rapid ART initiation (ideally same day ART but must be within 7 days of diagnosis) results in improved outcomes across the HIV treatment cascade, including greater ART adherence and faster viral suppression benefitting the individual's health while reducing community transmission. Rapid ART initiation for key populations should be offered at expanded points of entry, meeting the clients where they can best be served, including at community testing sites, drop-in centers, STI clinics, private clinics, primary care clinics, drug treatment centers and/or hospitals.

Comprehensive case management teams must support rapid and same day ART initiation for newly diagnosed key populations members and KPLHIV whose treatment has been interrupted and ensure their re-engagement and treatment continuity. Comprehensive case management teams can be composed of HIV counselors, peer navigators, mental health providers, clinicians, and monitoring and evaluation (M&E) staff, many of whom ideally are KPLHIV themselves. In settings where KP members are newly diagnosed with HIV in a community setting, an integrated case management approach can facilitate linkage from the community to public health systems for rapid ART initiation and continuity of care or from a generalized testing site to a KP community clinic. Peer navigation and case management ensure continuity of care.

KP providers and facilities (e.g., KP drop-in centers) should be targeted for one-stop-shops for the provision of ART and as a hub from which peer outreach/navigation operates for prevention (including PrEP), diagnostics, and treatment continuity support. Likewise approaches that refer KP into ART services, drug treatment centers in the case of PWID, or non-KP services must ensure that KP are assigned peer navigators and/ or case managers to ensure and track referrals, and to provide behavioral support and community care.

Differentiated key populations case management is important to ensure a person-centered approach; some clients require a more intensive package of services than others. These care services evolve where an unstable client enters the program with intensive needs, stabilizes and later, after ensuring viral suppression, needs less care, or conversely, where new social challenges create barriers and interruptions in care that must be flagged for immediate follow up. Case management includes assessing the need for frequent, personalized, person-centered support and counseling from the time they enter the program until sustained viral suppression is achieved and maintained. During this period, regular communication with the client and checks with their peer navigator or health care team can help identify missed appointments (e.g., drug pick-ups, viral load tests) and alert case managers of the urgent need for active follow-up. A client can be considered stable and only require maintenance when they adhere to their clinical

care and ART schedule and are virally suppressed. Their check-ins may be online and less frequently in-person, with the need for event driven (i.e., reminder for VL testing) reminders. For ART clients facing barriers that can make it harder to maintain regular clinical care and ART adherence (i.e., homelessness, substance use, living a long distance away from ART access points, complaints of mistreatment or stockouts at public sector clinics, etc.), and for those who have fallen out of care previously, continuation of intensive follow-up is required. Peer navigators play a critical role in the case management team. Navigators are often KPLHIV and/or non-clinically trained liaisons who are able to establish trusted relationships with key populations. Persons selected as navigators should receive rigorous training on HIV care and treatment, local healthcare systems, social and legal systems, motivational interviewing, stigma, discrimination, ethics and client protections, and violence reduction and prevention. Navigators can assist newly diagnosed or out-of-care KPLHIV to overcome barriers related to managing their HIV infection. They can help key populations navigate healthcare systems by providing several services, such as appointment scheduling, reminders, transportation assistance, and accompaniment to healthcare appointments. Properly trained navigators can also help link key populations to social services, provide psychosocial counseling and help address personal factors, such as violence and substance use, which may hinder care-seeking behavior. Integrating these components can help key populations initiate and adhere to treatment, improve transmission and treatment literacy, and achieve undetectable viral loads. Whether the KP program initiates KPLHIV on treatment or provides referrals, peer navigators are critical staff required to ensure care across services.

A fundamental need exists for improving the interface between health facilities, community health workers, and key populations civil society organizations and networks to address ART initiation and maintenance for key populations. PEPFAR key populations programs should focus on making facility-based services more KP-friendly, stigma-free, and KP-competent, by strengthening the relationship between facility staff and key populations community members. Facility-based health care workers should receive regular training on person-centered services for key populations that are co-designed and co-facilitated by key populations civil society groups. Community-based key populations outreach providers can play a critical role in this process by ensuring an integrated KP strategy creates a seamless clinical experience for key populations clients. An integrated data system or data-sharing agreements between facility and community partners is fundamental to scaling an integrated case management approach.

**Considerations for Transgender Individuals.** Current evidence suggests stronger continuity of treatment and viral suppression rates for transgender individuals on ART when gender-affirming care including gender-affirming hormone therapy (GAHT) is provided.[396,397] Where possible, PEPFAR programs should leverage provision of GAHT services to increase uptake of HIV services in drop-in-centers and targeted clinical settings for transgender clients utilizing an approach that coordinates resources from different sources, aligns with country government policies and funder mandates to provide optimal service, and considers the sustainability of these services. For more information on ensuring quality and client centered care for transgender populations please reference PEPFAR funded resources including an online self-learning course and transgender healthcare services manual.[398,399]

**Considerations for People in Prisons and Other Enclosed Settings**

Despite global reductions in HIV incidence and mortality, the prevalence of HIV and other infectious diseases is much higher among prisoners than in the general population.[400] A systematic review and meta-analysis of global and cross-country prevalence of HIV among prisoners showed that HIV prevalence was highest in sub-Saharan Africa.[401] As countries close in on 95-95-95 achievements, it may be prudent for countries to assess whether segments of their undiagnosed and untreated populations are among those in correctional settings. Universal test and treat interventions were shown to be feasible in corrections settings in Zambia and South Africa and achieved levels of same-day ART initiation, continuity to treatment, and viral

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[396] Rodriguez-Hart, C (2021) GENDER-AFFIRMING SURGERY ASSOCIATED WITH HIGH VIRAL SUPPRESSION AMONG TRANSGENDER PWH, CROI Conference, 2021.

[397] Nathan A Summers, Trang T Huynh, Ruth C Dunn, Sara L Cross, Christian J Fuchs, Effects of Gender-Affirming Hormone Therapy on Progression Along the HIV Care Continuum in Transgender Women, *Open Forum Infectious Diseases*, Volume 8, Issue 9, September 2021, ofab404, https://doi.org/10.1093/ofid/ofab404

[398] TransHealth101: https://ihri.org/transhealth-101-is-now-ready/

[399] Center of Excellence in Transgender Health, Chulalongkorn University. (2021). The Thai Handbook of Transgender Healthcare Services. https://ihri.org/wp-content/uploads/2021/09/The-Thai-Handbook-of-Transgender-Heatlhcare-Services.pdf

[400] Golrokhi, R., Farhoudi, B., Taj, L., Pahlaviani, F. G., Mazaheri-Tehrani, E., Cossarizza, A., SeyedAlinaghi, S., Mohraz, M., & Voltarelli, F. A. (2018). HIV Prevalence and Correlations in Prisons in Different Regions of the World: A Review Article. *The Open AIDS Journal*, *12*(1), 81–92. https://doi.org/10.2174/1874613601812010081

[401] SAYYAH, M., RAHIM, F., KAYEDANI, G. A., SHIRBANDI, K., & SAKI-MALEHI, A. (2019). Global View of HIV Prevalence in Prisons: A Systematic Review and Meta-Analysis. *Iranian Journal of Public Health*. Published. https://doi.org/10.18502/ijph.v48i2.816

load suppression as those in community settings.[402] As prisoners eventually transition back into communities, case management systems that facilitate MMD and linkage to ART outside the correctional settings are critical for continuity of treatment for these vulnerable populations.

**Differentiated Service Delivery for Key Populations**

Differentiated service delivery is a person-centered approach to HIV care and treatment that offers stigma free services adapted to the needs of different groups of key populations. Such models are crucial for key populations, as they may require specialized services, face additional barriers to access care and treatment services, and are criminalized, highly stigmatized and may face threats or actual violence.

Peer navigators and health care workers should work with clients to ensure awareness of service options and support them to select the services best fitting their particular needs.

Differentiated service delivery for KPLHIV should include:

- Clinical service delivery at KP-friendly and competent general facilities, KP-specific structures (drop-in centers (DICs), one-stop shops) and in the community (community ART teams)
- Extending or adapting service hours to better suite specific KP needs
- a range of options for drug dispensing, to include multi-month dispensing, both at initiation and for refills, group refills, and community-based drug delivery. Other decentralized methods for drug distribution including through private pharmacies, hospitals, and automated dispensing tools should be considered.
- Community based viral load sample collection
- Access to relevant non-HIV services (such as: care and treatment for opportunistic infections, STIs, non-communicable diseases, and counseling)

KP DICs are designed to ensure continuity in prevention, treatment, and care services through an integrated approach for outreach, biomedical prevention, HIV testing, STI control, treatment initiation and MMD, VL sample collection and processing, cervical cancer prevention, family planning, psychosocial support and counseling, GBV services and legal services. DICs can also

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[402] Herce, M. E., Hoffmann, C. J., Fielding, K., Topp, S. M., Hausler, H., Chimoyi, L., Smith, H. J., Chetty-Makkan, C. M., Mukora, R., Tlali, M., Olivier, A. J., Muyoyeta, M., Reid, S. E., & Charalambous, S. (2020). Universal test-and-treat in Zambian and South African correctional facilities: a multisite prospective cohort study. *The Lancet HIV*, *7*(12), e807–e816. https://doi.org/10.1016/s2352-3018(20)30188-0

play a fundamental role in reaching children of key populations and their partners, mainly through index or social network testing.[403] Some DICs offer a referral model providing prevention and care only and others also offer treatment initiation and dispensation. To ensure a nationally viable model for key populations, the DIC alternative is especially needed for key populations who require intensive support whereas key populations who are in stable HIV care can have the option to be referred to government services that have been designed to serve key populations or be offered more of a maintenance approach. Beyond clinical and psychosocial services, DICs can offer a safe space for key populations, where they can engage in IEC activities and obtain information about HIV prevention and harm reduction options available to them. When designing DICs, partners should take into consideration the unique needs of the key populations served, including adapted service days and hours and, in some cases, separate client flow systems (separate entrance, staggered service hours, etc.) for different subpopulations that would otherwise refuse to attend the DICs. Partners should also expand services to more KP-led or managed drop-in centers. Community advisory boards and/or community consultations can guide partners in determining the optimal model depending on the context.

UNAIDS reports the ART coverage gap among key populations to be greater than most other populations although accurate data is problematic. At an agency level CDC and USAID now track referrals from PEPFAR case finding sites to ART sites where KP are verified as initiated on treatment allowing peer navigators to ensure linkage at high rates. While data from PEPFAR-supported work is promising, national policy remains important to address. PEPFAR's policy priorities for increasing linkage, initiation, and continuity on treatment for key populations include same-day initiation and MMD through differentiated services including community ART initiation and refill; task sharing to allow nurses and lay workers to provide care, treatment, and VL sample collection and transportation. Further general guidelines are also contained in the WHO's Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations (2016).[404]

**Viral Load Coverage for Key Populations**

Globally, PEPFAR program viral load coverage among key populations is 70%, with VLS being 94% for all KP groups, as of FY21Q3. Differentiated service delivery points that facilitate viral load testing are essential components of KP programs delivering person-centered services and

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[403] https://www.fhi360.org/sites/default/files/media/documents/epic-long-term-hiv-adherence-guide.pdf
[404] https://www.who.int/hiv/pub/toolkits/keypopulations-2016-update/en/

need to be integrated within the national lab collection and transport systems, for timely access to the VL testing and results. For example, in both Kenya and Haiti the KP clinical providers have access to the VL system online allowing them to provide VL results to the key populations for whom they facilitate sample collection. Community VL sample collection is a viable alternative that can accompany community ARV distribution, particularly for hard-to-reach key populations who otherwise would be missing their VL testing. For further guidance on community-based VL sample collection, see Section 6.4.5. All partners that provide VL services to key populations need to ensure they are tracking and reporting the KP disaggregate within these indicators in alignment with MER guidance.

In settings where clinical services, including viral load testing, are provided by general population facilities, belonging to (disaggregation) a KP group is often missed from the data. Facilities and KP implementing partners need to work together to document viral load coverage and results for key populations. Countries using separate databases to track KP indicators need to ensure correct data collection and triangulation with data entered in the national DHIS system.

While all other KP groups have seen recent increases in viral load coverage, people in prisons and enclosed settings have seen a decrease in VLC over the fiscal year, from 75% in FY20Q4 to 40% in FY21Q3. Programs working with prisons need to identify reasons behind this trend and collaborate with institutional authorities to develop adequate viral load sample collection and processing mechanisms. Alternative sample collection modalities, such as dry blood sampling should be considered, if appropriate and allowed by national guidelines.

**Scale-up of Undetectable = Untransmittable (U=U) messaging for Key Populations**

The U=U campaign was launched after four large studies conducted from 2007 to 2016 among thousands of serodifferent couples did not show a single case of sexual HIV transmission from a virally suppressed partner. The idea that someone living with HIV, who is both on treatment and virally undetectable, cannot transmit the virus to a sexual partner is revolutionary. Data are lacking on non-sexual exposures to HIV, but it is likely that the risk of HIV transmission related to parenteral exposure is greatly reduced when individuals are virally suppressed. Similarly, it is unclear whether this messaging should apply to vertical transmission related to breastfeeding. U=U messaging has the potential to reduce stigma toward PLHIV, including self- stigma; increase demand for HIV testing and ART, including early initiation of treatment; improve treatment adherence; and increase understanding that a suppressed VL is important to maintain the long-term health of PLHIV. The concept of U=U can also strengthen advocacy

efforts for universal access to effective treatment and care, and messaging around U=U should be well-integrated into HIV prevention, care, and treatment programs, including those serving key populations. Demand creation toolkits to develop U=U campaigns are available to all PEPFAR agencies. Prevention Access Campaign is the leading site for U=U information, resources, and news.[405]

**Return to Treatment**

Return to Treatment (RTT) of KP clients whose treatment has been interrupted is a high priority for all treatment sites and requires coordinated facility and community efforts. When KPLHIV receive treatment at MOH facilities, KP IPs should coordinate with facilities to identify those with IIT, reach them through peer educators, who will also navigate the RTT process with the clients. Similarly, peer educators are instrumental in facilitating RTT of KPLHIV who receive their clinical services in KP-specific facilities (drop-in centers, one-stop shops). Return to treatment should be guided by the same principles that apply for the general population (see Section 6.1.3).

**Migration and Key Populations**

Key populations are often mobile, migrating within or between countries, with a negative impact on their access to HIV services. Migration increases vulnerability, through social, economic, cultural, and legal factors, low income, fragile work arrangements, and uncertain legal status all impacting health seeking behavior, including antiretroviral treatment adherence. When accessing health care in a different country, migrants often face discriminatory policies and practices, police harassment, poor availability of services, negative attitudes from health care workers, language barriers, and additional stigma. In many countries, health care access is often linked to residency status. In the absence of reliable EMR systems, even accessing services within the same geographic area can become a challenge and lead to inadequate service provision.

Programs should consider ways to ensure that migrant key populations have access to the full range of HIV care and treatment services they need, and that mobility doesn't result in interruption in treatment, suboptimal ARV regimens, or lack of viral load testing. Whenever possible, facilities should communicate with each other to optimize treatment outcomes. Clinical services should be customized to individuals' specific needs, also considering their upcoming

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[405] www.preventionaccess.org

travel plans, if applicable, and providing referrals to trusted KP-friendly facilities at the new destination. Whenever possible, multi-month dispensing should be prioritized.

## 6.5.1.4 Structural Interventions for Key Populations

Summary of section edits:

- Updated critical enabling strategies to account for the safety and security of implementers of KP interventions
- Updated a section reference to align with 2023 COP/ROP Guidance section numbering

WHO 2016 Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations HIV epidemics[406] note there are "socio-structural factors that limit access to HIV services, constrain how these services are delivered and diminish their effectiveness." WHO guidelines therefore recommend addressing a series of critical enablers, which are "strategies, activities and approaches that aim to improve the accessibility, acceptability, uptake, equitable coverage, quality, effectiveness and efficiency of HIV interventions and services."

In the PEPFAR context, these critical enablers are expansive and should include various strategies that place KP-leaders, organizations, and communities at the center of these services, including:

- Promoting and funding KP leaders and organizations themselves to implement, monitor and advocate for comprehensive KP services.
- Assisting KP clients, beneficiaries, and communities in knowing their rights--the right to health, the right to stigma-free health services, the right to equal treatment before the law, the right to dignity, among others.
- Formalizing systems that respond to the needs of key populations harmed by health facility-, community- and law enforcement perpetrated- stigma, discrimination, and violence (SDV) linked to their KP and/or HIV status, as well as documenting such events towards mitigating future violations.
- Engaging stakeholders within government and local community structures, such as law enforcement, judicial systems, religious and community leaders, and parliamentarians to

[406] https://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

link health programming with human rights, (including advocating for legal frameworks that decriminalize behaviors practiced by key populations);

- Developing plans and budgets for the safety and security of implementers of KP interventions; and
- Maintaining a do no harm focus of all PEPFAR programming by promoting an ethical code of conduct in serving key populations

Based on the MSMIT,[407] SWIT,[408] IDUIT,[409] and TRANSIT[410] toolkit guidance, PEPFAR recommends the following structural interventions for KP programs:

***KP community leadership:***

"Nothing about us without us" is a mantra PEPFAR has adopted for the KP service delivery. Hence, KP programming requires legitimate KP leaders to be treated with dignity and to be in decision-making and implementation roles throughout the development and delivery of biomedical, behavioral, and structural interventions. For key populations, this might include the following:

- Engaging KP community leaders in the design, development, implementation, and evaluation of HIV programming. This engagement may be formal by increasing funding to KP-led organizations as implementing partners, hiring KP leaders to work on programming at every level, and/or working with more nascent KP community networks

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[407] United Nations Population Fund, Global Forum on MSM & HIV, United Nations Development Programme, World Health Organization, United States Agency for International Development, World Bank. (2015). Implementing Comprehensive HIV and STI Programmes with Men Who Have Sex with Men https://www.unfpa.org/sites/default/files/pub-pdf/MSMIT_for_Web.pdf

[408] World Health Organization, United Nations Population Fund, Joint United Nations Programme on HIV/AIDS, Global Network of Sex Work Projects, The World Bank.(2013) Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions., . http://apps.who.int/iris/bitstream/handle/10665/90000/9789241506182_eng.pdf?sequence=1

[409] United Nations Office on Drugs and Crime, International Network of People Who Use Drugs, Joint United Nations Programme on HIV/AIDS, United Nations Development Programme, United Nations Population Fund, World Health Organization, United States Agency for International Development. (2017). Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions . https://www.inpud.net/sites/default/files/IDUIT%205Apr2017%20for%20web.pdf

[410] United Nations Development Programme, IRGT: A Global Network of Transgender Women and HIV, United Nations Population Fund, UCSF Center of Excellence for Transgender Health, Johns Hopkins Bloomberg School of Public Health, World Health Organization, Joint United Nations Programme on HIV/AIDS, United States Agency for International Development. Implementing comprehensive HIV and STI programmes with transgender people: practical guidance for collaborative interventions . https://www.unfpa.org/sites/default/files/pub-pdf/TRANSIT_report_UNFPA.pdf

to increase their leadership and decision-making in KP programs (see Section 2.5.3 and 6.6.2.1).[411]

- Convening groups of KPLHIV or young or older key populations in group sessions led by a counsellor to discuss risk, risk negotiation, violence and other personal issues thereby strengthening their collective agency to work together.
- Engaging KP peer navigators or peer educators to provide information and linkage to services for KP-peer groups.
- Ensuring an explicit focus on key populations in PEPFAR-supported community led monitoring (CLM) activities (see 2023 COP/ROP Guidance Section 3.2.1.3).
- A component of this engagement may require capacity strengthening activities assisting KP leaders in strengthening their skills to deliver HIV programs. Capacity-strengthening structural interventions for key populations might include the following:
    - Strengthening leadership and administrative competencies of KP leaders and KP-led CSOs in the areas of financial management, governance, human resources, HIV service delivery and strategic information capacities. This effort is best implemented over time (vs. one-off training), working with local organizational coaches or twinning arrangements with more capacitated KP-led or competent CSOs.
- Technical assistance (above-site) to support ministries' ability to meaningfully engage KP communities, monitor KP performance data and coordinate KP programming nationally.
- Electronic tracking/monitoring of client-level HIV care and treatment outcomes among key populations (in a way that is not personally identifying and has support of KP members in the community) to prevent duplication and mitigate treatment interruption.

***Knowing one's rights:***

Based on UNAIDS guidance, PEPFAR KP programs should promote legal literacy, informing key populations (and PLHIV) about their human rights and national and local laws relevant to HIV. This knowledge enables key populations to organize around these rights and laws and to advocate for concrete needs within the context of HIV. The approach also promotes systems in

[411] "Strategies for reducing police arrest in the context of an HIV prevention programme for female sex workers: evidence from structural interventions in Karnataka, South India" https://onlinelibrary.wiley.com/doi/full/10.7448/IAS.19.4.20856

place where KPs can seek legal redress, such as patients' rights groups, ombudsperson offices and national human rights institutions.[412]

***Mitigating KP/HIV-associated stigma, discrimination, and violence in healthcare settings:***

Stigma, discrimination, and violence are firmly established as key barriers that impede scale-up of HIV prevention, treatment, and support services. Moreover, the populations most likely to experience HIV-related stigma, prejudice, negative attitudes, denial of services and abuse are too often key populations. External and internalized stigma, which creates fear of rejection at many levels, deters key populations from seeking access to appropriate HIV services and health care. To achieve PEPFAR's ambitious targets for epidemic control, barriers like stigma, discrimination and violence must be addressed.

Effective KP programs address stigma, discrimination, and violence by engaging KP leaders and building KP-competency in the program (e.g., hiring experienced and empathetic staff and training them to address the unique needs of key populations). Various virtual and in-person training curricula exist to strengthen KP-competency at healthcare facilities and in community settings. Because key population individuals' interaction at a facility is not limited to clinicians, these trainings work best when given to all persons at a healthcare facility, including administrators, security personnel, custodial staff, pharmacists, and laboratorians. More successful models include supporting "KP champions" that are placed in healthcare facilities that key populations can seek out when visiting a facility. Frequent contact with key populations can help build empathy, humanize stigmatized persons, and break down stereotypes. These programs are often integrated into person-centered differentiated HIV services models or comprehensive case management models that link community level peer educators and navigators with KP-competent facilities and clinical providers.

Beyond health care work in-service sensitization and training, to reduce stigma in the health care setting in the long term, training should be incorporated into higher education curriculum for healthcare workers. For example, Gender Dynamix, a transgender led organization in South Africa has developed a curriculum so that medical and nursing students are sensitized and trained on gender identity, gender-affirming care, the contextual risks of HIV infection and barriers to accessing HIV services that transgender individuals face.

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[412] UNAIDS. (2019). *Rights-based monitoring and evaluation of national HIV responses* . https://www.unaids.org/sites/default/files/media_asset/JC2968_rights-based-monitoring-evaluation-national-HIV-responses_en.pdf

PEPFAR and other funders support routine data collection utilizing a standardized methodology for measuring stigma and discrimination via the PLHIV HIV Stigma Index 2.0. Implemented by OU-specific PLHIV networks, with support from and collaboration with the Global Network of People Living with HIV/AIDS (GNP+), UNAIDS, and the International Community of Women Living with HIV (ICW) the PLHIV Stigma Index 2.0 has a specific focus on the how key populations living with HIV are affected by stigma and discrimination. (See Section 2.2.2).

***Social Protections:***

Structural interventions addressing social determinants of health by providing protections would change the conditions (e.g., social, economic, and physical) in which people are born, live, work, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Since key populations are highly marginalized, HIV programs must consider how they address these factors. Structural interventions to address social determinants of health for key populations might include the following examples:

- Supporting, connecting, and referring KP to legal literacy or legal services—e.g., FSW harassed through colonial vagrancy laws or MSM and transgender individuals in criminalized settings.
- Safe space and shelter for members of highly marginalized key populations and their children. Programming should recognize the precarious living conditions of some key populations, and support temporary housing situations, assisting clients in finding more permanent homes. PEPFAR funding cannot support the provision of housing for those at-risk and recommends referring to existing resources (see also more information below on emergency response grants).
- Connecting and referring key populations to organizations that provide food parcels for unemployed, homeless or KP that are living with HIV who have been ostracized from their families.
- Addressing gender-based violence, including intimate partner violence, prevention and response programs that focus on the lived realities of key populations and that also increases their risk to HIV. See Section 6.6.2.1 on Gender Based Violence.
- Ensuring KP have access to psychosocial support, such as psychologists and social workers, as part of HIV programs will help KP in taking up and adhering to HIV prevention interventions and treatment by addressing mental health, harmful substance use, stigma, discrimination, violence, food insecurity, homelessness, child support

services, desire for gender-affirming care, disclosure as LGBTI+ or HIV positive to family and friends and other structural barriers that KP face.

***Promoting Rights/Policies:***

Policies are formal guidance adopted to bring about change. Procedures refer to the implementation of a policy and typically specify a process. Structural interventions can involve changes to institutional policy or procedure, governmental policy, or legislation. For key populations, this might include the following:

- Policies to protect the privacy and confidentiality of clients and their personal information
- Rights, stigma and discrimination policies and practices are posted, addressed specifically in trainings, and enforced
- Creating zero-tolerance policies at health facilities to prevent PLHIV and KP-specific discrimination and enforce consequences
- Integrating policy into CSO bylaws that increase the role of KP leaders in governance and management of CSOs serving key populations
- Formalized procedures for reporting healthcare stigma and discrimination against PLHIV and key populations
- Supporting legal environment assessments or other reviews of the legal and policy environment (see Section 2.2.2)
- Working proactively and deliberately with other USG entities at post and headquarters to advance the directives in President Biden's Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World, which includes directives to U.S. government agencies to ensure that United States diplomacy and foreign assistance promote and protect the human rights of LGBTQI+ persons, including strengthening existing efforts to combat the criminalization by foreign governments of LGBTQI+ status or conduct and expanding ongoing efforts by agencies involved in foreign assistance, to promote respect for the human rights of LGBTQI+ persons and advance nondiscrimination
- Preventing stigma and discrimination against health workers attending to KP clients

OUs and their implementing partners should be aware of the Equal Rights in Action (ERA) fund[413] which provides small grants to local organizations around the world who work to promote and defend the human rights of marginalized groups.

***Do no harm:***

Bottom line, PEPFAR programming should not contribute to the societal harm often inflicted on key populations due to severe stigma, discrimination, and violence. At times, by simply offering services to these marginalized communities, risks may be heightened due to exposure of service delivery mechanisms. PEPFAR KP programming must balance target achievement with the safety and security of these marginalized communities.

KP task forces or fora are an important platform for communities to interface with PEPFAR and government stakeholders to monitor and track progress on issues pertaining to safety and security. PEPFAR OUs should consult with key population-led organizations, UNAIDS, and other stakeholders to determine the best strategies to provide support in preventing and addressing instances of violence and harassment against individuals and community-based organizations. Support to mitigate safety and security concerns facing key populations could include:

- Convening with government and non-governmental stakeholders to discuss safety and security strategies.
- Building core knowledge and skills among implementing partners on the connections between violence and HIV, and best practices for preventing and responding to violence. A project brief is available to provide recommendations and a checklist for implementing partners on addressing violence available online.[414]
- Emergency funding to cover incidents, including but not limited to emergency shelter, legal fees, mental and psychosocial support. PEPFAR key populations programs should also be aware of potential resources available through the emergency response grants of the LGBT Fund, a previous partnership among the Elton John AIDS Foundation, PEPFAR and UNAIDS.[415] OUs should also be aware of the Dignity for All LGBTI Assistance Fund.[416]

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[413] https://www.ndi.org/equal-rights-action-fund

[414] https://www.fhi360.org/sites/default/files/media/documents/resource-linkages-safety-security-toolkit.pdf

[415] https://frontlineaids.org/our-workincludes/rapid-response-fund/

[416] https://freedomhouse.org/programs/LGBTI-assistance

Finally, PEPFAR will expect that all implementing partners serving key populations maintain an **ethical code of conduct** which delineates how to work with key populations in a safe, dignified, non-discriminatory, non-exploitative, ethical, and supportive way. These codes should be developed with local OU-based KP leaders, KP-led and competent organizations, and recipients of service—including key population-led groups—working together to ensure ownership in its implementation. Included should also be KP-inclusive non-discrimination hiring and personnel policies and practices, which are to be assessed by implementing agencies during contract negotiations. If there are any allegations (or documented occurrences) of violations of these codes, swift action from PEPFAR country teams and implementing agencies to identify the facts, take appropriate response measures, and ensure community members are engaged and apprised of remediation steps is expected.

## 6.5.2 Sustainability of KP Programming

Programs that provide targeted services to key populations are highly dependent on a reliable and long-term source of financial support and are often the main source of prevention, testing, and treatment for key populations. Without targeted support to ensure that key populations are not left behind, PEPFAR will not achieve sustained responses to epidemic control. Therefore, it is vital that public sector and private sector, including KP-led CSOs and KP-competent NGOs, sustain and diversify funding streams from domestic resources for KP and PLHIV, or through raising their own revenue through sales and marketing as social enterprises, or a combination of approaches. Domestic budgets for costed strategic plans that prioritize KP programming from the public sector as well as community-based, targeted programs, all with KP community engagement and leadership in the planning, implementation, and oversight, ensure better access and utilization of key populations who are essential to sustainability of national responses as they approach epidemic control.

Expanding social health insurance coverage and social contracts is a critical opportunity to KP CSOs as well as social enterprises who may generate revenue by capitalizing on populations willingness to pay for HIV or non-HIV products and services. Developing social enterprise models includes market analyses, willingness to pay studies, seed funding grants, business and strategic planning, structural analyses, and targeted support to address enablers and challenges, and capacity building and peer to peer coaching and mentoring to CSO organizations and their staff on technical, financial and strategic management, marketing and franchising. These interventions can be paired with innovative financing that help CSOs access

low-interest loans to secure needed capital to establish new service lines or revenue-generating ventures as well as subsidizing commodities or use of innovation grants to jump start development. Simultaneously, countries must improve the enabling environment for private sector work through improved policy and regulation that make it easier for CSOs to social contracts with the government, become accredited or registered as organization or clinics, secure public or private loans and start new business ventures. PEPFAR recognizes these efforts will not be appropriate for all settings due to challenging policy environments; these efforts do not preclude other PEPFAR efforts to strengthen the broader enabling environment or address stigma and discrimination, and do not substitute for PEPFAR supported KP or community service delivery. They are rather an opportunity to promote innovative models where possible and a longer-term strategic approach to supporting KP-led service delivery. For example, five non-governmental organizations (NGOs) in the Dominican Republic are the largest providers of HIV services and are heavily dependent on donor financing. PEPFAR/USAID supported analyses for the NGOs to explore alternative revenue sources besides donor funds and to improve operational efficiency and business planning. As a result, one NGO secured a large grant from a private foundation. A second is launching a dermatology wing, which will generate substantial revenue from insurance and out-of-pocket payments, helping to cross-subsidize free HIV care. Further guidance on supporting KP CSOs is described below.

#### 6.5.2.1 Key Population-Led Civil Society Organizations Financing

Over the past fifteen years, PEPFAR, the Global Fund, and UNAIDS have promoted a wide range of policies and invested significant resources in establishing and sustaining community-led KP led CSOs to provide a range of HIV services to their constituents. In doing so, locally-led KP CSOs have been shown to be a valuable partner. Evidence has shown that the provision of funding resources to CSO initiatives improves the reach and the quality of services provided while enhancing linkages, and leading to a sustainable, long-term response to HIV. These findings have in recent years led UNAIDS, The Global Fund to fight AIDS, TB and Malaria, the World Bank and PEPFAR to call for greater investments in community-led organizations to accelerate and expand the response to HIV and has resulted in the UNAIDS release of several guidance documents recommending investment in community-led organizations (UNAIDS 2016, 2018, 2019a), culminating in the 2019 Global AIDS Report, titled *Communities at the Centre*. Numerous challenges, however, threaten the long-term sustainability of KP CSOs. For example, with the emergence of other health demands or crises, such as the COVID-19 pandemic, funds

may be shifted to address these acute needs and donor and local resources may be less available to support KP CSOs delivering HIV services. There are also complex regulatory, organizational, and societal barriers that must be addressed in order for KP CSOs to receive domestic funding.

While PEPFAR has focused on increasing funding to local organizations, PEFPAR's goal moving forward is to support capacity development for enhanced and diversified funding sources for KP CSOs. PEPFAR must provide high level technical assistance to address barriers and seed the funds needed in order to shift from donor dependency to primarily local public and private resources for the financial and managerial requirements for KP CSO operations.

**Financial Sustainability**

Generally, there are two specific options, and one blended pathway, that KP CSOs may use to acquire reliable and long-term financial support. The first is obtaining grants and contracts from public domestic sources. The second is private 'self-financing' of services using proceeds from the sales of products or services, including direct services, to clients or external organizations or institutions. A blended pathway uses a mix of both of these approaches.

**OPTION 1 - Direct acquisition of domestic grants and contracts**

PEPFAR's 2019 Responsibility Matrix found that a relatively small portion of local governments were primary funders of KP HIV prevention or treatment services, in contrast to HIV services provided to the general public. Clearly, KP CSOs are heavily reliant on non-governmental, and non-domestic, resources to support a wide range of services. Their economic and financial situation remains fragile and any shifts of financing priorities or budget levels to other target populations, disease groups, or countries will have a detrimental impact on the survival of most KP CSOs, even while key populations and their partners bear the burden of the largest proportion of new infections globally and are essential to the sustainability of all national AIDS responses. PEPFAR teams should foster institutional partnerships and technical assistance plans to strengthen KP CBOs and address organizational and structural barriers.

For CSOs that are able to acquire grants and contracts, several structural elements are essential for their viability, including organizational capacity for:

- Professional management, grants support, contracting, financial and monitoring staff
- Capacity to successfully submit grant applications
- Close collaborations and communications with grant organizations

In order for these elements to be realized, several key enabling environment factors are necessary:

- Government and donor laws and policies in place for social contracting.
- CSO and KP CSO formation, registration, and accreditation systems that allow access to domestic grants, contracts, and social health insurance reimbursement.
- Protections for key populations to provide access and use services.
- Capable government contract management offices.

**OPTION 2 - Self-Financing**

The second financing option, Self-Financing, relies on the ability of the CSO to raise capital for direct delivery of services, either within or outside contractual arrangements, and having a diversified portfolio of products and services.

For 'Self-Financing', the following elements should be developed and strengthened through targeted TA:

- Professional finance, management, operations, and accounting staff
- Business research followed with marketing and sales, and targeted branding
- Strategic planning/franchising
- Open market opportunities to acquire seed funding, capital, and investments
- Information technology
- Regulatory compliance mechanisms: and strategic partnerships to build administrative and management capacity
- In order for these elements to be realized, several key enabling environment factors are necessary:
    - Protections for key populations to access and use services
    - A level field for competition
    - Non-discriminatory practices.

**OPTION 3 – Blended Financing**

The third, and likely optimal, option is a blending of both Options 1 and 2. It may be challenging to ensure that organizations have sufficient capacity to effectively manage and account for both types of financing approaches. Failure in any one of these could risk the overall structure and functioning of the organization. Careful consideration and planning are essential in concurrently pursuing both options.

*Beyond the Challenges of Financial Sustainability*

While financing is frequently the focus of sustainability efforts, as discussed above, organizational and performance management and accountability is essential to the success of an organization. Underlying these issues is the need to establish a responsive and enabling legal/policy environment to allow for the establishment and effective management of KP CSOs without barriers to resources or limits on access by clients. The legal/policy environment (national and subnational) affects the authorization and functioning of the organization and clients accessing services; the organization's internal financial and operational management capacity; and the ability of KP CSOs to form strategic partnerships at the public and private levels to deliver a wide array of HIV services, prevention, testing and counseling, social services, and HIV treatment.

Several other formidable challenges that KP CSOs face related to sustainability include:

- Challenges in diversifying the HIV services offered to fully meet the needs of key populations.
- Inadequate capacity to develop business plans for sustainability.
- Lack of access to capital on preferential terms.
- Failure to fully integrate into national health systems and insurance schemes, thereby limiting their ability to sustain themselves and provide diverse and quality services.
- Difficulty accessing quality assurance and accreditation processes and tools due to the nature of funding and targeted service delivery.
- For additional information on building a sustainable KP CSO, including leveraging self-financing mechanisms, legal and policy considerations, and building organizational capacity for management, government, and operations, please reference PEPFAR's KP Sustainability white paper. To review, please reach out to your Agency KP ISME or email the S/GAC Program Quality Team at sgacprogramqualityteam@state.gov.

## 6.5.3 Considerations for Monitoring Key Populations Programs

### 6.5.3.1 KP Surveys and Surveillance

Summary of section edits:

- Language was added to address how BBS implementation can be expedited and to strengthen requirements around KP and community engagement.

Demographic and health surveys, such as PHIAs, rarely capture reliable information on key populations. Bio behavioral surveys (BBS) use sampling designs and methodologies for populations that lack a ready-made sampling frame to generate population-level estimates on HIV prevalence and progress toward 95-95-95 targets among key populations. WHO and UNAIDS recommend that BBS of key populations be conducted every two-to-three years.[417] OUs that have not conducted BBS for key populations in the past two years should work with in-country partners, including The Global Fund, to ensure regular surveillance activities are planned during COP22.

Many countries are overdue for BBS and PSE. To ensure data become available as quickly as possible, countries should begin protocol development before the COP year starts. Countries can expedite this by building upon old protocols, or by utilizing the CDC's template protocols for respondent-driven sampling and time-location sampling surveys and three-source capture-recapture population size estimation. WHO's *Biobehavioural Survey Guidelines for Populations at Risk for HIV* (who.int) also have questionnaire banks to facilitate questionnaire development.

Electronic data collection can save time and improve data quality. To help expedite questionnaire programming, the CDC has developed open data kit code aligned with WHO questionnaire banks. Of course, hiring more interviewers and counselors can speed data collection but can increase costs. An alternative is to use audio-assisted computer interviews (ACASI), as has been done in Uganda, to increase the number of people at a time who can respond to the questionnaire. Finally, data management can be conducted and code for analysis can be written during data collection to reduce the workload required after data collection. Priority actionable results should be shared with key stakeholders in the form of a summary sheet within two months of the end of data collection and the full survey report within six months.

BBS should be conducted in locations with the highest estimates of key populations, and/or those that reflect the HIV epidemic of the country. Sample sizes should be large enough to conduct analyses of outcomes for key populations living with HIV, including estimates of knowledge of status, treatment coverage, and viral load suppression.[418] Specific and detailed

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[417] https://apps.who.int/iris/bitstream/handle/10665/258924/9789241513012-eng.pdf
[418] https://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en/

guidance on calculating sample sizes is found in the WHO Blue Book.[419] BBS should also estimate the size of each key population group in relevant locations through the use of multiple-source capture-recapture or other empirical population size estimation (PSE) methods.

Population size estimates are needed to inform policymaking, resource allocation, and measurement of impact via denominator data. Many countries lack robust size estimates and instead rely heavily on mapping and enumeration of hot spots and other select areas. While physical hot spot mapping and enumeration provide useful data, more robust PSE methods are needed to ensure reasonable estimates of KP, including those that are less visible and not likely to be counted via hotspot mapping and enumeration. As key populations increasingly embrace the internet and mobile applications, they may have shifted away from physical venues in some settings. Hence, virtual hot spots or sampling should be considered in population size estimation exercises, as appropriate. Robust methods should (1) include methodologies that scientifically sample the virtual space of key populations who meet partners online, (2) use scientific approaches to estimate the full population size based on a joint analysis of physical (e.g., derived from multiple-source capture-recapture) and virtual (web-based) size estimation data in areas where no BBS will be conducted due to insufficient sample sizes, PSE should be conducted on their own, ideally using at least a three-source capture-recapture approach.[420]

Country teams planning to conduct PSE should include in COP22 a plan to obtain robust estimates of key populations with reasonable upper and lower bounds.

Engagement and capacity strengthening of KP community members is vital for the success of BBS and PSE, including survey design, formative research, implementation, results validation, and development and implementation of recommendations. Engagement must occur with a diversity of KP-led organizations, including national level KP consortia, where they exist. In highly stigmatized or criminalized contexts, release of data about key populations can potentially create safety and security risks; engagement of KP members in BBS and PSE design and implementation is therefore imperative. Involving key populations members in survey planning can facilitate gaining support for the survey from other KP members and

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[419] http://apps.who.int/iris/bitstream/handle/10665/258924/9789241513012-eng.pdf?sequence=1

[420] Son, V. H., Safarnejad, A., Nga, N. T., Linh, V. M., Tu, L., Manh, P. D., Long, N. H., & Abdul-Quader, A. (2019). Estimation of the Population Size of Men Who Have Sex With Men in Vietnam: Social App Multiplier Method. *JMIR public health and surveillance*, *5*(2), e12451. https://doi.org/10.2196/12451

encourage survey participation. KP members play a critical role in advising matters of safety and security, including how, if at all, to engage law enforcement during survey planning and implementation, to ensure the safety and security of survey participants. KP members should be included in the survey technical working group, and where appropriate and feasible, on survey teams, as survey investigators, and/or report and publication co-authors. Priority results should be shared with key stakeholders within two months of the end of data collection and prior to the release of a report. A full report should be shared with key stakeholders within six months of the end of data collection, including Chair and PPM.

### 6.5.3.2 Unique Identifier Codes & Special Considerations for KP

A number of models for following key populations across the cascade are available including:

a) The program model where a PEPFAR-funded program registers all key populations and tracks them with a unique identifier code (UIC) across services, from outreach to PrEP continuation for key populations who are HIV negative or from outreach to treatment and continued viral load suppression for KPLHIV, including any wraparound or complementary services such as STI and TB diagnosis and treatment or violence prevention and response. Increasingly individual-level data management system such as DHIS2 tracker capture is replacing paper- and Excel-based systems.
b) An integrated KP program and clinical tracking model where the KP program assigns KP members a UIC and through collaboration with referral clinics matches that KP member's UIC with the individual's ART number. KP indicators along the continuum of care can then be generated for the government while protecting identification of individuals in the KP data system. At the same time, if KP members consent, their treatment and viral load status could be shared with the KP program to allow for peer navigators to better fulfill their role as case managers. Interoperability between the KP individual-level information system, such as a DHIS2 tracker instance, and the national electronic client tracking system is necessary to facilitate data exchanges.
c) A clinical tracking model where KP classification is first recorded in health service registers (rather than outreach), which, like model (b) above, also allows for KP data disaggregation while maintaining confidentiality, data safety and security during data collection and storage so that clinic records cannot be used to harm KP clients. The first priority of data collection and reporting of program data for key populations must be to DO NO HARM.

The models (b) and (c) are optimal as they can link KP data across sites given that the clinical record system is national. PEPFAR-funded programs should work with the Ministry of Health and in cases where government is not trusted with KP data, other partners to build and/or strengthen UIC client tracking systems and optimize data completeness and quality through the provision of written SOPs/guidelines and on-the-ground TA. KP UIC should be confidential and secure, non-stigmatizing; client generated; easy to recall; unique for each client i.e., cannot be replicated for or by another client; and allow mobility within or across SNU without duplication of the client across service delivery points. Section 6.6.8 highlights best practices in regard to data collection and digital health investments, including those for KP.

Numerous countries have developed systems to link clinical and community-level data across the cascade and/or to National AIDS Program ART registries to better inform interventions that seek to improve enrollment in care and initiating and sustaining key populations on treatment. For example, in Eswatini KP clients are tracked via a hybrid a/b model. Community-based KP implementing partners that provide initial outreach, prevention, testing, and treatment enroll clients in the community-based DHIS2 information system at the first service encounter. If a KP client tests positive or knows their status as HIV positive but is not yet on treatment and wishes to initiate or restart ART with the community KP partner they have that option and will receive ART at a community site. Follow-up visits will be entered into the DHIS2 tracker including vial load testing, TB screening, preventative treatment, STI screening among other services. KP clients who test positive and wish to initiate ART a public health facility of their choosing will be referred, linked to care, and followed using the national electronic medical record system (EMRS). Built interoperability between the community-based DHIS2 system and the EMRS allows the KP implementing partners to contribute to the national information system for clients they are following so that governmental implementing partners can continue to monitor and report on KP-disaggregated treatment indicators, while maintaining confidentiality, data safety, and security of KP clients. The KP partner is also able to query the EMRS allowing it to provide community case management services to KPLHIV who experience interruptions in treatment or who are for other reasons virally unsuppressed if on ART at a governmental health facility. The integration of the community and facility-based information systems is a step towards sustainability of KP community programs as the Ministry of Health is interested in understanding the clinical cascade for KP and providing KP-friendly services.

Any work on UICs and health data must be approached from a “do no harm” standpoint where KP community members and networks provide guidance on a trusted approach, with

appropriate data safety and client confidentiality policies enforced. To reiterate, the first priority of data collection and reporting of program data for key populations must be to DO NO HARM. This applies to data collection, access, storage, transfer, and use. System and data encryption should be employed to ensure data and system safety. All staff must be trained on confidentiality, and confidentiality agreements and explicit personally identifiable information (PII) protections must be in place. Even in situations where implementation of UICs is determined to pose no risk to the community, the program should recognize that stigmatized and criminalized communities may have reason to fear such systems, and extensive dialogue may be required before the system can be implemented.

### 6.5.3.3 Monitoring of Key Populations Programs

Key populations commonly access prevention and testing services through KP specialized non-governmental organization (NGO) service delivery partners and, in some cases, can only access antiretroviral therapy at government facilities. While PEPFAR MER indicators are essential in tracking 95-95-95 progress, these standard indicators do not necessarily capture the comprehensive set of interventions and linkages that are implemented among key populations. Supplemental KP program monitoring using customized indicators is not required by S/GAC but recommended by USAID and CDC for program improvement and to accurately demonstrate results for KP across the entire cascade. Supplemental indicator systems must protect identifying information of key populations and prevent intentional or unintentional harm.

In Mozambique (FY21 Q3) the cascade outcomes demonstrate that while a treatment linkage rate could be calculated as 18% using MER indicators, the use of the customized indicator TX_NEW_VERIFY can effectively indicate that actually 99% of the newly diagnosed key populations were successfully linked and initiated on ART, despite only a small proportion being reported by treatment clinical partners. Custom indicators are also used to track and report clients progress from treatment initiation to VL suppression, as well as through the PrEP cascade.

Additional agency specific information on the use of customized indicators and indicator reference sheets to improve monitoring of the KP clinical cascade can be found in the

CDC/USAID Key Populations Cascade Monitoring Guide.[421] These are supplemental indicators, and notably utilization of customized indicators does not substitute for but rather extends complete and accurate MER indicator reporting. Countries should establish data quality assessment and assurance processes for all customized indicators to ensure consistency, accuracy, and integrity. Customized indicators should undergo regular data quality assessments (DQAs), in alignment with the reporting frequency.

As information systems have evolved to track and improve individual client and overall HIV cascade outcomes safely and accurately, so too have program opportunities and responsibilities to analyze routine program data to identity population segments and clients facing elevated risks. For example, by identifying the differentiating characteristics of clients who are more likely to receive positive results from HIV testing, not initiate on, sustain access to antiretroviral therapy (ART), or to achieve viral suppression, programs can develop tailored and preferred service solutions that would improve health outcomes for these individuals and others like them.[422]

The PEPFAR funded project has published a guide with case studies on how individual-level data on KP populations can be safely used for continuous quality or program improvement. To this point, in Indonesia and Vietnam individual-level data is being used to predict which clients are most likely to experience an interruption in treatment. In Vietnam, the program found that PWID, people who did not identify as KP and those who had experienced an interruption in treatment (IIT) more than 180 days ago were less likely to reengage in care when recontacted. Individual-level data was used to determine that PWID were less likely to return for a second PrEP visit. And finally, for case finding, in Indonesia, MSM, transgender individuals, people with an unsuppressed viral load and those with negative feeling about themselves were more likely to refer contacts who tested positive.

Lastly, PEPFAR also recognizes the importance of tracking transgender individuals as a specific key population, and not a subset of another KP group. While size estimations are often lacking and challenged due to relatively low overall population sizes, PEPFAR teams should conduct

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[421] USAID and CDC. (2020). Key Population Cascade Monitoring Guide . https://drive.google.com/file/d/11uT9cvn4ZAOiURnzS6ObT4yrBOfzUaVS/view

[422] FHI 360. Brief guide: Client risk segmentation to optimize the impact of HIV programming. EpiC, 2021 . https://www.fhi360.org/sites/default/files/media/documents/epic-client-segmentation-guide.pdf

analysis of past and current programs specific to transgender individuals to improve the tracking and monitoring of services among transgender populations.

## 6.5.4 Considerations for Children of Key Populations, Adolescent and Young Key Populations

### 6.5.4.1 Children of Key Populations

Stigma and discrimination experienced by key populations, as well as their high levels of mobility, can negatively impact their children's essential access to health, education, and child protection services. Due to limited access to comprehensive HIV care and treatment services, compounded by sensitivities regarding their parent(s) as key populations and/or persons living with HIV (PLHIV), the increased risk of HIV and other poor health and protection outcomes for children of key populations may be overlooked by clinical and community programs.

An essential first step in providing comprehensive services to children of KP is to assess the number of children whose parents are KP or living with/married to a person who identifies as KP. Approaches to estimate the number of children whose parents are KP include analyzing existing KP program data and integrating questions about current number of children in KP population size estimation work or bio behavioral surveillance surveys. In 2020, with PEPFAR support, an analysis was conducted in 10 countries in sub-Saharan Africa to estimate the population size of children of female sex workers and of MSM.

A KP-competent, sensitive, and confidential family-centered approach is fundamental to engage key populations and their families. Programs should prioritize differentiated care models that improve access to and uptake of early infant diagnosis (EID) and PMTCT services (see Section 6.2.4 Prevention for Women and PMTCT), pediatric HIV testing including index testing for biological children <19 years of age (Section 6.3.2.1 Pediatric Index Testing Considerations and Section 6.3.2.2 Case Finding in OVC) see Section 6.3.1.5 Index Testing and Section 6.5.1.2 Index Testing for Key Populations), linkage to ART (see Section 6.1.1 Linkage for Children and Families), and continuity of treatment to achieve viral suppression, as well as other critical health, psychosocial and economic strengthening interventions.[423] This approach should build upon current service delivery platforms through integration of KP, family planning (FP),

[423] Srivastava, M., Dastur, S., Ficht, A., & Wheeler, T. (2018, July). Addressing service delivery needs of children of key populations. Child Survival Working Group. http://www.childrenandaids.org/sites/default/files/2018-07/01-Addressing-the-service-delivery-CSWG.pdf

prevention of mother-to-child transmission (PMTCT), pediatric HIV, DREAMS, and Orphans and Vulnerable Children (OVC) services, as appropriate. All programs will need to be implemented by trusted providers within a carefully designed system that maintains confidentiality of HIV status of key populations and their children.

**Key Services for Children of KPs**

*PMTCT*

Pregnant and breastfeeding KPs should have access to KP-competent PMTCT services, including dual HIV and syphilis rapid tests and maternal retesting during pregnancy and breastfeeding periods, either in general population facilities or in settings catering primarily to KPs (drop-in centers). Additional to the standard ANC package of services, pregnant and breastfeeding KP individuals should receive counseling and support in line with their specific needs and those who are living with HIV and their children should be offered enrollment in the OVC program. (See OVC Section 6.6.3).

*Case Finding*

Identifying biological children of key populations living with HIV (KPLHIV) should be prioritized in case finding programs, with a focus on identifying and offering testing to biological children (<19 years of age) of KPs living with HIV or with unknown HIV status (see Section 6.3.2.1 Pediatric Index Testing Considerations).

*Continuum of Care and Coordination with OVC Comprehensive Program*

KP, OVC and clinical Implementing partners must coordinate to ensure that children of key populations are included in the bidirectional referral and linkage processes, and that all HEI and CLHIV of key populations are linked to appropriate testing or treatment services, maintain treatment continuity, and are offered enrollment in comprehensive OVC programs (see Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic Section 6.6.3). HIV-negative children of key populations should also be assessed for eligibility for the OVC program and offered enrollment, if appropriate (and if new enrollment slots are available). KP implementing partners (IPs) should work closely with OVC and clinical IPs and establish strong bidirectional referral systems and data sharing agreements, while respecting the ethical considerations needed relative to consent and confidentiality (Section 6.6.3 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic). A new resource for OVC programs working with key populations is also available at

https://www.fhi360.org/resource/providing-care-and-support-children-female-sex-workers-training-orphan-and-vulnerable.

Sites offering primarily services for key populations, such as in drop-in centers (or one-stop shops), should ensure child-friendly, safe spaces and services for the children of key populations or if preferred, strong referral mechanisms to health facilities. Providers in facilities should be trained to provide safe, family-centered, and non-judgmental services to key populations and their children, should KPs prefer to bring their children to that site. Peer educators and other outreach staff working with KPs in the community should inform them about available HIV prevention, care, and treatment services for their children at either KP drop-in-centers or other sites serving the general population. If referring to other sites, strong coordination with clinical IPs is essential to ensure children receive HIV services.

PEPFAR programs have demonstrated that innovative and integrated approaches can successfully reach children of key populations. Some examples include:

- Implementing a Peer-to-Peer approach to provide targeted need-based services for children of key populations and their households.
- Training and engaging KP members as Community Case Workers to provide services to their fellow key populations.
- Escort services for HIV testing (including early infant diagnosis), drug refills, and viral load testing for children of KPLHIV.
- Counselling FSW caregivers if their children are not yet tested, on treatment or virally suppressed.

Moreover, KP caregivers and adolescents living with HIV can be provided economic support to improve household resilience.

*Preventing, identifying, and addressing abuse*

As children of key populations are at greater risk of abuse, in particular sexual abuse, further considerations must be made regarding screening and protection of these children from physical, sexual, or psychological abuse, especially when they reside in or are exposed to

settings where their parents engage in sex work or injecting drug use (See Section 6.6.2.1 on Gender-Based Violence and Violence Against Children).[424]

It is important for local and national governments as well as in-country KP, OVC, and clinical staff, civil society organizations and IPs to support KP programs to safely and accurately assess and document the number and needs of children of key populations in communities in order to adequately resource providers and adapt service delivery models. To learn more about programmatic examples, please contact your Key Populations Headquarters ISME.

Using size estimates PEPFAR South Africa is piloting a collaboration between OVC and KP partners in the provinces of Gauteng Province, and Kwa-Zulu Natal where the estimated number of CoFSW living with HIV is greatest. In Gauteng, the collaboration between the USAID-funded OVC partner HIVSA and their sub-partner Future Families along with the USAID funded KP partner Wits RHI was initiated organically in January 2021. Together they developed a tailored package of services for children of KP via case management. The package includes health, psychosocial support, nutrition, education, and protection services, ranging from identifying, testing, linking/referring children to HIV care and nutritional assessment to homework support and violence prevention and screening. In addition, a separate tailored package of services for the KP parents or caregivers includes:

- Counseling on disclosure practices
- Support to children
- Skills building in childcare and development (health, nutrition, early childhood development)
- Establishment of child protection and risk mitigation policies

Key steps at the start of the collaboration include a KP sensitization training provided to Future Families staff via WHRI, as well as strengthening referral pathways between the two partners.

To ensure success, programs for children of KPs should also be implemented in collaboration with national ministries of health and local government structures. In South Africa, HIVSA's Preventing HIV/AIDS in Vulnerable Populations (PHVP) Program funded by USAID aims to contribute towards HIV epidemic control by enhancing the quality, comprehensiveness and sustainability of care and support services to improve resilience, health and well-being of

[424] Beard, J., Biemba, G., Brooks, M. I., Costello, J., Ommerborn, M., Bresnahan, M., ... & Simon, J. L. (2010). Children of female sex workers and drug users: a review of vulnerability, resilience and family-centred models of care. Journal of the International AIDS Society, 13, S6-S6.

Orphans and Vulnerable Children, Adolescents and Youth, in line with the South African Government (SAG) strategic goals for health and social development. In Tshwane Health District, Gauteng Province, PHVP sub-partner, Future Families, collaborated with the KP partner Wits RHI (WRHI) to initiate service delivery and support for children of FSW:

- A total of 229 children of FSW ages 0-17 (130 females and 99 males) were enrolled in the PHVP program
- Care plans were developed mapping out the needs of each child enrolled
- All 229 were referred for HTS after receiving HIV education
- 5 children tested positive (2.1% positivity) and were linked to ART and are receiving adherence support
- All 229 are provided services according to their care plans and the service package

Given their highly vulnerable status, mobility, and elevated risks of marginalization, discrimination, and criminalization, protection of children of key populations and their families must be the utmost priority. Offering key populations and their family's access to safe clinical and community programs will significantly advance efforts to reduce the pediatric treatment gap and ensure these children and families have equitable access to with life-saving HIV services as well as critical protection and socio-economic services.

## 6.5.4.2 Adolescent and Young Key Populations (AYKP)

Adolescents and young people from key populations are at significant HIV risk, higher than that of their older peers in these populations.[425] Studies are limited, but they consistently show that adolescents and young people from key populations are even more vulnerable than older cohorts to STIs, HIV and other sexual and reproductive health problems.[426] [427] Young people who identify as members of these populations are especially hard to locate and are disproportionately impacted by HIV due to widespread discrimination, stigma and violence

[425] WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update. https://www.who.int/publications/i/item/9789241511124
[426] Delany-Moretlwe, S., Cowan, F. M., Busza, J., Bolton-Moore, C., Kelley, K., & Fairlie, L. (2015). Providing comprehensive health services for young key populations: needs, barriers and gaps. Journal of the International AIDS Society, 18(2 Suppl 1), 19833. https://doi.org/10.7448/IAS.18.2.19833
[427] WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update. https://www.who.int/publications/i/item/9789241511124

combined with the vulnerabilities of youth.[428] Key findings from a multilateral report highlighted four domains with major gaps that need to be addressed when designing HIV programs for adolescent and youth key populations: Education, Parental and Peer Support, Communication and Mental Health.[429] Strategies are needed that meaningfully engage adolescent youth and key populations in partnering to advance understanding and assessment of their own needs, and in designing and delivering effective, gender sensitive programing with respect for sexual and gender diversity serve dual but complementary aims.

Programs should ensure that young people are given the opportunity to increase 21st-century skills, and promote increased acceptability, access, and uptake of measures to support SRHR, HIV prevention and well-being such as:

- Provide teacher training and resources to challenge teachers' own discriminatory attitudes about sexuality, gender, HIV and AYKP; promote understanding of rights-based and gender-sensitive approaches; develop skills to support students' critical thinking; promote students' skill-building through activity-based learning; and expand coaching systems and rewards to support teachers' performance and motivation.
- Design and launch non-threatening initiatives with and for parents to increase understanding of sexual and reproductive health and rights (SRHR), including sexual orientation and gender identity, build skills to promote communication with their children about SRH and HIV prevention, and support parent role models who have navigated challenges around their own children's sexuality, gender identity and sexual behaviors.
- Capitalize on adolescents' widespread use of social media and online apps to develop youth friendly and engaging materials to disseminate accurate information about SRH, including HIV/STIs, condom promotion, sexuality, HIV testing and teenage pregnancy.
- Integrate competent and evidence-based mental health services inclusive of AYKP in existing youth-friendly health services.

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[428] Delany-Moretlwe, S., Cowan, F. M., Busza, J., Bolton-Moore, C., Kelley, K., & Fairlie, L. (2015). Providing comprehensive health services for young key populations: needs, barriers and gaps. Journal of the International AIDS Society, 18(2 Suppl 1), 19833. https://doi.org/10.7448/IAS.18.2.19833

[429] UNICEF. (2019). *LOOKING OUT FOR ADOLESCENTS AND YOUTH FROM KEY POPULATIONS Formative assessment on the needs of adolescents and youth at risk of HIV: Case studies from Indonesia, the Philippines, Thailand and Viet Nam*https://www.unicef.org/eap/media/4446/file/Looking%20out%20for%20adolescents%20and%20youth%20from%20key%20populations.pdf

- Train, capacitate and expand existing youth friendly SRH programs and clinics to provide competent, gender-responsive, and person-centered services to AYKP, LGBTQ+ and heterosexual youth.

PEPFAR programs should implement successful strategies to reach these young key populations living with HIV or at risk for HIV prioritizing outreach activities (virtual and in-person), peer referrals and expansion of person-centered differentiated models of care, as well as addressing the multifaceted needs of youth, such as civic engagement, education, and employment. Strategic coordination with other partners including DREAMS and other youth programming and ensuring bi-directional referral mechanisms are also key. It is also important to support the implementation of adolescent and youth responsive health systems including HIV testing, PrEP, condoms and lubricants, immediate linkages to care and treatment, STI testing and treatment, FP/SRH services, and GBV/IPV prevention and mitigation.

For example, in Zimbabwe, the PEPFAR KP and DREAMS partners have worked together to ensure that young sex workers and vulnerable adolescent girls and young women are identified and provided the appropriate DREAMS package of primary and secondary services. Young sex workers and vulnerable AGYW are identified through different entry points. First, the KP partner works in nine DREAMS districts and supports young peer outreach workers to use a microplanning approach to reach young sex workers and vulnerable AGYW in the community. In addition, other DREAMS partners may identify these AGYW as part of a standardized screening and enrolment process which includes asking about transacting sex. Young sex workers and vulnerable AGYW who are identified by other DREAMS partners are then linked to the KP partner for age specific and youth friendly services, including the primary package for DREAMS and clinical services including HIV testing, SRH (STI, FP), PrEP and ART provision, and VL sample collection. The KP partner employs a differentiated service delivery approach which includes “GiRLS Clubs” (community safe spaces) to deliver the primary package, mobile and moonlight outreach services, and virtual peer follow up and PrEP adherence support. The KP partner also refers these vulnerable AGYW and young sex workers to other DREAMS partners for other components of the secondary package of services such as education assistance or comprehensive economic strengthening. These efforts are fully coordinated with the MOH/NAC, integrated into PEPFAR wide DREAMS program planning and monitoring process and the partner utilizes the DREAMS database to report services provided and to track performance against MER and custom indicators. Through these efforts the PEPFAR Zimbabwe program has been able to increase their reach and provision of HIV prevention care and

treatment services for these often difficult to reach and highly vulnerable and at-risk young sex workers and AGYW.

## 6.6 Cross-Cutting

This section of the Technical Considerations covers services that support PEPFAR programming across testing, prevention, and treatment portfolios. While in some instances one agency, donor, or stakeholder appears to play a leading role in supporting or implementing a cross-cutting service, all PEPFAR staff and stakeholders benefit from an awareness and understanding of how these elements contribute both to the mission of HIV epidemic control, to COP22 planning, and to the Implementation Themes noted in Section 2.2.

What's New in Cross-Cutting for COP22

- New Gender Equality section on the impact of gender equity and equality, and integrating gender-transformative approaches into prevention programming, the clinical cascade, workforce, and health systems (Section 6.6.2)
- Added guidance on routine and clinical enquiry for Gender Based Violence and Violence Against Children (6.6.2.1)
- Justice for Children is no longer a stand-alone initiative, rather these activities have been incorporated into DREAMS and/or OVC (6.6.2.1)
- Added guidance regarding: 1) TB screening for C/ALHIV among OVC and referrals for children with presumed TB by OVC cadres, 2) conducting outlier analysis to determine geographic alignment with highest pediatric patient load, focusing on pregnant & parenting adolescents, emphasizing family-centered approach for C/ALHIV (Section 6.6.3)
- Adjusted wording around the Faith and Community Initiative (FCI) from implementation in the 10 FCI OUs to encouraging PEPFAR OUs to reference and implement evidence-based FCI models with core funding (6.6.4)
- New psychosocial support section with expanded guidance on PSS and integrating evidence-based interventions across PEPFAR programs (Section 6.6.5.2)
- Mental health section reorganized into two sections, mental illness and psychosocial support (Section 6.6.5.1, Section 6.6.5.2)

## 6.6.1 Laboratory

Laboratory functions across the health systems at point of service delivery and above, form a critical part of the PEPFAR portfolio. These interventions support several key programmatic areas across the prevention and clinical cascade. Over the years, PEPFAR has supported countries in building sustainable capacities in all areas of the laboratory. Over time, there has been transitioning of laboratory testing in support of chemistry and hematology to countries and other partners. While most countries have effectively gravitated towards this transition, a few others are still in the process to do so. Moving forward, PEPFAR laboratory support will be limited only to viral load, HIV diagnosis for adults, infants and children, HIV recency testing, CD4, TB testing, including LAM for AHD and CrAg. In addition, support for creatinine (an exceptional chemistry test) should continue for PrEP participants. It is expected that at this time all countries would have fully transitioned testing for other parameters to country national programs.

**FAST Commodities Tab**

All laboratory-based commodities and general procurements should be identified within the FAST laboratory commodities tab as defined by the drop-down selections. Specific additions have been made to accommodate POC Omega CD4 tests, pediatric VL whole blood collections, a variety of sample collection methodologies, as well as potential blood based self-tests. Past Chemistry and Hematology laboratory sections have been removed from the commodities tab. These products can no longer be budgeted for in the COP FAST commodities tab. For laboratory commodity needs that are not specifically identified by a drop-down minor category within the FAST, ‘other’ categories have been provided. When using an ‘other’ category specific details regarding test, brand, and other identifying information must be provided. Commodities that fall into the ‘other’ categories will be reviewed and approved on a case-by-case basis during COP budget and FAST reviews.

### 6.6.1.1 Diagnostic Network Optimization (DNO)

Past suboptimal coordination among laboratory stakeholders has resulted in a) the procurement of more instruments than needed to meet current and projected HIV-related access and patient demand, b) stock-outs of reagents and consumables required to run instruments, c) poor instrument service and maintenance, d) low testing coverage, inefficient instrument utilization, and e) fragmented data and quality systems. To address this programmatic gap, it is recommended that all PEPFAR supported countries should work collaboratively with country

ministries of health and other stakeholders to conduct a comprehensive DNO. Functional DNO will be considered as one of the laboratory sustainability indicators for countries that have attained HIV epidemic control. DNO is a data-driven network mapping and geospatial analysis of the country diagnostic landscape with the intent to increase access to testing and network efficiencies, decrease total cost per test, understand components of specimen-to-result turnaround time and create greater visibility and a more competitive and dynamic marketplace.[430] A complete DNO should review and address the following indicators to ensure appropriate access, coverage, turnaround time, and testing efficiency: 1) number and location of laboratories, 2) instrument type (conventional/POC) and sample type, 3) sample referral and transportation systems, 4) utilization and capacity of instruments 5) data systems and connectivity, 6) supply chain, 7) HR, 8) waste management system, and 9) funding. DNOs should only be implemented through broad stakeholder buy-in with the local government political will and consensus and should include detailed operational plans where all stakeholders align resources and coordinate national implementation efforts. Ultimately, this will provide effective network coverage where all patients have access to timely diagnostic testing. DNO should be achieved using a stepwise approach, beginning with a baseline network assessment (e.g., per COP minimum requirements) that defines the current network structure, laboratory capacity, quality, and testing coverage and efficiency by laboratory catchment area to identify gaps or needs. If this review identifies numerous and widespread gaps, or the country has additional needs that require modification or significant change to the network structure, then a comprehensive DNO exercise should be performed.

As part of a strategically tiered and responsive national diagnostic network, efforts should be made to use both centralized and POC instruments complementarily to facilitate rapid, actionable VL and EID testing, especially for infants and pregnant/breast-feeding women and those with non-suppressed viral load (VL).[431] The integration of POC into the centralized HIV diagnostic network must be done according to an evidence-informed and patient-centered strategy. PEPFAR supported countries considering updating their networks or transitioning to new platforms (Conventional or POC) should consider conducting or refining their existing DNO to ensure appropriate selection, placement, and integration of POC and conventional instruments.

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[430] Kameko et al. (2021) https://dx.doi.org/10.3390/diagnostics11010022
[431] Alemnji et al. (2020). J. Acquir. Immune. Defic. Syndr. 84:S56–S62

Countries that have completed baseline network assessments and supported additional investments in comprehensive DNO activities are better prepared to respond to pandemics as exemplified throughout the COVID-19 pandemic. For example, implementation of DNO recommendations and investments in multiplexing of instruments, supply chain, waste management, sample transportation, and data systems in Cameroon, Nigeria, and Zimbabwe were leveraged to simultaneously scale up COVID-19 and HIV molecular diagnostic testing.[432]

Despite all COVID-19 related challenges, VL testing coverage in Nigeria had a steady increase from FY20Q3 to FY21Q4 due to functional a DNO (Figure 6.6.1.1.1). Also, Uganda, one of the PEPFAR supported countries with well-structured and functional DNO, developed an action plan that enabled this country to quickly implement an integrated HIV, TB, and COVID-19 diagnostic network (6.6.1.1.2).

*Figure 6.6.1.1.1: Steady increase in VL testing coverage in Nigeria from FY20Q3 to FY21Q4 during COVID-19*

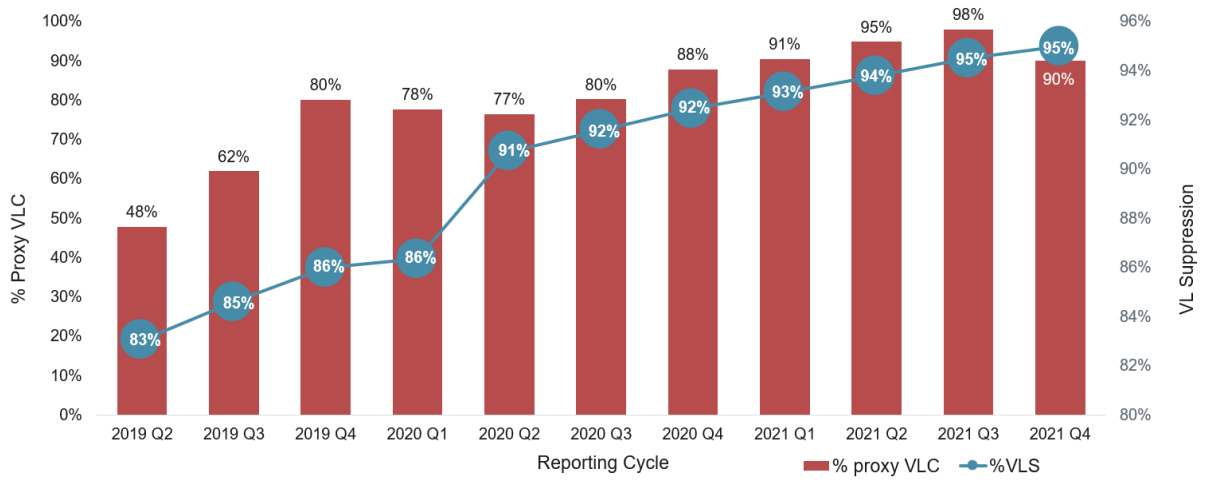
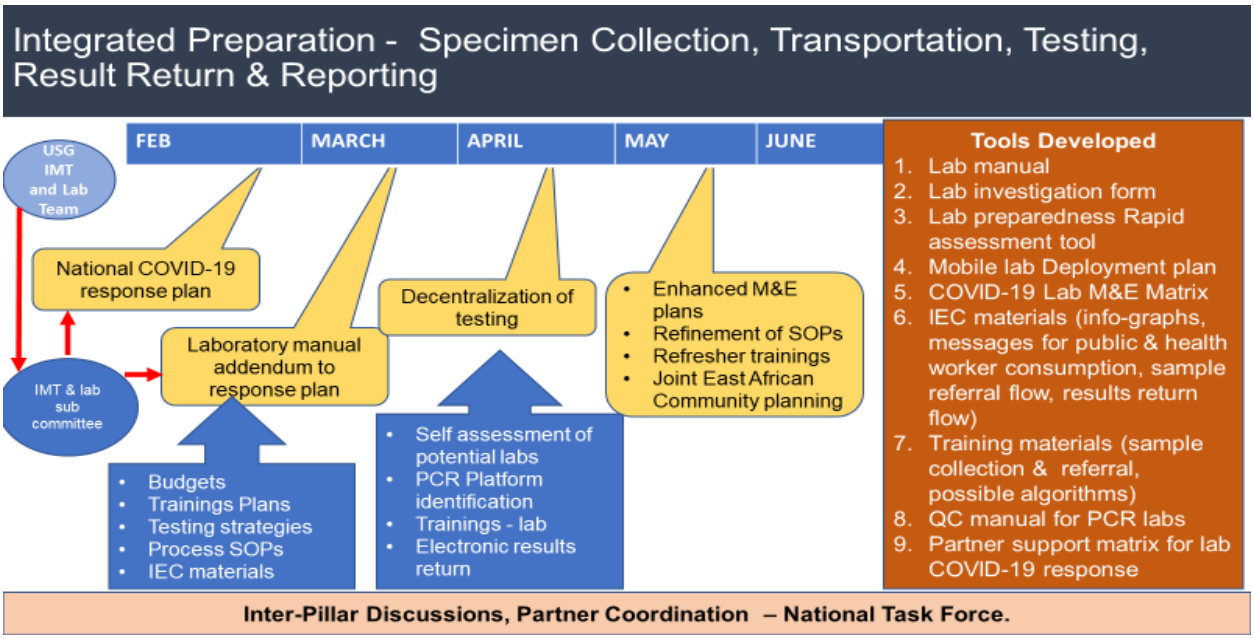



*Figure 6.6.1.1.2: Uganda integrated HIV, TB, and COVID-19 Diagnostic Network Action Plan (DNAP)*

[432] IAS (2020) https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium




**Laboratory Data Systems and Dashboards**

Setting up diagnostic integrated data systems that incorporate Laboratory Information Management Systems (LIMS) which are linked to or interfaced with data systems within the facilities to ensure improved turnaround time for results delivery and minimize errors associated with manual data entry continue to be challenging. In some settings, this has resulted in discrepancy in test results obtained from LIMS and patient records within the facility. This seriously affects patient management and availability of data for analysis to make informed decision on program performance. To address this, country programs must ensure that 1) every viral load and EID laboratory has a functioning LIMS, 2) all VL and EID LIMS are connected to a central data repository, 3) all laboratories transmit data to a national dashboard that can be used to monitor VL and EID coverage and testing network efficiency, and viral load suppression. Additionally, countries should strive to implement electronic test ordering and results return capability at high-volume facilities or hub laboratories via a remote test order module of the LIMS or EMR integration, as well as ensure interoperability between the LIMS and other health and surveillance systems in the country. For instance, Kenya viral load programs not only set up LIMS that interfaced with facility data systems, including remote login options, and tracking sample movement and results, but also established national dashboards that serve as platforms for analyzing and visualizing data from all laboratories and facilities real-time. These dashboards also have the possibilities to track supply chain data, ensuring proper forecasting, planning, and avoiding stock-

outs.[433] To further address data gaps, it is recommended that country programs should collaborate with Ministry of Health and other stakeholders to establish dashboards for real-time analysis and utilization of VL, EID, TB, and other data at the national levels. Programs should procure and use laboratory based and POC instruments with connectivity capacity, so they are interfaced with LIMS and other national data systems.

### 6.6.1.2 Laboratory Global Purchasing and Service Level Agreements to Streamline Supply Chain

In FY2020, PEPFAR implemented global purchasing and service level agreements (SLAs) for viral load (VL) and early infant diagnosis (EID) reagents, consumables, and services to shift laboratory program procurement to all-inclusive pricing models. These agreements were negotiated to achieve specific PEPFAR goals: improved system performance through greater data visibility and standardized SLAs across countries, reduced cost and transparent pricing, and enhanced supply chain security. Through these awards the total savings across all PEPFAR-supported countries may reach approximately $5 million this year (CY21) over last year's savings of >$20 million. Each supplier's SLA establishes rigorous key performance indicators to improve maintenance response times, machine uptime, error rates, on-time delivery of reagents, frequency of end-user training, and instrument connectivity and reporting solutions. To address issues around instrument breakdown/sample backlog due to poor service and maintenance contracts, stock-outs, discrepant/volume commitment pricing, and high unit-cost-per-test for reagents, all countries should stop outright instrument procurement and pursue the PEPFAR supported Global Purchasing and Service Level Agreements that incorporate the all-inclusive pricing approaches. This should be applied to both centralized and POC instruments, including procurement of cartridges. PEPFAR funds should not be used to procure or service CD4 instruments. Where CD4 instrumentation is not available, programs should consider use of the VISITECT technology. This should be done in collaboration with country Ministry of Health and other stakeholders to ensure a single country efficient pooled procurement approach. Functional all-inclusive pricing will be considered as one of the laboratory sustainability indicators for countries that have attained HIV epidemic control.

[433] https://cquin.icap.columbia.edu/wp-content/uploads/2020/12/Kenya_Viral-Load-Access-Presentation_Annual-CQUIN-Meeting-2020_v16.11.20.pdf

**Improvement in data collection and reporting**

The data and connectivity provisions of the global SLAs are supported by data use agreements and are expected to enhance forecasting and reagent re-supply with near real-time information and improve data availability for diagnostic network monitoring and optimization efforts. Countries are expected to enable data connectivity through SLAs and LIMS to validate manufacturers monthly and quarterly reporting. To achieve improved visibility of laboratory commodities, PEPFAR supported laboratories should continue to improve monthly site level consumption and commodity inventory data reporting for all HIV VL and EID testing sites (laboratory and POC). Regular data collection and review across site and central levels will improve future commodity forecasting efforts, ultimately reducing the likelihood of stockouts.

All PEPFAR country interagency teams that support laboratory testing and laboratory commodity procurement should develop a data sharing strategy at the country level to improve testing and supply chain visibility and coordination. Interagency PEPFAR teams should routinely review data collected at the site and central levels necessary for uninterrupted lab service delivery and reliable commodity availability (e.g., stock levels at central stores, monthly testing numbers, seasonal demand shifts, backlogs, instrument failures, site level inventories, site level consumption, commodity delivery dates at central and site levels, etc.). PEPFAR leads and teams should ensure that national laboratory supply plans are collectively updated monthly, and leads should also engage monthly with Global Fund Principal Recipients and Ministries of Health to accurately track partner shipments and potential order delays within national supply plans. Where traditional supply chain system reporting systems can be complemented, laboratories that have functional and connected LIMS or diagnostic connectivity systems should be used to collect and monitor site-level stock management to inform monthly reporting of stock levels between PEPFAR country procurement and program teams.

## 6.6.1.3 Laboratory Continuous Quality Improvement and Accreditation

Quality laboratory services have been at the nexus of successful PEPFAR programs. PEPFAR and other institutions (WHO, ASLM, GF, African CDC, Ministry of Heath) have been involved in strengthening laboratory systems to support efficient and sustained program implementation. With the 95/95/95 targets, PEPFAR support for laboratory continuous quality improvement (LCQI), defined as the process of routine implementation of lab quality management systems (LQMS) elements with monitoring and evaluation, and improvement projects to resolve deficiencies and improve quality, within the tiered laboratory network should continue

throughout the three testing phases (pre, analytical, post) to ensure timely, accurate and reliable results for patient care. Furthermore, efforts to harmonize LCQI with specimen referral and results return systems in the lab-clinic interface should be optimized to ensure continuity of care services for increased access and appropriately managing patients.

Countries should ensure the following:

- Use the WHO AFRO African Society for Laboratory Medicine (ASLM) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and other relevant checklists to assess and monitor improvement of laboratories. Laboratories improvements should be evaluated using the WHO/SLIPTA 5-star recognition structure and/or receive and maintain accreditation by an authorized body (e.g., CAP, SANAS, CADCAS, KENAS). For instrument-based point of care testing facilities, the WHO stepwise process for improving the quality of point of care testing sites (SPI-POCT) checklist[434] should be used to assess and monitor POCT facilities. Following several years of PEPFAR support to strengthen quality laboratory services, at least VL, EID and TB culture laboratories should seek accreditation to international standards.
- Develop a cadre of laboratory personnel for decentralized training and implementation of proven LQMS training programs such as Strengthening Laboratory Management Toward Accreditation (SLMTA) and SLMTA-related trainings to implement a sustainable, cost-effective, and practical LQMS. To assure retention of long-term PEPFAR investments in LCQI and LQMS, these programs should be part of the regional and national health system framework.
- Train and certify laboratory technologists' competencies for performing different tests.
- Support for laboratories to enroll into external quality assessment programs to monitor quality of various tests (EID, viral load, TB, CD4, CrAg, creatinine etc.), routinely evaluate program performance, and implement corrective actions, if needed.
- It is recommended that countries should use only instruments/assays prequalified by WHO or approved by PEPFAR and conduct small scale verifications in-country as opposed to repeating costly and time-consuming repeat large scale in-country evaluations on endorsed instruments and assays.
- Develop a laboratory accreditation maintenance plan to support laboratory sustainability of ISO accreditation standards and PEPFAR investments towards accreditation with

[434] WHO (2015) https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf?sequence=1

dedicated country/MOH funding to maintain accreditation status (reaccreditation) once achieved.

Accreditation of national public health laboratories will be considered as one of the laboratory sustainability indicators for countries that have attained HIV epidemic control.

### 6.6.1.4 Multi-disease use of Diagnostic Testing Platforms for HIV, TB, COVID-19, and HPV

Summary of section edits:

- Transitioned terminology from "multiplex" to "multi-disease" to align with 2023 COP/ROP guidance

Current diagnostic gaps in the HIV and TB response could be supported through optimal use of existing technologies. Several technologies, including laboratory-based and near-POC and POC assays, currently exist that can be used to diagnose and monitor multiple diseases, including HIV and TB but also COVID-19, hepatitis C, human papilloma virus (HPV), and other STIs.[435] Multiplex testing can also be used to diagnose and monitor different parameters within the same disease for example VL and EID among HIV patients. Multi-disease testing and diagnostic integration has the following potential advantages: 1) provide diagnosis in a one-stop-shop, 2) help respond to global co-infection crisis, 3) improve test efficiency and TAT, 4) lower testing cost, 5) provide an opportunity to diagnose and monitor treatment for patients with advanced HIV disease, as well as 5) follows WHO recommendation for use of multi-disease testing devices in integrated laboratory networks.[436] When disease-specific priorities are accounted for and implemented appropriately, this approach can lead to improved access and service delivery. For example, data presented during AIDS 2020 showed that during COVID-19 outbreak, multi-disease testing and integrated diagnostic approaches in Cameroon, Nigeria and Zimbabwe, led to quicker testing/result turnaround time, safe and secure specimen referral and transport, and rapid expansion of COVID-19 testing in these countries.[437] Furthermore, a multi-disease HIV and TB testing evaluation in Zimbabwe led to increased instrument utilization and faster and increased rates of clinical action for HIV+ infants and PLHIV on ART experiencing viremia

[435] UNITAID (2018) https://unitaid.org/assets/multi-disease-diagnostics-landscape-for-integrated-management-of-HIV-HCV-TB-and-other-coinfections-january-2018.pdf
[436] WHO (2017) https://apps.who.int/iris/handle/10665/255693
[437] https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium

without negatively impacting TB testing and treatment services.[438,439] Also, in Uganda, multi-disease use of instruments that included integrated sample and demand for TB testing led to improved efficiency in the utilization of these platforms for TB testing (Figure 6.6.1.4.1). It should be noted that in situations where instrument testing capacity is less than the capacity needed (for example POC instrument with less testing capacity), there should be testing prioritization to ensure that key programs are not overwhelmed or neglected. The drive towards multi-disease diagnostic integration was reaffirmed through the Addis Ababa declaration on the HIV Viral Load Movement. This is a Call to Action by all 55 Member States of the Africa Union for countries to promote the use of innovative approaches including but not limited to integrated technologies.[440] In PEPFAR-supported countries, there are opportunities to multiplex diagnostic platforms with significant positive impact as mentioned above. It is recommended that country programs should consider multiplex testing options to address diagnostic gaps. However, any joint use or multiplexing of instruments needs to be done within the context of country national and subnational disease burdens and should focus on patient access to testing in line with strategies and objectives from all relevant disease programs. It is therefore important to clearly define which components of the testing networks (e.g., instrument multi-disease, combined specimen transport) would benefit from an integrated approach. There are disease-program specific HIV and TB diagnostic network assessment and tools. These evidence-based tools can be used together to evaluate disease-specific priorities and identify opportunities for multi-disease use of new or existing diagnostic platforms and support modelling and planning of activities. Engagement with other stakeholders (WHO, GF, UNITAID, EGPAF, UNICEF, African CDC, CHAI, etc.) within the Integrated Diagnostic Consortium (IDC) is necessary to ensure a coordinated and efficient approach.

*Figure 6.6.1.4.1: Use of Multi-Disease Instruments in Uganda leads to Efficiency of GeneXpert (2019)*

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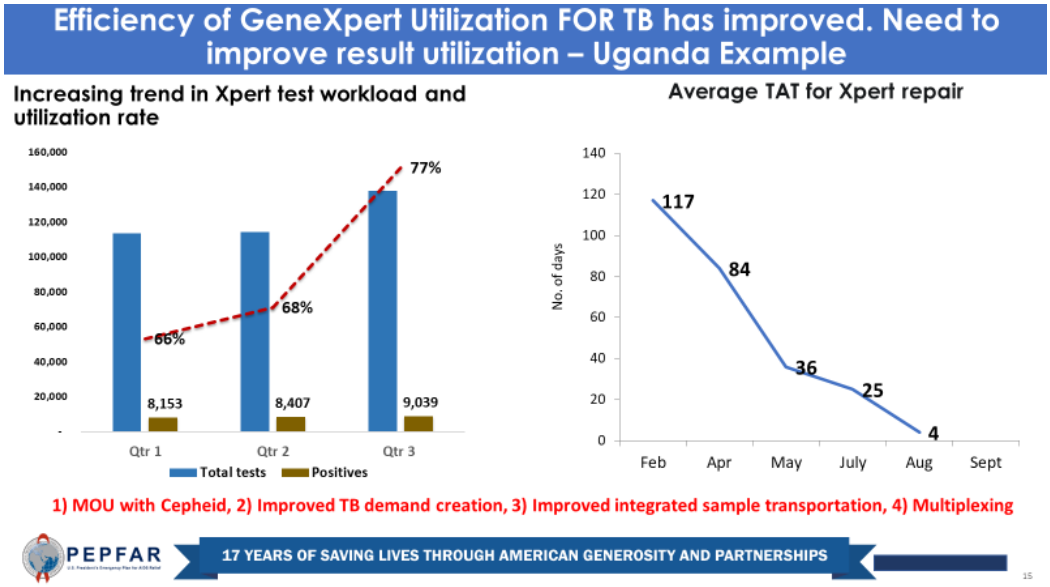
[438] Ndlovu et al. (2018) https://doi.org/10.1371/journal.pone.0193577
[439] Melody et al. (2021) https://pubmed.ncbi.nlm.nih.gov/34310372/
[440] African CDC (2019)




## 6.6.1.5 Biosafety and Waste Management

Diagnostic laboratories generate waste in different categories to include chemical, infectious, radioactive, controlled substances, pharmaceutical, multi-hazardous, sharps, and non-hazardous.[441] Each has its own characteristics and requirements for removal. PEPFAR has over the years worked closely with country Ministry of Health and other stakeholders to ensure safe disposal of laboratory waste through provision of training on waste management, construction of incinerators, procurement of disposal containers and necessary protective material. This has worked well, and countries have been able to manage and safely dispose waste material based on in country resources and capacity. However, many country programs are currently faced with the management and safe disposal of viral load and EID waste containing the guanidinium thiocyanate, (GTC) a chemical contained in several HIV molecular diagnostic platform reagents.[442] Proper disposal of waste containing this chemical requires high temperature incineration, up to about 1000 °C, not feasible using commonly available incinerators. Facilities using products containing GTC need access to an appropriately maintained, high temperature incinerator on-site, or regular waste transportation to a compliant high temperature incinerator. Some countries are collaborating with cement factories or other in country institutions with incinerators with such capacity to manage this waste product. One

[441] WHO (2014) http://www.who.int/water_sanitation_health/publications/safe-management-of-waste-summary/en/
[442] Collins et al. (2010) https://doi.org/10.1016/j.hazl.2021.100030

recent recommendation is for diagnostic platform manufacturers utilizing GTC to be responsible for the management of this waste and to consider including this in the overall cost per test. Another option could be for diagnostic manufacturers to contribute to funding an integrated national waste management system, i.e., incinerators at central facility and support for transportation of waste. PEPFAR OU teams should work closely with Ministry of Heath, diagnostic manufacturers, and other stakeholders to ensure safe disposal of GTC and other laboratory waste.

**Global Health Security**

The Global Health Security Agenda (GHSA) encourages countries to set up national tiered laboratory systems able to reliably conduct tests on varied diseases of public health importance. The current PEPFAR laboratory strategy aims to achieve this objective and provides training and platforms to support laboratory capabilities. Hence, PEPFAR OU teams are encouraged to coordinate with the Ministry of Health and other stakeholders in identifying and implementing laboratory activities that could be leveraged to support multiple diseases testing, including HIV, TB, COVID-19, and global health security threats. In countries with specific GHSA funding from the U.S. government, opportunities for strategically leveraging personnel and laboratory resources should be explored. Many countries that have these systems in place were able to leverage them to support rapid scale-up of COVID-19 testing.[443]

## 6.6.2 Gender Equality

Gender inequality is a significant barrier to the achievement of sustained epidemic control. Gender inequality results in unequal access and use of HIV prevention, care, and treatment services; it impacts individuals' ability to initiate and practice healthy behaviors, exercise their right to live free from violence, stigma, and discrimination and achieve the highest attainable standard of health. The links between gender inequality, gender-based violence, and HIV are clear. Gender-based violence is a significant human rights violation that is deeply rooted in and driven by gender inequality. Research has shown that exposure to or perpetration of violence is a proximate determinant of HIV acquisition and transmission.[444] A systematic review and meta-

[443] IAS (2020) https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium

[444] Heise, L., & McGrory, E. (2016). Violence against women and girls and HIV: Report on a high level consultation on the evidence and its implications, 12–14 May, 2015. Greentree Estate. STRIVE Research Consortium, London School of Hygiene and Tropical Medicine. http://strive.lshtm.ac.uk/system/files/attachments/STRIVE_Greentree%20II.pdf

analysis concluded that exposure to gender-based violence, particularly intimate partner violence (IPV), is associated with lower use of antiretroviral therapy (ART), half the odds of self-reported ART adherence, and significantly worsened viral suppression among women.[445] Experience of IPV has been shown to negatively affect uptake of early infant HIV testing and HIV status disclosure among postpartum women, threatening progress to PMTCT.[446] Evidence from the Partners PrEP study noted that women who reported recent IPV were at increased risk of lower PrEP adherence.[447]

Gender norms that sanction gender-based violence and unequal power relations drive gender inequality and often restrict girls' and women's access to HIV and sexual and reproductive health services. Female health workers routinely face safety concerns, such as harassment and gender-based violence, and carry a high burden of unpaid work, exacerbated by the COVID-19 pandemic. Gender inequality also impacts boys' and men's access to HIV testing and treatment services. Across the PEPFAR program, boys and men are less likely than girls and women to know their HIV status, initiate or remain on lifelong treatment, or attain viral suppression.[448] Members of key populations and gender and sexual minorities, including LGBTQI+ individuals experience high levels of gender-related stigma, discrimination, and violence (see Section 2.2.2 and Section 6.5).

In alignment with UNAIDS 10-10-10 targets of less than 10% of women, girls, people living with HIV, and key populations experiencing gender inequality and violence by 2025, PEPFAR must intentionally integrate gender transformative and trauma-informed approaches into HIV program implementation and service delivery that respond to the unique needs of different populations (AGYW, men and boys, KP, etc.). These efforts are necessary to respond to the structural barriers fueled by gender inequality that impede access to and uptake of critical prevention and

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[445] Hatcher, A. M., Smout, E. M., Turan, J. M., Christofides, N., & Stöckl, H. (2015). Intimate partner violence and engagement in HIV care and treatment among women. *AIDS, 29*(16), 2183–2194. https://doi.org/10.1097/qad.0000000000000842

[446] Hampanda, K. M., Nimz, A. M., & Abuogi, L. L. (2017). Barriers to uptake of early infant HIV testing in Zambia: the role of intimate partner violence and HIV status disclosure within couples. *AIDS Research and Therapy, 14*(1) . https://doi.org/10.1186/s12981-017-0142-2

[447] Roberts, S. T., Haberer, J., Celum, C., Mugo, N., Ware, N. C., Cohen, C. R., Tappero, J. W., Kiarie, J., Ronald, A., Mujugira, A., Tumwesigye, E., Were, E., Irungu, E., & Baeten, J. M. (2016). Intimate Partner Violence and Adherence to HIV Pre-exposure Prophylaxis (PrEP) in African Women in HIV Serodiscordant Relationships: A Prospective Cohort Study. *JAIDS Journal of Acquired Immune Deficiency Syndromes, 73*(3), 313–322. https://doi.org/10.1097/qai.0000000000001093

[448] MenStar Coalition: Why Men? (2021). MenStar Coalition. https://www.menstarcoalition.org/why-men

treatment services that are key to reaching sustained epidemic control. Gender transformative approaches, as defined by the Interagency Gender Working Group (IGWG), refer to policies and programs that seek to transform gender relations to promote equality and achieve program objectives by: 1) fostering critical examinations of inequalities and gender roles, norms, and dynamics, 2) recognizing and strengthening positive norms that support equality and an enabling environment, and 3) promoting the relative position of women, girls, and marginalized groups, and transforming the underlying social structures, policies, and broadly held social norms that perpetuate gender inequalities.[449]

The gender transformative interventions that country teams must implement to reduce gender inequality within HIV programs and services may include but are not limited to:

**HIV Prevention**

- Implement evidence-based gender norms change interventions that have successfully impacted HIV prevention outcomes, such as SASA![450], outside of DREAMS SNUs. Evidence-based interventions that engage and support men in recognizing and challenging gender norms and improving HIV outcomes include Yaari Dosti,[451] Program H,[452] One Man Can,[453] and Men as Partners.[454] See also Sonke Gender Justice[455] for resources on norms change activities to improve HIV outcomes for men.
- Use gender-sensitive approaches, such as Mina[456] or Coach Mpilo[457] to improve linkage to HIV testing services for boys and men. See the MenStar Strategy[458] for more information on interventions to improve linkage to testing services for men.

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[449] More information on gender transformative approaches and the gender integration continuum can be found at https://www.igwg.org/training/programmatic-guidance/
[450] SASA!: https://raisingvoices.org/sasa/
[451] Yaari Dosti: https://www.popcouncil.org/uploads/pdfs/horizons/yaaridostieng.pdf
[452] Program H: https://promundoglobal.org/programs/program-h/
[453] One Man Can: https://www.saferspaces.org.za/uploads/files/OMC_Case_Study.pdf
[454] Men as Partners: https://www.engenderhealth.org/our-work/gender/men-as-partners/
[455] Sonke Gender Justice: https://genderjustice.org.za/project/community-education-mobilisation/
[456] Mina: https://menstarcoalition.org/lost-to-follow-up/mina-for-men-for-health/
[457] Coach Mpilo: https://www.psi.org/2020/06/coach-mpilo/
[458] MenStar Strategy: https://www.menstarcoalition.org/strategy/

- Deliver gender-sensitive and trauma-informed post-violence care services that meet the unique needs of different populations (girls and women, boys and men, key populations, LGBTQI+ individuals), including gender affirming services for key populations and LGBTQI+ individuals. See Section 6.6.2.1 for more information on post-violence care.

**HIV Clinical Cascade**

- Refer to the MenStar Strategy for activities to address the structural barriers to finding, reaching, engaging, and retaining men in the HIV clinical cascade.
- Integrate age-appropriate GBV case identification, first-line support, and clinical and non-clinical GBV care into HIV services (See Section 6.6.2.1 for details).
- Consider conducting a root cause analysis to identify specific gender-related barriers to uptake of testing and treatment services and continuity in treatment to inform programming (e.g., need permission from their partner to test for HIV; if their status is disclosed, worried that their partner will leave them, fearful of intimate partner violence, fearful of appearing sick or weak).

**Personnel and Systems**

- Work with civil society and partner country governments to promote laws and policies that advance gender equality and prevent GBV and VAC, such as laws and policies that ensure access to education for all AGYW, recognize marital rape as a form of sexual violence, decriminalize same-sex relationships, etc. This is essential to creating a broad institutional framework in which HIV programs and services are delivered with equity and equality.
- Support the development of a diverse, gender-equitable, gender-affirming, and trauma-informed health and social service workforce that advances women, non-binary, and gender minorities' leadership opportunities and fosters safe work environments with fair remuneration and non-discrimination. This may be advanced through HRH policy development, pre- and in-service training, and mentoring and supportive supervision.
- Support the development and/or maintenance of robust gender-sensitive data systems that utilize measures and metrics of gender equality, gender-based violence, and structural barriers (e.g., beliefs/perceptions of gender roles and equality, and experiences of stigma and discrimination), to improve planning, delivery, and monitoring of HIV services.

- Partner with diverse stakeholders, including local change agents, the private sector, community and faith leaders, health providers, education and justice sector representatives, and other stakeholders that may be deeply embedded in particular societal and gender norms (e.g., the military) to deliver gender transformative programming to ensure that the responsibility of shifting norms does not rest solely on the shoulders of those most harmed by them (e.g., women, girls, and LGBTQI+ individuals).

### 6.6.2.1 Gender-Based Violence and Violence Against Children

Violence can lead to reduced access to and use of essential health services, while undermining efforts to effectively respond to HIV/AIDS. Gender-based violence (GBV) continues to be a pervasive threat that persists through harmful gender norms, inequality, and silence – and has been exacerbated among women during the COVID-19 pandemic. Populations such as AGYW and members of KP groups (e.g., female sex workers, transgender people, MSM, and PWID) experience elevated rates of GBV, and women and girls remain disproportionately affected globally by disturbingly high rates of violence, particularly intimate partner violence (IPV) and sexual violence. An estimated one in three women worldwide has been beaten, coerced into sex, or otherwise abused in her lifetime. GBV has been demonstrated to foster the spread of HIV by limiting women's ability to negotiate safe sexual practices, disclose HIV status, and access services due to fear of reprisal. IPV is the most common form of violence experienced by women globally.[459,460,461] While GBV encompasses a wide range of behaviors, PEPFAR is predominantly focused on prevention and response to physical and sexual violence because of their inextricable links to HIV infection; including marital rape, sexual assault or rape, female genital cutting/mutilation, sexual violence against children and adolescents; and child marriage.

Similarly, violence against children undermines prevention and treatment outcomes and sets the stage for poor long-term health consequences and diminished well-being for children. PEPFAR-

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[459] Hatcher, A. et. al. Intimate partner violence and engagement in HIV care and treatment among women: a systematic review and meta-analysis. AIDS. 2015, 29:000–000.

[460] Pulerwitz, J. et. al. (2017).*Unpacking the influence of gender on HIV testing and treatment uptake: Evidence from Mpumalanga, South Africa*. Project SOAR.

[461] Ann Gottert, Julie Pulerwitz, Nicole Haberland, Sheri A. Lippman, Kathleen Kahn, Aimée Julien, Amanda Selin, Rhian Twine, Dean Peacock, and Audrey Pettifor. (2017). *Which gender norms are linked to IPV, and HIV-related partner communication? New evidence from a population-based sample in South Africa.* Scientific pitch presented at SVRI, Rio de Janeiro, Brazil, 18–21 September.

supported Violence Against Children Surveys (VACS) show high rates of several forms of violence against children including physical, emotional, and sexual violence in HIV-affected communities. VACS results show that children and youth frequently experience more than one form of violence. In Tanzania, for example, more than 80% of adolescent males and females aged 13 to 24 years who experienced sexual abuse as a child also experienced physical violence.[462]

A strengthened continuum of response between violence prevention and clinical post-violence response services should be integrated into the HIV cascade at key points, including HIV prevention interventions (e.g., through PrEP, DREAMS, and OVC), HIV testing (particularly index testing, recency testing, and partner notification), HIV care and treatment, PMTCT, ANC, and OVC services.

**Safeguarding Against Violence within PEPFAR Programming**

Prevention of violence against children starts with ensuring that children are safe while accessing services and within PEPFAR programs. To that end, PEPFAR implementing agencies and partners are responsible for establishing, implementing, and monitoring child safeguarding policies and procedures to protect children from harm. In alignment with PEPFAR agency MOAs, funding agreements must include minimum Child Safeguarding Standards (See MOA annex[463]) and require implementing partners to ensure compliance with partner country and local child welfare and protection legislation or international standards and guidelines (See Keeping Children Safe[464]), whichever gives greater protection, and with U.S. law, where applicable.

***Prevention.*** For more information on evidence-based GBV and VAC prevention activities, please see Section 6.2.2.2 on DREAMS, Section 6.2.3 on primary prevention of HIV and sexual violence for 10-14 year-olds, and Section 6.6.3 on OVC. OUs should also consult the DREAMS Guidance[465] for specific strategies used in DREAMS. PEPFAR has developed a country specific

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[462] UNICEF, U.S. CDC, & Muhimbili University of Health and Allied Sciences. (2011). *Violence against children in Tanzania: Findings from a national survey 2009*. United Republic of Tanzania. https://www.togetherforgirls.org/wp-content/uploads/2017/09/2009_Tanzania_Findings-from-a-Violence-Against-Children-Survey.pdf

[463] PEPFAR Child Safeguarding MOA Annex.

[464] Keeping Children Safe: Information on the International Child Safeguarding Standards can be found at https://www.keepingchildrensafe.global/blog/2019/02/15/implementing-child-safeguarding-standards/ and https://www.keepingchildrensafe.global/wp-content/uploads/2020/02/KCS-CS-Standards-ENG-200218.pdf

[465] PEPFAR DREAMS Guidance. (Rev 2021). PEPFAR DREAMS GUIDANCE — PEPFAR Solutions Platform.

workshop called SVAC 101 to educate faith and traditional leaders, as well as community leaders on sexual violence against children, and to encourage their commitment to preventing and responding to SVAC. OUs interested in implementing these workshops should contact the S/GAC Gender or OVC leads. Additional resources tailored to key populations programming are available through the PEPFAR-funded LINKAGES and EpiC projects,[466] which developed a guide and training manuals to support the integration of violence prevention and response activities with HIV prevention, care and treatment services. Likewise, PEPFAR programs must address structural barriers that sanction and perpetuate gender inequality and contribute to gender-based violence faced by these populations.

**GBV Case Identification**

GBV case identification is a key technical priority for PEPFAR programming in order to facilitate survivors' access to and uptake of HIV prevention, testing, and care and treatment services, including support for survivors' successful use of PrEP or ART. Per WHO guidelines,[467] universal screening is NOT recommended in PEPFAR programs. Rather, PEPFAR recommends a hybrid approach of using both routine and clinical enquiry in our HIV programs. PEPFAR has chosen to recommend this hybrid approach, informed by the WHO clinical and policy guidance, which states that routine enquiry may be considered in the context of HIV testing and counselling, as well as when assessing conditions that may be caused or complicated by IPV, such as adverse reproductive health outcomes. Therefore, PEPFAR requires routine enquiry as part of safe and ethical index case testing services and partner notification services and the provision of PrEP and recommends using clinical enquiry within care and treatment services. When a case is identified using routine or clinical enquiry, providers should incorporate violence-informed HIV service delivery, to mitigate the effects of violence on core HIV clinical outcomes (e.g., tailored adherence counseling to treatment or PrEP, disclosure support, other strategies that mitigate risks while enabling service access).

***Routine Enquiry.*** Routine enquiry for IPV is defined as asking all clients who present for specific services (such as HIV services) about their experiences of violence or fear of violence. There are tools available for conducting routine enquiry in PEPFAR, for example an IPV risk

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[466] LINKAGES Project: https://www.fhi360.org/resource/linkages-violence-prevention-and-response-series

[467] World Health Organization. (2013). *Responding to intimate partner violence and sexual violence against women: WHO Clinical Policy and Guidelines.* https://www.who.int/reproductivehealth/publications/violence/9789241548595/en/

assessment. For PEPFAR, routine enquiry is required as part of index case testing/partner notification services and counseling and initiation of PrEP and may be warranted in other HIV service settings (e.g., Care & Treatment and ANC/PMTCT) to avoid exacerbating a harmful situation and to ensure sensitive delivery of those same services to clients experiencing IPV. Identifying PLHIV in HIV clinical services who are survivors of violence helps to ensure post-violence care services are provided in a timely manner, supporting improved engagement with treatment, and ultimately viral suppression. Routine enquiry is also used as part of eligibility screening for DREAMS enrollment, and as part of OVC case management.

The five minimum requirements for routine enquiry that must be in place include:

- A private setting
- Confidentiality ensured
- A standard operating procedure, job aid, or algorithm that outlines the steps that counselors/clinicians take if a client discloses experience or fear of violence
- Providers trained on how to ask and respond to violence to provide age-appropriate first-line support when violence is suspected or disclosed
- A system for referrals to local clinical and non- clinical GBV response services using discrete referral cards, or the provision of post-violence clinical care at the site itself for clients who disclose violence

***Clinical Enquiry.*** Clinical enquiry means that providers are trained to identify potential signs and symptoms of violence. When a trained clinician identifies someone who exhibits these signs and symptoms, the clinician THEN asks the client about experience of violence, rather than asking everyone about experiences of violence. Survivors may present at facilities for other reasons, including HIV services. As such, HIV clinical service providers are often the first point of contact for survivors of violence and are in a unique position to assess and support survivors' needs. By identifying survivors, providing them with first-line support, and referring them to local GBV response services, providers are also helping to improve survivors' ability and likelihood of service uptake and adherence to key HIV prevention and care interventions, such as PrEP or ART.

All care and treatment providers should be trained on how to identify signs and symptoms of violence, and how to ask those who exhibit these signs and symptoms about experience or fear of violence. See WHO guidance for more specific information.[468,469,470]

***Post-Violence Care.*** Implementing partners who provide post-GBV care services must:

- Provide training and supportive supervision to both providers and IPs on first-line support (empathetic listening, inquiring about needs and concerns, validating their experience, enhancing safety, and connection to other support, which may include referrals to additional services).[471] Providers should work to provide immediate, trauma-informed, client-centered support to meet the overall emotional, physical, safety, and support needs of survivors. (See Behavioral Health Section 6.6.5)
- Provide immediate access to and provision of the full minimum package of comprehensive and age-appropriate post-violence clinical services that must be offered per WHO Guidelines[472] and the GEND_GBV MER indicator definition and meet the expressed needs of survivors. These services must be client-centered and trauma-informed and should include:
    - Rapid HIV testing with referral to care and treatment as appropriate
    - PEP, if the person is reached within the first 72 hours
    - STI screening/testing and treatment
    - Emergency contraception (EC), if the person is reached within the first 120 hours
    - Counseling (other than counseling for testing, PEP, STI and EC)
    - Treatment of serious of life-threatening medical issues (e.g., lacerations, broken bones) and the necessary forensic interviews and examinations

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[468] World Health Organization. (2014). *Health care for women subjected to intimate partner violence or sexual violence: A clinical handbook.* WHO. https://www.who.int/reproductivehealth/publications/violence/vaw-clinical-handbook/en/

[469] World Health Organization. (2017). *Responding to children and adolescents who have been sexually abused: WHO Clinical Guidelines.* WHO. https://www.who.int/publications/i/item/9789241550147

[470] World Health Organization. (2019b). *WHO Guidelines for the health sector response to child maltreatment.* https://www.who.int/publications/i/item/who-guidelines-for-the-health-sector-response-to-child-maltreatment

[471] World Health Organization. (2019). *Caring for women subjected to violence: A WHO curriculum for training health-care providers.* WHO. https://www.who.int/reproductivehealth/publications/caring-for-women-subject-to-violence/en/

[472] World Health Organization. (2013). *Responding to intimate partner violence and sexual violence against women.* World Health Organization. https://www.who.int/reproductivehealth/publications/violence/9789241548595/en/

- Ensure no service charges or user fees of any kind, including for clinical services, transportation fees, fees for filling out, filing, or copying forms, etc.
- Focus on improving quality of clinical post-GBV care through routine program monitoring and quality improvement processes and providing active referrals (when feasible) to other services that survivors may need (e.g., police, shelter, etc.).[473,474]
- For survivors <age 18, ensure that safe placement (with parent or other appropriate adult guardian identified by the survivor when possible) is assured in coordination with OVC program and with child protection authorities.

In some contexts, the extent to which GBV services exist and are available to accept client referrals may not be known. Sites should identify local clinical and nonclinical GBV response services that are accessible and of good quality where survivors can be referred.

PEPFAR OU teams should assign GEND_GBV targets and budgets to implementing partners that are able to deliver the full package of clinical-post violence care at the sites they support. GEND_GBV reporting should include disaggregates by age, sex, and type of post-violence service per the MER Guidance. Partners are encouraged to track the full PEP cascade (including eligibility, initial uptake, through to completion of medication course and HIV test) in order to improve timely uptake and completion of this essential HIV prevention intervention for survivors. A GEND_GBV target-setting tool has been developed to help teams set targets. OU teams should utilize the two cross-cutting gender and GBV budget attributions and also note the guidance on GBV budget considerations (see details in Section 5.9.2.1).

### *Violence Against Children Prevention and Response through OVC Case Management*

While prevention and response to VAC is the responsibility of all PEPFAR implementing agencies and partners, OVC programs play a unique role in addressing violence against children due to their frequent interaction with children and households and their relationships with community leaders, and child welfare and protection systems. Safety from violence is one of four program areas addressed by OVC programs (see 6.6.3) which are responsible for

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[473] MEASURE Evaluation. (2019). *Tools for gender-based violence data.* https://www.measureevaluation.org/resources/newsroom/news/tools-for-gender-based-violence-data.html
[474] *GEND_GBV Rapid Data Quality Review Tool.* (2019). MEASURE Evaluation. https://www.measureevaluation.org/resources/publications/tl-19-43.html

assessing exposure to violence, making, and following up on appropriate referrals to child protection authorities and support services when needed, and working with children and families to reduce exposure to violence. Safety of all OVC household members should be monitored as part of case management and toward achievement of household graduation benchmarks found in MER 2.6.

Having at least one safe, supportive, and loving adult caregiver is essential to children's overall well-being and specifically to reducing their risk of HIV infection or adhering to ART. OVC programs are encouraged to work in tandem with government and civil society to strengthen local child welfare and protection capacity and to extend coverage for those at highest risk of violence. This includes for example working at county/district level to ensure "fiscal space" in budgets to recruit, train, supervise and retain credentialed child welfare staff, and extending access to services through modalities such as child helplines.

***Violence Against Children Surveys (VACS).*** Several OUs have conducted Violence Against Children Surveys (VACS). In OUs where a VACS has been conducted, the data should be used to plan violence prevention and response programming, in a similar way to PHIA data being used to plan clinical cascade programming. VACS is one source of data that can inform COP22 programming for DREAMS (Section 6.2.2.2), OVC (6.6.3), primary prevention of sexual violence (Section 6.2.3), and gender-based violence and violence against children (Section 6.6.2.1). In addition, these data can be used to inform approaches to the clinical cascade, because some forms of violence can affect an individual's ability and willingness to participate in HIV services.

Some OUs may wish to conduct a VACS survey as part of the COP22 plan. OUs that wish to propose a new or repeat VACS should do this in consultation with their Chair and PPM. As part of this planning, the Gender Team at S/GAC can assist OUs with information on the requirements, timelines, and costs of conducting a VACS.

## 6.6.3 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic

Although the rate of orphaning due to AIDS continues to decline with the expansion of treatment, significant risks and vulnerabilities remain for infants, children, and adolescents as a result of HIV/AIDS. In COP22, children and families continue to be affected not only by the HIV epidemic, but also by COVID-19; OVC programs must continue to evolve and to focus on the key challenges for children in the epidemic, specifically continued transmission of HIV from mother to

child, the pediatric treatment gap, advanced disease, and low virologic suppression rates, the high rate of sexual violence against adolescent girls, and the risk to children of losing a caregiver due to adult interruption in treatment and poor viral suppression rates with additional considerations for COVID-19 prevention and mitigation for enrolled families and OVC program staff.

OVC's long-standing and vast community presence coupled with a focus on the socio-economic factors affecting children and families affected by AIDS, are essential to closing gaps for the most vulnerable children. Due to regular interaction with households and communities, OVC programs are able to identify children and families who don't present in clinics or receive appropriate VL monitoring, trace mothers with infants who don't return for EID and other PMTCT milestones as well as those who experience treatment interruption and provide support to those who struggle with treatment adherence. By employing a case management model that is both child-centered and family-based, PEPFAR's OVC platform helps clients navigate access to health, social, legal, and economic support.

**Key Challenges for Children in the AIDS Pandemic**

Children face a range of risks beginning in the perinatal period, through late adolescence and the transition to young adulthood. Each stage impacts the next until the cycle regenerates, and today's adolescents mature and become the parents of tomorrow's infants. Eliminating intergenerational risk requires tailored strategies that target specific phases of the lifecycle including early childhood and adolescent-focused programs, while also addressing the unique needs of diverse subpopulations at risk.

Importantly even in situations of adversity and risk, children and their caregivers have many strengths. PEPFAR OVC programs employ a strengths-based case management approach and a participatory model that promotes the unique assets every individual and family possess and that seeks opportunities to engage and involve children and families in the design and monitoring of OVC programs. Chief among those at risk are children and adolescents living with HIV. While significantly more children are on treatment as a result of funding and technical support from PEPFAR, treatment coverage and viral suppression among children and adolescents remain a challenge. Closing the treatment gap will depend greatly on finding "well" or asymptomatic children living with HIV who remain undiagnosed. As of 2020, UNAIDS estimates global treatment coverage for children under the age of fifteen at only 54%, indicating that almost half of children living with HIV are without lifesaving treatment, remain unidentified, and in danger.

As children become young adults, their risk of acquiring HIV through sexual transmission increases sharply. OVC programs are uniquely positioned to address the myriad factors that put adolescents at risk. Adolescent girls who have lost a parent, for example, have an earlier sexual debut than their male counterparts do. Furthermore, adolescent girls who have lost a parent or who are living with a caregiver who is ill due to HIV have higher rates of transactional or other unsafe sex and higher exposure to physical and emotional abuse. Violence Against Children Surveys (VACS) in multiple PEPFAR countries show that forced and coerced sex among girls and young women can occur at very young ages. To prevent and protect girls from violence, OVC programs must work closely with DREAMS, and share in the investment in primary prevention of sexual violence and HIV in pre-teen and young adolescent girls and boys aged 10-14**.** Further guidance on support to strengthening child protection systems can be found in Section 6.6.2.1 Gender-Based Violence and Violence Against Children.

Pregnant, breastfeeding, and parenting adolescents are particularly vulnerable groups. HIV-negative adolescent parents are at risk of HIV acquisition and ALHIV parents are at higher risk of IIT compared to other age groups/populations. During pregnancy and breastfeeding, interruption in treatment from PMTCT services greatly increases the likelihood of vertical HIV transmission. Therefore, OVC programs can provide client-centered support to pregnant women living with HIV and their infants most at risk for interruption in treatment or missing EID, such as in pregnant adolescents and adolescent mother-baby pairs.

Adolescents living with HIV also benefit from the added comprehensive support available through the OVC platform. Adolescents are keenly sensitive to real or perceived stigma and are at a stage when they seek to establish their independence which makes treatment continuity challenging (see Section 6.1.2.2 Differentiated Service Delivery for Adolescents and Youth). Programming should be tailored to address their unique needs as it relates to living healthy, to supporting adherence and positive health outcomes, to understanding risks and benefits of disclosure, to building healthy relationships and to remaining in school. Adolescents on ART in South Africa who had access to multicomponent interventions, including parental monitoring, support groups, and social transfers such as cash and food provisions, exhibited greater adherence to treatment than those who did not.[475] For the OVC platform, the focus for adolescents is two-fold: continuity of treatment and living a productive, healthy life.

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[475] Cluver, L. D. (2016). Achieving equity in HIV-treatment outcomes: can social protection improve adolescent ART-adherence in South Africa? AIDS Care, 28(sup2), 73–82. https://doi.org/10.1080/09540121.2016.1179008

To achieve both prevention and treatment goals for children, PEPFAR implements two distinct but complementary OVC program strategies. The OVC Comprehensive program, is a time and resource intensive strategy focused on those children and their families with known high-risk characteristics including and especially HIV infection. The OVC Preventive program provides evidence-based violence and HIV prevention interventions to the wider community of at-risk girls and boys in high burden SNUs between ages 10-14. It is critical for children and families to be at the center of program design for both the Comprehensive and Preventive programs and to be continually engaged throughout the program cycle. Older adolescents and family members as well as civil society members who advocate for them, should play a role in monitoring the program's outcomes.

**OVC Comprehensive Program**

The Comprehensive Program is characterized by greater intensity and range of services, addressing household vulnerability, over longer periods of time, and includes the target populations listed in the first row of Figure 6.6.3.1: OVC Comprehensive & Preventive Program below. Recruitment through clinical services to identify children already in PEPFAR-supported HIV treatment and PMTCT sites is a key strategy for the comprehensive program area. The Comprehensive Program also works closely with Key Population programs to identify children, including children of FSWs living with HIV, for assessment and potential enrollment into the OVC program (for further guidance please see Section 6.5.4 Considerations for Young Key Populations, Children of Key Populations, and People in Prison and Other Enclosed Settings).

Please refer to Section 2.1 for Trends by Country for AIDS-related orphans.

Identification of OVC program participants should also occur through child protection authorities and community referrals to identify children who are survivors of sexual violence as well as children who have lost parents due to AIDS. OVC programs should continue to work with local authorities and community leaders to strengthen child protection systems to prevent and respond to violence and to children without family care. Building the capacity of local child protection and family welfare authorities and service providers (as well as related health and education counterparts) is critical to a sustainable response to children affected by AIDS and other adversities. For further guidance on VAC please see Section 6.6.3 "Gender-Based Violence and Violence Against Children."

OVC community cadres must help to find children who are living with HIV (including those who are older and/or asymptomatic), but whose lack of routine contact with health centers makes them less likely to be diagnosed through traditional clinic-based HIV testing. In COP22,

PEPFAR will continue to prioritize the scale-up of safe and ethical index testing of biological children (<19 y/o, with unknown HIV status) of current adults and siblings diagnosed with HIV.

Through household visits, OVC frontline providers are key to identifying children of index clients, supporting access to testing in facilities or in the community, and ensuring linkage to and continuation on treatment. For more information about pediatric index testing please see Section 6.3.2.1 Pediatric Index Testing Considerations and Section 6.3.2.2 Case Finding in OVC. OVC frontline providers are also essential to supporting both timely testing for HIV-exposed infants and the introduction of optimized ART regimens. To facilitate the latter, clinical IPs and facilities should assist in training OVC staff and frontline case workers on the fundamentals of ART and ART optimization, including new ARVs such as pDTG using language that is understandable by community cadres and members. In continuation from COP21, at least 90% of children (<age 18) in PEPFAR supported treatment sites in high volume clinics within high burden SNUs, should be offered enrollment in OVC programs.

Identification via clinics should focus on children with poor viral suppression and history of interruption in treatment/returned to care, children newly initiating treatment, infants of mothers at risk of interruption in treatment in the PMTCT cascade or missing EID (especially adolescent mothers during and after pregnancy), adolescents transitioning to adult treatment, and biological children of adult index cases. In addition, CLHIV with biological siblings or biological parents who have unknown HIV status whose households may require support with index testing and linkage to treatment should also be a focus.

OVC staff placed in clinics (e.g., as linkage coordinators, case managers, etc.) should have the capacity to assess health and socio-economic child and family needs and to offer appropriate referrals and support linkages where possible. All CLHIV should be offered enrollment and on acceptance should receive adherence and continuity of treatment support including treatment literacy, age-appropriate family-centered disclosure and nutritional assessment and counseling. It is critical that all CLHIV and caregivers are screened for TB symptoms periodically at community encounters as appropriate based on local TB burden as defined by NTB with linkage facilitated to TB prevention or diagnostic evaluation services (see Section 6.4.3.1 for further details on TB screening among CLHIV). The provision of economic and social support including for example transport subsidies or school assistance should be based on need and not be part of a predetermined package for all CLHIV.

Having a healthy, supportive parent has the greatest potential to impact child well-being. Therefore, supporting continuity of treatment for parents and caregivers (especially those who

are virally unsuppressed, just returned to care, newly diagnosed or new on treatment, and/or adolescent parents) is critical to safeguarding children's futures. Parenting skills are critical throughout childhood from early infancy through adolescence. For the most destitute households, parenting skills should be coupled with economic and food security interventions to achieve prevention and treatment outcomes for children.[476]

OVC programs have a child-centered, family-based focus and therefore all children in the household, as well as primary caregivers deemed at risk based on assessment, should be assessed and regularly monitored for progress made on the Graduation Benchmarks (see https://www.state.gov/wp-content/uploads/2021/09/FY22-MER-2.6-Indicator-Reference-Guide.pdf) through case management. The graduation benchmarks were established to ensure that children and families build resilience against risks in the long term not just in the immediate timeframe. Graduation occurs when children and families are deemed stable (or able to access external support without PEPFAR help such as government-provided cash transfers) and no longer require PEPFAR specific OVC support; this enables OVC programs to newly enroll vulnerable children and families in need of critical care and support.

Case files for each family should include family assessment forms, HIV Risk Assessment forms, Graduation Benchmark forms (baseline and follow-up), referral forms, case notes, and case plans with specific benchmarks in the domains of healthy, stable, safe, and schooled, to be monitored and met over time as outlined in the MER 2.6 OVC_SERV reference sheet. Additionally, case management needs assessments and family plans should go beyond PEPFAR benchmarks to identify priorities from the family's perspective and detail activities which can help them achieve these objectives.

In order to ensure client-centered care that bridges clinical and community resources, OVC programs should work with clinics and child welfare services, as well as KP programs and HTS programs when appropriate, as part of multi-disciplinary teams, conducting routine case conferencing. Programming and coordination between partners are critical to ensure that services offered by different entities are accessed and utilized by the children, parents, and caregivers most in need.

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[476]Cluver, L. D. (2014). Cash plus care: social protection cumulatively mitigates HIV-risk behaviour among adolescents in South Africa. AIDS, 28(Supplement 3), S389–S397. https://doi.org/10.1097/qad.0000000000000340

In high burden SNUs, OVC IPs should be assigned to one or more PEPFAR-supported clinics and to a surrounding community catchment area. OVC IPs should employ case managers to either be stationed at or rotate through the highest volume clinics to ensure smooth coordination and referrals between clinicians, clinic-based social workers, and community social and case workers. OUs that do not already have a consensus definition for high-volume pediatric sites should consider employing outlier analysis.[477] Either TX_CURR <15 or <20 can be used given that both are proxy measures for the OVC population (<18).

So that roles and responsibilities between health and community services are clear, PEPFAR supported clinics and OVC service delivery organizations (and coordinating implementing partners as needed) should continue reinforcing and operationalizing Memoranda of Understanding (MOUs). The MOUs are required to address key issues such as bi-directional referral protocols, pediatric case finding including index testing, support for ART optimization such as training on the pediatric DTG transition, case conferencing, shared confidentiality, joint case identification and routine and frequent data sharing between the clinics serving OVC beneficiaries and the OVC IPs (related to ART status and regimens, date of last viral load test, viral load suppression status, and index testing where possible), so that OVC IPs have real time and accurate clinical information for the OVC beneficiaries that they serve. This will begin a PEPFAR-wide process of moving the OVC program in the direction of reporting clinically confirmed, rather than self-reported, health information in OVC indicators. In addition, in PEPFAR-supported SNUs, clinical staff and clinical IPs should play a key role in training community case workers to build their knowledge in areas such as ART optimization and drug administration, viral load testing and suppression, continuity of treatment, age-appropriate disclosure, and "Undetectable = Untransmittable" messaging (more information about the role clinical implementing partners should play in supporting training for OVC staff on ART optimization, please see Section 6.4.1.2 Pediatric ART Optimization). Likewise, OVC IPs can help train clinic staff to understand the factors (e.g., socioeconomic, cultural, experience of violence) that impact health-seeking behaviors (e.g., HIV and EID testing, keeping clinic appointments, initiating ART, or transitioning to a new ARV such as pDTG), adhering to medication, and returning for viral load test and results; and to recognize which families and children are most in need of OVC program support.

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[477] See example at https://ideadata.org/sites/default/files/media/documents/2018-02/Step_by_Step_Outlier_Analysis.pdf

**OVC Preventive Program**

The Preventive Program focuses on children aged 10-14 years in high burden SNUs.[478] For boys and girls, the developmental period of pre-teen and young adolescence not only entails unique opportunities but also rising exposure to risks including sexual violence particularly for girls. Because this group is "at risk" for HIV but does not have known risk exposure, the OVC Preventive Program approach is different from the Comprehensive Program both in intensity and length. The main focus for this group is evidence-based programming that prevents sexual violence, delays sexual debut, and prevents HIV. This area includes interventions (discussed in detail in Section 6.2.3) that engage parents, teachers, and community members, including faith and traditional leaders, in protecting children and adolescents from violence, and supporting healthy decision-making as children mature.

Children in the Preventive Program area should be recruited in groups from community settings of high burden SNUs, such as schools, community centers, and faith-based groups. Both in- and out-of-school children should be targeted for inclusion into the Preventive Program. Where possible, these interventions should engage schools through teachers and education ministries to expand coverage and promote sustainability of the intervention.

As shown in Figure 6.6.3.2, monitoring of this target population is distinctly different from the Comprehensive Program, and does not involve providing case management or monitoring against graduation benchmarks. Measures for completion of the evidence-based curricula should be put in place and monitored.

OVC investments in the preventive program area should be complementary to DREAMS in order to maximize AGYW-focused prevention activities. In DREAMS SNUs, some AGYW may be enrolled in both DREAMS and the OVC Comprehensive Program based on their needs. For example, DREAMS beneficiaries that would benefit from a family-based case management approach or who need more intensive child protection support should be referred to the OVC Comprehensive Program. AGYW ages 10-20 in the OVC program that need more intensive HIV prevention support should be referred to the DREAMS program where available or to DREAMS-like services (see Sections 6.2.2.2 and 6.2.2.3).

[478] The age range for primary prevention will be aligned with DREAMS target beneficiaries beginning in FY22. Programs should begin to transition their targeting in the interim.

The OVC Comprehensive and Preventive strategies are outlined in the table below and are described in greater detail in appropriate sections of the COP22 Guidance. It is important to note that while these two program areas are intended to be distinct approaches, they are not mutually exclusive and should be closely coordinated within OVC projects. For example, facilitators in the Preventive Program must be trained to recognize risk signs and to make referrals to the Comprehensive Program (and/or DREAMS) when they observe that children require more intensive support. Agencies should support coordination of this process and ensure communication and planning between IPs who may be providing different services. Additionally, 10-14-year-old children enrolled in the Comprehensive Program may receive an eligible primary prevention of HIV and sexual violence intervention as part of their package of services included in their case plan.

*Figure 6.6.3.1: OVC Comprehensive & Preventive Program Areas*

| Program Area | Target Population | Recruitment Modality | Program Approach | Relevant COP22 Guidance Sections |
|---|---|---|---|---|
| **OVC Comprehensive** | • Children and adolescents living with HIV<br>• Children of adults living with HIV at risk treatment interruption; children who have lost parents to AIDS<br>• HEI at high risk of treatment interruption (i.e., pregnant and adolescent mothers and their infants)<br>• Children of female sex workers (especially FSWLHIV)<br>• Survivors of sexual violence | • HIV clinical sites (pediatrics, adult treatment, PMTCT)<br>• Child welfare services<br>• Traditional and community leaders | • Family-based case management<br>• Monitor against graduation benchmarks<br>• Provision and/or linkage to supportive socio-economic services | • 6.3.2.2 Case Finding in OVC<br>• 6.6.2.1 Gender-Based Violence and Violence Against Children<br>• 6.5.4 Considerations for Children of Key Populations, Adolescent and Young Key Populations |
| **OVC Preventive** | • Boys and girls aged 10-14 years in high burden SNUs | • Schools<br>• Community and faith youth groups | • Provision of single, evidence-based primary prevention of HIV and sexual violence intervention by trained facilitators in group settings<br>• No case management<br>• Not tracked against benchmarks | • 6.2.3 Primary Prevention of HIV and Sexual Violence for 10-14 Year Olds<br>• 6.2.2.2 The DREAMS Partnership |

### Targeting and Budgeting Considerations

For planning purposes, PEPFAR Operating Units and partners should determine the split of targets and funding between the OVC Comprehensive and Preventive program areas through an analysis of the data below in the relevant high burden subnational units (SNUs). OU teams should also perform an analysis of the extent to which the priority subpopulations identified in

Figure 6.6.3.1 are currently represented in the OU's OVC cohort to ensure coverage. Where transitions may need to be made to accommodate a greater proportion of children living with or exposed to HIV, teams should work with local partners to conduct a planned and responsible transition.

When setting DataPack targets for the different program models, the only individuals who should be targeted under the OVC Preventive program are those 10-14-year-old boys and girls who are not receiving services through the OVC Comprehensive program or DREAMS. While individuals may be enrolled in multiple models, DataPack targets must be mutually exclusive: each individual is counted under only one program model. Therefore, the DataPack targets for OVC Preventive may be smaller than the total number of individuals who will complete an approved curriculum. Budgeting should still reflect the total number of individuals served in the Preventive program.

Data Sources:

- Prevalence and incidence by age/sex and SNU for persons <age 15 and 15-19 [PHIA, UNAIDS/Spectrum]
- Estimates of children and adolescents living with HIV by age/sex & those served by PEPFAR [PHIA, UNAIDS, MER]
- Violence statistics by age/sex [VACS]
- Key populations estimates (including children of key populations)
- Orphan estimates by age/sex, single vs. double orphan [DHS, MICS]
- FY21Q4 MER results, particularly:
    - OVC_SERV <18 Comprehensive disaggregate, by age/sex and participation status, graduation rate
    - OVC_SERV Preventive disaggregate
    - OVC_SERV DREAMS disaggregate
    - Program data on the overlap of individuals enrolled in multiple OVC models, both within 1 IP and across multiple IPs in the same/neighboring districts
    - OVC_HIVSTAT
    - Comparison of OVC_HIVSTAT_POS with TX_CURR <15 and <20 for proxy OVC program coverage of PEPFAR-supported C/ALHIV on ART by district

- <15 and 15-19 results for clinical cascade indicators, including HTS_TST, HTS_TST_POS, HTS_INDEX, TX_NEW, TX_CURR, TX_PVLS, TX_ML and TX_RTT
- PMTCT_ART, PMTCT_STAT, PMTCT_STAT_POS, PMTCT_HEI_POS (particularly newly positive pregnant women, pregnant/ breastfeeding women with elevated viral load, and adolescent/young mothers)
- GEND_GBV <15 and 15-19

Due to the size of the program and epidemiological context in the following specific OUs, it is recommended that the focus for OVC be only on the Comprehensive program area, although HIV and sexual violence prevention may be incorporated as part of the services offered where possible. These OUs include Burundi, Cameroon, DRC, Dominican Republic, India, South Sudan, and Ukraine.

Budgeting for the different program models should incorporate findings from program data, recent analyses of case management costs,[479] as well as costs of the different prevention interventions.[480] Given the greater intensity of resources required for the Comprehensive Program, it is anticipated that costs of service delivery for this area will be higher than those for the Preventive Program.

The total earmark of 10% for Orphans and Vulnerable Children will be met through the above described Comprehensive, Preventive and DREAMS Program and will not include drugs, HTS, or diagnostics such as: pediatric and adult OI and ART drugs, post-exposure prophylaxis (PEP) or PrEP (pre-exposure prophylaxis), medical procedures, medical diagnostics, or lab services.

**OVC Programs in the Context of COVID-19**

The COVID-19 pandemic has brought about unprecedented health and socioeconomic challenges to communities around the globe, disrupting health and social services, closing schools, and restricting economic activities. There are concerns in regard to increases in child marriages, teen pregnancies, GBV and violence against children as well as increased

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[479] Measure Evaluation. (2019). The Cost of Case Management in Orphans and Vulnerable Children Programs: Results from a Mixed-Methods, Six-country Study. https://www.measureevaluation.org/resources/publications/tr-19-327.html

[480] World Health Organization (2018). INSPIRE Handbook: Action for Implementing the Seven Strategies for Ending Violence Against Children.

apprehension around mental health and substance abuse. COVID-19 has also resulted in an increase in the death of parents and grandparent caregivers.

PEPFAR OVC program staff, stakeholders, and community members have worked together to meet these challenges with rapid adaptations and client-centered/community-led solutions and have featured innovative solutions such as adapting case management to a remote platform during lockdowns, helping children access MMD, and introducing a hybrid in-person/virtual parenting program. COP22 will require continued measures to preserve the continuity of PEPFAR services and to protect the gains we have made for the children and families enrolled. In addition to ensuring that children can access HIV services and rapidly responding to child protection concerns, programs should be routinely assessing their enrollees to identify illnesses and deaths in the household likely to necessitate more intensive intervention. Programs should be using the latest technical guidance for PEPFAR OVC programs during COVID-19.[481]

## 6.6.4 Faith and Community Engagement

Summary of section edits:

- Wording was updated to reflect that Faith and Community Initiative (FCI) central funding has ended and PEPFAR encourages OUs to integrate effective FCI models into core COP programming.
- Four new Faith and Community Steering Committee recommendations for OUs to drive effective engagement are provided.

PEPFAR prioritizes enhanced engagement with communities, including faith communities and leaders, to accelerate the uptake of optimized testing, enhance differentiated service delivery, and achieve durable viral suppression to address gaps (specifically in finding men and children) and reach sustainable HIV epidemic control.

In COP19 and COP20, PEPFAR's Faith and Community Initiative (FCI) investments in 10 high-burden countries (Botswana, Eswatini, Haiti, Kenya, Lesotho, Malawi, Tanzania, Uganda, Zambia, Zimbabwe) generated evidence-based, and client-centered models, underscoring the need for including FBO engagement when improving treatment access, continuity of treatment, and outcomes. As such, enhanced engagement with faith communities and implementing FCI

[481] https://www.state.gov/pepfar/coronavirus/

models with PEPFAR core programming, represents an opportunity to address gaps in sustainable HIV epidemic control.

FCI Models prioritize finding men, youth, and children living with HIV and linking and them into continuing care. Existing PEPFAR programs, e.g., OVC and DREAMS platforms (Sections 6.6.3 and 6.2.2.2) and HTS (Section 6.3.1.8) are encouraged to leverage community structures, communities, and leaders, including faith communities and leaders, and harness both their trusted access and the synergies generated from the collaboration based on evidence from FCI investments. The goal is to rapidly advance PEPFAR priorities, including evidence-based treatment and biomedical prevention interventions. PEPFAR will also continue to collaborate with faith and other community leaders to increase the acceptance and uptake of behavioral interventions such as condoms and lubricants through core programming. These models also directly support the aims of MenStar (Section 2.5.2). Strong cooperation and coordination with communities of faith and civil society organizations to build lasting collaborations will advance not only the faith and community engagement priorities but also PEPFAR's ability to leverage social capital, increase impact, and sustain epidemic control.

For COP22, OUs are encouraged to engage the unique assets and capacities of community organizations and communities, including FBOs and Faith Communities and to implement FCI Best Practices models, in order to advance and sustain community, including faith community, engagement activities, as described below.

OUs are strongly encouraged to continue supporting, or to develop a coordinating structure (i.e., a Steering Committee (SC) or build upon existing forums or steering committees, to achieve rapid results. Identifying pre-existing structures within the government or inter-faith organizations will contribute to the sustainability of the committee and ensure country-level capacity to continue engaging communities, including faith communities, in HIV services. At this point in PEPFAR it has become critical to systematically develop plans for monitoring and measuring the impact of these effective community and FBO interventions that continue to facilitate achieving the desired clinical outcomes and reaching both the 95-95-95 targets and epidemic control.

Four New Faith and Community Steering Committee recommendations for OUs to drive effective engagement:

- Engage high-level faith and community leaders with influence, through national-to-local leadership structures, to accelerate PEPFAR priorities (see COP23 Guidance).
- Ensure MOH support for the SC by including their input in the development process

- Coordinate a stigma-free HIV prevention and treatment agenda based on integrated compassionate care for all; and health security agenda, including COVID vaccine uptake.
- Promote PEPFAR and UNAIDS priorities (see COP/ROP23 Guidance).

Countries are encouraged to work with the IPs providing services at the community level to measure and monitor those interventions that make the most impact at different levels (1st, 2nd, & 3rd - 95) of the cascade so that they are aligned appropriately and proactively funded.

The following key tasks are essential for the SC to successfully engage communities, including, faith communities to support activities that end stigma and discrimination:

1. Work with PEPFAR technical team to review HIV treatment and prevention literacy messages.
2. Disseminate more broadly the new 'Messages of Hope' across relevant infrastructures.
3. Facilitate HQ–led and in-country trainings for IPs, FBOs and partner country governments.
4. Ensure a formal strategic information (SI) plan which documents, evaluates, validates, and disseminates the relevance, outputs, and outcomes of the Community and FBO interventions.

The Steering Committee members and their collaborators act together to oppose all discrimination based on race, sex, gender, sexual orientation, religion, ethnicity, or occupation as well as stigma and discrimination surrounding COVID-19 that undermine effective public health response to the dual pandemics and, uphold PEPFAR's commitments to serve all people living with HIV or at risk of HIV.

Implementation Resources, Solutions, and Tools (for additional information, see COP/ROP23 Guidance)

There are multiple resources for men, youth, and children living with HIV and linking them into continuing care in communities including faith communities. In COP22, the PEPFAR community, including faith-engaged programs and staff, should safely support, maintain, and extend HIV testing and decentralized treatment services for men, youth, and children by providing accurate information and reliable sources to faith leaders and faith communities about COVID-19 and HIV, raising awareness and increasing demand for MMD, and psycho-social support.

**Resources and Tools for USG OU teams to reduce stigma and discrimination, strengthen treatment literacy and prevention, and protect health security** (see COP/ROP23 Guidance for additional details): Train leaders and disseminate Messages of Hope through community, including faith-based community structures. Resources for USG OU teams:

- Implementation Guide for Engaging Communities of Faith, HQ Messages of Hope for Men and Children Tool, and HIV Educational Update[482]
- Messages of Hope for HIV prototypes[483]
- Messages of Hope for COVID-19[484]
- Treatment Adherence in the Context of HIV and AIDS in Africa: Training Manual for Religious Leaders[485]
- Faith Matters, CDC (adapted from Families Matter[486])

**Resources, Solutions, and Tools for Closing Treatment Gaps:** Expand HIV Testing, including targeted self-testing; improve linkage to treatment; and promote continuing in care. Best Practices for engaging faith & community leaders and FBOs.

- *Faith-Engaged Community Posts, Zambia (Circle of Hope)* – Further details and training available at the Faith and Community Site[487] and Circle of Hope, PEPFAR Solutions Faith-Engaged Community Posts.[488] In Zambia, FCI supported the decentralized provision of client-centered care by faith-engaged staff through non-descript community posts located in hotspots. Continuous engagement of leaders, particularly trusted and vetted faith leaders,

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[482] https://www.faithandcommunityinitiative.org/fci-implementation-resources

[483] https://www.faithandcommunityinitiative.org/hiv

[484] https://www.faithandcommunityinitiative.org/covid-19

[485] https://seafile.ecucenter.org/d/08b03e1bbd554f149d5e/

[486] Miller, Kim. https://www.cdc.gov/globalaids/publications/fmp-2-pager-final-jan-2014.pdf

[487] Makangila, G., Mwango, A., Shah, M., N.K., Zulu, I., Essiet-Gibson, I., Erickson Mamane, L., Agolory, S., & Hillis, S. (2020, July). Faith-engaged community posts associated with over 1200% increase in new HIV case ascertainment, with high linkage and retention, Zambia [Poster Session]. AIDS 2020, Virtual https://www.faithandcommunityinitiative.org/aids2020-faith-models

[488] https://www.pepfarsolutions.org/solutions/2019/9/30/circle-of-hope-using-faith-based-community-outreach-posts-to-increase-hiv-case-finding-linkage-and-retention-on-treatment-in-urban-and-rural-settings-in-zambia

and the use of expert clients to build community trust. This program succeeded in reaching more men, women, and children, and led to a greater than 12-fold increase in HIV case-finding with 95 percent of clients linked to care and 92 percent maintained in a continuity of care. Recognizing its remarkable success, the Zambian Ministry of Health is scaling the program nationally. During the COVID-19 pandemic the faith-engaged community post model sustained exceptional performance and demonstrated a 41 percent index testing positivity yield and 100 percent linkage to ART.

- *Faith-Engaged Highly Targeted HIV Self-Testing in Urban Settlements, Kenya (EDARP) –* After training in MINISTRY OF HEALTH standards for targeted HIVSTs, community health workers (CHWs) who were faith leaders, and health workers provided highly targeted dissemination of HIVSTs during home visits, emphasizing patient-centered partner notification services and linkage to care. New case ascertainment and yield were doubled and increased even more during active community transmission of COVID-19; this model also has a comprehensive system for promoting high linkage at the Faith and Community Initiative site.[489]
- *Maximizing Same-Day Antiretroviral Treatment (ART) Initiations, Eswatini (The Luke Commission) -* Providing immediate access to senior-level staff for late adopters significantly increased ART initiation, at Faith and Community Initiative.[490]
- *Co-location of Testing Sites on Premises of Religious Venues, Zambia* (Further information available in the May 2021 New Foundations of Hope Webinar[491]). Religious venues may be sites where many people can be reached easily for testing, treatment, multi-month dispensing, and engagement in outreach to surrounding communities. The health structure, a kiosk or trailer near a church, mosque, or other property, may have high yield and high

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[489] Bauer, R., & Motoku, J. (2020, July). Engagement of faith leaders in targeted HIV self-testing increased case identification and new linkages to treatment in Nairobi, Kenya [Poster session]. AIDS2020, Virtual . https://www.faithandcommunityinitiative.org/aids2020-faith-models

[490] VanderWal, E., Benzerga, W., & Lukhele, N. (2021, July). Maximizing Same-Day Antiretroviral Treatment (ART) Initiations by Implementing an HIV Testing and ART Initiation Escalation Plan, Integrated Screening, and Client Education [Poster Session]. AIDS2020, Virtual. https://www.faithandcommunityinitiative.org/aids2020-faith-models

[491] May 2021 NFH Webinar https://www.faithandcommunityinitiative.org/nfh-webinars

volume when a collaborating influential faith and community leader disseminates HIV and health messages; such sites often has extended/weekend hours and offers compassionate care. In Zambia, co-location of testing sites on the premises of churches in informal settlements during FY21Q1-Q3 led to high positivity yield in pediatric clients (19%) all other male clients (19%), as well as showing success with identifying positive index clients and positive contacts for these same age bands, with an overall 51% indexing yield. While 20 facilities constitute 8% of the FY21 service delivery footprint, they consistently perform above their footprint in case-identification (19%), contribution to clients new on HIV treatment (20%), and contribution to clients currently on HIV treatment (13%), for the FY21Q1-Q3 period. Furthermore, the FBO health posts perform as well as the non-FBO health posts in key quality of care indicators including continuity in treatment (99% for both) and viral suppression (95% for both). Additionally, the model provides a road map for service sustainability and community ownership. Given the co-location of these health posts on FC partner church ground, the program vested ownership in the faith partner and leveraged a pre-existing institutional arrangement. The ownership of the facilities and the involvement in service delivery and program management/monitoring have been priceless in empowering the FC partners to be active partners and drive meaningful and sustained impact.

- *Adaptation of Circle of Hope (CoH), Zimbabwe -* Zimbabwe replicated the CoH Faith-Engaged Community Post (CP) model with the launch of five decentralized CPs offering comprehensive HIV service delivery. Since the inception of the CPs, there has been a notable increase in HIVST reactivity ranging from 18% to 37% for females and 4% to 24% for men (Sept. 2020-Aug. 2021). Refinements to a more targeted distribution of HIVST that leverages the social capital of FCI Champions, despite the COVID-19 pandemic restrictions, have resulted in more males (n=699) than females (n=628) reached with the HIV testing service at community posts; a high yield resulting from those testing positive by HIVST kit presenting for confirmatory testing (males, 63% and females, 73%; males, Linkage 97%). The CP model achieved high linkage rates due to the walk strategy, same-day initiations, and intensive follow-up of those clients not linked to ART care. Moreover, the safe delivery of comprehensive, client-centered HIV services offered through the CPs has contributed to the decongestion of healthcare facilities, a strategy that proved essential, especially during the COVID-19 pandemic.
- *Community Adolescent Treatment Program (CATS)* – CATS is tailored for children, adolescents and young adults living with HIV, this model offers a comprehensive range of

services from peer community representatives and navigators, including faith-engaged influencers. CATS facilitators, particularly those who are active members of faith communities or networks, can be trained to act as positive role models, including serving as Faith Champions to strengthen networks of social protection, create demand for HIV testing, delivery HIV self- testing to at-risk youth, and support case identification, linkage to, and continuing in care for children and youth, at Community Adolescent Treatment Program, PEPFAR Solutions.[492]

- *Baby Shower Initiative-* (Further information available in the June 2021 New Foundations of Hope Webinar[493]) A church, mosque, or other faith venue congregation-based approach implemented in Nigeria whereby baby shower events are coupled with health assessments and testing for HIV and other chronic illnesses with subsequent ART linkage support for HIV-positive participants. Studies have shown improvements in HIV case-finding and linkage among pregnant women and significantly improved case-finding among their male partners, as reported here[494] and shown in the video clip.[495] This approach illustrates how faith settings can be instrumental in targeted testing that results in increased uptake of HIV testing and high positivity by reaching male partners of HIV-positive pregnant women who may otherwise not be reached in a healthcare setting (e.g., ANC).[496]

**Resources from the South-to-South Virtual Faith and Community "New Foundations of Hope" Webinar Platform** build the capacity of faith and community leaders across OUs to replicate faith-engaged models above that close 95-95-95 gaps in HIV epidemic control for PMTCT, pediatrics, adolescent girls and young women, adolescent boys and young

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[492] https://www.pepfarsolutions.org/adolescents/2018/1/13/zvandiri-peer-counseling-to-improve-adolescent-hiv-care-and-support

[493] June 2021 NFH Webinar https://www.faithandcommunityinitiative.org/nfh-webinars

[494] Gbadamosi, S. O., Itanyi, I. U., Menson, W. N. A., Olawepo, J. O., Bruno, T., Ogidi, A. G., Patel, D. V., Oko, J. O., Onoka, C. A., & Ezeanolue, E. E. (2019). Targeted HIV testing for male partners of HIV-positive pregnant women in a high prevalence setting in Nigeria. PLOS ONE, 14(1), e0211022.

[495] https://www.youtube.com/watch?v=guPobd1-cTg

496 Montandon M, Efuntoye T, Itanyi IU, Onoka CA, Onwuchekwa C, et al. (2021) Improving uptake of prevention of mother-to-child HIV transmission services in Benue State, Nigeria through a faith-based congregational strategy. PLOS ONE 16(12): e0260694.

men, and women and men.

## 6.6.5 Behavioral Health

Person-centered care for people who engage with HIV testing, prevention, and treatment services must recognize and address critical challenges that cause barriers to success, as well as key facilitators. Behavioral health issues, including mental illness and addiction, are recognized to negatively impact treatment success. Also, the ability of service providers to provide psychosocial support to help persons in their care manage stressors and address social, emotional, spiritual, and environmental wellbeing can be vital for successful prevention, testing, and treatment.

While PEPFAR cannot cover comprehensive health and behavioral health services for all people who receive HIV testing, prevention, and treatment services, teams should prioritize behavioral health interventions when they demonstrate a substantial impact on overall program success, and support interventions that are evidence-based. While psychosocial support interventions are commonly integrated into the work of PEPFAR supported staff, specialized mental health or addiction services are not. Where possible, collaboration and coordination with other behavioral health programs and services supported by other funders is encouraged.

### 6.6.5.1 Addressing Mental Illness in HIV Prevention and Treatment Services

There is a complex, bidirectional relationship between mental, neurological, and substance use disorders and HIV disease. Syndromes such as anxiety, depression, substance use disorders, post-traumatic stress disorder (PTSD) and psychotic illness are common in individuals living with HIV.[497,498] Mental health disorders and psychiatric illness can[499] be a risk factor for HIV exposure that complicates the disease course and treatment. These disorders have been

[497] Rezaei S, Ahmadi S, Rahmati J, Hosseinifard H, Dehnad A, Aryankhesal A, et al. Global prevalence of depression in HIV/AIDS: a systematic review and meta-analysis. BMJ Support Palliat Care. 2019.
[498] Patel, P., et al., Noncommunicable diseases among HIV-infected persons in low-income and middle-income countries: a systematic review and meta-analysis. AIDS, 2018. 32 Suppl 1: p. S5-S20.
[499] Brandt, C., et al., Anxiety symptoms and disorders among adults living with HIV and AIDS: A critical review and integrative synthesis of the empirical literature. Clin Psychol Rev, 2017. 51: p. 164-184.

associated with decreased testing for HIV,[500] reduced likelihood of initiating ART and continuing in treatment,[501,502,503,504] poor ART use, and lower likelihood of virological suppression.[505,506] In addition, psychosocial factors that commonly[507] co-occur with both mental disorders and HIV, such as violence, trauma, stigma, and other social determinants, may additionally impact HIV treatment outcomes.[508]

Depression is the most frequently studied mental health disorder in people living with HIV. Reports from both high-and-low-income settings estimate that up to 60% of PLHIV have depressive symptoms at a given time and this may impact HIV treatment outcomes. The odds of continuous ART therapy (adherence) are 83% better if a person is treated for depression, whereas the risk of treatment interruption is 35% greater among those who do not receive depression treatment.[509] Interventions that address both treatment interruptions and depression have been shown to improve virological suppression.[510] A recent systematic review looked at the effect of behavioral health interventions for A/YLHIV on engagement in care and other health outcomes, and found that PSS and mental health interventions improved adherence to

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[500] Senn TE, Carey MP. HIV testing among individuals with a severe mental illness: review, suggestions for research, and clinical implications. Psychol Med. 2009;39(3):355-63.
[501] Tao J, Vermund SH, Qian HZ. Association Between Depression and Antiretroviral Therapy Use Among People Living with HIV: A Meta-analysis. AIDS Behav. 2018;22(5):1542-50.
[502] Cholera R, Pence BW, Gaynes BN, Bassett J, Qangule N, Pettifor A, et al. Depression and Engagement in Care Among Newly Diagnosed HIV-Infected Adults in Johannesburg, South Africa. AIDS Behav. 2017
[503] Uthman OA, Magidson JF, Safren SA, Nachega JB. Depression and adherence to antiretroviral therapy in low-, middle- and high-income countries: a systematic review and meta-analysis. Current HIV/AIDS reports. 2;21(6):1632-40. Epub 2016/06/03.
[504] Rooks-Peck CR, Adegbite AH, Wichser ME, Ramshaw R, Mullins MM, Higa D et al. Mental health and retention in HIV care: A systematic review and meta-analysis. Health Psychol. 2018;37(6):574-85.
[505] Gonzalez JS, Batchelder AW, Psaros C, Safren SA. Depression and HIV/AIDS treatment nonadherence: a review and meta-analysis. Journal of acquired immune deficiency syndromes (1999). 2011;58(2):181-7.
[506] Pence BW, Mills JC, Bengtson AM, Gaynes BN, Breger TL, Cook RL, et al. Association of Increased Chronicity of Depression With HIV Appointment Attendance, Treatment Failure, and Mortality Among HIV-Infected Adults in the United States. JAMA Psychiatry. 2018;75(4):379-85.
[507] Kane, J.C., et al., A scoping review of health-related stigma outcomes for high-burden diseases in low- and middle-income countries. BMC Med, 2019. 17(1): p. 17.
[508] Hatcher, A.M., et al., Intimate partner violence and engagement in HIV care and treatment among women: a systematic review and meta-analysis. AIDS, 2015. 29(16): p. 2183-94.
[509] Sin NL, DiMatteo MR. Depression treatment enhances adherence to antiretroviral therapy: a meta-analysis. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine. 2014;47(3):259-69.
[510] Safren SA, O'Cleirigh C, Tan JY, Raminani SR, Reilly LC, Otto MW, et al. A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in HIV-infected individuals. Health Psychol. 2009;28(1):1-10..

ART, increased viral suppression and undetectable viral load.[511] Although the association between mental health disorders and HIV treatment interruptions has been well-documented, studies are just beginning to document the association between mental health disorders and incomplete adherence to biomedical HIV prevention such as daily oral PrEP.[512]

Given the linkage between mental health and poorer HIV-related outcomes, screening for and treatment of mental health and substance use disorders for people accessing HIV prevention or treatment services is warranted. Mental health issues are prevalent in key populations and attention to these populations is critical to prevention and treatment success.[513,514,515,516]

Several challenges impede the integration of mental health screening and care into PEPFAR settings. These include mental health stigma which is a challenge for engaging patients, providers, and policy makers in mental health initiatives. Another important barrier is diagnostic: many HIV care settings do not currently include mental health screening, and therefore clients remain undiagnosed. Other challenges include the global shortage of trained mental health workers, and treatments for mental health often include multiple components and vary based on symptom presentation. Service delivery is another challenge and effective models are struggling

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[511] Laurenzi, C. A., Toit, S., Ameyan, W., Melendez-Torres, G., Kara, T., Brand, A., Chideya, Y., Abrahams, N., Bradshaw, M., Page, D. T., Ford, N., Sam-Agudu, N. A., Mark, D., Vitoria, M., Penazzato, M., Willis, N., Armstrong, A., & Skeen, S. (2021). Psychosocial interventions for improving engagement in care and health and behavioural outcomes for adolescents and young people living with HIV: a systematic review and meta-analysis. *Journal of the International AIDS Society, 24*(8). https://doi.org/10.1002/jia2.25741

[512] Velloza J, Baeten J , Haberer J, Ngure K , Irungu E, Mugo N , Celum C, Heffron R, Partners Demonstration Project Team Effect of Depression on Adherence to Oral PrEP Among Men and Women in East Africa J Acquir Immune Defic Syndr 2018 Nov 1;79(3):330-338.

[513] Ali, Ryan, & De Silva. (2016). Validated screening tools for common mental disorders in low and middle income countries: A systematic review. *PLoS One, 11*(6):e0156939.

[514] Parcesepe, Mugglin, Nalugoda et al., 2018. Screening and management of mental health and substance use disorders in HIV treatment settings in low- and middle-income countries within the global IeDEA consortium. Journal of the International AIDS Society, 21, e25101.

[515] Bruckner TA, Scheffler RM, Shen G, Yoon J, Chisholm D, Morris J, et al. The mental health workforce gap in low- and middle-income countries: a needs-based approach. Bulletin of the World Health Organization. 2011;89(3):184-94. Epub 2011/03/08.

[516] Demyttenaere K, Bruffaerts R, Posada-Villa J, Gasquet I, Kovess V, Lepine JP, et al. Prevalence, severity, and unmet need for treatment of mental disorders in the World Health Organization World Mental Health Surveys. JAMA: the journal of the American Medical Association. 2004;291(21):2581-90.

to scale.[517] The result is that a majority of mental health concerns are untreated in low-and-middle income countries.

There are opportunities to make new advances as well. Mental health training resources in the prevention setting, particularly those designed to identify life threatening issues, could be integrated into programming for vulnerable populations. Evidence-based components to promote mental health can be incorporated to promote engagement, help prevent any deleterious impacts of mental health disorders, and help to establish skills for life-long coping and resilience.

HIV testing settings can serve as an entry point to screening for mental health disorders and substance use, to address stigma and ensure that people with mental health conditions have access to voluntary services. A review of screening tools validated for use in low-and-middle income countries identified specific tools for common mental health symptoms including, depression, anxiety, PTSD, and substance use.[518] Evidence-based psychosocial support interventions are covered in Section 6.6.5.2 and should include clear referral pathways for mental health disorder and substance use services. Specific interventions for substance use disorders are covered in Section 6.5.

To meet the challenge of mental health diagnosis in HIV treatment settings, programs must consider who to screen and when and how to conduct screenings.[519] Due to the broad prevalence of mental health conditions, there may be value in screening all patients at program entry and at regular intervals thereafter. Mental health screening may also have value during specific intervals such as in cases of first- or second-line treatment failure. A recent review evaluated several screening tools that have been validated in resource limited settings which can

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[517] Acharya, B., Ekstrand, M., Rimal, P., Ali, M. K., Swar, S., Srinivasan, K., Mohan, V., Unützer, J., & Chwastiak, L. A. (2017). Collaborative Care for Mental Health in Low- and Middle-Income Countries: A WHO Health Systems Framework Assessment of Three Programs. *Psychiatric services (Washington, D.C.)*, *68*(9), 870–872. https://doi.org/10.1176/appi.ps.201700232

[518] Uthman OA, Magidson JF, Safren SA, Nachega JB. Depression and adherence to antiretroviral therapy in low-, middle- and high-income countries: a systematic review and meta-analysis. Current HIV/AIDS reports. 2;21(6):1632-40.

[519] Reynolds CFR, Patel V. Screening for depression: the global mental health context. World Psychiatry. 2017;16(3):316-7

be employed by professionals or paraprofessionals.[520] Training on screening and symptom recognition should be provided.[521]

Once individuals have been identified as meeting symptom criteria, they should be provided with relevant mental health services and/or substance use services, either in the HIV treatment setting or through a referral for mental health services and/or substance use services provided by a different agency. There are numerous evidence-based pharmacological and psychological interventions that have been shown to improve mental health. Among people living with HIV, large meta-analyses and systematic reviews suggest that a variety of therapeutic approaches and modalities can improve mental health outcomes;[522,523] further, evidence also suggests that some mental health interventions can also lead to improvements in HIV-related outcomes.[524,525,526] The following five methods are of demonstrated benefit in scaling up treatment for mental disorders, and may be appropriate in resource-constrained environments:

1. **Task sharing to non-mental health specialists, especially general clinicians, social workers, case managers, and community health workers, including adherence counselors**. Task sharing is a crucial way to increase the availability of mental health care in settings where trained professionals are scant. Studies show that mental health care delivered through task sharing approaches is effective and more likely to be

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[520] Ali G-C, Ryan G, De Silva MJ. Validated Screening Tools for Common Mental Disorders in Low and Middle Income Countries: A Systematic Review. PloS one. 2016;11(6)

[521] WHO Training resource: https://apps.who.int/iris/bitstream/handle/10665/259161/WHO-MSD-MER-17.6-eng.pdf?sequence=1

[522] Passchier, Abas, Ebuenyi, & Pariante. 2018. Effectiveness of depression interventions for people living with HIV in Sub-Saharan Africa: A systematic review and meta-analysis of psychological and immunological outcomes. Brain, Behavior, and Immunity, 73, 261-273.

[523] Asrat, Schneider, Ambaw, & Lund. 2020. Effectiveness of psychological treatments for depressive symptoms among people living with HIV/AIDS in low- and middle-income countries: A systematic review and meta-analysis. Journal of Affective Disorders, 270, 174-187.

[524] Wagner, Ghosh-Dastidar, Robinson, Ngo, Glick, Mukasa, Musisi, & Akena. 2017. Effects of depression alleviation on ART adherence and HIV clinic attendance in Uganda, and the mediating roles of self-efficacy and motivation. AIDS & Behavior, 21, 1655-1664.

[525] Safren, O'Cleirigh, Tan, Raminani, Reilly, Otto, & Mayer. 2009. A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in HIV-infected individuals. Health Psychology, 28, 1-10.

[526] Sin & DiMatteo. 2014. Depression treatment enhances adherence to antiretroviral therapy: A meta-analysis. Annals of Behavioral Medicine, 47, 259-269.

successful with appropriate training and supervision of lay health workers.[527]This document describes psychoeducation content for adolescent depression and other emotional disorders that should be provided in a non-specialized health setting https://www.who.int/maternal_child_adolescent/documents/global-aa-ha-annexes.pdf. Other resources for training may be found here: https://apps.who.int/iris/bitstream/handle/10665/259161/WHO-MSD-MER-17.6-eng.pdf?sequence=1 and here https://www.who.int/mental_health/policy/education/en/

2. **Differentiated or stepped care interventions, where patients receive a different level of intervention, depending on their mental health care needs.** For example, a patient may initially receive task-shifted support from a community health worker, and only move to direct care from a mental health specialist if they do not benefit from this first-line approach. Measurement-based care, a type of differentiated care in which mental health symptoms are routinely evaluated and used to inform clinical care, potentially through a structured protocol based on symptom severity, may be useful in scaling up treatment for mental disorders.
3. Transdiagnostic approaches in which it is recognized that mental health disorders often co-occur and may have a shared underlying pathology. As a result, a consolidated intervention can be deployed which addresses symptoms across multiple mental health diagnoses and therefore creates efficiencies for mental health care. An example of the trans-diagnostic approach is the Common Elements Treatment Approach (CETA)[528] Transdiagnostic approaches may also be extended to address co-occurring psychosocial and structural factors, such as stigma, substance use, and violence.[529]
4. Technology: The COVID-19 pandemic has accelerated digital interventions. There is strong evidence in high-income countries that telemedicine for mental health is

[527] Patel, V., Chowdhary, N., Rahman, A., & Verdeli, H. (2011). Improving access to psychological treatments: lessons from developing countries. Behaviour research and therapy, 49(9), 523–528 . https://doi.org/10.1016/j.brat.2011.06.012

[528] Murray, L.K., et al., A Common Elements Treatment Approach for Adult Mental Health Problems in Low- and Middle-Income Countries. Cogn Behav Pract, 2014. 21(2): p. 111-123

[529] Murray, L.K., et al., Effectiveness of the Common Elements Treatment Approach (CETA) in reducing intimate partner violence and hazardous alcohol use in Zambia (VATU): A randomized controlled trial. PLoS Med, 2020. 17(4): p. e1003056.

effective,[530,531] and evidence in resource constrained countries is emerging suggesting that interventions are feasible and can lead to improvements in mental health.[532,533] Outcomes for mental health apps are more mixed.[534] Digital mental health interventions are just beginning to be tested in low-and-middle income countries, with some evidence that they are feasible and some small pilot trials suggesting they lead to improvements in mental health.[535]

5. Collaborative care: Collaborative care is a model where mental health care is integrated into health care, such as HIV care, and involves collaboration between the HIV care specialist and the individual providing mental health treatment. Measurement-based care may be incorporated into collaborative care models. The model of mental health collaborative care may include a more intensive case management model for PLHIV with significant mental health needs.

Age-appropriate services across the lifespan are required. Consideration should be given for subpopulations who present a special challenge including:

1. Adolescents and youth: The first presentation of psychiatric illness often occurs in adolescence and is commonly undetected. This age cohort is at high risk for HIV and interruptions to treatment. The services required for this group are different from those needed by older individuals. The service providers, both lay and professional, in the facility and the community should be trained to screen for mental health and substance use disorders. Guidance for mental health promotion may be found here

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[530] Bashshur, Shannon, Bashshur, & Yellowlees. (2016). The empirical evidence for telemedicine interventions in mental disorders. *Telemedicine journal and e-Health, 22*, 87-113.

[531] Sin, Galeazzi, McGregor, Collom, Taylor, Barrett, Lawrence, & Henderson. (2020). Digital interventions for screening and treating common mental disorders or symptoms of common mental illness in adults: Systematic review and meta analysis. *Journal of Medical Internet Research, 22*(9), e20581.

[532] Nachega, J. B., Leisegang, R., Kallay, O., Mills, E. J., Zumla, A., & Lester, R. T. (2020). Mobile Health Technology for Enhancing the COVID-19 Response in Africa: A Potential Game Changer?. *The American journal of tropical medicine and hygiene*, *103*(1), 3–5. https://doi.org/10.4269/ajtmh.20-0506

[533] Araya, R., Menezes, P. R., Claro, H. G., Brandt, L. R., Daley, K. L., Quayle, J., Diez-Canseco, F., Peters, T. J., Vera Cruz, D., Toyama, M., Aschar, S., Hidalgo-Padilla, L., Martins, H., Cavero, V., Rocha, T., Scotton, G., de Almeida Lopes, I. F., Begale, M., Mohr, D. C., Miranda J 2021 Effect of a Digital Intervention on Depressive Symptoms in Patients With Comorbid Hypertension or Diabetes in Brazil and Peru: Two Randomized Clinical Trials. JAMA, 325(18), 1852–1862. https://doi.org/10.1001/jama.2021.4348

[534] Weisel, Fuhrmann, Berking, Baumeister, Cuijpers, & Ebert. 2019. Standalone smartphone apps for mental health—A systematic review and meta-analysis. *NPJ Digital Medicine*, 2, 118.

[535] Acharibasam & Wynn. (2018). Telemental health in low- and middle-income countries: A systematic review. *International Journal of Telemedicine and Applications*, 2018, 9602821.

(https://www.who.int/publications/i/item/guidelines-on-mental-health-promotive-and-preventive-interventions-for-adolescents).

2. Pregnant and breastfeeding women: Several studies have documented an increase in suicidality in pregnant and breast-feeding women with HIV in resource limited settings. Risk factors for suicidality included intimate partner violence, non-disclosure to the primary partner, depression, and anxiety.[536,537,538] Support for disclosure and screening for depression may be helpful and the perinatal period may be an important window for screening for psycho-social issues.
3. Older adults: this is a growing population in PEPFAR programs and screening for cognitive disorders in addition to other serious mental health conditions may be helpful.

## 6.6.5.2 Psychosocial Support

Psychosocial Support (PSS) interventions address the interlinked social, emotional, spiritual, and environmental wellbeing of individuals, families, and groups in order to cultivate health and wellness practices and improve HIV prevention and treatment outcomes. PSS is an essential element of effective person-centered care across the prevention and clinical cascades, focused on broadly applicable information and skills, improving participants' support structures, ability to evaluate mood and manage stressors, and mitigating barriers to wellness. Interventions may be provided through facility and community-based platforms, aligned with team-based care principles (Section 6.6.7), and should be gender-affirming, age appropriate, trauma-informed, culturally informed and responsive, and tailored to the unique needs of the focus population or individual. These interventions are not intended to address severe forms of common mental health conditions that impact HIV-affected populations or provide mental health assessment or treatment, including psychotherapy.

[536] Rodriguez VJ, Mandell LN, Babayigit S, Manohar RR, Weiss SM, Jones DL. Correlates of Suicidal Ideation During Pregnancy and Postpartum Among Women Living with HIV in Rural South Africa. AIDS and behavior. 2018;22(10):3188-97. doi:10.1007/s10461-018-2153-y

[537] Jones DL, Rodriguez VJ, Alcaide ML, Weiss SM, Peltzer K. The Use of Efavirenz During Pregnancy is Associated with Suicidal Ideation in Postpartum Women in Rural South Africa. AIDS Behav. 2019;23(1):126-31. doi:10.1007/s10461-018-2213-3

[538] Knettel BA, Mwamba RN, Minja L, Goldston DB, Boshe J, Watt MH. Exploring patterns and predictors of suicidal ideation among pregnant and postpartum women living with HIV in Kilimanjaro, Tanzania. AIDS (London, England). 2020;34(11):1657-64. doi:10.1097/qad.0000000000002594

PEPFAR has integrated PSS throughout prevention, care and treatment portfolios and approaches, tailored to participants' needs across life-stages, including children, caregivers, adolescents, adults, key populations, and priority populations. While these interventions provide valuable support to PEPFAR programs, there remains a need to be more intentional and targeted in our approach to PSS. Governments have recognized the value of PSS and incorporated interventions into national HIV prevention and care guidelines for long-term sustainability (e.g., Kenya Ministry of Health[539]).

While more informal methods of PSS exist, often delivered by lay or peer facilitators in the community, PEPFAR programs should focus on those approaches that are evidence-based and tailored for the intended participants and outcomes. Evidence-based or evidence-informed psychosocial practices should be incorporated into the delivery of routine PEPFAR prevention, care and treatment services, including within DREAMS, OVC, and Key Population programs. Interventions can be implemented by a range of healthcare and peer support workers through various modalities including, clinic visits, home visits, support groups (including peer support and groups that link psychosocial support with ART delivery such as teen clubs), social media, digital support, and telephone contact. Intervention facilitators should be trained and able to develop supportive, trusting, non-judgmental relationships, to maximize participant engagement in programming; this requires investment in ongoing training, supervision, and support for facilitators (please refer to HRH guidance in Section 6.6.7 on health workforce protections and supporting MH and PSS services for healthcare workers). Where possible, implementing partners should train and support facilitators who are members of these communities, particularly in the case of support group leaders (e.g., PLHIV, KP, AGYW). PSS intervention packages should be context specific and differentiated according to the needs and experiences of different subpopulations. The highest ethical standards should be maintained when implementing these interventions, including voluntary participation, confidentiality, privacy, and the best interests of each participant. Lack of participation should not affect access to ART or other services.

PSS interventions are essential when addressing issues around HIV-related stigma and discrimination that impact case finding, care and treatment as well as prevention. Adults and

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[539] National AIDS & STI Control Program (NASCOP), Ministry of Health Kenya. (2018). *Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya (2018 Edition).* https://www.nascop.or.ke/new-guidelines/

youth living with HIV face levels of internalized stigma (i.e., self-stigma), perceived/anticipated stigma (i.e., social denial), and/or enacted stigma (i.e., prejudice, discrimination). This can produce feelings of fear, shame, rejection, and violence surrounding their status disclosure.[540] Stigma is associated with low levels of social support and adjustment, psychological distress, poor adherence to ART, and interruptions to treatment. Addressing the impact of stigma provides pathways to reduce these barriers to care and improve the quality of life and well-being of each participant.[541,542] PSS interventions that build resilience to adverse experiences, especially among adolescents, can support lifelong prevention and treatment.

There are many aspects of PSS, but not all will be discussed in this section. In PEPFAR programs, PSS interventions should include the following characteristics:

- Well-defined, demonstrably evidence-based or evidence-informed interventions with SOWs and SOPs to support consistency and integrity of delivery across facilitators, platforms, and partners
- Interactive social and emotional learning and coping skills, which may include components such as cognitive behavioral skills-building programs, emotional regulation, problem-solving, interpersonal skills, mindfulness, assertiveness, resilience, and stress management[543]
- Training tailored to the type of facilitator role (e.g., expert clients, peer-providers, case managers) and target population, including training in first-line support (e.g., LIVES, VAC) for all facilitators

The following types of complementary psychosocial approaches are recommended and can be used in combination:

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[540] Camlin, C. S., Charlebois, E. D., Getahun, M., Akatukwasa, C., Atwine, F., Itiakorit, H., Bakanoma, R., Maeri, I., Owino, L., Onyango, A., Chamie, G., Clark, T. D., Cohen, C. R., Kwarisiima, D., Kabami, J., Sang, N., Kamya, M. R., Bukusi, E. A., Petersen, M. L., & V Havlir, D. (2020). Pathways for reduction of HIV-related stigma: a model derived from longitudinal qualitative research in Kenya and Uganda. *Journal of the International AIDS Society, 23*(12). https://doi.org/10.1002/jia2.25647

[541] Basha, E. A., Derseh, B. T., Wubetu, A. D., Engidaw, N. A., & Gizachew, K. D. (2021). Factors Affecting Social Support Status of People Living with HIV/AIDS at Selected Hospitals of North Shewa Zone, Amhara Region, Ethiopia. *Journal of Tropical Medicine, 2021,* 1–7. https://doi.org/10.1155/2021/6695298

[542] Okonji, E. F., Mukumbang, F. C., Orth, Z., Vickerman-Delport, S. A., & van Wyk, B. (2020). Psychosocial support interventions for improved adherence and retention in ART care for young people living with HIV (10–24 years): a scoping review. *BMC Public Health, 20*(1). https://doi.org/10.1186/s12889-020-09717-y

[543] Geneva: World Health Organization. (2021, April 28). *Updated recommendations on service delivery for the treatment and care of people living with HIV.* https://www.who.int/publications/i/item/9789240023581

1. Motivational interviewing – a collaborative, client-centered counselling style focused on increasing motivational readiness for behavioral change
2. Psychoeducation based on Growth Mindset. This has been found to improve mental health even when provided alone
3. Basic coping skills, such as cognitive coping
4. Family-based support – involving children/ adolescents and their caregivers, to strengthen communication, problem-solving and negotiation skills
5. Peer support and social networks – which are structured peer-driven interventions

PSS interventions are related to but distinct from mental health interventions (see Section 6.6.5.1), and may be provided within a tiered intervention structure, where the majority of clients engage in broader support interventions and a subset may be referred to a higher level of mental health care. Facilities should begin to incorporate training on the use of standardized screening tools for common mental health and substance use concerns that could benefit from PSS services, including identification of safety concerns (see Section 6.6.5.1 for additional information on screening tools). PSS facilitators should be trained to identify when a higher level of mental health care may be appropriate and have access to clear and established referral pathways. Strong collaboration between community and clinical providers is essential to provide support and linkage to needed services, as opposed to relying on passive referrals within the broader system.

**PSS Across the Life Span**

***Children and Families.*** Evidenced-informed PSS practices underpin PEPFAR's approach to prioritize child-centered, family-focused care to improve the outcomes for children. PEPFAR OVC programs have consistently offered PSS interventions to children, adolescents and families affected by HIV to mitigate challenging household environments and build resilience in children, adolescents, and families. Family-based psychosocial interventions may be provided through OVC and DREAMS programs, including, for example, evidenced-based parenting programs for parents of 10-14-year-olds (Section 6.2.3) or KP-focused interventions (Section 6.5.1).

OVC and care and treatment programs are in the unique position to provide referrals for mental health services for children, adolescents, and caregivers through the comprehensive case management services approach and case management programs respectively provided in the facilities, community, and home-based settings. Supportive counseling and structured PSS for C/ALHIV, caregivers, and other priority subpopulations are key to improving treatment

outcomes, including disclosure support for parents/caregivers of children living with HIV. PEPFAR's pediatric programs support a number of family-based interventions, for example ARIEL clubs,[544] described further in Section 6.1.2.1 and Figure 6.6.5.2.1 below.

***Adolescents and Young Adults.*** PEPFAR is supportive of recent WHO guidance that states psychosocial interventions should be provided to all adolescents and young people living with HIV (A/YLHIV).[545] PSS is considered critical to both the mental and physical health of A/YLHIV.

While there may be short-term increases in cost to implement PSS intervention for A/YLHIV, this may offset the longer-term economic and social costs of poor health outcomes for A/YLHIV, as was shown with VLS for ALHIV in Zimbabwe's Zvandiri intervention.[546] PSS interventions designed to be implemented by lay counsellors or peer mentors may be less costly.[547,548,549,550] Costs may also be reduced by using digital strategies for delivery.[551,552]

Interventions led by peers and near-peers have been found to be particularly effective with adolescent populations. Young people should be meaningfully engaged at each stage of PSS

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[544] ARIEL Clubs: https://www.pepfarsolutions.org/infants-children/2018/1/13/ariel

[545] Geneva: World Health Organization. (2021, April 28). *Updated recommendations on service delivery for the treatment and care of people living with HIV.* https://www.who.int/publications/i/item/9789240023581

[546] Mavhu, W., Willis, N., Mufuka, J., Bernays, S., Tshuma, M., Mangenah, C., Maheswaran, H., Mangezi, W., Apollo, T., Araya, R., Weiss, H. A., & Cowan, F. M. (2020). Effect of a differentiated service delivery model on virological failure in adolescents with HIV in Zimbabwe (Zvandiri): a cluster-randomised controlled trial. The Lancet Global Health, 8(2), e264–e275. https://doi.org/10.1016/s2214-109x(19)30526-1

[547] Bhana, A., Mellins, C. A., Petersen, I., Alicea, S., Myeza, N., Holst, H., Abrams, E., John, S., Chhagan, M., Nestadt, D. F., Leu, C. S., & McKay, M. (2013). The VUKA family program: Piloting a family-based psychosocial intervention to promote health and mental health among HIV infected early adolescents in South Africa. AIDS Care, 26(1), 1–11. https://doi.org/10.1080/09540121.2013.806770

[548] Bermudez, L. G., Ssewamala, F. M., Neilands, T. B., Lu, L., Jennings, L., Nakigozi, G., Mellins, C. A., McKay, M., & Mukasa, M. (2018). Does Economic Strengthening Improve Viral Suppression Among Adolescents Living with HIV? Results From a Cluster Randomized Trial in Uganda. AIDS and Behavior, 22(11), 3763–3772. https://doi.org/10.1007/s10461-018-2173-7

[549] Nestadt, D. F., Saisaengjan, C., McKay, M. M., Bunupuradah, T., Pardo, G., Lakhonpon, S., Gopalan, P., Leu, C. S., Petdachai, W., Kosalaraksa, P., Srirompotong, U., Ananworanich, J., & Mellins, C. A. (2019). CHAMP+ Thailand: Pilot Randomized Control Trial of a Family-Based Psychosocial Intervention for Perinatally HIV-Infected Early Adolescents. AIDS Patient Care and STDs, 33(5), 227–236. https://doi.org/10.1089/apc.2019.0021

[550] Fatti, G., Jackson, D., Goga, A. E., Shaikh, N., Eley, B., Nachega, J. B., & Grimwood, A. (2018). The effectiveness and cost-effectiveness of community-based support for adolescents receiving antiretroviral treatment: an operational research study in South Africa. Journal of the International AIDS Society, 21, e25041. https://doi.org/10.1002/jia2.25041

[551] Whiteley, L., Brown, L. K., Mena, L., Craker, L., & Arnold, T. (2018). Enhancing health among youth living with HIV using an iPhone game. AIDS Care, 30(sup4), 21–33. https://doi.org/10.1080/09540121.2018.1503224

[552] Christodoulou, J., Abdalian, S. E., Jones, A. S. K., Christodoulou, G., Pentoney, S. L., & Rotheram-Borus, M. J. (2019). Crystal Clear with Active Visualization: Understanding Medication Adherence Among Youth Living with HIV. AIDS and Behavior, 24(4), 1207–1211. https://doi.org/10.1007/s10461-019-02721-3

planning, implementation and monitoring to ensure the specific needs of sub-populations, such as young parents, adolescent KPs, AGYW, and adolescents with disabilities, are addressed. When implementing peer-led PSS interventions, adequate training, support, supervision, and mentorship for the peer leaders, including established pathways to engage trained social workers and counselors, are essential to sustainable and effective programming.

Comprehensive prevention programs often engage near-peer mentors to facilitate evidence-based programming, such as through the DREAMS Partnership with AGYW. DREAMS implementing partners and AGYW have identified the critical need for support to address environmental stressors and emotional wellbeing. DREAMS OUs may explore integrating PSS training for mentors to support AGYW's emotional resilience, self-efficacy, coping skills, and social wellbeing, such as psychological first aid (see Section 6.2.2.2 Identifying New Solutions to Fill Programming Gaps for additional guidance and Figure 6.6.5.2.1 below).

***Adults.*** Research indicates PSS continues to be a central need into adulthood and is an important factor to improving HIV outcomes such as treatment continuity and VLS.[553,554,555] Interventions that emphasize emotional benefits, counseling and emotional support, such as those in the MenStar Strategy,[556] should be leveraged to reduce treatment gaps. The availability of high-quality PSS is especially important during stressful life events, such as for women living with HIV who screen positive for precancerous lesions or present with suspected cervical cancer. Older adults comprise a growing proportion of individuals in HIV treatment programs and may have unique needs, especially in the context of COVID-19, where they may be isolated. Information in clear language with large fonts from multiple trusted sources (family, health care providers, media) with frequent repetition that can be easily understood by people with and without cognitive impairment are key to improved health and mental health. PSS interventions are beneficial for adults participating directly in PEPFAR programming as well as those in the

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[553] Berg, R. C., Page, S., & Øgård-Repål, A. (2021). The effectiveness of peer-support for people living with HIV: A systematic review and meta-analysis. *PLOS ONE, 16*(6), e0252623. https://doi.org/10.1371/journal.pone.0252623
[554] Chime, O. H., Arinze-Onyia, S. U., & Obionu, C. N. (2018). Do peer support groups have an effect on medication adherence? A study among people living with HIV/AIDS in Enugu State, Nigeria. *Proceedings of Singapore Healthcare, 27*(4), 256–264. https://doi.org/10.1177/2010105818760923
[555] Siril, H. N., Kaaya, S. F., Smith Fawzi, M. K., Mtisi, E., Somba, M., Kilewo, J., Mugusi, F., Minja, A., Kaale, A., & Todd, J. (2017). CLINICAL outcomes and loss to follow-up among people living with HIV participating in the NAMWEZA intervention in Dar es Salaam, Tanzania: a prospective cohort study. *AIDS Research and Therapy, 14*(1). https://doi.org/10.1186/s12981-017-0145-z
[556] MenStar: https://menstarcoalition.org/wp-content/uploads/2020/07/MenStar-Strategy-2-02-2020-FINAL.pdf

broader community reached through social norms change interventions, such as SASA!.[557] Interventions such as SASA! support engagement in health systems and HIV prevention, shift harmful social norms within communities, and have been found to prevent gender-based and intimate partner violence (see Section 6.6.2 for additional information on the impact of gender equality and GBV).

***Key Populations (KPs).*** Intersecting social stigmas, and criminalization in some contexts for KPs (e.g., sex work, drug use, and same- sex behavior) present additional challenges for these populations highly affected by HIV. KPs, including MSM, TG, Sex Workers, PWID, and prisoners, experience perceived and internalized stigma as well as structural and societal discrimination that negatively affect mental health. This relationship is further compounded by the unfortunate stigma around mental health challenges in society and among patients and providers.[558] Therefore, PEPFAR follows WHO Comprehensive Guidance on KPs which supports both peer and professional mental health (Section 6.6.5.1) and PSS services as a part of comprehensive KP programming.[559]

***Pregnant and Breastfeeding Women (PBFW).*** Women living with HIV (WLHIV) are at risk for elevated stress during pregnancy and the immediate postpartum period due to fears about status disclosure to a partner, vertical transmission, as well as her own health and wellbeing.[560] Moreover, women who are newly diagnosed during the ANC period typically experience more profound psychological distress, which can result in depression and anxiety. Young mothers may experience further challenges that are exacerbated by lack of support, isolation, and limited access to services. PEPFAR supports PSS interventions for PBFW, through structures such as Mentor Mothers and young mother support groups, that have been linked to improved maternal and child health outcomes as well as positive HIV clinical outcomes, including treatment continuity for mother and baby and reduced vertical transmission.[561]

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[557] SASA!: https://raisingvoices.org/sasa/

[558] Remien, R. H., Stirratt, M. J., Nguyen, N., Robbins, R. N., Pala, A. N., & Mellins, C. A. (2019). Mental health and HIV/AIDS. *AIDS, 33*(9), 1411–1420. https://doi.org/10.1097/qad.0000000000002227

[559] World Health Organization. (2016). *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations.* WHO. https://www.who.int/publications/i/item/9789241511124

[560] World Health Organization. (2003). *HIV-infected women and their families: psychosocial support and related issues.* WHO. https://www.who.int/hiv/pub/prev_care/en/PsychosocialSupport.pdf

[561] Odiachi, A., Al-Mujtaba, M., Torbunde, N., Erekaha, S., Afe, A. J., Adejuyigbe, E., Galadanci, H. S., Jasper, T. L., Cornelius, L. J., & Sam-Agudu, N. A. (2021). Acceptability of mentor mother peer support for women living with HIV in North-Central Nigeria: a qualitative study. *BMC Pregnancy and Childbirth, 21*(1). https://doi.org/10.1186/s12884-021-04002-1

**EXAMPLES OF PSS INTERVENTIONS AND RESOURCES**

The table below includes examples of evidence-based PSS interventions but is not comprehensive. Please refer to the DREAMS Guidance,[562] MenStar Strategy,[563] OVC Guidance (Section 6.6.3) and differentiated service delivery for children (Section 6.1.2.1), adolescents (Section 6.1.2.2), and adults (Section 6.1.2.3) for additional information on how to integrate PSS into these programs.

*Figure 6.6.5.2.1: Summary of PSS Interventions by Target Populations and Intended Outcomes*

| ***Target Population*** | ***Intervention*** | ***Intended Outcome*** |
|---|---|---|
| Children and Adolescents living with HIV | Ariel Adherence Clubs (Tanzania)[564] | Improve treatment adherence, and clinic retention |
| Adolescents living with HIV | Operation Triple Zero (OTZ; Kenya)[565] | Intermediate outcomes include increased appointment adherence and case management. Long term outcomes found an increase proportion of VLS and retention on ART, and a reduction in mortality among AYPLHIV |
| Adolescents living with HIV | Community Adolescent Treatment Supporters | This approach helps youth increase treatment literacy, motivate adherence, increase treatment |

[562] DREAMS Guidance: https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf
[563] MenStar: https://menstarcoalition.org/wp-content/uploads/2020/07/MenStar-Strategy-2-02-2020-FINAL.pdf
[564] Ariel: https://www.pepfarsolutions.org/solutions/2018/1/13/ariel-adherence-clubs-increase-retention-and-adherence-among-children-and-adolescents-living-with-hiv-in-tanzania-fzwjc?rq=ariel%20clubs
[565] OTZ: https://www.pepfarsolutions.org/solutions/2018/10/30/operation-triple-zero-empowering-adolescents-and-young-people-living-with-hiv-to-take-control-of-their-own-health

| | | |
|---|---|---|
| and Young Mentor Mothers | (CATS), Zvandiri (Zimbabwe)[566] | continuity, and improve psychosocial well-being, self-esteem, self-worth and confidence. |
| Women, Children, and Adolescents | Mothers2mothers (m2m)[567] | Peer-based service delivery, shown to improve HIV health outcomes for women, children and adolescents, including treatment continuity and PMTCT |
| Adolescents and their Parents | Parenting for Lifelong Health (PLH) for Parents and Teens[568] | PLH, a training program for parents and their 10- to 17-year-olds, seeks to establish nurturing caregiver-teen relationships and reduce the risk of violence against teens in and outside the home. It also aims to strengthen the ability of caregivers to provide a protective environment. |
| All PLHIV | HIV Treatment Adherence Counseling and Retention Guide (EpiC)[569] | A motivational interviewing and communication skills job aid to inform and support people living with HIV to plan for and remain on lifelong treatment |
| All People | Psychological First Aid (PFA)[570,571] | PFA can be provided by community members and lay workers and seeks to support adaptive coping immediately after extremely stressful events through compassionate and practical strategies. It gives a framework for supporting people in ways that respect their dignity, culture and abilities. |

[566] CATS: https://www.pepfarsolutions.org/adolescents/2018/1/13/zvandiri-peer-counseling-to-improve-adolescent-hiv-care-and-support
[567] Mothers2mothers: https://m2m.org/our-impact/
[568] PLH: https://www.who.int/teams/social-determinants-of-health/parenting-for-lifelong-health
[569] EpiC: https://www.fhi360.org/sites/default/files/media/documents/epic-hiv-adherence-counseling-retention.pdf
[570] World Health Organization. (2011). *Psychological First Aid: Guide for Field Workers (Illustrated ed.).* WHO. https://www.who.int/publications/i/item/9789241548205.
[571] Additional information is available through the National Child Traumatic Stress Network: https://www.nctsn.org/treatments-and-practices/psychological-first-aid-and-skills-for-psychological-recovery/about-pfa

## 6.6.6 Emergency Commodity Fund

Prior-year funds that have been deposited into the HIV/AIDS Working Capital Fund and that are considered part of "The Emergency Commodities Fund" (ECF) remain available for obligation to support certain countries during periods of enormous financial uncertainty, evolution in global treatment guidelines, and continued interdependence of donor funding, subject to applicable law and to policy and legal approval. Use of the ECF is intended to be limited. The ECF is not intended to be a parallel solution that bypasses criteria of accountability and efficient grants management or effective procurement and supply chain practices. All ECF funding will continue to be utilized for the purpose of providing emergency support to countries on an as needed and justified basis, consistent with applicable law and the completion of any necessary procedures. All countries benefiting from the ECF may be expected to reimburse use of the ECF in full. Use of the ECF requires the approval of the Global AIDS Coordinator.

Countries in need of support from the ECF should work with their OU team to develop a decisional memo, which describes the conditions which lead to needing emergency support. This memo should include all relevant information to help PEPFAR leadership to make a decision. Subjects which may aid this include economic conditions of the partner country, epidemiological data, root causes for increased demand of the needed product and information on PEPFAR program performance, especially if that performance is impacted by a lack of the needed product. Country teams should collaborate on the memo with their supply chain country lead as well as the OGAC commodity team, using the ECF template. PEPFAR leadership will normally make a decision within two weeks of the memo's submission. The timeline may be extended if there are any questions that cannot be quickly answered by the OGAC Commodity team or the memo drafter. Once PEPFAR leadership has made a decision, all stakeholders will be notified and (if approved) the order will need to be placed by the OU team.

A secondary option for appealing to the ECF is through the Ministry of Health or partner-country government. This option anticipates the MOH will provide repayment, expeditiously. If this option is pursued, please reach out to the PEPFAR Coordinator.

## 6.6.7 Optimizing HRH Staffing for Maximum Impact and Sustainability

Summary of section edits:

- Wording was updated to reflect the focus on sustainability in PEPFAR's new strategic direction, and to make the section more "evergreen" in relation to the ongoing realities of COVID.
- Guidance on HRIS investments has been updated to align with COP/ROP23 Guidance which states that HRIS investments must be made into government systems rather than PEPFAR-specific HRIS.

PEPFAR has long invested in health workforce staffing to rapidly scale up HIV services. PEPFAR's significant staffing investments, a nearly $2 billion-dollar investment in COP21, has enabled significant gains toward HIV epidemic control in many countries and made possible rapid HIV service delivery adaptations during the COVID-19 pandemic. To shift greater focus to sustainability and enable future transition of the workload supported by PEPFAR into country systems, it is time for PEPFAR to pivot focus toward strengthening regional and national leadership and ownership of local institutions to plan and manage the configuration of the multidisciplinary health workforce required.

COVID-19 has taken a toll on health workers globally and exacerbated health workforce challenges across PEPFAR countries. In response to these and other challenges, the U.S. Government launched the Global Health Worker Initiative (HWI). PEPFAR programs should ensure that their human resources for health (HRH) investments align with and advance the HWI priorities

In planning for COP22, countries should prioritize: 1) continuing to ensure the safety and well-being of the workforce[572]; 2) supporting decent work and fair pay for all workers; 3) further optimizing health workforce staffing investments; 4) promoting gender equality to build a diverse, gender equitable, and gender-affirming workforce that advances women, non-binary, and gender minorities leadership opportunities and fosters safe work environments with fair remuneration and non-discrimination ; and 5) prioritizing key above site investments to advance workforce sustainability under local leadership, using a whole of market approach.

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[572] World Health Organization. *Protecting, safeguarding and investing in the health and care workforce.* (Seventy-fourth World Health Assembly. 26 May 2021). Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_ACONF6-en.pdf

In particular, PEPFAR OUs should advance dialogue with countries' Ministry of Health, Public Service Commission or equivalent, Ministry of Finance, private sector, and other stakeholders, to plan for requirements for health workforce sustainability and ensure optimized PEPFAR HRH staffing investments complement government and private sector staffing availability and needs.

**Health Workforce Protection:** Health workers supporting HIV service delivery should be protected and safeguarded from violence, sexual harassment, and discrimination. Working within a prolonged COVID-19 response has taken a toll on the physical and emotional well-being of health workers. Health workers have worked under extremely difficult conditions with higher rates of COVID-19 infection than the general population. In addition to professional stress, there have been reports of increased violence and discrimination against health workers attributed to pandemic-related misinformation and stigma. Women health workers, in particular, have had higher rates of COVID-19 infection and have faced safety concerns such as increases in gender-based violence. PEPFAR-supported programs should continue to prioritize the safety and well-being of health workers and revive some of the 'care for the caregiver' practices that were essential to supporting the workforce in the early days of the HIV pandemic, as described in PEPFAR's COVID guidance. Workers should be provided PPE, and services should be modified to the extent possible and necessary to protect health workers. Practices introduced during COVID may be considered for long-term implementation, such as offering telehealth services that include end user capacity building programs and system set-up support as an alternative to in-person services and other innovations to decongest service delivery sites. Ensuring a safe working environment is vital for supporting health worker's physical and mental health. PEPFAR-supported programs should promote national policies and workplace safety standards for health workers, advocate for digital health policies and infrastructure that supports the use of digital tools and innovative practices to decongest health facilities, and support building skills to increase resilience, provide routine wellness checks, and ensure access to psychosocial support and mental health services.

**Decent Work and Fair Pay:** All workers supporting PEPFAR programs should receive fair remuneration for their efforts. As noted below (under Sustainability), PEPFAR-supported clinical and ancillary health workers should be supported under terms that are aligned with government recognized cadres, pay scales and qualifications. Community health workers and peer workers should receive compensation aligned with partner-government policies. In instances where country policies do not specify payment, PEPFAR country programs should proactively engage, along with other donors, to promote country policy reforms. In addition, OUs must utilize

recruitment practices that advance a diverse and inclusive health workforce, including in leadership positions, that is reflective of local populations being served. All workers should be set up to succeed in their job, with a proper orientation, opportunities for continuing skill and knowledge development, career pathways where possible, and provision of the supplies and tools required to do their job properly.

**Optimizing Investments in Health Workforce Staffing:** Efficiently and effectively achieving and sustaining HIV epidemic control requires a data driven approach to health workforce decision-making and management. Two key questions that guide optimization are (1) is the right skill-mix of workers at the right locations? and (2) do health workers have the capacity and support required to provide equitable and competent care? Countries should actively advance monitoring and realignment of the workforce to meet programmatic objectives, particularly in light of COVID-related service delivery shifts. This can be done through the establishment and use of health workforce datasets, and through strong human resource management systems, including:

- *PEPFAR HRH Inventory:* The PEPFAR HRH Inventory, an annual PEPFAR reporting requirement for all IMs as of FY21Q4, provides a comprehensive dataset to inform requirements and allocation of HRH. The Inventory is used to understand the entire footprint of PEPFAR-supported staff (staff providing service delivery, as well as those providing non-service delivery activities and technical assistance), their cadre composition, roles and expense, and distribution across SNUs, PSNUs and above site. Countries should use the Inventory in combination with other data sources (like partner workplans) to optimize investment of the PEPFAR-supported workforce. Key MER indicators should be compared to the staff responsible for meeting those program targets to assess the adequacy of staff in relation to program priorities, and staff should be redistributed and repurposed as needed to align with program targets and budgets. Further discussion of the use of the HRH Inventory to inform program planning is included under Section 7.2. To the degree possible, OUs should collaborate with Global Fund and the Ministry of Health to map the complete national complement of health workers supporting HIV service delivery.
- *Human Resource Information Systems (HRIS):* PEPFAR investments in Human Resource Information Systems (HRIS) should result in increased ability of country governments and PEPFAR teams to use HRH data for decision making at national, subnational, facility and community levels. All HRIS must be fully owned and operated

by governments and integrated into government systems. PEPFAR should not invest in standalone systems that primarily meet PEPFAR's needs, rather than the partner country's needs. The PEPFAR HRIS Assessment Framework (HAF) can be used to assess the maturity of HRIS implementation. Continued investments in HRIS should include an explanation of how existing efforts are aligned to the WHO minimum data sets for HRH registries and are yielding greater data use, resulting in effective and efficient HRH regulation, training, recruitment, allocation, and retention. HRIS investments should enable tracking HRH down to the facility level on a routine basis. For PEPFAR OUs operationalizing sustainability planning, investments in HRIS or equivalent are a core element, critical to ensure the sustainability and transition of PEPFAR-supported HRH. OUs should advocate for collaborative use of data sets between the Ministries of Health and Education to ensure the medical education systems are meeting the needs of the country.

- *Team-based Care:* Countries should further define and optimize multidisciplinary team-based approaches for HIV service delivery, including case management, to support client-specific needs, including continuity of treatment. Efforts should not be limited to PEPFAR staffing models but extend to supporting partner-country governments to advance multidisciplinary team-based approaches for partner-country government staff. This includes building stronger working relationships between facility-based staff and CHWs and/or other community-based staff counterparts to ensure strong linkages between community and facility-based services. Integration of HIV services should be pursued where it has the potential to yield further efficiency gains and advance client-centered care, as well as support sustainability of services. The backbone of an effective team-based approach is clearly delineated roles and responsibilities and written communication of employees' updated scopes of work (SOW), supported by mentoring, supportive supervision, clear referral, and care coordination procedures. Care coordination procedures should include provider workflow and handoff, which must be monitored over time and regularly realigned for greater efficiency and client-centered care, in partnership with partner governments.
- *Quality Service Provision:* Countries should continue to support improvements in the quality of services delivered by PEPFAR, partner government and private sector health workers, while also leveraging opportunities for greater efficiency in the systems utilized. In many countries, TA support to improve quality is a large portion of PEPFAR's workforce expenses. Streamlining this TA support, utilizing flexible training and

supportive supervision models, and working through local organizations to the fullest extent possible should be prioritized. Efforts should also be in place to integrate quality improvement practices within country systems and to ensure that investment has broader sustained impact for long-term HIV services. For example, programs should invest in the capacity of, and partner with, training institutions and professional councils to ensure that education and professional development requirements include opportunities to develop HIV skills.

- *Performance management:* Routine use of HRH data is essential to drive improvements in HRH performance and productivity, including challenges during COVID-19. As PEPFAR makes advances in use of HRH data to drive programming through the new HRH Inventory, OUs should work, in partnership with partner country governments, to improve use of data to monitor staff performance and assess the impact of HRH work on outcomes related to provision of quality, client-centered HIV care. This is critical for driving improvements and improving accountability for sustained epidemic control.

**Diverse, Gender Equitable, and Gender-Affirming Workforce:** PEPFAR's workforce support should promote equality and sustainability through building a diverse, gender equitable, and gender-affirming workforce. A special focus should be placed on hiring PHIV, especially in patient-facing roles, and PEPFAR-supported sites should be actively supported to welcome HIV+ staff. PEPFAR should advance women, non-binary, and gender minority leadership opportunities at all levels and foster safe work environments with fair remuneration and non-discrimination – this may include preparing and positioning DREAMS beneficiaries for healthcare worker roles. This may be supported through HRH policy development, pre- and in-service training, and staffing recruitment, management, and retention practices. Country programs should also work with partner country governments to promote health worker protection and wellness with particular focus on addressing gender-based violence among the health workforce, as women are the majority of the global health and care workforce. Finally, PEPFAR programs should conduct outreach and stigma and discrimination reduction programs specific to health workers, as many health workers do not know their status due to fears of discrimination from their coworkers.

**Sustainability:** COVID-19 has further underscored the importance of having an adequate and well-supported health workforce in place. Many of the rapid adaptations and pivots that PEPFAR has made to maintain service provision during COVID-19 have been possible because of our long-term and significant investment in health workforce staffing. COVID-19 has further

highlighted countries' health workforce gaps and capacity constraints, including for workforce planning and management. As countries advance toward epidemic control while continuing to respond to the COVID-19 pandemic, it is important to advance dialogue and planning for long-term HRH sustainability. Sustainability planning is an important priority for all PEPFAR-supported programs.

- *Institutionalizing Efficient Models:* Optimizing the health workforce, as described above, is a vital component of sustainability planning. HRH sustainability planning should be informed by understanding of workforce requirements to support the package of HIV services for maintaining HIV epidemic control. This should include consideration of further integration of HIV services into primary health care platforms and understanding of updated roles/responsibilities of staff to deliver HIV care as part of integrated services.
- *Alignment to Partner Government Systems:* PEPFAR supports a diversity of health worker cadres supporting HIV services. Alignment of HRH support to partner country government systems is key for advancing HRH sustainability planning, including any planned absorption of workload supported by PEPFAR by country government public sector health workforce. PEPFAR-supported clinical and ancillary health workers should be supported under terms that are aligned with government recognized cadres, pay scales and qualifications. OUs should work with IPs to rationalize the roles, responsibilities, pay scales, and qualifications across IPs aligned with local government systems. Alternative types of hiring and remuneration of health workers that can yield a more flexible and resilient workforce (e.g., contracting) should also be considered when thinking about absorption of workload and HRH required for sustained epidemic control.
- *Informal Cadres:* The COVID-19 pandemic has further highlighted the critical role community health workers and lay cadres play within DSD for HIV treatment models—both facility and community-based DSD models. PEPFAR teams should first work to streamline roles and compensation, ensuring decent work and fair compensation across the various community and lay workers, including PLHIV and peer support cadres supported in countries. Teams should then identify opportunities to formally integrate roles and responsibilities of cadres who are not formally recognized by country governments into country systems, including processes for certification and continued education and training. This is a critical first step to advance sustainability of the community-based work that PEPFAR has supported which will be important long-term. This will also help identify what roles/responsibilities, if any, may need to be considered outside of the public sector. PEPFAR-supported programs should work with partner

governments to plan for a rationalized and integrated community and lay health workforce that can be sustainably maintained.

- *Resource Mobilization and Donor Coordination: Financing requirements for the health workforce should be connected to broader domestic resource mobilization efforts to advance greater shared responsibility for HIV services.* In addition to working with partner country governments on issues pertaining to the public sector financing of the health workforce, OUs, in partnership with partner country government, should advance mobilization of private capital to increase the role of the private sector workforce in delivery of HIV services, in line with plans to further decentralize HIV services and universal health care policies and programs. Countries should also prioritize HRH for government co-financing investment. This should be done in coordination with other bilateral and multilateral donors with HRH investments.
- *Local Organizations:* Strengthening local organizations is key to developing a sustainable HRH plan. OUs, in partnership with partner countries, should expand the capacity of local organizations to work with partner-country governments in support of key HRH functions such as planning, management, and training. Local organizations should be inclusive of the whole-of-market, including government, parastatals, private-for-profit, and not-for-profit organizations.

## 6.6.8 Impact-Driven Information Systems and Data Management Investments

Summary of section edits:

This section was updated based on feedback from the 2022 Data Summit and to align with: (**1**) the current PEPFAR vision for impact driven information systems and data management; (**2**) reliance on partner government owned or endorsed one-health information ecosystem; (**3**) tight collaboration across agencies; and (**4**) improved alignment with WHO person-centered strategic information. The section now provides considerations for unified digital health ecosystems, and for national integrated, longitudinal individual level data repositories. These efforts can help sustain PEPFAR's strategic information investments.

As PEPFAR moves to a more sustainable roadmap the data required for managing PEPFAR programs become a byproduct of the data useful to those providing and collecting it: the people PEPFAR serves and the people on the service delivery frontlines. In accordance with this

strategy, country-operated or endorsed systems should be supported, PEPFAR-operated systems should be considered for transition to the partner-country government, and all systems should be capable of sharing data. In addition, PEPFAR health information system and data management investments should advance the vision of securely bringing together individual-level, longitudinal data in the form of a national data repository for appropriate in-country programmatic use and curated deidentified data sets for programmatic transparency (See COP/ROP23 Guidance Section 3.2.3).

As PEPFAR increases reliance on nationally owned or endorsed systems, OU teams may encounter seeming differences between PEPFAR and country reporting needs. These dissolve with national individual level data repositories that allow data to be aggregated in multiple ways. For example, if PEPFAR uses 28 days to identify individuals who have interrupted treatment and the country uses 60 days, a viable approach would be to use the individual data elements to derive the number of days, allowing calculation of both metrics according to their definitions. In situations where collecting certain data elements may pose increased risk of harm or stigma for a patient, OU teams—in collaboration with partner-country ministries—should exclude this information from the national individual-level data repository and consider alternative population-level surveillance methods for this information.

PEPFAR recognizes that each country and its information systems are at different stages related to this strategy. Therefore, PEPFAR understands that phased and multi-pronged approaches are needed to meet the aforementioned strategic goals. PEPFAR country teams should contact HQ for technical assistance as they consider their respective pathways.

### 6.6.8.1 Advancing National Unified Health Information Ecosystems

Unified health information ecosystems pull together digital and paper-based health information systems into a cohesive, integrated, interoperable digital network that together meet partner government, PEPFAR, and other stakeholders' data needs. This network can consist of one or more software applications for the same or different types of data (e.g., clinical, community, laboratory, commodities, etc.) but ensures data points are collected only once and shared across the ecosystem where needed. For example, if a doctor orders a lab test for a patient, this information would be shared with the laboratory information system. Then, the laboratory information system would share the result with the clinic's information system. Wherever the information is digitized it should be shared electronically. When information is paper based, it

should be digitized as close to the service delivery point as possible. Refer to the following WHO (Digital health (who.int)), USAID (A Vision for Action in Digital Health | U.S. Agency for International Development), and CDC (CDC Global Health Strategy | CDC) publications to learn more.

The unified health information ecosystem includes individual-level data collected at various service delivery points as well as individual-level data collected via other surveillance and/or survey activities. PEPFAR recognizes that different data collection systems may be used for each type of assessment. That said, whenever possible, integrating nonservice delivery data within the respective information systems can reduce the burden and cost of these critical data streams.

Ideally, the least amount of data necessary for client care and provider efficacy is entered at the point of service. This data should then be shared with district, provincial, and national data centers in a format that facilitates following client care over time without exposing client identity. Doing this will help national authorities and authorized donors observe HIV program performance and progress and empower programs to shape data-informed and sustainable solutions. The aforementioned approach includes:

- Instances in which data captured at the point of service—either in clinics or in the community—are integrated to allow data exchange across applications and diseases.
- Scenarios where source data systems fully respond to service providers' needs and data are used at site, subnational, and national levels for patient care and management and to support operational planning, monitoring, and reporting across stakeholders.
- Situations where system controls securely protect patient and beneficiary identifiable data.
- Instances where data need to be rapidly exchanged across systems and there are minimal transcription errors from multiple entries (e.g., ordering lab tests and electronically returning results.

Although each country is in a different place on the path to this ideal state, thoughtful investments and collaboration with partner governments and other donors can drive progress. The following are some concrete examples of encouraged investments:

- Information system for multiple diseases

    - In sites with only HIV-specific systems investments, work with partner governments and donors to fund system expansion to incorporate other disease areas into the electronic medical record.
    - In sites with generalized systems across relevant programming, work to ensure those systems support the capture and use of data necessary for PEPFAR reporting.
- Data exchange between information systems
    - In sites with person-based digital clinic level systems and electronic laboratory information systems, work with partner governments and donors to daily exchange lab order and result data electronically between these systems.
    - In sites with paper-based records and electronic laboratory systems, consider supplementing the paper-based system with a mobile phone accessible option for lab order submissions and result return.

### 6.6.8.2 Supporting National, Integrated, Longitudinal Person-Level Data

PEPFAR information systems have traditionally focused on digitizing patient and other beneficiary data at the service delivery level and on analyzing and using data aggregated at the site for government and PEPFAR monitoring requirements. However, when aggregated data are used, it can be difficult to resolve discrepancies in the results across data sources. Discrepancies are easier to resolve when individual-level data are integrated and deduplicated across sites. For COP23, PEPFAR health information system and data management investments should advance national individual-level data repositories that securely bring together data over time in the format collected for use at service delivery (See COP/ROP23 Guidance Section 3.2.3).

Making information in national integrated, longitudinal, person-level data repositories available to all stakeholders—at an appropriate level of access—ensures data are maximally leveraged for health management, disease surveillance, and decision-making. This includes secure access to deidentified, individual-level data sets curated for directed analyses, as well as preformatted dashboards and customizable report interfaces for routine situational awareness to manage HIV and other health threats. This transparency may also electronically satisfy monitoring requirements. Ideally, this would include:

- De-duplicated data across sites to help programs understand patient movement between sites and to ensure providers have the necessary resources and patient medical history to deliver proper care
- Linked data across facility and community systems, such as for clients engaged in differentiated service delivery models to support delivery of integrated care, tracking patient outcomes, and inform commodity management
- Data that help ministry staff at subnational levels follow up when treatment interruptions occur and when contact tracing people at risk for HIV infection
- Robust de-identification of curated data sets and stringent role-based access to protect client confidentiality and ensure data are available at the analytic points as needed

Not only do the described repositories enrich understanding of how patients seek services, but they also support data-informed service delivery evolution and facilitate other individual level analyses. **Figure 6.6.8.2.1** depicts the multiple components of a national integrated, longitudinal, individual-level data repository. Such repositories start with data feeding—individual-level data from service delivery are fed to the national-level. As data are fed into the system, they are integrated (or brought together) from across sites and data sources. This is followed by ongoing data quality review and by generating up-to-date, topic-specific, deidentified data sets for authorized use.

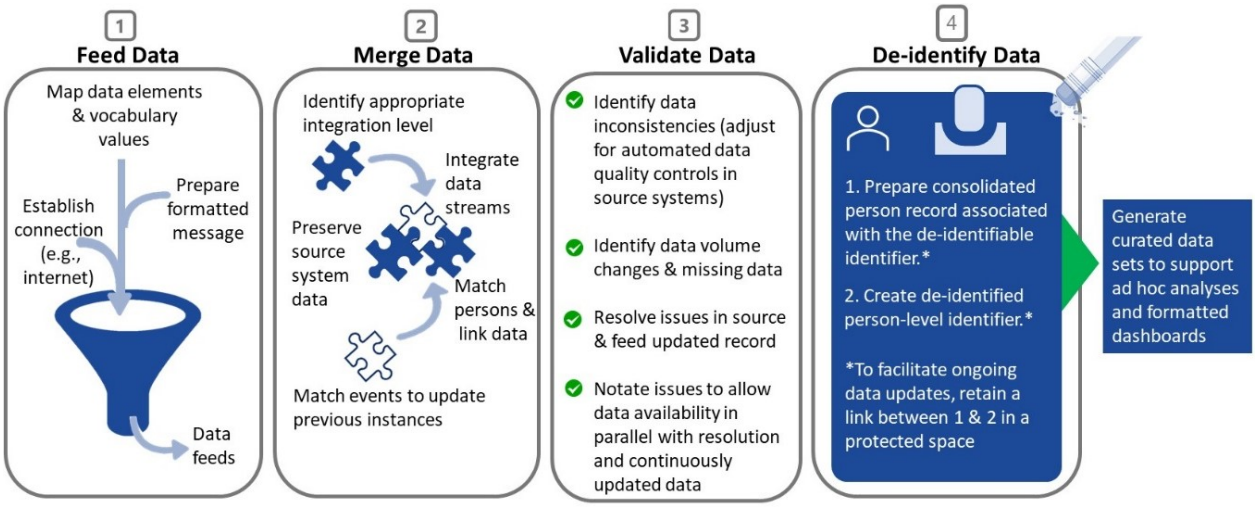


**Figure 6.6.8.2.3: Data Management Considerations for Reviewing Implementation of a National Data Repository**

Data within environments depicted in **Figure 6.6.8.2.1** include personally identifiable information. Consequently, each environment must include strict information security controls to ensure data confidentiality and protect individuals' privacy. The below section on data access sharing and use provides further considerations.

**Figures 6.6.8.2.2–6.6.8.2.4** present considerations to assess existing national data repositories and inform plans for enhancements or for developing new national integrated, longitudinal, individual level data repositories. The figures also present steps for improvement in cases where desired characteristics may be lacking. The repository characteristics are grouped by policy data management and technical features.

Policy considerations ensure the partner country owns or endorses the national data repository (See **Figure 6.6.8.2.2**). Policy considerations also address data governance—focusing on appropriate access for all stakeholders and on partnerships (e.g., coordinating across donors' investments) to advance partner-country priorities and strategies.

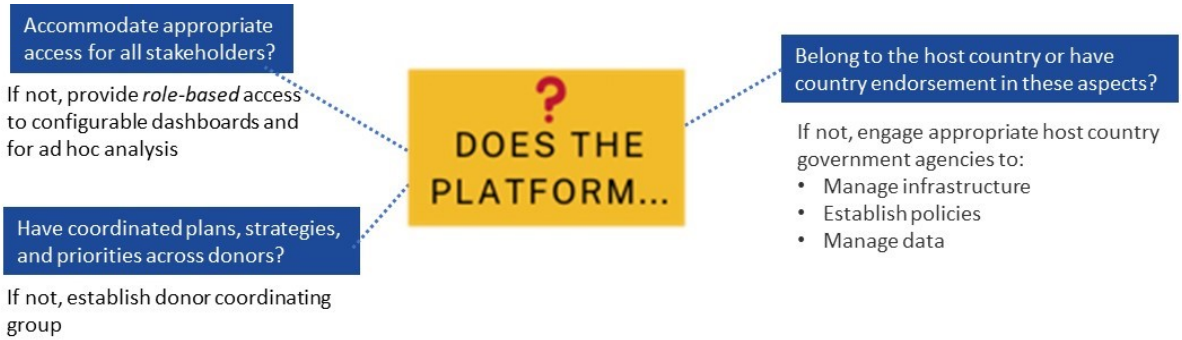


**Figure 6.6.8.2.2*:* Policy Considerations for Reviewing Implementation of a National Data Repository**

Data management considerations relate to the ongoing process of reviewing the data to ensure accuracy and precision (**Figure 6.6.8.2.3**). Data management also relates to ongoing processes that allow tracing an individual's progress over time (i.e., matching and linking records/instances of the same person and their events), and standardizing vocabulary values (e.g., using a consistent value for a facility name).

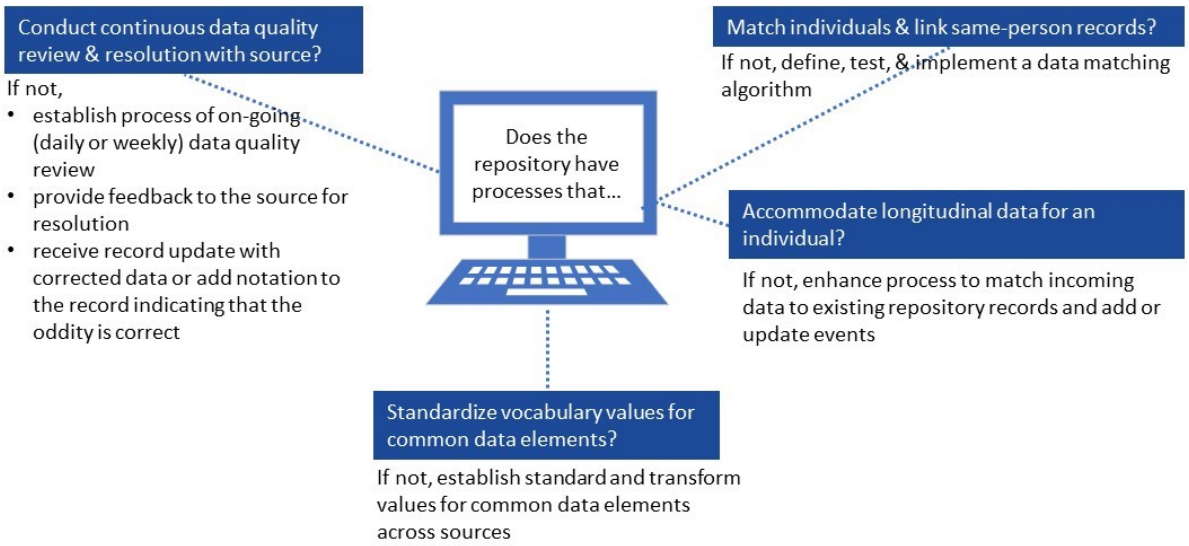


**Figure 6.6.8.2.3*:* Data Management Considerations for Reviewing Implementation of a National Data Repository**

Lastly, technical considerations include update frequency, source data preservation, multi-disease accommodation, multidata source and type integration, standardized data formats, and an integrated analytics platform (**Figure 6.6.8.2.4**).

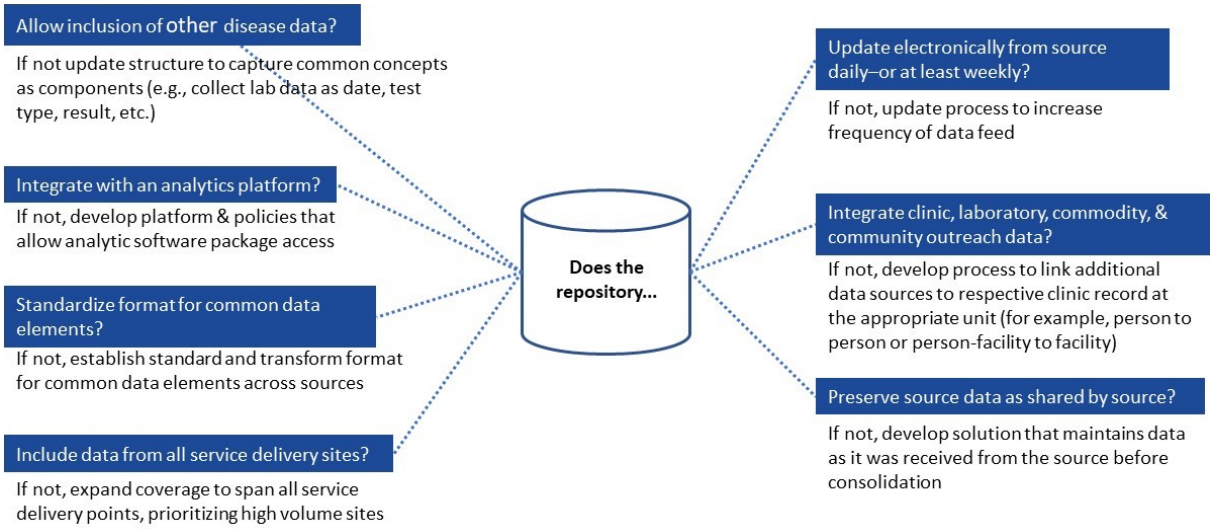


**Figure 6.6.8.2.4*:* Technical Considerations for Reviewing Implementation of a National Data Repository**

To learn more about this approach, please reach out to the PRIME Team at S/GAC for access to the PEPFAR-developed webinar: *Operationalizing Use of Integrated Longitudinal Person-Centric Data to Support HIV Programming*.

## 6.6.8.3 Operationalizing National Unified Health Data Ecosystems

### Cost of Sustaining

Systems investments do not end once the system is deployed. Resources for ongoing operations and maintenance costs should also be considered. These costs include addressing system bugs, incorporating enhancements to improve or add functionality, and replacing end-of-life system hardware. These costs may be offset by the cost-efficient nature of unified national information systems (e.g., they eliminate parallel processes and allow multiple systems at a site to leverage one computer network).

Sustainable information-systems costs may also include infrastructure, such as power and connectivity, if not established in the operating area. Some OUs have worked with local telecom providers to negotiate clauses that reduce payment when connectivity interruptions occur. Some OUs have also installed solar panels at service delivery points to ensure consistent power.

Moreover, system sustainability should account for ongoing staffing needed to capture, manage, and organize data sets that are designed to facilitate specific use (e.g., supporting a national dashboard to monitor VMMC progress). Staffing should also include individuals skilled in software development lifecycle roles—including business analysts, designers, developers, quality-assurance specialists, and user training and support specialists.

Key to sustainability are the efforts to institutionalize activities that are associated with information systems and data management through ongoing engagement with country ministries—including ministries of defense—for active involvement in day-to-day systems operations and data capture, management, review, and visualization, as well as the systems development lifecycle. To sustain its investments, PEPFAR supports the capacity development of a country workforce having the knowledge, skills, and abilities to accurately record person-centric services; continually review and resolve potential data quality issues; and appropriately curate data sets, dashboards, and other outputs for data use, as well as individuals to lead informatics-savvy public health organizations[573] and to support software development lifecycles. PEPFAR seeks to advance this through Public Health Technical Corps and other means.

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[573] The Task Force for Public Health: Public Health Informatics Institute. (2019). Retrieved from: https://phii.org/module-1/introduction/.

## Advancing Maturity

There are many ways to determine the maturity of unified health data ecosystems. One way to assess maturity is to look at the data within the system to ascertain if it is well-governed and available to meet the needs for all system stakeholders. **Figure 6.6.8.3.1** provides examples of key questions that one could ask to understand what information is available. For example, "Are data in the national data repository updated quarterly, daily, or weekly?" If not, the next step involves identifying the barriers to daily or weekly updates and then addressing those barriers.

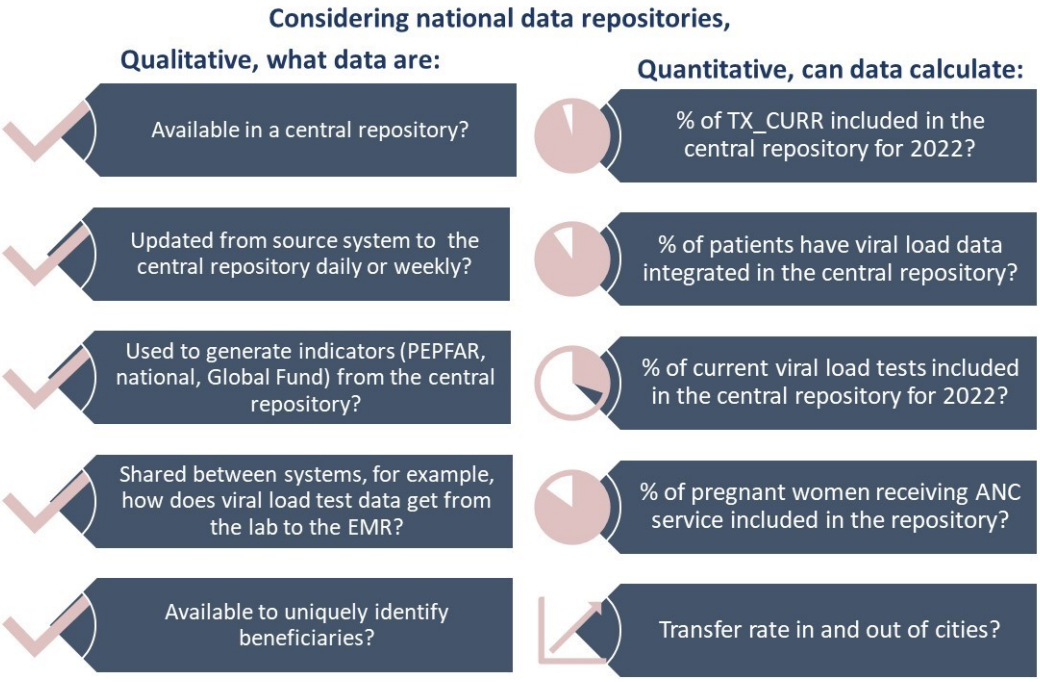


**Figure 6.6.8.3.1**: **Diagnosing Data within the Ecosystem**

The Informatics-Savvy Organization framework is also useful to assess maturity, address challenges, and focus resources. This framework has the following 3 interdependent capabilities that need to work seamlessly together:

- **Supportive Policy and Governance:** Ideally, national approaches would promote the following: appropriate data use; prioritized information and communication technologies; protection of information privacy and confidentiality; investment in system security; and implementation of ongoing processes for the review and resolution of data issues.

- **A Suite of Integrated National Information Systems:** Such systems would ideally be well-designed and effectively used—and support single-point data capture that could be leveraged throughout the ecosystem.
- **A Skilled Workforce**: Recording, integrating, managing, curating, and using data takes skill. So does supporting information and communication technology tools to ensure data availability, reliability, completeness, and timeliness.

**Partnerships**

The importance of teamwork cannot be overstated; particularly international partnerships between organizations is critical for the success of strategic information investments. And although fostering partnerships requires significant time, effort, and maintenance, the benefits are significant.

PEPFAR collaborates with local and global partners to ensure alignment to the Digital Development Principles and Digital Donor Principles.[574,575] Both frameworks outline how to build nimble health information systems architecture and use global data standards to facilitate system extension to support other public health concerns (e.g., TB, COVID-19). PEPFAR supports and endorses coordination among digital health investments across donors to maximize their impact. Several donors and stakeholders are involved in fighting the HIV/AIDS epidemic, as well as ones focused on other health concerns, that should be considered. Each type of partner has its own approach, needs, benchmarks, and operational processes to align for collaboration. These include the following, just to name a few:

- **Global Fund, WHO, Others**: These entities have extensive aid portfolios and often engage and collaborate with other entities to drive further value and development. They have a broad reach and impact.
- **Public-Private Partnership**: These partnerships are between the public sector and private organizations and provide value for both. With a clearly articulated value proposition, these partnerships can provide opportunities for further engagement, development, and impact.

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[574] Principles of Digital Development. Retrieved from: https://digitalprinciples.org/https://digitalprinciples.org/

- **Inter-Agency Partnerships**: Partnerships between government agencies are critical to driving the PEPFAR agenda. Collaborations among USG agencies (e.g., CDC, USAID, DOD, HRSA, S/GAC, and others) cements the path toward sustainable development.
- **National and Local Governments**: Partnerships with partner-country governments serve to create sustainable paths and solutions to long-term benefits for the population. It is imperative that partner-country governments are involved in decision-making, dissemination, and sustainability efforts.
- **National Public Health Institutes:** These organizations play a critical role in supporting countries in their fight against HIV. They can play a pivotal role in coordinating and disseminating best practices.
- **Civil Society Organizations:** These are networks of people that include **t**raditional health practitioners, community elders, and leaders; local and international non-governmental organizations; faith-based groups; religious leaders living with HIV groups; professional associations; organizations representing people living with HIV; activist and advocacy groups, including those representing key and priority populations; human rights groups; women's rights groups; men's health groups; youth organizations; religious leaders living with HIV groups; access to justice and rule of law groups; groups representing other populations highly affected by the epidemic, such as people with disabilities, women, and girls; PEPFAR program beneficiaries or end users; community associations; champions of data-driven decision-making; and not-for-profit organizations at national, district, and local levels (e.g., Rotary, Lions Clubs, and other global and local groups).

Continuous engagement, teamwork, leadership development, and sustainable execution are critical to maintaining positive collaborations that promote progress.

### Data Governance

Data governance includes legislation, policies, and strategies that define the country context and priorities, as well as systems, processes, and norms that support appropriate collection, access, use, and other data interactions. Good data governance successfully balances the value of accessing and using public health data against the rights of individuals (and communities) represented in the data. In 2021, the WHO convened a Data Governance Summit, where stakeholders reached consensus about the need to designate health data as a global public good and initiated discussions on some of the discrete actions necessary to

support this agenda. The creation of a publicly owned set of Health Data Principles has complimented these efforts—providing a comprehensive set of guiding principles to support good health data governance and prioritize a rights-based agenda. Key data governance considerations for PEPFAR-supported platforms include:

- **Data Ownership**: It's important to identify and acknowledge data ownership—including actions that ensure data owners have true decision-making authority related to the data. Data owners may be individuals, communities, partner countries, or other stakeholders.
- **Data Sharing and Use**: Defining the purpose of data collection and limiting subsequent data interactions to those with a justified need to know is essential (see below).
- **Policies and Regulations**: Policies should prioritize the interests of individuals and communities.

Working with the sensitive data that PEPFAR produces, collects, and processes requires strict information security controls. Such controls support the public health value of collecting and using data while also protecting against potential risks that inappropriate data use or access may pose to program participants and communities. These potential risks exist for all forms of data and require robust data governance systems and associated norms. Essentially, the risk of sharing confidential or sensitive information increases the more easily it can be shared with individuals who do not have a clear need to access the information.

### Data Governance Enabling Environment

The data and digital governance enabling environment includes applicable legislation, policies, and frameworks for partner countries, multi-country regions, and the U.S. Government. Relevant policies may include: data protection (e.g., data protection regulations or acts), public health surveillance policies, emergency declarations that outline situational data collection, aggregation, or sharing, health data legislation, data and digital strategies, and statistical policies. To understand the country context, it's important to review any relevant documentation, including laws, policies, guidance, strategies, etc., that may apply to creation, collection, storage, access, use, sharing, or disposal of data containing personal identifiable information. Identify any potential content gaps in these policies—particularly for those of the partner country—, as well as any potential conflicts or discrepancies between partner-country policies and USG and/or PEPFAR policies. Data protection and data governance policies may be in different stages, including:

- **In Draft**: Be aware of when partner-country policies are expected to be approved or enacted and create plans to mitigate potential conflicts with PEPFAR data interactions.
- **Enacted**: Consider how PEPFAR policies and data processes interact with enacted policies and potential ramifications of gaps or conflicts.
    - Policies may not have structures or mechanisms to support implementation; review the policies to ascertain the level of practical implementation and enforcement (e.g., commissions that monitor and enforce provisions, accountability, and transparency). Key aspects of enforcement include monitoring as well as transparency and accountability mechanisms.

**Data Access, Sharing, and Use**

Public health data use and access must be predicated on a legitimate "need to know" basis. Access models should recognize and accommodate different stakeholder needs matrixed across users and all "levels" of the system—from the community- and patient-level (e.g., lab, clinic, hospital), through subnational and national levels (e.g., public health institute or ministry of health), and above (e.g., PEPFAR, WHO, regional centers). Electronic platforms support access by ascribing designated permissions to each user based on their specific needs.

Data sharing and use agreements define access, use, and sharing principles to be applied across the digital health data ecosystem. These agreements are between multiple stakeholders (whether within or external to the country)—data owner(s), data requestor(s), and other stakeholders with designated roles as stewards or processors. For PEPFAR, the agreements should be inclusive across agencies and provide for a range of uses, including monitoring progress and impact of the HIV program, as well as the digital health information system investment. The agreements should also not conflict with overarching PEPFAR data sharing and use requirements (see PEPFAR Data Governance Guidance).[576]

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[576] Relevant resources: PEPFAR Data Governance Guidance, ADS 579 (May 2021 + new/pending version) and ADS579 reference , Considerations for Using Data Responsibly at USAID

## 6.6.8.4 Recent Infection Surveillance Among Newly Diagnosed PLHIV

Summary of section edits:

- This section was 6.6.8.1 in the 2022 COP/ROP Guidance Technical Considerations Section.
- Language was updated to reflect the new implementation guidance developed in response to the PEPFAR Scientific Advisory Board recommendations on Recent Infection Surveillance
- Language was updated to emphasize that recent infection results are not used to inform clinical or case management, and individual-level results are not actionable, as well as update language on implementation status in PEPFAR countries.

As of FY22, HIV recency testing for surveillance is being implemented in over 25 PEPFAR countries, with a number still in planning and training stages. High quality data from recency surveillance programs in these countries will be used to mount effective and appropriate public health responses and help bring countries within reach of 95-95-95 goals.

In COP23, PEPFAR is taking an increasingly measured and focused approach to implementation of recency testing for surveillance. Recognizing that the highest quality recency surveillance data will come from regions with high levels of recency testing coverage, also indicating an enabling policy environment and a united MoH and PEPFAR team that are scaling together, OUs should focus on scaling up recency testing in a way that will provide the highest quality data to inform effective public health responses. Specifically:

- **PSNUs at ≥50% RTRI coverage and w/ VL confirmation (RITA) or strong CBS system** should continue to scale-up recency surveillance activities fully, aiming to get to 100% RTRI and RITA coverage as quickly as possible. This will provide high quality data that can be used to inform appropriate public health responses.
- **PSNUs with <50% RTRI coverage** should continue implementation of recency surveillance activities at current levels, but pause any further scale-up
- **For PEPFAR-supported recency activities, the OU should meet one of the following:**
    a. Include VL/RITA in algorithm
    b. Be actively working to include VL (e.g., protocol amendment submission within FY23)

c. If VL/RITA not included (i.e., if OU has strong CBS), then needs detailed justification with COOP, S/GAC, and Chair approval

Continuing from previous guidance, all persons newly diagnosed with HIV age 15 years or older should be offered recency testing and testing should be conducted only for those who consent. As part of program monitoring and continuous quality improvement, OU teams are encouraged to track the number of RTRIs offered, rates of uptake, and reasons for gaps in coverage (e.g., test kit unavailable, site/provider not trained or activated, client declined or ineligible, etc.).

While initiating or bringing recency testing to scale as a part of surveillance, PEPFAR teams should consider: 1) planning and developing a comprehensive approach, in consultation with HQ, IPs, master trainers and ISMEs, to implement recency testing in a phased manner to assure quality; 2) training of trainers by HQ ISMEs, IPs, and OU team to serve and develop a pool of in-country experts/ISMEs; 3) planning and conducting series of step-down trainings and certification of testers/test providers; 4) integrating recency testing into existing HIV testing services with trained/certified personnel; 5) using standardized site-level data collection tools (both electronic and paper-based) and a central dashboard to monitor quality and analyze aggregate data; and 6) routine monitoring and use of data, to assess quality of testing and for forming effective public health responses. As stated in more detail above, PEPFAR is now requiring that HIV recency testing include viral load (VL) testing, as part of a recent infection testing algorithm (RITA) to improve the classification of recency status of individuals testing recent on rapid test for recent infection (RTRI). In some cases, a strong case-based surveillance system may be utilized instead of VL testing to improve the classification of recency status of individuals testing RTRI recent.

RTRI and RITA results, whether recent or long-term, do not change HIV-positive status as confirmed by national guidelines and do not impact clinical or case management of the client. Recency testing (RTRI or RITA) has no impact on clinical or case management of an individual nor on that individual's health, and results should not be used to prioritize downstream contact tracing efforts. Index testing should be offered to all PLHIV as standard of practice and in accordance with safe and ethical index testing standards. As such, it is strongly recommended that recency results (RTRI or RITA) not be returned to individuals, in any setting—recognizing that countries might need to defer to the ethical guidelines or processes established by local MOH or IRBs to inform such a decision.

Information below provides guidance for implementing quality-assured recency testing. Best practices from early implementers of recent infection surveillance are available on the TRACE eLearning Hub.

**Training**

All trainings should include didactic sessions (which can be done virtually, if needed) and hands-on practice to perform the RTRI. Training modules must cover the purpose of RTRI, pre-test counseling, client consent, and confidentiality, data use and public health response, site supervision, continuous quality improvement, and monitoring. In addition, if a country decides to return results to individuals, testers should be trained to use appropriate language during both pre and post-test counseling. Additional modules must include adequate hands-on training to ensure competency of testers and understanding of SOPs to conduct recency testing, quality assurance elements, interpretation, and data management. All new data collection forms and tools should be reviewed with trainees and trainings should include sufficient opportunity to practice data collection using the appropriate technology that will be utilized in the field (either paper-based or tablet-based electronic data collection, or both).

For quality assurance, competency of trainees should be assessed through written exam (oral exam if necessary) and practical exam at the end of training. In addition to three quality control (QC) specimens, hands-on training should include *10 or more* well characterized specimens comprising of recent infections, long-term infections, and negatives. Only trainees who pass the practical exam and written exam should be certified to perform the RTRI. Template agendas and generic training presentations are available on the eLearning Hub and should be customized by an in-country team or working group to adapt to their respective context. HQ ISMEs, working with IPs and in-country staff, will play a lead role in conducting trainings and assisting in the development of training panels, quality control specimens, training of trainers, and step-down trainings, as needed. Countries should maintain a roster of trainings indicating performance and certification of the trainees which should be shared with HQ ISMEs for documentation purposes. In settings with SARS-CoV-2 transmission, trainings will need to be adapted to be consistent with local transmission prevention regulations and S/GAC guidance. This will likely include appropriate personal protective equipment (PPE), smaller class size, social distancing, symptom screening, and virtual training, if appropriate.

Countries restarting recency surveillance activities after significant pause (>1 month) due to COVID-19 restrictions (or other reasons) should re-assess testing competency through QC specimen panels for staff performing recency testing and conduct refresher trainings as needed.

Refer to Considerations for Recency Surveillance Activities after COVID-19 Pause USG Internal Considerations from PEPFAR Recency Community of Practice for more information.[577]

**Monitoring**

RTRI is a point-of-care test for surveillance that requires periodic quality monitoring at sites conducting recency testing to ensure the quality of training, implementation, testing, and test performance. The monitoring should be done by trained personnel using a standardized tool, such as the Stepwise Process for Improving the Quality of HIV Rapid and Recency Testing (SPI-RRT) checklist, which is further described in Section 6.3.1.1 of the COP guidance under HIV Rapid Testing Continuous Quality Improvement and is available on the eLearning Hub. All sites should have a monitoring visit within the first month of implementation. Subsequent visits may depend on indication of quality issues from aggregate data review, QC results or proficiency testing (PT) performance. However, visits should be conducted at least quarterly to ensure continuous quality of testing at sites. If any issues are identified, corrective actions, including retraining should be conducted immediately.

For countries that have paused recency activities because of the COVID-19 pandemic, a Reactivation Checklist has been developed to support teams to assess readiness of sites to re-start recency testing.

**Quality Assurance and CQI**

Routine QC testing and PT programs for HIV rapid testing should also incorporate PT for RTRI by including well-characterized specimens as part of the panels for sites performing recency testing. Performance of RTRI sites should be continuously monitored internally by site supervisors through routine review of testing practices and logbooks and externally by program managers/auditors through periodic site visits using the SPI-RRT. During the first six months of implementation, quality of the program should be more closely monitored. It is recommended to conduct on-site direct observation of RTRI testing during site activation (e.g., use of QC panel per certified tester) or during other site visits. Supervisory teams should conduct site visits at least quarterly or sooner if problems are identified or suspected. Root cause analyses should be conducted, and corrective action plans should be developed and followed up when gaps are identified. National HIV recency dashboards, developed and managed by Ministries of Health,

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[577] https://pepfar.sharepoint.com/:b:/r/sites/COVID-19/OtherResources/COOP%20Considerations%20for%20Recency%20During%20COVID%2008.24.2020%20FINAL.pdf?csf=1&web=1&e=PfodwH

allow for an overview and stratified view of RTRI testing, service coverage, kit performance, QC specimen performance, and testing quality at reporting sites. Ongoing review of real-time data can quickly identify quality related issues, trigger root cause analyses, and help take corrective actions in a timely manner to strengthen program performance. Compiled recency surveillance data on a dashboard, disaggregated by sex, age, geography, and other key variables, can be used by country teams to assess plausibility of recent infections based on epidemiology of transmission patterns in the country. Any major deviation from the expected patterns of recent infections should trigger review of testing and data quality. The quality of HIV diagnostic testing using the national algorithm will impact individuals eligible for RTRI. PEPFAR OU teams should therefore consider, when appropriate, including a refresher of the HIV testing algorithm, specimen collection, and DBS preparation for viral load during recency trainings.

**Community Engagement around HIV Recency Testing**

A community engagement plan should include initial consultations to introduce recency testing, its purpose, and risks/benefits. Likewise, it should provide an opportunity for community members to describe their perceived risks/benefits, provide vital information about their communities, propose considerations for program implementation, and determine jointly-led solutions to any concerns raised. Routine (e.g., quarterly, or more frequent) community consultations should be used to remain engaged and concerns and considerations from community members should be addressed prior to and during program implementation in order to secure community buy-in for recency testing if they concur.

Best Practices for Community Consultations:

- Country programs should demonstrate plans have been made for pre- and post-test counseling for clients and, in the rare cases where results are returned to clients, referral to services for those who fear or experience repercussions from test results.
- Country programs should have a “community action plan” that is in place to identify and respond to any challenges or social harms that that may arise during program implementation (testing, return of results, and/or data use) and advocate for appropriate changes.
- Country programs should consider including community representatives at sites of HIV recency testing to provide direct support to their community members.

## 6.6.8.5 HIV Recency Surveillance and Response Among Newly Diagnosed PLHIV

Summary of section edits:

- This section was 6.6.8.2 in the 2022 COP/ROP Guidance Technical Considerations Section.
- Wording was updated to clarify the policy around discouraging including recency results in patient records and adding "Case management" wording to replicate language in 6.6.8.4.
- Deleted specific terms to shift recency surveillance framing from "outbreak"-type response

Routine assessment of the direction of the HIV epidemic through ongoing surveillance of newly diagnosed HIV infections remains essential to ensure that prevention and clinical interventions are efficiently and effectively delivered to persons at risk of acquiring or transmitting HIV infection. Conducting rapid tests for recent infection (RTRI) along with viral load (VL) testing as a part of a recent infection testing algorithm (RITA) among persons newly diagnosed in routine HTS, has facilitated establishment of HIV recent infection surveillance systems globally. RTRI or RITA results for an individual client should not be used to change the type or extent of clinical care or case management provided. Routine analysis of these data is used to monitor epidemiological trends in recent infections and signal recent HIV transmission among subgroups and geographic locations. Programmatically, these signals of recent transmission can be investigated further to identify and address missed opportunities within routine HIV testing, treatment, and prevention services in order to prevent ongoing transmission; these missed opportunities may be limited to a cluster or also exist at a district, regional, or national level and/or may be limited to specific sub-groups (e.g., AGYW or key populations). Best practices from early implementers of recent infection surveillance are available on the TRACE eLearning Hub.

In COP23, country teams should consider the following elements in building and maintaining a reliable surveillance system of new infections: 1) engagement of multidisciplinary expertise from laboratory, surveillance, prevention, treatment, testing, M&E, key populations, data management, and informatics; 2) collaboration with Ministry of Health officials to develop and implement policies that endorse the use of RTRI testing among persons diagnosed in routine HIV testing services; 3) engagement of civil society to explain benefits of recent infection surveillance to accelerate epidemic control, 4) strategies for transitioning from phased to full-

scale implementation for countries that have started recent infection surveillance; 5) integration of RTRI test kit procurement in national supply chain; 6) development or configuration of health information systems for data capture, management, and automated analysis and data visualization at national and sub-national levels on a dashboard (including availability of user-friendly visualization tools); 7) integration of recent infection surveillance with broader national HIV case surveillance where it exists; 8) continuous quality improvement plan to ensure quality of testing and surveillance data, and 9) use of recent infection surveillance data to monitor trends in recent infections and identify, investigate, and respond to potential relative hotspots of recent infection transmission. Results from HIV recency testing done as a part of surveillance is reported quarterly through the MER indicator HTS_RECENT. Country teams should work with HQ, ISMEs, and IPs to maximize data use for public health response.

Information below provides recommendations on building an HIV recent infection surveillance system, including role of site level staff and implementing partners, and informatics considerations around data collection, data management, and data visualization.

**Role of site level staff and implementing partners in recent HIV infection surveillance and response**

- Ensure high quality recency testing for all eligible and consenting, newly diagnosed HIV-positive persons by well-trained, certified testers
    - Ensure RTRI testing is performed by trained, certified testers that were trained using the TRACE format of 3 QCs and at least 10 TPs (Refer to Section 6.6.8.4)
    - Collect, transport, and track blood sample (as plasma or dried blood spot specimens) for viral load testing in laboratory for cases identified as potential recent infections by RTRI
    - Include use of barcodes or other electronic tracking systems to ensure linkage and prevent transcription/completion errors
    - As part of routine monitoring for HTS, monitor and improve tester performance by participation in quality assurance activities, proficiency testing program, and supervisory visits
    - Perform 3 QC tests using characterized specimens once a month and as otherwise indicated to ensure test kit and tester performance

    - Communicate any concerns related to the quality of recency testing or unusual results to appropriate above-site entity

- Collect, report, and visualize recent infection surveillance data through appropriate data systems (electronic or paper) in real-time
    - Securely store all data to protect client privacy and confidentiality
    - Support complete, accurate, and timely reporting of MER indicator (HTS_RECENT) and narratives
    - Screen for and document previous HIV diagnoses and ART use
    - Ideally this data collection, reporting, and visualization should be part of a holistic HIS framework that includes case surveillance, as described in the beginning of Section 6.6.8

- Ensure that all persons newly diagnosed with HIV receive appropriate package of HIV prevention and treatment services, regardless of RTRI or RITA result
    - Support prompt referral to prevention (e.g., PrEP, VMMC) or treatment services, as appropriate, and offer safe and ethical index testing to all individuals newly diagnosed with HIV.
    - Monitor and report any adverse events or social harm related to recency testing, especially those associated with return of results in countries that have decided to do so.
    - Identify major barriers to recency surveillance and implement activities to help overcoming them.

- Collaborate with above-site partners in detection, investigation, and response to relative hotspots of recent transmission at site, subnational, and national levels and/or in specific sub-populations
    - Provide context on current policies, practices, and program services at facility or in catchment area
    - Facilitate access to site-level data and other information as needed to conduct investigation
    - Contribute to development of response action plan and help implement and monitor items in the plan that are site-specific

**Informatics and availability of data**

Countries should consider leveraging existing health information systems (HIS) and data flows for HIV recency surveillance as infrastructure and feasibility allow. Electronic systems should be able to, at minimum, capture individual-level data, including demographics and recency-specific data, using a unique identifier and be able to link and deduplicate records at the site and/or at the above-site level. To facilitate inclusion of VL for RITA, interoperability with the lab information system, or a process in place of this, is essential to link all test results that are needed for surveillance. Any information systems that capture individual level data should be responsive to the need for alignment with country specific guidance on digital health standards including data security and confidentiality, strategy, and policies to the extent that they exist. If such alignment is expected but not technically feasible, an explanation of the long-term plan and strategy is needed. Timely dissemination of recency data within the USG/MOH is essential so results can be understood, and relevant actions can be taken.

**Data Collection**

- Refer to the principles for digital development available at https://digitalprinciples.org and in Section 6.6.8
- Countries should build upon the HIV case surveillance initial case report form with recent infection test and algorithm added (if applicable). If data collection relies in part on transcription from paper-based record/s registries, consider using automated tools to support bulk transcription of records.
- Systems are expected to include features to ensure high quality data capture and to support data quality assurance processes.
- PEPFAR highly recommends against recording recency test results in the client's medical record.

**Data Management**

- Servers: Depending on the requirements of the country, data can either sit on out-of-country (cloud-based) or in-country virtual (cloud-based) or physical servers and be integrated with HIV case surveillance. Countries should engage in discussions around data ownership, data governance, and data sharing as early as possible as part of holistic data strategy.

- Depending on electronic vs. paper-based data collection, the database or above-site repository should allow for the potential of a dashboard to retrieve real-time data, after review and data quality checks as necessary.
- Security standards and practices should be implemented to ensure the transmission, storage and archival of recency data is protected. These include strong security support to store identifiable information on HIV status; using VPN if possible; and managed authentication system.

**Data Visualization and Use for Public Health Response**

Automating analysis and strengthening recent infection surveillance through data visualization simplifies data for use and equips health officials with reliable, timely, and actionable information, which enables rapid response to the HIV epidemic in their countries. Each country's HIV recency dashboard should provide a template for visualizing data on recent infection to support data use in three domains upon which countries can build additional analysis depending on available data and need. The three domains are 1) monitoring quality of RTRI testing and test performance, 2) monitoring epidemic trends to characterize recent HIV infections, and 3) guiding public health response to better target program resources. Additional guidance and templates for data visualization are available on the TRACE eLearning Hub. It is important that countries share aggregate data in dashboard form with HQ ISMEs and key stakeholders to assist with data quality, review, and analysis. This will help promote data use to monitor trends in recent infections and identify potential hotspots of recent transmission and guide subsequent investigation and public health response. Example public health response strategies and tools are available on Response Tools Section of the TRACE eLearning Hub. Ultimately recency is a key tool to help drive a Public Health Response to new clusters HIV transmission and help understand which sub-populations are at greatest risk, so that Epidemic Control can be effectively sustained.

## 6.6.9 Sustainability of the HIV Response

Summary of section edits:

This is a rewrite of Section 6.6.9 of the technical consideration section that was in COP/ROP22 Guidance on sustainability. PEPFAR's strategy for sustainability has advanced significantly since last year, and this new sustainability section reflects technical considerations related to

the new strategic priorities and alignment with the PEPFAR 5-Year Strategy.

### 6.6.9.1 HIV Response Sustainability Framework

PEPFAR defines sustainability as a country having and using its enabling environment, capable institutions, functional systems, domestic resources, and diverse capacities within the national system (including the government, community, and faith-based, for profit and non-profit private sectors) to sustain achievement of 95-95-95 goals; to ensure equity in its HIV response; and to protect against other public health threats.

The transformation of the HIV response—from one in which PEPFAR plays a substantial financing and functional role to one in which countries take on increasing leadership and management of all aspects of the HIV response—requires a thoughtful, measured, and most of all, country-led process. Key stakeholders in this process include national governments, civil society organizations, local partners, regional institutions, networks of PLHIV, communities, community-led organizations, multilateral organizations, GF (and any country coordinating mechanisms or CCMs) etc. In advancing sustainability as the second pillar of PEPFAR's Five-Year Strategy, PEPFAR is not implying that funds will be suddenly cut in the future. Rather, PEPFAR-supported countries should take advantage of what is anticipated to be a long runway (i.e., leverage PEPFAR resources to build the systems and enabling environment required to eventually sustain the HIV response).

**A Transformation in Functional and Financial Responsibility:** While every national HIV response may look different, PEPFAR has identified some common elements that may be needed to sustain the response such as (but not limited to): (**1**) a "whole-of-market" approach that engages all relevant stakeholders, including communities, to equitably reduce new infections, morbidity and mortality; (**2**) a national government financially supporting essential HIV services through domestic resource mobilization and prepared to meet emerging needs; (**3**) sufficient functional (e.g., technical, leadership and managerial) capacity within the country's local institutions to sustain delivery and impact of key HIV programs, services, health systems, and resources; (**4**) HIV service delivery integrated into broader public and private care delivery systems; (**5**) a robust public health response to monitor track and respond to HIV, which can also benefit management of other existing and emerging health threats; (**6**) routinized quality

assurance to effectively manage and monitor HIV services; and (**7**) HIV systems and services that promote equity, dignity, and human rights.

**The HIV Response Sustainability Framework:** The HIV Response Sustainability Framework (See **Figure 6.6.9.1.1**) is intended to help PEPFAR country teams think through an approach that supports strengthening a country-led HIV response. PEPFAR country teams can use this framework to guide discussions, with the understanding that not all aspects will apply in every country.

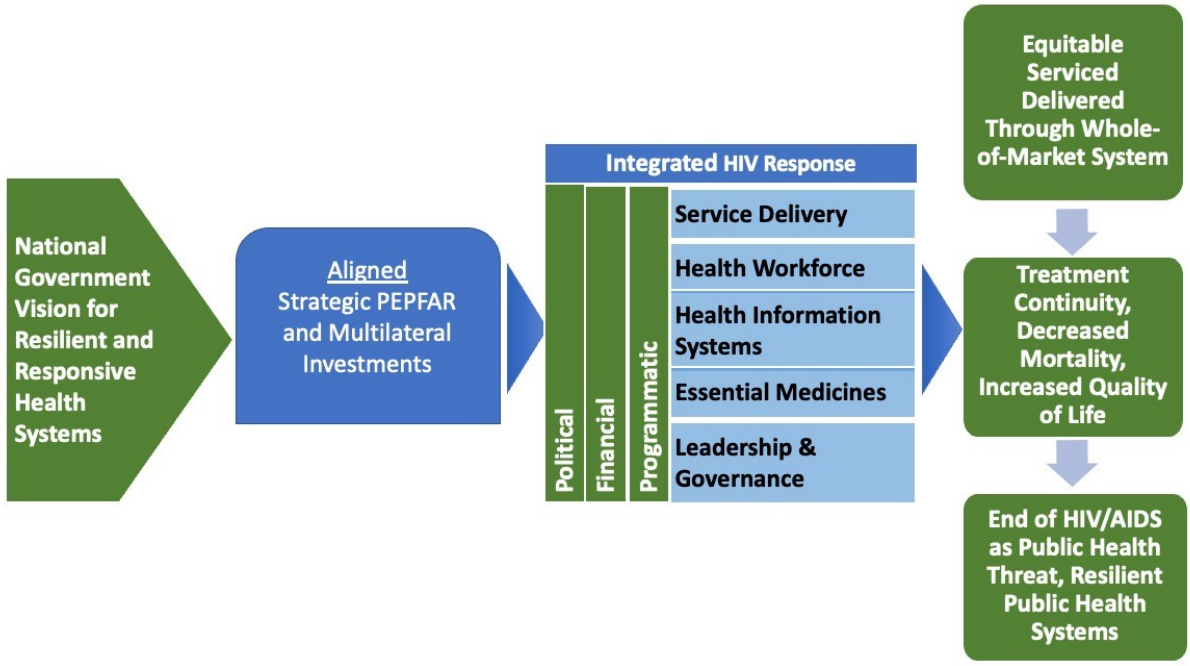


**Figure 6.6.9.1.1 HIV Response Sustainability Framework**

1. **National Priorities and Vision:** The driving force behind the HIV Response Sustainability Framework, and PEPFAR's approach to sustainability, is the partner-country government's, local civil society's, and communities' vision for a resilient and responsive health system. The national strategy for the health system, and a vision specific to integrating HIV into the health system, must guide PEPFAR investments. This approach also aligns with the 2021 Political Declaration and the Global AIDS Strategy. PEPFAR recognizes that each country has a different vision for their health system, and strategies vary in the degree to which the HIV response is incorporated into an overall national health strategy.

For most countries, integrating the HIV response into national systems will require development of a Measurable Sustainability Roadmap that lays out a vision for how HIV services will be delivered in the future, and the commensurate health systems required. Developing a strong Roadmap will require transparency about current investments from PEPFAR, other multilaterals, and major donors. This includes specifying the resources provided and functions donors are performing, so that partner-governments can build a realistic idea of what sustaining the response entails. Supporting partner-country governments to develop their own integrated quality HIV service delivery models that are effective but less resource intensive, is paramount. PEPFAR country teams should be open to trying new models and supporting national governments as they determine what works best for their context.

2. **Investment Alignment**: PEPFAR funding allocations are likely to remain flatlined, or decrease slowly over time—as, most likely, will those of other multi-lateral donors. In this environment, every dollar and type of donor investment that supports the HIV response or other development purposes, needs to be aligned to maximize impact. PEPFAR investments must align with national priorities, including those of affected communities. As such, PEPFAR OU teams are encouraged to work closely with the Global Fund, other donors, multilateral organizations, and civil society to maximize efficiencies and identify innovations.

   Thus far, PEPFAR and the Global Fund have collaborated on annual financial resource alignment activities. Now, PEPFAR and the Global Fund will expand resource alignment to human resources for health (leveraging PEPFAR's Human Resources for Health Inventory) and commodities. PEPFAR is also engaging other multilateral organizations and regional bodies to develop a shared vision and global strategy for sustaining the HIV response. PEPFAR OU teams should engage with partner-country governments, multilateral representatives in the country/region, local CSOs, communities, and other key stakeholders to help align investments to the local level, as described in the below section on Convening Sustainability Stakeholders. Alignment is an ongoing process and, to be effective, it will require transparency and mutual accountability among all parties.

3. **Local, Integrated HIV Response:** To support this transformation, every single PEPFAR implementing partner should focus not only on targets to reach 95-95-95, but also on strengthening national public health systems to end HIV/AIDS as a public health threat.

In service of an emergency response, PEPFAR directly built multiple health systems—in some cases resulting in systems operating in parallel to the national HIV response. This approach has served its purpose, but PEPFAR OU teams should support working *through* national systems as opposed to standalone systems and processes. This sort of program transformation will require careful consideration of how each element of the HIV response should be implemented, with the goal of ensuring that eventually all investments are made with a dual purpose of sustainably strengthening health systems and ending HIV/AIDS as a public health threat by 2030. Efforts to support national capacity building should include CSOs (KP-led, women-led, community-led), local partners, training institutions, and the private sector. This will foster funding stream diversification—including funds from national governments—and support delivery of quality HIV services with reduced reliance on technical support from international organizations.

When deliberating on investments that must be transformed, each core investment made in service delivery, health workforce, essential medicines, health information systems, leadership, and governance, should be considered from the lens of the enabling environment required to sustain such investments. This enabling environment includes political, programmatic, and financial domains. Collectively, these domains support the effectiveness of core investments in the HIV response.

4. **Equitable Services:** A "whole-of-market" approach can help stakeholders achieve the shared vision of ending HIV/AIDS as a public health threat and sustainably strengthening public health systems. A "whole-of-market" approach requires inclusive systems that incorporate CSOs, local networks of people living with HIV, local partners, private sector, training institutions, and others in the national HIV response. Fostering this type of inclusivity may require an above-site investment expansion that supports the long-term capacity of such organizations and institutions to plan, lead, and manage all aspects of the HIV response.

   PEPFAR must also focus on institutionalizing policies and practices that promote equity. Throughout this transformation, PEPFAR must help ensure that ART continuity remains paramount, people living with HIV have improved quality of life, and morbidity and mortality continue to decrease. Importantly, there is some risk in the transformation

process—PEPFAR OU teams will need to develop a risk-mitigation strategy to reduce loss of gains in the HIV/AIDS response.

**Strengthening the Enabling Environment:** As highlighted in the PEPFAR 5-Year Strategy, the core health systems functions that comprise an enabling environment cross several domains: political, programmatic, and financial.

- ***Political:*** The political domain relies on national government leadership, private sector involvement , engaged communities and civil society, and information transparency. Policies and governance that promote an equitable response are necessary to end HIV/AIDS as a public health threat. Furthermore, policies that support planning, coordination and monitoring, and institutional and organizational capacity development are also essential.
- ***Programmatic:*** The programmatic domain includes the broader health ecosystem of health security and pandemic preparedness and response. The critical inputs of human resources for health and commodities laboratory systems and data for decision-making, surveillance, research, performance management, quality management, capacity building, and management and supervision all fall within this domain. Much of PEPFAR's investments have been in the programmatic domain—including prevention as well as care and treatment service delivery. To further establish service delivery as part of the enabling environment, PEPFAR will need to support the integration of HIV services and systems into broader service-delivery systems.
- ***Financial:*** The financial domain includes the systems that ensure sufficient financial resources to sustain the HIV response. These systems include ensuring adequate financial and expenditure cost data; identifying and exploiting technical and allocative efficiencies; public financial management systems; domestic resource mobilization; and market openness.

Importantly, all three domains require leadership from communities and civil society organizations in the HIV response. This includes:

- Ensuring community representation and leadership at all levels of decision making,
- Engaging civil society,
- Promoting and sustainably financing community-led service delivery,
- Fostering direct client representation,

- Addressing stigma and discrimination,
- Centering equity through community-led discussions and decision making,
- Implementing community-led monitoring,
- Ensuring the national structures address gender equity, human rights, stigma, and discrimination.

**Transforming Core Investments:** PEPFAR has traditionally invested in 6 areas: (**1**) quality HIV services; (**2**) strategically placed and well-trained health workers to deliver services; (**3**) commodities purchases and their timely delivery; (**4**) data collection and analysis to accurately target the response; (**5**) financial support and management systems; and (**6**) leadership and governance.

Of course, there are multiple sub-area investments within each core investment (e.g., HIV services span testing, prevention, treatment and care, etc.). And, as with other sub-program areas, each country may have slightly different priorities and/or models. Within these core investments, PEPFAR OU teams should work closely with the national government, civil society, communities, and other key stakeholders to identify priorities and models that PEPFAR could support to help end HIV/AIDS as a public health threat by 2030 and sustainably strengthen public health systems.

**Transformation Principles:** In this endeavor, PEPFAR must change how the engagement with stakeholders, particularly partner-country governments, occurs. PEPFAR's guiding principles of respect, humility, equity, accountability, transparency, impact, and sustained engagement are central to this effort. PEPFAR must also shift internal business processes to allow flexibility, co-creation, leading from behind, tailoring the HIV response, continuous and consistent communication, explicit trade-offs, identification of win-win opportunities, and integration. PEPFAR is currently at the beginning of this transformation.

**Sequencing the Transformation:** Transformation does not have to—nor should it—occur all at once. PEPFAR has invested in the HIV response for 20 years, and it will take time to transform the HIV program. Each country may want to prioritize a different area to start, and, moreover, the approach may differ even among subnational units. For some countries it may make sense to concentrate initial efforts on transforming the HIV commodities program and slowly fold in an assessment of HRH and monitoring and reporting systems. Once these factors are addressed, financing considerations may become the focus. Other countries may want to start transforming

all major program areas at once but work at a slow and steady pace. PEPFAR is committed to supporting partner-country governments, civil society, communities, and other stakeholders to identify what will work best for the country's context, while remaining agile during the transformation.

## 6.6.9.2 Convening Sustainability Stakeholders

**Who Is at the Table?**

PEPFAR works across multiple ministries and stakeholders (including local and global CSOs, and communities themselves) to implement a comprehensive and equitable HIV program. To appropriately plan for sustainability, it's crucial that all relevant government entities—including ministries of finance—and all relevant stakeholders are engaged. PEPFAR OU teams should consider conducting a stakeholder review with the country's ministry of health to ensure all groups are included. Stakeholders include, but are not limited to, local organizations, civil society organizations, networks of PLHIV, community-led organizations, communities, UNAIDS, GF, other multilateral organizations, representatives from beneficiary groups, and the private sector. It is important to be as inclusive as possible during this process.

Note, S/GAC is actively working with the Global Fund and UNAIDS Headquarters on sustainability related issues. These discussions are ongoing, and all agency headquarters should be sharing information with PEPFAR OU teams.

**Who Has the Authority to Convene?**

The PEPFAR Coordination Office should convene the initial discussions to introduce sustainability priorities as articulated in PEPFAR's Strategy. After these initial meetings, the partner-country government should determine the subsequent plan for coordination and convening while working with CSOs and communities, with PEPFAR OU teams playing only a supporting role. Questions to consider in the initial meetings include:

- Will there be a steering committee or a technical working group?
- Who will chair the group?
- What will group membership look like?

- How will members be held accountable for participating in the discussion and creating sustainability priorities?
- What will be the group's deliverables (policy, agreement, etc.)?

While these decisions may be within the partner-country government's authority, engagement and leadership from all stakeholders (including communities) is essential. All stakeholders should provide recommendations and insights into the long-term convening structure.

On the partner-country government side, deciding which ministry should lead the group and its convening requires careful consideration–and each partner-country government may have different viewpoints. Some questions to consider include:

- What planning and convening structure does the partner-country government want to use? If one already exists, a new structure does not need to be established.
- How will sustainability planning build on existing or previous planning conducted at the national level, if applicable?
- Should certain technical leads and/or financial experts be included? Which multi-lateral partners and other donors should be included?
- How will CSOs, communities, and local organizations (including KP-led organizations) be incorporated into the process and decision-making?
- How will the U.S. Government be involved?

**What is the Convening Structure?**

Each partner-country government will need to determine the type of sustainability planning and convening structure to create, but only if one does not already exist. For example, will there be a steering committee that manages all subgroups, or will it be reminiscent of a technical working group that has workstreams managed within it? It is important that all stakeholders engaged in the structure have an ongoing means to provide feedback and receive progress updates.

When establishing the sustainability planning group, it will be important to consider group logistics. For example:

- How often will the full group meet?
- What are subgroups expected to do?

- How do subgroups relate to the larger body?
- Is there an implementation planning process?
- How will that process relate to the PEPFAR COP/ROP process?
- How will this group effectively link to the partner-country government financial process?
- What are the expectations for ministry of finance representatives and to what extent should they be involved?

**How Does the U.S. Government Relate to This Convening Structure?**

As already discussed, the sustainability planning and convening structure needs to be led by each partner-country government. PEPFAR teams should lead from behind and maintain a collaborative planning role while also providing realistic parameters for USG involvement. This is not a passive role for PEPFAR OU teams; rather, it's an opportunity to listen to the partner-country government to learn about national priorities while including those of civil society and communities.

### 6.6.9.3 Finding Efficiencies to Enable Investing in Sustaining the Response

Sustaining the HIV response will require strengthening locally led program implementation, increasing domestic leadership and investments, and leveraging alternative sources of health financing and service delivery. As donor resources become increasingly constrained, national governments will have to alleviate dependence on external resources and take on greater leadership to ensure core elements of the HIV response remain intact. Competing demands for public funding has renewed focus on how PEPFAR, along with its partners and other donors, can assist national governments with more efficiently and effectively mobilizing existing resources.

To optimize resource allocation, PEPFAR OU teams should leverage all available program and financial data (e.g., epidemiological, monitoring, budget, expenditure, resource alignment, activity-based costing and management, Planning Activities for Systems Investments or Planning Activities for Systems Investments Tool (PASIT) Sustainability Index Dashboard 2021, and Responsibility Matrix 2021). Using these data will help PEPFAR OU teams reduce program costs, improve efficiency and effectiveness, and ensure alignment across funding sources. Section 7.0 of the COP/ROP23 Guidance outlines an approach PEPFAR teams should

consider when analyzing data to identify cross-program and technical area efficiencies and opportunities to close program gaps, while sustaining the response and supporting health systems and security. Making every dollar count requires that PEPFAR programs, in collaboration with partners, continue using program and financial data to target interventions to reach those most in need and ultimately maximize impact.

PEPFAR OU teams should consider the following to help identify potential efficiencies:

- What is the totality of the HIV funding landscape? Which funder has primary fiscal versus functional responsibility for various program elements? Data sources to assess this include the Responsibility Matrix from 2021 and Resource Alignment Country Profile.
    - Does the information in the data sources provide a reasonably complete picture of the national HIV response funding landscape?
    - Does the information help PEPFAR OU teams identify where multiple funders are operating in the same space?
    - What is the strategic alignment of investments across PEPFAR and the Global Fund?
    - Do current fund allocations match program priorities and needs?
    - Is there potential for duplication in the way resources are currently allocated?
    - Are there funding gaps and/or inefficiencies?
    - How can PEPFAR and the Global Fund, in partnership with the partner-country government, further optimize HIV investments—especially considering the current operating environment?
- Are PEPFAR investments aligned and focused on the right activities for the targeted populations that provide the highest value for available resources (e.g., is there allocative efficiency)?
- Are PEPFAR investments being made in activities and interventions that are effective (e.g., differentiated service delivery or integrated services or using different service delivery platforms) and give the program and beneficiaries the maximum benefit (e.g., is there technical efficiency)?
- Which core PEPFAR investments are essential to sustain the program—namely, availability of commodities, health care workers, and health service delivery systems?

- How could PEPFAR recalibrate investments to make them better-aligned and synergistic with other funders, support sustaining the program and closing gaps, and strengthen country health-system capabilities?
- Given resource constraints, what resource allocation mix and prioritization makes sense for PEPFAR to: (**1**) optimize service delivery, (**2**) maintain a reasonable level of non-service delivery activities that directly support ending HIV as a public health threat and sustainably strengthen health systems, and (**3**) target above-site activities that address key barriers?
    - Does the proportion of service delivery (SD) versus non-service delivery (NSD) reflect what is expected for the program? What is the right balance and level of NSD activities that make the most sense for the program (e.g., as a country get close to achieving 95-95-95 goals, do they need the same level of training and supportive supervision)?
    - Based on historical trends, status, and trajectory of the national HIV response, what shifts/adjustments in resource allocation should be anticipated?
- How can PEPFAR better understand the categories of program spending in SD and NSD after excluding "tangible" categories (e.g., commodities, HRH, and supplies)? How can resource allocation be further optimized?

It's also clear that sustaining the gains will require that PEPFAR leverages resources from the government sector and private markets. Therefore, in addition to current models of health financing support, PEPFAR will need to consider additional and innovative financing approaches and instruments.

### 6.6.9.4 Identifying Priority Systems Gaps for Investment

As part of the COP/ROP23 process, PEPFAR OU teams should identify key systems gaps that require investment to overcome barriers to a sustained national HIV response. Section 7 of the COP/ROP23 Guidance describes a high-level process for finding efficiencies within the PEPFAR program to help end HIV/AIDS as a public health threat and sustainably strengthen public health systems. PEPFAR OU teams should also identify priority systems gaps where resources can be used to most effectively strengthen national public health systems that sustain the HIV response. Importantly, all above-site systems investments in COP/ROP23 must be entered into the PASIT and budgeted within the FAST. (Please see the PASIT user guide for

more information.) A description of why these gaps were selected, and the strategy for closing them, should be summarized in the COP/ROP23 Strategic Direction Summary (SDS).

## 6.6.10 Local Partner Definition

Summary of section edits:

This is a new technical consideration that defines local partners, which was previously included in PEPFAR COP/ROP 2022 Guidance.

Under PEPFAR, a "local partner" may be an individual, a sole proprietorship, or an entity. However, to be considered a local partner, the applicant must submit supporting documentation at the time of application demonstrating their organization meets at least one of the three criteria described below. In the local partner definition, a region is defined as one of the 2020 State Department/ ForeignAssistance.gov sub-regional groupings (e.g., Southern Africa, Central Africa, Central America, etc.).

**Individual:**

An individual must be a citizen or lawfully admitted permanent resident of and have their principal place of residence in the country or region served by the PEPFAR program with which the individual is or may become involved, and a sole proprietorship must be owned by such an individual

Or

**Entity other than a sole proprietorship (such as, a corporation or not-for-profit) must meet all three areas of eligibility:**

ONE:

- **Either**: Must be incorporated or legally organized under the laws of, and have its principal place of business in the country served by the PEPFAR program with which the entity is involved
- **Or**: Must exist in the region where the entity's funded PEPFAR programs are implemented

TWO:

- **Either**: Must be at least 75% beneficially owned at the time of application by individuals who are citizens or lawfully admitted permanent residents of that same country
- **Or**: At least 75% of the entity's staff (senior, mid-level, support) at the time of the application must be citizens or lawfully admitted permanent residents of that same country

THREE:

- Where an entity has a Board of Directors, at least 51% of the members of the Board must also be citizens or lawfully admitted permanent residents of such country.

Or

**Government Ministries and Parastatals:**

Partner government ministries (e.g., ministry of health), sub-units of government ministries, and parastatal organizations in the country served by the PEPFAR program are considered local partners. A parastatal organization may be fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations.

In the above definition, a region is defined as one of the 2020 State Department/ ForeignAssistance.gov sub-regional groupings (e.g., Southern Africa, Central Africa, Central America, etc.), which are shown in **Figure 6.6.10.1.**

*Sub-Regional Groupings*

| East Asia & Pacific | Europe & Eurasia | Middle East & North Africa | South & Central Asia | Sub-Saharan Africa | Western Hemisphere |
|---|---|---|---|---|---|
| **East Asia** | **Central Europe & Balt** | **Gulf States** | **Afghanistan/Pakistan** | **Central Africa** | **Caribbean** |
| China | Bulgaria | Bahrain | Afghanistan | Burundi | Anguilla |
| Hong Kong | Czechia | Iran | Pakistan | Cameroon | Antigua and Barbuda |
| Japan | Estonia | Iraq | **Central Asia** | Central African Republic | Aruba |
| Macau | Hungary | Kuwait | Kazakhstan | Chad | Barbados |
| Mongolia | Latvia | Oman | Kyrgyzstan | Congo (Brazzaville) | British Virgin Islands |
| North Korea | Lithuania | Qatar | Tajikistan | Congo (Kinshasa) | Cayman Islands |
| South Korea | Poland | Saudi Arabia | Turkmenistan | Equatorial Guinea | Cuba |
| Taiwan | Romania | United Arab Emirates | Uzbekistan | Gabon | Curaçao |
| **Oceania** | Slovakia | Yemen | **South Asia** | Madagascar | Dominica |
| American Samoa | Slovenia | **Israel & Palestinian Territo** | Bangladesh | Rwanda | Dominican Republic |
| Australia | **Eurasia** | Israel | Bhutan | Sao Tome and Principe | Grenada |
| Christmas Island | Armenia | West Bank and Gaza | British Indian Ocean Territory | **East Africa** | Guadeloupe |
| Cocos (Keeling) Islands | Azerbaijan | **Levant** | French Southern and Antarctic Lands | Comoros | Guyana |
| Cook Islands | Belarus | Jordan | Heard Island and McDonald Islands | Djibouti | Haiti |
| Federated States of Micronesia | Georgia | Lebanon | India | Eritrea | Jamaica |
| Fiji | Moldova | Syria | Maldives | Ethiopia | Martinique |
| French Polynesia | Russia | **North Africa** | Nepal | Kenya | Montserrat |
| Guam | Ukraine | Algeria | Sri Lanka | Mauritius | Puerto Rico |
| Kiribati | **South-Central Europe** | Egypt | | Seychelles | Saint Barthélemy |
| Nauru | Albania | Libya | | Somalia | Saint Kitts and Nevis |
| New Caledonia | Bosnia and Herzegovina | Morocco | | South Sudan | Saint Lucia |
| New Zealand | Croatia | North Africa | | Sudan | Saint Martin |
| Niue | Kosovo | Tunisia | | Tanzania | Saint Vincent and the Grenadines |
| Norfolk Island | Montenegro | | | Uganda | Sint Maarten |
| Northern Mariana Islands | North Macedonia | | | **Southern Africa** | Suriname |
| Oceania | Serbia | | | Angola | The Bahamas |
| Palau | **Southern Europe** | | | Botswana | Trinidad and Tobago |
| Papua New Guinea | Cyprus | | | Bouvet Island | Turks and Caicos Islands |
| Pitcairn Islands | Greece | | | Eswatini | U.S. Virgin Islands |
| Samoa | Turkey | | | Lesotho | **Central America** |
| Solomon Islands | **Western Europe** | | | Malawi | Belize |
| Timor-Leste | Andorra | | | Mayotte | Costa Rica |
| Tokelau | Austria | | | Mozambique | El Salvador |
| Tonga | Belgium | | | Namibia | Guatemala |
| Tuvalu | Bermuda | | | Reunion | Honduras |
| Vanuatu | Denmark | | | Saint Helena | Nicaragua |
| Wallis and Futuna | Faroe Islands | | | South Africa | Panama |
| **Southeast Asia** | Finland | | | Zambia | **North America** |
| Brunei | France | | | Zimbabwe | Canada |
| Burma | Germany | | | **West Africa** | Mexico |
| Cambodia | Gibraltar | | | Benin | Saint Pierre and Miquelon |
| Indonesia | Greenland | | | Burkina Faso | United States |
| Laos | Guernsey | | | Cabo Verde | **South America** |
| Malaysia | Holy See | | | Côte d'Ivoire | Argentina |
| Philippines | Iceland | | | Ghana | Bolivia |
| Singapore | Ireland | | | Guinea | Brazil |
| Thailand | Isle of Man | | | Guinea-Bissau | Chile |
| Vietnam | Italy | | | Liberia | Colombia |
| | Jan Mayen | | | Mali | Ecuador |
| | Jersey | | | Mauritania | Falkland Islands (Islas Malvinas) |
| | Liechtenstein | | | Niger | French Guiana |
| | Luxembourg | | | Nigeria | Paraguay |
| | Malta | | | Senegal | Peru |
| | Monaco | | | Sierra Leone | South America |
| | Netherlands | | | The Gambia | South Georgia and the South Sandwich Islands |
| | Norway | | | Togo | Uruguay |
| | Portugal | | | Western Sahara | Venezuela |
| | San Marino | | | | |
| | Spain | | | | |
| | Svalbard | | | | |
| | Sweden | | | | |
| | Switzerland | | | | |
| | United Kingdom | | | | |

**Figure 6.6.10.1 Sub Regional Groupings**

# 6.7 Site Safety

What's New in Site Safety for COP22:

- Added information about hepatitis B vaccination in staff members (Section 6.7.1)
- Added section on COVID-19 outbreak investigation (6.7.2)
- Added information about environmental cleaning (6.7.4)
- Expanded section on sterilization practices. (6.7.4)

PEPFAR is committed to providing prevention and treatment services in an environment that is safe for both recipients of care and for staff. The COVID-19 pandemic has highlighted the need

to focus attention on site safety, COP22 gives further details on requirements that are already in place. Infection prevention and control plans for site safety should, at a minimum, include protocols for triage and prevention of respiratory diseases like COVID-19 and tuberculosis; environmental cleaning; waste management, disinfection and sterilization procedures for reusable equipment used for VMMC and cervical cancer screening; standard, contact, and respiratory precautions; and safety measures to prevent and manage safe injections, needlestick injuries, and other occupational hazards. Each site should have designated and trained personnel responsible for infection prevention and control with sufficient time and authority to implement and oversee quality improvement-based activities. Details about these aspects of site safety and provided below.

## 6.7.1 Infection Prevention and Control

Summary of section edits:

- Replaced SIMS 2.0–4.0 reference with SIMS 4.1.

The COVID-19 pandemic has highlighted the need for robust infection prevention and control (IPC) programs that protect clients and staff. Management of COVID-19 in the health care environment and outbreak response has emerged as a key activity of IPC practitioners and has enhanced the need for all levels of controls: administrative and environmental as well as personal protective equipment. A survey of international research sites conducting human immunodeficiency virus (HIV) therapeutic clinical trials suggested that there were significant differences in practice between clinical sites. Sites that did not have dedicated resources to IPC, including dedicated personnel, were unlikely to have established policies and procedures for isolation, hand hygiene, respiratory hygiene and injection safety.[578] Monitoring IPC activities, prevention of infection in health workers (HW), specific policies regarding hand and respiratory hygiene, safe injection practices and ongoing education of IPC practitioners, have all been shown to be important in reducing health care-associated infections.[579] Well-conceived and carefully implemented infection prevention programs reduce illness, prevent death, improve

[578] Godfrey, C., C. Villa, L. Dawson, S. Swindells and J. T. Schouten (2013). "Controlling healthcare-associated infections in the international research setting." J Acquir Immune Defic Syndr 62(4): e115-118.
[579] Godfrey, C. and J. T. Schouten (2014). "Infection control best practices in clinical research in resource-limited settings." J Acquir Immune Defic Syndr 65 Suppl 1: S15-18.

continuity of services, and save money. Active support of IPC activities fosters a culture of safety in the health care setting.

WHO has outlined the minimum IPC requirements for healthcare facilities and national levels.[580] All programs are should review or assess facility level progress toward meeting these minimum requirements and to identify key areas for improvement.

One of the most important minimum requirements is the presence of a dedicated, trained IPC team that varies in composition and skill depending on the level of care provided (e.g., outpatient clinic, acute care hospital). At a minimum, all PEPFAR implementing partners and all PEPFAR supported facilities or programs that provide patient care or testing should have an IPC focal point or committee with training in IPC and in QI/QA principles for program improvement, and dedicated time and budget to implement priority IPC program activities.

All program systems investments should include provisions for IPC including administrative, environmental controls and personal protective equipment (PPE).

The functions of the IPC Focal point or Committee include regularly reviewing and implementing national IPC guidelines (or international IPC guidelines if no up to date national guidelines are available); serving as POC for occupational health exposures and pre-employment screening; monitoring IPC supplies including personal protective equipment (PPE), soap/alcohol based hand rub (ABHR), and cleaning/disinfection solutions; training new workers in IPC before they start to work; providing regular IPC updates to all workers; monitoring key IPC indicators such as hand hygiene compliance, injection safety, and respiratory hygiene for TB and COVID-19; monitoring for healthcare acquired infections (including TB and COVID-19) in HCWs and patients; ensuring safe waste management and adherence to recommended and appropriate environmental cleaning practices; ensuring appropriate reprocessing (cleaning, disinfection, sterilization) of medical devices; and providing information/feedback to key stakeholders (e.g., facility administration, healthcare worker staff) on the progress of IPC implementation.

All PEPFAR supported healthcare facilities and programs should have standard operating procedures (SOPs) for IPC including TB and COVID-19 IPC, injection safety, environmental cleaning, waste management, medical device disinfection and sterilization, standard and transmission-based precautions, laboratory safety, and monitoring for key IPC indicators based

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[580] WHO 2019 https://www.who.int/infection-prevention/publications/core-components/en/

on priorities (e.g., mask use, patient triage/ isolation, hand hygiene. IPC training for frontline staff should be regularly offered and tracked. IPC programs should employ multimodal prevention strategies such as continuous quality improvement (CQI) for priority IPC issues. All facilities should maintain proper staffing levels and ratios and physical environment in line with national standards or WHO minimum requirements.

**Administrative and environmental controls:** Facility-level administrative and environmental control measures should be prioritized.

*Administrative controls* are the policies, procedures, training, and other administrative functions that help to reduce risk of infection. In all settings and environments, administrative control measures have a significant impact in reducing the spread of infectious diseases. Administrative controls include immunization policies for HCWs, use of telehealth, separation of patients with suspected or confirmed communicable diseases and training of HCWs.

*Facility control* measures constitute the framework for setting up and implementing additional and disease-specific control measures at the level of the facility and include the development of policies and procedures for prevention and control of transmission of pathogens such as COVID-19 and tuberculosis (TB). These measures include establishing sustainable IPC infrastructure, ensuring access to laboratory testing, establishing optimal patient flow, HCW screening, establishing waiting areas to prevent overcrowding, triaging and separating those with respiratory symptoms upon facility entry and fast-tracking services for them and ensuring adequate ventilation, including through opening of windows and moving waiting rooms and triage areas outdoors whenever possible.

SOPs should be in place that prevent the spread of infections by identifying, separating, investigating, and treating patients and staff with symptoms. These policies should be regularly reviewed, and implementation of the SOPs should be addressed using a continuous quality improvement approach.

*Environmental controls* are the physical modifications that may be used to reduce risk. Examples include ensuring appropriate ventilation in facilities (including open window policies and conduction of some activities outside), and the use of transparent glass or plastic barrier at triage stations to reduce the transmission of airborne pathogens.

**Standard precautions:** Standard precautions are the minimum level of infection prevention activities and should be used in the care of all patients.[581] These include hand hygiene, appropriate use of personal protective equipment, environmental cleaning, respiratory hygiene/cough etiquette, and protection against bloodborne pathogens.

- Hand hygiene: Hand hygiene, including handwashing and the use of alcohol- based hand rub (ABHR). is a critical intervention for the prevention of many healthcare-associated infections including surgical site infections associated with VMMC.[582] The WHO has provided guidance on when and how to perform hand hygiene and with UNICEF is sponsoring an initiative entitled "Hand Hygiene for all Global Initiative" Resources, including an inexpensive method for local manufacture of an ABHR are available online.[583]

Products should be accessible at the point of care and hand washing supplies such as soap and single use towels, or ABHR, should be readily available. Community health workers should have access to materials for hand hygiene and should be instructed in their use.

**Personal Protective Equipment (PPE):** The use of PPE should be guided by risk assessment and the extent of contact anticipated with blood and body fluids, or pathogens. PPE includes clean non-sterile gloves, clean non-sterile fluid-resistant gowns, medical masks of different types for different purposes, and eye protection or face shields. The COVID-19 pandemic has highlighted the need for PPE. COP budgets should include funding for PPE to protect PEPFAR supported staff and beneficiaries, if not available from other sources and necessary to maintain safe operations and client continuity of care.

Implementing partners should ensure that facility and community-based staff providing HIV services are equipped with PPE appropriate to their job duties (e.g., HIV testing, handling of drugs, working with clients with suspected or diagnosed TB and COVID-19, etc.), in accordance

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[581] https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html

[582] Gyan, T., K. McAuley, N. A. Strobel, C. Shannon, S. Newton, C. Tawiah-Agyemang, S. Amenga-Etego, S. Owusu-Agyei, B. Kirkwood and K. M. Edmond (2017). "Determinants of morbidity associated with infant male circumcision: community-level population-based study in rural Ghana." Trop Med Int Health 22(3): 312-322.

[583] Peters, A., T. Borzykowski, E. Tartari, C. Kilpatrick, S. H. C. Mai, B. Allegranzi and D. Pittet (2019). ""Clean Care for All-It's in Your Hands": The 5 May 2019 World Health Organization SAVE LIVES: Clean Your Hands Campaign." Clin Infect Dis . https://www.who.int/water_sanitation_health/sanitation-waste/sanitation/hand-hygiene-for-all/en/

with available local guidelines for use of PPE. Appropriate disposal of PPE is covered in the waste management section.[584]

**Environmental cleaning** See Section 6.7.4

**Respiratory hygiene and cough etiquette:** Respiratory hygiene and cough etiquette refers to the practice of "covering the cough": individuals who are coughing should cover their nose and mouth when coughing/sneezing with tissue or mask, dispose of used tissues and masks, and perform hand hygiene after contact with respiratory secretions. Appropriate signage should be displayed prominently in all facilities, and hand hygiene resources, tissues and masks should be available in common areas and areas used for the evaluation of patients with respiratory illnesses. In all cases clients who are coughing should be given a medical mask and segregated.

**Injection safety:** Re-use of injection equipment is associated with the transmission of bloodborne viruses such as HIV, hepatitis B, hepatitis C and the development of bacterial infections such as abscesses and is prohibited in PEPFAR facilities. Prohibited re-use includes the reintroduction of injection equipment into multi-dose vials (including re-injection of the needle into the multidose vial and re-use of the syringe used to draw up medication from the multi-dose vial), re-use of syringe barrels or of the whole syringe[585] IPC focal points should ensure that facilities and programs have sufficient supplies of adequate injection equipment (including blood drawing equipment), appropriate disposal of injection equipment (including sharps containers and safe disposal procedures for the sharps containers), training of HCW, and monitoring of injection safety practices, to ensure injection safety for HCW and patients.

Accidental needle-stick injuries in health workers occur while drawing blood, during drug injection or handling contaminated sharps. Post exposure prophylaxis for HIV should be available within 72 hours everywhere that injections are given, or blood is drawn. In countries that have hepatitis B vaccination programs, health care workers should be sensitized to the need for vaccination and linked to those programs.

**Transmission- based precautions**: Some infectious diseases require additional precautions beyond standard precautions because of the specific mode of transmission that might be

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[584] https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/medical-waste.html
[585] https://aidsfree.usaid.gov/resources/pepfars-best-practices-vmmc-site-operations-0

present.[586] Types of transmission-based precautions include contact precautions, droplet precautions and airborne precautions. Different diseases require different types of precautions. Contact Precautions are intended to prevent transmission of infectious agents which are spread by direct or indirect contact such as on environmental surfaces or intact skin and require the use of gowns and gloves. Diarrhea is an example of a condition that requires contact precautions. Droplets are relatively large respiratory particles and droplet precautions are used to prevent the spread of respiratory pathogens through coughing, sneezing, and talking. Droplet precautions include the use of contact precautions and the use of medical/surgical masks to protect the respiratory tract of HCW from spread of pathogens in respiratory droplets. Influenza is an example of a pathogen spread by droplets. Airborne spread refers to disease that are spread by smaller particles that small respiratory droplets that remain suspended in the air. More protective masks, such as N95 respirators, are used to protect HCWs from airborne spread of diseases. Tuberculosis and measles are examples of diseases spread by this route. COVID-19 may be spread via both large and small respiratory droplets or aerosols that may be suspended in the air temporarily.[587] See https://www.cdc.gov/infectioncontrol/basics/transmission-based-precautions.html

**Universal source control,** in which all visitors and clients of a facility wear face coverings as appropriate per facility and national protocols (medical mask or non-medical mask), together with continuous medical masking in which health care workers wear a well-fitting medical mask wear a medical mask from the beginning of their shift to the end (without exceptions), has been shown to reduce infections in health care workers and transmission of SARS CoV2 in facilities. In the outpatient environment, source control most commonly refers to respiratory illnesses such as tuberculosis and COVID-19. In **every** health care encounter, individuals with cough should be given a medical mask and separated from other patients.

With respect to COVID-19, contact and droplet precautions are recommended for COVID-19 protection. Airborne precautions including N95 respirators are recommended for staff performing aerosol generating procedures (AGPs). These procedures include tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, and bronchoscopy. With respect to TB, airborne precautions are

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[586] https://www.cdc.gov/infectioncontrol/basics/transmission-based-precautions.html
[587] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html

recommended for TB protection. Source control is recommended in all healthcare settings to prevent the spread of COVID-19 and TB.[588]

Tuberculosis is an airborne infection and requires airborne precautions. As detailed above, all individuals who are coughing should be given a medical mask and separated from the general clinic population. The careful collection and handling of infectious material such as sputum, adherence to appropriate ventilation requirements such as outdoor waiting rooms and/or an open window, cross-ventilation policy is critical to preventing transmission of tuberculosis in the clinical setting. Fit tested N95 respirators are recommended for health care providers caring for patients with tuberculosis. Many countries will have comprehensive TB control policies and WHO also provides IPC recommendations for reducing the spread of TB in HCF.[589]

**Quality management and measuring outcomes of IPC practices:** There are a number of methods for evaluating infection prevention interventions and a continuous quality improvement approach facilitates the identification and mitigation of deficiencies. SIMS 4.1 contains several CEEs that relate to infection prevention (see below). At a minimum, OUs, IPs, and facilities should review previous SIMS data to understand baseline IPC practices. IPs and facilities should use the SIMS CEEs to regularly monitor their progress in implementing IPC practices outside of any official SIMS assessments by the OUs.

CEE #: S_01_06 TB Infection Control [ALL SITES-GEN]
CEE #: S_01_07 Waste Management [ALL SITES-GEN]
CEE #: S_01_08 Injection Safety [ALL SITES-GEN]
CEE #: S_10_02 Laboratory Biosafety [LAB]
CEE #: S_05_02 Adverse Event (AE) Prevention and Management [VMMC]
CEE #: S_01_20 Assessment & Utilization of Performance Data in QI Activities [ALL SITES]

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[588] https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/index.html
[589] WHO Guidelines on Tuberculosis Prevention and Control (update 2019) https://www.who.int/publications/i/item/9789241550512

## 6.7.2 Occupational Health

Health care workers (HCWs) are at risk for acquiring infections from patients and may put patients and other staff at risk if they have a transmissible infection. The WHO estimates that between 14 and 35% of all COVID-19 infections are in health care workers.[590]

An ongoing challenge during the COVID-19 pandemic has been to determine how best to minimize the risks posed by asymptomatic and pre-symptomatic transmission in healthcare settings. During the COVID-19 pandemic, outbreaks in healthcare facilities have occurred and robust systems to rapidly detect and respond to COVID-19 cases must be established in both inpatient and outpatient facilities.

As part of an outbreak response, IPC focal points must be equipped to conduct a risk assessment of HCW exposures, and appropriately manage HCW with close contact to confirmed COVID-19 cases. Timely investigation along with rapid access to testing during a health facility outbreak should be made available for all exposed staff consistent with any existing country outbreak investigation protocol. Exposure includes direct contact with an infected HCW or exposure within 1 meter of a COVID-19 patient without PPE for >15 minutes.[591,592] Furthermore, HCW quarantine, testing, and return to work policies must be effectively implemented in response to COVID-19 facility outbreaks. PEPFAR supports following local recommendations with respect to return to work, quarantine, and clinic closures, and headquarter staff will work with country teams to support the development and sharing of SOPs in line with national guidelines. The WHO has guidance on human resource management in the health care setting for COVID-19 which may be useful.[593]

Each instance of a COVID-19 healthcare-associated facility outbreak is an opportunity to re-evaluate IPC policies and practices and retrain staff on key infection control measures as well as strengthen COVID-19 primary prevention and IPC practices to reduce onward transmission.

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[590] Reuters, COVID-19 in Health Care workers 17 Sept 2020

[591] https://apps.who.int/iris/bitstream/handle/10665/331496/WHO-2019-nCov-HCW_risk_assessment-2020.2-eng.pdf?sequence=1&isAllowed=y

[592] https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/public-health-management-hcw-exposed.html

[593] https://www.who.int/publications/i/item/WHO-2019-nCoV-health_workforce-2020.1

It is now incontrovertible that universal source control and continuous medical masking prevent transmission of COVID-19 to health care workers[594] Continuous medical masking refers to the practice of all staff wearing a medical mask at all times in the facility including during non-patient care activities. Universal source control for COVID-19 means that all visitors and clients of the facility should wear face coverings.

Both the WHO and the CDC have recommended time-based criteria for terminating isolation in individuals who test positive for COVID-19.[595,596] The updated criteria reflect recent findings that patients whose symptoms have resolved may still test positive for the SARS-CoV-2 by RT-PCR for many weeks. Despite a positive test result, these individuals are not likely to be infectious. Specific recommendations for healthcare workers are congruent with the general recommendations.[597]

COVID-19 has illustrated the importance of occupational health and PEPFAR is committed to the health of all individuals it supports. HCW acquisition and transmission of other respiratory diseases is important clinically. Tuberculosis in health care workers, including drug resistant TB, is well documented. Pre-employment screening, followed by repeated testing at defined intervals and after exposure, facilitates management of inadvertent exposures and treatment of early disease which may reduce morbidity and mortality for health care workers and reduce transmission to patients or other health care workers in the clinical setting. Blood borne illnesses are important and reporting and monitoring occupational exposure by HCWs and post-exposure management, including testing and counseling and PEP provision, are essential for occupational health management among HCWs. This priority is reflected in SIMS S_01_08 Injection Safety [ALL SITES-GEN] which requires PEP starter packs in areas where phlebotomy is performed. Vaccine-preventable illnesses (VPIs) in HCW are an important focus of occupational health programs. Hepatitis B, varicella and seasonal flu are important clinical entities that can be occupationally acquired and can disrupt clinical care in a facility. Automated systems for tracking the health status of employees have been developed for resource-rich settings and can be easily adapted for use in RLS.

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[594] Wang X, Ferro EG, Zhou G, Hashimoto D, Bhatt DL. Association Between Universal Masking in a Health Care System and SARS-CoV-2 Positivity Among Health Care Workers. JAMA: the Journal of the American Medical Association. 2020.
[595] https://www.who.int/publications/i/item/10665-336265
[596] https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html
[597] https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

## 6.7.3 Waste Management

The different types of medical waste are documented here: https://www.who.int/news-room/fact-sheets/detail/health-care-waste. In most PEPFAR programs medical waste includes infectious waste, or waste contaminated with blood and other bodily fluids; sharps waste; pharmaceutical waste such as expired or damaged drugs and vaccines, and laboratory waste.

Policies and procedures, consistent with national guidelines (or international guidelines if no updated national guidelines are available) should be in place for the appropriate management of each of these categories including detailed standard operating procedures for the safe disposal of medical waste. SOPs should include persons responsible for waste disposal, frequency of activities, supplies needed, step by step procedures for the implementation of safe waste disposal, including PPE and other resources used to protect HCWs, and protocols for monitoring of safe medical waste disposal. Schedules for collection, transport and destruction should be in place, and collection should occur reliably and at fixed times to ensure sites are not overstocked with waste or improperly dispose of waste.

All waste should be labeled as waste according to the waste type: infectious, chemical or pharmaceutical, general health care waste, sharps, etc. HCWs involved with waste handling should receive tailored training on recommended waste management practices.

Disposal of toxic **laboratory reagents** is covered in the laboratory section (Section 6.6.1.5)

Information about best practices for **waste management in VMMC** programs is available online via WHO.[598]

**Pharmacies** should have clearly documented policies and procedures, and individuals delivering ART should understand the basic principles of expiry dates, and appropriate disposal of unusable pharmaceuticals.

All sites that store pharmaceuticals should adhere to the "First to expire, first out" stock rotation system, meaning that the products are stored with the soonest expiration first, such that it is

[598] https://www.who.int/water_sanitation_health/facilities/health-care-waste-publications/en/
Safe Management of Wastes from Healthcare Activities, 2nd edition. WHO (2014)
https://www.who.int/water_sanitation_health/publications/safe-management-of-wastes-from-healthcare-activities/en/

dispensed first, but still with enough time remaining that the patient will consume it before it expires.[599] If a product will not be consumed before expiration, then it should be separated from usable product. Expired products or products that will expire before they can be consumed should be segregated and secured in a separate location, apart from usable pharmaceuticals. For pharmaceuticals, the type of product being wasted should be documented and incorporated into the supply chain management system to inform future forecasts and procurement plans, in an effort to minimize waste.[600]

## 6.7.4 Cleaning, Disinfection, and Sterilization

Environmental cleaning refers to the cleaning and disinfection (when needed, according to risk level) of environmental surfaces (e.g., bed rails, mattresses, call buttons, chairs) and surfaces of non-critical patient care equipment that only contacts intact skin (e.g., IV poles, stethoscopes). Environmental cleaning is critical to prevent the spread of infections that can be potentially transmitted via contact with contaminated surfaces and equipment.

IPs and PEPFAR supported facilities that provide patient care should review their current cleaning and disinfection programs and should ensure that they have policies and SOPs related to environmental cleaning and disinfection that are consistent with national guidelines (or international guidelines if there are no updated national guidelines available). SOPs should include persons responsible, frequency of activities, supplies needed, step by step procedures for implementation of cleaning and disinfection of the environment and non-critical medical equipment, PPE and other resources used to protect HCWs, and monitoring standards.[601]

One of the most critical components of an effective facility environmental cleaning program is the proper administration, oversight, and training of cleaners. Cleaning programs are often contracted services, cleaners may not be properly trained, and oversight may be lacking. This may result in inadequate cleaning and contaminated environmental surfaces that could facilitate transmission of pathogens, including viruses, and resistant bacteria. IPs and facilities should

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[599] *FIFO, FEFO, LIFO: What is the meaning?* (2021, January 6). Gmp-Compliance.Org. https://www.gmp-compliance.org/gmp-news/fifo-fefo-lifo-what-is-the-meaning

[600] World Health Organization, Charter, Y., & World Health Organization. (2014). Safe management of Wastes from Health-care Activities. World Health Organization.

[601] CDC and ICAN. Best Practices for Environmental Cleaning in Healthcare Facilities in Resource-Limited Settings. Atlanta, GA: US Department of Health and Human Services, CDC; Cape Town, South Africa: Infection Control Africa Network; 2019. Available at: https://www.cdc.gov/hai/prevent/resource-limited/index.html and http://www.icanetwork.co.za/icanguideline2019/

provide basic training on cleaning and disinfection to all new employees at HCFs and periodic updates to all employees. IPs and facilities should provide in-depth training on environmental cleaning to the cleaning staff including the role of waste management and resources for cleaning staff to protect themselves against communicable diseases and chemicals used for cleaning/disinfection.

**Medical equipment reprocessing:** Given cost and waste management challenges of disposable instruments, PEPFAR prioritizes the use of reusable instruments where appropriate and feasible instead of disposable kits. However, to minimize the risk of disease transmission, medical equipment must be designed to be reprocessed, and must be reprocessed according to manufacturer specifications.

Medical equipment reprocessing involves a complex series of steps with multiple potential failure points. If not correctly done every time, clients are at risk for infectious complications. Complete reviews of this topic are available in materials from CDC[602] and WHO.[603]

The recommended level of decontamination for medical equipment depends on the potential for infectious complications during intended use. Medical equipment can be classified as non-critical (touches intact skin, e.g., blood pressure cuff), semi-critical (touches mucous membranes or non-intact skin, e.g., vaginal speculum), or critical (touches sterile body surfaces/cavities, e.g., surgical instruments). Cleaning, followed by disinfection, or sterilization is the basic sequence for reprocessing medical equipment; the specific requirements for each item depend on whether it is critical, semi-critical, or non-critical.

For medical equipment reprocessing, **cleaning** refers to the removal of visible organic and inorganic matter and is the vital first step for all equipment prior to disinfection or sterilization. Cleaning physically removes rather than kills microorganisms. Cleaning is usually performed manually with water and detergents or enzymatic cleaners, and mechanical action. **Disinfection** refers to a process that kills most microorganisms on inanimate objects. There are three levels of disinfection. Low- and intermediate-level disinfection are needed for environmental cleaning. Once an item has been cleaned, low and intermediate level disinfection is performed per

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[602] CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (updated May 2019) https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

[603] Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO and PAHO (2016) https://www.who.int/publications/i/item/9789241549851

manufacturer's instructions including type of disinfectant and how long it must remain in contact with the item.

High level disinfection (HLD) is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. After a semi-critical item has been cleaned, it is disinfected by an appropriate HLD method as detailed by the manufacturer. Chemical disinfectants appropriate for HLD, and processes for their use, can be found in the WHO and CDC references above.

**Sterilization** is a process that eliminates all forms of microbial life, including spores that cause tetanus. It is important to recognize the complexity of instrument reprocessing and how each step in the pathway from a dirty instrument at the end of one procedure, to the same instrument being sterile at the beginning of the next procedure, is absolutely essential for client safety. A variety of sterilization methods are described in the references above. Steam under pressure, as in an autoclave, is the principal sterilizing method used in PEPFAR facilities, although chemical sterilization is also used. There are four parameters of steam sterilization: steam (moisture), pressure, temperature, and time. The basic principle of steam sterilization is to expose each clean item to direct steam contact at the required temperature and pressure for a specified length of time.

Although an autoclave is the most visible component of instrument reprocessing, programs must resist complacency about sterility just because they have a functional autoclave. An autoclave is just one component of the instrument reprocessing system – the combination of people, equipment, policies, and practices that repeatedly takes instruments from dirty to sterile. This system can be illustrated by considering the basic steps of reprocessing and the activities associated with each. Again, detailed descriptions of these steps are available in the CDC and WHO references above.

1. Pre-cleaning:
    a. Immediately after use, remove gross soil by wiping with a damp cloth.
    b. Do not soak, but keep instruments moist (e.g., cover with damp towel). If instruments dry completely, it can make adherent bioburden very difficult to remove.
2. Cleaning:
    a. Manually clean instruments with a soft bristle brush using detergent and water to remove all visible soil. Machine assisted cleaning (e.g., ultrasonic cleaners) acceptable as well although not widely available in resource limited settings.

b. After cleaning, allow to air dry then visually inspect to ensure all contamination removed prior to packaging.

3. Packaging:

a. Ensure all clean and dry instruments are in the open position and place in autoclave-safe pouch or tray with appropriate wrapping.

b. Chemical indicators should be placed inside the package and on the outside (if the interior one not visible through clear packaging).

c. Package label should contain at least the name of contents, sterilization date, autoclave ID, and load number. Package label and autoclave logbook should allow easy identification and tracking of all items by load number and date to facilitate retrieval of all involved items if a cycle sterility issue discovered later.

4. Sterilization:

a. Autoclaves should be installed, used, and maintained per manufacturer's instructions for use, including instructions on water source.

b. Load autoclave per manufacturer's recommendation to allow steam penetration of all items and start cycle.

c. Once complete, mark load number and cycle parameters (such as time, pressure, and temperature) in logbook, check visible sterility indicators, and inspect packaging for evidence of retained moisture or damage.

d. Monitor sterilization with chemical indicators (each package), physical indicators (each load), and biological indicators (daily) after each cycle to verify completion of a successful sterilization cycle

e. Sterilizers should be routinely inspected and maintained according to the manufacturer's instructions.

5. Sterile pack storage and use:

a. Store sterilized packages in a manner to reduce potential for contamination (i.e., clean, dry, and temperature and traffic-controlled area, elevated from floor and away from walls).

b. Organize storage to allow first in-first out retrieval.

c. Providers should inspect sterile packaging for damage and appropriate appearance of internal and external sterility indicators prior to instrument use.

The entire reprocessing system relies on dedicated, well-trained individuals overseeing the process. SOPs for each step of the process, frequent quality assurance activities, and CQI are critical to assist sites in carrying out this process correctly every time.

## 6.8 Surveys-Surveillance, Research, and Evaluation (SRE) Technical Considerations

Summary of section edits:

An interagency SRE ST3 team was established to review past feedback and draft updated SRE guidance. This newly added technical consideration reflects the team's recommendations.

PEPFAR funds SRE activities to understand and address countries' epidemics, translate efficacious interventions tested in controlled environments to real-world contexts where resources are more limited, complement routine program data by filling data and knowledge gaps, and provide the evidence basis for decision- making and public health action.

Focused on ensuring and enhancing accountability, impact, and learning, as well as adapting in real-time, PEPFAR recommends using all available data assets and systems and a combination of analytic, evaluation, and research methods and designs to enhance PEPFAR program contributions to country progress toward averting new infections and reaching & maintaining 95-95-95 goals.

Countries at or near epidemic control may have unique needs and uses of SRE activities. As PEPFAR-supported countries get closer to 95-95-95 and epidemic control, the precision of the data becomes more critical to understanding the epidemic and program response. Fewer people living with HIV are to be found, tested, initiated, and maintained on treatment and to become virally suppressed. Thus, understanding where the programs are at in the context of the need becomes more important to inform program activity. Likewise, understanding precisely what the flow of clients is, and the reasons for the clients to be in situations such as retesting or interrupting and returning to treatment, becomes ever more important. Examples of the specific use of SRE for accelerated programming in countries at or near epidemic control include a "saturation strategy" of HIV service-delivery systems, augmented linkage to care, and the use of community health workers (CHW) to support a differentiated service delivery (DSD) model.

While there are many completed PEPFAR-funded studies and excellent routine data sources to consider and draw on when faced with a priority question—and before assuming the need for primary data collection/new SRE—there are instances when evidence and data are not available, accessible, or of good enough quality to answer priority questions. These are the instances in which advocating for new SREs is appropriate and essential.

The SRE Decision Tree (See **Figure 6.8.1**) can help teams identify the programmatic area of challenge, the research question to address this issue, and the proper action items.

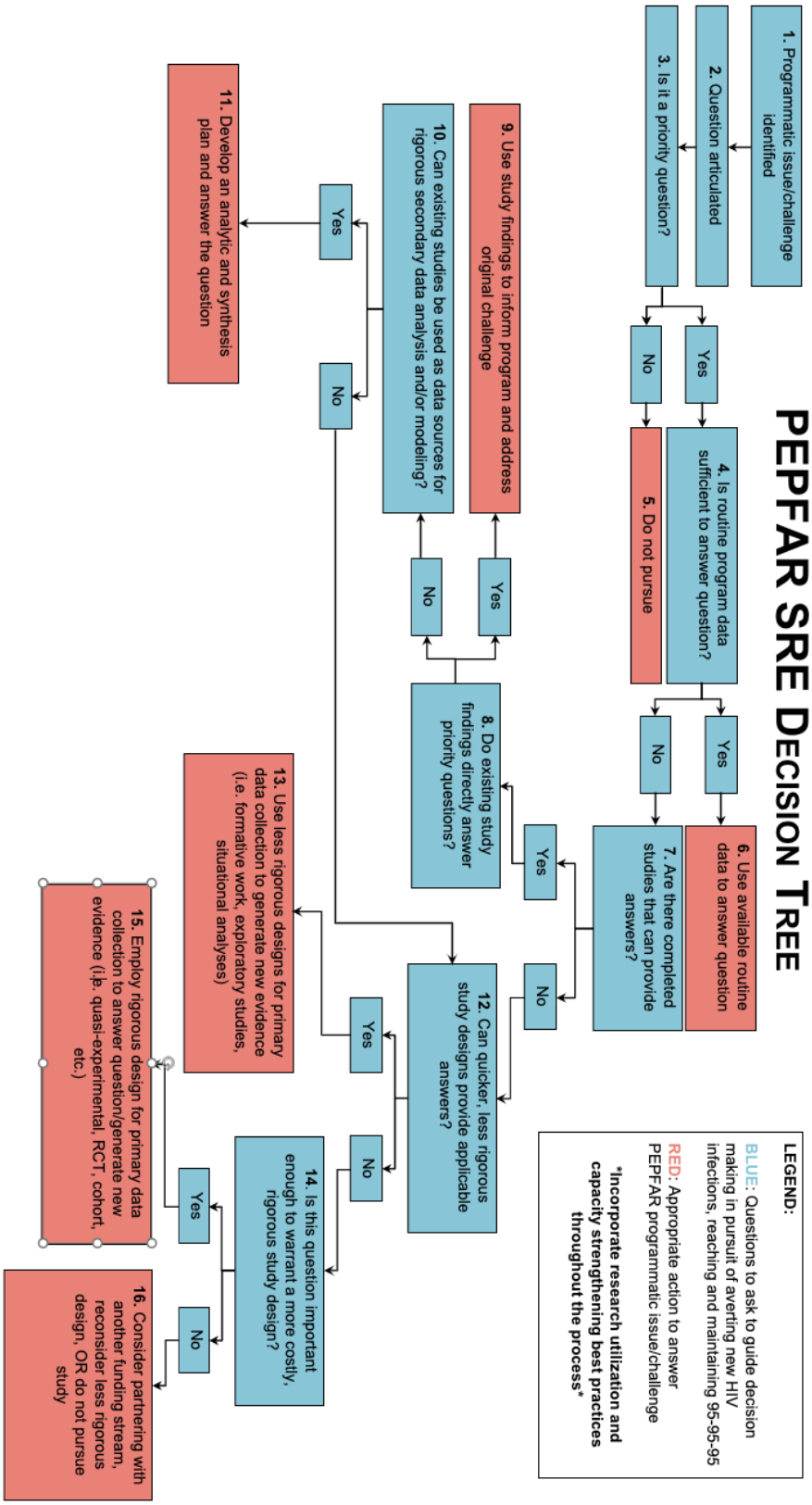


**Figure 6.8.1 SRE Decision Tree.**

If there is enough evidence and justification to necessitate an SRE activity, teams should work to determine which activity best meets the need of the data gap. In addition, teams should account for the time required to incorporate these activities into their priorities, planning, complexity or challenge of the environment, design for an evaluation, proper implementation/execution, results-sharing, and potential delays (e.g., IRB approvals, disasters, political unrest, pandemics, etc.)

Examples of the main SRE activities PEPFAR supports are provided in **Figure 6.8.2**.

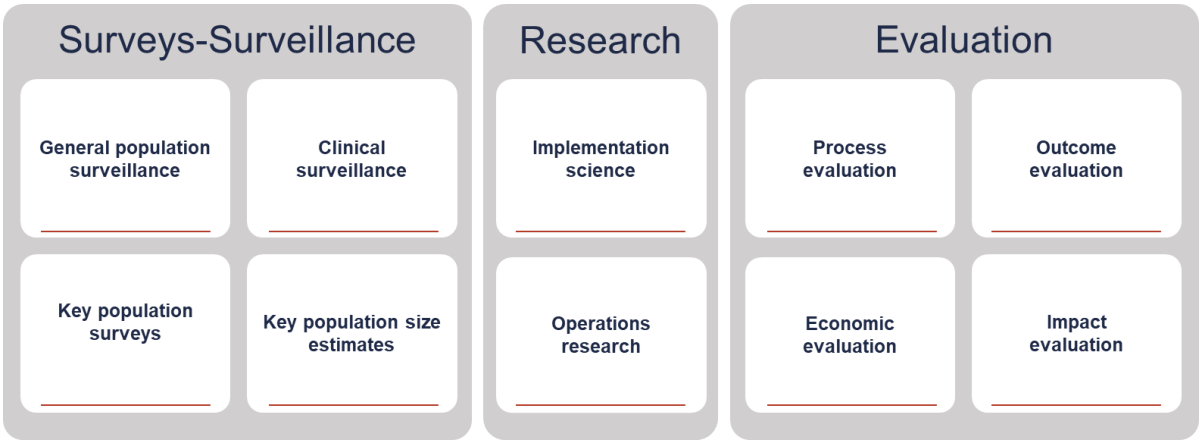


**Figure 6.8.2 Examples of SRE Activity Types:** (**1**) Surveys-surveillance, which includes general population surveillance, clinical surveillance, key population surveys, and key population size estimates; (**2**) research, which includes implementation science and operations research; and (**3**) Evaluations, which includes process, outcome, economic and impact evaluations.

PEPFAR defines surveys-surveillance as the systematic collection, analysis, and interpretation of health data to describe and monitor health events. These data are used to inform public health action through the planning, implementation, and evaluation of public health interventions and programs.[604] Surveys-surveillance activities are essential to understanding OU epidemics and assessing OU progress toward global targets. Results from PEPFAR-funded surveys-surveillance activities inform programmatic planning to ensure resources are allocated to areas and populations with the greatest burden and unmet need. Triangulation of SRE and program data allows for an improved understanding of current gaps in ARV coverage and viral suppression across geographic areas and population groups.

[604] Guidelines for evaluating surveillance systems. *MMWR*. https://www.cdc.gov/mmwr/preview/mmwrhtml/00001769.htm. Published May 6, 1988. Accessed October 19, 2022

PEPFAR supports four types of surveys-surveillance activities: **(1)** general population surveillance—including PHIAs and other special epidemiologic and surveillance studies; **(2)** clinical surveillance—including pediatric, ANC, mortality, HIV drug resistance, and case surveillance; **(3)** key population surveys—including MSM, FSW, transgender, PWID, and other priority population surveys, **(4)** population size estimates—including MSM, FSW, transgender, PWID, and other priority population size estimates. When distinguishing between case surveillance and other HIS efforts, countries should note the following considerations:

- Activities related to both major phases of case surveillance: **(1)** planning and development and **(2)** implementation and scale-up should be recorded in the SRE Tool.
- Planning and development activities can include designing a new HIS or adapting existing HIS to accommodate case surveillance. This should involve the use of a unique identifier and the ability to link key sentinel events for people living with HIV over time.
- Implementation and scale-up activities include the actual production of individual- level case surveillance data from the new or adapted HIS and use of these data to inform the HIV response in-country. Please note that building or adapting HIS does not automatically imply case surveillance, as these systems can also be used for other purposes (e.g., procurement, logistics, etc.). During the COP23 approval meeting, country teams must describe and present the complementary or unique activities for case surveillance from routine EMR or HIS activities.

As mentioned in Section 3.1.5.2 of the COP/ROP23 Guidance, a National HIV Surveillance Plan should be developed with country governments to determine surveillance priorities and how to operationalize them to inform the public health response. This plan should specifically address the country's unique data needs, gaps, and priorities by describing the frequencies, locations, populations, sampling designs, and key metrics for surveys as well as all key surveillance systems (case surveillance, recency surveillance, ANC/PMTCT surveillance, HIV DR, pediatric, and mortality surveillance) with expected milestones such as geographic coverage, key data elements, and timeliness of reporting. These national plans should be multi-year and are developed jointly by a MOH-led TWG that includes all key stakeholders.

For more information about survey/surveillance strategies and approaches (especially regarding aligning survey/surveillance activities with OU's national strategies), please see Section 3.1.5.2 in the COP/ROP23 Guidance.

## Research Activities

An ongoing challenge for program implementation is translating efficacious interventions tested in controlled clinical trial settings to real-world contexts where personnel, financial, and other resources are more constrained. PEPFAR defines research as **(1)** a systematic, intensive study intended to increase knowledge or understanding, apply new knowledge to needs or **(2)** a systematic application of knowledge to the production of useful materials, devices, and systems or methods. This includes design, development, and improvement of prototypes and new processes to meet requirements.[605] PEPFAR primarily supports two types of research:

a. Implementation Science (IS)—the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice and to improve the quality and effectiveness of health services, in part through the study of influences on health care professionals and organizational behavior. For more information on IS guidance, see Section 3.1.5.1 of the COP/ROP23 Guidance.

b. Operations Research (OR)—the scientific approach to decision-making about how to design, operate, and improve programs and systems, usually under conditions requiring the allocation of scarce or finite resources.

PEPFAR supports these two types of research to establish facts, advance knowledge, and reach new conclusions. Countries can use IS and OR to identify solutions to problems that limit program quality, efficiency, and effectiveness, or to determine which alternative service delivery strategy would yield the best outcomes.

Monitoring client clinical outcomes and service acceptability is a critical part of all PEPFAR programs and should be performed as part of routine program implementation, monitoring, and evaluation. For example, monitoring of barriers and facilitators to service uptake can be done by routinely assessing client experiences or prospectively assessing uptake after changes in implementation. These types of retrospective or prospective observational approaches should aim to strengthen program implementation. PEPFAR is committed to implementing robust

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[605] NIH Grants Policy Statement. National Institutes of Health. https://grants.nih.gov/grants/policy/nihgps/HTML5/introduction.htm. Published December 2021. Accessed October 19, 2022.

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program- monitoring to track progress toward global targets. However, certain more-specific questions cannot be answered using routine data; PEPFAR-funded evaluation activities help fill this gap. In combination with routine program monitoring, the information made possible by program evaluations provides the evidence basis for decision-making and public health action, ensures an equitable approach to public health practice, fosters greater effectiveness and efficiency by service providers, prioritizes the importance of demonstrating programmatic outcomes, and encourages accountability.

**Evaluation Activities**

PEPFAR defines evaluation as the systematic collection and analysis of information about the characteristics and outcomes of a program—including projects conducted under such program—as a basis for making judgments regarding the program, improving program effectiveness, and informing decisions about current and future programming.[3] PEPFAR supports 4 types of evaluation activities: process, outcome, impact, and economic. Full definitions of these evaluation types can be found in the Evaluation Standards of Practice (ESoP) Version 3.1.2 (available on DATIM—Data for Accountability, Transparency, and Impact Monitoring Support). All PEPFAR-funded evaluation activities should be included in the COP23 SRE Tool. The ESoP 3.1 contains 11 standards to which all PEPFAR evaluations must adhere to improve evaluation, planning, implementation, oversight, and quality across PEPFAR programs. The ESoP responds to recommendations by the Government Accountability Office (GAO) and the Institute of Medicine (IOM), as well as stipulations within the congressional reauthorization and requirements established under the Foreign Aid Transparency and Accountability Act of 2016, to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. PEPFAR ensures compliance with Foreign Aid Transparency and Accountability Act (FATAA) by aligning monitoring and evaluation activities with PEPFAR strategies and objectives. The monitoring and evaluation information is used to generate evidence that informs decisions related to program design while taking into consideration time and budget constraints.

**Impact Evaluations**

In the context of PEPFAR, there is a narrow opportunity to implement impact evaluations. Impact evaluations (as defined in the OMB circular) are often not operationally or financially practical since they require substantial time and funding to establish a counterfactual and attribution. Often, other programmatic changes or guidance have been implemented in the meantime, which affect the usefulness of the results. S/GAC uses routine granular site and

age/sex program data to manage its programs and, in doing so, is aligned with the approaches outlined in the OMB circular. When a new intervention is needed for a particular population or program area, PEPFAR carries out those interventions and uses routine granular site- level age/sex data to determine the intervention's effectiveness and make more real-time changes. PEPFAR has robust longitudinal data by site and age/sex that are frequently sufficient to respond to priority program evaluation questions.

As a result, PEPFAR adopts the following guidelines around impact evaluations:

- PEPFAR does not generally support entirely new or untested approaches but rather encourages contextual innovations and adaptations to evidence-based therapeutic and program interventions.
- In the context of PEPFAR, the complex, specialized design, substantial investment, and long-time horizon of impact evaluations have typically made them impracticable. Often, other policy or programmatic changes have been implemented before observation is complete or results are available, which affects the practicability and usefulness of this approach.
- Instead, PEPFAR has relied on routine, granular, site-level data, selected process and outcome evaluations, operations research, and PHIAs to assess innovations and adaptations and to measure outcomes and impacts of PEPFAR-supported programs.
- There are above-site and non-direct service-delivery interventions and innovations that are not well captured with the routine program data and that may require implementation of a nonroutine, SRE-type activity. The most practical and cost-effective evaluation design should be explored before more rigorous designs are considered.
- The COP/ROP planning, however, serves as the process through which OUs can propose pilot programs or interventions and associated implementation science or operations research (including impact evaluations) for consideration in PEPFAR.
- To be considered as part of a COP/ROP, a proposed pilot program or intervention must be aligned with PEPFAR COP/ROP guidance and in support of OU epidemic and program priorities, and the associated impact evaluation must be appropriate and practicable for the OU context and portfolio.
- For the reasons described, OUs are advised to consider whether alternative methods of monitoring, evaluation, or research are justifiably sufficient to assess the effectiveness of a proposed pilot program or intervention.

The OUs should follow the SRE guidance for submission of a proposed impact evaluation and its related data-collection in the context of a novel intervention or pilot program and be prepared to discuss both in detail during the review period.

**To further support a sustainable response, OU teams should align PEPFAR-supported SRE activities with the host country's national HIV survey-surveillance, research, and evaluation strategic plan(s).** Ideally, national SRE-related strategic plans would be developed by a technical working group and led by the ministry of health, in partnership with implementing partners and key stakeholders such as PEPFAR and the Global Fund country-coordinating mechanism. PEPFAR teams are encouraged to promote regular meetings among host-country SRE counterparts to assess adherence to the plan and update the plan as new priorities and developments emerge. In countries where a plan does not already exist, PEPFAR teams should work to facilitate development of a strategic plan with host- government counterparts. In some cases, a plan might be a module within a larger national HIV control strategy or framework.

Countries are recommended to approach their surveys-surveillance, research, and evaluation portfolio planning by determining the *Who* (target populations), *What* (measures), *Why* (are the measures needed), *Where* (location of data collection), *When* (frequency of data collection), and *How* (surveillance/survey/evaluation design). To the extent possible, distribute SRE activities across time to avoid excessive strain on resources in a single year. The plan should also inform out-year budget-relevant activities, such as COP planning, GF applications, and other resource mobilization. Examples of activities that could be included on a national SRE plan are population-based surveys (e.g., PHIA, DHS, Integrated HIV Bio-behavioral surveillance survey (IBBS), case surveillance, costing studies, and drug resistance surveillance. Countries that are at or near HIV sustained impact may have unique needs and uses of SRE activities. As PEPFAR-supported countries move closer to 95-95-95 and sustained HIV impact, the precision of the data becomes more critical to understanding the epidemic and program response. Fewer people living with HIV are to be found, tested, initiated, and maintained on treatment, and thus fewer people are to become virally suppressed. Consequently, understanding where the programs are in the context of the need becomes more important to inform program activity. Likewise, understanding precisely what the flow of clients is, and the reasons for the clients to be in situations such as retesting or interrupting and returning to treatment, becomes ever more important. Examples of the specific use of SRE for accelerated programming in countries at or near sustained HIV impact include a "saturation strategy" of HIV service delivery systems,

augmented linkage to care, and the use of community health workers (CHW) to support a differentiated service delivery (DSD) model.

Whenever possible, PEPFAR-funded SRE activities should be led by and carried out through local not-for-profit organizations including government (e.g., ministries of health), civil society (e.g., community-based organizations), or academic (e.g., schools of public health) entities to facilitate data ownership, data utilization, and strengthen country capacity.

## 6.9 Technical Considerations for Addressing Barriers to Health Equity: Stigma, Discrimination, and Human Rights

Summary of section edits:

This is a new section providing technical and implementation considerations to support requirements outlined in COP/ROP23 Guidance Section 3.1.1.4.

COP/ROP23 Guidance has several requirements in support of advancing equity, addressing stigma and discrimination, and advancing human rights. The following are specific implementation considerations and recommendations.

***PLHIV Stigma Index 2.0***

The PLHIV Stigma Index 2.0 is a tool to measure stigma and discrimination among people living with HIV and to chart progress in reducing occurrences.[606] Since the 2008 launch of the PLHIV Stigma Index, shifts in the HIV/AIDS epidemic, growth in the evidence base on how stigma affects different populations, and changes in the global response to HIV have highlighted the need to update the Index. The PLHIV Stigma Index 2.0 provides teams with adapted questions that distinguish experiences by gender identity, population, and individuals born with HIV. The index examines varied experiences of sex workers, MSMs, lesbians, transgender individuals, and people who inject drugs. It provides an expanded health care section with an emphasis on the HIV care continuum. The PLHIV Stigma Index 2.0 utilizes a standardized methodology incorporating existing validated scales to measure internal stigma and mental health with an

[606] https://www.stigmaindex.org/about-the-stigma-index/

additional scale to measure resilience of people living with HIV. This revised, USG-compliant version supports baseline data collection about the stigma and discrimination experiences that people living with HIV have had. This version will be helpful for evaluating the impact of interventions on reducing stigma and should be used to inform future HIV program planning.

PEPFAR teams are required to either support partner-country PLHIV network-led implementation of the revised PLHIV Stigma Index 2.0 or complement GF or another donor financing implementation of the PLHIV Stigma Index 2.0. The OUs in which a PLHIV Stigma Index has not been conducted within the last 3 years are required to commit funding to its implementation or ensure another financing source has been identified in COP/ROP23.

The PLHIV Stigma Index 2.0 must be carried out in collaboration with the "PLHIV Stigma Index International Partnership"—composed of GNP+, ICW, and UNAIDS—and must adhere to the following principles:

1. Leadership of PLHIV networks involved in all phases of implementation
2. 2020 standardized methodology
3. Sampling frame inclusive of all subpopulations, with specific attention to ensuring the inclusion of populations that often encounter barriers to their access to health, including women, young people, people who use drugs, sex workers, gay men and otherMSMs, and transgender people.
4. Quality assurance and reliability of data using the official review process
5. Data security and sharing that follows ethical standards and appropriate written agreements
6. Dissemination of analyses, reports, and presentations that include authors from networks of people living with HIV and according to the parameters of the national network

At the country level, coordination should include routine meetings with all in-country stakeholders, including people living with HIV networks, KP groups, and civil society organizations, to discuss project goals prior to implementation, assess implementation progress, and discuss findings.

Implementation of the PLHIV Stigma Index 2.0 is required every 3 years, and, during interim years, focus should be on concerted action to address findings. Completion of the PLHIV Stigma Index 2.0 should be accompanied by a response/action plan that is discussed and agreed upon by all stakeholders. The response/action plan should directly address findings and clearly outline necessary responses and action steps, with an emphasis on community leadership. This response/action plan should be completed within a reasonable timeframe that allows enough time for proper redress of highlighted issues in advance of the next iteration of the PLHIV Stigma Index 2.0 in the OU. In many contexts, COVID-19 has interrupted implementation of the PLHIV Stigma Index 2.0; nonetheless, implementation of the revised PLHIV Stigma Index 2.0 remains a PEPFAR priority. All PEPFAR OUs must ensure implementation of the PLHIV Stigma Index 2.0 (whether through PEPFAR or other funds) within the required 3-year timeframe, taking care to be attentive to local COVID-19 conditions

***Recommended Minimum Package:***

1. Programs must continuously monitor stigma- and discrimination-related indicators. This is essential for understanding and addressing how stigma and discrimination affect the ways people living with HIV and key populations access and use HIV services. Recommendations include:
    - Implementint (or supporting the implementation of) the PLHIV Stigma Index 2.0 routinely (i.e., every 3 to 5 years)
    - Support on-going community-led monitoring (CLM) activities
2. To ensure a comprehensive response to eliminate stigma and discrimination (S&D) at scale:
    - Support government, community, civil society, faith leaders and other key stakeholders to triangulate data on stigma and discrimination from PLHIV Stigma Index 2.0, CLM, Bio-Behavioral Surveys, and Demographic and Health Surveys to inform development (or updating) of comprehensive national plans, including selection of key interventions by setting (i.e., community, health care, workplace, education, justice, emergency)
    - Engage with other donors—such as GF, UNAIDS, WHO, and UNICEF—to ensure that comprehensive national plans are fully funded (since PEPFAR may only be able to focus supporting health-focused activities in select settings)
3. To reduce and mitigate stigma and discrimination:

- Support key interventions in health facility and community settings[607] (See Section 6.5). While all 6 settings of the Global Partnership to Eliminate all forms of HIV-related Stigma and Discrimination[608] are important, PEPFAR will mainly support activities in health care and community settings. Countries are welcome to make the case for implementing stigma and discrimination reduction activities in other settings to support uptake and utilization of HIV services.

***Key Interventions:***

- Total Facility Approach[609] to reducing stigma and discrimination in health facilities (PEPFAR best practice ready for adaptation and scale)
- Psychosocial support activities for people living with HIV, key populations to address/mitigate internalized, or self-, stigma (e.g., group therapy treatment[610], support groups, peer mentors, etc.)
- Providing technical assistance to communities to analyze and use data from CLM and the PLHIV Stigma Index 2.0 to influence change at a local and national level
- Activities to reduce the key actionable drivers of S&D (fear of infection through nontransmissible contact, shame/blame, lack of knowledge of how harmful stigma is) across all relevant levels (individual, family, community, organizational, and policy). For example:
    - U=U activities in clinic[611] and community settings

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[607] UNAIDS. Evidence for eliminating HIV-related stigma and discrimination—Guidance for countries to implement effective programmes to eliminate HIV-related stigma and discrimination in six settings (unaids.org)

[608] NAIDS. Global Partnership to Eliminate All Forms of HIV-related Stigma and Discrimination. Global Partnership for Action to Eliminate All Forms of HIV-Related Stigma and Discrimination | UNAIDS

[609] https://www.pepfarsolutions.org/solutions/2020/1/16/transforming-service-delivery-for-improved-outcomes-a-total-facility-approach-to-reducing-stigma-and-discrimination

[610] Jackson SD, Wagner KR, Yepes M, Harvey TD, Higginbottom J, Pachankis JE. A pilot test of a treatment to address intersectional stigma, mental health, and HIV risk among gay and bisexual men of color. *Psychotherapy*. Published online January 13, 2022. doi:10.1037/pst0000417

[611] U=U Guidance for Implementation | in Clinical Settings - AIDS Institute Clinical Guidelines (hivguidelines.org)

- Support interventions with adolescents living with HIV (e.g., clinic-based peer-mentoring[612], support groups[613], engagement with families to increase understanding of HIV and reduce stigma experienced in the household[614])
- Community mobilization to shift harmful gender norms that drive stigma and discrimination and impede access to HIV services[615]
- Training on stigma, discrimination, and violence for key duty bearers (health care workers, police, educators, religious leaders, etc.)[616]
- Relationship building between law enforcement and key populations to create positive outcomes[617]

- Activities to increase access to justice for people living with HIV and key populations who experience rights violations in the health care setting (e.g., community[618] paralegals, supporting development and implementation of reporting, monitoring, and redressal mechanisms for experience of stigma and discrimination in health facilities[619], etc.)

***Intervention Considerations by Countries and Their Progress toward 95-95-95 Goals***:

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[612] Denison JA, Burke VM, Miti S, et al. Correction: Project YES! Youth Engaging for Success: A randomized controlled trial assessing the impact of a clinic-based peer mentoring program on viral suppression, adherence and internalized stigma among HIV-positive youth (15-24 years) in Ndola, Zambia. *PloS One*. 2020;15(4):e0232488. doi:10.1371/journal.pone.0232488

[613] Stangl AL, Mwale M, Sebany M, et al. Feasibility, Acceptability and Preliminary Efficacy of Tikambisane ('Let's Talk to Each Other'): A Pilot Support Group Intervention for Adolescent Girls Living With HIV in Zambia. *J Int Assoc Provid AIDS Care*. 2021; 20:23259582211024772. doi:10.1177/23259582211024772

[614] Denison JA, Packer C, Nyambe N, et al. Family Connections randomized controlled trial: assessing the feasibility and acceptability of an intervention with adolescents living with HIV and their caregivers in Ndola, Zambia. *AIDS Care*. Published online March 25, 2021:1-10. doi:10.1080/09540121.2021.1902935

[615] Leddy AM, Gottert A, Haberland N, et al. Shifting gender norms to improve HIV service uptake: Qualitative findings from a large-scale community mobilization intervention in rural South Africa. Mavhu W, ed. PLOS ONE. 2021;16(12):e0260425. doi:10.1371/journal.pone.0260425

[616] Geibel S, Hossain SMI, Pulerwitz J, et al. Stigma Reduction Training Improves Healthcare Provider Attitudes Toward, and Experiences of, Young Marginalized People in Bangladesh. *Journal of Adolescent Health*. 2017;60(2):S35-S44. doi:10.1016/j.jadohealth.2016.09.026

[617] Scheibe A, Howell S, Müller A, et al. Finding solid ground: law enforcement, key populations and their health and rights in South Africa. *Journal of the International AIDS Society*. 2016;19(4 (Suppl 3)). doi:10.7448/ias.19.4.20872

[618] Schaaf M, Falcao J, Feinglass E, Kitchell E, Gomes N, Freedman L. "We all have the same right to have health services": a case study of Namati's legal empowerment program in Mozambique. *BMC Public Health*. 2020;20(1). doi:10.1186/s12889-020-09190-7

[619] Williamson RT, Fiscian V, Olson RU, Poku FN, Whittal J. A Reporting System to Protect the Human Rights of People Living with HIV and Key Populations. Health Hum Rights. 2017;19(2):211-222. (link: A Reporting System to Protect the Human Rights of People Living with HIV and Key Populations)

For countries further from 95-95-95 goals:

- Stigma and discrimination–reduction efforts need to be more focused on removing impediments to HIV prevention, care, and treatment services (e.g., integrating stigma reduction into HIV services and addressing stigma at the community and general-population level to reduce stigma so people living with HIV, key populations, and adolescent young girls and women are more comfortable seeking prevention, care, and treatment services)
- Focused S&D reduction/mitigation efforts likely needed for key populations and vulnerable populations
- Support communities through CLM and PLHIV Stigma Index to identify and remove S&D that are impeding access to and continuity of HIV prevention, care, and treatment services

For countries closer to 95-95-95 goals:

- Focused S&D reduction/mitigation efforts likely needed for key populations and vulnerable populations to ensure that countries can go the last mile and not stop at the achievement of global targets
- Focus on institutionalizing and maintaining S&D reduction efforts (e.g., pre-service training on S&D, human rights, violence, and adding to core curricula at nursing/medical school, police training colleges, teacher training colleges, human resources professionals, etc.)
- Advocacy efforts may be needed to codify best practices for S&D reduction in policy/law (e.g., ensure key populations are protected and not criminalized, reducing age of consent to HIV testing to enable adolescents to test more easily and to test without fear of stigma, etc.)

**Other Resources:**

A country-by-country overview of various HIV-related laws and policies is now available online from UNAIDS.[620] In addition, the HIV Policy Lab[621] systematically gathers and monitors laws and policies around the world, inclusive of some human rights–related laws and policies. The OUs

[620] http://lawsandpolicies.unaids.org/
[621] HIV Policy Lab. https://www.hivpolicylab.org/

should review their country's LGBTQI Report Card[622] to assess its attainment of core human rights protections for LGBTQI individuals and to inform the COP requirements outlined in this section. The OUs may also wish to view resources at the Global Commission on HIV and the Law.[623] Further information about addressing stigma, discrimination, violence, and human rights specific to key populations can be found in Section 6.5 of this document.

# Appendix 1: Summary of Edits

This table conveys a summary for each edited section

- Sections 6.6.8 was completely redrafted.
- Section 6.6.9 and its associated sub-heads: 6.6.9.1, 6.6.9.2, 6.6.9.3, and 6.6.9.4, were completely redrafted.
- Section 6.6.10 is a new technical consideration that defines local partners.
- Section 6.8 (Surveys-Surveillance, Research, and Evaluation) is a new technical consideration.
- Section 6.9 (Technical Considerations for Addressing Barriers to Health Equity: Stigma, Discrimination, and Human Rights) is a new technical consideration.

| Section Number | Section Title | Edit Summary |
|---|---|---|
| 6.1.1 | Linkage to ART, Early Engagement, and Treatment Literacy | Section updated to identify that longitudinal patient centered data is preferred. |
| 6.1.2.1 | Differentiated Service Delivery for Children | Wording was updated to align with policy that all children irrespective of age should be eligible for multi-month dispensing (MMD) of ART. |
| 6.1.3.2 | Interruptions and Re-engagement in Treatment | Updated to include recommendations for clinical management of individuals returning to care and the use of longitudinal data for understanding interruptions. |

[622] Council for Global Equality. LGBTQI Report Cards - Council for Global Equality. globalequality.org. Accessed November 7, 2022. http://globalequality.org/reports/international-publications-on-lgbt-human-rights/267

[623] hivlawcommission.org

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| 6.2.1 | Pre-Exposure Prophylaxis (PrEP) | • New product information was updated.<br>• Updated to align with new WHO guidance on differentiated and simplified pre-exposure prophylaxis for HIV prevention (https://www.who.int/publications/i/item/9789240053694).<br>• Updated to align with status-neutral service delivery considerations. |
| 6.2.2.2 | The DREAMS Partnership | • The "DREAMS Maintenance" section was changed to "DREAMS programming in saturated SNUs" and wording was updated to remove the maintenance plan requirement.<br>• "GeneXpert" and replace with "multi-disease testing platforms" so as not favor one manufacturer or instrument given there are many options on the market. |
| 6.2.4.1 | Prevention in ANC and PMTCT | • Added "DREAMS" to the section<br>• Wording was updated to state that HIV/dual test procurement and integration into testing programs should be done where treatment for syphilis is readily available and ministries of health should work to ensure treatment availability at time of testing. |
| 6.2.5.1 | Voluntary Medical Male Circumcision | • Clarified assent and consent language<br>• Wording on target setting models and testing protocols was updated. |
| 6.3 | HIV Testing Services Strategies: Reaching & Maintaining Global 95-95-95 Goals | • Table 6.3.1 was updated to align with current PEPFAR guidance for HTS within VMMC programs.<br>• Clarified frequency of retesting for key populations.<br>• The paragraph on "Sustainability Planning for HTS" was removed because sustainability considerations are covered in COP/ROP23 Guidance.<br>• Aligned technical considerations with COP/ROP23 guidance on the use of HTS to support re-engagement to HIV treatment services |
| 6.3.1.3 | Infant Diagnosis: Birth Testing, Integrating POC for Early Infant Diagnosis (EID) | Stringent preconditions for birth testing such as: coverage by 2 months for infant virologic testing is >95%, and availability of immediate treatment regimens for neonates who are identified as HIV+, have been removed because countries are following WHO testing guidance and conducting birth testing without this threshold. |
| 6.3.1.5 | Index Testing | • Removed content that is either obsolete or redundant with material and resources available on PEPFAR Solutions Platform<br>• Provided links to relevant PEPFAR Solutions Platform pages |
| 6.3.1.6 | HIV Self-Testing | • Updated to align with current WHO and PEPFAR guidance to promote user choice and therefore to encourage countries to have a mix of blood-based and oral fluid HIVST assays<br>• Updated to align with WHO's and PEPFAR's current guidance for use of HIVST within PrEP programs. |

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| | | • Updated list of HIVST kits that have been pre-qualified by WHO<br>• Updated to emphasize that use and disclosure of results should be voluntary and never forced or coerced<br>• Updated to emphasize the importance of support mechanisms for if and when individuals using HIVST request additional information |
| 6.3.1.7 | Optimized Provider-Initiated Testing and Counseling (PITC) | • Removed Figures 6.3.1.7.1 and 6.3.1.7.2 to strengthen alignment with current HTS program guidance<br>• Updated guidance on use of HIV risk screening tools within PITC settings to further emphasize need for validated tools and to increase focus on highly sensitive HIV self-testing |
| 6.3.1.9 | Community Engagement and Ensuring Quality of HIV Testing Services | Removed obsolete information on SIMS |
| 6.3.2 | Case Finding for Pediatrics | • Wording was updated to be person-centered.<br>• Wording was updated to encourage country teams when setting targets to recalibrate historical testing positivity as needed to ensure adequate HTS commodities are procured to close the case finding and treatment gaps for children. |
| 6.3.2.1 | Pediatric Index Testing Considerations | • Text related to yield (positivity) was removed because case finding for children should not focus on yield.<br>• Language was added to allow for KP and OVC community cadres to support caregivers with HIV mucosal screening of children at home.<br>• Clarification was provided on the use of HIVST as a screening—not a diagnostic—test. |
| 6.3.5 | HIV Testing within Prevention Services | • Renamed section to align with WHO's current approach to providing HTS within HIV prevention programs and to abate confusion over the purpose of HTS within prevention programs<br>• Acknowledged KP programming in the introduction; this was an inadvertent omission from COP/ROP22 Guidance<br>• Revised PrEP bullet to align with current WHO and PEPFAR guidance to promote user choice of blood-based and oral fluid HIVST assays<br>• Revised PrEP bullet to align with current WHO and PEPFAR PrEP implementation guidance to broader use of HIVST within PrEP programs |

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| 6.4.1.2 | Pediatric ART Optimization | • As pediatric treatment continues to evolve, PEPFAR is supportive of ABC/3TC/DTG (pALD) use and country teams should plan accordingly for this product. A protease-inhibitor based regimen is recommended for children with virological failure on DTG or intolerability of DTG. For infants <3 years of age, the LPVr 40/10 mg granules are the preferred product.<br>• PEPFAR funds cannot be used to procure the "4-in1" ABC/3TC/LPV/r capsule until it is FDA approved. For children that are at least 3 years of age, the preferred protease inhibitor product is DRV/r 120/20 mg. |
| 6.4.1.3 | Adolescent and Adult ART Optimization | Wording was updated to include children ≥3 kg and ≥4 weeks of age to be transitioned and maintained on a DTG based regimen. |
| 6.4.2 | Identification and Treatment of Advanced HIV Disease | • Clarification added regarding TB screening in individuals with advanced HIV disease<br>• Cryptococcal guidance was updated to align with WHO guidance |
| 6.4.2.2 | Identification and Treatment of Pediatric Advanced Disease | Text was added to address mortality in CLHIV under 5 years to: (1) support mortality surveillance systems and cause of death audits to allow for targeted mortality prevention efforts; (2) ensure CLHIV newly initiating ART are provided with intensive case management until viral suppression is achieved; and (3) ensure malnutrition is diagnosed and treated early, especially during the first 6 months of ART initiation. |
| 6.4.2.3 | Reducing Mortality and the Aging Cohort | New language was added to address integrated care for adults with comorbidities. |
| 6.4.3 | TB/HIV | Reference to Xpert MTB/RIF Ultra and Truenat MTB Plus with MTB Rif Dx as the currently available mWRDs is outdated and inconsistent with WHO policy. Several other multi-disease testing mWRDs are now available. Wording was updated to reflect these points. |
| 6.4.3.1 | TB Case-Finding Among People Living with HIV | Wording was added to clarify that:<br>• C-Reactive Protein (CRP) blood testing can be done as a point-of-care test or at higher levels of the laboratory network (e.g., centralized laboratory).<br>• WHO recommends rapid molecular diagnostic tests (mWRDs) universally for people living with HIV new or re-engaging in care.<br>• Abnormal chest radiography, including by computer-aided detection (CAD) software, can be regarded as a positive TB clinical screening result.<br>• Bacterial resistance to anti-TB medications can be determined via molecular or phenotypic screening methods. |

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| 6.4.3.2 | Optimizing Treatment for People with TB and HIV | • Wording was added to reflect that in areas with high HIV and TB coinfection, HIV and TB screening, prevention, and care, should be fully integrated with one another.<br>• A recommendation for TB treatment optimization for C/ALHIV was added. |
| 6.4.4 | Cervical Cancer Screening and Treatment | • Removed MER data results from the CXCA-TX in the "Cervical Cancer Screening Approach" paragraph<br>• Clarified that not all aspects of the benchmark list must be achieved prior to transitioning to HPV testing<br>• Clarified that while PEPFAR funds cannot be used to procure HPV vaccines, PEPFAR sites may administer HPV vaccines procured through non-PEPFAR funding |
| 6.4.5 | Approach to Viral Load Testing | • This section was revised to indicate that PSC (plasma separation card) is another sample collection tool.<br>• A reminder that point-of-care VL testing requires plasma samples (not DBS or PSC) was added. |
| 6.4.7 | Monitoring for HIV Drug Resistance (HIVDR) | Wording was updated to better reflect current CADRE protocol. |
| 6.4.8 | Integrated Women's Health | Tenofovir, lamivudine, and dolutegravir (TLD) regimen language was updated. |
| 6.5 | PEPFAR's Key Populations Approach and Strategy | Wording was updated to delete the reference to an illustrative table. |
| 6.5.1 | Providing Quality, Person-Centered HIV Services with Key Populations in Prevention, Diagnosis, Treatment, and Care | Language on PEPFAR's opposition to so-called "conversion therapy" was enhanced, in line with the June 2022 White House Executive Order. |
| 6.5.1.1 | Prevention for Key Populations | • Language on PEPFAR's opposition to so-called "conversion therapy" was enhanced, in line with the June 2022 White House Executive Order.<br>• Wording was added to reflect the FDA approval of long-acting injectable cabotegravir.<br>• Changes were made to reflect recently released WHO consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment, and care for key populations. |
| 6.5.1.4 | Structural Interventions for Key Populations | • Updated critical enabling strategies to account for the safety and security of implementers of KP interventions<br>• Updated a section reference to align with new guidance section numbering |

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| 6.5.3.1 | KP Surveys and Surveillance | Language was added to address how BBS implementation can be expedited and to strengthen requirements around KP and community engagement. |
| 6.6.1.4 | Multi-disease use of Diagnostic Testing Platforms for HIV, TB, COVID-19, and HPV | Transitioned terminology from “multiplex” to “multi-disease” to align with 2023 COP/ROP Guidance Document. |
| 6.6.4 | Faith and Community Engagement | • Wording was updated to reflect that Faith and Community Initiative (FCI) central funding has ended and PEPFAR encourages OUs to integrate effective FCI models into core COP programming.<br>• Four new Faith and Community Steering Committee recommendations for OUs to drive effective engagement are provided. |
| 6.6.7 | Optimizing HRH Staffing for Maximum Impact and Sustainability | • Wording was updated to reflect the focus on sustainability in PEPFAR’s new strategic direction, and to make the section more “evergreen” in relation to the ongoing realities of COVID.<br>• Guidance on HRIS investments has been updated to align with COP/ROP23 Guidance which states that HRIS investments must be made into government systems rather than PEPFAR-specific HRIS. |
| 6.6.8<br>**REDRAFTED** | Impact-Driven Information Systems and Data Management Investments (Previously "Public Health Surveillance and Information Systems") | This section was updated based on feedback from the 2022 Data Summit and to align with: (**1**) the current PEPFAR vision for impact driven information systems and data management; (**2**) reliance on partner government owned or endorsed one-health information ecosystem; (**3**) tight collaboration across agencies; and (**4**) improved alignment with WHO person-centered strategic information. The section now provides considerations for unified digital health ecosystems, and for national integrated, longitudinal individual level data repositories. These efforts can help sustain PEPFAR’s strategic information investments. |
| 6.6.8.4 | Recent Infection Surveillance Among Newly Diagnosed PLHIV | • This section was 6.6.8.1 in the 2022 COP/ROP Guidance Technical Considerations Section.<br>• Language was updated to emphasize that recent infection results are not used to inform clinical or case management, and individual-level results are not actionable.<br>• Language on implementation status in PEPFAR countries was updated. |
| 6.6.8.5 | HIV Recency Surveillance and Response Among | • This section was 6.6.8.2 in the 2022 COP/ROP Guidance Technical Considerations Section.<br>• Wording was removed to clarify the policy around discouraging including recency results in patient records. |

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| | Newly Diagnosed PLHIV | • "Case management" wording was added to replicate language in 6.6.8.1. |
| 6.6.9 (and associated sub-heads: 6.6.9.1, 6.6.9.2, 6.6.9.3, and 6.6.9.4) **REDRAFTED** | Sustainability of the HIV Response (Previously "Planning for Sustainable Epidemic Control") | This is a rewrite of Section 6.6.9 of the technical consideration section that was in COP/ROP22 Guidance on sustainability. PEPFAR's strategy for sustainability has advanced significantly since last year, and this new sustainability section reflects technical considerations related to the new strategic priorities and alignment with the PEPFAR 5-Year Strategy. |
| **Individual:** | **Individual:** | **Individual:** |
| 6.7.1 | Infection Prevention and Control | Replaced SIMS 2.0–4.0 reference with SIMS 4.1. |
| 6.8 **NEWLY ADDED TECH CON** | Surveys-Surveillance, Research, and Evaluation (SRE) Technical Considerations | An interagency SRE ST3 team was established to review past feedback and draft updated SRE guidance. This newly added tech con reflects the team's recommendations. |
| 6.9 **NEWLY ADDED TECH CON** | Addressing Barriers to Health Equity: Stigma, Discrimination, and Human Rights | This is a new section providing technical and implementation considerations to support requirements outlined in COP/ROP23 Guidance Section 3.1.1.4. |