PEPFAR 2022 Country and Regional Operational Plan (COP/ROP) Guidance for all PEPFAR-Supported Countries

What's New in COP/ROP22

COP22 guidance emphasizes themes of Completing the Mission (95/95/95), Building Enduring capabilities, and Building Lasting Collaborations. COP22 shifts language from "client-centered" to "person-centered."

Equity has been added to Accountability, Transparency, and Impact as a guiding pillar for PEPFAR and a key theme for COP22. Persistent inequalities experienced by children, key populations, and adolescent girls and young women are prioritized.

Language. In this document, PEPFAR has begun to modify language to move from 'client-centered' toward a 'person-centered' or 'people-centered' orientation. This change is in alignment with the UNAIDS Global AIDS Strategy and with operating principles noted in Section 1.3, and it emphasizes recognition that individuals served by PEPFAR-supported partners are not only clients with HIV as a single condition to be addressed in visits related to diagnosis and treatment: they are people who make their own decisions and deserve to have their rights and preferences respected with differentiated services adapted to their life course and social context.

Minimum Program Requirements are updated to demonstrate progress in equity, stigma, discrimination, and human rights, to add KP-led and women-led organizations among local partners, and to include infection prevention and control activities with quality assurance and continuous quality improvement functions and increase flexibility for targeted assessments.

Quality Assurance standards supported by SIMS will be updated to better translate Minimum Program Requirements into site standards and increase flexibility for targeted assessments. (Section 3).

Testing guidance is updated, highlighting the need for a strategic mix of testing modalities that adapts as countries approach treatment saturation and takes into account positivity rate, cost, number of positives, and epidemiologic impact. Safe, ethical index testing should be offered to all who are eligible, including newly diagnosed PLHIV. Case finding for undiagnosed children living with HIV is a high priority requiring specific planning and investment.

Sustainability Guidance is updated as more countries are at or near 95/95/95 benchmarks, underscoring PEPFAR's need to move toward a vision for sustained epidemic control. Sensible adaptations moving toward sustainability will be incorporated into COP22 planning.

Technical Considerations have been updated, and highlights of "What's New" are included at the beginning of each section. Selected highlights included here.

- Approach to CD4 testing revised to allow identification and improve management of advanced HIV disease (6.4.2.1)
- Intensified TB case finding among PLHIV: 2021 WHO updated guidelines (6.4.3)
- Updated cervical cancer screening and treatment guidelines and algorithm (6.4.4)
- Key Populations Approach and Strategy consolidated and updated. (6.5)
- New Gender Equality section (Section 6.6.2) and added guidance on clinical enquiry for Gender Based Violence and Violence Against Children (6.6.2.1)
- Behavioral health content reorganized into two sections: Mental Illness and Psychosocial Support (6.6.5.1, 6.6.5.2)

COP Planning Steps (Section 7) is updated with analytic recommendations and examples for programs that are approaching epidemic control.

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Part A: COP/ROP22 GUIDANCE: STRATEGY

EXECUTIVE SUMMARY

PEPFAR Country/Regional Operational Planning for FY2023 (COP/ROP22) planning represents a momentous and pivotal twentieth year for PEPFAR implementation. As PEPFAR teams have worked with country governments and other stakeholders to scale HIV services, nearly 20 million people living with HIV are now sustained on lifesaving, continuous antiretroviral treatment, and 94% of those tested are virally suppressed. Globally, over 20PEPFAR-supported countries are at, or approaching, UNAIDS targets that represent conditions of epidemic control of HIV, where the number of new cases falls below the declining number of deaths among people living with HIV. We recognize this great accomplishment has been made possible by the generosity and commitment of the people of the United States, Congress, as well as the passion, dedication, and partnership of many organizations and individuals around the world.

PEPFAR's unprecedented achievement has progressed in spite of the devastating impact of COVID-19 across the world. PEPFAR teams, partners, and health systems have substantially helped country governments respond to this new pandemic, while adapting PEPFAR interventions in important ways to sustain and advance HIV prevention, care, and treatment efforts in the context of COVID-19.

COP22 guidance for program implementation in FY2023 highlights themes proposed for the PEPFAR Strategy for 2021-2025, which is under development, moving PEPFAR countries toward sustained epidemic control of HIV by supporting equitable health services and solutions, building enduring national health systems and capabilities, and establishing lasting collaborations.

Key areas for focus as stakeholders approach planning for COP22 guidance for implementation in FY2023 include the following:

- PEPFAR must focus on equity across the PEPFAR enterprise and use an equity lens to ensure services are tailored for those who have not yet fully experienced the benefits of HIV epidemic control, including key populations,[1] children, adolescent girls and young women, and other priority populations. Specific resources, program design and

[1] Key populations are defined here and elsewhere in COP guidance as: Men who have sex with men, transgender people, sex workers, people who inject drugs, and people in prisons and other enclosed settings.

leadership by members of impacted communities, and accountability to the people being served are key elements of planning.

- PEPFAR teams will plan for sensible adaptations and changes in program design as PEPFAR transitions from broad and rapid scaling to sustaining effective, efficient prevention and treatment services.
- Plans should ensure that PEPFAR's actions are supporting enduring public health systems and capabilities. That is, people and systems that serve the PEPFAR mission, but are trained and designed to be resilient public health assets for a long-term public health response to HIV, which can be adapted for responses to other public health threats and emergencies.
- PEPFAR programs will actively connect and seek to align efforts of funders, country governments, communities, and other stakeholders to advance a unified strong and effective multi-sector national vision to support HIV prevention, care, and treatment efforts.

Much work remains in completing PEPFAR's mission. More than ever before, COP22 represents an opportunity to reinforce the gains and progress to date, redouble efforts to ensure equity, and lay groundwork for long-term, sustained control of the HIV epidemic and a world without AIDS.

Notes on Language

In this document, PEPFAR has begun to modify language to move from 'client-centered' toward 'person-centered' or 'people-centered' orientation. This change is in alignment with the Global AIDS Strategy and operating principles noted in Section 1.3, and it emphasizes recognition that individuals served by PEPFAR-supported partners are not only clients whose preferences about services matter: They are people who make their own decisions and deserve to have differentiated services adapted to their context, where their rights and preferences respected.

PEPFAR believes that using more inclusive language can be a powerful way of ensuring that people are respected, and services are inclusive and welcoming. We also acknowledge that PEPFAR works with many stakeholders and using fully inclusive language in COP guidance and throughout PEPFAR will require some time as stakeholders achieve consensus and move together. In the meantime, PEPFAR partners are expected to plan and implement services that are fully inclusive and welcoming for all people PEPFAR serves, at all sites, and in all communities.

1.0 PEPFAR MANDATE AND PRINCIPLES

1.1 Background

The United States Government (USG) launched the President's Emergency Plan for AIDS Relief (PEPFAR) in response to the global AIDS crisis in 2003. Congress passed, with strong bipartisan support, the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (US Leadership Act), which became law just 4 months after President George W. Bush issued a call to action in the State of the Union Address that year. In the 19 years since its inception, PEPFAR has invested more than $100 billion in the global AIDS response, the largest public health effort against a single disease by any country in history, saving more than 20 million lives, preventing millions of HIV infections, and accelerating progress toward controlling the global epidemic.

1.2 Mandate and Authorities

The PEPFAR Extension Act of 2018 extends PEPFAR provisions in the Leadership Act through 2023. The Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC) is housed within the U.S. State Department under the Secretary of State and provides oversight of PEPFAR. The U.S. Global AIDS Coordinator is a presidentially appointed position with advice and consent of the Senate and holds the rank of Ambassador-at-Large. The U.S. Global AIDS Coordinator position leads S/GAC and oversees the entire PEPFAR program, including the implementation in the field by U.S. government implementing agencies as further overseen by the U.S. Chiefs of Mission.

The U.S Global AIDS Coordinator leads all U.S. Government (USG) international efforts to combat HIV and AIDS. In this capacity, the U.S Global AIDS Coordinator transfers and allocates funds to relevant executive branch agencies for the purposes of combatting HIV/AIDS globally and provides grants to or enters into contracts with non-governmental organizations (NGOs) to carry out such work. The Global AIDS Coordinator provides oversight and coordination of all resources and international activities of the USG to combat the HIV/AIDS pandemic, including all programs, projects, and activities of the USG relating to the HIV/AIDS pandemic under the U.S. Leadership Act. Specific duties include:

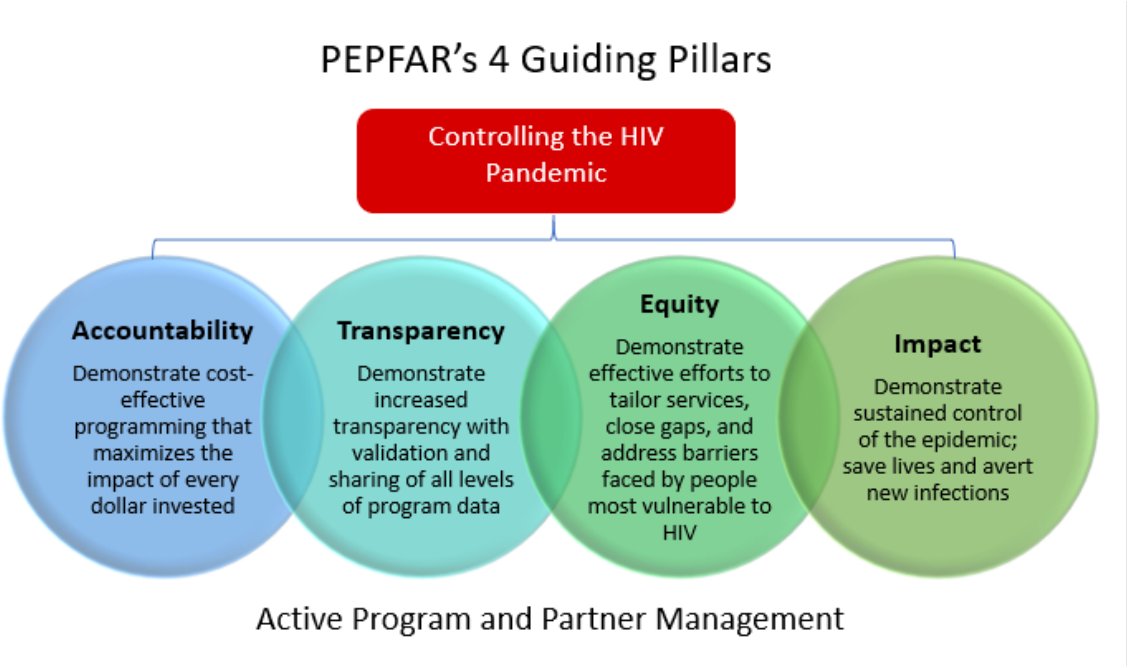
- Ensuring program and policy coordination among relevant executive branch agencies
- Ensuring alignment of program activities with agency expertise and for program success
- Coordinating interagency efforts related to HIV/AIDS program implementation
- Resolving policy, program, and funding disputes among the relevant executive branch agencies
- Avoiding duplication of effort
- Directly approving all activities of the United States (including funding) related to combatting HIV/AIDS in the countries in which the United States is implementing HIV/AIDS programs as part of its foreign assistance program
- Establishing due diligence criteria for all recipients of funds appropriated for HIV/AIDS assistance pursuant to the authorization under the U.S. Leadership Act and all activities necessary to assess the measurable outcomes of USG HIV/AIDS activities.

Many of these duties are administered through the annual Country Operational Planning/Regional Operational Planning (COP/ROP) process. The COP/ROP is developed as part of an annual assessment, planning, budgeting, and monitoring cycle led by S/GAC.

1.3 Principles

During the process of drafting the PEPFAR Strategy for 2021-2025, which is under development, and in harmony with the emphasis of the UNAIDS Global AIDS Strategy, it became clear that Equity should be added to Accountability, Transparency, and Impact as a guiding pillar in PEPFAR's approach to HIV Epidemic Control. In addition, a variety of discussions and listening sessions with PEPFAR team members and stakeholders led to the development of ten Core Operating Principles and Values listed below, which describe how we aspire to conduct our work as a PEPFAR enterprise.

Figure 1.3.1 PEPFAR's 4 Guiding Pillars



PEPFAR Core Operating Principles and Values

1. Local Ownership: Support an HIV response that is owned and led by partner governments, communities, local partners, and people impacted by HIV.

2. Person-Centered: Ensure that HIV and other health services are delivered with people at the center, recognizing and responding to what is important to people receiving PEPFAR-supported services and affirming of their human rights.

3. Evidence-Based: Drive expansion of HIV prevention and treatment interventions that are firmly grounded in the latest scientific and programmatic evidence base, to ensure optimal health outcomes.

4. Data-Driven: Ensure program and policy decisions are driven by the most robust, granular, and transparent data available to reach those with the greatest need and at highest risk, with the capacity to rapidly adapt to optimally meet the needs of clients and respond to emerging threats.

5. Diversity, Equity, Inclusion, and Accessibility (DEIA): Uphold, promote, and advance DEIA principles and practices across all PEPFAR programs, business practices, and workforce. Support zero tolerance for exploitation or discrimination based on sexual orientation, race, religion, disability, age, or gender.

6. Gender-Responsive: Work to ensure PEPFAR programs support gender equity and equality, and are gender-affirming, including by preventing and combating discrimination on the basis of gender identity or sexual orientation.

7. Collaboration and Partnership: Strengthen cooperation, coordination, and shared responsibility with partner country governments, civil society (including faith-based, key populations-led, women-led, and other community organizations), the private sector, multilateral institutions, and people living with HIV.

8. Agility and Adaptability: Maintain agility and adaptability in the face of emerging threats, changing conditions, and new opportunities.

9. Resilience: Foster the resilience of countries, communities, partners, and individuals to confront and overcome adversity and sustain long-term impact.

10. Linkage and Integration: Where beneficial and appropriate, link to and integrate HIV services with other related U.S. government health investments and development priorities to support progress toward achieving UN Sustainable Development Goal (SDG) 3 while also advancing other interdependent SDGs.

1.4 Roles of S/GAC Staff

PEPFAR Chairs. To execute S/GAC's authorities, each PEPFAR Chair serves as the most senior S/GAC representative for an assigned Operating Unit (OU). Each Chair facilitates high-level programmatic strategy for that OU and guides technical, financial, and operational matters, in accordance with all applicable law, regulations and policy guidance, on behalf of S/GAC, with the overall goal of achieving sustained epidemic control. Responsibilities include overall strategic direction of the PEPFAR program and business processes for assigned OUs, directing and monitoring PEPFAR-funded activities with the field interagency team and headquarters Country Accountability and Support Team (CAST). Chairs also convene and guide staff engaged in that OU, such as the PEPFAR Program Manager, S/GAC Intra-office Liaisons and Implementation Subject Matter Experts (ISMEs), plus establish and maintain productive working relationships with key USG and non-USG stakeholders engaged in the PEPFAR program. See Section 5.8 for information on the CAST model.

PEPFAR Program Managers (PPM). To support the execution of S/GAC's mandate, each PEPFAR Program Manager serves as the day-to-day point-of-contact for an assigned OU. The PPM works alongside the Chair on the programmatic strategy for that OU, including work on

technical, financial, and operational matters, in accordance with all applicable law, regulations and policy guidance, on behalf of S/GAC, with the overall goal of achieving epidemic control. PPMs are responsible for coordinating and facilitating collaboration among Field and HQ staff involved in the ongoing implementation and management of PEPFAR activities in the assigned OUs; supporting the PEPFAR Chair to establish and maintain productive working relationships among stakeholders; and managing, coordinating, and facilitating the implementation of the PEPFAR program and PEPFAR business processes for their assigned OUs.

S/GAC Liaisons. To facilitate program review and planning processes, S/GAC has assigned Liaisons from the S/GAC Program Efficiency Team (PET), Data Use for Impact Team (DUIT), and Management and Budget Unit (M&B) to each OU. Liaisons work with the Chair and PPM, providing analytic and data visualization assistance, reviewing, and summarizing COP/ROP tools, databases, and budgets to facilitate completion of key business processes and support decision-making. Liaisons also work with OU field teams to help address questions and troubleshoot with SI and finance colleagues during COP, POART, OPU and end of year reporting activities, particularly providing technical assistance and expertise on COP/ROP tools .

1.5 Roles of PEPFAR Country Coordination Offices

PEPFAR Coordinators. Each PEPFAR OU has an in-country PEPFAR Coordinator or designated Point of Contact for coordination, and some larger programs also have a Deputy Coordinator. The PEPFAR Coordinator reports to the Deputy Chief of Mission (DCM) or U.S. Chief of Mission (COM) who has primary country-level oversight of the PEPFAR program for that specific country. The PEPFAR Coordinator also may supervise other PEPFAR Coordination Office staff. PEPFAR programs are planned in country and thus the U.S. Ambassadors in country are the lead of that respective country's plan. The PEPFAR Coordinator is a liaison among Embassy sections, including in country USG implementing agency staff. The role also communicates directly with the PEPFAR Program Manager and PEPFAR Chair at S/GAC and facilitates interagency planning, reporting, and other external engagement to help ensure optimal complementarity of PEPFAR-funded interventions with other programs in country, such as those of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

2.0 PEPFAR STRATEGY AND PRIORITIES

2.1 Global Update

2.1.1 Progress Towards Epidemic Control

HIV treatment and prevention services have had a dramatic impact on new infections and all-cause mortality among people living with HIV. Many PEPFAR-supported countries are at a point now where the number of people needing HIV treatment services is not increasing year after year, HIV prevalence is decreasing, and incidence and mortality have been cut in half over the last 10 years. These are important markers of progress for the HIV pandemic – reducing death and illness and reducing its long-term financial impact. In countries that have reached HIV epidemic control, it was accomplished without a vaccine, through implementation of prioritized programs to reach the UNAIDS 2025 Global Targets of 95-95-95. Implementation of effective programs in an equitable manner has been pivotal in this effort to control HIV, to save lives, and to have a stabilizing impact on financial and health systems.

Over the course of several devastating surges, the global COVID-19 pandemic has tested the resilience and durability of the PEPFAR program. Communities have continuously adapted in response to COVID-19 over the past 22 months. With partner country governments, PEPFAR programs have adapted, using granular data to proactively respond to COVID-19 and to ensure HIV prevention and treatment services are available in an accessible and safe manner. Understanding potential changes in HIV incidence and demographic shifts, particularly in the under 35-year-old population, is a priority for PEPFAR to mitigate the impacts of COVID-19 on HIV disease burden.

The Population-based HIV Impact Assessment (PHIA) surveys continue to measure critical epidemiologic and program outcomes at subnational levels, providing data on progress by population and geography as well as information on gaps in routine health information data. The Lesotho and Zimbabwe PHIA surveys, completed in 2020 prior to COVID-19 surges, showed the impact of focused implementation of treatment and prevention services over the past 5

years. Data from the second round of PHIA surveys in Botswana, Uganda, Malawi, and Zambia later this year will provide a more comprehensive understanding about successes and remaining gaps in each of these countries.

Zimbabwe, Lesotho, Namibia, Eswatini and Rwanda have reached over 73% community viral suppression for all adults (Figure 2.1.1.1), reflecting achievement of the UNAIDS 2020 90-90-90 viral suppression target. Zimbabwe and Lesotho have shown that population and geographic focus can also achieve this milestone by age/sex bands (Figure 2.1.1.3 – Figure 2.1.1.5). In order to continue to maintain epidemic control, the 15- to 24-year-old population must be a focus for 95-95-95 (Figure 2.1.1.3). Reliable, timely, disaggregated routine health data from laboratories, clinical facilities, and pharmacies are critical for day-to-day patient and program management. As treatment and prevention programs have effectively scaled, the data systems have also been scaling and should be institutionalized as enduring capabilities in partner countries.

Figure 2.1.1.1: Progress towards 95/95/95 across select countries in Southern, East and West Africa

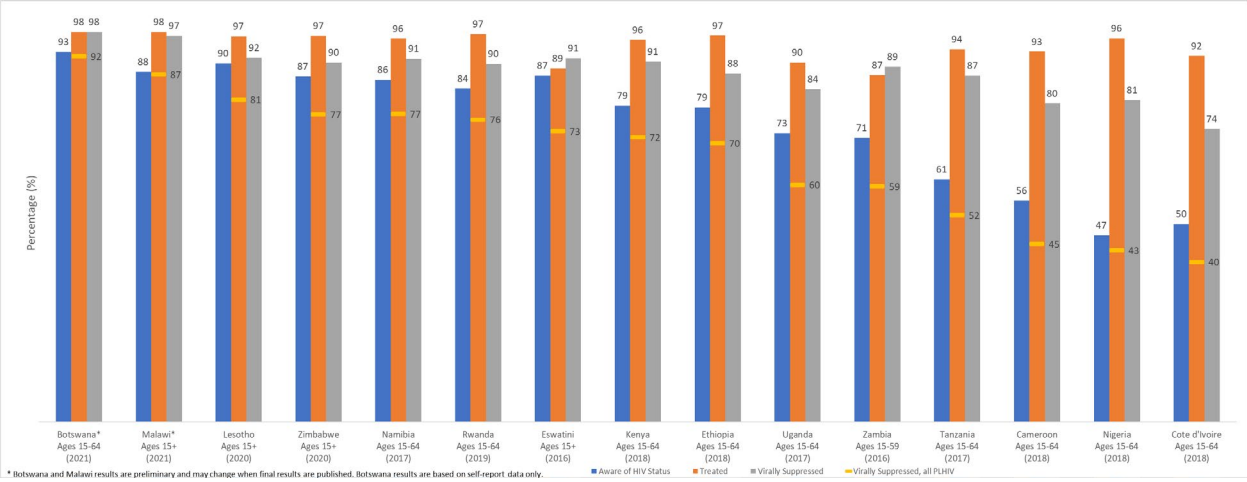


Figure 2.1.1.2: Projected progress towards 95/95/95 across select countries in Southern, East and West Africa

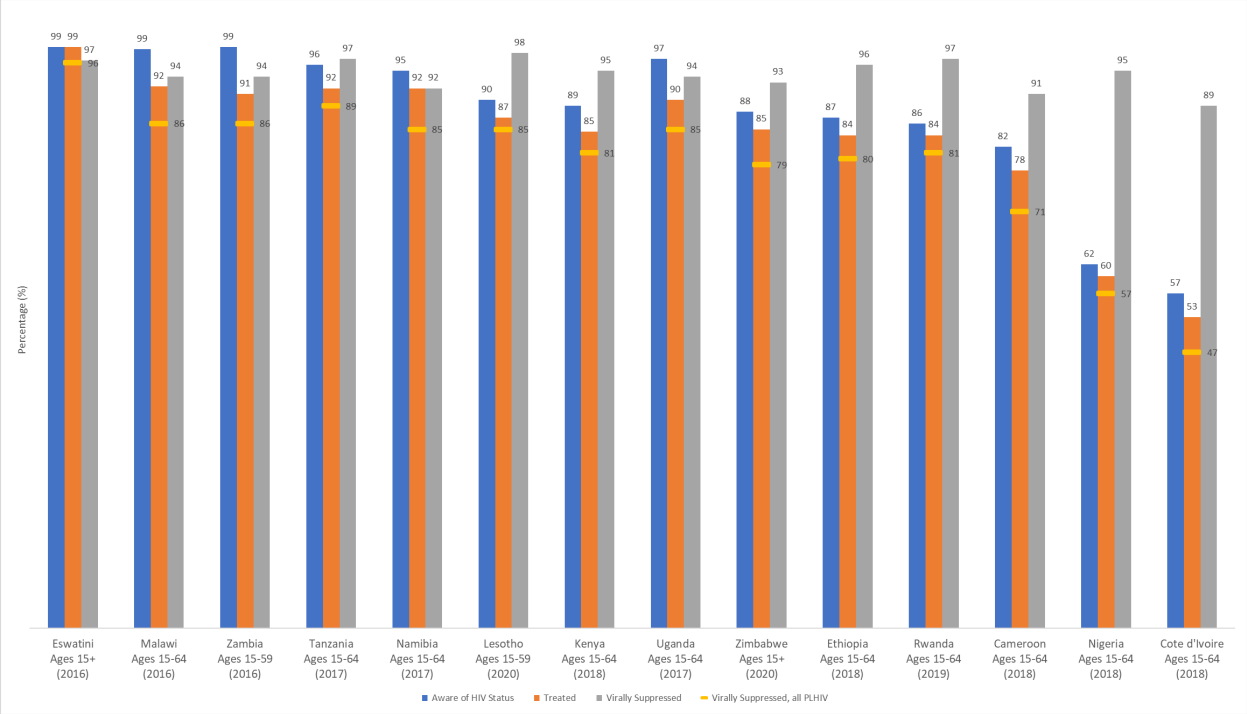
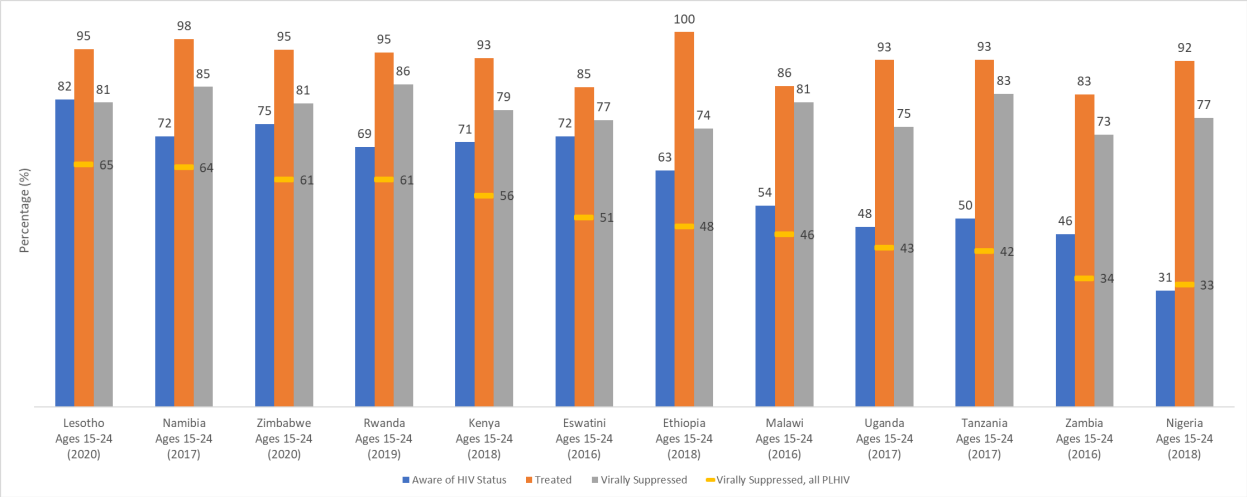


Figure 2.1.1.3: Progress towards 95/95/95 among 15- to 24-year-olds across select countries in Southern, East and West Africa[2]



[2] Progress Towards 95/95/95 tables, including 15–24-year-olds and adult males and females; Source: PEPFAR PHIA; Note: Those treated are shown as a percent of those aware of their HIV status; those virally suppressed are shown as a percent of those treated

Figure 2.1.1.4: Progress towards 95/95/95 among adult men across select countries in Southern, East and West Africa

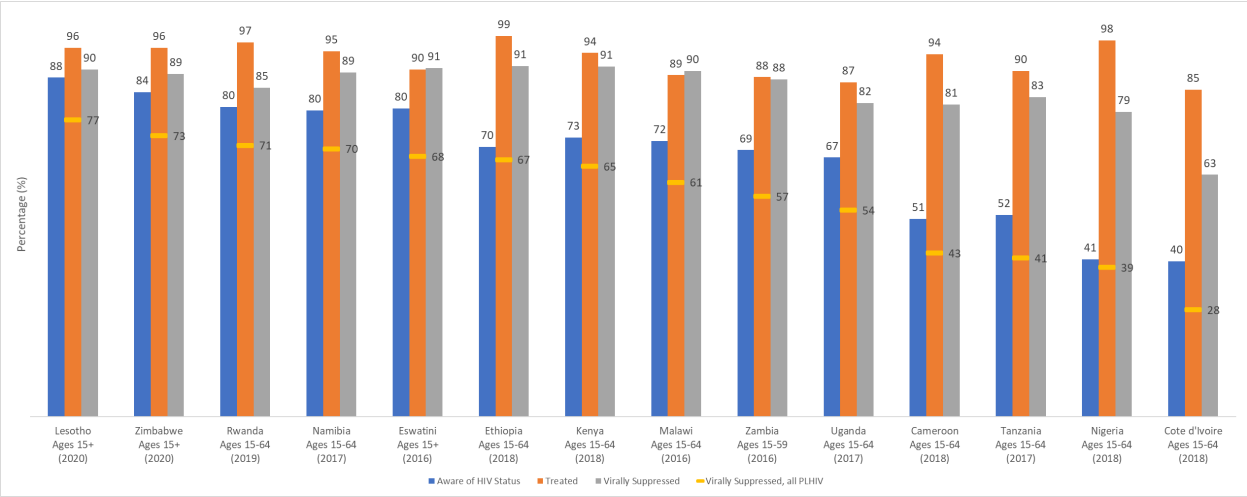
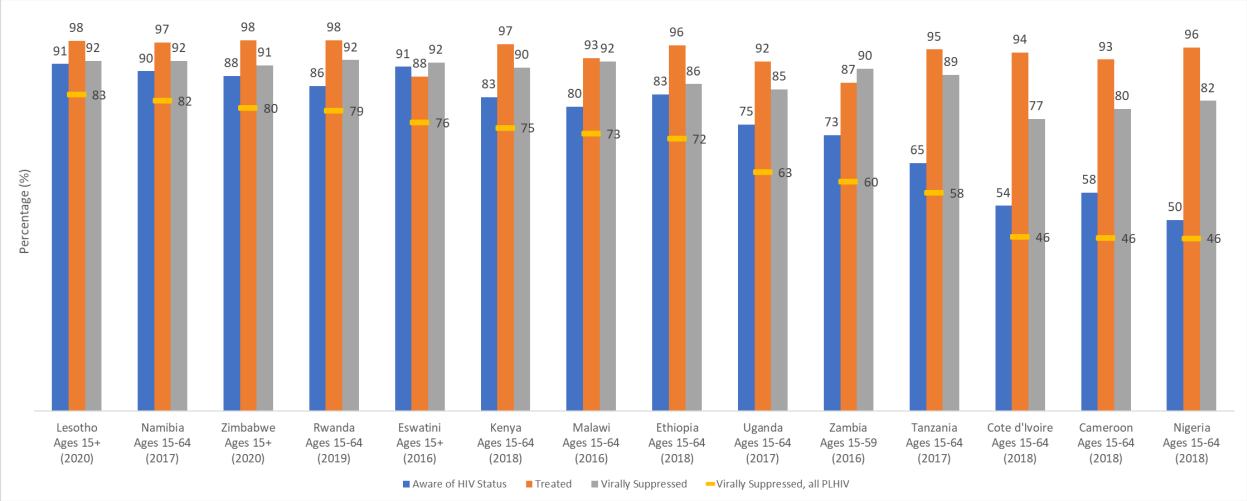


Figure 2.1.1.5: Progress towards 95/95/95 among adult women across select countries in Southern, East and West Africa



PEPFAR defines national HIV epidemic control as the point at which the total number of new HIV infections falls below the total number of deaths from all causes among individuals with HIV[3] (the classic R_0 to R_i approach to infectious diseases), with both new infections and deaths among people living with HIV low and declining. Country graphs starting at 2.1.1.24 show time trends which allow us to categorize countries' epidemic trajectory and clinical cascade. Low HIV incidence alone may not be sufficient for sustained epidemiologic impact: for example, countries

[3] PEPFAR Strategy for Accelerating Epidemic Control, 2017-2020.

that have demographic shifts such as a 'youth bulge' may experience increasing numbers of HIV infections without major increases in incidence.

Figure 2.1.1.6 shows the relationship of trends for all-cause mortality among people living with HIV (PLHIV) and new HIV infections in Zimbabwe, a country that in 2004 had 18% HIV prevalence, nearly 100,000 new infections annually and devastating HIV-related mortality. Through treatment and prevention services Zimbabwe now has fewer than 25,000 new infections annually. HIV prevalence is now 13%, and people living with HIV are benefiting from treatment and thriving.

Figure 2.1.1.6: New infections vs total deaths among PLHIV in Zimbabwe

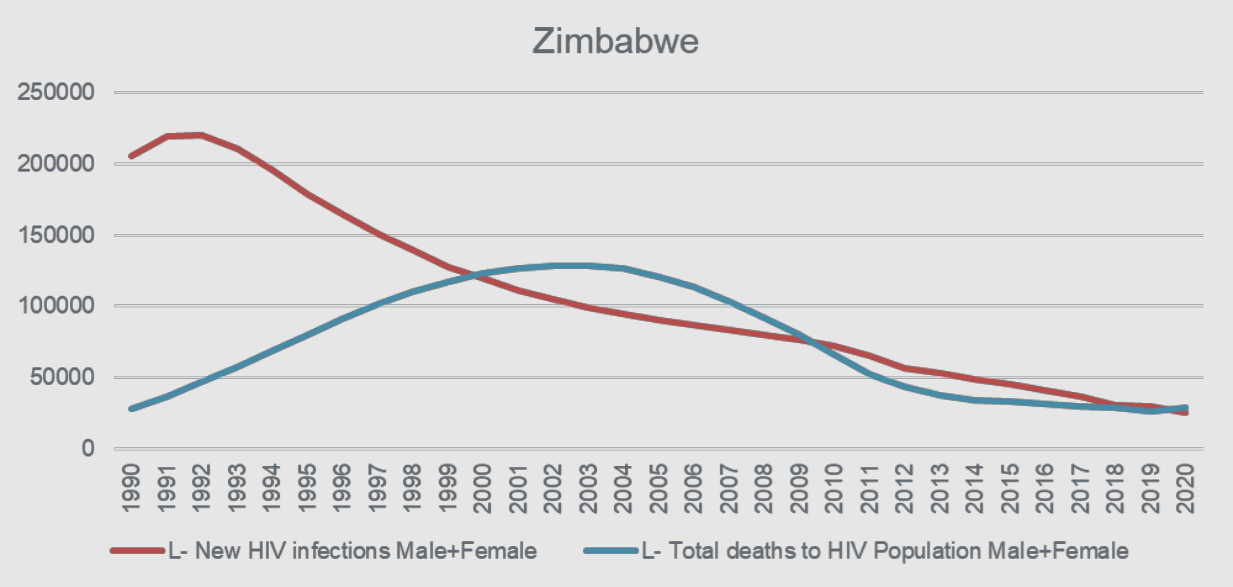
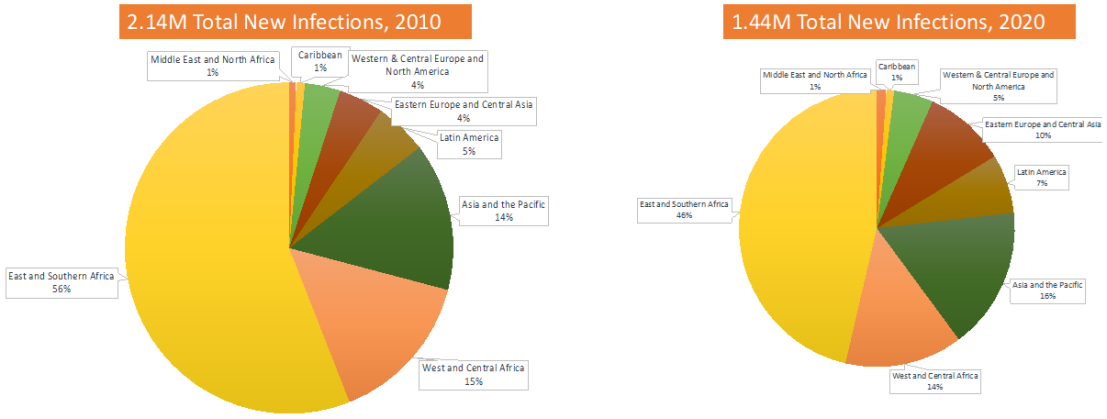


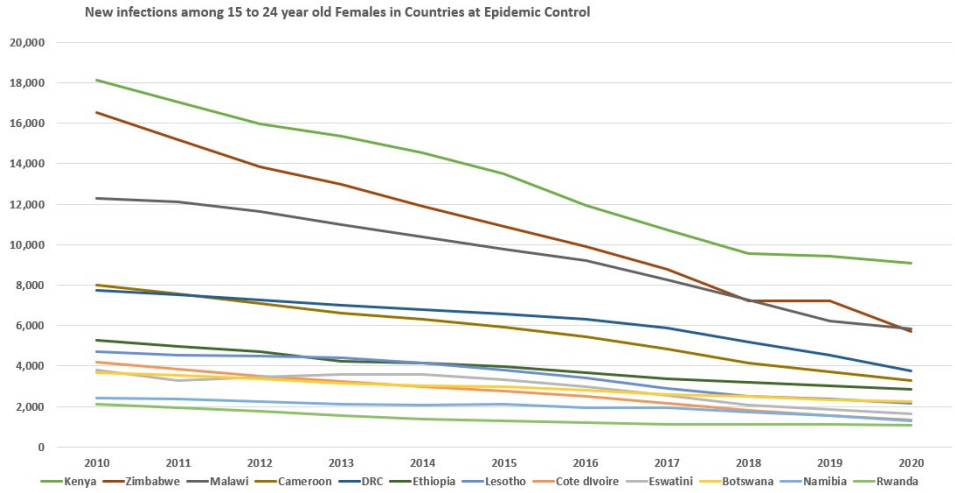
Figure 2.1.1.7: Change in New Infections by Region 2010 – 2020



Globally, since 2010 there has been a 34% reduction in new infections (Fig. 2.1.1.7). The largest declines in new infections are in East and Southern African (ESA) countries with declines of 43%, while new infections in Eastern Europe and Central Asia increased in the same time period. People in South Africa and Mozambique experienced nearly half of the 670,000 new infections in the ESA region, followed by Zambia, Tanzania, and Uganda. New infections in West and Central Africa declined by 37%, in the Caribbean by 28%, and in Asia by 21%. Reaching 95/95/95 in these countries is essential to control the global HIV pandemic.

Despite the youth bulge in ESA, dramatic decreases in new infections among young people are also occurring. Countries achieving epidemic control have also demonstrated dramatic declines of over 50% in new infections among adolescent girls and young women, and in Zimbabwe the decline for adolescent girls and young women was 65% (Figure 2.1.1.8 - Figure 2.1.1.11). Despite this remarkable impact, great disparities still exist between 15- to 25-year-old males and females, where new infections among young males are half those of young females. Males in Zimbabwe had a 75% decrease in new infections over the 10-year time period (Figure 2.1.1.10). This pattern is seen across all countries in East and Southern Africa. Further driving down incidence among adolescent girls and young women is a critical challenge, particularly with the growing population of adolescent girls and young women resulting from the youth bulge. New infections in countries not at epidemic control are sustained at high levels and similar to 2010 (Figure 2.1.1.9 and Figure 2.1.1.11).

Figure 2.1.1.8: New Infections among Females 15- to 24-years-old in countries at Epidemic Control[4]



[4] Source: UNAIDS 2021 Estimates

Figure 2.1.1.9: New Infections among Females among 15 to 24 years old in countries not at Epidemic Control[5]

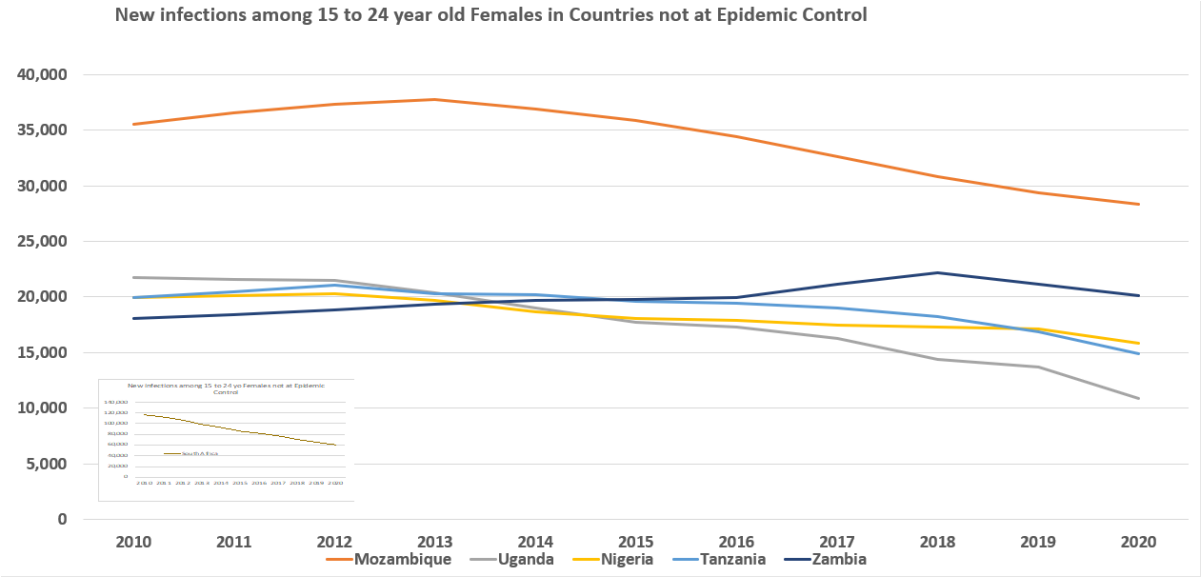
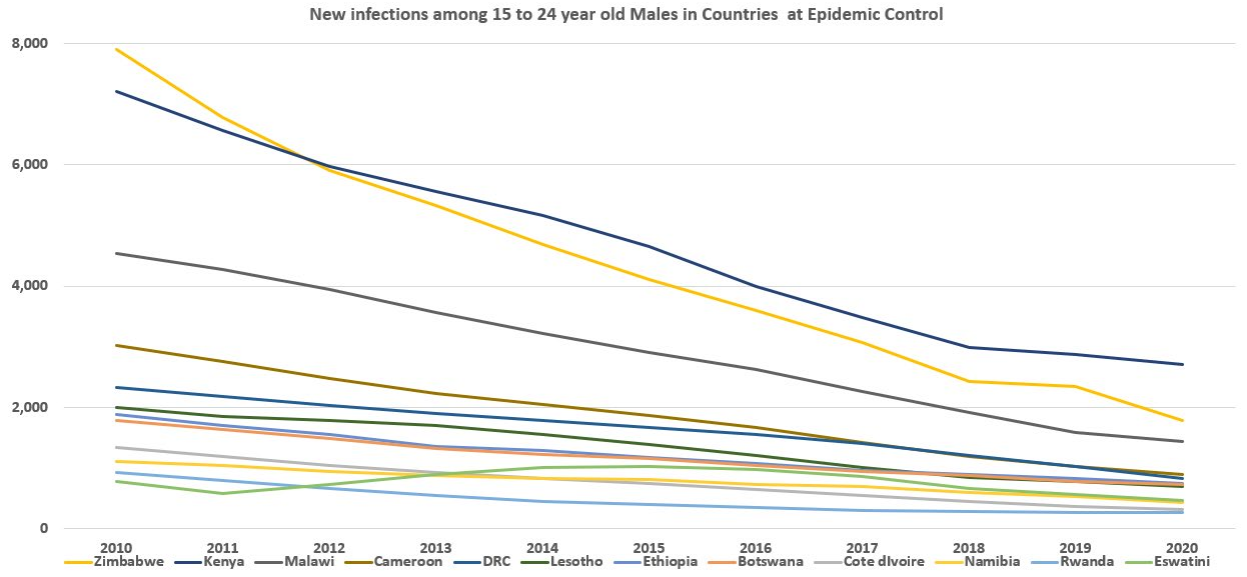
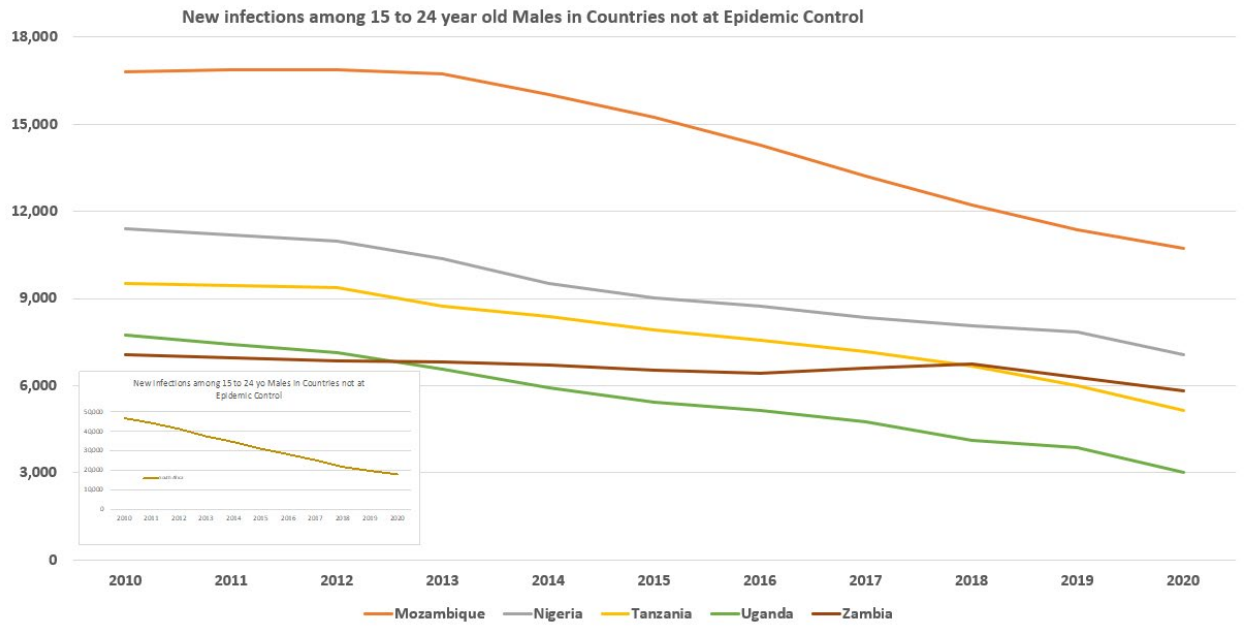


Figure 2.1.1.10: New Infections among Males 15 to 24 years old in countries at Epidemic Control[6]



[5] Ibid.
[6] Ibid.

Figure 2.1.1.11: New Infections among Males 15 to 24 years old in countries not at Epidemic Control[7]

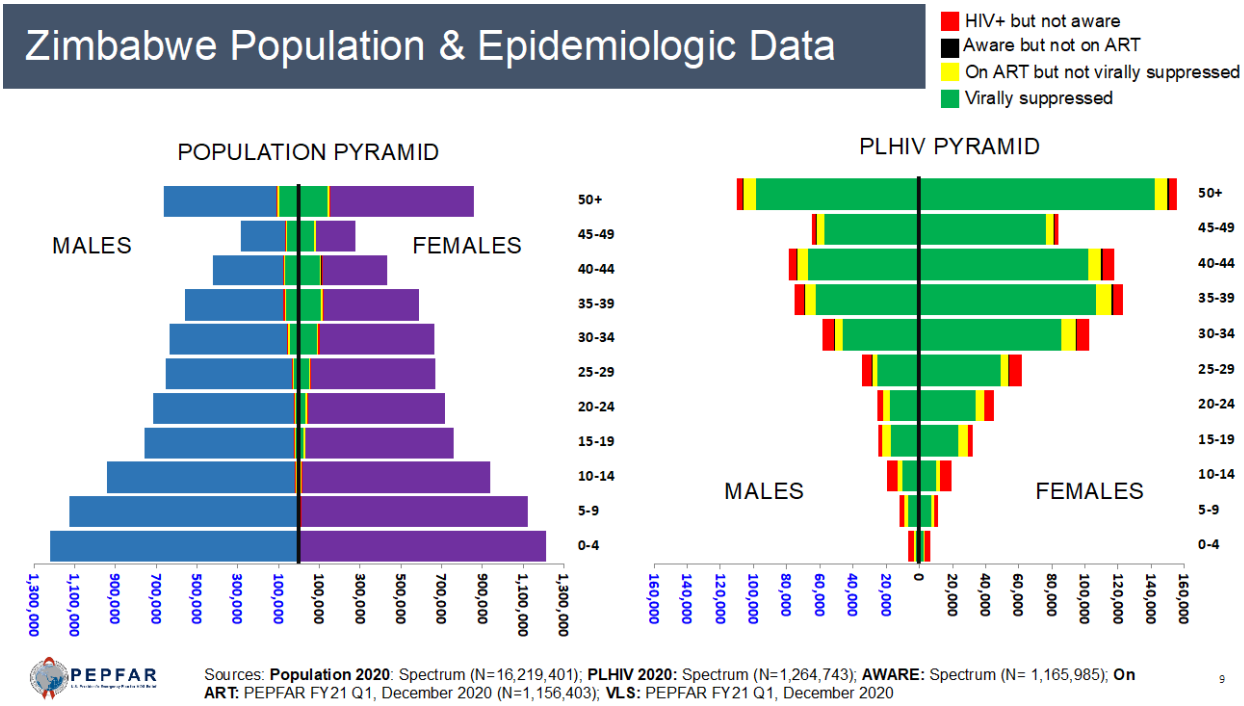


Results from the 2020 Zimbabwe PHIA demonstrate that an equity-driven approach, using granular data to identify gaps and continually make real-time program changes, can lead to effective and sustainable progress towards epidemic control. Zimbabwe demonstrates nearly optimal ART coverage reflected in their national numbers, with 96% of men and 98% of women who know their status on ART in 2020, compared to 88% and 89% coverage, respectively, in the 2016 PHIA. To reach these high levels of coverage, Zimbabwe evolved their broad case finding program to concentrate on closing gaps in particular regions and among particular population groups, including key populations and children. Zimbabwe also shifted their focus from new treatment initiation to maintenance of people living with HIV on continuous treatment with high levels of viral suppression. By triangulating site-level data and SIMS-based monitoring, Zimbabwe adjusted and improved sites for better client care. Impressively, Zimbabwe was able to impact the epidemic trajectory for young adults, reducing the annual HIV incidence among 25-34-year-olds from 0.81 (PHIA 2016) to 0.5 (PHIA 2020), with improvements in the clinical cascade for 15-24-year-olds, moving from 87% (PHIA 2016) to 95% (PHIA 2020) of young adults who know their status on ART and increasing from 43% to 58% in population VLS.

[7] Ibid.

This definition of epidemic control does not suggest near-term elimination or eradication of HIV, as may be possible with other infectious diseases, but rather suggests a decline of persons with HIV in a population, achieved through the reduction of new HIV infections when mortality among people living with HIV is steady or declining, consistent with natural aging. This can be observed through a comparison of the general population pyramid and the HIV population pyramid. In Zimbabwe, the general population shows a higher proportion of the population among younger age groups while the HIV population pyramid shows HIV infections primarily among older age groups (Fig 2.1.1.12).

Figure 2.1.1.12: Zimbabwe general population pyramid and HIV population pyramid



As shown in the Population and HIV Epidemiologic pyramid, the growing number of people over 50 on ART is remarkable. This trend is also seen across all PEPFAR-supported programs: Over 20% of the PEPFAR HIV treatment population is above 50 years old. In line with UNAIDS, PEPFAR has expanded its MER indicator age groups to effectively monitor progress and serve people as they age with HIV.

Overall, total new infections are drastically lower in countries at epidemic control, and the majority of new infections in these countries are among people under 35 years of age (Figure 2.1.1.13). Strategies that reach young people to achieve 95/95/95 in all age/sex strata are critical to maintain control. In addition, prevention programs must be appropriately focused and

targeted to prevent an increase in new infections in these groups. PEPFAR recognizes that there is a lack of epidemiologic information on key populations: size estimates, prevalence, incidence, burden, and understanding risk behaviors are vital parameters which are needed to provide equitable services. HIV prevention and treatment cascades for KP have been established by PEPFAR, but they only reflect beneficiaries. Denominators for KP and members of key populations living with HIV have not been as available as they are for general population. Addressing this vast information gap is a priority for PEPFAR. As a starting point, understanding the risk profile of new infections, including the proportion of new infections among key populations, can help inform programming decisions.

Figure 2.1.1.13: Distribution of new infections by age/population and country

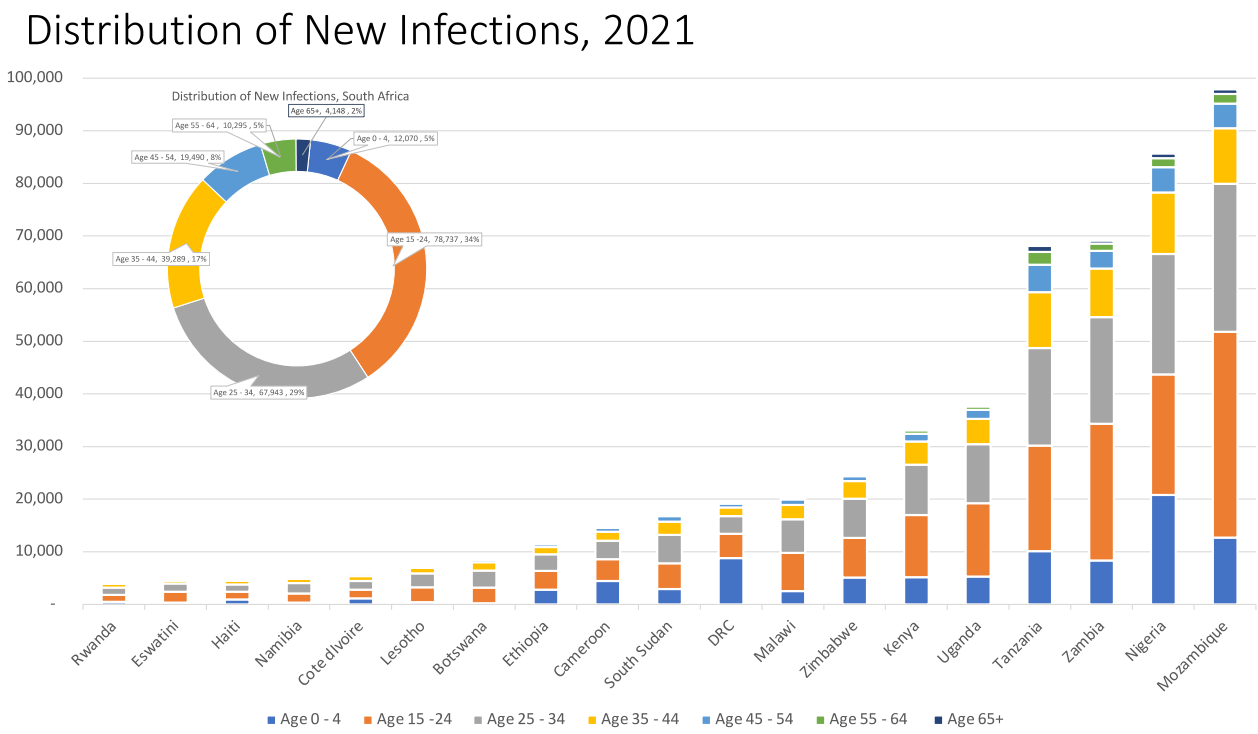


Figure 2.1.1.14: Distribution of PLHIV not on ART by age/population and country

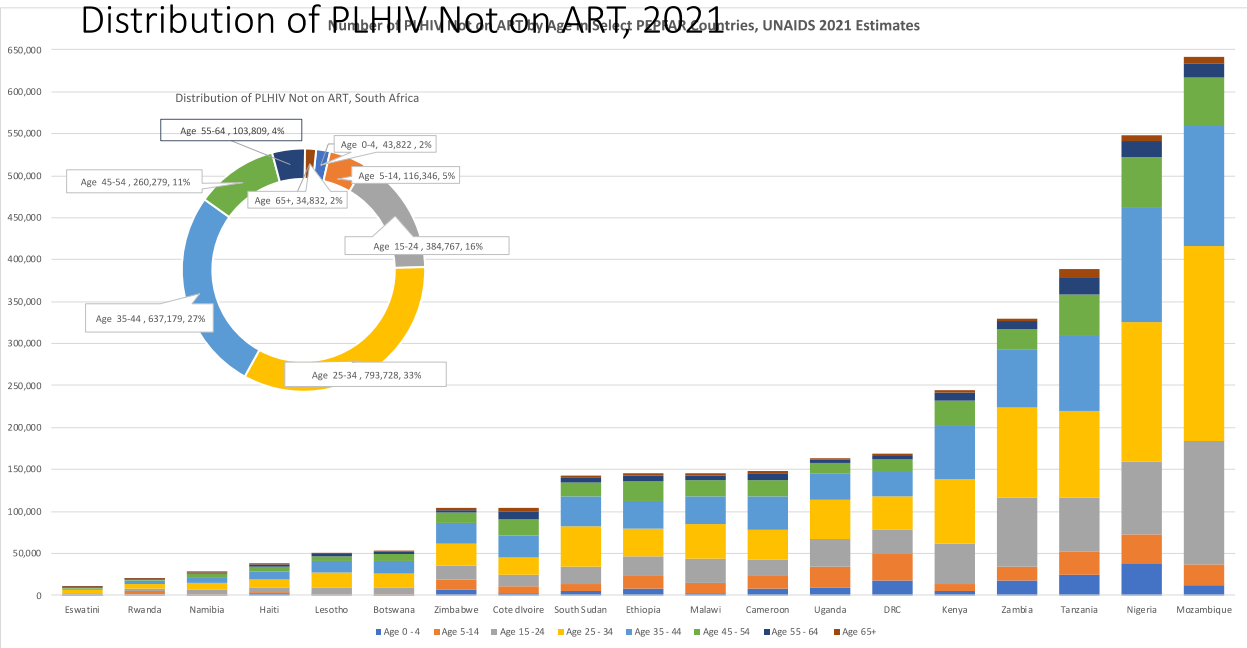
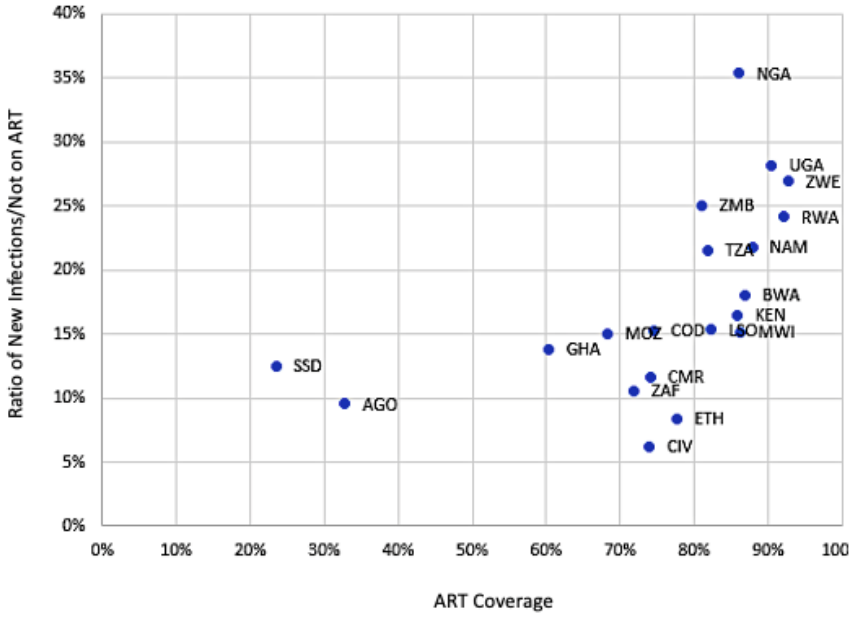


Figure 2.1.1.15: Ratio of new infections to people not on ART by country



Focusing on pediatric infections, we see similar declines in new infections by region (Figure 2.1.1.16). Fewer babies are now born with HIV due to effectively scaled PMTCT programs, and the population of children living with HIV is aging (Figure 2.1.1.17). However, the clinical cascade for children demonstrates lower performance than the cascade for adults. The second

95 is low in South Africa, Mozambique, Zambia and many West African countries and viral load suppression is substantially lower than it is in the adult populations across most countries (Figure 2.1.1.16). Updating service delivery models to make ART services convenient for children and their parents and ensuring transition to optimal regimens are of paramount importance. Thirteen countries account for 75% of the Global HIV Treatment gap for children totaling 780,000 children in need worldwide (Figure 2.1.1.18).

Figure 2.1.1.16 Trends in New HIV Infections Among Children by Region

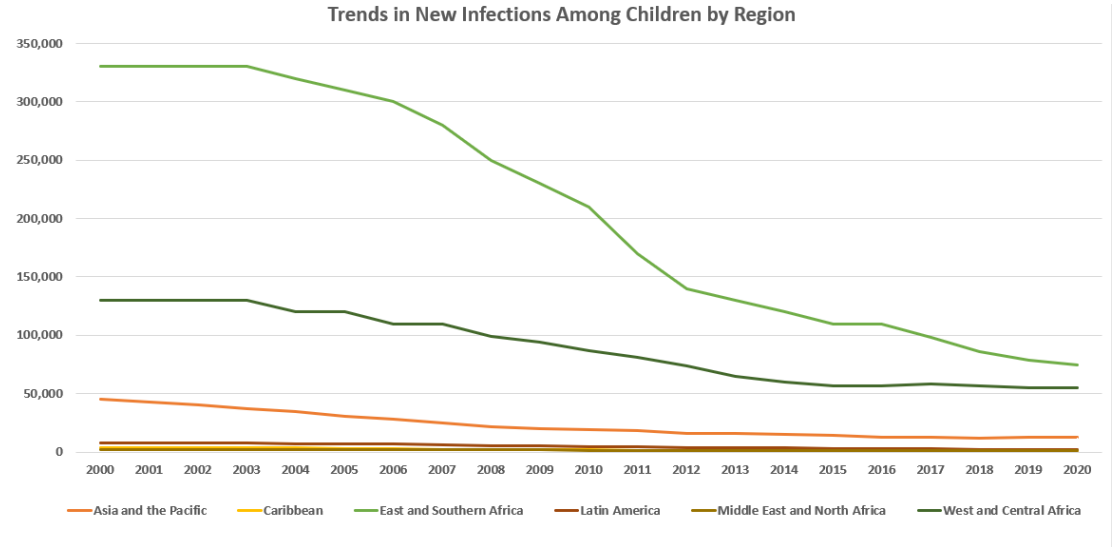
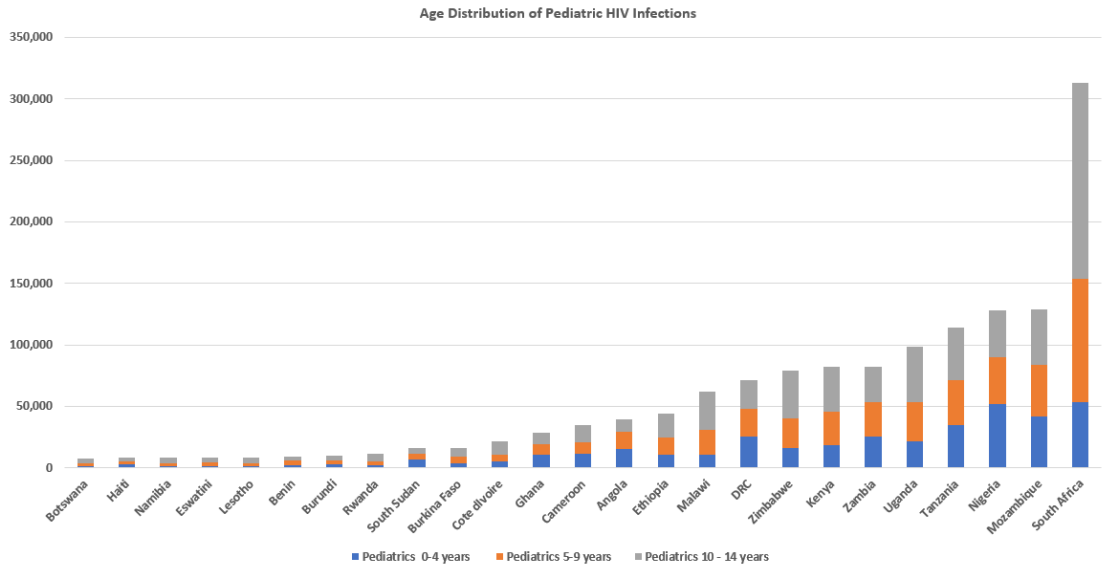
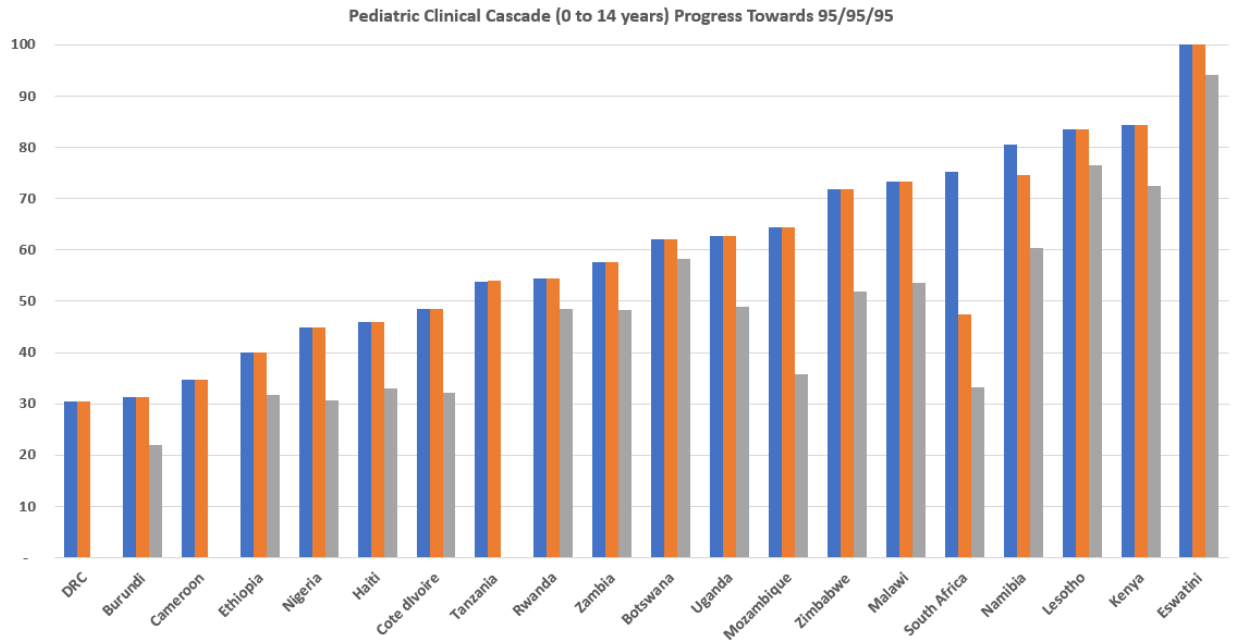


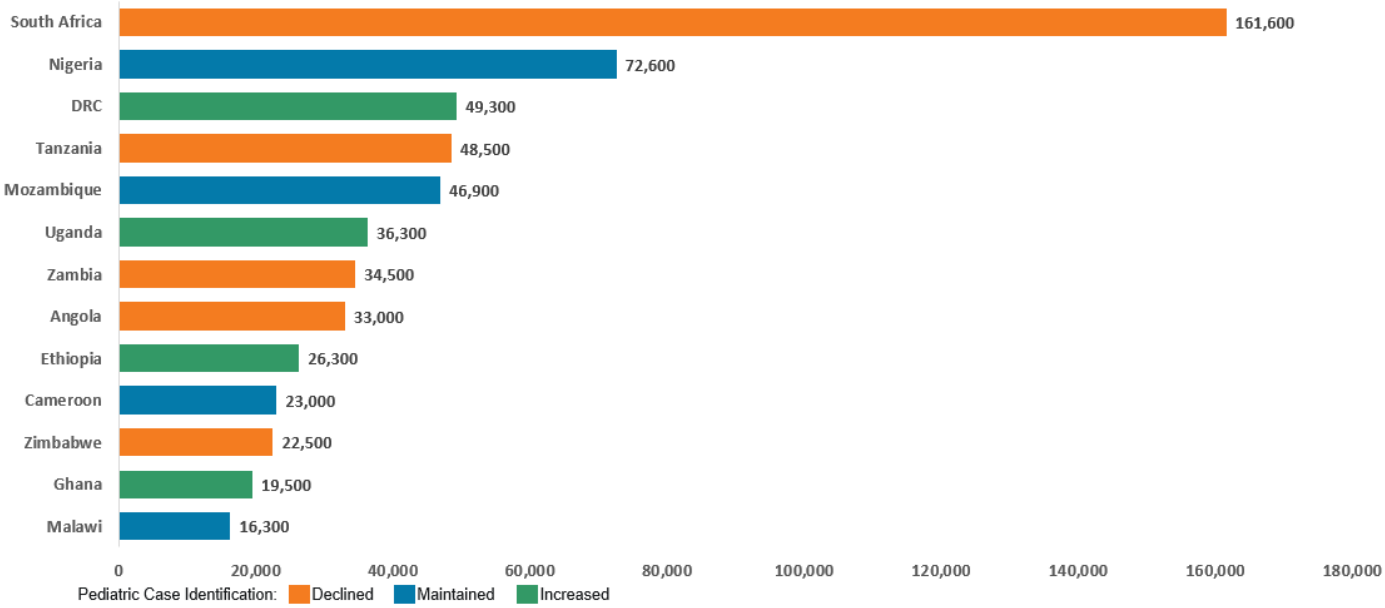
Figure 2.1.1.17: Age Distribution of Pediatric Infections[8]



[8] Ibid.

Figure 2.1.1.18: Estimated Pediatric Clinical Cascade[9]





PEPFAR's impact has also resulted in a decrease in the number of children losing parents due to AIDS (Fig 2.1.1.20). This is evident in decrease in the number of AIDS-related orphans and

[9] Ibid.

also in their age distribution (2.1.1.20): over half of orphans are aged 12 to 17, followed by 6 to 11 years old. OVC programs continue to evolve to meet the needs of older orphans and vulnerable children with supportive and relevant services. Focusing support and prevention services through programs like DREAMS mitigates HIV risk. Estimated orphanhood remains high in countries that have not achieved 95/95/95 (Figure 2.1.1.21).

Figure 2.1.1.20: Trends in Orphanhood in Countries at Epidemic Control[10]

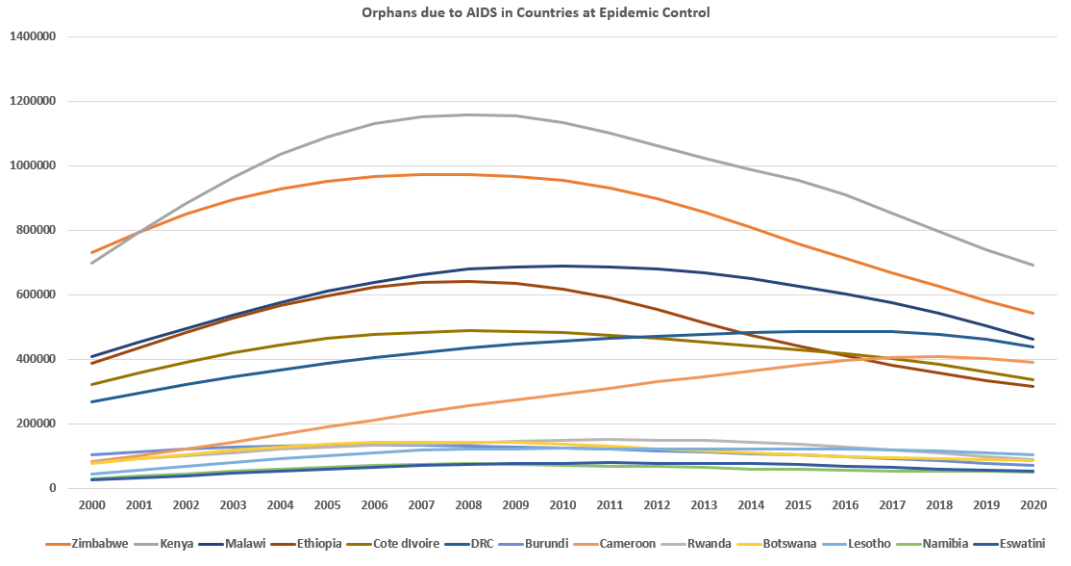
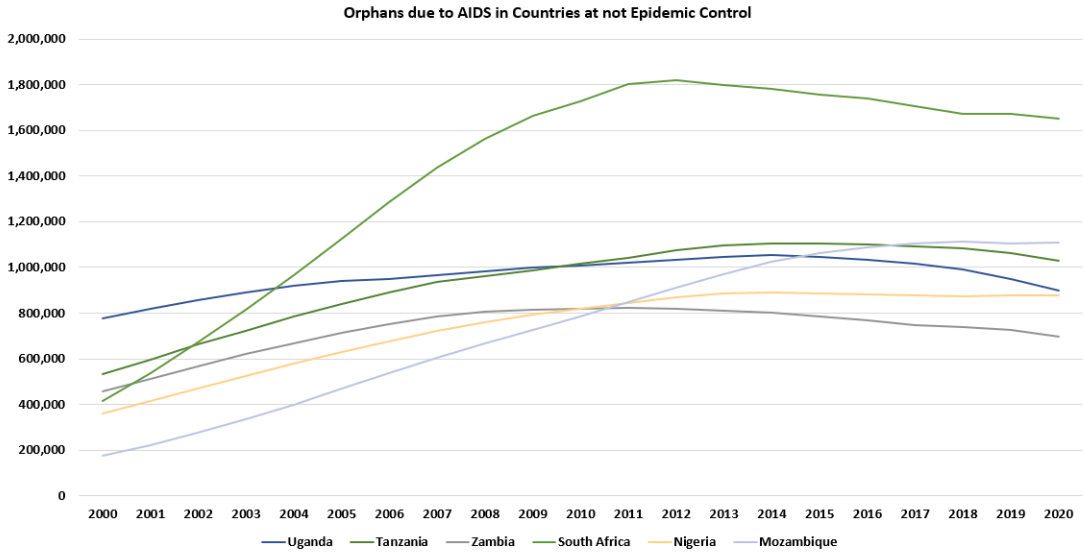
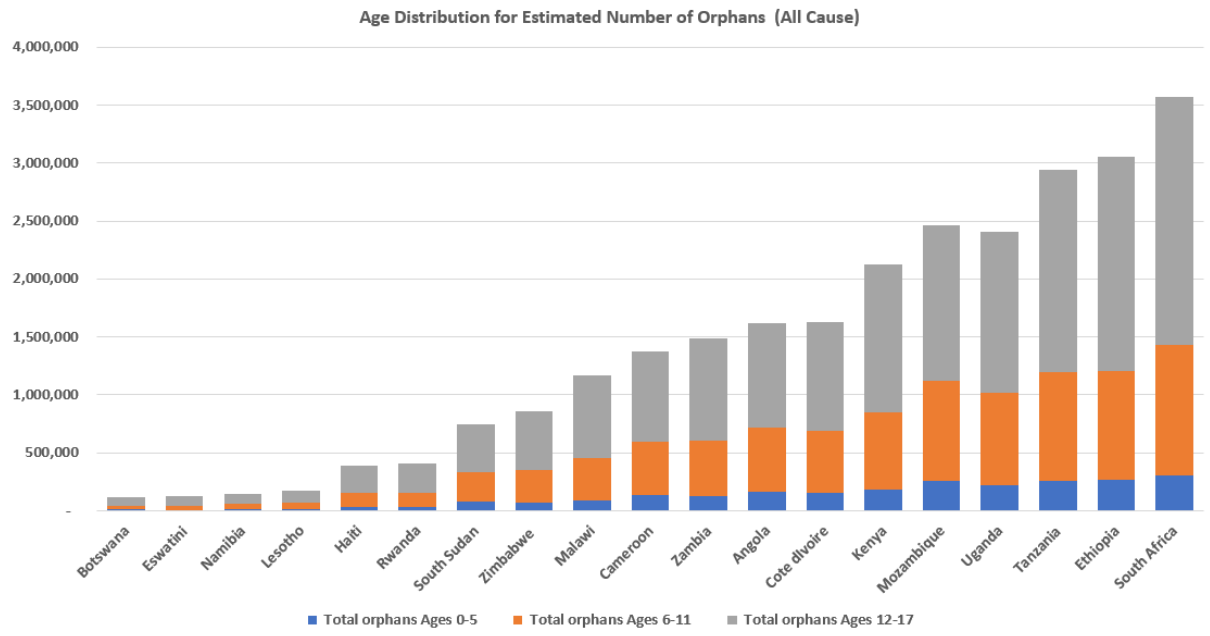


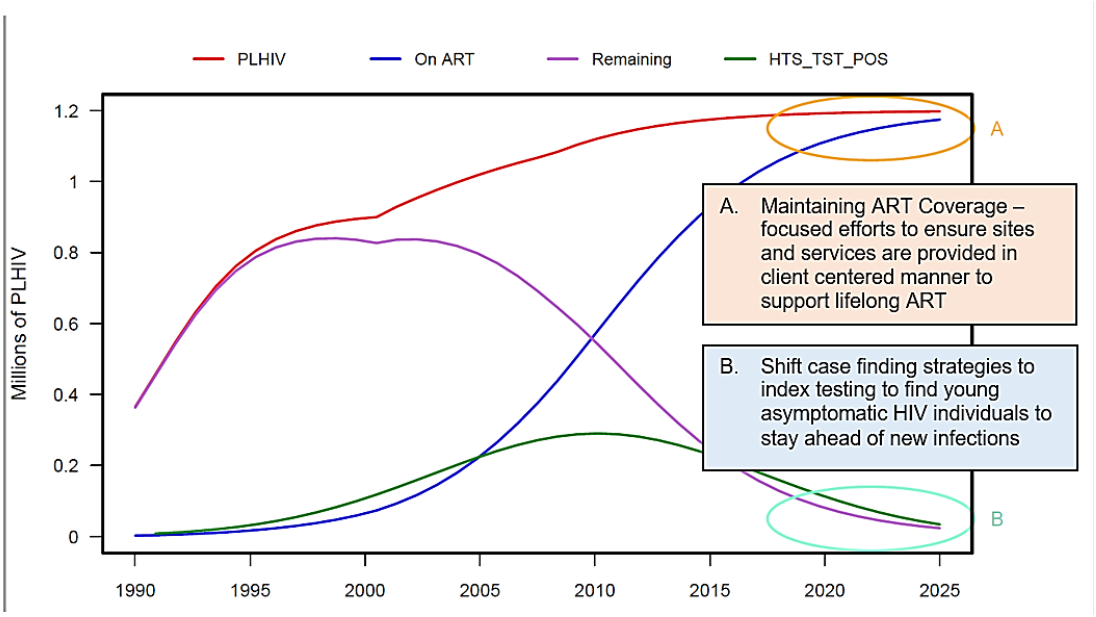
Figure 2.1.1.21: Trends in Orphanhood in Countries not at Epidemic Control[11]



[10] Ibid.
[11] Ibid.

Figure 2.1.1.22: Age Distribution of Orphans and Vulnerable Children[12]





When the remaining undiagnosed individuals represent less than 20% of total people living with HIV, we know from the PHIA (Figure 2.1.1.3) that asymptomatic, younger individuals and those

[12] Ibid.

with recent infections are more likely to be undiagnosed. In order to reach these individuals, HIV case finding must be active, through safe and ethical index testing, targeted testing, and self-testing. Fewer and fewer individuals should be diagnosed with symptoms in the facility years after infection. Children living with HIV who may have been missed through PMTCT programs should also be found through a robust and safe index testing program. In countries with 70%-80% ART coverage, effective, safe, and ethical index testing is critical to epidemic control maintenance and should be offered to every person newly diagnosed with HIV.

As countries reach 95/95/95 goals and achieve epidemic control, they must adapt their plans and design their activities and policies to sustain epidemic control for the long term. Epidemic control maintenance will require disease-specific surveillance, the capability to detect and investigate outbreaks using relevant tools, including recency infection surveillance, treatment literacy of patients, and continued excellence in ART services to achieve continuous treatment, durable viral load suppression, and rapid return to treatment of those whose treatment is interrupted.

Analysis of site level inputs to maintain epidemic control is pivotal to ensure investments are aligned where the need is the greatest. The first round of human resources for health (HRH) data will allow us to examine the types of health care workers and other technical capacity needed to (1) effectively sustain clients on lifelong ART (clinical and community) (2) provide prevention services (3) manage and maintain reliable data and surveillance, lab, and supply systems.

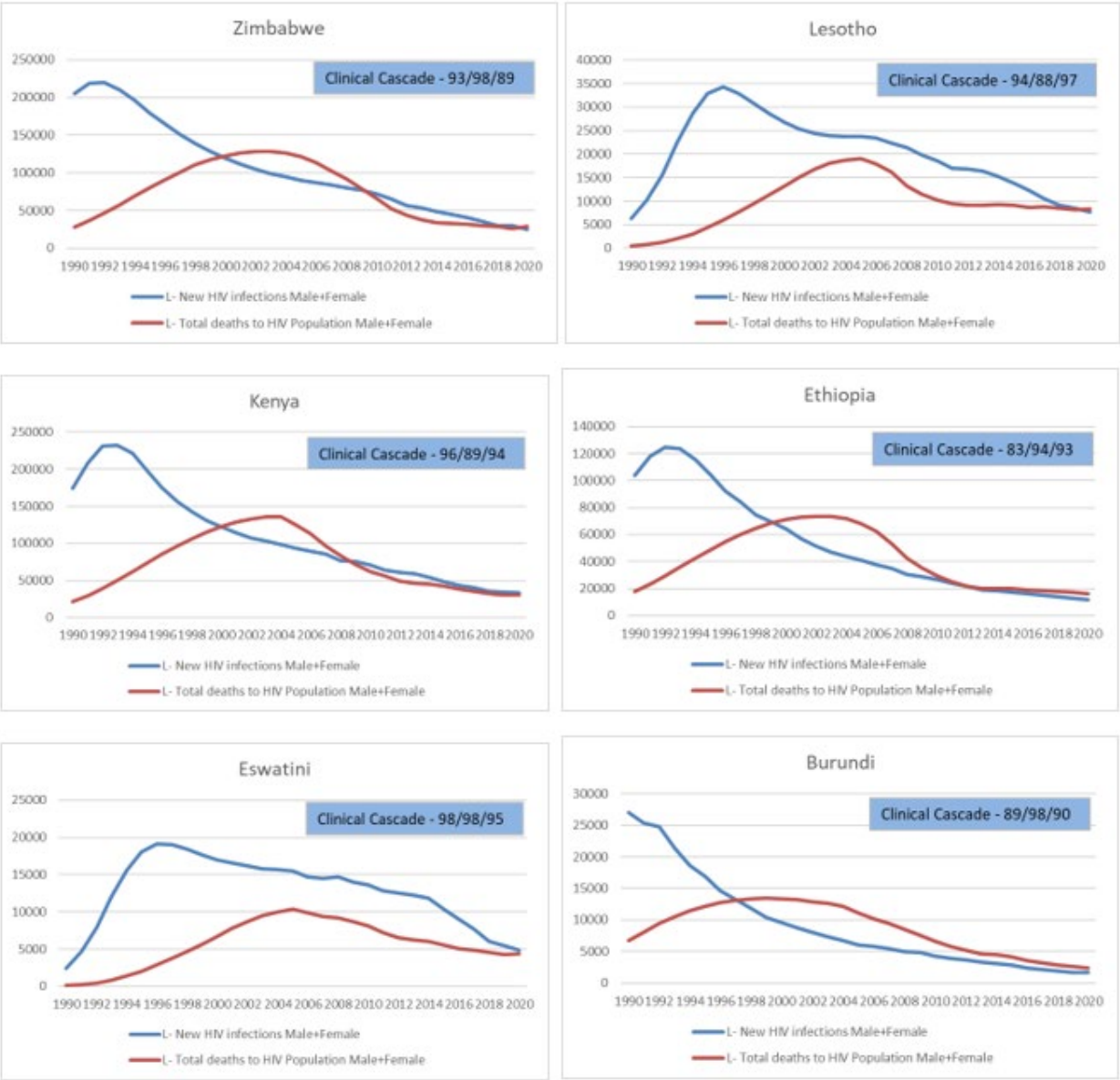
Over the past six years, general population approaches have evolved to targeted implementation strategies by age/sex and will need to continuously be refined based on new infections. Understanding the proportion of (1) key populations in each of these age groups, (2) targeting those adolescent girls and young women at higher risk with DREAMS services, (3) defining needs for PrEP and scaling services to deliver PrEP in highest risk populations, (4) zeroing in on VMMC gaps, (5) closing the pediatric gaps with effective and well-tolerated regimens (6) applying innovative case-finding approaches to rapidly identify people with new and undiagnosed long-term infections and (7) ensuring people on ART who do not have sustained viral load reductions are identified early for ART optimization. Detailed data analysis examples described in Section 7 support planning that aligns resources to maintain epidemic control and addresses remaining gaps, key focus areas for COP22.

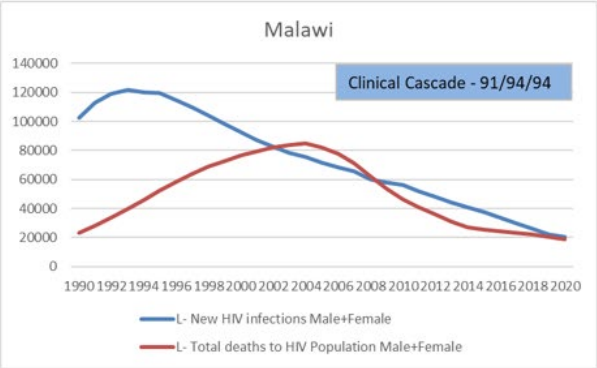
With COVID-19, country programs must work with partner governments to adapt these programs to ensure continuity and maintain critical supplies while complying with government

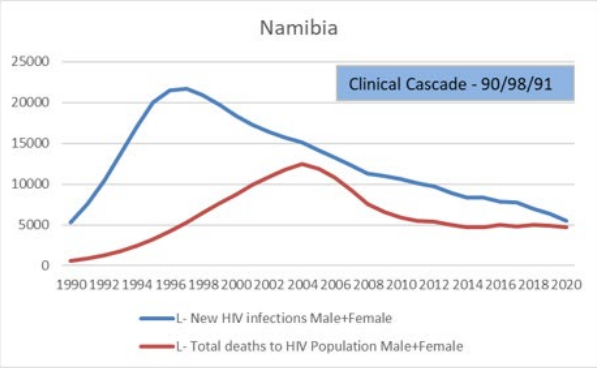
directives or policies for social distancing. Thus, emphasis is placed throughout this guidance on optimizing program and systems investments to support, achieve, and sustain epidemic control, even under the extraordinary circumstances of a parallel pandemic.

Country charts presented in Figures 2.1.1.24 through 2.1.1.28 are organized by progress towards HIV epidemic control and 95/95/95. Understanding and addressing the remaining gaps and barriers to achieve both of these program goals in light of COVID-19 are priorities for COP22.

Figure 2.1.1.24: Countries that are at Epidemic Control and 73% community viral load suppression




Malawi
Clinical Cascade - 91/94/94
140000
120000
100000
80000
60000
40000
20000
0
1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018 2020
L- New HIV infections Male+Female
L- Total deaths to HIV Population Male+Female


Namibia
Clinical Cascade - 90/98/91
25000
20000
15000
10000
5000
0
1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018 2020
L- New HIV infections Male+Female
L- Total deaths to HIV Population Male+Female

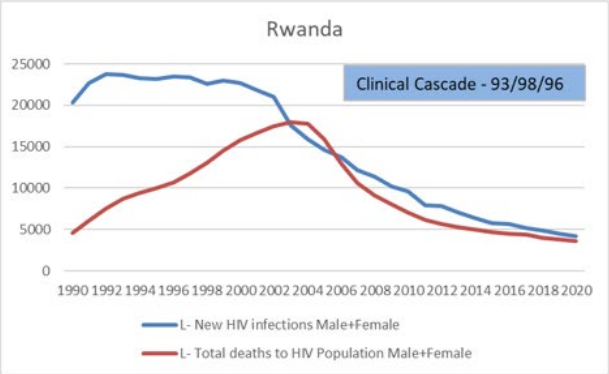

Rwanda
Clinical Cascade - 93/98/96
25000
20000
15000
10000
5000
0
1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018 2020
L- New HIV infections Male+Female
L- Total deaths to HIV Population Male+Female

Figure 2.1.1.25 Countries that are at epidemic control but not at 73% community viral load suppression

Figure 2.1.1.26 Countries near epidemic control and near 73% community viral load suppression

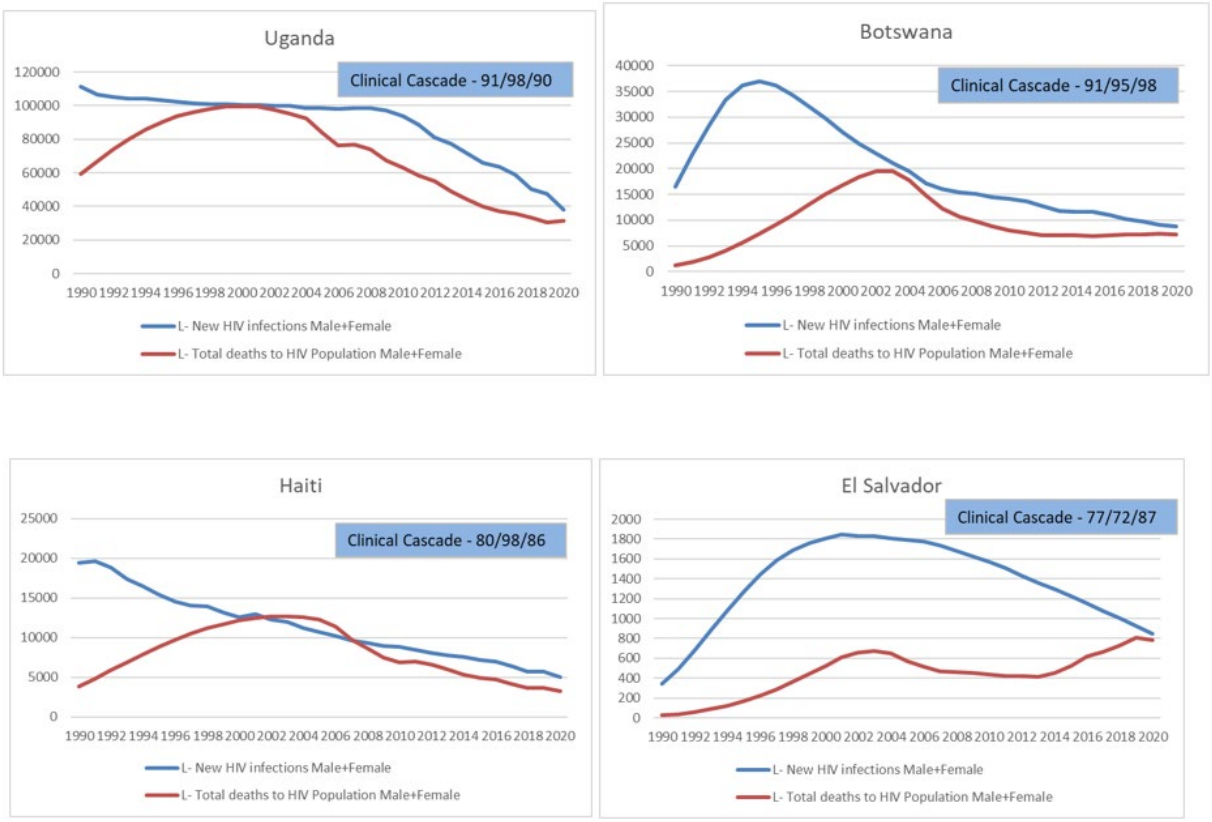


Figure 2.1.1.27: Countries with declines in new infections and mortality but not at epidemic control or 73% community viral load suppression

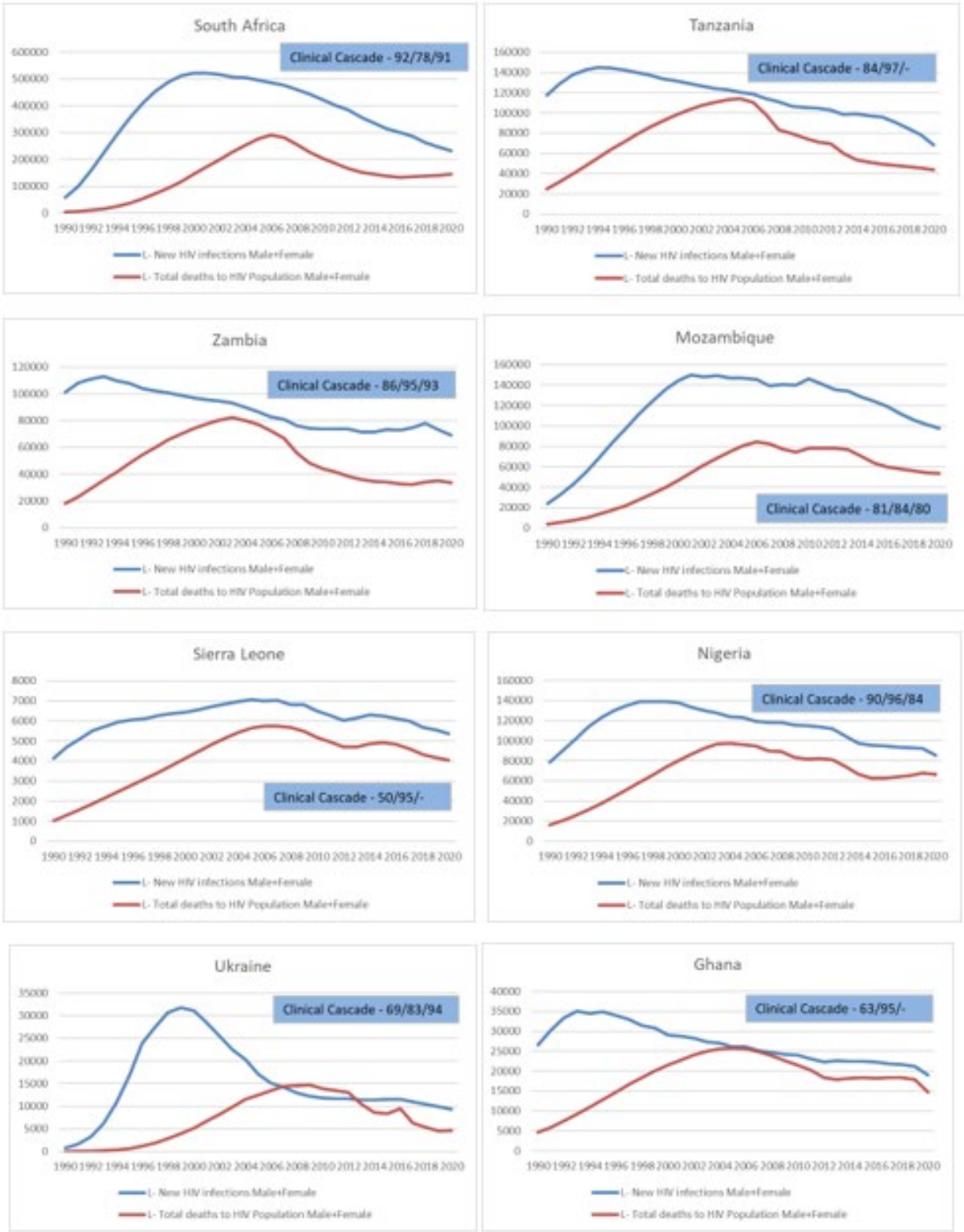
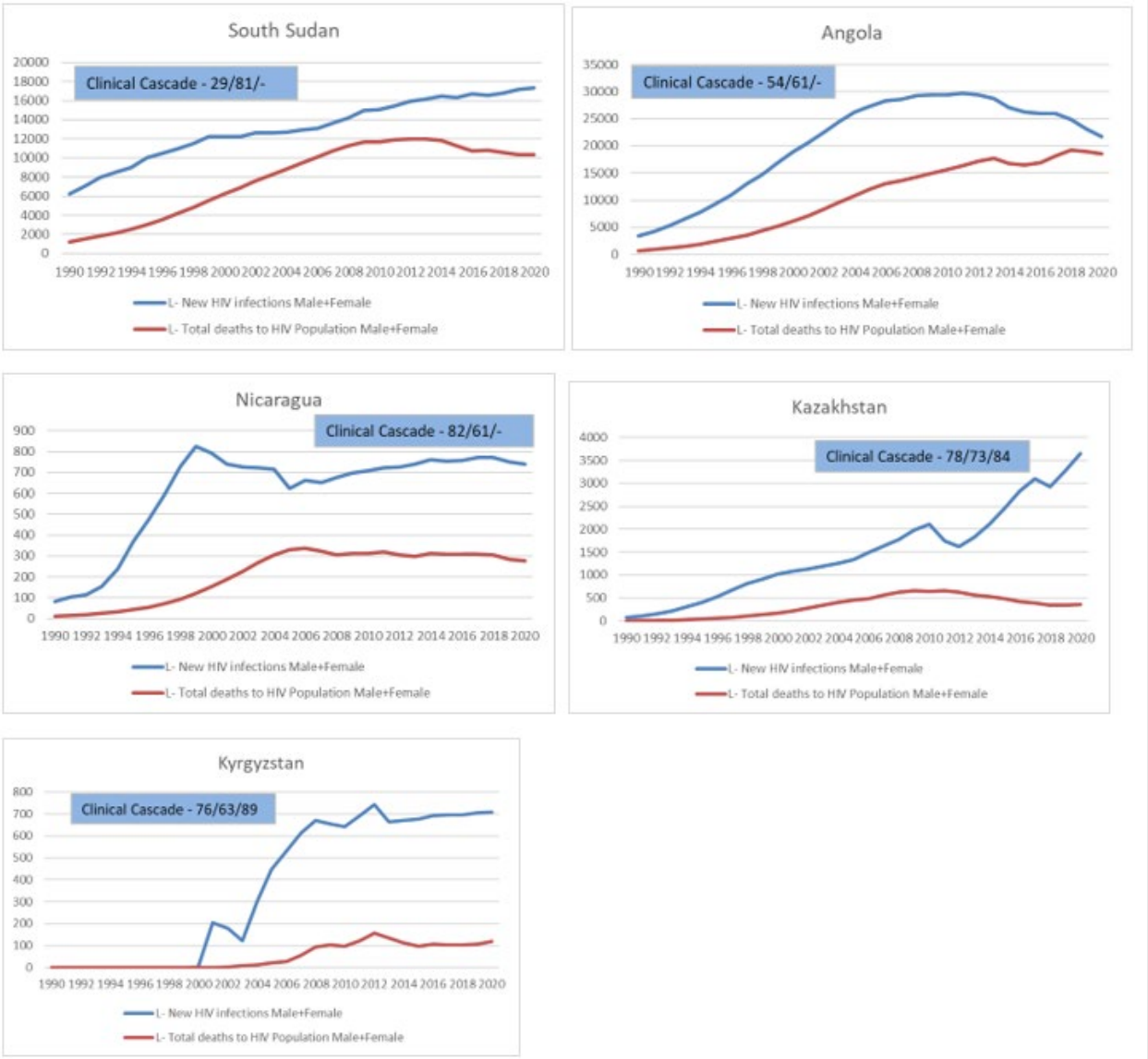


Figure 2.1.1.28: Countries with increasing new infections or mortality



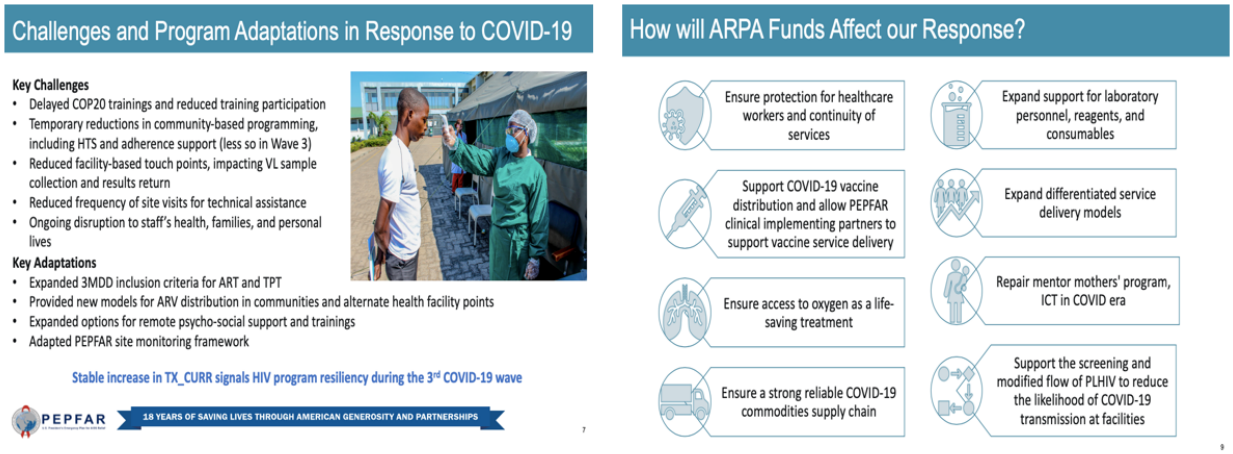
2.1.2 Program Updates

COVID-19 continued to test the resilience of the country systems that PEPFAR built to provide HIV prevention and treatment services including surveillance, laboratory, human resources, and supply chain. PEPFAR teams have worked with partner country governments and other stakeholders to scale HIV services for nearly 20 million people living with HIV who are sustained on lifesaving, continuous ART and 94% of those tested are virally suppressed. PEPFAR demonstrated that epidemic control is achievable through focusing and prioritizing the most impactful programs, now the priority is to ensure the systems can operate in a routine manner to

maintain this level of epidemiologic success and address the remaining population gaps. PEPFAR has prioritized programs to reach the 1st and 2nd 95 and now must tighten focus of that work on the populations that remain off treatment and turn its broader attention to the 3rd 95 and ensuring program requirements to sustain epidemic control are fully implemented and institutionalized. These achievements were realized through the use of granular population and geographic data – countries must utilize individual level data to close the remaining population level gaps.

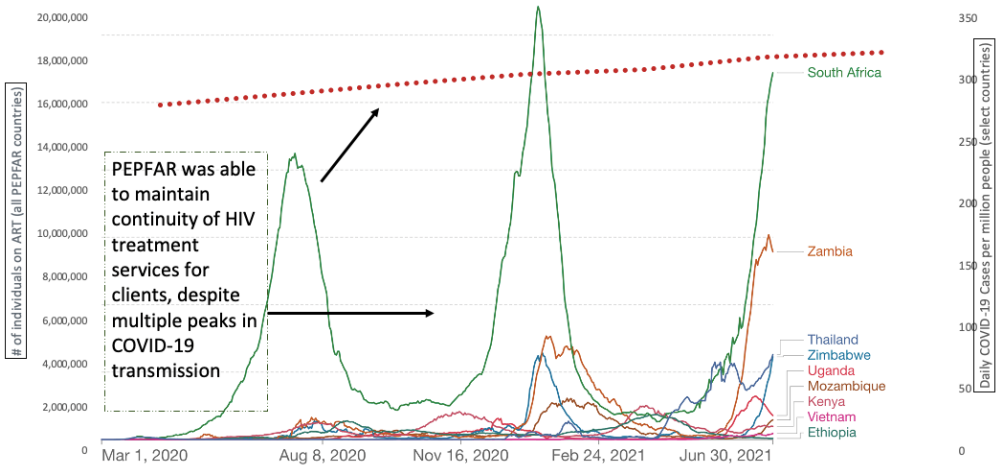
Since March 2020, PEPFAR has provided weekly COVID-19 adaptation technical guidance to country programs considering epidemiologic data, methods of HIV service delivery, site safety including considerations for health care workers and beneficiaries. Country teams have followed COVID-19 epidemiology along with HIV data to ensure that relevant practices are adapted to maintain HIV services and help respond to COVID-19. Figure 2.1.2.1 demonstrates the detailed monitoring by PEPFAR Mozambique for effective and safe program implementation. All PEPFAR-supported countries have made similar adaptations. These adaptations have led to maintaining nearly 19M people on ART (Figure 2.1.2.2).

Figure 2.1.2.1: HIV Program Adaptations due to COVID-19



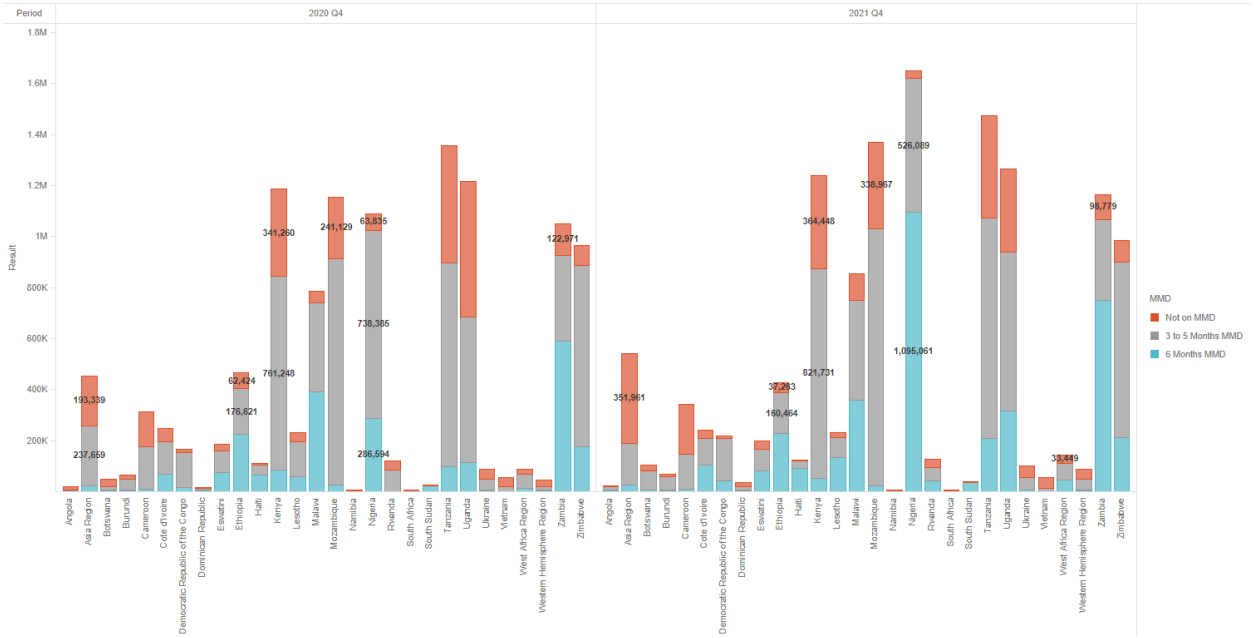
Despite the COVID-19 pandemic, in FY21, HIV services around the globe have not only been protected, but they have accelerated. PEPFAR has supported at least 20 countries to achieve epidemic control of HIV or reach the 90-90-90 HIV treatment targets. HIV treatment services were provided to 18.96 million men, women, and children (compared with 17.2 million last year). PEPFAR reached 2.9 million adolescent girls and young women with comprehensive HIV prevention services (compared with 1.6 million last year). PEPFAR supported 1.0 million people

to newly enroll on antiretroviral pre-exposure prophylaxis (PrEP) to prevent HIV infection (compared with 312,000 million last year).



Over the past 12 months through COVID-19, patient-centered services have continued to expand, multi-month dispensing is a critical policy and activity to make ARVs accessible in a convenient and safe manner. Prior to COVID-19, governments were cautious on adapting their service delivery models and health care systems to allow for this type of access but now realize that this is a necessity for continuity of life-long HIV services. Effective management of commodities is essential to maintain MMD options for clients, some countries are reverting in access (Figure 2.1.2.3).

Figure 2.1.2.3: MMD Implementation Changes 2020 to 2021[13]



Despite the overall increase in the number of people on ART globally, there continues to be losses of patients from treatment this year as in the last 3 years. All PEPFAR programs continued to bring new patients into treatment even with COVID-19 challenges, but many country programs had fewer patients on treatment at the end of the year than expected, implying treatment interruption of many short- or long-term patients. This is the challenge that PEPFAR must continue to address to maintain epidemic control.

One critical component to sustain epidemic control is to ensure all patients are tested for viral load annually and results are available for effective clinical management (i.e., suppressed viral load). Viral load testing coverage is as low as 50% in some high disease burden countries (Figure 2.1.2.4). Even though the PHIA results demonstrate over 72% community viral load suppression, the routine clinical and laboratory systems are not testing all HIV patients or making these data available in the patient record – this must be addressed in COP22. Of those who are tested, adults over 30 years have the highest suppression; of concern are younger populations, calling for specific strategies for pediatric populations and 15- to 30-year-olds (Figure 2.1.2.5). While continually improving services for younger populations, PEPFAR continues to adapt particularly as the overall treatment population ages – and addresses unique needs to maintain these populations on ART (Figure 2.1.2.6). In 2018, PEPFAR announced it

[13] Source: PEPFAR Panorama, Treatment: Global Dossier, MMD Chapter, Multi-month Dispensing Trends Page

would provide TB Preventive Therapy for all ART clients to reduce morbidity, since then 2.8 million people on ARTs have completed TPT (Figure 2.1.2.7), completion rates vary by country.

Figure 2.1.2.4: Viral Load Testing Coverage by Country[14]

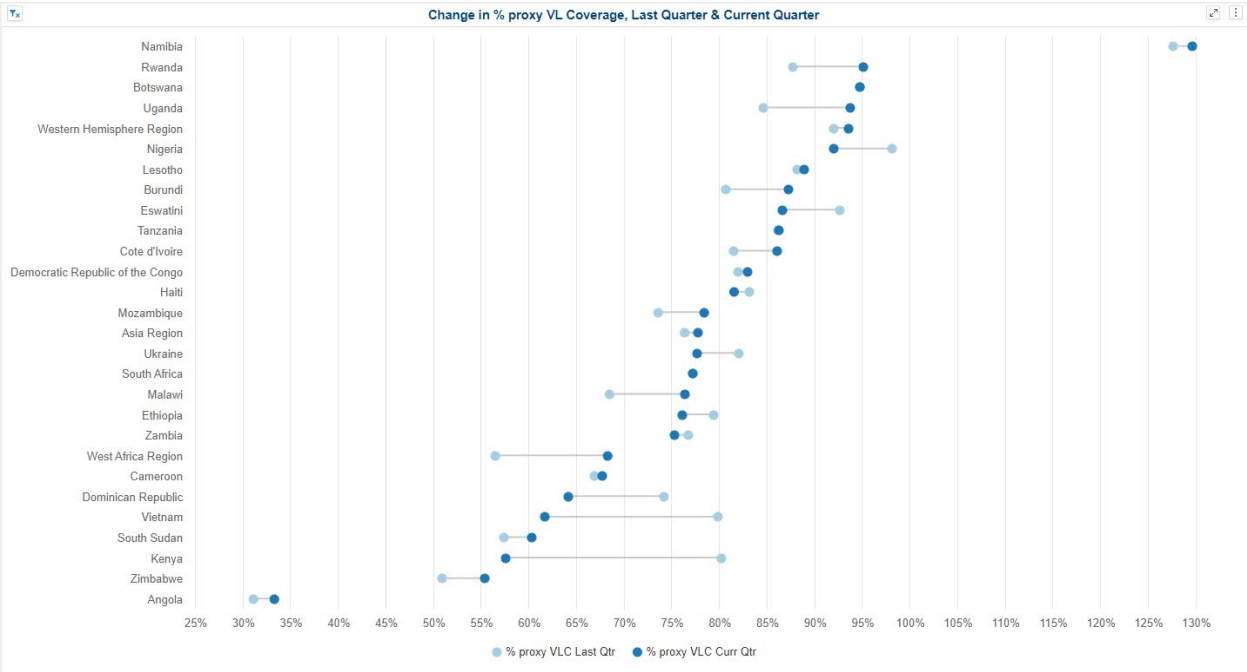
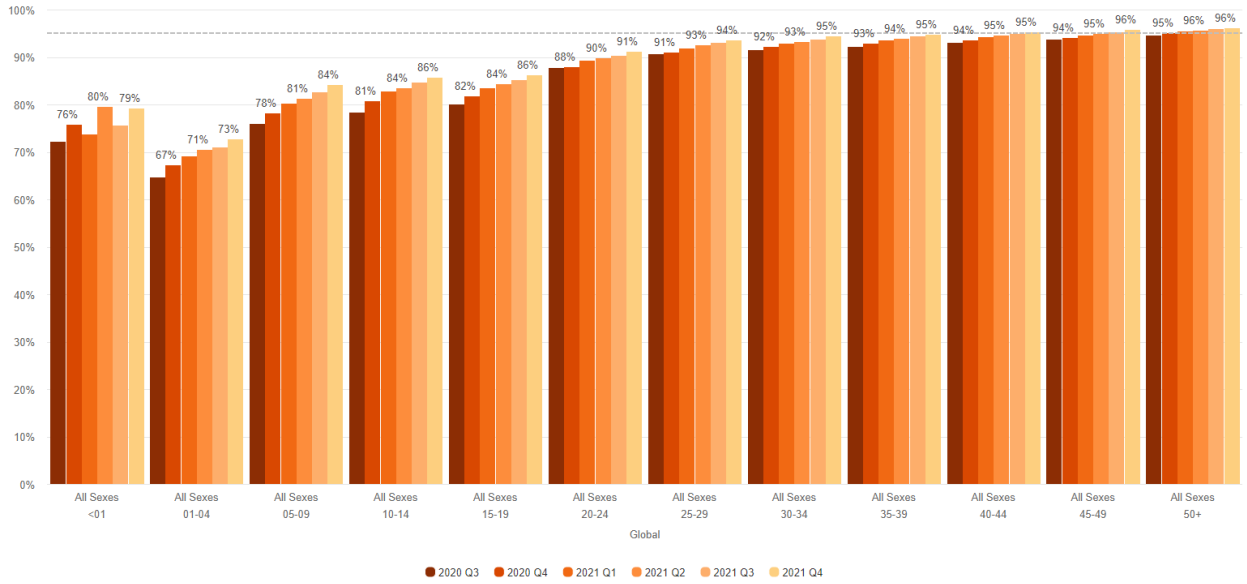


Figure 2.1.2.5: Viral Load Suppression by Age Group [15]



[14] Source: PEPFAR Panorama, Viral Load: Global Dossier, All Populations Chapter, VLC – Dumbbell Chart Page
[15] Source: PEPFAR Panorama, Viral Load: Global Dossier, All Populations Chapter, VLS – Bar Chart Page

Figure 2.1.2.6: Treatment Current by Age Group at FY21Q4[16]

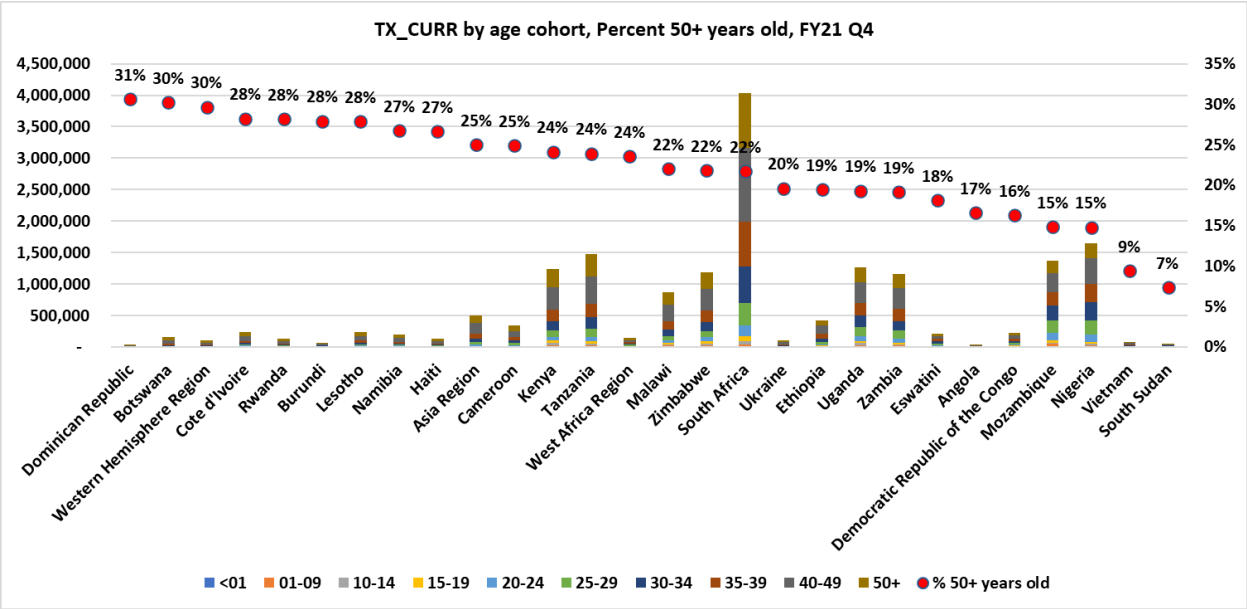
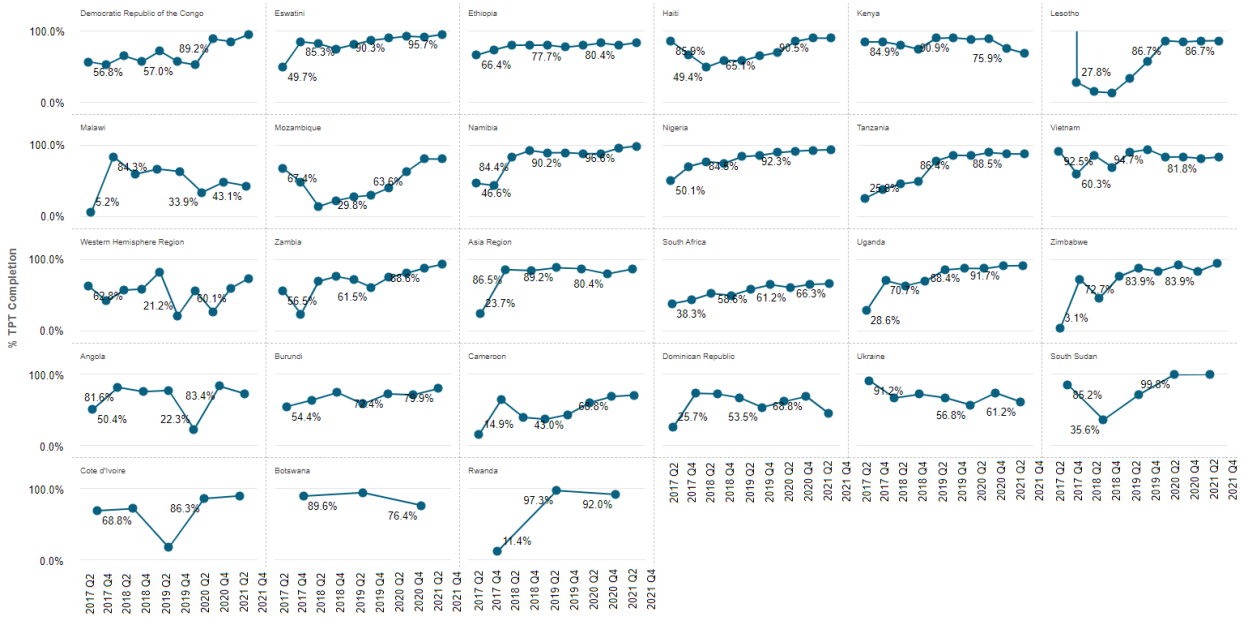


Figure 2.1.2.7: TPT Completion Rates for ART Clients



PEPFAR continues to optimize HIV testing strategies to combat the today's HIV epidemic. To maximize effectiveness of testing efforts requires a strategic mix of testing modalities, including safe and ethical index testing offered to all newly identified people living with HIV and social network testing as important methods to control infectious disease and asymptomatic

[16] Source: DATIM

transmission, as well as link people at risk to prevention services, including PrEP. Testing strategy should take into account an assessment of the positivity rate (percent of tests that are positive, sometimes called yield), the cost per infection detected, the productivity (number of infections detected), and the epidemiologic impact (proportion of people identified who have a recent or asymptomatic infection). Figures 2.1.2.9 and Figure 2.1.2.10 show the modalities where HIV positive males and females were identified in FY21. Countries at epidemic control and 90/90/90, must continuously use data on where new infections are coming from to refine active case finding to prevent rising infections (Figure 2.1.1.13). Testing methods should be continuously realigned with the changing epidemiology and new infection data. Yield by modality should inform testing effectiveness for epidemiologic impact. Over the 12 months ending in September 2021, approximately 2.5 million HIV positive individuals were identified, resulting in about 2.4 million new people on treatment and 1.6 million net new overall.

Understanding the proportion of the 2.5 million people that are retesting for reengagement in treatment is pivotal at this stage in the epidemic. Adjusting treatment programs to minimize loss and reduce barriers for reengagement will help clients stay on life-long ART.

Figure 2.1.2.8: Proportion of HIV positive results by Modality for Males, FY21 Q1 – Q4

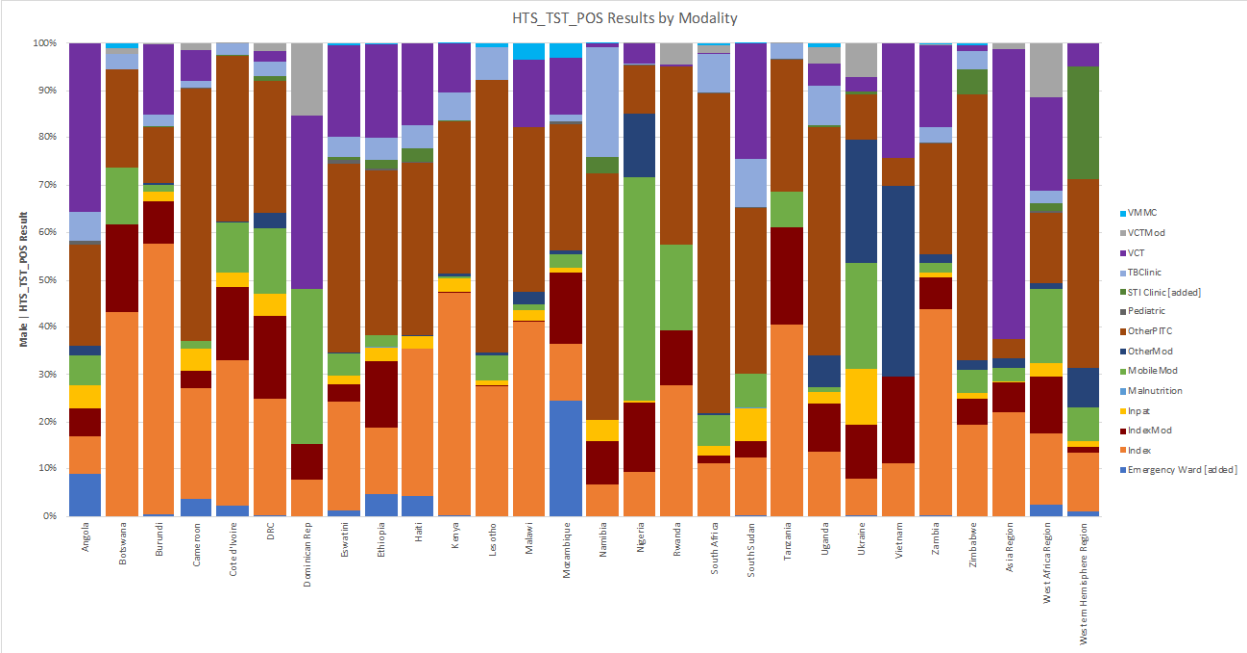


Figure 2.1.2.9: Proportion of HIV positive results by Modality for Females, FY21 Q1 – Q4

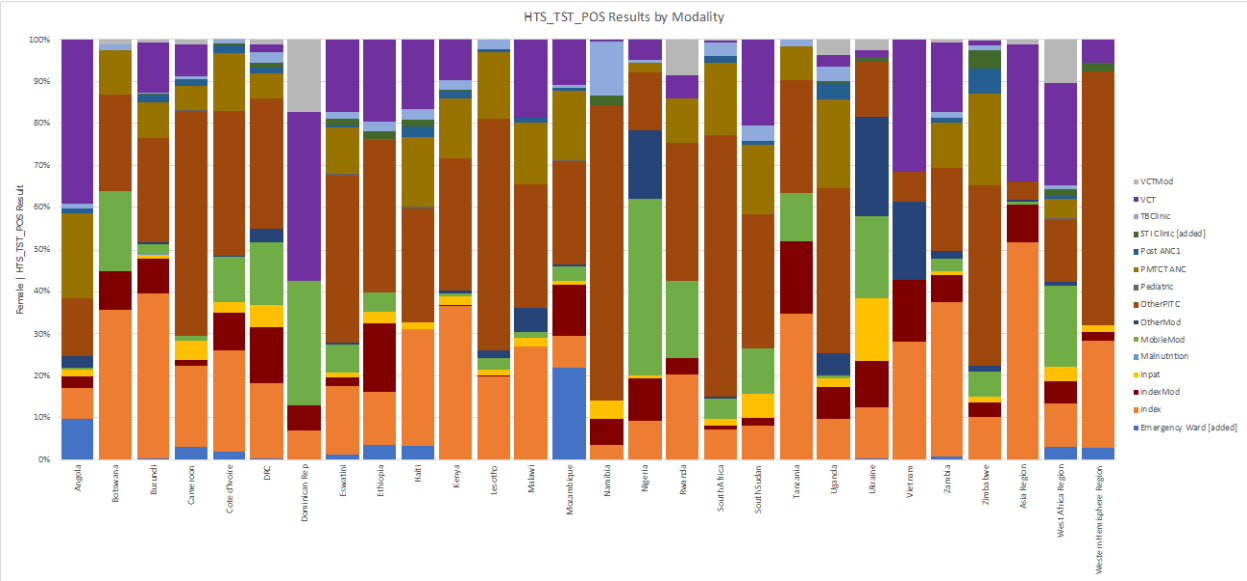
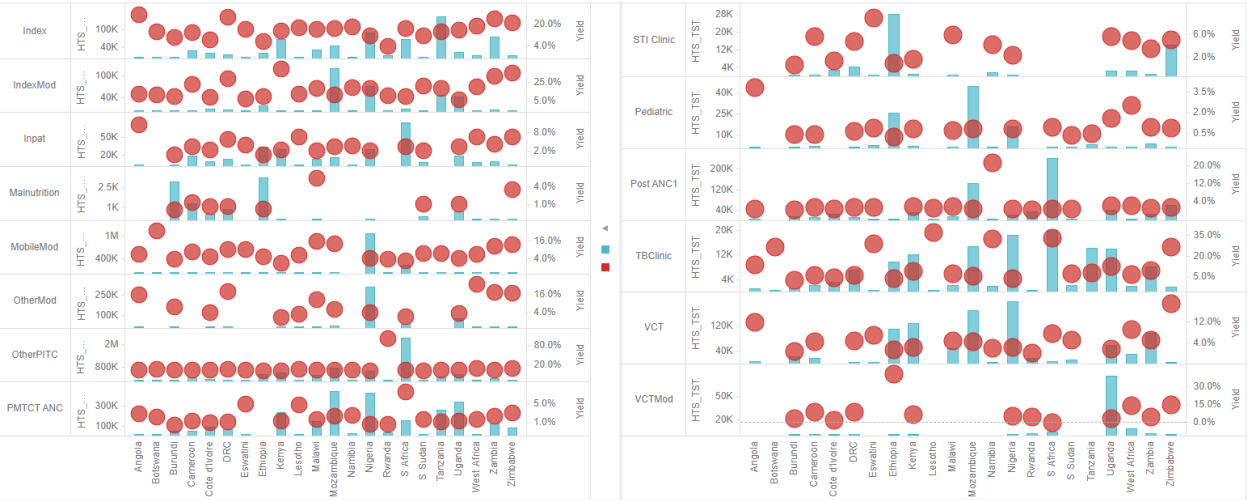


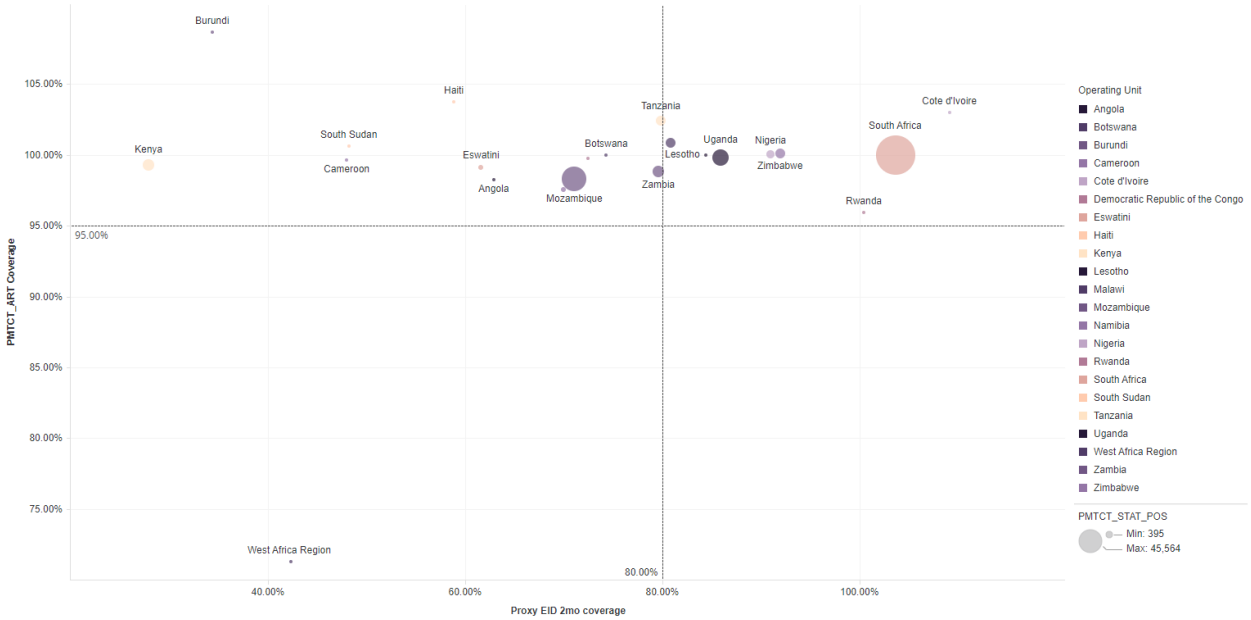
Figure 2.1.2.10: HIV Yield by Modality by Country[17]



HIV Testing of pregnant women and ART coverage is high across most PEPFAR-supported countries, closing the EID gap in the countries remains a priority. Figure 2.1.2.11 highlights the countries where there is low EID coverage and ART coverage. These gaps persist primarily in countries that have not reached epidemic control or 95/95/95.

[17] Source: PEPFAR Panorama, Clinical Cascade: Global Dossier, HTS: Modalities Chapter, Testing & Yield by Modality Page

Figure 2.1.2.11: PMTCT ART Coverage by Proxy EID 2-Month Coverage by Select Countries, FY21 Q1-Q4[18]



As noted in Figure 2.1.1.14, the number of children living with HIV has decreased over the past 10 years; as such, programs and targets have been adjusted accordingly (Figure 2.1.2.12). The change in the MER indicator age bands in FY19 provided the specificity needed to address remaining gaps for the 1st and 2nd 90. Addressing the issues in VLS for children may be related to service delivery models or using NVP based regimens (Figure 2.1.2.13). Enduring service delivery models for HIV-positive children and their parents are still evolving. Maintaining HIV-positive children on ART as they become teenagers and young adults is complex as they are also going through adolescence. Identifying the gaps in programs for children requires detailed pediatric cohort analysis.

[18] Source: PEPFAR Panorama, PMTCT-HEI: Global Dossier, HIV-Exposed Infant (HEI) Chapter, Transmission Risk Bubble Graph Page

Figure 2.1.2.12: Number of children (<15) newly diagnosed in PEPFAR programs by age band[19]

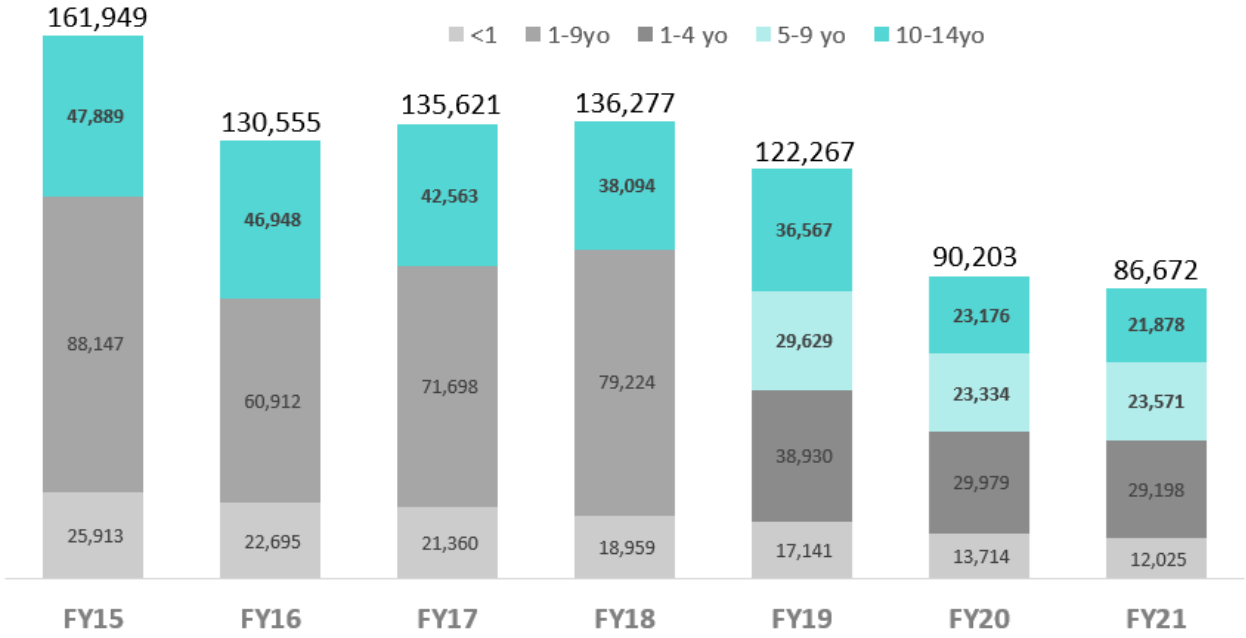
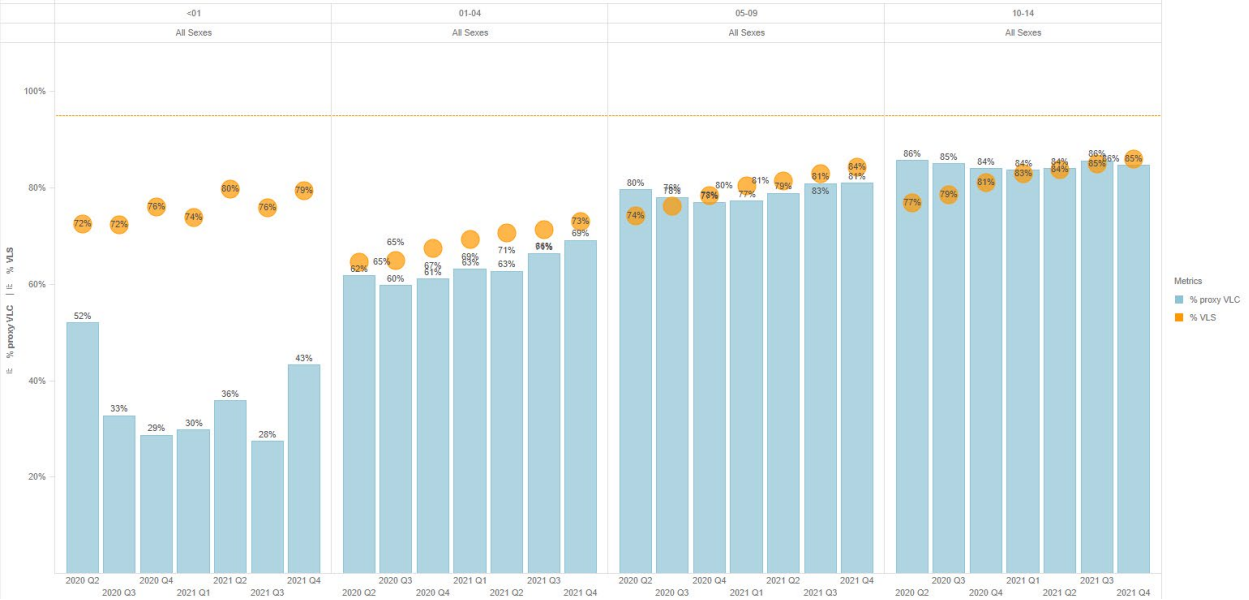


Figure 2.1.2.13 – Trends in Viral Suppression and coverage for children <15 years old[20]



[19] Source: DATIM

[20] Source: PEPFAR Panorama, Viral Load: Global Dossier, All Populations Chapter, VLC & VLS – Bar Chart Page

Key Population programs for prevention and treatment services continue to scale despite COVID-19 pandemic. PrEP services are scaling for all key populations; however, without specific denominators we don't know the exact need for PrEP and treatment services. The clinical cascade including linkage and viral suppression is improving across the program.

Figure 2.1.2.14: Trends in PrEP Scale Up Among Key Populations[21]

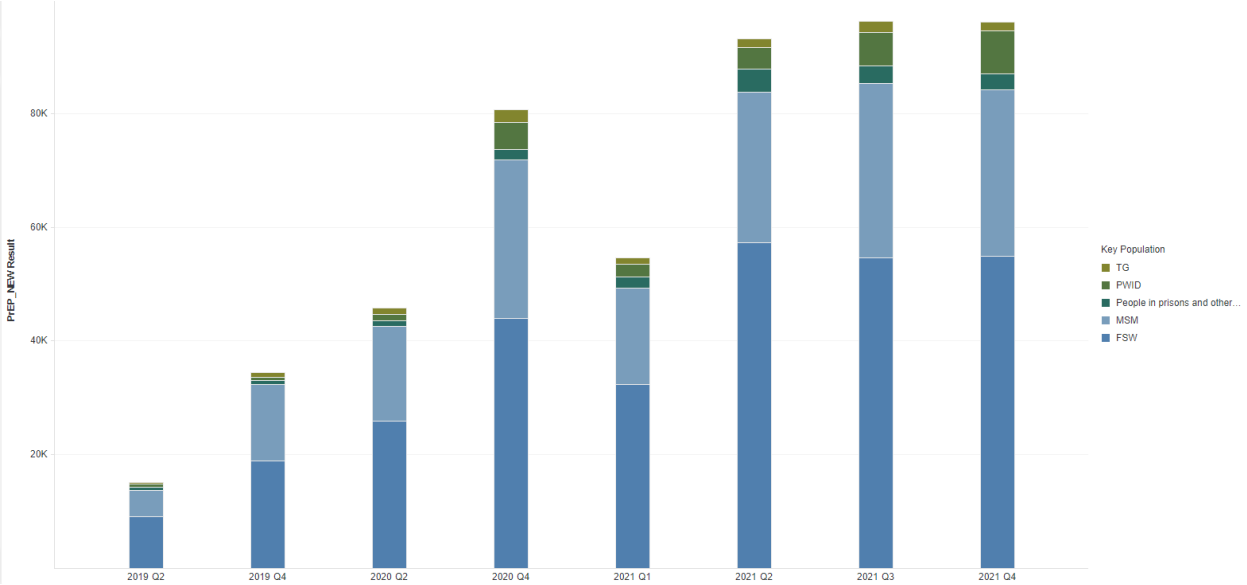
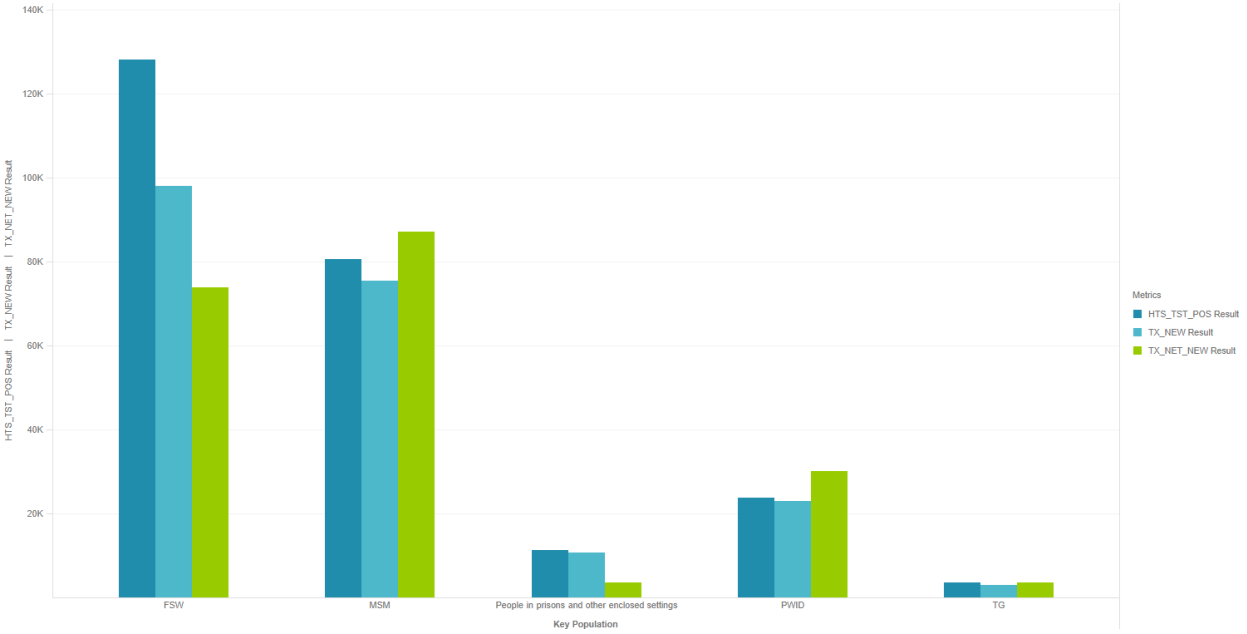


Figure 2.1.2.15: Clinical Cascade among Key Populations, FY21 Q1-Q4[22]



[21] Source: PEPFAR Panorama, Prevention: Global Dossier, Chapter 2: PrEP Chapter, KP New on PrEP Page
[22] Source: PEPFAR Panorama, Treatment: Global Dossier, Treatment & KP Chapter, Treatment Cascade by KP Page

Figure 2.1.2.16: Trends in ART Scale Up Among FSW and PWID[23]

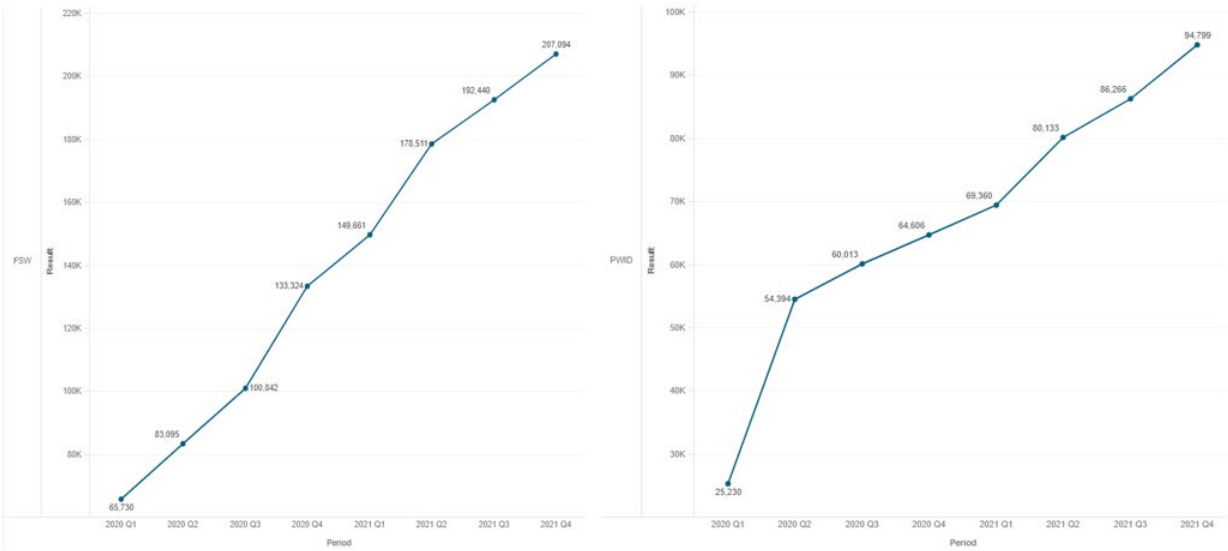
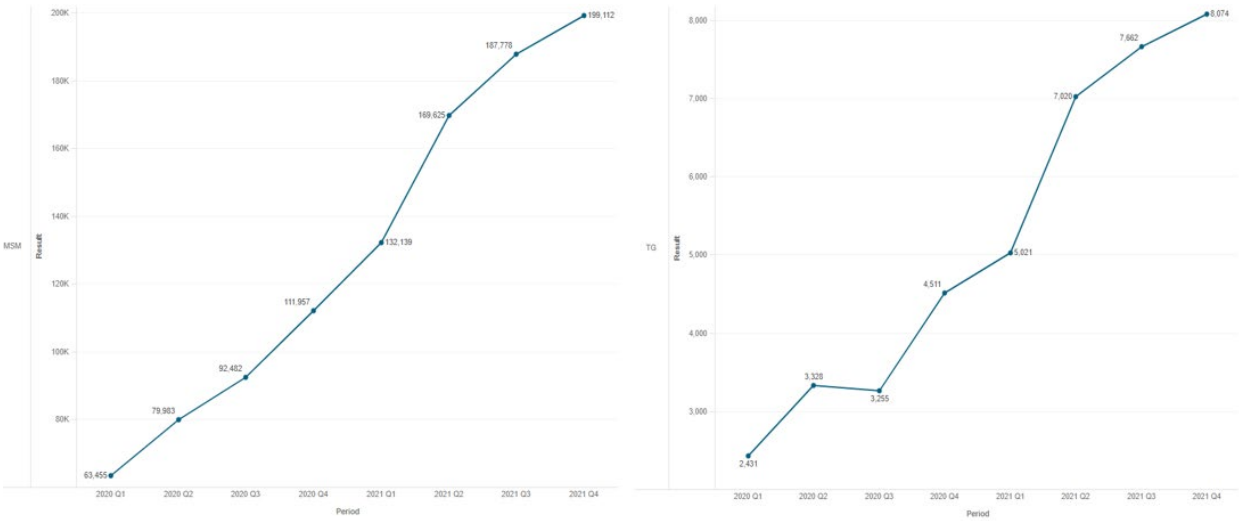


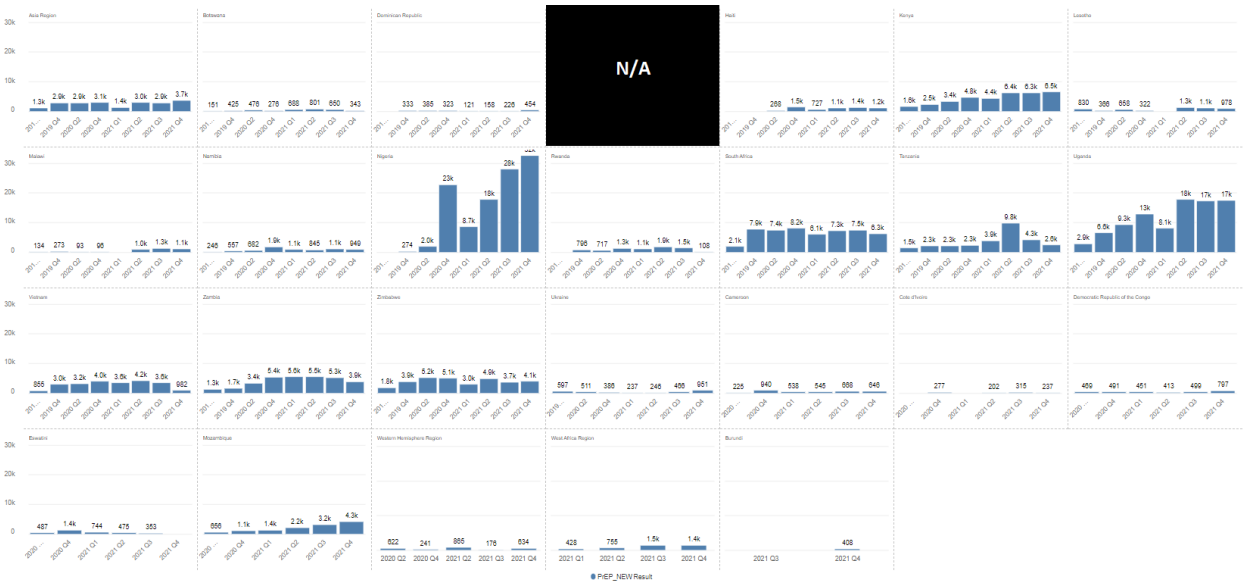
Figure 2.1.2.17: Trends in ART Scale Up Among MSM and Transgender People[24]



[23] Source: PEPFAR Panorama, Treatment: Global Dossier, Treatment & KP Chapter, TX_NEW/TX_CURR Trends by KP Page (TX_CURR)

[24] Source: PEPFAR Panorama, Treatment: Global Dossier, Treatment & KP Chapter, TX_NEW/TX_CURR Trends by KP Page (TX_CURR)

Figure 2.1.2.18: Trends in Pre-exposure prophylaxis (PrEP_NEW) Scale Up Among Key Populations[25]



Cumulatively, PEPFAR has supported over 28 million voluntary medical male circumcisions (VMMC) in Eastern and Southern Africa to help protect men and boys from HIV infection (Fig 2.1.2.19). COVID-19 restrictions on gatherings in most of the PEPFAR-supported countries over the past 12 months caused a pause in VMMCs (2.1.2.20), but they are rebounding. Using data through FY21, PEPFAR will assess the setbacks on the VMMC program due to COVID-19. PEPFAR is working with UNAIDS to generate coverage estimates for VMMC by age at the subnational level to facilitate program planning.

[25] Source: PEPFAR Panorama, Prevention: Global Dossier, Chapter 2: PrEP Chapter, Trends by KP Page

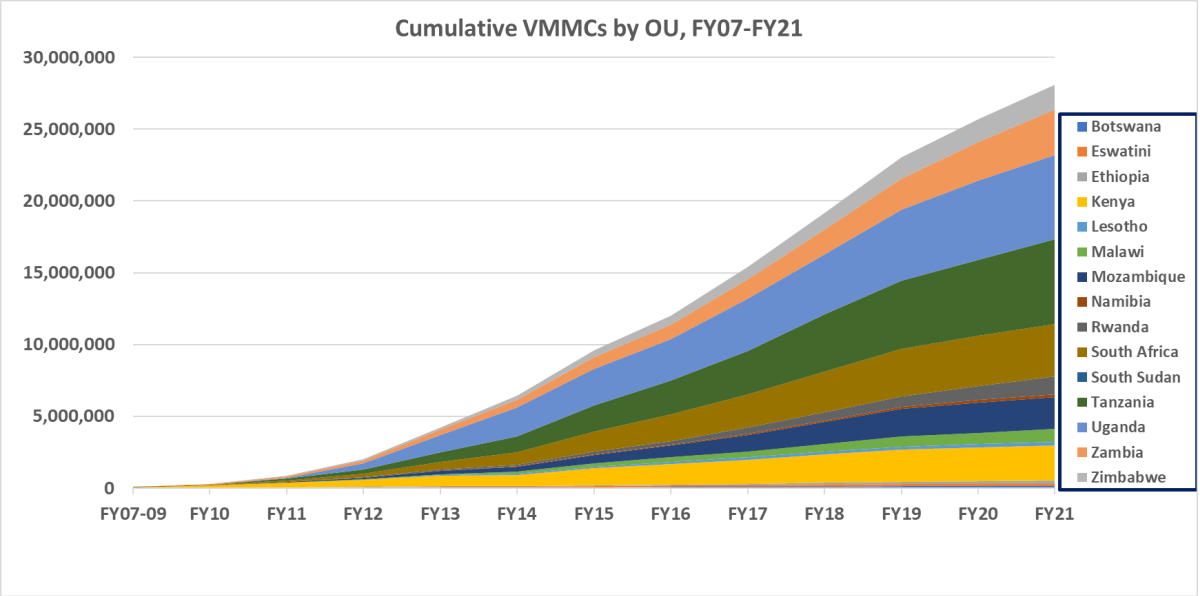
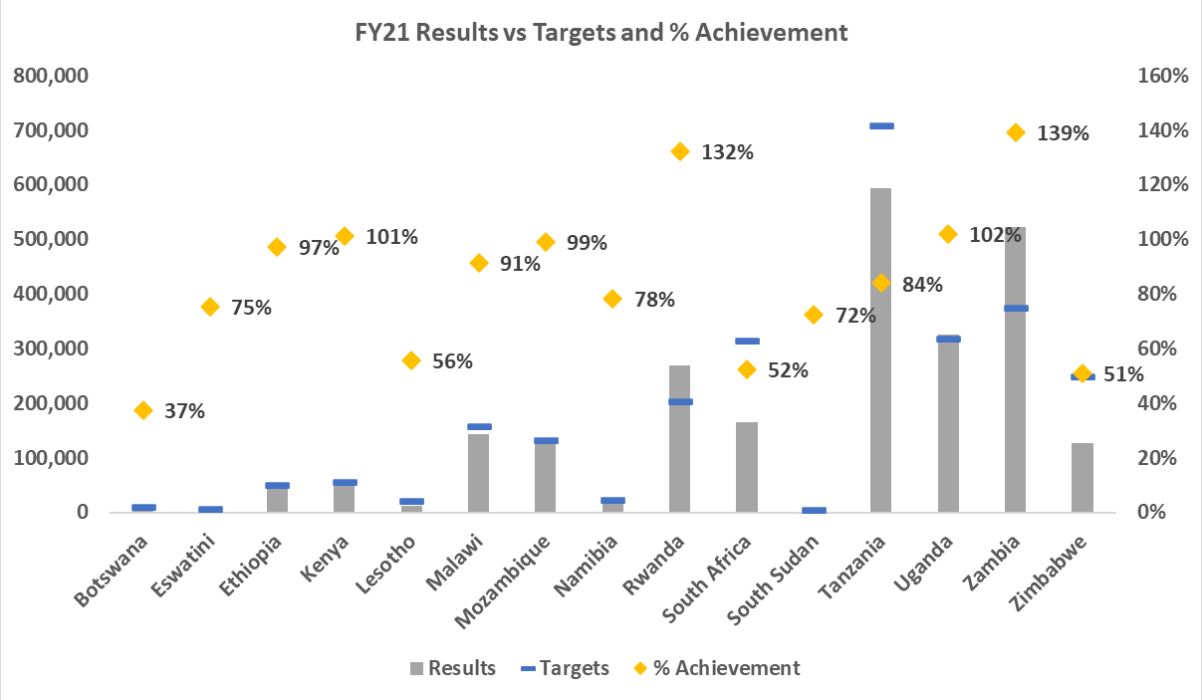


Figure 2.1.2.20: VMMC Planned FY21 Targets and Results by OU



The DREAMS program continued to be impacted by COVID-19 with partial lockdowns and restrictions on in-person gathering. DREAMS continued to adapt programming to meet local gathering requirements which often resulted in delivering remote or virtual prevention. We do not know the impact of virtual prevention services and continue to assess delivery methods. In

FY20, PEPFAR observed continuing declines in new diagnoses among adolescent girls and young women (*Figure 2.1.2.21)* through the middle of FY20 before lockdowns. Encouraging PrEP results in FY21 included doubling the number of adolescent girls and young women newly accessing PrEP (PrEP_NEW) - a critical prevention service for this vulnerable population (*Figure 2.1.2.22)*.

Figure 2.1.2.21: Declines in New Diagnoses Among AGYW

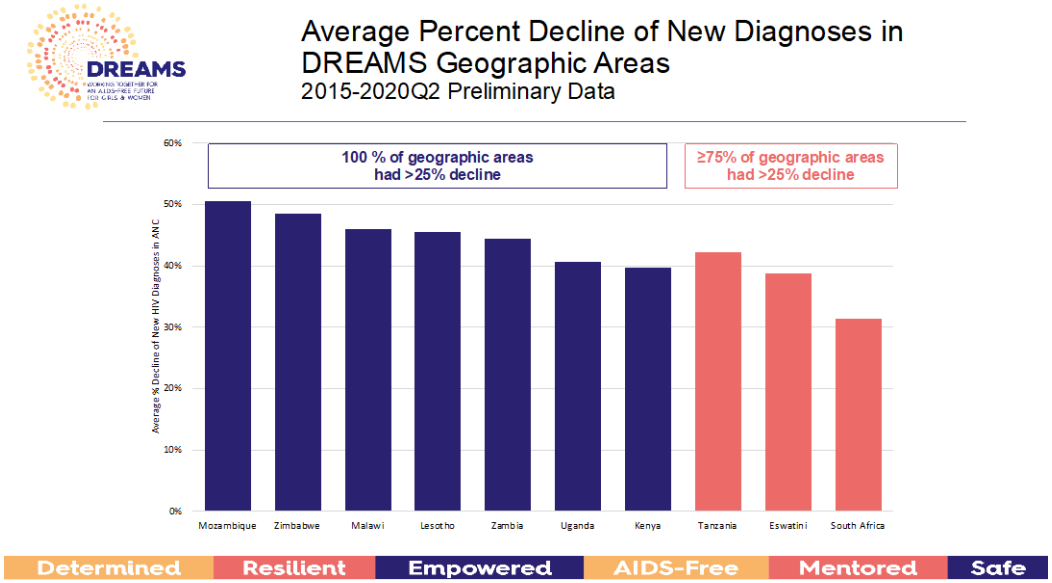
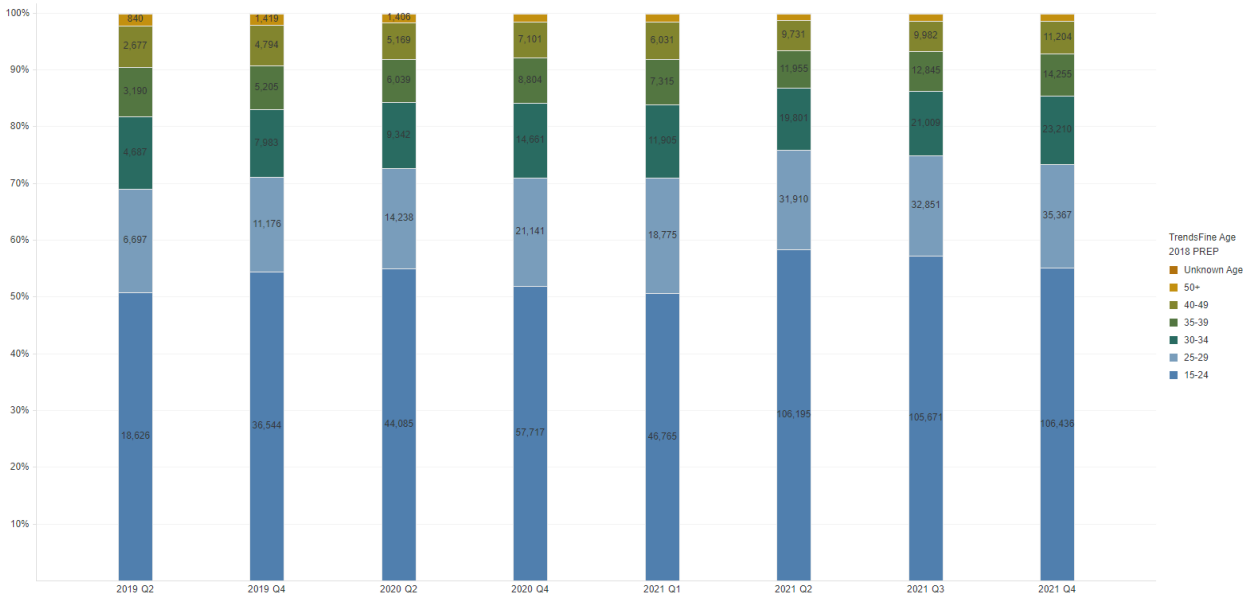


Figure 2.1.2.22: Trends in PrEP Scale Up Among Females across all OUs[26]



[26] Source: PEPFAR Panorama, Prevention: Global Dossier, Chapter 2: PrEP Chapter, AGYW on PrEP Page

Establishing triangulation of routine data from surveillance, program, laboratory, pharmacy, and recency surveillance provide essential real-time guidance for changing program direction, which survey data can only provide periodically. The Zambia recency surveillance system (Figure 2.1.2.23) found that in 2020, 1 in 12 newly diagnosed individuals acquired HIV within the last year and 15- to 24-year-old individuals and women had a higher prevalence of recent infection. These data were collected through program implementation where HIV testing is occurring and not a probabilistic-sampling frame. Recency surveillance provides information about new and chronic infection patterns (cutting edge of the epidemic), insights on where recent infections may be diagnosed, and demographic patterns – including age, sex, and geography. These data can also help identify where there are gaps in the clinical cascade from diagnosis to viral suppression, population, and geography. Recency data are even more needed in light of COVID-19 to identify pattens in recent infections.

Figure 2.1.2.23: Characteristics of persons enrolled in Zambia recent infection surveillance program, 2020[27]

Table 1. Characteristics of persons enrolled in Zambia recent infection surveillance program, 2020

	Clients with confirmed long-term infections (%)	Clients with confirmed recent infections (%)
Sex		
Male	748 (94.4)	44 (5.6)
Female	1,025 (89.3)	123 (10.7)
Age group		
15-24	299 (84.5)	55 (15.5)
25-34	737 (91.4)	69 (8.6)
35-44	517 (94.0)	33 (6.0)
45+	220 (95.7)	10 (4.3)
Province		
Lusaka	1,065 (90.0)	118 (10.0)
Copperbelt	708 (93.5)	49 (6.5)
Testing modality		
Index	175 (94.1)	11 (5.9)
PMTCT	506 (92.0)	44 (8.0)
VCT	641 (91.7)	58 (8.3)
PITC	192 (90.6)	20 (9.4)
VMMC	6 (85.7)	1 (14.3)
Other	253 (88.5)	33 (11.5)
Total	**1,773 (91.4)**	**167 (8.6)**

[27] https://theprogramme.ias2021.org/PAGMaterial/PPT/1666_4330/IAS_2021_recency_poster.pdf

2.2 COP22 Vision and Implementation Themes

COP22 guidance for program implementation in FY2023 includes themes from the draft PEPFAR Strategy for 2021-2025, which is under development. The vision is for sustained epidemic control of HIV by supporting equitable health services and solutions, enduring national health systems and capabilities, and lasting collaborations.

Ongoing assessment of PEPFAR's progress recognizes the remarkable progress across many PEPFAR-supported countries toward 95-95-95 targets for HIV epidemic control, as well as the paramount importance of recognizing inequalities that are posing barriers to success and advancing equitable services and solutions. This requires an overarching 'equity lens' with consistent efforts to target and adjust PEPFAR activities in order to reach 95/95/95 benchmarks of epidemic control, not only in aggregate OU-wide measures, but particularly for populations that are disproportionately impacted by new infections and/or not reaching benchmarks for epidemic control. Evolving goals of the PEPFAR Strategy have been used to develop Implementation Themes for COP/ROP22, listed below:

Goal 1 is to Accomplish the Mission – that is, to achieve and sustain epidemic control using Evidence-based, Equitable, Person-Centered HIV Prevention and Treatment Services. As countries approach and attain the 95-95-95 goals, it is important to adapt the program from one focused on rapid scaling of ART coverage and other services to one that consistently and effectively supports continuity of treatment and person-centered services for all people living with HIV. This takes a public health approach to identify and specifically support populations falling short of the benchmarks or populations where new transmission is occurring by utilizing public health systems aligned with national or subnational public health entities for case surveillance and recency. Person-centered care recognizes that the cohort of persons living with HIV is aging and require attention to improving quality and breadth of care to lower mortality of those in treatment. *COP22 plans will continue to mark OUs reaching epidemic control of HIV, focus increasing attention on populations experiencing gaps, and support needed adaptations of the program as it moves from scaling to sustaining HIV impact.*

Goal 2 is to Build Enduring Capabilities – Resilient and Capacitated Country Health Systems, Communities, Enabling Environments, and Local Partners. As PEPFAR succeeds in supporting countries to attain the UNAIDS 95-95-95 goals, it has been building and strengthening systems and infrastructure for health services, including laboratories, specimen transportation networks, health workforce, supply chain infrastructure and systems, health

records and national data systems. In many cases these systems have been a lifesaving infrastructure for support of COVID-19 public health response from testing to vaccination. In large part, these systems were designed to become a long-term asset of the partner country health care and public health system. In some cases, they needed strengthening and adaptation to support COVID-19 in addition to HIV. *COP22 plans will address how health systems built and supported by PEPFAR are sustained and rooted as capabilities owned, integrated, and delivered in the country. Country teams will review and address barriers to local responsibility for the HIV response. Recognizing the important role of community-led efforts as critical to sustain HIV impact, COP22 will also address support for community systems and capabilities and creating enabling environments to address discriminatory policies, gender-based violence, and other inequities that stand in the way of progress and human rights.*

Goal 3 is to Build Lasting Collaborations: Strengthen Cooperation and Coordination for Greater Impact, Burden Sharing, and Sustainability. PEPFAR was brought into existence as an emergency plan to respond to the global HIV/AIDS crisis. As more and more countries achieve epidemic control of HIV and with time and support are able to sustain it, we must broaden the base of support, to catalyze and support aligned national programs where country government, PEPFAR, Global Fund, other multilateral partners, and civil society play to their strengths in support of a unified, nationally-aligned program. *COP22 plans will provide evidence of movement toward cooperation, coordination, and accountability across U.S. government, donors, country government leaders, community leaders representing HIV-impacted populations, and multilateral institutions in the design and leadership of HIV services.*

2.2.1 Focusing on Equity

Health Equity can be defined as the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically, or geographically.[28] While equality extends the same services to everyone, equity tailors services and advances policies to achieve optimal outcomes for all.

Equity Lens or Inequalities Lens can be described as an approach that prioritizes actions that reduce inequalities and advance equity, including actions to address the underlying social determinants of inequality.

[28] World Health Organization. (2021). Social Determinants of Health. https://www.who.int/health-topics/social-determinants-of-health

Like other pandemics and health problems, HIV thrives on the margins. Poverty, lack of access to services, discrimination, and marginalization create conditions where protection from HIV acquisition is not present, where diagnosis is delayed, and where people face substantial barriers to services and uninterrupted treatment.

Some definitions of health equity emphasize the ways in which health outcomes are grounded and intertwined in social, economic, and political advantage or disadvantage. Disadvantage and inequities advance when human rights are denied, and effectively addressing inequities requires focused and sustained efforts to protect and advance human rights. The COVID-19 pandemic has demonstrated the vulnerability of poor and marginalized people around the world, as the impact of SARS-CoV-2 was most pronounced on people who were disenfranchised, marginalized, and financially vulnerable. HIV demonstrates a similar disproportionate impact on disenfranchised, stigmatized, and marginalized populations.

The UNAIDS 2021-2026 Global AIDS Strategy[29] recognizes that inequalities are central to the global delays and gaps in accomplishing the goals of HIV Epidemic Control, and that addressing inequalities will be essential to success. Prominent inequalities impacting global and PEPFAR progress can be found among children, adolescent girls and young women, and key populations.[30] For each of these population categories, substantial focused attention and investment has been made in provision of HIV services, yet it has not been of sufficient scale and impact to achieve intended outcomes. A substantial gap in identification of children living with HIV has led to over 800,000 children living with HIV not on treatment, a gap which persists even as unacceptable HIV-related mortality among children <5 years of age continues. In sub-Saharan Africa, adolescent girls and young women experience 25% of new HIV infections, while representing only 10% of the population. Worldwide in 2020, 65% of all new infections occurred among key populations and their sex partners, reflecting unrealized opportunities for prevention.

PEPFAR has championed a data-driven approach and accountability for results. This requires that as OUs approach and even attain epidemic control as determined by national aggregate measures, PEPFAR country teams and national programs must take deliberate and specific action to identify and address gaps in coverage for testing, treatment, and viral load suppression among populations that are not meeting those benchmarks.

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[29] UNAIDS (2021) Global AIDS Strategy 2021-2026 — End Inequalities. End AIDS. www.unaids.org/en/Global-AIDS-Strategy-2021-2026

[30] UNAIDS (2021) 2021 UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS . www.unaids.org/en/resources/documents/2021/2021-global-aids-update

An equity lens for sustaining epidemic control of HIV for the long term must also recognize that public resources are inherently constrained and that those limited funds must support the most vulnerable and disadvantaged. From a sustainability perspective that wants to ensure equity, we have to explicitly ensure that donor and public spending are targeted where the needs are the greatest.

It is imperative that USG teams as well as implementing partners are cognizant of populations that are not achieving 95/95/95 objectives of HIV epidemic control, and also equipped to actively address barriers faced by these populations. Equity does not *only* mean equal access to the same services as others. It means that services are tailored to the unique needs of populations facing unique risk of new HIV infection, delayed diagnosis, or treatment that does not successfully achieve durable viral suppression. In many cases, including that of key and priority populations, this requires that impacted communities are engaged in the design, leadership, implementation, and monitoring of services.

Pediatric outcomes have lagged significantly below adult outcomes in most PEPFAR partner countries. COP resources must be allocated with an equity approach to close gaps in pediatric HIV care. PEPFAR programs should set goals, objectives, and targets for eliminating vertical transmission and ending pediatric AIDS. Accountability for reaching these goals and targets will be addressed in budgeting and expenditure analysis, HRH planning, program management, and monitoring and evaluation. Programs with significant gaps will conduct dedicated, regular review and monitoring of pediatric and PMTCT programs in quarterly focused meetings or calls. Impacted families should be included in program design, and community-led monitoring should address child and family-centered care. Pediatric partners should work closely with OVC partners to ensure that case management and socio-economic support are provided to mothers of infants and children at greatest risk of poor outcomes.

In PEPFAR partner countries, the gender gap remains a critical inequality for new infections and other HIV-related outcomes. Gender inequality can impact individuals of all gender identities and expressions. To close gaps for Gender Equity, PEPFAR programs will expand evidence-based, gender-transformative programming across the HIV clinical cascade and HIV prevention outside of DREAMS PSNUs. Programs will engage men and boys as allies and stakeholders in preventing violence and changing harmful gender norms. To address gender-based violence (GBV), programs will identify and respond to GBV (case identification, first-line support, clinical care) and link survivors to evidence-based HIV prevention, including PrEP, or provide active linkage to HIV treatment services. A new section addressing gender

equality has been added COP/ROP22 Guidance (Section 6.6.2). Programs should integrate sexual and reproductive health services (e.g., family planning, STI testing and treatment) into HIV prevention, care and treatment, and MCH clinical services and ensure service platforms are adolescent- and youth-friendly and are gender-affirming. The Minimum Program Requirement on local partners is updated to include women-led partners.

Members of key populations face risks of HIV acquisition many times higher than the general population. To close gaps for key populations, PEPFAR programs will continue to focus on what has worked well, including scaling of PrEP services and KP-specific differentiated service delivery across the cascade. With COP/ROP22 guidance, updated Minimum Program Requirements will advance funding to KP-led organizations and raise expectations for progress in an enabling policy environment to address structural barriers for key populations. PEPFAR will continue to promote regular key populations size estimation exercises as part of PEPFAR's planning cycle in all countries, and plan for a sustainable approach to address gaps in size estimates and bio-behavioral data collection. PEPFAR will also expand community-led monitoring specific to key populations.

PEPFAR will need to apply an equity lens as it strategically approaches sustainability strategy as well, as key and priority populations facing gaps in coverage continue to require tailored, community-led services and programs. In some cases, services for key and priority populations might be slower to engender political will and public commitment, so USG support and alignment with multilateral and private sector donors and sponsors may need to be sustained as partner countries assume increasing responsibility for leading and supporting other elements of an aligned National HIV strategy.

In keeping with its principles, PEPFAR's approach to equity must be grounded in data. Program services are most readily tailored and measured by PEPFAR teams, and they must be designed, implemented, and monitored with an equity lens. However, beyond programs are policies and systems that, intentionally or not, create inadequate outcomes for key and priority populations and children, and pose major barriers to progress, including laws that criminalize or marginalize members of key populations or criminalize HIV, and a lack of political will to provide equitable services to at-risk communities. Engagement and advocacy with Ministries of Health, as well as other government sectors, and civil society are necessary. In some cases, CSOs that represent affected populations may be helpful allies and may also need support to build advocacy capacity; in some cases, strategic alignment with human rights priorities of the U.S. Embassy or partner government will help advance more equitable policies and systems.

2.2.2 Stigma, Discrimination, Violence, and Human Rights

New in COP22, PEPFAR has introduced a new Minimum Program Requirement: Evidence of progress toward advancement of equity, reduction of stigma and discrimination, and promotion of human rights to improve HIV prevention and treatment outcomes for key populations, adolescent girls and young women, and other vulnerable groups (see Section 2.6).

HIV-related stigma, discrimination, and violence, reduce access to, and use of, essential health services, and undermine efforts toward effective responses to HIV/AIDS. In contrast, inclusiveness, equal treatment and respect for all, along with evidence-based policies and practices that reflect those principles, all facilitate uptake of essential health services and bolster effective responses to HIV/AIDS. The UNAIDS 10-10-10 targets require focus on removal of societal, including legal barriers (specifically stigma, discrimination, punitive policy environments, and violence) that limit access to or utilization of HIV services.[31] PEPFAR is committed to joining other institutions (multilateral, global and local) to end stigma, discrimination, and violence and to foster an enabling environment that will increase access to, and uptake of, HIV prevention, treatment, and care services for all people living with and affected by HIV/AIDS; especially adolescents, young people, persons with disabilities, women, and key populations (e.g., men who have sex with men, transgender people, sex workers, people who inject drugs, and people in prisons and other closed settings).

Notably, President Biden issued the 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. Specifically, this directive includes 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.[32]

Below are a list of actions, considerations, and requirements that, taken together, are all part of a framework to promote human rights and eliminate HIV-related stigma, discrimination, and

[31] https://www.unaids.org/sites/default/files/2025-AIDS-Targets_en.pdf
[32] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/04/memorandum-advancing-the-human-rights-of-lesbian-gay-bisexual-transgender-queer-and-intersex-persons-around-the-world/

violence by creating an enabling environment that amplifies the successful implementation of HIV prevention, care, and treatment services.

Stigma, Discrimination, and Violence

Stigma can be described as a dynamic process of devaluation that significantly discredits an individual in the eyes of others, such as when certain attributes are seized upon within particular cultures or settings and defined as discreditable or unworthy. When stigma is acted upon, the result is discrimination. **Discrimination** can refer to any form of arbitrary distinction, exclusion or restriction affecting a person, usually (but not only) because of an inherent personal characteristic or perceived membership of, or an association with, a particular group.[33] At times, this discrimination can lead to violence—behavior involving physical force intended to hurt, damage, or kill someone or something.[34]

To control the epidemic, it is imperative that OUs identify and understand the often-complex dynamics driving HIV-related stigma, discrimination, and violence, and implement innovative, evidence-based, community-led approaches to address the specific types of stigma (experienced, perceived, anticipated, internalized, compound or layered, or intersectional and secondary) at all points in the HIV service-delivery cascade. Findings from a programmatic assessment of PEPFAR implementing partners found that the majority of surveyed IPs saw stigma and discrimination as a barrier to accessing HIV services at primary healthcare facilities, and that significant portions of all cadres of health facility staff had witnessed stigmatizing behavior.[35] The same assessment found that implementers reported gaps in the availability of written and posted policies regarding patient rights, related enforcement procedures, formal systems for patient advocacy, and robust processes for recording and responding to patient complaints,[36] despite these being indicators of quality for PEPFAR's Site Improvement through Monitoring System (SIMS).[37]

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[33] UNAIDS . UNAIDS Terminology Guidelines (2015). https://www.unaids.org/sites/default/files/media_asset/2015_terminology_guidelines_en.pdf

[34] https://www.un.org/sites/un2.un.org/files/udhr.pdf

[35] Rodriguez, E.M., Wells, C. (2019, July 23). Interventions and Best Practices to Eliminate Stigma and Discrimination in PEPFAR Programs: Results from a Programmatic Assessment [Conference presentation]. 10th IAS Conference on HIV Science, Mexico City, Mexico. http://programme.ias2019.org/Programme/Session/51

[36] ICAP Global Health. (2020). *Eliminating HIV-related Stigma and Discrimination: Global Lessons from PEPFAR-supported Programs*. https://icap.columbia.edu/tools_resources/eliminating-hiv-related-stigma-and-discrimination-global-lessons-from-pepfar-supported-programs/

[37] https://www.state.gov/wp-content/uploads/2021/03/MASTER_SIMS-4.1-Site-Tool-_8March2021.pdf

Additionally, there is a need to address the structural- and policy-level barriers that perpetuate discrimination as it relates to HIV. Stigma, discrimination, and violence are frequently targeted at people living with HIV and TB, and key and other vulnerable populations, including young people and women. Yet the impact reaches beyond these populations. Other key stakeholders, including health providers, supportive community members, human rights defenders, and supportive religious and political leaders, can also suffer from the effects of these systemic and structural barriers.

Any post-violence care provided by PEPFAR implementing partners should take into account WHO guidelines and sensitivity training to reduce violence-survivor stigma among healthcare workers. More information on PEPFAR's approach to gender equality and GBV can be found in the Gender Based Violence and Violence Against Children section of the Technical Considerations (Section 6.6.2 and 6.6.2.1).

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.[38] Since the 2008 launch of the PLHIV Stigma Index, shifts in the HIV 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 field teams adapted questions distinguishing experiences by gender identity, population, and individuals born with HIV. It examines varied experiences of sex workers, men who have sex with men, lesbians, transgender individuals, and people who inject drugs. It provides an expanded healthcare 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 additional scale to measure resilience of people living with HIV. This revised U.S. government-compliant version supports baseline data collection about experiences of stigma and discrimination of people living with HIV and 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 Global Fund or another donor financing implementation of the PLHIV Stigma Index 2.0. OUs in which a PLHIV Stigma

[38] https://www.stigmaindex.org/about-the-stigma-index/the-people-living-with-hiv-stigma-index-2-0/

Index has not been conducted within the last three years are required to commit funding to its implementation in COP22.

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 ensure 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 other men who have sex with men, 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 PLHIV networks, key populations 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 three 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 three-year timeframe, taking care to be attentive to local COVID-19 conditions.

Human Rights

PEPFAR's human rights guiding principles include respecting, protecting, and fulfilling human rights, thus affirming the dignity of people living with and vulnerable to HIV, and supporting an enabling environment that promotes access to information and services. Affected populations have the right to be heard in all matters affecting them, in addition to rights and freedoms to appropriate information, thought, and expression.

UNAIDS and others have identified specific laws, policies, and practices[39] that discourage equitable, accessible services, especially for populations that are particularly vulnerable and being left behind in the global response:

- Criminalization of HIV non-disclosure, exposure, and transmission
- Laws that fuel harmful gender norms
- Criminalization of key populations, and other practices that leave key populations vulnerable to unethical treatment, discrimination, and human rights violations (e.g., forced anal exams)
- Age of consent laws for service access

Analyses have shown that countries where key populations are criminalized see lower levels of HIV status knowledge and HIV viral suppression; conversely, countries with laws advancing non-discrimination, human rights institutions, and gender-based violence response saw significantly better knowledge of HIV status and viral suppression rates.[40]

Approaches to better address policies, laws, human rights might include:

1. supporting civil society organizations to reform national policies
2. supporting partner governments to reform and implement policies
3. monitoring policies and their implementation, with partners (e.g., SID, National Commitments and Policies Instrument).

In addition, UNAIDS[41] has previously identified seven key program areas to reduce stigma and discrimination and increase access to justice in national HIV responses:

- Stigma and discrimination reduction

[39] https://www.unaids.org/sites/default/files/media_asset/2020_global-aids-report_en.pdf
[40] Kavanagh, M. M., Agbla, S. C., Joy, M., Aneja, K., Pillinger, M., Case, A., Erondu, N. A., Erkkola, T., & Graeden, E. (2021). Law, criminalisation and HIV in the world: have countries that criminalise achieved more or less successful pandemic response? *BMJ Global Health*, *6*(8), e006315. https://doi.org/10.1136/bmjgh-2021-006315
[41] https://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pd f

- Training for health care providers on human rights and medical ethics
- Sensitization of lawmakers and law enforcement agents
- Reducing discrimination against women in the context of HIV
- Legal literacy
- Legal services
- Monitoring and reforming relevant laws, regulations, and policies

WHO has also identified a series of critical enablers and recommended policies or practices to define a comprehensive HIV response for key populations.[42] See also technical considerations for key populations (Section 6.5).

COP/ROP Requirements

Recognizing the important role of community-led efforts as critical to sustain epidemic control, COP22 will also address support for enabling environments to address discriminatory policies, gender-based violence, and other inequities that stand in the way of progress and human rights that impact HIV services.

The below are requirements for PEPFAR countries to support a sustainable, non-discriminating, enabling environment. OUs should detail how they will meet these requirements during COP22 strategic planning meetings and ensure they are coordinating with existing efforts of other partners and stakeholders such as the Global Fund and UNAIDS. Specific activities and budgets must be delineated in COP22 submissions.

0. Develop a plan, timeline, and resource allocations to measure, document, and mitigate HIV-related stigma, discrimination, and violence. This plan should:
    a. reflect regular CSO engagement and review of CLM findings.
    b. demonstrate coordination with relevant existing working groups, including PEPFAR interagency, other U.S. Mission sections, U.S. Department of State Bureaus, and community representatives, including key populations. This is particularly important in countries where the Chief of Mission has identified concerns about human rights violations and abuses and about on-going repression of key and priority population communities and CSOs as these relate to service provision for HIV. Plans should demonstrate, in light of the Presidential Memorandum referenced above (to strengthen existing efforts to combat the

[42] WHO. (2016, July 1). *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*. World Health Organization. https://www.who.int/publications/i/item/9789241511124

criminalization by foreign governments of LGBTQI+ status or conduct abroad, to promote respect for the human rights of LGBTQI+ persons and advance nondiscrimination), close coordination with Human Rights Officers at post

c. demonstrate coordination with related initiatives in-country supported by other donor, multilateral organizations, and partners (see further below on assessments). Overall, PEPFAR teams should work collaboratively with other partners to ensure coordinated, concerted action at the country level to fund and implement recommended, comprehensive programmatic strategies to address stigma and discrimination at scale and promote partner government leadership; ensure technical support and assistance is provided (both to government and civil society) at country level for development of funding applications, national plans and their implementation and monitoring; identify key gaps and priorities

d. consider activities to promote undetectable = untransmissible (U=U) messages, trainings for healthcare providers, violence response mechanisms, and other interventions.

e. be captured in the FAST, Table 6, and other applicable COP tools. Additionally, teams should ensure coordination with the UNAIDS Global Partnership for Action to Eliminate all forms of HIV Related Stigma and Discrimination and the Global Fund's Breaking Down Barriers Initiative, where applicable.[43]

1. Include a section on non-discrimination in the design and administration of programs in all PEPFAR trainings, including but not limited to, trainings held for implementing partners and other direct service providers receiving PEPFAR funds.

2. Reinforce that all PEPFAR-funded implementing partners have zero-tolerance policies in place that protect participants from all forms of abuse, unethical behavior, and misconduct (i.e., sexual, physical, emotional, and financial abuse, discrimination, coercion, exploitation, and neglect), to be assessed during contract negotiations, in accordance with local and U.S. laws, regulations and policies. (See also Section 4.0 Agency Partner Performance and Management Guidance).

3. Work with IPs to maintain a posted "Patients' Bill of Rights" (translated into local languages for all to understand) in all common areas within all facilities and community

[43] See also: https://www.unaids.org/sites/default/files/media_asset/global-partnership-hiv-stigma-discrimination_en.pdf and https://www.theglobalfund.org/media/1213/crg_breakingdownbarriers_qa_en.pdf

sites. Note, this requirement and associated redress mechanisms is a SIMS standard/CEE.

4. Designate an in-country, interagency point-of-contact (POC) whose responsibility will be the coordination of human rights-centered programming—actively liaising and coordinating efforts with local human rights leaders and champions, rights-focused CSOs, government, and other development partners (e.g., UNAIDS, GFATM, other diplomatic missions, Department of State or other USG human rights funding, USAID DRG/DDI mission colleagues, among others).
5. Maintain an in-country, interagency point-of-contact (POC) whose responsibility will be the oversight of the PEPFAR USG staff Gender and Sexual Diversity (GSD) Training and ensure that a system is in place to track PEPFAR USG staff compliance with this training requirement at the OU level. At the headquarters level, each PEPFAR implementing agency must also identify a POC to carry out the same functions. In 2018, the GSD training was updated to be more inclusive of GSD issues among all key populations. Each new PEPFAR USG staff member, both field and headquarters, must complete the online version of the GSD training within two months of their hire date. The training is available for all PEPFAR USG staff and IPs at PEPFAR Virtual Academy, and also at USAID University (for USAID staff). Alternatively, trainers via implementing agencies and other partners such as HP+ are available to conduct face-to-face trainings. However, resources to facilitate and host GSD in-person trainings must be covered by the OU and in consultation with agency HQ staff. For IPs, especially those IPs serving KPs, it is highly recommended that similar GSD trainings are offered, strengthening commitments to reduce barriers for people accessing services.
6. In addition, once a year, the GSD POC is required to convene a panel(s) to discuss PEPFAR's engagement around GSD, inclusive of lesbian, gay, bisexual, transgender, and intersex (LGBTI) individuals; key populations; people with mental health concerns; and adolescent girls and young women. Teams should consult HQ for additional guidance and resources. Teams should aim to support panels that are as diverse and inclusive as possible. Ensure that legal environmental assessments (LEAs), or similar assessments, are conducted every three years and data are gathered to develop effective strategies to optimize patient care, improve program monitoring, and strengthen access to and quality of services provided while engaging other relevant embassy staff/sections in these analyses. LEAs identify barriers to accessing prevention,

treatment, care, and support services, and inform action to address these barriers, with a focus on access to justice and the reduction of stigma, discrimination, and violence. OU teams may use the UNDP Legal Environment Assessment Tool as a guide, or other methodologies as appropriate. Other methodologies include HP+ Policy Assessment and Action Planning (PSAP) process, UNAIDS National Commitments and Policies Instrument, CDC AIDS Law Briefs, and Global Fund assessments of human rights-related barriers to HIV services (see below). UNAIDS Fast Track Guidance on Human Rights may also serve as a useful tool.[44]

PEPFAR OUs should ensure that LEAs are coordinated with and not duplicative of other initiatives, such as the Global Fund Breaking Down Barriers Initiative, and efforts of other embassy staff/sections, such as the Political and Economic sections. The Global Fund will continue scaling up of programs to reduce human rights-related barriers to HIV services in 20 countries, including the following PEPFAR OUs: Benin, Botswana, Cameroon, Democratic Republic of Congo (province level), Cote d'Ivoire, Ghana, Honduras, Indonesia (selected cities), Jamaica, Kenya, Kyrgyzstan, Nepal, Mozambique, Philippines, Senegal, Sierra Leone, South Africa, Uganda, and Ukraine. In these countries, the Global Fund has supported research teams to conduct detailed baseline and mid-term assessments of human rights-related barriers that should be shared with PEPFAR field teams, when available. These assessments, as completed, are available publicly and serve as the basis for national plans for a comprehensive response to human rights-related barriers.[45]

If an LEA, Global Fund Breaking Down Barriers assessment and plan, or similar activity has recently been conducted, OU teams should support or participate in processes to review findings, identify gaps, chart strategic priorities, determine next steps, and monitor progress. In countries where policy, legislative or other frameworks further entrench inequalities and marginalization, it is important to support dialogue between national and local governments, members of populations impacted by the epidemic, and other key stakeholders, while seeking to ensure safety and confidentiality as appropriate.

[44] https://www.unaids.org/sites/default/files/media_asset/JC2895_Fast-Track%20and%20human%20rights_Print.pdf
[45] https://www.theglobalfund.org/en/funding-model/throughout-the-cycle/community-rights-gender/

A country-by-country overview of various HIV related laws and policies is now available online from UNAIDS.[46] In addition, the HIV Policy Lab[47] systematically gathers and monitors laws and policies around the world, inclusive of some human rights-related laws and policies. OUs should review their country's LGBTQI Report Card[48] to assess its attainment of core human rights protections for LGBTQI individuals and to inform the COP requirements outlined in this section. Further information about addressing stigma, discrimination, violence, and human rights specific to key populations can be found in Section 6.5.

2.2.3 Attaining Epidemic Control: Approaching 95/95/95

To approach achievement of national 95/95/95 goals for HIV diagnosis, care, and treatment, is a remarkable public health accomplishment, but not an occasion to lessen commitment to persons living with HIV and to effective programming. A number of adaptations and changes should be anticipated and planned and programmed for, in consultation with stakeholders. Stakeholders should begin discussing and anticipating adaptations of the program well in advance of achieving the 95/95/95 benchmarks, so that adaptation to a program reaching treatment saturation may be tailored to the country context. A few examples are included here.

1. Aggregate achievement of these goals may not be experienced in all areas and for all populations. Careful assessment of accomplishment among districts, demographic disaggregated age and sex strata, and key and priority populations must be done to identify groups needing tailored services for testing, prevention, and treatment. Any populations that have not met 95/95/95 benchmarks, including children, adolescent girls and young women, and key and priority populations, should have specific, targeted, and budgeted plans.
2. Testing strategies should be assessed, adjusted, and tailored to ensure safe, effective, and ethical testing of those at high risk, as well as populations where people are at particular risk from delayed diagnosis (e.g., children of people living with HIV). Testing strategy should be assessed for its success in finding new cases, in connecting high risk individuals to prevention services, and potentially as a path to reengagement in treatment for persons living with HIV with a prior positive test.

[46] http://lawsandpolicies.unaids.org/
[47] https://www.hivpolicylab.org/
[48] http://globalequality.org/reports/international-publications-on-lgbt-human-rights/267

3. Treatment programs should be designed to optimize long-term, continuous treatment, and address re-engagement of clients who have experienced treatment interruption as well as those who are newly diagnosed. Functions of partners may evolve or specialize based on need and capability. For example, partners who are successful at efficiently and effectively sustaining a stable cohort of patients on continuous treatment might not be the same partners who excel at case finding and engaging populations where new cases are occurring.
4. Government public health authorities aligned with HIV prevention, care and treatment efforts may build capacity to conduct public health surveillance for new infections, investigate and target case finding resources for outbreaks of recent infections, and to track individual treatment outcomes.
5. HIV prevention programs, including PrEP and other biomedical interventions, will need to be scaled and optimized, especially for adolescent girls and young women and key and priority populations where the rate of new infections remains substantial.

Additional adaptations of PEPFAR programs to treatment saturation may be developed as stakeholders carefully assess the current state of the HIV epidemic and consider the trajectory of HIV prevention, care, and treatment toward sustained epidemic control.

2.2.4 Sustaining Epidemic Control: Building Blocks of Sustainability

PEPFAR-supported countries are reaching epidemic control, the first step in fulfilling the vision to combat HIV. Now PEPFAR must turn to the next, critical task: sustaining HIV impact. Sustaining HIV epidemic control will require joint efforts between PEPFAR, partner governments, civil society, private sector partners, and other stakeholders such as the Global Fund and other donors operating in each country. While PEPFAR will remain a priority of the U.S. Government, it will not remain in the forefront of delivering HIV services worldwide forever. PEPFAR expects countries to assume greater leadership and functional responsibility for their national HIV responses, including shaping and integrating service delivery, building technical capacity, and increasing levels of financial responsibility. Over time, PEPFAR's role will transform from a direct funder of services, into an accountability partner, supporting governments and communities to sustain services to all citizens. PEPFAR will focus on its role as a catalyst, broker, advocate, and investor in emerging innovations in HIV/AIDS control, while being available to support countries if there are unexpected setbacks as well.

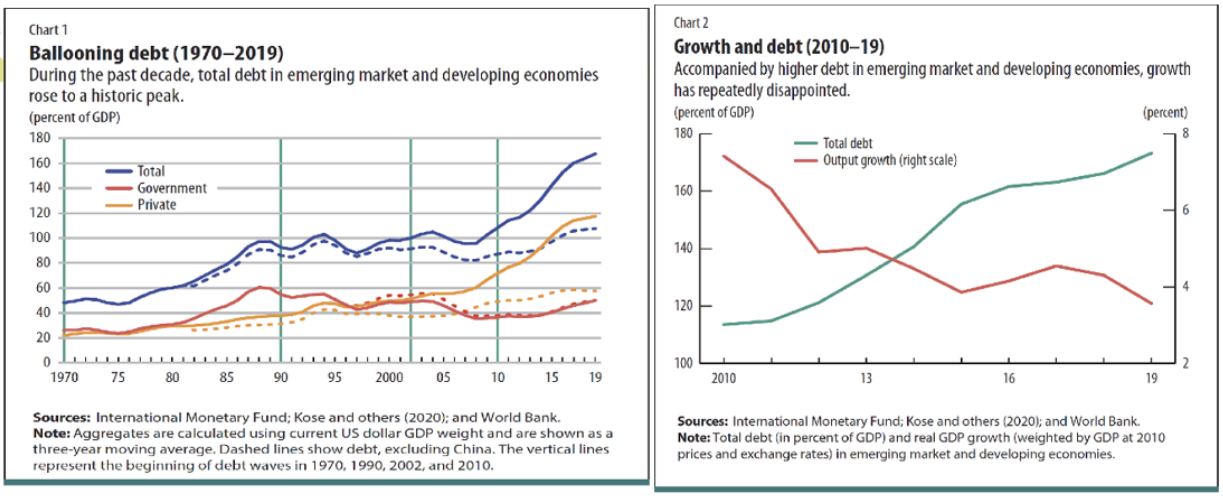
Sustaining epidemic control within this context requires that countries have the functional and financial capacity to maintain key programs at scale. This includes effective and efficient services, systems, and input required to equitably control the HIV and AIDS epidemic, while providing adequate financing. In the face of reductions of financial, managerial, and technical assistance from external donors. sustained epidemic control of HIV is achieved when partner governments and communities and other local actors:

- Program Characteristics
    - Can maintain the total number of new HIV infections below the total number of deaths from all causes among people with HIV (R0 < 1)
    - Viral load suppression of 85% for all ages, genders, and population groups
    - Have a robust public health capacity to monitor and track HIV outbreaks as well as other existing and emerging health threats
    - Have an environment that fights stigma and discrimination, and promotes human rights and equity in the HIV response
- Management Characteristics
    - Ensure an enabling/nimble policy is in place to support sustained HIV outcomes
    - Possess sufficient technical and human capacity to manage and maintain the scale of key programs, services, systems, and resources stewarded by local institutions, communities, and other local actors
    - Possess technical and human capacity to introduce and adapt effective and efficient models and programs
    - Invest sufficient domestic financial resources that are used efficiently and effectively to sustain essential HIV services and meet emerging needs.
    - Possess management and monitoring capacities to deliver quality assured HIV services and commodities

Ensuring sustainability is at the forefront of planning. COVID-19 has affected countries' economic growth and strained health systems, diverting resources and attention to urgently addressing the repercussions from repeated COVID-19 waves. The projected long-term negative impacts of COVID-19 on PEPFAR-supported countries may make discussing sustainability seem unrealistic, and something that should be delayed until the world has recovered. However, sustainability planning is an opportunity to strengthen the systems that will sustain HIV service delivery, as well as underpin disease surveillance and rapid response

efforts. Building capacity and selectively transferring responsibility will strengthen governments' responses to COVID-19, and future health threats.

Figure 2.2.4.1



Preparing for a strong, resilient transformation takes time, and seizing the opportunity, now, to begin the work will allow PEPFAR-supported countries to leverage PEPFAR's resources towards greater strengthening of their health system for sustained epidemic control. Beginning transformation in the midst of COVID-19 may seem daunting but will allow countries to rapidly identify and address what is required for resilient health systems. The following are guiding questions to support the initial stages of transition planning:

1. Are there misalignments or gaps between investments in program areas required for a sustainable response sustainability and related outcomes?
2. Are there areas that would be relatively easy and straightforward to transition to the host-partner country government and/or local partners to take on greater responsibility?
3. How will countries teams begin engaging with the partner government during COP22 implementation to ensure sustainability of core elements of the HIV response?
4. Does the country have a history of supporting transitioned programs?
5. Are certain communities receiving HIV services criminalized and do they face persecution/ a lack of service in a transition?

PEPFAR can support this transformation by recognizing that such efforts will be buffeted by repeated COVID-19 waves, constricted by economic landscapes, and future unknown threats.

Above all, now is the time for countries to plan, transform, and establish capacity for a sustainable and resilient system that can sustain epidemic control despite constantly changing circumstances.

Sustainable epidemic control places sustainability at the same level of priority as epidemic control. PEPFAR's singular focus on 95-95-95 has been transformational in reaching epidemic control. The smaller disease burden present once epidemic control is reached makes sustainability more attainable—making epidemic control a precondition for sustainability. However, epidemic control is not a requirement for program transformation— countries can, and should, embark on transformation while still striving to reach and maintain 95-95-95.

Under PEPFAR's new strategy currently under development, PEPFAR-supported countries must make an intentional shift to balance both attaining 95-95-95 and building capacity to sustain epidemic control of HIV. Concurrently supporting both goals require a new look at planning models, investment priorities, and ways in which success and outcomes are measured. At times there will be an inherent tension, as transformation is expected to be complex and sometimes be messy and may have a temporary negative impact on the 95s. Recognizing this tension allows intentional decision-making with long-term goal of durable sustained epidemic control at the forefront. In order to sustain them for the long-term, partner country governments may want or need to structure their HIV programs differently than how PEPFAR currently structures the programs. For many countries, incorporating HIV into primary service delivery will be the most realistic method for maintaining services. Recognizing and accepting this likelihood allows PEPFAR programs to start planning for how to minimize the risks of that transformation to the quality of services delivered.

Sustainability efforts should focus on financial and functional responsibility. Sustaining epidemic control requires myriad responsibilities of the partner country. These responsibilities can be broken into two broad categories: Functional and Financial. Functional responsibility consists of an enabling environment, locally-led HIV services and systems, and domestic resources, while financial responsibility consists of adequate resource mobilization, budgeting and financial monitoring, resource alignment, and understanding and managing cost. See above.

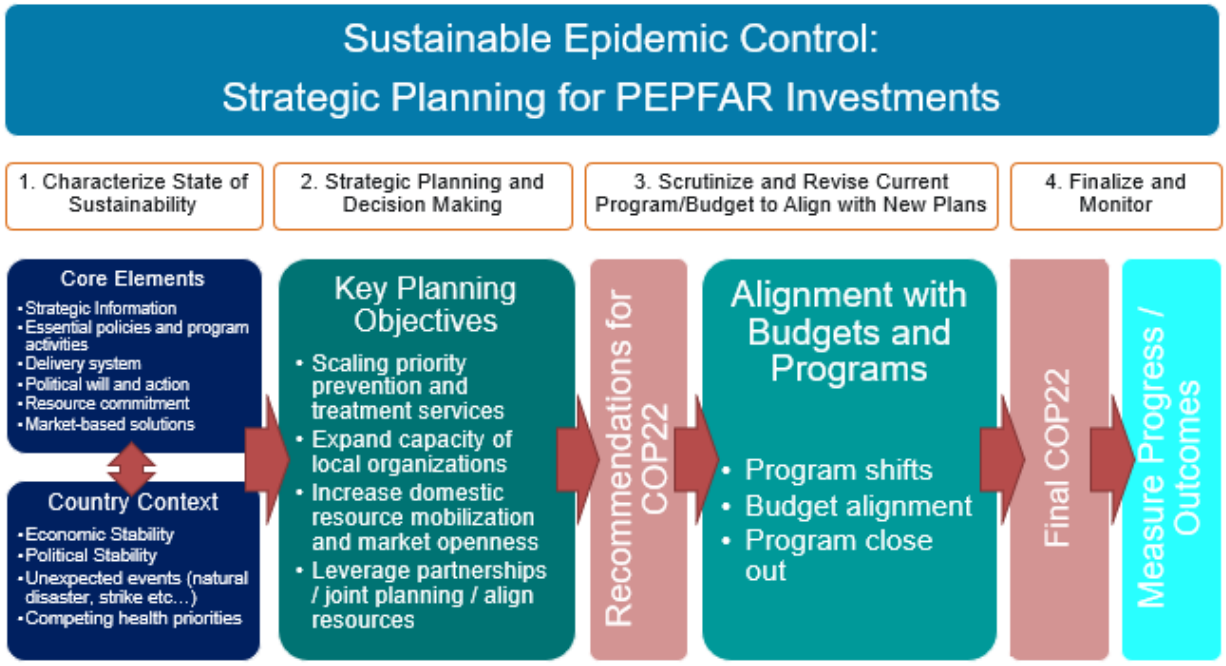
Principles of transformation. Inherent in long-term sustainability planning is the unpredictability of how transformation will occur. It is impossible to predict the myriad factors, including PEPFAR's future funding levels, political will, global events such as COVID-19, and

local disturbances such as natural disasters or unrest, that will impact the timing and composition of PEPFAR's transformation.

However, even in an environment of uncertainty, PEPFAR programs can and should follow several guiding principles to build trust and shared responsibility between all stakeholders.

- **Inclusion:** Cast a broad net to identify and include stakeholders in all discussions on the transformation process, from inception through execution.
- **Equity:** Ensure that as transformation occurs equity remains a key goal to ensuring health services to all citizens.
- **Transparency:** Be honest with what we know and don't know. Share data. Share changes as they occur. Make sure all stakeholders are clear on timing and reasoning.
- **Predictability:** Strive to introduce predictability wherever possible. Agree upon timelines. Use program outcomes and impact as benchmarks for transformation.
- **Flexibility:** Stay agile in case of sudden changes in context, program, or funding. Transformation never goes as planned; agility is central to success.
- **Commitment:** Commit to the outcome. Actively identify threats and prospects. Sequence actions to address risks and take advantage of opportunities. Acknowledge failure as part of the process and commit to trying again.

Figure 2.2.4.2 Strategic Planning for PEPFAR Investments



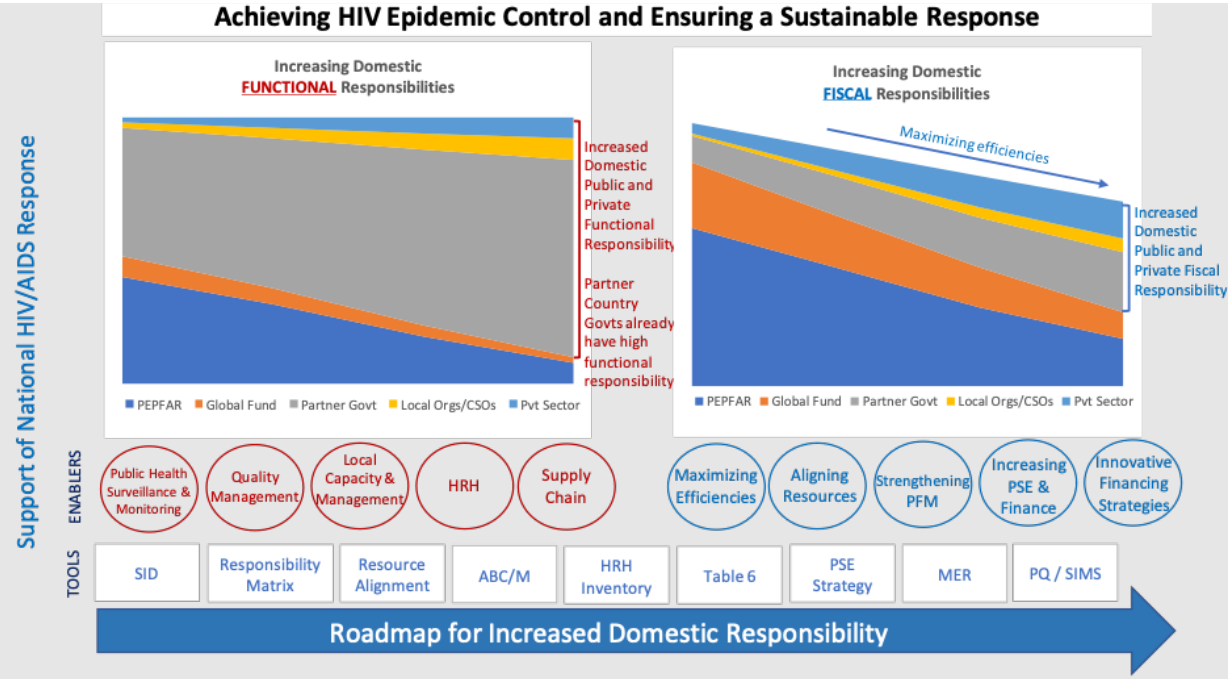
Transformation requires durable partnership. Every PEPFAR OU is responsible for managing its relationships accordingly.

All plans must be tailored to local context, and thoughtfully sequenced. Each PEPFAR-supported OU has a unique context and is in a slightly different position to epidemic control. PEPFAR's sustainability planning, therefore, cannot be prescriptive and static.

Rather than focusing on a prescribed order, PEPFAR programs should focus on the attributes required for transformation. These attributes include investing in co-creating transformation plans, building functional and financial capacity, harmonizing funding sources, finding efficiencies, and making sure data systems are institutionalized into routinized government business processes. Focusing on defined attributes allows PEPFAR programs to have a shared transformation framework and language, while customizing plans, timelines, and sequencing to each OU's unique circumstances.

PEPFAR has a host of resources and tools already in use to inform sustainability planning, as shown in Figure 2.2.4.3. These tools, while each useful on its own, are most powerful when intentionally used in concert to contextualize and holistically plan for sustainability. For detailed information on how to leverage these tools to begin planning for sustainability, as well as more information on the attributes of transformation, see Section 6.6.9.

Figure 2.2.4.3: Achieving HIV epidemic control and ensuring a sustainable response



2.3 Goal 1: Accomplish the Mission – Achieve Sustained Epidemic Control of HIV through Evidence-based, Equitable, People-Centered HIV Prevention and Treatment Services

2.3.1 HIV Testing Services: Reaching & Maintaining Epidemic Control

PEPFAR has made great strides in HIV testing and supporting partner countries to achieve the first 95, with FY21 Q4 results exceeding program case finding targets for many OUs. Across PEPFAR-supported countries, there are 5.7 million people living with HIV and who are not on ART; 75% of this unmet need is in Tanzania, Zambia, Nigeria, Mozambique, and South Africa. While a number of countries have achieved the first 90 benchmark, notable gaps persist among demographic and geographic subpopulations (Figure 2.3.1.1), viral suppression among all people living with HIV is less than 80% (Figure 2.1.1.1), HIV incidence and new infections continue, and some individuals cycle in and out of treatment for different reasons. Although many sub-Saharan African countries report that > 80% of people living with HIV know their HIV status (Figure 2.3.1.2),[49] these achievements are not evenly distributed across all subpopulations, ages, and sexes (Figures 2.3.1.1 and 2.3.1.4). Gaps in the testing of infants and children exposed to HIV have left more than 40% of children living with HIV undiagnosed; many were not tested for HIV during early infancy, presenting significant challenges with pediatric HIV case finding.[50] Additionally, in many PEPFAR partner countries, a greater proportion of adult males living with HIV remain undiagnosed (Figure 2.3.1.5). Section 2.1 reviews epidemiologic Figures 2.1.1.24 – 2.1.1.28.

[49]Giguère, K., Eaton, J. W., Marsh, K., Johnson, L. F., Johnson, C. C., Ehui, E., Jahn, A., Wanyeki, I., Mbofana, F., Bakiono, F., Mahy, M., & Maheu-Giroux, M. (2021). Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000-20: a modelling study using survey and HIV testing programme data. *The lancet. HIV*, *8*(5), e284–e293. https://doi.org/10.1016/S2352-3018(20)30315-5

50 UNAIDS. (2021). *2021 UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS*. https://www.unaids.org/sites/default/files/media_asset/2021-global-aids-update_en.pdf

Figure 2.3.1.1 Countries Reaching the HIV Treatment Cascade Targets, 2020[51]

	90–90–90 value (all)	90–90–90 value (children aged 0–14 years)	90–90–90 value (women aged 15+ years)	90–90–90 value (men aged 15+ years)	Viral suppression level (all)
Eswatini	>98–>98–95	>98–>98–91	>98–>98–95	94–>98–94	97
Switzerland[a]	93–>98–96				88
Rwanda	93–>98–96	54–>98–89	96–>98–96	93–>98–96	89
Qatar[a]	93–>98–96		>98–>98–81	90–97–>98	86
Botswana	91–95–>98	62–>98–94	94.5–>98–>98	88–87–97	85
Slovenia	90–97–96				85
Uganda	91–>98–90	63–>98–78	96–>98–92	88–97–89	85
Malawi	91–94–94	73–>98–73	94–94.9–95	90–92–94	85
Zimbabwe	93–>98–89	72–>98–72	96–>98–91	92–>98–88	82
Kenya	96–89–94	84–>98–86	>98–92–94	91–83–94	81
Namibia	89.9–98–91	81–92–80	92–>98–93	86–94–89	80
Cambodia	84–>98–97	60–>98–88	82–>98–98	86–>98–97	81
Lesotho	94–87–97	83–>98–92	94.6–92–97	93–79–97	80
Burundi	89–>98–89.7	31–>98–70	>98–>98–91	85–96–89	79
Uruguay					79
Norway					79
Thailand	94–84–97	>98–76–87	92–86–97	96–81–97	77
Zambia	86–95–93	58–>98–84	89–94–94	84–95–93	76
Croatia	84–88–>98		80–92–>98	84–87–>98	73

- Reached the 90–90–90 targets
- Reached only the 73% viral load suppression target
- Not reached the 90–90–90 target
- Data not available

[51] UNAIDS. (2021). *2021 UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS*. https://www.unaids.org/sites/default/files/media_asset/2021-global-aids-update_en.pdf

Figure 2.3.1.2 Achievement of 90-90-90 Cascade among PHIA Countries[52]

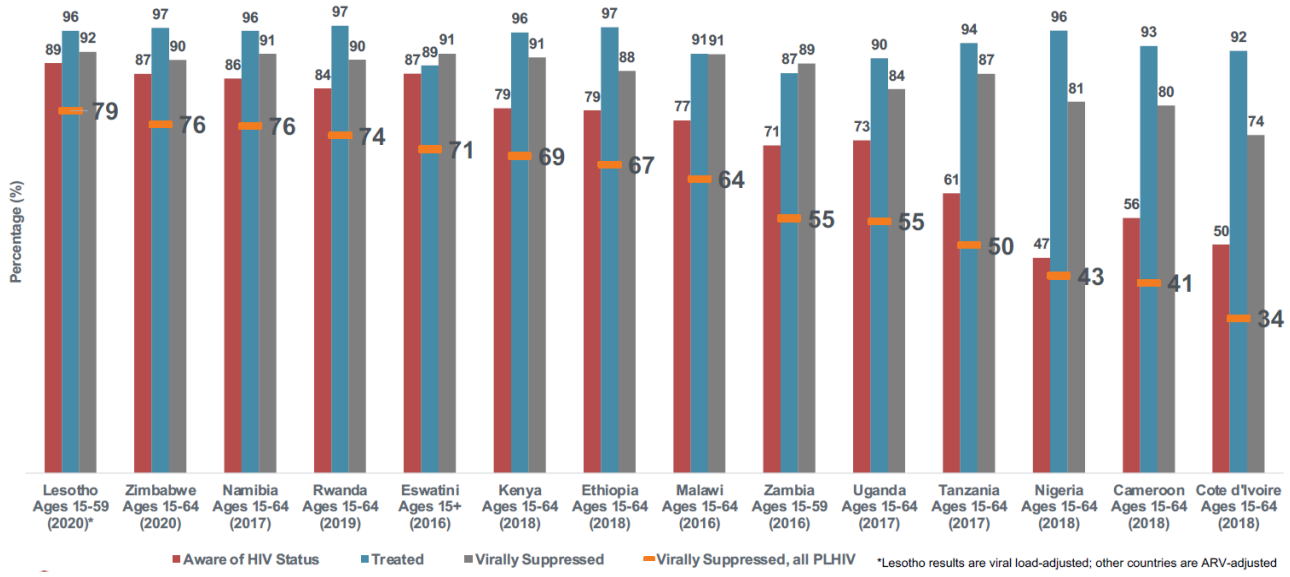


Figure 2.3.1.3 National Estimates of Knowledge of Status in sub-Saharan Africa, 2020[53]

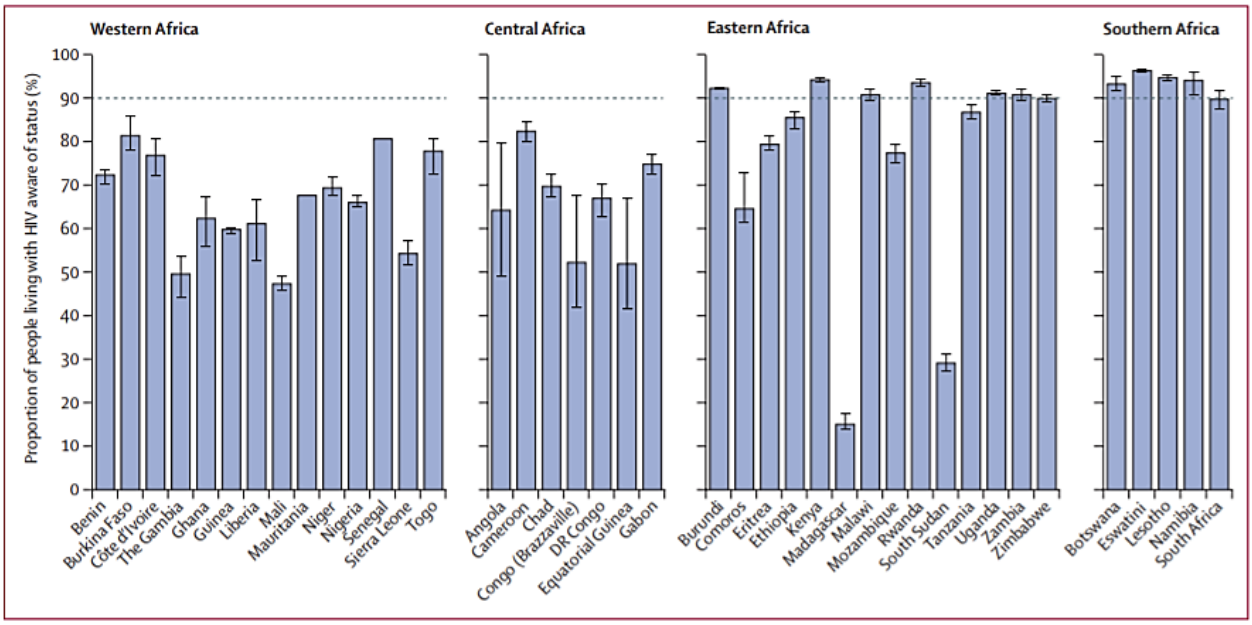
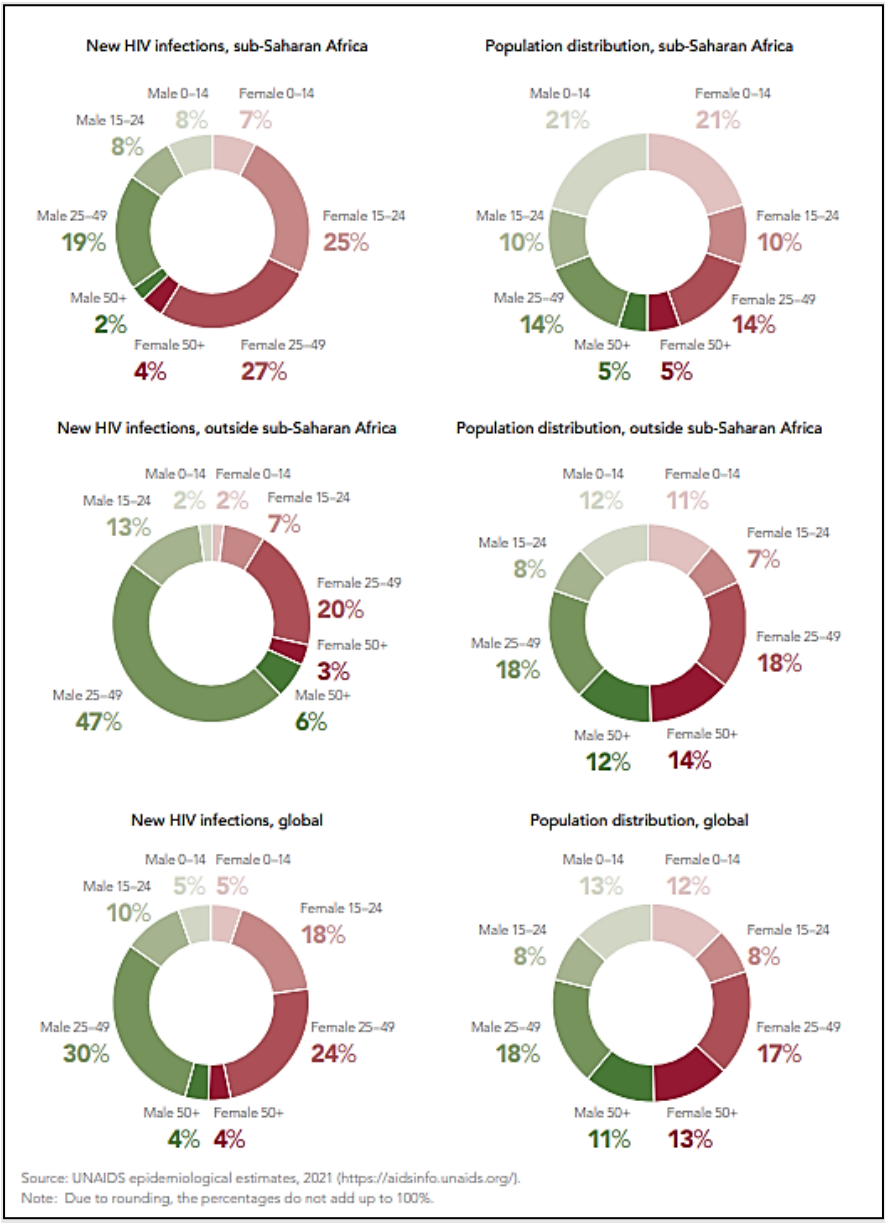


***Figure 3:* National estimates of knowledge of HIV status in sub-Saharan Africa, 2020**
Bars show the proportion of people living with HIV who know their HIV status, with 95% credible intervals represented with vertical lines. The horizontal dashed line represents a threshold of 90% knowledge of status.

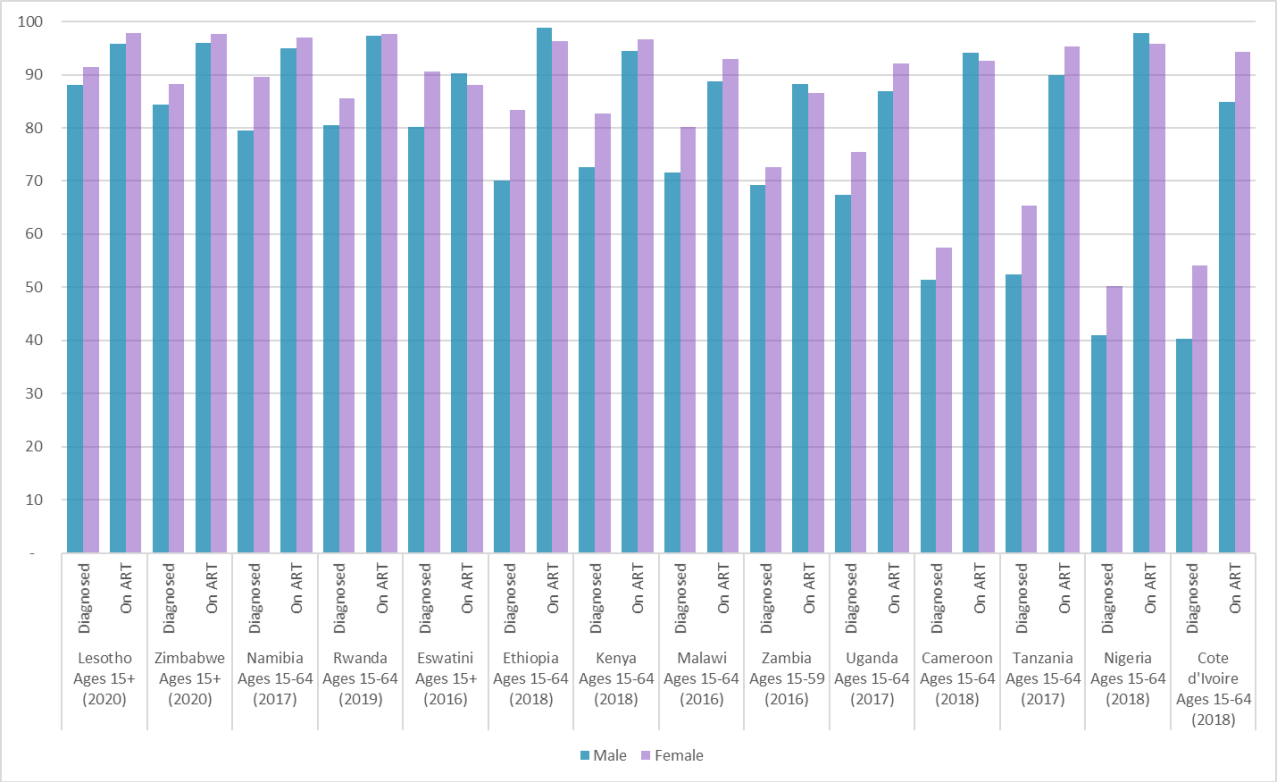
[52] ICAP. Population-Based HIV Impact Assessment. PHIA Project. https://phia-data.icap.columbia.edu/
[53] Giguère, K., Eaton, J. W., Marsh, K., Johnson, L. F., Johnson, C. C., Ehui, E., Jahn, A., Wanyeki, I., Mbofana, F., Bakiono, F., Mahy, M., & Maheu-Giroux, M. (2021). Trends in knowledge of HIV status and efficiency of HIV testing services in sub-Saharan Africa, 2000-20: a modelling study using survey and HIV testing programme data. *The lancet. HIV*, *8*(5), e284–e293. https://doi.org/10.1016/S2352-3018(20)30315-5

Figure 2.3.1.4 Distribution of New HIV Infection and of the Population, by Age and Sex, 2020[54]



[54] UNAIDS. (2021). *2021 UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS*. https://www.unaids.org/sites/default/files/media_asset/2021-global-aids-update_en.pdf

Figure 2.3.1.5 Achievement of the 1st 95 and 2nd 95 Targets by Sex[55]



HIV testing services represent an essential pathway to identifying two important subgroups of individuals: 1) Persons living with HIV in need of initial linkage or re-engagement to treatment, and 2) individuals who are HIV negative, yet at high-risk, and therefore will benefit from evidence-based prevention interventions. It remains imperative to apply a person-centered approach with every person who receives HIV testing services. Individuals should receive positive, consistent counseling on the benefits of timely HIV testing, treatment, and prevention services.

Programs need to strategically implement case finding approaches and modalities to maximize case detection, and these strategies should be tailored to the target population(s) that must be reached to close ART gaps. In almost all countries, gaps in case-finding for men, children/adolescents, and marginalized populations are disproportionately high (Figure 2.3.1.4). Effort should be given to developing innovative and efficient ways to close these gaps and include strategic partnerships with communities and subpopulations PEPFAR serves. (See Section 6.3.1.9 for additional guidance on community engagement.)

[55] ICAP. (2016-2021). *Population-Based HIV Impact Assessment*. PHIA Project. https://phia-data.icap.columbia.edu/

As part of the 2021 Political Declaration on AIDS,[56] one of the targets for 2025 established by the UN General Assembly is access to and use of comprehensive packages of HIV prevention services by 95% of people at risk of HIV infection. PEPFAR recognizes the importance of HIV testing as a minimum standard of all evidence-based prevention strategies, and HIV testing is a critical marker for monitoring the impact of prevention services. (See Section 6.3.5 for additional considerations on HIV testing for prevention services.)

For countries at HIV epidemic control, case-finding must progress to reach, test, and identify undiagnosed individuals living with HIV more effectively including new infections. HIV epidemic control is not static and while partner countries, SNUs and sub populations may reach epidemic control or 95-95-95 benchmarks, it will not be easy to maintain this state. Thus, it is essential that a combination of facility- and community-based HIV testing approaches are implemented to meet the evolving prevention and treatment needs of a country to achieve and maintain HIV epidemic control across geographic units and subpopulations. To account for the changing HIV epidemic, Table 2.3.1.1 highlights the anticipated evolution of HIV testing modalities as countries approach and achieve equitable epidemic control across all subpopulations.

Table 2.3.1.1 Anticipated evolution of HIV testing modalities as countries approach and achieve equitable epidemic control across subpopulation groups (including age and sex bands) (on next page)

[56] UNAIDS. (2021, June 9). *Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030*. https://www.unaids.org/en/resources/documents/2021/2021_political-declaration-on-hiv-and-aids

HIV Testing Modality	Before Equitable Epidemic Control	Approaching Equitable Epidemic Control	After Achieving Equitable Epidemic Control
HTS for Case Finding			
Offering safe and ethical index testing to all people living with HIV (prioritizing individuals newly diagnosed and previously diagnosed individuals without viral suppression)	High priority; standard of care	High priority; standard of care	High priority; standard of care
Social Network Strategy (for KP and other networks)	High priority	High priority	Medium priority
HIV Self-Testing	Medium priority; targeted use	High priority; targeted use to address gaps	Prioritize subpopulations where there are new infections and those who would not seek facility-based HTS
TB Clinics	High priority; standard of care.	High priority; standard of care.	High priority; standard of care.
STI	High priority; standard of care	High priority; standard of care	High priority; standard of care
PITC	High priority for broad PITC	Dependent on context: Targeted PITC for subpopulations or SNUs that have reached 95/95/95; Broad PITC for subpopulations or SNUs that have not yet achieved 95/59/95.	High priority for targeted PITC
Targeted Community Testing	High priority	High priority	Medium priority; highly targeted to populations with high incidence only and integrated with other health services to improve cost-effectiveness
HTS for Prevention Services and Prevention Monitoring			
HTS in ANC and PNC settings for PMTCT	High priority; standard of care	High priority; standard of care	High priority; standard of care
HTS for PrEP	High priority; standard of care	High priority; standard of care	High priority; standard of care
HTS for VMMC	Low priority; recommend, but not required	Low priority; recommend, but not required	Low priority; recommend, but not required
HIV Self-Testing	Low priority	Low priority	Medium priority
Surveillance			
Case-based Surveillance/Sentinel event monitoring	Establish surveillance system	Start implementing surveillance	Implement fully functional surveillance system

2.3.2 Person-Centered Prevention

As PEPFAR countries approach the 95-95-95 goals, 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. As all teams use an equity lens to tailor well-coordinated, effective services for populations at substantial risk of HIV acquisition, they must sustain an effective and accessible prevention program. 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. As public health surveillance and HIV testing programs identify HIV-seronegative people, prompt engagement with prevention services including PrEP, and where appropriate, VMMC services for men are vital opportunities. 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.

Like treatment programs, prevention programs must maximize their ability to provide continuous, person-centered service starting with seamlessly integrating evidence-based, efficient services as a vital part of an integrated HIV response. Prevention programs are well positioned to take lessons from differentiated service delivery for treatment programs. To ensure effective and durable service delivery, community resources, systems, and partnerships should be mobilized across testing, treatment, and prevention. Prevention activities must be well targeted and evidence-based and should aim to address both structural and personal barriers that heighten vulnerability to or increase the likelihood of HIV infection. This may include structural interventions for key populations and others for whom stigma, discrimination, or legal marginalization pose barriers to engagement as well as interventions designed to make prevention products themselves such as PrEP, condoms, and lubricants simpler for people to access, and centering them on people's needs and lives. For 10–14-year-olds, there is an increased focus on evidence-based primary prevention of sexual violence and preventing early sexual debut (e.g., preventing any form of coercive/forced/non-consensual sex). Evidence-based prevention messages must be included in school curricula other platforms that have been shown to reach this age group and should reach older community members and leaders with critical programming to shift community norms around violence and gender. This primary prevention includes evidence-based programming to prevent sexual violence, to prevent HIV, and to help communities (including communities of faith) and the families of youth with support and education which should also be integrated with orphans and vulnerable children (OVC) programs. Trauma-informed services and first-line support (e.g., LIVES) should be provided to

survivors of sexual violence, with a focus on the treatment of trauma symptoms, including how to access emergency ARVs, contraception and counseling (See Section 6.6.2.1 Gender-Based Violence and Violence Against Children). More discussion of specific prevention interventions is described in Technical Considerations Section 6.2 Primary Prevention.

PEPFAR supports the WHO guidelines on the use of PrEP as part of a package of comprehensive prevention services that includes risk reduction education and counseling, condom promotion, VMMC, and structural interventions to reduce vulnerability to HIV infection. New ARV-based prevention products such as PrEP rings, long-acting injectable ARVs, long-acting oral PrEP, implants, and more are entering the marketplace and teams should consider developing multi-year plans which anticipate new product introduction, building off oral PrEP experience. Plans should be person-centered. A person-centered approach to the incorporation and delivery of prevention services will expand access and empower people to make informed choices among the expanding array of HIV prevention options. 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 new options and formulations to consider as part of a package of comprehensive prevention services.

As OUs approach epidemic control, prevention programming remains critical, however, the population groups in need of prevention services may change over time. For example, as community viral load suppression increases, there may be a greater focus on enhancing strategies to identify vulnerable populations that remain at increased risk for HIV acquisition and tailoring prevention programs to meet population specific needs. To achieve this end, PEPFAR programs should routinely review in-country individual level data at the most granular disaggregated level available. HTS, CBS, and recent infection surveillance data can be utilized to monitor epidemiological shifts and identify areas of ongoing transmission, which may include specific population groups or geographies, that may signal a need for adapting or retargeting prevention programming. To ensure continued impact, it will be important to maintain data systems enabling granular data analysis for program targeting and to determine a sustainable testing strategy in partnership with the right mix of targeted prevention interventions, one that will optimize budget, align with peoples' and communities' needs, and maintain epidemic control status.

2.3.3 Person-Centered Continuous ART

All PEPFAR programs, regardless of current ARV coverage levels, must implement strategies to support continuous and uninterrupted person-centered ART. The strategies are expected to be available in each site providing HIV testing, care, treatment, and prevention services ensuring that all clients that start ARVs, have a continuous access to optimized regimens.

PEPFAR programs must work with local health system and community stakeholders, to design and implement services that remove barriers to continuous care, especially those that drive out stigma and discrimination, increase equity, and maximize provider responsiveness to put clients at the center of care. Services that are person-centered recognize the agency of clients—their right to make their own choices. Providers strive to enter a partnership with the person living with HIV that honors their needs, preferences, and motivations along with their family and/or significant others. In PEPFAR, services should also emphasize privacy, dignity, and voluntary participation. The vision for successful continuous ART is life-long, person-centered service, where the health system and affiliated organizations in the community demonstrate respect for clients' convenience and choices and make it as easy as possible for clients to remain on uninterrupted ART across the lifespan and across changing life circumstances. Key supporting elements of PEPFAR implementation—up-to-date policies, partner management, data-driven decisions, and quality management—must consistently focus on clients and align to support a client-centered approach in every PEPFAR-supported site, for every client. In addition, an equity lens must be applied to tailor services for vulnerable populations including adolescent girls and young women, key and priority populations, and children and families.

As OUs approach treatment saturation, the primary focus of treatment must be sustained equitable service to keep all clients on continuous treatment and welcoming back any clients that may have disengaged in treatment in the past.

2.3.4 PEPFAR Adaptations to COVID-19

Since March 2020, PEPFAR has been issuing weekly technical guidance to protect HIV services and respond to COVID-19. PEPFAR has focused on four key priority areas as country teams, headquarters experts and leaders, and partner governments have responded to the global pandemic of COVID-19. These represent principles of PEPFAR's COVID-19 response extending into COP22.

1. **Ensuring continuity of HIV treatment and prevention services.** In practice this means separating drug delivery from clinical care, substantially increasing the use of multi-month dispensing of ART, including PrEP, and making delivery of medication convenient and decentralized. Adaptions to deliver prevention services safely and/or virtually and to supply chain procedures have been made so that interruptions are minimized.
2. **Leveraging the country health systems and infrastructure supported by PEPFAR to strengthen country COVID-19 response.** PEPFAR has been proactively leveraging its platform to support HIV while also addressing COVID-19 screening, diagnostics, infection prevention and control, and vaccine readiness and administration in the best interest of HIV clients, beneficiaries, and communities in which they live.
3. **The safety of PEPFAR-supported clients and health care workers is of critical importance.** PEPFAR has bolstered the guidance for infection protection and control in clinics, purchased PPE, advanced use of effective safety policies, practices, and procedures. Reducing client contact with health facilities where appropriate, advancing use of electronic communication where possible reduces the burden on health facilities and allows for improved client interactions.
4. **Extending flexibility to the PEPFAR country teams** within the PEPFAR's mandates and authorities to the extent possible to take into account COVID-19-related needs, in the context of seeking to achieve the best possible HIV outcomes.

In support of country teams' success in adapting PEPFAR as country health systems respond to the rapidly changing COVID-19 context, S/GAC has led an interagency team of experts who together have regularly updated technical guidance on adaptations, reflecting both technical expertise of USG and international experts, and aiming to be responsive to country context and pressing concerns. The PEPFAR technical guidance on adaptations to COVID-19 can be found at this link: https://www.state.gov/pepfar/coronavirus/.

2.3.5 Maintaining Health and Reducing Mortality Among People Living with HIV by Addressing Comorbidities

Treatment of HIV through continuous, person-centered services supported by PEPFAR has made it possible for millions of people to enjoy not only a greater lifespan, but also more years in good health without serious illness. Mortality among people living with HIV is an independent measure of program quality, perhaps the ultimate measure, and lowering mortality will require successful programmatic implementation across the HIV prevention and treatment cascade.

Individuals at highest risk for mortality include older individuals, children (particularly those under 5), and people with advanced disease.

Across PEPFAR, one in five persons living with HIV on ART is now over the age of 50, a proportion that will continue to grow over time. Older individuals may develop age-associated comorbidities that can affect life expectancy. The COVID-19 pandemic has highlighted the importance of chronic diseases and comorbidities as health program and policy decisions and adaptations are made. Providing client-centered services requires PEPFAR-supported providers to be cognizant of important non-HIV health conditions impacting their clients and, wherever possible, to address them.

Children. A treatment gap has persisted for children across the cascade and ensuring adequate testing and treatment for this population is of paramount importance. Of particular concern is reported mortality in children for whom diagnosis is delayed. Children under 5 years of age who have been identified as HIV-positive and initiated on treatment have the highest death rate among all age groups in PEPFAR. Programs must put particular emphasis on improving the three 95s across the pediatric cascade, including improving EID coverage/linkage and rapid adoption of pediatric DTG.

Tuberculosis and Advanced Disease. Individuals with advanced disease have a significant mortality, and early identification, linkage, and ART treatment initiation are critical to reducing mortality (see Section 6.4.2). TB is the leading cause of death among all people living with HIV; therefore, regular TB screening, rapid TB diagnosis, rapid treatment initiation, and TPT are critical for reducing mortality (see Section 6.4.3). A package of interventions has been identified that reduces mortality in individuals with advanced disease, and PEPFAR supports implementation of this package (see Section 6.4.2).

Cervical Cancer. Cervical cancer is the number one cause of cancer mortality for women in African countries served by PEPFAR, and HIV infection magnifies the risk six-fold. For this reason, the Go Further partnership launched precancerous lesion screening and treatment services in selected high-risk PEFPAR countries. All countries utilizing PEPFAR resources for cervical cancer services are expected to adhere to the specific guidance (see Section 6.4.4) and report on the indicators developed during FY18.

Sexually Transmitted Infections (STI). 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. As for all services, a systems

approach with coordination of resources from different sources and alignment with country government policies and funder mandates is necessary to provide optimal service.

Other Comorbidities. PEPFAR cannot provide comprehensive health care as a vertical integrated program for people living with HIV. However, as OUs attain equitable epidemic control and plan for long-term, continuous HIV treatment services, country teams are encouraged to leverage PEPFAR systems, to build connections within country health care systems, and to strengthen partnerships among funders and donors to expand access for detection and treatment of comorbidities.

OUs may consider addressing additional comorbidities (for example, viral hepatitis, noncommunicable disease, mental illness) in a way that is prioritized based on their impact on HIV treatment and the health of the clients. Addressing additional comorbidities using funds from the COP envelope should only be proposed if it is built on a solid PEPFAR HIV service delivery platform and can be done without adverse impact on HIV services; it is discouraged if epidemic control has not been achieved equitably across regions and populations in an OU (Goal 1). It should also be designed with Goals 2 and 3 in mind—for example, leveraging enduring lab, supply chain, HRH, and information systems, as well as securing partnership and alignment with national health programs, other U.S. government health and development programs, and donors wherever possible.

More specifically, within PEPFAR OUs, districts (SNUs) that have demonstrated equitable achievement of the 95/95/95 goals may offer, as part of operational plan strategy, funding for more comprehensive services for people living with HIV, such as diagnosis and treatment of hepatitis B and C, diabetes mellitus (DM) or hypertension (HTN). The bar for additional services is high to ensure additional work is built onto a reliable, secure, and enduring system of service delivery. Both HTN and DM diagnosis and support will require the same attention to quality and continuity of treatment that is needed to achieve HIV epidemic control targets. Diagnostic testing and treatment for these conditions must be affordable enough to feasibly bring to scale among people living with HIV within the OU. Country teams should work directly with their supply chain activity managers and USAID for forecasting and procuring test kits and pricing information. If these additional services are funded in the COP as PEPFAR programming, they must be offered equitably and without discrimination, and user fees must not be charged. Programs should refer to the updated WHO recommendations on hepatitis B and C testing.

2.4 Goal 2: Build Enduring Capabilities

2.4.1 Public Health Capabilities to Sustain Epidemic Control

PEPFAR's work with partner countries to achieve 95/95/95 targets and achieve control of the HIV epidemic reflects major successes of both clinical health care and public health, as well as synergies that occur when health care and public health are aligned to achieve population health goals.

As PEPFAR country teams work with stakeholders and partners to attain equitable epidemic control, sustain people living with HIV on lifelong person-centered care and treatment, and help align a variety of systems and partners in a united national effort, it is important to consider public health capabilities that are needed to support a sustained HIV prevention and treatment program that is resilient and capable of supporting a coherent public health response for HIV, and also flexible and resilient enough to address additional health threats. In general, the Ministry of Health and subnational public health entities should be positioned as central players in assessment, policy development, and assurance and implementation. However, to be effective in protecting and promoting the health of populations, it is important to envision and align a larger Public Health System where other parts of government, community organizations, public and private clinical providers, and a variety of other actors join governmental public health entities to lead, shape, and support public health efforts in a multi-sector, multifaceted, sustained effort.

Critical public health capabilities that must be addressed for long-term HIV epidemic control include the following.[57]

1. Ensuring Availability of Critical Strategic Epidemiologic Information. For HIV, this includes governmental functions related to disease surveillance, health information systems, investigation, and response, and epidemiologic assessment including assessment of inequalities and trends.

2. Strengthening Key Public Health Institutions and Infrastructure. This represents the institutional infrastructure and political authorization to do effective assessment, policy development, and assurance activities. It includes the capacity and authorization to engage

[57] Bloland, P., Simone, P., Burkholder, B., Slutsker, L., & De Cock, K. M. (2012). The role of public health institutions in global health system strengthening efforts: the US CDC's perspective. *PLoS medicine*, *9*(4), e1001199. https://doi.org/10.1371/journal.pmed.1001199

stakeholders and partners fully and meaningfully in assessment, planning and policy development, and implementation and program monitoring.

3. Establishing Strong Public Health Laboratory Networks. For HIV this means optimized lab network, as well as specimen referral networks, supporting information systems designed to support timely production of results, disease surveillance and program monitoring. As demonstrated in the COVID-19 pandemic, an effective laboratory network must be designed with resilience to respond to public health threats and emergencies as well as sustained, aligned countrywide efforts as for HIV.

4. Building a Skilled and Capable Workforce. Public health entities often have a dual function that includes ensuring the technical and leadership workforce for public health is in place and equipped and ensuring a sufficient skilled and representative workforce is serving across the health sector.

5. Implementing Data Driven Public Health Programs. The capacity to lead, coordinate, and manage public health programs with quality and fidelity, whether run by the ministry, a partner government agency, or delegated, is a key public health capability. Programs must be proactive responding to the data to keep control of an infectious disease.

6. Supporting Critical Operational/Applied Research. While research efforts can seem like a lower priority during public health program implementation, the ability to conduct applied research ethically and efficiently under real-world implementation conditions can be vital for shaping programs as they evolve.

As PEPFAR teams and partner countries approach and attain epidemic control, prioritizing and aligning work to build sustainable public health capabilities will be critical for long term success.

2.4.2 Surveillance and Information Systems

Durable, interoperable surveillance and health information systems with release of timely data are an important aspect of PEPFAR's strategic goals. PEPFAR seeks to build the enduring core capabilities of partner governments and communities to lead, manage, and monitor the HIV response in an effective, equitable, and enduring manner. Well-planned and developed surveillance and health information systems are a vital part of this goal. Such systems form the critical central nervous system of an effective public health response. For countries at or near epidemic control, patient-level information systems are critical in this phase of the epidemic to ensure there is appropriate action at the patient level so that providers can be alerted when patients have treatment interruption and/or are virally unsuppressed. Timely implementation of

well-tolerated ARV regimens and convenient and supportive HIV services (short wait times, convenient multi-month drug dispensing) are all essential for patient and community viral suppression, and reliable patient-level information is critical so that providers can deliver person-center care. This includes but is not limited to electronic medical record systems that enable patient monitoring to ensure continued engagement in treatment, allowing clinicians to track patients, including transfers, and accurately capture patient data to improve ART continuity and facilitate appointment scheduling and reminders (e.g., by bulk SMS).

These patient level data should be interoperable and integrated in such a way that they provide actionable overviews of the HIV epidemic at the site, community, national and sub-national levels, while ensuring data confidentiality and security. Dashboards that summarize and review the geography and population groups of recent infections, hotspots and clusters of transmission, and aggregate drivers of interruptions in treatment or lack of viral suppression, based on the patient level data systems, can help partner governments in concert with local communities focus interventions and resources where they are most urgently needed. The patient level data should be incorporated into case surveillance systems, to understand the current dynamics of the HIV epidemic, which populations and people are most at risk, so that interventions can be targeted with assistance of the relevant community organizations. These case surveillance systems should be supplemented with regular survey and surveillance activities, such as household surveys and bio-behavioral surveys that include recency and viral suppression, as needed. All these systems need to respect and protect the confidentiality and privacy of the people's data they contain. Ideally, the communities of people living with HIV and those most at risk, should also have their own durable, actionable data systems that help them collate and analyze their community-led monitoring feedback. This can help these communities engage in the HIV response, including directing and advocating resources where they are most needed. More specific programmatic direction is in Section 6.6.8.

2.4.3 Sustaining Epidemic Control: Leadership Capacity and Functional Systems

For an effective transformation of the program, PEPFAR teams will need to continue focusing on how systems work both formally and informally, working in concert with partner governments and communities. Understanding a diverse set of country context variables, like institutional culture, constitutional tradition, or civil service structures, will be necessary to consider in developing a sustainable response. There are many informal practices that will shape a functional system and

will simply not be understood from focusing on boxes on an organizational chart. Teams will have to adapt activities, better define the problem, allow for a gap between theory and behavior and promote effective leadership to make systems work together in the most optimal way. Developing leaders who understand and effectively work within structures and traditions will be an important focus for sustainability. Formal control structures will never take the place of self-controls based on well-functioning systems.

How does the PEPFAR Program build a Functional System?

PEPFAR must start with a framework of an ideal system to sustain epidemic control that must be adapted to realities on the ground. These realities include:

- Variable control regimes
- A gap between rules and behavior
- Risk management regimes that balance programmatic and fiduciary risk-variable decision-making structures and traditions
- Civil service merit systems
- Varied legal and constitutional systems
- Unstable funding sources

When confronted with a range of on the ground realities, teams should appreciate that transformation is not a short term, linear project. It will take time, require effective staging of reforms, flexibility, and the ability to adapt to setbacks and unforeseen events.

Proper Problem Diagnosis

The most important basis for all change is engaging in proper and continuous problem diagnosis. The suite of sustainability tools is constructed to look at the response holistically and provide a high-level roadmap to proper problem diagnosis. The SID considers the range of structures, policies and enabling conditions for a sustained response. It charts progress over time, but it also points to the ability to have a functional system without an ideal structure. Table 6 can be used alongside other information and data to improve understanding where barriers and current PEPFAR programming do and do not align. The responsibility matrix helps provide a high-level road map to local responsibility and emphasizes a phased and gradual approach from areas where PEPFAR has had primary responsibility. It will enable teams to consider safety nets and other supports as the transformation of PEPFAR having primary responsibility to local entities having primary responsibility for the response. In the end, there is no substitute from continuous

assessment of the functionality of the system and a willingness to understand that real problems may be masked by superficial problems.

Successful Reform Strategies

Successful reforms will be calibrated to the specific risks and dynamics of national systems. Within the contextual risks, teams should:

- Focus on desired cultural shifts (organizational cultures principally)
- Mobilize all levels of behavior, formal and informal
- Have persistent and committed leadership
    - Program transformation needs to be owned by many actors,
    - Needs daily monitoring and attention

Reforms fail because one size does not fit all and there are no best practices, rather there are best available practices. Reforms fail because they are focused on process, not behavior. Reforms fail because they are instrumentalists (we need a functioning lab system) as opposed to outcome oriented (95% of patients of ART should be virally suppressed). Reforms fail because there is always a gap between rules and behavior, between policy/process and practice. Reforms fail because donors want more than what political, economic, and social systems can handle. In short, for each necessary activity, PEPFAR will need to describe an ideal but insist on a minimum level of outcome.

Changing Rules and Structures does not Necessarily Change Behavior, Leadership Matters

The lynchpin to success is a laser focus on leadership, people who can not only manage a process but ensure the informal systems, internal culture, and behaviors of actors within the system change and that program direction and adaptation respond to evolving challenges.

2.4.4 People-Centered Supply Chain Modernization

To support people-centered ART, Case Finding, and Prevention Services, PEPFAR-supported countries must drive toward more people-centered supply chains to achieve HIV epidemic control and maximize product availability, quality, and affordability as well as convenience for

the individual.[58] Beginning with ARV optimization, expansion of Multi-Month Dispensing (MMD),[59] person-appropriate use of Decentralized Drug Distribution,[60] and innovative re-supply solutions, countries must show they have a strategy for a supply chain that meets the evolving and future programmatic needs.

Each country's supply chain strategy and operations must demonstrably:

- Strengthen the collection, management, and use of supply chain-related data for enhanced process improvement, transparency, and accountability of commodity ordering, distribution, and final mile delivery.
- Work towards reliable and consistent data systems (paper to digital) that enable evidence-based decision-making at all levels of the health system, appropriate to the contexts of each country program and across technical areas (prevention, treatment, and lab (see Section 6.6.1.2 Laboratory Global Purchasing and Service Level Agreements for more guidance on lab data).
- Introduce and scale differentiated service delivery options for eligible patients, including increasing decentralized drug distribution access points, to better meet patient preferences, improve treatment adherence, and enhance viral load suppression.
- Enhance supply chain sustainability and reduce operational dependencies on PEPFAR supply chain partners by working with commodity vendors to increase private sector management of commodity delivery and distribution activities.

    1. Ensure quantifications are based on data and all stakeholders are included in the exercise. ARVs quantified are on the PEPFAR Tiered ARV List (ideally Tier one) to guarantee treatment optimization (see section on ARV optimization and Section 7.2.6 Commodities Planning for details but contact HQ with any questions) .

[58] Coulter, A., & Oldham, J. (2016). Person-centred care: what is it and how do we get there? Future Hospital Journal, 3(2), 114–116. https://doi.org/10.7861/futurehosp.3-2-114

[59] Hoffman, R. M., Moyo, C., Balakasi, K. T., Siwale, Z., Hubbard, J., Bardon, A., Fox, M. P., Kakwesa, G., Kalua, T., Nyasa-Haambokoma, M., Dovel, K., Campbell, P. M., Tseng, C. H., Pisa, P. T., Cele, R., Gupta, S., Benade, M., Long, L., Xulu, T., . . . Rosen, S. (2021). Multimonth dispensing of up to 6 months of antiretroviral therapy in Malawi and Zambia (INTERVAL): a cluster-randomised, non-blinded, non-inferiority trial. The Lancet Global Health, 9(5), e628–e638. https://doi.org/10.1016/s2214-109x(21)00039-5

[60] Barnabas, R. V., Szpiro, A. A., van Rooyen, H., Asiimwe, S., Pillay, D., Ware, N. C., Schaafsma, T. T., Krows, M. L., van Heerden, A., Joseph, P., Shahmanesh, M., Wyatt, M. A., Sausi, K., Turyamureeba, B., Sithole, N., Morrison, S., Shapiro, A. E., Roberts, D. A., Thomas, K. K., . . . Celum, C. (2020). Community-based antiretroviral therapy versus standard clinic-based services for HIV in South Africa and Uganda (DO ART): a randomised trial. The Lancet Global Health, 8(10), e1305–e1315. https://doi.org/10.1016/s2214-109x(20)30313-2

- Plan for and regular implementation of safe collection and environmentally sound disposal of pharmaceutical and other waste in accordance with best practices (see also Sections 6.6.1.5 Biosafety and Waste Management and 6.7.3 Waste Management).[61]
- Make progress towards reducing long-term dependence on donor funding and refocus technical assistance to support increasing responsibility for oversight of the public health supply chain as the principal stewards for commodity availability and security.
- Accelerate utilization of private sector capabilities and infrastructure where appropriate, including outsourcing elements of the supply chain[62] to maximize efficiency and effectiveness. Focus on segments such as warehousing and distribution is expected as private sector markets for these services continue to grow. Enhanced performance and increased visibility to the point of care are supply chain priorities that also provide opportunities to engage the private sector (for example, performance-based outsourcing and exploring vendor managed inventory, beyond lab) .
- Proactively monitor and mitigate procurement and supply chain related risk through routine performance data analysis using standardized metrics.[63]
- Support third party monitoring (TPM) for assessment and oversight of local partners and supply chain programs to mitigate and manage: performance, commodity leakage, warehousing, distribution, fair pricing, and open procurement processes, in an effort to increase transparency as well as continuous process improvement while avoiding conflict of interest.
- Provide multilateral coordination, to monitor shipments from all sources, while sharing data to promote transparency and avoid over- or understock situations.
- Collaborate with donors and other stakeholders to receive the most competitive prices for commodities and required logistics. This collaboration would benefit from including market-shaping initiatives, intended to drive prices down, ensuring that existing resources can satisfy more of the existing needs.
- Proactively share knowledge and data between supply chain and clinical implementing partners through appropriate channels related to in-country availability of commodities,

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[61] World Health Organization, Chartier, Y., & World Health Organization. (2014). *Safe Management of Wastes from Health-care Activities*. World Health Organization.
[62] GHSC-PSM. (2014, May 1). *Technical Report: Logistics Outsourcing and Control Management in Public Health*. Ghsupplychain.Org. https://www.ghsupplychain.org/sites/default/files/2019-07/LogiOutsContMana.pdf
[63] I.S.C.G. (2021, January 1). *Harmonization of Key performance indicators*. Https://Isghealth.Org/Key-Performance-Indicators/. https://isghealth.org/key-performance-indicators/

upcoming shipments, requests for stock distributions, and recommendations made by technical working groups to shift provider prescribing patterns to mitigate stock-out risks.

PEPFAR supported countries should be prepared to present their supply chain strategy, including procurement, through commodity availability at facility level, for modernization during the virtual COP Planning meeting for COP22. The brief and discussion should include each of the salient points addressed above and the timeline for implementation.

For more information on the above please see references and these sites:

2020 ARV Summit materials

EpiC DDD Resource Library

PSM DDD Resource

The Interagency Supply Chain Group website

The Logistics Handbook

The Procurement and Supply Management Toolbox

The National Supply Chain Assessment

The Outsourcing Toolkit

The Framework on Distribution Outsourcing in Government-Run Distribution Systems

2.4.5 Using PEPFAR Capabilities to Address COVID-19 and Other Health Threats

The COVID-19 pandemic required PEPFAR programs to safely sustain effective HIV treatment and prevention services in the face of substantial health system disruption and risk caused by COVID-19. At the same time, the systems and program infrastructure built and strengthened by PEPFAR has been an invaluable asset to countries for HIV, but also in COVID-19 response from testing to vaccine administration. PEPFAR teams should consider health systems that, while focused for HIV service delivery, could have dual or broader multi-purpose that respond to HIV but could also be appropriately leveraged for additional health threats. While PEPFAR's design, funding, and authorization are specifically for HIV, the systems and capabilities created for HIV use should be resilient and adaptable such that they can readily support additional use. As an example, PEPFAR laboratories and data systems were designed, built, and resourced for use within PEPFAR's HIV mission, but came quickly into use for COVID-19 diagnostics and surveillance. While PEPFAR funding for purposes beyond HIV is limited, additional donor funds (Global Fund) and U.S. government efforts including American Rescue Plan Act of 2021 (ARPA) have been used to strengthen existing systems and add functionality, rather than build new

vertical systems/platforms for exclusive COVID-19 use in parallel with PEPFAR systems and platforms.

Specific, timely guidance about leveraging PEPFAR infrastructure and staff for COVID-19 and other disease responses is shared as needed by S/GAC.

2.4.6 Sustaining Delivery of HIV Services by Local Partners

To sustain epidemic control, it is critical that the full range of HIV prevention and treatment services are owned and operated by local institutions, governments, and community-based and community-led organizations, including faith-based organizations, key populations-led organizations, women-led organizations, veteran led, those led by and serving youth and adolescent girls and young women, and people living with HIV (including children and adolescents). The intent of transitioning to local partners is to increase the delivery of direct HIV services, along with non-direct services provided at the site, and establish sufficient capacity, capability, and durability of these local partners to ensure successful, long-term, local partner engagement and impact. For effectiveness and sustainability, PEPFAR promotes organizations that can effectively and sustainably reflect the communities that they serve.

This transition is a priority for all OUs and Regional Programs. In 2018, PEPFAR set a goal that by the end of FY19, 40% of new funding going to partners, by agency, must be local, and by the end of FY20, 70%. From a funding perspective, the FY19 benchmark was achieved globally, with 47% of all PEPFAR funding going to local partners in FY19. Significant progress has been made toward the FY20 goal as well, with the overall number of partners that are local surpassing 70% in FY20. However, currently, at the start of FY22, the 70% benchmark has still not been achieved for the total amount of funding that is going to local partners. COP20 and COP21 (FY21 and FY22) both have 54% of funding going to local partners, up from 52% in COP19/FY20. Additional progress may still be revealed within COP20 and COP21 as to be determined (TBD) partners are identified and awarded if these awards go to local partners.

In COP22, each OU must continue to advance towards this goal of 70% of funding going to local partners, keeping in mind the context of the local partner mix and types of public and private partners available to provide essential services. In OUs that have not met the 70% target, capacity-building and mentorship efforts for local partners should be prioritized in COP22 planning, with funding set aside to support this work, and with specific, measurable, and time-bound benchmarks identified for the lifetime of the capacity-building efforts, culminating in the transition to local partner implementation. COP22 continues the emphasis of increased

engagement of local partners, including government agencies at national and local levels; peer-led groups; community organizations, including faith-based organizations and KP, youth and women-led organizations; and private sector entities. The transition to local partners builds capacity for national and regional responses to HIV and TB and is critical to sustaining core programs over time.

In spite of the overall progress in the local partner transition being stalled between COP20 and COP21, certain program areas and activities within the PEPFAR program have seen progress in the local partner transition during this time. Most notably, prevention programming, which lagged behind Care and Treatment considerably in transitioning to local partners, saw 53% of funding going to local partners in FY22, up from 46% in FY21. This change was driven by both USAID and CDC transitioning to local partners during this period, especially in the following countries: Ethiopia, Kenya, Mozambique, Tanzania, Uganda, and Zambia, among others. It is important to understand that FY22 results shown in this analysis represent the FY22 partners that were known at the start of FY22, when the analysis was completed. Partners not yet identified at this time or not yet formally awarded and named in PEPFAR systems were excluded from this analysis. This may include a significant number of partners who are local. Complete and final results for FY22 will not be available until all partners have been identified.

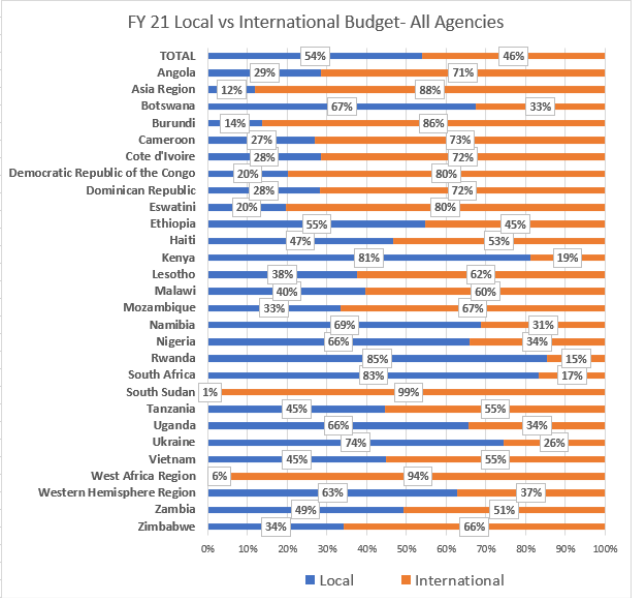
The following graphs show details of transition progress, expressed as the proportion of total funding going to local and international partners in the FY21 and FY22 (COP20 and COP21) cycles. The source of this data was the COP budgets as entered in the FAST (or OPU workbooks) and uploaded in FACTS Info. These graphs show all agencies combined, then also show the progress of HHS/CDC and USAID separately. The following parameters are used in this local partner funding analysis:

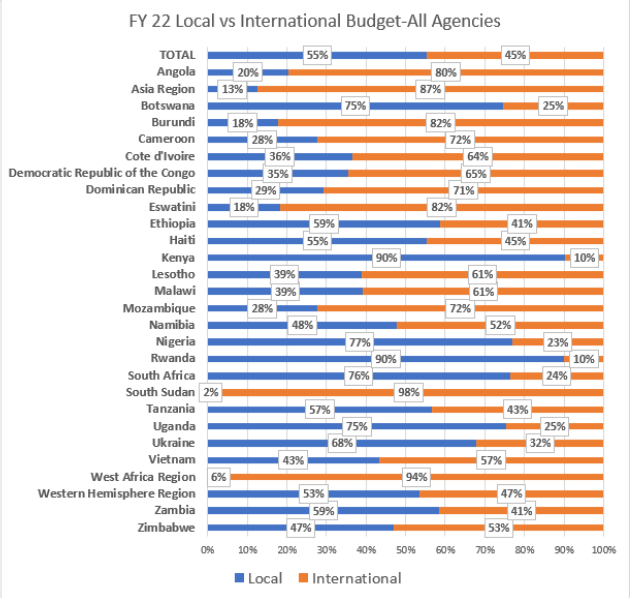
- Placeholder mechanisms (also known as TBD mechanisms) whose local or international designation is unknown because the partner has not yet been identified and named in PEPFAR systems are excluded
- United States Government Management and Operations costs are excluded
- Major commodities procurement mechanisms are excluded (GHSC RTK and PSM mechanisms)
- Peace Corps is removed since Peace Corps does not make awards to prime partners that are external to Peace Corps
- Centrally managed mechanisms are included
- Total funding (new plus applied pipeline) amounts are used

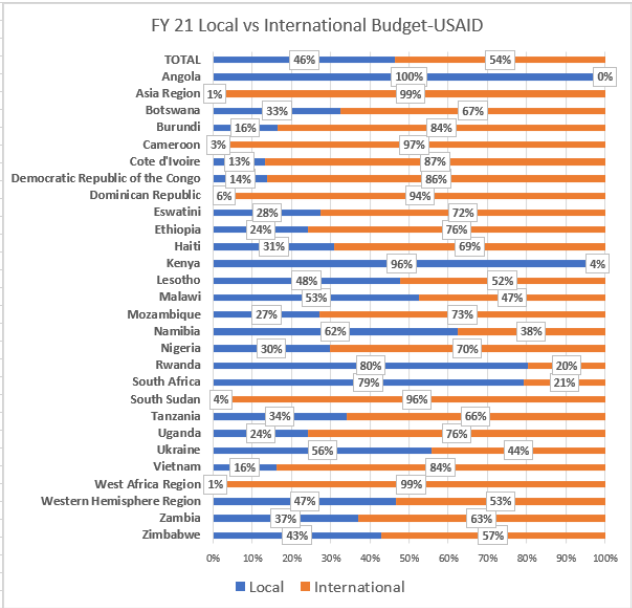
- Funding amounts are by year of implementation, not year of planning

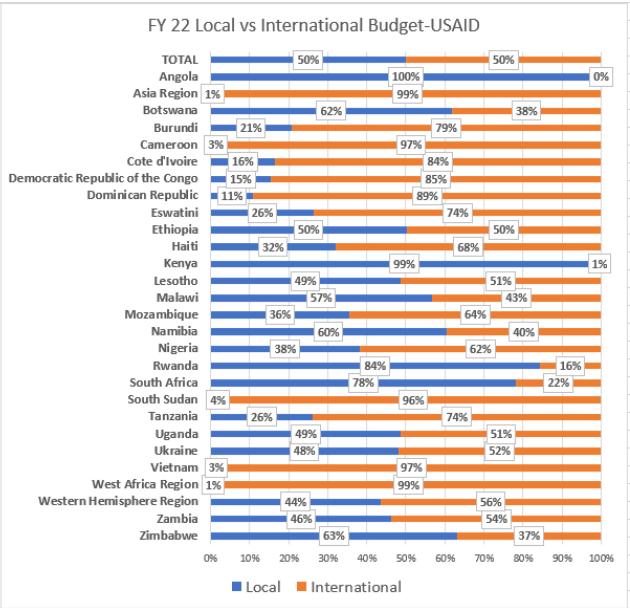
The local partner proportions shown in the graphs below may include regional partners who are not indigenous to the OU, but instead are based in the region. Please reference the definition of local partner used by PEPFAR below. Data in the below graphs is current as of January 7, 2022.

Figure 2.4.6.1 FY 21-22 Total Funding by Local and International Partner Charts









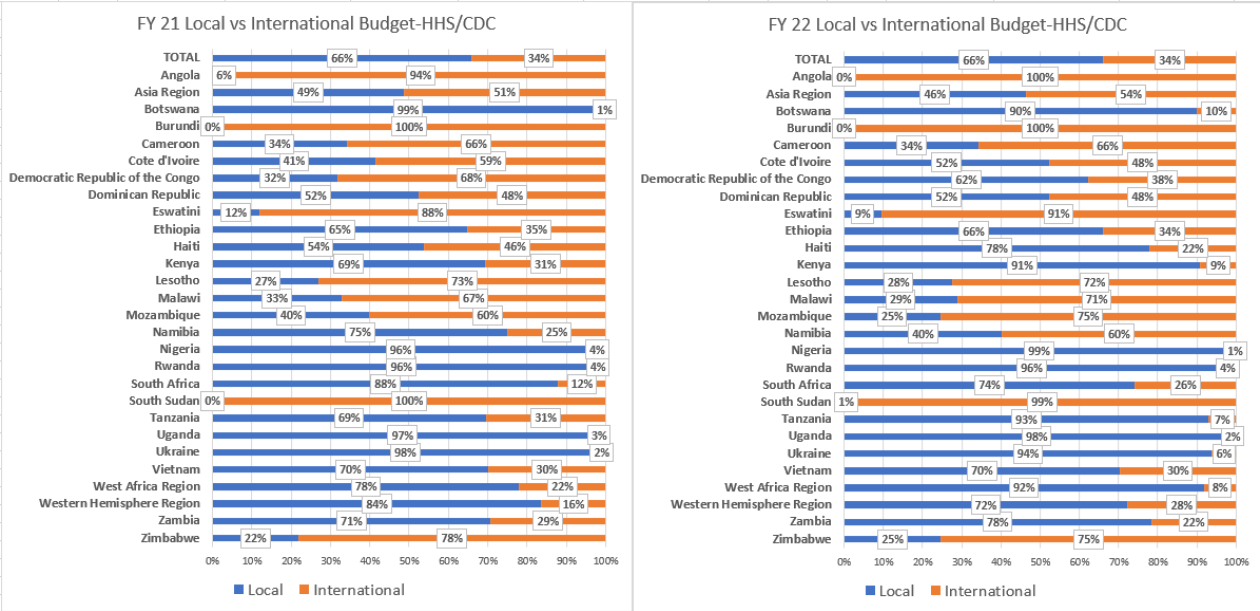
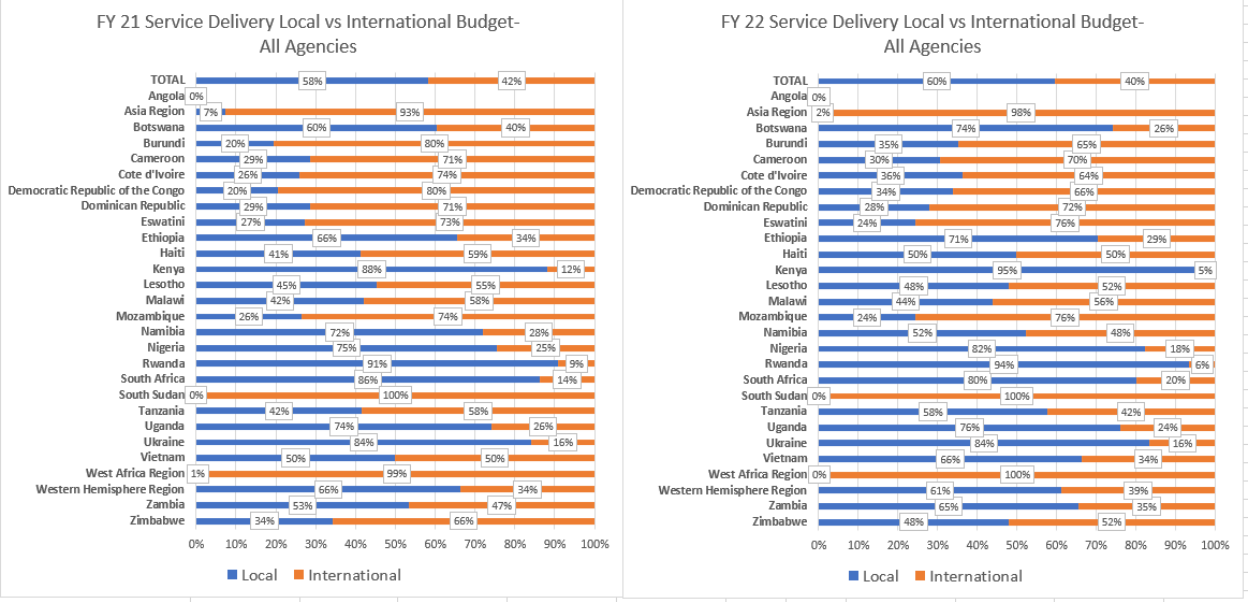
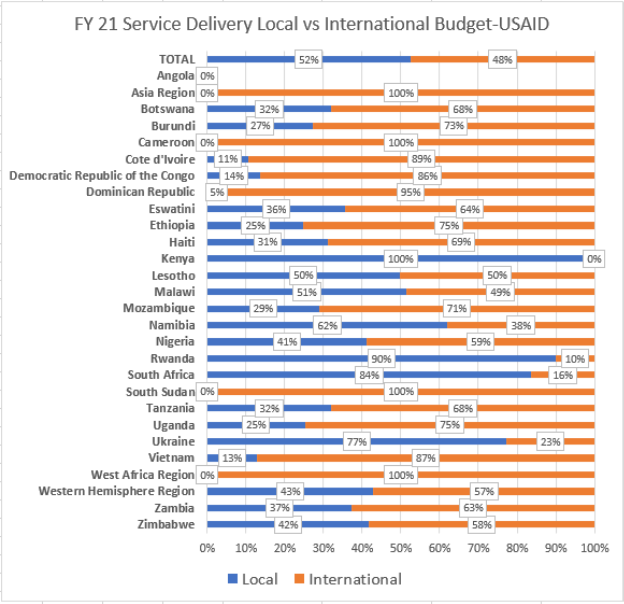
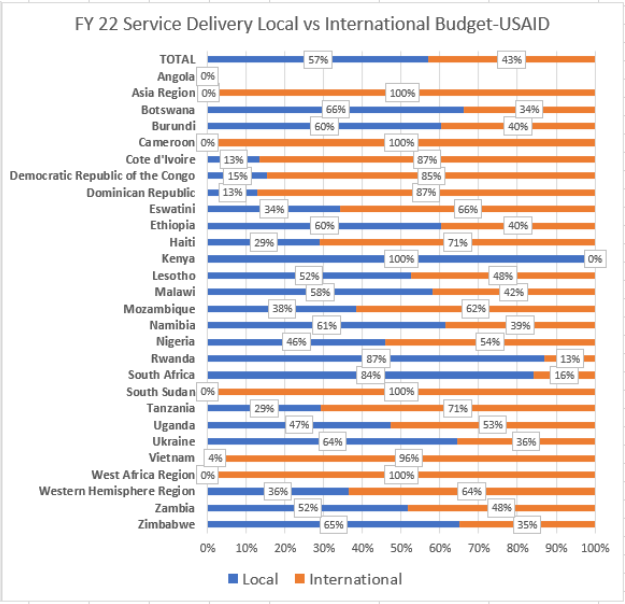
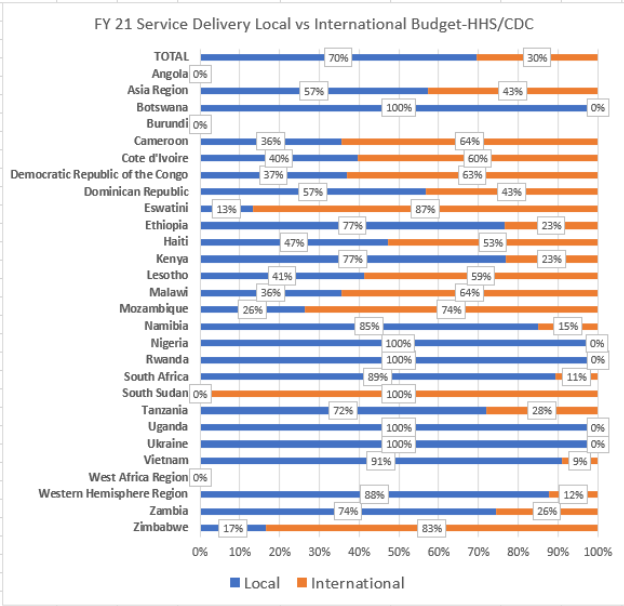


Figure 2.4.6.2 FY 21-22 Total Funding for Service Delivery by Local and International Partner Charts




FY 21 Service Delivery Local vs International Budget-USAID
TOTAL 52% 48%
Angola 0%
Asia Region 0% 100%
Botswana 32% 68%
Burundi 27% 73%
Cameroon 0% 100%
Cote d'Ivoire 11% 89%
Democratic Republic of the Congo 14% 86%
Dominican Republic 5% 95%
Eswatini 36% 64%
Ethiopia 25% 75%
Haiti 31% 69%
Kenya 100% 0%
Lesotho 50% 50%
Malawi 51% 49%
Mozambique 29% 71%
Namibia 62% 38%
Nigeria 41% 59%
Rwanda 90% 10%
South Africa 84% 16%
South Sudan 0% 100%
Tanzania 32% 68%
Uganda 25% 75%
Ukraine 77% 23%
Vietnam 13% 87%
West Africa Region 0% 100%
Western Hemisphere Region 43% 57%
Zambia 37% 63%
Zimbabwe 42% 58%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Local International


FY 22 Service Delivery Local vs International Budget-USAID
TOTAL 57% 43%
Angola 0%
Asia Region 0% 100%
Botswana 66% 34%
Burundi 60% 40%
Cameroon 0% 100%
Cote d'Ivoire 13% 87%
Democratic Republic of the Congo 15% 85%
Dominican Republic 13% 87%
Eswatini 34% 66%
Ethiopia 60% 40%
Haiti 29% 71%
Kenya 100% 0%
Lesotho 52% 48%
Malawi 58% 42%
Mozambique 38% 62%
Namibia 51% 39%
Nigeria 46% 54%
Rwanda 87% 13%
South Africa 84% 16%
South Sudan 0% 100%
Tanzania 29% 71%
Uganda 47% 53%
Ukraine 64% 36%
Vietnam 4% 96%
West Africa Region 0% 100%
Western Hemisphere Region 36% 64%
Zambia 52% 48%
Zimbabwe 65% 35%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Local International


FY 21 Service Delivery Local vs International Budget-HHS/CDC
TOTAL 70% 30%
Angola 0%
Asia Region 57% 43%
Botswana 100% 0%
Burundi 0%
Cameroon 36% 64%
Cote d'Ivoire 40% 60%
Democratic Republic of the Congo 37% 63%
Dominican Republic 57% 43%
Eswatini 13% 87%
Ethiopia 77% 23%
Haiti 47% 53%
Kenya 77% 23%
Lesotho 41% 59%
Malawi 36% 64%
Mozambique 26% 74%
Namibia 85% 15%
Nigeria 100% 0%
Rwanda 100% 0%
South Africa 89% 11%
South Sudan 0% 100%
Tanzania 72% 28%
Uganda 100% 0%
Ukraine 100% 0%
Vietnam 91% 9%
West Africa Region 0%
Western Hemisphere Region 88% 12%
Zambia 74% 26%
Zimbabwe 17% 83%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Local International

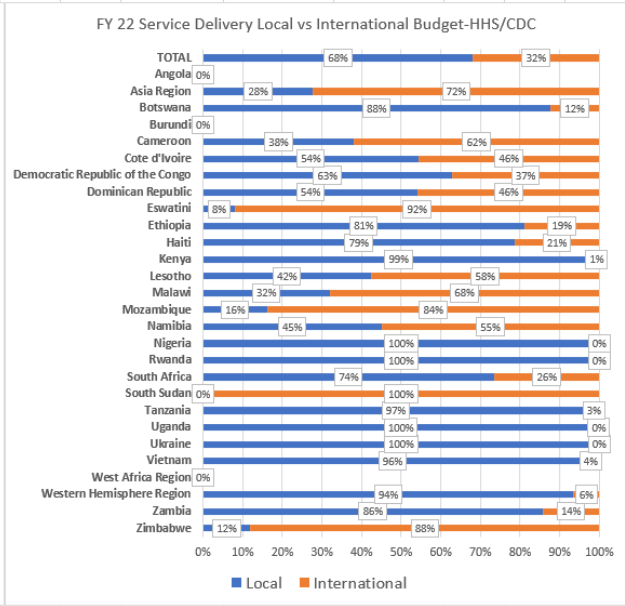
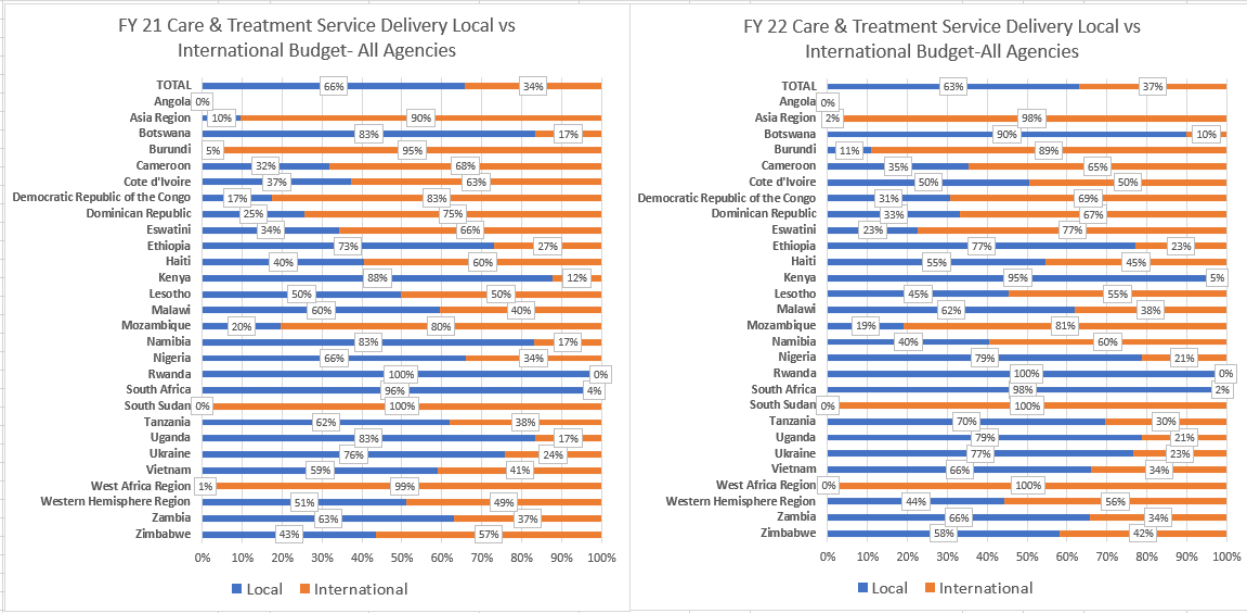
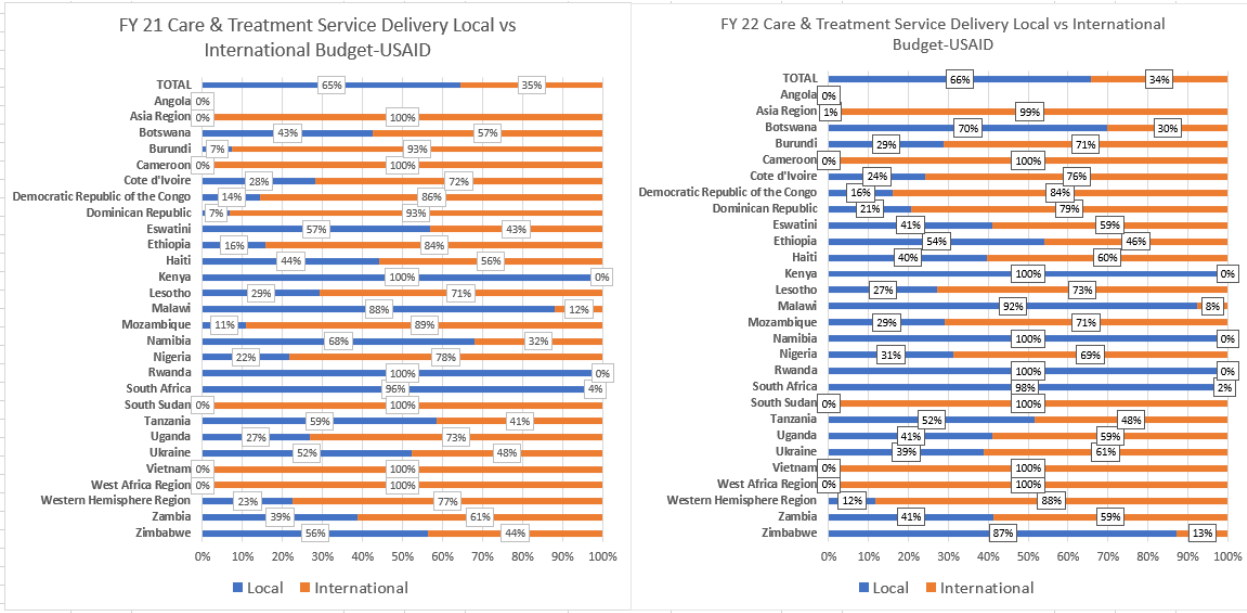

FY 22 Service Delivery Local vs International Budget-HHS/CDC
TOTAL 68% 32%
Angola 0%
Asia Region 28% 72%
Botswana 88% 12%
Burundi 0%
Cameroon 38% 62%
Cote d'Ivoire 54% 46%
Democratic Republic of the Congo 63% 37%
Dominican Republic 54% 46%
Eswatini 8% 92%
Ethiopia 81% 19%
Haiti 79% 21%
Kenya 99% 1%
Lesotho 42% 58%
Malawi 32% 68%
Mozambique 16% 84%
Namibia 45% 55%
Nigeria 100% 0%
Rwanda 100% 0%
South Africa 74% 26%
South Sudan 0% 100%
Tanzania 97% 3%
Uganda 100% 0%
Ukraine 100% 0%
Vietnam 96% 4%
West Africa Region 0%
Western Hemisphere Region 94% 6%
Zambia 86% 14%
Zimbabwe 12% 88%
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
Local International

Figure 2.4.6.3 FY 21-22 Total Funding for Care & Treatment Service Delivery by Local and International Partner Charts





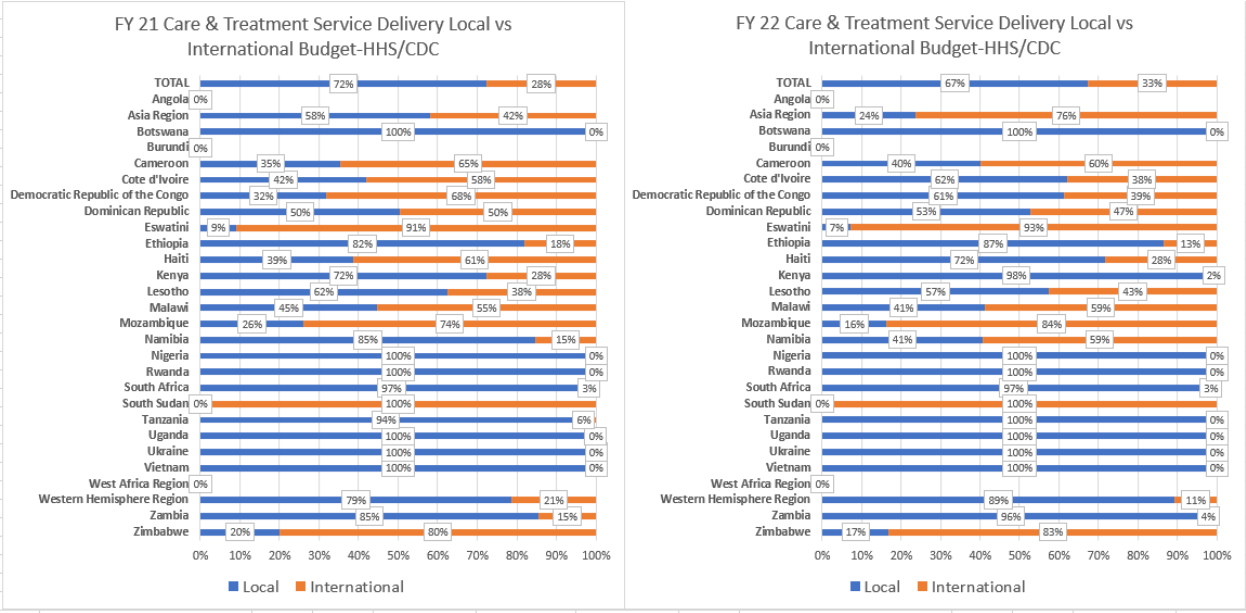
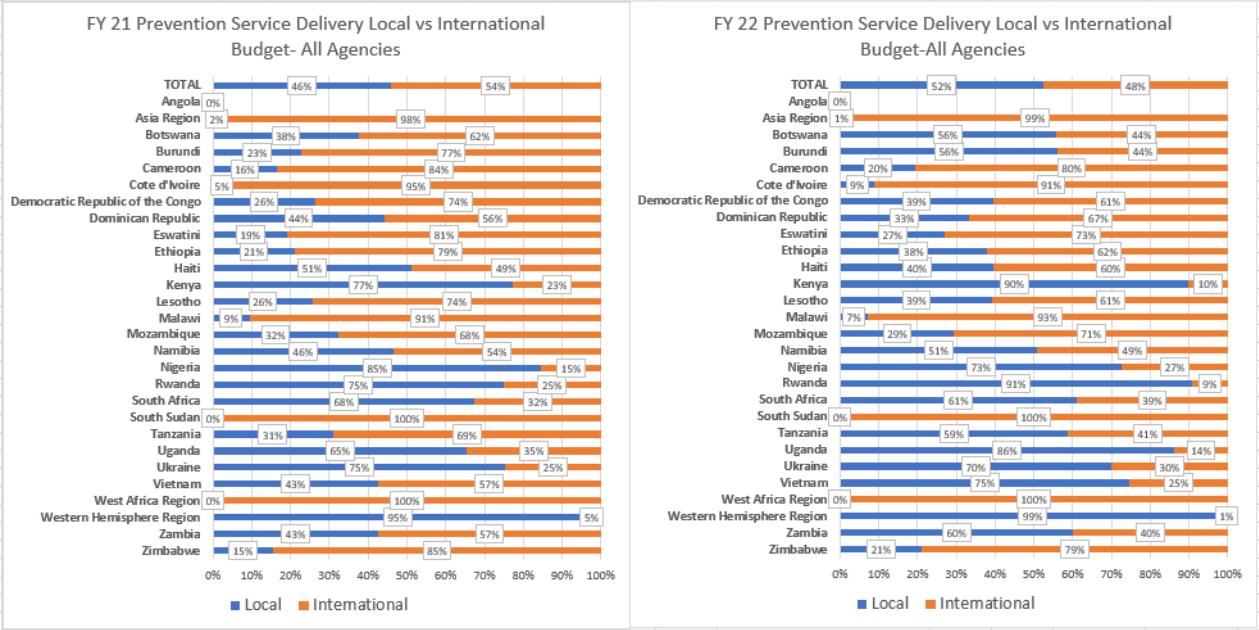
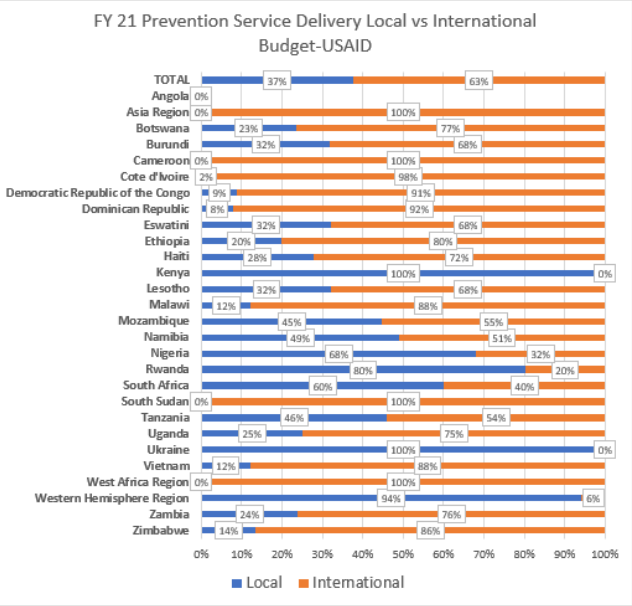
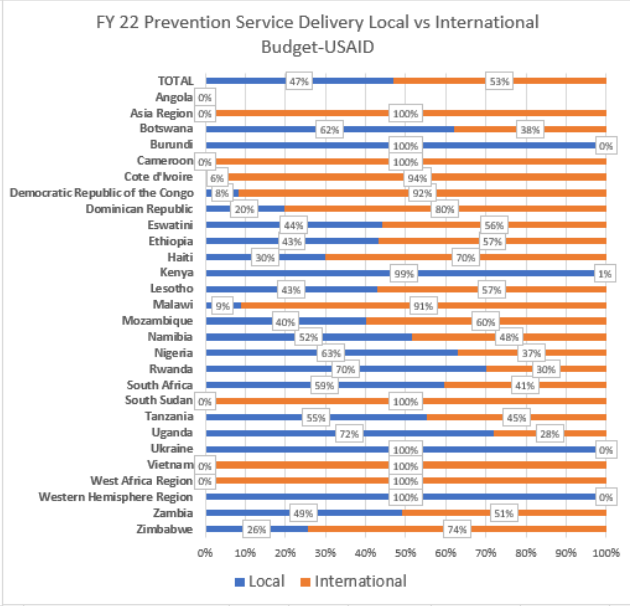
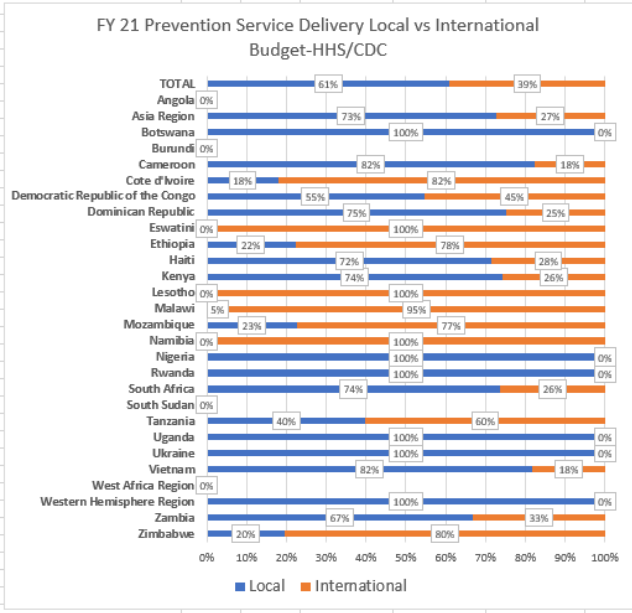


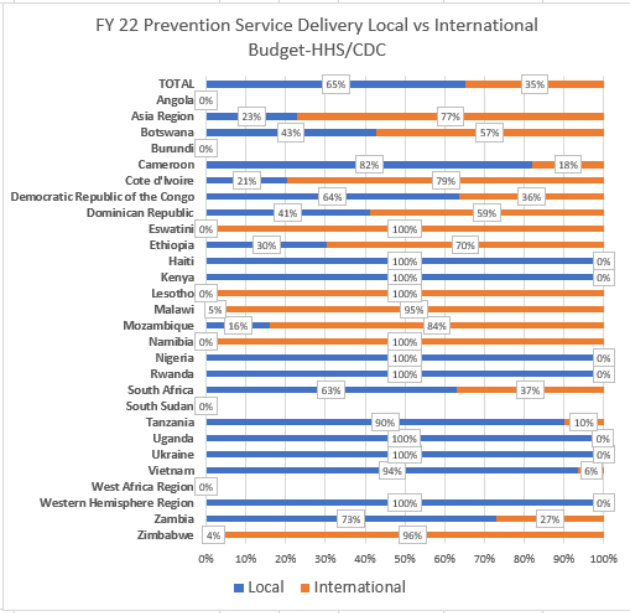
Figure 2.4.6.4 FY 21-22 Total Funding for Prevention Service Delivery by Local and International Partner Charts





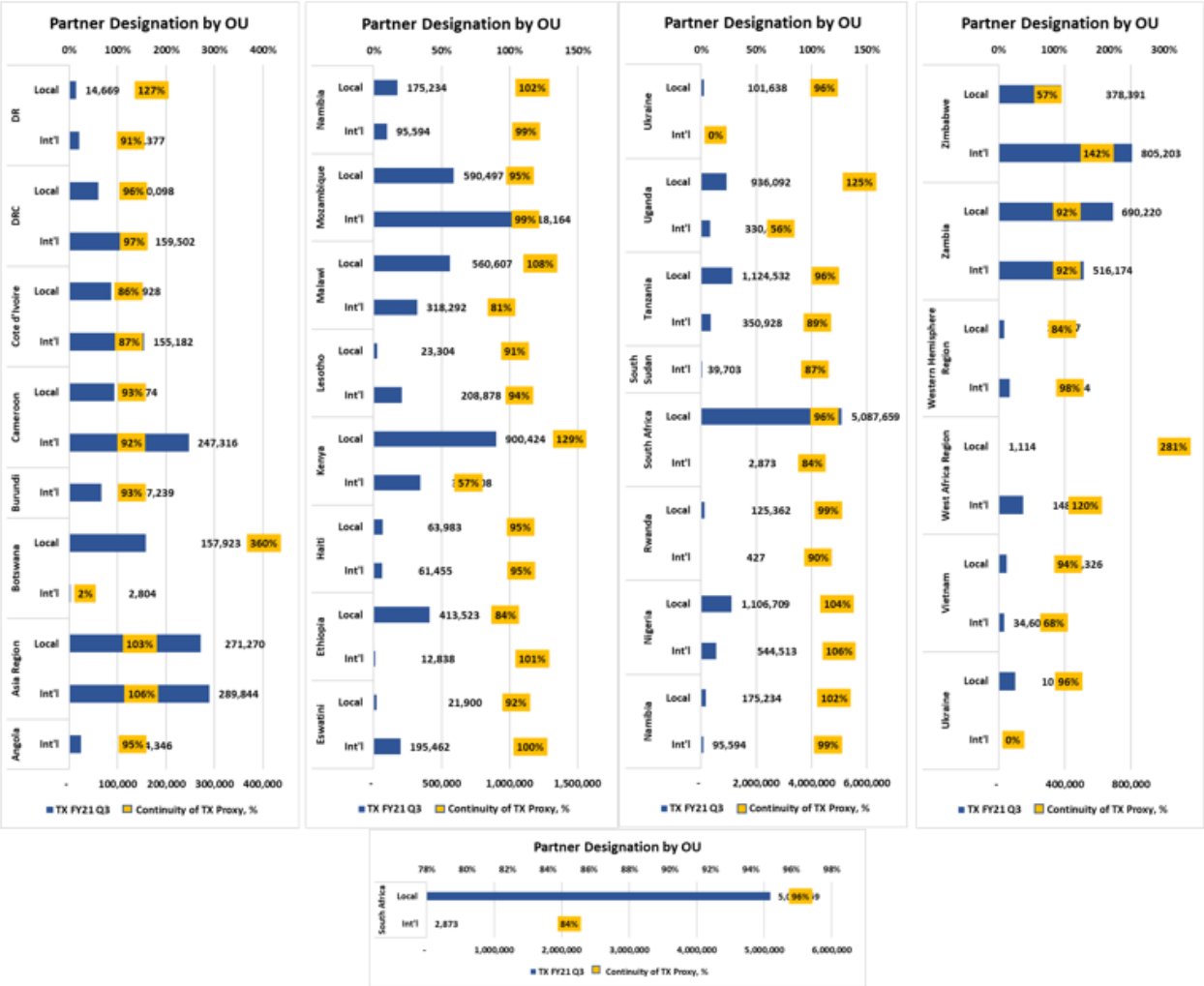






Under the challenging time of COVID-19, local partners have been critical – demonstrating their capacity to ensure that clients receive the services they need, exemplified by their results maintaining clients on continuous treatment in FY20 compared to international partners in Figure 2.4.6.5. The retention (continuity of treatment) proxy (annual calculation, in yellow) may be affected by some partners not continuing into FY20 or only starting in FY20.

Figure 2.4.6.5: Local and International Partner Results in Maintaining Clients on Continuous Treatment by OU in FY21



1. Definition of a Local Partner: 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 demonstrating their organization meets at least one of the three criteria listed below at the time of application. In the below 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 the table below.

Individual
An individual must be a citizen or lawfully admitted permanent resident of and have his/her principal place of business 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:		
1	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
2	either	must be at 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 application must be citizens or lawfully admitted permanent residents of that same country
3		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.

Figure 2.4.6.6: Sub Regional groupings

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				

2.5 Goal 3: Building Lasting Partnerships by Strengthening Coordination and Cooperation

To achieve sustained control of the HIV/AIDS epidemic, it is essential that PEPFAR teams actively and routinely coordinate and communicate with stakeholders including partner country governments, multilateral organizations, other bilateral donors, the private sector, and civil society, including KP-led, community-led, women-led, and faith-based organizations, among others.

Goal 3 of the draft PEPFAR 2021-2025 Strategy under development highlights the opportunity and the imperative to both continue the vital work of coordinating and communicating in a way that heightens impact and accountability, and also to build lasting strategic partnerships that strengthen the available services and add resilience to OU efforts to institutionalize the work needed to sustain HIV epidemic control.

For COP22, teams are expected to actively engage stakeholders in all aspects of strategic planning. To this end, **each PEPFAR OU team is required to conduct a country-centered strategic planning consultation with local stakeholders by the end of January 2022/early February 2022.** The retreat will be used to introduce and discuss all COP22 tools, guidance, results, and targets, as well as the proposed trajectory and strategy for COP22. Following COP22 submission, teams are expected to plan for continued engagement with external stakeholders through routine sharing of data on at least a quarterly basis from the PEPFAR Oversight and Accountability Response Team (POART). As communication and coordination advance to alignment and partnership, participation by stakeholders in POART calls is encouraged.

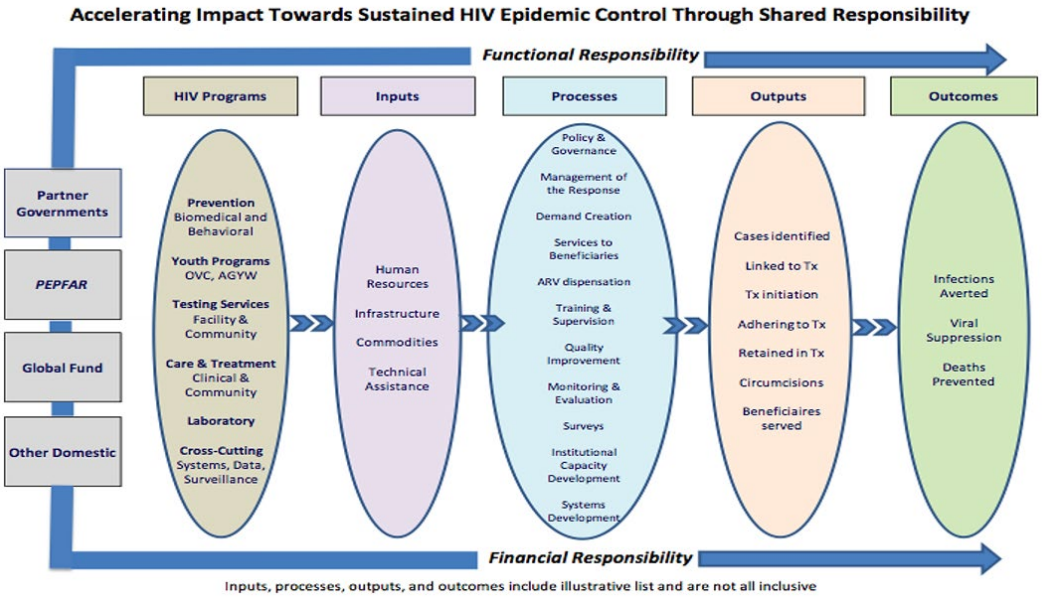
2.5.1 Partner Country Governments

PEPFAR is committed to continually strengthening its partnership with country governments to ensure alignment between PEPFAR support and national priorities and investments. Collaborative planning between PEPFAR and partner-country governments is critical to ensuring that prioritized interventions are scaled, geographic priorities are shared, and that all available resources for HIV/AIDS in the country are utilized optimally. Every year, PEPFAR country teams—in close collaboration with partner countries and the Global Fund—ensure that dollars strategically align to address gaps and solutions for impact while maximizing transparency, efficiency, quality assurance, and accountability of resources. OU teams must regularly consult and communicate with the Ministry of Health (at various levels), the National AIDS Control Authority (or its equivalent), the Ministry of Finance, other relevant ministries (e.g., Defense, Education), and relevant government leaders, e.g., Office of the President and/or Prime Minister. This engagement is critical to ensure that PEPFAR's role in the national response is clear.

One of the COP Minimum Program Requirements (MPR) is to increase domestic resources expended. Undertaking greater financial responsibility for the HIV response is a core component of PEPFAR's Sustainability Framework (below). Increasing the domestic financial responsibility to sustain HIV epidemic control takes time to achieve. Part of this can be met through the co-

financing requirements under the Global Fund grants, which need strong transparent and accountability measures. Outside of the co-financing requirements, mission teams can also contribute to achieving the MPR by providing evidence-based advocacy and communication on increasing domestic expenditures in the HIV response with various country government entities. This is the best way to enhance political will and increase government financial commitment to HIV where and when possible. In the time of COVID-19, where economies have contracted and government debt ballooned, it is also important to emphasize efficiency in resource use while also ensuring that budget commitments and allocations are not redirected away from supporting the HIV response. This means looking into base spending and identifying activities that may not be necessary or should be right sized while maintaining core services on the ground.

Figure 2.5.1.1 Accelerating impact towards sustained HIV epidemic control through shared responsibility



Partner country governments may also serve as key PEPFAR implementing partners through government-to-government (G2G) agreements. This direct funding of the partner-country government can provide opportunities to improve coordination of PEPFAR programs with the national response, and it can also strengthen technical, management, and financial systems in the long term for sustained epidemic control. It can also pose unique challenges and risks that must be taken into account in the COP planning process. USAID's G2G Risk Management and Implementation Guide provides a good starting point when identifying and addressing vulnerabilities and threats that teams should consult. Agencies should also consult any other relevant agency guidance.

2.5.2 Multilateral and Private Sector Partner Engagement

Multilateral Partners

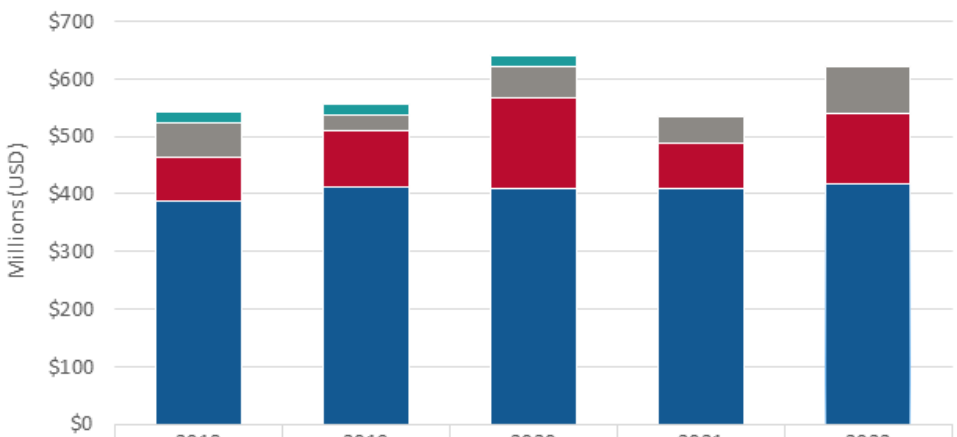
Multilateral partners, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria, UNAIDS, WHO, the United Nations Children's Fund (UNICEF), the World Bank, and others, play a critical role in supporting our mutual goal of HIV epidemic control. Often, they have core competencies that differ from PEPFAR and other donors and can play a significant role in influencing partner government policy and program decisions, addressing implementation challenges, and coordinating and aligning efforts across the partners. OU teams must proactively engage multilateral stakeholders from the earliest phase of COP planning.

The U.S. government contributes up to one-third of all Global Fund dollars for AIDS, TB and malaria activities. PEPFAR teams must seek to ensure PEPFAR, partner country, and Global Fund resources strategically align to maximize impact. In October 2019, the Global Fund held its 6th Replenishment conference, meeting its $14 billion pledge goal and launching a new funding cycle covering the 2020-2022 period, which aligns with implementation in 2021-2023. This new cycle coincided with the COP20 season. The overlap in COP20 and Global Fund planning provided an opportunity for countries to consider all resources at one time and plan holistically using shared epidemiologic data, program results, outlays, and planning levels. Portfolio optimization—the process by which more Global Fund funding can be added by the Global Fund to an existing Global Fund grant, which has an intervention registered in the Unmet Quality Demand (UQD) register—offers an opportunity to recipient countries to access additional Global Fund resources to further support the national response. PEPFAR continues to collaborate with the Global Fund and others to better align resources, avoid duplication, drive efficiency, and improve the cost data and resource estimations of HIV treatment and prevention programming. The multiyear Resource Alignment collaboration provides harmonized financial data to better understand HIV investments across PEPFAR, the Global Fund, and partner country government; enhances strategic collaboration and coordination during program cycle planning; and advances efforts around domestic responsibility and resource mobilization to ultimately ensure financial and programmatic sustainability of HIV programs. PEPFAR is also actively engaged in Global Fund Board- and Committee-level dialogues on the development of the Global Fund's 2023-2028 strategy.

In addition to the amounts appropriated by the U.S. Congress, under the Global Health Programs account, under regular annual appropriations acts for U.S. contributions to the Global

Fund, the U.S. Congress has made available $3,500,000,000 in Economic Support Funds under the American Rescue Plan Act of 2021 (ARPA) for a U.S. contribution to the Global Fund for COVID-19 related programming. The U.S. government intends, subject to the completion of applicable congressional notification procedures, to provide this additional contribution in support of the Global Funds' COVID-19 Response Mechanism (C19RM). The Global Fund Board created the C19RM in April 2020 to finance interventions in countries receiving Global Fund investments to mitigate the effects of COVID-19 through 1) control and containment interventions such as personal protective equipment, diagnostics, and treatment; 2) COVID-19 risk mitigation measures for HIV, TB, and malaria programs; and 3) expanding the reinforcement of key aspects of national health systems. Countries may request C19RM funds through March 31, 2022, and deploy funds through December 31, 2023. PEPFAR OUs should continue to work through the Country Coordinating Mechanism (CCM) to ensure that activities proposed for C19RM funding are clearly defined, communicated, and complementary to those supported by funding from PEPFAR and other sources, i.e., donor or domestic funds. PEPFAR OUs should also work with CCMs to ensure that proposed activities are responsive to and reflective of communities' input and priorities.

Figure 2.5.2.1 Trends in Total HIV Investments by Funder, 2018-2022



	2018	2019	2020	2021	2022
Other Funders	$18,233,135	$18,017,091	$18,077,365	$-	$-
Domestic Gov't	$61,254,029	$27,202,329	$53,673,416	$45,723,684	$82,950,900
Global Fund	$74,125,219	$97,849,934	$158,674,256	$79,772,475	$121,288,922
PEPFAR	$388,567,080	$412,892,816	$409,237,739	$408,949,999	$418,425,000

Using the FY21 Q4 data analysis for HIV and TB/HIV co-infection, resource alignment data, the availability of trend data across OUs, SID analysis, the Global Fund Principal Recipient data, and commodities consumption and forecasting data, OU teams must support the government to

convene relevant stakeholders to review the PEPFAR Country overall strategic direction for COP22. In addition, teams can use this joint planning process as an opportunity to identify emerging priorities that can be funded through grant savings and the Global Fund's Portfolio Optimization process. PEPFAR OU teams are also encouraged to be apprised of technical assistance needs—in consultation with Global Fund and UNAIDS contacts—and convey these to HQ to inform the allocation of Global Fund technical assistance resources as applicable.

Quality health services are essential to ensure that optimal health outcomes are met on a daily and routine basis. Existing or emerging barriers to continuous ART coverage, such as high levels of treatment interruption, high morbidity or mortality rates, or increased incidence of HIV transmission between partners, need to be identified and resolved in real time. Additionally, quality health services need to be person-centered, equitable, and efficient. Diligent and sustained attention to quality is required to reach sustained epidemic control. This expectation for COP22 should be the same as expectations for programs funded with Global Fund dollars.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is another critical partner of PEPFAR. PEPFAR OU teams along with UNAIDS and its 11 UN agency co-sponsors must collaborate early and throughout the COP process to solicit each other's input and support. UNAIDS, including its Secretariat at the global and country levels and co-sponsoring agencies, is an effective partner in working with countries to advance the shared goal of achieving epidemic control, reaching 95/95/95 by 2030. The Global AIDS Strategy 2021-2026 developed by UNAIDS is focused on the intersecting inequalities that continue to drive the epidemic and provides a framework to get the response back on track to reach its goals by 2025. The Global AIDS Strategy received political endorsement at the highest level in the 2021 HIV AIDS Political Declaration at the United Nations General Assembly High Level Meeting in June 2021. UNAIDS and its 11 UN agency co-sponsors are instrumental in building support for global data, PEPFAR's approaches and its alignment and harmonization with programs supported by partner-country governments, the Global Fund, and others.

Within this coordination, data regarding the current epidemiology and response must reflect a shared and consistent understanding of the total national response. The decision by UNAIDS and WHO to adopt definitions on global indicators in line with those of PEPFAR help foster a better understanding of national responses and bring the organizations in better programmatic alignment. As is common practice, any differences in this understanding of the epidemic must be resolved before COP finalization.

Multilateral stakeholders must be invited to participate throughout the in-country COP preparation process, including the COP22 Meetings. PEPFAR teams must work with multilateral organizations to identify in-country representatives to participate in the COP22 Meeting. PEPFAR OU teams must also engage multilateral partners at other stages in the PEPFAR operating model, including before and after POART calls, during site visits, and when external technical assistance visits occur, as are appropriate for country context given the overlay of the COVID-19 pandemic constraints. Section 2.5.3 includes best practices to ensure engagement with multilateral partners and civil society organizations is meaningful.

Private Sector Partners

No one government or entity can address the HIV epidemic alone. Success relies on building meaningful and wide-ranging partnerships with the private sector at global and local levels. Scalability and sustainability of programs is more likely to be achieved with support of and collaboration with the private sector. In addition, partnerships with the private sector can offer opportunities for pursuing innovative strategies that may later be replicated. Teams should build partnerships with a diverse set of private sector stakeholders, including private for-profit institutions, social enterprises, foundations, and private sector health delivery systems (for example, private pharmacy chains, private provider networks and clinics, or private hospitals). Offering HIV services in private sector health pharmacies, clinics and drug shops can benefit PEPFAR programs in several ways. For example, private sector services can increase access and uptake of HIV prevention and treatment services for people who live far from public clinics, find hours inconvenient, or experience long wait times associated with accessing services in public sites. Established models for offering HIV services through the private sector include distribution of HIVST kits through pharmacies, provision of PrEP within private clinics, ARV pick-ups at private clinics and pharmacies, and the full provision of ART services through private providers.

Private Sector Engagement (PSE) strategies and Public Private Partnerships (PPPs) are enablers that engage expertise, core competencies, skillsets, and/or encourage coordination of resources investments (in-kind, cash, or other) to seek to achieve epidemic control. It is important to note that private sector engagement may not necessarily result in a formal public private partnership, but rather, is an engagement strategy that engages with the core business and/or competencies of the private sector to seek to achieve a country's and PEPFAR's goals. For example, PEPFAR may work closely with pharmaceutical or diagnostic manufacturers, in a manner consistent with applicable law and regulation, to inform them on the challenges they may

wish to consider when creating new products or technologies. PEPFAR Country Teams should engage, consistent with applicable law and regulations, with private sector partners and potential stakeholders early and often to identify opportunities for innovation and potential solutions to programmatic needs, interests, and challenges. PEPFAR defines formal PPPs as collaborative endeavors that coordinate technical expertise and contributions from the public sector with expertise, skillsets, and contributions from the private sector (financial or in-kind) to achieve epidemic control. It is essential to align PPPs with programmatic goals, challenges, or gaps and work collaboratively with other technical areas to accelerate outcomes and results. PPPs can be used to advance PEPFAR's goals and programmatic approaches in a more efficient and effective way. Partnerships can also be used to bridge the gap between innovation and scale. In this model of partnership, a partner invests in a proof of concept to create a new evidence-base, while PEPFAR supports the transition from innovation to sustainable, scaled implementation.

PSE and PPPs also can help PEPFAR programs and services adapt a people-centric approach. As the needs of beneficiaries change, so should country programming, and PPPs can be utilized to ensure people-centricity in program design. Using private sector expertise such as behavioral science, user-centered design, or market segmentation, PPPs can help drive programming in a way that maximizes impact for epidemic control. For example, in DREAMS and MenStar, user-centered design work implemented by the private sector provided insights into how country programming can be adopted to be more people-centric and effective in reaching targets.

When a potential PPP includes the State Department, then **S/GAC must be consulted on all such proposed PPPs to ensure appropriate State Department approval**. For further information on U.S. Department of State approval policies regarding PPPs, see 2 FAM 970.[64] **USG implementing agencies also should consult internally to ensure their policies and procedures on PPPs and PSE are being followed.** Partnerships should also be in line with national policies and regulations set by country governments.

The following are examples partnerships that support country programming to be more effective and/or people-centric:

Global Partnerships:

MenStar Coalition

[64] https://fam.state.gov/FAM/02FAM/02FAM0970.html

The MenStar Coalition is a public-private partnership that includes PEPFAR (represented by the U.S. Department of State), the Elton John AIDS Foundation, Unitaid, the Global Fund, the Children's Investment Fund Foundation, Johnson & Johnson, and Gilead Sciences. Its goal is to reach an additional one million men with HIV treatment services and aims to reach over 95% viral suppression among adult men. Specifically, each partner brings unique capabilities to meaningfully engage. MenStar brings together the HIV service delivery capacities of the public sector with the consumer-oriented marketing acumen of the private sector to optimize efforts in reaching men. The Coalition takes a coordinated people-centered approach to identify underlying barriers to men's testing, linkage to HIV treatment, and achievement of viral suppression. Powered by insights developed by the Coalition and the Bill & Melinda Gates Foundation, the MenStar Coalition[65] has developed and refined innovative demand creation and supply side programs to improve healthcare for men at each stage of the HIV treatment cascade. Country programs should use the insights referenced above to adapt/design their programs in a way that directly address the barriers for men to access HIV services. To help in doing so, Operational Guidance has been created which provides a step-by-step process on how to operationalize the MenStar approach into country programs.[66] Additional MenStar information and resources including the strategy, core package of services, and country program examples, can be found here and on SharePoint at MenStar on SharePoint.

DREAMS: Determined, Resilient, Empowered, AIDS-Free, Mentored, Safe

The DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) public-private partnership includes: PEPFAR, the Bill & Melinda Gates Foundation, Girl Effect, Gilead Sciences, Johnson & Johnson, and ViiV Healthcare. The ambitious DREAMS Partnership focuses on the reduction of HIV incidence among adolescent girls and young women by delivering a multi-sectoral, comprehensive package of evidence-based interventions. Technical Guidance is provided in Section 6.2.2.2. Private sector partners contributed unique expertise to strengthen and complement PEPFAR's programming, including: a financial grant for the procurement of PrEP for adolescent girls and young women; independent implementation science research and impact evaluation studies to measure DREAMS results; market

[65] https://www.menstarcoalition.org/being-client-centered-2/

[66] https://pepfar.sharepoint.com/sites/MenStar/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FMenStar%2FShared%20Documents%2FCountry%20Team%20Operational%20Guidance%20and%20M%26E%2FMenStar%20Operational%20Guidance%2Epdf&parent=%2Fsites%2FMenStar%2FShared%20Documents%2FCountry%20Team%20Operational%20Guidance%20and%20M%26E

segmentation analytics and peer-to-peer programs to better understand girls' needs; brand creation, media, and communications expertise to reach girls; and capacity building for community-based organizations.

Go Further: Ending AIDS and Cervical Cancer

Go Further is a public private partnership committed to creating a healthier future for women. Partners include the George W. Bush Institute, UNAIDS, Merck, and Roche. The partnership aims to reduce new cervical cancer cases by 95 percent among women living with HIV in 12 African countries (Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Tanzania, Uganda, Zambia, and Zimbabwe). To achieve the goals of Go Further, the partners coordinate their support in these select countries to integrate and scale up cervical cancer screening and precancerous lesion treatment services for all women on antiretroviral therapy between the ages of 25 and 49. See Section 6.4.4 for technical considerations.

Collaborating to Save Children

As a follow-on to PEPFAR's remarkable impact with the ACT Initiative, PEPFAR helps facilitate and expedite the research, development, approval, introduction and uptake of optimal drugs and formulations for infants, children, and adolescents. PEPFAR joined the Holy See and UNAIDS to convene a series of High-Level Dialogues with leaders of major diagnostic and pharmaceutical companies, multilateral organizations, governments, regulators, non-governmental including faith-based organizations, and others who are directly engaged in providing services to children living with and vulnerable to HIV. During these dialogues, key stakeholders agreed to specific good faith commitments to focus, accelerate, and collaborate on the development, registration, introduction, and roll-out of the most optimal HIV and TB pediatric formulations and diagnostics for children living with HIV. Referenced in the 2021 WHO updated HIV guidelines[67] and summarized in Section 6.4.1.1, all countries should prioritize rapid policy adoption and procurement of DTG starting at 3 kg and 4 weeks of age. PEPFAR will continue to leverage its work with private sector partners to support pediatric programs at scale.

Partnering on People-Centered Supply Chain Modernization

PEPFAR will increasingly collaborate with the private sector on solutions to modernize the supply chain. The private sector can play an important role in delivering a people-centered supply chain, which brings our commodities to the beneficiary rather than our beneficiaries to the commodities.

[67] https://www.who.int/publications/i/item/9789240031593

Specifically, PEPFAR will draw upon the private sector's insights on beneficiary preferences, and their expertise for getting products to people as quickly, efficiently, and accurately as possible. As countries shift from operating their own supply chains to outsourcing and managing supply chains, the private sector will play a role in sourcing, warehousing, logistics, transporting, and final mile delivery. PEPFAR may also adopt innovations from industry to deliver efficiently to patients by using cutting-edge technology and the latest insights.

Differentiated service delivery is a people-centered approach to HIV care and treatment that tailors services to different groups of people living with HIV. Programs may consider utilizing decentralized service delivery models for ART distribution for stable patients through private sector channels. This may include decentralized drug distribution such as alternative pick-up points in communities; retail, community, or pop-up pharmacies; home delivery; and/or automated systems such as lockers or Pharmacy Dispensing units (PDU). These models can help reduce patient travel times and waiting times while decongesting public facilities and reducing stigma. Country programs should ensure these approaches are in line with national policies for ART distribution. See Section 6.1.2 for further detail.

In addition to partnerships with private sector partners, OUs may also consider partnerships with private providers (GPs, clinics, pharmacies, labs, drug shops, etc.), which are essential to expand access to services and improve people-centered care. The private sector is often the preferred source of healthcare services, particularly for urban, higher income, and other key population groups. Common partnership models with private providers include formal contracting through government or donor funds or facilitating access to commodities, training, or other technical support. For additional information see Section 2.4.4 People-Centered Supply Chain Modernization.

Country Based Partnerships:

As OUs continue to implement partnerships and/or increase private sector engagement opportunities, it is critical that in-country stakeholders are engaged as early as possible during the COP process to help explore strategies, commitments, and the possibility of aligning with PEPFAR priorities in an intentional way. OU teams should consider leveraging private sector partnerships to help meet targets in a more efficient and effective way or to help fill gaps and address challenges in programming. OU teams are encouraged to seek out partnerships with local and national private sector entities.

Accountability for PEPFAR's participation in PPPs is essential and integrated within the routinized processes for reporting of results for PEPFAR programs. Entering a non-binding Memorandum of Understanding (MOU) is a critical tool in which all partners are expected to outline in detail expected roles and procedures for addressing ongoing PPP activities throughout the life cycle of the partnership. When an MOU involves the State Department (in addition to or instead of another U.S. government implementing agency), then S/GAC and other State Department offices have additional oversight responsibilities for the PPP. **Therefore, S/GAC must be consulted on all such proposed PPPs (including any proposed MOUs) to ensure appropriate State Department approval**. USG implementing agencies also should consult internally to ensure their policies and procedures are being followed.

The PPP toolkit[68] provides USG OU teams additional detail to help with private sector engagement and PPP development during the COP.

2.5.3 Active Engagement with Community and Civil Society

The full participation of community stakeholders and civil society in every stage of PEPFAR programming and planning, from advocacy to service delivery, is critical to the success and sustainability of PEPFAR and the global effort to combat HIV.[69] Civil society has been a leading force in the response to HIV since the beginning of the epidemic, providing expertise and relationships with local communities that non-indigenous organizations often struggle to achieve. Civil society provides an understanding of the political and cultural environment, and should inform the development of service delivery models, and actively participate in planning, delivering, and monitoring such services. It is key to ensure that community and civil society have a voice in finding solutions to combatting HIV commensurate with the burden of disease in a district or province. Civil society organizations (CSOs) provide services that are crucial to realizing impact on the epidemic, advocating on behalf of beneficiary populations, holding governments accountable, promoting human rights to combat stigma and discrimination against key populations, people living with HIV and other vulnerable groups, advancing inclusion for persons with disabilities, identifying challenges to and gaps in health care delivery, supporting

[68] https://pepfar.sharepoint.com/sites/PSE/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FPSE%2FShared%20Documents%2FPPP%20Toolkit&p=true

[69] UNAIDS & Stop AIDS Alliance. Communities Deliver: The Critical Role of Communities in Reaching Global Targets to End the AIDS Epidemic. Geneva and Hove: 2017. Available from http://www.unaids.org/en/resources/documents/2017/JC2725_communities_deliver.

data collection and innovation, providing independent views of programming and processes, and promoting transparency. It is important that affected populations have a voice from the beginning in helping design programs and throughout program implementation. PEPFAR-supported programs should set an example that encourages partner governments to create a conducive enabling environment for civil society engagement. Meaningful engagement with communities and CSOs remains a requirement and a critical theme of the PEPFAR program for COP22.

As in years past, civil society organizations will be invited to participate in the COP22 strategic planning meetings, as well as approval meetings, in a manner consistent with applicable laws and regulations.

Additionally, PEPFAR expects all OUs to continue to collaborate with civil society organizations in maintaining or establishing community-led monitoring activities, whereby service beneficiaries, through local, independent civil society organizations, formally and routinely monitor the quality and accessibility of treatment services and the patient-provider experience at the facility level. Findings of community-led monitoring (CLM) should be regularly reviewed by USG teams, and triangulated (where possible) with other PEPFAR data streams such as MER and SIMS, with the aim of informing and monitoring facility-level service delivery changes with health system leaders and facility staff that ultimately make services more accessible, palatable and of higher quality to people (see Section 3.2.3 for more information and requirements).

Civil society organizations participating in the COP strategic planning meetings will be asked to reflect on progress to date, including findings and recommendations from initial CLM activities, as applicable, for their country during the meeting.

Whom to Engage?

The community stakeholders and CSOs engaged in the COP process must reflect the HIV disease burden of the country and the full range of populations affected by HIV in the country, including key, priority, and other vulnerable populations like youth, women and young girls, gay men and other men who have sex with men, sex workers, transgender persons, prisoners and other people in enclosed settings, and people who inject drugs. Establishing and/or maintaining linkages with networks and coalitions is important to achieving broader civil society representation. Vital to success is the inclusion of people living with HIV and key population-led, competent, and trusted CSOs, as well as recognizing “Greater Involvement of People living with HIV/AIDS” (GIPA) principles, a detailed plan for engaging individuals at the center of HIV

epidemics, with particular emphasis made to the sociocultural and gatekeepers within the community as they tend to directly influence stigma issues in communities.

Civil society organizations may include: traditional health practitioners, community elders, and leaders; local and international non-governmental organizations; networks/coalitions; faith-based groups; professional associations; activist and advocacy groups, including those representing key and priority populations; organizations representing people living with HIV; human rights groups; women's rights groups; men's health groups, youth organizations; access to justice and rule of law groups; groups representing other populations highly affected by the epidemic, such as persons with disabilities and woman 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).

In addition to engaging implementing partners who are vital to the process, PEPFAR OU teams are required to engage smaller, local, KP-led civil society organizations, youth-led or youth-serving organizations, women-led organizations, and community groups to gather community input and feedback. OU teams must seek the inclusion of a diverse range of CSOs in consultations, considering that this process requires proactive outreach to ensure all affected populations are represented. Additionally, PEPFAR teams must include organizations from outside of the capital (e.g., by phone and internet) to ensure that a range of interests are represented. Strong consideration must be given to continue hosting the quarterly POART consultations remotely (e.g., by phone or webinar, as is outlined below) to allow maximum participation.

Engagement during COP Meetings

In 2022, external partners will be invited to participate throughout the in-country COP preparation process, during COP22 Meetings, and as COPs are being finalized. For CSO representation at the COP22 Meetings, information will be forthcoming. In some countries, dynamics within civil society might affect consensus building and unified representation. PEPFAR teams must therefore engage with constituent civil society groups early and often to allow for internal civil society processes prior to the COP22 Meetings and COP submission. S/GAC will also once again invite colleagues from global and regional network and advocacy organizations to participate in the COP22 Planning Meetings, so that they may offer their expertise to the processes and support the efforts of in-country CSO representatives.

It is always good practice to consult with members of a community about issues related to disclosure. For example, some individuals would rather their names not be published, or their names included in electronic files, public lists of meeting attendees, etc.

As in the past, S/GAC will encourage these global and regional networks to engage with local community and CSO leaders as appropriate prior to the COP22 planning meetings, to ensure advocacy efforts are aligned with the needs of the local OU context.

Ensuring Continued Meaningful Engagement

For COP22, PEPFAR teams are expected to continue to expand their collaborations with local civil society, including activists, advocacy groups, and service delivery organizations. PEPFAR teams must continue to solicit input proactively from civil society regarding their goals, priorities, targets, and budgets in drafting their COP as outlined below. Particular attention must be given to including civil society and activist groups that are not funded directly by PEPFAR. Civil society partners must be invited to share candid feedback to improve PEPFAR-supported programming without fear of losing access to PEPFAR processes or resources. PEPFAR teams are also encouraged to establish terms of reference for the engagement of civil society organizations, and especially those that are also local implementing partners.

As national governments assume greater ownership of their HIV responses, the sustainability of this ownership will rely heavily on civil society partners to adequately address the health needs of their citizens. Meaningful engagement with PEPFAR can model this partnership and build the capacity of local CSOs to meet this challenge, better preparing them to play a leadership role now and in the future with partner-country governments. Meaningful engagement must be more than simply sharing information with community groups and civil society organizations. Various models of community engagement[70] acknowledge a continuum of public or community engagement where community has an increasing impact on decision making, ranging from unidirectional information sharing on one end, to allocating full decision-making to communities on the other. PEPFAR teams should work to ensure increasing degrees of community participation in decision-making.

The table below highlights the major ways in which PEPFAR teams and stakeholders must work collaboratively in COP22.

[70] https://www.iap2.org/resource/resmgr/pillars/Spectrum_8.5x11_Print.pdf; https://www.atsdr.cdc.gov/communityengagement/

Figure 2.5.3.1: COP22 stakeholder engagement (subject to final considerations for virtual COP meetings and final dates) (on next page)

PEPFAR Team Action	Stakeholder Action	Dates
Distribute critical data and COP22 materials to stakeholders: • COP Guidance • Planning Level Letter • COP21 SDS and Approval Memo • Q4 results via Spotlight	Analyze materials to prepare for COP22 discussions at Strategic Planning Retreat Identify areas of successful performance that can be leveraged going into COP22 Develop recommendations on site-level or non-service delivery activities that should not continue Global and regional CSO request information from applicable OUs	• COP Planning Tool templates released to teams January 7, 2022 • COP Guidance released January 19, 2022
Invite local stakeholders to Country Strategic Planning Retreat Review materials and preparations with stakeholders	Attend Country Strategic Planning Retreat Provide with PEPFAR teams with recommendations for COP22 focus, based on analysis of Q4 results and other observation of program performance, including initial findings from community-led monitoring activities	Country Strategic Planning Retreat • No later than the week of February 7, 2022 Note: depending on the OU, this meeting may be virtual or in-person • Single OUs at Epidemic Control have a pre-Retreat Meeting January 27, 2022

Arrange for stakeholder participation in COP22 meetings Document stakeholder feedback and PEPFAR response Share meeting materials with stakeholders Use the Self-Service App to create DataPack flatpacks; share with stakeholders prior to initial and final tools submission at minimum, and more as needed.	Participate in S/GAC pre-meeting webinar for stakeholders Actively participate in COP22 planning meetings Provide feedback on activities, targets, and approaches Include initial findings from community-led monitoring activities	• March 1-25, 2022
Share SDS with stakeholders	Review SDS and communicate to PEPFAR coordination offices if it is not aligned with COP22 meeting agreements/strategies Global and regional CSOs request SDS from PEPFAR Coordination offices	~ One week prior to final submission to S/GAC: • SDS is submitted to S/GAC at least seven days before Approval Meeting
Invite stakeholders to COP/ROP22 In Country Approval Meetings. Share meeting materials with stakeholders.	Actively participate in COP/ROP22 approval meetings to ensure presented strategies and approaches are aligned with COP/ROP22 planning meeting agreements	April 25 - May 13, 2022
Invite and engage stakeholders to meet prior to each quarterly POART call to	Participate in pre-POART stakeholder meetings; offer analysis and	COP22 POART schedule is not yet defined; ensure the OU calendar of events is

engage their feedback and recommendations for program improvement	recommendations to remove barriers and bottlenecks	updated well in advance of meetings so stakeholders are aware of key dates well ahead of time

All PEPFAR OUs submitting COPs are required to create and share a country-specific calendar of events that details when documents will be shared and when meetings will be conducted so CSOs are able to plan and effectively support COP development and execution.

2.5.4 Enhancing Engagement with Faith-Based Organizations and Faith Communities

PEPFAR's success has been built in partnership with community, including faith-based organizations (FBOs), and faith-based and traditional communities. In most countries in Southern and Eastern Africa, 70-90% of the population regularly attend religious services and participate in religious communities.[71] These communities of faith are deeply embedded regionally, with national structures, and often have unique institutional capacity and established, durable relationships of trust. To address key gaps toward achieving HIV epidemic control and ensuring justice for children, PEPFAR launched the Faith and Community Initiative (FCI) in 10 countries in COP19. For COP22 and beyond, the original 10 FCI countries, countries investing core funding in FCI activities, as well as other PEPFAR country teams are encouraged to invest core COP funding for evidence-based FCI activities that accelerate reaching men and children (Section 6.6.4) and to prevent and respond to violence against children (Section 6.6.2.1). Utilizing the expertise of PEPFAR programming and leveraging the extensive social capital of faith and other communities will result in greater progress in reaching and sustaining the goal of HIV epidemic control. PEPFAR requires all partners to oppose all stigma and discrimination based on race, sex, gender, gender identity, sexual orientation, religion, ethnicity, or occupation; and to uphold PEPFAR's commitments to serve all people living with HIV or at risk of HIV.

At this juncture of the epidemic, when finding the healthy client to help him/her continue in care is critical to epidemic control, PEPFAR must seek to expand its outreach to all partners who can help in this endeavor, including FBO partners, faith-based health providers, faith

[71] Pew Research Center. (2016). Pew-Templeton: Global Religious Futures Project. Global Religious Futures Project. http://www.globalreligiousfutures.org/

communities, and traditional partners, with the aims of leveraging their influence and compassion, for impact. This combination of community partners and structures can be leveraged by FCI and other FBO partners to address barriers to screening; advance evidence-based models for demand creation, including peer-led programs and use of digital platforms such as short video clips; increase uptake of targeted testing; reduce stigma; and raise awareness about increased mortality risks from non-adherence and interruptions in treatment that are related to faith healing in congregations. PEPFAR aims to identify more people at risk, with the aim of maintaining and extending the gains in the HIV response in the context of COVID-19, by supporting the following goals:

- Increasing communities, including faith communities', awareness of evidence-based, people-centered HIV prevention and treatment services.
- Leveraging the unique access and trust of certain communities, including faith communities, to sustain gains in HIV epidemic control by capitalizing on skills in case-finding, indexing and contact tracing, testing, care, and psychosocial support for both HIV and COVID-19.
- Leveraging community structures, to integrate COVID-19 risk prevention communications and vaccine demand creation for at-risk populations and people living with HIV.
- Increasing literacy in HIV prevention, care, and treatment for community leaders, including faith leaders by leveraging existing structures, including indigenous and inter-faith digital (e.g., Mobile-based e-referral systems, SMS, or WhatsApp reminders) and virtual platforms (e.g., Facebook, Instagram, etc.).
- Direct engagement with the mothers within relevant communities, including communities of faith, in early childhood or adolescent testing and treatment; and in providing direct support to children and families.
- Identifying and reaching men at increased risk for HIV and inviting them for HIV testing, including self-testing, and ensuring those who test positive initiate and continue to receive care and treatment.
- Finding children and adolescents with HIV and ensuring those who test positive initiate and continue in treatment, with particular attention to family index testing (including appropriate use of HIVSTs for preschool and school-aged children and adolescents) and to the challenges for adherence.

- Expanding Faith and Community Initiative 'best practices' models that link highly targeted HIVSTs/HTS to initiating treatment and continuing in care (Section 6.6.4).
- Expanding client base of neighborhood, including faith engaged, community sites to increase convenient access to ARV pick-ups and MMD among index clients and contacts.
- Educating people living with HIV about similarities between conditions that have overlapping symptoms, such as TB and COVID-19, and ensuring that clients with symptoms are identified and referred for diagnosis and treatment.
- Addressing stigma and discrimination for TB, COVID-19, and HIV by expanding engagement of community leaders, including faith leaders, affected by COVID-19, HIV, and TB.
- Increasing buy-in for and uptake of cervical cancer screening services among women and educating men about the importance of screening and supporting partners.
- Addressing stigma among all survivors (male and female, all ages) of sexual violence
- Preventing and responding to sexual violence among children is a shared norm or value among many community leaders, including faith leaders; this includes building on such communities' influence to change the culture around sexual violence so that they help promote post-violence clinical care, a survivor-centered response, and a culture of reporting (Section 6.6.2.1).
- Supporting DREAMS and OVC programming.

2.6 Minimum Program Requirements

All PEPFAR programs–bilateral and regional–were expected to have a set of minimum program requirements (MPRs) and supporting policies in place by the beginning of COP20 implementation (October 2020; FY2021). Adherence to these policies and practices is essential to the success of all PEPFAR programs at the national, subnational, and service-delivery levels (e.g., facility, school, community). Evidence demonstrates that lack of any one of these policies/practices significantly undermines progress toward reaching and sustaining epidemic control and results in inefficient and ineffective programs.

For COP/ROP22, as noted in Section 2.2, a new MPR (#9) is introduced relating to equity, reducing stigma and discrimination, and progress on human rights. In addition, updates to MPRs

#11 and #13 should be noted, and please see Section 6.6.8. for important data and systems confidentiality, privacy, and security guidance to inform MPR #16.

All PEPFAR programs are expected to meet all of the policy and program requirements below, and the COP22 Planning Meetings will include a review of the status of each requirement, including assessment of implementation using SIMS and MER. See Section 3.2.1 for details on minimum site standards. To the extent that any requirement(s) have not been met by the time of the COP22 Planning Meeting, the PEPFAR OU team will need to present a detailed description of existing barriers and the remediation plans proposed that will allow them to meet the requirement(s) prior to the beginning of FY2023. The list will be included in the Strategic Direction Summary (SDS), as well.

Failure to meet any of these requirements by the beginning of FY2023 may affect the OU budget. The minimum requirements for continued PEPFAR support are included in the table in Figure 2.6.1 on the next two pages.

Figure 2.6.1: COP22 Minimum Program Requirements – Services and Systems[72,73,74,75,76,77,78,79,80,81]

Care and Treatment	
1.	Adoption and implementation of Test and Start, with demonstrable access across all age, sex, and risk groups, and with direct and immediate (>95%) linkage of clients from testing to uninterrupted treatment across age, sex, and risk groups.[72]
2.	Rapid optimization of ART by offering TLD to all PLHIV weighing ≥30 kg (including adolescents and women of childbearing potential), transition to other DTG-based regimens for children who are ≥4 weeks of age and weigh ≥3 kg, and removal of all NVP- and EFV-based ART regimens.[73]
3.	Adoption and implementation of differentiated service delivery models for all clients with HIV, including six-month multi-month dispensing (MMD), decentralized drug distribution (DDD), and services designed to improve identification and ART coverage and continuity for different demographic and risk groups.[74]
4.	All eligible PLHIV, including children and adolescents, should complete TB preventive treatment (TPT), and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.[75]
5.	Completion of Diagnostic Network Optimization activities for VL/EID, TB, and other coinfections, and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including 100% access to EID and annual viral load testing and results delivered to caregiver within 4 weeks.
Case Finding	
6.	Scale-up of index testing and self-testing, ensuring consent procedures and confidentiality are protected and assessment of intimate partner violence (IPV) is established. All children under age 19 with an HIV positive biological parent should be offered testing for HIV.[76]
Prevention and OVC	
7.	Direct and immediate assessment for and offer of prevention services, including pre-exposure prophylaxis (PrEP), to HIV-negative clients found through testing in populations at elevated risk of

[72] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization, September 2015 https://apps.who.int/iris/bitstream/handle/10665/186275/9789241509565_eng.pdf
[73] WHO policy brief, Considerations for introducing new antiretroviral drug formulations for children. Geneva: World Health Organization, July 2020
[74] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization, 2016
[75] Latent Tuberculosis infection: Updated and consolidated guidelines for programmatic management . Geneva: World Health Organization, 2018
[76] Guidelines on HIV self-testing and partner notification. Supplement to consolidated guidelines on HIV testing services. Geneva: World Health Organization, 2016 https://www.who.int/hiv/pub/self-testing/hiv-self-testing-guidelines/en/
[77] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization; 2015 (http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en)
[78] United Nations General Assembly: Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030. 8 June 2021 https://undocs.org/A/RES/75/284
[79] The practice of charging user fees at the point of service delivery for HIV/AIDS treatment and care. Geneva: World Health Organization, December 2005
[80] Technical Brief: Maintaining and improving Quality of Care within HIV Clinical Services. Geneva: WHO, July 2019
[81] Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021.

	HIV acquisition (PBFW and AGYW in high HIV-burden areas, high-risk HIV-negative partners of index cases, key populations and adult men engaged in high-risk sex practices) [77]
8.	Alignment of OVC packages of services and enrollment to provide comprehensive prevention and treatment services to OVC ages 0-17, with particular focus on 1) actively facilitating testing for all children at risk of HIV infection, 2) facilitating linkage to treatment and providing support and case management for vulnerable children and adolescents living with HIV, 3) reducing risk for adolescent girls in high HIV-burden areas and for 10-14 year-old girls and boys in regard to primary prevention of sexual violence and HIV.
	Policy & Public Health Systems Support
9.	In support of the targets set forth in the Global AIDS strategy and the commitments expressed in the 2021 political declaration,[78] OUs demonstrate evidence of progress toward advancement of equity, reduction of stigma and discrimination, and promotion of human rights to improve HIV prevention and treatment outcomes for key populations, adolescent girls and young women, and other vulnerable groups.
10.	Elimination of all formal and informal user fees in the public sector for access to all direct HIV services and medications, and related services, such as ANC, TB, cervical cancer, PrEP, and routine clinical services affecting access to HIV testing and treatment and prevention.[79]
11.	OUs assure program and site standards, including infection prevention & control interventions and site safety standards, are met by integrating effective Quality Assurance (QA) and Continuous Quality Improvement (CQI) practices into site and program management. QA/CQI is supported by IP work plans, Agency agreements, and national policy.[80]
12.	Evidence of treatment literacy and viral load literacy activities supported by Ministries of Health, National AIDS Councils and other partner country leadership offices with the general population and health care providers regarding U=U and other updated HIV messaging to reduce stigma and encourage HIV treatment and prevention.[81]
13.	Clear evidence of agency progress toward local partner direct funding, including increased funding to key populations-led and women-led organizations in support of Global AIDS Strategy targets related to community-, KP- and women-led responses
14.	Evidence of partner government assuming greater responsibility of the HIV response including demonstrable evidence of year after year increased resources expended
15.	Monitoring and reporting of morbidity and mortality outcomes including infectious and non-infectious morbidity.
16.	Scale-up of case surveillance and unique identifiers for patients across all sites.

3.0 QUALITY SERVICES

3.1 Quality Assurance and Quality Improvement within PEPFAR

Quality, person-centered services are essential to ensure that optimal health outcomes are met today and into the future. Quality management represents all systems and activities undertaken by PEPFAR-supported teams, partner countries, and stakeholders to ensure excellence and consistency. For COP22, all PEPFAR country programs must incorporate explicit quality management practices, including Quality Assurance (QA), Quality Improvement (QI), Continuous Quality Improvement (CQI), and Community-Led Monitoring (CLM) activities, into service delivery and partner management to attain or sustain epidemic control. The quality focus in COP22 will be to verify that (where applicable) Minimum Program Requirements (MPR) are being met at the site level and using key data, notably select SIMS and MER metrics, as tools for quality management.

PEPFAR, like WHO, defines key principles and concepts related to quality, HIV and health care should be:

- Effective: providing evidence-based health care services to those who need them.
- Safe: avoiding harm to people for whom the care is intended.
- Person-centered: providing care that responds to individual preferences, needs, and values.

In order to realize the benefits of quality health care, health services are:

Timely: reducing waiting times and sometimes harmful delays for both those who receive and those who give care.

Equitable: providing care that does not vary in quality on account of age, sex, gender, race, ethnicity, geographical location, religion, socioeconomic status, disability, occupation, linguistic or political affiliation.

Integrated: providing care that is coordinated across levels and providers.

Efficient: maximizing the benefit of available resources and avoiding waste.[82]

Quality assurance (QA) – an activity that measures performance against standards at a specific point in time. The principal tool across PEPFAR that assesses whether sites meet PEPFAR's shared quality standards is via the Site Improvement through Monitoring System (SIMS).[83]

Quality improvement (QI) – an activity designed to continually improve performance as part of a routine process, designed to test changes in program services, continually measure the effects of these changes, and use data to address gaps to improve clinical performance and health outcomes over time. PEPFAR endorses the use of evidence-based QI approaches[84] and the use of existing community-led monitoring data reflecting person-centered service needs. Acceptable CQI practices and principles, such as Plan-Do-Study-Act (PDSA) cycle models.

QA and QI are distinct but intersecting components as shown in Figure 3.1.1. QA assesses minimum standards, and QI is an on-going process—typically referred to as Continuous Quality Improvement (CQI). CQI is best integrated into program management and implementation, designed to engage site staff to identify barriers and facilitators of providing quality services, and empowering them to take action to improve results. In addition, HIV testing and laboratory have supplemental and more detailed quality management systems. Details on these QA and QI can be seen in Sections 6.3.1.1 and 6.6.1.3.

[82] Delivering quality health services: a global imperative for universal health coverage. Geneva: World Health Organization, Organisation for Economic Co-operation and Development, and The World Bank. (2018). https://www.worldbank.org/en/topic/universalhealthcoverage/publication/delivering-quality-health-services-a-global-imperative-for-universal-health-coverage

[83] PEPFAR, 2021. https://www.state.gov/pepfar-fy-21-sims-guidance-materials/

[84] Hill, J.E., Stephani, AM., Sapple, P. *et al.* The effectiveness of continuous quality improvement for developing professional practice and improving health care outcomes: a systematic review. *Implementation Sci* **15,** 23 (2020). https://doi.org/10.1186/s13012-020-0975-2

Figure 3.1.1: Intersections between Quality Assurance and Quality Improvement as means to achieve and sustain quality services

As many countries have achieved or approach epidemic control, QA/QI investments should:

- Triangulate data streams to assess standards against target achievement and performance management. This includes use of SIMS, SID/MilSID, and MER as tools for evaluating MPRs, as well as identifying quality issues and solutions. See Section 2.5.
- Transition from PEPFAR QA/QI strategies used during scale up to reflect current epidemic control status and efficiencies needed as programming shifts to ensuring local capabilities and resilient systems.
- Ensure efficient use of existing data sources (PHIA, MER, SID, SIMS, QI projects and networks, lab accreditation, HIVRTCQI, supply chain, HRH, CLM) to attain epidemic control, prior to implementing additional QA/QI data collection exercises.
- Collaborate with Ministries of Health and development partners to catalyze and invigorate the large number of HIV professionals, across cadres, that have received QA/QI training and skills at sites and above sites as facilitated by agencies and PEPFAR-supported implementing partners over the past years. Focus on use of existing expertise and understanding within national and multi-lateral QA/QI forums to implement policies.
- Utilize PEPFAR's Sustainability Index and Dashboard (SID)/Military SID (MilSID) findings to advance political and partners' buy-in for on-going quality control and assurance systems, especially lab, commodities security, and efficient human resource investments. See Section 6.6.9 for details.

- Transfer PEPFAR QA/QI approaches and adaptable tools, such as SIMS and Data Quality Assessment (DQA), for use by development partners and Ministries of Health for sustained quality assurance systems and global metrics.[85]
- Apply learning from PEPFAR supported QI projects, lab, and commodity systems, such as HIVRTCQI, and specialized technical expertise into on-going national technical assistance and within development partner investments. This included the evidence-based examples using Extension for Community Health Outcomes (ECHO)[86] and use of Granular Site Management.

3.2 Attaining Quality Services

PEPFAR is continuously driving investments to deliver programs and services to achieve epidemic control for all, build resilient systems, and respond to people's HIV service needs. Core to attaining epidemic control within PEPFAR are meeting minimum program requirements at the site level using SIMS, alongside QI activities to respond to community-led monitoring results. Together these results provide a pathway for precise above-site, site, and population-specific investments for OUs near or working to achieve epidemic control.

To meet gaps identified through standardized assessments (MPRs, SIMS), it is recommended that sites optimize the use of existing evidence, available resources, and capacities that apply evidence-based quality improvement (QI) approaches. Evidence-based QI approaches most often use a plan, do, study, act (PDSA) methodology that analyzes the issue and identifies a plan, tests it by doing it, studies the results achieved over time, and then uses those results to determine actions for continuous improvement.[87]

[85] Data quality assessment of national and partner HIV treatment and patient monitoring data and systems implementation tool. Geneva: World Health Organization (2018). https://apps.who.int/iris/bitstream/handle/10665/274287/WHO-CDS-HIV-18.43-eng.pdf?sequence=5&isAllowed=y

[86] Aliyu, A., El-Kamary, S., Brown, J., Agins, B., Ndembi, N., Aliyu, G., Jumare, J., Adelekan, B., Dakum, P., Abimiku, A., & Charurat, M. (2019). Performance and trend for quality of service in a large HIV/AIDS treatment program in Nigeria. *AIDS research and therapy*, *16*(1), 29. https://doi.org/10.1186/s12981-019-0242-2

[87] Knudsen, S.V., Laursen, H.V.B., Johnsen, S.P. *et al.* Can quality improvement improve the quality of care? A systematic review of reported effects and methodological rigor in plan-do-study-act projects. *BMC Health Serv Res* 19, 683 (2019). https://doi.org/10.1186/s12913-019-4482-6

3.2.1 Minimum Site Standards

All PEPFAR programs–bilateral and regional–were expected to have the following minimum program requirements in place by the beginning of COP20 implementation (FY2021). Note that MPRs represent a continuum from National policy to site-level implementation. Some MPRs are most meaningfully addressed at the national or PEPFAR implementing agency level, and some MPRs have clear correlates in terms of site-level QA and CQI. In FY2022, PEPFAR recommends that OUs that have met MPRs confirm the quality of reported results at the site level, using two key data sources, both SIMS and MER. The combination of SIMS and MER at the site level will be referred to as minimum site standards (MSS). To ensure that OUs reporting successful implementation of MPRs have evidence that program requirements have reached PEPFAR supported sites, tracking both data sources verifies foundational elements are in place, and can sustain quality results into the future. It should be noted that MSS will not demonstrate achievement of MPRs, this is especially true in when MER indicators track events but do not have a denominator or given PEPFAR coverage variability.

Below is a chart that defines how SIMS and MER data combined will be used in combination and align to each MPR.

Figure 3.2.1.1

Minimum Program Requirement	**Minimum Site Standards**	
	Quality: Using SIMS 4.2 CEEs	**Results:** Using MER 2.6
Care & Treatment		
1. Adoption and implementation of Test and Start, with demonstrable access across all age, sex, and risk groups, and with direct and immediate (>95%) linkage of clients from testing to uninterrupted treatment across age, sex, and risk groups.	S_02_2, 3, 20 S_03_10	HTS_TST, HTS_TST_POS, TX_NEW, PMTCT-EID, PMTCT-HEI_POS, PMTCT_FO PMTCT_STAT, PMTCT_STAT_POS, PMTCT_ART

		OVC_HIVSTAT SC_CURR
2. Rapid optimization of ART by offering TLD to all PLHIV weighing >30 kg (including adolescents and women of childbearing potential), transition to other DTG-based regimens for children who are >4 weeks of age and weigh >3 kg, and removal of all NVP- and EFV-based ART regimens.	S_ 02_20	SC_ARVDISP SC_CURR
3. Adoption and implementation of differentiated service delivery models for all clients with HIV, including six-month multi-month dispensing (MMD), decentralized drug distribution (DDD), and services designed to improve identification and ART coverage and continuity for different demographic and risk groups.	S_02_6, 24 S_03_13 S_04_5 S_02_2, 19 S_03_9 S_04_2	MMD: TX_CURR SC_CURR
4. All eligible PLHIV, including children and adolescents, should complete TB preventive treatment (TPT), and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.	S_02_10, 11, 27, 28 S_3_17, 18 S_4_10, 11, 18	TB_PREV
5. Completion of Diagnostic Network Optimization activities for VL/EID, TB, and other coinfections, and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including 100% access to EID and annual viral load testing and results delivered to caregiver within 4 weeks.	S_02_4, 5, 12, 22, 23, 29 S_03, 11, 12, 19, S_04_3, 4, 12, 19	TX_PVLS TX_CURR PMTCT_EID PMTCT_HEI_POS PMTCT_FO TX_TB
Testing and Case Finding		

6. Scale-up of index testing and self-testing, ensuring consent procedures and confidentiality are protected and assessment of intimate partner violence (IPV) is established. All children under age 19 with an HIV positive biological parent should be offered testing for HIV.	S_02_8 S_03_15 S_04_08 S_ 07_8, 9, 10, 11	HTS_INDEX HTS_SELF
Prevention & OVC		
7. Direct and immediate assessment for and offer of prevention services, including pre-exposure prophylaxis (PrEP), to HIV-negative clients found through testing in populations at elevated risk of HIV acquisition (PBFW and AGYW in high HIV-burden areas, high-risk HIV-negative partners of index cases, key populations and adult men engaged in high-risk sex practices).	S_01_9 S_03_7 S_06_6 S_07_*new (new to address linkage to prevention services)*	PREP_NEW PREP_CT AGYW_PREV KP_PREV PP_PREV
8. Alignment of OVC packages of services and enrollment to provide comprehensive prevention and treatment services to OVC ages 0-17, with particular focus on 1) actively facilitating testing for all children at risk of HIV infection, 2) facilitating linkage to treatment and providing support and case management for vulnerable children and adolescents living with HIV, 3) reducing risk for adolescent girls in high HIV-burden areas and for 10-14 year-old girls and boys in regard to primary prevention of sexual violence and HIV.	S_06_ 4, 7, 8	OVC_SERV OVC_HIVSTAT AGYW_PREV HTS_TST HTS_TST_POS TX_NEW
Systems and Policy		
9. In support of the targets set forth in the Global AIDS strategy and the commitments expressed in the 2021 political declaration,	Most activity and monitoring at OU level (see	NA

OUs demonstrate evidence of progress toward advancement of equity, reduction of stigma and discrimination, and promotion of human rights to improve HIV prevention and treatment outcomes for key populations, adolescent girls and young women, and other vulnerable groups.	Section 2.2.2 for assessment options); S_01_03 applies at site level;	
10. Elimination of all formal and informal user fees in the public sector for access to all direct HIV services and medications, and related services, such as ANC, TB, cervical cancer, PrEP, and routine clinical services affecting access to HIV testing and treatment and prevention.	S_01_*new (to be created for all sites)*	NA
11. OUs assure program and site standards, including infection prevention & control interventions and site safety standards, are met by integrating effective Quality Assurance (QA) and Continuous Quality Improvement (CQI) practices into site and program management. QA/CQI is supported by IP work plans, Agency agreements, and national policy.	S_01_19, 20 S_01_ *new* *(4 new CEEs on IPC in set 1D)*	LAB_PTCQI
12. Evidence of treatment literacy and viral load literacy activities supported by Ministries of Health, National AIDS Councils and other partner country leadership offices with the general population and health care providers regarding U=U and other updated HIV messaging to reduce stigma and encourage HIV treatment and prevention.	S_01_3 S_01_*new (to be created around evidence of Tx and VL literacy)*	TX_PVLS

13. Clear evidence of agency progress toward local partner direct funding, including increased funding to key populations-led and women-led organizations in support of Global AIDS Strategy targets related to community-, KP- and women-led responses	Not applicable - monitored at OU level	NA
14. Evidence of partner government assuming greater responsibility of the HIV response including demonstrable evidence of year after year increased resources expended.	Not applicable - monitored at OU level	Partner country indicators
15. Monitoring and reporting of morbidity and mortality outcomes including infectious and non-infectious morbidity.	Not applicable - monitored at OU level	TX_ML
16. Scale-up of case surveillance and unique identifiers for patients across all sites	Not applicable - monitored at OU level	EMR_SITE HTS_RECENT

3.2.2 Quality Minimum Site Standards Using SIMS

The Site Improvement Through Monitoring System (SIMS) is a quality assurance method that defines PEPFAR standards at the site level. SIMS is grounded in standards against which performance can be assessed and area(s) for improvement identified. By design, SIMS supports OUs to achieve epidemic control by checking for foundational components of resilient services, such as implementation of national guidance, standard operating procedures, trained and accountable staff, and consistent client care as documented in facility registers and patient records.

SIMS standards cover all aspects of site service delivery, including prevention, HTS, treatment, viral load suppression, supply chain management, and policies that advance HIV programming. SIMS content, planning and implementation is streamlined, utilitarian and integrated into core PEPFAR processes.

As such, SIMS assessment results can be used to strengthen alignment with global and national standards and facilitate program improvement and performance as an integrated component of

overall quality management and/or improvement strategies. This is achieved through prioritizing site selection based on program needs, and program gaps as determined by the OU team; tailoring site assessments based on country and programmatic context; and following up on low quality services after remediation has occurred.

SIMS standards can also be used to assess whether elements of minimum program requirements have been implemented at the site level. In addition, OUs can elect to assess PEPFAR program standards for specific populations (children, adults, key populations, and PBFW), and for supportive program investments depending on the portfolio.

Each year **SIMS Prioritization Lists** are developed by OUs with interagency coordination prior to the start of the fiscal year and can be updated (if needed) on a quarterly basis. In FY2022, DATIM will also be used to track the aggregate number of planned SIMS assessments prospectively. This additional metric has been included to better understand the OU's intentions for oversight and quality assurance across the program, as compared to the realities over the year. This additional metric is not a target.

Given the flexibility in the use of SIMS and challenges through COVID-19, in FY2022 OUs were recommended to strategically plan SIMS assessments for new partners, new sites, new program areas in scale-up, alongside performance challenges. In the case where a USG staff cannot travel to the site during the assessment, on-going use of the tools and metrics can be applied by implementing partners and MoH staff. This 'self-assessment' is important for ensuring quality and that improvements are targeted to achieve PEPFAR minimum requirements. See SIMS 4.2 Guidance for more details.

Using SIMS Data for Action

PEPFAR encourages the systematic use of SIMS data at various levels, from the site to national QA/QI bodies, and across OUs at the agency and global level.

SIMS data collected according to PEPFAR policy is entered into DATIM is available for use internally and externally. Internal systems from the OU, agency, and global level continue to evolve to support standardized SIMS data use and interpretation. Within Panorama, two dossiers utilize SIMS data to correlate findings related to MER and describe the service package; these are the SIMS-MER dossier, and Patient Experience dossier. In addition, global and OU specific de-identified SIMS Structured Datasets, are publicly available in Spotlight.[88]

[88] Site Improvement through Monitoring System (SIMS): PEPFAR Panorama Spotlight

SIMS is a complex data set, that is not usually representative, but offers many insights for action. It is most useful when used collaboratively towards epidemic control and to enhance the service experience for people benefiting from PEPFAR programs. For example, when iSMEs had exhausted efforts to gain consensus to update an out-of-date policy for cervical cancer screening and treatment, the SIMS team stepped in to help. The interagency team presented SIMS scores for the relevant CEEs during a routine coordination meeting attended by PEPFAR, agencies, Ministry leadership, and partners. Seeing the consistent red scores in all sites assessed, prompted the discussion to acknowledge the clear gap at the national level and take action to update the policy.

PEPFAR also encourages the use of SIMS data to consider how to achieve minimum standards within and beyond the site. SIMS data trends should activate subject matter experts and TA providers where gaps emerge, support the transfer and documentation of solutions from one site to another where success has been achieved, or enlist the help of QI technical assistance where persistent complex challenges occur. Here are a few examples of when this has occurred:

- SIMS CEEs related to index case testing of children of people living with HIV are frequently red/yellow, so the PEPFAR interagency community responded by developing a comprehensive tool to provide complete coverage for children and OVC case identification regardless of testing positivity rate.[89]
- Coordinating QI technical assistance, especially in border settings with higher rates of interruption, and need novel approaches in multi-month dispensation of ARVs to meet client's needs around employment schedules and COVID-19 travel regulations

3.2.2.1 SIMS 4.2 Update

In FY2022, a new SIMS 4.2 Implementation Guide and Site Tool will be available for use. This update was preceded by a global SIMS data review, listening sessions with diverse stakeholders, and then a strengths, weaknesses, opportunities, and threats (SWOT) analysis with agency points of contacts. As result, the areas for change will enhance SIMS relevance and usefulness in FY2022. Included in the update are:

- Some CEEs will be allowed to be collected remotely and submitted while maintaining the safety and confidentiality of personal data

[89] PEPFAR Solutions Pediatric COOP Tools www.pepfarsolutions.org

- A new type of SIMS assessment, which is concentrated on particular CEEs, to meet the current program oversight needs and challenges that may be more specific
- Reduced reporting of SIMS Above Site assessments into DATIM at the global level
- An updated list of required CEEs that aligns to MPRs, and including new CEEs on IPC, site safety, treatment and viral load literacy, and user fees.

A key feature of the update includes review of the MPR and results of SIMS which track the quality and results at the site level. Details on the SIMS 4.2 Update will be announced in early 2022 with stakeholders informed and supported to begin implementation by FY2022.

3.2.3 Community-Led Monitoring

New in COP/ROP22:

- OU Community-led Monitoring activities must include an explicit focus on key populations or affected populations where relevant and where/if it does not already exist. Key populations are defined here and elsewhere in COP guidance as: men who have sex with men, transgender people, sex workers, people who inject drugs, and people in prisons and other enclosed settings.

Principles and best practices

PEPFAR recognizes the importance of engaging with communities in the development and implementation of HIV programming. PEPFAR teams must involve community advocates, groups, and civil society organizations in all aspects of COP development and presentation (see Section 2.5.3). Beginning in COP20 and continuing in future COPs, OUs are required to fund the development and implementation of community-led monitoring activities.

As PEPFAR continues to confront the challenges of assuring ART continuity in clients who may not view themselves as sick, collaboration with communities and clients is urgent and critical. This collaboration can help PEPFAR-supported programs and facilities ensure they are providing quality services that clients want to utilize. Collaboration with community advocates, community groups, civil society organizations, and clients can help PEPFAR-supported programs and health institutions diagnose and pinpoint persistent problems, challenges, and barriers with service uptake at the site and facility level to improve health outcomes. Most importantly this collaboration can identify workable solutions that overcome these barriers and ensure clients have access to these services.

For example, in Uganda, data resulting from CLM has been used to inform improvement of PEPFAR-supported programs. CLM conducted in FY21 revealed gaps in awareness of HIV services by clients at PEPFAR-supported facilities. For example, 57% of clients surveyed reported that they were not aware of the presence of a support club at the facility or within the community. Knowledge of where to obtain PrEP and information on how to use PrEP were also lacking among those surveyed. Only 33% of clients surveyed reported knowledge of where to obtain PrEP if needed and only 29% reported that they were provided with information on how to use PrEP. CLM illuminated these gaps in important components of HIV service delivery from the client perspective that may otherwise have gone undiscovered or unquantified. As a result, the PEPFAR Uganda team was able to take action aimed at closing these gaps. The "Bring Back to Care" campaign was launched in Q4 of FY21 to address these gaps in the clinical cascade, along with e-peer (online) support programming that ensures continuity of support, even if clients are unable or unwilling to attend in-person support club meetings. Additionally, PEPFAR partners, the Ministry of Health, and CSO's are working together to develop effective PrEP education, demand creation, and treatment literacy campaign materials. These efforts are valuable to improve prevention interventions and reduce interruption in treatment, especially as COVID-19 continues to impact care seeking and how HIV services are delivered.

Community-led monitoring (CLM) is a process initiated, led, and implemented by local community-based organizations and other civil society groups, networks of key populations, people living with HIV, and other affected groups or other community entities that gathers quantitative and qualitative data about HIV services and develops and advocates for solutions to the gaps identified during data collection. The focus is on getting input from recipients of HIV services, especially key populations and underserved groups, in a routine and systematic manner that will translate into action and change. CLM is central to PEPFAR's person-centered approach because it puts communities, their needs, and their voices at the center of the HIV response.[90]

Through the use of quantitative and qualitative indicators, CLM initiatives have monitored a wide range of issues that are associated with accessible, equitable, effective, and quality HIV service delivery. It is important that beneficiary populations are leading in the monitoring of services designed for them.

[90] See also https://www.state.gov/community-led-monitoring/

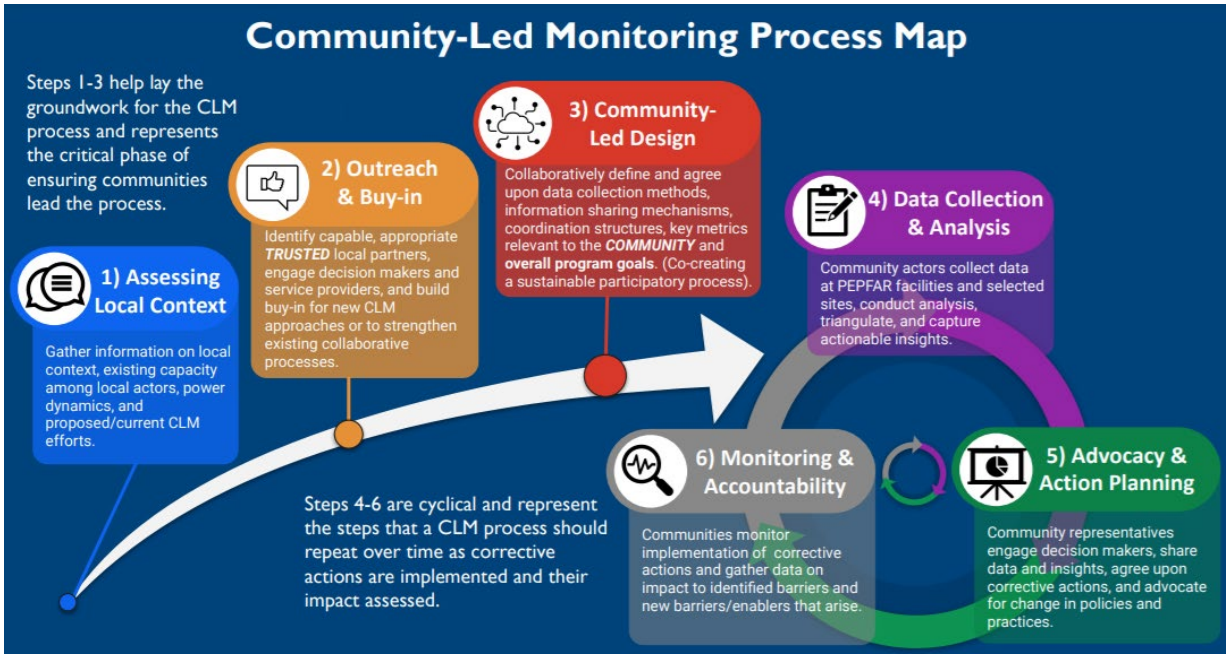
In COP22, all PEPFAR-supported programs are required to continue to fund and regularly report on community-led monitoring activities in close collaboration with independent civil society organizations and partner country governments. PEPFAR should encourage partnerships with regional and global networks to assist local beneficiaries in implementing systematic and robust monitoring activities with a focus on improvement of quality of care for everyone, particularly in countries where communities feel it is unsafe to conduct monitoring activities. Community-led monitoring is an evolving area for PEPFAR; best practices will continue to emerge as PEPFAR studies existing community monitoring frameworks and implements its own. PEPFAR will continue to engage local and global community groups in the planning, implementation, and refinement of these community monitoring platforms.

Community-led monitoring activities, though funded by PEPFAR, should be driven by independent and local community groups and civil society organizations. Civil society organizations participating in the COP strategic planning meetings will be asked to reflect on progress to date, including initial findings and recommendations of community-led monitoring efforts in their OU to inform future direction for COP22.

New in COP22, OUs are required to ensure their CLM activities include an explicit focus on key populations, where not already the case. This does not mean key populations are the only focus of CLM activities, but rather must be included. There can be multiple ways of meeting this requirement (e.g., ensuring KP-led organizations are among the funded monitoring organizations, ensuring KP-specific modules in monitoring tools, among others). At a minimum, there must be deliberate leadership of key population communities in the design of the approach. Importantly, inclusion of a focus on key populations in CLM should not be limited to KP- specific sites or programs (which CLM may wish to monitor as well). Rather key populations mostly access health services through general population clinics, and these are frequently sites where KP issues are least well understood and where KPs may experience the most discrimination and stigmatization when trying to access health care services. It’s important that the focus on key populations in CLM gathers data on KP service delivery in these sites as a priority.

The following is a process map (Figure 3.2.3.1) illustrating the six steps that a CLM process is advised to consider throughout the design and implementation phases. It is important to note that each step should be allocated the time and resources necessary for their completion or routinization.

Figure 3.2.3.1: Community-Led Monitoring Process Map



The list below describes what CLM is not, and distinguishes CLM from other methods of obtaining client feedback or input, and is partially inspired by the foundational work of the International Treatment Preparedness Coalition:[91]

Community-led Monitoring is NOT:

- simply adding some community-or client-focused indicators to already established government monitoring systems. This approach does not permit community leadership in design and implementation.
- the same as patient satisfaction surveys. Patient satisfaction surveys may be very useful to improve the quality of services and the client's experience of care, and there may be some overlap with CLM, but they are distinct from CLM. Patient satisfaction surveys are usually driven by healthcare providers, tend to focus on the effectiveness of services, and may not focus on the elements prioritized by communities.
- a survey or study conducted to understand what communities experience. This type of assessment may be useful, but it is not community-led, nor is it routinized to drive change and ensure accountability.

Core principles of PEPFAR CLM include:

[91] https://itpcglobal.org/wp-content/uploads/2020/02/Community-Led-Monitoring-Brief_full.pdf

- The collective objective of CLM is to develop a shared understanding of the enablers and barriers to quality HIV services in a manner that is community-driven and collaborative, productive, respectful, and solutions-oriented.
- CLM should be utilized to advance equity and to support improvement in programs, especially for populations who have not yet fully experienced the benefits of HIV epidemic control.
- CLM must be conducted by independent and local civil society organizations. CLM should be led by community organizations; it should not be led by government institutions or multilateral bodies. PEPFAR IPs (including those that may be civil society organizations themselves) currently working on service delivery at the site level generally do not meet this requirement for CLM; this includes implementing partners who sub-contract/sub-grant to local civil society organizations. This is to help ensure the objectivity and independence of CLM is maintained. In developing or refining CLM activities, OUs should consider the level of trust CSOs have among key communities and stakeholders. However, in specific circumstances a PEPFAR IP or subgrantee who does site level service delivery may be included as a CLM partner if that organization meets the other requirements of a strong CLM partner, such as being community or KP-led and is not conducting monitoring of their own sites.
- OUs should also consider and, where possible, support the capacity building needs of implementing CSOs in health service monitoring, data collection and analysis, and evidence-based advocacy. This should include leveraging support from other multilateral organizations or others that are also supporting CLM efforts in-country.
- Whenever possible, CLM projects should be implemented by a central coordinated structure. PEPFAR Ambassador Grants should be used as an option in all OUs where these mechanisms are already available. Where this mechanism is unavailable or not practical, OUs may consider other partners that meet the requirement and principles of objectivity, independence, and maximizing direct funding to community organizations OUs may propose funding for additional staff support to oversee this CLM portfolio if they did not do so in prior COPs.
- PEPFAR teams must ensure a process that allows for community leadership of the specific metrics, measures, or tools to be used for CLM, with consultation and input from partner country governments and PEPFAR teams. Metrics or measures should be tailored to a given context and address the needs and concerns of community members.

- The scope and scale of community-led monitoring should be determined by community members in each OU (in consultation with PEPFAR in-country staff) but should be based on need. For example, focusing on a geographic area or limited number of sites, focusing on access to treatment services among men within a specific community, etc. CLM has emerged as a solution to challenges with ART continuity and preventing interruptions in treatment; at a minimum, PEPFAR CLM should focus on these aspects of HIV service delivery. However, communities may also prioritize other components of HIV services, in addition to addressing ART continuity challenges.
- Monitoring data should be additive and not duplicate collection of routine data already available to PEPFAR through MER. Additional monitoring data includes: information from beneficiaries about their experience with the health facility, information about barriers and enablers to access and sustained engagement in services, information related to quality of services, information related to the quality of interactions between clients and health workers (including ensuring stigma free and confidential service delivery) verification of the implementation of national level policies (e.g., elimination of user fees) at the facility level etc.
- CLM activities can utilize SIMS tools as desired or deemed useful, though there is no expectation to use them and there is no expectation that data from community-led monitoring activities will be reported to S/GAC through current PEPFAR reporting mechanisms (such as SIMS, MER, or ER). SIMS tools may be utilized for specific and select SIMS CEEs (or Standards) that assess patient-provider experience. SIMS tools are publicly available.
- CLM mechanisms must be action oriented. That is, it is not enough to simply collect patient reports or descriptions of experiences, (i.e., client satisfaction surveys) but there must be an associated follow-up process with the health facility, that is community-led (where safe) and that includes the involvement of USG staff, commitment to corrective public health action, and community advocacy to improve service outcomes.
- CLM is a routine, cyclical process. One-off assessments are not sufficient and must be routinized to ensure follow up and continuous improvement.
- CLM should be developed and implemented in collaborative spirit with appropriate service sites and should not be organized as a supervisory and/or punitive mechanism.
- A key part of CLM is advocating for improvements in service delivery. Results from CLM must be presented safely by community members to in-country PEPFAR teams on a

quarterly basis (through a presentation or a report followed by a constructive discussion) in an environment that will foster honest and genuine discussion of results, including of negative outcomes. At a minimum, PEPFAR USG staff should share these findings with IPs on a quarterly basis. Community members should not be tasked with sharing findings with service delivery partners or partner governments, though they may do so where it is safe. PEPFAR teams must be directly involved in necessary follow up actions and oversight of IPs to strengthen the quality of service provision.

- PEPFAR teams must ensure they are triangulating CLM findings with other PEPFAR data sources, including MER results and SIMS scores, and using these data to both foster site level improvements and as part of their partner management approach (Section 4).
- Implementers of CLM are encouraged to coordinate and triangulate their activities with other multilateral organizations engaged in CLM (e.g., The Global Fund) to facilitate information sharing and ensure efficient use of resources
- The routinized process for collecting, analyzing, and sharing of CLM data should be clearly established and articulated at the country level among all stakeholders. As part of a commitment to transparency and accountability, community-led monitoring findings should be made as accessible as possible for use by all stakeholders while ensuring safety and confidentiality. Where possible and relevant, transparency may include sharing data, best-practices, and monitoring tools with other country teams. PEPFAR's data governance guidance on public release of site level MER data is meant to prevent deductive disclosure of client identity. Although CLM is a distinct data stream from MER, the PEPFAR data governance guidance may serve as a useful framework for CLM as it establishes general policy for data management, including access, roles and responsibilities, data security, and other considerations such as deductive disclosure risk mitigation. PEPFAR teams should ensure with community CLM implementers there are clear processes that govern public release of CLM findings.
- CLM in COP22 should ultimately build upon CLM activities carried out in COP21; and the same should be ensured for subsequent COPs. The intention should be to build a CLM program that is sustainable and contributes continually and tangibly to program improvement.

3.3 Sustaining Quality at Epidemic Control

After demonstrating that quality services can be attained, PEPFAR will strategically transition investments to sustain quality at the national level. Recommended activities described in this section encourage continued engagement of the QI community trained through PEPFAR investments, sustained quality in lab systems, and the use of QA tools to beyond PEPFAR policy, including the adoption of some SIMS core essential elements (CEEs) into national systems.

Central to the ability to transition to epidemic control investments is preparing stakeholders for changing priorities, with more efficient and precise quality contributions for equity across sub-populations and broadening the base of support for quality assurance at this stage of the epidemic. Diplomatic efforts will be needed to supplement existing political good will and advance shared interests of development partners and multi-lateral mechanisms. PEPFAR and multilateral partners (Global Fund, WHO, and the private sector) have shared interests in on-going quality assurance measures, especially those around commodity and lab systems, adverse event monitoring, and ensuring data quality and accessibility.[92] Throughout the transition, it will be critical to drive collective support for locally driven community engagement that can sustain successes for the long term. For instance, PEPFAR supported laboratories have attained 4-star quality improvement ratings and achieved ISO 15189 accreditation. As programs attain epidemic control, there is need for systems in place to sustain and maintain these gains.

3.3.1 A CQI Culture

A Continuous Quality Improvement (CQI) culture reflects a mindset that all HIV services should improve over time for all clients. This culture thrives with dialogue, openness, and accountability. To attain epidemic control, multiple quality improvement investments were made across PEPFAR programming, these resulted in improved services delivered by thousands of qualified resource people in facilities, at CSOs, and across agencies. Transitioning the skills and knowledge rooted in meeting standards and delivering people-centered results should continue to sustain epidemic control. During this time, the focus will shift to use CQI for evolving care models that meet clients with what they need, when they need it. This requires local ownership of CQI at all levels, in line with national policy and frameworks, that integrates the CQI approach into service delivery and routine measurement.

[92] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/

For example, when reviewing CLM data in an OU where most clients are refilling ARVs on time per their appointments, the findings showed that clients had many complaints about the quality of the service, including long wait times. This is a case, the team should apply a CQI mindset to use skills in root cause analysis, to brainstorm and select change ideas, and track performance to meet the goal of an acceptable wait time.

3.3.2 Transitioning QA for Sustainability

PEPFAR has been discussing and preparing key leadership to transition HIV quality assurance from an internal mechanism to broader support, in relation to the epidemic and its impact of the nation. OUs should review Sustainability Index Dashboard (SID)/Military SID (MilSID) information collected in 2019 and 2021 to identify critical QA investments and progress. These investments may be defined by those that continue to need PEPFAR support, to activities that can be supported with calculated collaboration using a Memorandum of Understanding (MOU), and remaining QA investments that need political endorsement and advocacy across development partners to supplement for success. Populations needing additional review for equitable quality assurance investments include key and priority populations, children and adolescents living with HIV, including OVC, and adolescent girls and young women at higher risk for HIV acquisition.

This section outlines ways to extend the use of existing PEPFAR QA tools and insights towards sustainable and relevant systems. For example, in 2021 SIMS tools were reviewed to assess their applicability in Universal Health Coverage (UHC) space, the findings identified that 40% of SIMS 4.1 Site and Above-Site CEEs scored non-HIV standards, and indeed had utility in addition to HIV. Non-HIV specific services included in SIMS are health systems, commodities and data quality, integrated services, comorbidities, and combined prevention packages.

3.3.2.1 Supporting OUs to Transfer QA into National Systems

To achieve the MPR number 10, OUs assure program and site standards are met by integrating effective Quality Assurance (QA) and Continuous Quality Improvement (CQI) practices, including into national policy. These national policies are a road map for coordination and collaboration at epidemic control that should be reflected into partner and PEPFAR supported sites.

As OUs transition to sustain epidemic control, OUs will need to include QA/QI as part of their technical assistance support in more efficient ways for the current context. It should be noted that programming is no longer scaling up complex new interventions but sustaining efficient differentiated service delivery that meets client’s needs. Efforts that were previously intensive in

person training on well understood concepts, may be realigned for more a virtual and on-going orientation to keep CQI activities relevant for the sustained workforce.

Another critical area for sustaining QA/QI, is by identifying opportunities to embed necessary QA/QI metrics and capabilities into existing national systems. This is a precise way of integration that can produce long term data and results.

4.0 PARTNER PERFORMANCE AND MANAGEMENT

4.1 Principles and Expectations

Pursuant to the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Leadership Act), ‘‘the Global AIDS Coordinator shall have primary responsibility for the oversight and coordination of all resources and international activities of the United States Government to combat the HIV/AIDS pandemic, including all programs, projects, and activities of the United States Government relating to the HIV/AIDS pandemic under the United States Leadership Against HIV/AIDS…Act”. It is critical to ensure programmatic performance of all U.S. taxpayer dollars as PEPFAR continues implementation consistent with the Leadership Act. PEPFAR is building upon previous efforts and the PEPFAR Strategy for Accelerating Epidemic Control (2017-2020) with broad stakeholder input and experience implementing during the global COVID-19 pandemic to inform the new PEPFAR Strategy: Vision 2025 (2021-2025) under development.

- Global policies align with WHO guidelines and policies for optimal programming and communicated through State Department transmitted cables and COP guidance annually.
- New policies are immediately communicated and part of that year’s COP guidance. If policies have fiscal implications, additional funding is linked to that policy adoption.
- Administration policies are communicated in the same processes through cables and annual COP guidance.
- At the request of U.S. Ambassadors in country, PEPFAR limits policy requirements to the annual COP processes to streamline adoption and implementation in country as part of our COP streamlining process.
- Since March 2020, supplementary PEPFAR Technical Guidance in the Context of the COVID-19 Pandemic has been updated and disseminated routinely with responses to questions from OUs about using PEPFAR resources and adapting programs to implement safely and mitigate negative impacts as the COVID-19 situation in countries continues to evolve over time.

PEPFAR is committed to seeking to protect participants from all forms of abuse, unethical behavior, and misconduct (i.e., sexual, physical, emotional, and financial abuse, discrimination, coercion, exploitation, and neglect) in PEPFAR-supported programming and has zero tolerance for such actions or failures to address these actions proactively, safely and in a manner respectful to the rights and needs of program participants. For details on prevention and response to gender-based violence and violence against children see Section 6.6.2.1. For prevention and response to unethical behavior, misconduct and coercion in Index Testing see Section 6.3.1.5. For specific approaches to ensure key populations programs are voluntary, confidential, non-judgmental, non-coercive, and non-discriminatory see Section 6.5. Accountability must be enforced at the individual and institutional levels, and agencies must ensure that safeguarding policies, procedures, codes of conduct, and monitoring tools are actively used by agency personnel and IPs to protect all participants and respond appropriately when incidents occur.

The PEPFAR team in country is responsible for seeking to ensure partners implement the COP as planned and provide solutions to concerns raised during the COP planning process, as appropriate. The USG implementing agencies are fully responsible for the implementation of the PEPFAR funds allocated or transferred to them by S/GAC.

In order to effectively manage IP performance, all agencies implementing PEPFAR programming should plan and propose budgets for achievable SNU targets and PEPFAR teams should communicate that these targets are their expected achievements. Teams should submit targets that are achievable and verifiable, and budgets will be adjusted by S/GAC to match targets. Agencies are expected to monitor the program achievements, including both target achievement and trends in performance, in relation to financial data (including outlays and partner level expenditures as available) to determine the significant areas of underperformance as described below. A mechanism will be determined to be underperforming through a comprehensive review of performance across all indicators and metrics assigned to the mechanism. What rises to the level of underperformance for one mechanism may not for another. Underperformance may be related to one single indicator, if the indicator is of critical strategic performance for the mechanism, such as TX_NET NEW or TX_CURR for a partner implementing HIV treatment, or a mechanism may only be determined to be underperforming if the mechanism has widespread underachievement across many indicators or metrics. Identification of underperformance may be made by the Chair and PPM with inputs from field and headquarters teams, as part of S/GAC's oversight role. Preferably, agencies should also proactively identify any of their own mechanisms

that they believe to be underperforming. Once underperformance has been determined, rapid action on behalf of the agency is required in order to remediate the problem. As a consequence of underperformance, agencies are expected to identify the barriers-internal and external- to achievement that drove the underperformance, and to put in place specific management interventions based on timing and level of underperformance. Any partner with EITHER (1) <15% of target achievement at 3 months; or (2) less than 40% of target achievement at 6 months, must have a complete review of performance data (including trends in performance) and expenditures to date by program area, implement remediation, and conduct intensive follow-up. These elements (i.e., review, remediation, and follow-up) should be incorporated into the existing IP work plans. An additional quarter of consistently poor performance by the IP should also result in implementation of a documented Performance Improvement Plan (PIP) or Corrective Action Plan (CAP), in accordance with implementing agency policy. PIP indicators should reflect the core issue. If the issue is linkage of people who test positive to treatment, the indicator measured should be linkage (individuals in TX_NEW greater than 95% of HTS_TST_POS). If the issue is continuity of treatment, it should be TX_NET_NEW over the quarter equal to 95% of TX_NEW. With a third quarter of consistently poor performance by the IP, implementing agencies should notify S/GAC of the actions the agency is implementing to address partner non-performance, including options for a shift to new partners. There may be exceptions during extraordinary pandemic or disaster responses. When considering performance in the context of emergency-related implementation pauses, agencies should continue to document how partners have adapted programs and ensure they have managed budget pipelines within the parameters of PEPFAR guidance to recover progress as swiftly as possible when safe to do so.

Table 4.1.1 Agency management of underperforming IPs

	Performance threshold [A]	Program	Budget
Quarter 1	<15% target reached	Review and intensive follow up	Establish plan for spending
Quarter 2	<40% target reached	Review and PIP/CAP	Establish plan for spending
Quarter 3	<70% target reached	Consider options, including option to remove IP or replace with a new IP	Consider options, including options of reallocating funding to new IP

The performance thresholds apply to all indicators except treatment current and OVC_SERV. In the HIV treatment program, most clients are continuing on treatment year after year and current on treatment (TX_CURR) performance should be between 98% and 100% of the target. This can be adjusted in country context where HIV treatment services are still scaling up and the treatment new target is greater than 10% of treatment current. OVC programs are also similar in that there are clients continuing services from the previous year; if the IP is less than 80% of their target at Q2 performance review should be triggered. Similarly, DREAMS programs may carry over some AGYW across fiscal years who are completing the DREAMS program.

Implementing Partners need to prepare actionable work plans that align with strategic direction, budgets, interventions, above-site activities, and targets from COP22. CQI methodology should be integrated into the work plans. The work plan budgets should be arrayed according to the PEPFAR financial classification of interventions and cost categories. Moving beyond *monitoring* to *management for change* requires an understanding of **what** is being implemented, **how** it is being implemented, the **scale** of implementation, the **quality** of implementation, and the **cost** of that implementation. It is incumbent upon PEPFAR headquarters and in-country agency leadership and staff to ensure that financial indicators (as per annual ER and semi-annual outlays reporting), quarterly results (MER and SIMS) and other relevant data, such as trends from community-led monitoring, are provided to S/GAC and to the full interagency team with integrity and in a timely and transparent manner in order to ensure robust analysis by all parties. This is to ensure a shared understanding of partner performance across the PEPFAR program.

Core elements of effective partner management include:

- A structured framework for implementing partner management should be established for each mechanism at the time of award and revisited annually at the time of work plan approval and must be in line with the COP. USG Agency AOR/COR and activity managers are responsible for designing and carrying out partner management plans to ensure accountability for PEPFAR funds.
- Routine performance monitoring through USG/implementing partner review of OU-, SNU-, and site-level program results (including data completeness and quality), with frequency (weekly, monthly, or quarterly) determined by partner performance. This must include PEPFAR's main quarterly and annual data streams: MER, SIMS, and ER, triangulated periodically with client and/or community feedback via CLM or other processes.

- Effective financial monitoring to ensure 1) planned resources and spending is aligned with technical priorities as defined in the implementing partner work plan, as well as the PEPFAR Budget & Projected Expenditure Template (which should align) at the site level prior to signing approval vouchers and 2) current spending or projected spending does not or will not exceed approved operational plan budget.
- Establishing a clear link between the COP22 budget, the COP21 budget and associated work plans and the COP20/FY2021 expenditure reporting.
- Ensuring all funding projected to be outlaid during the 12 months of FY2023 must be represented in the approved COP22 budget. This is unchanged from previous guidance, please see Section 4.2 for more details.

Work plans must include:

- MER indicators to assess performance and demonstrate impact. For instance, for treatment, this includes critical indicators across the clinical cascade (i.e., HTS_POS, TX_NEW, TX_NET_NEW, TX_CURR—not just TX_NEW). Relationships between the indicators must be clearly established in the work plans. In other words, new on treatment should be 95% of those who test positive, as testing will have been focused to find new clients, net new on treatment must be 95% of new clients to demonstrate retention of clients on treatment. Interventions should be implemented to scale and with fidelity to programmatically contribute to quarter over quarter net increases in the treatment population (as measured through TX_CURR). Other MER indicators to understand any program losses and measure the number of people returning to treatment must be used (this includes TX_ML and TX_RTT). Ultimately, this means ensuring at least 95% VLS at the site and SNU level.
- Measures to track expenditures in alignment with PEPFAR Financial Classifications Reference Guide. This reporting should reflect actual expenditures based on partner implementation and will be interpreted within the context of what partners were approved to implement.
- Measures to ensure the quality of interventions (using SIMS at a minimum), especially the delivery of patient-centered services.

Successful implementing partner management leads to the translation of findings into action by:

- Improving the quality and delivery of services to ensure all beneficiaries/clients receive client-centered services that promote continuous ART, engagement in lifelong treatment and viral load suppression.
- Using findings to course correct implementation and mitigate challenges at the partner and site level, including the impact of COVID-19.
- Monitoring performance against indicator targets and financial reporting against budget for effective impact monitoring.
- Offering partners technical assistance in shifting resource allocations when needed.
- Making use of headquarters and other resources to share information, expertise, sample SOPs and/or other tools that improve processes and enhance accountability.

4.1.1 Performance Monitoring

Quarterly results reviews, coinciding with results reporting in DATIM and the interagency POART process, are required to allow for in-depth integrated analysis of partner performance and pre-POART call engagement with implementing partners. Between quarterly reviews, program performance results for priority technical areas should be reviewed regularly via reporting from the implementing partner to the USG management team, including any analyses of barriers and facilitators or root cause analysis to providing client-centered services—taking into account the impact of COVID-19 surges during specific time periods. At a minimum, results reviews should take place monthly. When partner performance is of concern, USG management teams should increase frequency up to weekly results reviews and remediation actions, utilizing frequent benchmarks to monitor progress (as per guidance above in Section 4.1). Implementing partners should be encouraged to review program data weekly where appropriate to provide an early warning system for performance trends.

More specifically, to monitor performance, financials, and remediation effectively and routinely, the following programmatic and operational components should be included (in addition to the principles described above in Section 4.1):

- Routine data completeness and quality review (including all PEPFAR data streams – MER, SIMS, ER, Outlays and Obligations etc.).
- Performance review down to the site level by partner and sub-national unit (SNU)-type with age/sex/priority population disaggregates.

- Use and integration of a CQI and QA methodology at the site level to address barriers, identify and remediate bottlenecks and improve quality of services and the client experience.
- Inclusion of findings from community-led monitoring of patient experience to understand the enablers and barriers to continuity in treatment services at the site level (see Section 3.2.3).
- Strategic review of progress through the cascade and linkages from a patient point of view including in depth review of unmet need and coverage across cascade.
- Complete and updated site organization charts, including HRH investments (PEPFAR-supported and otherwise).
- Site ranking by yield by volume, linkage, and treatment continuity; identification of positive and negative deviants for further investigation/analysis and transfer of lessons learned, where appropriate.
- Routine patient/client satisfaction data that is being used to improve service delivery and patient experience.
- Semi-annual reporting of Agency outlays by implementing mechanism via FACTS Info, in formats similar to the fiscal years 2017-2021 reporting.
- Reporting of PEPFAR program expenditures.
- Tracking of commodity procurement and distribution to both ensure sufficient quantities of required commodities have been procured in a timely fashion, and that shipment arrive on time, and are quickly delivered to sites.
- Detailed, actionable work plans, including implementing mechanism budgets by financial classification intervention and by cost category, planned interventions, expected targets and/or benchmarks, and integration and use of CQI methodology. COP22 work plans will be submitted to S/GAC after COP approval starting in June.
    - Within work plans, if performance-based financing, structural or individual incentives for results and other innovative financing models are used, they should be discussed between the partner and funding agency, and a risk management strategy with documented internal controls should be aligned with the PEPFAR country strategy before implementation.
- Evidence of linkages between facilities and community-based implementing partners to improve collaboration, delivery of services, reporting of data, and understanding of barriers and facilitators of providing client-centered services. MOUs and/or physical co-

location of staff should be implemented to promote seamless and successful hand-offs and mitigate competition for targets.

- Review of partner-level HRH data as collected in the HRH inventory to ensure appropriate staffing levels and types at all sites and geographies and to ensure alignment of HRH footprint to mechanism's programmatic activities, including alignment to MER indicators.
- Adhere to all principles of Budget Execution in Section 5.9.4.

4.1.2 Financial Monitoring

Strengthening the transparency and reporting of financial indicators to ensure that financial monitoring—analysis of how a *planned* budget is being or has been *executed*—is a key COP22 priority. USG management teams are required to use this financial data to inform programmatic decision-making and implementing partner management to ensure spending is commensurate with results. Spending (both USG outlays and partner expenditures) must align with the approved PEPFAR operational plan and implementing partner budget as outlined in the COP budget and the annual mechanism work plan as provided in the PEPFAR Budget and Projected Expenditure Template. Over-outlaying is neither approved nor acceptable. If spending is outpacing target achievement or monthly burn rate toward the approved annual budget, teams should be prepared to discuss why and develop a remediation plan where necessary.

4.1.3 Remediation Planning

As described in the sub-sections above, regular monitoring allows for immediate course correction for poor program or financial performance. However, when an issue is identified, the USG management team should determine an appropriate remediation strategy, track the date of implementation, and be prepared to shift the allocation of targets and resources among partners if performance does not improve quarter over quarter. As a part of this planning, lessons learned from other successful partners as well technical shifts (global or PEPFAR guidance, policy shifts in country, etc.) should be embedded in any remediation strategy. Formal Partner Improvement Plans (PIPs) should be implemented in cases of underperformance, as per parameters described throughout this section. See also Section 4.2 on Oversight and Accountability.

4.2 Oversight and Accountability

Clear target setting with appropriate level of budget as well as continuous partner management and partner improvement is critical. The U.S. implementing agencies and the in-country team must hold partners accountable for the outcomes and impact of PEPFAR funds and work to ensure there is no fraud, waste, and abuse of these funds. Consistent with the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, the Offices of Inspectors General (OIG) of several PEPFAR-funded implementing agencies jointly develop coordinated annual plans for oversight activity in each fiscal year (see Fiscal Year 2020 Inspectors General Coordinated Oversight Plan[93] which includes focus areas for action each year.

PEPFAR Implementing Agencies also should ensure funding mechanisms (contracts, cooperative agreements, and grants) and partner management plans include appropriate actions to prevent, identify, report, and respond to programmatic and financial fraud, waste, or mismanagement. Whether funding large international organizations, government institutions, or small local partners, PEPFAR programs often operate in a larger environment of fraud risk, and agencies may use a variety of tools and approaches to ensure accountability for PEPFAR funds and accuracy of reported accomplishments. Along with performance management, strategies may include engaging relevant agency staff and OIGs to facilitate trainings for in-country staff and partners, implementing organizational risk assessments that identify opportunities to improve internal controls and key management practices of funded partners, conducting proactive and responsive data quality assessments at multiple levels, and following guidance from respective OIGs as needed to document and/or facilitate a response to fraud warning signs, allegations, or findings, among other actions.

Scenarios such as these below should result in greater investigation, increased oversight, and implementation of corrective action and mitigation strategies: (1) lack of concurrence between numbers of persons identified as HIV positive and number of persons initiated on treatment; (2) lack of alignment between program results (such as number of persons on treatment) and results from large population-based surveys of HIV, like the PHIAs; (3) lack of alignment between data showing complete utilization of commodities budgets without achievement of related treatment and viral load coverage targets; (4) lack of concurrence between program performance data and

[93] Foreign Assistance To Combat HIV/AIDS, Tuberculosis, and Malaria Fiscal Year 2021 Inspectors General Coordinated Oversight Plan, August 2020, https://oig.usaid.gov/sites/default/files/2020-08/Fiscal%20Year%202021%20Inspectors%20General%20Coordinated%20Oversight%20Plan%20for%20Foreign%20Assistance%20to%20Combat%20HIVAIDS%2C%20Tuberculosis%2C%20and%20Malaria.pdf

data on stockouts of commodities. All valid, reliable, and available data sources should be used to reconcile results and ensure any claims or statements of achievement are being met. Data sources may include relevant data about patient experiences collected through CLM efforts, along with standard PEPFAR data streams such as MER, SIMS, ER, etc.

In addition to ensuring PEPFAR-supported funding mechanisms (contracts, cooperative agreements, and grants) and partner management plans include appropriate actions to prevent, identify, report, and respond to programmatic and financial fraud, waste, or mismanagement, PEPFAR implementing agencies must ensure non-discrimination policies or statements are in place in funding mechanisms that support PEPFAR's priority of non-discriminatory services. PEPFAR teams and agencies should also respond to and investigate immediately allegations of discriminatory behavior on the part of implementing partners.

5.0 COP BASICS

5.1 What is a COP/ROP?

The COP/ROP[94] documents U.S. government-planned annual investments linked to specific results in the global fight against HIV/AIDS to ensure every U.S. dollar is maximally focused and traceable for impact. It is the basis for approval of annual U.S. government bilateral HIV/AIDS funding in most partner countries. The COP also serves as a tool for allocation and tracking of budget and targets, an annual strategic plan for U.S. government-funded global HIV/AIDS activities, and the coordination platform with the Global Fund to ensure elimination of duplication. Data from the COP are essential to complying with PEPFAR's commitment to transparency and accountability to all stakeholders.

5.2 Which Programs Prepare a COP?

PEPFAR utilizes two organizational structures related to specific planning processes:

1. Bilateral programs/operating units
2. Regional platforms

For COP22, all PEPFAR programs in the two organization structures will follow the planning and submission process, including timelines, described in this document.

Bilateral Programs (single OUs) required to complete COP22 using the planning and submission process described in this guidance document include:

> Angola, Botswana, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Dominican Republic, Eswatini, Ethiopia, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, South Sudan, Tanzania, Uganda, Ukraine, Vietnam, Zambia, and Zimbabwe

Regional Platforms are an organizational structure in PEPFAR using a hub-and-spoke or distributed assets model to plan PEPFAR financial and technical resources that are currently

[94] Throughout this document, the term 'COP(s)' includes Regional Operating Plans (ROPs) except as specified, and the term 'country teams' includes regional teams for programs completing a ROP.

being implemented in the region into one Regional Operational Plan (ROP). Regional Platforms required to complete ROP22 using the planning and submission process described in this guidance document include:

- Asia: Burma, Cambodia, India, Indonesia, Kazakhstan, Kyrgyz Republic, Laos, Nepal, Papua New Guinea, Philippines, Republic of Tajikistan, Thailand
- Western Hemisphere: Brazil, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, Trinidad & Tobago
- West Africa: Benin, Burkina Faso, Ghana, Liberia, Mali, Senegal, Sierra Leone, and Togo

5.3 COP/ROP Timeline

The complete COP/ROP22 process will occur over approximately four months starting with the release of COP/ROP22 related tools on January 7, and COP/ROP22 guidance and the OU specific Planning Level Letters (PLL) on January 19, 2022. In order to ensure the fullest engagement possible with the community and stakeholders, PEPFAR OU teams/regions are required to conduct a strategic planning retreat, either in-person or virtual, with local stakeholders and implementing partners. This retreat should take place on either the week of January 31, 2022, or the week of February 7, 2022, and be used to introduce and discuss all COP22 tools, guidance, results, targets, and discuss the trajectory and strategy for COP/ROP22 development.

COP22 Guidance Release Date: January 19, 2022, on both PEPFAR SharePoint and https://www.state.gov/pepfar/

COP22 Strategic Direction Summary (SDS) Template will be on the COP/ROP Resources SharePoint landing page January 19, 2022. The DataPack, FAST, Table 6/SRE, and Commodities Supply Planning Tool will be released to OU teams January 7, 2022.

COP22 Strategic Planning Meetings: Week of February 7, 2022, at the latest.

No later than the week of February 7, 2022, all PEPFAR programs are expected to host a strategic planning retreat, either in-person or virtual, with their local stakeholders to analyze new data, discuss performance throughout FY21, modifications that are occurring right now to improve performance, and reach consensus on the proposed COP22 direction. **Programs should plan for either in-person or virtual engagement as needed based on local context**

of COVID-19 and restrictions on in-person gatherings and travel. Key elements of this retreat include:

1) Building on the review of FY21 Quarter 4 (Q4) and Annual Program Review (APR21) program results and key analyses to highlight programmatic successes, needs and gaps. This review is to ensure all participants share an understanding of epidemiologic data, key programmatic data, achievements and gaps, funding landscape and must include the presentation of:
    a. A summary of the areas highlighted in the PEPFAR FY21 Q4 Corrective Action Summary (CAS), including annual data from the Site Improvement Monitoring System (SIMS), and the Sustainability Index Dashboard (SID) 2021, and funding landscape using the Resource Alignment data
    b. Analyses of programmatic achievement and the impact of COVID-19 in key areas, including viral load suppression, conducted on the current geographic and population priorities to determine whether these should be reviewed and revised to include new areas/populations for saturation.
    c. Sex and age-band analyses to highlight gaps in services between males and females and adults and children.
    d. Analyses of current performance and financial data, including outlay data, and expenditure results at all relevant levels, including partner, that can inform proposed COP22 national, district, and partner level targets and budgets.
    e. Analyses of Human Resources for Health Inventory data also should be reviewed with performance results and progress in other above site and non-service delivery objectives at all levels of investment.
2) In-depth dialogue about technical approaches, specific interventions and other solutions needed to accelerate epidemic control and reinforce local capacity. Discussions must:
    a. Include the identification of specific activities and solutions that address gaps in effective implementation and populations reached, particularly in retaining young adults and men in life-long ART, which will be implemented immediately.
    b. Utilize information from COP21 partner work plans and strategic objectives to review partner performance, discuss successes and challenges, and determine areas for continued investment, areas requiring immediate revision, updates and areas needing new strategies and solutions or realignment of partners, and timeline to implementation.

3) Discussions focused on monitoring and management to ensure programs are implemented effectively and with fidelity, specifically highlighting strategies for partner and quality management. These discussions must prioritize and emphasize:
    a. The use of data inputs from the MER, SIMS, SID, semi-annual outlays, expenditure, and other sources to monitor progress.
    b. The identification and development of comprehensive data inputs to monitor and manage partner performance in an open and transparent manner, and specific timelines for improvement.
    c. Development of quality management programs located at service delivery points to improve health outcomes and partner performance (see Sections 2 and 3).
4) A consensus on the proposed strategy for COP22, including national, district, and partner level targets and budgets.

During this period, PEPFAR teams should also consider building on regular and meaningful dialogue with implementing partners by hosting an implementing partner meeting to review data and discuss the proposed COP22 direction.

Sustaining HIV Impact Countries: Based on current program data and UNAIDS projections, select countries that are currently at epidemic control will have focused discussions around program design, transforming from surge activities for case finding and treatment initiation to activities that sustain substantial cohorts on ART and maintain viral suppression. Program design and support for sustained epidemic control will be customized based on each partner country's technical, managerial, and financial capacity. These countries are Botswana, Eswatini, Kenya, Lesotho, Namibia, and Uganda.

Headquarters Review of Tools:

Given the continued COVID-19 pandemic, virtual COP22 Planning Meetings (in previous years these were in-person meetings in regional locations, such as Johannesburg, South Africa and Bangkok, Thailand) will allow intensive input, review, and refinement of COP22 plans with S/GAC, interagency advisors, and other stakeholders in advance of virtual In-country COP Approval Meetings.

Teams will submit the validated information pre-populated in the Resource Alignment Funding Landscape Table the first week in February. Prior to the COP22 Meetings, teams will submit to headquarters for review the DataPack (targets); FAST (budgets); Supply Planning Tool (commodities); and Table 6 Excel Workbook (non-service delivery activities) with Surveys-

Surveillance, Research, and Evaluation (SRE) Tool. Headquarters teams will review these tools and provide feedback to teams so that teams can make relevant adjustments prior to the COP22 meetings. The DataPack (targets), FAST (budgets), Supply Planning Tool (commodities), and Table 6 Excel Workbook (non-service delivery activities) will be submitted on a rolling basis seven days prior to the virtual planning meeting, based on the following groupings (as defined below):

- Group 1: Week of March 7, 2022
    - Single OUs
        - Nigeria, Rwanda, Cameroon, Mozambique, Ukraine, South Sudan, South Africa
    - Sustaining Impact OUs
        - Lesotho
- Group 2: Week of March 14, 2022
    - Single OUs
        - Burundi, Dominican Republic, Zimbabwe, Tanzania, Côte d'Ivoire, Ethiopia, Democratic Republic of Congo, Angola, Malawi
    - Sustaining HIV Impact OUs
        - Uganda
    - Regional Platforms
        - West Africa Region
- Group 3: Week of March 21, 2022
    - Single OUs
        - Vietnam, Zambia, Haiti
    - Sustaining Impact OUs
        - Kenya, Botswana, Eswatini, Namibia
    - Regional Platforms
        - Western Hemisphere Region, Asia Region

This submission timeline will allow headquarters to review and provide feedback so teams can make relevant adjustments prior to the COP22 Virtual Planning Meeting described below. Building on successes and country progress over the past several years and adapting to COVID-19 related health and safety considerations, for COP22 S/GAC will convene the headquarters and field teams for a COP22 Virtual Planning Meeting between February 28 - March 25, 2022. Throughout these discussions, teams will review critical policy requirements, key activities, and

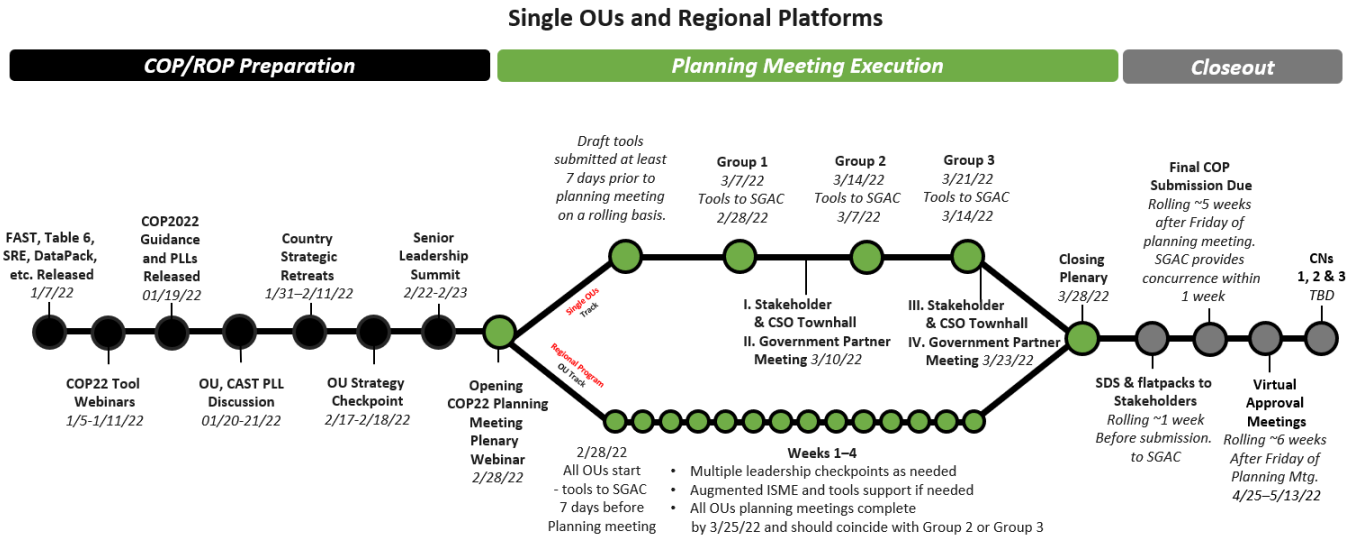
progress to reach epidemic control. PEPFAR teams, headquarters staff, partner country leadership, community and international civil society representatives, and multilateral stakeholders will identify and agree on critical solutions and operationalizing these to advance each OU's ability to reach and sustain epidemic control. Key outputs from the meeting will be partner level budgets, targets, management solutions and priorities in sustainability planning.

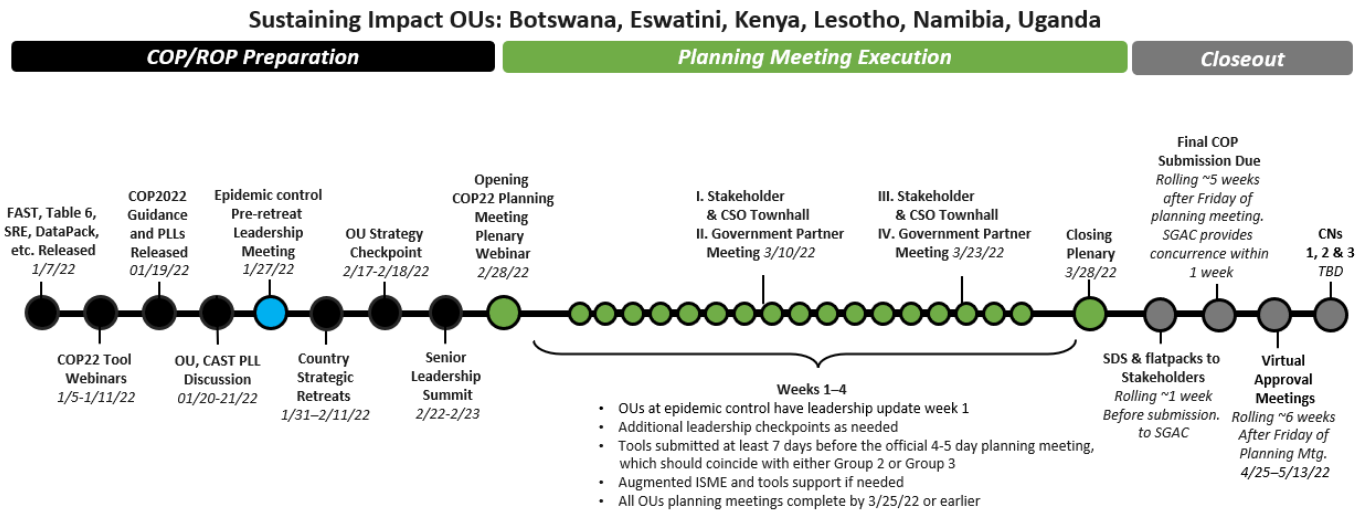
<u>COP22 Virtual Meetings</u>:

The Virtual COP22 Meeting dates have three tracks. The first track is for single OU programs, while a second track has been developed for regional programs in order to allow flexibility around more frequent touch points with headquarters support teams. The third track is for the six 'Sustaining HIV Impact' countries, which will allow them to follow along with their designated country grouping timeline, while ensuring there is flexibility if needed, and more frequent check-ins with headquarters support teams.

The following visual represents overall timing of the Virtual COP Planning Meetings, however it is important to note these tracks are neither positive nor negative. This model is only intended to illustrate the concurrent timelines for single OUs, the 'Sustaining HIV Impact' OUs, plus regional OU processes as each works in collaboration with subject matter experts, S/GAC focal points for tools and systems, and country leadership to finalize COP22 strategies, and to complete tools required for COP22 submission.

Figure 5.3.1 The Three-Track Virtual COP Planning Meeting Overview





<u>Virtual COP Planning Meeting Dates</u>

- Group 1: Week of March 7, 2022
  - Single OUs
    - Nigeria, Rwanda, Cameroon, Mozambique, Ukraine, South Sudan, South Africa
  - Sustaining HIV Impact OUs
    - Lesotho
- Group 2: Week of March 14, 2022
  - Single OUs
    - Burundi, Dominican Republic, Zimbabwe, Tanzania, Côte d'Ivoire, Ethiopia, Democratic Republic of Congo, Angola, Malawi
  - Sustaining HIV Impact OUs
    - Uganda
  - Regional Platforms
    - West Africa Region
- Group 3: Week of March 21, 2022
  - Single OUs
    - Vietnam, Zambia, Haiti
  - Sustaining HIV Impact OUs
    - Kenya, Botswana, Eswatini, Namibia
  - Regional Platforms
    - Western Hemisphere Region, Asia Region

Each single OU and regional platform will participate in one Virtual COP22 Planning Meeting. The COP22 Virtual Planning Meetings are expected to be 3-4 half days to increase data-driven decision making and consultation with stakeholders, to be decided in consultation between Chair, PPM, CAST, and the field team. The COP22 Meetings will include PEPFAR field and headquarters teams, partner country leadership, global and local community and civil society representatives, private sector, and multilateral stakeholders. The COP22 Meetings will focus on reviewing policies, key activities, and progress to reach and sustain epidemic control.

The goals are:

- Respond to S/GAC and HQ review of COP22 proposal and address outstanding items.
- Identify and agree on critical solutions and effective means of operationalization to advance each country's ability to accelerate epidemic control.
- Review and validate priorities to promote sustainability and increase local responsibility for the HIV response, particularly for those OUs at epidemic control.

Key outputs will be agreement on partner level budgets, targets, and management solutions. Sessions will look at common themes in program implementation across PEPFAR countries and learn about innovations and best practices that can be applied across countries.

COP22 Submission Due Dates:

- **Group 1**: April 19, 2022 *(*to account for Easter Monday)*
- **Group 2**: April 22, 2022
- **Group 3**: April 29, 2022

S/GAC will review, exchange with teams as needed and concur within a week of receiving submissions.

Consistent with previous COP processes, all single OUs and regional platforms will submit the final COP22 in all indicated systems on a rolling basis in the five weeks following the conclusion of their Group's COP22 Meeting. Extra time has been given this year in order to ensure country teams have sufficient time to complete all COP22 deliverables and tools with stakeholder engagement. The COP22 timeline is summarized in Figure 5.3.2 and the required COP22 elements checklist is found in Figure 5.4.1.

For COP22, S/GAC will manage approvals during virtual country meetings led by PEPFAR Country Chairs with PPMs, headquarters Agency Points of Contact, PEPFAR field program

leadership, partner country leadership, local community and civil society representatives, and private sector and multilateral stakeholders.

COP22 Virtual Country Approval Meeting Dates:

All COP22 Country Approval Meetings should take place between April 25 - May 13, 2022. Approval meetings will occur on a rolling basis ~6 weeks after the conclusion of the COP22 Planning Meeting.

Figure 5.3.2 summarizes COP21 process, milestones, and timeline

Key Milestones	Dates
Release of COP22 Tools: FAST, DataPack, Table 6, SRE, Supply Planning Tool	January 7, 2022
Release of COP22 Guidance and COP/ROP22 Planning Level Letters	January 19, 2022
Pre-retreat Meeting for Sustaining Impact Countries	January 27, 2022
In-country Planning Retreat	No later than week of February 7, 2022
Opening Plenary Webinar	February 28, 2022
Rolling submission and review of tools (DataPack, FAST, Table 6 Excel Workbook and SRE Tool) at least seven days prior to planning meeting.	• Group 1: February 28, 2022 • Group 2: March 7, 2022 • Group 3: March 14, 2022
COP22 Planning Meetings	• Group 1: Week of March 7, 2022 • Group 2: Week of March 14, 2022 • Group 3: Week of March 21, 2022
COP22 Submission Due	• Group 1: April 19, 2022 • Group 2: April 22, 2022 • Group 3: April 29, 2022
COP22 Virtual or Country Approval Meetings	All COP22 Approval Meetings should take place between April 25 – May 13, 2022

5.4 Required COP Elements Checklist

Figure 5.4.1 summarizes COP22 elements and supplemental document checklist

Tool	Requirement	System of Completion / Tool / Template (location of tool/template)	Pre-COP22 Meeting Tool Submission
DataPack **(for IM x PSNU level target setting)**	**All OUs**	**Tool** *(SharePoint: OU HQ Collaboration page)*	**Yes**
FAST *Budget and cross-cutting allocations*	**All OUs**	**Tool** *(SharePoint: OU HQ Collaboration page)*	**Yes**
Table 6 Excel Workbook	**All OUs**	**Template** *(SharePoint: OU HQ Collaboration page*	**Yes**
Surveys-Surveillance, Research, and Evaluation (SRE) Tool	**Any OU with Surveys-Surveillance, Research and/or Evaluation activities for COP19-21**	**Template** *(SharePoint: OU HQ Collaboration page*	**Yes**
Resource Alignment Funding Landscape Table	**All OUs**	**Template** (OU teams receive pre-populated country profiles with PEPFAR and GFATM data to validate)	**Yes**
Strategic Direction Summary (SDS)	**All OUs**	**Template** *(SharePoint: COP/ROP Resources page)*	**No**
Commodities Supply Planning Tool	**All OUs**	**Template**	**Yes**

Management and Operations:	**All OUs**		
Agency Cost-of-Doing Business, including applied pipeline	**All agencies with CODB costs**	**FAST**	**Yes**
FACTS Info Staffing Data Module	**All agencies with staff**	**FACTS Info**	**No**
Agency functional staff Charts	**All agencies with staff**	**No Template**	**No**
Chief of Mission Letter	**All OUs**	**No Template**	**No**

*No site level targets are required in COP22.

*All supplemental documents (requirements that are not completed through data entry within FACTS Info or DATIM) are submitted within the documents library in FACTS Info.

5.5 Seamless Planning, Implementation, and Learning

To achieve greater impact with its programming, over time, PEPFAR has moved toward a seamless planning, learning and implementation process, as illustrated in Figure 5.5.1. POART reviews, results reporting, SIMS, PHIAs, Demographic and Health Surveys (DHS), table 6 above-site analyses, financial and costing reports, and other data streams all provide critical, up-to-date information. This confluence of information allows OU field teams, with support from headquarters, and in consultation with other stakeholders, to proactively plan and make incremental, real-time changes to programs. These changes are expected to translate into greater impact, effectiveness, resiliency, and sustainable systems.

The continuous use of data in real time improves program performance and generates new knowledge that helps design or implement high impact solutions, adaptive practices, innovations, and meaningful actions. This process provides an annual opportunity for OU teams to deliberately step back for a higher-level strategic review to identify where programmatic adjustments or changes are needed, financial sustainable strategies can be applied, and innovative solutions adopted to address critical gaps to achieve and maintain epidemic control.

The rapid, efficient use of data has resulted in substantial progress over the past COP cycles. For example,

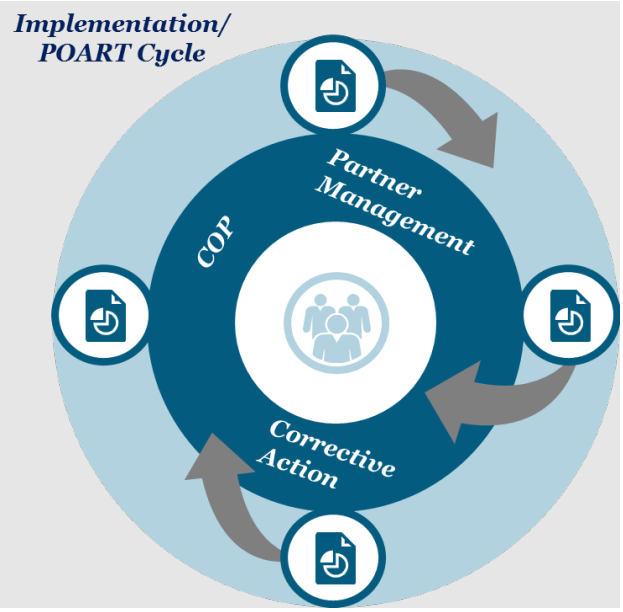
- Site-level data for real-time evaluation of sites with greater than 50% men compared to women **new** on treatment highlighted the substantially lower coverage among men. The data have been used to find those sites with evidence of enrolling men and children <15 years old on treatment, analyze their successes, and articulate their solutions for wider implementation.
- Real time data reviews have identified sites that have greater than 75% linkage of key populations to testing and treatment and have translated across the findings to scale.
- Site level data analysis also has led to significant efforts in COP20 going into COP21 to identify causes of client loss and implement solutions that improve the quality of services and ART continuity – especially among young adults.
- Above-site table 6 analyses as well as use of financial and costing data has helped identify areas for improved partner efficiency, justify engaging new partners, and develop strategies to achieve sustainable programming through new collaborations or blended financing approaches.

Figure 5.5.1 PEPFAR's seamless planning, learning, and implementation process

Efficient and effective planning requires close collaboration and partnerships with other multilaterals, including the Global Fund as well as other development partners. Each OU team, in consultation with local and international stakeholders, will review country contexts and budget, priority geographic areas, populations and non-USG investments. This review includes Global Fund, private sector, and other development partners to validate that the investment priorities agreed upon in COP22 are strategically aligned, coordinated, and correct. Teams must ensure that the PEPFAR program is aligned with its development partner investments, such that activities are strategically focused and coordinated towards effective use of resources and achievement of common goals. Teams will use the information generated by the FY21 program implementation cycle (annual program results, outlays, expenditures, and costing) in reaching or maintaining epidemic control. Information will include FY21 Q4 POART analysis and discussions related to site and non-service delivery achievements, table 6 above-site investments, plus data from other sources to identify gaps in reaching epidemic control by age bands, sex, and priority

sub-national unit (PSNU). This information and analyses will lead to the identification of efficient and effective solutions required to address any gaps and eliminate key barriers that are inhibiting progress toward or maintaining epidemic control as well as designing sustainable systems with local government stakeholders.

Figure 5.5.2 PEPFAR's seamless planning, learning, and implementation/POART cycle



COP22 will continue to focus on translating solutions, adaptive practices, and innovations into full-scale implementation in a rapid and efficient manner. This includes using program and financial data analyses to ensure that implementing mechanism (IM) programmatic activities, targets, and budgets are aligned accordingly and efficiently. SNU-level targets will be developed before finalizing and submitting the COP. OU teams will engage stakeholders early and continuously through their COP planning process, including conducting either in-country or a virtual strategic planning retreat. This is expected to support engagement with a variety of stakeholders to review country results and real time data and identify achievements, gaps, and areas for financially sustainable strategies. Engagement will also include discussion of COP22 strategic objectives, budgets, targets, solutions, innovations, and priority locations to reach agreement on the overall COP22 strategic direction. Teams should use the Self-Service App to create DataPack flatpacks to share with stakeholders prior to initial and final tools submission at a minimum but should do as frequently as needed to keep stakeholders informed.

5.6 Coordination Among U.S. Government Agencies

A key hallmark of PEPFAR is its collaborative and inclusive 'whole-of-government' approach that rests on a robust and productive U.S. government interagency response under the Chief of Mission at the country level. All agencies working in a country or region are required to work together in an open and transparent manner. This includes jointly gathering, sharing, and analyzing all available programmatic, epidemiologic, and financial data to inform decision-making, including partner work plans, and partner- and site-level data. Interagency engagement of stakeholders in quarterly analysis and COP planning is also a critical component of this whole-of-government approach, under the leadership of the State Department. PEPFAR Country Coordinators are positioned to facilitate data sharing across the interagency to inform dialogue with key stakeholders and the development a unified, transparent country operational plan. **It is essential that all U.S. Government agencies working on HIV/AIDS programs in a country participate in COP discussions, even if virtually.**

It is equally important to ensure that all PEPFAR investments are linked and/or harmonized in an optimal and efficient manner. For example, PEPFAR-supported facility and community service providers, regardless of agency or implementing partner affiliation, need to establish working relations across sites. This will help ensure a contiguous treatment-prevention system. In addition, above-site investments need to support all PEPFAR-supported sites and services, as appropriate for reaching epidemic control and development of sustainable financial strategies, regardless of agency or IP affiliation.

Country programs may have several sources of U.S. Government HIV/AIDS funding (e.g., State, USAID, Global AIDS Program [GAP] funds). Nevertheless, all HIV/AIDS programming decisions must be made jointly as an interagency U.S. Government team, with final approval issued by S/GAC. **An important demonstration of this joint decision-making is the requirement that all draft scopes of work for new/renewed procurements will be shared and reviewed in an interagency manner at the country level before being included in COP22 and before being submitted for official agency acquisition and award processes.** Sharing and reviewing scopes of work for new/renewed activities early helps to avoid duplication and helps the aim of seeking to ensure that all new activities fit within the overall country strategy.

In preparing the COP and throughout the year, PEPFAR programmatic staff are required, as needed, to consult with other relevant offices in all agencies. These offices might include human resources, management, financial, general services, scientific review, acquisition, grants, general

counsel, and policy officials at the appropriate levels to ensure that there is sufficient administrative and management support to facilitate PEPFAR activities. For example, the Embassy Management and Human Resources Offices are key partners in evaluating current and planned staffing for program management, oversight, and accountability. Similarly, all procurement and assistance actions are coordinated with the appropriate agency's procurement office prior to COP approval and during implementation. Each agency utilizes established agency financial forecasting systems during COP implementation, and it is the onus of the agency to ensure approved COP activities can be funded and implemented in accordance with S/GAC approval and funding letters to agencies. Agencies ensure partners are accountable for the results they were funded to achieve and are required to link partner spending to results. Agency headquarters should have situational awareness of programmatic and financial performance of their partners. As in prior years, successful implementation of COP22 will require ongoing data analyses via the quarterly POARTs, routine interagency discussion, and routine consultations with stakeholders. These internal and external-facing discussions facilitate a unified U.S. Government approach that is aligned with the priorities of partner country governments and local communities. This ongoing dialogue continues to routinize data sharing and transparency. Moreover, it provides an opportunity to share evidence-based solutions, adaptive practices, and new innovations to address implementation challenges identified through POART reviews. If any agency does not have staff or activities in country, the OU team may still draw on that agency through the POART and COP processes to solicit the needed expertise.

5.7 Brief Introduction to PEPFAR Implementing Agencies

PEPFAR takes a whole-of-U.S. Government approach, and in accordance with the Leadership Act, several USG agencies play a unique and fundamental role in PEPFAR implementation.

U.S. Agency for International Development (USAID) USAID's HIV/AIDS program has been at the forefront of the global HIV response since 1986, leveraging strategic partnerships and global health expertise to help control one of the world's most serious public health challenges. As a principal implementer of PEPFAR, USAID provides support to over 50 countries.

USAID's approach to HIV/AIDS provides global leadership to advance HIV epidemic control and sustainability, supports country-led efforts for long-term sustainability and results, and applies science, technology, and innovation to support the implementation of cost-effective, cutting-edge, sustainable, and appropriately integrated HIV/AIDS interventions at scale. USAID

aims to achieve and sustain HIV/AIDS epidemic control by achieving the globally recognized 95-95-95 targets.

U.S. Department of Health and Human Services

U.S. Centers for Disease Control and Prevention (CDC) The CDC is the U.S. public health agency. As a primary PEPFAR implementing agency, CDC builds upon scientific and technical expertise from decades of HIV control experience and provides support to deliver high-impact, sustainable prevention, care, and treatment of HIV to millions of people globally. The CDC works with Ministries of Health to strengthen local health infrastructure, including the policy, financing, and public health systems necessary to underpin this infrastructure, in surveillance and laboratory activities, workforce planning, allocation, management and treatment continuity, and epidemiological capacity. CDC promotes the use of data to inform public health policies and strategies, to iteratively improve HIV programming, and measure the impact of global health interventions.

The **National Institutes of Health (NIH)** has intramural scientists conducting basic research on HIV/AIDS, administers extramural grants related to HIV research, care, and treatment (implementation science), and helps capacitate the health workforce via Fogarty International Center training grants.

The **Health Resources and Services Administration (HRSA)** is the lead provider of domestic HIV care and treatment services to vulnerable and underserved population, having successfully reached 567,903 clients with a viral suppression rate of 88.1% in 2019.[95] HRSA leverages US-based service delivery expertise to support PEPFAR sites with targeted technical assistance, mentoring, and skill sharing to address key barriers to epidemic control. HRSA builds on the success of its domestic HIV program to help PEPFAR countries improve access to high-quality integrated HIV prevention, care and treatment services and align with PEPFAR strategies.

The **U.S. Food & Drug Administration (FDA**) approves antiretroviral medications that can be used by PEPFAR, and also acts as a liaison with the WHO's prequalification unit to share information.

The **Office of Global Affairs (OGA)** supports policy and program coordination on behalf of the Department of Health and Human Services for PEPFAR.

[95] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2019. hab.hrsa.gov/data/data-reports. Published December 2020.

U.S. Department of Defense (DoD): The DoD HIV/AIDS Prevention Program (DHAPP) is based in San Diego, CA, and administers funding, conducts training, and provides technical assistance for military to military (mil-mil) PEPFAR programs in focus countries and other bilateral countries. DoD PEPFAR also encompasses the U.S. Military HIV Research Program (Walter Reed Army Institute of Research) efforts, which focus on military to civilian (mil-civ) partners in three African countries in high burden communities where it also conducts HIV vaccine research. Combined, these DoD programs support HIV/AIDS prevention, treatment, care, strategic information, human capacity development, and program and policy development in host militaries and civilian communities of 55 countries around the world.

The U.S. Peace Corps: Peace Corps Volunteers (PCVs) work in partnership with host countries and local governments to enhance the capacity of organizations from the community to the national level, ultimately promoting an understanding of the epidemic and encouraging the adoption of healthier behaviors. PCVs provide long-term capacity development support to non-governmental, community-based organizations, including faith-based organizations, with particular emphasis on ensuring that community-initiated projects and programs provide holistic support to people living with and affected by HIV/AIDS. PCVs play a unique role in targeting hard-to-reach populations and instituting change through sustainable community efforts.

The U.S. Department of Commerce provides support by furthering private sector engagement and fostering public-private partnerships. The Department of Commerce creates and disseminates sector-specific strategies for various industries, detailing concrete examples of how the private sector can be engaged in HIV/AIDS.

The Census Bureau, within Commerce, also assists countries with collecting census data and provides support with data analysis and surveys.

The U.S. Department of Treasury works with Finance Ministries in select countries to broaden awareness of the substantial economic costs of the epidemic, and the need to ensure resilient and financially secure health systems. Treasury helps these ministries prepare public budgets to assume a greater share of the costs for HIV/AIDS programs and to provide technical assistance to build state capacity in public financial management.

5.8 Aligning Headquarters Resources to Improve Accountability and Support the Field

PEPFAR must harness the collective expertise of its headquarters staff across all agencies in an increasingly efficient manner and ensure rapid uptake of innovative solutions into PEPFAR's business practices. To better support OU teams to engage in a meaningful and deliberate planning, learning, and implementation process, the PEPFAR headquarters (HQ) country accountability and support team (CAST) model has been established to directly support operating units (OUs) at the country and regional levels. The CAST is an integrated management structure responsible for measurable achievement and contributions towards HIV epidemic control. The end result is a more focused, impactful, and efficient use of headquarters resources to address epidemic control gaps, resiliency of programs, and design of innovative strategies to achieve sustainable systems, identified in the field at the OU and SNU levels. This includes a more direct and regular engagement between agency staff, Chairs, PPMs, and the Field where data are available, and decisions are made at the OU level.

CAST members include the PEPFAR Chair, PEPFAR Program Manager (PPM), and agency points of contact (POCs) for respective implementing agencies. A guiding principle for CASTs is maintaining a unified PEPFAR team approach to achieve program outcomes, impact, and sustainability. This includes having a shared responsibility to analyze available data and recommend guidance or feedback, engage in problem solving, identify promising best practices, and develop new innovations or scale proven solutions. Furthermore, the CAST coordinates technical assistance (TA), delivered virtually or in-person, to a specific OU to address areas for course correction and/or accelerating achievement of program goals. PEPFAR TA is intended for all agencies in country, regardless of the agency of the HQ Implementation Subject Matter Experts (ISMEs) delivering the TA. Other key participants supporting each CAST include specific ISMEs, while the DUIT, PET and M&B Liaisons plus Interagency Collaborative for Program Improvement (ICPI) provide analytic support across all HQ structures, and Communities of Practice (CoOPs) focus on changing practices in the field and adapting-then scaling promising solutions, adaptive practices, and innovations with demonstrated impact to help ensure implementation addresses identified barriers to epidemic control or sustainability of services.

5.9 Budget Considerations

5.9.1 Mandatory Budget Earmarks

Planning for mandatory earmarks should be fully integrated into the COP planning process. This funding should complement and enhance the country program, reflect sound and effective allocations to partners with high outlay/expenditure rates and associated results and ultimately, allow for PEPFAR to continue meeting legislative requirements and Congressional expectations. Any changes to the earmark amounts designated in the Planning Level Letter must be approved by the S/GAC Management & Budget (M&B) team, in consultation with the Global AIDS Coordinator (GAC), and recorded in FACTS Info.

5.9.1.1 Orphans and Vulnerable Children

The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 directs that 10 percent of PEPFAR's funds appropriated to carry out the provisions of section 104A of the Foreign Assistance Act of 1961 (which includes Global Health Program funds appropriated for PEPFAR purposes) be used for Orphans and Vulnerable Children (OVC) programming. OVC are defined as "children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects." OVC funding serves the dual purpose of mitigating the impact of HIV and AIDS on children and adolescents as well as the prevention of HIV- and AIDS-related morbidity and mortality.

Funds used to meet that OVC programming requirement will be comprised of funding for the comprehensive OVC program, primary prevention of HIV and sexual violence among 10–14-year-olds, and DREAMS activities that reflect the objectives of mitigation and prevention and serve "children orphaned by, affected by, or vulnerable to HIV/AIDS." A description of the purpose, and illustrative activities for each, is contained in Sections 6.6.3 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic, and 6.2.3 Primary Prevention of HIV and Sexual Violence for Vulnerable 10-14 Year Olds of this document. Funding from other activities may be applied centrally if they conform to the purposes and activities outlined in the succeeding sections describing OVC programming. The following will not be included for purposes of meeting the 10% OVC programming (earmark) requirement: funding

for 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.

The OVC earmark during COP planning will be based on the OVC beneficiary group and the DREAMS initiative, and will subtract out commodities, testing and some care and treatment. The OVC earmark is calculated according to the following formula:

OVC Earmark =

85% (DREAMS initiative funding
- commodities planned under DREAMS
- Any HTS interventions planned under DREAMS initiative
- Any C&T interventions planned under DREAMS initiative)

+

100% (Interventions for OVC Beneficiaries
- commodities planned under any initiative for OVC beneficiaries
- Any HTS interventions planned for OVC beneficiaries)

+

Proportional Program Management: the amount of program management that counts towards the earmark will vary by mechanism and will be determined by calculating the proportion of the mechanism's non-program management work that counts towards the OVC earmark, and applying that proportion to the program management cost

5.9.1.2 Care and Treatment Budgetary Requirements and Considerations

The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 directs that at least 50% of PEPFAR's funds appropriated in a given fiscal year to carry out the provisions of section 104A of the Foreign Assistance Act of 1961 (which includes Global Health Program funds appropriated for PEPFAR purposes) must be dedicated to treatment and care for people living with HIV. To reach this global requirement, each country or region submitting a 2022 COP or ROP will be notified of their specific care and treatment requirement within the COP22 country or regional-specific planning level letter. The care and treatment earmark is calculated by summing the planned funding for a number of care and treatment-related interventions.

The care and treatment earmark is calculated according to the following formula:

- 100% Care and Treatment (C&T) Program Areas
- 50% Testing (HTS) Program Areas
- 100% Above Site Program: Laboratory System Strengthening
- 70% Pregnant and Breastfeeding Women Beneficiary Group
- Proportional % Program Management (Proportional Program Management will vary by mechanism and will be determined by the amount of other interventions at the mechanism that count towards the C&T earmark)

If upon submission of the COP/ROP, the allocation resulting from the above formula is not greater than or equal to the OU care and treatment requirement, further discussion will be required to reach this mandatory earmark with COP22 resources as well as any other new resources from other fiscal years that are subject to earmark requirements.

5.9.2 Other Budgetary Considerations

Our partners in Congress may also include in appropriations legislation or related reports other language regarding or affecting the use of PEPFAR funds that may emphasize priorities from their unique perspectives and may indicate levels of funding for those priorities which they expect the program to achieve in addition to any mandatory requirements reflected in such legislation. Some may fall into the category of what is sometimes referred to as “soft” earmarks. It is vitally important that implementation occur consistent with all applicable legislation, and also in a manner responsive to other concerns that may be expressed in non-legally binding language. If any new provisions or language are included in any applicable full year appropriations act that becomes relevant to COP22 funding, S/GAC and the implementing agencies will communicate any changing or new expectations or requirements for teams to incorporate such provisions in their planning processes. Any such changes in amounts designated in the Planning Level Letter must be approved by the S/GAC (M&B) team, in consultation with the GAC, and recorded in FACTS Info.

5.9.2.1 Water and Gender-based Violence

For COP22 submissions, PEPFAR will assign control levels based on final COP21 attributions, adjusted for any changes in the total budget envelope provided for the OU as appropriate. During the COP22 formulation process, an OU may program more than the control amounts but cannot program less than the control amount. Exact required investment levels will be reflected in the

COP22 planning level letter. Exceptions to these requirements require approval by the M&B team, in consultation with the GAC, and will be recorded in FACTS Info.

5.9.2.2 Discretionary Budget Requirements

In addition to the specific budget requirements listed in this guidance, the Global AIDS Coordinator may impose discretionary minimum, maximum, or exact budget requirements. These requirements will be communicated either in planning level letters or supplemental guidance as well as suggested methods for meeting the requirement. Examples include budgeting for Cervical Cancer, Community Led Monitoring (CLM), DREAMS, USAID Condoms Funding, and Voluntary Medical Male Circumcision (VMMC). Exceptions to these requirements require approval by the M&B team, in consultation with the GAC, and be recorded in FACTS Info.

5.9.3 Abstinence, Be Faithful/Youth (AB/Y) Reporting Requirement

Primary prevention (AB) activities are those that help youth through evidence-based primary prevention of sexual violence and HIV (i.e., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut). This primary prevention includes programming to support healthy decisions, and to help communities and families surround these youth with support and education and should be integrated with orphans and vulnerable children (OVC) programs.

As a reminder, in COP21, PEPFAR transitioned away from budget codes. Abstinence, Be Faithful/Youth (AB/Y) programming, formerly captured in the HVAB budget code, is now captured by using a combination of prevention program areas and beneficiaries, which are identified in the formula below. The numerator captures those interventions that are Abstinence, Be Faithful/Youth (AB/Y) programming, and the denominator approximates all sexual prevention activities. The proportion of Abstinence, Be Faithful/Youth (AB/Y) programming as a proportion of all sexual prevention activities is calculated by dividing the numerator by the denominator:

Numerator

Prevention: primary prevention of HIV and sexual violence

(For OVC, OVC caregivers, young people and adolescents, children, young women and adolescent females, girls, young men and adolescent boys, and boys)

+

Prevention: community mobilization, behavior, and norms change

(For OVC, OVC caregivers, young people and adolescents, children, young women and adolescent females, girls, young men and adolescent boys, boys, adults, not disaggregated)

Denominator

Prevention: primary prevention of HIV and sexual violence (all populations)

+

Prevention: **community mobilization, behavior, and norms change** (all populations)

+

50 % Prevention: **Not disaggregated** (all populations)

If AB/Y-programmed activities do not reach a 50 percent threshold of all sexual prevention funding, as calculated by the formula above, in any country with a generalized epidemic, S/GAC is required to report to the appropriate Congressional committees on the justification for the decision. In such cases, teams should provide brief justifications and explain the rationale for prevention programming decisions given the epidemiologic context, contributions of other donors, and other relevant factors. The written justifications should be uploaded as 'Budgetary Requirements Justification' to the document library of FACTS Info.

5.9.4 Budget Execution

Throughout the budget cycle, beginning with the COP planning process and continuing through full implementation of programming, PEPFAR operating unit interagency teams are responsible for ensuring that the planning and implementation of each COP is consistent with the budget approved by S/GAC, and documented in FACTS Info with details at the implementing partner level, and USG cost of doing business (CODB) level. The approved COP budget levels reflect the total resources–both newly appropriated funds and pipeline (funds appropriated in prior fiscal year appropriations acts) applied to the COP22 implementation cycle–that a country or region is approved to obligate during **the 12-month implementation period** (01 October 2022 to 30 September 2023). <u>All partners to which the USG funding Agency expects to outlay funding during the implementation period must be recorded in FACTS Info, including anticipated outlays of prior year funding if unliquidated, and outlays as part of closing out an Award</u>.

Outlays are defined by OMB as payments to liquidate an obligation. Consequently, within the COP process, outlays are cash drawdowns initiated by the implementing partner, whether or not

the funds have actually been spent by the implementing partner. Expenditures refers to the implementing partner's use of funds.

The signed COP Approval Memo constitutes the final approval, which locks in the partner and CODB budget levels in FACTS Info. From this point, each PEPFAR implementing Agency is accountable for outlaying funds to its implementing partners at no more than the approved level, and not exceeding the approved COP budget, unless with prior authorization by S/GAC. Accordingly, agencies should work closely with implementing partners to initiate cash drawdowns appropriately within the approved COP budget. Similarly, any implementing partner not documented in FACTS Info at the time of the approval should not carry out activities and should not spend associated funds, unless with prior authorization by S/GAC. Critically, agencies should routinely monitor site-level results against partner expenditures and ensure low-performing partners spend funds appropriately. The following is expected for the current implementation of COP22 and future planning cycles:

- During the COP22 implementation period, it is expected that total country or regional outlays for this period do not exceed the total funding level (inclusive of new appropriations and pipeline), as stated in the Approval memo. Consequently, agency outlays to each individual IP over this period should not exceed the amounts programmed for that partner as approved and documented on FACTS Info for COP22.
- During program implementation, the interagency team may identify a need for an agency to outlay to an implementing partner an amount that exceeds the approved level or need to rectify an error or omission in the original COP22 submission. In such instances, the agency (at the field or headquarters) must work with the PEPFAR Coordinator or POC to submit a request for an Operational Plan Update (OPU) to gain approval for the new budget level and ensure correct documentation of revised funding levels. An OPU and approval is required regardless of whether the intent is to increase outlays using pipeline or new funds. The OPU must include table which documents funding shift (i.e., where funding is decreased so that the increase can be accommodated while staying within the overall budget control for the OU). This must be transparent to all in-country PEPFAR agencies as it impacts the whole program.

To the extent consistent with applicable legal restrictions and procedures on the relevant fiscal year funds, including any relevant or required Congressional Notifications, Agencies should fully utilize their expiring and older funds before obligating or expending newest appropriated funds, in order to obligate and expend funds before they expire. Due to this budgetary approach, the

appropriation year of funds that are outlaid in support of an approved COP activity may not match the distribution of new and applied pipeline funds, as documented in FACTS Info. This is acceptable, as long as 1) the use of the pipeline funds is consistent with any legal and policy restrictions and procedures applicable to use of those funds, 2) total outlays at the end of the fiscal year are equal to or less than the total approved funding level for each individual partner or CODB category, and 3) implementing partners are not allowed to accumulate pipeline greater than their award.

A mechanism's overhead should reflect all indirect and other program management costs, unless during close-out. The level and proportion of program management budget (excluding Negotiated Indirect Cost Rate Agreement (NICRA) costs, which cannot be changed) compared to the overall budget may influence decisions to approve a mechanism during COP planning as part of analyzing efficiency in implementing for results.

An implementing partner must never expend funds for the sake of decreasing pipeline and not accomplishing funded activities. In other words, all partner expenditures must be in accordance with the approved COP level. Moreover, in such a case, the partner will appear much more costly, which will jeopardize future funding and consideration for that partner.

It is expected that Awards may have a multi-year life cycle. Total Award budgets must take into account all anticipated start-up (when implementation costs may be less) and close-out costs (when implementation may be winding down). Start-up and close-out costs should be included in the budget allocated to the implementing partner in the appropriate COP cycle (during the 12 months in which the funds are anticipated to be outlaid by USG) and documented and approved in FACTS Info. Close-out costs are not optional; and during the COP process, Chairs and PPMs must work closely with Agency POCs to ensure close-out costs are properly budgeted for. Close-out costs may not be forgone in order to free up funding for programmatic activities, as this will require unnecessary OPUs later on. Supplemental HOP funding for the same in-country partners will not be provided. Thus, all costs must be fully budgeted for in the field.

To decrease start-up and close-out costs, PEPFAR equipment purchased with USG funding should be transferred from closing mechanisms to new mechanisms where appropriate. The final year of a mechanism's implementation (e.g., cases in which a PEPFAR OU is buying into a broader agency mechanism for the last time, even if the agency mechanism itself is not closing) may include a budget with few or no targets, in order to account for close-out costs, such as NICRA, and costs required to close out a mechanism, or end a PEPFAR activity within a broader agency mechanism.

When one IM closes and another opens, both may be active in the same geographic location, during the transition period. The implementing partners' workplans should reflect this geographic overlap in transition. However, there should be no interruption in service delivery of prevention, treatment, or OVC services. If this occurs, these programs will be moved to another partner to manage.

Financial analysis plays an indispensable role in performance monitoring (e.g., achieving MER targets, achieving above-site benchmarks, and achieving SIMS standards of program quality). PEPFAR Program managers must fully understand whether the program in their OU is reaching its anticipated MER targets, achieving its programmatic strategy, and complying with quality and sustainability standards. They must also analyze financial performance, including outlays by the USG funding agency, and expenditure by the implementing partner at the mechanism level. Such financial analysis will help PPMs arrive at a more comprehensive view of an IM's overall performance. Hence, PPMs should include financial analysis in POART discussions and other partner management conversations. PEPFAR recognizes the need for a standardized, program-wide approach. Chairs and PPMs should understand and compare contextualized IM expenditures for implementing partners that carry out similar interventions, so that they can identify best practices, correct potential inefficiencies, and/or adjust funding.

Planning discussions for COP22 begin from a review of COP20 implementation, both in terms of interventions carried out by each implementing mechanism, and their budgets. The information needed for such a review is captured in existing contracts and work plans. Sharing the results across the full interagency group is imperative to inform robust conversations and analysis to determine the COP22 directions and priorities. Also see Section 7.0 on Planning Steps.

6.0 Technical Considerations

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

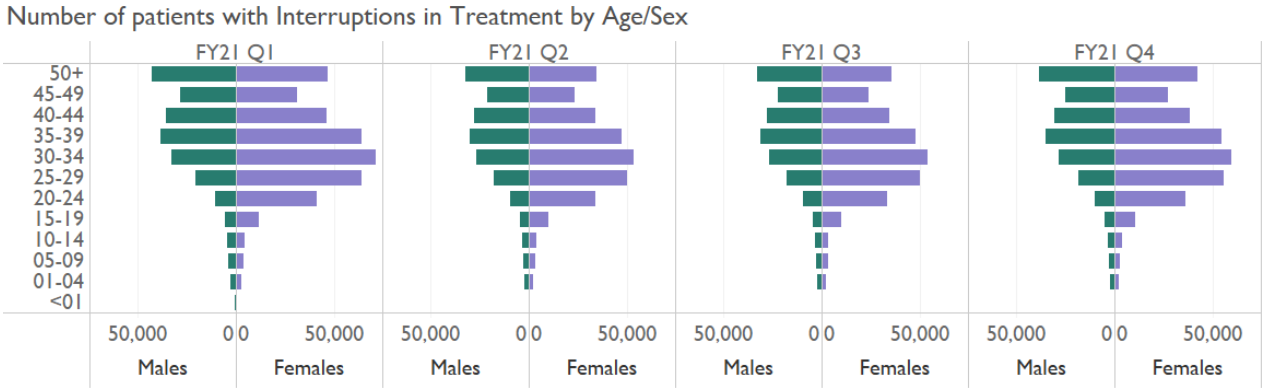
does not start at the facility door, evidenced-based efforts must extend where appropriate into the communities and households of clients and potential clients.

- 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

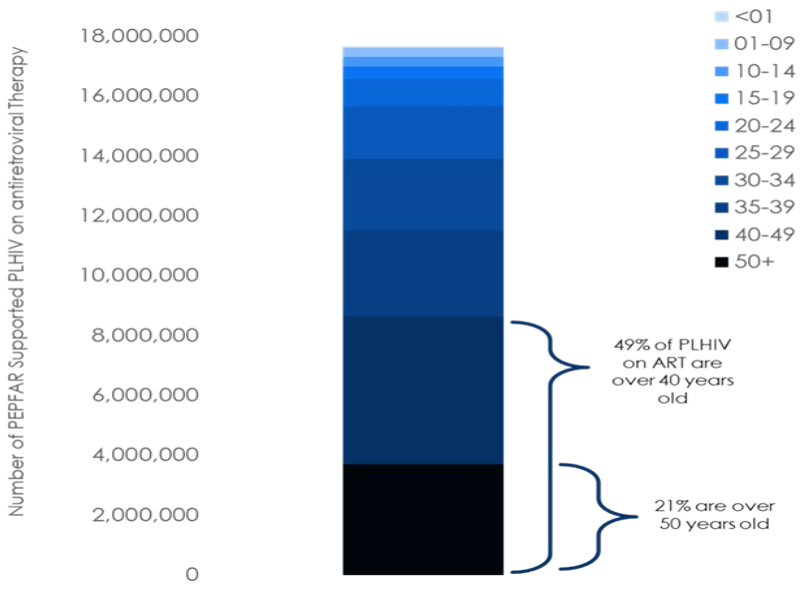


Adolescents/Youth: This group has special challenges with successful therapy that include diminishing caregiver oversight, lack of youth-friendly services, and inadequate preparation for the transition to adult HIV treatment. Approaches must be tailored to age and developmental stage and gender-sensitive (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

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.[96] 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[97] and across agencies[98]

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.

[96] Consolidated Guidelines for Testing in a Changing Epidemic, WHO (2019). https://www.who.int/publications/i/item/WHO-CDS-HIV-19.31
[97] https://www.pepfarsolutions.org/solutions/tag/linkage+to+care
[98] 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.[99] 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. 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

[99] 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 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.[100] PEPFAR data can help to identify who is at highest risk of treatment interruptions and where interruptions are most frequent, using disaggregated age, sex, and location data. See Section 7.

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.

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.

[100] 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

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.[101] 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 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

[101] 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

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.[102]

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 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

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

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,[103] 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.

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

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[104,105,106,107]

   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[108]

   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.

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

[105] 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

[106] 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

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

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

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.[109] 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[110,111]
   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

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

[109] https://www.pepfarsolutions.org/women/2018/1/13/improving-access-to-hiv-treatment-services-through-community-art-distribution-points-in-uganda
[110] Data from Adherence Clubs in the Western Cape, South Africa (paper 1, paper 2, paper 3, PEPFAR solutions write up)
[111] 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.

- 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.[112]

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.
- 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.

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

6.1.2.1 Differentiated Service Delivery for Children

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.

CLHIV two years of age and older are 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.[113] 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 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 2 years and older 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

[113] 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.

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.[114] 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.[115]

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 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

[114] 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

[115] 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

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[116] (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 (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

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

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.[117] 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 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.

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

- 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.[118]
- Coordinate tracking of A/YLHIV for appointment reminders/missed appointments using A/YLHIV peer navigators.
- 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.

[118] 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

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,

[119] UNAIDS. 2019 . https://aidsinfo.unaids.org

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]

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[120] Nuwagaba-Biribonwoha H et. al. Adolescent pregnancy at antiretroviral therapy (ART) initiation: a critical barrier to retention on ART. J Int AIDS Soc. 2018 Sep;21(9): e25178

[121] Abuogi, L. L., J. M. Humphrey, C. Mpody, M. Yotebieng, P. M. Murnane, K. Clouse, L. Otieno, C. R. Cohen and K. Wools-Kaloustian (2018). "Achieving UNAIDS 90-90-90 targets for pregnant and postpartum women in sub-Saharan Africa: progress, gaps and research needs." J Virus Erad 4(Suppl 2): 33-39.

[122] Atuhaire, P., S. Hanley, N. Yende-Zuma, J. Aizire, L. Stranix-Chibanda, B. Makanani, B. Milala, H. Cassim, T. Taha and M. G. Fowler (2019). "Factors associated with unsuppressed viremia in women living with HIV on lifelong ART in the multi-country US-PEPFAR PROMOTE study: A cross-sectional analysis." PLoS One 14(10): e0219415.

[123] https://www.unicef.org/sites/default/files/2018-07/UNICEF-WomenHIV-Complete-Web-2018-07-18.pdf

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

[124] Thomson KA et al. Navigating the risks of prevention of mother to child transmission (PMTCT) of HIV services in Kibera, Kenya: Barriers to engaging and remaining in care. PLoS One. 2018 Jan 24;13(1): e0191463
[125] Kim et al. Why Did I Stop? Barriers and Facilitators to Uptake and Adherence to ART in Option B+ HIV Care in Lilongwe, Malawi. PLoS One. 2016 Feb 22;11(2): e0149527.
[126] Puchalski R et al. What interventions are effective in improving uptake and retention of HIV-positive pregnant and breastfeeding women and their infants in prevention of mother to child transmission care programmes in low-income and middle-income countries? A systematic review and meta-analysis.; the PURE consortium. BMJ Open. 2019 Jul 29;9(7): e024907.
[127] Myer, et al. Integration of postpartum healthcare services for HIV-infected women and their infants in South Africa: A randomized controlled trial. PLoS Med 15(3): e1002547. 2018

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,

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[128] Igumbor JO, Ouma J, Otwombe K, Musenge E, Anyanwu FC, Basera T, Mbule M, Scheepers E, Schmitz K. 2019 Effect of a Mentor Mother Programme on retention of mother-baby pairs in HIV care: A secondary analysis of programme data in Uganda. PLoS ONE 14(10): e0223332. https://doi.org/10.1371/journal.pone.0223332

[129] Agudu et al. The Impact of Structured Mentor Mother Programs on 6-Month Postpartum Retention and Viral Suppression among HIV-Positive Women in Rural Nigeria: A Prospective Paired Cohort Study. J Acquir Immune Defic Syndr. 2017 Jun 1;75 Suppl 2:S173-S181

[130] Ambia et al. A systematic review of interventions to improve prevention of mother-to-child HIV transmission service delivery and promote retention. J Int AIDS Soc. 2016 Apr 6;19(1):20309

[131] https://www.who.int/hiv/pub/arv/hiv-differentiated-care-models-key-populations/en/

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.

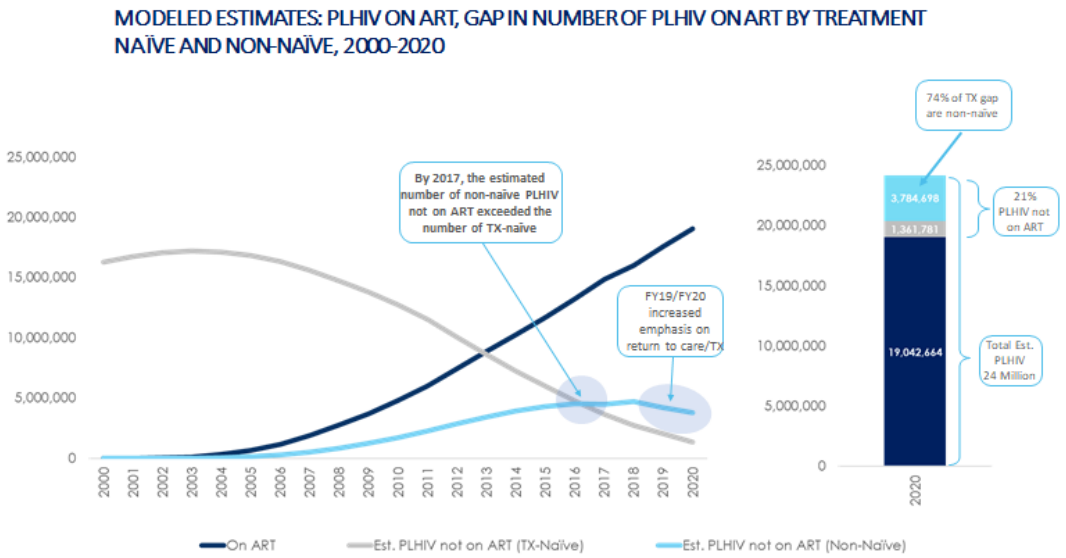
6.1.3 Continuity of Treatment

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[132] 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.

[132] 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.

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



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[133] 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

[133] 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-

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

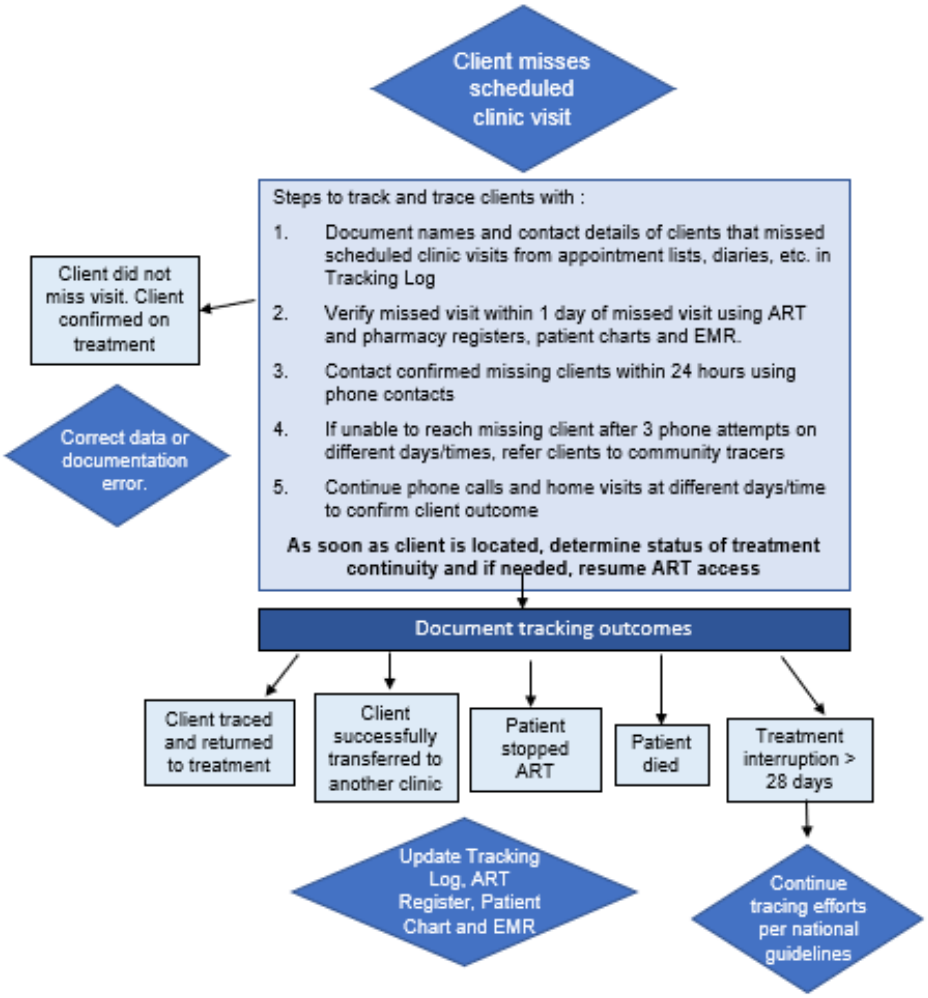
Tracking and tracing efforts have benefited from coordination with community health workers, CSOs and government food security efforts especially when mitigation efforts for COVID-19 are in place. Coordination with OVC programming to improve household food security and provide short-term emergency food 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

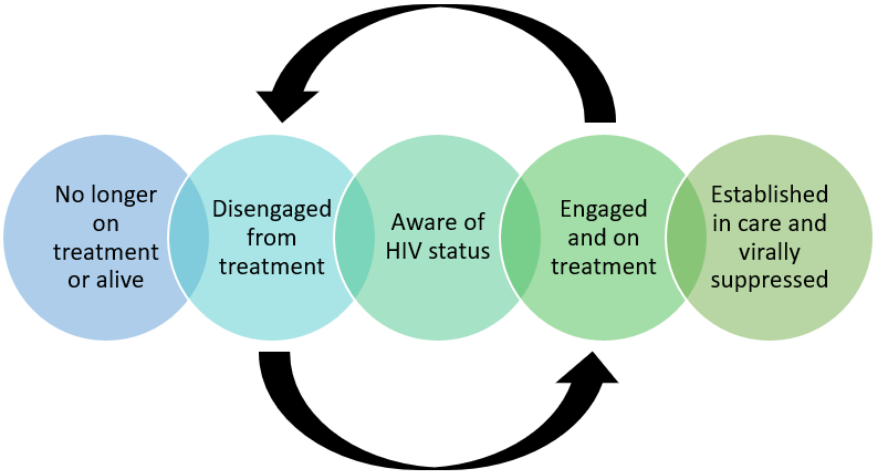
There is a growing recognition that the continuum of care is cyclical with periods of engagement and disengagement.[134] This movement in and out of treatment has been described by some as 'churn.'[135] Planning for these interruptions is an integral part of chronic disease management. In COP22 PEPFAR supports a "welcome back to care" approach which is personalized and attempts to understand the reason for disengagement, is empowering, and is actively supported by both services and providers (both clinical and non-clinical).[136]

[134] 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

[135] 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

[136] 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

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 electronically.[137] A smart phone app for use by pharmacists was demonstrated in Botswana, and other digital solutions may be helpful.[138]

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[139] 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,[140] however, several MER

[137] 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

[138] 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

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

[140] 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

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.

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 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)
- When clinical HIV testing is restricted (due to COVID-19, for example), OUs may consider self-testing for PrEP continuation testing, with blood tests preferred over oral fluids (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)

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.[141,142,143,144] WHO guidelines recommend offering oral PrEP to those at substantial risk of HIV infection.[145] Oral PrEP is a proven, safe, scalable intervention that can drastically reduce new HIV infections.[146] In 2020, WHO guidelines recommended the PrEP ring as an additional prevention choice for women. 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 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)

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[141] 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

[142] 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

[143] 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

[144] 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

[145] 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/

[146] 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 .

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.[147] 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 and inconsistent condom use 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.[148] 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.

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

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

driven PrEP (ED-PrEP) option for MSM (See Section 6.5 PEPFAR's Key Populations Approach and Strategy) and include stigma reduction education for PrEP providers. The WHO is currently reviewing and updating guidance on the populations for whom ED-PrEP dosing is indicated and teams should ensure they are aware of the latest guidelines. 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.

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.[149,150,151] 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.

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

[149] https://www.who.int/hiv/pub/prophylaxis/en/
[150] https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf?ua=1
[151] https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1

guidelines. Clients starting PrEP who then have an exposure to HIV before full protection from PrEP has been achieved should be considered for PEP.[152]

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.

The vaginal PrEP ring is a woman-controlled prevention product that has been approved and is available as an alternative option.[153] 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.

Long-acting injectable cabotegravir (CAB-LA) is under FDA review, and approval could be issued during COP21; national registrations and implementation studies will commence thereafter. CAB-LA, delivered by an injection every two months, could provide a discrete, long-acting PrEP option for users.

Islatravir (formerly MK-8591), an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) formulated as a once-monthly oral pill, is under evaluation in clinical trials for the treatment and prevention of HIV-1 infection. In January 2021, interim findings from the phase

[152] https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf?sequence=1
[57] https://www.ema.europa.eu/en/news/vaginal-ring-reduce-risk-hiv-infection-women-non-eu-countries-high-disease-burden

2b clinical trial in adults found that once-monthly oral Islatravir for pre-exposure prophylaxis of HIV had a favorable pharmacokinetic, safety, and tolerability profile.[154]

Lenacapavir is an investigational long-acting HIV capsid inhibitor in development for the treatment and prevention of HIV infection. It is currently being investigated in a phase 3, double blind trial as a subcutaneous injectable PrEP option administered every six 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.[155] 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 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

[154] https://www.merck.com/news/merck-presents-interim-findings-from-phase-2a-clinical-trial-evaluating-investigational-once-monthly-oral-islatravir-for-the-prevention-of-hiv-1-infection-at-hivr4p-2021/
[155] https://www.avac.org/infographic/years-ahead-hiv-prevention-research

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 creatinine testing results. 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. The WHO supports the use of HIV self-testing during the COVID-19 pandemic only as an interim measure and is currently reviewing evidence on the use of HIV self-testing for oral PrEP initiation and monitoring. Oral fluid-based HIV self-tests are usually not recommended for PrEP users due to a lower sensitivity and longer window of detection. Blood based self-tests are preferred over oral fluid self-tests, if available. However, providers could consider use of self-tests only when other options are not available, in situations where a PrEP client has been adherent and when the local COVID-19 context prevents them from accessing a HIV testing with a blood sample using the approved national algorithm. 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 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 not necessarily 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.[156] 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 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

[156] https://prepitweb.org/

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.[157] 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.[158]

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

AGYW in Eastern and Southern Africa remain up to 14 times more likely to be infected with HIV than their male peers.[159] 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.[160] Incidence rates over 5/100 women were seen in several South African sites, with the highest rate being 6.8/100 women.[161] 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.[162] 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, 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.

[159] PHIA Project Resources. https://phia.icap.columbia.edu/resources/. ICAP. 2020.
[160] 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
[161] 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.
[162] 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 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

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.

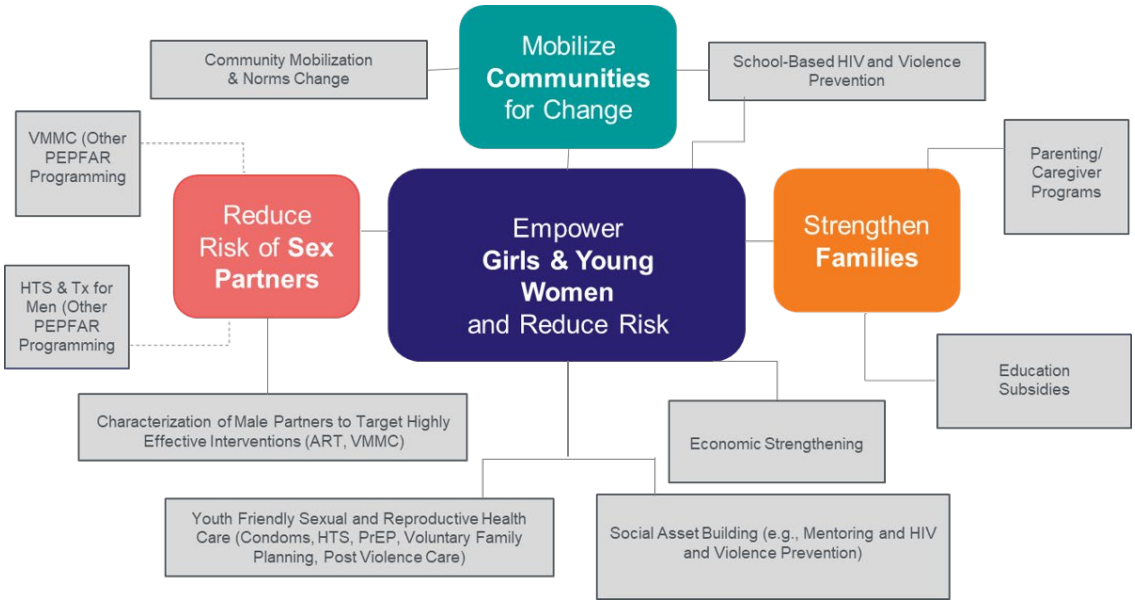
Modeling data of new HIV diagnoses in ANC among AGYW since 2015 continue to show impressive declines in DREAMS geographic areas in the 10 original countries. As of Worlds AIDS Day 2020, all DREAMS geographic areas showed a decline of new HIV diagnoses among AGYW, and the majority (62%) showed a decline 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,[163] 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)

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

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, AGYW should receive training and support that will prepare them for their roles, including opportunities for professional growth where possible.[164]

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[165], 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.

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

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

Specific sub-groups of AGYW may experience more risk and vulnerability factors as outlined in the DREAMS guidance.[166] 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[167] for details and promising practices on layering and linkage. In COP22, all DREAMS OUs should budget for reliable 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.[168] 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.[169] 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

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[166] Ibid.

[167] Ibid.

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

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

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
- 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[170] and Process Resources[171] on PEPFAR SharePoint.

DREAMS Maintenance. As DREAMS SNUs reach saturation, country teams should develop and implement maintenance plans to maintain saturation across all DREAMS age bands to sustain DREAMS contributions to prevention and epidemic control. Maintenance planning should be a fluid, country-led process that must balance potential maintenance cost savings against the needs of other DREAMS investments, such as geographic expansion or implementation of contextual interventions. Country teams should explore partner government, private sector, and other non-DREAMS programming and resources for delivering components of the core package

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

based on AGYW's needs and overall planning for post-epidemic control. When developing maintenance plans, country 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 band in a DREAMS SNU is saturated, but at least one age-band is still in process
    - Full saturation: When all age bands have been saturated
- Maintain core package of interventions by age group,
- Target for smaller numbers of AGYW; consider that the remaining AGYW who have yet to complete the DREAMS program may be among the hardest to reach (e.g., out of school AGYW, young women who sell sex or engage in transactional sex), and
- Account for epidemic control within country and/or SNU

To maintain saturation in each DREAMS SNU, country teams should appropriately target to reach AGYW the most vulnerable to HIV, including those who "age-in" to DREAMS and "age-up" between DREAMS age bands in maintenance SNUs. Maintenance targets are expected to be reduced; in a phased maintenance approach, targets should shift to the age band(s) not yet saturated. Data sources used to estimate saturation (e.g., census, population size estimates, etc.) should be used to inform targets set in maintenance districts. Please see the Program Completion and Saturation section of the DREAMS Guidance for more information.[172]

To support the scale-up and sustainability of DREAMS and other critical HIV prevention interventions for AGYW, teams should initiate planning with key stakeholders to support the future transition of elements of the core package into the existing work of national ministries and local governments.

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[173]) should be reported under OVC_SERV (as well as under AGYW_PREV). This requires co-planning and tracking of targets, budgets, and

[172] PEPFAR. (2021). PEPFAR DREAMS Guidance (revised). https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf
[173] 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

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 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[174] and UNAIDS Global Standards for Adolescents[175] 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

[174] 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/

[175] 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

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.

***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[176] and PEPFAR Technical Guidance in the Context of the COVID-19 Pandemic[177] 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

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[176] 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

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

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 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[178]

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[179]), 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).

[178] PEPFAR. (2021). PEPFAR DREAMS Guidance (revised). https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf
[179] Health Policy Project. (2014). *Gender and sexual diversity training: A facilitator's guide for public health and HIV programs*. 398_GSDGuide.pdf (healthpolicyproject.com)

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-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.[180,181] 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.[182] 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 GeneXpert 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

[180] 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

[181] 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

[182] 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

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 the current DREAMS Guidance[183] 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[184]

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

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

[184] 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.

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 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[185] 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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[185] 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.[186] Essential HIV case-finding services for PBFW and children should be maintained, including maternal testing and diagnostic

[186] 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

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.[187]

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

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:

- 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)

[187] 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

- 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.[188, 189] Pregnant and breastfeeding AGYW are also at increased risk of poor outcomes, including mother to child transmission of HIV, maternal mortality, and stillbirth.[190] 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-

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[188] 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

[189] 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

[190] 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

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, 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):

- 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.[191] 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 breastfeeding, the risk of vertical transmission is extremely low.[192,193] 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.[194,195,196] 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.

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

[192] 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

[193] 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

[194] 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

[195] 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

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

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).[197] 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.

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 where treatment is provided to patients who test positive for syphilis.

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.[198] In addition, women who acquire HIV during pregnancy have a high risk of

[197] WHO global guidance on criteria and processes for validation: Elimination of Mother-to-Child Transmission of HIV and syphilis, 2nd edition, Nov 2017.
[198] 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

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.[199] Close to one quarter of infant infections globally are estimated to occur because of maternal acquisition of HIV during pregnancy and breastfeeding.[200] It is for this reason that effective strategies for the prevention of mother to child transmission (PMTCT) should include routine HIV testing of PBFW 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.[201] 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.[202]

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[203] noted that "pregnancy outcomes and early infant growth did not differ

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Prospective Per-Coital-Act Analysis Among Women With HIV-Infected Partners, The Journal of Infectious Diseases, jiy113, https://doi.org/10.1093/infdis/jiy113

[199] Global AIDS Update 2021: https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update

[200] Ibid.

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

[202] 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/

[203] 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.

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
- 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.[204]

PrEP Initiation and Continuation for Contacts of Index Testing Clients

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).[205] 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

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

[205] 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.

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 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.[206,207] It is important to note that there are some differences in the approaches and requirements for

[206] 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.

[207] 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.

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.

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

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.[208] 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.[209] 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 the modeling groups 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 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)[210] against survey and VMMC program data to ensure that the coverage and target estimates are as accurate as possible. The

[208] 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/
[209] 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
[210] www.vmmcipt.org/

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. DMPPT2 functionalities are being transitioned into the UNAIDS annual estimates process with VMMC coverage estimates outputs from the DMPPT2 exported into the Naomi model or Spectrum. Transition work is nearing completion and outputs should be ready in time for COP planning. Technical assistance beyond the COP planning period is available through Avenir Health to address data issues or discrepancies identified during in-country VMMC data validation exercises.

VMMC should be performed within a minimum package of required 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 (with deferral of surgical circumcision until treated) and treatment/referral, HIV testing prior to circumcision for men and their partner as indicated and 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 sufficiently mature to provide informed consent. 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).[211] 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. 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.

[211] 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

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[212] 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, community engagement, and multisector partnerships. More information is available from the WHO.[213]

HIV Testing: Given low prevalence of HIV infection among VMMC clients, approaches to voluntary HIV testing in VMMC programs should follow existing guidance on targeted testing

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

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

performed in other contexts. Specifically, programs should only test appropriate clients based on risk behaviors and factors, including age and sexual debut and monitor testing yield to tailor testing strategies. 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. Risk assessment tools should be used to target and provide HIV testing to clients at risk of HIV infection. An HTS package that may include HIV counseling, HIV information, and optional HIV testing should be provided. Men who opt out of testing and who may be at risk of acquiring HIV according to the HIV risk assessment should receive information on alternative places and/or methods to test at a later time. At this point, programs should show a clear track record of or plan for decreasing testing among low-positivity groups of clients. Planning for testing in VMMC should be included in the overall COP plans to optimize HTS strategy, assessing testing positivity across modalities, and programming where it adds to the overall strategic mix of HTS modalities. VMMC 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[214] 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

[214] Ibid.

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 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.[215]

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.[216]

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

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

[216] 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

    - Obtain client consent for the selected mode of virtual follow-up
    - 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[217] 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.[218]

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

[218] 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.*[219] *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 monitoring and evaluation. Demand creation for VMMC should include interventions geared toward various segments of the male population as well as secondary audiences

[219] 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.

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.[220]

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 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

220 https://www.usaid.gov/sites/default/files/documents/1864/pepfar_best_practice_for_vmmc_site_operations.pdf

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[221] prepared by the Global 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

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

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.[222]

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.

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

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

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.[223]
- 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.

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

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

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)
- 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. 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 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. **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	HIV testing remains optional, and an HIV test is not required before VMMC. However, HTS should be provided and targeted to clients at risk of HIV. Proper use of validated risk assessment tools is encouraged. See Section 6.2.5.1 for additional information on HTS for VMMC programs. See Section 6.3.1.7 for additional information on risk screening.

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.[224,225] 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[226]

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.

[224] 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

[225] 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

[226] Ibid.

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:

- Routine retesting of key populations as part of minimum standard programming,
- 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**. An ongoing challenge is when programs perpetuate a message of needing to frequently retest low risk, "worried well" individuals who may have recently tested HIV negative or who previously tested HIV positive. This may include persons who are in denial about their status, who may believe they have been "cured" of HIV, or who may have experienced a treatment interruption and wish to reengage in treatment services.

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 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.

Sustainability Planning for HTS

As countries approach epidemic control, HTS will remain essential for ongoing monitoring of programmatic achievements and identifying and following up on new infections to stem further transmission. Sustainability anticipates that the full range of HTS approaches will need to be owned and operated by local governments and community-based or -led organizations. As countries approach and attain HIV epidemic control (Goal 1), it is important to build lasting public health capabilities (Goal 2) and align partners with a longer-term vision of sustaining HTS services within an overall public health approach (Goal 3). National alignment strategies can begin to assign responsibility for specific elements in the strategic mix of HTS delivery with providers capable of delivering them. In addition, building partnerships that tie service delivery functions, including commodity procurement and distribution, with public health surveillance, assessment, and planning functions should be considered as part of an overall vision and plan for supporting sustained epidemic control. (See Sections 2.1.2, 2.2.4, 2.4 and 2.5 for additional considerations regarding program sustainability.)

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).[227] 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

[227] 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

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 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%.[228] 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).[229] 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").[230]

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.

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

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.
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.[231]

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.[232]

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

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

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 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.[233,234,235,236] 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)

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.[237]

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-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.[238]

[233] WHO (2015) https://www.ncbi.nlm.nih.gov/books/NBK316036/
[234] Hsiao et al. (2017) J Int AIDS Soc. 20(Suppl 6):21758
[235] Eaton et al (2017) Clin Infect Dis. 2017 Aug 1; 65(3):522-525.
[236] Lasry et al (2019) PLoS ONE 14(7): e0218936.
[237] Hampanda et al. (2017) https://doi.org/10.1186/s12981-017-0142-2
[238] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext#secd1175567e1778

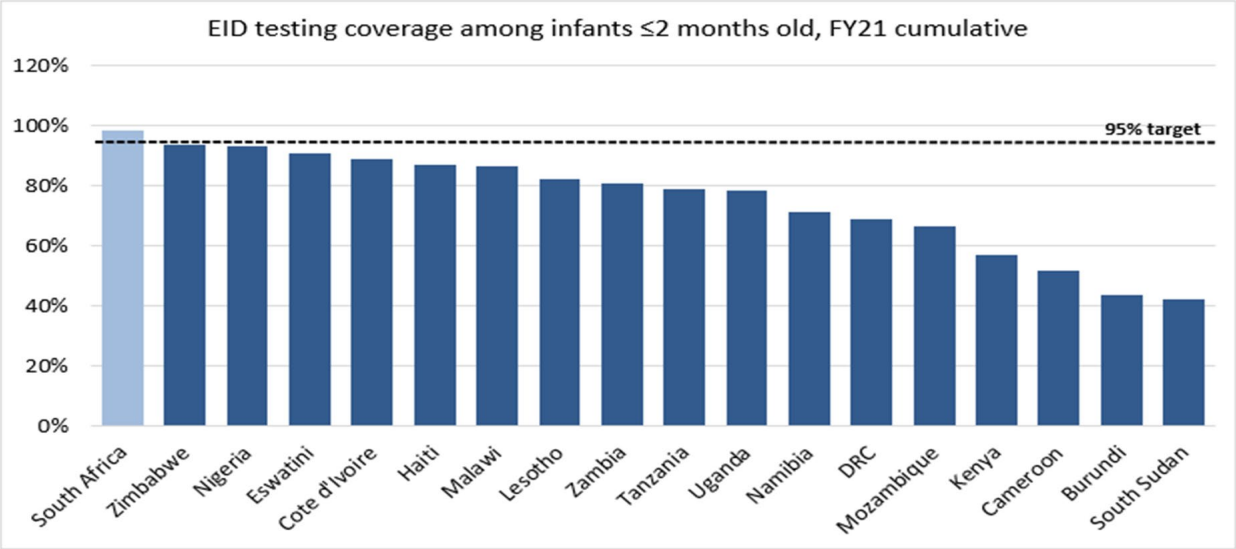
As of FY21Q4, only 1 of the PEPFAR-supported countries has reached the goal of achieving 95% testing coverage of HIV-exposed infants by age 2 months and linking 95% of infants with HIV infection promptly to treatment (Figure 6.3.1.3.1). PEPFAR teams should work with countries and other stakeholders to 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.[239] 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[240] 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 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.

[239] WHO (2021) Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (who.int)
[240] WHO (2018) http://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf

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 required 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) immediate treatment regimens (raltegravir-based regimens are preferred) are available for neonates who are identified as HIV+, as immediate availability of infant-friendly formulations and staff competence in initiating newborn HIV-infected infants on ART is critical to ensure impact of birth testing, and

3) Systems and processes are in place to adequately support mother-baby pairs to remain engaged in care and that infants who initially test negative at birth receive recommended EID services at 4-6 weeks. HIV testing at or near birth will predominantly detect *in utero* infections. Birth testing should complement, not replace, the 4-6-week NAT test.

- 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[241] 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-

[241] 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.[242] 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[243] and Malawi[244] 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[245] 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.

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,

[242] WHO (2019) https://www.who.int/diagnostics_laboratory/evaluations/190918_prequalified_product_list.pdf?ua=1
[243] Jani etal. (2018). AIDS. 32(11):1453-1463
[244] Mwenda et al. (2018) Clin Infect Dis. 10.1093/cid/ciy169.
[245] 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

and outpatient, led to improvements in testing numbers and positivity yield.[246] 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.[247] 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.[248] 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 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-

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

positive infants across multiple countries.[249,250] 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.[251] 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[252] 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. This project led to 100% of enrolled infants receiving EID and results at 6-week well child visits.[253] The main components of the interventions included: MBPs enrolled at 6-week

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[249] 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
[250] https://www.thelancet.com/pdfs/journals/lanhiv/PIIS2352-3018(19)30033-5.pdf
[251] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6401209/
[252] Lorna et al. (2021) https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25651
[253] 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

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.[254]

(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.[255,256]

(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.[257] 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.[258] 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 positively impact early retention, maternal viral suppression, uptake of infant testing services, and integration of maternal and child health services.[259]

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[254] CFM: Improving mother-baby pair retention in integrated maternal and child health and HIV services in Eswatini — PEPFAR Solutions Platform (BETA)
[255] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5922496/
[256] https://www.praekelt.org/momconnect
[257] https://www.hindawi.com/journals/bmri/2016/5625364/
[258] https://icap.columbia.edu/wp-content/uploads/Cameroon-QICIP-Success-Story.pdf
[259] https://differentiatedservicedelivery.org/Models/PostNatalClubs

6.3.1.5 Index Testing

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)."[260]

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 5Cs minimum standards (consent, counseling, confidentiality, correct test results, and connection to appropriate HIV prevention and treatment services).[261] Additional key considerations for implementing safe and ethical index testing services are described below.

- Index testing services should always be voluntary. Index testing is a completely voluntary service offered to persons living with HIV to support them in getting their partner(s) and children tested for HIV. Index testing should always be client-centered and focused on the needs and safety of the index client and their sexual partner(s), needle-sharing partner(s), and/or biological child(ren).

[260] WHO. (2019, December 1). *Consolidated guidelines on HIV testing services*. https://www.who.int/publications/i/item/978-92-4-155058-1
[261] 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

Index clients should be provided with all available and applicable HIV prevention, care and treatment services, whether or not they agree to participate in index testing services. Index clients should not be pressured into sharing the names of their partner(s) or child(ren) and should be informed of their right to decline participation in index testing services throughout the process, not just during the elicitation interview. Individuals may opt-out of index testing services for any or no reason and do not need to provide a reason for not participating in index testing services.

- Informed consent should be obtained prior to the elicitation interview *and* before contacting partners. Informed consent (verbal or written) must be obtained from the index client prior to the elicitation interview and before contacting partners, even when individuals are offered the option of anonymously submitting names and contact information for their sexual and needle sharing partner(s).

  As part of the consent process, providers should give information about the risks and benefits of index testing, answer any questions or concerns raised by the index client, and obtain either written or verbal consent from the index client prior to proceeding with the elicitation interview. Consent should also be obtained prior to contacting partners if the client opts for the provider or contract referral approach. Guidance on how to obtain consent for index testing services can be found in PEPFAR's Guidance on Implementing Safe and Ethical Index Testing. Programs should continually evaluate informed consent procedures to ensure they are properly conducted. Programs may also consider tracking reasons why clients decline index testing services (keeping in mind that clients do not have to give a reason for their refusal) for quality improvement purposes.

- The confidentiality of the index client and all named contacts should be maintained at all times. Programs must have confidentiality protections in place prior to the start of index testing services, including safe storage of client-level data. The identity of the index client should never be revealed and no information about partners should be conveyed back to the index client unless explicit consent from all parties is obtained. Whenever possible, names of contacts other than biological children (e.g., sexual and/or needle-sharing partners) should be kept separate from the names of index clients to prevent accidental breaches in confidentiality. One method for doing this is to assign all index clients a unique ID number. This number can be used in place of the index client's name in all records related to index testing services. Programs may also consider having separate index testing registers for family testing (spouse and biological children) and partner notification (extramarital partners,

same sex partners, needle sharing partners, etc.). Under no circumstances should the name of the index client be shared with community organizations notifying partners in the community; this is to prevent the partner from accidentally learning the index client's identity. Only information required to contact the partner should be shared with these organizations. (See Section 6.5.1.2 for important index testing considerations for key populations.)

- All index clients should be assessed for intimate partner violence and offered first line support if they disclose violence. A risk assessment for intimate partner violence (IPV) should be conducted for each named partner. This assessment includes asking index clients a set of standardized questions to determine if they are currently experiencing or are afraid of experiencing violence from the partner. All index testing sites must be able to provide, at a minimum, an immediate first line support to clients that report IPV, including a safety check and referrals to clinical and non-clinical services (if not provided on site) to ensure survivors have timely access to IPV services. If any concerns regarding IPV are identified, index testing should not continue until the safety of the index client can be assured. Moreover, index testing should not be offered if the site is unable to inquire about IPV and respond appropriately.
- All index testing programs should institute an adverse event monitoring and reporting system. Index testing programs must institute a robust mechanism for detecting, monitoring, reporting, and following up on any adverse events associated with index testing services. At a minimum, this adverse event system should include site-level monitoring as well as opportunities for individuals to provide anonymous feedback (e.g., drop boxes, hotlines, etc.). Where resources allow, programs should include CLM activities as part of their adverse event monitoring systems, and all CLM activities must be appropriately planned to meet the program participants' needs. All reports of serious or severe adverse events (from site monitoring, community monitoring, and/or client feedback) must be investigated and follow-up steps and actions identified and implemented to prevent similar adverse events from occurring in the future. If an adverse event is determined to be a result of a provider's failure to abide by the minimum standards for index testing, he or she should immediately stop offering services until they have been re-trained, and the issue or issues have been corrected. Providers should not be allowed to conduct index testing if remediation proves unsuccessful.

PEPFAR remains committed to ensuring that all PEPFAR-supported sites meet the minimum standards described above through routine monitoring (e.g., the SIMS and other program monitoring activities). PEPFAR teams and Agencies must respond to and immediately

investigate any allegation of unethical behavior, misconduct, or adverse event related to the provision of index testing services.

PEPFAR believes that working collaboratively with diverse stakeholders is essential to improve the quality and effectiveness of the services we support. As such, PEPFAR will continue collaborating with civil society partners, government leaders, and PEPFAR 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.

Operational Considerations for Implementing Safe and Ethical Index Testing Services

This section describes the operational considerations that should be taken into account when implementing index testing services.

Offer index testing to all persons living with HIV, including children and adolescents living with HIV. Index testing should be routinely offered to all persons living with HIV, including children and adolescents, who are either newly diagnosed or attending ART/PMTCT services. It is especially important to offer index testing services to persons living with HIV who are not virally suppressed because of the high risk of HIV transmission associated with unsuppressed viral loads. Index testing programs should also coordinate with early infant diagnosis (EID) programs to ensure HIV-exposed infants are tested by/at 2, 12, and 18 months. (See Sections 6.3.1.3 and 6.3.1.4, and 6.3.2.1 for important EID and pediatric index testing considerations.)

Use the 10-4 approach to implement index testing services. Index testing is a multi-step intervention that requires collaboration between many types of providers and programs for successful implementation. Previous PEPFAR guidance recommended seven steps for implementing index testing. However, these seven steps have been expanded to include three additional steps in response to PEPFAR's Guidance on Implementing Safe and Ethical Index Testing. These 10 steps are summarized in Figure 6.3.1.5.1.

As outlined in step 6, a client-centered approach to index testing includes offering a range of options to support the index client to get each named partner/child tested for HIV. There are four main approaches for notifying contacts of index clients and offering them HIV testing services.

1. Provider Assisted Referral: With the consent of the index client, the healthcare worker (or community extender) directly contacts the client's partner(s) and/or biological child(ren)* and informs them that they were potentially exposed to HIV or informs them that they are eligible for HIV testing and healthcare services. The healthcare worker then offers voluntary HTS to the individual and/or biological child, and maintains the confidentiality of the index client,

partner(s), biological child(ren), biological parent(s) and/or caregiver(s) throughout the entire process.

2. Provider Assisted Delayed Referral or Contract Referral: The index client enters into a "contract" with the index testing provider whereby the client agrees to bring and/or refer their partner(s) and child(ren) to HTS within two weeks. If the partner(s) and/or child(ren) do not access HTS within this period, the provider contacts the partner(s)/biological child(ren)* directly and offers them voluntary HTS while maintaining the confidentiality of the index client, partner(s), biological child(ren), and/or legal guardian throughout the entire process.
3. Dual Referral: A trained provider sits with the index client and his/her partner(s) to provide support as the client discloses his/her HIV status. The provider also offers voluntary HTS to the partner.
4. Client Referral: The index client takes responsibility for encouraging their partner(s) and/or biological child(ren)* to seek HTS. This is often done using an invitation letter or referral slip.

   *If a biological child is younger than the legal age to consent to HTS, the child's biological parent and/or caregiver should be contacted.

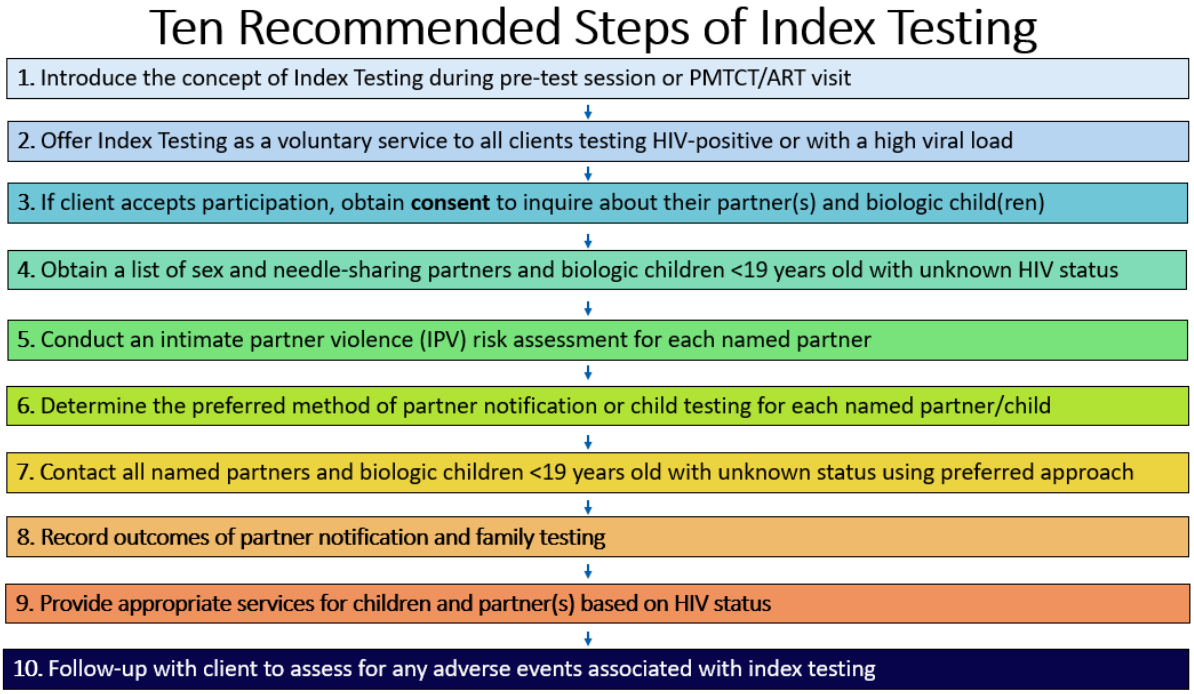
Index testing providers should work with index clients to determine the option that best meets the client's needs and circumstances. Providers should also keep in mind that clients may prefer different options for different types of contacts. Partner assisted approaches do NOT require the index client to disclose his/her HIV status to their partner(s). Testing of contacts can be done anonymously by a trained professional in cases where the index client does not immediately want to disclose his or her HIV status to the partner. Other anonymous pathways to partner notification and index testing, such as targeting HIV and other health services together with index testing and allowing index clients to anonymously submit names and contact information of their partners, should also be made available.

The mnemonic device, 10-4, can help providers remember the 10 steps and four approaches to index testing. Index testing training materials are available on the PEPFAR Solutions Platform. These materials include scripts, job aids, and tools for documenting index testing services that programs can adapt to their own context. Updated training materials will be posted on the PEPFAR Solutions Platform as soon as they become available.

Index testing requires well trained counselors and providers who know how to build rapport with their clients. Index testing services require trained personnel and resources to conduct interviews, notify partners/children, offer HTS, and promptly link individuals to either prevention or treatment services. Training healthcare workers to deliver compassionate, rights-based,

comprehensive index testing services is therefore critical for success. Programs should ensure adequate resources are available to properly train, support and supervise index testing providers, keeping in mind that the elicitation of partners and biological children can take up to 30 minutes per client. Both health care professionals and lay workers (e.g., lay counselors, community health workers) should be trained to provide index testing services to allow them to work as part of a multi-disciplinary team to offer index testing services to all persons living with HIV. Where resources are limited, PEPFAR recommends prioritizing individuals who are newly diagnosed as HIV-positive or virally unsuppressed for index testing services. Programs are encouraged to consider ensuring index testing providers are adequately trained in trauma-informed care.

Figure 6.3.1.5.1 Ten Recommended Steps of Index Testing



Building trust and rapport between the index testing provider and client is key. Anecdotally, countries have noted that while some individuals may only share information about one partner at the time of diagnosis, once they see that there were no challenges with the first partner, they are often willing to share information about additional partners. *Therefore, elicitation of contacts should be considered as an ongoing process rather than a one-time intervention*. More experienced counselors appear to have better results than those who are newer to HTS. These experienced counselors can be called upon to peer mentor newer providers. Programs should also provide supportive supervision visits to index testing providers at least quarterly to provide

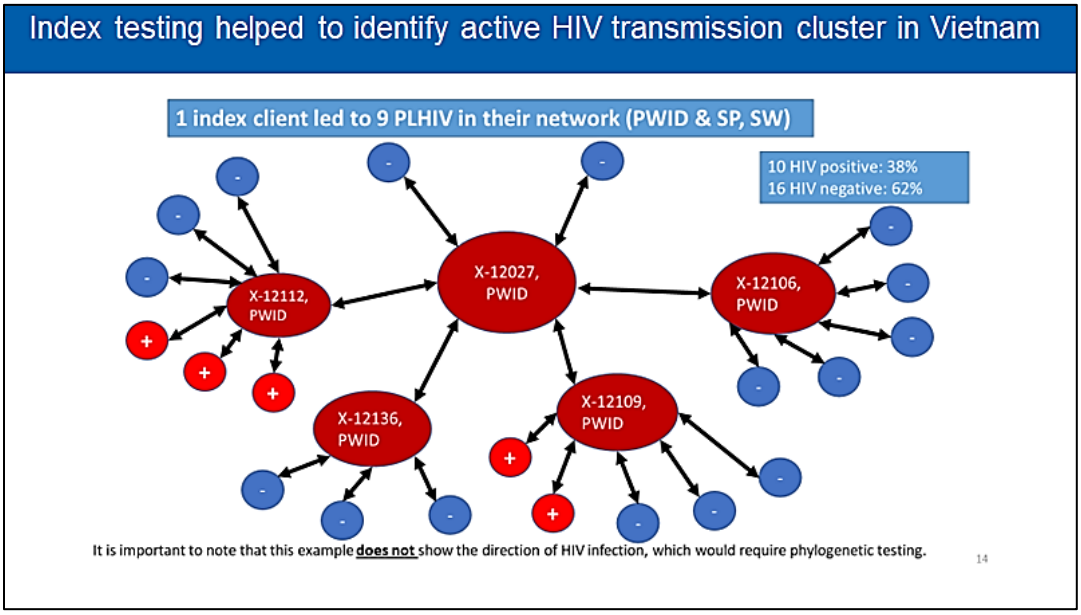
additional support and capacity building. Case conferences, where index testing providers are brought together to discuss strategies for addressing difficult cases, can be another method for allowing these providers the opportunity to learn from each other.

Index testing requires collaboration and cooperation between community and facility programs. Index testing is an intricate intervention with multiple steps that requires consistent collaboration and cooperation between community and facility programs. Facility programs can share contact lists and information for partner(s)/child(ren) in need of assisted partner notification approaches with community implementing partners. These community partners can then trace partner(s) and children, offer them HTS, and link newly diagnosed persons living with HIV to ART services at the facility. They can also assist with re-engaging into ART services individuals previously diagnosed with HIV yet who have experienced an interruption in care or treatment. Geographic coordination and collaboration will also be needed between sub-national units to reach contacts who may not live in the same district or province as the index client.

Organizations should establish a memorandum of agreement articulating expectations for collaboration and a data sharing agreement in place **before** beginning index testing services. This agreement should include a description of how each organization will maintain the confidentiality of client information and how often they will share information. Such memorandums are especially important for bidirectional collaboration between community and facility implementing partners. A data sharing template can be found on the PEPFAR Solutions Platform.

Offer index testing to all contacts living with HIV until the sexual network Is completed. Programs have traditionally been more successful in reaching the spouse or main sexual partner of an adult index client but have had more difficulty reaching additional sexual partners. Programs should reach beyond the index client's principal sexual partner to other sexual contacts, remaining consistently adherent to the PEPFAR minimum standards for safe and ethical index testing. In addition, when a partner tests HIV seropositive, he/she/they become(s) a new index client, and the index testing process starts over from the beginning. Programs should continue to offer index testing to all contacts living with HIV until the sexual network is complete. In Vietnam, this approach led to the discovery of an active HIV transmission cluster and nine newly diagnosed individuals living with HIV from a single index case (Figure 6.3.1.5.2).

Figure 6.3.1.5.2: Demonstration of how Index Testing Services Helped Identify an Active HIV Transmission Cluster in Vietnam



Link all named contacts to appropriate services based on their current HIV status. The goal of index testing is to break the chain of HIV transmission by offering HTS to persons who have been exposed to HIV and linking them to appropriate services based on their HIV status. All named contacts who test HIV-positive should be immediately linked to HIV treatment and, if applicable, to PMTCT services. Contacts who are HIV seronegative, including those in a serodifferent relationship with the index client, should be linked to person-centered HIV prevention services including sexual and reproductive health services, condoms, PrEP, VMMC, and DREAMS. (Please see the following Sections for specific guidance on person-centered prevention strategies: Section 6.2.4 - Prevention for Women and PMTCT, Section 6.2.5 - Prevention for Men, and Section 6.5.1.1 - Prevention for Key Populations.)

Integrating Index Testing with Other HIV Testing Approaches

Index testing services should be integrated into complementary and synergistic HTS approaches to maximize the number of contacts who are reached with HTS. These approaches include provider-initiated testing and counseling (PITC), HIV self-testing (HIVST), and social network strategies (SNS).

The PITC modality accounts for the highest volume of tests and diagnoses in many PEPFAR-supported countries. All persons living with HIV identified through the PITC modality should be offered index testing services. HIV testing providers in PITC programs should be cross trained

in how to conduct index testing services to facilitate the integration of these two modalities. Similarly, TB providers, who often do both TB and HIV testing, should be trained on index testing services given the high rates of TB/HIV co-infection in many countries. (See Section 6.3.1.7 for further information on PITC.)

HIVST is another option for offering the contacts of index clients HTS. Index clients can be given HIVST kits to take to their sexual/PWID partner(s) and/or biological child(ren) (≥ 2 years of age) to screen them for HIV. Providing HIV self-test kits also allows index clients to broach the topic of HIV testing with their partner(s) without the need to disclose their own HIV status first. It also provides them with the option to test with their partner(s) if they so choose. All contacts with a reactive (positive) HIV self-test kit will need to be linked to further HIV testing services and promptly linked to appropriate HIV prevention and treatment services. (See Section 6.3.1.6 for additional information on HIVST.)

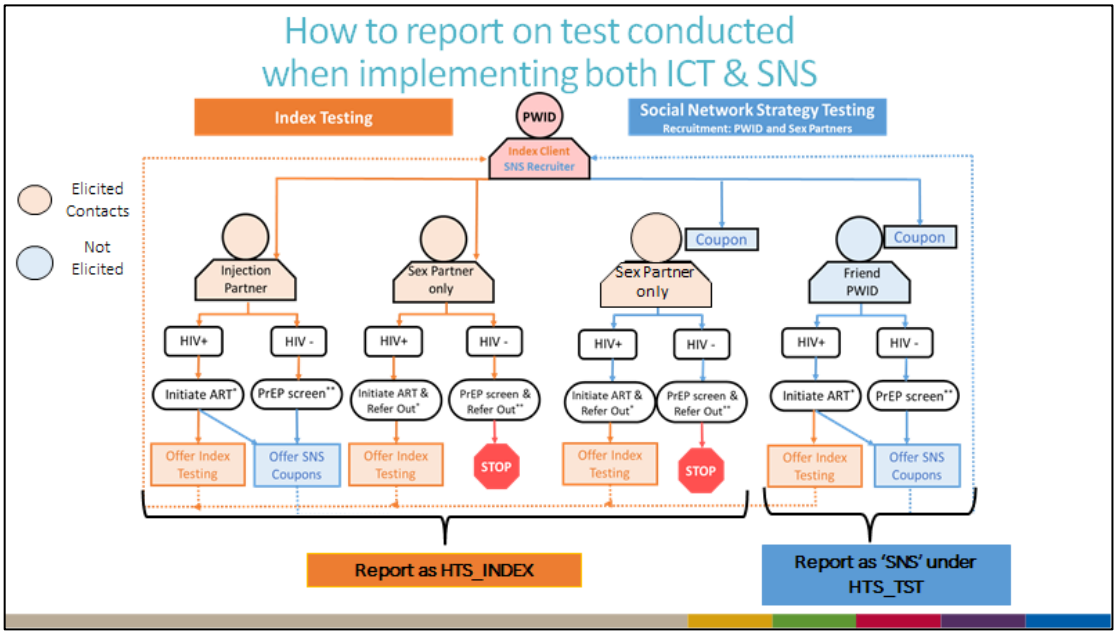
Social network strategies (SNS) can complement index testing in two ways:

1. There may be contacts that the index client does not disclose during the elicitation process who need to be tested for HIV. Asking clients to identify other individuals in their social network who may be at high risk for HIV and in need of an HIV test allows index clients to name these contacts without necessarily revealing that they are a sex or needle sharing partner. Similarly, providing recruitment coupons to an index client allows the individual to recruit their undisclosed contacts for testing.
2. Index clients may have contacts that they would like to notify and refer on their own (e.g., the client referral approach). Providing recruitment coupons to the index client provides an alternative, less direct way for them to encourage their partner(s) to receive HTS without the need to directly tell the partner that they have been exposed to HIV and need to get tested.

In most situations, the counselor conducting SNS may not be the same counselor providing index testing services. Also, since recruits (individuals who return through the SNS approach) are not routinely asked about their relationship (i.e., sexual/needle-sharing partner or acquaintance with similar risk), it will be difficult for providers to track if the recruit is an elicited contact of an index client or someone from the social network. Therefore, in accordance with MER 2.6 guidance, when someone returns with a SNS coupon the individual should be reported under the HTS_TST SNS modality (if not named by the index client during the elicitation process), or under index testing (if the person is a named contact). The IP should be tracking SNS as a stand-alone testing modality if they are conducting other community-based approaches that are also coded as ‘other community.” Figure 6.3.1.5.3 provides further

guidance on how to report on MER indicators when implementing both index testing and SNS. See Section 6.5.1.1 for additional considerations for prevention for Key Populations.

Figure 6.3.1.5.3: Guidance on how to report on MER indicators when implementing both index testing and social network strategies



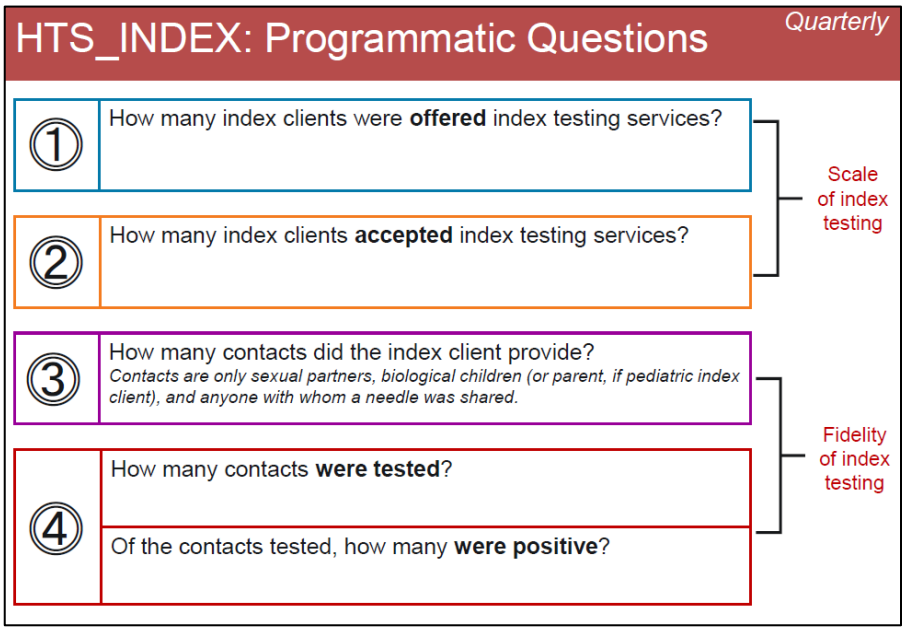
Data Utilization to Scale-Up and Monitor Index Testing Services

Over the past five years, countries have made significant progress in implementing index testing services. However, many countries have not yet fully scaled-up index testing services and the quality of index testing programs varies widely. Programs should use the index testing cascade from the HTS_INDEX indicator to monitor the scale and fidelity of index testing services (Figure 6.3.1.5.4).

Comprehensively understanding and reviewing the index testing cascade is critical to ensure that gaps are closed and areas for improvement are identified. The denominator for this cascade should include all newly diagnosed individuals (HTS_TST_POS) and individuals with an unsuppressed viral load. Programs should aim to offer index testing services to all index clients identified. There is no predetermined expected testing positivity for biological children, and each OU should determine the appropriate index testing positivity for adult contacts as necessary for the local epidemiological context. Index testing positivity should be disaggregated by age and sex (especially separating adult vs. pediatric contacts (≥15 years and <15 years, respectively) to better understand gaps and identify areas for improvement along the cascade. (See Section 6.3.2.1 for further guidance on pediatric index testing considerations.) Where

available, programs should use recency testing data to identify geographic and demographic areas or groups with high rates of recent transmission, and target index testing and other HIV services to these areas. (See Sections 6.6.8.1 and 6.6.8.2 for additional recency testing considerations.)

Figure 6.3.1.5.4: Key Programmatic Questions to Monitor the Scale and Fidelity of Index Testing Services



Importantly, no single data source can fully monitor the quality and accountability of index testing services. Programs should use a variety of sources including minimum site assessment results, SIMS, and MER to comprehensively understand what gaps may exist in implementing safe and ethical index testing services and the remediation efforts that are needed. Panorama's Patient Experience dossier allows programs to review SIMS standards for index testing (related to confidentiality, safety, connection to services, voluntariness, and consent) in conjunction with MER index cascade data. Community-Led Monitoring can be another important component for monitoring the quality of index testing services. (See Section 3.2.3 for additional guidance on Community-Led Monitoring.) Where resources and community interest allow, PEPFAR teams should work with civil society organizations and people living with HIV networks to monitor index testing services to ensure they meet the needs of beneficiaries. The Quality Assurance and Accountability section of PEPFAR's Guidance for Implementing Safe and Ethical Index Testing describes these monitoring and action plans in greater detail.

6.3.1.6 HIV Self-Testing

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.[262] In November 2019, WHO issued guidance that HIVST should be offered as an approach to HIV testing services.[263]

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, compared to standard facility-based HTS and positivity and linkage rates are comparable to facility-based testing.[264] HIVST is acceptable and feasible in a variety of settings and populations, and potential social harms and misuse are rare.[265] 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.[266]

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. Due to increased sensitivity, blood based self-tests are preferred over oral fluid self-tests, if feasible.

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

[263] 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

[264] 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

[265] 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

[266] 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

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 *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.[267] Linkage rates can be improved when linkage support interventions are included with HIVST kit distribution.[268] 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

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[267] 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

[268] 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

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 of the British Medical Journal[269] and the Journal of the International AIDS Society.[270]

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,[271] 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.[272]

During COVID-19, some settings experienced disruptions to HIV services and began using HIV self-tests to maintain essential services–including for initiating and monitoring ongoing PrEP. WHO supports the use of HIV self-testing during COVID-19 as an interim measure[273] and is currently reviewing evidence on the use of HIV self-testing for oral PrEP initiation and

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[269] 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

[270] 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

[271] 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/

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

[273] WHO. (2020, June 1). *Maintaining essential health services: operational guidance for the COVID-19 context, interim guidance*. https://www.who.int/publications/i/item/WHO-2019-nCoV-essential_health_services-2020.2

monitoring; updated WHO guidance is anticipated to be available in early 2022. Oral fluid-based HIV self-test is usually not recommended for recipients of PrEP due to lower sensitivity. However, providers could consider use of these tests when other options are not available, especially in situations when the individual has been consistently adhering to PrEP.

Procurement of HIVST Kits

As of September 2021, four HIVST kits below have been pre-qualified by WHO:

1. Chembio Diagnostics HIV self-test (SURE CHECK HIV): this blood-based test, which detects antibodies to HIV-1/2, demonstrated sensitivity of 99.4% and specificity of 100%, when comparing untrained HIV self-test users to trained professionals. This HIVST was pre-qualified by WHO in November 2019.
2. OraQuick HIV self-test kit: this oral/buccal mucosal test kit has a sensitivity of 92% and specificity of 99%. This HIVST can be used in individuals ≥2 years of age and used in children when supervised by a caregiver. OraSure Technologies guarantees a $2.00 USD price point for all customers and countries (excluding freight, importation duties and taxes, and in-country delivery costs)
3. Mylan HIV Self-test: manufactured by Atomo[274] , this blood-based assay with a sensitivity of 99.8% and a specificity of 99.8%, was pre-qualified by WHO in July 2019. This kit can now be purchased for programmatic use and is procurable through a Unitaid agreement at $1.99 US (excluding freight, importation duties and taxes and in-country delivery costs) for 135 countries, from March 2021 through December 2026.
4. INSTI HIV blood-based Self-test: manufactured by bioLytical, Canada, this blood-based INSTI assay has a sensitivity of 99.8% and a specificity of 99.5% and was pre-qualified by WHO in November 2018.[275]

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.

[274] WHO. (2019, October). *Prequalified In Vitro Diagnostics Public Report.* https://www.who.int/diagnostics_laboratory/evaluations/pq-list/191003_amended_pqpr_0320_090_00_mylan_hiv_self_test_v2.pdf
[275] WHO. (2021). *Prequalified In Vitro Diagnostics*. https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

Monitoring and Reporting HIVST Kit Distribution

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)

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.[276]

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.

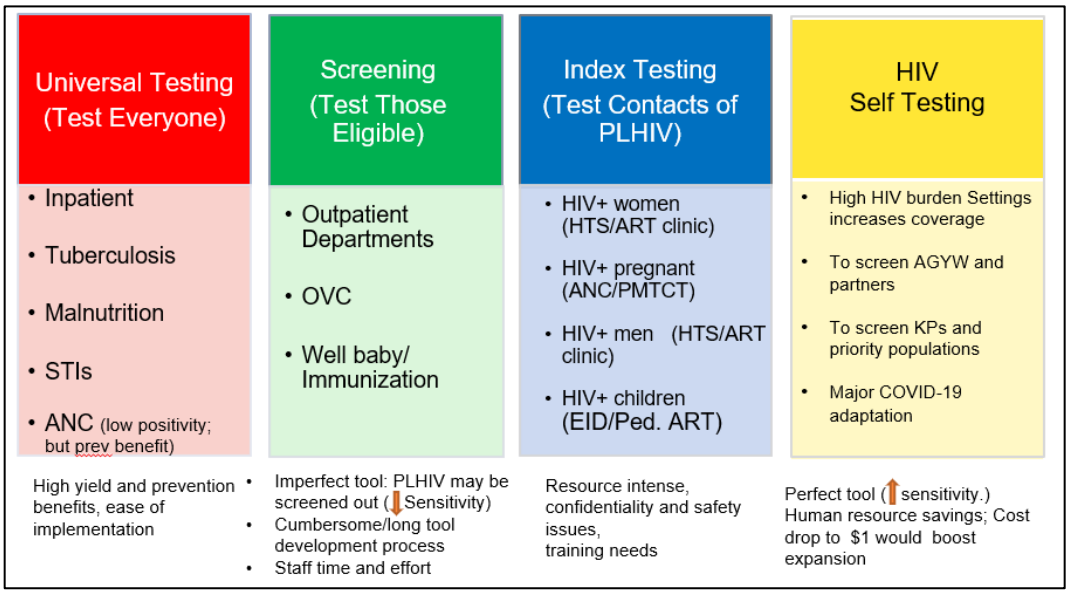
[276] Cohn, J., Whitehouse, K., Tuttle, J., Lueck, K., & Tran, T. (2016). Paediatric HIV testing beyond the context of prevention of mother-to-child transmission: a systematic review and meta-analysis. *The lancet. HIV*, *3*(10), e473–e481. https://doi.org/10.1016/S2352-3018(16)30050-9

Of the four strategies outlined in Figure 6.3.1.7.1, 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.[277] (See Section 6.3.1.6 for additional HIV self-testing guidance and considerations.)

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

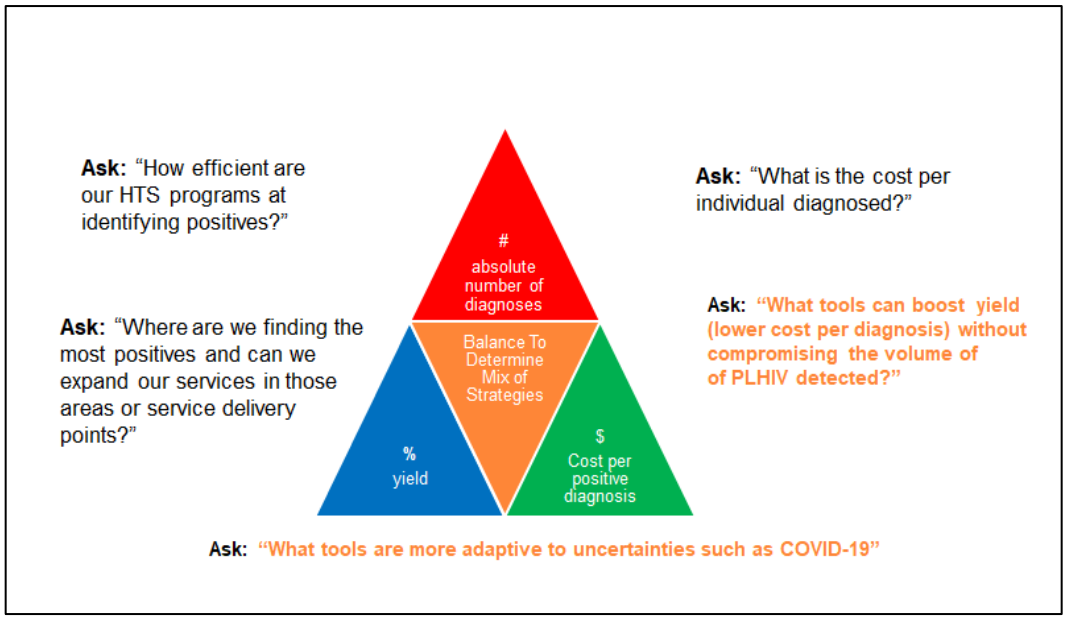
It is important to align HIV case finding and testing policies with data on ART coverage, potential gaps in testing, cost of testing (across all funders), and COVID-19 mitigation efforts (Figure 6.3.1.7.2). In generalized epidemics, hospital medical wards usually have a high concentration of persons 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.

Figure 6.3.1.7.1: Strategies to Strengthen Case Finding through PITC



[277] 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

Figure 6.3.1.7.2: PITC Decision-Making Considerations



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 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.[278]

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*.[279]

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 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,

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

[279] 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

- 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.[280]

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 had poor health in the last 3 months or been hospitalized, swollen lymph nodes,

[280] 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

intermittent diarrhea, oral thrush[281] history of TB or TB symptoms, pus coming from ear, discharge, or sores in genital area.[282,283,284,285]

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

Using 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. HIV risk screening tools have been promoted in PEPFAR guidance and applied in at least 14 countries (12 Africa; 1 Asia; 1 Europe). Reports on HIV and TB screening tool indicate extreme variability in sensitivity, specificity, and tool performance among countries and between population groups. Tools are heterogenous in the types and content of screening questions (e.g., time since last test as excluding criteria may be 3, 6, or 12 months). Some countries are demonstrating improvements, as evidenced by increased testing positivity *and* increased volumes of individuals newly diagnosed with HIV. However, standardized implementation has been challenging due to the time taken for development, validation, and uptake.

PEPFAR has not funded rigorous evaluation of HIV screening tools in most countries and given the increased human resources needed to enhance the uptake and utilization of screening tools, the cost benefits of these tools are yet to be assessed. However, many lessons have been learned:

- Tools should strive to do no harm while balancing optimizing testing positivity and case finding volume
- Where possible, continue to advocate for more rigorous assessments by context and population.

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

[282] 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;

[283] 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

[284] 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

[285] 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

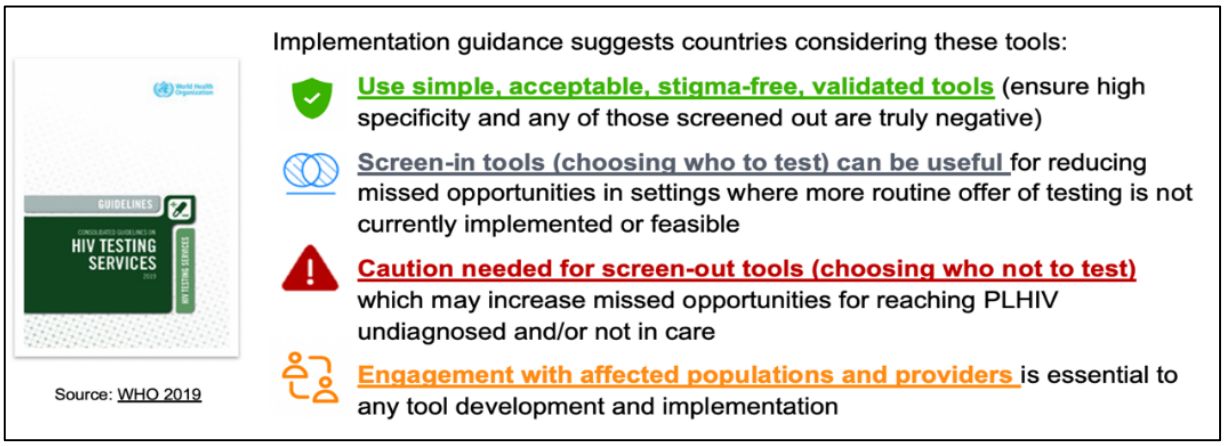
- The systems built around the screening tool are critical to success beyond sensitivity and specificity of the question sets. There are critical human resource needs, strategies for privacy and client flow, records marking, counseling quality and sensitivity of questions asked appropriately in safe spaces.
- Programs must assess outcomes/performance with testing positivity and case finding volume.
- Maintaining options for monitoring coverage of screening is important.
- The use of HIVST in clinical settings as a screening tool has shown promise (Malawi and South Africa have provided strong examples).

The rationales for and benefits of implementing HIV screening tools are multifold:

a. Determine who is at risk and provide strategic, focused testing services by systematically offering HTS to individuals at risk for HIV acquisition and minimizing unnecessary retesting.
b. Implement cost-saving measures through allocative efficiency (greatest impact for lowest cost) and streamlining testing in settings with HRH challenges.
c. Increase risk awareness/perception through HTS counseling.
d. Inform resource prioritization for testing (e.g., p24 Ag, RNA) and prevention (e.g., PrEP) services.

WHO has conducted systematic reviews and has provided recommendations and guidance for HIV screening tools (Figure 6.3.1.7.3).

Figure 6.3.1.7.3: WHO Recommendations for HIV Risk Screening[286]



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

Although those seeking outpatient services are generally less ill than those admitted to inpatient wards, in generalized epidemic settings, targeted HTS should also be implemented in medical 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.[287] In order to avoid being overly reliant on individuals presenting to a facility with symptoms (e.g., advanced HIV disease), PITC programs should leverage *validated*, screen-in* risk screening tools to ensure that at-risk individuals are offered HTS and not prematurely excluded from receiving HTS. Programs must balance testing in this context with additional targeted and active case finding approaches.

*A validated HIV risk screening tool meets specific conditions:

1. Is non-stigmatizing (i.e., sensitive questions are asked in private spaces)
2. Has high sensitivity (i.e., reduces false negatives and does not screen out or misclassify a large % of true positives as not at risk); and
3. Must be easy and quick to administer.

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.

[287] 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

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.[288] 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.*

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

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 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,[289] PEPFAR supports the scale-up of data-driven models such as the Circle of Hope Faith-Engaged Community Posts.[290] 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.[291] Among key populations, HIV testing uptake is highest when combined with

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[289] 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

[290] 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*.

[291] 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

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.[292]

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 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

[292] 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

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.[293] 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.[294] 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

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,

[293] 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

[294] 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.[295]

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.

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

SIMS 4.1 includes a list of existing Core Essential Elements (CEEs) related to Standards for Monitoring Ethical and Safe Services and new CEEs were implemented in 2020 to align with PEPFAR's minimum standards for safe and ethical index testing. Programs are encouraged to incorporate SIMS assessments into their routine site monitoring programs which cover the provision of ethical and safe index testing services to individuals and their contacts (sexual partners, needle-sharing partners, and/or biological children <19 years of age). SIMS tools can be used by any implementing partner as a resource to ensure quality. If conducted in the absence of an USG staff member, this is a called a SIMS self-assessment and is permissible. However, per S/GAC policy, SIMS self-assessment data should *not* be submitted to DATIM. In SIMS 4.2, whose release is planned to align with COP22, it is anticipated that CEEs related to monitoring ethical and safe services will be required in any comprehensive assessment.

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.[296] 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.

[296] 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

6.3.2 Case Finding for Pediatrics

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 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.[297]

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,[298] 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. 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.[299]

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

[297] UNICEF, 2020AIDSinfo I UNAIDS, Coverage of people receiving ART – by age (Global AIDS Monitoring 2020; UNAIDS estimates, 2021.
[298] MER structured database available on PEPFAR Panorama Spotlight, April 2021
[299] 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).

sexual violence are identified, receive appropriate medical care including HIV testing, and 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.[300,301,302] 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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[300] 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

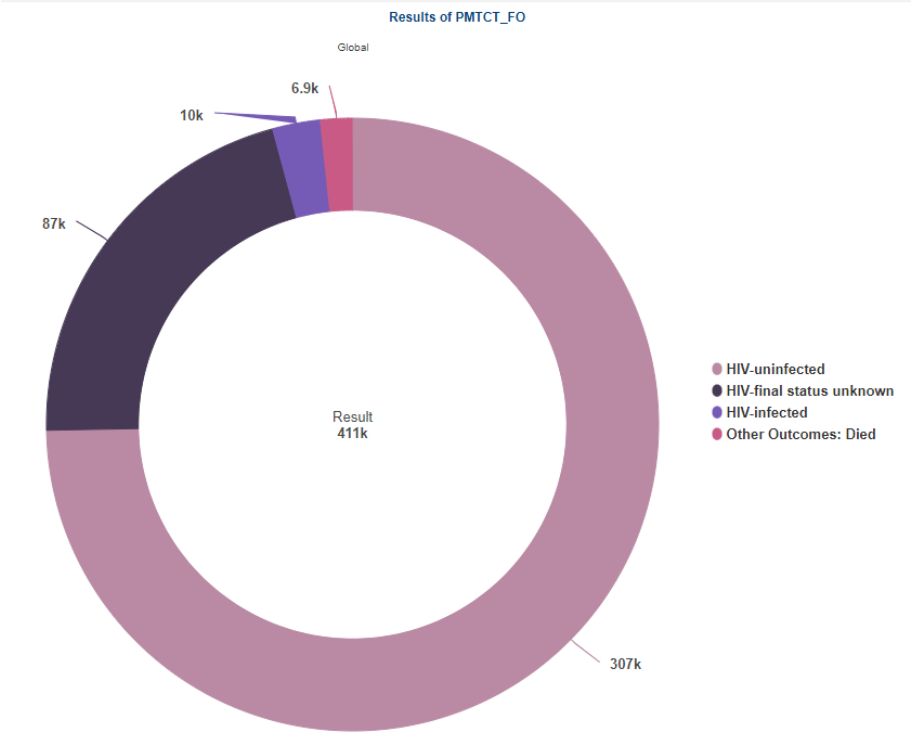
[301] Newell ML, Coovadia H, Cortina-Borja M, Rollins N, Gaillard P, Dabis F; Ghent International AIDS Society (IAS) Working Group on HIV Infection in Women and Children. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. Lancet. 2004 Oct 2-8;364(9441):1236-43. doi: 10.1016/S0140-6736(04)17140-7. PMID: 15464184. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext#articleInformation

[302] 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.[303]



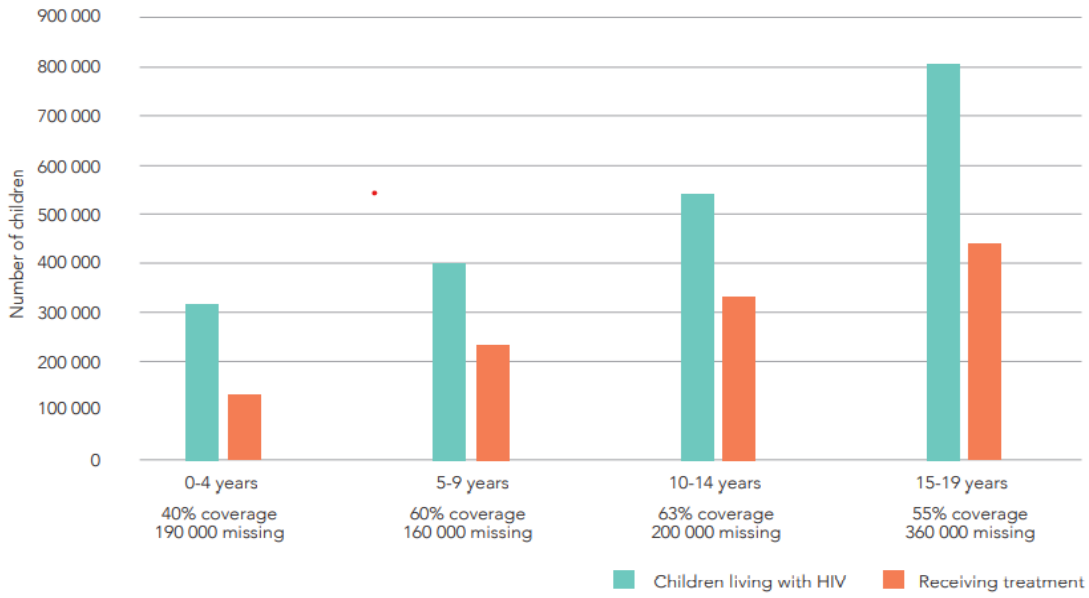
Children and adolescents (≤19 years old)

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

[303] Source: Panorama, *PMTCT-HEI Global* Dossier, *Overall Results of PMTCT_FO*, November 20, 2020 FY20 data

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 HIV-positive children 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 HIV-positive children 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.

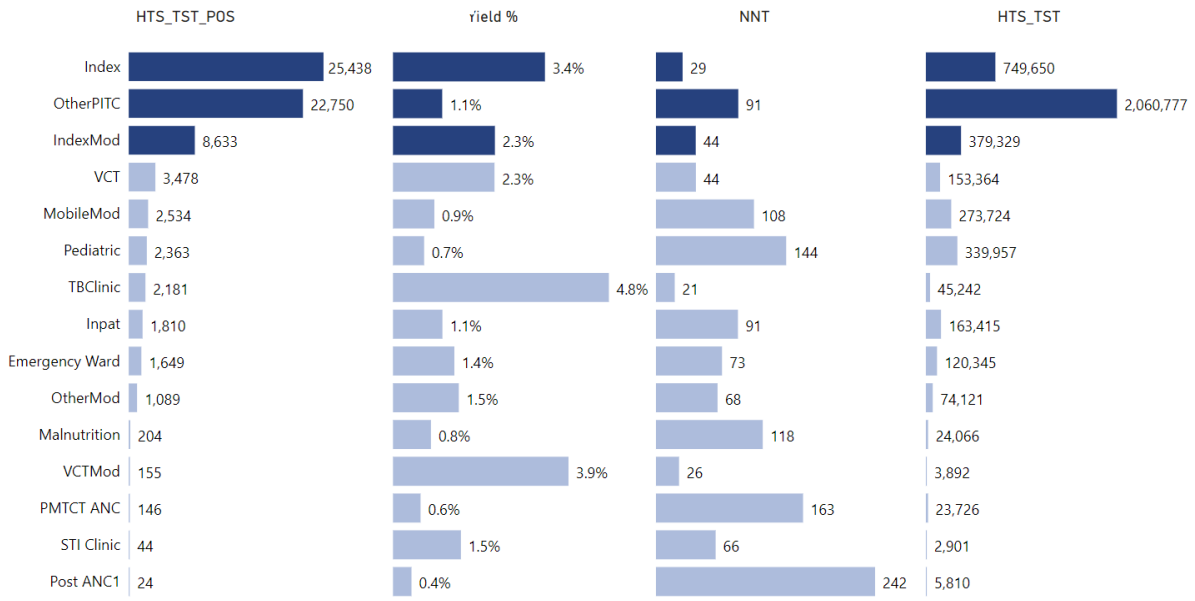
Testing monitoring for these sick entry points should be routinely conducted to ensure that they remain prioritized, effective, and efficient modalities from which to identify CLHIV. Routine inpatient department (IPD) testing is still appropriate in many high HIV burden areas (e.g., prevalence ≥5%). 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-positive 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-positive Test Results for Children (1-14 years) across HIV Testing Modalities by Yield, NNT and Number of HIV Tests, FY21Q1-4[304]



6.3.2.1 Pediatric Index Testing Considerations

The most effective strategy to reach C/ALHIV before they become sick in all settings is through index testing. There is no target yield (or positivity) for children tested through index testing; the yield can be higher than the general HIV prevalence for children even though it is usually substantially lower than that for adults tested through index testing. See Section 6.3.1.5 for more information on index testing.

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

[304] Source: MER Structured Database, November 20, 2021 FY21 APR data

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[305] 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.[306]

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. 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

[305] 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.
[306] 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.

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.[307]

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.

[307] 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

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.[308]

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, 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.[309] However, as with all testing approaches, it is imperative to ensure that youth are not being coerced to conduct an HIVST.[310,311] Although HIVST holds the potential to increase HTS

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[308] 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

[309] Ibid.

[310] 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.

[311] 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

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 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

annual self-testing for HIV in Blantyre, Malawi: A community-based prospective study. PLoS Med, 2015; 12(9):e1001873.

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.[312] 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 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.[313] 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.

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[312] 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.
[313] Ibid.

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.[314] Maternal retesting is increasingly important to help reach targets on eliminating vertical transmission and the UNAIDS 95-95-95 goals.[315]

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.[316]

Evidence shows that:

1. Pregnancy, itself, may be a risk factor for HIV acquisition.[317]
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.[318]

[314] *Adolescent HIV prevention*. (2021, July). UNICEF. https://data.unicef.org/topic/hivaids/adolescents-young-people/

[315] 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

[316] UNAIDS epidemiological estimates 2020. http://aidsinfo.unaids.org/

[317] 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.

[318] Thomson KA et al. Conference on Retroviruses and Opportunistic Infections (CROI), 2018; Boston; Abs. 45

3. Acute HIV infection is associated with elevated viral loads that increase risk of transmission.[319] 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).[320]
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 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.[321] 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.[322] 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

[319] Lehman DA, Farquhar C. Biological mechanisms of vertical human immunodeficiency virus (HIV-1) transmission. Rev Med Virol. 2007;17(6):381–403T
[320] 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)
[321] Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020.
[322] 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

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:

- 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.[323] 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

[323] For facility assessment checklists, see Maternal retesting resource document on PEPFAR SharePoint

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.

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.[324] and target PrEP in high-risk pregnancy and in postpartum/breastfeeding women.[325] Such tools, once adapted and validated, can be incorporated into the comprehensive HIV prevention package during pregnancy and

[324] 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

[325] 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.

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 for Prevention Services

UNAIDS call for "95% of people at risk of HIV infection [to] use appropriate, prioritized, person-centered and effective combination prevention options by 2025."[326] 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 VMMC, PrEP monitoring, ongoing testing services for negative partners of discordant couples, OVC programs, DREAMS programs, ANC, and post-ANC services.[327]

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 significant risk of acquiring HIV should be linked to other prevention services including PrEP programs.

[326] UNAIDS. (2021). *2025 AIDS TARGETS*. https://aidstargets2025.unaids.org/
[327] 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

- **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. While HCW-provided HTS aligned with the national HTS algorithm is preferred, HIV self-testing (HIVST) may be acceptable if other testing options are not available (e.g., due to COVID-19-related restrictions). Due to test sensitivity, blood based HIVST is preferred over oral HIVST. (See Section 6.3.1.6 for additional HIVST considerations.) If HIV seroconversion is detected among an individual taking PrEP, the individual should be immediately linked to treatment services. (See Sections 6.2.4.2 and 6.2.5.2 for additional considerations for PrEP for women and men, respectively.)
- **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.[328] (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)

[328] 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

- Added information about the aging cohort and the burden of co-morbid disease (6.4.2.3)
- (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[329] 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.[330] 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.[331]

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[329] 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

[330] https://clinicalinfo.hiv.gov/en/guidelines/perinatal/dolutegravir-tivicay-dtg

[331] 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.[332,333] 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.[334] 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.[335] PEPFAR supported programs have increased proxy <2-month EID coverage from approximately 72% in FY20 to approximately 84% in FY21;[336] 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).

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

[332] 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.
[333] 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.
[334] Data source: 2020 UNAIDS Estimates (AIDSinfo | UNAIDS)
[335] 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
[336] Panorama. *PMTCT-HEI Global* Dossier. *PMTCT and HEI Cascade* Chapter. [Accessed 30 November 2020.]

during breastfeeding.[337] An infant at high risk of acquiring HIV is one *whose mother* meets any of the following criteria:[338]

- 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 (with or without a negative test prenatally).

The WHO 2018 guidance on *HIV Diagnosis and ARV use in HEI*[339] 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

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.[340] Building upon the momentum from meetings convened at the

[337] 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.
[338] 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
[339] *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
[340] World Health Organization. Global Accelerator for Paediatric Formulations Network (GAP-f). Geneva, Switzerland: World Health Organization; 2021

Vatican31Fbeginning in 2016,[341] 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.[342,343,344] In 2021, WHO released updated pediatric DTG dosing guidelines[345] for pediatric DTG 10 mg formulations, an updated optimal formulary for pediatric ARVs,[346] and implementation guidance for transitioning to optimal pediatric HIV regimens.[347] 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

[341] Rome Action Plan. Paediatric HIV & TB : Rome Action Plan. 2020
[342] 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
[343] 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
[344] World Health Organization. Considerations for introducing new antiretroviral drug formulations for children. Geneva, Switzerland: World Health Organization; 2020
[345] 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
[346] World Health Organization. The 2021 optimal formulary and limited-use list for antiretroviral drugs for children. Geneva, Switzerland: World Health Organization; 2021
[347] World Health Organization. Transitioning to the 2021 optimal formulary for antiretroviral drugs for children: implementation considerations. Geneva, Switzerland: World Health Organization; 2021

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[348] 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.

USG, through PEPFAR, expects that all countries will actively and promptly transition all CLHIV (including those on NNRTI or LPV/r or other protease inhibitors) onto a DTG-based regimen as quickly as possible; full implementation should be completed or at least well underway in COP21; programs that have not completed full transition by the end of COP21 should complete their transition no later than December 2022. 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 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. A fixed dose combination of ABC/3TC/LPV/r (30mg/15mg/40mg/10mg "4-in1" capsules is currently under review by the FDA. Although the product **might** be approved in 2022, PEPFAR does not anticipate procuring small amounts of this product (for <10% who can't tolerate DTG) until **after** OUs have successfully adopted DTG 10 mg and have no remaining pediatric "2in1" LPV/r stock. 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

[348] 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.

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:[349] DTG is a component of the preferred first line ARV regimens in WHO guidance.

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 TAF[c] + 3TC (or FTC) + DTG ABC + 3TC + RAL[d]
Special circumstances[d]	AZT+3TC+LPVr[b]	ABC + 3TC + EFV[e] (or NVP[f]) AZT + 3TC + EFV[e] (or NVP[f]) 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[350]

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

[349] World Health Organization. The 2021 optimal formulary and limited-use list for antiretroviral drugs for children. Geneva, Switzerland: World Health Organization; 2021
[350] 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.

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 Toolkit[351] 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

[351] https://www.newhivdrugs.org/

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 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

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[352] 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[353] and there is no statistical difference between the risk among women taking DTG and the background risk[354] 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.[355] 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.[356]

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

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[352] 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

[353] Zash R et al. Update on neural tube defects with antiretoviral exposure in the Tsepamo study, Botswana, IAS Virtual July 2021 Abs #2562

[354] 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

[355] Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (who.int)

[356] https://clinicalinfo.hiv.gov/en/guidelines/perinatal/table-5-situation-specific-recommendations-use-antiretroviral-drugs-pregnant

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.[357,358] 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 and adults treated for HIV in PEPFAR-supported programs should have been transitioned to either DTG-based treatment, or if <20 kg, an alternative optimal regimen and formulation. **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 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

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[357] 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

[358] 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

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

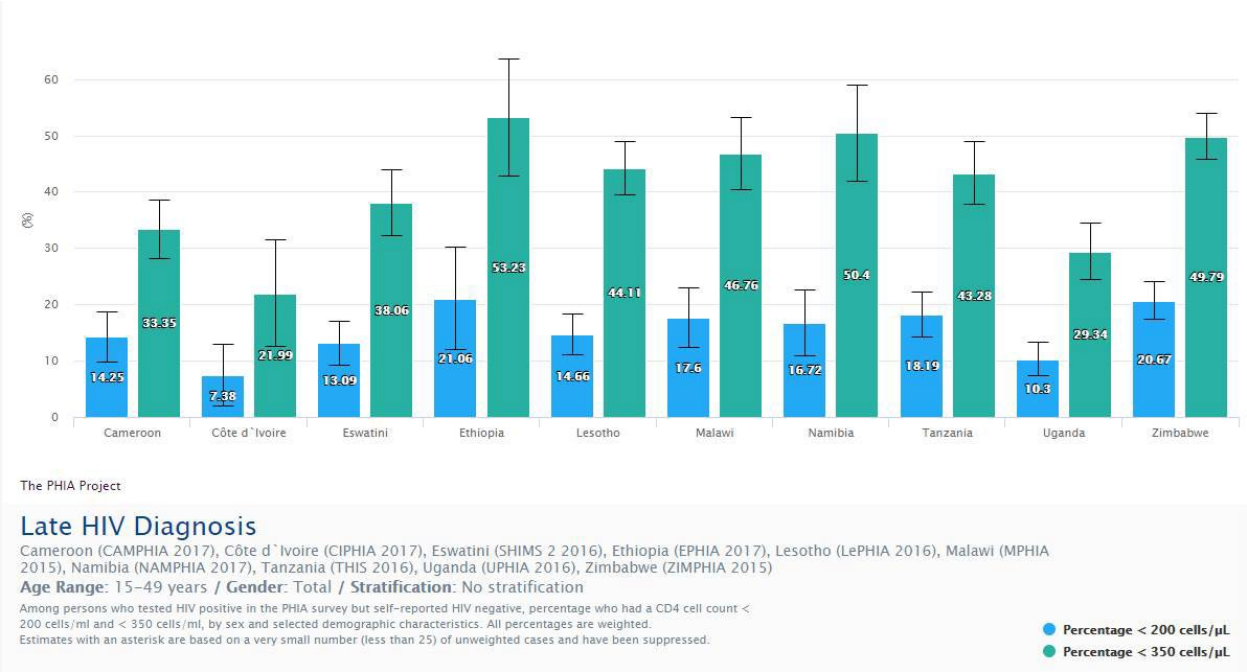
Individuals with advanced HIV disease require a more intensive level of care and experience a greater morbidity and mortality than those without advanced disease. The proportion of people with advanced disease at HIV diagnosis continues to decline with expanded testing efforts and universal ART policies 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.[359] 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 [360] (See Figure 6.4.2.1).

In the AFRICOS cohort, the proportion of individuals with advanced disease remained near 20% until 2019[361] 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.[362]

[359] https://www.who.int/publications/i/item/9789240008045
[360] https://phia-data.icap.columbia.edu/visualization.
[361] Oboho et al. Advanced HIV Disease among Adults in the African Cohort Study (AFRICOS) ID Week 2020
[362] Zaniewski E et al, JAIDS, 2020) http://www.ncbi.nlm.nih.gov/pmc/articles/pmc7343336/

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 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[363,364] 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

[363] https://apps.who.int/iris/bitstream/handle/10665/255884/9789241550062-eng.pdf
[364] 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

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 treatment as indicated. Urinary TB-lipoarabinomannan (LF-LAM) is recommended by PEPFAR in individuals with advanced disease in addition to additional groups as noted in Section 6.4.3.1 on TB case finding. These interventions should happen in parallel, not sequentially. Initiation of TB therapy in individuals who are presumed to have TB or have a positive LF-LAM should never be delayed.
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. 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.[365] 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).[366] 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

[365] https://www.who.int/publications/i/item/9789240031593
[366] https://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_dec2014/en/

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%.[367] PCP has an estimated case fatality rate of nearly 20%.[368] Prompt recognition, and institution of specific 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.[369] 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 one week of amphotericin B deoxycholate (AmB) given with flucytosine. Fluconazole plus flucytosine and AmB with fluconazole are listed as alternatives. Recent data support the use of a single dose of liposomal amphotericin B together with flucytosine and fluconazole, and future guidelines may include this regimen.[370] 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

[367] 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.
[368] 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.
[369] http://www.who.int/hiv/pub/guidelines/cryptococcal-disease/en/
[370] Lawrence D Single high-dose liposomal amphotericin based regimen for treatment of HIV-associated Cryptococcal Meningitis: results of the phase-3 Ambition-cm Randomised Trial IAS 2021 abstract 2370

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 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,[371] 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

[371] https://www.medicaldevice-network.com/news/omega-who-prequalification-visitect-test/

functional, the VISITECT test is preferred as it does not require any instruments to meet low throughput testing needs.

To achieve optimal CD4 testing,[372] 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 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

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

[372] 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

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 July 2020, WHO released a technical brief[373] 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 implementation and outcomes for children. No family should incur fees for the commodities and medications needed to prevent or treat advanced HIV disease.

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[373] World Health Organization. *Package of care for children and adolescents with advanced HIV disease: stop AIDS.* Geneva, Switzerland: World Health Organization; 2020.

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

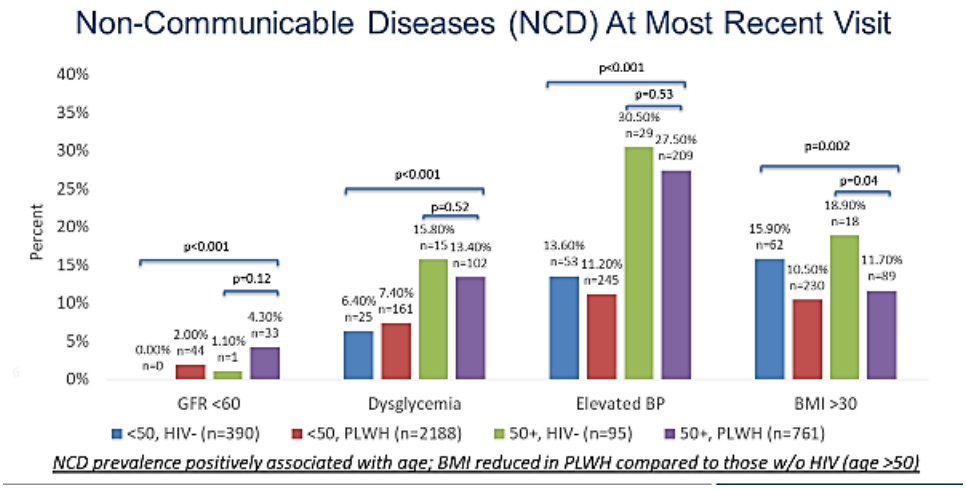
Vaccinations
- Pneumococcal vaccine
- Human papillomavirus
- Measles
- BCG

[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

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.[374] 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



[374] 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.[375,376]

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, PEPFAR has allowed the delivery of drugs for comorbid conditions to be delivered with ART. With additional support of the MOH, ongoing screening and continued long-term treatment of NCDs, may be helpful in reducing morbidity and mortality in this population. The use of differentiated service delivery models may add value.

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.

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[375] 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

[376] 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

6.4.3 TB/HIV

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.[377] 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-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:[378]

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 at each visit at health facilities.[379] 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.

[377] https://www.who.int/publications/m/item/impact-of-the-covid-19-pandemic-on-tb-detection-and-mortality-in-2020
[378] https://www.unaids.org/en/resources/documents/2021/2021_political-declaration-on-hiv-and-aids
[379] 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-

- 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 (i.e., Xpert MTB/RIF Ultra and Truenat MTB Plus with MTB Rif Dx) with rapid return of patient results. People living with HIV, especially those under presumption of extrapulmonary TB and/or severe illness or advanced HIV disease, should be tested by urine lipoarabinomannan (LF-LAM) assays per national guidelines.
   - 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

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**, 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. Chest X-ray screening for adults and adolescents, including computer-aided detection (CAD) software, where feasible, where an abnormal radiograph suggestive of TB is considered a positive screening result.
3. Molecular WHO-recommended rapid diagnostic tests (mWRDs) such as Xpert MTB/RIF Ultra and TrueNat MTB Plus for adults and adolescents.
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.

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.[380] 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.

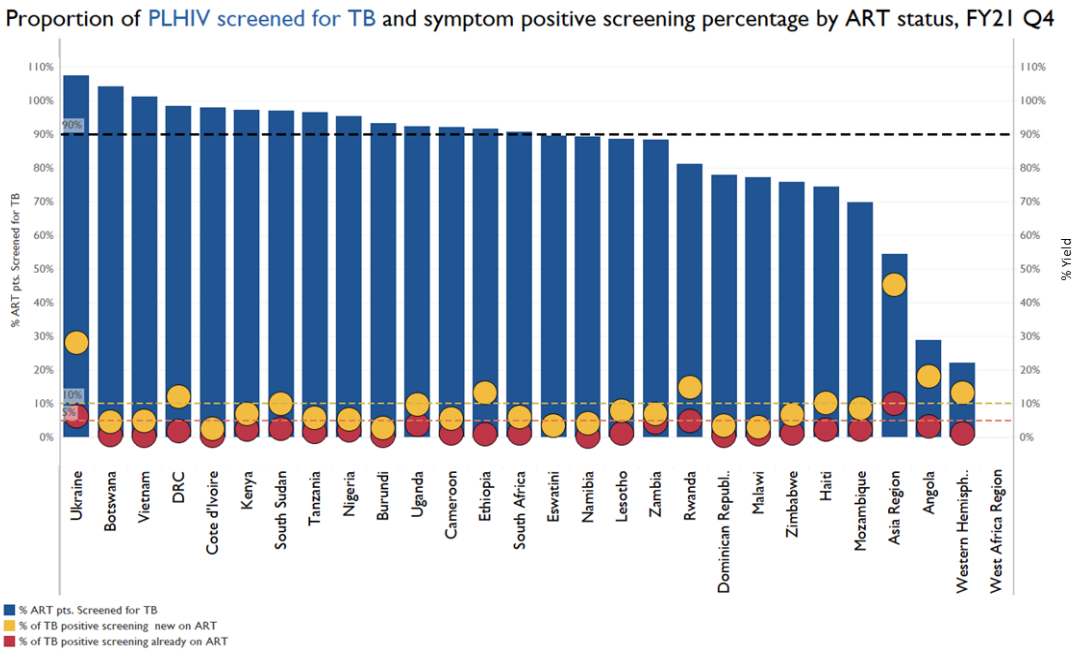
The proportion of people living with HIV expected to screen positive for TB varies widely by the country's TB epidemiology and clinical characteristics (like average CD4 cell count), but as a general rule, countries should anticipate that at least 15% of newly enrolling, ART-naive patients and approximately 5% of previously enrolled patients would screen positive for TB symptoms. Where 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

[380] https://www.who.int/publications/i/item/9789240022614

symptom screening was done poorly and resulted in missed opportunities to prevent TB morbidity and mortality.[381] 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.[382] 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.[383]

Figure 6.4.3.1.1: Screening Yield for TB by ART status in FY21 Q4 (PEPFAR programs)



[381] 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.
[382] 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.
[383] 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.[384] 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 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.[385] Furthermore, there is evidence that the symptom screen has even lower sensitivity (51%) for detecting TB disease among children on ART.[386] 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

[384] 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.

[385] 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

[386] 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.

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 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.[387] In addition, urine should be collected for LF-LAM testing, which should be routinely available for diagnostic testing of children presenting with TB symptoms.[388] Where appropriate, programs should ensure mWRDs testing (e.g., Xpert Ultra, TrueNat MTB Plus, and MTB RIF Dx) for children is done using both sputum and non-sputum specimen types (including stool) according to the WHO policy guidance for each test type.[389] 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

[387] 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
[388] 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.
[389] https://www.who.int/publications/i/item/9789240029415

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.[390]

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 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.

[390] 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

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).[391]

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 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 nucleic acid amplification tests for detection of resistance to Isoniazid (INH), fluoroquinolones, and other second-line anti-TB medicines. 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

[391] WHO Consolidated Guidelines on TB, Module 3. Diagnosis July 2021. Available at: https://www.who.int/publications/i/item/9789240029415

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. Besides contributing to early detection and treatment of tuberculosis, 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.[392] 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 advanced disease regardless of CD4 count

[392] 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/

- 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.

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.[393] 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

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

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.[394]

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

[393] 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

[394] WHO Guidelines. HIV Prevention, Infant Diagnosis, Antiretroviral Initiation and Monitoring. March 2021. https://www.who.int/publications/i/item/9789240022232

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 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 should be offered screening and timely linkage to care and treatment, as well as preventive services including TPT for PLHIV in all settings, i.e., PMTCT/MCH, OVC and Key Populations programs. TB treatment or 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.[395] 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.[396,397] 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

[395] https://www.pepfarsolutions.org/solutions/2019/1/4/tb-hiv-collaborative-activities

[396] 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.

[397] https://www.who.int/tb/areas-of-work/digital-health/Digital_health_EndTBstrategy.pdf

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 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.

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) for the duration of their TB treatment course.[398] 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

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

[398] 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

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).[399] 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 less treatment interruption due to adverse events.[400] 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.[401] 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.

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[399] https://www.who.int/publications/i/item/9789240001503
[400] https://www.acpjournals.org/doi/10.7326/m20-7577
[401] 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

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.[402] 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 continue to be used as the regimen of choice for children.[403,404,405] 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

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[402] 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.

[403] Hsu KH. Isoniazid in the prevention and treatment of tuberculosis. A 20-year study of the effectiveness in children. *JAMA*.1974; 229: 528-533

[404] 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

[405] 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

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[406]

	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% (63-97%)	80.9% and 65.5% (20-93%)
Hepatotoxicity	None	None (2-17%)	None (1.2-1.6%)
Adverse Events	0.6% (G3 only)	None (2-64%)	0.2% (G3 only) (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 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.[407] 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.[408] 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

[406] 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.
[407] Mathad JS, Gupta A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. Clin Infect Dis. 2012;55:1532–49
[408] https://apps.who.int/iris/bitstream/handle/10665/331170/9789240001503-eng.pdf p4, p22

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.[409] 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 tablet for CLHIV >14-24.9 kg.[410] 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.[411]

WHO recommends the consideration of vitamin B6 (pyridoxine) coadministration to PLHIV receiving INH to prevent peripheral neuropathy.[412] 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.

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[409] IMPAACT 2001. CROI https://apps.who.int/iris/bitstream/handle/10665/331170/9789240001503-eng.pdf p.28)
[410] 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
[411] https://www.who.int/publications/i/item/9789240002906

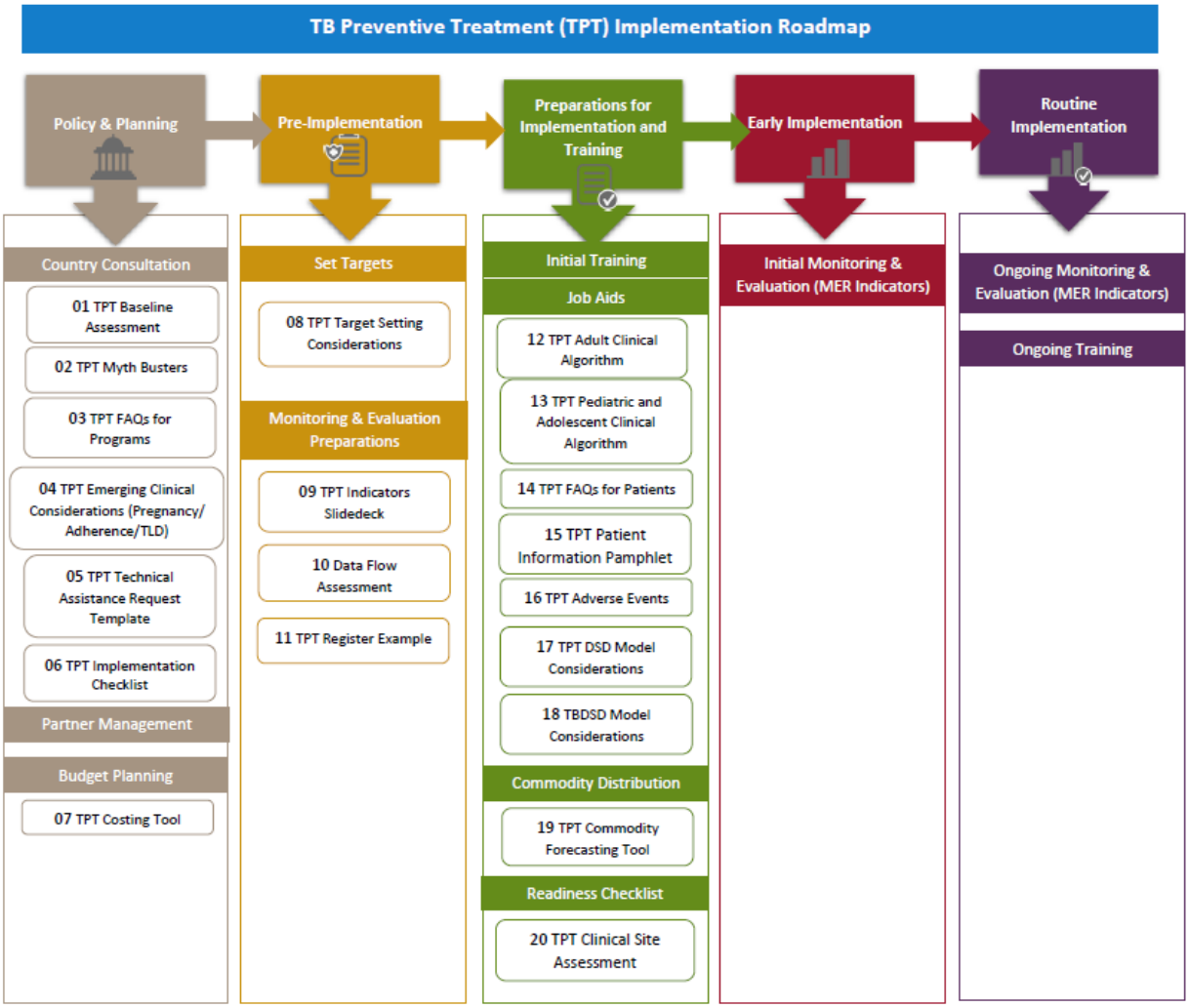
There are many important considerations in the implementation and scale-up of TPT from commodity planning to clinician education to monitoring for adverse events and reporting (see Figure 6.4.3.3.2 which shows TB preventive Treatment Implementation Roadmap). A full suite of tools to assist with program implementation and scale-up is available on PEPFAR Solutions (see TB Preventive Treatment Implementation Tools).[413] 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 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.

[413] PEPFAR Solutions: TB Preventive Treatment Implementation Tools
https://www.pepfarsolutions.org/resourcesandtools-2/2018/9/25/tpt-implementation-tools

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.[414]

[414] https://differentiatedservicedelivery.org/Models/Treatment

Preventing TB Transmission

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

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.[415] 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 2020, and of these 67% died from the disease.[416] Women living with HIV (WLHIV) are six times[417] 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*[418] in 2020 with the following 2030 targets:

- Vaccinate 90% of eligible girls against HPV;

[415]Global Cancer Observatory: https://gco.iarc.fr
[416]Ibid.
[417]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
[418]Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization; 2020.

- 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 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 vaccination, 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.[419] 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

[419] WHO Guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. July 2021.

6.4.4.1) depending on resources, health worker force, and complete attainment of all of the following "benchmarks" prior to transition:

- ≥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 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 does not meet all of the above "transition benchmarks," 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

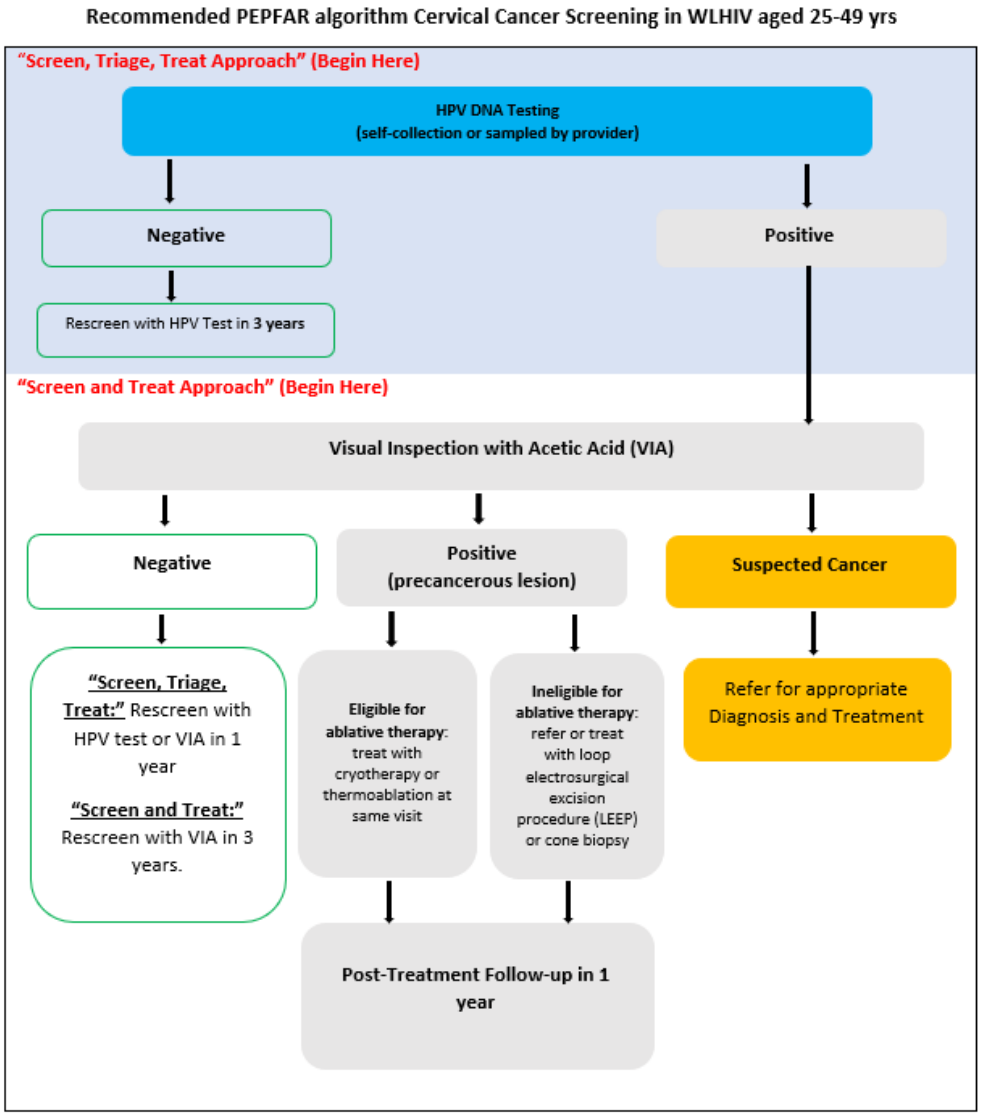
should be available in the ART clinic or in affiliated clinics on-site such as women's health or maternal child health clinics for WLHIV to utilize. We do not recommend screening or treatment services for people during pregnancy or for two months post-partum.

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.[420] 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 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.

[420]Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization 2020.

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

By FY2021 Q2, over 2 million screenings have been done for cervical cancer, of which over 1.9 million were first-time screenings. Of those screened, 6.9% (156,425) were found to need either treatment for pre-invasive lesions or had suspected cancer. 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

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.

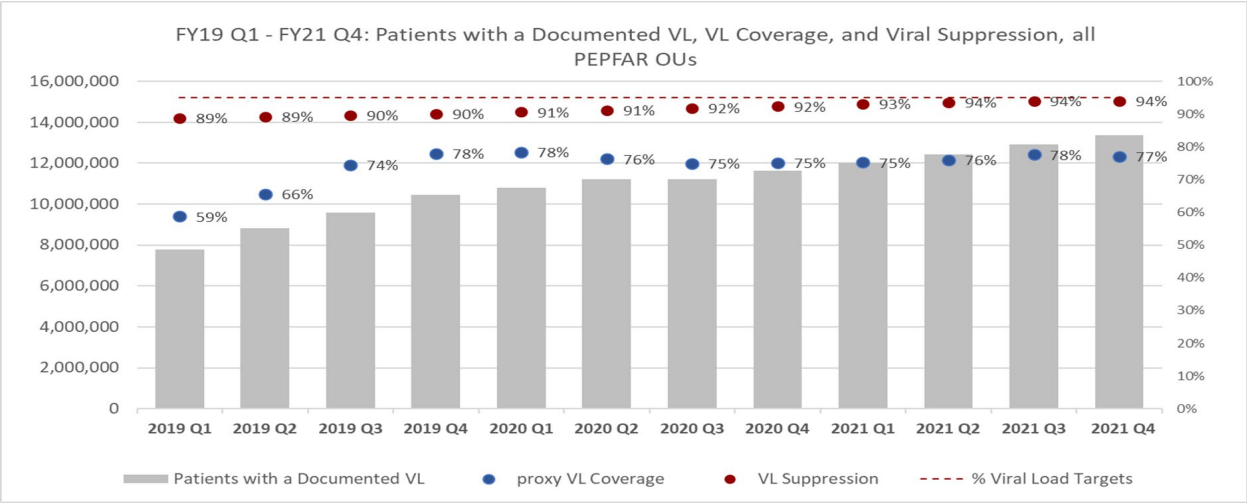
Creating demand for VL remains a challenge in many national HIV programs. The following education points should be widely disseminated by all providers, community health workers and counselors doing HIV testing.

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[421] 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.

Use of Dried Blood Spot (DBS), Plasma Separation Card (PSC) and other alternatives

DBS 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. 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. Considering this, programs should prioritize the use of POC for VL testing among infants and children using fingerstick or heel prick approaches as mentioned in Section 6.4.5.1. The use of DBS should be considered only in situations where POC testing capacities do not exist. OUs should be sure to order pediatric VL commodity bundles in the FAST which includes capillary tubes and butterfly needles for younger children.

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

[421] https://www.senaite.com/

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.[422] 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.[423] 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.[424] Hence, POC testing could be used to improve the viral load testing coverage gap among PBFW.

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

[422] Moyo (2019) https://pubmed.ncbi.nlm.nih.gov/31914002/
[423] UNAIDS (2020) https://www.unaids.org/sites/default/files/media_asset/start-free-stay-free-aids-free-2020-progress-report_en.pdf
[424] WHO (2021) https://www.who.int/publications/i/item/9789240031593

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.[425] 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.

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.

[425] Alemnji et al. (2020) J. Acquir. Immune. Defic. Syndr. 2020, 84, S56–S62.

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),[426] 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

[426] https://theprogramme.ias2021.org/Abstract/Abstract/1018

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.[427] 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.[428] Community/home-based services including obtaining specimens for VL testing and delivering results should be 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

[427] WHO (2021) https://www.who.int/publications/i/item/9789240031593
[428] WHO (2020) https://www.who.int/publications/i/item/978-92-4-001037-6

clear understanding of the viral load protocols and are capacitated to transfer and transmit this information to KPs within the community.

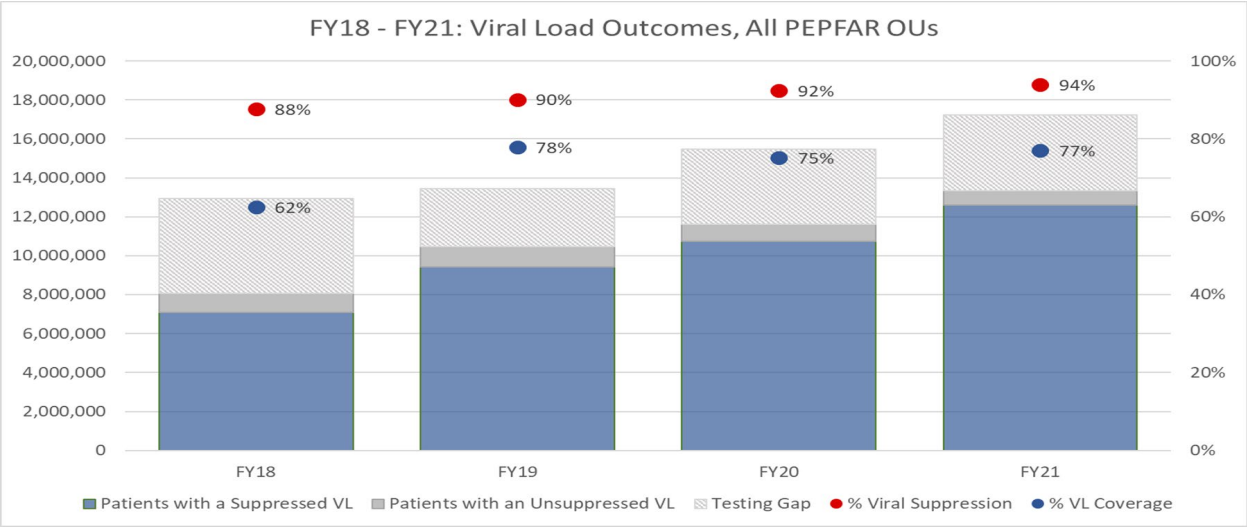
5. 6-Month (MMD). PEPFAR recommends 6-month MMD to decrease the burden of medication access on PLHIV, reduce treatment interruptions and ensure VL suppression. In many countries, MMD has been scaled-up rapidly as a means of reducing congestion and foot traffic in facilities especially during the COVID-19 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.[429] 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

[429] https://www.senaite.com/

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 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

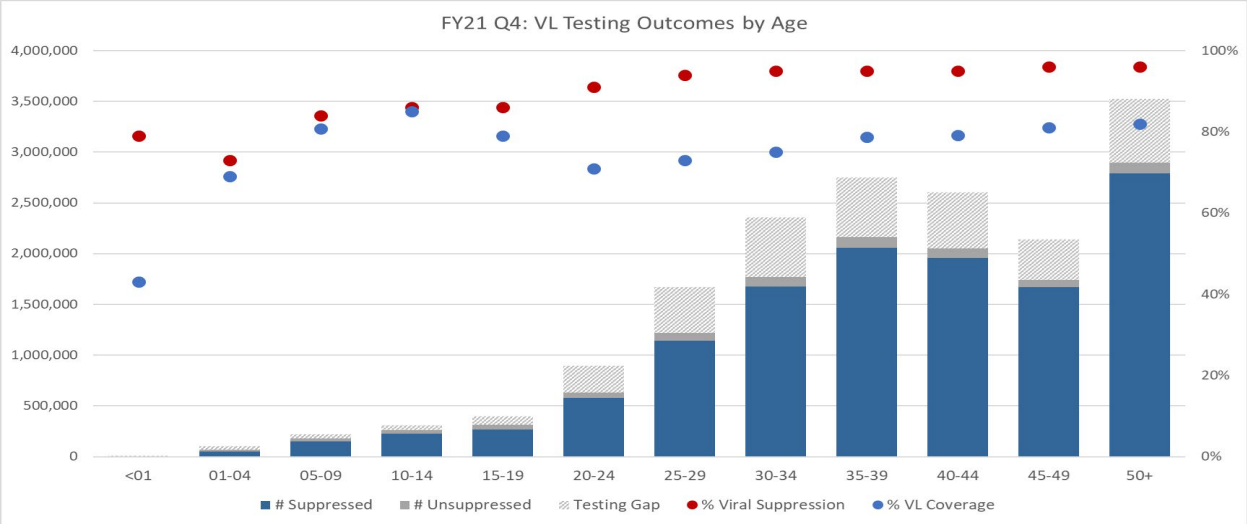
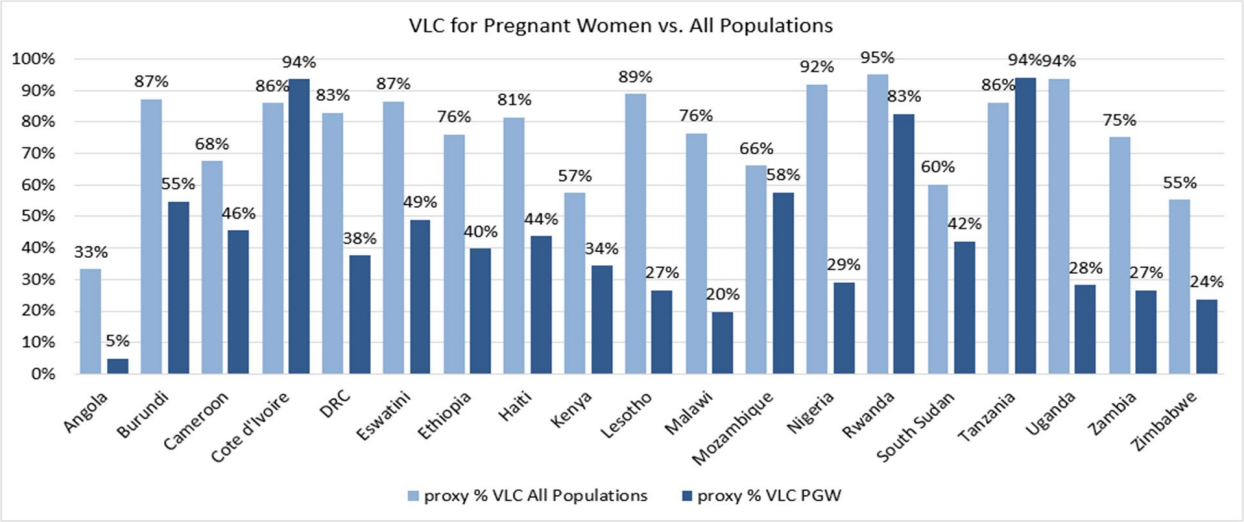


Figure 6.4.5.2.3: Proportion VLC for All Populations and Pregnant Women by OU (FY21Q4)



6.4.6 Approach to Virological Non-Suppression

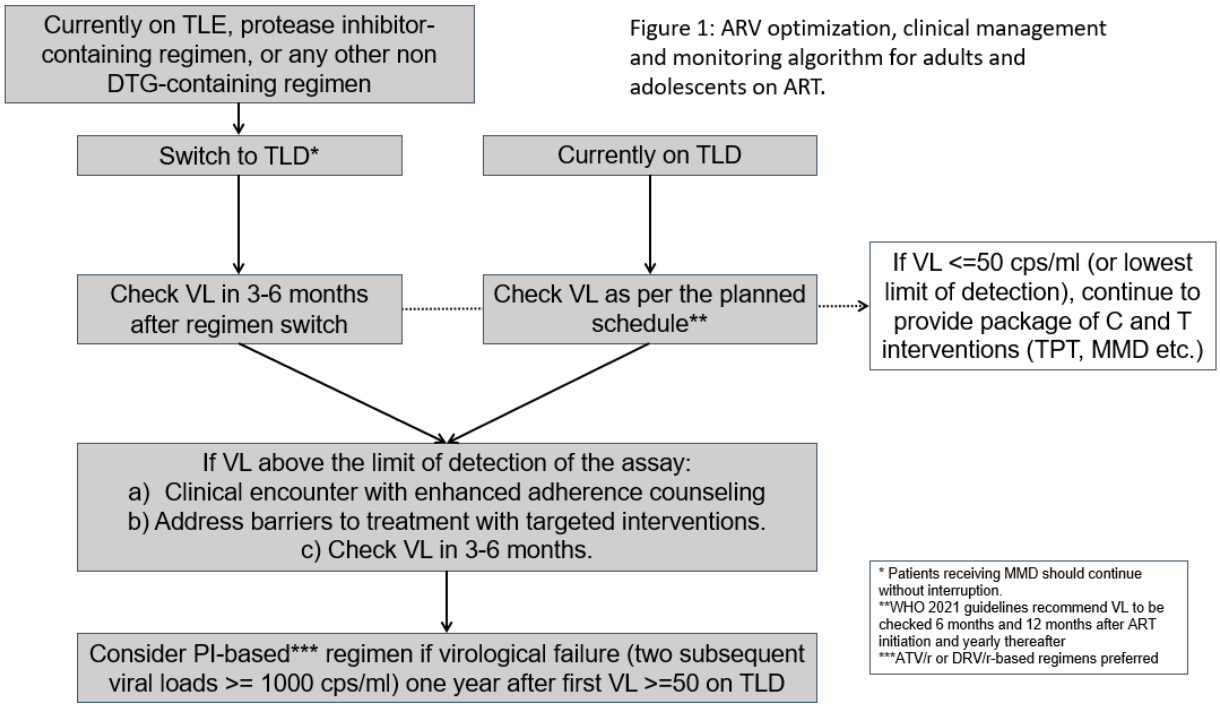
The goal of antiretroviral therapy is virological suppression (VS), which should be achievable by all PLHIV. Virological non-suppression is defined as any detectable VL greater than 50 copies/ml. All individuals on an efavirenz-based regimen, regardless of VL result, should be switched to TLD as soon 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,[430] increased all-cause mortality and serious non-AIDS events.[431] Low level viremia (LLV) in the AFRICOS cohort was associated with an increased risk of several NCDs.[432] 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.[433]

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

[430] 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

[431] 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

[432] Esber,A et al. CROI 2020 abstract 712 https://www.croiconference.org/abstract/persistent-low-level-viremia-is-associated-with-noninfectious-comorbidities/

[433] 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.[434,435]

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).

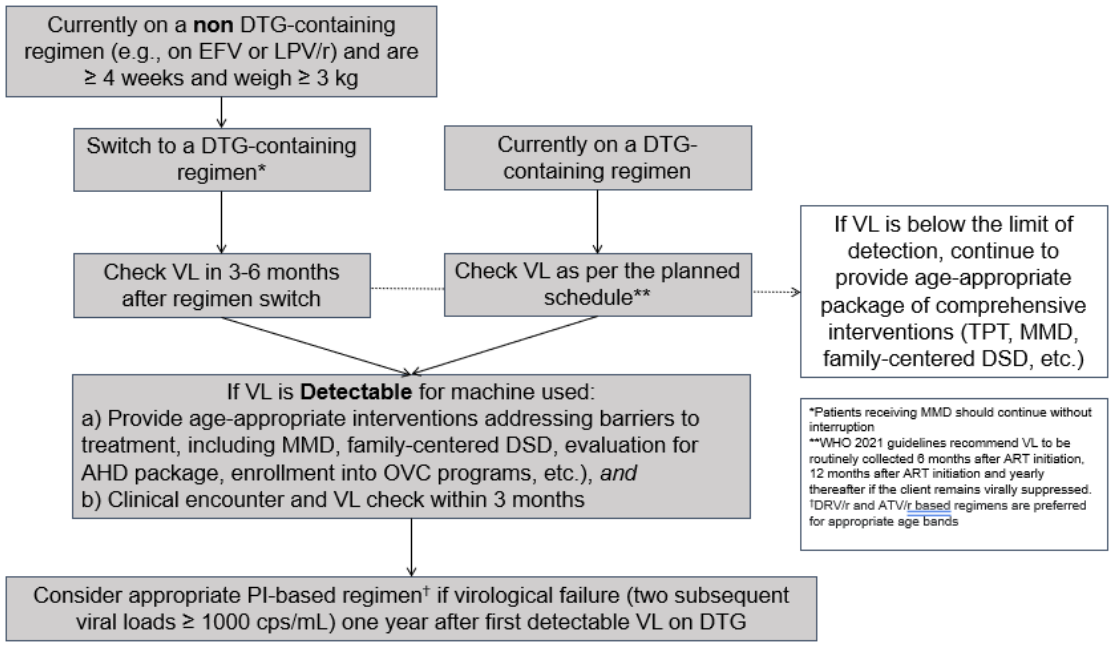
Programs must ensure that infants and children have access to routine viral load (VL) monitoring services, with appropriate phlebotomy, POC instrument, and/or dried blood sample (DBS) specimen collection materials (Section 6.4.5.2). Programs must also strengthen the management of infants and children 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 should have two subsequent VLs ≥1000 cps/mL one year after the first detectable VL on**

[434] 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

[435] 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

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[436] and *Zvandiri*[437] in PEPFAR Solutions[438]). See Section 6.1.3.1 on adherence support for children and families. See EGPAF toolkit[439] 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.[440] 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 counselling and received the recommended follow-up viral load test.[441] Some individuals may be experiencing a prolonged period of viremia with its attendant health challenges.

[436] 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

[437] PEPFAR Solutions. Zvandiri: Peer Counseling to Improve Adolescent HIV Care and Support. Washington, DC: PEPFAR Solutions; 2018.

[438] 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.

[439] Elizabeth Glaser Pediatric AIDS Foundation. Disclosure of HIV Status Toolkit for Pediatric and Adolescent Populations Washington, DC: PEPFAR Solutions; 2018.

[440] MSF (2016) https://msfaccess.org/making-viral-load-routine

[441] WHO (2019) https://www.who.int/hiv/pub/vct/hiv-molecular-diagnostic/en/

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.[442] 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.[443] 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)

Data support transition to TLD regardless of viral load (VL) suppression or the presence of dual NRTI resistance.[444,445,446] 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.[447]

[442] Paul et al. (2019) http://www.croiconference.org/sessions/point-care-viral-load-testing-improves-hiv-viral-suppression-and-retention-care
[443] Boeke et al. (2021) https://onlinelibrary.wiley.com/doi/epdf/10.1002/jia2.25663
[444] 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.
[445] 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.
[446] 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
[447] 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.

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.[448] 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.

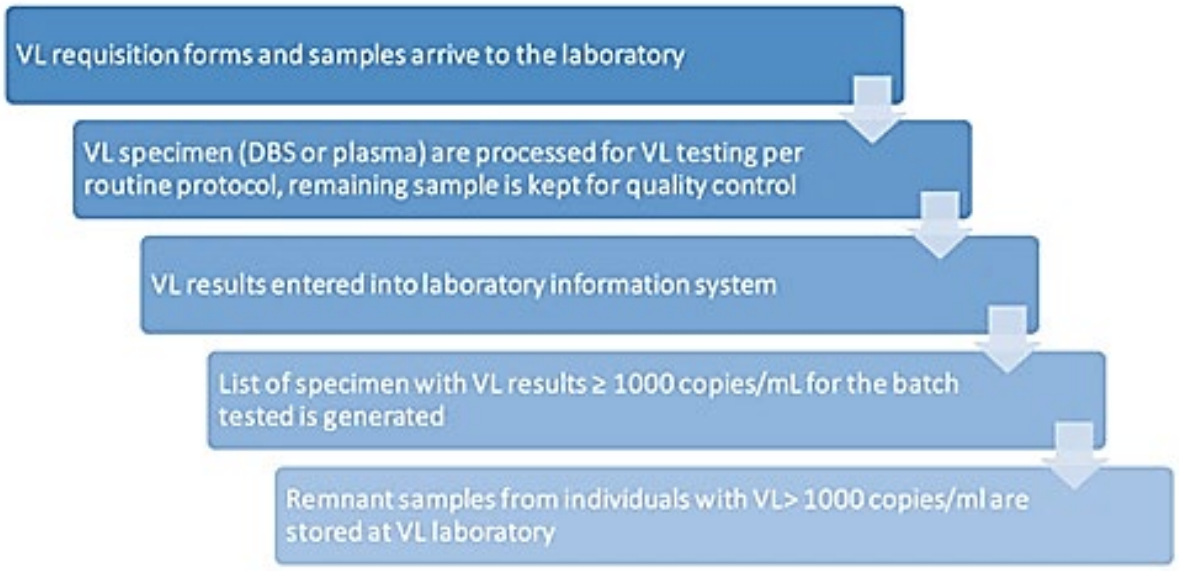
HIVDR monitoring activities supported by PEPFAR should:

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 one or more high viral load after at least 9 months on TLD or another dolutegravir-based regimen.
        - Sampling the second viral load specimen may be desirable where sample can be tracked longitudinally. Virological failure (defined as more than one consecutive sample with >1000cps/ml) is not required for inclusion in the CADRE sampling cohort.
    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). Please note children should be included in these cohorts.
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.

[448] 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

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

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.[449] 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.

[449] 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.

Increasing evidence has found integrated family planning and HIV service delivery is critical to both reduce vertical transmission of HIV and prevent unintended pregnancies.[450] The WHO released New Recommendations for Contraception for Women at High Risk of HIV affirming the following principles:[451]

- 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.

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.[452] 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.[453] 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

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[450] 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

[451] 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

[452] UNAIDS. 2025 AIDS Targets (2021)

[453] Ibid. https://aidstargets2025.unaids.org/#:~:text=The%202025%20targets%20prioritize%20sexual,to%20life%2Dsaving%20treatment%20services.

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 significantly declining estimate of neural tube defects risk associated with dolutegravir use around conception.[454,455] 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.

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[454] 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).
[455] Zash. AIDS 2020. Abstr OAXLB0102.

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
- 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

According to the UNAIDS 2021 Global AIDS Update, at the end of 2019, individuals from key populations[456] 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.[457] 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.[458] In order to advance epidemic control, PEPFAR teams should

[456] "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.
[457] https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update
[458] https://www.unaids.org/sites/default/files/2025-AIDS-Targets_en.pdf

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:

- 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.[459]

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 includes a focus on all activities related to data collection, analysis and use of strategic

[459] 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/

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 populations6. 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 (illustrative example forthcoming) 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

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.[460] 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 does not support this. 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.[461] See Section 6.6.2 on Gender Equality for more information on PEPFAR's commitment 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."[462] 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

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460 https://differentiatedservicedelivery.org/Portals/0/adam/Content/2a0WxWUHfUKtul1mKWdmGQ/File/Decision%20Framework%20Key%20Population%20Web_Post_Conference_FINAL.pdf

461 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

462 https://www.unaids.org/sites/default/files/media_asset/JC2236_guidance_partnership_civilsociety_en_0.pdf

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 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

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.

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 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) may receive FDA approval during COP22 and 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).[463,464,465] 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 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.

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[463] Glidden DV, Anderson PL, Grant RM. PharmacologysupportsonDemandPrEP.LancetHIV.2016;3(9):e405–e6.
[464] 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.
[465] 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.

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.[466,467] 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.[468] 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.

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.[469] Data on the use of PrEP to prevent HIV from parenteral exposure come from the

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[466] 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.
[467] 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.
[468] 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
[469] 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

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.[470] In a separate analysis the authors concluded that adherence improved outcomes, however one of the arms included daily directly observed therapy.[471] 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.[472,473] 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 educators and advocates, counselors, leaders, monitoring and evaluation staff, pharmacists, regulatory officials, and program planners/managers.[474] 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

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[470] 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.

[471] Ibid.

[472] 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.

[473] 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.

[474] WHO. (2017). WHO PrEP Implementation Toolkit. https://www.who.int/tools/prep-implementation-tool

evaluation, including program monitoring, assessing site-level service delivery capacity, target setting, program cost estimation, and ARV supply forecasting.[475] 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 treatment and antiretroviral outcomes for individuals living with HIV.[476,477] A meta-analysis suggested that OAT was associated with an average reduction in all-cause mortality of 25%.[478]

OAT has been shown to improve linkage to other care including viral hepatitis screening and treatment.[479] 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

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[475] *PrEP-it –*. (2021, July 20). PrEPWatch. https://www.prepwatch.org/resource/prep-it/

[476] 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.

[477] 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.

[478] 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.

[479] 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.

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.[480]

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.[481] 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

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[480] 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

[481] 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

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 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.[482] Other drugs that increase the clearance of methadone include rifampicin and phenytoin. Fluconazole decreases clearance and individuals on that drug may require less methadone.[483] 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.

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[482] 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

[483] 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

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.[484] Left untreated, multiple negative health outcomes 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.[485] 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[486] Rapid diagnostic tests for syphilis (treponemal test) are available, cheap and allow for a same-day “screen and treat”

[484] 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

[485] 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

[486] 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

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.[487] 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

[487] 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

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.[488]

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[489] 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

[488] 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

[489] Ibid.

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 program resources on how various ICT platforms can be utilized for KP programming, please reference PEPFAR supported Going Online tools.[490]

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).[491] 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

[490] FHI360 Going Online to Accelerate the Impact of HIV Programs. https://www.fhi360.org/resource/going-online-accelerate-impact-hiv-programs
[491] https://www.pepfarsolutions.org/resourcesandtools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

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 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.[492,493]

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.[494] Additionally, Witzel et al. have cataloged successful strategies in their systematic review of HIVST among KP.[495]

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[492] 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.

[493] 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.

[494] 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

[495] 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.

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 key populations recommends flexible, mobile, and venue-based options to expand the pool of at-risk individuals who have access to testing.[496,497] 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.[498,499]

6.5.1.3 Continuity of Treatment for Key Populations: Initiation to Undetectable

Comprehensive Case Management from Initiation to Undetectable

[496] WHO. (2016, June). *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations.* https://www.who.int/publications/i/item/9789241511124
[497] International AIDS Society. (2018). *A Decision Framework for HIV testing services*.
[498] 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).
[499] 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

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.

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.[500,501] 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.[502,503]

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.[504] 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.[505] 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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[500] Rodriguez-Hart, C (2021) GENDER-AFFIRMING SURGERY ASSOCIATED WITH HIGH VIRAL SUPPRESSION AMONG TRANSGENDER PWH, CROI Conference, 2021.

[501] 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

[502] TransHealth101: https://ihri.org/transhealth-101-is-now-ready/

[503] 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

[504] 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

[505] 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.[506] 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 play a fundamental role in reaching children of key populations and their partners, mainly

[506] 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

through index or social network testing.[507] 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).[508]

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 need to be integrated within the national lab collection and transport systems, for timely access

[507] https://www.fhi360.org/sites/default/files/media/documents/epic-long-term-hiv-adherence-guide.pdf
[508] https://www.who.int/hiv/pub/toolkits/keypopulations-2016-update/en/

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.[509]

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 travel plans, if applicable, and providing referrals to trusted KP-friendly facilities at the new destination. Whenever possible, multi-month dispensing should be prioritized.

[509] www.preventionaccess.org

6.5.1.4 Structural Interventions for Key Populations

WHO 2016 Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations HIV epidemics[510] 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 link health programming with human rights, (including advocating for legal frameworks that decriminalize behaviors practiced by key populations); and
- Maintaining a do no harm focus of all PEPFAR programming by promoting an ethical code of conduct in serving key populations

[510] https://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

Based on the MSMIT,[511] SWIT,[512] IDUIT,[513] and TRANSIT[514] 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 to increase their leadership and decision-making in KP programs (see Section 2.5.3 and 6.6.2.1).[515]
- 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.

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[511] 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

[512] 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

[513] 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

[514] 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

[515] "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

- 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 Section 3.2.3).
- 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 place where KPs can seek legal redress, such as patients' rights groups, ombudsperson offices and national human rights institutions.[516]

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

[516] 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

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.

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[517] 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

[517] https://www.ndi.org/equal-rights-action-fund

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.[518]
- 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.[519] OUs should also be aware of the Dignity for All LGBTI Assistance Fund.[520]

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

[518] https://www.fhi360.org/sites/default/files/media/documents/resource-linkages-safety-security-toolkit.pdf
[519] https://frontlineaids.org/our-workincludes/rapid-response-fund/
[520] https://freedomhouse.org/programs/LGBTI-assistance

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

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.[521] 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. 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.[522] Specific and detailed guidance on calculating sample sizes is found in the WHO Blue Book.[523] 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

[521] https://apps.who.int/iris/bitstream/handle/10665/258924/9789241513012-eng.pdf
[522] https://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en/
[523] http://apps.who.int/iris/bitstream/handle/10665/258924/9789241513012-eng.pdf?sequence=1

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.[524]

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 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. 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 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:

[524] 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

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.[525] 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

[525] USAID and CDC. (2020). Key Population Cascade Monitoring Guide . https://drive.google.com/file/d/11uT9cvn4ZAOiURnzS6ObT4yrBOfzUaVS/view

service solutions that would improve health outcomes for these individuals and others like them.[526]

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 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

[526] 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

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.[527] This approach should build upon current service delivery platforms through integration of KP, family planning (FP), 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

[527] 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

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).[528]

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

[528] 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.

- 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 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.[529] 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.[530] [531] 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 combined with the vulnerabilities of youth.[532] 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.[533] 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-

[529] WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update. https://www.who.int/publications/i/item/9789241511124

[530] 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

[531] WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update. https://www.who.int/publications/i/item/9789241511124

[532] 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

[533] 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

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.
- 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.[534] 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.

[534] Kameko et al. (2021) https://dx.doi.org/10.3390/diagnostics11010022

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).[535] 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.

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.[536]

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

[535] Alemnji et al. (2020). J. Acquir. Immune. Defic. Syndr. 84:S56–S62
[536] IAS (2020) https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium

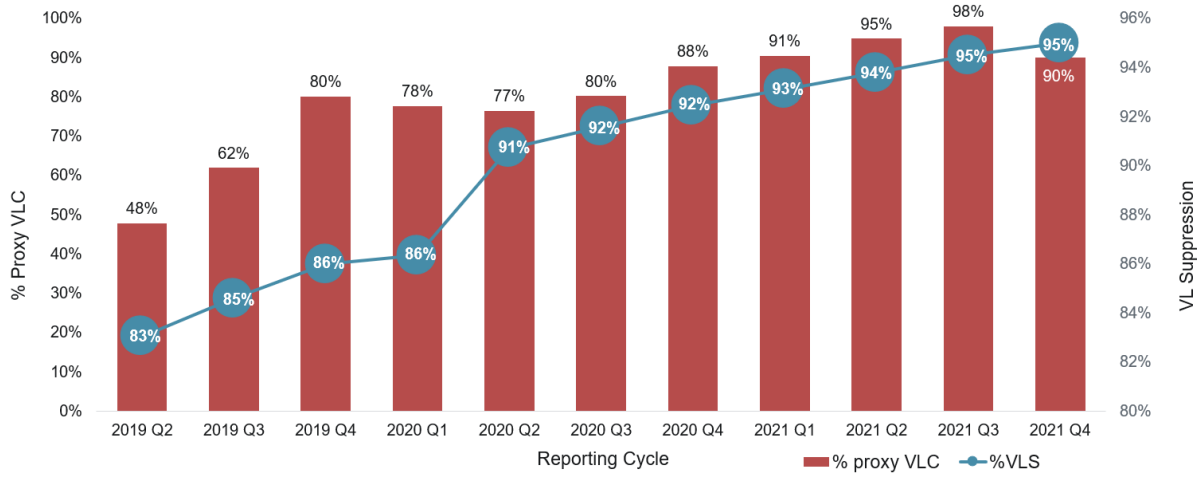
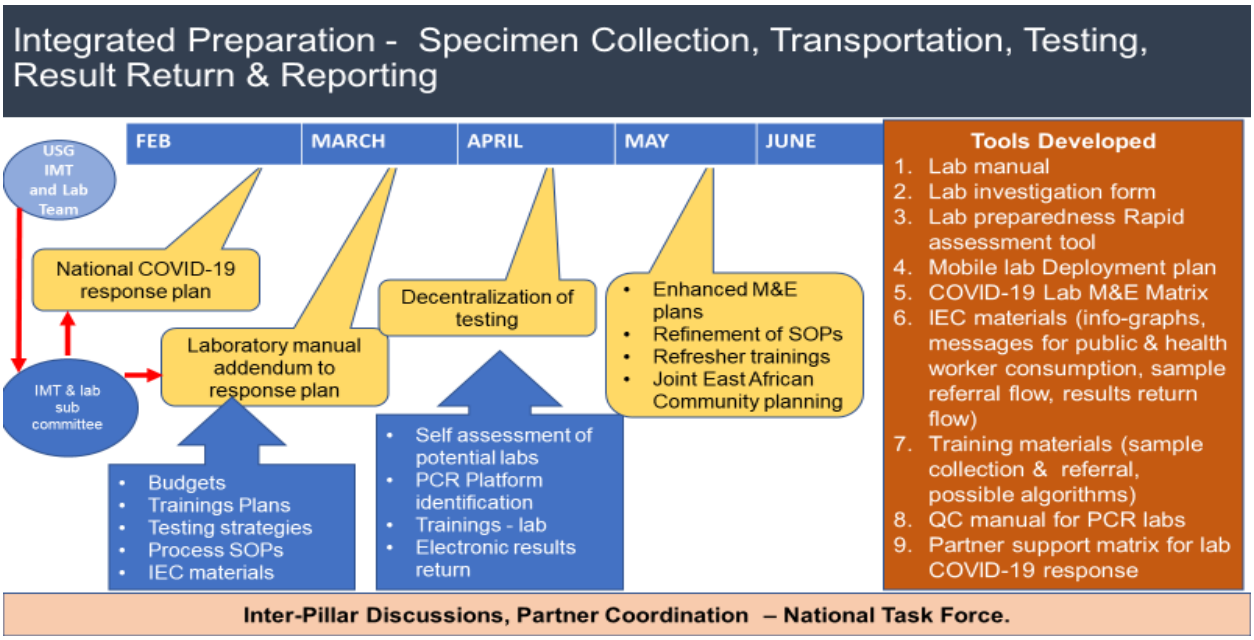


Figure 6.6.1.1.2: Uganda integrated HIV, TB, and COVID-19 Diagnostic Network Action Plan (DNAP)



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.[537] 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

[537] https://cquin.icap.columbia.edu/wp-content/uploads/2020/12/Kenya_Viral-Load-Access-Presentation_Annual-CQUIN-Meeting-2020_v16.11.20.pdf

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.

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[538] 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.

[538] WHO (2015) https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf?sequence=1

- 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 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 Multiplex use of Diagnostic Testing Platforms for HIV, TB, COVID-19, and HPV

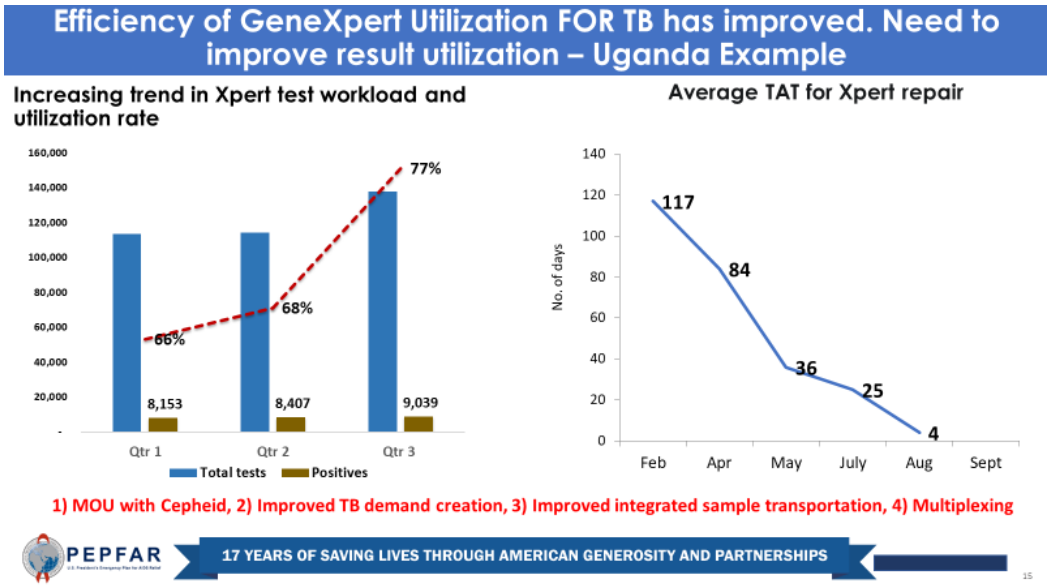
Current diagnostic gaps in the HIV and TB response could be supported through optimal use of existing technologies. Several technologies, including laboratory-based and near-POC and POC assays, currently exist that can be used to diagnose and monitor multiple diseases, including HIV and TB but also COVID-19, hepatitis C, human papilloma virus (HPV), and other STIs.[539] Multiplex testing can also be used to diagnose and monitor different parameters within the same disease for example VL and EID among HIV patients. Multiplexing 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.[540] 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, multiplexing and integrated diagnostic approaches in Cameroon, Nigeria and Zimbabwe, led to quicker testing/result turnaround

[539] UNITAID (2018) https://unitaid.org/assets/multi-disease-diagnostics-landscape-for-integrated-management-of-HIV-HCV-TB-and-other-coinfections-january-2018.pdf
[540] WHO (2017) https://apps.who.int/iris/handle/10665/255693

time, safe and secure specimen referral and transport, and rapid expansion of COVID-19 testing in these countries.[541] Furthermore, a multiplexing 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 without negatively impacting TB testing and treatment services.[542,543] Also, in Uganda, multiplex 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 multiplex 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.[544] 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 multiplexing, 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 multiplexing 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: Instrument Multiplexing in Uganda leads to Efficiency of GeneXpert (2019)

[541] https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium
[542] Ndlovu et al. (2018) https://doi.org/10.1371/journal.pone.0193577
[543] Melody et al. (2021) https://pubmed.ncbi.nlm.nih.gov/34310372/
[544] 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.[545] 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.[546] 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 recent recommendation is for diagnostic platform manufacturers utilizing GTC to be responsible

[545] WHO (2014) http://www.who.int/water_sanitation_health/publications/safe-management-of-waste-summary/en/
[546] Collins et al. (2010) https://doi.org/10.1016/j.hazl.2021.100030

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.[547]

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.[548] A systematic review and meta-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-

[547] IAS (2020) https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium

[548] 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

reported ART adherence, and significantly worsened viral suppression among women.[549] 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.[550] Evidence from the Partners PrEP study noted that women who reported recent IPV were at increased risk of lower PrEP adherence.[551]

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.[552] 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 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

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[549] 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

[550] 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

[551] 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

[552] MenStar Coalition: Why Men? (2021). MenStar Coalition. https://www.menstarcoalition.org/why-men

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.[553]

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![554], 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,[555] Program H,[556] One Man Can,[557] and Men as Partners.[558] See also Sonke Gender Justice[559] for resources on norms change activities to improve HIV outcomes for men.
- Use gender-sensitive approaches, such as Mina[560] or Coach Mpilo[561] to improve linkage to HIV testing services for boys and men. See the MenStar Strategy[562] for more information on interventions to improve linkage to testing services for men.
- 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.

[553] More information on gender transformative approaches and the gender integration continuum can be found at https://www.igwg.org/training/programmatic-guidance/
[554] SASA!: https://raisingvoices.org/sasa/
[555] Yaari Dosti: https://www.popcouncil.org/uploads/pdfs/horizons/yaaridostieng.pdf
[556] Program H: https://promundoglobal.org/programs/program-h/
[557] One Man Can: https://www.saferspaces.org.za/uploads/files/OMC_Case_Study.pdf
[558] Men as Partners: https://www.engenderhealth.org/our-work/gender/men-as-partners/
[559] Sonke Gender Justice: https://genderjustice.org.za/project/community-education-mobilisation/
[560] Mina: https://menstarcoalition.org/lost-to-follow-up/mina-for-men-for-health/
[561] Coach Mpilo: https://www.psi.org/2020/06/coach-mpilo/
[562] MenStar Strategy: https://www.menstarcoalition.org/strategy/

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.[563,564,565] 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-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

[563] 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.
[564] Pulerwitz, J. et. al. (2017).*Unpacking the influence of gender on HIV testing and treatment uptake: Evidence from Mpumalanga, South Africa*. Project SOAR.
[565] 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.

aged 13 to 24 years who experienced sexual abuse as a child also experienced physical violence.[566]

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[567]) 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[568]), 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[569] for specific strategies used in DREAMS. PEPFAR has developed a country specific 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

[566] 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
[567] PEPFAR Child Safeguarding MOA Annex.
[568] 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
[569] PEPFAR DREAMS Guidance. (Rev 2021). PEPFAR DREAMS GUIDANCE — PEPFAR Solutions Platform.

available through the PEPFAR-funded LINKAGES and EpiC projects,[570] 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,[571] 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 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

[570] LINKAGES Project: https://www.fhi360.org/resource/linkages-violence-prevention-and-response-series
[571] 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/

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.[572,573,574]

Post-Violence Care. Implementing partners who provide post-GBV care services must:

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[572] 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/

[573] 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

[574] 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

- 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).[575] 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[576] 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
- 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.).[577,578]

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[575] 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/

[576] 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/

[577] MEASURE Evaluation. (2019). *Tools for gender-based violence data.* https://www.measureevaluation.org/resources/newsroom/news/tools-for-gender-based-violence-data.html

[578] *GEND_GBV Rapid Data Quality Review Tool.* (2019). MEASURE Evaluation. https://www.measureevaluation.org/resources/publications/tl-19-43.html

- 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 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.[579] For the OVC platform, the focus for adolescents is two-fold: continuity of treatment and living a productive, healthy life.

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.

[579] 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

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.[580]

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

[580]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

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.

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.[581] 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

[581] See example at https://ideadata.org/sites/default/files/media/documents/2018-02/Step_by_Step_Outlier_Analysis.pdf

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.

OVC Preventive Program

The Preventive Program focuses on children aged 10-14 years in high burden SNUs.[582] 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

[582] 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.

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).

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 • Children of adults living with HIV at risk treatment interruption; children who have lost parents to AIDS • HEI at high risk of treatment interruption (i.e., pregnant and adolescent mothers and their infants) • Children of female sex workers (especially FSWLHIV) • Survivors of sexual violence	• HIV clinical sites (pediatrics, adult treatment, PMTCT) • Child welfare services • Traditional and community leaders	• Family-based case management • Monitor against graduation benchmarks • Provision and/or linkage to supportive socio-economic services	• 6.3.2.2 Case Finding in OVC • 6.6.2.1 Gender-Based Violence and Violence Against Children • 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 • Community and faith youth groups	• Provision of single, evidence-based primary prevention of HIV and sexual violence intervention by trained facilitators in group settings • No case management • Not tracked against benchmarks	• 6.2.3 Primary Prevention of HIV and Sexual Violence for 10-14 Year Olds • 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,[583] as well as costs of the different prevention interventions.[584] 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 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.[585]

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[583] 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

[584] World Health Organization (2018). INSPIRE Handbook: Action for Implementing the Seven Strategies for Ending Violence Against Children.

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

6.6.4 Faith and Community Engagement

PEPFAR's Faith and Community Initiative (FCI) 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 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 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 increase the proportion of men and children living with HIV who know their status, are linked to care, and have viral load suppression, as well as to strengthen biomedical prevention interventions recommended by national governments, including VMMC and PrEP. These priorities include 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 develop a coordinating structure (i.e., a Steering Committee) 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. 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 reach men and children:

1. Work with PEPFAR technical team to review HIV messages for men, youth, and children.
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 Guide and Tools

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 adjusting psycho-social support in accordance with COVID-19 mitigation strategies.

Activity 1: 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[586]
- Messages of Hope for HIV prototypes[587]
- Messages of Hope for COVID-19[588]
- Treatment Adherence in the Context of HIV and AIDS in Africa: Training Manual for Religious Leaders[589]
- Faith Matters, CDC (adapted from Families Matter[590])

Activity 2: Expand HIV Testing, including targeted self-testing; improve linkage to treatment; and promote continuing in care. Best Practices for advancing case-finding by 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[591] and Circle of Hope, PEPFAR Solutions Faith-Engaged Community Posts.[592] 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, 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.

[586] https://www.faithandcommunityinitiative.org/fci-implementation-resources
[587] https://www.faithandcommunityinitiative.org/hiv
[588] https://www.faithandcommunityinitiative.org/covid-19
[589] https://seafile.ecucenter.org/d/08b03e1bbd554f149d5e/
[590] Miller, Kim. https://www.cdc.gov/globalaids/publications/fmp-2-pager-final-jan-2014.pdf
[591] 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
[592] 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

- *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.[593]
- *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.[594]
- *Co-location of Testing Sites on Premises of Religious Venues, Zambia* (Further information available in the May 2021 New Foundations of Hope Webinar[595]). 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 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

[593] 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

[594] 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

[595] May 2021 NFH Webinar https://www.faithandcommunityinitiative.org/nfh-webinars

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, 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.[596]
    - *Baby Shower Initiative-* (Further information available in the June 2021 New Foundations of Hope Webinar[597]) A church congregation-based approach implemented in Nigeria

[596] https://www.pepfarsolutions.org/adolescents/2018/1/13/zvandiri-peer-counseling-to-improve-adolescent-hiv-care-and-support
[597] June 2021 NFH Webinar https://www.faithandcommunityinitiative.org/nfh-webinars

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[598] and shown in the video clip.[599] 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).[600]

Activity 3: Decrease stigma to address continuity of treatment Materials/Training for USG OU teams: All the materials/training listed in Activity #1 above include information on reducing stigma and related continuity of treatment, particularly in the context of exclusive reliance on faith-healing in congregations or communities.

In the context of COVID-19, the expansion and integration of these FCI models must be done in accordance with national and local COVID-19 mitigation regulations. Faith leaders and FBOs should use the Messages of Hope on COVID-19[601] to promote physical distancing, hand hygiene, covering of face and mouth, quarantine and isolation measures, among others and accelerate community mitigation of the impact of COVID-19. Other practical recommendations for religious leaders and faith communities in the context of COVID-19 can be found here.[602]

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

[598] 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.
[599] https://www.youtube.com/watch?v=guPobd1-cTg
600 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.
[601] https://www.faithandcommunityinitiative.org/covid-19
[602] https://www.who.int/publications/i/item/practical-considerations-and-recommendations-for-religious-leaders-and-faith-based-communities-in-the-context-of-covid-19

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.[603,604] Mental health disorders and psychiatric illness can[605] be a risk factor for HIV exposure that complicates the disease course and treatment. These disorders have been associated with decreased testing for HIV,[606] reduced likelihood of initiating ART and continuing in treatment,[607,608,609,610] poor ART use, and lower likelihood of virological suppression.[611,612] In

[603] 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.
[604] 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.
[605] 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.
[606] 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..
[607] 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.
[608] 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
[609] 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.
[610] 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.
[611] 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.
[612] 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.

addition, psychosocial factors that commonly[613] co-occur with both mental disorders and HIV, such as violence, trauma, stigma, and other social determinants, may additionally impact HIV treatment outcomes.[614]

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.[615] Interventions that address both treatment interruptions and depression have been shown to improve virological suppression.[616] 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 ART, increased viral suppression and undetectable viral load.[617] 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.[618]

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

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[613] 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.

[614] 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.

[615] 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.

[616] 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..

[617] 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

[618] 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.

treatment services is warranted. Mental health issues are prevalent in key populations and attention to these populations is critical to prevention and treatment success.[619,620,621,622]

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 to scale.[623] 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,

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[619] 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.

[620] 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.

[621] 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.

[622] 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.

[623] 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

depression, anxiety, PTSD, and substance use.[624] 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.[625] 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 be employed by professionals or paraprofessionals.[626] Training on screening and symptom recognition should be provided.[627]

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;[628,629] further, evidence also suggests that some mental health interventions can also lead to improvements in HIV-related

[624] 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.
[625] Reynolds CFR, Patel V. Screening for depression: the global mental health context. World Psychiatry. 2017;16(3):316-7
[626] 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)
[627] WHO Training resource: https://apps.who.int/iris/bitstream/handle/10665/259161/WHO-MSD-MER-17.6-eng.pdf?sequence=1
[628] 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.
[629] 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.

outcomes.[630,631,632] 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 successful with appropriate training and supervision of lay health workers.[633]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

[630] 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.

[631] 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.

[632] Sin & DiMatteo. 2014. Depression treatment enhances adherence to antiretroviral therapy: A meta-analysis. Annals of Behavioral Medicine, 47, 259-269.

[633] 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

diagnoses and therefore creates efficiencies for mental health care. An example of the trans-diagnostic approach is the Common Elements Treatment Approach (CETA)[634] Transdiagnostic approaches may also be extended to address co-occurring psychosocial and structural factors, such as stigma, substance use, and violence.[635]

4. Technology: The COVID-19 pandemic has accelerated digital interventions. There is strong evidence in high-income countries that telemedicine for mental health is effective,[636,637] and evidence in resource constrained countries is emerging suggesting that interventions are feasible and can lead to improvements in mental health.[638,639] Outcomes for mental health apps are more mixed.[640] 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.[641]
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.

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[634] 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

[635] 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.

[636] Bashshur, Shannon, Bashshur, & Yellowlees. (2016). The empirical evidence for telemedicine interventions in mental disorders. *Telemedicine journal and e-Health, 22*, 87-113.

[637] 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.

[638] 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

[639] 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

[640] Weisel, Fuhrmann, Berking, Baumeister, Cuijpers, & Ebert. 2019. Standalone smartphone apps for mental health—A systematic review and meta-analysis. *NPJ Digital Medicine*, 2, 118.

[641] Acharibasam & Wynn. (2018). Telemental health in low- and middle-income countries: A systematic review. *International Journal of Telemedicine and Applications*, 2018, 9602821.

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 (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.[642,643,644] 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

[642] 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

[643] 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

[644] 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

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.

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[645]).

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

[645] 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/

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 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.[646] 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.[647,648] 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[649]

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[646] 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

[647] 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

[648] 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

[649] 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

- 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:

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,[650] 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).[651] 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.[652] PSS interventions

[650] ARIEL Clubs: https://www.pepfarsolutions.org/infants-children/2018/1/13/ariel

[651] 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

[652] 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

designed to be implemented by lay counsellors or peer mentors may be less costly.[653,654,655,656] Costs may also be reduced by using digital strategies for delivery.[657,658]

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 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).

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[653] 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

[654] 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

[655] 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

[656] 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

[657] 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

[658] 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

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.[659,660,661] Interventions that emphasize emotional benefits, counseling and emotional support, such as those in the MenStar Strategy,[662] 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 broader community reached through social norms change interventions, such as SASA!.[663] 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.[664] Therefore, PEPFAR follows WHO Comprehensive Guidance on KPs which

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[659] 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
[660] 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
[661] 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
[662] MenStar: https://menstarcoalition.org/wp-content/uploads/2020/07/MenStar-Strategy-2-02-2020-FINAL.pdf
[663] SASA!: https://raisingvoices.org/sasa/
[664] 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

supports both peer and professional mental health (Section 6.6.5.1) and PSS services as a part of comprehensive KP programming.[665]

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.[666] 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.[667]

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,[668] MenStar Strategy,[669] 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.

[665] 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
[666] 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
[667] 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
[668] DREAMS Guidance: https://www.pepfarsolutions.org/s/2021-08-17-DREAMS-Guidance-Final-March-2018-Update_PEPFAR-Solutions.pdf
[669] MenStar: https://menstarcoalition.org/wp-content/uploads/2020/07/MenStar-Strategy-2-02-2020-FINAL.pdf

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)[670]	Improve treatment adherence, and clinic retention
Adolescents living with HIV	Operation Triple Zero (OTZ; Kenya)[671]	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 and Young Mentor Mothers	Community Adolescent Treatment Supporters (CATS), Zvandiri (Zimbabwe)[672]	This approach helps youth increase treatment literacy, motivate adherence, increase treatment continuity, and improve psychosocial well-being, self-esteem, self-worth and confidence.
Women, Children, and Adolescents	Mothers2mothers (m2m)[673]	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[674]	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.

[670] 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
[671] 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
[672] CATS: https://www.pepfarsolutions.org/adolescents/2018/1/13/zvandiri-peer-counseling-to-improve-adolescent-hiv-care-and-support
[673] Mothers2mothers: https://m2m.org/our-impact/
[674] PLH: https://www.who.int/teams/social-determinants-of-health/parenting-for-lifelong-health

All PLHIV	HIV Treatment Adherence Counseling and Retention Guide (EpiC)[675]	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)[676,677]	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.

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 country team to develop a decisional memo, which describes the conditions which lead to needing emergency support.

[675] EpiC: https://www.fhi360.org/sites/default/files/media/documents/epic-hiv-adherence-counseling-retention.pdf
[676] World Health Organization. (2011). *Psychological First Aid: Guide for Field Workers (Illustrated ed.).* WHO. https://www.who.int/publications/i/item/9789241548205.
[677] 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

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 country 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

PEPFAR has long invested in health workforce staffing in order to rapidly scale up HIV services. Staffing is a key cost driver of PEPFAR programs, at a nearly $2 billion-dollar investment in COP21, representing the important role that health workers play in achieving HIV epidemic control. The diversity of health worker staffing supported by PEPFAR has enabled reconfiguration of HIV service delivery models to support decentralized service delivery and community level services. These investments have made possible further adaptations to ensure continuity of HIV service provision through the COVID-19 pandemic.

COVID-19 has taken a toll on health workers globally and exacerbated health workforce challenges across PEPFAR countries. In response to the challenges, there have been innovations made in how HIV services are being delivered, with a focus on using health workers more effectively and extending access to clients. As PEPFAR focuses on sustaining epidemic control, we must determine how to institutionalize these innovations as part of country systems' routine service delivery and align staffing investments to support these shifts.

In planning for COP22, countries should prioritize: 1) continuing to ensure the safety and well-being of the workforce[678]; 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 (See Section 6.6.2 Gender Equality for additional guidance); and 5) prioritizing key above site investments to advance workforce sustainability under local leadership, using a whole of market approach.

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 to protect health workers, 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

[678] 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

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):* Human Resource Information Systems (HRIS) or the equivalent are critical to track and ensure availability and use of national HRH data. Investments in HRIS should result in increased ability of PEPFAR teams and country governments to utilize HRH data for decision-making at national, sub-national, and facility levels. Countries should use the PEPFAR HRIS Assessment Framework (HAF) 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 Private Sector Providers: 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.
- *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 Public Health Surveillance and Information Systems

Data and information are the lifeblood and currency of public health; these are increasingly being digitized and enabled by Information and Communication Technologies (ICT).[679]

[679] Schwab, K. (2015). The Fourth Industrial Revolution: what it means, how to respond. *Foreign Affairs.* Retrieved from: *https://www.foreignaffairs.com/articles/2015-12-12/fourth-industrial-revolution]*

Cognizant of the importance of Digital Health, the World Health Assembly issued resolutions WHA58.28 (2005) on eHealth,[680] WHA66.24 (2013) on eHealth standardization and interoperability,[681]and WHA71.7 (2018) on Digital Health.[682] Countries have increasingly instituted eHealth / digital health strategies — so have PEPFAR's implementing agencies. PEPFAR has as its core mission building capacity to define, develop, maintain, and assess efficient, high-quality, secure, and sustainable health information systems (HIS) that meet the information needs of each level in the care, treatment, and prevention of HIV/AIDS, tuberculosis, and related conditions. PEPFAR supports standards for interoperability as well as data security and confidentiality policies to enable linking of disparate systems and tracking of the UNAIDS/PEPFAR epidemic 95-95-95 control goals.

To sustain its investments, PEPFAR supports capacity development of individuals to create, lead, and manage informatics-savvy public health organizations.[683] PEPFAR works in partnership with local and global partners to ensure alignment to the Digital Development Principles[684] and Digital Donor Principles.[685] Both frameworks provide steps on how to build nimble health information systems architecture and use global data standards to enable systems to be extended to support additional disease domain issues outside of only HIV/AIDS (e.g., COVID-19); we also contribute to communities such as the Data Use Community, OpenHIE, and OpenMRS as part of our commitment to open-source tools and ensuring sustainability of the systems we develop. PEPFAR's investments in totality contribute to sustainable HIV epidemic control and strengthening of countries' digital health and health systems.

Challenges Identified within Current Informatics Ecosystem

The PEPFAR community recognizes challenges in three core areas of digital health investments:

I. Policy & governance

[680] World Health Assembly (WHA) Resolution. (2005). WHA58.28. Retrieved from: http://www.who.int/healthacademy/media/WHA58-28-en.pdf?ua=1

[681] World Health Assembly (WHA) on eHealth standardization and interoperability (2013). WHA66.24. Retrieved from: https://apps.who.int/iris/bitstream/handle/10665/150175/A66_R24-en.pdf?sequence=1&isAllowed=y

[682] World Health Assembly Resolution on Digital Health. (2018). WHA71. Retrieve from: https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R7-en.pdf

[683] The Task Force for Public Health: Public Health Informatics Institute. (2019). Retrieved from: https://phii.org/module-1/introduction/.

[684] Principles of Digital Development. Retrieved from: https://digitalprinciples.org/

[685] Principles of Donor Alignment. Retrieved from: https://digitalinvestmentprinciples.org/

- Absence of national digital Health Information System (HIS) strategies, architecture, standardized terminologies, and use of standardized exchange formats to link data from multiple sources
- Lack of focus on privacy, confidentiality, (cyber) security of personal identifying information (PII), and systems.
- Over-reliance on donor funding and lack of a strategy for sustained financing

II. Information systems:
    - Varying data elements and incompatible formats in disparate systems as barriers to using data to drive programmatic impact across service delivery points and modalities
    - Information silos, i.e., poorly designed, non-standardized, non-sustainable information systems that don't share information or leverage common information and communications technology (ICT) architecture or resources
    - Inadequate standardized software development processes and project management practices
    - Lack of institutional frameworks to catalogue and evaluate usability and effectiveness of information systems
    - Parallel development of standards and solutions with significant functional overlap and minimal differentiation, impeding resource sharing
    - Support for parallel reporting systems instead of efforts to leverage and strengthen national data and health care systems

III. Workforce:
    - Insufficient information technology capacity at all levels, ranging from systems architects to software developers to UX/UI designers
    - Insufficient capacity around data at all points in the data lifecycle: data generation, management, and use, leading to variability in the reliability, completeness, and timeliness of data
    - Lack of a specific informatics workforce strategy that describes the needed public health informatics capabilities and positions and plans for recruiting, hiring, and retention of that workforce

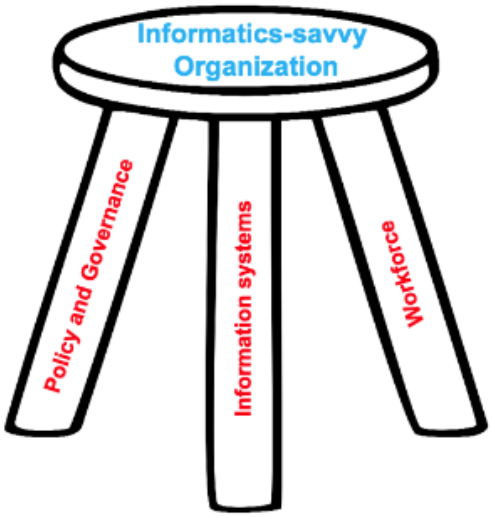
Vision for PEPFAR Digital Health

PEPFAR supports the use of the Informatics-Savvy Organization (ISO) framework (Figure 6.6.8.1) to address challenges, focus resources, and manage progress toward a vision for

effective use of public health data. In order to achieve this vision, PEPFAR must support partner governments around these three core capabilities to achieve its goals:

- A national level vision, policy, and governance approach outlining the use of information and information and communication technologies as strategic assets
- A skilled workforce capable of using information and information technology tools
- A suite of well-designed and effectively used information systems available to support the partner government strategy

Figure 6.6.8.1: Informatics-Savvy Organization Framework



The three legs of the stool are interdependent and have to work seamlessly together to support the vision for a functional, interoperable, and secure HIS. Technical considerations to achieving the PEPFAR vision are outlined along these core pillars.

PEPFAR supports policy and governance objectives to enable the development and sustenance of an OU's digital health investments. Data governance should be supported through national strategies, guidelines, and procedures on digital health, data protection, and others on healthcare and/or data management. These policies ensure that data are appropriately governed, accessible, secure, and quality-controlled throughout the collection-to-use lifecycle (PEPFAR Data Governance Guidance).

Policy and Governance support to OUs may include:

- Guiding national and regional strategies and guidelines to support digital health initiatives including assistance in developing digital health strategies, equitable access to

and skills development in digital health (addressing the digital gender gap) and Unique IDs to support patient care

- Ensuring the privacy, confidentiality, and security of patient information (including interpreting and facilitating compliance with applicable data protection regulations)
- Ensuring consistent health information exchange (HIE) standards to facilitate electronic data exchange and interoperability
- Supporting interpretation and implementation of best practices for data access, use, and sharing
- Instituting standard software development including end-user input and project management practices
- Monitoring and measuring digital health progress and impact

Examples of Priority Policy and Governance Topics

Data and Systems Confidentiality, Privacy, and Security

OUs, first and foremost, should ensure the privacy and confidentiality of the individuals that receive care and services. There also needs to be a careful consideration for unintended consequences due to collecting, analyzing, and reporting individual level data. Specifically, any work on unique identifiers (UIDs) and health data must be approached from a "do no harm" standpoint for all clients and in a context in which KP community members and networks provide guidance on a trusted approach, with appropriate data safety and patient confidentiality policies enforced. For example, the United Nations Development Programme (UNDP) has developed guidance and recommendations on how to address critical ethical, technical, and human rights considerations when investing in digital health systems.[686]

Cyber incidents can have serious consequences for PEPFAR's mission of addressing the global HIV epidemic. The populations supported by PEPFAR trust that their data are properly secured. If these data were stolen, changed, or made unavailable by a cyber breach, this trust would be impacted, and individuals could be put at risk. Because of this, securing our PEPFAR data and information systems is critical.

OUs should support Ministries as they draft and enact national health data privacy and data protection regulations, confidentiality, and security guidelines and standards, including

686 United Nations Development Programme (UNDP). Guidance the rights-based and ethical use of digital technologies in HIV and digital health programmes. Retreived from: https://hivlawcommission.org/digital-guidance/

enactment of appropriate policies that support patient literacy with digital systems and hold health systems and governments accountable in use of their data, and perform information system security assessments. All policies and guidance should include training on how to prepare and use security remediation action plans.

Regulations in various countries may present guidance with respect to health data privacy, confidentiality and security that is at odds with PEPFAR data collection, sharing, case-based surveillance, and infectious disease tracing/tracking needs. Country teams should work with their respective Ministry of Health and National government contacts to encourage identification of potential regulatory conflicts and country migration towards policy, guidance, and implementation models for addressing health data privacy, confidentiality, and security consistent with appropriate health data sharing needs both within and outside of the country.

Cyber breaches reporting requirement

PEPFAR is developing a method to report cyber breaches. Country teams and implementing partners are required to report cyber incidents of any personally identifiable information (PII) within 24 hours of a suspected breach. A cyber incident is an event that could jeopardize the confidentiality, integrity, privacy or availability of digital information or information systems. Examples could include, loss or theft of a computer or mobile device containing PII, ransomware infections preventing access to PII data, or an unauthorized actor changing PII data in an electronic health record information system. If a breach occurs, country teams and partners must report the breach as outlined by the reporting chain documented by their sponsoring agency. Agency staff outlined in the cyber incident reporting chain must undergo cyber incident training to ensure they understand best practices on cyber incident response and remediation.

Detailed communication is forthcoming.

Use of standards to drive digital health

OU teams and Ministries should adopt, use, and maintain a consistent electronic health information exchange (HIE) policy and standards set for data exchange to support interoperability within each country and internal parties.

Consistent standards should be identified for each of the following areas:

- Health data element definitions (i.e., minimum required dataset elements and their representations)

- Health messaging formats
- Health data terminologies
- HIS and ICT systems security (e.g., data encryption, data integrity)
- ICT (e.g., internetworking)
- Patient matching/profile exchange

Data access, use, and sharing

Public health data use and access must recognize and accommodate different stakeholder needs that are matrixed across the stakeholder and all "levels" of the system (from the community- and patient-level (e.g., a lab, a clinic, a hospital), through subnational and levels (e.g., a public health institute or ministry of health), and above (e.g., PEPFAR, WHO, regional centers). Across DATIM (and other enterprise data systems) stakeholder needs and systems interactions should be managed through role-based permissions. Role-based permissions assign approved access, use, and sharing permissions to entire groups instead of individuals.

Key stakeholders (and their roles) include:

- Data owners – data owners may exist at each level. The data owner controls use and access to data collected and/or generated at their respective level of ownership as well as sharing and use of data with other levels through data use and sharing agreements (see next section on Data Sharing/Use Agreements). Data ownership controls must be enabled by national regulations that recognize both ownership rights and responsibilities as well as support for data sharing outside of the data owner's sphere to support a broad variety of public, national and above-national needs. This necessitates development of informatics leadership at each of these levels and collaboration between levels to ensure that data collected at one level is available and formatted to best support secure use and analysis at other levels.
- Data users – each of the above levels may also include data users (e.g., sub-national-level organizations or partners that process data from facility-level sources), information developers (e.g., a national or above-national level organization that conducts data analysis and summarization), and/or knowledge creators (e.g., planning bodies that accomplish information synthesis and support decision-making).
    - Data users:
        - must comply with data use agreements with the data owner as well as legal and regulatory requirements.

    - have a set of responsibilities that must be fulfilled diligently in accordance with data use agreements to avoid data misuse, data loss impacts, and any disallowed further sharing of the data. This necessitates ongoing data user training to ensure data is only used for its allowed and intended purposes. It also necessitates the implementation of controls on access so that only those data required to support the PEPFAR mission and goals are provided to a given user based on the user's role(s).
- Data stewards – data stewards ensure adherence to data management guidance such as for data quality, data completeness, data integrity, data timeliness, data security, data breach response, and the records management lifecycle (e.g., data creation, labeling, retention/maintenance, distribution, archive, and disposal). The data steward also controls and limits access to the data available to each user role (and thus, each data user). Data stewardship thus encompasses the set of roles and responsibilities that one or more individuals undertake in relation to data at different points in the data lifecycle to ensure the ongoing utility of the data from collection to transformation into information to synthesis into knowledge (e.g., combining public health data with national census and environmental data to make decisions about new policies and cross-cutting actions). Data stewards require high integrity plus appropriate training and skills to fulfill these various roles and responsibilities.

Policy and governance planning must encompass each of these stakeholder groups.[687]

Data Sharing/Use Agreements (DSA/DUA)

A data sharing/use agreement defines the standard data access, use and sharing principles to be applied when sharing digital health data between data owners and data requestors (whether within or external to the country). Discussions required to prepare these documents ensure consensus among stakeholders; the agreements themselves foster:

- advancement of public health intervention by permitting analyses that allow for the fullest possible understanding of health challenges; and
- promotion of a culture of data management as well as data sharing and access by leveraging digital health technologies; and

[687] Some available data use resources for implementation and consideration include: USAID Development Data, ADS 579 (May 2021 + new/pending version),Geographic Data Collection and Submission Standards, ADS579saa, and Considerations for Using Data Responsibly at USAID.

- development of new solutions and ensure that decisions made are based on the best available evidence.

Implementing agencies, specifically, can provide technical assistance and toolkit including a generic standard data sharing agreement template to strengthen data use and sharing guideline development/customization, guideline implementation and its evaluation to strengthen overall data governance capabilities.

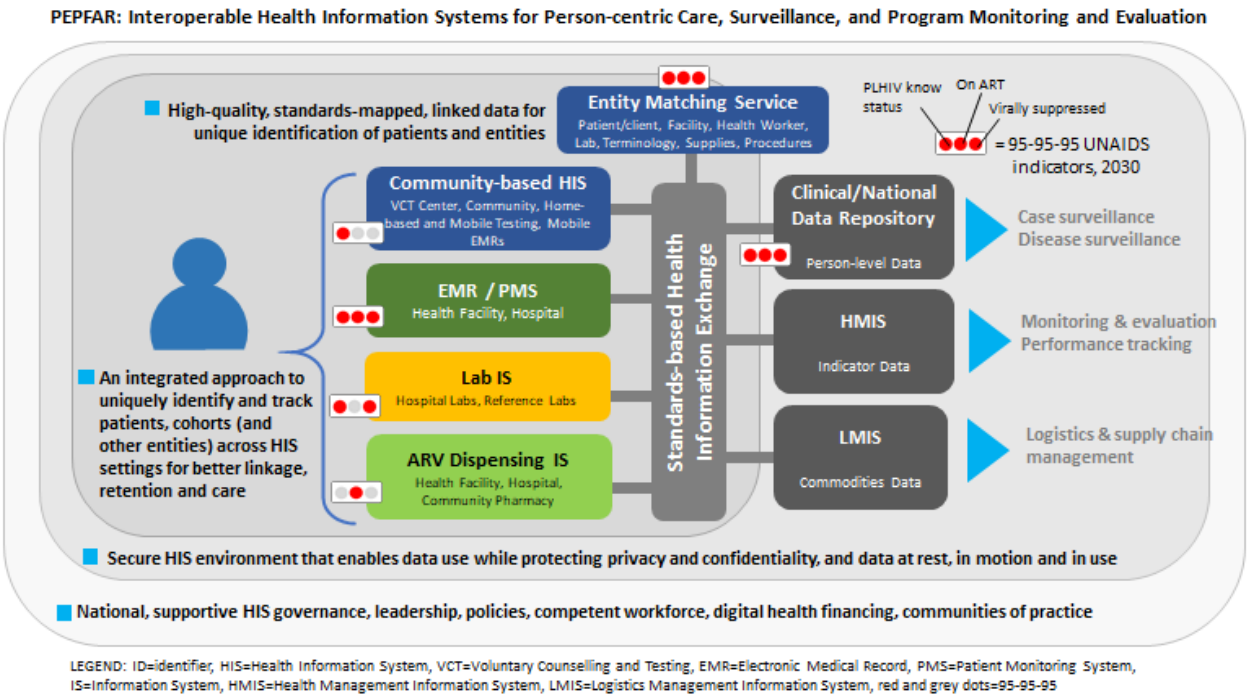
One important consideration when entering into these DSA/DUA with partner country/MoHs is that the agreements do not conflict with overarching PEPFAR data sharing/use requirements (see PEPFAR Data Governance Guidance). OUs and Implementing Agencies should ensure that there are no conflicts between PEPFAR's uses for data and what the agreement explicates.[688] Furthermore, data sharing should be an integral aspect when developing data governance policy. Data security and data sharing are inextricable linked and should thus be reflected as such when designing, developing, and implementing data governance policies and procedures.

INFORMATION SYSTEMS

In addition to the activities under the data governance and policy leg of the ISO stool, PEPFAR also supports the development and use of information systems that are standards-based, interoperable, and meet the requirements of end users and their programmatic needs (see Figure 6.6.8.2). Software may be open source or proprietary but should be sustainable and able to exchange data with other systems where appropriate. Sharing of system development and implementation experience is encouraged through participation in communities and/or peer-to-peer learning and sharing. Managing the development, implementation and support of complex software systems must be done transparently using clearly defined metrics and follow industry-accepted best practices. Finally, information systems must reflect the needs of the users – whether patients, clinicians, government staff or donors – and should be monitored for performance and evaluated for effectiveness and impact.

[688] Relevant resources: PEPFAR Data Governance Guidance, ADS 579 (May 2021 + new/pending version) and ADS579 reference , Considerations for Using Data Responsibly at USAID

Figure 6.6.8.2: Interoperable Health Information Systems for Person-Centric Care, Surveillance, and Program Monitoring and Evaluation



LEGEND: ID=identifier, HIS=Health Information System, VCT=Voluntary Counselling and Testing, EMR=Electronic Medical Record, PMS=Patient Monitoring System, IS=Information System, HMIS=Health Management Information System, LMIS=Logistics Management Information System, red and grey dots=95-95-95

Outlined below are the typical types of systems that are generally funded in PEPFAR and can be used for clinical, community, and prevention settings:

a. *Community-Based Health Information Systems (CBHIS*): An information system involved in data collection, management, and analysis of health social, economic, or other services that exist within a community outside of health facilities delivered through community organizations, non-governmental organizations, faith-based organizations, and other groups working either alongside formal health services or in places where there are no health facilities.
b. *Electronic Medical Records/Patient Medical System (EMR/PMS*): The digital version of a patient's medical records that are captured in systems like OpenMRS, LAMIS and SmartCare.
c. *Lab Information Systems (LIS): A software system that records, manages, and stores data for clinical laboratories.*
d. *Clinical/National Data Repository for case-based surveillance (CNDR): A data repository housin*g the patient journey along the continuum of care.

e. *Pharmacy Information Systems (PIS)*: A system that captures patient demographic data, dispensing history, and inventory data including stock orders, receipts, and issues and has the capability to register daily transactions and produce monthly reports.
f. *Health Management Information Systems/Service (HMIS)*: An information system that stores and reports routinely collected aggregate health care data and facilitates their analysis. Examples include DHIS2, etc.
g. *Logistics Management Information System (LMI*S): An information system of supply chain records and reports used to aggregate, analyze, validate, and display data from all levels of the logistics system that can be used to make logistics decisions and manage the supply chain.

Importantly, developing scalable, sustainable, and context-appropriate processes and systems that deliver data that drives impact are critical to meeting PEPFAR's current and increasingly sophisticated data needs. As such, country teams should continually consider, evaluate, and improve the nature of their current and future health system's investment by using the best practice standards such as those outlined within the Principles for Digital Development. These 9 principles are (1) Design with the User, (2) Understand the Existing Ecosystem, (3) Design for Scale, (4) Build for Sustainability, (5) Be Data Driven, (6) Use Open Standards, Open Source and Open Innovation, (7) Reuse and Improve, (8) Address Privacy & Security, (9) Be Collaborative, offer overarching as well as specific best practices, with a set of guiding questions, resources, and project lifecycle applications. To the extent possible, it is recommended implementing partners incorporate consideration of these principles when planning for any digital investments. Additionally, investments in population-based surveys and other data collection activities such as IBBS and Demographic and Health Surveys should complement partner country government data needs and requests.

Tools like the MEASURE Evaluation toolkit[689] can strengthen health information systems and improve maturity along these different principles for digital investments. For example, the Data Use Community (DUC), described in detail in the Implementation Considerations section of the document, has developed a maturity model to evaluate HIS using metrics to describe the function of each component of the HIS as well as its data use overtime and growth of the system. The DUC Maturity Model also helps to identify any gaps and supports the development of roadmaps to improve HIS capabilities related to processes, people, and systems, ultimately

[689] MEASURE Evaluation Toolkit. Retrieved from: https://www.measureevaluation.org/resources/tools.html

enhancing health program performance and population health. This Model has been vetted by our interagency colleagues and is currently being customized for the Ethiopia-CDC context.

Other considerations can also be made when making digital investments in clinical, prevention, and community-based systems. Specifically, PEPFAR implementing agencies may have specific recommendations to IPs for setting up an information systems project, general required capabilities, and funding considerations around the software development lifecycle, maintenance, and staffing (resources include National Academy of Medicine: Procuring Interoperability,[690] Health Metrics Network: Guidance for Health Information Systems (HIS) Strategic Planning Process,[691] and CDC's Digital System Assessment Toolkit[692]). Importantly, PEPFAR encourages and promotes develop of robust Health Information Systems that encompass all health conditions, not only HIV. One means by which to execute on ensuring HIS are disease domain agnostic is through implementation WHO's SMART Guidelines.[693]

Digital Health Investments in PEPFAR

Furthermore, understanding how PEPFAR and other cooperating agencies are investing in digital health is critical to maximizing the benefits received from such tools and will allow partners to leverage learnings and best practices across implementations. PEPFAR supports and endorses coordination amongst digital health investments across donors to maximize impact of investments. Digital Health Investments (DHI) information helps us understand how PEPFAR is investing in digital health to inform planning, align investments across donors, lower burden and increase utility of national digital health inventories, and identify scalable tools that help improve healthcare delivery. Additionally, analyzing DHI data against PEPFAR data sets including Table 6, Sustainability Index & Dashboard, Section 7 will further provide insight into our digital health landscape and its key role in improving programmatic outcomes.

The Digital Health Investments (DHI) Planning Tool was developed in close collaboration with an interagency Informatics Working Group (IWG), a broader Advisory Group comprising WHO (aligned to their Digital Health Atlas product), BMGF, and Global Fund with extensive

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[690] National Academy of Medicine: Procuring Interoperability. (2019). Retrieved from: https://nam.edu/wp-content/uploads/2019/08/Interop_508.pdf

[691] Health Metrics Network: Guidance for Health Information Systems (HIS) Strategic Planning Process. Retrieved from: https://www.measureevaluation.org/his-strengthening-resource-center/resources/GuidancefortheHealthInformationSystemsHISStrategicPlanningProcess.pdf

[692] CDC's Digital Health Assessment Toolkit. Available upon request.

693 World Health Organization. Smart Guidelines. (2021). Retrieved from: https://www.who.int/teams/digital-health-and-innovation/smart-guidelines

stakeholder feedback from across IPs and MoHs in Uganda and Zimbabwe and will be capturing information on system categories commonly seen in PEPFAR, which can be mapped to the WHO Digital Health Atlas[694] categories. The DHI Planning Tool is integrated with the DATIM/DHIS2 system and will be completed annually by each PEPFAR implementing partner. For this year, the data collected from a small group of participating OUs will be reviewed to identify opportunities for data use and Tool refinement to ensure it is generating the intended information.

Completing the DHI Planning Tool will be a requirement for most OUs in Q3 2022. The vision is for country teams to use this annual dataset to identify opportunities for strengthening and aligning digital health investments and to track the progress of how we are leveraging digital health solutions to improve health and programmatic outcomes.

Reviewing Digital Health Investments flagged in the FAST

As you are planning COP22, please conduct a detailed interagency review of digital health investments identified in COP21 FAST to ensure that your team is evolving these systems and tools to support program needs. Digital health investments are defined in the FAST guidance as electronic tools, systems, devices, and resources used to support health system needs. Note that beginning in FY22Q3, many country teams will begin to report more detailed data on specific digital health investments in the **Digital Health Investments planning tool (DHI)** These systems are used by PEPFAR USG staff, IP staff, and partner country government staff at the site, district, and national levels . A timely and iterative requirements-gathering and prioritization process that incorporates user feedback across the health system is essential to ensure systems are keeping up with the program needs. New systems development needs must be clearly identified and articulated prior to COP planning to ensure effective and efficient use of resources.

Example of technical considerations for specific types of systems

Use Case: Uganda LIS and EMR integration.

Laboratory information systems (LIS) have been implemented in nearly every PEPFAR-supported HIV viral load (VL) and early infant diagnosis (EID) conventional laboratory. These systems help laboratories manage and document specimens and workflows leading to improved documentation and data availability and reduced turn-around times. Laboratory data are critical

[694] World Health Organization's Digital Health Atlas. Retrieved from: https://digitalhealthatlas.org/en/-/

for patient management and disease surveillance and thus countries should strive to ensure that LIS are linked to surveillance systems and are interoperable with EMRs. Uganda has developed an in-house LIS (CPHL) that has been implemented for HIV VL and EID testing at the centralized laboratory, feeds into a National dashboard for VL and EID and is interoperable with the EMR at over 50 sites. The operability between the LIS and the EMRs was built using OpenHIM for data exchange and Fast Healthcare Interoperability Resources (FHIR) for messaging. Utilizing Open Health Information Mediator (OpenHIM) and standards including FHIR, Uganda plans to take advantage of the data exchange to introduce regional labs systems (ALIS) and additional lab tests.

Use-case: Case surveillance

In addition to facilitating patient monitoring and management at the individual patient-level, HIV data systems can contribute to HIV case surveillance (CS), which involves the routine and systematic reporting of diagnosed HIV cases in a population to a public health authority and subsequent reporting of their sentinel events throughout the course of infection. The primary objectives are to (1) establish a routine surveillance system of secured individual-level de-duplicated information on a national cohort of diagnosed PLHIV throughout the course of infection; and (2) use its data to routinely monitor epidemic trends and maximize programmatic impact to direct HIV resources to where they are needed the most. A fully functioning CS system provides the basis for our understanding of the burden of disease, and comprehensive information on gaps along the HIV care and treatment cascade (e.g., newly diagnosed cases, linkage to care, and ART continuity and viral suppression) to guide public health action in both civilian and military health systems adhering to utmost Data Security & Confidentiality guidelines according to international standards. As countries reach epidemic control, national HIV CS data will become essential for sustaining epidemic control by monitoring population-level trends in new diagnoses, different modes of transmission (risk behaviors), geographic location, and demographics including age and sex and prompting further investigation to rapidly identify and respond to potential gaps in HIV services--- such as interruptions in treatment including categories of attrition and challenges in access to or uptake of prevention interventions --- that may be contributing to transmission in the population, as a part of a comprehensive and sustainable Public Health Response to HIV. The establishment of HIV CS and use of its data remain a key priority for all PEPFAR programs in COP21. As of October 2020, 21 countries are planning, preparing, or implementing a HIV case surveillance system.

- Planning and Preparing: Botswana, Burma, Cambodia, DRC, Namibia, Senegal, Tanzania, Uganda, Ukraine, Mozambique
- Implementation: Ethiopia, Guatemala, Haiti, Honduras, Kenya, Malawi, Rwanda, Vietnam, Zimbabwe, Nigeria, Zambia, South Africa

CS begins with an initial HIV case report (electronic or paper based or a combination of both) that can originate from any HIV testing location and subsequently be updated to include sentinel events from HIV clinical, care and laboratory services. At a minimum, initial case reports should include date of diagnosis, age, sex, pregnancy status, timing of infection (e.g., recent infection status and/or timing of the last known HIV negative status), residence at time of diagnosis, linkage with index case(s); case reports on subsequent sentinel events should include longitudinal information on linkage to care, ART initiation (1st line, 2nd line and 3rd line regimens), any interruptions in treatment and subsequent return to treatment, CD4 results or WHO clinical stage, TB and TPT, viral load results, pregnancy outcomes, and death. Case reports can also include HIV index testing and networks, mode of HIV transmission (or risk behaviors) and sentinel events to monitor adverse events (e.g., co-infections drug toxicities and HIV drug resistance) that may negatively impact viral suppression targets. This needs to be done in a client-centered way that protects the confidentiality and privacy of patients and all PLHIV.

There are stages that a country should pass through as it reaches full implementation of a HIV CS system. These stages include a pre-planning phase where stakeholders are introduced to CS and its value as a public health tool; a planning phase where CS infrastructure is established (development of a HIV case reporting policy, client unique identification information, standards-based surveillance information system, and standard operating procedures); a small-scale implementation and evaluation phase; and a full-scale implementation phase where the system is nationally scaled and data are used routinely to guide effective and timely public health and programmatic response. To do so, it is crucial to have buy-in and commitment from ministries and local stakeholders to ensure long-term sustainability of CS activities.

Since COP21, countries have considered integrating HIV recency infection surveillance with CS to maximize the benefit and cost effectiveness of using surveillance data to improve HIV prevention, care, and treatment programs. Countries may also start with reporting diagnosed HIV cases and sentinel events occurring at or around the time of diagnosis (e.g., description of person, time, and place of new HIV diagnoses, baseline clinical status, and ART initiation), before including follow-up sentinel events (e.g., viral load results, birth outcomes, ARV toxicities, continuity or interruption of treatment, and drug resistance). CS data should be routinely

analyzed and disseminated to guide public health and programmatic response and be part of a holistic approach to data use. Data from CS must be released at minimum on a quarterly basis in a transparent manner to national stakeholders for programmatic prioritization of responses and planning; lower-level staff for supervision and monitoring and reporting; and health facilities and laboratories noting gaps in care/treatment to help guide patient clinical care. Patient-centered CS data reported by care providers should be used at all levels (partner, site, district, SNU, OU) to identify challenges with continuity of ART and interruption of treatment that may warrant a program management (system) response to address, as opposed to a limited provider-based response. Decisions on how records will be linked, matched, and deduplicated need to be made early on in the planning phase, and should consider the quality and coverage of unique IDs biometrics, and other unique information that can be used as minimum data elements and should align with the security and use case needs of the country.

Requirements for Case Surveillance

Functional case surveillance system requires complex interoperability of various software systems for data collection, storage, exchange, and reporting; ability to manage patient identity and link patient-level data across location and time while eliminating duplicates and ensuring security and confidentiality; reporting and visualization of relevant information to appropriate stakeholders for decision making; and supportive policy, governance, standards, and competent workforce. Exhaustively and systematically capturing programmatic requirements from case surveillance experts, end-users, and other stakeholders for the purpose of designing and developing software is a critical and necessary first step in case surveillance system development.

Although case surveillance requirements should be based on a recommended guidance (see above), and should be similar, if not the same across different countries, each implementation may have variations based on the local requirements. For example, in addition to the standard core data set, each country may have a different set of additional variables they want to collect for programmatic purposes. Similarly, patient identity management requirements may include national IDs, biometrics, and/or other forms of individual identifier to link records and remove duplicates. It is important to spend sufficient time and effort to capture programmatic requirements accurately and comprehensively prior to doing any development and not let software discussions or decisions lead the requirements discussion.

Additional detailed information about case surveillance system requirements can be found in the Health Information Systems Technical Assistance Consortium's (HISTAC) Overview of Data Integration Strategies and Implementation Components guide.[695]

Future vision of UID use in PEPFAR

PEPFAR includes UID/UIC as a Minimum Program Requirement. In addition to the basic elements on privacy and linkage around use of a UID, it is important to consider interoperability from a future program service delivery perspective, rather than UID/UIC as an end point.

Success is managing client identity across service delivery points and being able to track various services that are received or not received (e.g., interruption in treatment). Successful implementation of UID enables standardized data access and analysis. Explicated below are use cases of how to maximize ISO framework.

WORKFORCE

As PEPFAR transitions programs, services, and investments to partner governments, it becomes critical for PEPFAR to support development of the digital health workforce (in the right numbers, right skills, right places, and right positions) who can create, manage, and lead informatics-savvy public health organizations. This competent digital health workforce, a core pillar of the ISO, will enable partner governments to lead and sustain HIS development, innovation, and implementation; advocate for and lead the development of supportive workforce-related governance and policies; and further institutionalize and expand digital health workforce capabilities.

Digital health workforce development can be realized and sustained by supporting the countries to establish short- and long-term capacity development strategies to improve workforce governance, develop and maintain quality digital health workforce planning and management tools (e.g., digital health learning platforms including on-demand, workforce tracking systems and etc.) and support workforce growth within a rapidly changing digital health landscape by supporting ongoing and lifelong learning opportunities across all digital health workforce categories.

In this section, we provide a guidance roadmap with examples and guidance for increasing skills within the workforce, thereby increasing capability of using information and information

[695] An Overview of Data Integration Strategies and Implementation (DISI) Components. (2021). Prepared by the Health Information Systems (HIS) Technical Assistance Consortium (HISTAC). Forthcoming.

technology tools. Importantly, it should be highlighted that in addition to developing local government talent we also need to explore other approaches to leveraging the private sector.

Support to OUs could include:

- Supporting partner governments to develop short term and long-term digital health capacity development strategies
- Securing consensus to adopt standardized competency profiles and curriculum for digital health and health informatics among local academic institutions, currently offering relevant courses
- Collaborating with relevant public and private institutions to assess, define, and use minimum requirements for recruitment, placement, retention, continuing professional development, and career pathways that meet national digital health workforce needs, in particular in how it aligns with national digital health strategies
- Improving the quality of existing programs by supporting relevant mechanisms, including accreditation, faculty development
- Promoting collaborative engagement with regional bodies, relevant ministries, health informatics associations, and other relevant organizations to develop and maintain standards and a system for accreditation of digital health and health informatics training programs
- Promoting the establishment of mechanisms for certification of individual professionals and graduates. Certifying processes would also need to be aligned with professional bodies within countries, which poses additional challenges since digital health and health informatics are not widely recognized as unique professional cadres.
- Improving tracking of the digital health workforce through established Human Resource Information Systems
- Promoting innovation in education technology that supports digital health workforce capacity development, such as just-in-time mobile learning
- Promoting development and implementation of new programs (graduate level, in-service, and mentoring) for digital health and health informatics, including standard curricula
- Supporting the integration of digital health training into non-digital health programs like FETP and lab training programs and vice versa, as a mechanism to foster interdisciplinary and inter-professional practice
- Promoting the establishment and strengthening of career and professional development pathways within organizational and civil service contexts.

- Promoting establishment and strengthening of national policies that support development of civil service career tracks and job classifications and continuing education for informaticians and informatics
- Promoting the establishment and strengthening of national policies focused on gender to ensure equitable skills development and professional pathways in digital health
- Engaging the private sector through outsourcing or contracting

Table 6.6.8.3: Examples of Digital Health training programs

Program Level	**Program examples**	**Focus examples**
Basic	Digital Health (DH) Leadership and Strategy Development Training	DH 101 for executives
	Basic DH Training for DH staff	Electronic Medical Record (EMR) use for HF staff - data use/data quality
	DH 101 – Health Facility (HF) and DH Staff	
Intermediate	Intermediate DH Training	ISO-based projects & topics, project management
	Academic Programs	Fellowship, degree, certificate
Advanced	Advanced DH Training	ISO-based topics & projects, terminology management course, health information exchange, information security, core information systems (see figure 6.6.8.2)
	Advanced DH Leadership Training	DH Training for Technical Working Groups
	Academic Programs	MPH, PhD

Peer-to-Peer. Learning through a Community of Practice Approach

While there are many ways to synthesize field experiences into best practices, the *community of practice* model is ideal, in that it has simultaneous benefits to both practitioners and the

PEPFAR community-at-large. Participants come together specifically in peer support, but ultimately share conventions that can be considered de facto best practices if the community reaches sufficient scale and representation.[696] Decades of experience have shown repeated examples of the success of such networks when appropriately supported.[697]

Within the global health informatics community, community of practice models have not only been instrumental in the support and development of global public goods, but they have also created a robust milieu of peer learning and sustainable business ecosystems within countries. Projects such as OpenMRS and OpenHIE have catalyzed locally sustainable processes and technologies broadly deployed in dozens of countries around the world.

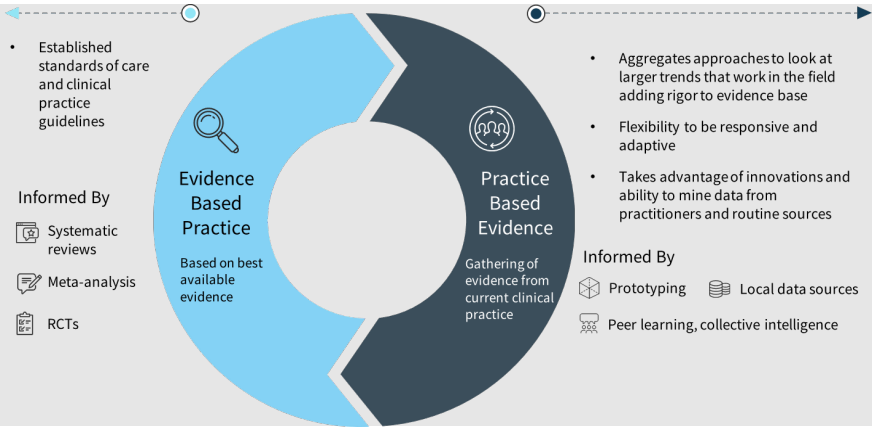
The Data Use Community

The PEPFAR endorsed Data Use Community (DUC) aims to apply best practices of communities of practice. Established in 2020, the DUC is an open community of organizations and individuals comprising global health field practitioners, researchers, and data systems experts passionate about improving health and healthcare data sharing.

Collaborative Identification of Solutions

The DUC forum allows the community to aggregate approaches to look at larger trends that work in the field, adding rigor to the evidence base. This approach allows flexibility to be responsive and adaptive, taking advantage of innovations and the experience of practitioners and routine data sources.

Figure 6.6.8.4: Relationship of Evidence to Practice



[696] Wenger, E., Trayner, B., & de Laat, M. (2011). Promoting and assessing value creation in communities and networks: a conceptual framework. *Rapport 18, Ruud de Moor Centrum*, Open University of the Netherlands.
[697] Anderson-Carpenter, K.D., Watson-Thompson, J., & Jones, M. (2014). Using Communities of Practice to support implementation of evidence-based prevention strategies. *Journal of Community Practice,* 22(1–2): 176–188.

Figure 6.6.8.5: Technical Interventions Framework: HIV Treatment Continuity

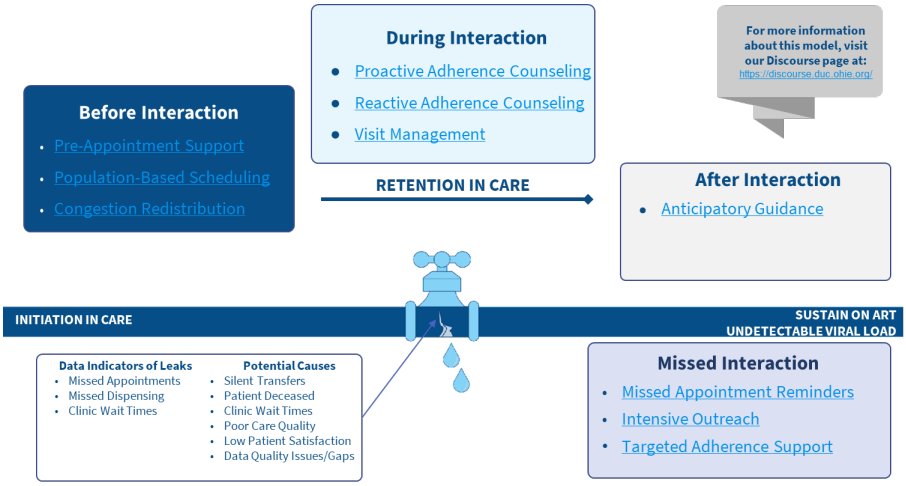
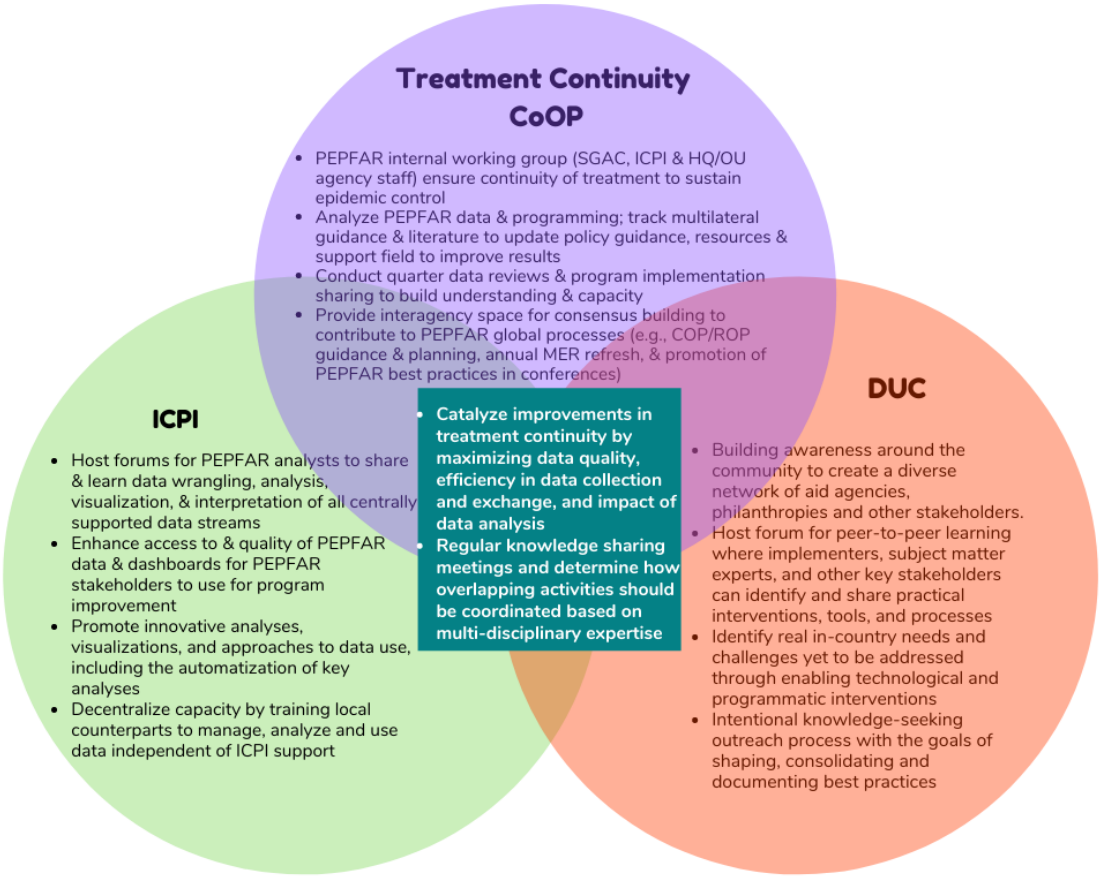


Figure 6.6.8.6: Venn Diagram showing ICPI-DUC-Treatment Continuity Collaboration



Communities supporting open-source systems and frameworks

Several other communities exist to support the development, deployment and updates of open-source systems and frameworks. Two well-known communities are OpenMRS and OpenHIE. The OpenMRS community has a robust mix of developers, implementers, standards experts, and medical and public health subject matter experts. This community collaboratively prioritizes the modules and functionalities to be developed and deployed based on the feedback from the users. Other stakeholders include funders, and ministries of health. The OpenHIE community works together to develop and support the framework for interoperable systems and is comprised of various communities that support tools, functions, or services that are part of the OpenHIE framework. The OpenMRS community, for example, is a member of the OpenHIE community. These communities promote the use of best practices and standards, provide mentorship and training opportunities, and to share experiences and priorities. PEPFAR countries can benefit from participating in and supporting these communities to build capacity for sustainable information systems.

Enhance South to South Learning. In achieving and sustaining an Informatics-Savvy Organization, here is an illustrative example of activities teams are able to do:

Use Case: Zambia's Innovative Use of Individual Level Data

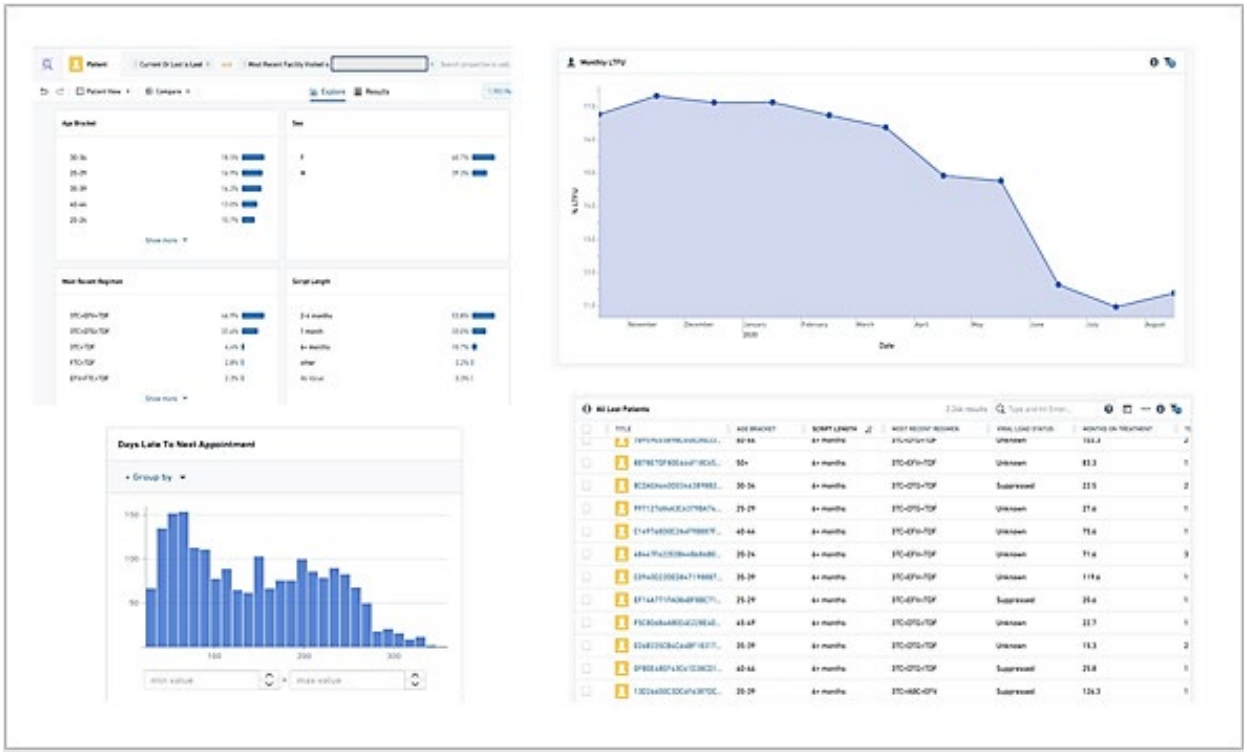
In 2020, the PEPFAR Zambia Interagency team began to use a data management and interoperability platform to monitor and evaluate programmatic decisions. The platform allows Zambia to drill down into many areas of interest including the ability to monitor the scale-up of MMD, compare stock level of TLD at the site level, track viral load coverage across different districts, etc. But most importantly, by making patient-level data securely available for analysis and use on a monthly basis, the team has been able to analyze the behavior and clinical outcomes of different patient cohorts quickly and accurately, including:

- Accurately track patients lost to follow up by using their missed appointment dates instead of proxies, enabling immediate corrective actions at the site level
- Evaluate the programmatic decision of transitioning children to TLD regimens by monitoring cohorts before and after the regimen transition.
- Identify facilities effectively completing exposed infant testing cascades by isolating infant cohorts and monitoring their progress as they age.

Accurate interruption in treatment (IIT) reporting enables site level improvements

Resolving patient identifiers across the HIS landscape and leveraging patient-level data such as next appointment dates, script lengths, and number of days late to missed appointment has helped the Zambia team understand IIT rates at more granular levels. They can now accurately categorize patients into buckets and differentiate between new, transfers, late, and many other categories.

Figure 6.6.8.7: Interruption in Treatment (ITT) Patient Cohort Analysis



This level of insight has enabled the Zambia team to confidently assess and improve continuity of treatment each month at the site level. In the example below (Figure 6.6.8.8), Zambia began transitioning more patients to 6-month MMD in February 2020. See the drop in IIT% the next month and continued advancing of the program. These insights at the patient-level have led to substantial improvements in retention rates every month in 2020, going from 17% in January 2020 to under 11% in July 2020, at this key site.

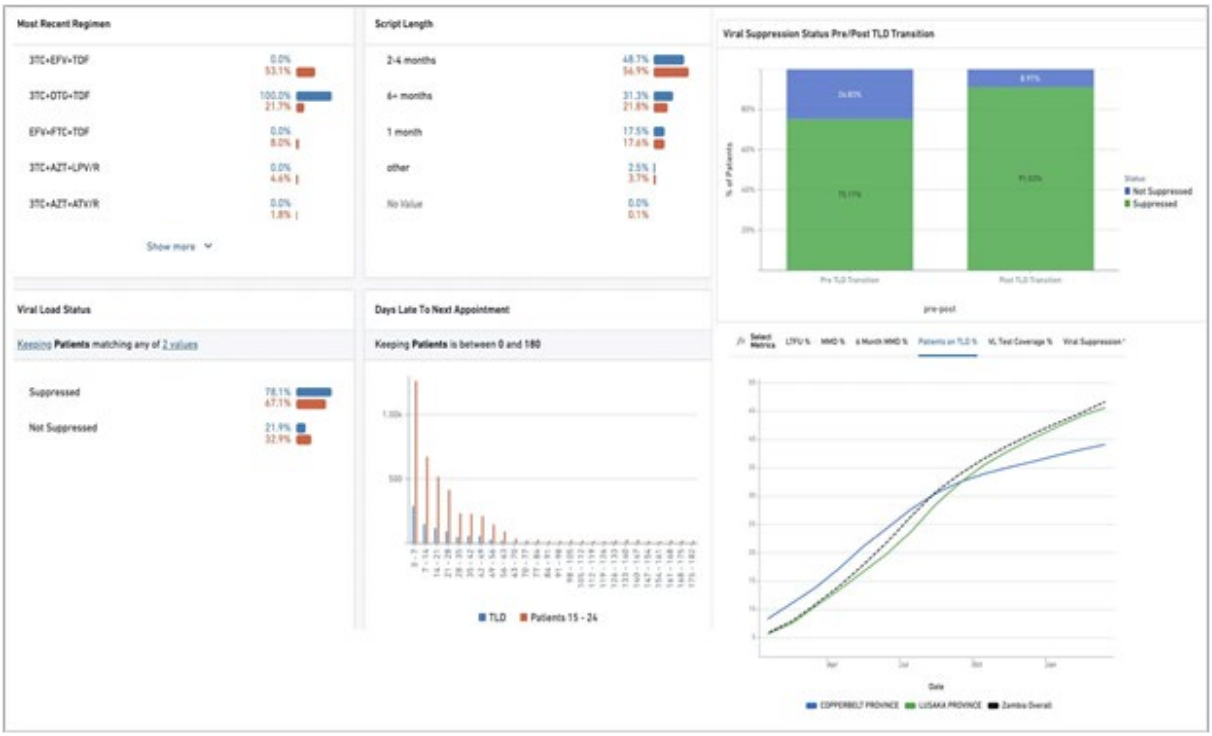
<u>*Cohort analysis allowed for evaluation of TLD regimen transition for pediatrics*</u>

Previously, pediatric care and treatment advisors had not been able to evaluate the effect of programmatic decisions on the health of children. However, as of Q3, access to patient-level indicators enabled the teams to evaluate their decision to transition children to TLD regimens. The team created a true cohort analysis, leveraging multiple variables including time on TLD,

baseline viral loads, date of transition disaggregated by partner, and viral load results pre-TLD transition.

Applying these patient-level variables across time, the team concluded that this programmatic decision was effective; viral suppression rates for patients transitioned to TLD improved from 75% to 91%.

Figure 6.6.8.8: Cohort Comparison, Pre and Post TLD Regimen Transition



<u>*Implementation Considerations for Success*</u>

- The platform is working as an integrated part of the Zambia Health Information strategy and architecture, combining data from EMR, commodity, and lab data sources. Further, data automatically flow between the National Data Warehouse and the platform, where the data is harmonized and made available for use in other tools.
- In addition, the platform's engineering team works to build in-country capacity for building the national ICT framework with the MOH and USG team.
- Strict access controls aligned with associated data use agreements allow users to see only the data they have permission to access, while protecting Personally Identifiable Information (PII) to the fullest extent. Access controls and user access approval has been led by the MOH and the PEPFAR Interagency team.

Support and enhance global partnerships

The U.S. Government continues to support regional efforts to improve the public health response across Sub-Saharan Africa, including support to the Africa Centers for Disease Control and Prevention (AfCDC) and other regional efforts to build regional public health capability. AfCDC was established at the head of states level within the Africa Union. USG, for example, has partnered since AfCDC's inception leveraging its authorities and convening powers to further the digital health agenda in the continent. Notable is support to two Task Forces that have produced "Framework for public health workforce development, 2020-2025" that defined the informatics-savvy national public health institute, competencies for public health informatician, applied and formal training programs, and set target for training and "African Union HIE Policy and Standards for Digital Health Systems" that is being planned for adaptation in Nigeria, Uganda, and Ethiopia. Building on these foundations, PEPFAR teams may use bilateral COP22 resources to support AfCDC and other regional entities to establish and capacitate regional referral centers to effectively detect and respond to emerging health threats, including new outbreaks of HIV. For all SSA countries, PEPFAR funds can be leveraged to support governments to coordinate with and report to AfCDC, including investments in HMIS and critical human resource capacity. In countries with a AfCDC regional reference center, PEPFAR resources can also be leveraged to address infrastructure challenges, particularly related to information technology, internet connectivity, and small renovation projects. PEPFAR resources can also be used to address staffing shortages within the regional reference centers.

Monitoring and planning for digital health investments

PEPFAR OUs should continue and expand emphasis on program sustainability with respect to transitioning ownership of digital health initiatives to partner governments with the introduction of a systematic approach that supports coordinated work across technical and non-technical areas. Relevant health information systems, a competent workforce, and enabling leadership, governance, and policies form three pillars of the informatics-savvy organization (ISO) to sustain and build on PEPFAR HIS investments.

PEPFAR OUs can benefit from MER, Table 6, and the Digital Health Investment Inventory data streams to: (1) provide baseline information on opportunities for improvement of capabilities, processes, and capacity and (2) develop COP plans that are strategically aligned with current and future investments. PEPFAR currently collects EMR_SITE data, which allows country teams to determine the overall coverage of PEPFAR-supported sites with a digital electronic medical records system. EMR_SITE can be used to track trends over time, as well as review

programmatic performance in the context of EMR utilization at the site level. Table 6, when applied to digital health investments, can help standardize project milestones and articulate how specific investments can address key systems barriers in country. Lastly, the Digital Heath Investment Inventory gives OUs the opportunity to landscape and categorize their investments to further align with partner governments, other donors, and across health domains.

A last consideration when planning for digital health investments is that of donor investments, and importantly, coordination of those contributions. Specifically, teams should allocate support to the PEPFAR/Ministry of Health Data Alignment activity[698] to ensure digital health strategies, policies, standards, and lessons learned throughout the activity inform data and systems investment plans. Other relevant Ministries should be included in the planning and investments. Strategic investments should align with the Data Value Chain (Figure 6.6.8.9) to continue to track investments in data management and information systems.

Additional references for this section.[699]

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[698] Early Stage Digital Health Assessment Tool: http://www.katicollective.com/what-were-thinking/introducing-the-early-stage-digital-health-assessment-tool

[699] CDC Global Digital Health Strategy (available by request).
USAID Digital Strategy 2020-2024 https://www.usaid.gov/usaid-digital-strategy
WHO Global Digital Strategy on Digital Health 2020-2025 https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf
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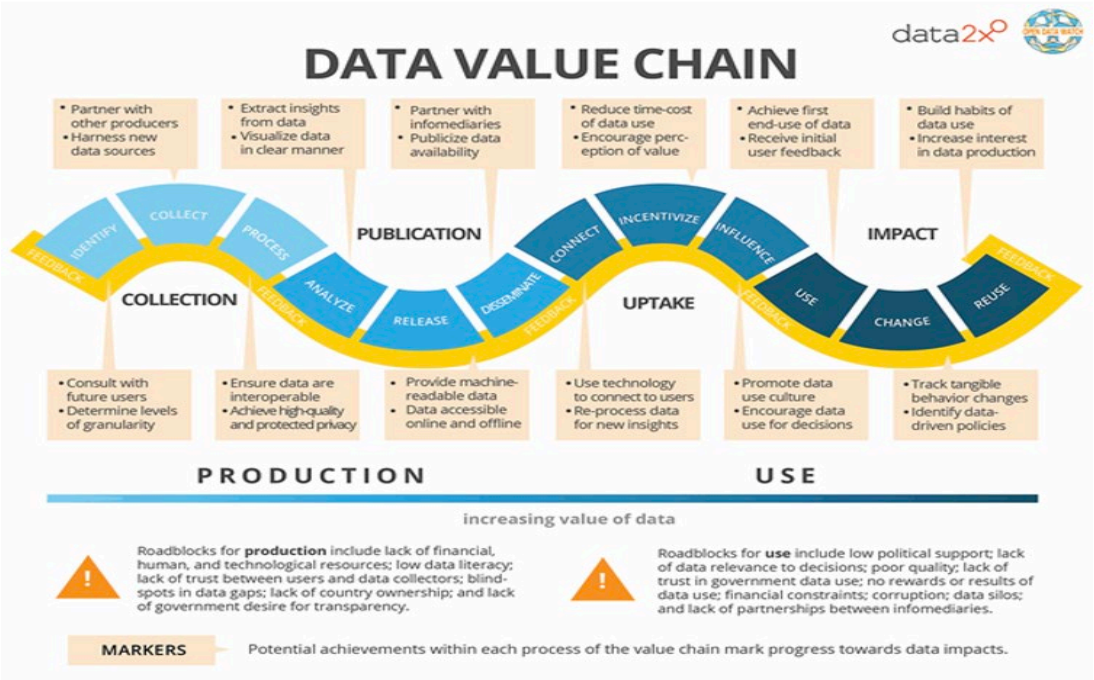
USAID Software Global Goods Valuation Framework, 2019. https://www.usaid.gov/cii/software-global-goods-valuation-framework

Figure 6.6.8.9: Data Value Chain



6.6.8.1 Recent Infection Surveillance Among Newly Diagnosed PLHIV

As of October 2021, HIV recency testing for surveillance has been implemented in 24 countries, and planning and training is ongoing in 7 others.

- Implementing: Cambodia, DRC, El Salvador, Eswatini, Ethiopia, Guatemala, Honduras, Kenya, Laos, Lesotho, Malawi, Namibia, Nicaragua, Nigeria, Panama, Rwanda, South Africa, Tanzania, Thailand, Ukraine, Uganda, Vietnam, Zambia, Zimbabwe
- Planning and training: Botswana, Brazil, Burundi, Dominican Republic, Jamaica, Kyrgyzstan, Tajikistan

In COP22, countries near or at epidemic control should have recency testing for surveillance at scale across all sites and all HTS service delivery points within each site, whether supported by PEPFAR or by other entities. 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. 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 in real-time; and 6) routine monitoring and use of data, in as close to real-time as possible, to assess quality of testing and for public health response. PEPFAR highly recommends 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). 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 management of the client. Recency testing (RTRI or RITA) has no impact on clinical case management of an individual nor on that individual's health. As such, it is recommended that results not be returned to individuals in any setting, but countries should 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.[700]

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.

[700] 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

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, 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 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.

6.6.8.2 HIV Recency Surveillance and Response Among Newly Diagnosed PLHIV

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 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 potential hotspots 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 COP22, country teams should consider the following elements in building and maintaining a real-time 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 real-time-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 6.6.8.1)
    - 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.
- Electronic medical records system, if present in countries, can be modified to include recency data collection.

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 Planning for Sustainable Epidemic Control

6.6.9.1 Developing a Plan for Sustainability

Working toward sustainability of PEPFAR funded activities and pivoting to sustained epidemic control programming is the important next phase of the in-country programs. OUs have utilized

Table 6 of the SDS to program above-site investments. These activities should strengthen and fill the partner country system gaps impacting the capacity and quality of services provided by local governments and providers as shown in the Sustainability Index Dashboard (SID). However, according to the 2019 Responsibility Matrix, most of the core programs in treatment and prevention are the primary responsibility of PEPFAR and the Global Fund. As we look toward a sustained epidemic control of HIV and a transformed program, adequate time for planning and implementation is required as the program evolves.

To effectively achieve epidemic control and pivot to a sustaining HIV impact, country teams will need a transparent multi-staged plan that was established through an inclusive process with all stakeholders. While this plan is not required in COP22, it is important that OUs leverage SID and RM 2021 conversations to start identifying potential areas of the program can shift to the responsibility of the partner government after agreed upon benchmarks have been achieved, aspects of responsibility can shift to the partner government. Each country will be asked to respond to three questions outlined in the SDS annex. These questions are designed to assist countries in beginning a thoughtful sustainability plan.

It is critical that the established framework is drafted in partnership with the partner government and all stakeholders, including other donors. All parties must agree to a clear set of roles, responsibilities, and expectations, during the period of capacity building and transformation. The framework for developing the sustainability plan requires:

1. Working with partner country governments, local institutions, and stakeholders to develop a joint plan with benchmarks.
2. Allowing partner countries to determine when shifts should occur, not everything should be at once.
3. No predetermined amount of time to complete any phase or all phases; and
4. Maintaining open and transparent communication.

The specific objectives for responsible sustainable epidemic control planning include:

1. Increase the capacity of partner governments and local institutions to assume greater responsibility for the functional and financial aspects of the national HIV program as initiated, in part, by PEPFAR's multi-year investments in Table 6.

2. Create a transparent and systematic planning process with specific benchmarks to signal the readiness for partner government to assume responsibility for activities and eventually budgets of predetermined program areas.
3. Create a partnership with local governments and institutions outlining roles and responsibilities for successful transitions; establish specific parameters for multi-year investments necessary to ensure a successful transition process and outcomes.
4. Create a process to monitor progress as well as whole of program risks and corrective actions and determine when to intervene due to unexpected challenges, barriers or unexpected events arise, and a safety net to protect against financial or commodity losses.

The process for sustainable epidemic control includes four key stages:

1. Consensus for transformation
2. Functional management capability
3. Functional financial management
4. Whole of domestic response

It is important to note that each of these stages includes multiple activities and benchmarks. While there are some desired outcomes, the benchmarks, and activities to achieve them are up to the countries to determine.

STAGE 1 - Consensus for transformation

Partner governments are the most critical partners in setting the path for sustainable HIV impact. Gaining consensus from the partner government to plan for sustainable epidemic control is important to ensuring successful implementation. The partner government, local institutions, and stakeholders, including other donors, Global Fund, and multilateral agencies, need to be part of establishing a responsible sustainability plan. This plan will determine how each stage will be implemented as well as the activities and benchmarks.

Stage 1 is completed in partnership with key government agencies, non-government institutions and private sector and multilateral partners to gain agreement on roles/responsibilities and ongoing collaborative monitoring and adjustments based on potential changes in the local environment. Sustainability plans should include a narrative describing government and local institution engagement and agreement on the specific areas of domestic transition and other relevant factors.

Numerous sources can be used to determine appropriate areas of transition. MER, SIMS, SID, FAST, Resource Alignment, Responsibility Matrix, IP and national capacity assessments, and other program resources are available. It's important to review the prior and current investments in above-site activities, as shown in Table 6 of the SDS, to identify areas that have benefitted from multiple years of investment and, thus, may be ready for full transition soon.

As the plans are being written, it is important to outline how and when the plan itself will be reviewed. These plans need to be activity based and should have a level of flexibility in cases when activities or benchmarks are taking longer to achieve. It is not in PEPFAR's best interest to rush to the next stage based on a predetermined time frame when the benchmark itself has not been reached to appropriate satisfaction.

STAGE 2 - Functional Management Capacity

As countries are developing their sustainability plan, it is important to look at the functional capabilities of the government to determine shifts. The first area that should be planned around is the functional management capability of the government and where there are gaps or barriers to responsibility.

As the functional management capacity is strengthened, it can then be determined which elements of the program should be shifted. This allows PEPFAR and the partner government to have greater confidence in the success of the shift of responsibility.

In stage 2 the management of the activity is the only area that would shift. The financial responsibility would remain with the USG. It is also important to note that not all intended activities need to shift at once. It could, and most likely should, be planned for activities to shift after achieving different benchmarks. This will allow for appropriate support to be provided during the transition periods.

STAGE 3 - Financial management capability

During stage 3, the financial management of activities should begin to shift responsibility. This does not require the partner government to take financial responsibility at this time however they should be planning for that eventuality in stage 4.

As with stage 2, the predetermined shifts should occur based on the achievement of benchmarks. It is important that the financial management shift be implemented in a transparent and flexible manner and support should be at the ready and provided if/when requested or necessary.

STAGE 4 - Whole of domestic response

This final stage is where the shift of financial responsibility occurs. Throughout out the previous stages, the partner government should be preparing for this final piece. This is critical in achieving a sustainable epidemic response allowing PEPFAR to move from its current role to advocate and advisor.

As with the previous stages, it is not expected that the full responsibility would occur at one time, it would gradually shift as benchmarks are achieved. This will allow the country to take on this role in a responsible manner while managing programmatic and financial risks.

As mentioned in Section 2.2.4, there are six principles of sustainable epidemic control. Implementing these principles throughout the four stages include:

1. Transparency

   This is a key component of sustainability planning. Open and transparent communication on the sustainability goal, process, and participating stakeholders supports trust between all parties. It will encourage participation and ownership because all parties will understand the entire process and to understand the full vision being planned and implemented.

2. Equity

   Equity should be considered across all sustainability planning and implementation. It is essential that where there is equity, it should be maintained, and where there is no equity, it should be worked toward. It is important that this is actively monitored and if the planning and implementation is not successful, real-time adjustments should be made to constantly improve upon achieving equity.

3. Predictability

The established plan should include predetermined benchmarks and agreed upon moments of review. These openly agreed to benchmarks allow all stakeholders to understand exactly what will happen and when. It is also important to establish a review process that includes times for stakeholders to come together and discuss the progress, achievements, and any barriers. This ensures that at no time will any party be caught unaware of the status of the plan.

4. Inclusion

   All stakeholders should be involved in the planning and implementation process. This includes members of the partner government, local institutions, donor community, CSOs, beneficiary groups, and the list can go on. This is to ensure that all aspects of planning have been considered.

5. Flexibility

   Sustainability planning is a continual process and as such it should be adaptive and responsive. It is important to account for unforeseen circumstances which requires the plans to be reviewed and adapted. These trip wires will be important to ensure the successful achievement of sustained epidemic control. It should be through a predetermined and transparent process that the plans are reviewed and updated if necessary.

6. Commitment

   Each partner government as well as stakeholders need to be committed to this process. Stakeholders should be fully invested in the sustainability plan process for successful implementation and sustained change to occur. During Stage 1 when the plans are being written, it will be important to set expectations for the final outcome, clearly define roles, and include how risks and opportunities will be documented and addressed. The risk management process should be transparent to all stakeholders. As concerns/priorities are recognized and addressed through the sustainability plan, stakeholders will see the value add and it will encourage their ownership of the process.

The country level plans for sustained epidemic control may all look different, however they should all include the following components:

1. A narrative, with accompanying benchmarks, outlining what needs to be achieved for each next action to start. The narrative should include the roles and responsibilities of the local government and key stakeholders, timeline, indicators, and outputs and outcomes. When developing benchmarks and indicators, take into account the nature of the activities (capacity building vs project performance). Reliance on performance indicators alone may inadvertently create short term focus to demonstrate improvement without addressing the root cause(s) and build sustainable systems that can effectively provide health services over the long term. This information can be used as a monitoring tool by the OU during the PEPFAR business cycle to report out on progress.
2. The inclusion of all above-site investments into Table 6 under a specific designation related to the sustainability plan with the elements required in Table 6 for monitoring progress and impact.

A monitoring plan and risk log which establishes the frequency the stakeholders will meet to review progress and discuss barriers. It should also be determined how risks will be monitored and reported on so that the appropriate mitigation measures can be put into place.

6.6.9.2 Programmatic Sustainability for HIV Services and Systems

Components for Sustained Epidemic Control

Comprehensive HIV surveillance focused on 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 design) are vital. For sustained HIV epidemic control, recent infections, and case-based surveillance (CS) are central in monitoring the epidemic and ensuring a public health response to emerging issues. The COVID-19 pandemic has highlighted the inherent inequities in the healthcare systems. All PEPFAR programs are expected to use program data to continue to monitor the epidemic and to tease out and address these inequities.

Critical above-site programmatic elements include HRH, HIV surveillance, supply chain, laboratory, and information systems. Advancing domestic resource mobilization ensures utilization of country resources for greater shared responsibility to sustain epidemic control. Activities should advance integration and alignment of key functions of the HIV program into government systems without compromising sustaining achievements in the HIV response.

Investments here are contingent on demonstrated political will and a policy environment that allows access to services.

Information systems need to be robust and implemented across health facilities. It is vital that partner governments work to utilize and maintain high quality, interoperable health information systems for population-level monitoring, patient-level monitoring, and program decision-making. Ongoing support for systems governance, interoperability, and workforce capacity is essential, especially as countries need to optimize supply chain logistics, laboratory utilization, and HRH staffing allocation based on site-level programmatic data. Patient-level information systems should be used to track clients across sites, outcomes, and over time. Countries should utilize these data for surveillance systems to allow tracking of all newly diagnosed individuals on ART, for an effective case-based surveillance system from first diagnosis to death. This system should feed real-time data for monitoring newly diagnosed cases, recent infections, ART coverage, and VL suppression. The Ministry of Health, subnational governments, and site level staff should be able to access data analytics training to effectively use the information system. HIS trainings and academic courses should be present in country to ensure skills can be acquired and updated. There should also be laws and policies in place that both encourage data openness and protect the data stored in information systems. In particular, laws and policies related to unique identifiers, data sharing, privacy and confidentiality, and standardizing collection and analysis support a sustainable information system.

A functional and effectively governed supply chain system is central to sustainable epidemic control. Countries need to ensure oversight of supply chain operations that is informed by data systems that provide quality data at central, regional and site level facilities. Infrastructure (warehousing/storage) and distribution systems need to be in place in order to consistently serve patients in all areas of the country. Countries need better inventory management systems to avoid stock outs and interrupted testing. Countries must routinely support the triangulation of supply chain and program site-level results. This should be performed in coordination with partner governments, supply chain technical assistance partners, and clinical partners. The root cause of anomalies found during this triangulation should be investigated by both supply chain and clinical partners.

Good governance and leadership are prerequisites for effective and efficient, country-led HIV responses. A country that can achieve sustainable epidemic control has appropriate laws, regulations, policies, and strategic planning processes, based on a culture of decision-making that is informed by data and meaningful engagement of relevant actors, including civil society

and the private sector. Laws, regulations, and policies to promote effective and efficient HIV programming include: those related to the provision of HIV-specific services; the creation of a functional and inclusive health and wellness system that benefits all ages, genders, socioeconomic groups, and key and vulnerable populations; as well as those that encourage public participation, transparency, and government accountability, and proscribe discrimination and stigmatization of marginalized individuals and communities, as well as laws that encourage data openness, privacy and confidentiality, and accountability.

Orienting service delivery toward person-centered HIV service integrated care is critical to reach at-risk populations, facilitate continued ART adherence, re-link those who disengage from clinical care, and sustain engagement with newly diagnosed people living with HIV. A mix of facility and community-based service delivery is integral to increase access to HIV services and achieve better health outcomes. Service integration is context dependent. For those living with HIV, maintaining quality HIV treatment services that ensure viral suppression while addressing other needs, such as co-infections, comorbidities, better nutrition, and mental health services, will enhance patient outcomes. HIV prevention and testing services will require more focused and targeted approaches which can be achieved in sync with recency testing. Quality management will become an increasingly important function of the HIV program to monitor the epidemic and quality of outcomes of those living with HIV. Monitoring the epidemic and the quality of services will also facilitate a public health response that sustains epidemic control.

Human Resources for Health (HRH), the partner country government, and the private sector's ability to support the health workers required for the provision of HIV services is necessary for long-term capacity to manage the HIV response. Alignment of HRH cadres and support (amount and type) to partner country government systems is key for facilitating absorption of workers required for sustained epidemic control, as is supporting a robust private sector market. To advance integrated patient-centered care, HRH staffing will need to be reconfigured toward integrated team-based care and case management. Please refer to Section 6.6.7 on HRH for more information.

Domestic resource mobilization is key to ensuring programmatic sustainability. As countries move toward epidemic control and sustainable epidemic control, there is a greater focus on ensuring domestic resources are available for the HIV response. Domestic resource mobilization (DRM) includes generating additional resources for HIV as well as more efficient use of domestic resources. Activities that generate additional resources include increased tax revenue and strengthened public financial management, such as increasing fiscal space,

greater budget allocation and execution. Reforms that lead to greater efficiency of spending include integrating HIV into existing health financing schemes and systems, rather than maintaining stand-alone HIV programs, and those that also put in place systems for maintaining achievements and quality of HIV service delivery.

In many countries, HIV prevalence is higher among the highest wealth quintiles. Free or subsidized HIV services from the public sector may not be well-targeted to these individuals. The private sector already serves people across the wealth quintiles, including through private hospitals and clinics, pharmacies, and traditional or non-formal providers. Furthermore, many private sector outlets may be a better fit for those less likely to seek care in the public sector, such as men, adolescents, or key population groups. PEPFAR programs typically do not provide funding to deliver services through the private sector, but these can be considered. Low- and middle-income countries often have limited fiscal space to increase public budgets for health and typically have small private sectors. Strengthening the private sector to deliver HIV/AIDS services can decongest public facilities and free up additional resources to control the HIV/AIDS epidemic.

PEPFAR should ensure that services through the private sector increase access and provide services to those willing to pay, and that costs for health care utilization (i.e., user fees) are not a barrier. In other words, expansion of services in the private sector will take a total market approach lens. PEPFAR programs must ensure that QI/QA support that is provided to strengthen private sector service delivery is aligned with the national framework. Service delivery indicators and data reporting for the PEPFAR supported private sector should meet the national and PEPFAR requirements.

Equity must be addressed in all the areas of HIV programming. This requires that those who are disadvantaged can access health services, are treated with respect, and at little or no cost. To ensure equity, HIV programs must target the most in need to reach those who need the public services the most. This will allow those who can afford to pay to move to the private clinics. To achieve sustainable epidemic control with equity, HIV programs will need to have four elements: data, systems strengthening, core competencies, and a sustainability pathway.

Greater engagement of local institutions implementing HIV services and above-site functions facilitates a greater shared responsibility for sustainable epidemic control. Building capacity of local institutions, including local governments, community, religious, and civil society organizations, ensures that these entities are ready to directly manage funds and deliver quality, high-impact services. Direct funding of local institutions by donors and ultimately by national

governments through formal, transparent, and regular processes for HIV service delivery, is a key component of sustained epidemic control.

National contributions to the HIV/AIDS response are critical both in progressing toward and sustaining epidemic control. While PEPFAR has historically emphasized the important role of national financial contributions, enabling policy environments, inclusive service delivery, and robust national systems in preparing for epidemic control, these elements of shared responsibility must be realized for countries to sustain epidemic control. PEPFAR's investment in partner governments and local institutions increases country capacity for local implementation and ensures services can be sustained without external partners.

Case Study: Lab Sustainability

The laboratory is critical in measuring and determining impact and successes of the three UNAIDS HIV treatment goals of 95-95-95 that are needed to reach epidemic control. In addition, the laboratory is very important in diagnosing and monitoring public health outbreaks and other diseases that may impact the gains of HIV epidemic control. Hence, sustainability of HIV epidemic control among countries will require that the following key laboratory areas are available and functioning:

1. Transition from outright instrument procurement to all-inclusive pricing approaches 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.
2. Complete diagnostic network optimization (DNO) at the national level to avoid issues around poor instrument service and maintenance, low testing coverage, inefficient instrument utilization, and fragmented data and quality systems.
3. Successful implementation of quality improvement and accreditation of national public health laboratory to ensure continued release of quality assured laboratory results to response to national public health needs, and
4. Availability of costed and dedicated funds to avoid interruption in testing due to lack of funds to support laboratory commodity and HR needs.

Case Study: Data Ecosystem-Building

Health Information Systems (HIS) are the basic infrastructure needed to manage healthcare data, and a functioning, quality HIS is critical to sustainable HIV services. It enables national and subnational governments, health facilities, pharmacies, laboratories, and CSOs to access patient, HRH, and supply chain data for integrated data analytics and to share these data

across service providers for reduced HIV service fragmentation. HIS help providers get the right treatment to the right patient at the right time for the most efficient use of resources and the best quality care.

PEPFAR has invested millions of dollars into developing the HIS infrastructure and networks needed for HIV services. However, to ensure these systems can be sustainably leveraged by government officials, healthcare workers, patients, and civil society, a healthy data ecosystem is needed.

Data Collaboratives for Local Impact (DCLI) was a partnership between PEPFAR and the Millennium Challenge Cooperation to build local data ecosystems for health from 2015 to 2021. DCLI started in Tanzania in 2016 and expanded to Cote d'Ivoire in 2018. The program focused on: 1) creating permanent centers of data use (e.g., data labs, coworking spaces), 2) building data skills locally and inclusively (e.g., workshops, training bootcamps, graduate courses, and capstone projects), 3) supporting the government's development of data-friendly policies for health, and 4) catalyzing health-related data innovations and partnerships for a whole-of-domestic response to public health (e.g., innovation challenges, accelerator programs). DCLI was designed to create permanent, sustainable changes that strengthen health systems, which improves not just the response to HIV, but to global health security as well.

In Tanzania, DCLI established the dLab as its data hub. The dLab created the first Masters of Data Science in East Africa with the University of Dar es Salaam, including a "PEPFAR Scholars" track that offers a capstone project with PEPFAR implementing partners. The dLab also trained over 2,000 people in data analytics, of which 59% were women.

The dLab partnered with the Government of Tanzania's Ministry of Health and the President's office of Regional Administration and Local Government to develop a Health Facility Data Guide that the government is rolling out nationwide, across all 6,400+ healthcare facilities in Tanzania.

The dLab also funded 53 local entrepreneurs and organizations to develop dozens of local solutions to support linkage to services, HIV/AIDS awareness, and DREAMS-related priorities. One awardee's tool has been used by more than 4 million people (as of September 2021) for real-time information on medication availability and wait times at nearby health facilities.

Even though PEPFAR funding came to an end, the dLab continues to strengthen the data ecosystem for health. It recently incorporated as a self-sufficient, locally led NGO, receiving over $720,000 in support on its own, including from the Ambassador's small grants program to better target HIV-awareness social media campaigns. Programs like DCLI that invest in the local

ability to support HIV programming can result in permanent, system-wide changes that can continue to build momentum.

Case Study: Supply Chain

Public health supply chains operate on a spectrum of responsibility where donors, the government and the private sector all have evolving roles as the system matures. The responsibility spectrum is illustrated by functional area in the two figures below. Countries may develop at different rates across the listed functional areas, meaning that a specific country may be classified as “Government Operated” for “Performance Management,” but “Autonomous” for “Procurement.” This type of staggered development is expected and any evolution on this spectrum is encouraged. Countries should seek out technical assistance which allows them to progress through the spectrum below, increasing capacity and efficiency with each step. PEPFAR teams should make investments that move supply chain systems away from government-managed logistics to more fully utilizing private sector capacity (i.e., manufacturer or supplier-managed distribution, distribution through private pharmacies or use of third-party logistics providers). In tandem, PEPFAR teams must strengthen partner government capacity to source low-cost, high-quality medicines and ensure national medical regulatory agencies monitor the quality and security of supply chains.

Figure 6.6.9.2.1 Supply Chain Archetypes

Supply Chain Archetypes - Moving Into the Next COP With An End Goal in Sight

Countries fall along a spectrum of models that minimally or fully engage the private sector

ARCHETYPES:	1. HUMANITARIAN	2. GOVERNMENT OPERATED	3. MIXED MODEL	4. AUTONOMOUS OR "PRIVATIZED"	5. FULL COMPETITION
Overview of Characteristics	• Present in conflict-prone settings or for public health emergencies • Time-limited supply chain that fades or merges over time.	• Traditional Central Medical Store (CMS) with limited autonomy. • Comes in a range of autonomy (w/in MOH, semi-autonomous, fully autonomous) • Supplies most of public sector meds, with limited competition with open market.	• Partially outsourced CMS. • Comes in a range of autonomy (w/in MOH or semi-autonomous) • Outsourced portion run by NGO or commercial logistics company. • Supplies large portion of public sector need with limited competition from other sources.	• The fully outsourced or "privatized" CMS. • Fully autonomous. • Outsourced to an NGO or commercial logistics company as a contract/concession. • Supplies portion of public sector meds, placing the CMS increasingly in competition with wholesalers.	• Fully reliant on open market (wholesalers, suppliers or retail pharmacies). • Patients pay out of pocket or seek reimbursement from insurers. • Government oversight on pricing & drug quality. • No Central Medical Store.
Funding Model	• Ad hoc • Donor-reliant • No steady stream of host govt. financing	• Budgets can be line in MOH budget; or • Revolving fund; or • Independent account w/ Treasury/MOF	• Budgets can be line in MOH budget; or • Revolving fund; or • Independent account w/ Treasury/MOF * Some meds not purchased with public funds sold	• Budgets can be line in MOH budget; or • Revolving fund; or • Independent account w/ Treasury/MOF * Some meds not purchased with public funds sold	• Health insurance • Out of pocket
Oversight	• Donor/govt. task team	• MOH oversight; or • Board of Directors (mostly occupied by MOH employees)	• MOH oversight; or • Board of Directors (mostly occupied by govt employees)	• Board of Directors (mixed, govt and private) • MOH oversight mainly programmatic	• Drug regulatory authority; • MOH; and • Insurance.

Supply Chain Archetypes - Moving Into the Next COP With An End Goal in Sight

Countries fall along a spectrum of models that minimally or fully engage the private sector

ARCHETYPES:	1. HUMANITARIAN	2. GOVERNMENT OPERATED	3. MIXED MODEL	4. AUTONOMOUS OR "PRIVATIZED"	5. FULL COMPETITION
Procurement	• Ad hoc procurement, typically not by CMS • Quantifications based on program targets	• Procurement by CMS • Quantification and supply planning based on consumption, where data is available.	• Procurement by CMS • Quantification and supply planning based on consumption, where data is available.	• Procurement by CMS • Quantification and supply planning based on consumption, where data is available. • Some vendor managed inventory.	• Demand aggregation and supply planning coordinated by a control tower at MOH • Suppliers respond to control tower to delivery to last mile.
Last Mile Chain of Custody	• Chain of custody typically an NGO providing disaster relief or humanitarian assistance.	• Storage provided in government owned and managed warehouses. • Distribution done through government owned and managed fleet.	• Storage provided by government and/or 3PL(s). • Distribution done through government and/or 3PL(s).	• Storage provided by 3PL(s). • Distribution provided by 3PL(s). • Could be single provider or segmented.	• Storage and distribution managed by suppliers (wholesaler, manufacturer or retailers).
Performance management	• Ad hoc measures of success.	• Common supply chain metrics (OTD, OTIF, etc).	• Common supply chain metrics (OTD, OTIF, etc).	• Common supply chain metrics (OTD, OTIF, etc). • For vendor managed inventory, shift to product availability.	• Shift towards product availability metrics (on the shelf).
Staffing of supply chain	• Staff hired by NGOs or civil servants.	• Civil servants; or • Limited authority to hire outside experts except on ad hoc basis.	• Civil servants or limited authority to hire supply chain experts. • Mixed with 3PLs/contracted staff running specific components.	• 3PLs/contracted staff. • Or for "privatized" or autonomous CMSs, supply chain professionals recruited.	• Fully private sector employees.

6.6.9.3 Financial Sustainability of the HIV/AIDS Response

Sustainable control of the HIV/AIDS epidemic will require strengthening locally-led program implementation; increasing domestic responsibility and investments; optimizing resource allocation and use; ongoing review and alignment between funding resources, programmatic costs and efficiency, epidemiology, and the macro-economic situation; advancing private sector

engagement; and identifying innovative financing mechanisms and promoting healthcare financing ecosystems. Sustainability will also need the creation of core competencies in health systems management at the country level and the use of evidence to plan and monitor progress for the next phase of the response. The COVID-19 pandemic has resulted in severe economic downturns across the world, and this coupled with a drop in commodity prices, oil, a steep decline in tourism and an increasing debt to GDP ratios means that the fiscal environment will remain severely constrained. Flat-lined international assistance and competing demands for public funding put a renewed focus on how PEPFAR along with its partners can assist governments not just mobilize more resources, but how to use these more efficiently and effectively.

Ensuring sustainable control of the HIV/AIDS epidemic will require more than ever stronger cooperation and coordination among stakeholders to advance greater domestic and locally led functional and financial responsibilities for elements of the response. This can be achieved through strategic alignment and complementarity across core HIV and broader health resources to maximize impact and value of PEPFAR, Global Fund, partner country, and other donor investments. It is also clear that sustaining our gains will require PEPFAR to leverage resources from not just the government sector but also private markets and therefore PEPFAR will need to consider additional and innovative financing approaches and instruments while not losing sight of the traditional health financing support we have always provided to countries.

To encourage increased financing from private, non-traditional funding sources, the PEPFAR program, along with its partners, is:

- Focusing on the efficient use of existing resources to ensure that maximum performance is achieved with limited funding,
- Sharing harmonized financial (budget allocation and expenditure) and program data with the Global Fund, partner country governments, civil society, and other donors to understand the complete picture of the HIV/AIDS funding landscape and progress towards epidemic control and facilitate better planning and monitoring,
- Engaging ministries of finance (MOFs) to ensure comprehensive HIV/AIDS programs are developed and funded in national budgets, with increasing proportions funded by partner country governments over time,
- Working with partner country governments and civil society to strengthen key processes and systems, including secure procurement and supply chains and financial management systems, to maintain services and sustain epidemic control; and

- Ensuring that the private sector has space to thrive and take on elements of HIV/AIDS service delivery and financing.

<u>Traditional Health Financing Approaches</u>:

This section addresses the traditional health financing instruments that should be considered to increase domestic resource mobilization and optimize allocation and use of resources.

- ***Public Financial Management***

  Aligned with PEPFAR's minimum program requirement of increasing domestic resources expended for HIV, the Public Financial Management (PFM) area of work includes budget formulation and execution, accounting and reporting in the health sector including HIV, as well as addressing system inefficiencies to maximize resource use. Efficient allocation and use of resources is essential especially in the backdrop of the COVID-19 pandemic that is constricting countries' economic growth. Strengthened PFM systems will support countries in maintaining the commitment of domestic health and HIV resource mobilization prior to COVID-19, depending on the macro-fiscal environment, and rapidly increasing budget execution while maximizing efficiency.

  Country teams should review what percentage of the HIV budget is coming from government contributions (including specific budget line items e.g., HIV-related commodities where applicable) versus resources available from donors and whether this has increased over the years. If government budget allocations continue to be low, then teams should think of ways in which they can engage with partner country governments to increase domestic resource mobilization for HIV. Given COVID-19 and its economic impacts, it might be equally important to ensure that cuts are not made to current levels of government spending on HIV and assess what safety nets exist to mitigate shortfalls that may arise. Specific activities should be considered that could directly support to ensure current levels of government allocation are maintained and where possible additional resources are made available.

  The next thing to consider is what percentage of the HIV budget is actually executed (expenditures) and has this improved from previous years. If budget execution is low, activities should be considered that will support improving budget execution, overcoming bottlenecks and allow for better management of resources.

- ***Improved collection, analysis and use of HIV/AIDS and related health financing data to drive efficiencies and improve resource allocation***

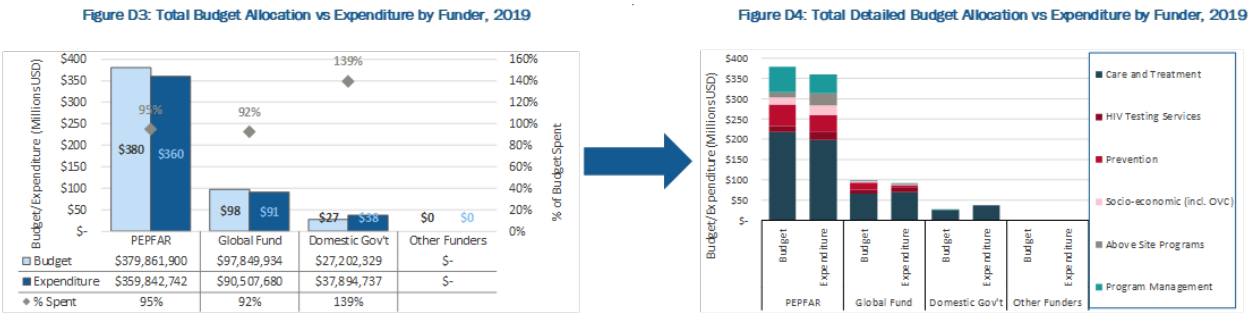
Achieving sustainable control of the HIV/AIDS epidemic requires timely and routine availability of reliable HIV/AIDS and related health services financing data for informed decision making by key stakeholders, including donors and partner country governments. This is even more important given the significant fiscal impact caused by COVID-19 on already constrained health sector resources. Increased transparency and availability of HIV/AIDS and related health and social program financing data alongside other programmatic data streams which are analyzed will provide a strong evidence base to inform program planning, budgeting, increased efficiency, and program impact. The routine availability of data and analyses are intended to optimize resource alignment, complementarity, allocation, and execution of all available resources. Data on observed cost of services triangulated with funding landscape data helps improve resources needs estimation, budgeting, and management of programs. Delivering more with every dollar means that the PEPFAR program in collaboration with partners must continue to use program and financial data to identify best possible strategies for resource allocation and solutions needed to reach the most people in need of HIV/AIDS services with available financial resources. Ultimately, in order to ensure cost-effective and sustainable programs that ensure people living with HIV and vulnerable populations do not experience financial hardship, it is important to improve transparency and availability of financing data to decision-makers.

In order to advance improved collection, analysis and use of HIV/AIDS and related health financing data, S/GAC has prioritized the following key initiatives:

→ ***Resource Alignment (RA):***

A PEPFAR and Global Fund joint collaboration that provides routine and harmonized budget and expenditure data across the three main HIV/AIDS funding sources i.e., PEPFAR/USG, the Global Fund, and partner country governments as well as, where available, data on other funders. This routinized collaboration provides harmonized data—across all countries with joint PEPFAR and Global Fund presence--on budgets and expenditures across the two donors and is intended to provide greater visibility on partner country government resources and where available data on other funders. This initiative supports better understanding of all available resources supporting the HIV/AIDS response in each country, ensures alignment, avoids duplication, and improves efficiency and accountability of programs. This initiative seeks to continually improve upon and build an increasingly robust data set each year.

Figure 6.6.9.3.1: Total Budget Allocation vs Expenditures by Funder



The Resource Alignment initiative is not intended to replace any other resource tracking activity e.g., National AIDS Spending Assessments (NASA), Global AIDS Monitoring (GAM) Reporting, National/System of Health Accounts (N/SHA), etc. and neither are partner country governments expected to adapt the harmonized financial classification for tracking their own HIV/AIDS and related health investments. Instead, the Resource Alignment initiative jointly created by PEPFAR and the Global Fund is intended to serve as a "Global Good" that leverages and improves upon existing data and provides timely and routine information to decision-makers at national and international levels for program planning, improving efficiency, and resource allocation.

→ ***Activity-Based Costing and Management (ABC/M):***

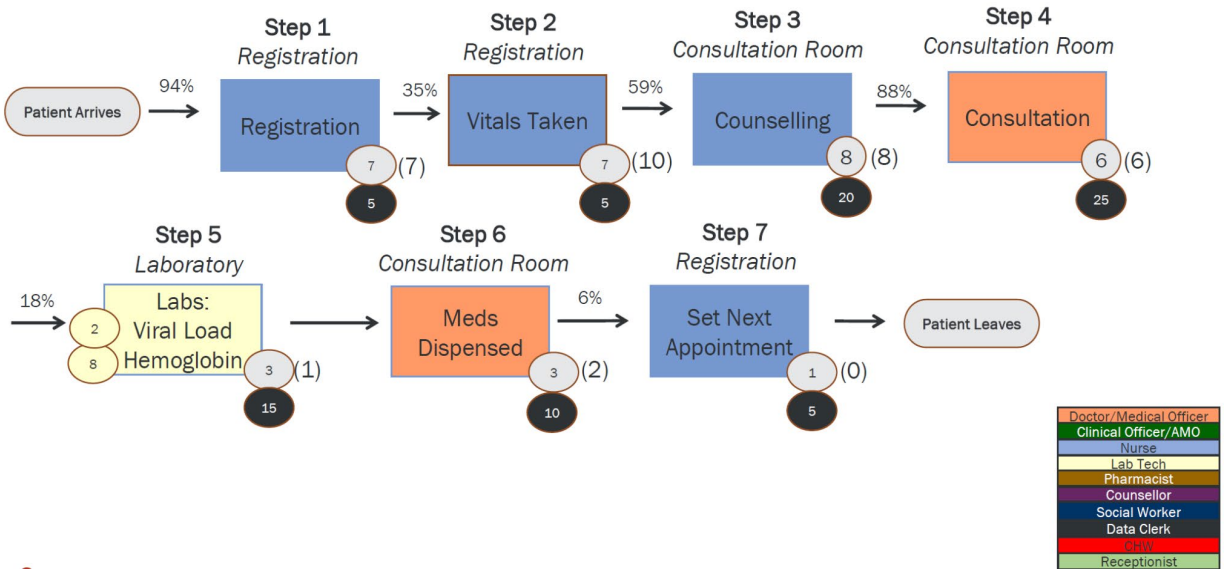
A consistent and standardized methodology, developed through consultation between HIV/AIDS global partners viz. PEPFAR/USG, the Global Fund and UNAIDS, to generate routine cost information for HIV/AIDS and related health services at all levels of support; and the resulting information can be used by managers and policy makers for improving resource allocation, program efficiencies and monitoring. The ABC/M initiative supports:

- Stakeholders identify observed costs for HIV/AIDS and related health services. In most countries, the actual cost of providing HIV/AIDS services is largely unknown or determined for one point in time, which is not as useful in a dynamic health service delivery system. This information is essential to facilitate eventual transition towards domestic financing and absorption of HIV/AIDS interventions into partner government programs and budgets.
- Estimate the partner country government's resource needs for financing delivery of HIV/AIDS and related health services through national health insurance schemes and government budget allocations.

- Facilitate a more financially sustainable and effective response for HIV/AIDS and related health service platforms via routine use of service delivery cost data.
- Fill key service delivery and data gaps needed to accelerate reach of HIV/AIDS prevention, testing, and treatment services for those left behind, which is necessary to control the epidemic.
- The goal of moving countries toward higher levels of country ownership and sustainability of HIV/AIDS and related health programs.

The results from Tanzania and Uganda are starting to shed very important light on the observed costs of providing HIV/AIDS services. It is not surprising that the costs of drugs and other commodities account for a big part of the costs. However, excluding these costs, initial indications are that the observed cost of interactions directly with patients as measured by ABC/M may represent relatively small portion of total costs of providing services. For the first time, it is possible to quantify the subsidy that HIV funding, like from PEPFAR, provides to the overall primary health care system. As an example, in both Tanzania and Uganda, staff at sampled facilities who are exclusive to the HIV/AIDS program spend anywhere between 30 and 35 percent of their time on non-HIV activities. This shows that decisions made exclusively from an HIV perspective can have broader ramifications on the broader health care system.

Figure 6.6.9.3.2: Illustrative Example of a Hospital Client Flow and HRH Contributions



Service delivery process maps are also an integral part of the ABC/M methodology and also as part of other methodologies used to determine health workforce staffing needs.[701] They track patients through every stage of their interaction with the health care facility. These process maps are showing that quality gaps persist and highlight the need to address these as part of optimizing the overall patient experience. While the observed cost of care at point of service is close to zero for the patient, they spend a fair amount of money on transportation and lost wages due to time spent traveling to the facility and waiting there to receive services. This can be a deterrent for many, including young men, to go and stay on treatment, and these findings underscore the need to see how services can be made more accessible for individuals. PEPFAR is now starting a process to look carefully at these expenditures to further optimize staffing models achieve HIV program goals under a flat budget scenario and ascertain staff roles that are truly essential for the long term.

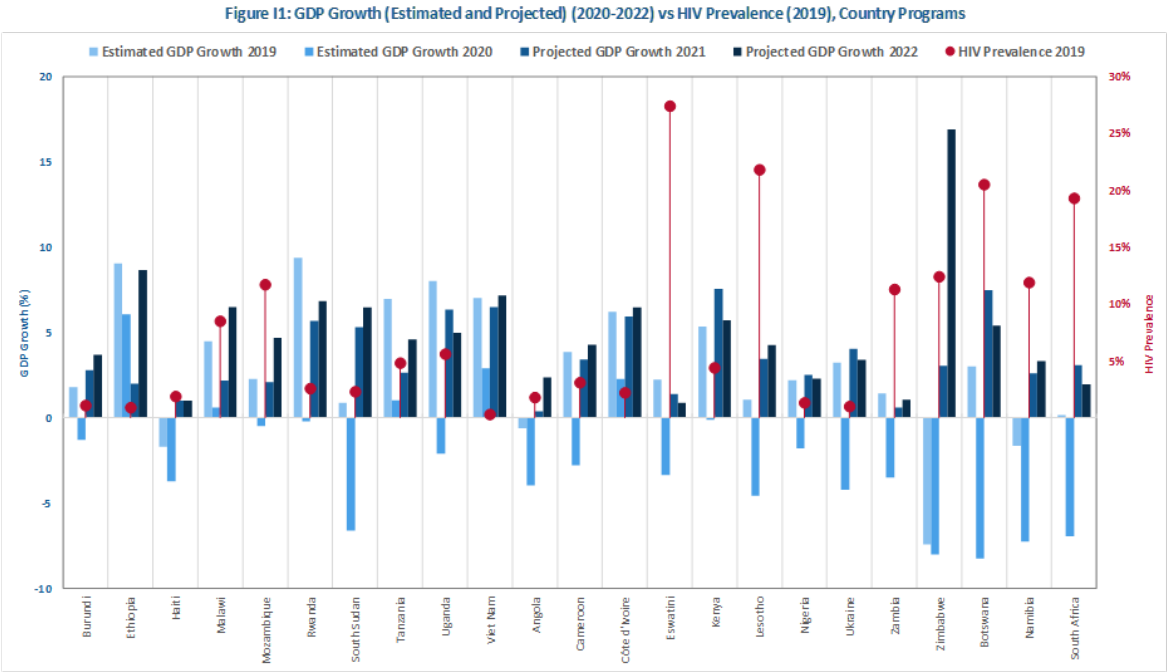
Country teams are strongly encouraged to consider implementing ABC/M. If more information is needed, please reach out to your Chair and PPM.

→ ***Monitoring Macro-Fiscal Environment in the Wake of COVID-19:***

It is by now widely understood that the COVID-19 pandemic has had severe economic repercussions. All indications are that the recovery in most countries will be slow and gradual, with most experiencing significant economic stressors for at least the next two to three years. PEPFAR is closely examining the macro-fiscal environments in its partner countries, with a special focus on those with the highest levels of HIV disease burden. The chart in Figure 6 below shows that low- and middle-income countries could have less of an ability to invest more of their resources (as had been previously planned in a pre-COVID-19 environment) into their HIV response. Further, given their understandable priority of restoring economic growth as quickly as possible, their ability or willingness to invest in overall health is likely to be severely constrained. Ensuring the sustainability of programs will need a renewed focus on how partner country governments can be assisted to not only mobilize more resources but how to use these resources more efficiently and effectively to maximize impact.

[701] https://datafi.thepalladiumgroup.com/wp-content/uploads/2021/02/Data.FI_Human-Resources-for-Health-Optimization-Solution_SB-20-04.pdf

Figure 6.6.9.3.3: Trends in Estimated and Projected GDP in PEPFAR Countries



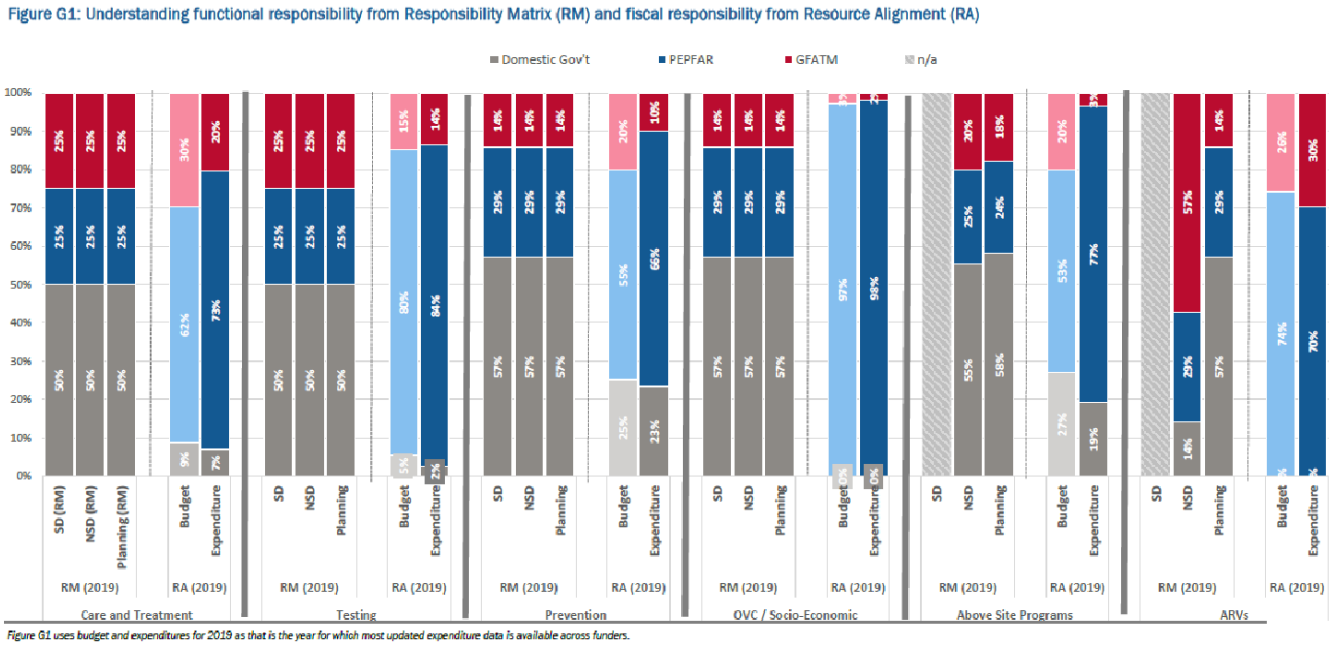
→ ***Human Resources for Health (HRH) Inventory:***

A new PEPFAR reporting requirement was introduced in FY21 to will provide detailed information on staffing support provided by PEPFAR programs at the level of service delivery, non-service delivery, and program support.

→ ***Integrated Analytics for Sustainability Planning*:**

Harnessing all available financial and program data available—including RA for budgets and expenditures, ABC/M for observed costs of services and programs, HRH inventory, Sustainability Index Dashboard (SID), Responsibility Matrix (RM), Monitoring Evaluation and Reporting (MER), program quality data, and macroeconomic data—to equip countries and donors in developing strategies and a roadmap for a sustainable HIV/AIDS response.

Figure 6.6.9.3.4: Understanding Functional Responsibility from RM and RA



PEPFAR country teams and the global community have the tools required for countries to achieve sustainable control of the HIV/AIDS epidemic. To make this goal a reality, key stakeholders will need routine availability of granular program funding landscape, and cost data to inform policy, decision-making, and shift in responsibilities. Availability of routine data on budget allocation, expenditures, and cost of services as well as detailed information on HRH support are critical for partner country governments, donors, private sector, and other partners for planning, to estimate resource needs, allocate resources, improve donor coordination and monitoring efforts, and increase program efficiency in pursuit of HIV/AIDS epidemic control and ensuring a domestically led sustainable and resilient response.

❖ ***Risk Pooling / Health Insurance***

Expanding and integrating HIV services into the benefit package of Social and Private Health Insurance schemes is a system change that will ensure long-term increases in financing for HIV services. Note that nascent health insurance schemes or schemes with low enrollment might not be good candidates for this activity. Consider the following steps:

- What is the maturity of the Social Health Insurance (SHI) program in a country? Is there a policy for SHI? How long the program has been implemented and what

proportion of the population is covered under this scheme. Does the government contribute to this scheme?

- Are HIV services integrated into the country's SHI scheme? What services are included in the benefits package? If it is not part of the benefit package are their actions that can be taken to support this? This can include an actuarial analysis to understand the cost of doing this and how to finance it. Once this analysis has been completed, what support is needed to change the benefit package and its implementation? If needed, conduct an actuarial analysis to understand the cost of adding HIV services to the benefit package. Use this analysis to develop ways in which these additional costs can be financed. Provide the needed technical assistance to implement these changes.
- If HIV services are integrated into SHI: What are the enrollment eligibility criteria for HIV services? What is the trend of obtaining HIV services using the social health insurance program? What percent of eligible PLHIV are enrolled in SHI? What percent of health facilities are participating in the SHI scheme? We should consider what kinds of support we can provide to ensure that PLHIVs receive these services through SHI.
- Similar inquiry can be made for private insurance programs.

❖ ***Contracting with Private Sector***

As large international donors such as PEPFAR and the Global Fund begin to redefine their support in countries for sustaining epidemic control, there is a growing need to explore the role of alternative financing avenues. Domestic private financing can help fill this gap and help to strengthen domestic ownership of sustainable HIV/AIDS services. Better understanding where there are existing and successful models of privately funded HIV/AIDS services, and where (and why) there are gaps, will help inform sustainable resource planning. Private sector lenders can bring not only reliable financial resources, but can also provide local strategic relationships, technical expertise, and innovative financing models. This can help improve the breadth of services that private providers can offer, while helping to expand the number of providers able to offer the full continuum of care. Increasing private sector engagement to broaden the resource base for HIV/AIDS and related health programming can help to ensure a domestically led and sustainable response. Better understanding the role that the private sector plays in supporting HIV/AIDS services and understanding barriers to financing can help identify

gaps in financial support, opportunities for strengthening the role of the private sector, and potential opportunities for innovative or blended finance vehicles.

Increasingly governments are starting to contract with private providers to deliver HIV care and treatment services. Contracting including strategic purchasing is not easy and governments might need support to do this adequately.

Things to consider include:

- Does a regulatory framework exist to contract with the private sector and have oversight in the quality of the provision of services?
- Is there a contracting unit in the Ministry, or elsewhere in government?
- What is the status of the policy environment for contracting?
- What health services does the government already contract with private providers? How can PEPFAR build on these platforms?
- What contracting arrangements does the government currently use to deliver other health services? (e.g., contracting in, contracting out, etc.)
- What kind of national or regional provider associations or networks exist that PEPFAR can partner with?

Once this assessment has been made think of the specific activities or support that can be put in place to improve the ability of governments to contract with the private sector for HIV services.

Blended and Innovative Financing Approaches:

Innovative financing approaches focus on country programs and specific activities that deliver high impact results, mobilize additional resources, and support leveraged investments across public and private sectors. These investment strategies are expected to add new resources to foster both proven as well as new approaches to address programmatic gaps and scale high impact solutions. Innovative financing instruments are expected to complement traditional financing such as grants, cooperative agreements, or other forms of public sector PEPFAR support to sustain epidemic control for HIV and leverage systems to detect and fight COVID-19.

For additional resources and strategies for identifying and implementing blended finance and innovative financing approaches refer to https://www.usaid.gov/cii/blended-finance and https://www.usaid.gov/sites/default/files/documents/1864/Blended-Finance-Roadmap-508.pdf

These new resources can catalyze the growth of small and medium-sized enterprises (SME's) in health at the frontlines of the HIV/AIDS response and COVID-19 pandemic. Furthermore,

innovative financing approaches can help incentivize local government partners to address institutional and policy barriers that limit access to affordable capital to expand successful all-market driven approaches such as commercial market development for HIV commodities, re-imagining supply chain management, local manufacturing of essential commodities, revenue-generating programs at CSOs, or collaborations with private health providers and pharmacies. Innovative financing includes a broad range of instruments, tools, and assets. These include conditional or catalytic funding as well as impact investments from philanthropy, market-based securities, risk guarantees, and other tailored debt or equity products expected to generate a return for private investors. These instruments have a wide spectrum of options for cost recovery and potential for return (see Figure 6.6.9.3.5). While considering innovative financing mechanisms it will be important to ensure that they conform to existing PEPFAR guidance on their permissibility.

Specific activities that can support innovative financing approaches for sustained HIV epidemic control should be considered. Examples include, market assessments, opportunity identification and definition, investment facilitation and transaction structuring, and other business advisory services.

Figure 6.6.9.3.5: Portfolio of innovative financing tools & spectrum of cost recovery/return

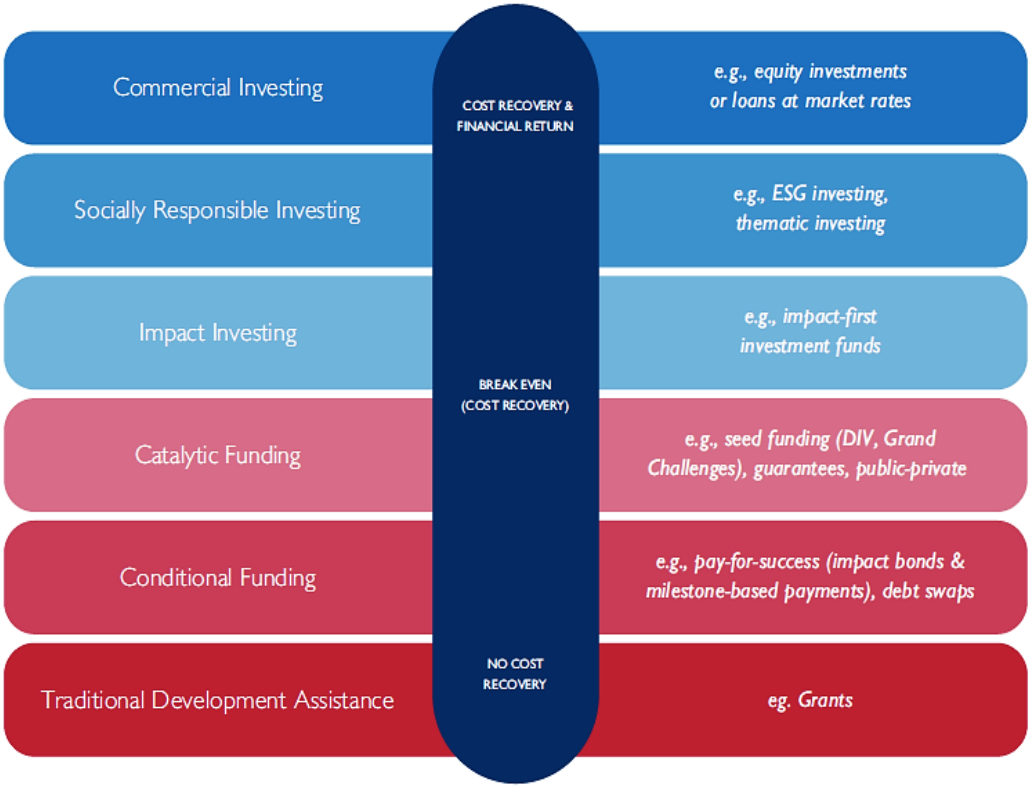


Figure 6.6.9.3.6: SNU Roadmap to Engage Innovative Financing to Maintain HIV/AIDS Epidemic Control

- **Categorize OU Epidemic Control Status and Market Attractiveness:** As an OU approaches or has reached epidemic control, a shortlisting of innovative financing options to target specific minimum program requirements (MPR) to maintain sustainable should be developed. Prioritizing innovative financing investments should be guided by an OUs epidemic control status and assessing market attractiveness to investors. SNU level analysis examining saturated or sustained may also be applied.
- **Define the programmatic gap or challenge:** Identify the key issue or barrier that contributes to a programmatic gap within a specific technical or above site activity. Also identify interventions that have been successful to mitigate gaps or achieve results.
- **Prioritize financing challenges:** Analyze the specific financing or costing model underlying the programmatic gap and possible interventions to address these challenges.
- **Evaluate the potential for innovative financing:** Determine the potential for adopting an innovative finance approach by evaluating the sustainability of the underlying high impact program or intervention; the potential for increased efficiency by engaging the private sector; and the presence and interest of investors.
- **Shortlist innovative finance options:** If there is potential for an innovative finance approach, shortlist options that both address the financing challenges or underlying costing model prioritized in step 3 and align with the OUs market attractiveness identified on step 1.
- **Identify activities for further engagement:** List the key follow-on activities to be undertaken in order to select the most appropriate innovative finance approach and identify the role(s) that the S/GAC Office of Financial and Program, Sustainability (OFPS) can facilitate a sustainability plan or specific transaction.

❖ **Leveraging Innovative Financing to Cultivate New Ideas to Achieve Sustainability**

Transitioning a country program to be financially self-reliant requires new approaches and investment strategies. Often-times, this is simply not ‘replacing’ government funding sources with private sector investors. Achieving financial independence requires new ideas to create sustainable system approaches. Country teams should engage in applied analytics inclusive of reviewing program results, cost, and other financial data to pinpoint investable opportunities.

Opportunities for identifying areas ripe for innovative financing can manifest itself in multiple activities in the field. These activities can include new communication technology platforms that improves clients’ ART continuity, partner management models that improve the efficiency of services delivered, last mile supply chain systems that are

client-centered, and local manufacturing of PPE supplies, diagnostics, and ARV's that minimize risk of stockouts. OUs must determine the types of interventions, incremental or breakthrough, where innovative financing investments are feasible and should be made, in order to achieve sustainable epidemic control.

- Incremental investments: Opportunities that are small, low-risk and have value that can be clearly measured because the impact variables are well known.
- Breakthrough investments: Opportunities that are new-to-OU or new-to-the client, producing significant growth or impact.

Furthermore, a successful high impact innovation is considered:

- A combination of creative ideas with achievable implementation models that are sustainable with additional catalytic or mezzanine financing needed to scale operations.
- Strategically aligned to core goals, principles, and data driven to justify implementation.
- Is timely and measurable for a given population or geography with expected minimum impact of 2x or greater of comparison baseline targets.
- Contributes leveraged resources (both human and financial) from non-USG partners.

Best practices to support innovative ideas to achieve program sustainability include:

- At the **idea stage**, an ability to gain insight from the community and an understanding of the potential impact of new administrative policies, emerging technologies, or service delivery models to achieve sustainable approaches.
- At the **development stage**, an ability to engage actively with the community to prove the validity of new innovative concepts and to assess impact potential, likelihood of sustainability, and risks, and the ability to leverage existing platforms into supporting catalyst or expansion of evaluating new technologies, services, administrative policies, and/or technical guidance.
- At the **implementation stage**, an ability to work with communities to roll out catalyst concept programs or larger scale up of proven innovative interventions, and to coordinate with both USG and local stakeholders for an effective launch and monitor progress to achieve short, intermediate, and long-range financial sustainability.

Country programs should consider activities to identify, apply, and/or scale health systems innovations within their annual operating plans. While activities within each

country program will differ, examples could include identifying and documenting private sector innovations to address core program challenges, planning and analysis to apply innovations in the PEPFAR context, build vs. buy assessments for core capabilities needed to sustain epidemic control, enabling environment reforms, and multi-stakeholder coordination on specific innovation areas.

Please contact SGAC_Sustainability@state.gov if your team needs support on aspects related to advancing financial sustainability or has a specific innovative financing opportunity and would like analytic or negotiation support with potential collaborators.

6.6.9.4 Addressing Threats to Sustainability Plans

A key component of sustainable programs, systems, and institutions is resilience to threats.

Corruption

There are many areas where the sustainability of the health sector, and HIV programs, can be threatened by corruption. When transitioning the funding of a program or the management of the program to a country government, it is important to be aware of and address potential vulnerabilities that can be exploited by corrupt actors. Corruption erects sometimes insurmountable barriers to access healthcare and poses significant strategic and reputational risks for the United States. Please refer to your agencies' enterprise risk management resources.

Procurement

Procurement in any sector is especially at risk of corruption, but the health sector is acutely vulnerable. The sheer number of touch points with gatekeepers across a supply chain and the control of what are often urgent and life-saving medicines and services affords corrupt actors plenty of opportunity and power.

From how and to whom contracts are awarded, to the multiple points of interaction, to the receipt of a medicine or service by a patient, transparency is key to reducing the corruption risks in procurement. Ensure contract selection criteria are clear, public, and promote fair competition. Establish independent monitoring and auditing systems that conduct regular risk assessments, evaluate due diligence, and publicize the results. Where possible, automate processes and/or digitize services to reduce the number of touch points. For further best practices on end-to-end transparency for public contracts, please see the Open Contracting Data Standard. Finally, ensure patients have a way to hold officials accountable if and when

corruption occurs. Reporting hotlines coupled with strong whistle-blower protections are effective anti-corruption tools both for deterrence and enforcement.

Priority Populations

Priority populations face additional challenges when encountering corruption. Women, including adolescent girls and young women often encounter more requests for bribes than their male counterparts in the health sector, and women, AGYW, and key populations (KP) are more likely to be asked to pay bribes in sexual acts.

Corruption in the Health Sector: Women and AGYW

Depending on how the role of women is structured in society and its social/cultural norms, women may use some public services more, like health, and thus be more exposed to the corrupt behavior of the gatekeepers of these critical resources. They more often serve in caretaker roles and need to seek health services not just for themselves, but also for their dependents. In addition, women also have reproductive health needs that can require frequent use of the health sector. A 2007 study by Alolo (*Gender and Corruption: Testing the New Consensus*) found that women in Ghana who were asked to pay bribes for reproductive health care were often unable to pay and would deliver at home, which increased the likelihood of complications. If these additional barriers to healthcare are not removed, women may find themselves needing to choose between ARVs and other kinds of healthcare or forgoing HIV services completely.

To begin to address this disparity, more data are needed. In many countries, corruption data is not sex-disaggregated, so the full extent of the disproportionate requests for bribes faced by women in the health sector is unknown. Work with Ministries of Health to partner with local anti-corruption bodies to ensure that data collected on corruption in the health sector is sex-disaggregated and public.

In some contexts, women do not have a basic awareness of governance concepts, especially if they have a lower social status or income or an ability to regularly access information. Public education and awareness campaigns on corruption in the health sector can provide women with knowledge of their rights when accessing health care and may empower women to find care elsewhere or report their experiences when encountering corruption.

Sextortion: Women, AGYW, and Key Populations

A form of gender-based violence that can affect all populations, but disproportionately affects women and AGYW is sextortion. Sextortion is bribery that uses sexual acts as currency.

Sextortion can be a particularly devastating experience of corruption and can result in long-term psychological, social, and economic consequences, including physical consequences like HIV and sexually transmitted diseases. Despite its level of harm, sextortion tends to go underreported due to the extremely personal acts involved. In addition, key populations that may have to keep their identities and/or work hidden and who also experience high rates of other kinds of gender-based violence may similarly suffer from disproportionate pressure to pay bribes in sexual acts.

The extent to which sextortion results in unwanted pregnancies, premature debuts, or HIV is unknown, but the risks make it important for health facilities to be aware of corruption vulnerabilities and to provide patients ways or link them to ways to report incidents. Instances of sextortion should be managed from end-to-end to ensure those affected can and do report this kind of corruption: from awareness-raising on the unlawfulness of sextortion, to the provision of confidential reporting channels, to real independent investigations and consequences.

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

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.[702] 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.[703] Well-conceived and carefully implemented infection prevention programs reduce illness, prevent death, improve 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.[704] 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).

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[702] 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.
[703] 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.
[704] WHO 2019 https://www.who.int/infection-prevention/publications/core-components/en/

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 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.[705] 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.[706] 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.[707]

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.

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[705] https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html

[706] 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.

[707] 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/

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 with available local guidelines for use of PPE. Appropriate disposal of PPE is covered in the waste management section.[708]

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[709] 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

[708] https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/medical-waste.html
[709] https://aidsfree.usaid.gov/resources/pepfars-best-practices-vmmc-site-operations-0

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 present.[710] 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.[711] 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

[710] https://www.cdc.gov/infectioncontrol/basics/transmission-based-precautions.html
[711] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html

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 recommended for TB protection. Source control is recommended in all healthcare settings to prevent the spread of COVID-19 and TB.[712]

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.[713]

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 2.0-4.0 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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[712] https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/index.html
[713] 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.[714]

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.[715,716] 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.[717]

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.

[714] Reuters, COVID-19 in Health Care workers 17 Sept 2020

[715] https://apps.who.int/iris/bitstream/handle/10665/331496/WHO-2019-nCov-HCW_risk_assessment-2020.2-eng.pdf?sequence=1&isAllowed=y

[716] https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/public-health-management-hcw-exposed.html

[717] 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[718] 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.[719,720] 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.[721]

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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[718] 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.
[719] https://www.who.int/publications/i/item/10665-336265
[720] https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html
[721] 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.[722]

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 dispensed first, but still with enough time remaining that the patient will consume it before it

[722] 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/

expires.[723] 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.[724]

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.[725]

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 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

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[723] *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

[724] World Health Organization, Charter, Y., & World Health Organization. (2014). Safe management of Wastes from Health-care Activities. World Health Organization.

[725] 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/

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[726] and WHO.[727]

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 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

[726] CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (updated May 2019) https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
[727] Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO and PAHO (2016) https://www.who.int/publications/i/item/9789241549851

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.

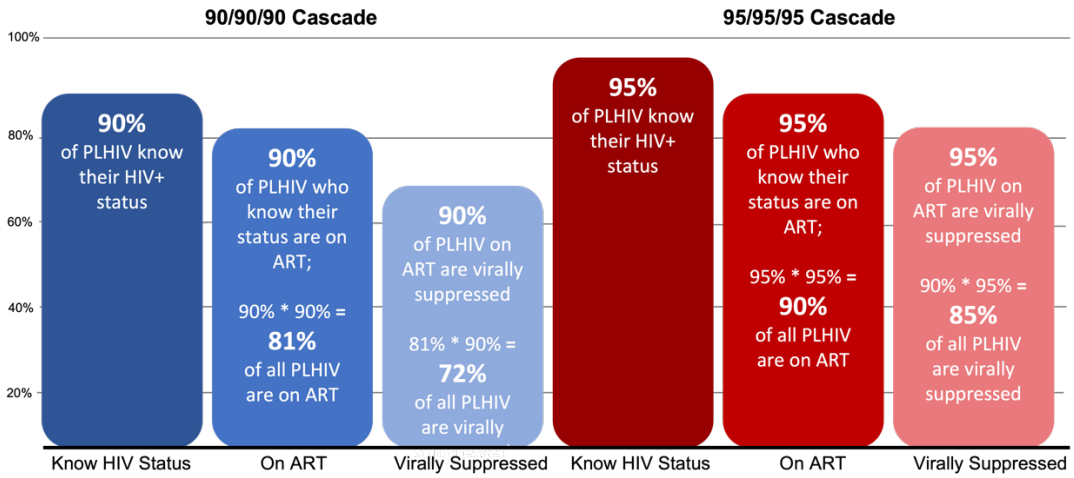
PART B: COP/ROP22 GUIDANCE: PLANNING STEPS AND USER GUIDE TO COUNTRY OPERATIONAL PLAN PREPARATION AND SUBMISSION

7.0 COP PLANNING STEPS

As referenced in Sections 1-3, PEPFAR programs are expected to use key data sources – case surveillance including any in-country individual data, MER, financial data (budget, expenditure and work plan budget), Table 6 and SRE reporting, the SID, the HRH inventory, PLHIV estimates, the Responsibility Matrix, Resource Alignment, community-led monitoring, and SIMS to assess the quality, impact and efficiency of the current program and to align resources for viral suppression, treatment, testing, prevention, and other interventions for all age groups to reach and sustain epidemic control of HIV. Such a comprehensive analysis becomes especially important in light of the COVID-19 pandemic and understanding its effects on the quality and effectiveness of HIV service delivery, achievement of results, and the overall national HIV response in the midst of dual pandemics.

Section 7 is designed to **demonstrate the link between analysis, planning, and operationalizing of the COP process for each U.S. government implementing agency and its respective implementing partners**. To strengthen PEPFAR USG implementing agencies' transparency, monitoring, and use of financial data, clear linkages are established between COP planning budgets and targets with implementing partner budget execution and results. Site-level (direct) service delivery (SD), site-level (technical assistance/service delivery quality) non-service delivery (NSD), and above-site (technical assistance support) programs (ASP) costs should be linked to (1) understand the full investment and (2) allow a transparent dialogue with governments as a country reaches and maintains epidemic control through sustaining population viral load suppression and focused prevention. It is essential to continually refine and evolve interventions to address people's needs of specific populations to reach each 95-95-95 (Figure 7.0.1). This includes ensuring everyone achieve and remain virally suppressed, maintaining a laser focus on ART continuity for all persons across sex and age bands, and focused testing and prevention interventions. Program funding must be aligned with viral suppression, treatment, testing, and prevention targets and assigned to partners based on their specific burden, the context in which they work, and past performance. This not only ensures that U.S. taxpayer dollars have the greatest impact, but also provides an early warning signal of fraud, waste, and abuse. Clear outcomes of all prevention programming will also be measured and documented; "reaching" an individual without directly linking them to prevention or treatment services is an example of program failure, not success.

Figure 7.0.1: Reaching 95/95/95 at the country level



The following is an example analysis to determine if PEPFAR investments are in the right places for impact and seeks to understand the drivers of low population viral load suppression, which is the recommended starting point for Section 7 analysis for all countries in COP22. A framework for these planning discussions is presented below. This framework is an illustrative example of the process of analysis/COP planning decision tree for country teams to utilize, however, it does not elaborate on how to do the analysis to arrive at the problem statement, which can be extensive. This analysis will be addressed in greater detail in Sections 7.1 and 7.2.

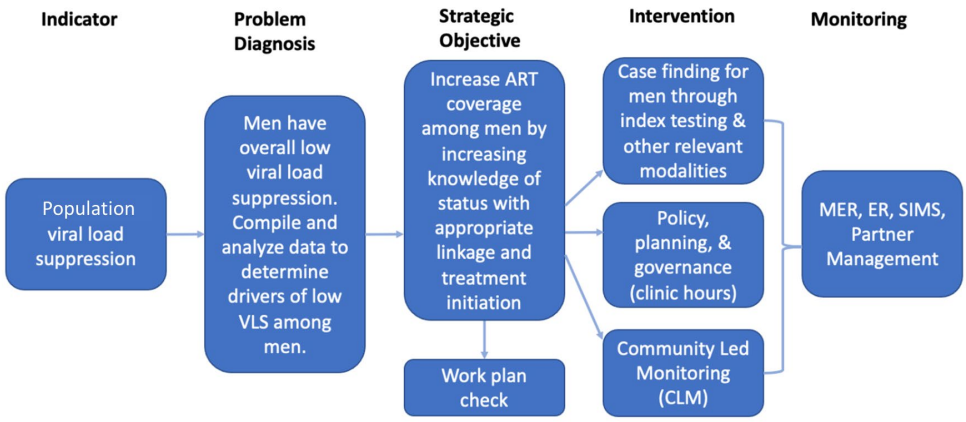
- **Problem Statement/Indicator:** In country X, through PEPFAR quarterly monitoring and triangulation with PHIA or other survey data, the team determines that men have low population viral load suppression (PopVLS).
- **Problem Diagnosis:** First, compile and analyze all site level data and any in-country individual level data are reviewed to determine PEPFAR site coverage, and then if any site, district, or partner had increased early HIV diagnosis in men leading to treatment linkage and VLS. If so, these sites were visited or otherwise contacted, and discussions are held with partners, site health staff, and peer navigators to understand what is happening and how this could be brought to scale. Reviewing in-country individual level data may help identify best sites to follow up, and what sub-groups were most at risk. If there are not clear examples of excellence, then it is key to determine why men are not being tested, linked, initiated on treatment, and virally suppressed. For example, conducting focus group interviews, soliciting client feedback, and conducting demonstration projects. Since determining VLS is dependent on viral load testing coverage, is there adequate viral load

laboratory testing capacity and transparent lab consumption data in country? Is adequate demand for viral load testing being created? Are there any stigma or treatment adherence issues to be addressed? What about 6 MMD and bundling refill appointments with VL sample collection for testing? Once solutions are identified, tested, validated and ready for scale, the next step would be to ensure that all sites and partners were making these adjustments and the following interventions might be necessary.

- **Intervention:** "Increase VLS among HIV+ men." To achieve this, will new policies be required? For example, is there a policy in favor of treatment literacy and community engagement, complete transition to TLD, 6 MMD, and equitable services? When will the MoH adjust policies and distribute circulars? Are the right laboratory machines, supplies, reagents, and technicians in place? In parallel, agencies should review data findings and evaluate partners and work plans to ensure they include the new, fully costed interventions.
- **Monitoring and Partner Management:** Relevant targets and outcomes are set for the relevant approach(es) to support effective monitoring and partner management. This includes ensuring site level TA is provided with an expectation of increased performance at the site and that implementing agencies monitor financial and programmatic performance using the relevant indicators and implementation of real time course correction. These discussions should continue through the POART process and other more frequent mechanisms, such as weekly monitoring and partner management in surge scenarios.

This figure shows the steps in decision making for interventions to address low viral load suppression for men.

Figure 7.0.2: Example COP planning decision tree

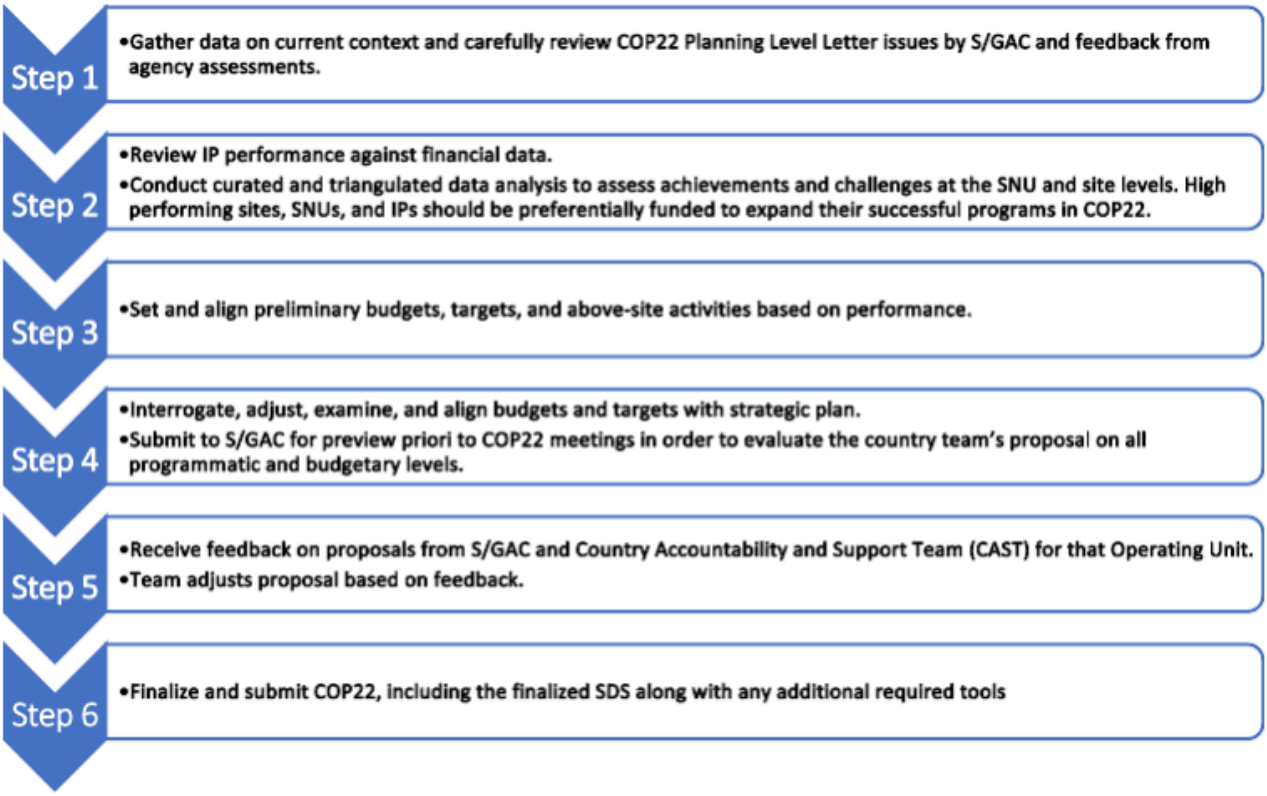


Modular Planning Steps

The COP22 process utilizes a flexible modular planning approach for further refining the innovative HIV prevention and treatment strategy that needs to be scaled, specific to the country context, defined in previous COP cycles. These steps emphasize using integrated data analysis to refine programming, target setting, and budgeting and to ensure quality partner performance for increased impact. The recommended order for these steps is illustrated in Figure 7.0.3.

Successful implementation of the COP process requires the review of key analyses and decision points that involves meaningful engagement across technical areas. The analyses to be reviewed for COP22 planning are a continuation of the program and partner performance routinely discussed during the quarterly POART process. This section offers guidance following the process on key steps countries can take to meet planning requirements and draft a technically strong Strategic Direction Summary (SDS). The SDS should be solution focused on what will be different to address specific viral suppression, treatment, testing, and prevention programmatic gaps, how this will be monitored, and how the country will course correct.

Figure 7.0.3: COP22 process planning steps



As noted elsewhere in COP22 Guidance, country teams are required to engage civil society, partner government and communities inclusive of vulnerable and key populations. These discussions must reflect all communities and community-generated solutions and engage aforementioned stakeholders consistently throughout the entire COP cycle. A collaborative, iterative process requires meaningful partner engagement throughout.

7.1 Planning Step 1: Review Data on Current Program Context, Progress Towards Epidemic Control, Program Performance, and Financials

In COP22, country teams will focus on different analysis tracks and planning questions based on the country's achievement of or progress towards HIV epidemic control as defined in Section 2.1.1. Examples of data visualizations, analyses, interpretations, and deep dive questions that countries should conduct or consider during the COP22 budget and target setting process are presented throughout for countries "At or Near Epidemic Control" and countries "Not at Epidemic Control."

COP22 Planning Step 1 should flow from the quarterly POART process analyses, which should focus on who is missing from viral suppression, treatment, and prevention and how they will be found and supported to access treatment and prevention services. In turn, these analyses and findings should be tied to effective partner management practices.

Planning discussions for COP22 will begin from this foundation, reviewing how previous COPs were or are being implemented – in terms of interventions being pursued by each implementing mechanism as well as budget levels allocated to those interventions – as documented in existing contracts, cooperative agreements, and work plans. **Sharing collaboratively-identified data analyses and their relevant solutions across the full interagency, where feasible, is imperative to inform robust conversations and analyses to establish COP22 direction and priorities and COP22 Implementing Partner work plans.**

COP22 planning discussions must expand beyond closing the final gaps in reaching epidemic control and into making plans for *sustaining* epidemic control of HIV. All countries should consider their programs from a sustainability lens. As teams review the current program context it will be critical to understand not only gaps to epidemic control in their country, but also the distribution of responsibilities (using the Responsibility Matrix) among the various actors and

areas of the program where local or government ownership is missing. Teams must ask—what aspects of the program can be transferred now to country ownership? What barriers must be addressed to allow a country-owned response? What programming should begin, or be maintained, in COP22 in order to move the country closer to sustainable HIV impact? Countries should build upon COP21 SID discussions to establish COP22 direction, priorities, and programming that substantially moves the needle on sustainability. More information on sustainability planning is available in Section 6.6.9.

Planning Step 1 requires that country teams, with their stakeholders, compile the analyses, decisions, key outcomes, and recommendations from POARTs and other year-end reviews. A proposed structure, with data sources, is as follows:

- **Understanding the full funding envelope**: To ensure maximum alignment and impact of all HIV and related health resources, teams should use data from Resource Alignment that will provide the totality of HIV investments across PEPFAR, Global Fund, partner country government and, where data are available, other funders. In addition, teams should use ODA (Other Donor Assistance) data to understand related health investments.
- **Understanding the full multilateral investments**: Teams will be able to understand current and future Global Fund investments using the Resource Alignment data. Joint review and alignment of investments between Global Fund grants and the COP program must be demonstrated at all levels for both communities and governments.
- **Understanding underlying epidemiology:** Relevant demographic, epidemiologic, national/regional program data to the lowest SNU possible, by age and sex. A country's achievement of or progress towards epidemic control, as outlined in Section 2.1.1, should guide COP22 planning discussions. Sources: PHIA survey data, Biobehavioral Surveys (BBS), population size estimates, UNAIDS Spectrum or other modeling estimates, SABERS, DHS, National/Subnational MER data, the MoH Data Alignment Activity, and others.
- **Program Performance:** Information on achievement of expected results and whether basic quality standards are being met, at the SNU, site, and IM level, including providing person-centered services. Sources: MER, SIMS site and above-site data, CQI, and community-led monitoring data.
- **Above-site interventions:** Information on the above-site barriers to epidemic control, the activities to address them and status of achievement of benchmarks. Sources:

Table 6 and SIMS Above-site Assessments, POART recommendations and any post-POART Corrective Action Summaries (CAS).

- **COP22 Planning Level Letters and HQ feedback.**
- **Financial Performance (budgets, outlays, expenditures):** Information on how financial resources are budgeted, outlaid and spent by IMs. Sources: COP budgets, ER, Outlays/EOFY.
- **Planned Interventions:** Information on the current scope and scale of implementation of specific strategies at the IP level. Source: IP work plans.
- **Sustainability:** Information on the sustainability of the HIV response at the country level. Sources: SID, and country-specific sustainability framework.
- **Donor and Government responsibility:** Teams should understand the functional and financial responsibilities for the various aspects of the HIV response at the OU level. Sources: Responsibility Matrix, Resource Alignment, and other multilateral resources.
- **Supply chain (including all commodities):** Information on issues, consumption, and procurement of commodities at the OU level. Programs should map supply chain issues to performance. Sources: Commodities budgets for PEPFAR (CDC, DoD, and USAID) and other Procurement Services Agents (The Global Fund or the partner government or other), Logistic Management Information System, Lab Information Management Systems, Commodity Forecast, and Supply Plan tools.
- **HRH supporting services:** Information on current IP staffing footprint and distribution/alignment across sites, HRH needs, and programming in relation to government or other donor HRH resources. Sources: HRH Inventories, Health Workforce Registries, HRIS (if available), IP work plans, MER indicators and National Health Workforce Accounts (where available).
- **Surveys, Research and Evaluation:** Information on funded surveys, research projects and evaluations. Sources: Table 6 and SRE Tool, Evaluation Standards of Practice (ESOP) database.

By the end of Planning Step 1, PEPFAR teams and stakeholders should have a common understanding of:

- the current HIV/AIDS programmatic context in the OU
- data available for the analysis in Section 7.2
- partner and program performance, quality, and progress
- financial performance

- programmatic gaps, barriers, and facilitators
- the underlying epidemiological context, including epidemic trends or shifts and driving factors and progress toward epidemic control, and
- multilateral and bilateral investments and how these will be integrated to advance HIV prevention and treatment

Based on available data and local program context, teams must identify (1) specific interventions or technical areas where the program is achieving or overachieving intended results (2) specific areas where the program is not achieving the intended results (3) specific interventions or technical areas where the quality of programming needs to improve to ensure delivery of person-centered services at the site level; and (4) alignment of future resources based on performance and gaps/needs. From this integrated data review, teams should be able to identify gaps and barriers that are hindering progress toward achieving or sustaining epidemic control. Progress towards epidemic control may vary across different age bands, sexes, and priority populations. This will impact the strategies needed to address those inequities; strategies may be different (e.g., different approaches to targets, strategies for service delivery and HR, etc.) between subpopulations within a country.

7.2 Planning Step 2: Identify Specific Program Gaps Based on Curated In-Country Analysis of Data on Performance Based on Progress Towards Epidemic Control

After collecting and reviewing the data in Section 7.1, the in-country PEPFAR team and all stakeholders should have a clear understanding of their current context and the path for reaching or sustaining epidemic control. Section 7.2 is a model for revisiting the programmatic and epidemiological data to reassess the current approach and determine ongoing and remaining gaps based on a country's current epidemic control status. This model begins with an understanding of the population viral load suppression rate in the country and then seeks to understand the drivers of any gaps in population viral load suppression by examining specific age and sex groups, geographies, funding levels, and other possible drivers.

Reviewing the most granular disaggregated data is critical as evidence continues to mount regarding age, sex, and other population-related disparities in accessing HIV prevention and

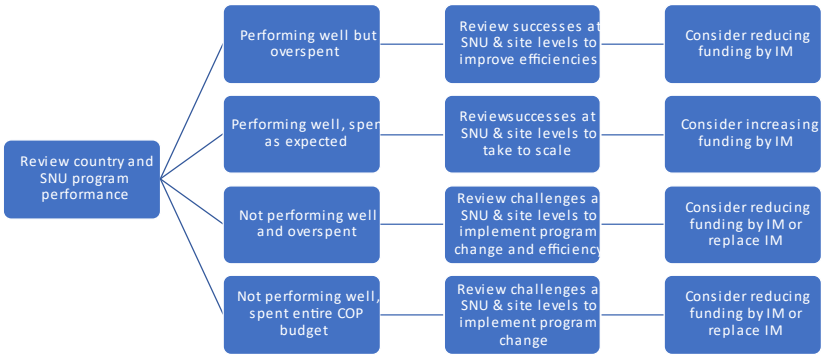
treatment services.[728] Country teams must continue focusing HIV activities on the populations with the highest HIV burden and unmet need, and therefore the highest likelihood of transmitting or acquiring HIV. Teams should give attention to program results by age/sex bands and subgroups (e.g., key or priority populations, AGYW, children) that may be falling behind in reaching epidemic control, identify the next set of PSNUs for program scale-up, and move resources that are freed up to these opportunities.

Planning Step 2 builds on Planning Step 1 by:

- Understanding progress toward sustainable epidemic control, including barriers, facilitators, and gaps in quality programming, and whether the program is having the intended impact (with data-driven consideration to effects of the COVID-19 pandemic)
- Triangulating data and examining investments at both site and above-site levels
- Exploring current investments and programming to understand what needs to change to achieve results at quality and scale, with a client-centered approach in mind
- Ensuring full understanding and focus of all other bilateral and partner government funding and resources using Resource Alignment data
- Aligning future programming and investments with performance
- Understanding gaps and barriers in developing a person-centered approach to service delivery at the site level

The overall flow/decision tree to accomplish these goals is shown in Figure 7.2.1 below.

Figure 7.2.1: Overall flow or decision tree of assessing performance by geographic area and IM[729]



[728] UNAIDS. (2014, September). *The Gap Report*. Retrieved from http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport

[729] Issues outside of a program's control (e.g., natural disaster, unfavorable policy environment, supply chain issues, etc.) should be considered during this process

Keeping this decision tree in mind, the below analyses offer a step-by-step guide to understand, comprehensively and holistically, a country's HIV epidemiology, historical program achievement, implementation, and gaps and barriers to inform COP22 planning. Suggestions for data interpretations are separated by Epidemic Control status to highlight how gaps and disparities may differ based on a country's proximity to Epidemic Control.

7.2.1 Cascade Analysis

Viral Load Suppression and Viral Load Coverage

Population viral load suppression (PopVLS), or the number of virally suppressed individuals among all PLHIV in a given country, PSNU, or population group, is the starting point for the Section 7 cascade analysis in all countries regardless of the country's epidemic control status. The COP22 DataPack will utilize PEPFAR program data in conjunction with HIV estimates to plan for programmatic PopVLS for all populations and geographies. It is important to understand the underlying epidemiology of HIV in a given country to identify the gaps in population viral suppression that inhibit reaching epidemic control. Teams should understand trends in viral load coverage and suppression, mapping out when geographies changed partners or new policies or funding changes were enacted. The following analysis will follow two different countries, one that has reached or is near epidemic control (Country A), and another that is not yet at epidemic control (Country B), from the starting point of PopVLS. This approach was selected because of the COP22 necessity for all countries to reach and maintain a viral load coverage rate of 95%, and a 95% viral load suppression rate of those PLHIV reached with a viral load test. If programs are enrolling clients into care, they must have the capacity to provide viral load testing to monitor the success of the care & treatment program and, most importantly, assure the best health outcomes for PEPFAR patients.

If available, use the most recent PHIA data to analyze progress towards population viral load suppression. If PHIA data is not available, use other population-level, PEPFAR-supported and approved survey or modelling data that estimates PLHIV and progress towards 95-95-95 (e.g., Spectrum and Naomi). In the absence of any population-level data, use PEPFAR programmatic data including MoH Data Alignment Activity and Central Support data to estimate PopVLS and progress along the cascade. The COP22 DataPack will incorporate Spectrum or other country specific PLHIV modeling estimates by age/sex and geography in the "Spectrum" and "Cascade" tabs. Country teams will utilize the DataPack identify gaps in VLC, VLS, and programmatic

PopVLS. The PEPFAR Panorama Epidemic Control Dossier may also be beneficial to visualize PopVLS.

Cascade analyses utilize conditional percentages for each of the 95s, that is, each subsequent percentage is based off the prior percentage calculation, e.g., the denominator for the percent on treatment (2nd 95) is the numerator from the percent of PLHIV who know their status (1st 95).

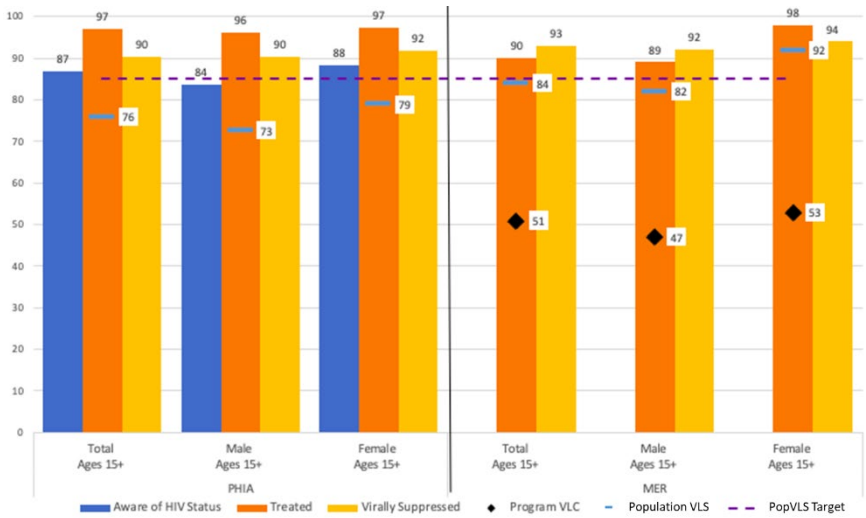
Population-level Viral Suppression

Population-level, household-based surveys are the best tools to assess progress towards PopVLS. PEPFAR uses PopVLS as a benchmark for progress towards epidemic control. While PopVLS utilizes and complements UNAIDS targets, reaching PopVLS does not necessarily mean a country has reached all other targets along the cascade or have reached epidemic control; strong performance in one area of the cascade can counteract lackluster performance in another and still result in a PopVLS rate above the benchmark. It is necessary to utilize both programmatic and epidemiological data across the cascade to assure sustainability and to close any remaining gaps in order to achieve all UNAIDS 95-95-95 targets and an overall PopVLS of 85%.

At or Near Epidemic Control: PHIA data for Country A in Figure 7.2.1.1 shows they have achieved overall PopVLS among adults 15+ for the 72% benchmark (90-90-90) but have not yet achieved 85% PopVLS (95-95-95), thus Country A has reached previous years' benchmarks, but is still working towards current programmatic benchmarks. Gaps remain for achieving 95% conditional VLS (3rd 95) and diagnosing PLHIV.

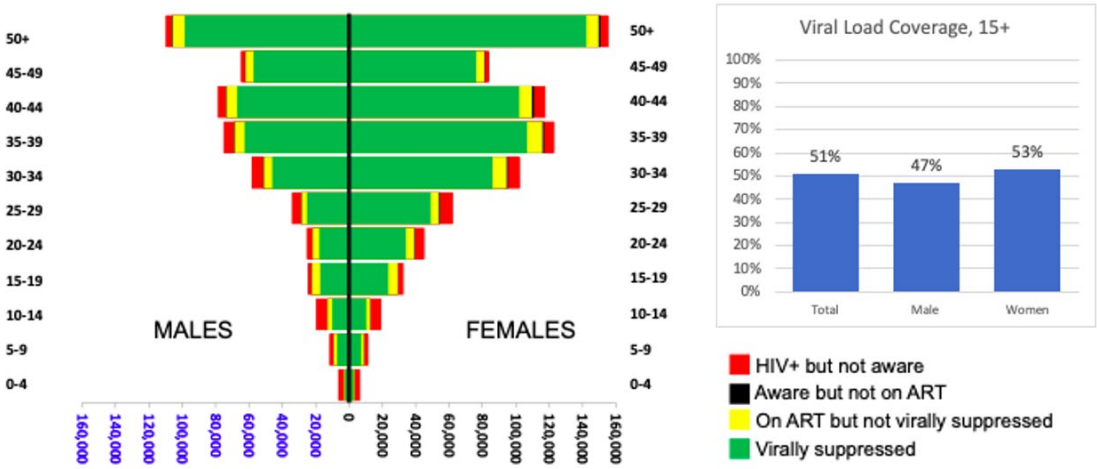
Comparing PHIA data to PEPFAR MER data across the cascade, we see higher VLS and program-adjusted VLS from MER across totals and by sex, but with very low VLC in PEPFAR program data. Because PEPFAR program data does not directly measure the first 95, Figure 7.2.1.1 does not show MER data for 1st 95; MER percent treated was calculated as TX_CURR/PLHIV estimate. MER program-adjusted VLS was calculated as (percent treated) x (percent virally suppressed). The MER results should inspire a team to look deeper into VLC and VLS data by geography, age, and sex to examine why these results differ, what gaps still exist, where these gaps exist, and best practices that can be leveraged to fill the gaps – particularly due to the low VLC results.

Figure 7.2.1.1: Comparison of PHIA and MER results for progress towards UNAIDS 95-95-95 targets among those 15 and older for Country A at/near epidemic control



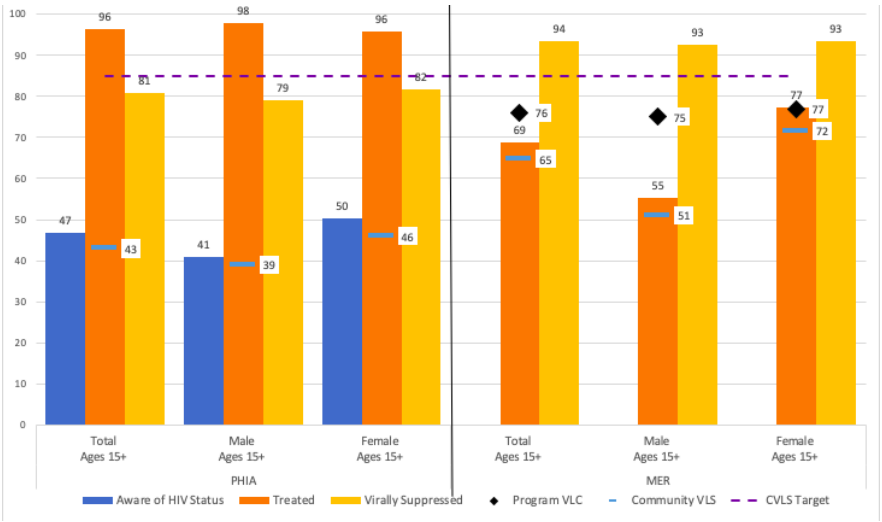
Looking across the cascade by age/sex bands and key populations status is important to understand the underlying epidemiology of a country and to identify gaps in PEPFAR programming to best inform the strategic direction. Triangulating data from multiple sources can help guide the preliminary analysis steps. Figure 7.2.1.2 below shows the clinical cascade by age and sex in the same country at epidemic control using a combination of Spectrum PLHIV estimates and PEPFAR programmatic data and highlights very low viral load testing coverage in the PEPFAR program. Low VLC in Country A is the largest driver of comparatively high MER VLS and programmatic-adjusted PopVLS vs. PHIA results in Figure 7.2.1.1 above and should be a major focus in programming for sustained epidemic control in COP22.

Figure 7.2.1.2: HIV clinical cascade and VLC gaps by fine age and sex in Country A at epidemic control



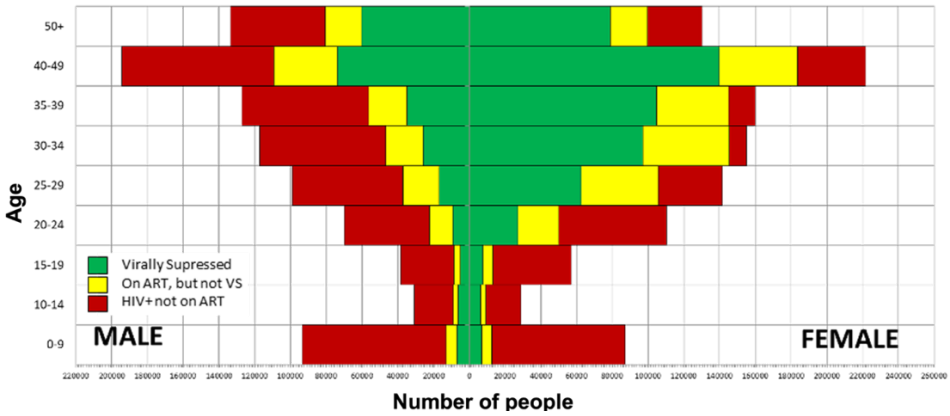
Not at Epidemic Control: The country in Figure 7.2.1.3 has made progress along the cascade but has not reached the 85% PopVLS target, in part due to large gaps in identification of PLHIV and continuity of treatment services. While 81% VLS achievement of those linked to care is good, due to the conditional nature of these percentages, there are still many PLHIV left who are not virally suppressed, not on treatment, and undiagnosed. It is important to understand VLS in the context of VLC. A low VLC may produce a biased VLS, because the people who get their viral load test done may be those who are much more likely to have continuous treatment and a suppressed VL. Teams must be forward thinking and analyze gaps within the viral load testing program. VLC and VLS are not only important for monitoring patient outcomes, but they are also indicators of ART program success.

Figure 7.2.1.3: Comparison of PHIA and MER results for progress towards UNAIDS 95-95-95 targets among those 15 and older for Country B not at epidemic control



COP22 recommends analyzing the cascade starting from gaps in VLC and VLS, despite any conditional progress along the cascade. Figure 7.2.1.4 highlights large gaps across the clinical cascade for all age and sex bands, with especially large gaps for viral suppression among men 20-49 and pediatrics 0-9 years. For the pediatric population it is imperative to examine VLC and VLS by fine age bands as a child's age impacts whether their ART regimen has been optimized and type of sample collection. Please see Sections 6.4.1.2, 6.4.5.2, 6.4.6.2 for further information on activities to improve VLC and VLS for pediatric populations.

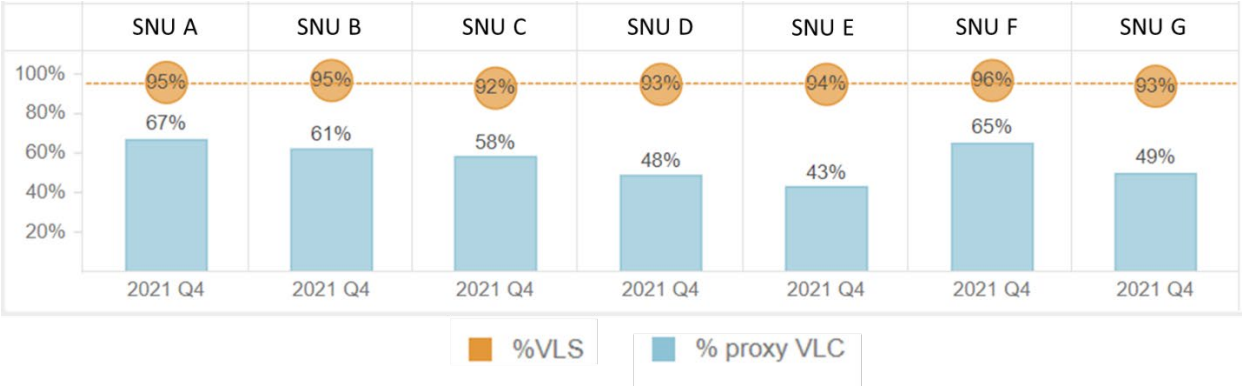
Figure 7.2.1.4: HIV clinical cascade gaps by fine age and sex for Country B



Understand drivers of low population viral load suppression and gaps

At or Near Epidemic Control: Comparing population-level VLC and VLS to programmatic VLC and VLS provides greater insight into the PEPFAR's program's impact and performance. VLC should be at least 95% for all clients. Figure 7.2.1.5 shows that suppression rates are high among PLHIV that have a documented VL test result, though viral load testing coverage is low across SNUs.

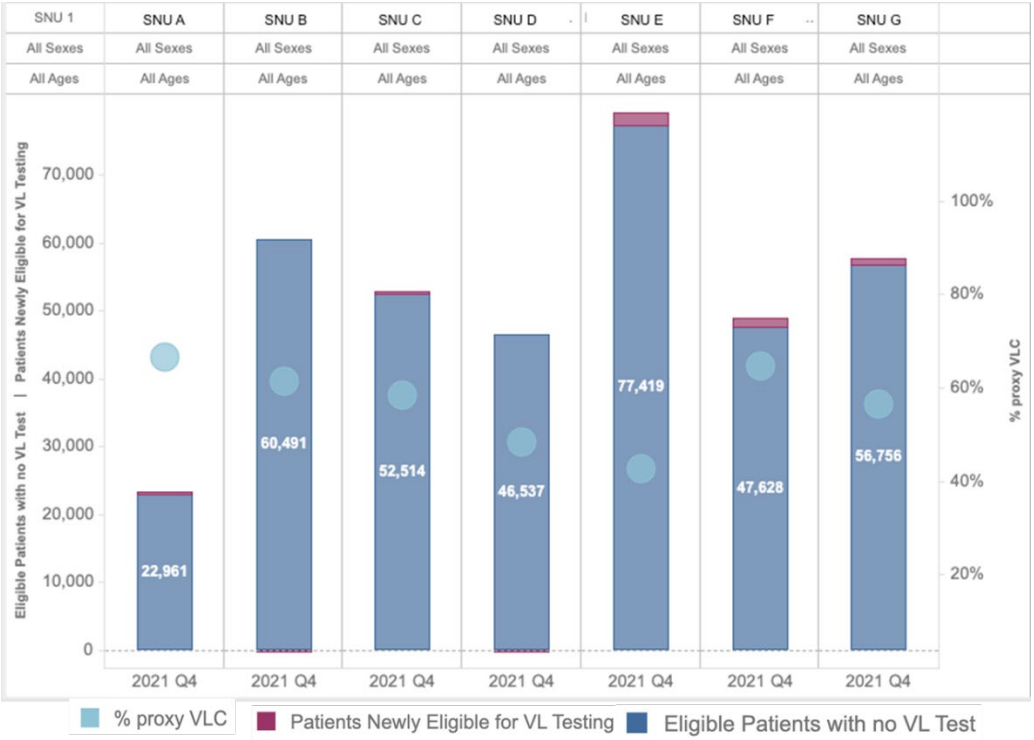
Figure 7.2.1.5: Viral Load Coverage and Suppression by SNU1 in Country A[730]



Figures 7.2.1.6 from PEPFAR Panorama Viral Load: Single OU dossier, VL Testing Demand shows that low VLC is a historical issue across SNU1's; low coverage is not due to clients becoming newly eligible for VL testing or increased demand.

[730] Source: PEPFAR Panorama Viral Load: Single OU dossier, VLC & VLS

Figure 7.2.1.6: Viral Load VL Testing Demand by SNU at FY21 Q4, Country A



Filtering the same dossiers differently can provide additional insight to gaps. Figures 7.2.1.7 and 7.2.1.8 compare VLC and VLS by age and sex between the SNU with the highest VL coverage, SNU A, to the SNU with the lowest coverage, SNU E.

Figure 7.2.1.7: VL Coverage and Suppression by Sex and Coarse Age Bands, Country A

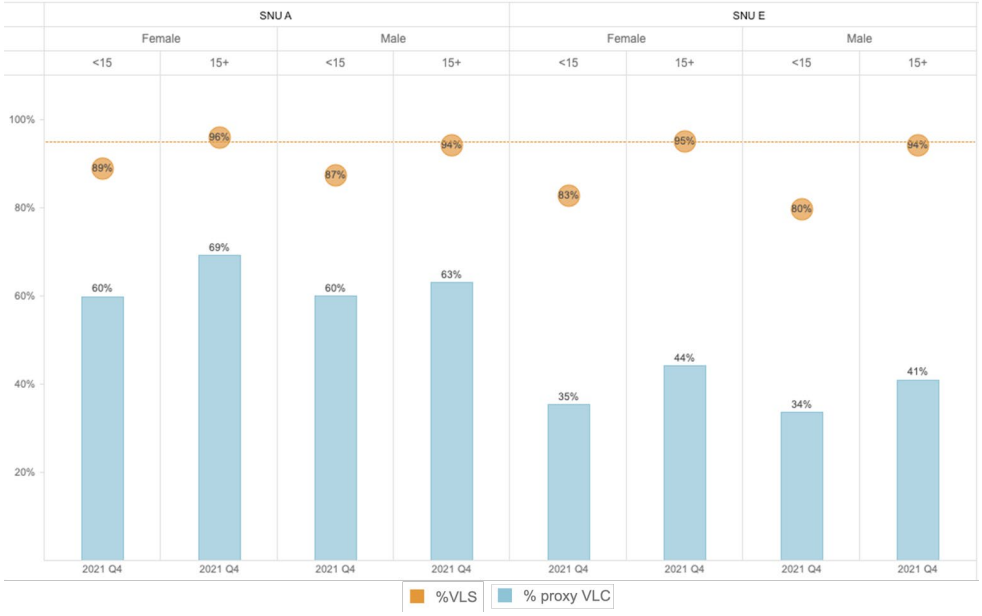


Figure 7.2.1.8: VL Coverage and Suppression <15 by semi fine age bands, Country A

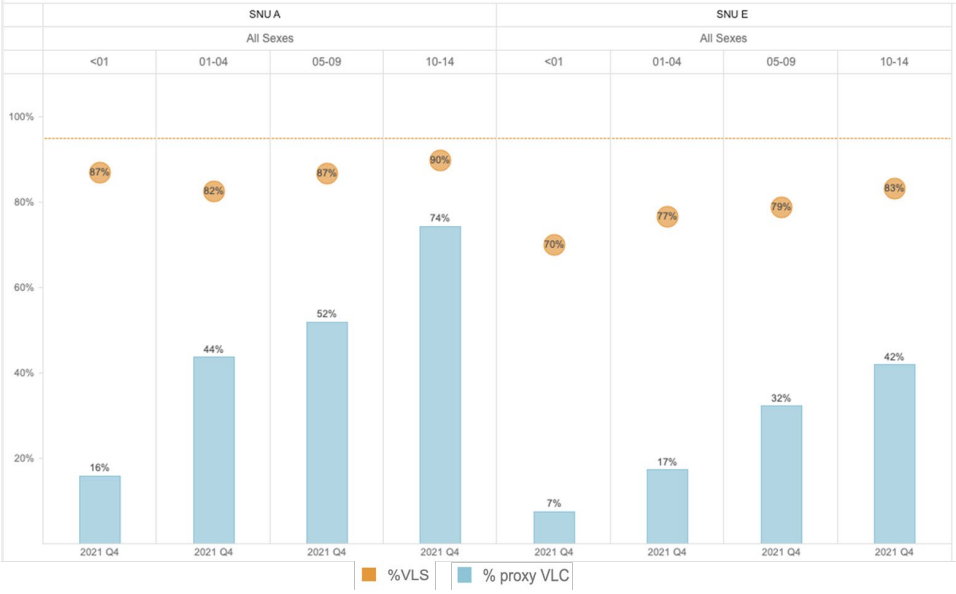
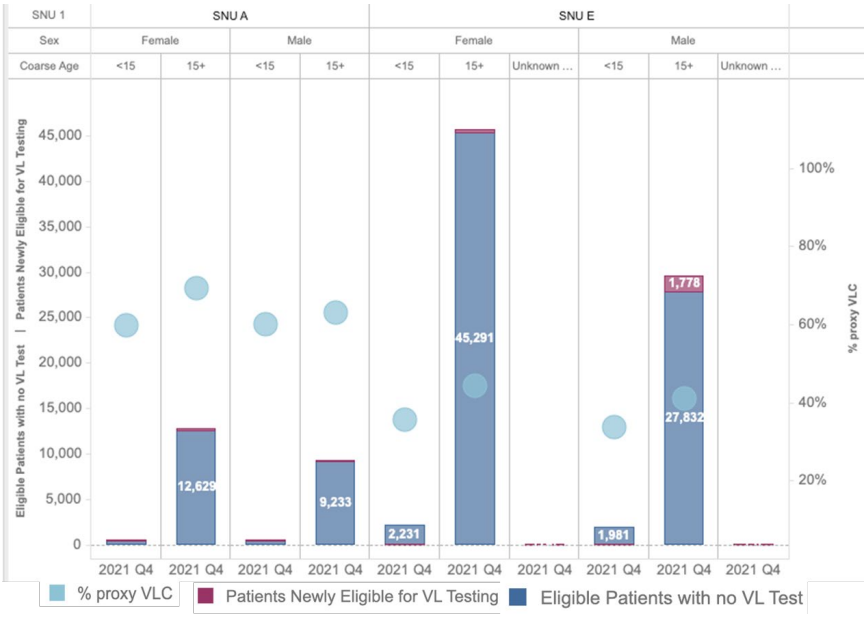


Figure 7.2.1.7 portrays clear gaps in SNU E and among those <15 years in both SNUs and across sex. Looking deeper into fine pediatric age bands shows rates of VLC and VLS increase by age band in both SNUs. It is important to prioritize pediatric care to ensure healthy outcomes.

Programs should target high burden, underperforming SNUs, sites, and populations. Figure 7.2.1.9 shows a large VLC gap of eligible patients with no VL test results among clients 15+ and females in SNU E.

Figure 7.2.1.9: Viral Load Coverage and Suppression by coarse age and sex for SNU A and SNU E in FY21 Q3, Country A



Identifying a gap is only the first step to enacting programmatic change. Panorama dossiers can be sliced and diced to provide granular and insightful information such as which IMs have the highest performance for specific programmatic areas by age and sex. Utilizing Figures 7.2.1.10 and 7.2.1.11, it is possible to compare VLC IM reach and efficiency among females 15+ years of age. This can help identify best practices to scale, look at trends to see periods where progress faltered, and provide additional support to any IM struggling to make or sustain progress. By looking at data in a comprehensive, systematic fashion, we can make informed decisions to enhance the care and treatment of PLHIV within PEPFAR's programs. A systematic, integrated, data-driven approach is not new for PEPFAR OUs; but flipping the cascade and reviewing program performance from PopVLS will not only ensure the prioritization of care and treatment activities, but it will also best prepare the OU for reaching and sustaining epidemic control. To identify, quickly address potential gaps and prevent or mitigate data quality issues, OUs are encouraged to follow the guidance for data review outlined in the new WHO/PEPFAR Viral Load Testing Data Quality module.

Figure 7.2.1.10: Trends in viral load testing gap, unsuppressed persons, and suppressed persons among females 15+ in SNU E with low VLC by implementing mechanism, Country A

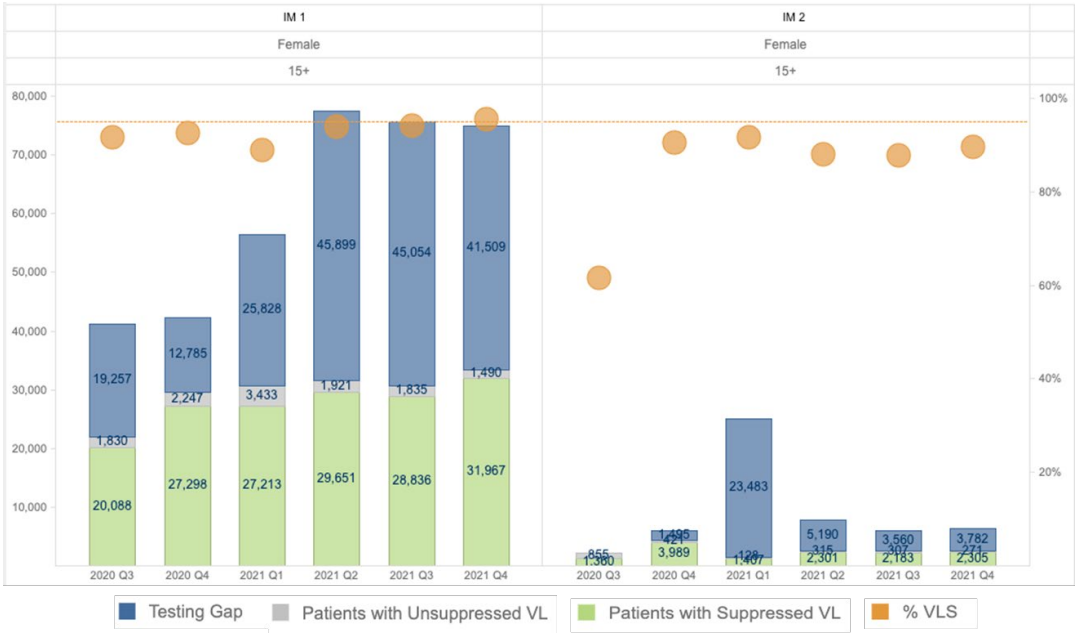
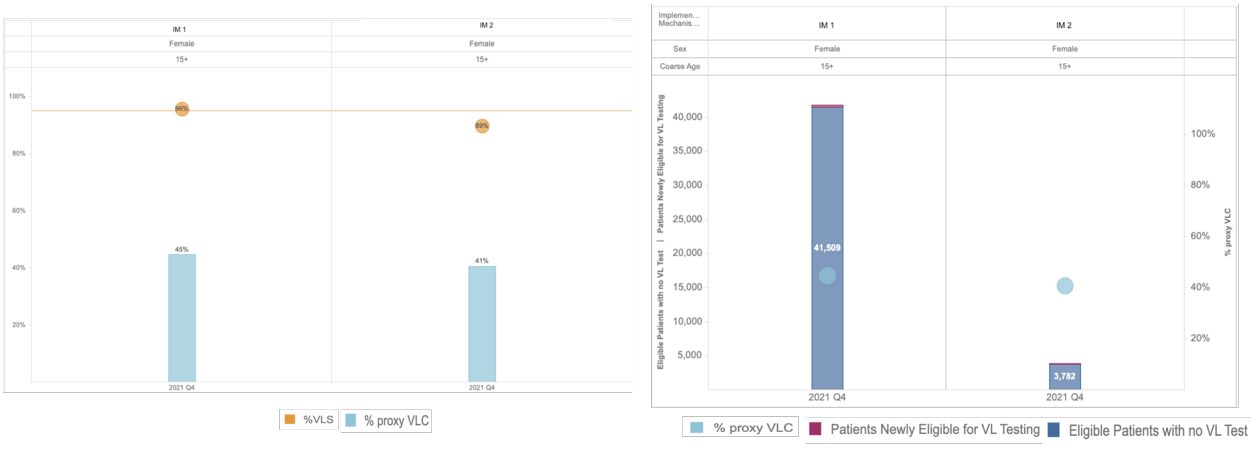
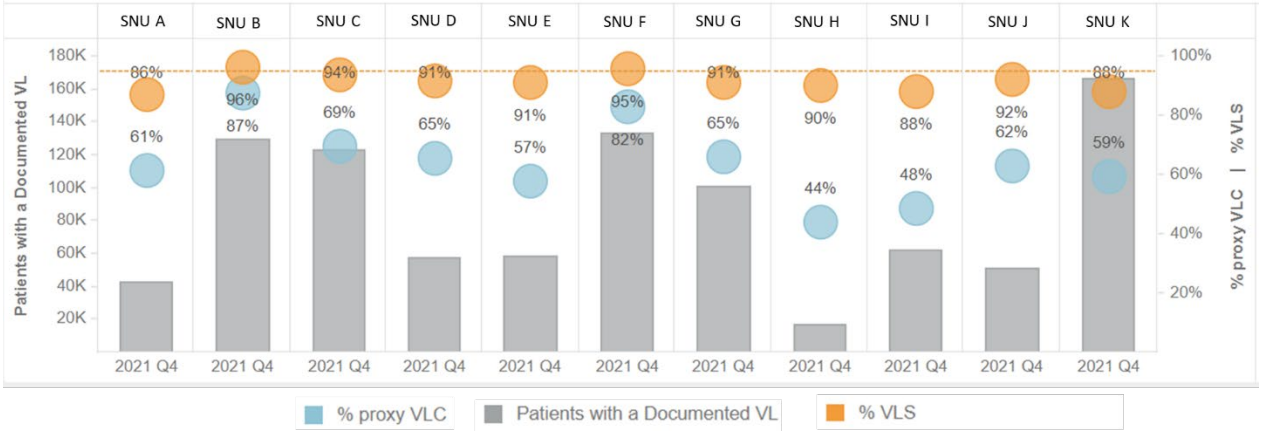


Figure 7.2.1.11: Viral Load: Single OU dossier, trends in VL coverage and suppression and testing demand among females 15+ in SNU E with low VLC by IM, Country A



Not at Epidemic Control: Figure 7.2.1.12, PEPFAR Panorama Dossier, Viral Load: Single OU dossier, VLC & VLS + TX_PVLS, D page, shows inconsistent rates of VLC across country B's PSNUs and overall low performance. It is essential to delve deeper into the specific regions/districts to see if there are trends in gaps or best practices.

Figure 7.2.1.12: Viral Load Coverage and Suppression by SNU, Country B



Figures 7.2.1.13 and 7.2.1.14 look closer at two SNUs by age and sex – one SNU with low VLC and VLS (SNU J) and a second with low VLC but high VLS (SNU H).

Figure 7.2.1.13: Viral Load: Single OU: Viral Load Coverage and Suppression, PSNU with low VLC and VLS, SNU J, Country B

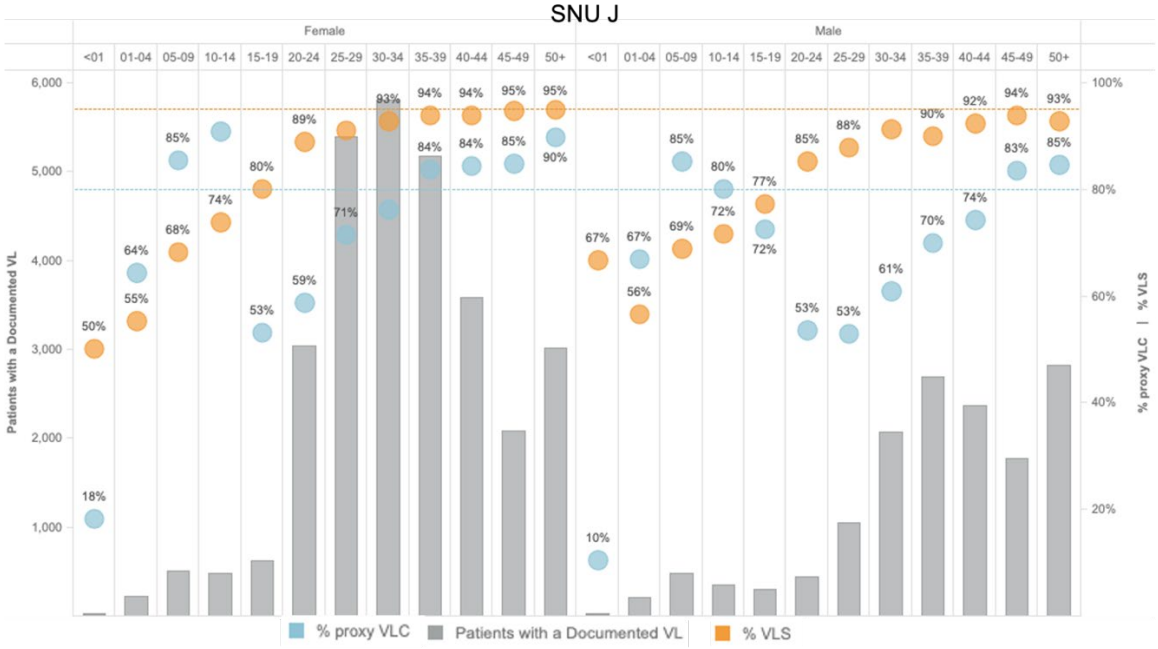
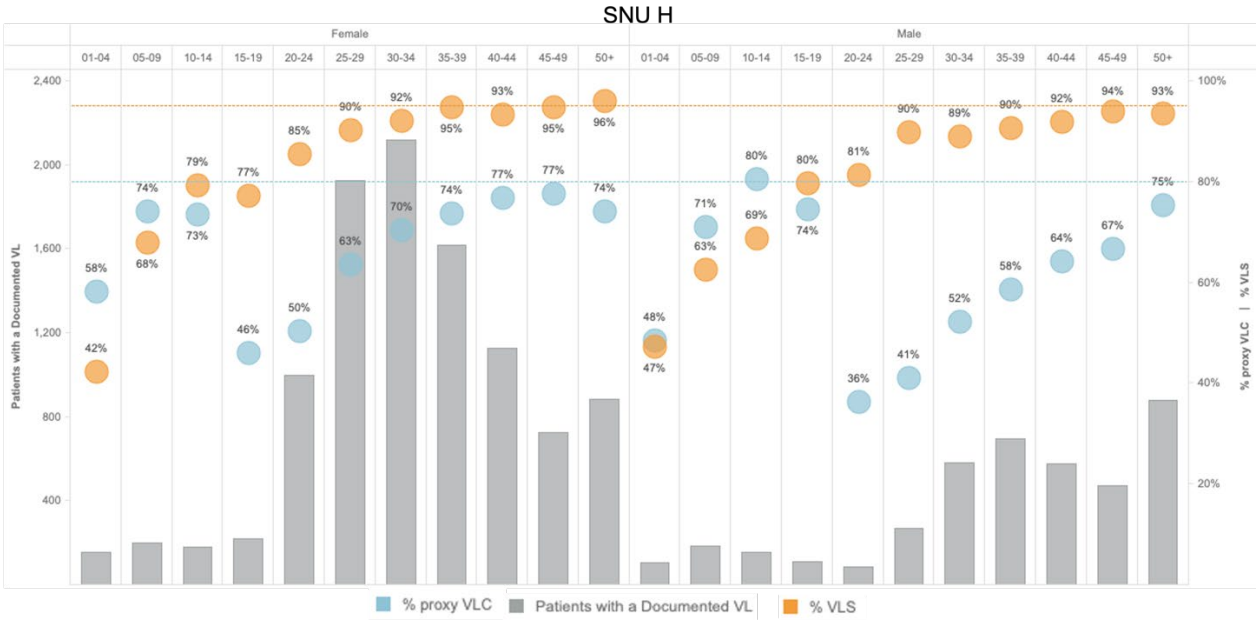


Figure 7.2.1.14: Viral Load: Single OU: Viral Load Coverage and Suppression, SNU with low VLC but high VLS, SNU H, Country B



There are similar trends in both SNUs – rates of VLC and VLS increase with age for both sexes, though are lower for males than females. Both VLC and VLS are low for those <5 years, with a second dip at 15-24 years old. While the VLC is the lowest for those <1 year old, programs

should take into consideration that this is a proxy calculation and determine what other information is needed to better explain and explore these findings. Gaps like this should spur further questions: Is there a difference in VLS by ART regimen? When are children being identified in the PMTCT/EID cascade and what are the linkage rates Where VLC and VLS do not show similar patterns, is the VLC adequate to correctly calculate VLS?

It is also important to look at the volume of untested and unsuppressed, not just the coverage rates. In Country B, Figures 7.2.1.15 and 7.2.1.16 show the largest burden of those eligible for VL testing but without a test result is in the 20–39-year-old age band, and among females.

Figure 7.2.1.15: Viral Load: Single OU: Viral Load Cascade, Country B

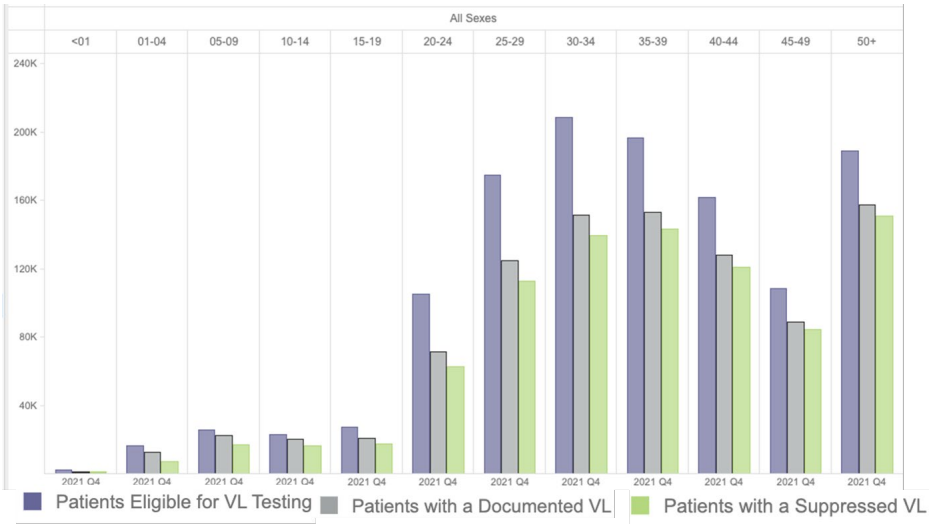
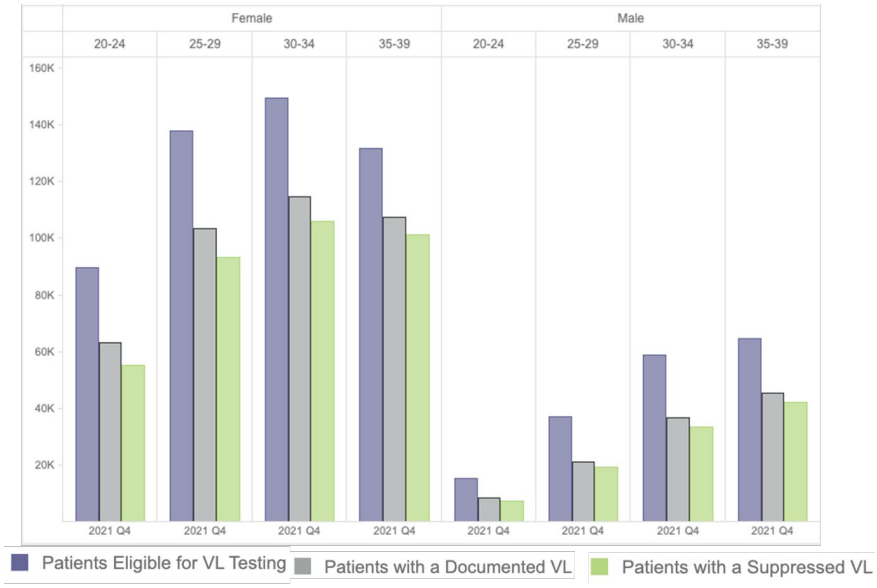
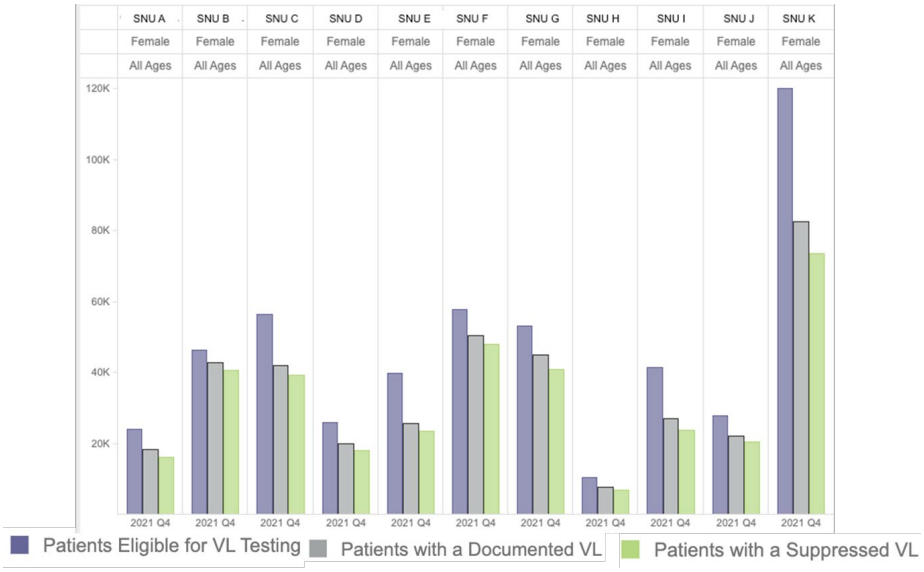


Figure 7.2.1.16: Viral Load: Single OU: Viral Load Cascade, by sex and 20–39-year fine age bands, Country B



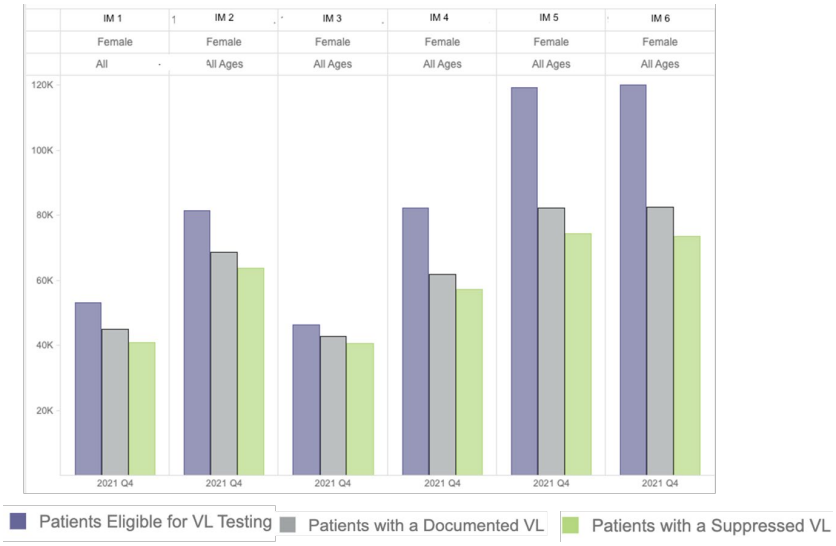
In the figures above, we identified females 20-39 as having the greatest unmet VLC need. In Figure 7.2.1.17, we look even further into the data to identify the SNU with the greatest VLC burden among this population.

Figure 7.2.1.17: Viral Load: Single OU: Viral Load Cascade by SNU for females aged 20-39 years, Country B



Viral load testing scale up should be focused on 20–39-year-old females in SNUs with the largest gaps (SNU B, D, E, I, J, L). Which IMs are having the greatest success in VL coverage for females aged 20-39? How can we best understand the driver to some IM success and other IM gaps within the same program areas for the same population?

Figure 7.2.1.18: Viral Load: Single OU: Viral Load Cascade Trends, by Mechanism for females aged 20-39 years, Country B



Additional Deep Dive Questions for Analyzing Viral Load Suppression

- Who are we missing?

  a. What is coverage of viral-load testing by age/sex/geography? What is coverage among key population groups?
  b. What are the barriers to at least 95% VL coverage?
  c. Are those eligible for annual viral load tests getting annual viral load tests? Are results being returned to the client record?
  d. Are patients being informed of the availability and implications of their viral load results?
     i. What are the procedures/ scripts for explaining unsuppressed VL?
     ii. What are protocols for enhanced counseling and retesting?
  e. What is VLS by age/sex/geography and key population group?
     i. What is the progress of ART optimization (DTG-based ART) and DSD/MMD scale-up?
  f. Recognizing that individuals with an unsuppressed viral load are a priority for being offered safe and ethical index testing services, to what degree is this happening?

See Section 6.4 and 6.6.1 for technical guidance on how programs can respond to data.

PLHIV - Continuity of Treatment

PEPFAR is committed to ensuring that every person living with HIV has access to optimized HIV treatment from the day they are diagnosed. Understanding treatment continuity requires understanding program components that contribute to program gains and losses. While treatment targets are set using relevant seroprevalence data available, PEPFAR tracks treatment continuity using MER indicators and when available using patient-level electronic medical systems against viral load suppression rates. See Section 6.1 on Continuity of Treatment for technical guidance on this section.

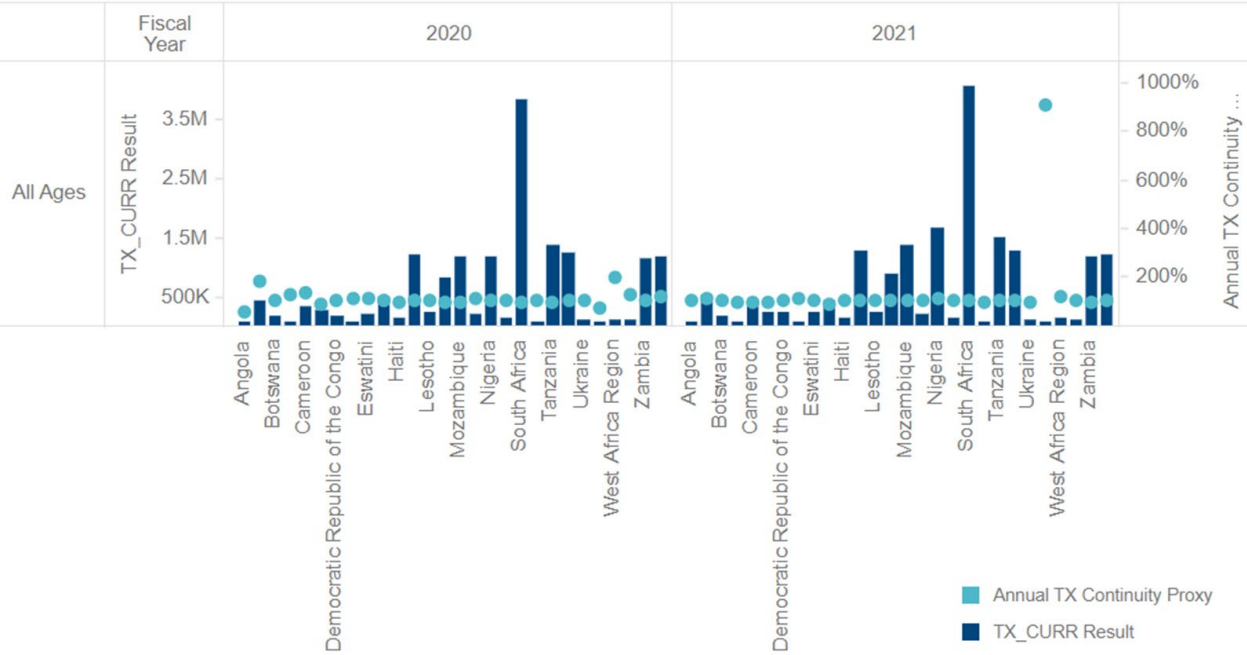
Deep Dive Questions for Continuity of Treatment in an OU:

- What is the TX_CURR in an OU and trends over time? How does this compare to TX_NEW? Does TX_NEW increase TX_CURR quarter to quarter?
- What is the TX_NET_NEW?
- What is the rate of MMD (multi-month dispensation) of ARVs in the OU? By sub-population and age band? Which client populations are not eligible for MMD and how might this affect client disengagement, reported as IIT?

- How have program coverage/mechanism shifts impacted TX_CURR, in either a positive or negative direction?
- What is the reporting coverage and rate for sites using TX_ML?
- What is the level of churn in an OU, PSNU and at the site level? Churn is the number of interruption (IIT) and return (RTT) events reported.
- Has the program identified sub populations (by age, sex, and location) at greatest risk for IIT and addressed this through programming that meets the needs of this sub population?
- What is patient feedback to determine barriers and obstacles for populations with high IIT?
- Has the program mapped areas of the greatest number of RTT quarter to quarter? Does this align with IIT events in the same spaces?

PEPFAR Panorama Dossier Treatment: Global (Figure 7.2.1.19) gives an overview of the Continuity of Treatment visuals that can help to answer these questions systematically across and within countries.

Figure 7.2.1.19: Continuity of Treatment across PEPFAR countries

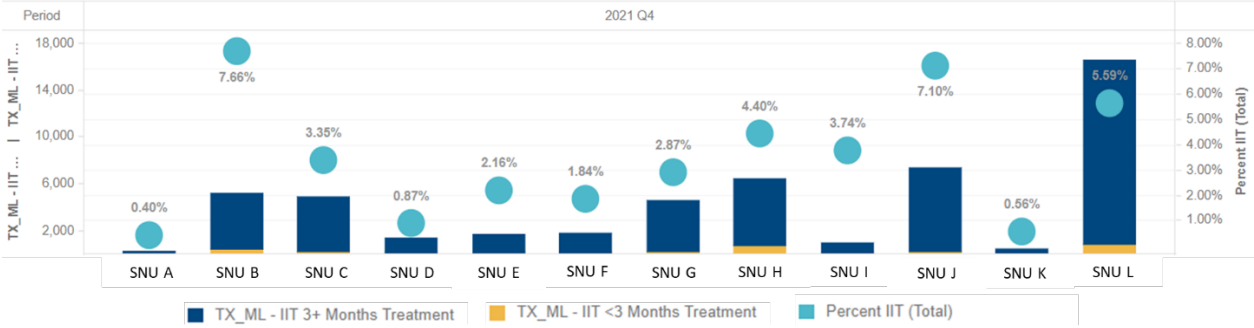


For countries not at epidemic control (see Figure 7.2.1.20), continuity of treatment should focus on increasing MMD and lowering the IIT across the country level will be key to accelerating towards saturation of services. For countries already at epidemic control (see Figure 7.2.1.21),

returning clients that ever-interrupted treatment and ensuring TX_RTT gains alongside a low IIT rate across SNUs will ensure sustained services evenly across local geographies reinforcing maintenance of epi control. The main question to ask during this type of data review is: when do clients on treatment interrupt treatment: early or after three months? Are there certain subpopulations and or local geographies with greater interruptions?

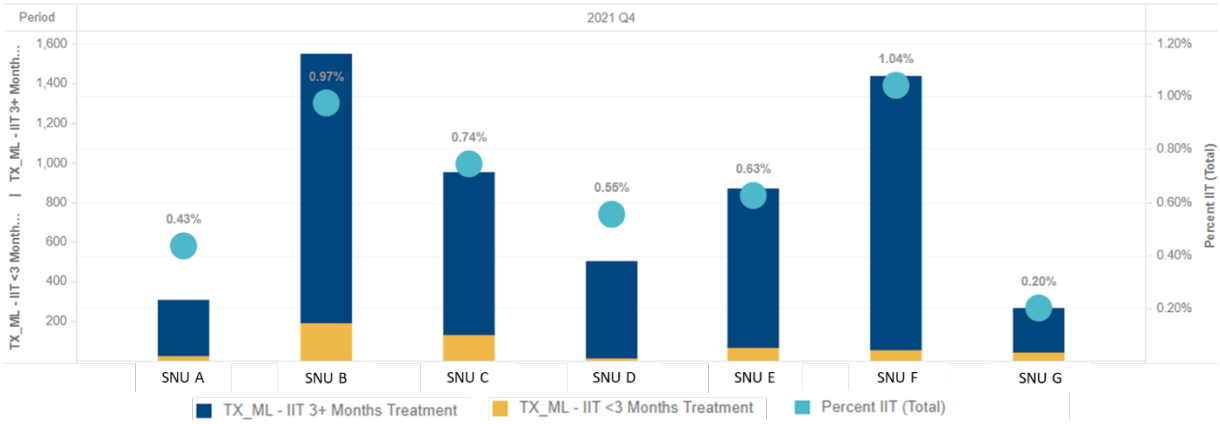
Not at Epidemic Control:

Figure 7.2.1.20: IIT differences across SNUs for Country B



At or Near Epidemic Control:

Figure 7.2.1.21: IIT differences across SNUs for Country A[731]

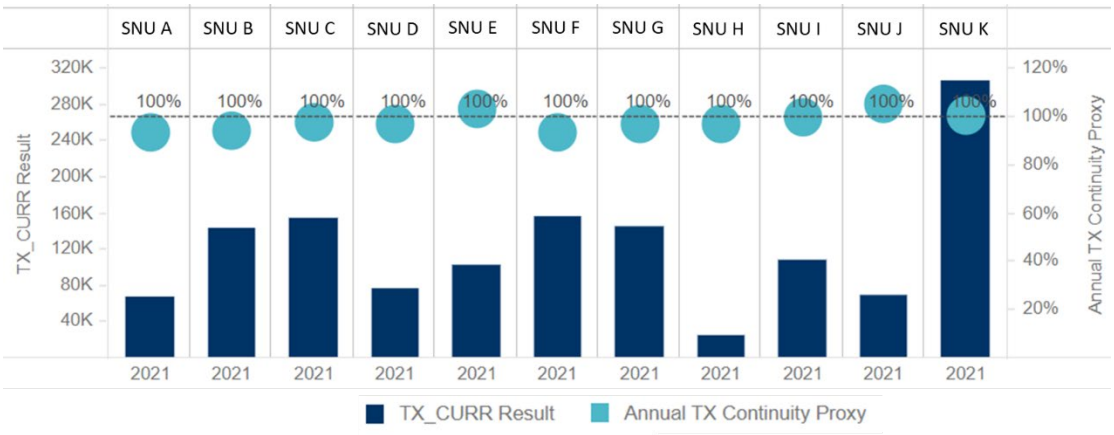


PEPFAR Panorama Dossier Treatment Single OU: IIT by Geography at the SNU 1 level shows variation in the number and percent of IIT across local geographies for both the countries not at epi control and at or near epi control (see Figures 7.2.1.22 and 7.2.1.23, respectively). It is essential to reflect on the OU context, and then review specific SNU practices to understand if there are lessons from top performing sites that can be replicated to improve furture performance.

[731] Data Sources: Panorama Dossier - Treatment Single OU: IIT by Geography and Age

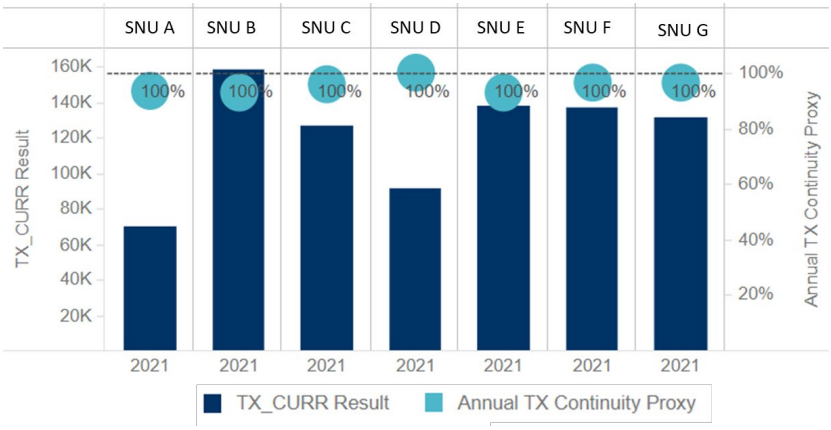
Not at Epidemic Control:

Figure 7.2.1.22: Treatment Continuity and TX_CURR differences across SNUs for Country B



At or Near Epidemic Control:

Figure 7.2.1.23: Continuity of Treatment and TX_CURR differences across SNUs for Country A[732]



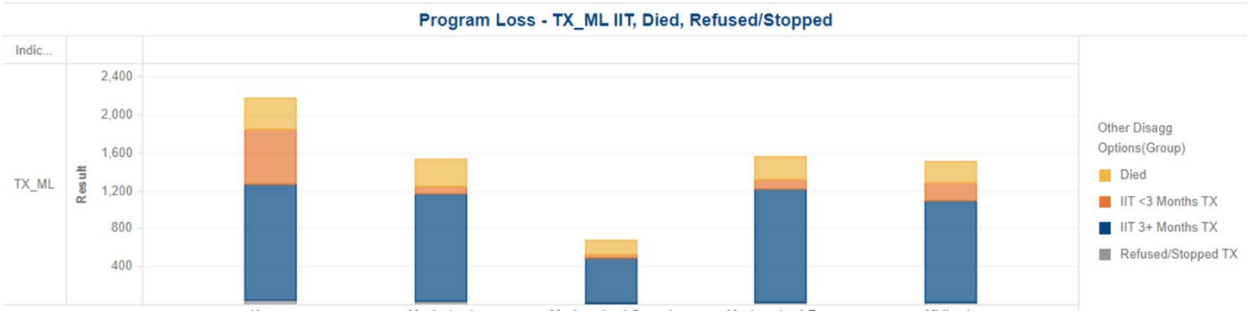
After reviewing the rate of IIT across local geographies, it is also important to identify the highest burden of IIT, often a small proportion of sites represent the opportunity to improve results. In addition, review client re-engagement (RTT) across these same geographies. Areas of high disengagement may need a focused return to treatment (RTT) to welcome back clients. One way to do this is by utilizing the Panorama Dossier Treatment Global: Continuity of Treatment Proxy and TX_Curr page, and observing if the same SNUs with high IIT rates also report high volume of clients. It is important to examine IIT in relation to specific clinic volume, urban vs. rural clinics, the distance people travel to get a to clinic, and whether or not MMD is offered at sites with high IIT.

[732] Data Source: Panorama Dossier Treatment Single OU (Site Level): Continuity of Treatment – Bar Graph

Not at Epidemic Control:

Figure 7.2.1.24: Program loss differences across SNUs, Country B

At or Near Epidemic Control:

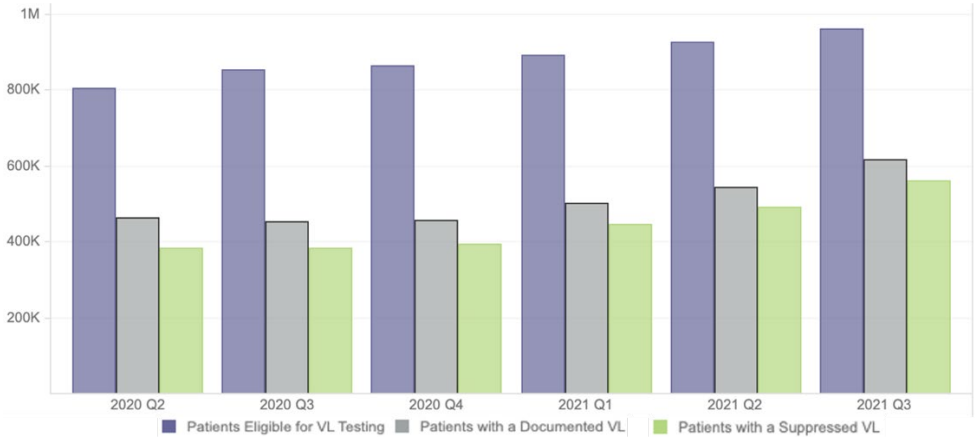


Another method for reviewing this data is through the Panorama program loss dossier (see Figures 7.2.1.24 and 7.2.1.25) and observing the reported contributors for loss across SNUs as compared with the same geography's IIT percent and retention.

Not at Epidemic Control:

After taking into account the IIT and RTT results by SNUs, triangulate individual level data and viral load data to observe if there is indication of influence on the continuity of treatment of PLHIV and their viral loads. In Figure 7.2.1.26 above, the viral load cascade has been pulled for the SNUs in the same country as previous figure examples for a country not at epi control, but this time we are looking at trend analysis.

Figure 7.2.1.26: Viral load testing and suppression trends for Country B

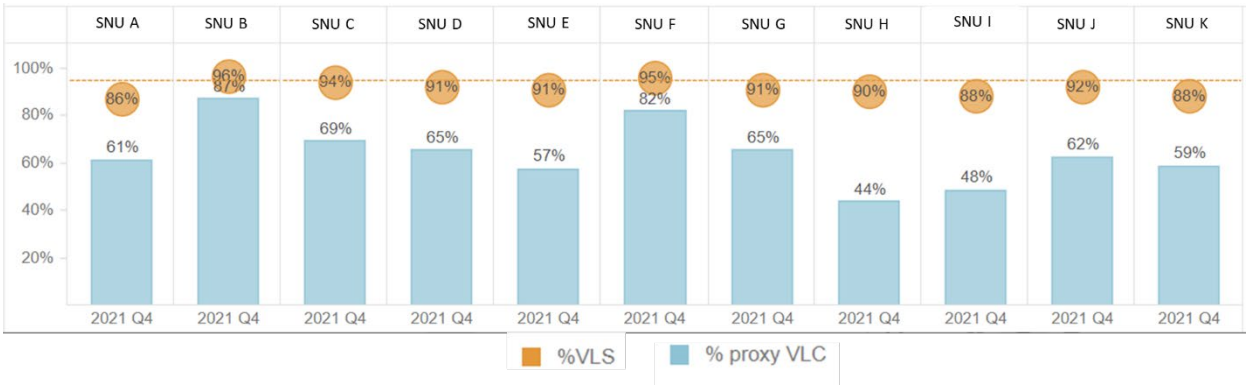


Low Viral Suppression

- Is there a relationship between commodity stock outs, client IIT and low VL Coverage and Suppression?
    - Data Sources: compare SC_ARVDISP for TLD transition, VLS indicator. For peds, DTG rollout and VLS indicator
    - Is the supply plan for lab products updated regularly with accurate and complete data to ensure lab stockouts are mitigated or avoided?
- Are there temporal associations with changes in policy, practice, expenditure, or IP?

Not at Epidemic Control:

Figure 7.2.1.27: VLS across SNUs in Country B[733]



Deep Dive Questions for Treatment

- What is linkage by age, sex, and geographic location and testing modality?

[733] Data Source: Panorama Dossier Viral Load: Single OU: VLC & VLS

- PEPFAR teams should be able to describe with data how many newly initiating ART patients can be expected from each of the HTS entry streams. What are the linkage rates among each partner? What are the IIT and RTT rates by site? When there is poor performance, have there been SIMS, DQA, or QI activities to better understand barriers to data quality, client engagement and access, including stock outs and HRH?
- What is the linkage rate at sites with the highest number of newly diagnosed PLHIV?
- Do initiation rates differ by sex? By age? By SNU?

- What is treatment program growth and ART continuity of all clients over time (TX_CURR over time), and in relation to treatment initiation (TX_NEW) and program loss (TX_ML), and program return to treatment (TX_RTT)?
- Which patients are eligible for multi-month dispensing accessing and using MMD options (TX_CURR_MMD)? Are all IPs reporting completely to TX_CURR_MMD? Are all patients eligible for TLD or DTG-based therapy? How many sites meet these criteria, and what is the volume of patients at those sites?
- Is there equity in treatment continuity? Is TX_ML data complete? If so, who (by age and sex) interrupts treatment more frequently? When do interruptions happen on treatment (early <90 days or over 3 months)? Does the geography of the site have an impact on ART continuity (i.e., urban vs rural)?
- Were there any documented instances of ARV stockouts (SC_CURR) and/or challenges with distribution of ARVs?

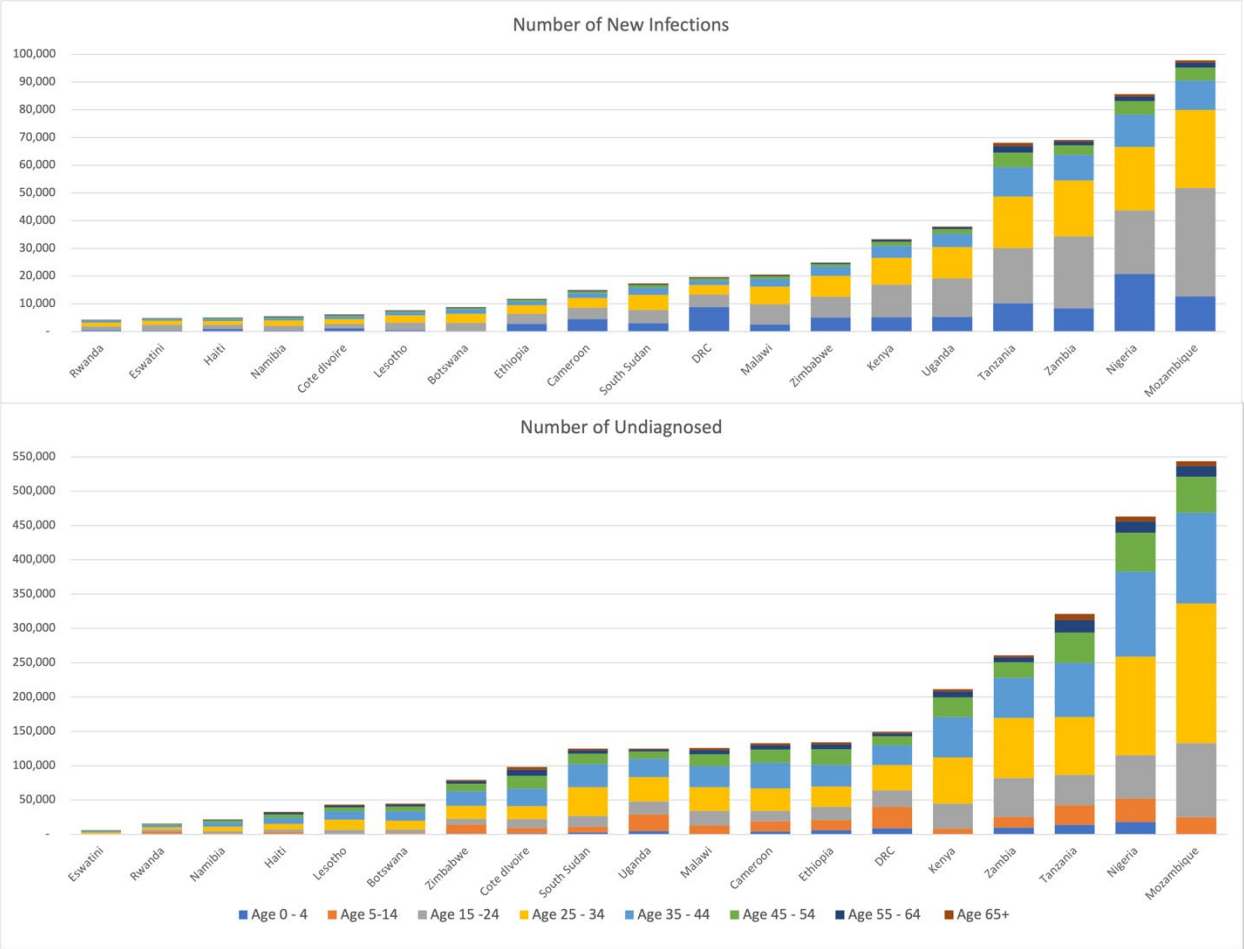
HTS for Case Finding

The strategic mix of HIV testing strategies (HTS) should evolve as countries achieve equitable epidemic control. To help guide COP22 planning, countries should conduct a modality mix analysis looking at the percent contribution of HTS_TST and HTS_TST_POS from each PEPFAR-support testing modality, with a granular look at SNUs, age/sex bands, subpopulations (including key and priority populations), and sites to see where new infections are being found.

Currently no PEPFAR partner country has achieved the first 95 across all SNUs and for all subpopulations. Therefore, each country should go through each of the actions outlined in Section 6.3.1. Recognizing the variance across partner countries achieving equitable epidemic control, Section 2.3.1 provides the anticipated evolution of HTS for case finding as countries

approach and achieve equitable epidemic control across subpopulation groups (including age and sex bands) (Table 2.3.1.1).

Countries must ensure that their testing and case finding strategy is specific and targeted to populations with the greatest volume of new infections and identified gaps in order to keep the new infection rate down. UNAIDS 2021 estimates in Figure 7.2.1.28 show that the number of new infections and undiagnosed PLHIV are greatest among the 15-34 years age groups followed by children 0-4 years old. Countries not at epidemic control have a greater volume of new infections within these age bands.



In addition, a UNAIDS special analysis estimates that key populations and their sexual partners (including male partners of FSW and female partners of PWID) account for 65% of new HIV infections globally and 39% of new infections in sub-Saharan Africa, suggesting that non-traditional KPs need a tailored approach to address needs.

As testing strategies evolve for countries nearing epidemic control, the strategic mix of testing strategies may vary across population due to identified gaps. This may include different mixes of testing modalities, different approaches to target setting, etc. All countries, including those that have reached epidemic control, will need to support a robust pediatric testing portfolio to reduce the gaps in reaching the pediatrics 1st 95.

Triangulated data analyses from sources including MER, PHIA, BBS, and in-country individual level data including case-based surveillance data are instrumental to identify high rates of positivity and new PLHIV among specific age groups, sex, geography, testing modalities, sites, priority, and key populations. Looking at who, how, and where new PLHIV are being identified is important to determine a sustainable testing strategy and strategic prevention package that optimizes budget, aligns with, or complements MoH priorities, and maintains epidemic control status.

If PHIA data is not available, analyzing program data for trends over time and percent achievement towards targets can serve as a proxy measure for how well case finding gaps across SNUs and subpopulations are being addressed. Traditionally, COP targets are set in accordance with specific, evidence-based measures and act as a proxy towards epidemic control.

Identifying case finding gaps and priorities

At or Near Epidemic Control:

In the figures below, Country A has the greatest case finding volume in SNU B; the highest testing positivity is in SNUs A, B, and I (Figure 7.2.1.29). By testing modality, the greatest volumes of testing (HTS_TST) occur in OtherPITC, PMTCT, and PostANC1. The testing modalities with the highest positivity (yield) include community index testing (IndexMod), community testing (OtherMod) and TBClinic (Figure 7.2.1.30). Examining by sex and age bands (Figure 7.2.1.31), it is evident that case finding volume and testing positivity is not equal across sex and coarse age bands. A successful HTS program will balance case finding volume and testing positivity (yield) outcomes to accelerate closing gaps in SNUs and among subpopulations (including age and sex bands) that have not yet achieved the first 95.

Figure 7.2.1.29: Case finding volume and testing positivity (yield) by SNU for Country A, at epidemic control

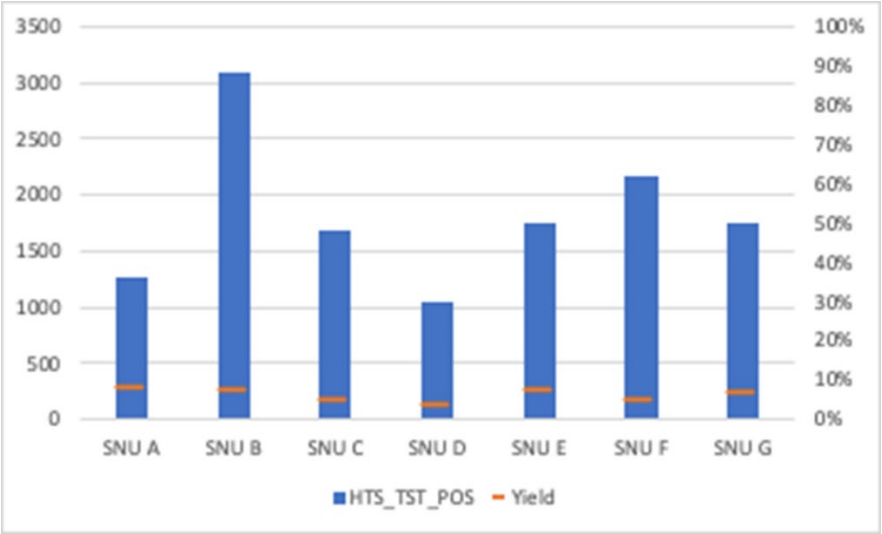


Figure 7.2.1.30: Testing volumes (HTS_TST) and positivity (yield) by modality for Country A

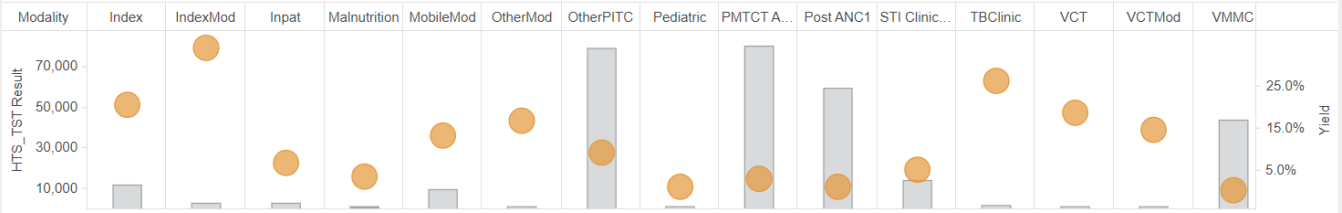
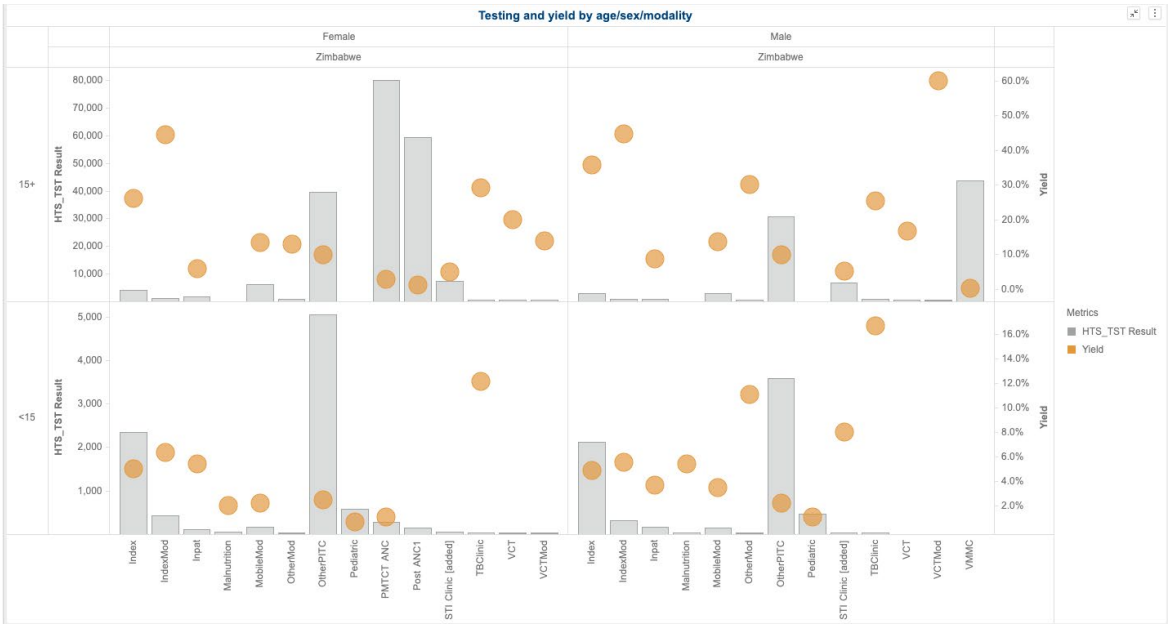
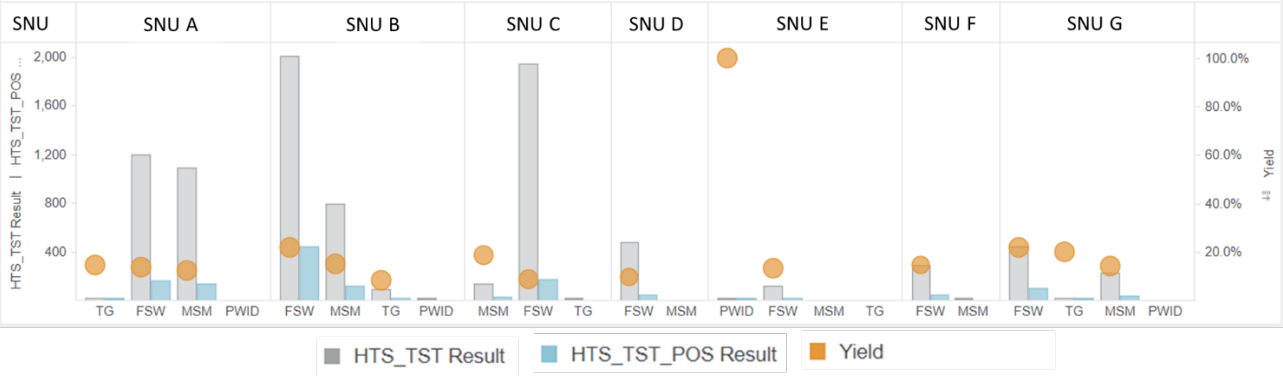


Figure 7.2.1.31: Testing positivity (yield) by age/sex/modality for Country A



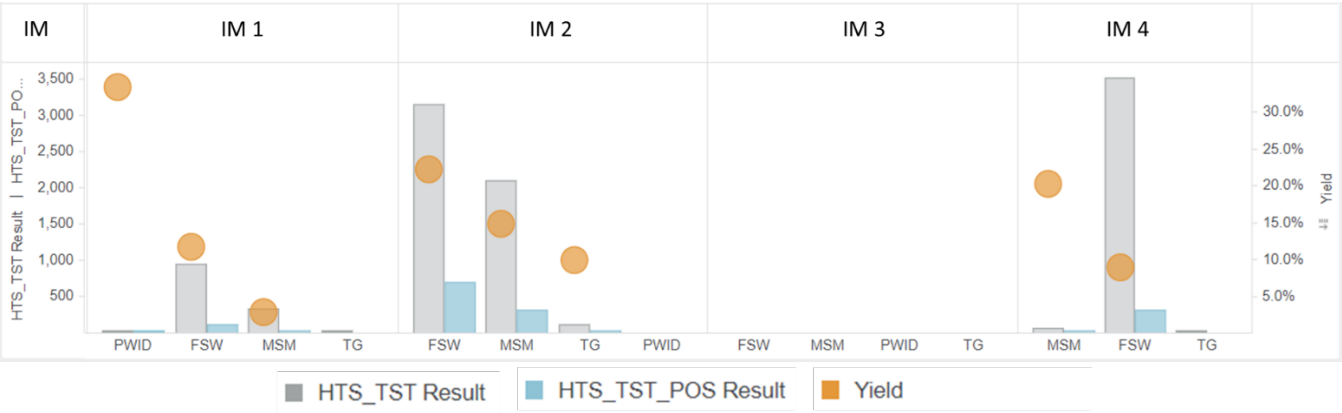
To continue the necessary deep dive, it is imperative to look at testing achievements and gaps across priority populations. Figure 7.2.1.32 and Figure 7.2.1.33 provide illustrative examples of HTS achievements among KP by SNU and IM, respectively. Viewing HTS data through different lenses - geographic, subpopulation, and IM/partner - provides countries the opportunity to identify and scale best practices to maximize impact.

Figure 7.2.1.32: Testing (HTS_TST), case finding (HTS_TST_POS), and testing positivity (yield) among KP, by SNU in Country A[734]



In analyzing testing positivity rates among key populations, Country A should identify those approaches (by SNU and mechanism) which are most successful and strategic at identifying new KPLHIV and reaching those previously unreached.

Figure 7.2.1.33: Testing (HTS_TST), case finding (HTS_TST_POS), and testing positivity (yield) among KP, by IM in Country A



[734] Source: Panorama: Testing: Single OU Dossier, HTS:KP Chapter, KP Pos: targets & results Sub-Chapter, Comparison Level: SNU1

Deep Dive Questions for Country at Epidemic Control

- Understand the regional age/sex/risk profile of new infections and remaining TOTAL individuals not on ART. Are these individuals undiagnosed, previously diagnosed but not on ART, or were on ART and stopped? Each group may have different strategies to reach them, particularly men; partnering with treatment services will be critical to allow treatment programs to evolve to meet the client's needs and maintain on ART.
- What are the effective active case finding strategies for the populations contributing to new infections, what are those strategies 'yielding' in the under 35 year old population by sex?

Not at Epidemic Control: For countries not yet at epidemic control, HTS for case identification and linkage to treatment should be a large programmatic emphasis. Teams should start their analysis looking at case finding volume and yield by SNU (Figure 7.2.1.34) and by modality (Figure 7.2.1.35).

Figure 7.2.1.34: Case finding volume and testing positivity (yield) by SNU for Country B

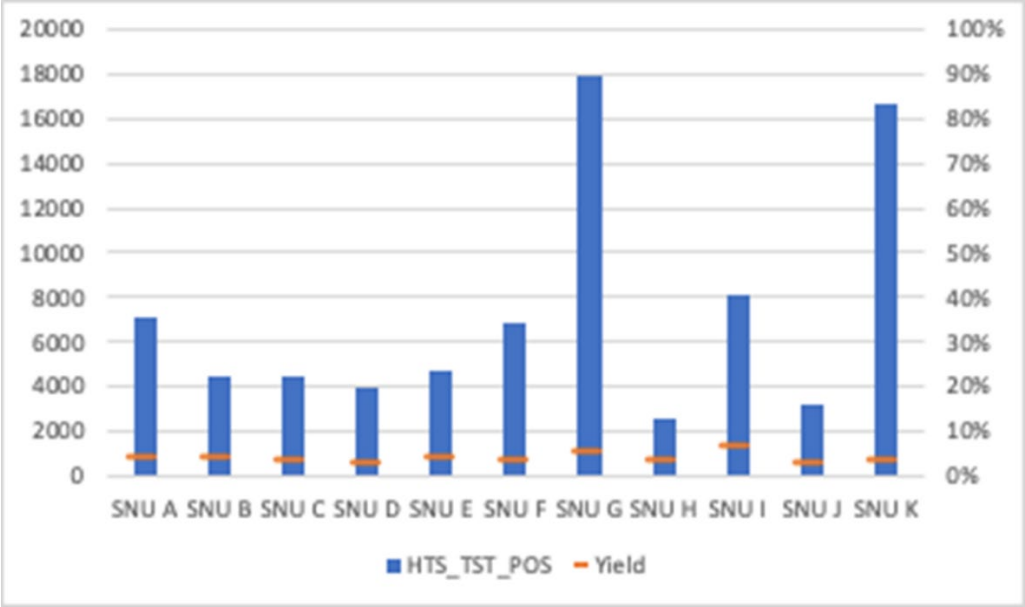
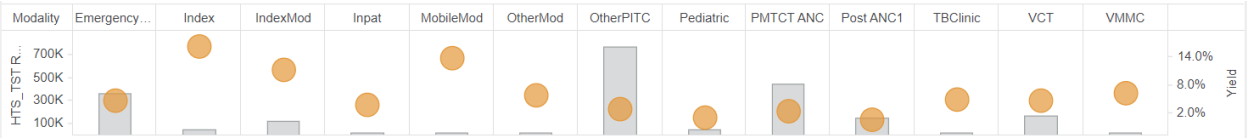


Figure 7.2.1.35: Testing volumes (HTS_TST) and positivity (yield) by modality for Country B[735]

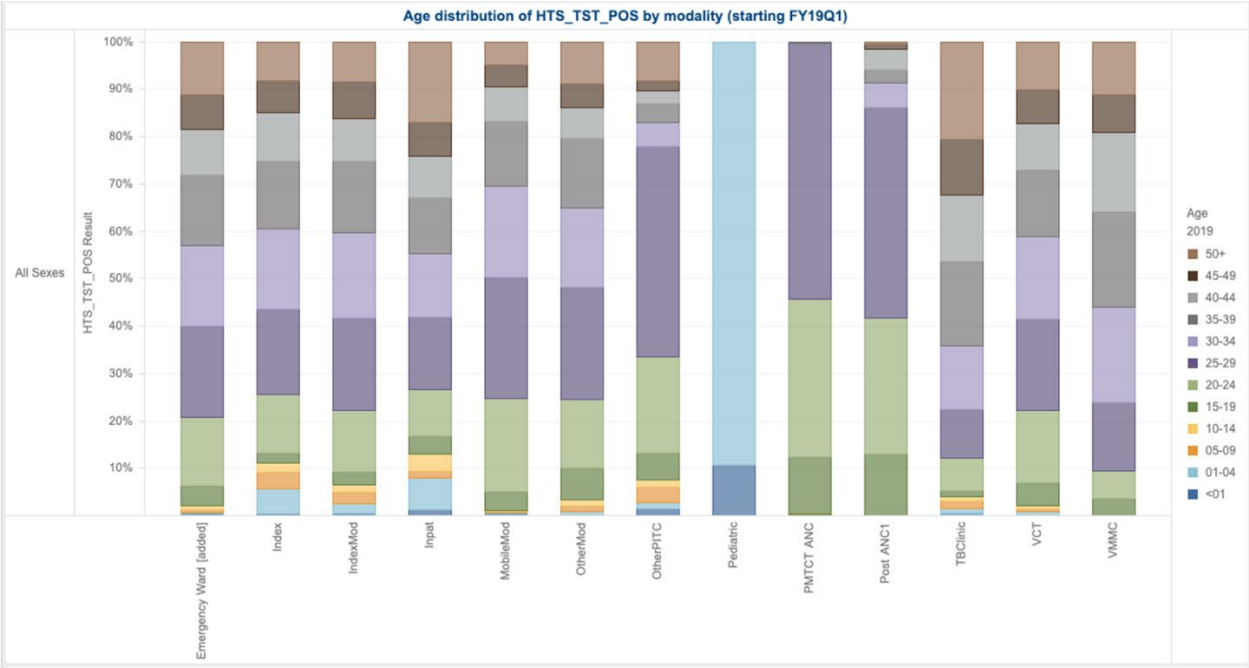


[735] Source: Panorama: Testing: Single OU: Testing and Yield: Modalities & KP

Programs must analyze case finding volume alongside ART coverage gap and testing positivity to mitigate missed case finding opportunities in an attempt to prioritize high positivity. This analysis begins by looking at MER results for HTS_TST and HTS_TST_POS to determine reach and yield alongside the pages from PEPFAR Panorama Dossier Testing: Single OU Testing and yield: Modalities.

Program results will not provide enough information to formulate a strong testing strategy across different implementing levels for countries not yet at epidemic control. If possible, use your recent PHIA or other household survey data to compare gaps in identification by age/sex bands with successful modalities for identifying specific age/sex bands. The below PEFPAR Panorama Dossier compares modality by age. There are additional ways to look at this information by age and sex to compare to demographic epidemiological gaps.

Figure 7.2.1.36: Testing: Single OU: HTS_TST Modality by Age



If survey or PHIA data are not available, analyzing program data for trends over time and percent achievement towards targets is another way to assess if a program is closing gaps in SNUs and subpopulations that have not yet achieved or sustained the first 95. Targets are set in accordance with specific, evidence-based measures and act as a proxy towards epidemic control. Figures 7.2.1.37 and 7.2.1.38 demonstrate performance against targets by SNU (ranked by percent target achievement) and across quarters, respectively. These visuals

highlight opportunities for improvement within SNUs and can be useful as programs prioritize technical assistance for sites and districts.

Figure 7.2.1.37: Case finding (HTS_POS) results and target achievement by SNU for Country B

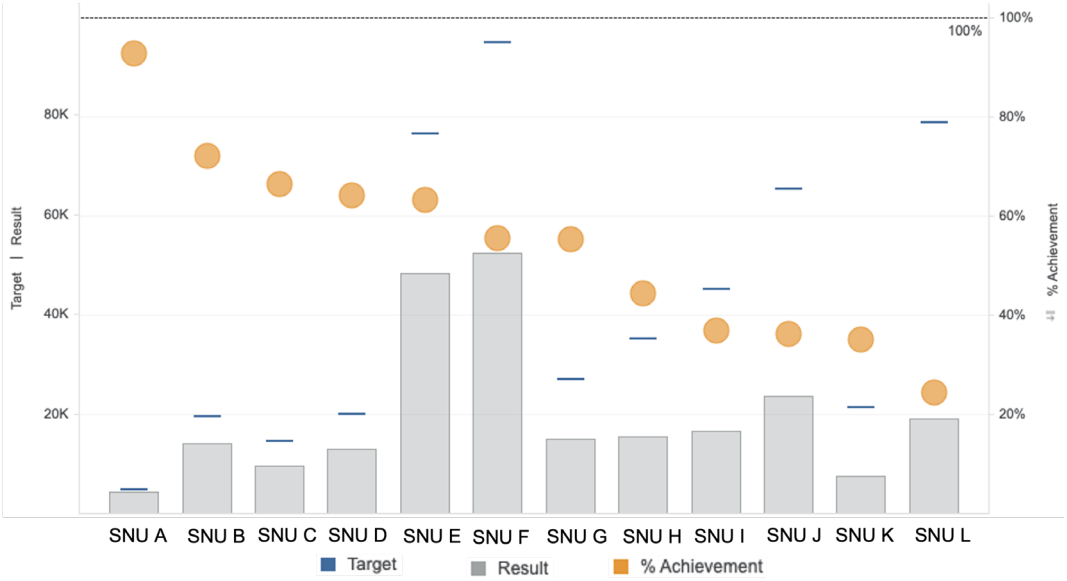
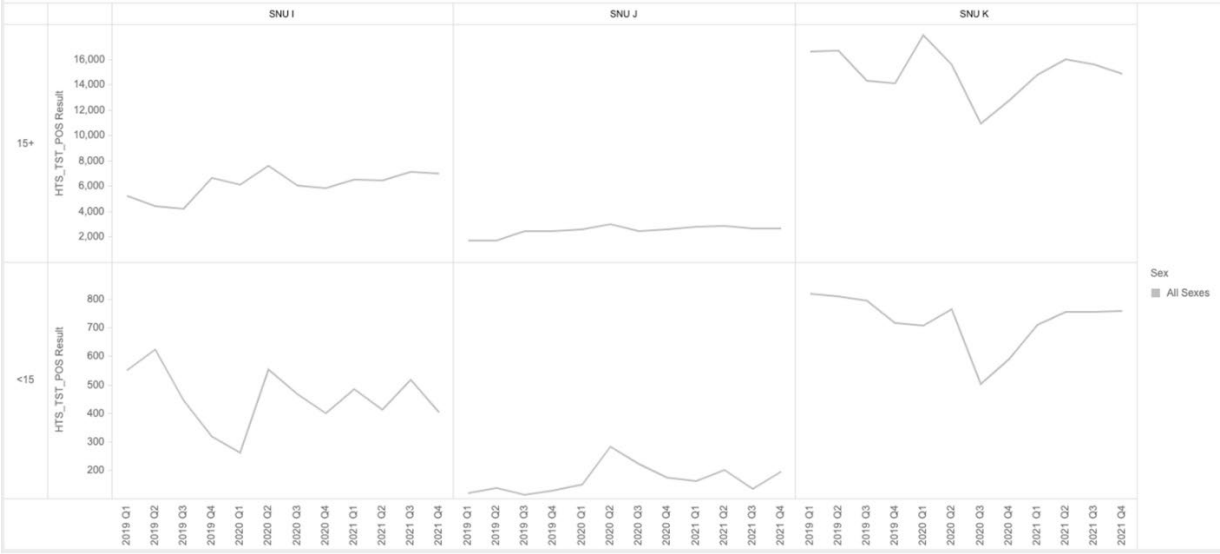


Figure 7.2.1.38: Case finding (HTS_POS) quarterly trends for coarse age bands in three low performing SNUs in Country B[736]



[736] Source: Panorama: Testing: Single OU Dossier, HTS_TST_POS Chapter, Pos: Pos trends by age sex Page, Comparison Level: SNU 1

Deep Dive Questions for Country not at Epidemic Control:

- Understand the total number of individuals not on ART by age/sex/risk. Are these individuals undiagnosed, previously diagnosed but not on ART, or were on ART and stopped? Each group may have different strategies to reach them particularly men, partnering with treatment services will be critical so treatment program evolve to meet the client's needs to maintain on ART.

Deep Dive Questions for All Countries for HTS for Case Finding:

- What is the strategic mix of testing modalities, given the country's epidemic and current ART coverage by SNU and subpopulation? (NB: This requires a balanced focus on case finding volume and testing positivity.)
- Index testing:
    a. What is the quality and scale of implementing index testing?
    b. How will the program improve offering safe and ethical index testing to all newly diagnosed PLHIV and all PLHIV known to be without viral suppression in accordance with Section 6.3.1.5? And all biologic children (< 19y) of PLHIV in accordance with Section 6.3.2.1?
    c. How many contacts (sex partners, needle sharing partners, and biologic children) are elicited and receive HTS? (by age/sex)?
    d. How is the program monitoring safe, ethical index testing? How are sites that have not currently met the criteria being supported for timely remediation?
- What strategies will be implemented to optimize OtherPITC, recognizing the need to balance case finding volume and testing positivity. What metric(s) will the OU use to determine optimized OtherPITC? (See Section 6.3.1.7 for guidance on Optimizing PITC.)
- How will unnecessary retesting be minimized? (See Section 6.3 for additional guidance on minimizing unnecessary retesting.)
- What testing modalities will be optimal for distribution and use of HIV self-test kits? (See Section 6.3.1.6 for additional guidance on HIV self-testing.). Which populations will be targeted and what interventions will be prioritized to amplify case finding (primary, secondary distribution; linkage strategies etc.)?
- How will HTS be prioritized and maximized in service delivery points where HTS is a minimum standard of care (e.g., STI clinics, TB clinics, PMTCT)? Are all key populations being reached as documented via KP_PREV offered or referred to HIV testing?

- What strategies will PEPFAR HTS partners implement to support 95% linkage across all subpopulations, including age and sex bands? (See *Deep Dive Questions for Treatment* for additional questions regarding linkage to ART.)

7.2.2 Cascade Funding Analysis

Financial & MER Integrated Analysis

The Financial Management: OU dossier in Panorama provides funding agency, partner and implementing mechanism detail down to the program, sub-program, beneficiary, sub-beneficiary, and service delivery levels of interest. The dossier helps to gain a better understanding of how IMs implemented their activities by understanding how they spent their budget, as measured by expenditures. Budget execution-the comparison of planned budget to expenditures-shows whether funding was spent as planned and thus can help explain if programmatic work was carried out as intended. If a mechanism only expended a small portion of the budget, this may indicate that the mechanism budget was overestimated during planning and thus may require a reduction in future cycles. Alternatively, it may indicate that the mechanism was simply not operational for some of the period of performance, potentially due to a delay in funds getting to the partner, or potentially due to other contextual drivers, like an inability to operate normally due to the COVID-19 pandemic. If outlays appear normal, then it may be necessary to consult with the partner if it is not already known why funding that was received was unable to be spent. Again, this is a possible scenario that may be encountered during the COVID-19 pandemic, but there could be other drivers of low budget execution as well, including increasing efficiencies, reduced needs for the specific type of programming, above-site policy barriers that first need to be resolved, or others. Depending on the findings in this analysis, course corrections may be necessary in the coming cycle to either reduce the mechanism budget or mitigate the risks to the extent possible that caused the break in activity.

Alternatively, if a mechanism overspent their budget, this may indicate mechanism inefficiency and a need to review spending with the partner and possibly reduce the IM's budget. It may also result in an increase to their budget if the partner's expenditures were deemed necessary and were commensurate with overachieving MER or other results. It may also help to understand if the IM both over-outlaid and overspent. If the mechanism had an isolated over-expenditure without over-outlay, this may indicate the timing of expenditures simply fell within one fiscal year; however, if the mechanism consistently overspends, mitigation may be necessary to ensure appropriate outlays and expenditures in commensurate fiscal years.

The Financial & MER Integrated Analytics dossier allows users to take their analysis a step further by comparing budget execution (expenditures/budget) vs. target achievement (result/target) by program and sub-programs of interest (e.g., Care & Treatment, HIV Testing, Orphans & Vulnerable Children, PrEP, and Voluntary Medical Male Circumcision). Mechanisms with low budget execution in a particular program area, for example, Care & Treatment, paired with high target TX_NEW, TX_CURR, and TX_PVLS achievement would provide an integrated look at program achievement. Conversely, high budget execution paired with low target achievement would be cause for further discussion to determine if budget may need to shift between program areas for the mechanism or targets may need to be reallocated to a more efficient mechanism. Country and mechanism operating contexts are always critical to keep in mind for any budget execution vs. target achievement analyses.

When completing a cascade analysis, it is helpful to first review how the proportion of program area budgets has shifted in your OU over time. Teams must evaluate performance both cross-sectionally (over one period) and across time periods to see how efficient the programs were implemented and discuss if refinement is needed for COP22. Programs that either have become significantly more or less efficient need to be discussed further for potentially increased or decreased funding, respectively. Due to a change in financial classification structure for budget beginning in COP19, it is generally recommended to limit program area financial trends from COP19 to present.

At or Near Epidemic Control

As demonstrated in Figure 7.2.2.1, in countries that prioritize viral load coverage in their COP strategy, often At/Near Epidemic Control countries, we would typically expect to see an upward trend in C&T: HIV Laboratory Services and ASP: Laboratory Systems Strengthening commensurate with increases in viral load coverage. These sub-program areas can serve as proxies for investment in viral load, though It is important to note the sub-program area values will underestimate the true investment in viral load activities due to some activities being lumped in the "C&T: Not Disaggregated"" and “ASP: Not Disaggregated” sub-program areas.

Figure 7.2.2.1: Budget Allocation for VLC Activities in Country A[737]

Program	Fiscal Year	2020	2021	2022
	Sub Program	Budget	Budget	Budget
		$6,769,406	**$9,408,000**	**$10,650,927**
C&T	HIV Laboratory Services	$6,769,406	$9,408,000	$10,650,927

Program	Fiscal Year	2020	2021	2022
	Sub Program	Budget	Budget	Budget
		$5,396,468	**$6,386,556**	**$6,516,955**
ASP	Laboratory systems strengthening	$5,396,468	$6,386,556	$6,516,955

It is also helpful to examine how the proportion of program area budgets within the OU has changed over time. As an OU moves closer to epidemic control, we expect adjustment from surging activities for case finding and treatment initiation to activities to that sustain substantial portions of the population on ART and virally suppressed. This scenario may not hold true in every country, which is why It is important to conduct a responsibility matrix and resource alignment review, outlined at the end of Section 7, below, to determine which entities are responsible for different aspects of the epidemic response and ensure that the PEPFAR budget is not overextended in an area of the epidemic response that is led by another stakeholder, and thus should not be the financial responsibility of PEPFAR. In countries where continued investment in HTS is necessary, teams may see budgets increasingly targeting specific beneficiary groups where there may be gaps/needs.

Figure 7.2.2.2: Country A Program Area Budget Trend[738]

Program Area Budget Trend

Operating Unit	Metrics			Budget			% Budget
	Program	2020	2021	2022	2020	2021	2022
Total		**$142,240,653**	**$178,228,566**	**$163,523,984**	**100%**	**100%**	**100%**
	Total	**$142,240,653**	**$178,228,566**	**$163,523,984**	**100%**	**100%**	**100%**
	C&T	$49,722,845	$75,810,246	$75,670,440	35%	43%	46%
	HTS	$21,668,343	$5,559,848	$5,637,510	15%	3%	3%
	PREV	$28,216,714	$40,865,179	$30,297,272	20%	23%	19%
	SE	$5,045,178	$7,502,195	$7,557,115	4%	4%	5%
	ASP	$10,302,084	$15,815,712	$15,309,809	7%	9%	9%
	PM	$27,285,489	$32,675,386	$29,051,838	19%	18%	18%

[737] Source: Panorama Financial Management: OU Dossier: Financial Attribute Grid
[738] Source: Panorama Financial Management: OU Dossier: Program Area Budget Trend

In Country A (Figure 7.2.2.2), we see that the share of C&T has steadily increased from 35% in FY 20 to 45% in FY22 and ASP has increased from 7% in FY 20 to 9% in FY22. Trending the opposite direction, HTS has decreased from 15% in FY 20 to 3% in FY22.

After reviewing your OU's financial analysis, transition to reviewing C&T budget execution vs. TX_PVLS target achievement in the Financial & MER Integrated Analytics dossier. In the below OU (see Figure 7.2.2.3), we see generally high TX_PVLS target achievement paired with strong C&T financial performance, as measured by C&T budget execution, at the mechanism level. Mechanisms A and B would require follow-up to see if increased C&T investment in those mechanisms would make the difference in helping those mechanisms reach their TX_PVLS targets. Mechanism C has similar TX_PVLS target achievement at 69% paired with C&T budget execution at 72%. Although it is positive that target achievement and budget execution are in alignment with each other, we would want to investigate further why the mechanism is having a difficult time spending their entire C&T budget and reaching their TX_PVLS targets.

Figure 7.2.2.3: C&T Budget Execution vs. Target Achievement in Country A[739]

Not at Epidemic Control

Conversely, in countries not yet at epidemic control, we would typically expect steady investment in C&T: HIV Laboratory Services and ASP: Laboratory Systems Strengthening (see Figure 7.2.2.4).

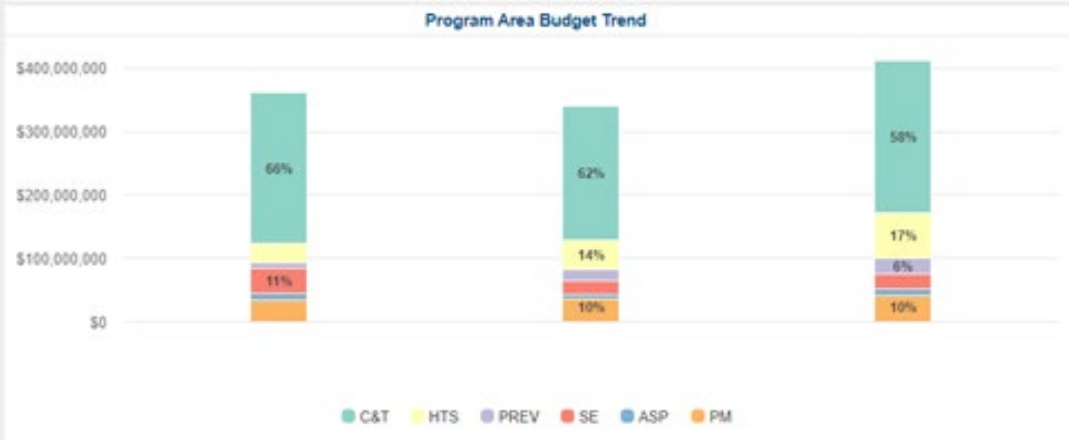
[739] Source: Panorama Financial & MER Integrated Analytics dossier: C&T Budget Execution vs. Target Achievement

Figure 7.2.2.4: Budget Allocation for VLC Activities in Country B[740]

Program	Fiscal Year	2020	2021	2022
	Sub Program	Budget	Budget	Budget
		$35,859,765	**$48,351,082**	**$46,370,602**
C&T	HIV Laboratory Services	$35,859,765	$48,351,082	$46,370,602

In OUs not yet at epidemic control, we typically expect steady, if not increasing, investment in HTS over time as the OU continues to find HIV positive cases (see Figure 7.2.2.5). The below OU shows a steady increase in share of HTS funding, from 8% in FY 20 to 17% in FY22. The share of C&T funding dropped from 66% in FY20 to 58% in FY22 with share of ASP funding staying stable at 3%.

Figure 7.2.2.5: Country B Program Area Budget Trend[741]



Program Area Budget Trend

Operating Unit	Metrics			Budget			% Budget
	Program	2020	2021	2022	2020	2021	2022
Total		**$361,148,524**	**$340,435,581**	**$411,122,129**	**100%**	**100%**	**100%**
	Total	**$361,148,524**	**$340,435,581**	**$411,122,129**	**100%**	**100%**	**100%**
	C&T	$238,315,020	$212,000,357	$239,695,670	66%	62%	58%
	HTS	$30,359,405	$46,189,977	$70,442,554	8%	14%	17%
	PREV	$8,566,324	$17,584,662	$25,069,492	2%	5%	6%
	SE	$38,529,503	$21,478,037	$23,399,064	11%	6%	6%
	ASP	$12,020,461	$7,992,508	$11,688,619	3%	2%	3%
	PM	$33,357,811	$35,190,040	$40,826,730	9%	10%	10%

Transitioning to the integrated analysis, we see that the OU has poor TX_PVLS target achievement across all mechanisms (see Figure 7.2.2.6). This is concerning, especially considering that most mechanisms have spent almost their entire C&T budget to achieve very

[740] Source: Financial Management: OU -> Overview chapter -> Financial Attribute Grid page
[741] Source: Financial Management: OU Dossier -> Financial Trends chapter -> Program Area Budget Trend page

low TX_PVLS results. In this situation, knowing that the OU is still far from epidemic control, it would be important to ensure a coordinated response across all in-country actors to determine sufficient resource alignment across different parts of the epidemic response. We can see from this analysis that the ability to access and spend funding is not the driver of these poor viral load results, but it would be critical to understand what the partners are spending this funding on-by reviewing the cost categories in expenditures and work plan budgets- such that they are able to spend their money, but in a way that does not produce desired outcomes. If cost categories are determined to be inappropriate, an adjustment to cost categories or the overall funding amount may be necessary. However, if cost categories are appropriate, the drivers may not be financial, and it would be critical for the team to reference their cascade, commodities, and other analyses to understand the drivers of these results.

Figure 7.2.2.6: C&T Budget Execution vs. Target Achievement in Country B[742]

Implementing Mechanism	Prime Partner	Funding Agency	C&T Budget	C&T Expenditure	% C&T Budget Expended	TX_PVLS Target	TX_PVLS Result	2021 TX_PVLS % Achievement
Total			$18,967,857	$17,842,668	94%	499,648	326,911	65%
					126%	547	190	35%
					107%	566	82	14%
					99%	140,944	93,260	66%
					99%	75,118	37,483	49%
					98%	38,617	24,928	65%
					97%	109,148	77,618	71%
					96%	121,583	86,822	71%
					85%	1,929	564	30%
					85%	10,196	5,944	58%

Since OUs not yet at epidemic control should place greater emphasis on testing, it may also be helpful to review HTS budget execution vs. target achievement, both for HTS_TST and HTS_TST_POS as well as the two testing modalities, HTS_INDEX and HTS_SELF, that are captured in the Financial & MER Integrated Analytics dossier to determine which modalities are yielding the best case-finding results. It is important to contextualize these analytics and statements to the population and to the overall treatment gap that is being addressed.

In the below example (see Figure 7.2.2.7), we see strong HTS budget execution paired with strong HTS_TST, HTS_TST_POS, and HTS_INDEX target achievement and variable HTS_SELF target achievement. Although testing is emphasized in OUs not yet at epidemic

[742] Source: Panorama Financial & MER Integrated Analytics dossier: C&T Budget Execution vs. Target Achievement

control, it remains important to right size a testing budget to meet the program's needs and to minimize unnecessary retesting.

Figure 7.2.2.7: HTS Budget Execution vs. Target Achievement in Country B[743]

HTS Budget Execution vs. Testing Target Achievement

Implementing Mechanism	Prime Partner	Funding Agency	HTS Budget	HTS Expenditure	% HTS Budget Expended	HTS_TST % Achievement	HTS_TST_POS % Achievement	HTS_INDEX % Achievement	HTS_SELF % Achievement
									2021
Total			$1,504,261	$1,677,697	112%	148%	141%	138%	43%
					78%	109%	22%	72%	102%
					100%	200%	116%	69%	62%
					100%	196%	206%	224%	24%
					153%	111%	106%	22%	122%

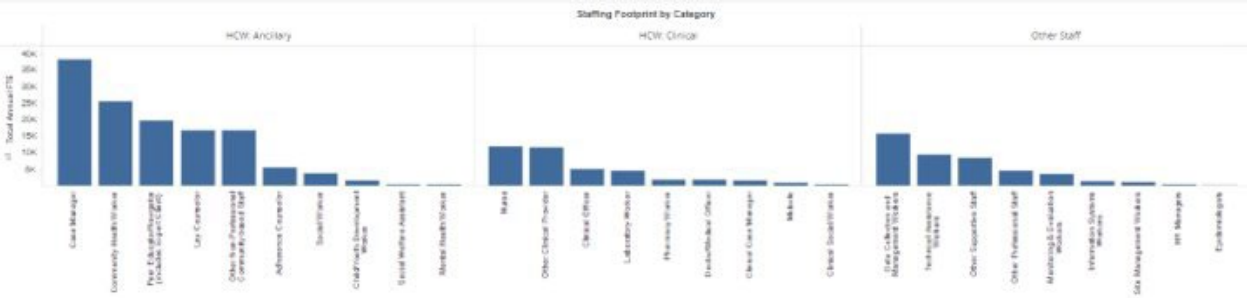
Human Resources for Health (HRH) and Cost Category Analysis

The Human Resources for Health (HRH) Dossier allows for analysis of HRH inventory data both globally and within a single OU. This dossier will help to highlight the breakdown of staffing within a specific OU—where health workers are located, what program areas they are supporting, and staffing expenditures.

OUs should work with partners to analyze their workforce composition (types of health workers) and geographic locations against the goals of the program to determine whether the current staffing footprint meets the needs of the program. Staffing composition should change as programmatic goals adapt. When programmatic goals are not being met, despite ample staffing, other factors, such as management or availability of supplies, should be evaluated to ensure health workers are operating in an enabling environment.

The staffing footprint, including titles and categories, should be reviewed first to understand the composition of PEPFAR's workforce (see Figure 7.2.2.8).

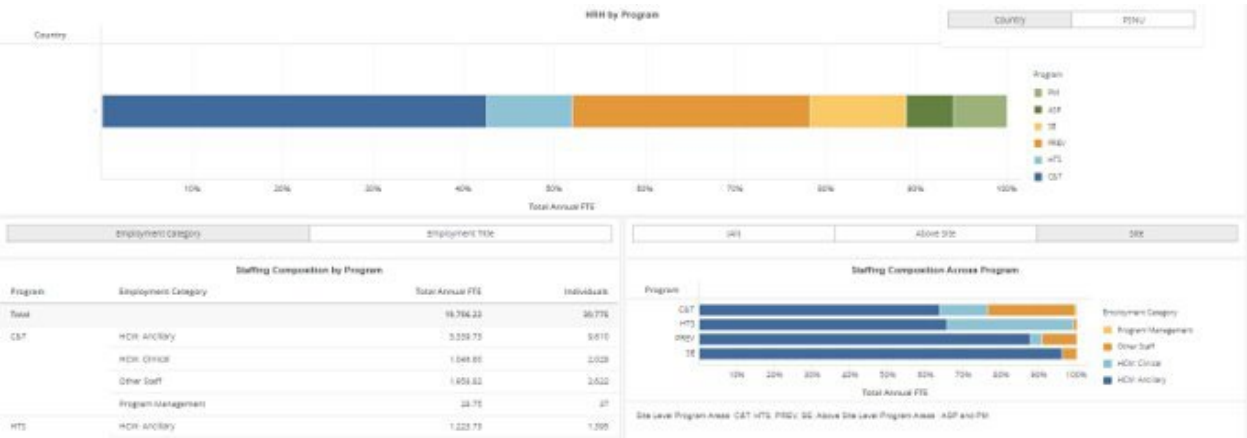
Figure 7.2.2.8: Human Resources for Health (HRH) by Staffing Footprint[744]



[743] Source: Panorama Financial & MER Integrated Analytics dossier: HTS Budget Execution vs. Target Achievement
[744] Data Source: Panorama HRH Dossier: HRH Staffing Footprint

After understanding the overall footprint, the composition of the workforce by the program area that they support should be reviewed (see Figure 7.2.2.9) to assess alignment of staffing with program area specific. Is there sufficient service delivery vs. non-service delivery staff? How do categorical HRH investments and program performance compare across programs?

Figure 7.2.2.9: Human Resources for Health (HRH) by Program Area[745]



OUs should also consider how the staff corresponds to program outcomes, such as return to treatment. Are staff supporting return to treatment adequate to meet MER targets? Are their opportunities for greater efficiency, or is there need for more investment? In Figure 7.2.2.10, HRH for treatment graph compares the percent of FTEs to the percent result of TX_RTT by SNU or PSNU.

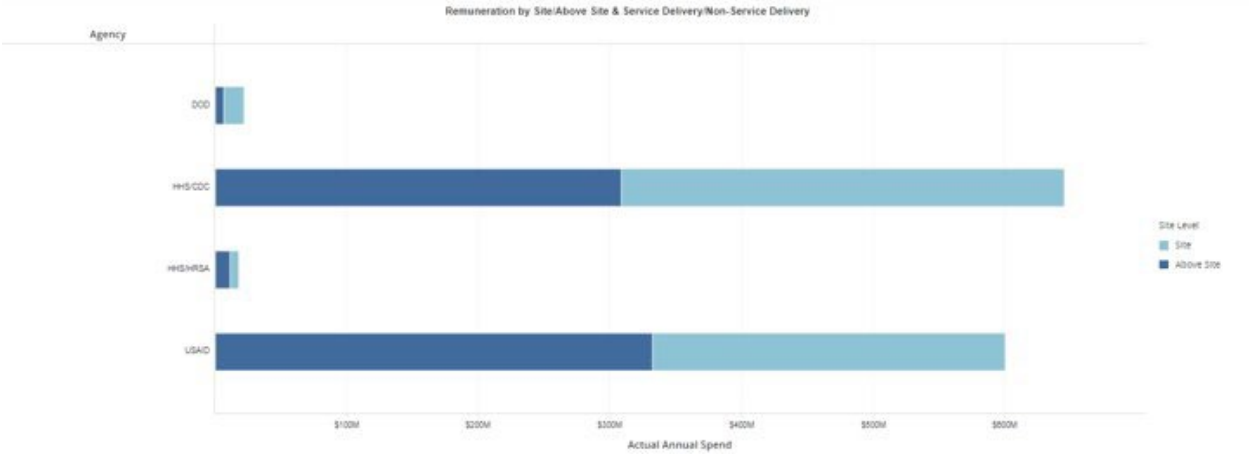
Figure 7.2.2.10: Alignment of HRH FTE and Annual Spend to Treatment Indicators[746]

[745] Data Source: HRH Dossier -> Staffing Footprint Chapter -> HRH by Program Area
[746] Data Source: Panorama HRH Dossier: HRH for Treatment

OUs who have identified weak linkage and continuity of treatment rates at certain sites, partners, or geographies, should leverage HRH data to understand if there is sufficient staffing (e.g., linkage and retention agents, adherence counselors, peer navigators, etc.) in the locations where the treatment results are suboptimal. OUs should also examine staffing by roles supported. As demonstrated in Figure 7.2.2.11, OUs can also examine the composition and associated expenditures going to service delivery and non-service delivery staff. Additionally, from a sustainability lens, it will be critical to view staff expenditures and salaries to determine where further alignment to country government pay scales is required. Please refer to the HRH Technical Considerations in Section 6.6.7.

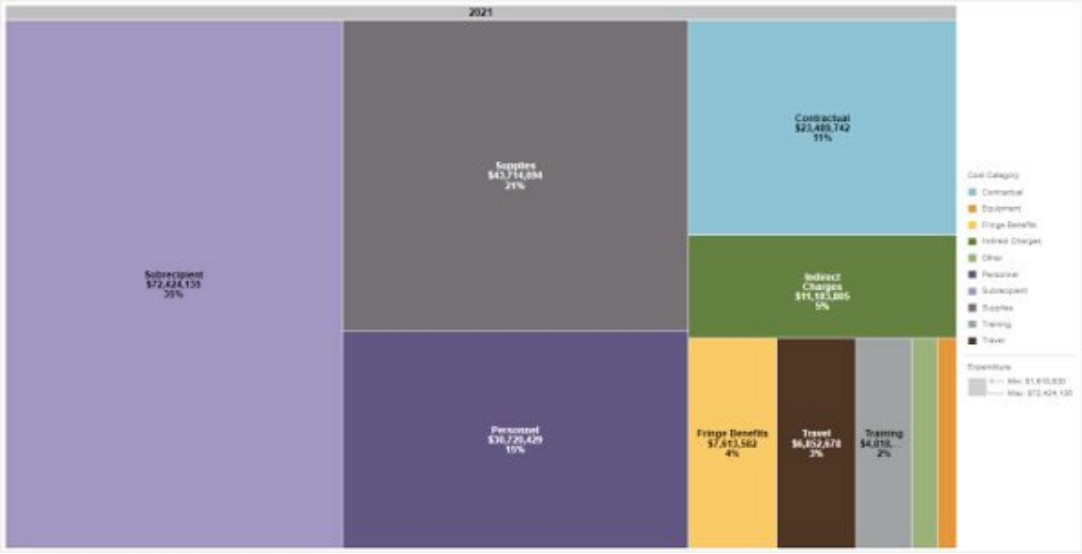
OUs can use cost category data to understand what each mechanism is actually buying. Large cost categories are often personnel, supplies, and contractual. Cost categories can reveal the types of healthcare workers supporting the mechanism. Healthcare worker cost categories include: “Contracted Health Care Workers- Ancillary”, “Contracted Health Care Workers- Clinical”, “Salaries – Health Care Workers – Ancillary”, “Salaries – Health Care Workers – Clinical” and “Salaries – Other Staff.” The cost category breakdowns indicate if staff are providing direct healthcare services to patients or operating in another capacity. For OUs accelerating their programs towards greater service delivery, it may be wise for partners to redirect their budgets into cost categories with a more direct impact on patient outcomes (for example, increased salaries and contracts for clinical health care workers or pharmaceutical supplies). Please consult the HRH inventory data which will show the expenditures for healthcare workers that work for a subrecipient to understand the amount of subrecipient expenditures that are for healthcare workers.

Figure 7.2.2.11: Remuneration by Site/Above Site and Service Delivery/Non-Service Delivery[747]



In the visuals below, we can see that the Country at or Near Epidemic Control (Figure 7.2.2.12) has lower spending on personnel than the Country not at Epidemic Control (Figure 7.2.2.13), and instead has greater spending in the cost category of Supplies, which could include pharmaceutical supplies or health equipment. However, one must take into account a country's broader implementation context (e.g., ongoing technical assistance in epidemic control country) that can lead to variation in cost category and commodity expenditures. It is important to triangulate this information with other data sources (e.g., Resource Alignment, SIDS, etc.) to determine the appropriate mix of cost category and commodity spending.

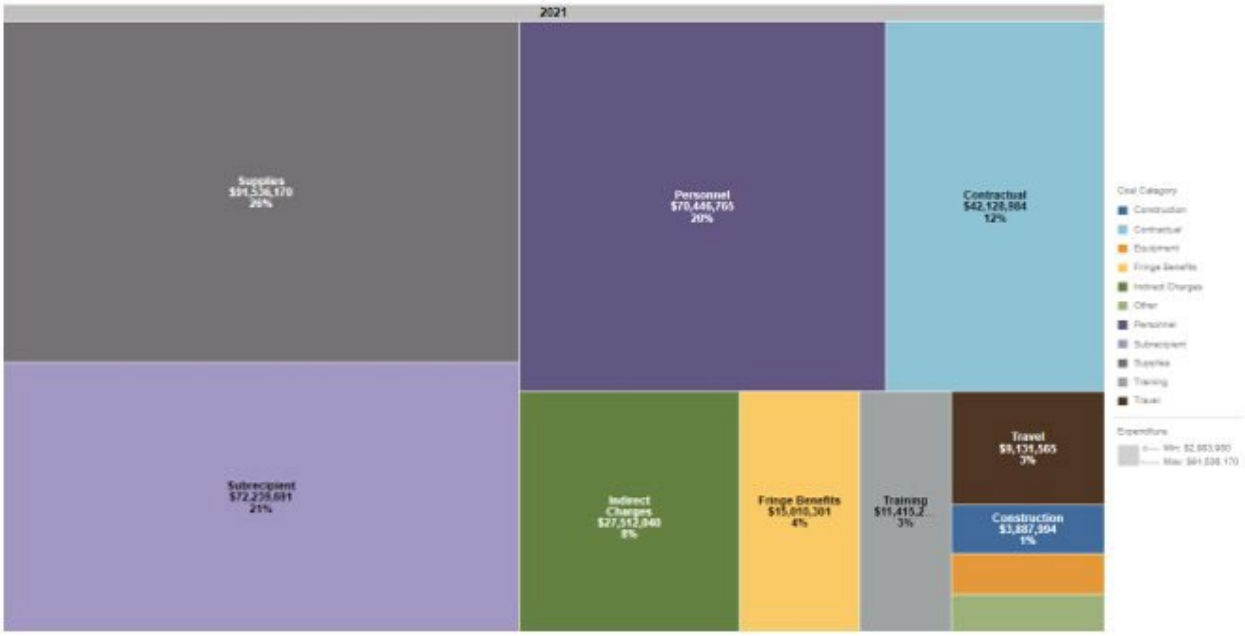
Figure 7.2.2.12: Cost Categories for Country A[748]



[747] Data Source: Panorama HRH Dossier: Remuneration by Site/Above Site and Service Delivery/Non-Service Delivery

[748] Data Source: Panorama Financial Management OU dossier: Cost Category Heat Map

Figure 7.2.2.13: Cost Categories for Country B[749]



Deep Dive Questions for HRH and Cost Categories:

- What is the entirety of the staffing footprint being supported? How many staff are supporting service delivery versus non-service delivery functions? What models of staffing are being used to support service delivery (e.g., roving models or full-time placements)
- Are PSNUs and associated facilities and community centers staffed with the right number and skill-mix of health workers to reach HIV targets? How is the PEPFAR program using data to optimize health worker investments to achieve program targets?
- Are HRH investments accelerating epidemic control? Have additive health workers at sites resulted in improved site-level performance? For example: does adding ART providers at a site increase TX_NEW?
- What is the role of community health and lay workers across the HIV cascade? Are these workers being optimized to implement activities to improve ART continuity, such as tracing to limit the number of patients experiencing interruptions in treatment and community ART dispensing? Are there clear and adequate roles for peer monitoring, outreach, and support?

[749] Data Source: Panorama Financial Management OU dossier: Cost Category Heat Map

- Is there a functioning information system or inventory to monitor the allocation, deployment, and productivity of partner-country health workers? Does this also capture community workers? Is the data from this system used to inform health worker optimization to support epidemic control?
- How are country governments and other donor-supported workers working with PEPFAR-supported staff at sites and contributing to HIV service delivery?
- Is the COVID-19 pandemic affecting staffing needs? If yes, how are staffing needs changing due to any service delivery reconfigurations/adaptations (e.g., telehealth)?

7.2.3 Prevention Programming

The prevention programming analysis includes identifying population groups with unmet need for prevention services, particularly those at highest risk of HIV acquisition. Data triangulation using available sources, such as MER, PHIA, BBS, CLM, or other country-specific individual level data, should be used to identify populations at disproportionate risk of onward transmission or HIV acquisition to best target prevention services. Program data can also be analyzed to assess coverage of prevention services and performance across implementing partners, mechanisms, geographies, and populations. Treatment as prevention should remain an important aspect of holistic prevention programming, as people living with HIV who achieve and maintain an undetectable viral load on treatment cannot sexually transmit HIV (U=U).

Prevention programming is an important aspect for both OUs at or nearing epidemic control and not at epidemic control, however, the population groups in need of prevention services may change over time. As treatment coverage and PopVLS increase, there may be a greater focus on prevention for key populations and other vulnerable groups rather than the general population. PHIA, BBS, CS, and recency testing data can be utilized to monitor epidemiological shifts and identify areas of ongoing transmission, which may include specific population groups or geographies, that may signal a need for targeted prevention programming.

Identifying Prevention Gaps

Planning for prevention programming starts with first outlining the underlying epidemiological context as previously described in the initial steps. MER, PHIA, case surveillance, BBS, and other in-country individual level data can be utilized to answer key questions that outline prevention needs and gaps:

- Where is ongoing HIV transmission occurring? Which populations have the greatest incidence? How are recent infections among newly diagnosed PLHIV characterized?

Who is at disproportionate risk of onward HIV transmission or acquisition and under what prevention gaps?

- What prevention interventions will address the need? How might prevention programming be targeted to a particular geography or population group?

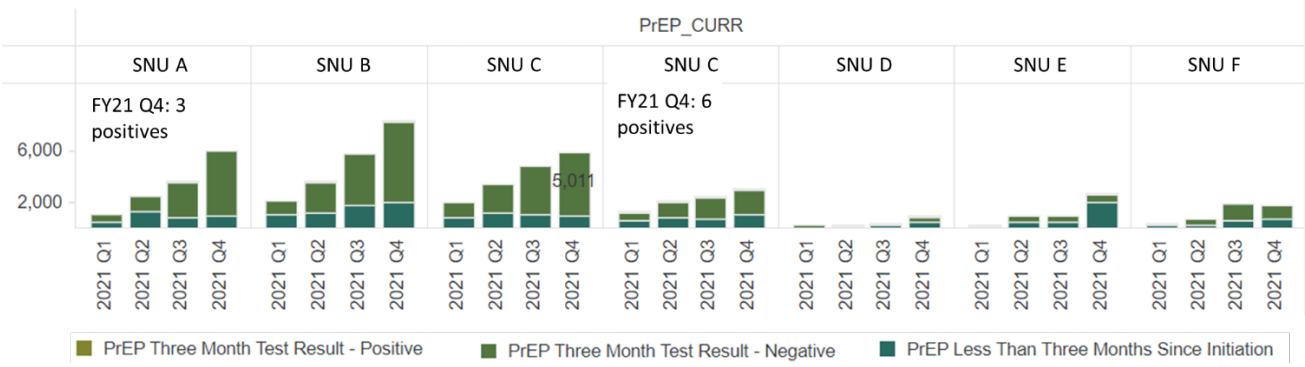
HTS for Prevention Monitoring

As countries approach, achieve, and sustain equitable epidemic control, implementing HTS for prevention monitoring must be scaled. New in COP22 guidance are technical considerations for implementing HTS for prevention services (Section 6.3.5). Recognizing the variance across partner countries achieving equitable epidemic control, Section 2.3.1 provides the anticipated evolution of HTS for prevention monitoring as countries approach and achieve equitable epidemic control across subpopulation groups (including age and sex bands) (Table 2.3.1.1).

For Countries at or Near Epidemic Control: As countries approach, achieve and sustain epidemic control, HTS is an invaluable tool to monitor and refine prevention programming to support programs sustaining epidemic control.

HTS is an essential component of PrEP programming, and any seroconversion among individuals using PrEP must be further investigated. Figure 7.2.3.1 demonstrates the 3-month HIV test result of individuals taking PrEP in Country A's PEPFAR-supported programs. It is anticipated that nearly all individuals receiving PrEP should remain HIV negative; therefore, any positive result warrants additional investigation. Therefore, in Country A, SNUs A and C require additional follow up.

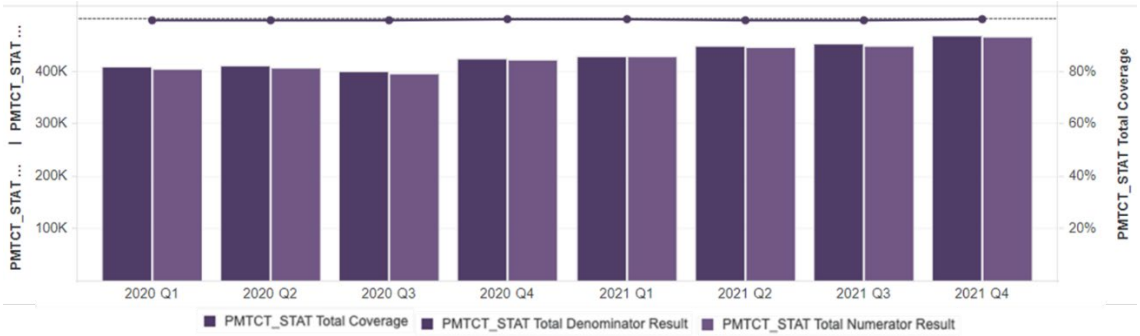
Figure 7.2.3.1 Three-month testing outcome among individuals taking PrEP in Country A [750]



[750] Source: Panorama: Prevention: Single OU Dossier, Chapter 2: PrEP, 3 Month Test Result Sub-Chapter, Comparison Level: SNU 1

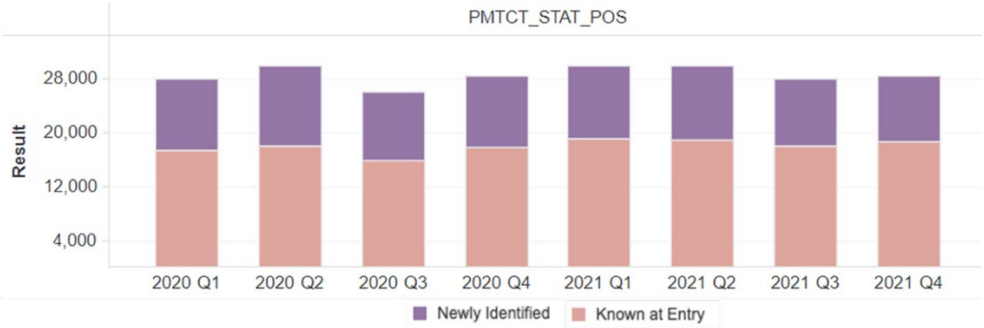
For Countries Not at Epidemic Control: While HTS for case finding remains a program priority for countries not yet achieving epidemic control, provision of HTS remains standard of care for PMTCT, PrEP, and VMMC. Ensuring all women receiving ANC have a known HIV status is imperative to the health of the woman, her infant, and her partners. Figure 7.2.3.2 highlights known HIV status among women receiving PEPFAR-supported ANC1 services in Country B. As shown, the OU has not yet achieved the anticipated 100% benchmark for known HIV status among women receiving ANC1 services. See Section 6.2.4 for technical considerations for PMTCT programs.

Figure 7.2.3.2: PMTCT_STAT Coverage and Results in Country B[751]



Several partner countries have been implementing PMTCT programs for years and a decreasing trend in the proportion of women newly identified as HIV+ during ANC is anticipated. Figure 7.2.3.3 demonstrates no marked decrease in volume or proportion of women newly identified as living with HIV. This concerning finding warrants further discussion and intentional planning focused on improving availability and access to HIV prevention services for women of reproductive age.

Figure 7.2.3.3 Quarterly trends of new vs. known diagnosis of WLHIV receiving ANC1 services, Country B[752]



[751] Source: Panorama: PMTCT_HEI: Single OU Dossier, Maternal Testing & Treatment Chapter, Uptake of Maternal Testing Trends Sub-Chapter

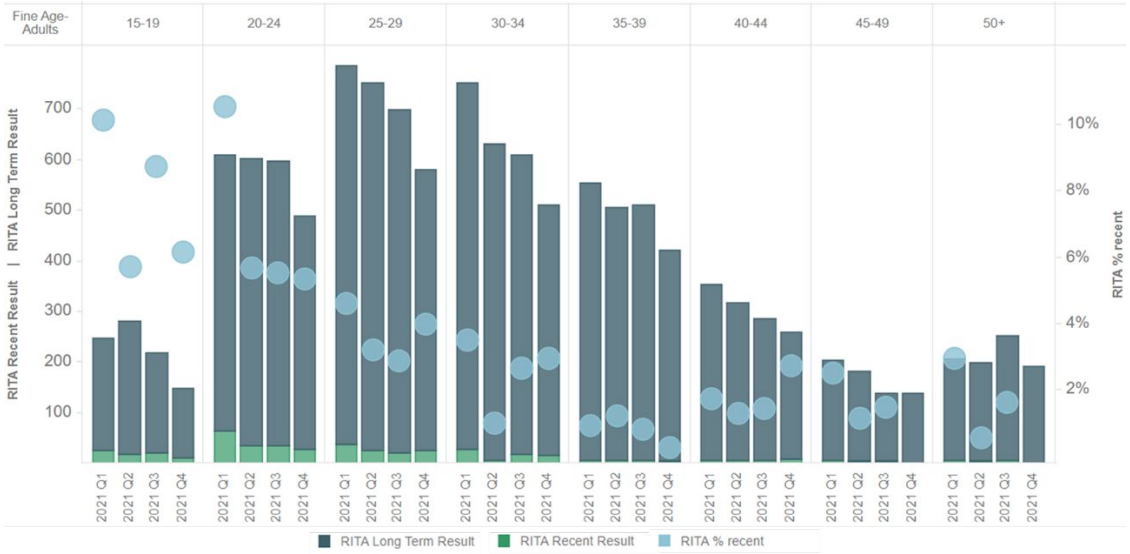
[752] Source: Panorama: PMTCT_HEI: Single OU Dossier, Maternal Testing & Treatment Chapter, Maternal Testing – TX Disaggs Trends Sub-Chapter

Recent Infection Surveillance

Recency testing data provides one source of information to identify potential hotspots of ongoing HIV transmission that may signal a greater need for prevention activities. These data, combined with other program signals (like viral suppression) as well as population attributes, cultural context, and past performance, my provide insights into prioritizing and tailoring prevention activities for greatest impact. The first example for the prevention analysis below examines trends in recent infection among newly diagnosed PLHIV across countries at or near epidemic control and not at epidemic control.

At or Near Epidemic Control: When looking at the proportion of newly diagnosed individuals with a recent infection by age and sex, there are consistent trends with younger individuals having a higher rate of recent infection. In Figure 7.2.3.4, 20–24-year-old females have the greatest overall number of recent infections, and the rate of recent infection is also higher overall among females. This may indicate a need for continued AGYW prevention program as well as targeted testing services for at-risk men who may be more likely to be diagnosed later.

Figure 7.2.3.4: Trends in % RITA Recent by Age/Sex in Country A[753]

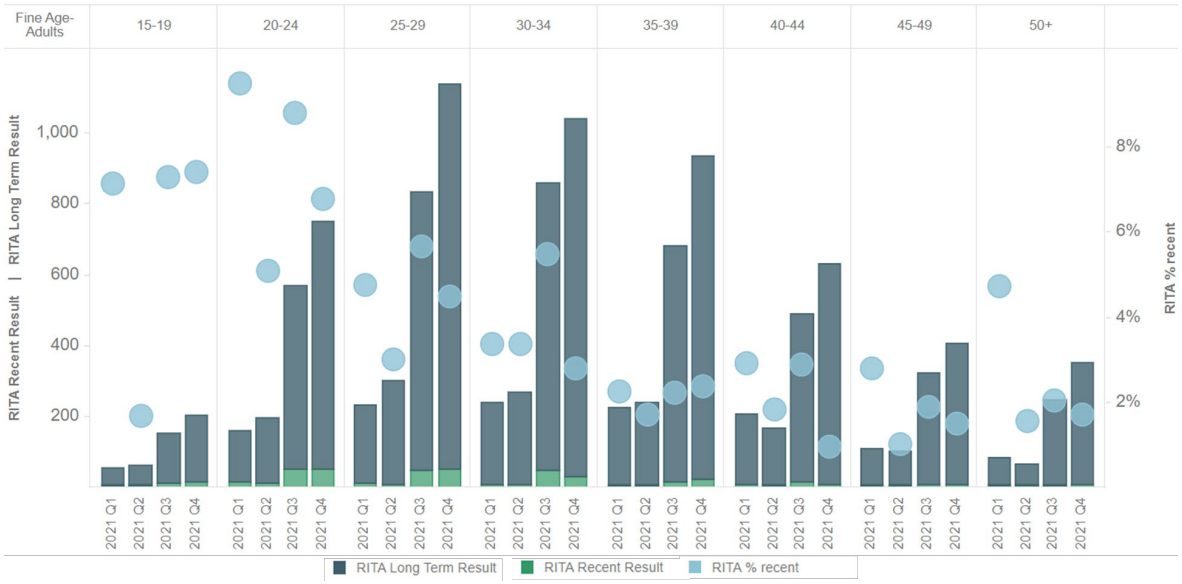


Not at Epidemic Control: Recency data may be more limited for countries that are in the early phases of implementation and Country B has a lower recency testing coverage among newly diagnosed PLHIV (see Figure 7.2.3.5). While the proportion of recent infections is higher among 15–24-year-olds, there are only small differences in sex in Country B compared to those

[753] Data Source: Panorama Recency Dossier: RTRI % Recent by Age/Sex Page

observed in Country A. Less variation in % recent is also seen across different age bands. This signals that there may be a need to reach a broader population with prevention services.

Figure 7.2.3.5: Trends in % RITA Recent by Age/Sex in Country B[754]



Examining Coverage of Prevention Programming

After identifying greatest areas of prevention need, previous progress and coverage of prevention services is assessed by exploring analytic questions such as:

- What is the coverage of prevention interventions, including VMMC, condoms and lubricants, PrEP, PEP, education, and other prevention services (especially among relevant geographic, target and key populations)? How does coverage align with need?
- What trends in performance against targets are observed over time? Do targets reflect coverage goals?
- What factors impact coverage and uptake of prevention services? How is equitable access promoted?
- Are HIV testing services linked to prevention interventions, assisting those who are HIV negative to stay negative?

Key Populations Prevention Continuum

The Prevention Continuum among Key Populations in the Prevention: Global dossier illustrates one example for assessing coverage of HTS and PrEP among KP groups.

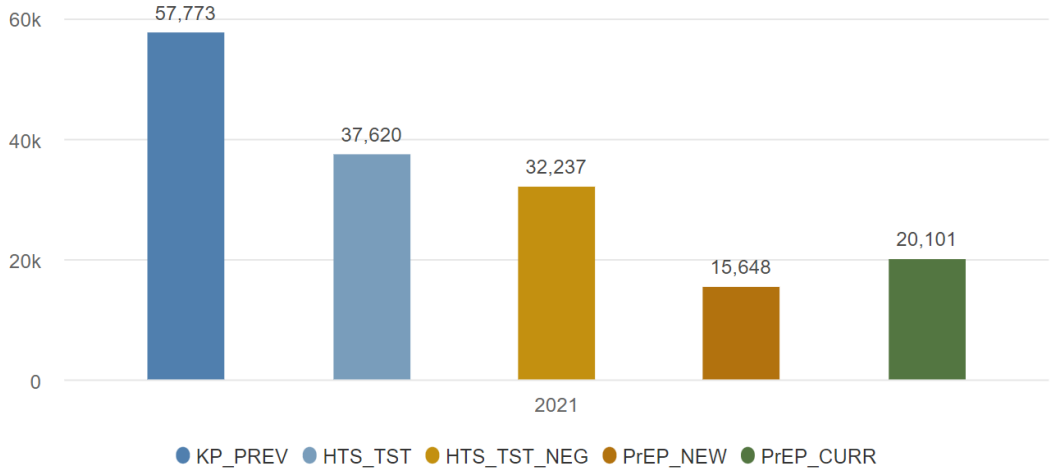
[754] Data Source: Panorama Recency Dossier: RTRI % Recent by Age/Sex Page

At or Near Epidemic Control:

For countries at or near epidemic control, it becomes especially important to understand coverage gaps at a more granular level. Focusing on the KP prevention continuum in Country A, potential opportunities to strengthen HTS coverage for MSM receiving HIV prevention services can be identified (see Figure 7.2.3.6).

Review of the KP_PREV testing and HTS_TST KP disaggregates indicates that there is both a high proportion of MSM that decline HTS and some potential gaps in linkage to HTS among MSM that receive referral. For MSM with a negative HIV test result, there may also be opportunities to expand PrEP coverage. Data from CLM, BBS, or other program data may be utilized to identify underlying factors that impact coverage. Coverage can also be assessed by a variety of other factors, including age and sex, geographic area, IP, mechanism, facility, and so on.

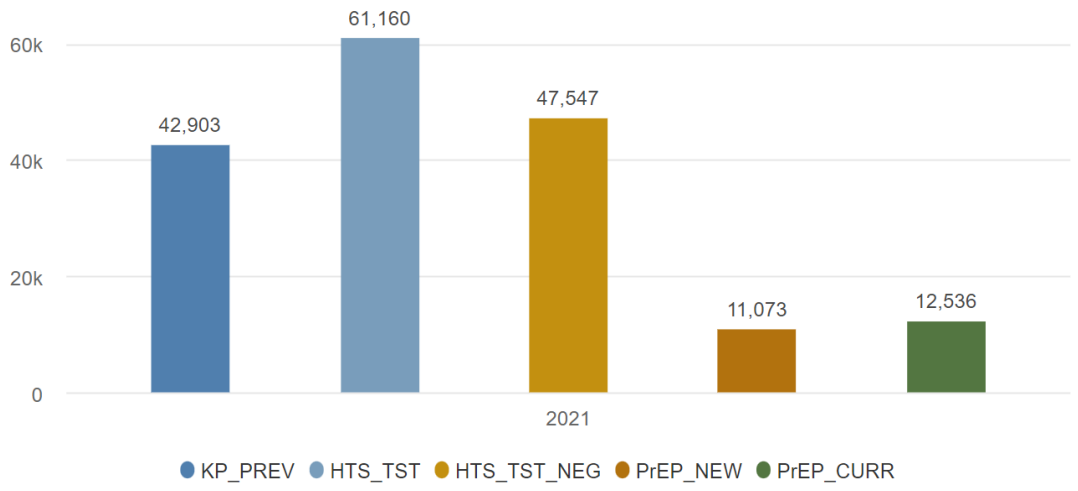
Figure 7.2.3.6: Prevention: Global: Prevention Continuum among Key Populations in Country A



Not at Epidemic Control:

In generalized epidemics working towards epidemic control, prevention activities focused on KPs may comprise a smaller proportion of prevention programming in comparison to the overall population as demonstrated with Country B in Figure 7.2.3.7 below. As seen in the prevention continuum, KP testing coverage is high, however, there may be opportunities to expand PrEP coverage for individuals testing HIV negative that continue to be at higher risk of HIV acquisition due to their KP status. Further analysis using other program or survey data can be used to better understand prevention coverage and need among this population and to examine potential barriers to uptake or access of prevention services.

Figure 7.2.3.7: Prevention: Global: Prevention Continuum among Key Populations in Country B



Deep Dive Questions for Prevention and Key Populations:

- Are prevention services targeting and reaching the appropriate populations? Modeling tools are available that can assist countries to estimate unmet need in priority populations for both VMMC and PrEP.
- Is PEP and PrEP available for all people at substantial risk of acquiring HIV including key populations, AGYW, pregnant and breastfeeding women, serodifferent couples, and other high-risk populations?
- Has saturation been reached in high-burden districts for VMMC?
- What are the existing barriers to uptake of prevention services? What strategies can be used to address these barriers and promote equitable access?
- What is the performance of the overall clinical cascade? What are the HIV testing modalities, volumes, and yields? What are rates of linkage to treatment, ART continuity, viral load testing coverage and viral load suppression?
- What data is being utilized to understand key populations size estimations, HIV prevalence, and ART coverage in a given geographic location? What is the proportion of prevention (KP_PREV) reach versus testing reach? What are the rates of linkage of testing to prevention services?
- What is the uptake of PrEP among relevant target populations, especially among those that have been reached and tested negative? What are the barriers to uptake?
    - How are MAT/OAT programs performing (where implemented)? To what extent can MER data be triangulated to understand coverage of ART services (e.g., HIV testing and treatment) among MAT/OAT beneficiaries?

Prevention Financial Analyses

In prior examples, the Financial Management: OU dossier was used to evaluate budget performance by IM across a variety of classifications. This dossier can also be used to evaluate past budget execution performance for beneficiary groups which can then be combined with target performance from other beneficiary-focused dossiers (e.g., Key Populations, DREAMS, Peds and Adolescents, etc.). With portions of beneficiary-focused funding falling under the Non-Targeted Populations designation, using beneficiary budget and expenditure data needs to be assumed as being an underestimate of actual spend or budget with further discussions and information informing this analysis. The dossier can also be used to analyze changes in the PrEP sub-program area budget and spending. These funds include not just PrEP commodity procurement but PrEP-related interventions and activities across beneficiary groups.

At or Near Epidemic Control: In Figure 7.2.3.8, Country A was responsive to the over- and underspending amongst beneficiary groups in FY20 with adjusted FY21 budgets. Majority of funds are almost evenly split between Females and Males. In Figure 7.2.3.9, Country A's overall PrEP budget increased, and funding strategically shifted from Non-Targeted Populations to Key Populations and other vulnerable groups. Countries at or near epidemic control should triangulate findings with MER data to determine if these financial changes align with new epidemiological information on where new infections or transmission networks are appearing and adjust expenditures and future budget allocations accordingly.

Figure 7.2.3.8: Country A Budget Execution by Beneficiary[755]

Beneficiary	Fiscal Year	2020	2021
Females	Budget	$16,103,467	$37,717,594
	Expenditure	$10,525,942	$33,922,228
	% Budget Expended	65%	90%
Key Pops	Budget	$2,325,943	$7,586,386
	Expenditure	$3,532,368	$8,190,501
	% Budget Expended	152%	108%
Males	Budget	$15,844,425	$21,121,897
	Expenditure	$20,445,764	$17,942,225
	% Budget Expended	129%	85%
Non-Targeted Pop	Budget	$103,659,730	$135,455,035
	Expenditure	$89,590,593	$129,093,915
	% Budget Expended	86%	95%
OVC	Budget	$7,845,310	$13,615,805
	Expenditure	$13,592,958	$14,139,812
	% Budget Expended	173%	104%
Pregnant & Breastfeeding Women	Budget		$1,417,879
	Expenditure		$1,277,090
	% Budget Expended		90%
Priority Pops	Budget		$293,743
	Expenditure		$36,883
	% Budget Expended		13%

[755] Data Source: Panorama Financial Management - OU dossier: Budget Execution Grid

Figure 7.2.3.9: Country A Funding for PrEP Sub-Program Area by Beneficiary[756]

Financial Attribute Comparison					
Sub Program	Fiscal Year Beneficiary	2020 Budget	2020 Expenditure	2021 Budget	2021 Expenditure
PrEP	Non-Targeted Pop	$395,196	$19,320	$1,369,903	$635,887
	Females		$12,951	$487,413	$429,395
	Key Pops			$1,144,998	$533,507

Not at Epidemic Control: In Figure 7.2.3.10, Country B significantly upped its funding for the Female beneficiary group while decreasing funds for Males. This may be reflective of a shift in programming, specifically DREAMS. In Figure 7.2.3.11, Country B also increased its total allocation for PrEP with an emphasis on the Non-Targeted Population. Countries not at epidemic control should triangulate findings with MER data to determine if these financial changes align with new epidemiological information on where new infections or transmission networks are appearing and adjust expenditures and future budget allocations accordingly.

Figure 7.2.3.10: Country B Budget Execution by Beneficiary[757]

Budget Execution			
Beneficiary	Fiscal Year	2020	2021
Females	Budget	$17,523,821	$57,831,793
	Expenditure	$11,683,119	$42,430,408
	% Budget Expended	67%	73%
Key Pops	Budget	$4,319,163	$5,877,723
	Expenditure	$5,133,460	$5,634,526
	% Budget Expended	119%	96%
Males	Budget	$28,927,971	$18,010,756
	Expenditure	$26,350,149	$14,880,604
	% Budget Expended	91%	83%
Non-Targeted Pop	Budget	$211,443,283	$264,452,399
	Expenditure	$199,031,364	$252,621,644
	% Budget Expended	94%	96%
OVC	Budget	$12,183,362	$12,746,463
	Expenditure	$10,562,673	$14,303,002
	% Budget Expended	87%	112%
Pregnant & Breastfeeding Women	Budget	$9,264,339	$15,721,944
	Expenditure	$14,412,712	$13,482,840
	% Budget Expended	156%	86%
Priority Pops	Budget	$7,019,427	$6,430,224
	Expenditure	$7,355,957	$6,275,173
	% Budget Expended	105%	98%

Figure 7.2.3.11: Country B Funding for PrEP Sub-Program Area by Beneficiary[758]

Financial Attribute Comparison					
Sub Program	Fiscal Year Beneficiary	2020 Budget	2020 Expenditure	2021 Budget	2021 Expenditure
PrEP	Females	$721,836	$481,253	$672,813	$340,034
	Non-Targeted Pop	$317,972	$608,092	$6,564,118	$6,373,168
	Key Pops		$11,723	$262,411	
	Pregnant & Breastfeeding Women		$89,523		

[756] Data Source: Panorama Financial Management - OU dossier: Financial Attribute Grid
[757] Data Source: Panorama Financial Management - OU dossier: Budget Execution Grid
[758] Data Source: Panorama Financial Management - OU dossier: Financial Attribute Grid

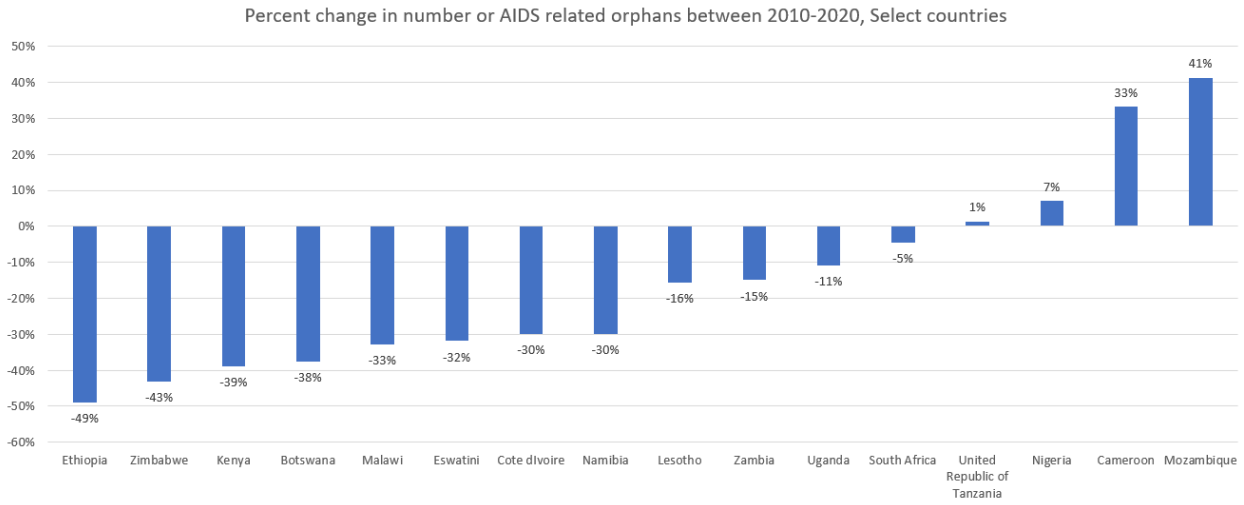
7.2.4 DREAMS and OVC Programming

Critical questions for OVC programming include whether we are increasing coverage of CALHIV aged 0-17, and if rates of exiting without graduation vary across IMs. Country teams should pay careful attention to risk trends across the age span, noting for example the significant gap in treatment coverage for CLHIV as well as lower VLS (most prominent among children <5 years), the high risk of morbidity and mortality among adolescent girls in East and Southern Africa, and a reduction in the number of children infected via vertical transmission. Countries should also look at trend data as the number of children orphaned by AIDS continues to decline in settings with advanced ART coverage (see figure 7.2.4.1 below). Important MER results from FY21_Q4 to take into consideration include the following:

- OVC_SERV<18, disaggregated by age and sex for age 0-17
- OVC with known HIV status (OVC_HIVSTAT) with close attention to OVC with unknown HIV status (OVC_HIVSTAT_UNKNOWN)
- Number of children living with HIV (HTS_TST positive<15), HIV+ Children (<15) TX_CURR, HIV+ Children (<15) with high VL, HIV+ Children (<15) Newly on ART, HIV+ Adolescents TX_CURR (15-19), HIV+ Adolescents (15-19) with high VL, HIV+ Adolescents (15-19) Newly on ART, TX_ML and TX_RTT among children<15 and adolescents 15-19
- Number of HIV-positive infants (PMTCT_HEI_POS), pregnant women (PW) who are newly positive, adolescent PW (10-19 years)
- Number of PLHIV (HTS_TST to estimate number of children living with HIV+ adult)
- KP data (HTS_TST_KP)
- GEND_GBV <19

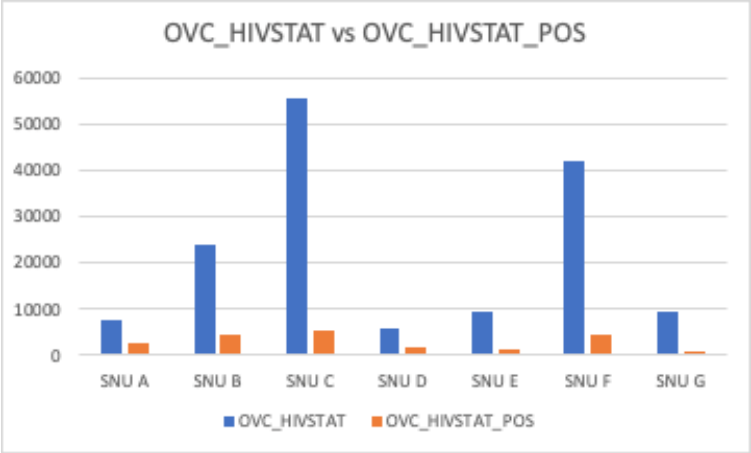
Estimates of orphaned children (by all causes) are generally available by age via DHS and MICS and via UNAIDS in regard to orphans due to AIDS. To better profile risk within this subgroup, it is important to look at disaggregation by age and by status (i.e., single vs. double orphan). Additional data, including Violence Against Children Surveys (VACS) and data on children out of school, school attendance, and school progression (particularly among adolescent girls) are useful to inform an understanding of vulnerability.

Figure 7.2.4.1: UNAIDS Estimates of AIDS-related Orphans (Single and/or Double) in Select Countries 2010-2020



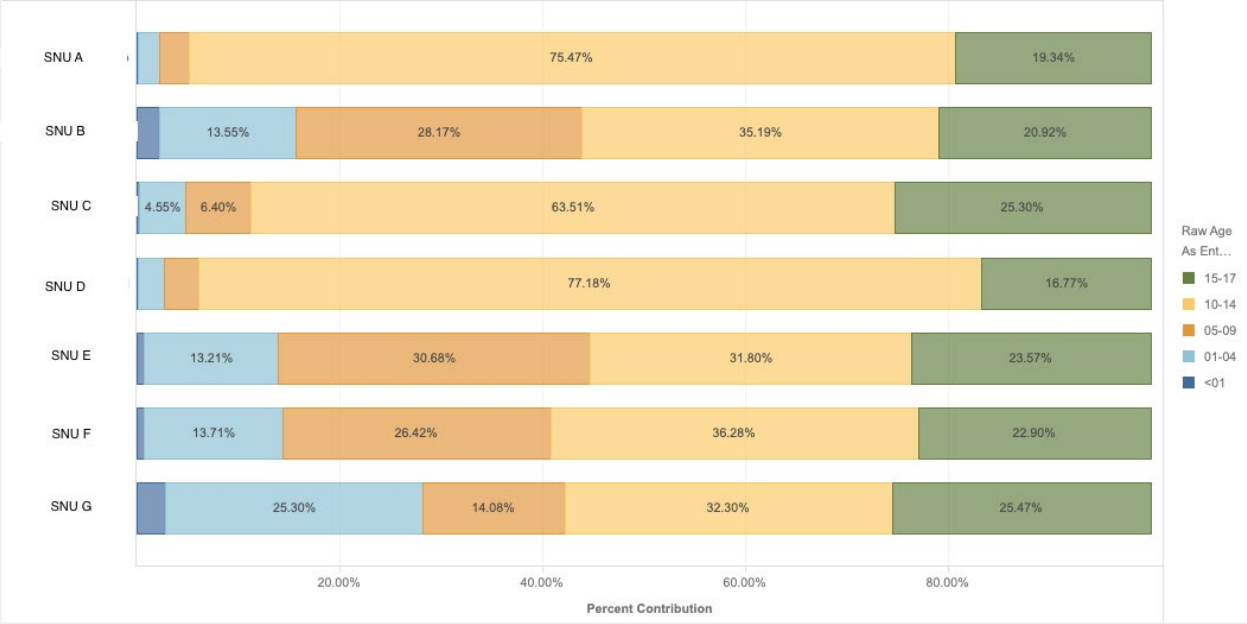
At or Near Epidemic Control:

Figure 7.2.4.2: HIV positive children in OVC Program, Country A



For all countries, it is important to look at the percentage of HIV positive children within the OVC cohort compared to the number of children enrolled in treatment in the surrounding area to assess current and future programmatic needs. This chart shows the number of HIV positive children within the OVC program. In countries at or near epidemic control, we expect to see fewer positive children. For older children this could be due to the reduced opportunity to become exposed to HIV through sexual behavior if most PLHIV are virally suppressed. And for younger children, countries at or nearing epidemic control should have a robust PMTCT program, therefore restricting exposure during pregnancy and breastfeeding.

Figure 7.2.4.3: *Percent Contribution of Each Age Band to OVC_SERV 18+ Total, Country A*[759]



Countries at or near epidemic control should have a higher proportion of HIV positive children in higher age bands than younger age bands, compared to countries not yet at epidemic control. If a country's OVC program has an increasing percentage of participants from older age bands, the OVC approach should begin to align with the country's C/ALHIV approach.

Figure 7.2.4.4: OVC Global: OVC_HIVSTAT: TX_CURR <20 vs OVC_HIVSTAT (left) and TX_CURR <15 vs OVC_HIVSTAT (right), Country A

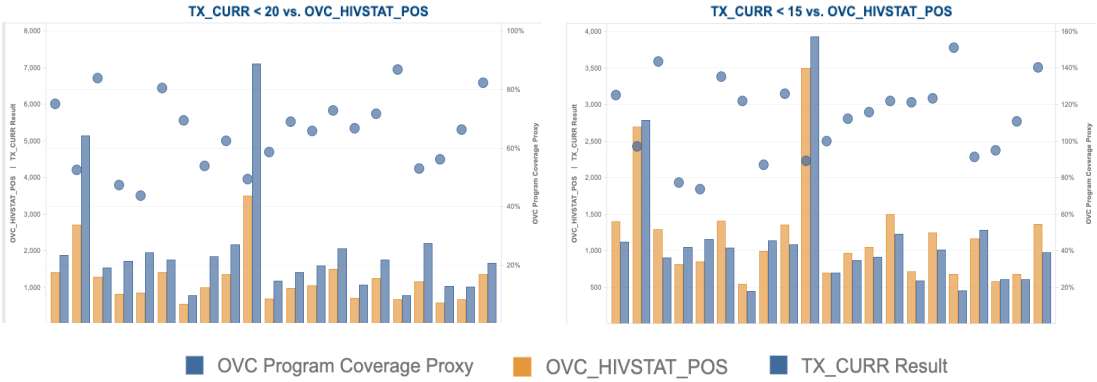
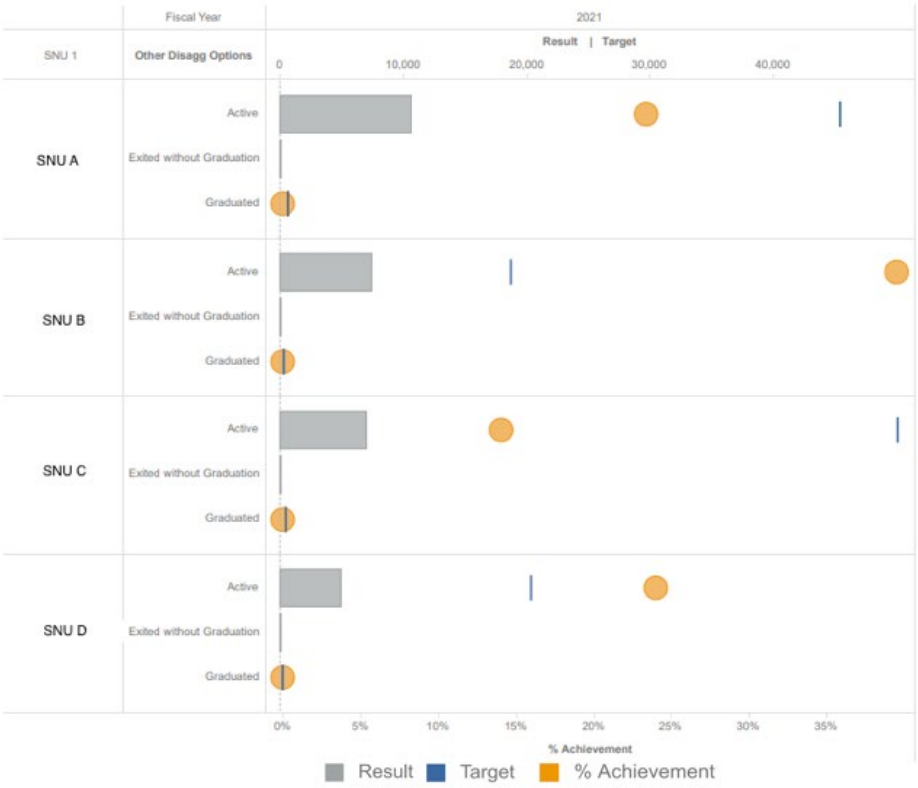


Figure 7.2.4.4 above shows a proxy estimate of OVC coverage. OVC_HIVSTAT only collects data on positive children under the age of 18, but TX_CURR is collected in 5-year age bands. Therefore, it is necessary to look at proxy coverage compared to both TX_CURR <15 and <20 to avoid over or under estimating results. The above figure has these results by PSNU. Please

[759] Source: OVC Global: OVC_SERV by Program Model: Age/Sex Proportion by Program Model

note the difference in scale. In this analysis, attention should be drawn to PSNUs with less than an 80% coverage for TX_CURR <15 coverage, and less than 60% coverage proxy for TX_CURR <20. These PSNUs should be flagged for further analysis of routinely collected program data that may extend outside of MER results. It is important to consider not just percent coverage, but also the volume of CLHIV not enrolled. High burden SNUs may be at the benchmark percentages but have a greater volume of children than SNUs not meeting the benchmarks. Attention should be given not just to SNUs with low coverage, but also those with high volume of C/ALHIV not enrolled in OVC programs. Country teams should review their programs to ensure OVC programs are geographically aligned with C/ALHIV burden; OVC target distribution should be similarly aligned with burden.

Figure 7.2.4.5: OVC Global: OVC_SERV by Program Status: Results by Program Status, Country A



Finally, it is important to look at the effectiveness of the program by looking at the “exit without graduation” disaggregate as an indication that children are exiting the program prematurely, as this suggests program failure. In Figure 7.2.4.5, Country A has very few results for “exited without graduation.” While this shows overall program effectiveness, it is necessary to triangulate these results with case files and other program monitoring such as SIMS to assess

overall programmatic gaps and achievement. The existence of “exited without graduation” rates of higher than 5% should be flagged to the relevant partner staff for a breakdown of the reasons for “exited without graduation” and to establish an action plan for preventing and reducing the number of beneficiaries exited without graduation.

Not at Epidemic Control:

For countries not at epidemic control it is also important to begin by examining the number of positive OVC being identified through the program (see Figure 7.2.4.6). The number identified are expected to be higher in countries not at epidemic control, which means teams also need to analyze their ability to link and care for newly identified positive children. Districts with higher proportion of HIV positive children in the OVC program should be analyzed further by age band to determine where additional preventive efforts (for example PMTCT) need to be scaled or reinvigorated to prevent pediatric infections. Teams may also want to compare budget information with districts with fewer HIV positive children in the program to see if it is necessary to realign the budget with geographic gaps.

Figure 7.2.4.6: Positives in OVC Program, Country B

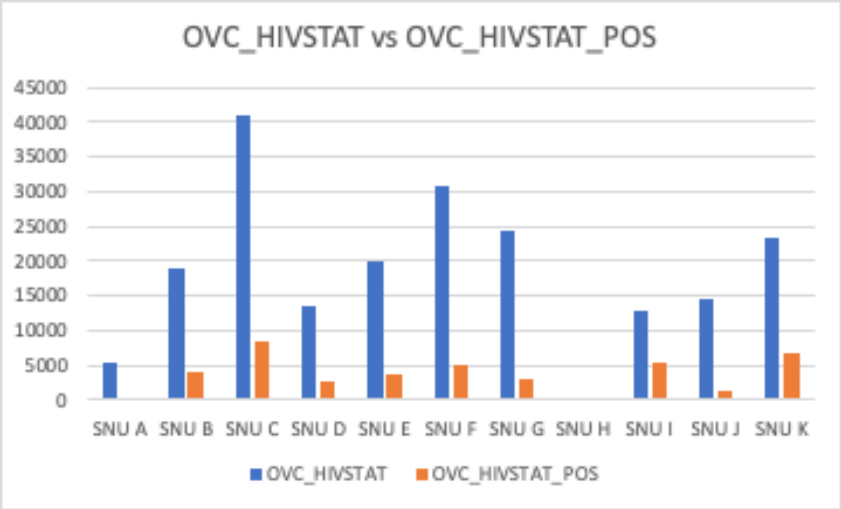
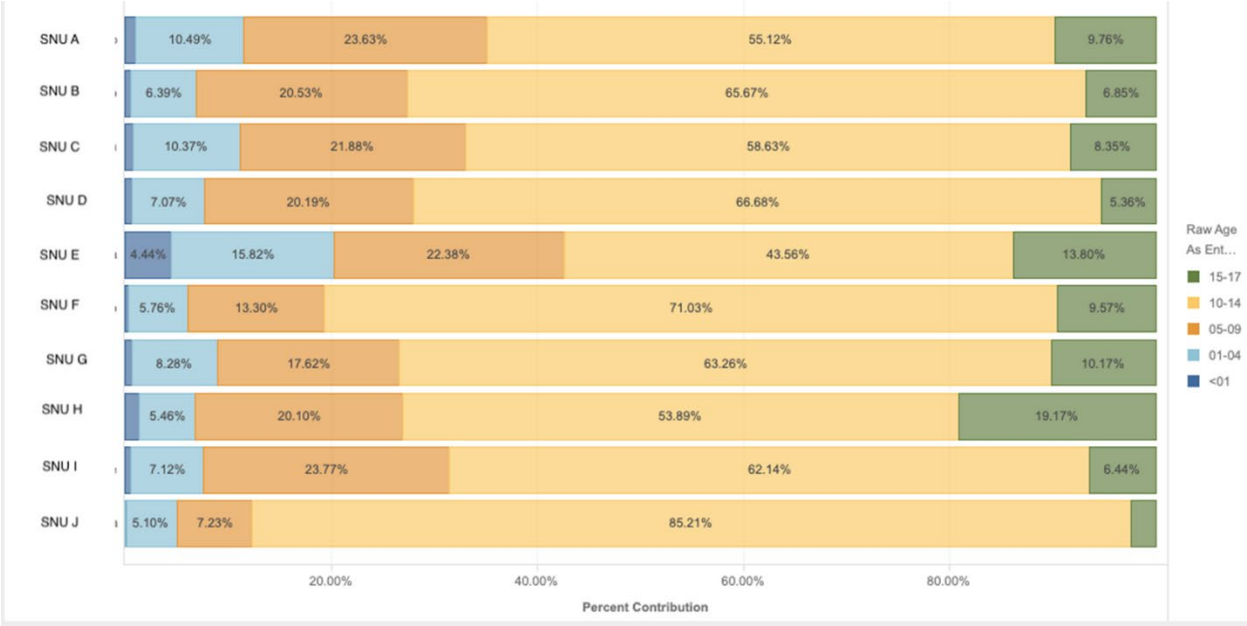
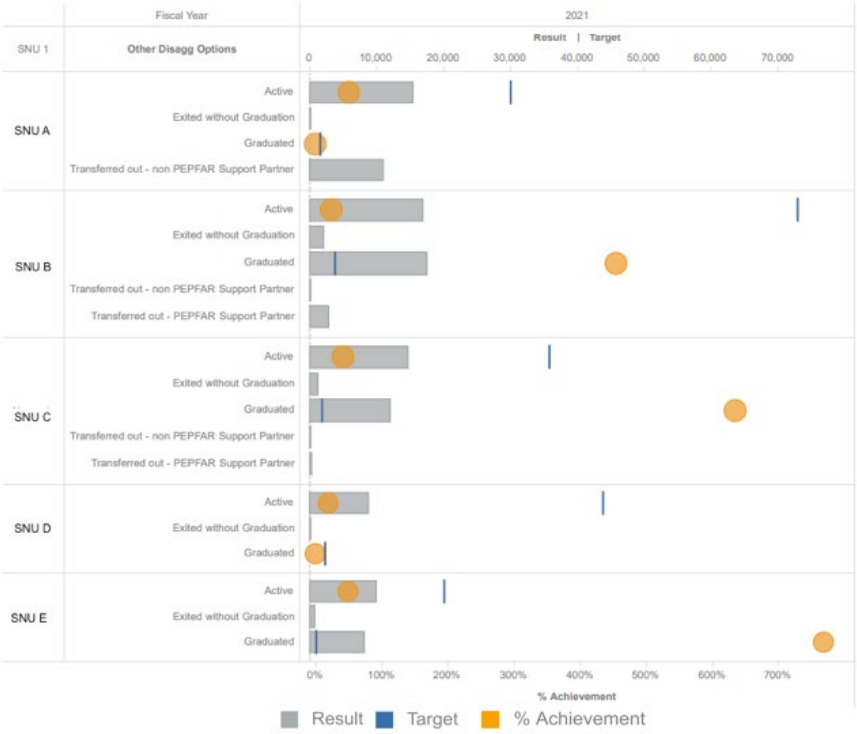


Figure 7.2.4.7: Percent Contribution to Each Age Band to OVC_SERV <18 Total, Country B



Countries not at epidemic control can expect to have an age breakdown similar to this one (see Figure 7.2.4.7), with a many of the participants in the middle age bands, and a growing number in the older age bands. Since these countries are not at epidemic control, programs must not lose sight on younger age bands. in younger children and continually analyze pediatric data, including treatment indices, as well as pay attention to treatment and PMTCT-related gaps in younger children. Knowing the age breakdown can help inform the necessary prevention and care package mix and the budget moving forward. Ultimately, it is important to look at age-related trends.

Figure 7.2.4.8: OVC Global: Program Results, Country B



The “exited without graduation” disaggregate can help indicate program shortcomings. In Figure 7.2.4.8, SNUs B, C, and E have “exited without graduation” rates above 5%, which should flag concern for country teams. It may be useful to look at “exited without graduation” rates over time to gauge whether the program has a poor record of follow up with children and/or inconsistency of service delivery.

Deep Dive Questions for OVC:

- What is the country’s current epidemiology of OVC and what are gaps and needs based on age groups?
- Within the OVC cohort, what % is CLHIV? How does this compare to TX_CURR <15 and TX_CURR<20 in the same PSNUs?
- What is OVC “exited without graduation” rate? Within OVC cohort, what is the age breakout? Age groups: 1-4: limited programming; 5-9: small group; 9-15: largest group of OVC and DREAMS

DREAMS Programming

Using expenditure data, we can select the “Females: Young Women & Adolescent Females” sub-beneficiary in the Financial Management: Operating Unit Dossier to identify the partners

working with the Adolescent Girls & Young Women (AGYW) population and determine the program areas partners work in to serve AGYW. Identify which partners have the majority of COP20 and 21 HTS budget and COP20 expenditures for AGYW programming and how that is allocated to program and sub-program areas.

At or Near Epidemic Control: While approaching epidemic control, Country A (Figure 7.2.4.9) still has a major footprint in socioeconomic and prevention activities among AGYW, especially in the primary prevention of HIV and sexual violence sub-program area. The country is also investing above-site programming to influence policy and health systems that service this priority population.

Figure 7.2.4.9: Country A's AGYW Funding by IM, Program, and Sub-Program

Financial Attribute Comparison

Operating Unit	IM	Program	Sub Program	Beneficiary	Fiscal Year	2020	2021
					Sub Beneficiary	Budget	Budget
Total						$1,602,498	$3,644,669
		ASP	Policy, planning, coordination & management of disease control programs	Females	Young women & adolescent females	$74,998	$225,000
		ASP	Policy, planning, coordination & management of disease control programs	Females	Young women & adolescent females		$210,000
		PREV	Comm. mobilization, behavior & norms change	Females	Young women & adolescent females	$37,500	$60,021
		PREV	Not Disaggregated	Females	Young women & adolescent females		$500,000
		PREV	Not Disaggregated	Females	Young women & adolescent females		$270,647
			Primary prevention of HIV and sexual violence	Females	Young women & adolescent females		$358,984
		SE	Legal, human rights & protection	Females	Young women & adolescent females	$767,750	$864,005
		SE	Legal, human rights & protection	Females	Young women & adolescent females	$722,250	$1,156,012

Not at Epidemic Control: In Figure 7.2.4.10, Country B has majority of its AGYW programming in two primary sub-program areas, primary prevention of HIV and sexual violence and community mobilization, behavior, and norms change. Funds are also heavily invested in Socioeconomic sub-program areas such as education assistance and economic strengthening.

Figure 7.2.4.10: Country B's AGYW Funding by IM, Program, and Sub-Program

Financial Attribute Comparison

Operating Unit	IM	Program	Sub Program	Beneficiary	Fiscal Year	2020	2021
					Sub Beneficiary	Budget	Budget
Total						$2,293,540	$6,880,883
		C&T	HIV Clinical Services	Females	Young women & adolescent females	$226,540	
		PREV	Not Disaggregated	Females	Young women & adolescent females		$478,230
		PREV	Not Disaggregated	Females	Young women & adolescent females		$2,070,225
		PREV	Primary prevention of HIV and sexual violence	Females	Young women & adolescent females		$60,400
		PREV	Not Disaggregated	Females	Young women & adolescent females		$1,362,620
		PREV	Not Disaggregated	Females	Young women & adolescent females		$82,358
		PREV	Not Disaggregated	Females	Young women & adolescent females		$44,523
		PREV	Comm. mobilization, behavior & norms change	Females	Young women & adolescent females		$12,143
		PREV	Not Disaggregated	Females	Young women & adolescent females		$250,000
		PREV	Comm. mobilization, behavior & norms change	Females	Young women & adolescent females	$37,000	
			Primary prevention of HIV and sexual violence	Females	Young women & adolescent females		$1,572,412
		PREV	Not Disaggregated	Females	Young women & adolescent females		$3,238
		PREV	Not Disaggregated	Females	Young women & adolescent females		$39,668
		PREV	Primary prevention of HIV and sexual violence	Females	Young women & adolescent females		$13,762
		PREV	Not Disaggregated	Females	Young women & adolescent females		$3,238
		SE	Education assistance	Females	Young women & adolescent females	$1,100,000	
		SE	Case Management	Females	Young women & adolescent females	$550,000	
		SE	Economic strengthening	Females	Young women & adolescent females	$83,000	$507,466
			Education assistance	Females	Young women & adolescent females	$297,000	$380,600

Deep Dive Questions for DREAMS:

- Have 90% of active DREAMS beneficiaries completed at least the primary package after being in DREAMS for 13+ months?
- Who are we missing in terms of performance on PrEP_NEW and PrEP_CURR by the relevant AGYW age band (and among high-risk AGYW)?

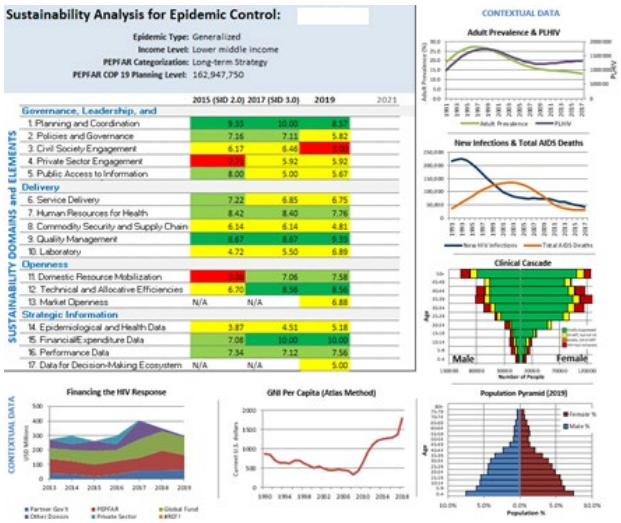
7.2.5 Above Site Programming

Policy and Systems Gap Analysis

Efficient and effective above-site program investments at the policy and systems levels continue to be an essential component of achieving PEPFAR goals, including identification and remediation of key barriers in the clinical cascade and shifting the national policies necessary to achieve and sustain epidemic control.

At or Near Epidemic Control: Each SID dashboard contains the same data points to provide an overview of the epidemic, HIV program, financing, and sustainability. The below dashboard highlights where the country has strengths and where there are potential gaps or barriers that the program should address. For example, there has been a decrease in score for the civil society engagement. In Figure 7.2.5.1 below, Country A has consistently low scores in Commodity Security and Supply Chain, how does this relate to issues around MER VLS and VLC highlighted in Section 7.2.1? What activities might be needed to strengthen this area? Additional details should be found in the SID report. Each country team should review where there are gaps or not to ensure that activities in Table 6 appropriately address the findings.

Figure 7.2.5.1: Country A SID Dashboard



Not at Epidemic Control: In Figure 7.2.5.2, this SID dashboard depicts a country where the scores have decreased and there are few funders financing the response. As there are a number of barriers and gaps that need to be addressed with fewer financing the response, it is important that they are coordinated. Additionally, as PEPFAR is the primary funder of the response, the program will need to be strategic in how they address the elements in table 6.

Figure 7.2.5.2: Country B SID Dashboard

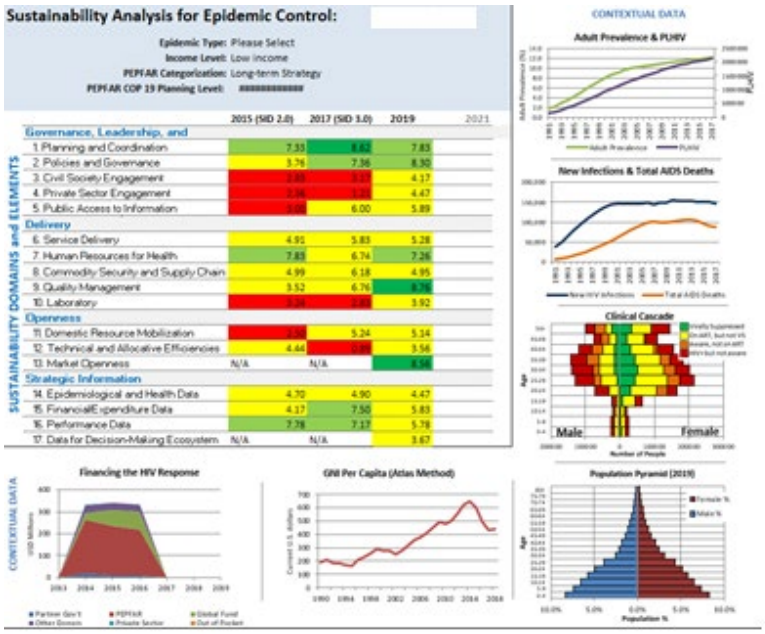
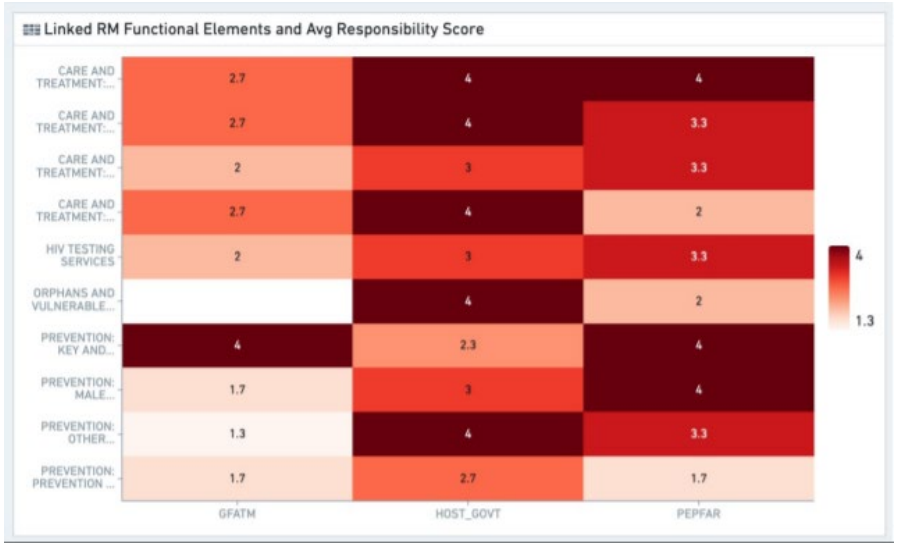


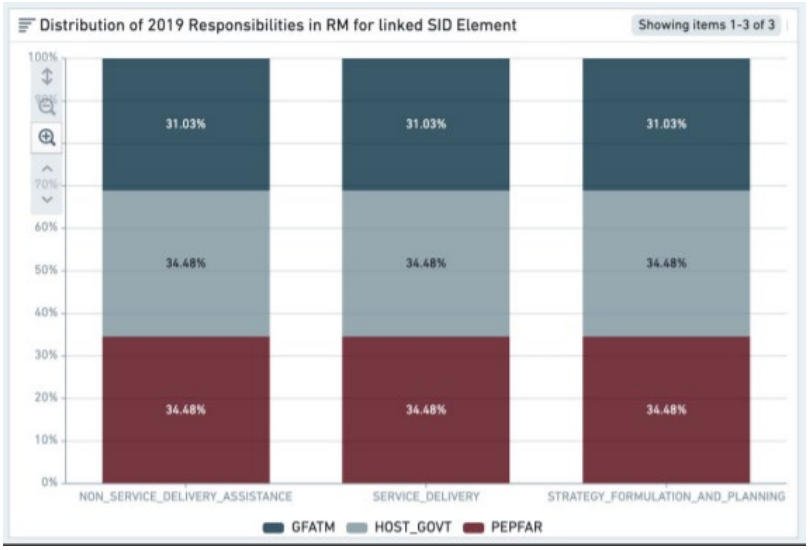
Figure 7.2.5.3: SID -linked RM Functional Elements and Average Responsibility Score



Using the SID and RM, country teams can gain interesting insight into the gaps and potential sustainability weaknesses of their programs. The above table in Figure 7.2.5.3 shows the RM

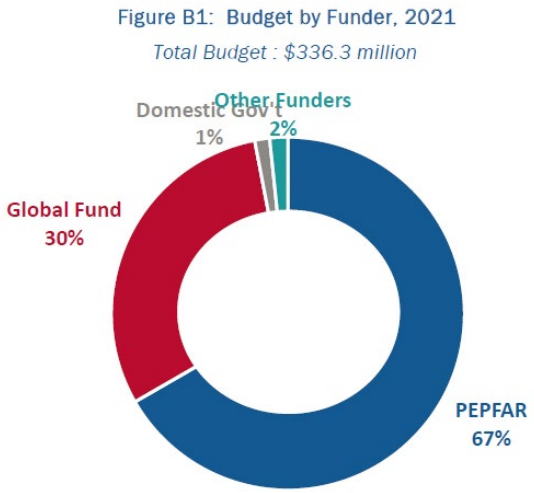
elements and responsibility scores in relation to funders. This allows the country to see where they need to dig a bit deeper to find out what is going on.

Figure 7.2.5.4: Distribution of 2019 Responsibilities in RM for linked SID Element



Cross referencing the SID and RM provides country teams with the above graph in Figure 7.2.5.4. Each column shows 100% of the budget for each element. Within the column is the break down, by percent, of how the element is funded. Over time, it is expected that the partner government will increasingly take on higher percentages of responsibilities for each element. These data points assist the partner government and all stakeholders to understand where shifts will need to be made and when they should be prioritized.

Figure 7.2.5.5: Budget by Funder, 2021



Using the Resource Alignment data, the above chart in Figure 7.2.5.5 provides a clear visual for the country team of who is funding the HIV response in country. This is an important piece of the sustainability puzzle as countries look to address gaps in policies and laws, they must also look to work with the partner government on creating a funding plan. These plans occur over a number of years and should be discussed in a transparent manner with all stakeholders. More on this is discussed in Section 6.6.9.1.

Deep Dive Questions for Above Site Programming:

- Are above-site program activities aligned to address barriers to advancing and sustaining epidemic control and improving site-level performance? How is the progress measured?
- Teams should review budgets and expenditures against the Table 6 activities. Is the funding for above-site programs aligned to the gaps identified? Are high priority gaps receiving sufficient funding? Low priority activities should have declining funding or funding should be reallocated to higher priority activities.
- What is the change in relevant MER indicators that can be attributed to respective Table 6 activities?
- For activities that have achieved COP21 benchmarks, what is the rationale for continuing in COP22? How many additional years of support is needed?
- For activities that have partially achieved COP21 benchmarks and continuing in COP22, what is the course correction?
- For activities that are not initiated or have not achieved any of the COP21 benchmarks and continuing into COP22, what is the rationale for continuation?
- Where relevant (especially for countries close to epidemic control), are investments in place to support systems for recency testing and case-based surveillance?

Deep Dive Questions for the SID:

- What were the major findings for each domain? Which elements represented sustainability strengths? Which elements were found to be vulnerabilities?
- Among those SID elements identified as sustainability vulnerabilities, which do stakeholders regard as priorities? Based on the indicators that comprise these elements, what specific aspects of these elements require improvement/investment?
- What are the priorities across partners? Are they aligned or in conflict? Do they complement each other?

- Is the country government or any development partners already working to strengthen these priority elements? How do those efforts align with the specific vulnerabilities identified in the SID?
- For priority elements not receiving support currently, which partner(s) (including both donors and government entities) are best placed to address these priorities and make the necessary investments? What is the plan forward for partner investments based on priorities? Should the country team develop a multiyear strategy in collaboration with PEPFAR and GFATM?
- Are there particular priority elements that require PEPFAR investments in COP22, and why is PEPFAR uniquely qualified or positioned for achievement of this priority? (Note: It is not expected that PEPFAR would support all investment needs.)
- Does the government prioritize commodities other than ARVs (e.g., VL reagents)? Are forecasts and supply plans available and updated regularly?

Recency Testing and Case-based Surveillance Coverage/Systems

Deep Dive Questions for Recency Testing and Case Surveillance:

- Is there a system for recency testing and case surveillance set up throughout the OU? Other individual level data systems? If no, what gaps?
    - Data Sources: (SID and SIMS, PHIA, BBS, MOH data, JEE results if available, or other external sources)
- Populations gaps in recency testing or case-based surveillance?
    - Data Source: Panorama Recency Dossier “Number of Sites” and “Recency Coverage”

7.2.6 Commodities Planning

Commodity procurement is based on data-driven forecasting and supply planning for the OU and should be aligned to the planned interventions and activities for reducing HIV burden. All ARVs quantified for should be on the PEPFAR Tiered ARV list, ideally, Tier One (see Table 7.2.6.1). Procurement of Tier Two ARVs will receive greater scrutiny than those in Tier One to truly optimize treatment for patients and ensure the most appropriate products, of the highest quality are provided to patients.

Table 7.2.6.1: PEPFAR Tiered ARV List (next page)

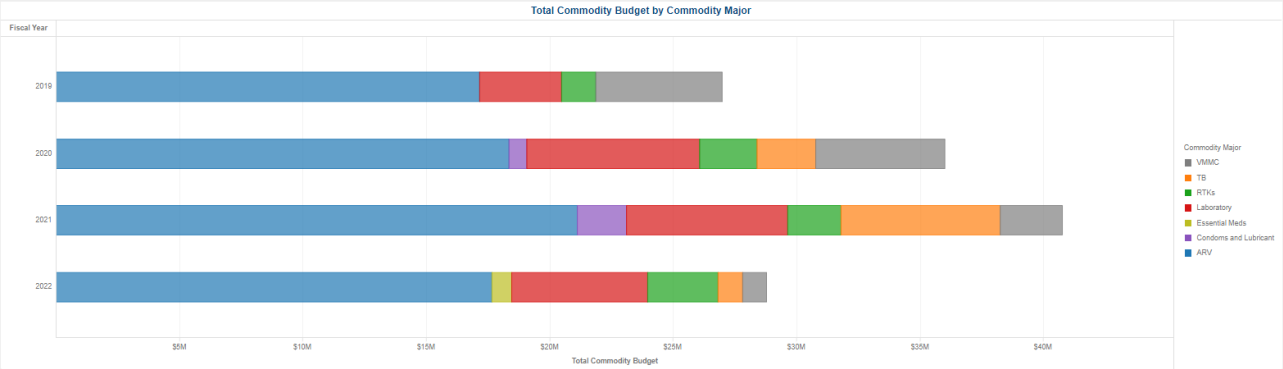
Tiers	Adult & Adolescent Treatment	Pediatric treatment	Postnatal Prophylaxis	PrEP
Tier One	Dolutegravir/Lamivudine/ Tenofovir DF (TLD) 50/300/300 mg Tablet, 180 Tablets	Abacavir/Lamivudine 120/60 mg Dispersible Tablet, 60 Tablets	Nevirapine 10 mg/mL Suspension w/ Syringe, 100 mL	Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets
	Dolutegravir/Lamivudine/ Tenofovir DF (TLD) 50/300/300 mg Tablet, 90 Tablets	Abacavir/Lamivudine 120/60 mg Dispersible Tablet, 30 Tablets	Nevirapine 10 mg/mL Suspension, 100 mL	Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets
	Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets	Dolutegravir 10 mg Tablet, 90 Tablets	Nevirapine 50 mg Dispersible Tablet, 60 Tablets	Dapivirine Vaginal Ring
	Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	Lamivudine/Zidovudine 30/60 mg Dispersible Tablet, 60 Tablets		
Tier Two	Abacavir/Lamivudine 600/300 mg Tablet, 30 Tablets	Abacavir/Lamivudine 600/300 mg, 30 Tablets	Zidovudine 10 mg/mL Solution w/ Syringe, 240 mL	
	Atazanavir/Ritonavir 300/100 mg Tablet, 30 Tablets	Darunavir [Prezista®] 75 mg Tablet, 480 Tablets	Zidovudine 10 mg/mL Solution, 240 mL	
	Darunavir 600 mg Tablet, 60 Tablets	Darunavir [Prezista®] 150 mg Tablet, 240 Tablets		
	Dolutegravir 50 mg Tablet, 90 Tablets	Dolutegravir 50 mg Tablet, 90 Tablets		
	Dolutegravir 50 mg Tablet, 30 Tablets	Dolutegravir 50 mg Tablet, 30 Tablets		
	Dolutegravir/Lamivudine/Abacavir (ALD) 50/300/600 mg Tablet, 30 Tablets	Lamivudine 10 mg/mL Solution w/ Syringe, 240 mL		
	Dolutegravir/Emtricitabine/ Tenofovir Alafenamide (TAFED) 50/200/25 mg Tablets, 90 Tablets	Lopinavir/Ritonavir 40/10 mg Oral Granules, 120 Sachets		

	Dolutegravir/Emtricitabine/ Tenofovir Alafenamide (TAFED) 50/200/25 mg Tablets, 30 Tablets	Lopinavir/Ritonavir [Aluvia®] 100/25 mg Tablet, 60 Tablets		
	Efavirenz/Lamivudine/Tenofovir DF (TLE400) 400/300/300 mg Tablet, 90 Tablets	Lopinavir/Ritonavir 100/25 mg Tablet, 60 Tablets		
	Lamivudine 150 mg Tablet, 60 Tablets	Raltegravir [Isentress®] 100 mg Granules for Suspension, 60 Sachets		
	Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets	Ritonavir 25 mg Tablet, 30 Tablets		
	Lopinavir/Ritonavir 200/50 mg Tablet, 120 Tablets	Ritonavir 100 mg Tablet, 60 Tablets		
	Ritonavir 100 mg Film Coated Tablet, 60 Tablets	Zidovudine 10 mg/mL Solution w/ Syringe, 240 mL		
	Tenofovir DF 300 mg Tablet, 30 Tablets	Zidovudine 10 mg/mL Solution, 240 mL		

The PEPFAR Commodity Procurement Dossier analyzes PEPFAR Commodities budget data across fiscal years. The dossier's source of data includes only PEPFAR's commodities procurements as entered in the FAST during the COP cycle. Data is aggregated at the OU level and can be analyzed by funding agency, commodity categories (major, minor, and item), program area and beneficiary groups. The following examples (Figures 7.2.6.1 and 7.2.6.2) will evaluate the past and current commodity budgets by commodity major categories.

At or Near Epidemic Control:

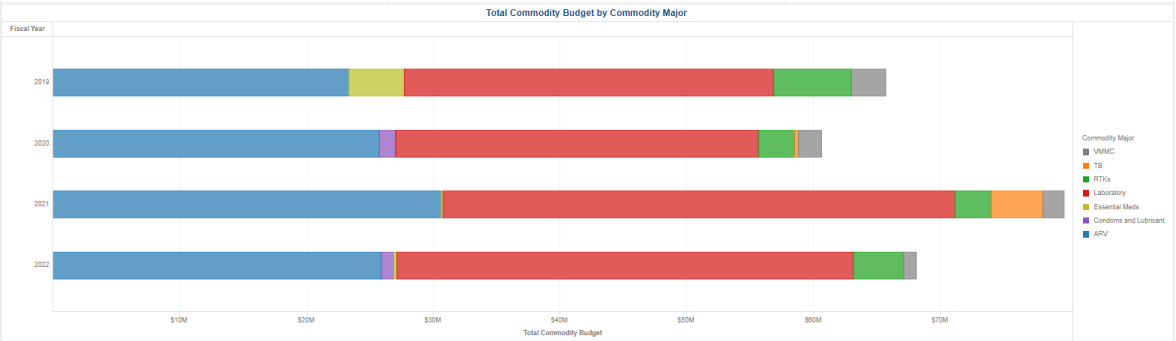
Figure 7.2.6.1: Country A's Total Commodity Budget Allocation by Commodity Major[760]



Fiscal Year	2019	2020	2021	2022	Total
Commodity Major	Total Commodity Budget	Total Commodity Budget	Total Commodity Budget	Total Commodity Budget	Total Commodity Budget
Total	$26,984,243	$36,004,438	$40,764,114	$28,770,335	$132,523,130
ARV	$17,162,707	$18,355,319	$21,108,902	$17,668,380	$74,295,308
Laboratory	$3,316,861	$7,017,455	$6,557,154	$5,492,171	$22,383,641
VMMC	$5,114,278	$5,226,563	$2,528,272	$954,656	$13,823,769
TB		$2,388,592	$6,434,766	$999,791	$9,823,249
RTKs	$1,390,397	$2,309,017	$2,147,861	$2,855,160	$8,702,435
Condoms and Lubricant	$0	$707,392	$1,987,159		$2,694,551
Essential Meds				$800,177	$800,177

Not at Epidemic Control:

Figure 7.2.6.2: Country B's Total Commodity Budget Allocation by Commodity Major[761]



Fiscal Year	2019	2020	2021	2022	Total
Commodity Major	Total Commodity Budget	Total Commodity Budget	Total Commodity Budget	Total Commodity Budget	Total Commodity Budget
Total	$65,754,219	$60,640,438	$79,784,838	$68,142,498	$274,321,993
Laboratory	$29,112,544	$28,655,706	$40,403,958	$36,030,791	$134,202,999
ARV	$23,367,729	$25,799,052	$30,658,233	$25,925,204	$105,750,218
RTKs	$6,187,446	$2,862,758	$2,863,755	$3,986,503	$15,900,462
VMMC	$2,714,803	$1,805,434	$1,630,245	$988,151	$7,138,633
Essential Meds	$4,371,097		$138,848	$211,849	$4,722,194
TB		$263,541	$4,089,999		$4,353,540
Condoms and Lubricant	$0	$1,253,947	$0	$1,000,000	$2,253,947

Deep Dive Questions for Commodities:

- Considering commodities from all sources, is there a sufficient supply of ARVs, test kits, and viral load reagents to support the programmatic targets?

[760] Data Source: Panorama PEPFAR Commodity Procurement: Total Commodity Budget by Commodity Major Grid/Graph

[761] Data Source: Panorama PEPFAR Commodity Procurement: Total Commodity Budget by Commodity Major Grid/Graph

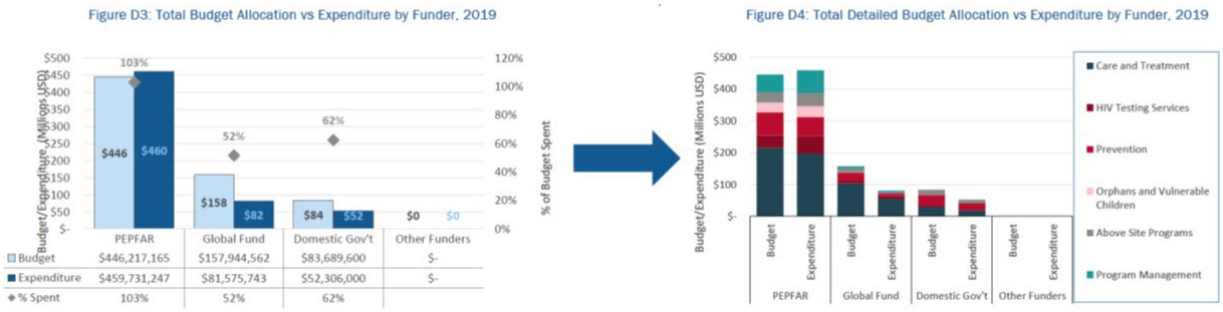
- Are forecasts done annually and supply plans updated routinely (monthly or quarterly) using accurate and complete data?
- Are the ARVs modern, high-quality regimens, or are older, outdated regimens still being used or procured?
- In consultation with the Supply Planning tool and the resource alignment tool, is PEPFAR procuring an appropriate number of commodities to support the OU response or is there a known gap? Are other stakeholders meeting their commodity obligations on time and in sufficient quantities? If not, has that caused a gap?
- Is the distribution of commodities – e.g., test kits, ARVs, viral load reagents - within country aligned with the needs of the program?
- Are stockouts drivers of weak programmatic outcomes? E.g., inability to provide viral load testing at scale, inability to provide MMD due to low stock levels, etc. Are data being shared across partners to pre-empt stockouts?

7.2.7 Strategic Alignment and Complementarity Across All Available Resources

Resource Alignment:

PEPFAR, the Global Fund, and partner country governments are the primary financiers of the HIV response. To improve strategic alignment, efficiency, and impact across all available HIV and broader health resources, it is important to understand the allocation and execution of resources across the three stakeholders and other funders where possible based on data availability (see Figures 7.2.7.1 and 7.2.7.2). PEPFAR and Global Fund's planning processes along with availability of routine Resource Alignment data provide country teams a unique opportunity to ensure investments are strategically aligned, there's no duplication, and spending is in line with program priorities and gaps. This will help determine who is paying for what, and whether investments across all stakeholders fully aligned towards the goals of achieving sustained epidemic control. Combining information from the Resource Alignment and MER can be used to assess possible duplication, gaps in funding, and pockets of inefficiencies. Triangulation of Resource Alignment, SID, RM, and MER can determine whether systems investments are adequately targeted to address issues in the clinical cascade and inform greater responsibility for and control of the HIV response by the partner country government.

Figure 7.2.7.1: Total Budget Allocation vs Expenditure by Funder, 2019, and Total Program Area Budget Allocation vs Expenditure by Funder, 2019



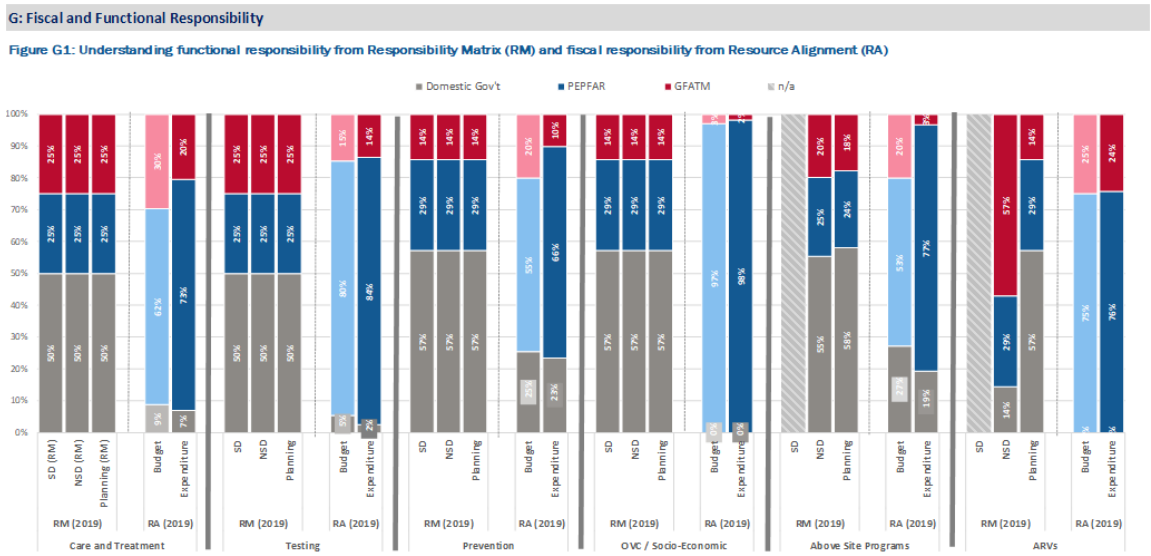
Deep Dive Questions for Resource Alignment:

- Does the information provide a reasonably complete picture of funding for the country's HIV response and help us understand where multiple funders operate in the same space?
- What is the strategic alignment of investments across PEPFAR and the Global Fund, and does the current allocation of funds match program priorities and needs?
- Is there a potential for duplication in the way resources are currently allocated? Are there any gaps in funding or pockets of inefficiencies?
- Are there specific areas or types of funds with low absorptive capacities? If yes, what are the possible reasons? How can that be addressed?
- How can PEPFAR and Global Fund in partnership with the partner country government further optimize HIV investments, especially considering the current operating environment?
- We understand that some partner country governments are potentially at risk of not meeting their HIV commitments considering the economic impact and fiscal pressures caused by COVID-19. Is there a need for PEPFAR and Global Fund to mitigate those risks?
- Have we identified areas where donors can support the partner government to prioritize resources based on program needs and advance domestic responsibility?
- Has the government taken over all commodity procurement? Are the partner government and PEPFAR relying on a third party (Global Fund or another) to provide most or all products in a certain commodity category?

Responsibility Matrix:

The Responsibility Matrix (RM) serves as an assessment of the functional responsibilities across the three major funders of the HIV response: PEPFAR, the Global Fund, and Partner Country Government. The triangulation of Resource Alignment, Responsibility Matrix, SID, and MER data can be used to identify areas where agency/partner government can prioritize resources based on program need and advance domestic responsibility. The example below (see Figure 7.2.7.2) demonstrates how fiscal responsibility and functional responsibility can be compared by combining information from the Resource Alignment and Responsibility matrices.

Figure 7.2.7.2: Understanding functional responsibility from RM and fiscal responsibility from RA



Deep Dive Questions for the Responsibility Matrix:

- Who is primarily responsible for elements that reflect lagging sustainability in the SID? Where is there a disconnect between financing and function? How should roles/responsibilities change to improve sustainability in this element?
- Across the elements and dimensions of the RM, are stakeholder responsibilities complementary or fragmented towards achieving sustainability in the HIV response? How can stakeholder resources be better leveraged in priority elements? What are the ways to improve coordination?

7.2.8 How should funding be allocated and aligned to performance at the IM, SNU, and site level?

As described at the beginning of Step 2, triangulated and integrated program data analysis at the OU and SNU levels should be overlaid with financial data where possible in order to align funding to performance. At the end of Step 7, country teams should:

(1) Cross-check their shortlisted IMs against budgets, outlays, and financial reporting by IM and agency to understand the scale and scope of each IM.

(2) Detail the main program areas and interventions that need to be scaled with fidelity to achieve epidemic control, with a focus on retaining patients in client-centered services

Teams will use this cross-check and detail to determine how to set preliminary budgets by IM and program area (i.e., using the concept of incremental budgeting, what needs to go up, and what needs to go down?). Based on this analysis, above-site investments, surveillance activities to be funded etc. can then be determined.

In general, well-performing, efficient SNUs and IMs should be preferentially funded to scale/expand programming while those under-performing or inefficient are opportunities for larger shifts based on the details of the situation and potential decrease in funding. Similarly, sites within SNUs that continue to demonstrate opportunities to grow efficiently should also be preferentially funded in a manner commensurate with SNU- level targets. Where relevant, new SNUs should be assessed based on trends in incidence/prevalence and the availability of resources, such as from the shifting of existing programming to domestic resources. Additional details about targets for such SNUs and IMs can be found in Section 7.5.

7.3 Planning Step 3: Set Preliminary Budgets, Targets, and Above-Site Activities

Based on the analyses in Step 2 and recommendations from S/GAC, **all country teams are expected to adjust the COP21 activities and Implementing Partner mix and associated budgets accordingly for COP22, including expanding funding and geographic reach of high performing partners in targeted areas, increasing impact by allocating additional funding to IMs that implement programs more efficiently, and limiting funding to the poorer performers. These changes should be evident in the COP22 plan.**

By the end of Planning Step 3, PEPFAR teams and stakeholders should have consensus on:

- Balanced IM intervention-level budget for COP22 in the FAST
- Proposed IM by SNU-level targets for COP22 in the DataPack
- Proposed above-site, non-service delivery activities for COP22 in Table 6
- Proposed surveys, surveillance, research, and evaluation activities for COP22 in the SRE Tool

COP REQUIREMENT: OU teams are required to utilize the DataPack and related tools for target setting. Detailed guidance on target-setting with DataPack will be provided in the DataPack User's Guide.

COP REQUIREMENT: OU teams are required to utilize the FAST and FACTS Info for budget submission. Detailed guidance on budget entry and use of the FAST will be provided in the FAST User's Guide.

COP REQUIREMENT: OU teams are required to utilize the Excel tool for Table 6 and the SRE Tool. Detailed guidance on entry and use of Table 6 and the SRE Tool will be provided in the Table 6/SRE Tool User's Guide.

7.3.1 Set Preliminary Budget

In COP22, the Funding Allocation to Strategy Tool (FAST) budget allocation tool uses the PEPFAR Financial Classification structure for classifying the purpose, targeted beneficiary population, and what will be purchased with the PEPFAR funding. This classification is common across both PEPFAR program expenditures and budgeting in the FAST, to be able to monitor expenditures against budget and improve planning and management of the PEPFAR investment.

The COP22 budgeting approach is the same as for COP18-21. The FAST will continue to be based on an incremental budgeting approach that is designed to assist OU teams in reviewing, understanding, and aligning the budget to the country's strategic direction. Incremental budgeting will leverage prior year COP budgets, expenditures, and work plan budgets, and in the COP22 FAST, teams will be asked to make incremental adjustments to the most appropriate baseline set of data from those three data streams. When determining implementing mechanism budgets in the COP22 FAST, adjustments up or down in funding levels, and changes to the programmatic work that is funded will be determined through analysis of 1) actual and projected spending levels as provided by the implementing partners (expenditures and work plan budgets), 2) partner performance (target achievement, trends comparative

analysis, implementation efficiency, and other performance indicators), 3) changes to scope of work as determined in strategic planning discussions, and 4) other relevant analyses.

The FAST is prepopulated with FY21/COP20 IM expenditure reporting, COP21 budgets, and COP21 Workplan values by intervention to facilitate the incremental changes for COP22. The entire budget should be represented in the FAST, including applied pipeline and new funding for all IMs across both bilateral and centrally funded initiatives. All projected FY23 outlays should be included in the COP22 budgets as either new funding or applied pipeline. Teams must include any/all outstanding IM close-out costs regardless of when the outlay will occur. Including close-out costs ensure sufficient funding to meet legal and contractual obligations.

In addition, when preparing FAST budgets, USG staff should consider required costs for program management needed by partners. Program management budgets in the FAST should reflect the IM's true program management costs, inclusive of all overhead and indirect charges. Program management budgets, just like all intervention budgets in the FAST, should be determined through a review of the activities included in the program management intervention(s) and a resulting agreement on the activities and the budget for the activities that have been approved for the COP cycle. This review should take place at the cost category level-understanding which costs within program management interventions should be continued and are necessary, and which should be discontinued. It is important to note that not all program management are negotiable and changeable as part of the COP budget finalization. With the shift away from budget codes, USG teams should also consider the level of detail of interventions within the FAST budget to ensure that they can document and quantify budgets for all parts of their program. It is important to note that in the COP22 budget, the interventions- or the selections for program areas and beneficiaries- will be the main source of information about an IM's budgeted activities. As such, teams are encouraged to disaggregate budgets at a level that allows for visibility and also accurate tracking of priority programming.

OU teams will use the FAST to draft initial budgets. Steps for using the FAST are outlined in the FAST User Guide on PEPFAR SharePoint. Based on the country-specific analysis in Section 7.2, here are some budgeting questions and considerations to assist with COP22 FAST completion:

Cascade Analysis

- What is the purpose of this funding? What is being done with the funding?
    - Is that objective aligned to the overall strategy of moving toward epidemic control?

- Is current investment achieving the intended objective?
    - Is this approach an appropriate intervention for the context, for the epidemic, and for the IM?

Cascade Funding Analysis

- Which partners should be expanded, and which partners should be contracted?
    - Partners whose performance has not improved must be replaced or their activities decreased, with another partner brought in.
- What needs to be added? What must be deleted?
    - A new IM with specific consideration for increasing the role of local partners in providing services.
- If appropriate, reduce funding for underperforming/overspending activities or where partner has demonstrated inefficient implementation.

Prevention, DREAMS and OVC, and Above Site Programming

- What needs to go up? For example:
    - Rapid scale-up or expansion to a new geographic area or population
- What needs to go down? For example:
    - Initial start-up costs incurred in COP19 or planned for COP20 that do not need to be repeated in COP21
    - New, less expensive drug or a price drop on the laboratory reagent
    - Shift of funding to achieve scale-up targets in a certain SNU
    - Completion of a one-off investment or project

Commodities Planning

In addition to the overall budget represented by IM-level interventions, additional entry is required when commodities are procured. The commodity tab entry is similar to the process for COP17-20 and is required for all IMs procuring commodities (i.e., ARVs, essential medicines, HIV rapid test kits, recency assays, condoms, VMMC kits and supplies, laboratory reagents or equipment). Efforts should be made for consistent categorization of commodities within and across countries and partners.

Commodity procurement should be based on forecasting and supply planning for the OU and should take into consideration existing stock levels, guidance from PEPFAR as to preferred regimens, algorithms, or methods as applicable (see Sections 2.3.4, 7.3.4 and 8.5), and procurement from other sources such as the partner-country government and the Global Fund.

In order to facilitate sound commodity procurement, PEPFAR OUs must mandate routine sharing of accurate stock, consumption, issues, and loss data among PEPFAR partners.

Additional Considerations

- Are HIV services being provided by local partners and, if not, what are the plans to increase coverage by local partners?
- Costs of providing HIV services among non-governmental, local partners given the lack of public support for HRH, lab, clinics, and other necessary resources to provide quality HIV services.
- Are accurate commodity data being routinely shared across all stakeholders?
- Macroeconomic issues such as inflation or nurse or doctor strikes may result in increased budgets

7.3.2 Setting Targets for Accelerated Epidemic Control in Priority Locations and Populations

Country teams should understand the initial SNU-level target outputs from the DataPack in advance of the January/February 2022 stakeholder strategic planning retreat. Teams should engage with stakeholders and IPs throughout the target setting process and should make the process as transparent as possible via the flatpack (Sections 2.5.3 and 5.5). The purpose of the initial budget is to identify a starting point for the discussions at the strategic planning retreat. Initial targets should align with the budgets provided and should assist in identifying strategic gaps that need to be addressed to align the country's strategic plan and planning envelope, to get to 95/95/95 at country level (see Figure 7.0.1). Targets should be set to MER 2.6 indicators. Be sure to review MER 2.6 indicator definitions and DataPack User Guide to guide target setting.

The COP22 development process provides a platform for OUs to review progress toward the COP21 goals and reevaluate which SNUs will be designated for saturation or aggressive scale-up in COP22 (Figure 7.3.2.1). Figure 7.3.2.2 shows the continuous nature of prioritization at the SNU level.

Figure 7.3.2.1: SNU prioritization for epidemic control COP22

Refreshing SNU Prioritization for Epidemic Control	
COP 21 SNU Prioritization	**Potential COP 22 SNU Prioritization**
Attained	Attained by default
Scale-Up Saturation	**Attained** (if >81%ART coverage is expected to be achieved among both adult and pediatrics males and females living with HIV by Q4 FY22) **Scale-Up Saturation** (If ART coverage >81% is **not** expected to be reached for adult and pediatric males and females living with HIV by 4FY22
Scale-Up Sustained	**Scale-Up Saturation** (if 81% target is achievable by Q4 FY 22) **Scale- Up Aggressive** (if 81% target is not achievable by Q4 FY22)
Sustained	**Scale-Up Saturation** (If the SNU is prioritized based on PLHIV for the next tranche of scale-up, and a target of 81% is achievable by Q4 FY22) **Scale-Up Aggressive**(If the SNU is prioritized based on PLHIV for the next tranche of scale-up, and a target of 81% is not achievable by Q4 FY22)
Central Support	**Central Support** (by default) **Sustained or Scale-UP** (if compelling case can be made to prioritize the SNU for scale-up or sustained based on HIV burden)

Attained SNUs: Geographic areas that have achieved ≥95% treatment coverage in both males and females within the following age bands: <1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, and 50+. Getting to >95% treatment coverage by both males in females within the finer age bands at sub-national levels will ensure that the country gets to 95/95/95 overall.

Scale-up: Saturation and Aggressive Scale-Up SNUs: Geographic areas with the highest HIV prevalence nationally that have not yet achieved 95% treatment coverage, particularly among the population groups experiencing the greatest burden of disease.

- Scale-Up: Saturation SNUs receive intensive PEPFAR support with a target of reaching 95% of people at all ages, gender, and risk groups, PLHIV on ART by 2022 and 2023.
- Scale-Up: Aggressive SNUs receive intensive PEPFAR support with an overall goal of an increased rate of 'new on ART,' but are not expected to reach 95% of PLHIV by 2022 or 2023.

Sustained SNUs: Sustained SNUs receive a package of services provided by PEPFAR that are different in each country and include passive enrollment via HIV testing and counseling on request or as indicated by clinical symptomology, care and treatment services for PLHIV, and essential laboratory services for PLHIV. As the high-burden Scale-Up Districts are saturated, Sustained Districts will be aggressively scaled to reach 95/95/95 goals.

Central Support SNUs: In Central Support SNUs, site-specific activities have transitioned to government or other support. Central Support Districts will continue to receive PEPFAR national

support for overarching activities, such as quality assurance and quality improvement (QA/QI) to ensure that patients continue to receive quality services.

Figure 7.3.2.2: Continuous nature of prioritization at the SNU level to reach epidemic control

SNU	COP	Prioritization	Results reported	Attained: 90-90-90 (81%) by Each Age and Sex Band to Reach 95-95-95 (90%) Overall																												Overall TX Coverage
				Treatment Coverage at APR by Age and Sex																												
				<1		1-4		5-9		10-14		15-19		20-24		25-29		30-34		35-39		40-44		45-49		50+						
				F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M					
SNU 1	COP 17	Scale-Up: Saturation	APR 17	45%	49%	55%	57%	65%	77%	63%	64%	77%	74%	80%	65%	62%	49%	60%	58%	77%	60%	81%	73%	80%	58%	77%	75%					65%
	COP 18	Scale-Up: Saturation	APR 18	66%	69%	71%	72%	75%	91%	81%	78%	83%	80%	91%	75%	77%	67%	78%	75%	91%	72%	93%	76%	91%	75%	94%	79%					81%
	COP 19	Scale-Up: Saturation	APR 19	81%	81%	83%	82%	82%	95%	85%	81%	87%	83%	95%	82%	90%	81%	89%	86%	95%	82%	96%	84%	95%	86%	95%	86%					86%
	COP 20	Attained	APR 20	83%	82%	85%	84%	85%	95%	87%	85%	92%	87%	95%	85%	92%	85%	90%	84%	95%	87%	97%	91%	95%	84%	96%	90%					92%
	COP 21	Attained	APR 21	86%	84%	85%	89%	83%	94%	86%	87%	94%	89%	95%	88%	95%	87%	89%	86%	95%	89%	97%	91%	95%	83%	94%	90%					92%
SNU 2	COP 17	Scale-Up: Aggressive	APR 17	27%	33%	47%	46%	73%	68%	35%	48%	56%	43%	59%	40%	68%	44%	67%	43%	70%	61%	66%	73%	77%	74%	57%	71%					47%
	COP 18	Scale-Up: Aggressive	APR 18	51%	60%	53%	59%	75%	77%	60%	46%	66%	51%	64%	42%	77%	50%	73%	45%	83%	66%	76%	75%	83%	80%	76%	69%					63%
	COP 19	Scale-Up: Saturation	APR 19	72%	71%	81%	77%	89%	88%	81%	83%	82%	79%	89%	65%	88%	77%	87%	81%	92%	77%	89%	89%	87%	83%	91%	93%					84%
	COP 20	Attained	APR 20	81%	82%	84%	82%	95%	91%	90%	83%	87%	85%	94%	82%	91%	83%	92%	85%	94%	82%	94%	95%	92%	87%	93%	95%					90%
	COP 21	Attained	APR 21	81%	82%	86%	82%	95%	92%	90%	84%	87%	86%	94%	83%	91%	84%	92%	85%	94%	82%	94%	95%	92%	87%	93%	95%					91%
SNU 3	COP 17	Sustained	APR 17	22%	26%	20%	21%	71%	39%	35%	37%	53%	29%	50%	39%	59%	36%	71%	49%	77%	55%	71%	60%	71%	68%	72%	68%					39%
	COP 18	Scale-Up: Aggressive	APR 18	30%	33%	25%	34%	81%	48%	40%	44%	51%	37%	54%	48%	61%	43%	81%	53%	83%	66%	73%	59%	81%	77%	74%	74%					50%
	COP 19	Scale-Up: Saturation	APR 19	45%	44%	38%	42%	84%	56%	46%	55%	56%	45%	70%	56%	66%	71%	84%	72%	88%	75%	91%	70%	84%	86%	81%	76%					63%
	COP 20	Scale-Up: Saturation	APR 20	61%	70%	66%	59%	91%	79%	71%	67%	79%	71%	84%	79%	80%	84%	91%	89%	94%	77%	92%	76%	91%	91%	83%	80%					82%
	COP 21	Attained	APR 21	81%	82%	83%	81%	93%	82%	81%	83%	85%	81%	85%	83%	91%	94%	93%	91%	95%	81%	95%	82%	91%	91%	85%	83%					90%
SNU 4	COP 17	Sustained	APR 17	39%	41%	60%	44%	60%	49%	56%	37%	60%	40%	65%	32%	82%	26%	50%	35%	57%	50%	74%	63%	74%	63%	70%	55%					45%
	COP 18	Sustained	APR 18	40%	44%	61%	47%	59%	53%	59%	40%	64%	44%	70%	41%	84%	31%	63%	37%	61%	55%	74%	66%	74%	66%	72%	47%					50%
	COP 19	Scale-Up: Aggressive	APR 19	49%	53%	70%	55%	70%	72%	62%	50%	71%	60%	81%	49%	86%	45%	66%	44%	70%	63%	77%	72%	77%	72%	75%	66%					62%
	COP 20	Scale-Up: Saturation	APR 20	67%	60%	75%	61%	76%	89%	83%	59%	83%	70%	93%	72%	93%	62%	72%	59%	83%	71%	86%	79%	86%	79%	90%	73%					81%
	COP 21	Scale-Up: Saturation	APR 21	67%	63%	79%	70%	75%	90%	88%	65%	89%	79%	93%	79%	94%	65%	75%	64%	85%	74%	89%	81%	87%	82%	94%	80%					85%
SNU 5	COP 17	Central Support	APR 17	N/A: no target required																												55%
	COP 18	Central Support	APR 18	N/A: no target required																												58%
	COP 19	Central Support	APR 19	N/A: no target required																												59%
	COP 20	Central Support	APR 20	N/A: no target required																												61%
	COP 21	Central Support	APR 21	N/A: no target required																												72%

In this example, SNU 1 was prioritized in COP15 to get 90% ART coverage (or saturation) by FY 17. The SNU did not reach saturation of 90% coverage at the SNU level by FY 17. The SNU then remains at scale-up saturation until it graduates into the next prioritization tier which is attained. In this example, you will see that SNU 1 will be designated as attained in COP18 with targets that will move the SNU to 90/90/90 by five-year age band to reach 95/95/95 overall by FY 19. In COP19 and COP20, SNU 1 then remains at attained. In COP22, new ART targets should be allocated to SNUs 3 and 4. SNU 2 has also already reached attained. SNU 3 has reached saturation but should accelerate treatment among age bands that have not yet reached saturation. SNU 4 will continue a path toward reaching saturation at the SNU level, although reaching attained may not be feasible by FY23.

In COP22, the next districts should be identified for saturation by FY 2023. SNUs that were identified as scale-up: aggressive in previous COP cycles should be revisited to see which ones can become saturated by FY 2022 or FY 2023.

A country nearing Epidemic Control should have a majority of SNUs at Attained prioritization:

[redacted]		SNU Prioritizations						
		Attained	Scale-Up: Saturation	Scale-Up: Aggressive	Sustained	Centrally Supported	No Prioritization	Total
HTS_INDEX	<15	19,286	-	-	-	-	41	19,327
	15+	14,248	-	-	-	-	656	14,904
	Total	**33,534**	-	-	-	-	**697**	**34,231**
HTS_TST	<15	26,227	-	-	-	-	81	26,308
	15+	89,057	-	-	-	-	1,520	90,577
	Total	**115,284**	-	-	-	-	**1,601**	**116,885**
HTS_TST_POS	<15	504	-	-	-	-	4	508
	15+	7,607	-	-	-	-	262	7,869
	Total	**8,111**	-	-	-	-	**266**	**8,377**
TX_NEW	<15	604	-	-	-	-	4	608
	15+	7,828	-	-	-	-	262	8,090
	Total	**8,432**	-	-	-	-	**266**	**8,698**
TX_CURR	<15	9,355	-	-	-	-	69	9,424
	15+	207,282	-	-	-	-	3,430	210,712
	Total	**216,637**	-	-	-	-	**3,499**	**220,136**
TX_PVLS	<15	8,733	-	-	-	-	66	8,799
	15+	195,937	-	-	-	-	3,201	199,138
	Total	**204,670**	-	-	-	-	**3,267**	**207,937**
CXCA_SCRN	**Total**	**40,359**	-	-	-	-	**650**	**41,009**
OVC_SERV	<18	62,211	-	-	-	-	-	62,211
	18+	12,619	-	-	-	-	-	12,619
	Total	**74,830**	-	-	-	-	-	**74,830**
OVC_HIVSTAT	**Total**	**43,360**	-	-	-	-	-	**43,360**
PMTCT_STAT	<15	238	-	-	-	-	-	238
	15+	23,545	-	-	-	-	-	23,545
	Total	**23,783**	-	-	-	-	-	**23,783**
PMTCT_STAT_POS	<15	10	-	-	-	-	-	10
	15+	7,624	-	-	-	-	-	7,624
	Total	**7,634**	-	-	-	-	-	**7,634**
PMTCT_ART	<15	10	-	-	-	-	-	10
	15+	7,574	-	-	-	-	-	7,574
	Total	**7,584**	-	-	-	-	-	**7,584**
PMTCT_EID	**Total**	**7,434**	-	-	-	-	-	**7,434**
PP_PREV	<15	7,256	-	-	-	-	93	7,349
	15+	46,886	-	-	-	-	6,307	53,193
	Total	**54,142**	-	-	-	-	**6,400**	**60,542**

A country not near Epidemic Control should use the analysis tools to identify the appropriate SNU prioritization and will have a range of results based on gaps and performance of SNUs:

Figure 7.3.2.4: COP MER Indicator Targets and Prioritization Table, Country B

Indicator	Age	Attained	Scale-up: Aggressive	Centrally Supported	No Prioritization	Total
HTS_INDEX	<15	3593	276053	5545	630	285821
HTS_INDEX	15+	6275	299635	7626	6496	320032
HTS_INDEX	Total	9868	575688	13171	7126	605853
HTS_TST	<15	9631	854217	19441	2893	886182
HTS_TST	15+	66859	5394336	265882	59971	5787048
HTS_TST	Total	76490	6248553	285323	62864	6673230
HTS_TST_PO	<15	186	16427	447	260	17320
HTS_TST_PO	15+	5609	302879	8894	6036	323418
HTS_TST_PO	Total	5795	319306	9341	6296	340738
TX_NEW	<15	186	18935	481	270	19872
TX_NEW	15+	5304	287050	8484	5741	306579
TX_NEW	Total	5490	305985	8965	6011	326451
TX_CURR	<15	1428	94464	3100	926	99918
TX_CURR	15+	42134	1638645	51782	27932	1760493
TX_CURR	Total	43562	1733109	54882	28858	1860411
TX_PVLS	<15	1272	80978	2700	730	85680
TX_PVLS	15+	37608	1425867	45303	23919	1532697
TX_PVLS	Total	38880	1506845	48003	24649	1618377
CXCA_SCRN	Total	7359	299750	0	4932	312041
OVC_SERV	<18	0	374177	0	0	374177
OVC_SERV	18+	0	55027	0	0	55027
OVC_SERV	Total	0	429204	0	0	429204
OVC_HIVSTA	Total	0	69736	0	0	69736
PMTCT_STAT	<15	0	0	0	80	80
PMTCT_STAT	15+	5704	1465123	182932	2150	1655909
PMTCT_STAT	Total	5704	1465123	182932	2230	1655989
PMTCT_STAT	<15	0	0	0	0	0
PMTCT_STAT	15+	937	112261	4788	579	118565
PMTCT_STAT	Total	937	112261	4788	579	118565
PMTCT_ART	<15	0	0	0	0	0
PMTCT_ART	15+	925	110183	4691	579	116378
PMTCT_ART	Total	925	110183	4691	579	116378
PMTCT_EID	Total	873	90232	0	557	91662
PP_PREV	<15	0	0	0	0	0
PP_PREV	15+	0	84315	0	40048	124363
PP_PREV	Total	0	84315	0	40048	124363
KP_PREV	Total	1716	50074	0	0	51790
VMMC_CIRC	Total	0	170686	6300	23366	200352
PrEP_NEW	Total	2074	47917	0	5001	54992
PrEP_CURR	Total	2436	57473	0	6001	65910
TB_STAT	<15	79	9373	0	151	9603
TB_STAT	15+	536	63169	0	1004	64709
TB_STAT	Total	615	72542	0	1155	74312
TB_ART	<15	35	2044	0	34	2113
TB_ART	15+	324	23075	0	314	23713
TB_ART	Total	359	25119	0	348	25826
TB_PREV	<15	488	38303	0	362	39153
TB_PREV	15+	14291	637179	0	9270	660740
TB_PREV	Total	14779	675482	0	9632	699893
TX_TB	Total	41761	1815926	0	28797	1886484
GEND_GBV	Total	135	58731	0	0	58866
AGYW_PREV	Total	0	131087	0	0	131087

Process for Prioritizing Locations and Populations for COP22

As a first step in reviewing the prioritization for locations and populations, teams should gather the following key data elements and potential data sources as outlined in Figure 7.3.2.5, and the analyses already conducted in Step 2 above. This is to ensure 95/95/95 by age and sex, and a clear understanding of who we are missing to achieve these goals, as highlighted in earlier steps as well.

Figure 7.3.2.5: Key data elements and potential sources

Key Data Elements and Potential Sources	
Data element(s)	**Potential Sources**
• Total population • HIV prevalence and trends • Total number of PLHIV • ART coverage by age, sex, and SNU • Coverage of prevention services • Estimated key and priority populations within high prevalence SNUs • HTS and PMTCT yield and ART volume	• Ministry of Health surveillance • Estimates from UNAIDS Spectrum and Subnational Estimates of HIV Prevalence Report • Surveillance studies supported by PEPFAR • Central Statistics Agency • U.S. Bureau of Census • PEPFAR program data • MOH program data

Multiple data sources and a number of contextual factors must be considered when PEPFAR teams review the geographic and priority populations prioritization for COP22. **The goal of this prioritization exercise and corresponding analysis is to continue to optimize resource allocation for maximum epidemiological impact.**

Once the data elements described above have been assembled, the teams should rank SNUs as follows:

- Sort SNUs by the total number of PLHIV from largest to smallest using latest estimates (i.e., where are the top 80-90% of PLHIV?)
- Calculate the percentage of total (national) PLHIV in each SNU
- Calculate the cumulative burden by SNU by summing and recording the percent of total PLHIV for each SNU entry.
- Sort SNUs largest to smallest by current ART coverage. ART coverage should be represented as a percentage for each SNU. Unmet need should be calculated using total PLHIV as the denominator. Unmet need will be auto calculated within the DataPack.

- Sort SNUs again by largest to smallest by positive yield based on PEPFAR PMTCT and HTS data; calculate estimated PLHIV based on PEPFAR program data and compare the ranking of SNUs to the ranking in steps 1 and 4 above

Cascade Analysis:

For countries at or near epidemic control:

- The clinical cascade shows that 90% of PLHIV know their status, and 90% of those are on ART. Teams should start the target setting process with Population Viral Load Suppression to:
  - Ensure 95% VLC in all PSNUs
  - Target 100% suppression and incorporate into the DataPack geographic areas and populations of greatest need for VLS, reduced IIT and return to treatment (RTT), and case finding
  - Reach 95-95-95 across the cascade by all age/sex populations
- From Step 2 analysis, identify program area priorities and adjustments from last year for budget
  - Revisit all testing spending
- Testing modality limitations
  - Maintain standard of care HTS and optimization of Other PITC (See Section 2.3.1 for anticipated evolution of HTS as countries approach and achieve equitable epidemic control, see Section 6.3 for guidance on HTS standards of care, see Section 6.3.1 regarding HTS for Case Finding, and see Section 6.3.1.7 for guidance on optimizing PITC.)

For countries not at epidemic control:

- Start target setting process to achieve 95-95-95, with an emphasis on 95% ART coverage
- From Step 2 analysis, identify program area priorities and adjustments from last year for budget
  - Revisit all testing spending
- Case finding to identify remaining undiagnosed PLHIV
  - More widespread testing across modalities, with a focus balancing testing positivity and case finding volume

Country teams should calculate the **net new patients** required to achieve at least 95% ART coverage and VLC for PLHIV (by age/sex) by SNU by end of FY 2023. In determining these targets, PEPFAR teams should adjust for scale-rate, mortality, and changes in program to ensure ART continuity for individuals on treatment The aim is to achieve saturation across the

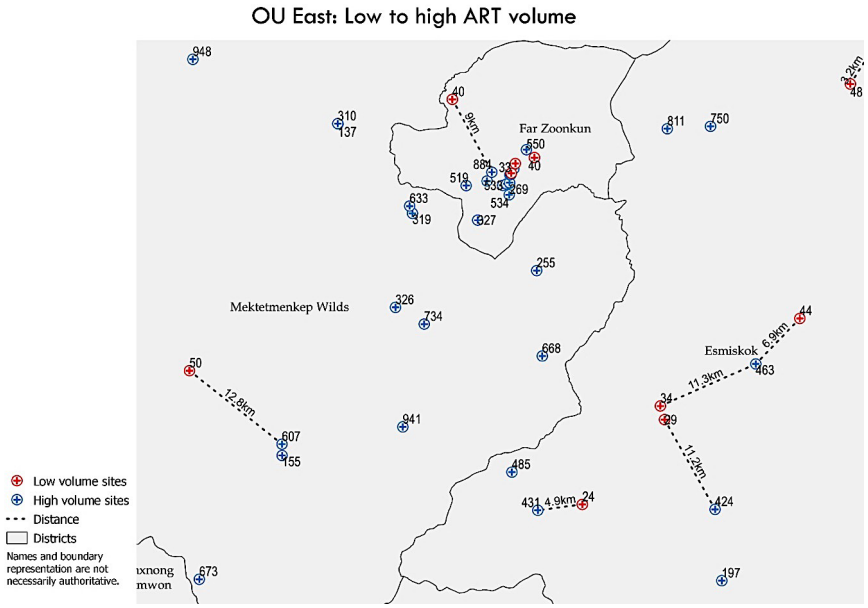
cascade. The following steps should be followed for geographical locales or program areas still not at 95% coverage until saturation is achieved across the entire country's program.

Each country context will be different and one method or standard selection criteria should not be applied across the board; however, there are key considerations PEPFAR teams should take into account when prioritizing SNUs:

- Prioritize **across** SNUs to give precedence to high disease burden geographic areas nationally and to the highest performing partners and districts. Funding and targets should move to those areas that are successful and can do more and funding should be constricted in low performing areas until performance improves.
  Because the distribution of HIV within a population is driven by factors that cause it to be non-random, it is important to examine the epidemiologic data across geographic areas. A ranking of SNUs based on HIV prevalence, together with consideration of the population size, will enable country teams to identify highest priority areas for the provision of evidence-based combination prevention services (HTS, PMTCT, ART, VMMC, condoms, and other targeted prevention for key and priority populations).

- Prioritize within high-prevalence SNUs to focus resources on the highest prevalence areas, highest volume sites, and highest prevalence population groups at the local level, with the highest performing SNUs (see Figure 7.3.2.6). Note that definitions of high volume, highest prevalence and highest performing SNUs may differ by OU depending on the epidemiologic-, program- and performance- context. Identify sites with challenges in ART continuity and volume of clients that can be consolidated to high quality sites. This should begin immediately with the shifting of resources and targets.

Figure 7.3.2.6: Example map illustrating SNUs with potential to consolidate sites based on volume



- Once high-burden SNUs are identified, further analysis within those bounded areas may be needed to refine the geographic targeting, as new infections may not be distributed randomly or evenly throughout the SNU. Furthermore, teams are urged to focus not just on localized “hotspots” within SNUs, but to utilize the available data to identify the population groups shouldering the greatest burden of disease within those bounded areas. Data analyses should clarify whether key population groups (e.g., MSM, PWID, SW) or other population groups, such as 15–24-year-old girls and women, account for the largest attributable fraction of new infections and teams should target prevention and treatment resources accordingly. Other sources of data (e.g., program, ANC surveillance) may help to inform resource optimization in the absence of population-based epidemiologic estimates.

  Finally, if a hotspot area within a lower-prevalence, sustained SNU meets criteria for a micro-epidemic with a high volume of new infections, the SNU in which it is located should be categorized as a scale-up SNU but only the hotspot area(s) within the SNU receive scale-up targets. In these cases, the number of PLHIV in the hotspot is needed to estimate current and target coverage levels. Teams should explain the need for a unique focus on these micro-epidemics and detail plans to achieve 95% ART coverage at these sites and accelerated coverage of combination prevention in the hotspot(s) within the SNU.

- Ensure that gaps in treatment coverage are understood by age/sex to ensure SNUs with high rates of interruptions in treatment or low treatment program growth (and high PLHIV burden) are appropriately prioritized.
- Ensure that gaps in quality of client-centered services is understood to ensure SNUs and populations with high unmet need are appropriately prioritized.
- Ensure that **local partners** are funded accordingly
- Strive for **attained status and saturation** within prioritized SNUs

  To reach 95/95/95 at the country level, PEPFAR teams are urged to design programs using available population size estimates and set complementary prevention and treatment targets necessary to saturate geographic areas and key or priority population groups. Saturation is defined as achieving 95% coverage of prevention or treatment services in those population groups within SNUs needing them.
  Finally, if ART coverage has exceeded saturation in an SNU (defined as >95% ART coverage among both males and females of all ages living with HIV), that SNU should be designated as **attained** (and the relevant programs within that SNU). The aim then is to achieve saturation levels of ALL core interventions relevant to the populations within the SNU to curb HIV transmission and improve health outcomes for PLHIV. Even after achieving attained or saturation status, the SNU should remain a priority SNU and continue to scale other core interventions, as resources permit and as dictated by epidemiologic need.

In setting targets to accelerate epidemic control and in completing the relevant section in the SDS, team should keep several factors in mind:

- Targets for epidemic control are distinct and mutually exclusive of expected volume to sustain support in other locations and populations.

  In Section 4 of the SDS, PEPFAR teams will present targets across all scale-up SNUs. In many OUs, we expect PEPFAR resources dedicated to scale-up to shift to scale-up areas and interventions; however, PEPFAR teams will need to budget for continued support to existing ART and PMTCT patients and OVC beneficiaries in other locations and programs.
- Target timeframe should be framed by goals beyond implementation in COP22.

  In COP22 teams should identify the areas for saturation by FY 2023. This timeframe is intended to provide a near-term goal post for PEPFAR teams to guide decisions as they set targets to accelerate ART coverage in priority areas.

- Program costs and trade-offs should be taken into account when setting targets for priority locations and populations.

  In determining targets for ART, combination prevention activities, and OVC, teams should review and use COP21 expenditures against budget, as well as the information on what interventions were funded and what was purchased (objects of expenditure). If available, costing data may be used as well. The financial data should be used to allocate resources within the available funding envelope and entered in the FAST. Teams should also keep in mind that achieving targets in one technical program (e.g., the treatment cascade) has an impact on funding available to achieve targets in another technical area (e.g., prevention through VMMC). There is no specific guidance applicable to all PEPFAR OUs on the most appropriate percentage of funds to allocate to combination prevention and support activities; however, teams are expected to meet earmarks (see Section 5.9.1); consider any central funding that may be available to assist with achieving targets in specific technical areas, and consider the type and magnitude of support provided by the partner country government and other stakeholders. The goal is to achieve epidemic control in prioritized geographic areas and populations as quickly possible. The mix of combination prevention interventions will vary by epidemiological context; teams should use any data available to optimize these allocations.

In addition to setting targets for current on ART and ART enrollment (newly initiated) by SNU, PEPFAR teams should determine how they will meet the enrollment target proposed by entry stream for ART. At minimum, 4 entry streams should be considered:

- **Previously diagnosed and clinical care patients living with HIV infection**

  One efficient way to increase enrollment for ART programs is to initiate clinical care of patients living with HIV on ART, as is consistent with WHO treatment recommendations. This population should have been already initiated on treatment in the previous COP cycles in most countries, but any remaining previously diagnosed patients should be immediately initiated on ART.

- **TB-HIV patients**

  Teams should initiate ART in all confirmed and presumptive TB patients diagnosed with HIV. PEPFAR teams should estimate how many individuals currently receiving TB treatment at TB sites will receive HIV testing and be linked effectively to ART sites as newly initiating ART patients.

- **HIV-positive pregnant women and HIV-exposed infants**

  HIV-positive pregnant women receiving care through PMTCT sites will initiate or continue ART over the period. Teams should estimate the number of women newly initiated on ART through PMTCT programs as a key entry stream for new on ART enrollment targets. Early infant diagnosis (i.e., HIV testing by 8 weeks of age; EID) of HIV-exposed infants (HEI) is another important opportunity for case finding and pediatric ART initiation.

- **Other priority and key populations**

  Improve linkage to ART services for PLHIV diagnosed through existing HTS programs. Strategic testing of high-yield populations such as the partners of index clients are also important opportunities for case finding, linkage, and ART initiation. PEPFAR teams should be able to describe with data how many newly initiating ART patients can be expected from each of the entry streams above and determine PMTCT and HTS targets accordingly.

Prevention Programming, DREAMS and OVC Programming, and Above Site Programming

Setting Targets for VMMC in Priority Locations and Populations

Geographic areas and only age groups (15+) with higher levels of unmet need should be prioritized within the overall strategy, i.e., between SNUs of equivalent HIV burden, the SNU with lower circumcision prevalence should be prioritized (similar for age bands). SNU prioritization should use PHIA or other recent nationally representative survey data of MC coverage as its primary basis, where available.

Setting Targets for Prevention Interventions in Priority Locations and Populations

Once teams have identified key and priority populations in the selected SNUs, they should develop best-possible estimates of population size. Teams should then develop a basic package of interventions for each population based on existing guidance, and analysis from Step 2, and set coverage targets for each population based on an evidence-based hypothesis about the levels of coverage necessary to achieve population-wide reductions in incidence. Key and priority populations should align with HTS, as appropriate. Remember the expectation is that key population prevention strategies will include testing or referral to testing as part of basic package; see Section 6.5.1 for further details on prevention packages for key populations.

For DREAMS SNUs, DREAMS services for adolescent girls and young women (AGYW), their families, and their communities should be taken into consideration for all target-setting, including

HTS_TST, PP_PREV, KP_PREV, PREP_NEW, and PREP_CT. Countries should strive to provide at least the primary package of interventions to 90% of active DREAMS recipients for each DREAMS age band (10-14, 15-19, and 20-24).

Setting Targets for OVC

Based on a comparison of current PEPFAR OVC coverage and estimates of the OVC population and inputs such as situational analyses, PEPFAR teams should use the analysis from Steps 1 and 2 to select locations and populations for program focus; and using the definitions provided in the MER 2.6 indicator reference sheets, set targets for OVC_SERV in the DataPack. Teams should note the data sources used and assumptions made. Importantly, all households with HIV and with children need a full OVC assessment.

The OVC program (as described in Section 6.6.3) has three components – 1) comprehensive, 2) Preventive, and 3) DREAMS. While setting OVC targets for the comprehensive component, teams should focus on OVC ages 0-17 years, with particular focus on children and adolescents living with HIV who require socioeconomic support, offering OVC program enrollment to at least 90% of children and adolescents (<18 years) living with HIV (TX_CURR<15 and <20, to cover OVC_HIVSTAT_POS<18) in PEPFAR supported treatment sites in high volume clinics within high burden SNUs. Additional subpopulations of focus within the OVC comprehensive program include children of KPs (especially children of FSW living with HIV), children whose parents are living with HIV, children orphaned by AIDS, HIV exposed infants whose mothers are at risk of not returning for timely EID and other key PMTCT benchmarks and child survivors of sexual violence (see Section 6.6.3). The OVC preventive program component targets 10–14-year-old girls and boys in high prevalence areas in regard to primary prevention of sexual violence and HIV (see Section 6.2.3). Through the third component OVC programs should collaborate and co-plan with DREAMS to address the prevention needs of adolescent girls 10-17 years in high HIV burden areas. Adolescent girls should be prioritized as they bear a disproportionate risk for HIV acquisition compared to their male peers. Where DREAMS and OVC overlap in SNUs, DREAMS and OVC teams and implementing partners should co-plan and set targets together to maximize efficiencies and ensure that the needs of the most vulnerable adolescent girls are met. Likewise, OVC teams should work with pediatric, PMTCT, and KP colleagues to ensure coordinated planning that results in greater support to children and adolescents living with HIV and HIV-exposed infants.

7.3.3 Person-Centered Supply Chain Plans

To conduct an accurate and complete forecasting, teams should include considerations that address: patient months of treatment, multi-month dispensing, buffer stock, expiry, warehousing and distribution chain, lead time for delivery to country and delivery to point of service, stock-outs, and influence on the ART supply chain. Additionally, country teams should confirm whether their country or region is eligible for subsidized procurement of ARVs for PrEP to potentially reduce procurement costs. Teams should consult commodities experts at USAID HQ for any technical assistance needed with commodity forecasting, confirming whether their country is eligible for subsidized ARV procurement, or any other PrEP commodities-related questions.

COVID-19 has negatively impacted supply chains globally causing shortages in active pharmaceutical ingredients and key manufacturing materials, and decreased shipping resources. Social distancing restrictions and lockdowns have delayed movement of commodities at ports of exit and ports of entry. Although many of these restrictions have eased, it can be anticipated that many of these barriers to logistical movement will remain in effect into COP22.

Countries should incorporate into their supply planning, mitigating strategies that address order staggering to prevent delivery delays, substituting products/formulations where necessary, and budgetary considerations as a result of increased costs for freight and shipping. Decentralized distribution approaches such as home deliveries, use of community or private pharmacies, or increasing pharmacy in a box or automated lockers should be scaled up utilizing appropriate sanitation procedures to protect against the transmission of infectious diseases. Countries should continue to scale-up programs for 6-month MMD for adults and a minimum of 3-month MMD for children. The logistics of MMD 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. A monitoring and evaluation system and data management systems should be in place to track these patients and oversee inventory management.

Updating the commodities planning tool and the FAST Commodities Tab E will continue to be required on a semiannual basis. However, updating the in-country supply plan should occur more regularly, at a minimum quarterly, but ideally monthly. A submission of an OPU may be required to address any budgeting increases for commodity procurement or reallocation of

excess funds within the commodities budget. The revised commodities supply planning tool, FAST commodities tab and an OPU submission will be required at the beginning of the FY Q3 period.

Country teams should continue to update national guidelines (to include TLD and optimized regimens for women and children living with HIV), ensure that the 18-month ARV supply plans are comprehensive and include the following:

- TLD transition should be complete
- Product registration
- Consideration for OU Minimum and Maximum stock levels (considering buffer stock)
- Stakeholder engagement
- Quantification, forecasting and supply planning
- Descriptions of facility level implementation, monitoring, and uptake
- Pediatric ARV optimization
- Scale-up of multi-month dispensing

7.3.4 PEPFAR-funded Surveys-Surveillance, Research, and Evaluation Activities

PEPFAR funds surveys-surveillance, research, and evaluation (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.

Surveys-surveillance activities are essential to understanding OU epidemics and assessing OU progress towards epidemic control. Bio-Behavioral Surveys and Population-Size Estimation activities are key activities for understanding and planning a responsive key population program. 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 improved understanding of current gaps in ARV coverage and viral suppression across geographic areas and population groups.

An ongoing challenge for program implementation is translation of efficacious interventions tested in controlled clinical trial settings to real-world contexts where personnel, financial, and other resources are more constrained. To address this challenge, PEPFAR primarily supports

two types of research—implementation science (IS) and operations research (OR)—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.

PEPFAR is committed to implementing robust program monitoring to track progress toward reaching epidemic control. However, certain more specific questions cannot be answered using routine data; PEPFAR-funded evaluation activities help to 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.

In COP22, S/GAC will lead a preliminary review and feedback process of all proposed surveys-surveillance, research, and evaluations (SRE) during the COP22 Strategic Planning Meetings. Section 8.4 of the COP2022 Guidance describes the SRE COP elements and submission process in greater detail.

7.3.5 Prioritize Activities in Table 6

Sustaining epidemic control is a key dimension of PEPFAR's business model. Ensuring sustained epidemic control means that PEPFAR teams, in-country stakeholders (e.g., government and civil society), and multilateral partners (e.g., UNAIDS, Global Fund) must align their investments to efficiently remove barriers to epidemic control and build capacity for countries to maintain HIV gains. With better coordination and accelerated impact with a focus on sustainability, PEPFAR can influence technical gains in-country and foster greater accountability, transparency, and use of evidence to accelerate progress toward epidemic control. For countries at the cusp of epidemic control, Table 6 is a necessary tool to plan for above-site investments and sustaining the gains made towards achieving epidemic control.

In COP22, efficient and effective systems investments continue to be an essential component of achieving PEPFAR's goals, including identification and remediation of key gaps in the clinical cascade and shifting the national policies necessary to achieve and sustain countries' 95/95/95 targets. Above-site investments may also be needed to address gaps in achieving Minimum Program Requirements, see Section 2.2. As part of COP22 SDS, field teams should describe

their strategy for attaining a steady state where PEPFAR's efforts to support and strengthen health systems lead to sustainable epidemic control. A mature, steady state is when the partner country health systems function effectively and efficiently with minimal donor support. Activities in Table 6 should be designed with the goal of reaching the steady state and the yearly benchmarks should show a clear pathway to monitor progress. To formulate the strategy, field teams should aggregate and analyze health systems investments using PEPFAR expenditure data for the Above-Site Programs (ASP) as available in PEPFAR Panorama over the last 3 years and describe achievements to date. The strategy toward a steady state should describe the rationale for continued investments in health systems and demonstrate the impact of these investments toward achieving sustainable epidemic control.

Complete the following before filling out your Table 6, based on your above analysis in Step 2.

- Determine the current programmatic needs and gaps that remain related to non-service delivery investments implemented above-site that are necessary to address program and system priorities and improve performance/achieve targeted outcomes using a variety of available data sources, including SID, MER, SIMS, DQAs, and other sources.
- Define needs based on strategic priorities vis-a-vis epidemic control priorities (95/95/95), systems gaps, and minimum requirements for PEPFAR programs
- Are top strategic priorities supported by systems investments (e.g., to ensure high quality client-centered services, program, and data)?
- Has COVID-19 further highlighted system strengths /weaknesses and changed priorities?
- Focus on gaps
- SID 2021 – Does SID 2021 highlight any gaps in sustainability that require above-site, non-service delivery investments?
- MER – Do program results indicate gaps in performance that require above-site investments?
- SIMS – Do SIMS assessment results indicate gaps in quality that require above-site investments?
- Other sources – Are there other sources (e.g., Global Fund Key Performance Indicators, other third-party or contextual indicators relevant to key aspects of the enabling environment affecting sustainability) that indicate gaps in above-site, non-service delivery investments?

- Are above-site barriers addressed and activities aligned to address barriers to epidemic control and improve site-level performance? How is the progress measured?
- How has COVID-19 impacted implementation of above-site investments? Do adjustments need to be made to strategic priorities in order to maintain accomplishments/gains in health systems?
- For countries that are close to achieving epidemic control, what above-site investments are required to sustain the gains and enable transition of PEPFAR's functional responsibility to the partner country?
- Teams should review expenditures and budgets against the Table 6 activities.
- What can discrepancies between budgets and expenditures reveal about the appropriateness and accuracy of above-site intervention budgets? Are they too high or too low to achieve benchmarks?
- Is the funding for above-site investments aligned to the gaps identified? Are high priority gaps receiving sufficient funding? Low priority activities should have declining funding or funding should be reallocated to higher priority activities.
- What is the change in relevant MER indicators that can be attributed to respective Table 6 activities?
- For activities that have achieved COP21 benchmarks, what is the rationale for continuing in COP22? How many additional years of support is needed?
- For activities that have partially achieved COP21 benchmarks and continuing in COP22, what is the course correction?
- For activities that are not initiated or have not achieved any of the COP21 benchmarks and continuing into COP22, what is the rationale for continuation?

7.3.6 Review and Revise Resource Alignment Table

The Resource Alignment collaboration between PEPFAR and the Global Fund has enabled routine availability of budget allocation and expenditure data across PEPFAR, Global Fund, Domestic Government and Other Funders where available to get a more granular understanding of the complete HIV funding landscape across countries. This information is key to efforts to make strategically aligned resource allocation decisions; avoid duplication; drive efficiencies; improve cost analysis, resource need estimations, and resource mobilization; advance greater domestic responsibility; and ensure a financially sustainable HIV response.

- The Resource Alignment collaboration has allowed for PEPFAR and the Global Fund financial data to be harmonized and validated at the headquarters level. However, domestic government and other funders data are less widely available and need to be verified and updated where necessary during the COP planning process.
- Each country team will receive a pre-populated resource alignment data verification table that will include domestic government and other funders HIV funding data as currently available from PEPFAR and the Global Fund data sources.
- Country teams will share the resource alignment data verification table with their partner country government counterparts and other stakeholders as needed with a request to verify and/or update data for domestic government and other funders (i.e., non-PEPFAR and non-Global Fund) HIV investments.
- Country teams do not need to verify PEPFAR and Global Fund data since this will be harmonized and validated at the headquarters level to populate the Resource Alignment country profiles.
- Country teams will send the completed resource alignment data verification tables to their Chair and PPMs with a copy marked to SGAC_Sustainability@state.gov preferably prior to their COP strategic planning retreats.
- Once these tables are received from the country teams, updated Resource Alignment country profiles reflecting HIV investments across PEPFAR, the Global Fund, domestic government, and other funders where applicable will be available to country teams for COP planning. These Resource Alignment country profiles are intended to facilitate a collaborative planning process, allow a fuller understanding of the totality of HIV investments in the country, and inform guided discussions around strategic alignment of investments across entities.
- The Resource Alignment country profiles will also make pre-populated “Investment Profile” tables available to country teams to include in their strategic direction summary (SDS).

7.4 Planning Step 4: Interrogate, Adjust, Examine, and Align Notional Budgets and Country-devised Targets with the Strategic Direction

The purpose of this step is to interrogate, adjust, examine, and ultimately align the initial budget, systems investments, and targets with the strategic direction for the OU, as reached by consensus during PEPFAR team and stakeholder discussions. This alignment must also consider supply planning and forecasting for the OU, for all key HIV commodities, even if the procurement is not using PEPFAR funding. Moreover, OUs should query the supply plan to determine if there is a forecasted gap for any product and make that gap clear to the entire PEPFAR team to enable PEPFAR to advocate for assistance from other donors.

Aligning the budgets and targets with the strategic direction is an iterative process beginning in mid-January and finalized in April. The overarching questions country teams must consider are:

- Will the planned strategic objectives (interventions) and their budgets result in planned targets? OUs must show how this will be different than FY22 and what improvements are being done in FY23.
- Did planned budgets and targets shift based on partner performance?
- Is the program reflective of funding adjustments to improve efficiency of program implementation?
- Are the planned targets, activities, and budgets in line with the identified strategic direction?
- Will the planned activities address barriers to achieving epidemic control?
- Is most of the work (defined by interventions) in the budget going toward the strategic direction from Step 2 or is there planned work that does not seem to correspond to the current strategic direction?
- Does the budget make the best use of available funds to pursue the OU's strategic plan?

With the budget, above-site and systems investment and targets in place, a qualitative analysis of the types of strategic objectives and solutions that were deemed appropriate for the country may identify gaps. If certain elements of the strategic approach are underfunded in the budget, teams must examine where funds can be redirected. If existing interventions correspond to an outdated strategic approach, funds must be redirected to objectives that align with COP22

strategic objectives. Teams must quantify the total funding in the budget that align with identified interventions and understand whether budget reflects overall strategic approach.

By the end of Planning Step 4, teams should have:

- Preliminary budgets and targets that are aligned with the proposed strategic plan
- A balanced, completed FAST budget that meets earmarks
- A completed DataPack
- A completed supply planning tool
- A completed Table 6 and SRE Tool
- All documentation required for the COP21 Meeting

The outcome of this incremental budgeting, targeting, and strategic alignment process will be updated to reflect targets and a budget that align with the COP22 strategic direction for the OU.

7.4.1 Recommended Process for Establishing and Entering Targets

A flowchart for PEPFAR's process for establishing and entering targets is below.

Figure 7.4.1.1: PEPFAR's process for establishing and entering targets

Implementing mechanism targets are produced in the DataPack. See DataPack User's Guide for detailed instructions**.** Where more than one partner may reach the same individuals at a

given site, country teams should take the opportunity to rationalize partners for increased efficiency.

7.4.2 Supply Chain Data Availability, Visibility and Use

PEPFAR and countries are facing new realities in the planning, managing, and monitoring of supply chains globally. Given the size and scope of the supply chain program and the commodities budget, PEPFAR expects more granular-level reporting of commodities data in pursuit of PEPFAR's 95/95/95 goals to ensure effective use of funding for commodities procurement. Facility level partners will be asked to report on the quantities of ARVs dispensed as well as the quantity of stock available on the shelf at the end of the reporting period. These data should be routinely reported through the Logistics Management Information System (LMIS) as well, which could be a data source for data submission.

Countries are tasked to improve the management of HIV product inventory, optimize the global TLD transition, manage country-specific multi-month dispensing (MMD) implementation, and facilitate a triangulation between clinical and stock level data at site level to ensure that national programs fully optimize cost effective ARV regimens. In order to achieve this goal, it is necessary to increase PEPFAR's visibility into the availability of HIV commodities across all levels (and stakeholders) of the supply chain (i.e., central, regional [sub-national], and site [facility] level), hence the supply chain MER indicators (SC_CURR and SC_ARVDISP). Additionally, visibility should be extended to current orders and plan for when deliveries of ARVs will arrive in-country, across all donors (PEPFAR, Global Fund, etc.) and procurement by the partner-country government.

Countries will meet the supply chain data visibility goal through the use of several tools:

- The Procurement Planning & Monitoring Report (PPMR-HIV) will capture data input by MOH or a designated Partner(s) in each country for central and sub-national level stock and anticipated shipment data (contact GHSC-PSM to start reporting) including, but not limited to, ARV, HIV RTK, and TPT commodities.
- The site-level data will be captured through an existing LMIS/eLMIS or by a designated facility staff member or a PEPFAR Partner already providing oversight at the facility in a standardized data collection tool: SC-FACT (Supply Chain – Facility-level AIDS Commodity Tracking).
- Commodity forecasts as they exist either in Excel, PipeLine, the Quantification Analytic

Tool (the QAT) or another software.

- MER metrics on stock availability at the end of the reporting period (SC_CURR) and ARVs dispensed during the reporting period (SC_ARVDISP).
- USAID will expand coordination efforts with the Global Fund (GF) to include GF commodities orders and shipment data to improve visibility and predictions of in-country stock levels.

There are currently 23 PEPFAR supported countries reporting into the PPMR-HIV for national and sub-national levels. Each country team must allot time and resources to do monthly monitoring of data collection and analysis for use in programmatic decision-making. These data must be openly shared to ensure they can be integrated into supply plans, and, through collaboration, any stock risk can be mitigated

Countries that are not currently reporting need to follow the several steps to begin the data collection process:

- Contact your HIV supply chain country backstop to start the process and for first contact with the PPMR-HIV Administrator
- Work with the PPMR-HIV Administrator to identify the country data sources for the commodity data (e.g., eLMIS, PipeLine, WMS) and the data owners.
- Share the PPMR-HIV Data Use Agreement with the data owners, obtaining consent from data owners where necessary
- Determine list of reporting locations (central, sub-national, facility)
- Develop list of products to be reported
- Begin data collection

Prior to the COP22 meetings, countries should understand their current commodity data collection status. After understanding the country data collection status, activities and corresponding budgets must be included in COP22 plans to initiate and continue commodity data collection as soon as possible with data collection at the national/sub-national level an immediate need and data collection at the facility level as a primary objective. Where possible, countries should proceed with discussions on formal data usage agreements now with country stakeholders including MOH officials and other donors to understand if any additional activities will be necessary to ease country concerns over data use and secure data storage that are an underlying foundation of this initiative.

While the need for data collection is immediate, plans should consider that the desired longer-term results are sustainable order and inventory management data collection mechanisms that make use of best practices in data management and data standardization. The following principles should be considered in planning for data collection in the medium and long-term:

- Promote sustainable data collection through implementation and maintenance of eLMIS solutions.
- Promote end-to-end visibility using global standards such as GS1 Healthcare standards for product names and labels. Work with local regulatory authorities to adopt the GS1 healthcare standard.
- Promote master data management. Most immediately, action the harmonization and regular updates of Master Product Lists and Master Facility Lists. The lists should also be harmonized with global programs (PEPFAR's Master Facility list and the MOH Master Facility List) to ensure consistency between the lists.
- Promote data quality through data usage not only by USG and Partner staff, but by MOH and facility staff as well.
- Reach out to USAID/W backstops as often as needed to help guide the adoption and usage of supply chain data standards.

Commodity data collection plans should be prepared and submitted at the COP22 Meeting and should include budget considerations.

7.5 Planning Step 5: Finalize SNU and IM Targets and Budgets

The FAST and DataPack must be completed and balanced to the planning level at the start of the COP22 Meeting.

Step 5 is to complete the COP22 Meeting with agreement on:

- IM level targets by PSNU
- IM level systems investments
- IM level budgets by intervention

No changes to IM by SNU targets, IM level systems investments and IM level budgets by strategic objectives should take place after the COP22 Planning Meetings.

As in COP21, S/GAC will import COP matrix IM-level budget fields (new funding source, applied pipeline amounts, new funding by cross-cutting attribute) at the end of the COP22 Planning Meeting.

7.6 Planning Step 6: Finalize and Submit COP

To finalize COP22, country teams must finalize the budget, targets, SDS, and all supplemental materials in advance of the COP22 approval meetings.

To complete the COP submission:

- Final FAST with budget balanced to planning levels, required applied pipeline, and mandatory earmarks
- Confirm the final budget in FACTS Info following COP approval and sign-off. Further information on FACTS Info entry is provided in Section 8 of this guidance and the FACTS Info User Guide
- Finalize and submit age and sex disaggregated indicator targets by PSNU and IM via the DataPack into DATIM
- Submit the SDS and supplemental documents

7.6.1 Develop Annual Work Plans and Targets

Keeping to the COP22 Meeting agreements (budgets by intervention and targets by IM by PSNU), implementing partners are asked to establish and submit detailed annual financial and activity work plans and targets. These work plans should correspond to the following items:

- OU strategic plan as articulated in the COP22 SDS
- Approved FAST
- Approved Table 6 / SRE Tool
- Approved targets in DATIM
- Agency contracts and cooperative agreements

8.0 COP ELEMENTS

8.1 Chief of Mission Letter

As in past COP/ROP cycles, PEPFAR teams are required to demonstrate Chief of Mission (COM) concurrence with their COP or ROP submission in a letter from the Chief of Mission[762] to the Ambassador-At-Large and Coordinator of U.S. Government Activities to Combat HIV/AIDS and U.S. Special Representative for Global Health Diplomacy. For Regional Programs, your Chair and PPM will confirm if COM letters are required for each country in the program, or if there will be 1-2 consolidated letters to submit with your ROP.

The purpose of the letter is to summarize progress, obstacles, and policy changes, as well as to concur with the objectives of the COP22. The COM letter is a place to articulate significant contextual factors in the OU that influence the PEPFAR program, including the impact of such factors and the team's plan to address them.

8.2 Strategic Direction Summary (SDS)

The SDS describes the strategic plan for the coming year, concentrating on changes between the current and future plans, as well as on the monitoring framework that will be used to measure progress. The SDS is submitted in FACTS Info as a supplemental document. A template for the COP22 SDS is available to ensure OU teams develop a comprehensive document that addresses all relevant topics. Descriptions in the SDS should focus on obstacles to implementation and plans to address those obstacles. The SDS must also contain the corrective actions currently being implemented to address the issues identified in the planning level letter and discuss how this will be corrected moving forward in COP22.

PEPFAR teams should use the guiding questions and adhere to the required tables and figures in the SDS templates to successfully meet this COP22 requirement.

The SDS template may be downloaded on the PEPFAR SharePoint COP22 website.

[762] Ambassador, Chargé, or Deputy Chief of Mission

Note: The COP22 SDS is a public document, to be shared with stakeholders during development and prior to submission and published on www.state.gov/pepfar upon approval. All data tables, graphics, figures, and language contained in the SDS should be drafted with this knowledge.

If sensitive information must be included in the SDS to provide for robust planning and discussion, it will be reviewed collaboratively with HQ and field teams to identify any sensitivity prior to being distributed outside of PEPFAR implementing agencies/partners and released into the public domain. Elements that may be useful for internal program planning, but not yet cleared by external owners (e.g., unpublished data provided by partner country governments) will be redacted if approval is not granted. Data that are likely to put certain populations at risk if published (e.g., geographic data on KP) will also be redacted.

NEW for COP22: SDS Appendix E: Assessing Progress towards Sustainable Control of the HIV/AIDS Epidemic

During COP22 planning, country teams will provide a brief (no more than 3-page) narrative addressing key sustainability questions to be included as an appendix to the SDS. This narrative will give some initial insights into where there may be potential opportunities to increase domestic responsibility of the HIV response and actions that can be taken during the next COP implementation year (FY2023) as part of a broader, long-term approach to achieving sustainable control of the HIV/AIDS epidemic. This narrative will specifically provide detailed answers to the following questions:

- Are there misalignments or gaps between investments in program areas required for a sustainable response and related outcomes?
- Are there elements that would be relatively easy and straightforward for the partner country government and/or local partners to take on greater responsibility?
- How will country teams begin engaging with the partner government during COP22 implementation to ensure sustainability of core elements of the HIV response?

8.3 Funding Allocation to Strategy Tool (FAST)

The COP22 FAST is a refinement of the COP21 tool, with no major changes either in the structure of the tool or in the data that is collected. Budget codes were retired in COP20 and will not be collected in the COP22 FAST, just as they were not collected in the COP21 FAST. The COP22 FAST will continue to take an incremental approach to budgeting and will be structured to

assist OU teams in reviewing, understanding, and aligning the budget to the country's strategic direction. Incremental budgeting in the COP22 FAST will leverage prior year COP budgets, expenditures, and work plan budgets, with teams using the COP22 tool to make incremental adjustments to the most appropriate baseline set of data from those three data streams. When determining implementing mechanism (IM) budgets in the COP22 FAST, adjustments up or down to the programmatic work that is funded will be determined through analysis of 1) actual and projected spending levels as provided by the implementing partners (expenditures and work plan budgets), 2) partner performance (target achievement, trends comparative analysis and other performance indicators), 3) changes to scope of work as determined in strategic planning discussions, and 4) other relevant analyses. Budgeting will continue to take place at the intervention and initiative level, as it has since COP19.

IMs implementing similar interventions and similar target volumes may have similar budgets, while IMs that cover all or most aspects of service delivery may have a very different budget from IMs that only partially support the service provision or are supporting non-service delivery interventions, even if the targets are similar. The IM-level interventions budgeted in the FAST should be reflected in implementing partner work plans, so that the link from OU COP22 planning to implementing partner management is clear. IM-level budgets, commodities, and cross-cutting attributes, as well as agency cost of doing business will be imported into FACTS Info from the FAST, and IM-level interventions will be used to monitor whether work plans are aligned to the approved COP.

8.4 Table 6 and Surveys-Surveillance, Research and Evaluation (SRE) Tool Excel Workbook

During COP22 planning, country teams will complete **Table 6** and the **SRE Tool**, a single Excel workbook describing activities for above-site programs, including surveys-surveillance, research, and evaluations (SRE). Tables from the workbook should be populated using interventions copied from the FAST, as per Section 7 of the COP guidance, and attached to the completed SDS as SDS Appendix C. S/GAC will preliminarily review Table 6 and the SRE Tool during the COP22 Strategic Planning Meeting and will provide a final review at the COP22 Approval Meeting. Prior to COP22 Meetings, Table 6 must also be disseminated to in-country CSOs and CSO COP22 Meeting participants.

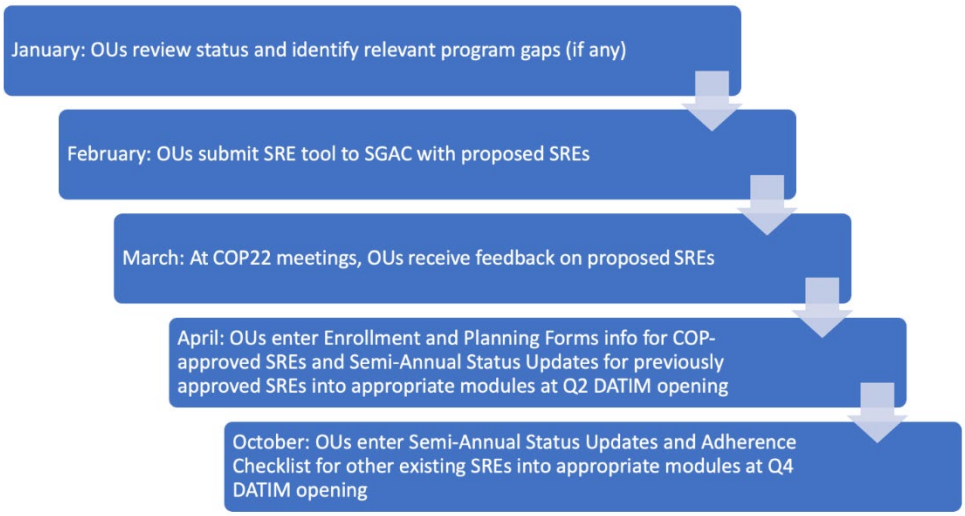
Table 6 should draw on the results of SID 2021 and previous year's performance as described in Section 7 . Proposals should also focus on addressing priority data and evidence gaps needed to guide program direction, quality and outcomes choosing in the most effective and efficient approach/methodology. Timeline, proposed budget, benchmarks, for the proposed activities will need to be detailed. This information will be used at the COP22 meetings to provide a view of countries' past ASP and assist in determining ASP for COP22.

The SRE Tool should draw on Table 6 and the previous year's SRE planning. Teams should use the tool to propose new SRE activities—defined and described in the sections that follow—and provide updates on ongoing activities. All proposed, newly commencing, ongoing, completed, not implemented, and discontinued SRE activities that are partially or fully COP- and TOM-funded must be submitted in the COP and approved by S/GAC prior to planning or funding. Information provided in the SRE Tool will be used at the COP22 Meetings to provide a view of countries' past SRE activities and assist in determining SRE activities needed for COP22.

As of the COP19 cycle, there are no longer centrally funded SRE activities with the exception of Population-Based HIV Impact Assessments (PHIAs). Research activities funded in COPs prior to COP18 that have not been executed will be canceled and monies reprogrammed.

Table 6 and the SRE Tool Excel workbook can be downloaded from the COP22 site on PEPFAR SharePoint. Teams should also consult the user guide for Table 6/SRE Tool in developing country-specific outcomes and annual benchmarks and proposing new SRE activities.

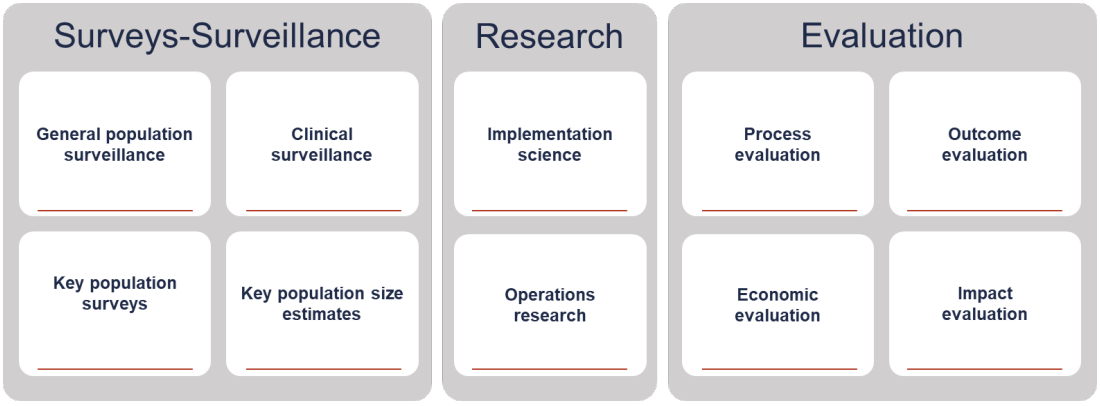
Figure 8.4.1: SRE process and timeline for COP22



Surveys-Surveillance, Research and Evaluation Activities

The following sections define and discuss PEPFAR-funded SRE activities, illustrated in Figure 8.4.2.

Figure 8.4.2: Examples of SRE activities



Surveys-Surveillance Activities

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.[763] Within the context of PEPFAR, surveys differ from surveillance only in that they are performed at one time point whereas surveillance involves ongoing monitoring over time.

PEPFAR supports four types of surveys-surveillance activities, each of which should be included in the COP22 SRE tool:

(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.

[763] Klaucke, et al. (1988) *Guidelines for Evaluating Surveillance Systems.* MMWR. 37(S-5);1-18 . https://www.cdc.gov/mmwr/preview/mmwrhtml/00001769.htm

Country teams should note that while PHIAs must be recorded in the SRE Tool, budget amounts for these activities should not. Moreover, 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 (Phase 1) 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 PLHIV over time. Implementation and scale-up (Phase 2) 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 COP22 approval meeting, country teams must describe and present the complementary or unique activities for case surveillance from routine EMR or HIS activities.

Research Activities

PEPFAR defines ***research*** as a systematic, intensive study intended to increase knowledge or understanding of the studied subject, applying new knowledge to meet a recognized need; or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.[764]

PEPFAR *primarily* supports two types of research:

(1) Implementation science—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 healthcare professionals and organizational behavior
(2) Operations research—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.

Research activities, regardless of type, should be submitted in the SRE Tool. However, routine monitoring of clinical and service outcomes should not be included in the SRE Tool as research.

[764] National Institutes of Health (2011) NIH Grants Policy Statement . https://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch1.htm

This includes cohort studies, barring those that have been previously approved or that are funded for enhanced data collection, which should both be included in the SRE Tool. Instead, most cohort studies should be approached as part of routine program implementation.

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.

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 (see PEPFAR Evaluation Standards of Practice 3.1).[765]

PEPFAR supports four types of evaluation activities: process, outcome, impact, economic. Full definitions of these evaluation types can be found in the Evaluation Standards of Practice (ESoP) Version 3.1 (available on DATIM Support). All PEPFAR-funded evaluation activities should be included in the COP22 SRE Tool. An implementing partner cooperative agreement (CoAg) level evaluations are small-scale evaluation study attached to a specific CoAg or contract of which the overall goal is to examine implementation fidelity and/or effectiveness of a specific intervention or activity under a CoAg/contact or of the entire CoAg/contract. CoAg level evaluations are included in the SRE tool however they are funded by a CoAg or contract under an implementing mechanism and not budgeted for in the SRE tool.

Evaluation requirements for COP22 are linked directly to the ESoP. The ESoP contains 11 standards to which all PEPFAR evaluations must adhere. The goal of the ESoP is 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,

[765] Foreign Aid Transparency and Accountability Act (2016) . https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf

to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. PEPFAR ensures compliance with FATAA through alignment of 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, impact evaluations (as defined in the OMB circular) are often not operationally, financially, or ethically practical since they require a counterfactual. 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 supports the use of these data for program evaluation. 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 inappropriate or 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 population-based HIV impact assessments to assess innovations and adaptations and to measure outcomes and impacts of PEPFAR-supported programs.
- COP/ROP planning, however, serves as the process through which OUs can propose pilot programs or interventions and an associated impact evaluation 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.
- 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 phase of COP/ROP planning.

8.5 Commodities Supply Planning Tool

The PEPFAR Commodities Supply Planning Tool will be required to be completed by all OU teams. This requirement is essential to ensure where PEPFAR is scaling services that related commodities are available. PEPFAR Coordinators should share this tool with their respective Ministry of Health and PEPFAR commodities planners. This tool, including the commodity gap analysis tool (part of the SPT) should be completed with visibility and information on all commodities, regardless of whether purchased or planned to be purchased by PEPFAR (i.e., it needs to consider commodities sourced by the partner-country government, the Global Fund, or other entities). Planning for COP22 logistical requirements must include participation and collaboration from the testing, PrEP, and Adult and Pediatric Care and Treatment teams, as well as Key Populations Investment Fund communities, to ensure that their commodity requirements are captured in the supply planning tool and budget considerations.

The Commodities Supply Planning Tool is an excel-based, interactive tool that enables countries to project the next 27 months of all commodities procured for the country's HIV epidemic response. The tool will require countries to report current stock on-hand, planned shipments, and needed shipments of ARVs, condoms and lubricant, laboratory products, rapid test kit, TB commodities, and VMMC products. The tool will populate forecasted inventory through the projection of orders and consumption of these products regardless of procurement agent (USAID, CDC, Global Fund, Country government, etc.) with a goal to avoid under- or overstocks of any product. The tool will also require countries to enter data regarding new commodities that will be introduced and used for HIV/AIDS, PrEP, and KPIF programs, such as: larger pack sizes for ARVs to promote multi-month dispensing, or new product introductions like the Dapivirine Vaginal Ring, or pediatric dolutegravir. New in COP22, the tool will also enable greater integration with PEPFAR program targets and will allow teams to identify commodities

gaps that are anticipated for COP22 so stakeholders can collectively determine how to close those funding gaps.

The Commodities Supply Planning Tool underwent numerous changes in COP21 that facilitate its completion and will carry through into COP22. The tool allows for the auto-population of supply plan data from Pipeline and enables a country supply team to request the inclusion of additional commodities in the drop-down lists built into the tool if they are not currently listed. Manual population is also available for countries that do not use pipeline. A user guide will also be available along with the tool on PEPFAR SharePoint. Members from USAID/SCH and S/GAC will be available to aid and support to countries completing this tool.

The Commodities Supply Planning Tool should be completed before completing the FAST commodities tabs. Upon completion of the Commodities Supply Planning Tool, the information contained within the tool should be transferred to the FAST Commodities-P Tab, and then supplemental information should be provided in the FAST Commodities-E Tab. These documents should be aligned to available budget, planned targets for the OU, and strategic directions for the COP22 implementation period. Moreover, the visualizations produced by the SPT and the Gap Analysis tool should be included in any COP Commodity discussions to identify risks and ensure that all stakeholders are aware of those commodity risks.

8.6 DataPack

The DataPack has been provided to OU teams in Microsoft Excel format and is intended to be a template and analysis tool to assist PEPFAR field teams meet the requirements for successful target-setting in COP22. The DataPack will assist reviewers in understanding the data analysis completed by the OU teams and limit the need for extensive verbal or written clarification around targets. The DataPack is submitted in FACTS Info as a supplemental document. Please note that the DataPack produces both SNU-level targets and IM level targets. Please consult the DataPack User's Guide for detailed guidance on how to use the DataPack and an overview of how to link the target-setting and budgeting processes. The ***DataPack*** can be downloaded from each OU's PEPFAR SharePoint HQ Collaboration page.

8.7 Resource Alignment

The Resource Alignment collaboration established in 2017 between PEPFAR and the Global Fund has enabled routine availability of budget allocation and expenditure data across

PEPFAR, Global Fund, Domestic Government and Other Funders where available to get a more granular understanding of the complete HIV funding landscape across countries. This information is key to efforts of the PEPFAR teams and its partners to make strategically aligned resource allocation decisions; avoid duplication; drive efficiencies, improve cost analysis resource needs estimations, and resource mobilization; advance greater domestic responsibility; and ensure a financially sustainable HIV response. HIV Resource Alignment country profiles will be available to country teams to inform strategic planning and coordination for sustained epidemic control, validating information where necessary, and for inclusion in their SDS investment profile section. More details are in Section 7.3.6.

Each country team will receive a pre-populated Resource Alignment data verification table. In close coordination with partner country counterparts and other stakeholders, PEPFAR country teams will verify and/or update domestic government and other funders data where available. Country teams will send the updated RA verification table to their S/GAC Chair and PPM with a copy marked to SGAC_Sustainability@state.gov preferably prior to their COP strategic planning retreats. This will enable generation of the Resource Alignment country profile which will be made available to country teams for their planning retreats. Country teams will not need to verify or validate PEPFAR and Global Fund data since this will be harmonized and validated at the headquarters-level for inclusion in the country profiles.

The Resource Alignment country profiles, with standardized format, transparent and rigorous methodology, harmonizing data across all funding sources--in particular PEPFAR and the Global Fund who represent a significant portion of the donor HIV contributions--will be an invaluable resource as country teams and stakeholders try to better understand the full funding landscape at a granular level, examine historical spending, and better align funding sources to make programs more efficient, impactful and sustainable.

Refer to Section 7.2.7 for guiding questions for PEPFAR country teams and key stakeholders to consider when reviewing the Resource Alignment country profiles and associated data.

Please contact the S/GAC Office of Financial and Programmatic Sustainability (OFPS) at SGAC_Sustainability@state.gov with any questions or request for support.

8.8 Implementing Mechanism Information

Please refer to the FAST User Guide on PEPFAR SharePoint for details on IM entry in FACTS Info.

As in COP21, placeholder new mechanisms were created for each implementing Agency in each of the OUs. These placeholder mechanism IDs will be included in the prepopulated COP22 tools and OU teams will assign the new mechanisms to placeholders as needed. Placeholder IMs may be TBDs, or the mechanism name and partner may already be known. These placeholder mechanism IDs are to facilitate the automated imports into FACTS Info and DATIM. Mechanism details should be entered into FACTS Info for all placeholder IMs that have any budget (new or applied pipeline) and/or targets for COP22.

If additional new mechanisms are needed beyond the allocated placeholders, this should be first created in FACTS Info and a new mechanism ID created prior to allocated budget or targets in the FAST or DataPack, respectively. Upon the creation of a new mechanism in FACTS Info, the "New Mechanism" tick box will be checked automatically.

Local Partners:

- Local partners, as defined in Section 2.4.6. have an essential role in establishing sustainable and efficient HIV prevention and treatment programs.
- It is expected that PEPFAR programs substantially increase the role of local partners in both direct service delivery and/or providing above-site or non-service delivery, site level support. Such local partners may include partner country government institutions, community organizations, including FBOs and local private sector.

Maximizing Efficiencies/Reducing Costs:

1) **To maximize efficiencies in administrative costs, countries should have no shared prime implementing partners with multiple agency agreements, including with partner governments.** If you feel that this is necessary in your country's context, you will be expected to submit a request for a waiver of this requirement through your PEPFAR Coordinator to the S/GAC OU Chair and PPM. Approval of this wavier must be granted by OGAC prior to pursuing or discussion an acquisition or assistance mechanism with the partner government.

2) To avoid duplication in program implementation by partner, agency, program area and geography, OU teams are not allowed to fund the same partners that are working in the same program area in the same facilities or geographic locale – independent of whether or not they are currently funded by one agency or different agencies. The following is allowed, however:

    - Different partners; same program area; same agency; different geographic locales

- Different partners; same program area; different agency; different geographic locales
- Different partners; different program area; different agency; same geographic locale
- Partners working in multiple geographic areas on technical assistance only

If an OU needs an exception to the allowed scenarios listed above, the OU will be expected to submit a request for a waiver of this requirement to the S/GAC OU Chair and PPM. Any waiver must be discussed in the interagency space, submitted by the PEPFAR Coordinator, and approved before the final COP approval.

8.8.1 Construction and Renovation

If funding is requested during COP planning for a construction or renovation project, the country team must fill out the form on FACTS Info. For instructions, please refer to the Quick Reference Guides (in the menu on the top left of FACTS Info), “How to Create and Edit a Construction Renovation Record.” All fields on the Construction/Renovation Project Plan form must be completed. All projects, regardless of amount, need to be submitted for approval. Cross-cutting attributions for construction and renovation for each IM should match the total of all IM project plans. For laboratory construction or renovation projects, supplemental information is required on biosafety level (BSL)-3 and BSL-2 enhanced. This information must also be entered into the form on FACTS Info.

8.8.2 Motor Vehicles, Including All Transport Vehicles

If funding is requested during COP planning for leasing or purchasing motor vehicles, the country team must fill out the form on FACTS Info. For instructions, please refer to the Quick Reference Guides (in the menu on the top left of FACTS Info), “How to Create and Edit a Motor Vehicle Record.” Any vehicles that are being funded out of the applied pipeline should be listed as zero-funded.

8.8.3 Funding Sources / Accounts and Initiatives

As noted elsewhere, please ensure that you are coordinating as a U.S. government team in determining funding decisions and that all U.S. government HIV/AIDS funding is being programmed as an interagency OU team. Please also ensure that your programming is consistent with your budget controls to ensure a smooth submission.

New resources consist of funds that have not previously been transferred to agencies. New resources may consist of funds appropriated in FY2022 or prior fiscal years. OU teams will be provided with control levels for new resources, broken down by the year of appropriation. New resources may come with specific programmatic requirements, including the requirement that they be used for mandatory earmarks or other directives as indicated below, in the planning level letter, or as communicated by S/GAC.

COP22 Funding Sources

Funding sources and accounts for implementing mechanism records by IM for COP22 funding will be entered into FACTS Info and imported into the FAST. OU teams are encouraged to think about the new planned COP22 resources and available pipeline funding as one funding envelope for the mechanism. A strong COP submission will reflect a strategic application of pipeline and allocation of new funds.

For new COP22 funds, there are as many as three accounts (GHP-State, GHP-USAID, and GAP) available to OU teams for programming. FACTS Info will be programmed with the available budgets for these three accounts. Not all OUs will have all accounts available to them.

The GHP-USAID account is the account appropriated directly to USAID and is available for USAID activities only, not USAID/WCF. The GAP account is applicable for HHS/CDC activities only.

Note: Only GHP-State and GHP-USAID will count towards the earmarks (Care and Treatment, OVC, GBV, and Water). Applied pipeline, GAP, and central funding will not count towards earmarks unless otherwise indicated.

<u>Applied Pipeline Resources:</u> Applied Pipeline funding amounts are determined during the End Of Fiscal Year (EOFY) process at the agency level. They consist of amounts programmed for implementation which will not be outlaid during the originally expected time period. OU teams must enter the amount of "**Applied Pipeline Funding**," that each mechanism will utilize in COP22 in addition to new resources. All "Applied Pipeline Funding" may only be used to the extent consistent with applicable legal restrictions and procedures on the fiscal year funds at issue, including any relevant or required Congressional Notifications. This applied pipeline data will reflect the amount of PEPFAR pipeline funding, from all accounts, that will be applied to the mechanism for COP22 implementation. The FAST will auto-sum the applied pipeline with the new COP22 funding requested, by funding account, to indicate the total funding (new + applied pipeline) allocated to each mechanism.

In COP22, the applied pipeline for each agency will be programmed in FACTS Info. OU Teams will not be able to submit their COP unless the total programmed applied pipeline is equal to the applied pipeline amount included in the country planning level letter and included as the budget control in the FACTS Info system.

Centrally-Funded Initiatives

All funding that is programmed to be outlaid during the period of COP implementation will be entered in FACTS Info from an import of the FAST. This includes bilateral COP22 funding, funding from the Working Capital Fund (for commodity procurement), and funding for any centrally funded initiatives. By capturing centrally funded initiatives in the FAST and FACTS Info, visibility of the totality of PEPFAR investment across implementing partners will be increased. The information required for a centrally-funded initiative or the Working Capital Fund is the same as for the main, bilaterally funded initiative –i.e., funding source allocation, intervention allocations, cross-cutting allocations, and construction and renovation and motor vehicles, as applicable.

Note: The FAST allows for budget to be entered for any initiatives currently opened for planning and with planned funding for the COP22 implementation period. The initiatives and benchmarks that are planned for COP22 may vary by OU and will be indicated in the planning levels. OUs may not plan funding to an initiative/benchmark not indicated for that OU.

Other Budget Technical Requirements

State ICASS and LNA costs may only be drawn from new GHP-State funding, not Applied Pipeline. State funding for ICASS and LNA should be designated to ‘State’, not regional bureaus (State/AF, etc.). State ICASS amount should be an exact match to the amount indicated in the PLL. LNA amounts should be broken out into three cost types: State LNA Staff Salaries and Benefits, State LNA Start-up/Recurring Costs, State LNA Other Misc. Benefits.

8.8.4 Government-to-Government (G2G) Partnerships

PEPFAR remains committed to supporting countries to sustain control of their HIV epidemics. Government-to-Government (G2G) partnerships are critical to advance the long-term success and sustainable implementation of comprehensive national HIV programs in the public sector in countries. As such, G2G partnerships, with a number of Ministries, including with Health, Finance, Education, Social Welfare, Youth and Sports, Gender, and others, are critical to ensure comprehensive HIV prevention and treatment programming (i.e., treatment, OVC,

DREAMS, etc.) is strengthened within the public sector to ensure its sustainability into the future.

The Department of State cable released 05 September 2012 by Secretary Clinton and AMB Goosby (MRN 12 STATE 90475) continues to be relevant and serves as the guidance document to be followed when establishing and executing new G2G Awards in COP22 and is posted on the COP22 site of PEPFAR SharePoint. We continue to encourage all agencies to enter into and utilize agreements with Ministries, as appropriate, and to expand and strengthen agreements with Ministries of Social Welfare, Women and Girls, Youth and Sports as well as Gender.

Direct G2G assistance includes **"Funding which is provided to a Host Government Ministry or Agency (including parastatal organizations and public health institutions) for the expenditure and disbursement of those funds by that government entity". Direct** G2G assistance can provide opportunities to improve coordination of PEPFAR programs with the national response, and it can also strengthen technical, management, and financial systems in the long term for sustained epidemic control. It can also pose unique challenges and risks that must be taken into account in the COP planning process, especially in cases of instability or conflict, or cases where there may be human rights concerns. USAID's G2G Risk Management and Implementation Guide,[766] which applies to USAID agreements, provides a good starting point when identifying and addressing vulnerabilities and threats that teams should consult as such direct G2G assistance is considered. Other agencies should review their own internal guidance for the formal G2G requirements applicable to their agency.

Pending the completion of the COP planning process, agencies with approved funding for G2G assistance mechanisms will provide S/GAC with the information necessary to notify funds for G2G assistance programming including amounts and recipients of such funds.

8.8.5 Public Private Partnerships

PEPFAR defines PPPs as collaborative endeavors that coordinate technical expertise and contributions from the public sector with expertise, skill sets, and contributions from the private sector to achieve epidemic control.

Global: Global PPPs are initiated and managed at the central (HQ) level. They may be funded on the U.S. government side by central funds, although they can also be funded through country

[766] https://www.usaid.gov/sites/default/files/documents/220sar.pdf

funds. These PPPs typically span multiple countries with multiple partners and overall coordination and strategy are set at the central (HQ) level.

Country-based: Country-based PPPs are initiated and managed at the country level. They are funded on the U.S. government side by the OU teams through the COP process. Countries are responsible for reporting on these programs in the COP and during regular reporting cycles. A PPP can be a program by itself, but it may also be added to an existing program or can be designed as part of a larger program to fill gaps as necessary. Beyond the development and launch of a partnership, it is essential to systematically document and provide timely information updates across all PPPs within the OUs portfolio. When reporting information please attempt to submit as much as possible even if incomplete.

For any of the above types of PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval. This includes conducting due diligence on prospective partners before an OU team forms or joins a partnership. For general information on U.S. Department of State policies regarding PPPs, see 2 FAM 970.[767] Other implementing agencies should also consult internally to ensure respective requirements are followed. As other interagency partners on the country team often work with the private sector, OUs should also meet with country Economic, Public Diplomacy, and Foreign Commercial Service Officers to find opportunities to expand and further leverage these partnerships to achieve PEPFAR goals.

OU teams should consider opportunities to leverage private sector expertise in topic areas such as supply chain, strategic marketing, market segmentation, communications, economic empowerment, digital health, and data analytics, among others, when exploring how the private sector can help increase the impact and efficiency of PEPFAR country programs.

Private Partnership Toolkit:

To help improve process development and knowledge management for PPPs, a Community of Practice Toolkit has been developed to identify, create, and strengthen PPPs. It is important to remember that an integral component of driving quality of partnerships within PEPFAR is through sharing of best practices.

[767] https://fam.state.gov/FAM/02FAM/02FAM0970.html

- OU Teams are encouraged to make use of the Public Private Partnership Toolkit[768] that was developed by S/GAC to assist PPP practitioners with engaging with the private sector, idea generation, formalization, management, and reporting of PPPs. The PPP toolkit, in coordination with targeted technical assistance, can support OU teams as they work through the various stages of PPP development process within their portfolios.
- For all PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval. Please contact the PSE team, as well as the State Department Office of Global Partnerships,[769] for additional information.

Idea Development	Formalization, Management, and Reporting	Additional Resources
1. Country Analysis Standard Operating Procedure	6. Due Diligence Guidance	14. PPP Webinar Series
2. Illustrative AGYW Landscape Analysis	7. Letter of Intent Template	15. Building Partnerships Best Practices
3. Illustrative Strategic Alignment Process and Framework	8. Memorandum of Understanding Template	16. Foreign Affairs Manual (FAM) – PPP (2 FAM 970) Guidance
4. Private Sector Meeting Preparation Guide	9. Partnership Press Release Example	17. Congressional Budget Justification for PPP Reporting
5. Illustrative Pitch Deck	10. Partnership Management & Oversight Example	18. Other Partnership Development Guidance Documents
	11. Illustrative PPP M&E Tool	
	12. PPP Reporting in FACTSInfo NextGen	
	13. Interagency PPP Funding Opportunities Guide	

In addition to the Community of Practice Toolkit the following key steps are recommended for developing PPPs and fostering meaningful private sector stakeholder engagement:

- Step 1 - Situational Gap Analysis: Use CAST processes and POART data to identify key programmatic and technical gaps ripe for partnership. Leverage data analytics platforms

768 https://pepfar.sharepoint.com/:f:/s/PSE/EqTWXDdmbyhGrIKqjvb4D5IBE41TwlgYR3AhHxdfjNNuEA?e=m2n3hX

769 https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/office-of-global-partnerships/

such as DATIM and Panorama to conduct analyses that assess performance (especially against targets) to identify the greatest gaps/needs/priorities within country programs.

- Step 2 - Private Sector Landscape Assessment: Conduct or review existing local and regional private stakeholder landscape analysis/assessment of companies and foundations likely to strategically align with the gaps identified. Assess key areas such as geographic priorities, technical priorities, business interests, and ease of outreach (i.e., are there existing relationships to leverage?); categorize private sector partners into tiers in terms of alignment with country program priorities. ***See Illustrative AGYW Landscape Analysis.***
- Step 3 - Approach and Convene: Approach private sector with the partnership opportunity and host convenings involving public, private, philanthropic, multilateral, civil society, and affected populations to advance partnership dialog. Ensure the most suitable/appropriate points of contact are chosen to engage – i.e., if the program needs strategic marketing expertise, ensure marketing contacts at private sector organizations are engaged. ***See sample PSE Meeting Preparation Guide***
- Step 4 – Conceptualize and Plan: Ensure dialogue occurs with a clear vision/goal of what PEPFAR is hoping to accomplish through the partnership, and what the value-add is that private sector can bring. In addition, be sure to articulate the benefits of engaging to the private sector (i.e., what's in it for them?). Develop a "pitch deck" that articulates these benefits of partnership with PEPFAR. ***See Illustrative Pitch Deck***
- Step 5 – Alignment and Formalization: Identify partnership goals and common objectives as the basis for a Memorandum of Understanding (MOU). Each partner should outline their respective roles and responsibilities to ensure accountability. This includes in-kind and/or financial commitments. It is also important to determine and articulate an appropriate governance structure to ensure accountability, improve decision making, and achieve stated goals and objectives. This structure may be in the form of an Advisory Council, Steering Committee, or independent entity and should be clear on decision-making processes and authorities. All elements should be clearly articulated in the MOU, although other formalization tools may also be used such as a Letter of Intent (LOI). ***See MOU & LOI template.***
- Step 6 - Approval: The Office of U.S. Global AIDS Coordinator and Health Diplomacy should be consulted on all such proposed PPPs (including any proposed MOUs and due

diligence requests of prospective partners) involving the Department of State to ensure appropriate State Department approval.

- Step 7 - Launch - Announce partnership through a press release and/or public signing to generate greater interest. Enhance the announcement through social media engagement.
- Step 8 - Implementation: Operationalize the partnership, generally through program implementation. Partnership oversight may include a committee comprised of partner representatives to discuss on-going partnership operations and management issues. This committee will convene quarterly or bi-annually to discuss reporting progress and to coordinate and strategize on partnership implementation. Note, this committee may be the same as or different than the aforementioned governance structure

Step 9 - Reporting: it is essential to identify key performance metrics, using MER indicators, if possible, to accurately track the results of the partnership activities against the goals of the PPP, and systematically document and provide timely information updates across all PPPs within the OUs portfolio through the COP and other reporting cycles. Various data analytics platforms can be used to measure progress including DATIM, and Panorama. ***See Illustrative PPP M&E Tool.***

9.0 COP PLANNING LEVELS AND APPLIED PIPELINE

9.1 COP22 Planning

Countries or regions should fund their program based on the COP22 planning level letter, finalizing the notional S/GAC provided budget to the level of in country ambition and final budgets and earmark requirements. COP22 should be planned to the stated level in the letter, which equals the sum of new resources (FY22 and prior fiscal year funds) and prior year available pipeline applied in support of COP22 activities. Final budget will depend on the targets the PEPFAR team submits, and any increased level of ambition submitted by countries or agencies, but all must be in the DataPack and FAST. The total notional budget in the planning letter represents a specific level of ambition and will not be final until the country submits targets. The pipeline available for implementation in COP22 has been provided by each of your agencies and validated by your agencies.

PEPFAR will continue to meet previously stipulated Congressional earmarks and fulfill the expectations around other key priority areas while S/GAC continues to communicate with Congress about their expectations and will make teams aware of any shifts for programmatic focus.

Earmarks for care and treatment and OVC can only be satisfied via programming of new resources and the amounts will be provided in the official planning letter. Other budgetary considerations can be satisfied through a combination of new and/or applied pipeline and will be stipulated in the official planning letter. The application of pipeline cannot be counted toward a team's fulfillment of earmark requirements, certain budgetary considerations and will be stipulated in the official planning letter.

9.1.1 COP Planning Levels

The COP22 planning level represents the total resources (regardless of whether they are new resources or prior-year pipeline resources) that a country or region plans to outlay during the 12-month COP22 implementation period in FY2023.

The COP planning level is the sum of new resources and pipeline applied to COP22 implementation (COP Planning Level = New Funding + Total Applied Pipeline). All outlays anticipated to occur during the COP22 implementation period must be included within the COP22 planning level. This includes outlays for all mechanisms: new, continuing, and closing.

Applied pipeline and new funding levels included within the planning level letter will be reflected in the FACTS Info system as each OU's budget control figures. A COP cannot be submitted if the total new and pipeline funds programmed are not equal to the budget control figures. Any changes to new funding or applied pipeline amounts must be requested by an OU Chair or PPM, approved by S/GAC M&B in consultation with the GAC, and updated in the FACTS Info system. COP submission in FACTS Info is not possible unless these updates are made at S/GAC headquarters.

If the total planning level exceeds the overall resource envelope required to achieve targets or is determined to be greater than a country or region's actual ability to outlay within a 12-month period, teams are encouraged to submit a final COP requesting a lower COP22 planning level, rather than creating TBDs and/or overfunding mechanisms, or stating a higher spend-rate than is feasible. A COP may not include any "unallocated" funds within the COP Planning Level.

OU teams must track quarterly and annual outlays by fiscal years and funding accounts to ensure PEPFAR funds are appropriately tracked and not overspent. Outlaying beyond the approved levels will be subtracted from agency resources to ensure only that agency is impacted, rather than the overarching PEPFAR country program. If partners underperform and outlay all of their funds, performance of that partner should be scrutinized to ensure that the outlays are explainable and justified given the specific context of the country and partner. Absent special considerations due to COVID-19 or certain fixed costs, underperforming partners are expected to under-outlay. The funding type field within COP22 is categorized as applied pipeline or new funding. The funding account categories are GHP-State, GHP-USAID, and GAP. The sum of these funding sources will equal the total resources expected to be outlaid by an individual mechanism (or CODB category) over the 12-month COP22 implementation period. When all mechanism funding sources and all M&O funding sources are added together, this total is equal to the requested outlay level for COP22, i.e., to the COP22 planning level. Applied pipeline will be tracked in both the FAST and in FACTS Info at the implementing mechanism, initiative, and intervention level.

9.1.2 Applied Pipeline

The End of Fiscal Year (EOFY) tool provides critical input into the determination of applied pipeline for future planning cycles. Pipeline resources deemed “excess pipeline” during the EOFY process will be reflected as applied pipeline and available for implementation within COP22 to the extent consistent with applicable law and regulations. COP submissions that do not sufficiently allocate pipeline may be subject to delays in approval.

The applied pipeline should include any prior year COP funding that will continue to be implemented and expended during the COP22 cycle (i.e., construction funding programmed in a previous year that continues to outlay during COP22), as well as the application of prior year funding deemed in “excess” as further explained below**.** All agencies within all countries or regions must monitor, analyze, and manage their pipeline throughout the year and ensure that its use is consistent with applicable law and regulations.

Every PEPFAR operating unit program requires a certain amount of pipeline to ensure there is no disruption to services due to possible funding delays or other unanticipated issues.

Three months’ worth of outlays are considered an acceptable amount of pipeline for the following PEPFAR OUs: Regional Program: West Africa Regional Program; Angola; Botswana; Burundi; Cameroon; Côte d’Ivoire; Democratic Republic of the Congo; Kenya; Lesotho; Malawi; Mozambique; Namibia; Nigeria; Rwanda; South Africa; Eswatini; Tanzania; Uganda; Ukraine; Vietnam; and Zambia.

The following PEPFAR OUs may maintain up to 4 months’ worth of outlays: Asia Regional Program; Western Hemisphere Regional Program; Dominican Republic; Ethiopia; Haiti; South Sudan; and Zimbabwe.

Pipeline above the acceptable level of 3 months (or 4 months for those OUs specified above) is considered “excess” and will be applied to the following COP. OUs may not receive additional funding if on-hand resources fall short of the allowable pipeline.

Funding for Peace Corps Volunteers (PCVs) and Peace Corps Response Volunteers (PCRVs) must cover the full period of their service, including approved extensions. Thus, Peace Corps programs in countries with PEPFAR-funded Volunteers must retain resources for costs outside of the current COP year in the pipeline. Any pipeline in excess of these costs outside of the COP year will be made available to apply in pipeline to the future COP.

Pipeline should be applied to a COP22 mechanism or CODB category (i.e., “applied pipeline”) in cases where the threshold for acceptable pipeline (3 or 4 months) has already been achieved.

Note: *Agencies should generally follow a “first-in, first-out” approach to budget execution, requiring the full utilization of expiring funds and older funds before any new FY22 funds are obligated and expended. For the purposes of implementing this approach this should be based on when the resources were originally appropriated, rather than when they expire (i.e., x-year resources should be spent first). Due to this budget execution approach, the actual fiscal year of funds that are outlaid in support of an approved COP22 activity may not match the approved COP22 applied/new funding breakdown. Agencies should carefully budget and program to ensure implementing partners only receive funds needed and there are minimal to no funds remaining in expiring grants and cooperative agreements. Agencies should also carefully ensure that their execution of resources under this approach does not result in a net decrease to any mandatory earmark levels.*

10.0 U.S. GOVERNMENT MANAGEMENT AND OPERATIONS (M&O)

10.1 Interagency M&O

As with prior years, all staff fully or partially funded by PEPFAR should be included as individual entries. Non-PEPFAR-funded staff who work more than 30 percent on PEPFAR should also be included as individual entries.

In COP22, interagency M&O requirements include a short narrative in the SDS to summarize the team's staffing and organizational analysis, an itemized list of the personnel implementing the OU program in FACTS Info, and allocation of operational costs in FACTS Info. Proposed Cost of Doing Business (CODB) funding levels are captured in FACTS Info and the FAST.

COP22 M&O Submission List:

- M&O Narrative in the SDS
- Staffing Data in FACTS Info
- Functional Staff Chart (as previously required, but updated to reflect any footprint or organizational changes) uploaded to FACTS Info Document Library
- Agency Management Charts (one per agency) uploaded to FACTS Info Document Library
- Agency Cost of Doing Business tab in FACTS Info

10.1.1 PEPFAR Staffing Footprint and Organizational Structure Analysis, Expectations, and Recommendations

The focus of the staffing and organizational structure review should be how PEPFAR staff are organized and funded to meet key tasks and core functions and deliver results. While OU footprints should follow rightsizing and good position management principles, the emphasis is not simply on the number of staff or vacancies vis-à-vis overall footprint. The focus should be on ensuring a balance of staff across interagency business process and coordination demands, agency partner management and accountability, and external engagement (and across

countries, for regional and country-pair programs). Further, the expectation is that staff fully or partially funded by PEPFAR are available and assigned to meet key interagency and intra-agency tasks throughout various PEPFAR business cycles (e.g., COP, quarterly reporting, POART).

First, teams should consider the core competencies and functions needed to achieve epidemic control. A first step will be to outline various PEPFAR-required (interagency and intra-agency) and agency-required (intra-agency) processes (e.g., COP, quarterly reporting, POART) and then use staffing data to measure and ensure coverage of tasks and functions. The Level of Effort Workload Management Indicators were introduced in 2017 to facilitate teams' assessments. Organizational structures may need to be shifted; for example, new teams may have to be created to manage each step of the COP process or technical working groups (TWGs) may need to be collapsed to streamline them. OUs should consider how to de-duplicate current activities across the team to maximize efficiency. How will the OU team handle key tasks during the year? Who is the lead? Who are the alternates and/or team members?

Second, the OU should analyze the staffing data and review the staffing footprint to determine whether there is alignment with the core competencies and functions. What do the data tell you about how the OU is managing the program and essential tasks? Are there skills for which training is needed or new/revised positions might be required? Is there a need to repurpose or update existing positions (whether filled or vacant) to meet key competencies and accomplish tasks? If space is available, is there a need for new positions? In lieu of new positions, is there a plan to bring in temporary duty assignment, intermittent, or temporary hire assistance at certain times of the year? Teams should consider the trajectory, including funding, of the program in reviewing the staffing footprint and organizational strategy.

Best Practices

For COP22, teams should consider the following best practices:

Consult with embassy and agency management support offices for help finding balance across the OU footprint.

Create or update the interagency charter, standard operating procedures, and/or manual to codify decisions made around core tasks and assignment of individuals and groups. As examples, OUs could consider including:

- SOPs for each working group or task team

- Principles for scheduling and capturing minutes/action-items from regular and ad-hoc meetings
- General communication principles including how and when information is shared and SOPs for email direct/copied recipients
- How to handle conflict, seek consensus, and come to decisions
- External engagement leads and principles
- Review of all PEPFAR-related Position Descriptions (vacant and encumbered) to ensure they are updated for PEPFAR 3.0 (e.g., data analysis, interagency work, SIMS site visits).
- Itemized training or other skill development needed across the team to achieve epidemic control and create a training schedule in partnership with S/GAC and agency headquarters.
- Identified positions that would benefit from a Framework Job Description (FJD or standardized position description for mid- and senior-level common positions that can be used by any agency or OU). See PEPFAR SharePoint for currently available FJDs that can be used as-is or as guides.

OUs should identify any additional HQ assistance needed to facilitate a staffing or organizational analysis, implement organizational changes, or provide training. This should include considering how the ISMEs may be leveraged to assist with programmatic challenges.

Note: Staffing information will not be available in the FAST and therefore, staffing levels will be assigned within FACTS Info. The FAST should include the summary budget for M&O so that the total budget can be represented and analyzed.

10.1.2 Strategic Direction Summary (SDS) Requirement

The SDS M&O narrative will:

1) Summarize the staffing and interagency organizational structure analysis conducted for COP22.

The following key questions should be addressed in the narrative:

- What changes did the team make to its U.S. government staffing footprint and interagency organizational structure to maximize effectiveness and efficiency to achieve program pivots? How was the baseline Level of Effort of current staff assessed to determine changes in staffing needs?

- How has the team ensured balance between interagency business process coverage and intra-agency partner management and technical roles?
- How will staff be utilized to meet SIMS requirements?
- What additional action does the team want to take that has a timeline beyond COP22 submission?
- Were missing skill sets or competencies identified? What steps are being taken to fill these (e.g., training, repurposing vacancies/encumbered positions)?
- Did the team alter existing, unfilled positions to better align with COP22 priorities?

Explain Vacant Positions, summarizing the steps being taken to fill vacancies of more than six months and actions have been taken to alter the scope of the position to balance interagency and intra-agency needs.

2) For each approved but vacant (as of March 1, 2022) position, the narrative should describe the reason(s) it is vacant and the plan and timeline for filling the vacant position. Vacant position narratives should be no more than 500 characters.

The narrative should also be entered directly into the Comments field within the Staffing section of FACTS Info. There should be one explanation for each staffing record marked as vacant. If the position has been previously encumbered, please provide the date that the position became vacant and whether the position has been recruited yet. If recruitment has occurred but the team has been unable to fill it, please indicate why (e.g., lack of candidates, salary too low, hiring freeze).

Submitting this information will help identify program-wide recruitment and retention issues and skill and knowledge gaps.

Justify Proposed New Positions

The SDS narrative should summarize the interagency analysis and decision making that culminated in the agreement to request funding for a new position, including whether space for the position has been validated with the Embassy Management Officer and Chief of Mission. Teams should provide justification for the proposal of new positions rather than repurposing existing filled or vacant positions. For direct-hire or Personal Services Contractor (PSC) positions that the team plans to fill with a U.S. citizen, indicate why this position cannot be hired locally. In addition, teams are encouraged to use term-limited appointments versus permanent mechanisms.

In the Comments field within the Staffing section of the FACTS Info PEPFAR module, OUs must describe how each proposed new position fits into the interagency and individual agency staffing footprints (e.g., meets changes in the program, addresses gaps, and complements the existing staff composition). New position narratives should be no more than 500 characters. All proposed positions (not previously approved in a COP) should be marked as planned in the staffing data.

In the COP22 review process, all proposed new positions will be rigorously evaluated for relevance to new business process needs and alignment with programmatic priorities. Because the approval threshold for new positions will be high, wherever possible, teams are advised to repurpose existing vacancies to fill new staffing priorities (particularly long-standing vacancies, i.e., those vacant for two or more COP cycles). Note that any proposed new positions should spend at least 50 percent of their time on PEPFAR activities.

Explain major changes to CODB

The SDS M&O narrative should summarize any factors that may increase or decrease CODB in COP22, including any changes due to COVID-19. Identify whether there are any trade-offs that will be required if the CODB request is not fully approved.

1) Outline any major scopes of work for which ISME assistance is requested during COP22 implementation.

10.2 Staffing and Level-of-Effort Data

OUs **must** update their staffing data within the FACTS Info (pre-populated with COP21 staffing data).

10.2.1 Who to Include in the Database

- **All** PEPFAR-funded staff must be included in the staffing data, which includes all fully or partially PEPFAR-funded (i.e., GHP, GAP, or other PEPFAR fund accounts) that are onboard (current), vacant (as of March 1, 2022), or proposed. This includes positions working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities to include: Any non-PEPFAR-funded current, vacant (as of March 1, 2022), and proposed positions that:
    - are involved in decision making for PEPFAR planning, management, procurement, and/or programmatic oversight activities,

or

- will spend at least 30 percent of their time working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities.

Hiring mechanisms Include:

- U.S. Direct Hire (USDH) (includes Department of State Foreign Service Officers, CDC appointed staff, military, and public health commissioned corps)
- Internationally recruited PSC (including Department of State Limited Non-Career Appointment)
- Personal Services Agreements (PSAs) (includes locally-recruited Eligible Family Members and Foreign Service Nationals)
- LE Staff, including locally hired PSC or PSA host country nationals, Americans, and third-country nationals (TCNs)
- Internationally recruited TCNs
- Non-Personal Services Contractors (also known as commercial, third party, or institutional contractors)
- Fellows
- Other employment mechanisms (for which there should be very few entries)

Any non-PSC/institutional contractor who is employed by an outside organization (e.g., CAMRIS, GHTAMS, ITOPPS) and provides full-time, permanent support to field operations and sits embedded with U.S. government staff that meet the inclusion criteria above. Do not include temporary or short-term staff. However, if the position slot is permanent and the incumbent rotates, please include the position and state “rotating” in the last and first name fields. The costs of these staff should be captured in the Institutional Contractor CODB field.

Temporary or seasonal hires should not be included but should be considered in overall footprints/organizational structures to achieve various business processes.

Peace Corps Volunteers should not be included in the staffing data as they are not U.S. government employees. However, Peace Corps staff should be included.

As a part of the cleaning and review process, HQ will review the submission to ensure that positions are marked as non-PEPFAR funded where appropriate to avoid skewing staffing

analyses. If a Mission picks up the position, it can then be marked as either partially or fully PEPFAR-funded.

10.2.2 Staffing Data Field Instructions and Definitions

OUs should update the staff demographic information in the following fields (data field definitions are included below) pre-populated from COP21. A complete and correct staffing matrix is needed for successful COP22 submission.

10.2.3 Attribution of Staffing-Related CODB to Technical Areas

Each position's entry should reflect the amount of time spent working on PEPFAR and whether the position is partially or fully PEPFAR-funded or non-PEPFAR-funded. The funded costs for all positions should be reflected in the U.S. government Salaries and Benefits CODB categories. There are separate CODB salary and benefit categories for:

- Internationally recruited staff, e.g., U.S. direct hire, U.S. PSC, and TCNs
- Locally recruited staff, e.g., host country national PSA staff, locally hired Americans and TCNs
- Department of State direct hires (FSO and LNA)

Salary costs for Institutional Contractors should be entered in the appropriate CODB category for non-PSC/PSAs.

For U.S. government Staff Salaries and Benefits and Staff Program Travel, OU teams will update their staffing data and enter the top-line budget amount for each CODB category, by fund account (see CODB guidance below). Based on the calculated FTE (for only those fully or partially funded PEPFAR positions) aggregated for each agency, a portion of the agency's top-line CODB budget amount will be attributed to relevant program areas and beneficiaries and to the M&O funding amounts.

For Institutional Contractors, teams will enter the planned funding amount for the appropriate technical areas, by fund account - i.e., the area(s) for which institutional contractors are providing personnel support on behalf of the U.S. government.

For Peace Corps staff in COP22, teams should attribute all PEPFAR-funded staff positions to the appropriate intervention in Management and Operations

10.3 OU Functional and Agency Management Charts

OU teams are asked to submit charts reflecting their functional and management structures. The functional staff chart and agency management charts should be uploaded as required supplemental documents to COP22.

The interagency chart should reflect the leadership and decision-making structures for the OU as well as permanent working groups or task teams involved in interagency program management and oversight and/or external engagement. Only leadership position and TWG titles should be included; do not include names of persons. Teams should update the chart as appropriate to reflect any organizational changes made based on its review of the staffing footprint and organizational structures to facilitate achieving the pivots and targets.

Along with the functional staff chart, OU teams should also submit copies of each agency's existing organizational chart that demonstrates the reporting structure within the agency. If not already indicated on those charts, please highlight the management positions within the agency organizations. One chart should be uploaded per each U.S. government agency, per OU.

The functional staffing chart and agency management charts are not intended to replace or duplicate existing agency organizational charts depicting formal reporting relationships or existing administrative relationships between staff within agencies.

10.4 Cost of Doing Business

U.S. government Cost of Doing Business (CODB) includes all costs inherent in having the U.S. government footprint in country, i.e., the cost to have personnel in-country providing technical assistance and collaboration, management oversight, administrative support, and other program support to implement PEPFAR and to meet PEPFAR goals.

A number of factors may drive changes in CODB, including global U.S. Department of State increases in Capital Security Cost Sharing (CSCS), ICASS costs, and Locally Employed (LE) Staff pay increases or separation pay (when applicable). In addition, as PEPFAR business processes evolve, teams must ensure that they are staffed and supported to successfully implement SIMS, POART, and enhanced routine program planning with civil society, governments, and the Global Fund.

As in previous years, the CODB should be manually entered into the FAST. Required elements, including total funds spent per CODB category, CODB category pipeline, planned amounts, and justification for incremental changes, is similar to previous guidance.

10.4.1 Cost of Doing Business Categories

By capturing all CODB funding information, data are organized in one location, allowing for clear itemization and analysis of individual costs. In addition to providing greater detail to headquarters review teams and parity in the data requirements for field and headquarters management costs, the data provides greater transparency to Congress, the Office of Management and Budget, and other stakeholders on each U.S. government agency's costs for managing and implementing the PEPFAR program.

Non-ICASS Administrative Costs: Please provide a detailed cost breakout of the items included in this category and their associated planned funding (e.g., $1,000 for printing, $1,000 for supplies). **Non-ICASS Motor Vehicles:** If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified and dollar amount specified.

U.S. Government Renovation: Describe and justify the requested project. Significant renovation of properties **not** owned by the U.S. government may be an ineffective use of PEPFAR resources, and costs for such projects will be closely scrutinized. The description should be no more than 1,000 characters and include the following details:

- The number of U.S. government PEPFAR personnel that will occupy the facility, the purpose for which the personnel will use the facility, and the duration of time the personnel are expected to occupy the facility.
- A description of the renovation project and breakout of associated costs. Include a description of why alternatives – facilities that could be leased and occupied without renovation – are unavailable or inadequate to meet personnel needs.
- The mechanism for carrying out the renovation project, e.g., Regional Procurement Support Office (RPSO).
- The owner of the property.
- The U.S. government agency which will implement the project, and to which the funds should be programmed upon approval. If the project will be implemented by DOS through RPSO, the funding agency should be the Department of State Bureau (e.g., State/AF).

Institutional Contractors: Describe the institutional contractor (IC) activities and why these activities will be conducted by an IC rather than a U.S. Direct Hire or PSC/PSA. Where possible, please provide the contracting company name and the technical area(s) which the IC(s) will support.

Once you have completed the steps for one agency, please repeat for all other agencies working in country.

There are eleven U.S. government CODB categories. The following list of CODB categories provides definitions and supporting guidance:

U.S. Government Staff Salaries and Benefits: The required costs of having a person in country, including housing costs not covered by ICASS, rest and relaxation (R&R) travel, relocation travel, home leave, and shipping household goods. This category includes the costs associated with technical, administrative, and other staff.

PEPFAR program funds should be used to support the percentage of a staff person's salary and benefits associated with the percentage of time they work on PEPFAR. The direct costs of PEPFAR, specifically the costs of staff time spent on PEPFAR, need to be paid for by PEPFAR funding (e.g., GHP-State, GAP). For example, if a staff person works 70 percent on PEPFAR, PEPFAR program funds should fund 70 percent of that person's salary and benefits. If the percentage worked on PEPFAR is 10 percent, then PEPFAR funds should fund 10 percent of the person's salary and benefits.

For agencies that cannot split-fund staff with their agency appropriations (such as USAID's OE funds), multiple staff may be combined to form one FTE and one of the staff's full salary and benefits will be funded by PEPFAR. For example, if two staff each work 50 percent on PEPFAR, PEPFAR funds should be used to fund the salary and benefits of one of the positions. If three staff each work a third of their time on PEPFAR (33% + 33% + 33%), PEPFAR funds should be used to fund the salary and benefits of one of the positions. If multiple staff work on PEPFAR but not equally (such as 10% + 20% + 70% or 25% + 75%), the full salary and benefits of the person who works the most on PEPFAR (in the examples, either 70 percent or 75 percent) should be funded by PEPFAR. This split should be reflected in the staffing data.

If the agency is paying for partner country citizen fellowships and is going to only train the fellows, then the funding can remain in an implementing mechanism. If the agency will receive a work product from the fellows, then this cost should be counted in M&O. Similarly, if agencies are paying for trainers who are U.S. government staff, then the costs associated with these staff

should be reflected within M&O. If the mechanism is paying for the materials and costs of hosting training, then the funding should be reflected in an implementing mechanism.

There are two categories of Salaries and Benefits:

- Internationally Recruited Staff
- Locally Recruited Staff

Staff Program Support Travel: The discretionary costs of staff travel to support PEPFAR implementation and management, except for required relocation and R&R travel, which are included above in U.S. government Salaries and Benefits) .

This includes the associated costs for technical assistance provided by non-PEPFAR funded staff. Other technical assistance funding (e.g., materials) should be reflected in an implementing mechanism. Teams should include SIMS related travel costs in this category. Refer to the OU's list of sites prioritized for SIMS assessments and ensure that the following costs are properly captured: driver travel, driver overtime, gas, lodging, and meals and incidental expenses (General Services Administration rate).

As in COP21, in COP22, technical assistance-related travel costs of HHS/CDC HQ staff for trips of less than three weeks will be included in the PEPFAR Headquarters Operational Plan (HOP) and funded centrally. Under this model, costs for short-duration technical assistance travel by HHS/CDC staff should not be included in COPs.

ICASS (International Cooperative Administrative Support Services):

ICASS is the system used in Embassies to provide <u>shared common</u> administrative support services and

<u>Equitably distribute</u> the cost of services to agencies.

ICASS charges represent the cost to supply common administrative services such as human resources, financial management, general services, and other support, supplies, equipment, and vehicles. It is generally a required cost for all agencies operating in country.

Each year, customer agencies and the service providers present in country, then update and sign the ICASS service "contract." The service contract reflects the projected workload burden of the customer agency on the service provision for the upcoming fiscal year. The workload assessment is generally done in April of each year. PEPFAR teams should ensure that every agency's workload includes all approved PEPFAR positions.

ICASS services are comprised of required cost centers and optional cost centers. Each agency must sign up for the required cost centers and has the option to sign up for any of the optional cost centers.

More information is available at https://fam.state.gov/Fam/FAM.aspx?ID=06FAH05.

ICASS charges must be planned and funded within the COP/ROP budget. However, ICASS costs are typically paid by agency headquarters on behalf of the team from the budgeted funding. Each implementing agency, including State, should request funding for PEPFAR-related ICASS costs within its M&O budget.

It is important to coordinate this budget request with the Embassy Financial Management Officer, who can estimate FY2023 anticipated ICASS costs for agencies. SGAC HQ will provide ICASS costs for State.

It is important to request all funding for State ICASS costs in the original COP submission, as it is difficult to shift funds at a later date. State ICASS costs are paid during FY2023 with new COP22 funding, not applied pipeline.

The Peace Corps subscribes to minimal ICASS services at post. Most general services and all financial management work (except Financial Services Center disbursing) are carried out by Peace Corps field and HQ staff. To capture the associated expenses, Peace Corps will capture these costs within the indirect cost rate.

Non-ICASS Administrative Costs: These are the direct charges to agencies for agency-specific items and services that are easy to price, mutually agreed to, and outside of the ICASS MOU for services. Such costs include rent/leases of U.S. government-occupied office space, vehicles, shipping, printing, telephone, driver overtime, security, supplies, and mission-levied head taxes.

In addition to completing the budget data field, teams are expected to explain the costs that compose the Non-ICASS Administrative costs request, including a dollar amount breakout by each cost category (e.g., $1,000 for printing, $1,000 for supplies) in the “Item Description” field.

Non-ICASS Motor Vehicles: If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified. For new requests in FY23, please explain the purpose of each vehicle(s) and associated cost(s) in the “Item Description” field. It is also a requirement that the total number of vehicles purchased and/or leased under Non-ICASS (Motor Vehicles)

costs to date (cumulative through COP21) are provided in this category. Teams should include new vehicle requests related to the completion of SIMS requirements in this category.

CSCS (Capital Security Cost Sharing): Non-State Department agencies should include funding for CSCS, except where this is paid by the headquarters agency (e.g., USAID).

The CSCS program requires all agencies with personnel overseas subject to Chief of Mission authority to provide funding in advance for their share of the cost of providing new, safe, secure diplomatic facilities (1) on the basis of the total overseas presence of each agency and (2) as determined annually by the Secretary of State in consultation with such agency.

The State Department uses a portion of the CSCS amount for the Major Rehabilitation Program (MRP).

It provides steady funding annually for multiple years to fund 150 secure New Embassy Compounds in the Capital Security Construction Program.

More information is available at http://www.state.gov/obo/c30683.htm.

Teams should consult with agency headquarters for the appropriate amount to budget in the COP/ROP.

Computers/IT Services: Funding attributed to this category includes USAID's information resources management (IRM) tax and other agency computer fees not included in ICASS payments. If IT support is calculated as a head tax by agencies, the calculation should transparently reflect the number of FTEs multiplied by the amount of the head tax.

CDC should include the IT support (ITSO) charges on HIV-program-funded positions; these costs will be calculated at CDC HQ and communicated to field teams for inclusion in the CODB.

USAID should include the IRM tax on HIV-program-funded positions.

Planning Meetings/Professional Development: Discretionary costs of team meetings to support PEPFAR management and of providing training and professional development opportunities to staff. Please note that costs of technical meetings should be included in the relevant technical program area.

U.S. Government Renovation:

Teams should budget for and include costs associated with renovation of buildings owned/occupied by U.S. government PEPFAR personnel.

Costs for projects built on behalf of or by the partner government or other partners should be budgeted for and described as Implementing Mechanisms.

Institutional Contractors (non-PSC/non-PSA):

Institutional and non-personal services contractors/agreements (non-PSC/non-PSA) includes organizations such as IAP Worldwide Services, COMFORCE, and all other contractors that do NOT have an employee-employer relationship with the U.S. government.

All institutional contractors providing M&O support to PEPFAR should be entered in M&O, not as an Implementing Mechanism template.

In addition to the budget information, teams must provide a narrative to describe institutional contractor activities in the "Item Description" field.

Costs associated with this category will be attributed to the appropriate technical program area within the FAST.

Peace Corps Volunteer Costs (including training and support):

Includes costs associated with Peace Corps Volunteers (PCV), Volunteer Extensions, and Peace Corps Response Volunteers (PCRVs) arriving at post between **October 1, 2022,** and **September 30, 2023**.

The costs included in this category are direct PCV costs, pre-service training, **Volunteer-focused** in-service training, medical support and safety and security support.

The costs excluded from this category are: U.S. government staff salaries and benefits, staff travel, and other office costs such as non-ICASS administrative costs, which are entered as separate CODB categories. Also excluded are activities that benefit the community directly, such as Volunteer Activities Support and Training (VAST) grants and **selected** training events. These types of activities should be attributed to the appropriate intervention in an Implementing Mechanism template.

Funding for PCVs must cover the full 27-month period of service. For example:

Volunteers arriving in June **2023** will have expenses in **FY2023 (four months), FY2024 and FY2025 (eleven months)**.

Volunteers arriving in September **2023** will have expenses in **FY2023 (one month), FY2024, FY2025, and FY2026 (two months)**.

PCV services are not contracted or outsourced. Costs are incurred before and throughout the Volunteer's 27-month period of service. Costs incurred by Peace Corps Washington and domestic offices, such as recruitment, placement and medical screening of Volunteers, are included in the HOP. Costs such as living allowance, training, and support will continue to be included in the COP/ROP.

Inclusion of Global Fund Liaison Costs (where applicable): For Global Fund Liaison positions (full or cost share), the percentage of the position that is PEPFAR funded should be reflected in the COP/ROP and allocated to the above CODB categories. Please contact S/GAC Multilat and copy your PEPFAR Program Manager with any questions about the funding stream for this position.

10.5 U.S. Government Office Space and Housing Renovation

Teams may include support for U.S. government renovation in their CODB submission. All other construction and/or renovation should be included in the Implementing Mechanism section of the COP/ROP. The terms are defined as follows:

> **Construction** – refers to projects that build new facilities or expand the footprint of an already existing facility (i.e., adding a new structure or expanding the outside walls).
>
> **Renovation** – refers to projects, intended to accommodate a change in use, square footage, technical capacity, and/or other infrastructure improvements to an existing facility. Significant renovation of properties not owned by the U.S. government may be an ineffective use of PEPFAR resources, and costs for such projects will be closely scrutinized.
>
> **U.S. Government Renovation** – refers to a renovation project of a U.S. government facility. Describe and justify the requested project.

All construction and renovation projects should be cleared by the U.S. Ambassador in country before submission to headquarters. The notes below outline how U.S. government renovation funds may be used.

PEPFAR Funding May Not Be Used for New Construction of U.S. Government Office Space or Living Quarters

Consistent with the foreign assistance purposes of PEPFAR appropriations, PEPFAR GHAI, GHCS, and GHP-State funding should not be used for the construction of office space or living

quarters to be occupied by U.S. government staff. The Embassy Security, Construction, and Maintenance (ESCM) account in the State Operations budget provides funding for construction of buildings to be owned by the Department of State. The Capital Investment Fund (CIF) is a similar account appropriating funds for USAID construction. Other agencies such as HHS/CDC and DOD have accounts that provide funding to construct U.S. government buildings. Implementing mechanisms may contribute to the ESCM account through the Capital Security Cost Sharing program.

PEPFAR Funding May Be Used to Lease Facilities

Where essential office space or living quarters cannot be obtained through the Embassy or USAID Mission, PEPFAR funds may be requested for U.S. government use facilities, in the context of a Country or Regional Operational Plan (COP/ROP), to rent or lease such space for a term not to exceed 10 years, if necessary, to implement PEPFAR programs.

PEPFAR Funding for Renovation of U.S. Government-Owned and Occupied Properties

Teams may request the use of PEPFAR funds to renovate U.S. government-occupied facilities in exceptional circumstances. The justification for using PEPFAR funds to renovate U.S. government-occupied facilities must demonstrate that the renovation is a “necessary expense,” essential to carrying out the foreign assistance purposes of the PEPFAR appropriation and should show that the cost of renovation represents the best use of program funds. The justification should also explain why appropriate alternative sources of funding for renovation are not available. The team must submit a comprehensive plan that includes an explanation of the unique circumstances around the request to renovate U.S. government-occupied facilities. The plan must have the support of the Ambassador. In addition to the “Item Description” narrative, teams must provide the total costs associated with renovation of buildings owned/occupied by U.S. government PEPFAR personnel under the CODB section. Note, renovation of facilities owned by the U.S. government may require coordination with the State Department’s Office of Overseas Buildings Operations (OBO) and other State Department bureaus and the clearance of the State Department/Office of the Legal Advisor.

10.6 Peace Corps Volunteers

For each OU and in aggregate, Peace Corps Washington will submit to S/GAC the number of PEPFAR-funded:

- Projected Volunteers on board as of October 1, 2022;

- Projected Volunteer Extensions on board as of October 1, 2022;
- Projected Peace Corps Response Volunteers on board as of October 1, 2022;
- New Volunteers proposed in COP22;
- Volunteer Extensions proposed in COP22; and
- New Peace Corps Response Volunteers proposed in COP22.
- Peace Corps Washington will obtain this information from Peace Corps country programs.

11.0 OTHER ELEMENTS

11.1 Small Grants Program

11.1.1 Proposed Parameters and Application Process

Eligibility Criteria

Any awardee must be an entirely local group.

Awardees must reflect an emphasis on community-based groups, including FBOs, and groups of persons living with HIV/AIDS.

Small Grants Program funds should be allocated toward addressing structural barriers to HIV services (e.g., stigma, discrimination and violence mitigation, poverty alleviation, educational attainment), democracy and governance (as related to the national HIV response), HIV prevention, care and support, community-led monitoring, or capacity building. They should not be used for direct costs of treatment.

When PEPFAR funds are allotted to Post for State to issue grant awards, the clauses below must be included in addition to the standard terms and conditions.

CONSCIENCE CLAUSE IMPLEMENTATION: An organization, including an FBO, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care;

(a) Shall not be required, as a condition of receiving such assistance—

(1) To endorse or utilize a multi-sectoral or comprehensive approach to combating HIV/AIDS; or

(2) To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and

(b) Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described in paragraph (a) above.

PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING:

(a) The U.S. government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(b)(1) Except as provided in (b)(2) and (b)(3), by accepting this award or any subaward, a non-governmental organization or public international organization awardee/sub-awardee agrees that it is opposed to the practices of prostitution and sex trafficking.

(2) The following organizations are exempt from (b) (1): U.S. organizations; the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.

(3) Contractors and subcontractors are exempt from (b)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

(4) Notwithstanding section (b)(3), not exempt from (b)(1) are recipients, sub recipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any sub award, or procurement contract or subcontract by:

(i) providing supplies or services directly to the final populations receiving such supplies or services in host countries;

(ii) providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or

(iii) providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

The following definitions apply for purposes of this provision:

Commercial sex act means any sex act on account of which anything of value is given to or received by any person

Prostitution means procuring or providing any commercial sex act and the practice of prostitution has the same meaning

Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act

The recipient shall insert this provision, which is a standard provision, in all sub awards, procurement contracts or subcontracts

Accountability

Programs must have definable objectives that contribute to sustainable epidemic control, including addressing stigma and discrimination, HIV/AIDS prevention, care, and/or (indirectly) treatment.

Objectives must be measurable.

Renewals are permitted only where the grants show significant quantifiable contributions toward meeting country targets.

Pre-Award Planning:

According to Department of State's Administration/Office of the Procurement Executive's (A/OPE) grant regulations, before any single/individual grant estimated over $25,000 can be signed by grants officers in the field, the grant documents going into the grant file must be reviewed for accuracy and completeness by S/GAC and the authorized program office in Washington, D.C. **If the award is over $25,000 the pre-award package must also be reviewed by the corresponding regional bureau at State.**

At least 60 days prior to award, posts planning to issue a grant with PEPFAR funds in the amount of $25,001 or more (for a single grant) must submit grant documents to the respective PEPFAR Program Manager and S/GAC Management and Budget for review via email.

PEPFAR Program Managers will review the pre-award package including the following documents for PEPFAR program specific accuracy and completeness (also see the S/GAC-PEPFAR Grant Review Checklist):

- DS-1909

- Award Specifics
- SF 424, 424-A, project and budget narratives
- Reporting Plan
- Monitoring Plan
- Competition or Sole Source justification
- Statement of Work (SOW)
- Other relevant pre-award documents (i.e., grant award panel notes, NOFO, audits, SAM.GOV, FAPIIS, funding documentation (i.e., CN or agency funding strip), NICRA, etc.)

The governing federal regulation for grants and cooperative agreements is 2 CFR 200. Allowability of costs can be view in section 2 CFR 200.420 Considerations for selected items of cost.

S/GAC strongly encourages Posts to minimize the number of grants exceeding $25,000 so that additional work and extended timelines are not required on behalf of both Post and S/GAC. Grants exceeding $25,000 must be awarded competitively (i.e., by issuing a Notice of Funding Opportunity (NOFO) and holding a grant panel for award selection). (It is a best practice to have a NOFO and grant review selection panel for all awards). In addition, grants exceeding $25,000 are required to have both a monitoring plan and a risk assessment as part of the pre-award package.

Key personnel involved in grants oversight

Federal Assistance Team:

Grants Officers (GOs), Grants Officer Representatives (GORs), and other staff involved in helping to oversee PEPFAR grants are part of the Federal Assistance Team. The Federal Assistance Directive (FAD) underscores the value of teamwork and communication for team members in sharing the program vision and goals.

It is important that members of the Federal Assistance Team avoid conflicts of interest, the appearance of conflicts of interest, as well as maintain impartiality.

Grants Officers (GOs) interpret laws, rules and policy and have the ultimate authority to manage the award and to direct changes. GOs must be U.S. direct hires at State (including eligible family members and locally employed staff who are U.S. citizens). WAE (while actually employed) personnel may be GOs on a case-by-case basis. Training to be a grants officer at

post for a level one warrant requires 40 credit hours; training for a level two warrant requires 56 credit hours. Please see training updates below.

Grants Officer Representatives (GORs) manage the programmatic aspects of the award and are appointed by the Grants Officer. A GOR must be a U.S. Direct citizen, a re- employed annuitant such as While Actually Employed (WAE), Personal Services Contractor (PSC) or personal services agreement (PSA), locally engaged staff (LES), or eligible family member. GORs may not be third party contractors.

Third-party contractors may not serve as GOs or GORs. Contractors may participate in many of the processes in grants management. However, contractors may not perform inherently governmental functions.

In addition, although grant awards for $100,000 or more must have a GOR assigned to them, grants officers may assign a GOR to grant that is below the $100,000 level. It is a best practice to have a GOR for each grant if possible.

Training Updates from A/OPE:

The State Department has recently updated training in grants management with the launch on-line training courses (PY472, PY474, PY476, PY478). The series of online courses are the equivalent to the in-person course PY260 - Federal Assistance Management and replaces the previous online course series. Starting October 1, 2020, with the release of the FY'21 Federal Assistance Directive (FAD), these new online courses replaced PY220, PY220, and PY224.

In-person	Number of Hours
PY260/Federal Assistance Management	40 hrs.
Total	**40 hrs.**

Online	Number of Hours
PY472/Federal Assistance: Pre-Award	16 hrs.
PY474/Federal Assistance: Award	4 hrs.
PY476/Federal Assistance: Post-Award	16 hrs.
PY478/Federal Assistance: Closeout	4 hrs.
Total	**40 hrs.**

Below are some examples of how you may use these online courses:

Applying for a first-time GOR certification?

- Register for PY472, PY474, PY467 and PY478.

Applying for a $100K GO warrant?

- Register for PY472, PY474, PY467 and PY478.

Applying for a higher-level GO warrant?

- Register for PY472, PY474, PY467 and PY478 (these courses will provide 40 hours of training). See the Training section of the A/OPE/AP/FA SharePoint site (must open in OpenNet or GO Virtual) for information on additional hours needed for higher warrant levels as well as a list of recommended training.

Renewing a GOR certification or $100K warrant?

- You will need 16 hours of refresher training. Register for PY472 or PY276.

Renewing a higher-level GO warrant?

- Consult the **Training** section of the A/OPE/AP/FA SharePoint site for information on the number of refresher training hours you will need, and consider registering for a combination of the new online courses.

For more information on training requirements and options, see the **Training** section of the A/OPE/AP/FA SharePoint site.

Submission and Reporting

Funds for the program should be included in the COP under the appropriate budget category.

Individual awards are not to exceed $250,000 per organization per year; the approximate number of grants and dollar amount per grant should be included in the narrative. Grants should normally be in the range of $5,000 - $25,000. In a few cases, some grants may be funded at up to the maximum award level for stronger applicants. Any award greater than $25,001 must be managed through the PEPFAR Coordination Office at Post. The labor-intensive management requirements of administering each award should be considered.

Once individual awards are made, the country or regional program will notify their PEPFAR Program Manager of which partners are awarded and at what funding level. This information will be added in the sub-partner field for that activity.

Successes and results from the Small Grants Program award should be included in the Annual Program Results and Semi-Annual Program Results due to S/GAC. These results should be

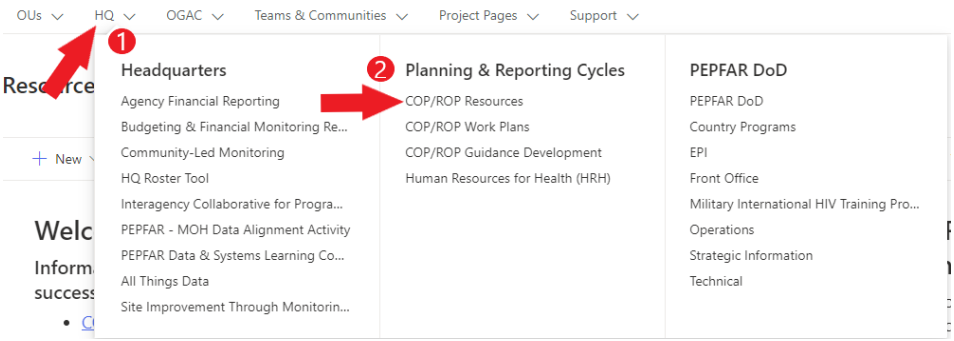
listed as a line item, like all other COP activities, including a list of partners funded with the appropriate partner designation.

11.2 PEPFAR SharePoint Contacts and Help Information

COP22 Resources on PEPFAR SharePoint:

Templates and guidance documents for COP22 development can be found on the PEPFAR SharePoint Planning and Reporting Cycles site. This site is available to U.S. government staff only. U.S. government users can access that site by navigating to HQ > COP/ROP Resources in the main menu from the PEPFAR SharePoint Homepage[770] as shown in Figure 11.2.1. (First, hover your mouse cursor over HQ, then click "COP"). Users may also access the COP site using this link: https://pepfar.sharepoint.com/sites/PR/COP.

Figure 11.2.1 How to find the COP page on PEPFAR SharePoint

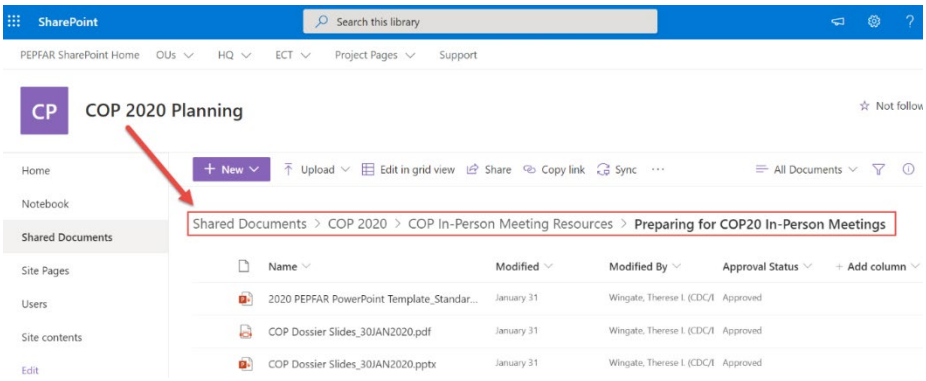


Internet Browser and Navigation within PEPFAR SharePoint:

PEPFAR SharePoint is supported by every major browser. "Open in Explorer" functionality requires Microsoft Internet Explorer web browser version 11 or later, running on Windows 8 or later. To navigate through several folders in PEPFAR SharePoint to find a certain document, view the path of the document, folder, or page to which you have navigated and click any previous layer to "navigate up."

[770] https://pepfar.sharepoint.com/

Figure 11.2.2 An example document path in SharePoint Online.



Logging in to PEPFAR SharePoint (users *with* existing accounts):

Please use this link to access PEPFAR SharePoint: https://pepfar.sharepoint.com/. Your Microsoft Account credentials are required to enter the site. These are the email address and password used to access your email at your host agency. For example, a user from the Department of State will enter their username as name@state.gov and use the associated password to that email address.

Obtaining a PEPFAR SharePoint Invitation (users *without* existing accounts):

PEPFAR SharePoint invitations should be requested by submitting a New Account Request[771] ticket through the Support Site. These tickets will be reviewed by the Support Team within one business day. The account should be created within two business days of the submission of the form. When the account is created, the new user will receive an email from the Support Team instructing them how to reset their password and set up the new account. This account will give the new user "Visitor" permissions to all of PEPFAR SharePoint. *Note: Typically, PEPFAR SharePoint accounts are limited to those with U.S. government e-mail addresses (ending in .gov, .mil, and wrp-n.org, or hivresearch.org). There are some exceptions for other personnel who work on the PEPFAR program in a variety of ways but who have different email domains. These account requests can take slightly longer to process.*

Obtaining access to specific pages within PEPFAR SharePoint:

Persons requiring access to specific pages within PEPFAR SharePoint should contact the Powerusers of the site(s) to request this permission. The Powerusers of any site can be located

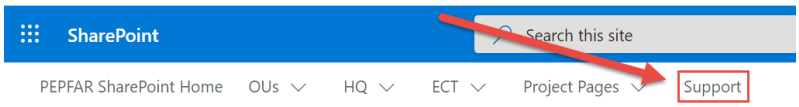
[771] https://pepfar.zendesk.com/hc/en-us/requests/new?ticket_form_id=204483

by clicking on the “PEPFAR SharePoint Home” main menu item, then clicking on “Poweruser Directory”. Email these individual(s) to request permissions to specific SharePoint sites.

Obtaining help for any issue related to using or accessing PEPFAR SharePoint:

For any questions related to access or the use of PEPFAR SharePoint in support of this year’s COP process, please contact the PEPFAR SharePoint Support Team using the support site. The support site can be accessed within PEPFAR SharePoint by navigating to Support > Support Site, or by using this link: https://pepfar.zendesk.com/hc/en-us.

Figure 11.2.3 How to access support in SharePoint Online



11.3 Acronyms and Definitions

Note: These and other useful PEPFAR, USG, and global health acronyms and abbreviations can be found in the PEPFAR Acronym App, developed by S/GAC and FSI, available for download in both the iOS app store and Google Play store.

A&A – Acquisition and Assistance

ABC – Abacavir Antiretroviral

ABC/M - Activity Based Costing and Management

ABHR – Alcohol-based hand rub

AB/Y – Abstinence, Be Faithful/Youth

ACT – Accelerating Children’s HIV/AIDS Treatment

AE – Adverse events

AFB – Acid-fast bacilli

AfCDC – Africa Centers for Disease Control and Prevention

AFRICOS – African Cohort Study

AGPs – Aerosol-generating procedures

AGYW – Adolescent girls and young women

AHD – Advanced HIV disease

AIDS – Acquired Immune Deficiency Syndrome

ALHIV – Adolescents Living with HIV

AmB - Amphotericin B deoxycholate

ANC – Antenatal Care

A/OPE – Administration /Office of the Procurement Executive

AOR – Agreement Officer’s Representative

APR – Annual Program Results

ARPA – American Rescue Plan Act

ART – Antiretroviral Therapy

ARV – Antiretroviral

ASLM – African Society for Laboratory Medicine

ASP – Above-site programs

ATS – Amphetamine-type stimulants

AYFS – Adolescent and youth friendly services

AYKP – Adolescent and young key populations

AZT – Zidovudine

B+ – Option B+

BBS – Bio-behavioral Survey

BF – Breastfeeding

BSL – Biosafety level

C19RM – COVID-19 Response Mechanism (Global Fund)

C&T – Care and Treatment

CAB-LA – Long-acting injectable cabotegravir

CADRE – Cyclical Acquired Drug Resistance Patient Monitoring

CAG – Community adherence group

CAP – Corrective Action Plan

CAS – Corrective Action Summary

CAST – Country Accountability Support Team

CATS – Community Adolescent Treatment Program

CBHIS – Community-Based Health Information System

CBIM – Coaching Boys into Men

CBO – Community-based organization

CBS – Case-Based Surveillance

CBVs – Community-based volunteers

CCM – Country coordinating mechanism

CDC – Centers for Disease Control and Prevention (part of HHS)

CEE – Core essential element

CETA – Common Elements Treatment Approach

CF – Case Finding

CFMs – Community Focal Mothers

CHWs – Community healthcare workers

CIF – Capital Investment Fund

CISGENDER - A term used to describe a person whose gender identity and/or gender expression aligns with the cultural norms and expectations associated with the sex that they were assigned at birth.

CLHIV – Children Living with HIV

CLM – Community-led monitoring

CNDR – Clinical/National Data Repository

CNS – Central nervous system

CODB – Costs of Doing the U.S. government's PEPFAR Business

COM – Chief of Mission

CoOP – Community of Practice

COP – Country Operational Plan

COR – Contracting Officer Representative

CoT – Continuity of Treatment

COVID-19 – Coronavirus Disease 2019

CP – Community Post

CQI – Continuous Quality Improvement

CQM – Continuous Quality Management

CrAg – Cryptococcal Antigen

CRP – C-Reactive Protein

CS – Case Surveillance

CSCS – Capital Security Cost Sharing

CSH – Child Survival & Health (USAID funding account; replaced by GHCS-USAID)

CSO – Civil Society Organization

CSW/SW – Commercial Sex Worker

CTX – Cotrimoxazole

CVLS – Community viral load suppression

CXR – Chest X-ray

DATIM – Data for Accountability, Transparency, and Impact Monitoring

DBS – Dried blood spots

DCLI – Data Collaboratives for Local Impact

DCM – Deputy Chief of Mission

DDD – Decentralized Drug Distribution

DDI – Development, Democracy, and Innovation (bureau at USAID)

DEIA – Diversity, Equity, Inclusion, and Accessibility

DFSD – Differentiated Service Delivery

DH – Digital Health

DHA – Digital Health Atlas

DHI – Digital Health Investments

DHIS2 – District Health Information Software 2

DHS – Demographic and Health Surveys program

DICs – Drop-in centers

DM – Diabetes mellitus

DMPPT2 – Decision Makers' Program Planning Toolkit, Version 2

DNO – Diagnostic network optimization

DOD – U.S. Department of Defense

DOS – U.S. Department of State

DP – Deputy Principal

DQA – Data Quality Assessment

DRC – Democratic Republic of the Congo

DREAMS – Determined, Resilient, Empowered, AIDS-free, Mentored, Safe partnership

DRG – Democracy, Human Rights, and Governance (office at USAID)

DRM – Domestic resource mobilization

DSA – Data sharing agreement

DSD – Direct Service Delivery

DTG – Dolutegravir

DTS – Dried tube specimen

DUA – Data use agreement

DUC – Data use community

DUIT – Data Use for Impact Team (part of S/GAC)

EAC – Enhanced Adherence Counseling

EAP – East Asian and Pacific Affairs (State Department Bureau)

ECF – Emergency Commodities Fund

ECHO – Extension for Community Health Outcomes

ECT – Epidemic Control Team

ED-PrEP – Event-Driven Pre-Exposure Prophylaxis

EFV – Efavirenz

EGPAF – Elizabeth Glaser Pediatric AIDS Foundation

EID – Early-infant diagnosis

EMR – Electronic Medical Records

EMTCT – Elimination of mother-to-child transmission

EOFY – End of Fiscal Year

EPI – Expanded Programme on Immunization

EpiC – Meeting Targets and Maintaining Epidemic Control

EPOA – Enhanced Peer Outreach Approach

EQA – External quality assessment

ER – Expenditure Reporting

ERP – External review panel

ESA – East and Southern Africa

ESCM – Embassy Security, Construction, and Maintenance

ESoP – Evaluation Standards of Practice

EUM – End use monitoring

EUR – European and Eurasian Affairs (State Department Bureau)

F – The Office of U.S. Foreign Assistance Resources

FAR – Federal Acquisition Regulation

FAST – Funding Allocation to Strategy Tool

FATAA – Foreign Aid Transparency and Accountability Act of 2016

FBO – Faith-based organization

FCI – Faith and Community Initiative

FDA – Food and Drug Administration (part of HHS)

FDC – Fixed dose combination

FETP – Field Epidemiology Training Program

FJD – Framework Job Description

FMP – Families Matter! Program

FOA – Funding Opportunity Agreement

FOP – Foreign Assistance Operational Plan

FP – Family Planning

FS – Foreign Service

FSN – Foreign service national

FSW – Female sex workers

FTE – Full-time equivalent

FY – Fiscal year

G2G – Government-to-government

GAC – Grant Approvals Committee (also Global AIDS Coordinator)

GAHT – Gender-affirming hormone therapy

GAM – Global AIDS Monitoring (Reporting)

GAO – Government Accountability Office

GAP – Global AIDS Program (CDC)

GBV – Gender-based violence

GFATM – The Global Fund to Fight AIDS, Tuberculosis and Malaria (also “Global Fund”)

GHI – Global Health Initiative

GHP – Global Health Programs

GHP-State – Global Health Programs within the State Department (funding account)

GHP-USAID – Global Health Programs within USAID (funding account)

GIPA – Greater Involvement of People Living with HIV/AIDS

GNP+ – Global Network of PLHIV (an NGO)

GO – Grants Officers

GOR – Grants Officer Representative

GSD – Gender and Sexual Diversity Training

GSM – Granular Site Management

GTC - Guanidinium thiocyanate

HAF – HRIS Assessment Framework

HCD – Human capacity development

HCF – Healthcare Facilities

HCN – Host Country National

HCW – Healthcare workers

HEI – HIV-exposed infants

HF – Health Facility

HHC – Household contacts

HHS – U.S. Department of Health and Human Services

HIE – Health Information Exchange

HIS – Health information systems

HISTAC - Health Information Systems Technical Assistance Consortium

HIV – Human Immunodeficiency Virus

HIVDR – HIV Drug Resistant (surveys)

HIV RT – HIV Rapid Testing

HIVRTCQI – HIV Rapid Testing Continuous Quality Improvement

HIVST – HIV self-testing (or self-tests)

HLD – High-level disinfection

HMIS – Health Management Information System

HTN – Hypertension

HOP – Headquarters Operational Plan

HP+ – Health Policy Plus (a USAID mechanism)

HPV – Human papilloma virus

HQ – headquarters

HRH – Human Resources for Health

HRIS – Human Resource Information Systems

HRSA – Health Resources and Services Administration (part of HHS)

HSV – Herpes simplex virus

HTS – HIV Testing Services (formerly HIV Testing and Counseling – HTC

HW – Health Workers

IAA – Inter-agency Agreement

IBBS – Integrated Bio-Behavioral Survey

IC – Institutional Contractor

ICASS – International Cooperative Administrative Support Services

ICF – Intensified Case Finding

ICPI – Interagency Cooperative for Program Improvement

ICT – Information and Communication Technology

ICW – International Community of Women living with HIV/AIDS

IEC – Information, Education, and Communication (materials)

IGWG – Interagency Gender Working Group

IIT – Interruption in Treatment

IM – Implementing mechanism

INH – Isoniazid

IOM – Institute of Medicine

IP – Implementing Partner

IPC – Infection prevention and control

IPD – Inpatient Department

IPT – Isoniazid preventive therapy

IPV – Intimate Partner Violence

IRB – Institutional Review Board

IRIS – Immune Reconstitution Inflammatory Syndrome

IRM – Information resources management

IS – Implementation science

ISME – Implementation Subject Matter Expert

ISO – International Organization for Standardization (also Informatics-Savvy Organization)

ITSO – IT support

IUD – Intrauterine device

IVT – Infant virologic testing

IWG – Informatics Working Group

JEE – Joint External Evaluation

KENAS – Kenya Accreditation Service

KP – Key populations

KPIF – Key Populations Investment Fund

KPLHIV – Key Populations Living with HIV

L&D – Labor and Delivery

LAM – Lipoarabinomannan

LARC – Long-acting reversible contraceptive

LCI – Local Capacity Initiative

LCQI – Laboratory continuous quality improvement

LE – Locally Employed (Staff)

LEA – Legal Environment Assessment

LEEP – Loop electrosurgical excision procedure

LGBTQI – Lesbian, gay, bisexual, transgender, queer, and intersex

LIS – Lab Information Systems

LIVES – Listen, Inquire about needs and concerns, Validate, Enhance safety, and Support

LLV – Low-level viremia

LMIS – Lab Management Information Systems

LNA – Limited Non-Career Appointment

LOI – Letter of Intent

LOE – Level of effort

LZN – Lamivudine/Zidovudine/Nevirapine

M&B – Management and Budget Unit (part of S/GAC)

M&E – Monitoring and evaluation

M&O – Management and Operations

MAT – Medication Assisted Treatment

MBPs – Mother-baby pairs

MCH – Maternal and Child Health

MER – Monitoring, Evaluation, and Reporting

MH – Mental Health

MICS – Multiple Indicator Cluster Surveys

MIPs – Mother-Infant Pairs

MLWH – Men living with HIV

MMD – Multi-Month Dispensing

MMS – Multi-Month Scripting

MMT – Methadone Maintenance Treatment

MNCH – Maternal and newborn child health

MOA – Memorandum of Agreement

MOF – Ministries of Finance

MOH – Ministries of Health

MOU – Memorandum of Understanding

MPR – Minimum Program Requirements

MRP – Major Rehabilitation Program

MSM – Men who have sex with men

MSRs – Minimum site requirements

MTCT – Mother-to-child-transmission

mWRD – Molecular WHO rapid diagnostic test

NAAT – Nucleic acid amplification test

NAE – Notifiable Adverse Event

NASA – National AIDS Spending Assessment

NAT – Nucleic acid test

NCDs – Non-Communicable Diseases

NEA – Near Eastern Affairs (Dept. of State)

NGO – Non-governmental organization

NICRA – Negotiated Indirect Cost Rate Agreement

NIH – National Institutes of Health (part of HHS)

NNT – Number needed to test

NOFO – Notice of Funding Opportunity

NRTTI – Nucleoside reverse transcriptase translocation inhibitor

NSD – Non-service delivery

N/SHA – National/System of Health Accounts

NTD – Neural Tube Defect

NTP – National TB Program

NVP – Nevirapine

O&O – Obligations and Outlays (report)

OAT – Opioid agonist therapy

OBO – Overseas Buildings Operations (Dept. of State)

ODA – Other donor assistance

OE – Operating expense

OFPS – Office of Financial and Programmatic Sustainability (part of S/GAC)

OGA – Office of Global Affairs (part of HHS)

OGAC – Office of the U.S. Global AIDS Coordinator and Health Diplomacy (Dept. of State)

OIG – Offices of Inspectors General

OMB – Office of Management and Budget

OPD – Outpatient Department

OPU – Operational Plan Update

OR – Operations research (also Odds Ratio)

OS – Office of the Secretary (part of HHS)

OTA – Office of Technical Assistance (Department of Treasury)

OU – Operating Unit

OVC – Orphans and Vulnerable Children

PA/PD – Public Affairs/Public Diplomacy

PASA – Participating Agency Service Agreement

PBFW – Pregnant and Breastfeeding Women

PCRV – Peace Corps Response Volunteer

PCV – Peace Corps Volunteer

PDR – Pre-treatment drug resistance

PDSA – Plan-Do-Study-Act cycle

PDU – Pharmacy Dispensing Unit

PEP – Post-exposure prophylaxis

PEPFAR – U.S. President's Emergency Plan for AIDS Relief

PEPFAR SharePoint – the website, available to U.S. government staff only, which houses COP templates and guidance

PET – Program Efficiency Team (part of S/GAC)

PFA – Psychological First Aid

PFM – Public Financial Management

PHC – Primary Healthcare Center

PHDP – Positive Health, Dignity, and Prevention

PHIA – Population-based HIV Impact Assessment

PHVP – Preventing HIV/AIDS in Vulnerable Populations

PI – Protease inhibitor

PII – Personally Identifiable Information

PIP – Performance Improvement Plan

PIS – Pharmacy Information Systems

PITC – Provider-initiated testing and counseling

PLH – Parenting for Lifelong Health

PLHIV/PLWHA/PLWA – People Living with HIV/AIDS or People Living with AIDS

PLL – Planning Level Letter

PM – Political-Military Affairs (State Department Bureau)

PMS – Patient Medical System

PMTCT – Prevention of mother-to-child HIV transmission

PNC – Postnatal Care

POART – PEPFAR Oversight and Accountability Response Team

POC – Point of care (also point-of-contact)

POCT – Point-of-care testing

PopVLS – Population viral loan suppression

POT – Pediatric optimization toolkit

PPE – Personal Protective Equipment

PPM – PEPFAR Program Manager

PPMR-HIV – Procurement Planning & Monitoring Report for HIV

PPP – Public-Private Partnership

PQ – Program Quality

PR – Principal recipient

PrEP – Pre-exposure prophylaxis

PrIYA – PrEP Implementation for Young Women and Adolescents

PS – Prevention Services

PSA – Personal Services Agreements

PSAP – Policy Assessment and Action Planning

PSC – Personal Services Contract (also Plasma Separation Card)

PSE – Private Sector Engagement (also Population size estimate)

PSNU – Priority sub-national unit

PSS – Psychosocial Support

PT – Proficiency testing

PTE – Path to Elimination

PTSD – Post-traumatic stress disorder

PWID – People who inject drugs

QA – Quality assurance

QAT – Quantification Analytic Tool

QC – Quality control

QI – Quality improvement

QMEC – Quality management for epidemic control

R&R – Rest and relaxation travel

RA – Resource Alignment

RCT – Randomized control trial

RH – Reproductive health

RITA – Recent infection testing algorithm

RM – Responsibility Matrix

RNR – Risk Network Referral

ROP – Regional Operational Plan

RPM – Regional Planning Meeting

RPSO – Regional Procurement Support Offices

RSL – Remote sample logging

RSSH – Resilient and Sustainable Systems for Health

RT – Rapid testing

RTK – Rapid test kit

RTRI – Rapid test for recent infection

RTT – Return to Treatment

SABERS – HIV Seroprevalence and Behavioral Epidemiology Risk Survey (DOD)

SCA – South and Central Asian Affairs (State Department Bureau)

SCMS –Supply Chain Management System

SD – Service Delivery

SDS – Strategic Direction Summary

SDV – Stigma, Discrimination, and Violence (linked to KP or HIV status)

S/GAC – Office of the U.S. Global AIDS Coordinator and Health Diplomacy (Bureau in the State Dept.)

SHI – Social Health Insurance

SI – Strategic Information

SID – Sustainability Index and Dashboard

SIMS – Site Improvement through Monitoring System

SLA – Service Level Agreement

SLIPTA - Stepwise Laboratory Quality Improvement Process Towards Accreditation

SMS – Short Message Service (e.g., text messaging)

SNS – Social network strategies

SNU – Sub-national unit

SOP – Standard Operating Procedure

SOW – Statement of Work (also scope of work)

SPI-RT – Stepwise Process for Improving the Quality of HIV Rapid Testing

SPI-RRT – Stepwise Process for Improving the Quality of HIV Rapid and Recency Testing

SRE – Surveillance, Research, and Evaluation

SRH – Sexual and reproductive health

SRHR – Sexual and reproductive health and rights

STI – Sexually transmitted infection

SVAC – Sexual violence against children

SW – Sex workers

SWOT – Strengths, Weaknesses, Opportunities, and Threats analysis

TA – Technical assistance

TAD – Take-away doses

TAF – Tenofovir alafenamide fumarate

TAT – Turnaround Time

TB – Tuberculosis

TBD – To Be Determined

TBT – TB preventative treatment

TCN – Third Country National

TDF – Tenofovir disoproxil fumarate

TDR – Transmitted drug resistance

TEE – Tenofovir/efavirenz/emtricitabine

TG – Transgender people

TGW – Transgender women

TIF – Technical Interventions Framework

TLD – Tenofovir/lamivudine/dolutegravir

TLE – Tenofovir/lamivudine/efavirenz

TMA – Total market approach

TPM – Third-Party Monitoring

TPT – TB preventive treatment

TRACE - Tracking with Recency Assays to Control the Epidemic

TRANSGENDER - An umbrella term used to describe a person whose gender identity and/or gender expression does not conform with the cultural norms and expectations associated with the sex they were assigned at birth. This term can describe a wide variety of cross-gender behaviors and identities. This term does not imply any specific sexual orientation.

TRP – Technical Review Panel

TTCV – Tetanus toxoid containing vaccine

TTFs – Tools, Templates and Frameworks

TWG – Technical Working Group

UHC – Universal Health Coverage

UICs – Unique identifier codes

UIDs – Unique Identifiers

UNAIDS – Joint United Nations Programme on HIV/AIDS

UNDP – United Nations Development Programme

UNFPA – United Nations Population Fund

UNICEF – United Nations Children's Fund

UQD – Unmet Quality Demand

U.S. – United States

USAID – U.S. Agency for International Development

USDA – U.S. Department of Agriculture

USDH – U.S. direct hire

USG – United States Government

U=U – Undetectable equals untransmissible (or untransmittable)

VACS – Violence Against Children Surveys

VAST – Volunteer Activities Support and Training

VCT – Voluntary counseling and testing

VIA – Visualized with 5% acetic acid

VL – Viral load

VLC – Viral load coverage

VLS – Viral load suppression

VMMC – Voluntary medical male circumcision

VPIs – Vaccine-preventable illnesses

V-POT – Virtual pediatric optimization toolkit

VS – Virological suppression

WAE – While Actually Employed

WCF – Working Capital Fund

WHA -– Western Hemisphere Affairs (State Department Bureau)

WHIP3TB – Weekly High dose Isoniazid and Rifapentine (P) Periodic Prophylaxis

WHO – World Health Organization

WISN – Workload indicator of staffing need

WLHIV – Women Living with HIV

WMS – Warehouse Management Software

YLHIV – Youth Living with HIV