PEPFAR 2021 Country and Regional Operational Plan (COP/ROP) Guidance for all PEPFAR Countries

What's New in COP/ROP21

COP21 guidance underscores four key implementation themes of client-centered services, community engagement, resilient and adaptive approaches, and support for sustainable capacity.

Terminology Updates

- COP21 guidance shifts language with "continuity of treatment" replacing "retention", and "interruption in treatment" replacing "loss to follow up" (LTFU).

Program Implementation-related updates

- COP21 guidance reinforces clients' agency (i.e., ability to choose and act), focusing on the therapeutic alliance (Sections 6.1.3 and 6.4.1)
- Update on progress transitioning to local partners. New analytics give more detail on progress transitioning funding and program implementation to local partners (Section 2.4.1).
- Models of innovative financing are highlighted including models for strengthening and directly financing KP-led CSOs for long term sustainability. (Sections 2.4.2, 6.6.10.1 and 6.6.10.5)
- Incorporated minimum requirements from last year's planning level letters into overall DREAMS guidance (e.g., hiring an interagency DREAMS coordinator, lead DREAMS ambassadors, etc.)
- Updates to DREAMS section on expansion requirements, developing maintenance plans for saturated SNUs and age bands, and focus on mentoring (Sections 6.2.2.2 and 6.2.2.3)
- Updated PrEP guidance notes global scale-up of PrEP continues for those at substantial risk of HIV acquisition and new biomedical prevention products are moving through regulatory approvals and under evaluation by PEPFAR. OUs should consider integrating new products such as the Dapivirine Vaginal Ring (DVR) and injectable long acting cabotegravir into PrEP and other prevention platforms as products move into the global marketplace (Section 6.2.1).
- Key Populations considerations for viral load coverage (Section 6.4.5), defining and addressing structural interventions among KPs (Section 6.6.2.2), and addressing service delivery and engagement of children from KPs. (Section 6.6.2.7)

- Updated considerations for VL coverage and VL suppression (Section 6.5.5)
- There are new sections on advanced disease for treatment of children (Section 6.5.2.2) and Optimization of ARV Prophylaxis for HIV-exposed infants (HEI) (Section 6.5.1.1). Some adolescent and youth sections are separated from pediatric sections in last year's guidance and there are separate sections for adolescents and youth (Sections 6.1.3.2, 6.3.3, 6.4.3).
- Optimal ART regimens for children weighing <20kg have been updated to prioritize DTG for all CLHIV (Section 6.5.1.2). Minimum Program Requirements are updated to reflect this (Section 2.2) and a new section was added on missed appointments, interruptions to care, and client tracking (Section 6.1.2)
- A new section on optimization of HIV prophylaxis for HEI introduces considerations for the rapid identification and treatment of infants with exposures to HIV during pregnancy, birth or the breastfeeding period (6.5.1.1).
- The advanced disease section for adults includes CD4 for individuals re-entering care with a sub-section on reducing mortality and a focus on site safety (6.5.2 through 6.5.2.3).
- In the context of SARS-CoV-2, COP 21 guidance highlights the need to ensure TB diagnosis, treatment, and prevention remain a priority and are coordinated with COVID-19 response, including testing and infection prevention and control. (Section 6.5.3)
- There is an expanded infection prevention and control (IPC) section (6.7.1).
- COP21 guidance includes new sections on occupational health (6.7.2), waste management and cleaning (6.7.3), disinfection and sterilization (6.7.4).
- COP21 recommendation for VL testing now includes the option of either delivery of results directly to patients or alerting them through SMS of the readiness of their results to strengthen client-centered approaches and initiate proactive counseling for viral load literacy (Sections 6.5.5 and 6.5.5.2).
- In COP20, there was a recommendation to use POC platforms for VL testing in PBFW. In COP21, this has been expanded to include the use of POC platforms for VL testing in infants and children as an aspect of family centered testing and improved optimization and effective instrument use (Section 6.5.5.1).
- In COP21, there is a reminder for all countries to implement transition 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 (Section 6.6.1)

- The VL/EID Community of Practice has put together best practices, tools and guidance that programs should consider using in efforts to close remaining gaps in 2-months EID testing coverage and linkage to HIV-positive infants to ART. (Section 6.3.1.4)
- Updated information on Economic Strengthening (Section 6.2.2.2)
- MMD and decentralized drug delivery accelerated by COVID-19, adaptations should continue

Process- and Policy-related updates

- Details on preparing for a Virtual COP21 Planning and Approval Meetings (Sections 2.5.3 and 5)
- References added to PEPFARs Guidance on Implementing Safe and Ethical Index Testing that was released in March 2020 and rolled out in all PEPFAR-supported OUs. Compliance with this guidance is on-going and will continue through COP21 (Sections 2.3.2 and 6.3)
- There is also new guidance for planning and implementing mechanism's close-out expenses. Budget planning should include discussions of results and efficiency. (Section 4.2)
- Updates on planning a COP21 budget without budget codes (Sections 5.9 and 9.2)
- Inclusion of new SIMS Standards (site and above-site) to be used for routine monitoring of compliance with PEPFAR Guidance on Implementing Safe and Ethical Index testing (Section 3).
- In COP21, a separate section has been included on the USAID Global Health Supply Chain Program–Procurement and Supply Management (GHSC-PSM) project's global purchasing and service level agreements (SLAs) with diagnostic manufacturers for VL and EID reagents, consumables and services. All countries should shift from outright instrument procurement to the PEPFAR supported SLAs which incorporate the all-inclusive pricing approaches (Section 6.6.1.2)
- Further Information on grants program training, oversight and implementation (Section 11.1)
- Table 6 has been modified to distinguish areas of increased domestic responsibility and time frame, benchmarks, and outputs.
- Reminder: MER 2.5 has been released for FY21. COP21/FY22 targets should be aligned with indicators and definitions per MER 2.5.

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Part A: COP/ROP21 GUIDANCE: STRATEGY

EXECUTIVE SUMMARY

Nearly, eighteen years ago, in the January 2003 State of the Union Address, PEPFAR was born as a clear expression of the compassion of the American people to stop the human suffering of the AIDS epidemic and bring hope and life to communities around the globe. When PEPFAR began, HIV was a death sentence in many parts of the world. Now, we have the historic opportunity to make what once seemed impossible possible: controlling the HIV/AIDS epidemic. The U.S. government has saved millions of lives and prevented millions of HIV infections through PEPFAR. Working together with our partners in more than 50 countries, we have moved the HIV/AIDS pandemic from crisis towards control – community by community, country by country. Globally, PEPFAR has helped replace death and despair with vibrant life and hope: according to UNAIDS, AIDS-related deaths have been cut by 60 percent since their peak in 2004, and new HIV infections have been reduced by 40 percent since their peak in 1998. Many countries have made tremendous progress, while others need to accelerate their efforts to achieve their commitment to the United Nations' Sustainable Development Goal (SDG) 3 for HIV.

PEPFAR's lifesaving work has been made possible through the U.S. government's unwavering commitment to the program and the American people's compassion and generosity. Over the past 18 years, PEPFAR has achieved remarkable lifesaving results.

- PEPFAR has supported lifesaving antiretroviral treatment for more than 17,189,244 people, including more than 683,800 children, helping secure the health and welfare of families around the world.
- PEPFAR has provided critical care and support for 6,745,304 orphans, vulnerable children, and their caregivers in FY2020 so they can survive and thrive.
- PEPFAR has supported more than 25,271,620 men and boys to receive voluntary medical male circumcision since 2004, including 2,448,796 in FY2020 alone.
- PEPFAR's investments have also strengthened the systems that drive effective, efficient, and sustainable health care. This includes having helped train 6,951 new health workers in FY2020 alone, reaching over 290,000 health and community workers overall to deliver and improve HIV care and other health services, creating a more robust health system for partner countries to confront other current and future health challenges.

COVID-19 Impact

During 2020, the coronavirus SARS-CoV-2 has quickly spread across the globe, dramatically impacting nearly all people worldwide as communities and countries took action to limit the impact of COVID-19 without a vaccine. COVID-19 has impacted PEPFAR, and rapid program adaptations and client-centered[1] solutions were essential to ensure continuity of HIV prevention and treatment services. The initial experience of PEPFAR since the onset of COVID-19 pandemic has been mixed, but key top-line aims – linking PLHIV with care and sustaining them on lifesaving treatment – have been met, as overall program growth continued and continuity of treatment for PLHIV was largely successful. However, while PEPFAR and partner programs have shown remarkable resilience on treatment continuity in the context of COVID-19, the pandemic's impact on PEPFAR's and Global Funds HIV, tuberculosis (TB), and malaria prevention programs has been devastating. The pain has been particularly acute for women and children as well as other vulnerable and marginalized populations, as these dual pandemics continue to reveal and exacerbate existing inequities in societies around the globe. COVID-19 has also shown the fragility of health care systems in some upper- and middle-income countries, which due to their relative wealth have lost their GAVI eligibility and that could impact their ability to access COVID-19 vaccines once they are available. We must meet these and other challenges swiftly and decisively to sustain – and in some cases to regain – hard-won progress against HIV, TB, and malaria. We must ensure that people are not faced with an impossible choice between food and health care. We must ensure that our investments reach the most vulnerable where they are, with what they need. And we must ensure that country and community health care systems are enduring, responsive, and resilient – capable of contributing to pandemic response and global health security for years to come.

To this end, during the COVID-19 pandemic, PEPFAR continues to move forward and implement life-saving measures for HIV services. In addition, PEPFAR systems and leadership have served as important assets with many of the laboratories funded and staff by PEPFAR as the source of COVID19 testing and human resources for health supporting country governments as they took action to control the impact of the COVID-19 pandemic.

Despite disruption from a second pandemic due to the novel coronavirus SARS-CoV-2, PEPFAR, with partner governments, multilateral partners, and communities, continues to move rapidly toward control of the HIV pandemic, without a vaccine or a cure. Achieving epidemic

[1] In this document, a client is defined as a recipient of services

control for HIV will be a remarkable accomplishment, saving millions of lives, significantly lowering the burden of HIV/AIDS in countries and communities, reducing the future costs required to sustain the HIV response, and building sustainable public health systems capacity in host countries.

PEPFAR remains a global leader in the use of granular data to drive health care results and increase impact. PEPFAR's support for large national household surveys – Population-Based HIV Impact Assessments (PHIAs) – to track progress and identify key gaps as high-burden countries move toward epidemic control, has provided crucial insights and context about program impacts and gaps, outputs and performance. PEPFAR program data and PHIA results show us that progress toward achieving HIV/AIDS epidemic control requires not only financial investment but also effective collaboration and mutual accountability among partner governments, stakeholders, and communities. Collaboration and accountability improve effectiveness, such as awareness of HIV status and treatment outcomes. U.S. government investments are most effective within a supportive policy environment, which includes implementation of internationally accepted HIV treatment and prevention practices.

To achieve HIV/AIDS epidemic control, and consistent with countries' commitments to Sustainable Development Goals and UNAIDS goals, PEPFAR is committed to ensuring a public health response where people of all ages, genders, gender identities, sexual orientations[2], and at-risk populations in communities who are living with HIV or at risk of acquisition learn their HIV status, receive lifesaving HIV prevention and treatment services, and are virally suppressed if they are HIV-positive.

As the threat of COVID-19 has impacted PEPFAR countries, PEPFAR country teams have accelerated interventions that permit clients to maintain continuous HIV treatment in the setting of lock downs and social disruption while ensuring safety of clients and providers. Multi-month dispensing of ARVs and decentralized drug distribution are client-centered innovations that reduce congestion in health care facilities and allow clients to spend less time in the clinic, where they could potentially be exposed to COVID-19. HIV testing services have been disrupted, but self-testing has been accelerated to a degree. Prevention services have been

[2] 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 beneficiaries, at all sites, and in all communities.

heavily impacted as in-person mass education events were halted, Voluntary Medical Male Circumcision (VMMC) was paused, and condom shortages occurred in some countries. Despite the barriers, some prevention areas such as pre-exposure prophylaxis (PrEP) continued to scale up and make use of adaptations such as multi-month dispensing (MMD) and decentralized drug dispensing (DDD). Many OUs have resumed prevention services with precautions to prevent the spread of COVID-19. However, it appears that barriers experienced by vulnerable groups (including key populations and adolescent girls and young women) have been exacerbated. Country teams should make up ground in these areas in COP20 implementation and COP21 plans.

COVID-19 has reconfirmed and magnified the urgency of provision of effective client-centered care, the key implementation theme for COP20. As country teams have focused on sustaining HIV prevention and treatment services in the context of COVID-19, they have aimed to provide access to the right service in the right place at the right time, as well as to be equipped with contingency plans and capacity to rapidly respond to unexpected events and maintain provision of service to sustain clients on continuous treatment. Namibia, for example, while hard hit by COVID-19 was able to take early steps prioritizing life-saving HIV treatment with clinic readiness, MMD, community dispensing, leveraging technology and other program adaptations that ensured continuity of essential HIV services[3].

Where PEPFAR successfully navigated disruption due to COVID-19 during 2020, it was a result of strong teams, local partners, dedicated health workers, and community-based organizations that worked to adapt and further innovate program implementation and models of service delivery so that the adverse impacts of the pandemic on HIV services were mitigated.

Throughout the COVID-19 pandemic, PEPFAR has remained committed to continuing essential HIV prevention and treatment services, while maintaining a safe healthcare environment for clients and staff. In order to meet our commitment to uninterrupted care and treatment for PLHIV and the prevention of deaths among PLHIV due to HIV associated co-morbidities, PEPFAR has been committed to adapting HIV services, so that PEPFAR beneficiaries have the best possible outcomes within the context of stretched healthcare systems. Up to date PEPFAR guidance related to COVID-19 can be found at https://www.state.gov/pepfar/coronavirus/.

[3] Hong, Stephen Y., et. al., ***Rapid Adaptation of HIV Treatment Programs in Response to COVID-19 — Namibia, 2020***, MMWR Morbidity and Mortality Weekly Report, 2020 Oct 23; 69(42): 1549–1551.

Despite the disruptions caused by the COVID-19 pandemic, a number of countries have achieved epidemic control in COP20, and others will achieve epidemic control in COP21. With continued improvement, most PEPFAR countries are on a path to achieving program coverage goals. With that in mind, PEPFAR programs should highlight four key themes in planning and implementation for COP21.

1. Client-Centered Services

Experience with COVID-19 has underscored the importance of a client-centered approach to service, as highlighted during COP20 planning. Clients are critical partners with providers in ensuring their own HIV treatment success. The scaling of multi-month dispensing, decentralized drug delivery, and services designed to adapt to clients' needs, preferences, and life events remain critically important.

In COP21, PEPFAR will further develop effective and efficient service delivery mechanisms that are responsive to client needs. This includes easy access to HIV and TB drugs and prevention commodities such as condoms and lubricants, other forms of differentiated service delivery, and different options for support of treatment continuity, in order to support patients where they are.

2. Community Engagement

HIV and COVID-19 both underscore the vulnerabilities too often created by stigma, discrimination, gender-based violence, economic hardship, displacement, and a lack of knowledge and power attributable to youth. COP21 plans must effectively serve key and vulnerable populations as well as others at the margins of society. COP21 plans must be designed to effectively address needs of vulnerable populations.

Further, successful PEPFAR programs have been able to leverage community assets and networks such as PLHIV, key populations, women's groups, faith organizations, employers and businesses, and civil society advocates, to improve outcomes.

During COP20, PEPFAR invested in expansion of community-led monitoring as a critical way to listen to community voices in assessment of program quality and design of client-centered services. COP21 plans should aim to realize PEPFAR's vision that clients and communities are at the center of what we do, crucial for both design and evaluation of our approach to service, including our approach to responding to COVID-19.

3. Resilient and Adaptive Approaches

The initial experience with the COVID-19 pandemic led to lockdowns, fears about risks from clinic visits, disruptions of supply chain, and social distancing requirements all of which threatened to disrupt HIV services. PEPFAR teams demonstrated the value and the critical importance of being equipped with contingency plans and capacity to rapidly respond and adapt to pandemic illness and other events (e.g., natural disasters, civil unrest) that can disrupt service delivery systems and patients' lives. PEPFAR teams and programs exercised resilience in sustaining HIV services despite disruption due to COVID-19, and COP21 plans should draw on lessons learned from COVID-19 to ensure systems of service delivery ***and the people who implement them*** are safe, secure, and resilient.

As one example, effective multilateral coordination and engagement with host governments and the Global Fund to Fight AIDS, TB, and Malaria, proved essential in adapting to an evolving global supply chain context, which must remain a focus moving forward to ensure stable sourcing of key commodities for these interventions.

4. Support for Sustainable Capacity

PEPFAR's success in preserving its gains despite the disruption caused by COVID-19 during FY2020 demonstrates key strengths of the design and approach of PEPFAR and the service delivery platforms and health worker and community staffing it supports. Notably, PEPFAR implements a public health approach to epidemic control through data-driven, accountable delivery of quality medical treatment and prevention services. Crucial strengths of PEPFAR's design include integration of public health with medical services and a focus on improving health outcomes through data-driven decisions that use laboratory, clinical, and epidemiological data. PEPFAR countries were positioned to mitigate the impact of COVID-19 in a variety of ways, and this is important to recognize particularly as countries work to sustain epidemic control of their HIV response beyond the achievement of 95/95/95 goals.

As PEPFAR supports countries to achieve their coverage goals, plans for COP21 should advance the ability of partner countries to equip themselves with the resources they need to assume increasing responsibility for the HIV response. As countries take on increased responsibility of sustaining the HIV/AIDS response, PEPFAR will provide support to mitigate inevitable difficulties of the responsibility shift. The economic effects of COVID-19 may be significant over the medium term, and PEPFAR teams will take care to ensure that gains are sustained. Shifts in functional responsibility may occur while maintaining some funding to support the country.

PEPFAR will work with partner governments, including subnational units, to ensure PEPFAR's data-driven public health model is successfully implemented down to the site level. OUs will help strengthen local disease surveillance capabilities with real-time detection of new infections, recency testing, and outbreak control. PEPFAR will also work with partner governments on the management and supervision of their health and laboratory systems to ensure HIV treatment and prevention services are maintained and modernized as the science of HIV changes. PEPFAR teams will also seek to expand client-centered services provided through local private sector and community groups.

Services for key populations and other vulnerable groups will continue to be a priority for PEPFAR program execution, regardless of politics or priorities within a country and ensuring direct line of support to community organizations to provide the critical peer led and community led services.

Finally, COP21 will end the use of budget codes and further maximize the usefulness of the PEPFAR Financial Classifications. These classifications began with expenditure reporting in COP18. Their use expanded to include the FAST in COP19 and partner workplans in COP20. In general, interventions created from the combinations of program areas and beneficiary categories better express programmatic intent and further facilitate mutual understanding. Elimination of budget codes significantly simplifies the FAST, improves the COP process, and aligns with PEPFAR's data-driven approach. Expanded use of PEPFAR's Financial Classifications can better translate plans into resources, ensures targets are both achievable and proportional to PEPFAR's investment, and allow prioritization of the most urgent and impactful activities when necessary.

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 18 years since its inception, PEPFAR has invested more than $95.65 billion in the global AIDS response, the largest public health effort against a single disease by any country in history, saving more than 18 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 certain basic 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 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, it 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 critical duties of the Global AIDS Coordinator are 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 US 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 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.

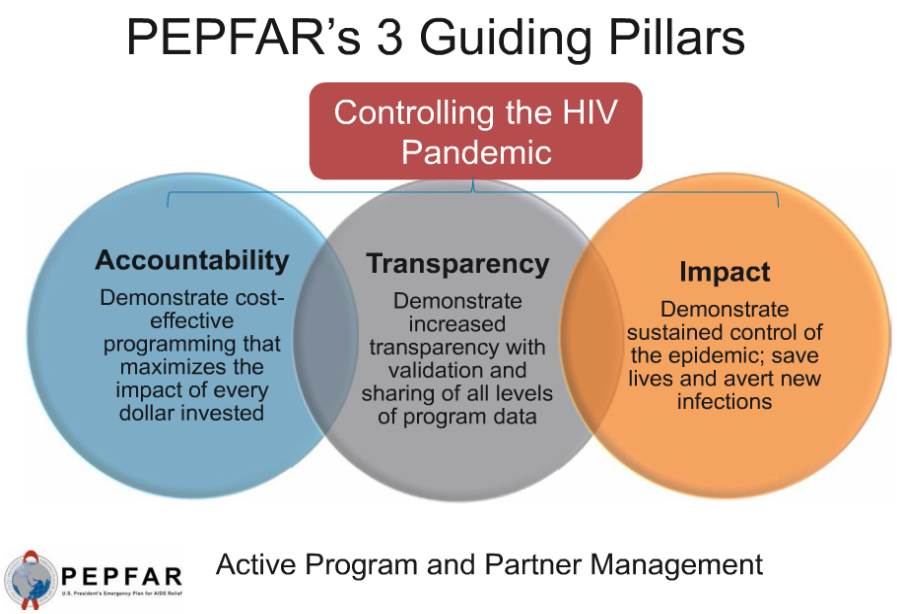
Many of these duties are substantially carried out by the U.S. Global AIDS Coordinator through the annual Country Operational Planning/Regional Operational Planning (COP/ROP) process. The COP/ROP is developed as part of an annual assessment, planning, budgeting and monitoring cycle led by S/GAC.

1.3 Principles

Over the 18 years of PEPFAR, several principles have been essential for success.

- Commitment to the person at risk or infected with HIV and to their continuity on ARV treatment/prevention services
- Commitment to use evidence-based practices and prioritize strategies that maximize impact
- Using data to drive policies and results
- Accountability, transparency, and impact in all activities

Figure 1.3.1 PEPFAR's guiding pillars



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 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.

1.5 Roles of PEPFAR Country Coordination Offices

PEPFAR Coordinators. Each PEPFAR OU has an in-country PEPFAR Coordinator, and 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

The COVID-19 pandemic tested and proved the resilience of the PEPFAR program. The pandemic presented many uncertainties, most importantly whether HIV-positive clients would be able to reliably and safely receive HIV medications and remain on their life-saving therapy. COVID-19 also magnified the urgency of implementing effective client-centered care – to bring services to clients in meaningful ways, where they are, but to also have sustainable, local contingency plans to keep patients on continuous treatment even under extreme, unexpected international crises. PEPFAR country teams have accelerated implementation of innovations such as multi-month dispensing, decentralized drug distribution, and adaptation of trainings, supportive supervision/mentorship, and certain client

services to remote platforms to continue necessary case identification, treatment, and prevention work. The work that PEPFAR, partner country governments, the Global Fund, and communities have done over the years to scale-up multi-month ART dispensing and implementation through local organizations has served HIV clients in an enduring manner through COVID-19. These efforts have led to continuity of care for PLHIV even during major global disruption and will need to be maintained and expanded in COP21, along with efforts to safely resume community and facility activities that were minimized or put on hold during 2020.

PEPFAR supports strategy and targets derived from the global communities of UNAIDS, WHO, and specifically from the Heads of State in their commitment to Sustainable Development Goal (SDG) 3 and are aligned to support the country's specific ambition towards those goals. The 2015 commitment by Heads of State and the broader global community to end the HIV/AIDS epidemic as a public health threat by 2030 (specifically SDG 3.3) was followed by a United Nations High Level Meeting on HIV/AIDS in June 2016 during which Heads of State further committed to the 90/90/90 Fast Track Strategy. Essential to the Fast Track Strategy is the achievement of 73% community viral load suppression (VLS) by 2020 and 86% community VLS by 2030; increased prevention interventions; the elimination of stigma and discrimination and ensuring all ages, genders and risk groups have access to life-saving prevention and treatment services. PEPFAR also supports country governments' commitment to the Three Frees – Start Free, Stay Free, AIDS Free.

Since 2016, PEPFAR and the Global Fund resources have been focused on achieving these global goals that have been translated to each country by UNAIDS and subsequently supported financially and technically by PEPFAR. To date, PEPFAR has utilized these global commitment targets as PEPFAR targets with commensurate program funding in 2016, 2017, and 2018 based on need and performance to achieve the goals set out by the Heads of State. Many countries have made tremendous progress towards these targets and others need to accelerate.

As we reach the end of 2020, PEPFAR must continue to innovate programs to reach clients with quality prevention and treatment services while addressing the challenges posed by the COVID-19 pandemic. Our collective hope is to reflect on progress and challenges for reaching our UNAIDS 2020 global goals and turn towards our 2030 global goals.

Over the past five years there has been tremendous progress towards reaching epidemic control by implementing the UNAIDS 90/90/90 treatment framework for adult men, adult women, and children (Fig 2.1.1) and dramatically increasing funding for and focus on effective primary prevention interventions. The U.S. Government, through the PEPFAR program, remains the largest funder of primary prevention interventions, leading the way in the implementation of VMMC for boys and men,

DREAMS for adolescent girls and young women, and access to PrEP and condoms for all populations. Globally, PEPFAR has helped replace death and despair with vibrant life and hope: according to UNAIDS, AIDS-related deaths have been cut by 60 percent since their peak in 2004, and new HIV infections have been reduced by 40 percent since their peak in 1997. Even with this progress, there remain numerous serious challenges to reaching full global epidemic control (95/95/95).

FY2020 was the year to document achievement of epidemic control across all ages and sexes. PHIA surveys to measure progress toward epidemic control were planned for eight countries this year: Zambia, Botswana, Zimbabwe, Lesotho, Malawi, Uganda, Eswatini, and Mozambique. Fortunately, Zimbabwe and Lesotho were able to complete their surveys, providing critical information for the direction of these programs, while others are currently on hold or delayed as a result of the COVID-19 pandemic. As shown by most recently completed national PHIAs (Fig 2.1.1), reaching 95/95/95 is possible, but maintaining it will be hard, especially when significant barriers exist for ART continuity, and programs will need to be adapted under COVID-19 restrictions. Maintaining epidemic control will be further challenged by the lack of national surveillance and service delivery systems to detect real-time new infections and respond with immediate prevention and treatment services. Projections based on these fully completed PHIAs (Fig 2.1.1), plus PEPFAR program data, and UNAIDS PLHIV estimates (Fig 2.1.2) suggest many countries across Eastern and Southern Africa have met the Community Viral Suppression goal of the 90/90/90 goals (community viral load suppression 73%) by 2020, even if the successes are not perfectly even across the three 90s and across all countries. For some countries, particularly in Western Africa and in some of the countries with the largest burdens of PLHIV, there are still challenges to reach epidemic control. According to programmatic data, more countries may have reached epidemic control, however we need PHIA surveys to document their current epidemic status. The early results from Lesotho and Zimbabwe demonstrate that with the right programming, not only can epidemic control be reached for both men and women, but gains can be protected and further strengthened. COP21 direction builds on PEPFAR programs' collective experience to take critical interventions to scale with fidelity as a means of reaching 95/95/95.

Despite worldwide government movement restrictions during COVID-19, PEPFAR programs continued to diagnose PLHIV, to provide life-saving treatment, and to support evidence-based activities to prevent transmission, where possible. Program results through FY20 show that many countries were successful in engaging and retaining older clients on ART, particularly those with signs and symptoms of the disease. However, younger clients (i.e., less than 35 years old) initiated on treatment, most of whom were likely to be asymptomatic, were not as successful with continuous

treatment as older clients (Fig 2.1.3). Moving forward, as the number of new infections continues to dramatically decrease and ART coverage with viral suppression among older populations stays above 75%, ensuring ART sites are effectively and efficiently tailored to younger, asymptomatic clients continues to be critical. Reducing stigma and discrimination for all PLHIV, especially for key populations, needs to be a key part of our client-centered care and will be monitored through the PLHIV Stigma Index. Reaching HIV-infected men continues to be critical; Figures 2.1.4 and 2.1.5 show greater progress towards finding and successfully treating adult women than adult men. Thus, to reach our goals, evaluating disaggregated quarterly program data by five-year age groups and sex, along with an updated measurement of patients currently on treatment, is essential for identifying gaps by population and geography.

Consequently, collective treatment and prevention priorities for COP21 include:

1. Scaling or maintaining solutions to address barriers to case finding and treatment continuity, particularly among young and asymptomatic clients, and ensuring all HIV-positive clients are engaged in continuous ART and enabled to maintain viral load suppression.
2. Ensure that PEPFAR prevention activities prioritize the populations with the greatest need so that VMMC, DREAMS, PrEP, and access to condoms are saturated in the highest prevalence and highest risk populations as evidenced by high yield, incidence or recency tests (See Section 6.3.6).

Figure 2.1.1: Progress towards 95/95/95 across select countries in Southern, East and West Africa

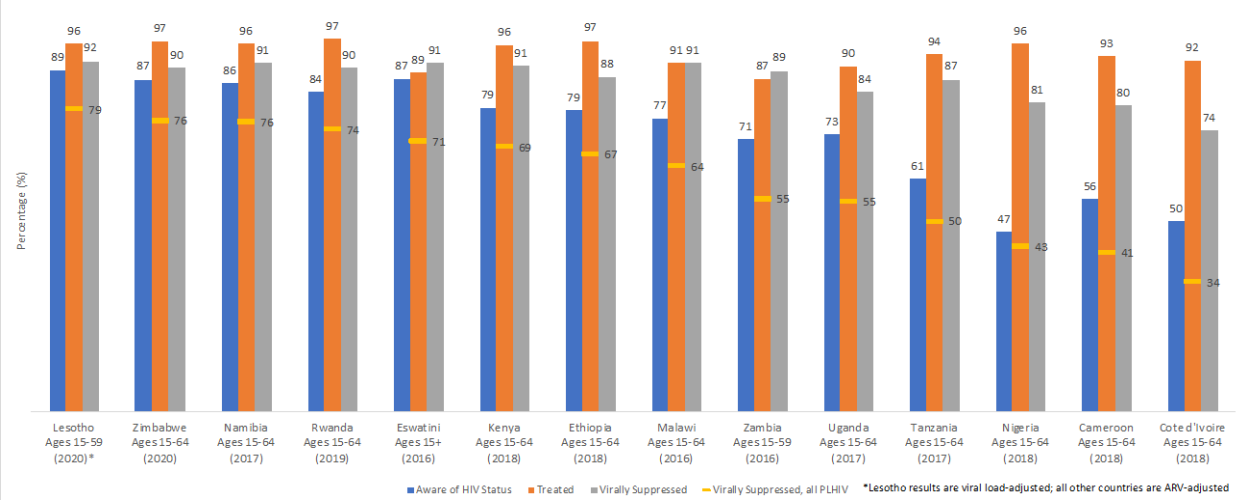


Figure 2.1.2: Projected progress towards 95/95/95 across select countries in Southern, East and West Africa

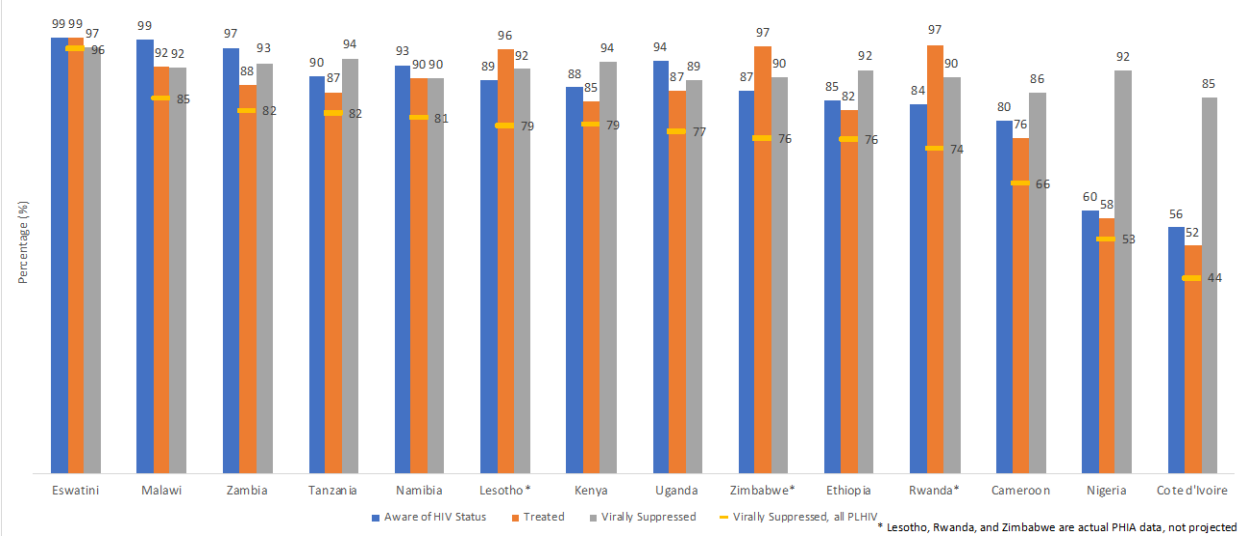


Fig 2.1.3: Progress towards 95/95/95 among 15 to 24 year-olds across select countries in Southern, East and West Africa[4]

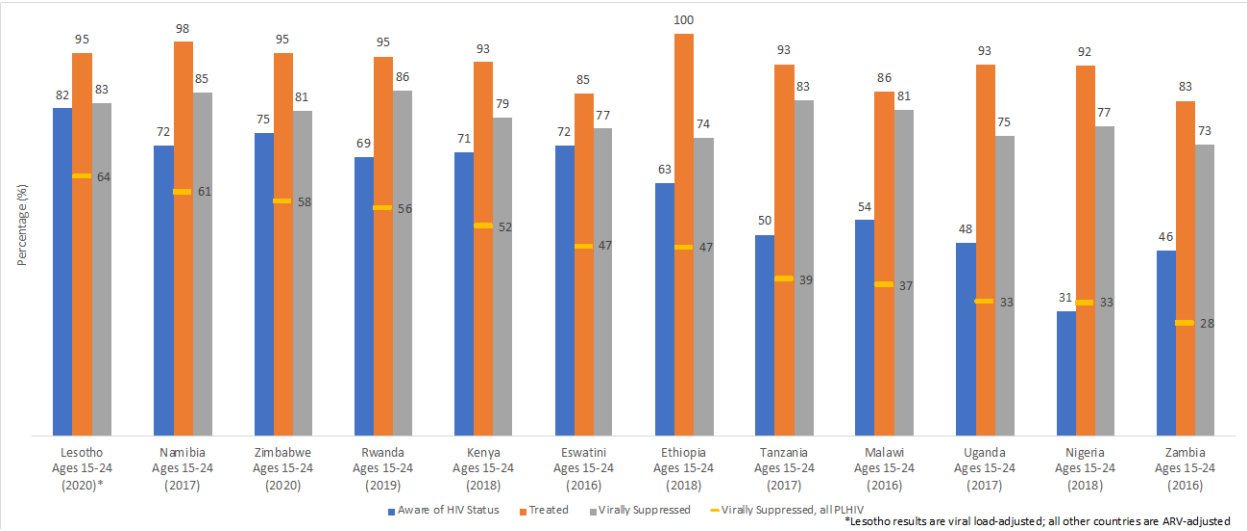


Fig 2.1.4: Progress towards 95/95/95 among adult men across select countries in Southern, East and West Africa

[4] 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

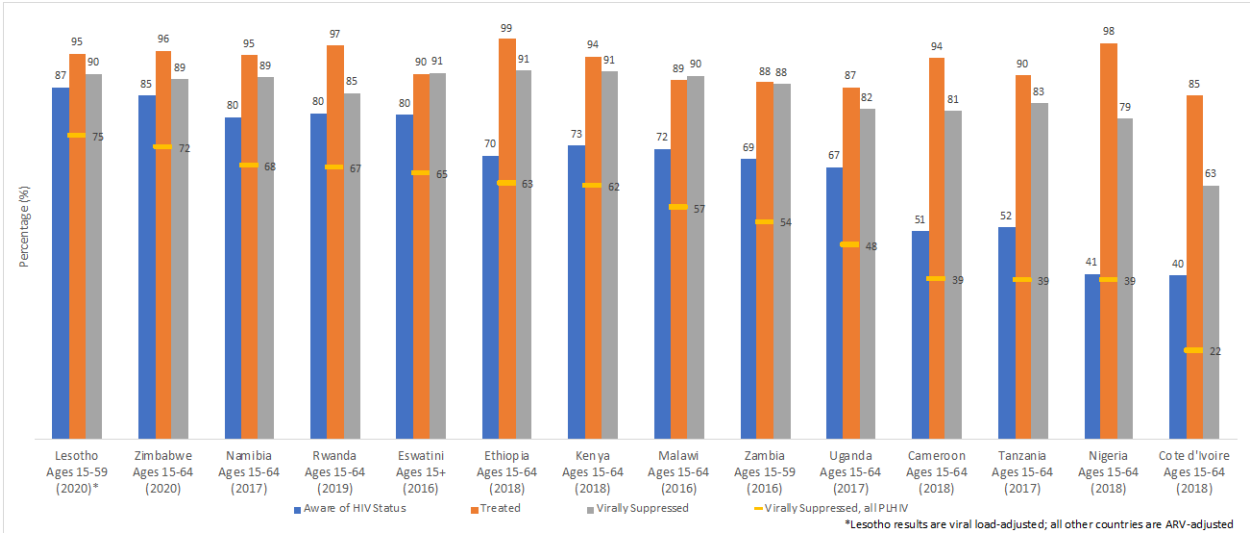
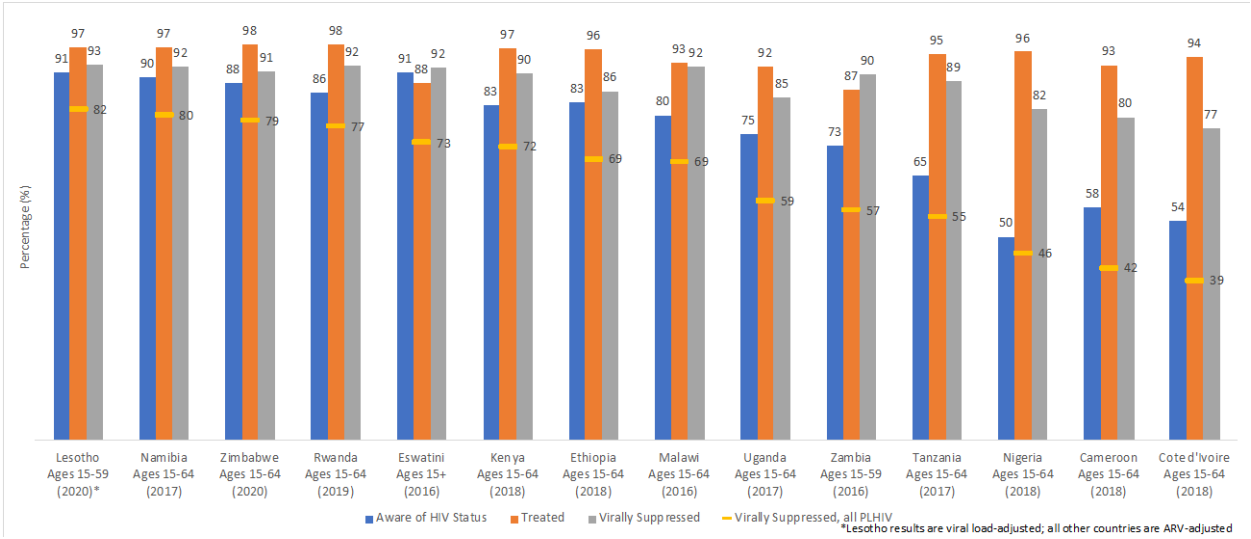


Fig 2.1.5: Progress towards 95/95/95 among adult women across select countries in Southern, East and West Africa



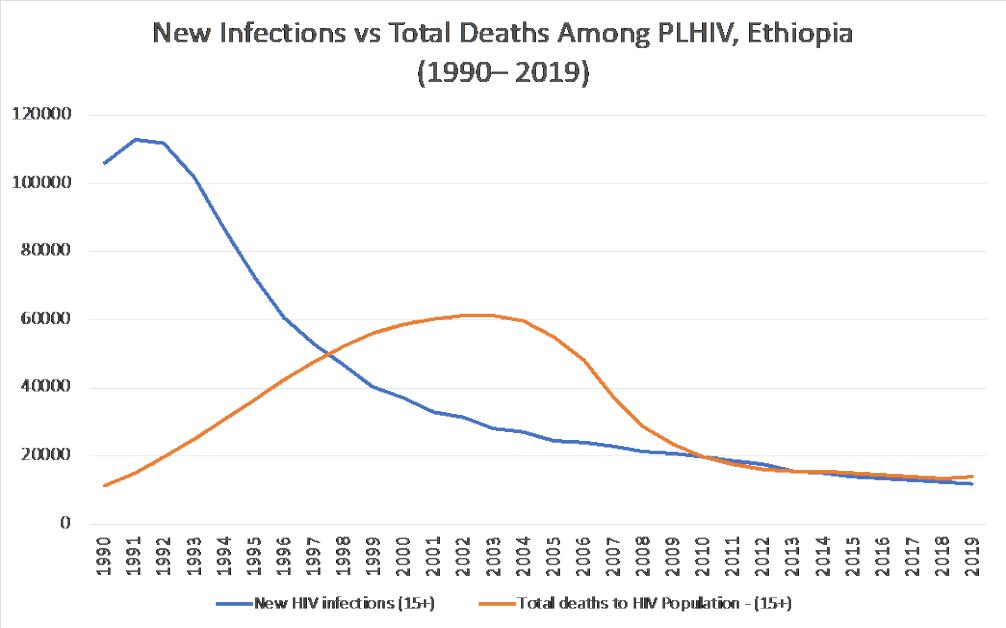
2.1.1 Progress Towards Epidemic Control

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 HIV-infected individuals[5] (the classic R_0 to R_i approach to infectious diseases), with both new infections and deaths among HIV-infected individual slow and declining. Figure 2.1.1.1 shows the relationship of trends for all-cause mortality among people living with HIV (PLHIV) and new HIV infections in

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

Ethiopia. As shown by Zimbabwe, Lesotho, Namibia, Eswatini and Rwanda, reaching over 73% community viral suppression across age/sex bands epidemic control is attainable.

Figure 2.1.1.1: New infections vs total deaths among PLHIV in Ethiopia

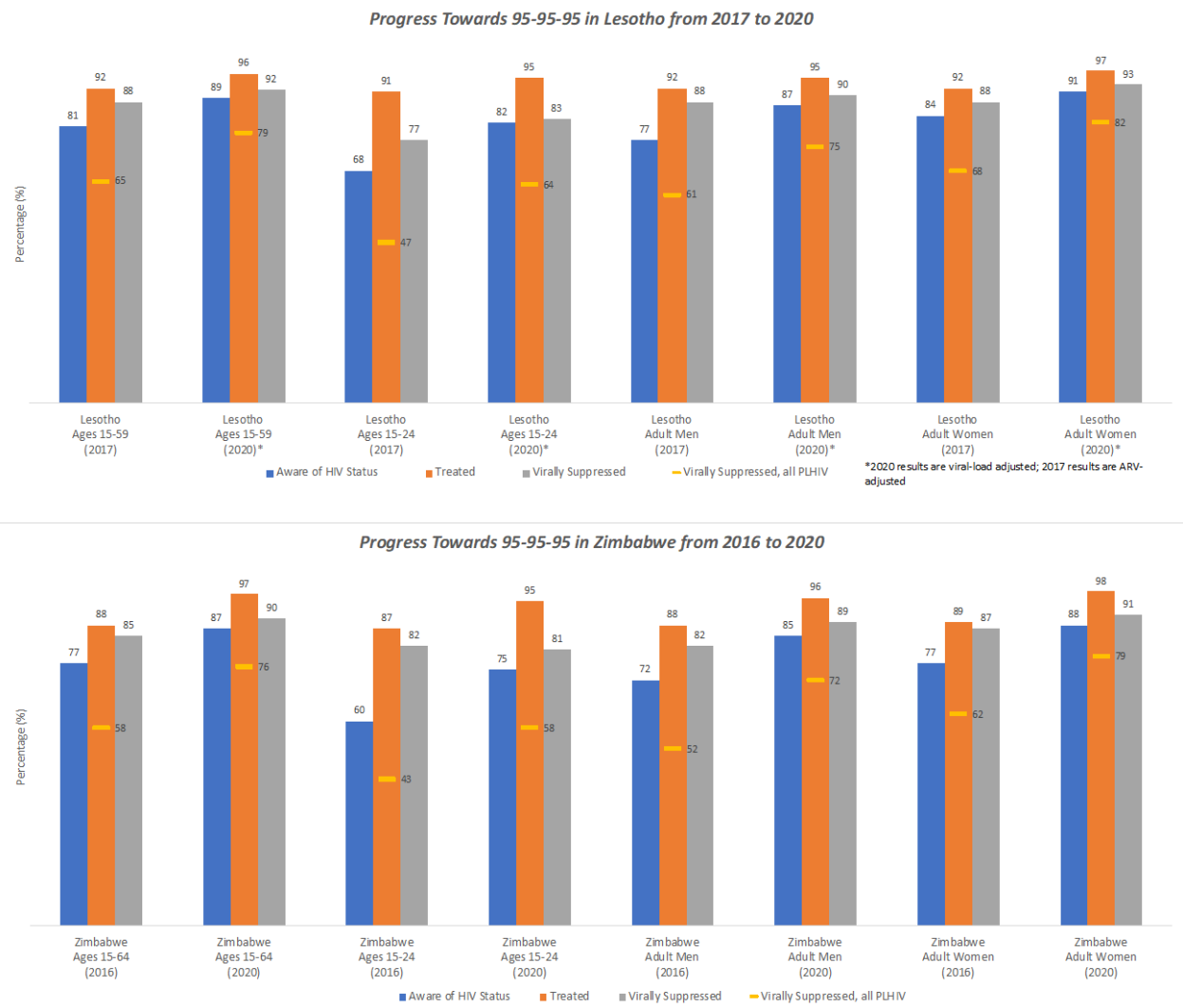


Results from Zimbabwe and Lesotho's PHIA results demonstrate that using the right data to identify gaps and continually make real-time program changes can make effective and sustainable progress toward epidemic control (Fig 2.1.1.2). Zimbabwe nears optimal ART coverage reflected in their national numbers, with 96% of men and 98% of women who know their status on ART in 2020, compared to previously 88% and 89% coverage, respectively, in 2016. 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 reduced their focus on new treatment initiation to maintenance of PLHIV on continuous treatment with high levels of viral load 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 of 25-34 year olds from 0.81 (PHIA 2016) to 0.5 (PHIA 2020), with improvements in the clinical cascade for 15-24 years old, from 87% (PHIA 2016) to 95% (PHIA 2020) of young adults who know their status on ART and increasing from 43% to 58% in community VLS.

Similarly, Lesotho further improved in their clinical cascade across all populations between their two PHIAs toward epidemic control, with their community VLS in adult males increasing from

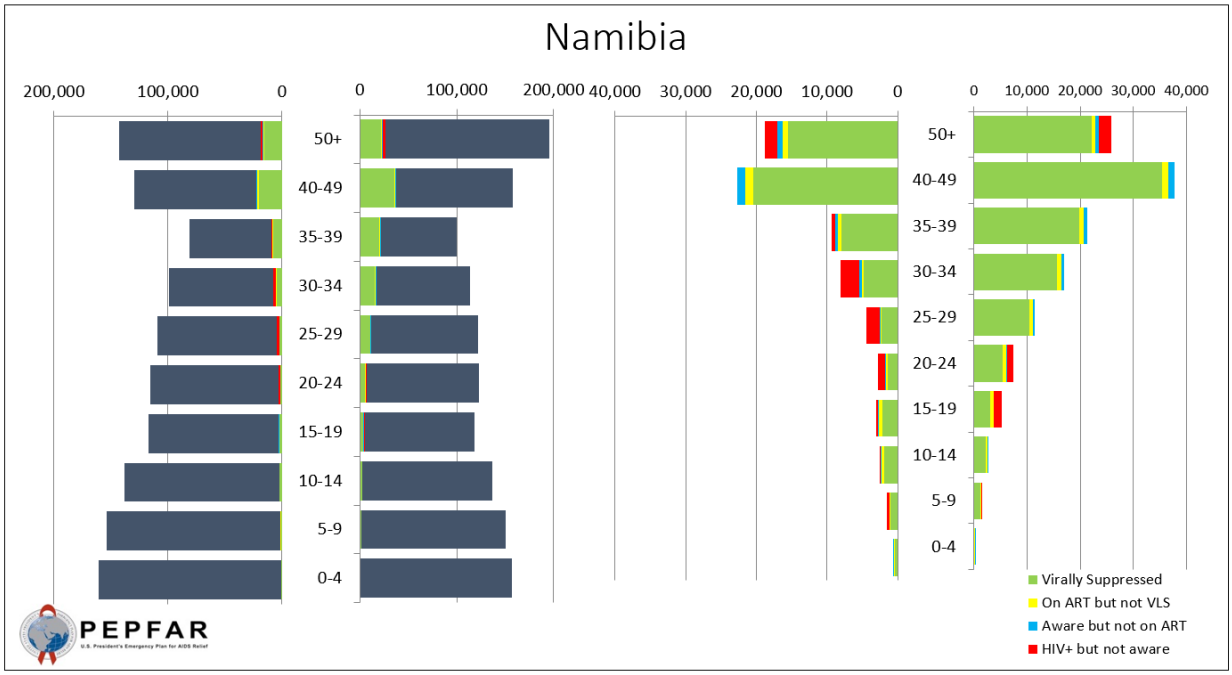
61% to 75% and in adult females increasing from 68% to 82%. Lesotho focused their case finding program to implement index testing with fidelity, to map transmission hotspots and to employ targeted mobile testing services to reach PLHIV not yet aware of their status. Using site-level data analysis, Lesotho identified well-performing sites for best practices as well as sites that needed additional technical assistance, and using age-sex disaggregated data, addressed gaps in male and adolescent services through establishment of men's clinics and adolescent corners. By analyzing and applying their data, Zimbabwe and Lesotho were able to focus their resources on addressing programming gaps to reach and maintain PLHIV on effective, life-saving treatment, achieving control of their country's HIV epidemic.

Figure 2.1.1.2: Progress Towards 95-95-95 in Lesotho and Zimbabwe from 2016/2017 to 2020



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 HIV-infected persons in a population, achieved through the reduction of new HIV infections when mortality among PLHIV is steady or declining, consistent with natural aging. This can be observed through a comparison of the general population pyramid and HIV population pyramid. In Namibia, 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 2.1.1.3).

Figure 2.1.1.3: General population pyramid and HIV population pyramid



This achievement is reached because of effective Prevention of Mother-to-Child Transmission (PMTCT), effective primary prevention interventions, and effective treatment of people living with HIV who continue to thrive and age. Under this scenario, HIV incidence should continue to sharply decline across high disease burden countries (Fig 2.1.1.4). Conversely, a country will not be able to maintain epidemic control if program efforts are not sufficiently sustained and new infections are allowed to rebound or if client viral suppression is not maintained. Figure 2.1.1.5 shows the significant declines in new infections and all-cause mortality since 2010 across countries supported by PEPFAR, with at least 25% reduction in mortality in about half of the countries. In some countries, like Kenya, there have been significant reductions of nearly 40% in new HIV infections and all-cause mortality. These impressive improvements in HIV infection and

mortality in PEPFAR countries have been achieved through scale-up of ART as well as prevention efforts. Figure 2.1.1.6 shows widely varying outcomes in select non-PEPFAR supported countries for the same indicators.

Figure 2.1.1.4: Sub-Saharan Africa Country Example of Epidemiologic Trends and Program Response

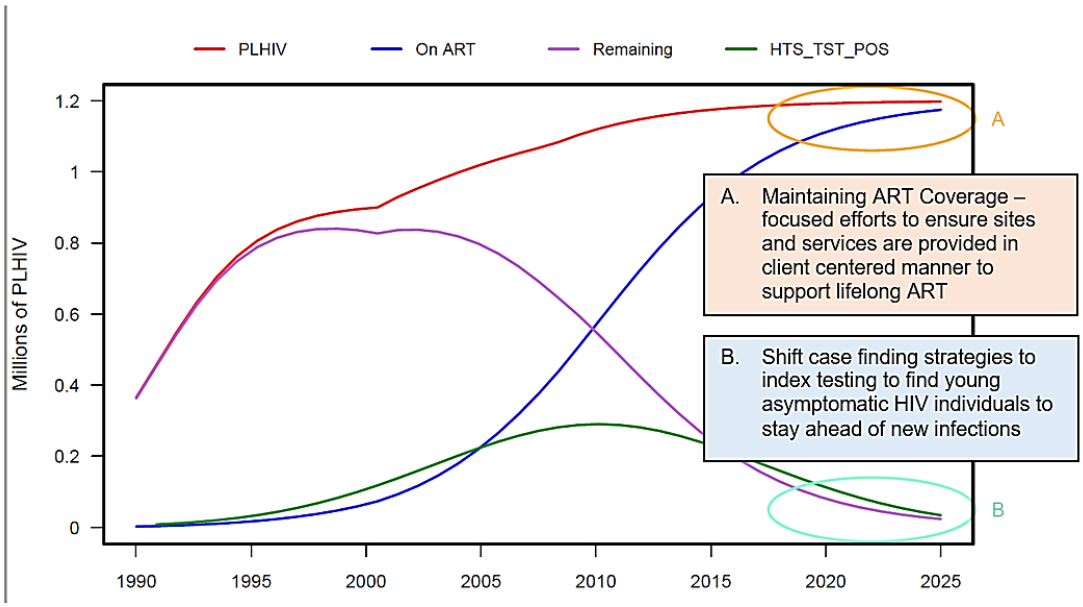


Figure 2.1.1.5: Change in new infections and all-cause mortality among Individuals 15 years of age and older across PEPFAR-supported countries.

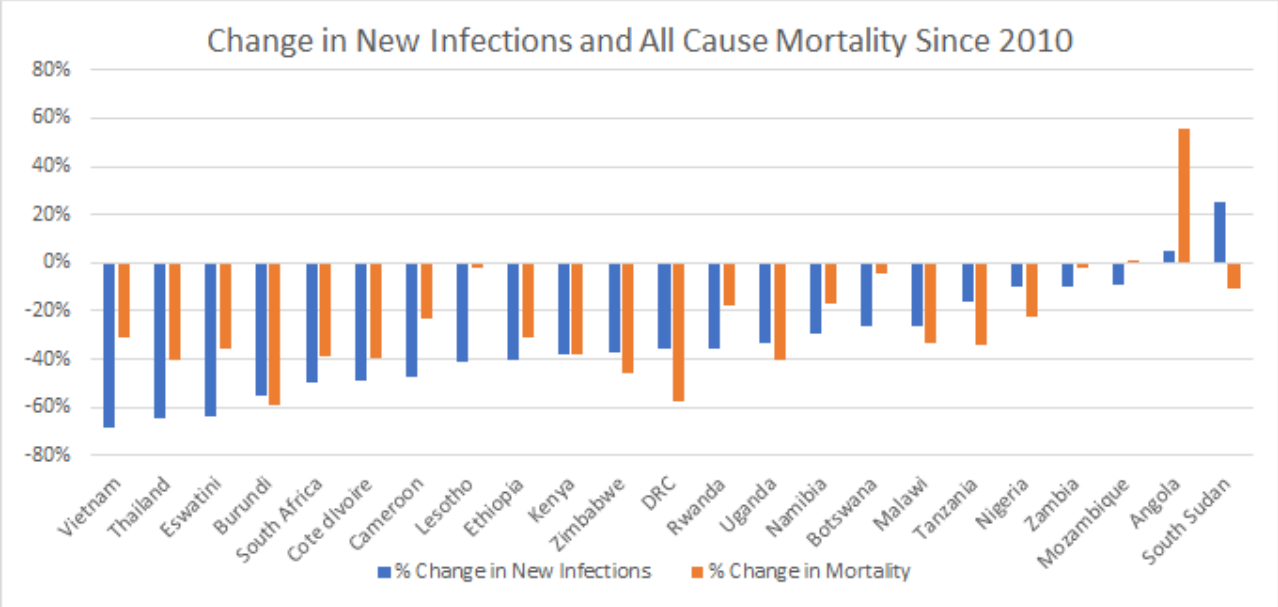
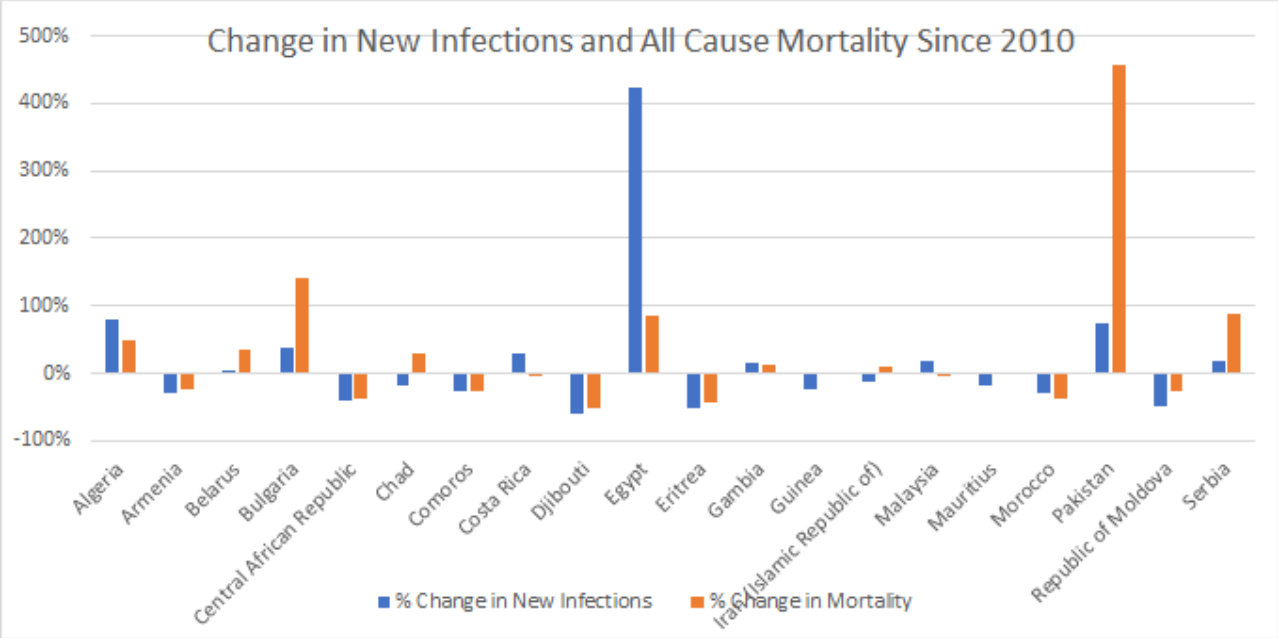


*Figure 2.1.1.6: Change in new infections and all-cause mortality among Individuals 15 years of age and older across select **Non**-PEPFAR-supported countries*



As countries achieve 90/90/90 and embark on 95/95/95, there needs to be a dramatic shift from case finding to maintaining viral suppression among PLHIV on treatment. Figure 2.1.1.4 illustrates that in the early 2000s over 70% of HIV-positive individuals were undiagnosed and needed testing and treatment. Since rollout of Test and Start beginning in 2015, ART coverage has dramatically increased and the remaining gap to 90% treatment coverage is much smaller (Circle A) while the number of PLHIV who are unaware of their status has declined (Circle B). Proportionally, the human resources that were needed for case finding while ART coverage was being brought to scale should be shifted to support continuity of services, and safe and ethical index testing becomes a more strategic and efficient method of case finding (see Section 6.3.1.5).

Patient-level information systems are critical in this phase of the epidemic to ensure there is appropriate action at the site level and 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. See Section 2.3.1.2 for further information.

When the remaining undiagnosed individuals represent less than 20% of total PLHIV, we know from the PHIA (Figure 2.1.3) asymptomatic, younger individuals and those 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, rather than waiting for the individuals to have signs and symptoms and be diagnosed 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, index testing will be the approach to epidemic control maintenance.

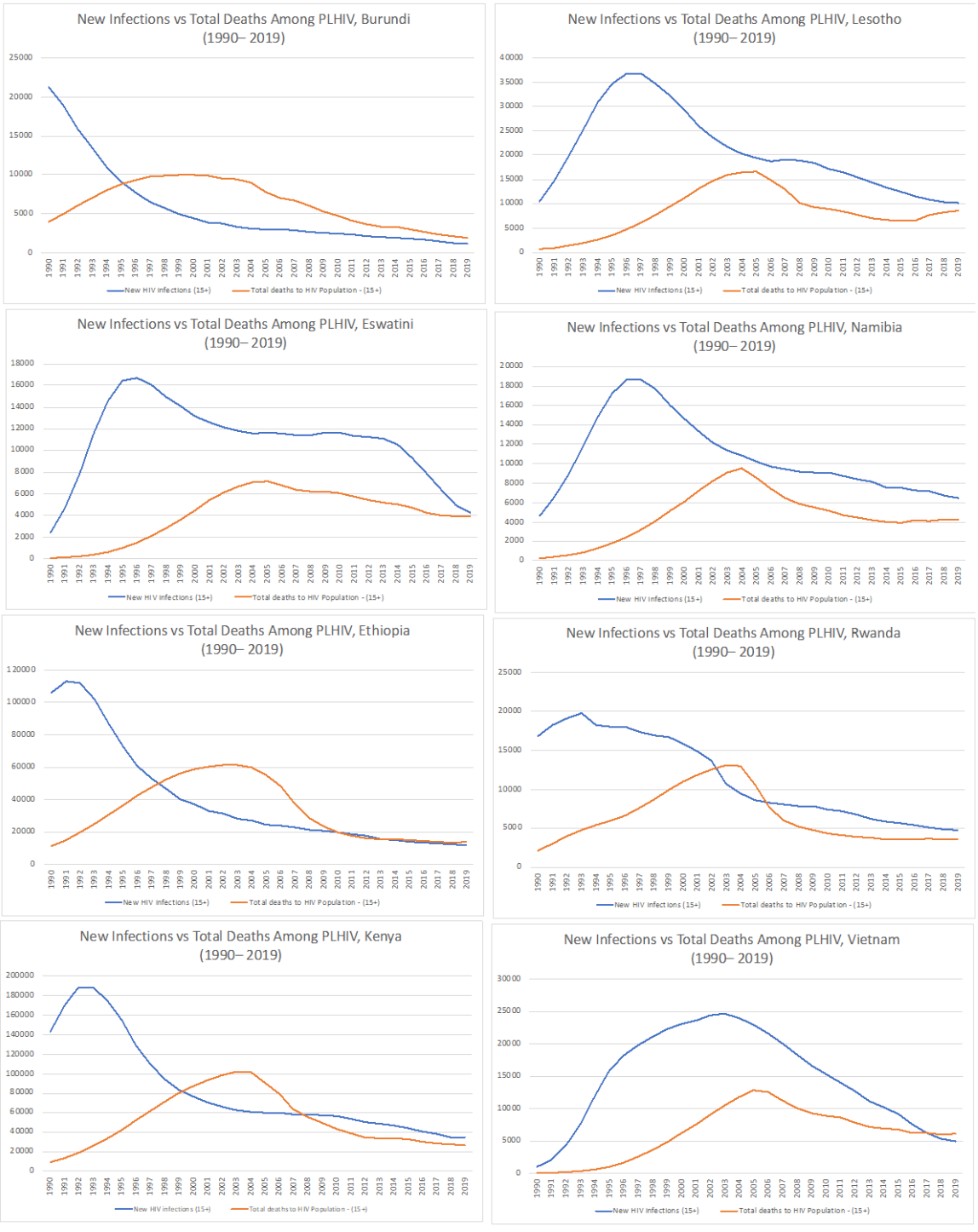
As countries reach 95/95/95 goals and achieve epidemic control, they must adapt their plans and design their activities to sustain and maintain epidemic control for the long term. Epidemic control maintenance will require disease specific surveillance, the capability to detect and investigate outbreaks, 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 alive but no longer in care.

Generalized population-based approaches should evolve into routine surveillance and case finding while protecting the safety of clients and health workers. In parallel, all country and field team program investments must be evaluated, refined and realigned accordingly. Strategic year-by-year shifts in personnel and investment priorities must move toward program activities aimed at sustaining epidemic control. With guidance and support from the COM, COP21 should identify at least three key barriers to increased domestic responsibility, and this process must document outcome-oriented discussions with each country's Ministries of Health, Social Welfare, Finance, and Justice. COP21 must include measurable goals for the country investments required to sustain critical public health functions, including the activities needed to sustain epidemic control. There is an expectation that these efforts will result in at least one diplomatic cable from each OU.

Countries need to continue the focus on primary prevention through VMMC, condom distribution, PrEP, elimination of mother-to-child-transmission of HIV, and DREAMS, which are essential activities for controlling and maintaining control of the pandemic. With COVID-19, country programs must work with host 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. Figures in 2.1.1.7 through 2.1.1.9 show countries' progress towards HIV epidemic control and implementing program strategies based on progress to date will be important for efficient and impactful use of resources.

Fig 2.1.1.7: Changes in new infections and all-cause mortality in adults (15+) in select PEPFAR supported countries

Countries that have achieved or are near achieving HIV epidemic control: dramatic declines in both total deaths among HIV-positive individuals and new HIV infections, with fewer new HIV infections than the number of deaths.



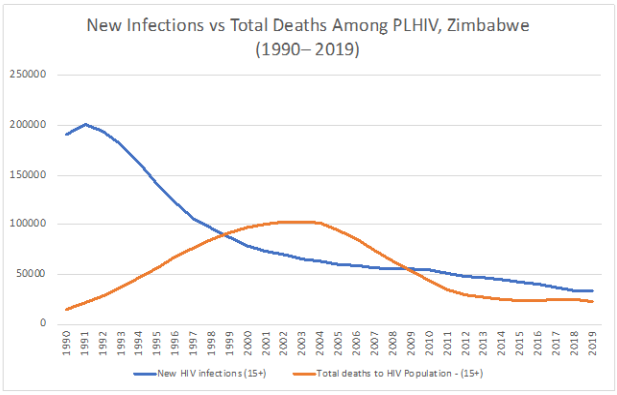
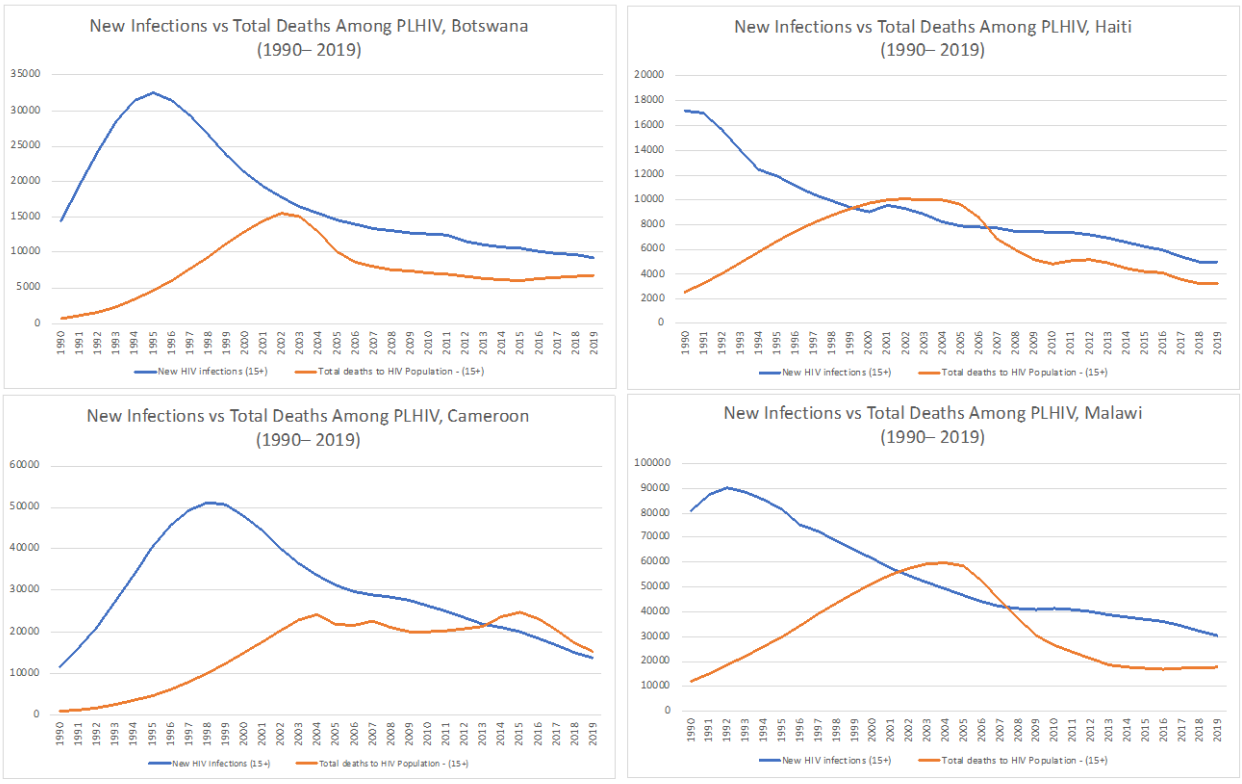
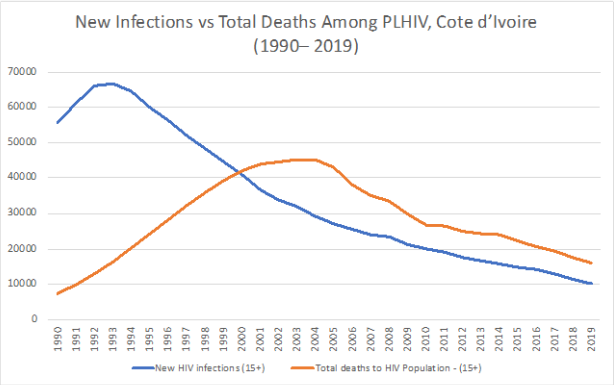
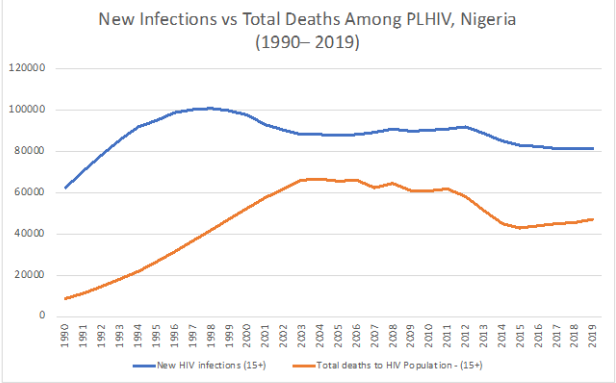


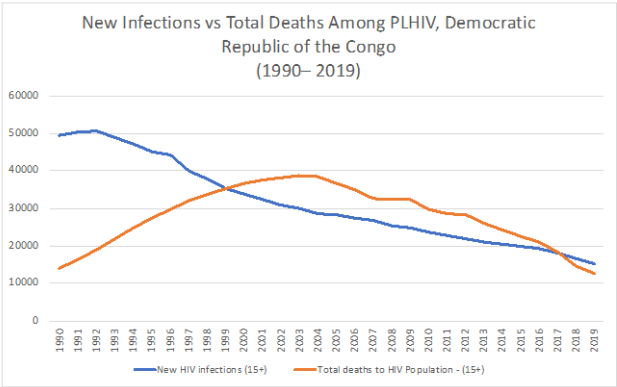
Figure 2.1.1.8: Changes in new infections and all-cause mortality in adults (15+) in additional PEPFAR supported countries

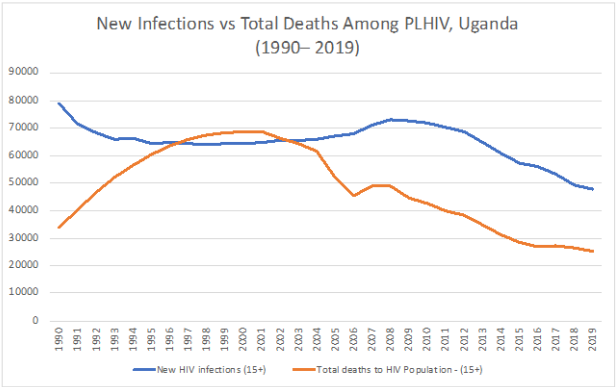
Countries where programmatic changes made over the last several years have resulted in an accelerated speed of declines in both total deaths among HIV-positive individuals and new HIV infections

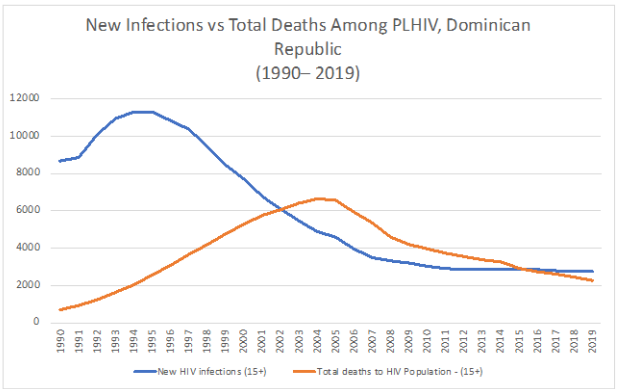


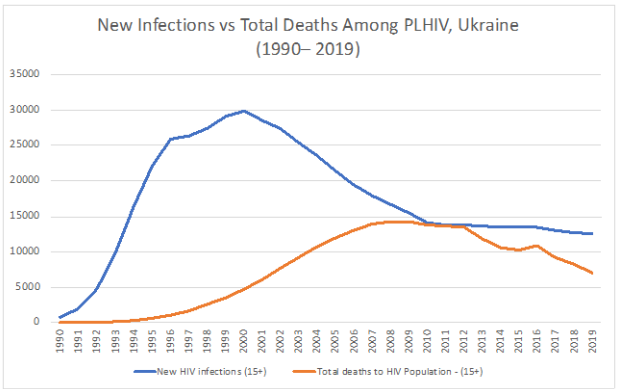

New Infections vs Total Deaths Among PLHIV, Cote d'Ivoire
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)


New Infections vs Total Deaths Among PLHIV, Nigeria
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)


New Infections vs Total Deaths Among PLHIV, Democratic Republic of the Congo
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)


New Infections vs Total Deaths Among PLHIV, Uganda
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)


New Infections vs Total Deaths Among PLHIV, Dominican Republic
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)


New Infections vs Total Deaths Among PLHIV, Ukraine
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)

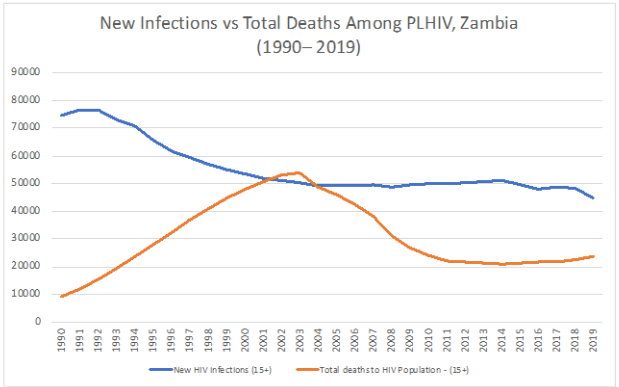
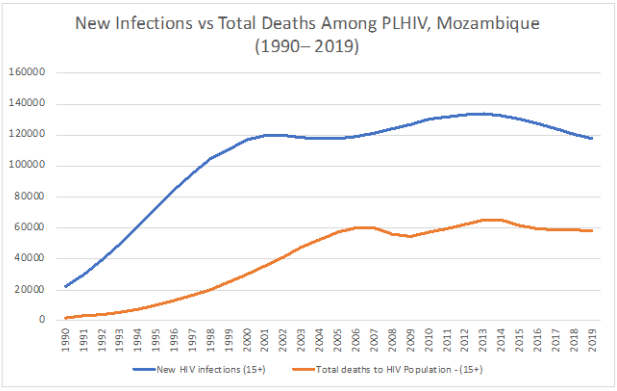
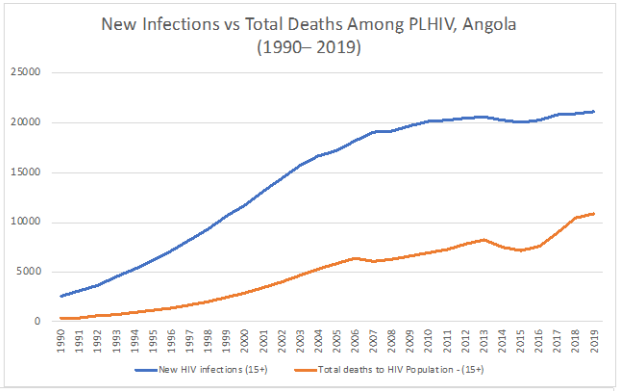
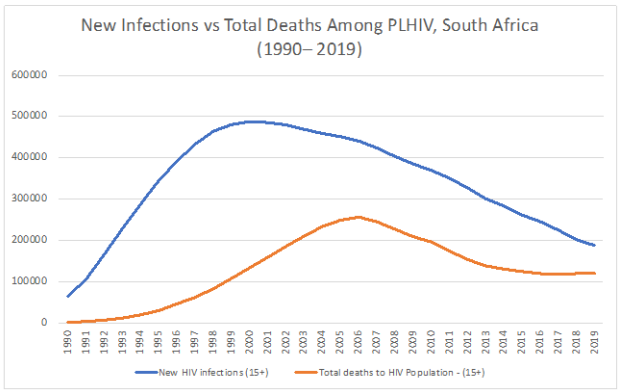

New Infections vs Total Deaths Among PLHIV, Zambia
(1990– 2019)
New HIV infections (15+)
Total deaths to HIV Population - (15+)

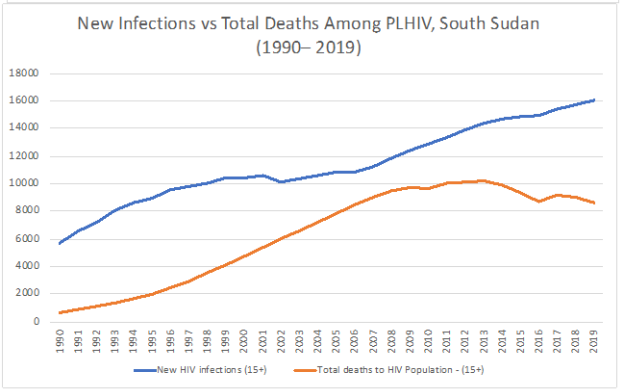
Figure 2.1.1.9: Changes in new infections and all-cause mortality in adults (15+) in additional PEPFAR supported countries

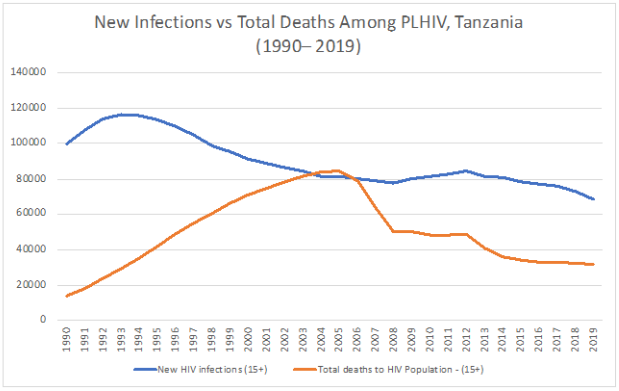
Countries where total deaths among HIV-positive individuals has not decreased: countries with large epidemics (e.g., South Africa) where progress must accelerate; countries in conflict (e.g., South Sudan) where the epidemic continues unchecked due to the difficulty of taking programs to scale; and other countries where there is still slow progress toward decreasing total deaths among HIV-positive individuals and continuity of treatment has not been achieved. Some of these countries have encouraging trends, where PEPFAR may be beginning to have the type of impact needed to change the course of their epidemics.











2.1.2 Program Updates

Tremendous progress has been made to scale programs to meet the needs of individuals that PEPFAR supports while also evolving the program to address the evolving epidemic across all countries.

HIV treatment services were provided to more than 17 million individuals, including over 683,809 children in FY20. Despite, globally increasing the number of people on ART, there continue to be significant 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 and accelerate improvements.

Through PMTCT programs, PEPFAR has enabled over 2.8 million babies of HIV-infected mothers to be born HIV-free.

HIV case finding approaches are becoming more targeted and efficient. During FY20, PEPFAR supported HIV testing services for 63.3 million people; while this is still a high volume of tests conducted given the remaining undiagnosed HIV individuals, it represents a welcome decreasing trend.

New HIV diagnoses among adolescent girls and young women have declined by 25 percent or more in the majority of the geographic areas implementing PEPFAR's pioneering DREAMS public-private partnership across 10 high-burden African countries.

PEPFAR provided critical care and support for more than 6.7 million orphans, vulnerable children, and their caregivers to mitigate the physical, emotional, and economic impact of HIV/AIDS.

Through the continuous use of granular data, site and partner management, and CQI, countries are finding and scaling solutions that address the current program needs.

Despite COVID-19 restrictions, HIV case finding approaches continue to be more efficient, with immediate linkage to care and treatment initiation. Zambia and Tanzania have shown that decreasing HIV testing by nearly half without compromising positivity yield is possible with laser focus on testing modalities and site-specific trainings (Fig 2.1.2.1 and Fig 2.1.2.2). From FY19

Q1 to FY20 Q4, Tanzania reduced their testing by over 3-fold, yet the number of PLHIV diagnosed was still within 15% of the FY19 Q1 results until the end of FY20, when their positivity slightly dipped. Testing efficiently can still result in high numbers of PLHIV diagnosed. However, maintaining individuals on ART (Fig 2.1.2.3), especially for men under 40 and women under 35, requires changes in service delivery to meet the needs of these populations (Fig 2.1.2.4). Disaggregated quarterly program data by five-year age groups and sex along with updated measurement of patients currently on treatment has uncovered clear gaps by population and geography (Figure 2.1.2.5). Understanding performance differences across the clinical cascade by population is key for COP21 (Fig 2.1.2.6 and Fig 2.1.2.7).

Figure 2.1.2.1: HIV Case Finding in FY20

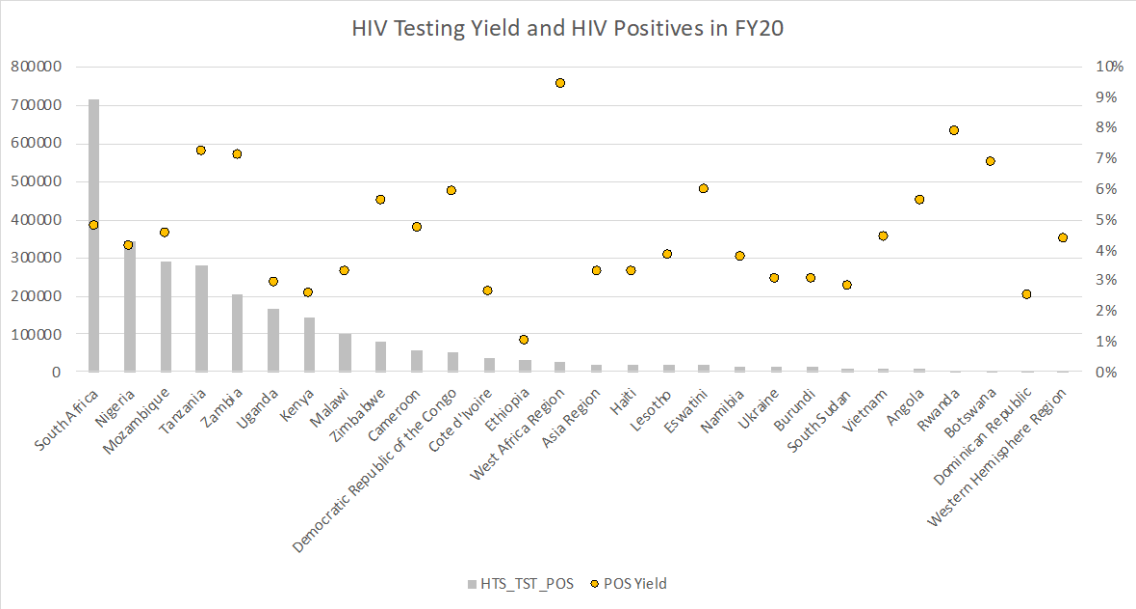
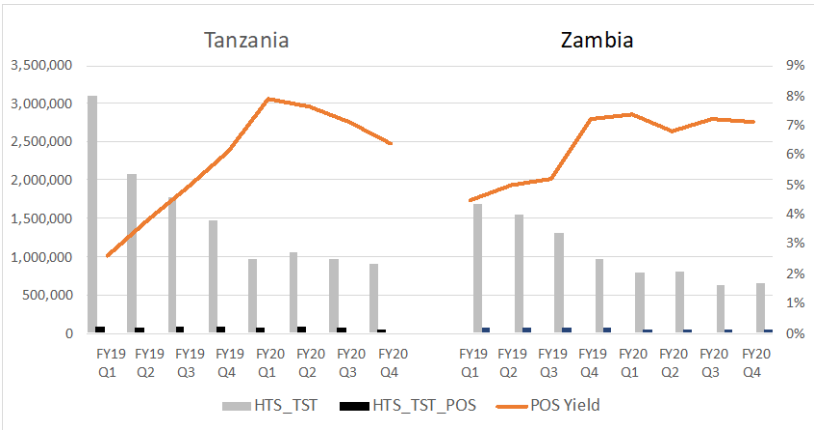


Figure 2.1.2.2: HIV Testing and Yield Trends



The HIV treatment program needs to support all individuals on continuous life-long ART. When looking at who is infected and who continues on ART, we see differences by population across the clinical cascade. Figure 2.1.2.3 shows the number of individuals newly initiated on ART and 'net change' over the 12-month period, meaning the actual increase or decrease in the number of patients on ART. COVID-19 pandemic related restrictions accelerated implementation of treatment program innovation, especially multi-month dispensation (MMD) of ARVs, to reduce interruption of critical treatment services. The rate of MMD implementation varies across the programs and these results can be seen by country in Figure 2.1.2.4 and Section 6.6.12. In countries like DRC and Zambia, transition of PLHIV to 3 or 6 month ARVs rapidly occurred this year as the realities of COVID-19 set in. Increasing availability of MMD helps with continuity of treatment, but PEPFAR-funded programs should continue to monitor current stock levels and future shipments of commodities to ensure demand does not exceed supply, and maintain a sense of urgency to improve site-level service quality and protect the gains that partner country programs have made over the past 17 years in treatment coverage and viral load suppression.

COP21 must address the potential negative impact of significant challenges to client ART continuity on the health outcomes of the people we serve, and the investment impact of the PEPFAR program. This is clear when we dig deeper into loss and see that we have missed opportunities in linking, retaining, and within specific age groups, finding those most likely to be HIV positive (Fig 2.1.2.5). Specific solutions for these populations at greater risk of interruption in treatment, particularly younger populations (children and adolescents/youth living with HIV), are urgently needed. Figures 2.1.2.6 and 2.1.2.7 show the HIV treatment growth by age/sex in two PEPFAR-supported countries, Rwanda and Uganda, in order to pinpoint where there are specific areas of intervention needed to maintain and grow the HIV treatment population within a country program. In Rwanda, where the HIV epidemic is nearly under control, the focus of the program will need to be maintaining the majority of clients on life-long treatment, but also ensuring the small population that may have ART interruptions – females 10-29 years old – also are identified and have continuous ART care. In contrast, Uganda is at a point of maintaining their older clients (over 35 years old) on treatment but is still missing many patients under 35 years old to be on continuous treatment.

Figure 2.1.2.3: Change in number of patients on HIV treatment

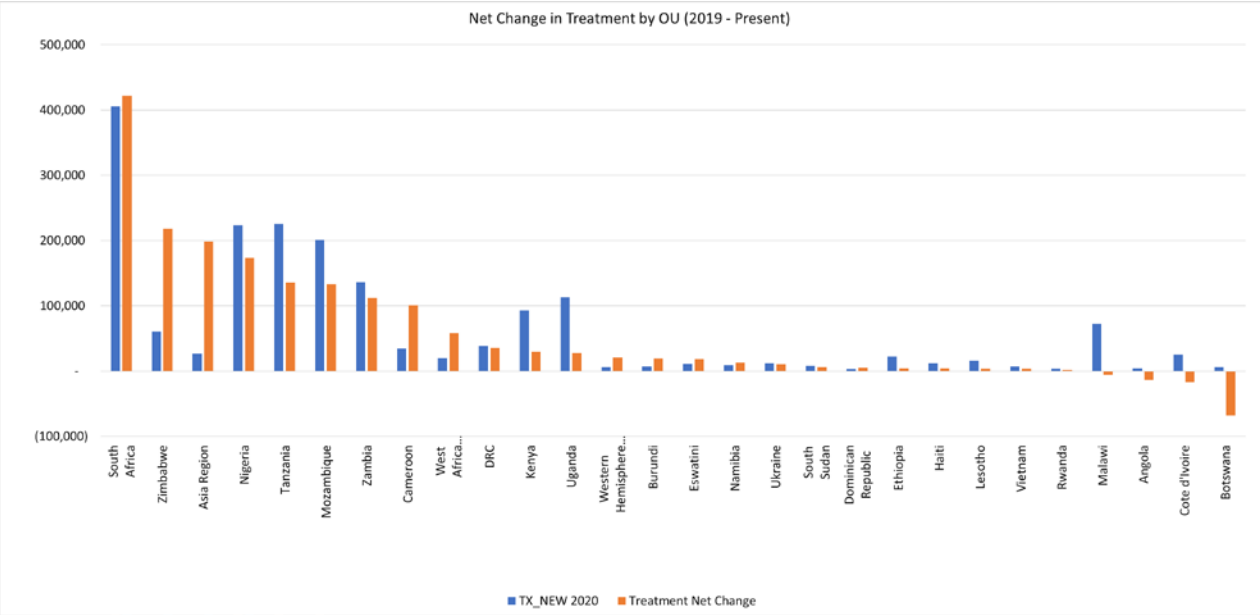
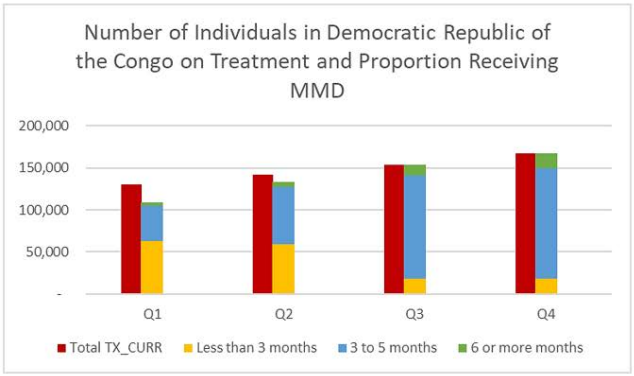


Figure 2.1.2.4: Progress of MMD for PLHIV in FY20: Democratic Republic of the Congo and Zambia



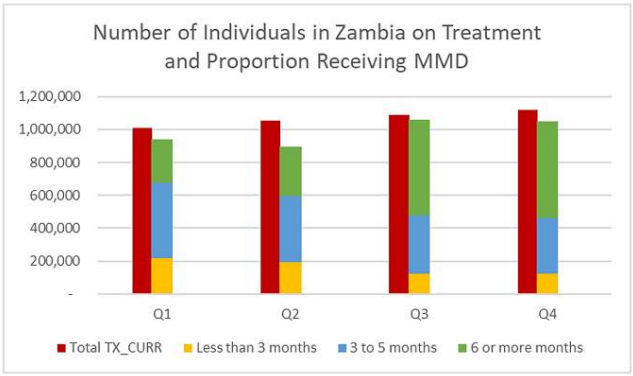


Figure 2.1.2.5: Patient Profiles with ART interruption 2019 Q to 2020 Q4 across countries

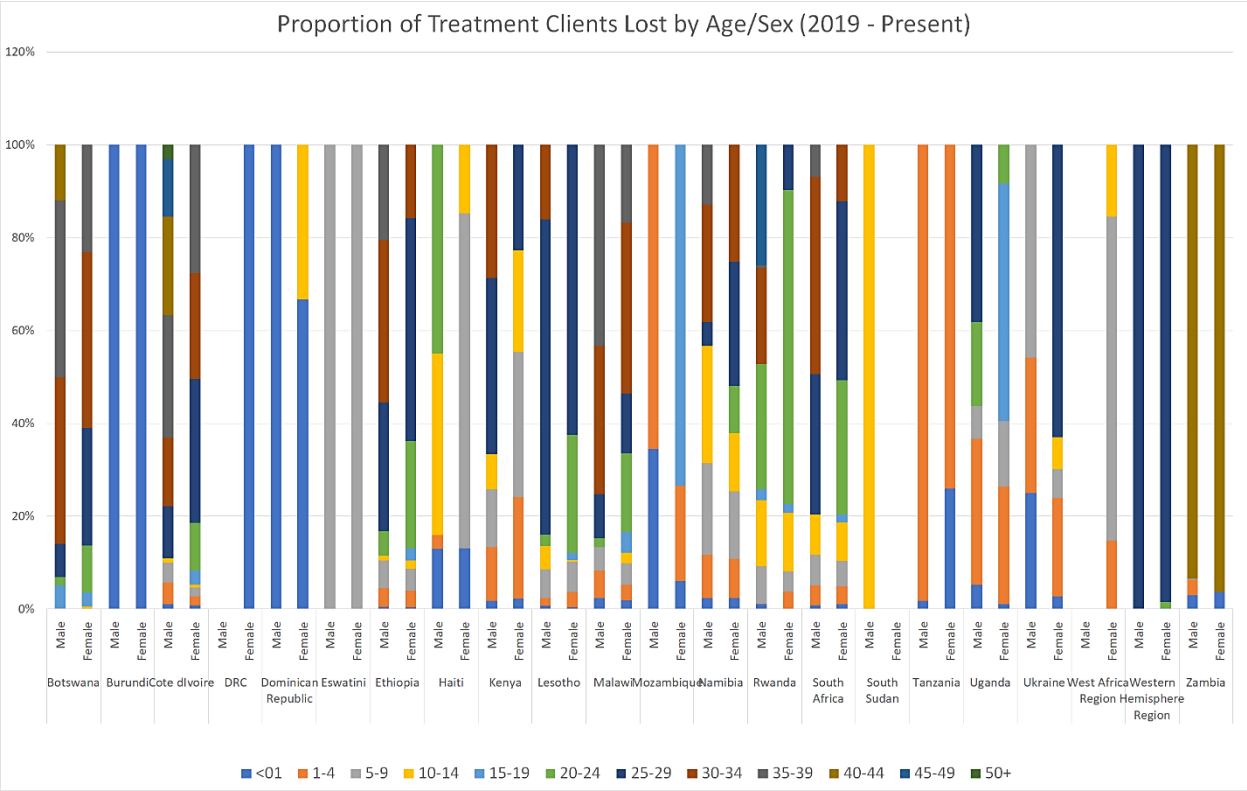


Figure 2.1.2.6: Net change in HIV treatment by sex and age bands in Rwanda 2019 Q4 to 2020 Q4

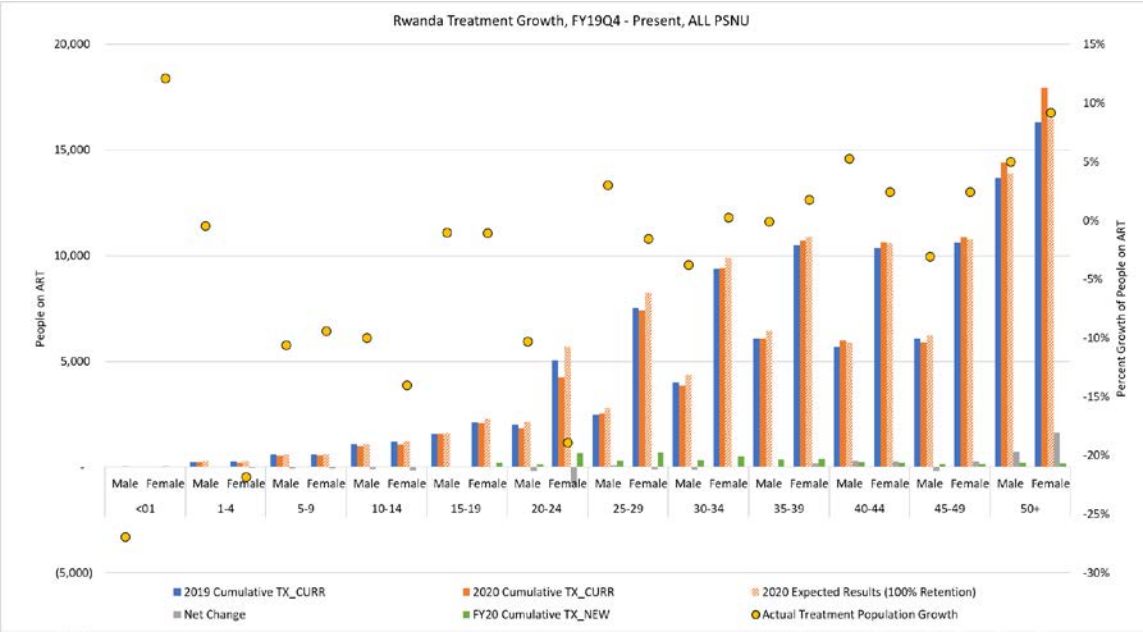
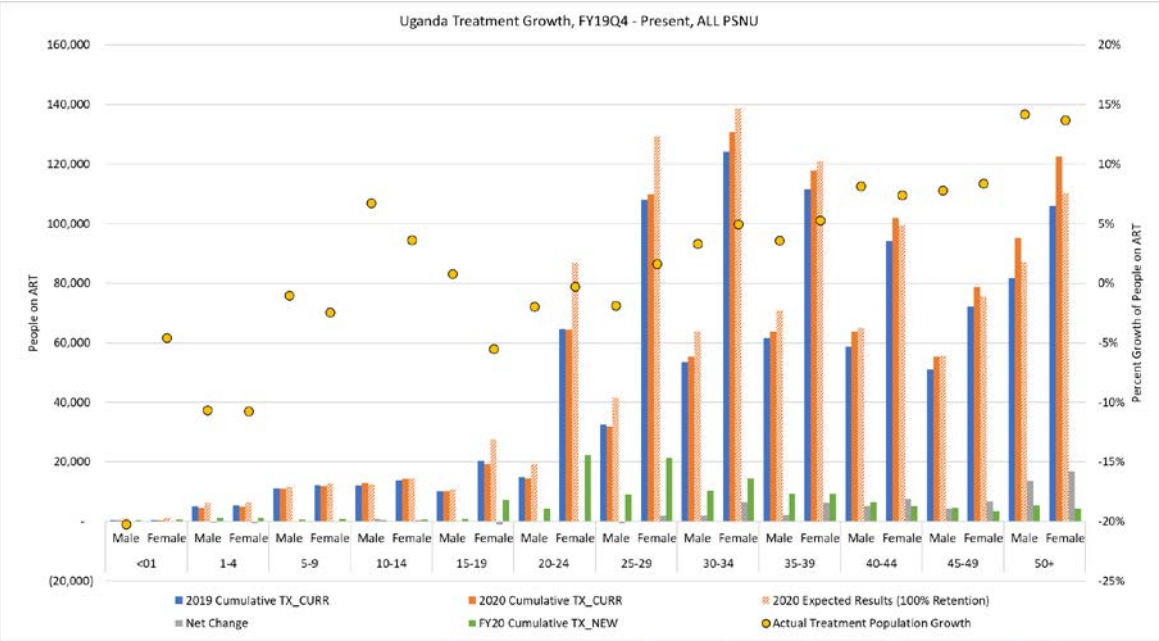
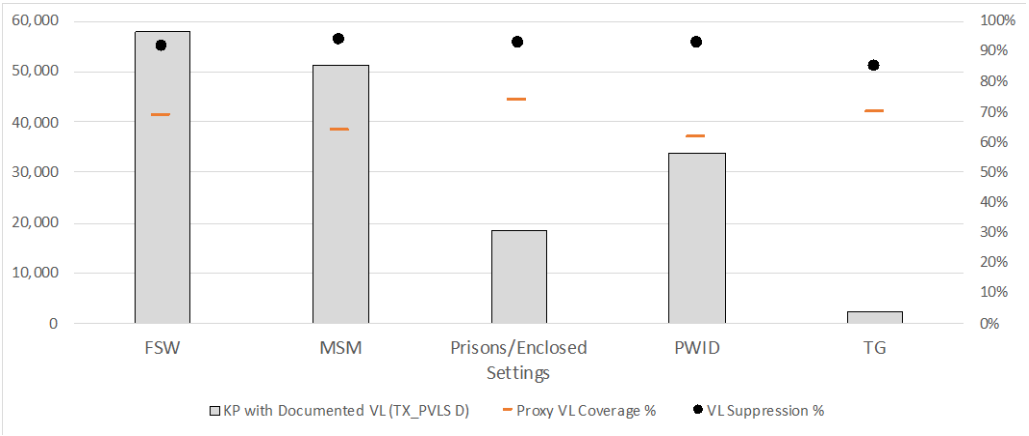


Figure 2.1.2.7: Net change in HIV treatment by sex and age bands in Uganda 2019 Q4 to 2020 Q4



KP access to prevention services and reduction of KP-specific stigma and discrimination continue to be a priority for PEPFAR programs. The addition of KP disaggregates to treatment indicators in FY2020 allowed for monitoring of KP programs beyond prevention services to effective, continuous HIV treatment for KP PLHIV. As reporting for KP clinical indicators improves, global data in Figure 2.1.2.8 indicate that VL suppression of KP PLHIV are fairly high at the end of FY2020, although expansion of VL coverage across KPs is still needed. Routine evaluation of KP programs and KP competency of facilities will be critical to overcome barriers for safe, client-centered initiation and maintenance of KP on ART. For further information, see Sections 6.2.6, 6.3.4, 6.4.5, and 6.6.2.

Figure 2.1.2.8: VL Coverage and Suppression of Key Populations for FY2020 Q4



Cumulatively, PEPFAR has supported over 25 million voluntary medical male circumcisions in Eastern and Southern Africa to help protect men and boys from HIV infection (Fig 2.1.2.9 and 2.1.2.10). COVID-19 restrictions on gatherings in most of the PEPFAR-supported countries caused a pause in VMMCs, but countries had been on track to meet their annual targets. PEPFAR is working with UNAIDS to generate coverage estimates for VMMC by age at the subnational level to facilitate program planning.

Figure 2.1.2.9: VMMC Results for FY2020

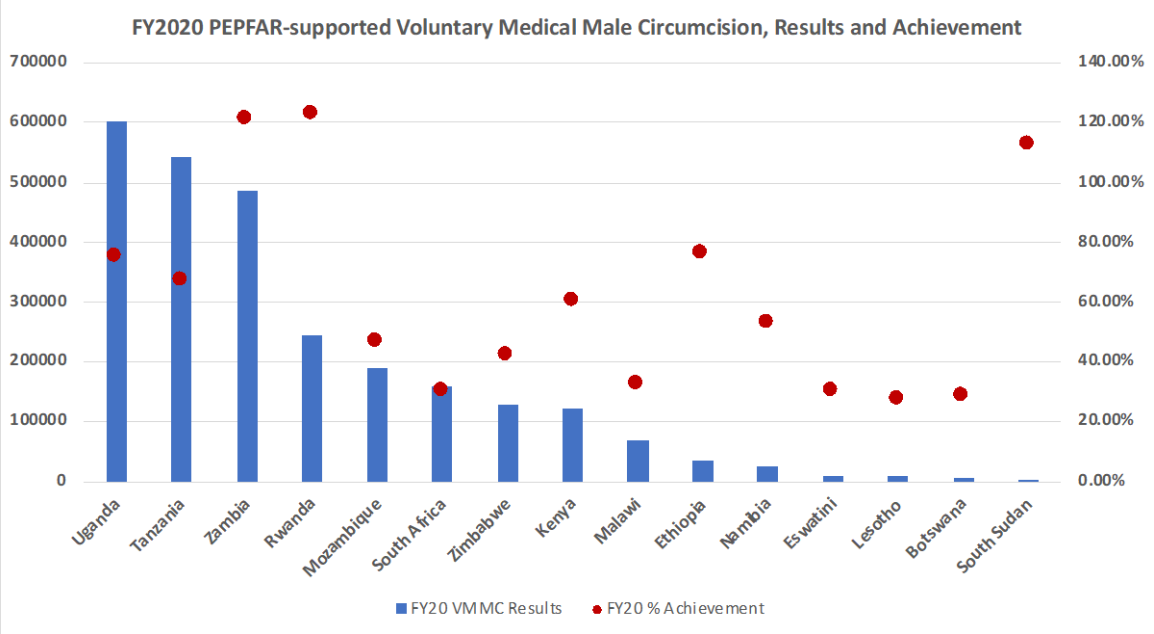
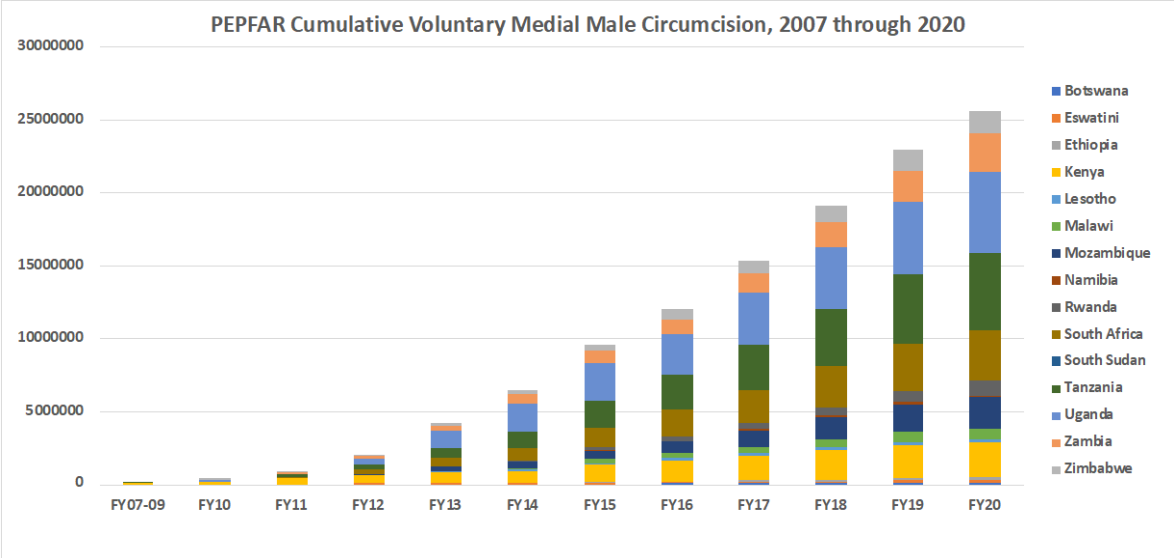


Figure 2.1.2.10: Cumulative VMMC Results From 2007 Through FY20Q4



Per PEPFAR COP20 Guidance, PEPFAR is no longer supporting VMMC in boys under age 15 except for limited demonstration projects for Shang Ring use in this age group. Recent analyses have demonstrated that types of adverse events occurred almost exclusively in boys under age 15, especially in those ages 10 and 11 (Fig 2.1.2.11 and 2.1.2.12). All glans injuries and 90% of fistulas occurred in those under age 15. Based on a survey in one country, fistulas occurring after VMMC are markedly underreported. Most country teams have successfully started to transition their VMMC programs during FY20, and all need to continue to intensify their efforts to identify males over age 15 for VMMC.

Figure 2.1.2.11: Number of Glans Injuries Reported to PEPFAR by Age, 2015-2019

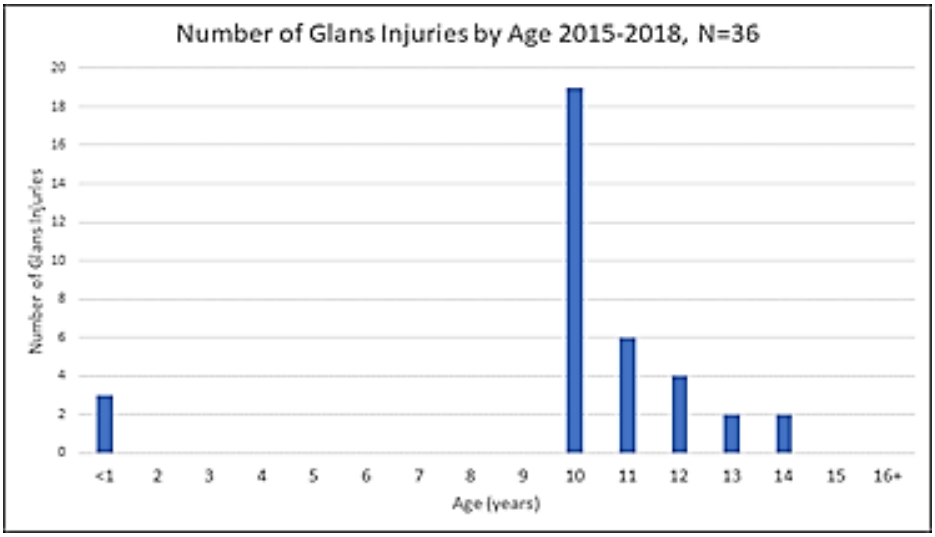
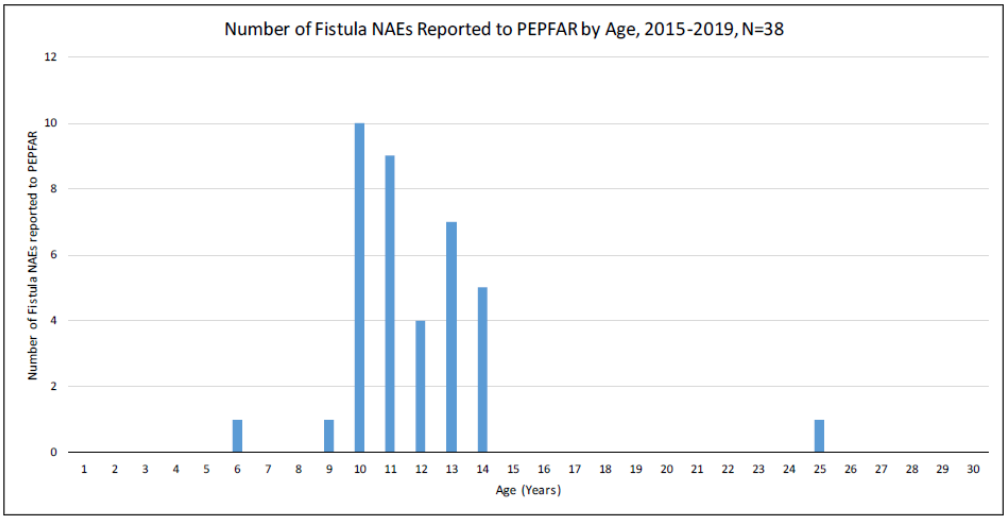
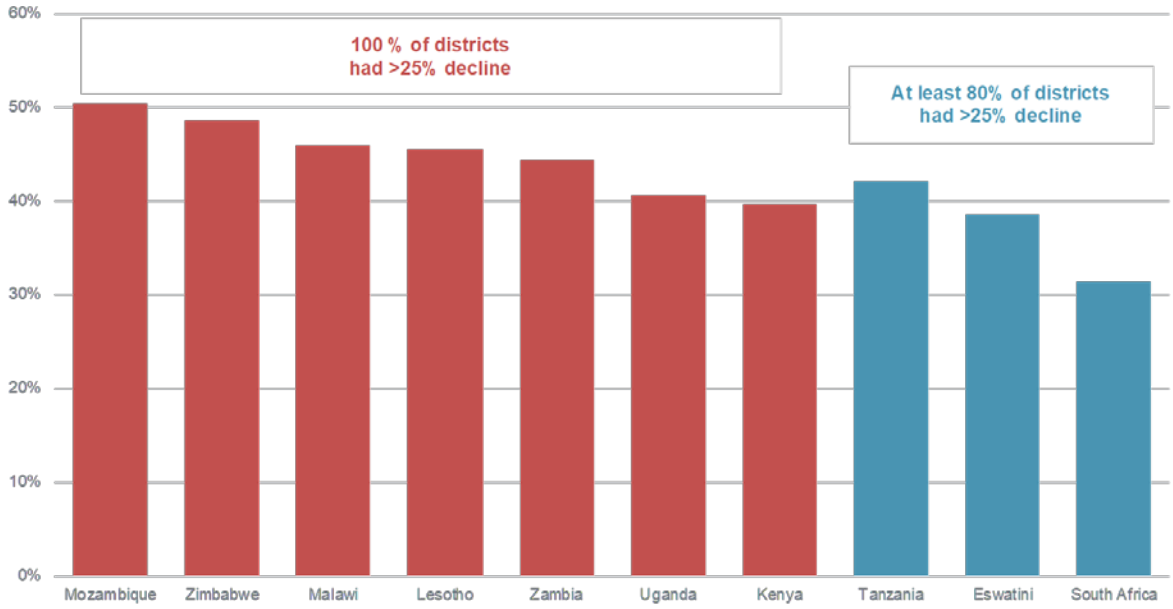


Figure 2.1.2.12: Number of Fistula Notifiable Adverse Events Reported to PEPFAR by Age, 2015-2019



The DREAMS program was one among the many prevention activities that were at least partially on hold in 2020 because of COVID-19 restrictions on gatherings. We applaud the continued progress in the DREAMS program and the impact on decreasing new HIV diagnoses in young women (Fig 2.1.2.13). As countries come out of COVID-19 lockdown restrictions, DREAMS activities need to be prioritized for resumption to continue this critical preventive program.

Figure 2.1.2.13: Average Percent Decline in HIV Diagnoses in ANC in DREAMS Districts (2015-2019)



Even during COVID-19, PEPFAR's Orphans and Vulnerable Children (OVC) programs continued to prioritize support to C/ALHIV, survivors of violence, and their families. PEPFAR worked with host country governments to ensure OVC staff and government child welfare workers are deemed essential personnel, and to ensure child helplines remain operational during lockdowns. To protect frontline workers and clients, case management protocols were developed to enable phone-based or virtual approaches, and in emergency cases where in person visits are recommended, OVC staff are provided with protective items such as masks and hand sanitizer. In many countries, OVC cadres are supporting MMD and continuity of care efforts by monitoring children's access to ART, and when needed, delivering ART refills from health facilities to local communities and households.

COVID-19 policies greatly tested the PEPFAR supply chain, critical for prevention and treatment commodities. Even with these challenges, the years of improvements in supply chain logistics through PEPFAR funding, rapid adaptations by the supply chain teams, continuous monitoring of supplies and markets, and coordination with agencies, governments, and other donors and stakeholders prevented

any major interruptions in ARV supplies, even allowing for increase in PrEP uptake (Fig 2.1.2.14) and MMD (Fig 2.1.2.4).

As shown in Figure 2.1.2.15, PrEP services have rapidly scaled up in many countries over the past two years. With incorporation of PrEP as a core programmatic requirement, PrEP-specific funding, and ambitious targets in COP20, PrEP access and uptake for those at risk of HIV infection is expected to accelerate even more globally (see Section 6.2.1).

As countries approach 95/95/95 and epidemic control, surveillance and recency testing are needed to guide targeted and effective community HIV prevention interventions for sustained, long-term epidemic control. Progress in recency testing has been made over recent years, although it has not been sufficiently scaled. Although these activities were postponed or scaled-back under COVID-19 restrictions, country programs in collaboration with the government, should strongly consider starting or resuming recency testing as soon as it is safe for extended provider-client interactions and counseling sessions.

Figure 2.1.2.14: Increase in Global PrEP

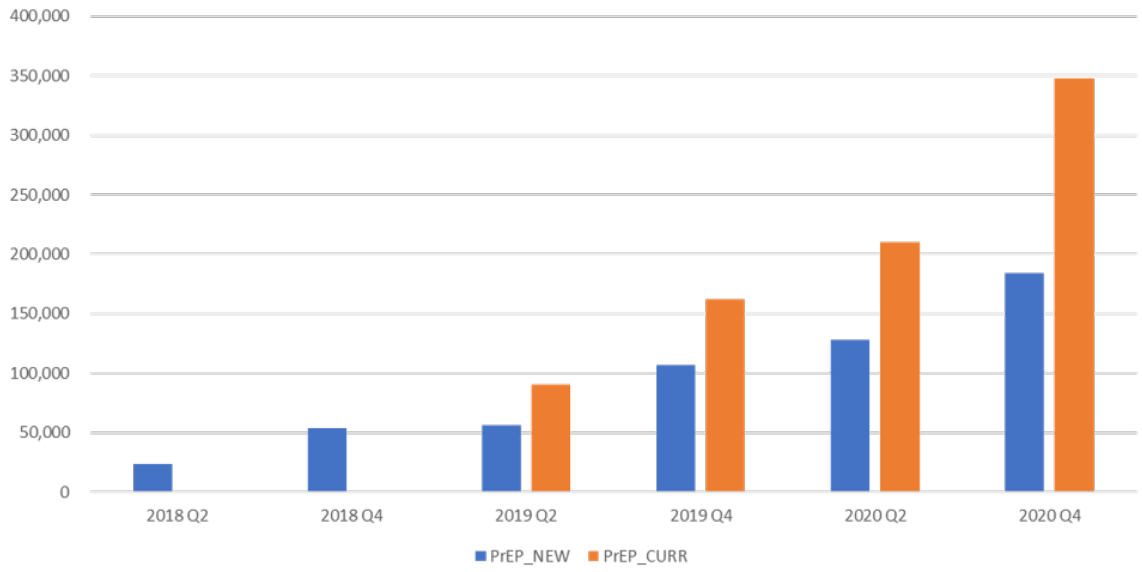
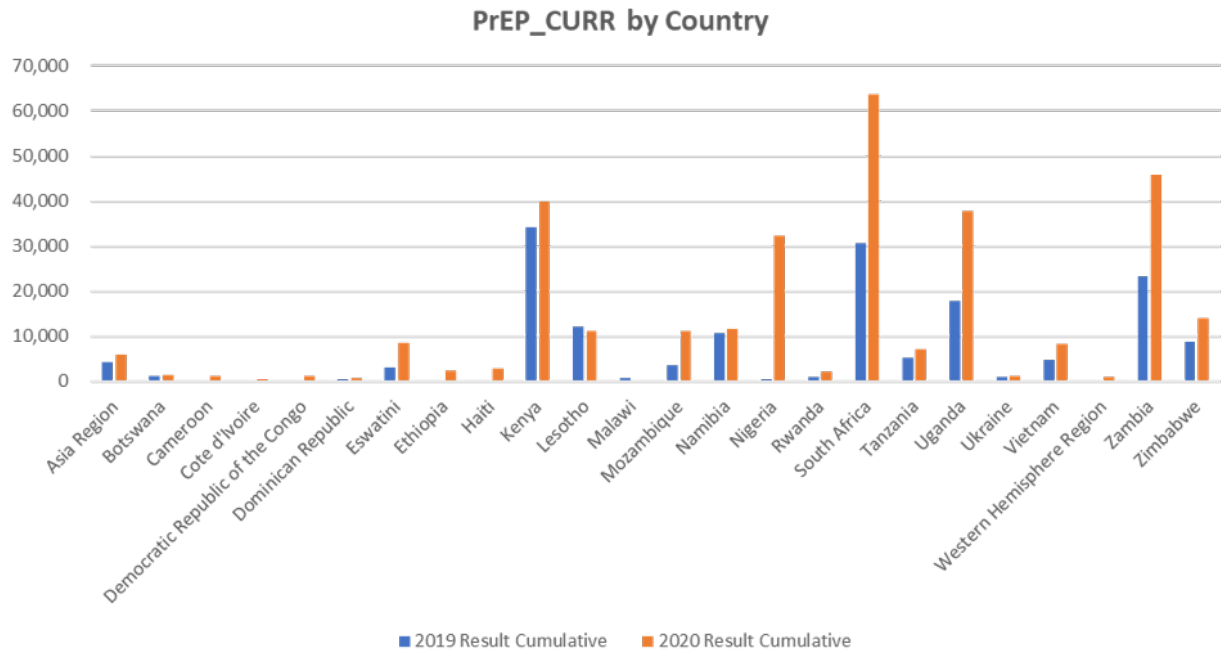


Figure 2.1.2.15 Increase in PrEP by Country/Region



2.2 Minimum Program Requirements

All PEPFAR programs – bilateral and regional– were expected to have the following minimum program requirements in place by the beginning of COP20 implementation (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 epidemic control and results in inefficient and ineffective programs.

All PEPFAR programs are expected to meet all of the requirements below, and the COP21 Planning Meeting will include a review of the status of each requirement, including assessment of implementation at the point of client services. To the extent that any requirement(s) have not been met by the time of the COP21 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 FY2021. The list will be included in the Strategic Direction Summary (SDS), as well.

Failure to meet any of these requirements by the beginning of FY2022 may affect the OU budget. The minimum requirements for continued PEPFAR support include the table on the following page.

PEPFAR programs in countries that will be near to or reach 95/95/95 in the COP20 implementation cycle are required to develop and implement plans to sustain their progress and effectively retain clients in quality HIV treatment programs. These plans should be informed by an analysis of funding priorities following epidemic control and should include a balanced portfolio of treatment and prevention activities such as DREAMS, PrEP, VMMC, and public health surveillance to ensure the country governments are able to continue to reduce new HIV infections. Results from the Sustainability Index and Dashboard (SID) 2019 should inform the OUs on their progress and gaps related to the policies and technical areas for inclusion in the sustainability plans. Resource alignment data should be used to understand the HIV funding landscape--especially with a more granular understanding of PEPFAR and GFATM investments--in a given country and who is paying for what services in order to enhance strategic collaboration and coordination and avoid duplication during the program planning cycle. Results from the Responsibility Matrix should inform the OUs on the current responsibility of PEPFAR towards epidemic control, which should be used to evolve, strengthen, and sustain the relative responsibilities of PEPFAR, government entities, and other stakeholders such as GFATM.

Figure 2.2.1: COP21 Minimum Program Requirements

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 treatment across age, sex, and risk groups.[6]
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.[7]
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.[8]
4. All eligible PLHIV, including children and adolescents, should complete TB preventive treatment (TPT) by the end of COP21, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.[9]
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
1. 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.[10]
Prevention and OVC

[6] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization, September 2015

[7] WHO policy brief, Considerations for introducing new antiretroviral drug formulations for children. Geneva: World Health Organization, July 2020

[8] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization, 2016

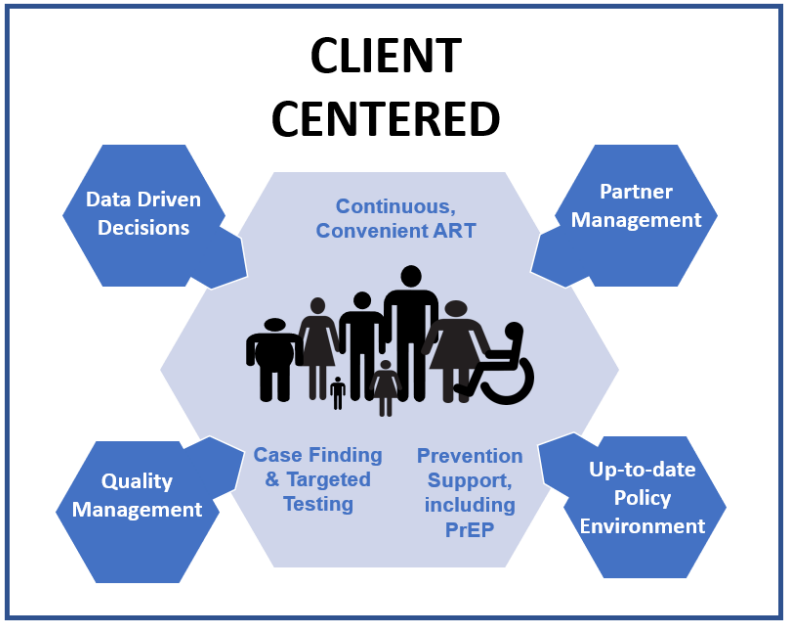
[9] Latent Tuberculosis infection: Updated and consolidated guidelines for programmatic management. Geneva: World Health Organization, 2018

[10] 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/

Prevention and OVC
1. 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)[6]
2. 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 9-14 year-old girls and boys in regard to primary prevention of sexual violence and HIV.
Policy & Public Health Systems Support
1. 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.7
2. OUs assure program and site standards are met by integrating effective quality assurance and Continuous Quality Improvement (CQI) practices into site and program management. CQI is supported by IP work plans, Agency agreements, and national policy.8
3. Evidence of treatment and viral load literacy activities supported by Ministries of Health, National AIDS Councils and other host 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.
4. Clear evidence of agency progress toward local, indigenous partner direct funding.
5. Evidence of host government assuming greater responsibility of the HIV response including demonstrable evidence of year after year increased resources expended
6. Monitoring and reporting of morbidity and mortality outcomes including infectious and non-infectious morbidity.
7. Scale-up of case surveillance and unique identifiers for patients across all sites.

[6] 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)
[7] The practice of charging user fees at the point of service delivery for HIV/AIDS treatment and care. Geneva: World Health Organization, December 2005
[8] Technical Brief: Maintaining and improving Quality of Care within HIV Clinical Services. Geneva: WHO, July 2019

2.3 Accelerating Epidemic Control with Client-Centered Services



2.3.1 PEPFAR's Number 1 Treatment Priority: Supporting Clients by Facilitating Continuous ART

As demonstrated in the figures in Section 2.1, some PEPFAR supported OUs have shown considerable progress in reaching epidemic control. There are variations among OUs, with some at or near 95/95/95 targets and positioned to adapt and evolve programs for sustained epidemic control, and some still working to scale case-finding and treatment to reach their goal. A review of global progress, however, demonstrates serious challenges in interrupted treatment across nearly all OUs, regardless of current levels of ARV coverage. Sustained epidemic control will not be reached if a large proportion of clients, whether new or long term, fails to stay on treatment and risk re-emergence of HIV viremia with its attendant consequences of morbidity, mortality, and increased risk of transmission.

In order to address this challenge in a timely and comprehensive manner, all PEPFAR programs, regardless of current ARV coverage levels, must implement strategies to support

continuous, client-centered ART. The strategies are expected to be scaled in each site providing HIV testing, care, and treatment services.

Services that are client-centered recognize the agency of clients—their right to make their own choices. Providers strive to enter a therapeutic alliance that honors the needs, preferences, and motivations of a client along with their family and/or significant others. In PEPFAR, client-centered services should also emphasize privacy, dignity, and voluntary participation. The vision for successful continuous ART is life-long, client-centered service, where the health system and affiliated organizations in the community demonstrate respect for clients' preferences and choices and make it as easy as possible for clients to remain on uninterrupted ART across the lifespan and across changing life circumstances. PEPFAR programs must, working with local health system and community actors, design services and interventions that remove all barriers to continuous care, including mental health and substance abuse services, and stigma and discrimination, and maximize convenience and responsiveness to client needs and preferences. A client-centered program will have tools and procedures supporting seamless transfers of care, unfettered ART refill pickups across sites, SNUs, and partners, and proactive plans for clients that move or migrate. The goal is to get ARV medications into the hands of clients in a timely and efficient manner.

As suggested in the figure above, four 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.

There are five core elements of strategy for advancing continuity of ART throughout PEPFAR for COP21.

1. Commitment by stakeholders to client-centered approaches to ensure immediate and easy access to ARVs and to remove barriers to treatment.
2. Immediate implementation of Minimum Program Requirements related to linkage and continuity of treatment at all sites.
3. Implementation of core, evidence-based site-level minimum standards for continuous ART as part of a client-centered service environment (see Section 2.3.1.1).
4. Specific, customized interventions to improve continuity and return to treatment after interruption, designed around specifically addressing challenges noted by current clients and clients returned to care, opportunities, and assets specific to the OU and its

communities. Simply finding and returning clients to the same site if issues persist will result in losing the client again. Site-specific issues must be addressed, and all technical assistance partners' performance evaluations must include specific goals for continuous treatment.

5. Implementation of quality management policies and practices to support and maintain site standards.

As PEPFAR moves toward accountability in ensuring site standards, OUs are encouraged to strategically consider the number, location, and types of sites that are best positioned to serve the HIV clients in a way that is convenient, responsive, and effective. Sites that cannot meet standards should be reconsidered as viable providers of services.

The primary treatment focus must be sustaining clients on treatment at all sites, in saturated districts moving away from all stand-alone testing counselors to equipping CHWs that can support continuity of ART and scale effective prevention efforts. All sites with substantial patient losses (identified through treatment current (TX_CURR) change year to year) with the exception of planned transfers, should suspend all testing, with exceptions to testing in inpatient wards and TB clinics, until treatment interruption is minimized. Continuing to add clients to programs that are failing clients cannot continue and these sites must have special attention to improvement. Additional investments should be made to high-performing sites, and encourage, if these sites are nearby, clients to move to these sites if logistically possible. To determine which sites fall into this category, country teams should assess which sites are true outliers when reviewing treatment cohort growth on a bell curve. Attention should be paid to age and sex bands and subgroups (e.g., key or priority populations) that may lag in reaching epidemic control. Resources made available should be shifted to support program scale-up in newly prioritized geographic areas.

Programs should also prioritize **within** high-prevalence SNUs to focus resources on the highest-prevalence areas, the highest-prevalence population groups, and the highest-performing facilities at the local level. Resources should be shifted without delay from sites with low performance on continuous ART and/or small numbers of clients to high-quality, high-performing sites that excel in client-centered service.

2.3.1.1 Site-Level MPRs Related to Linkage & Continuity of ART

All OUs are expected to fully implement key PEPFAR Minimum Program Requirements at every PEPFAR-supported site that has a known impact on continuity of ART. Site-level implementation of these 4 elements must be assessed to inform COP21 planning. In addition, an effective tracking and tracing system must be in place at each site.

Figure 2.3.1.1: Site Level Continuity-Related Performance Standards

Direct and immediate (>95%) linkage of clients from testing to treatment across age, sex, and risk groups.
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.
Elimination of all formal and informal user fees affecting access to HIV testing and treatment and prevention in the public sector for access to all direct HIV services and medications, and related services, such as ANC, TB, Cotrimoxazole, cervical cancer, PrEP and routine clinical services.
Adoption and implementation of differentiated service delivery and MMD models for ART clients that provide choices between facility and community ART refill pick-up location and between individual and group ART refill models. All models should consider a family-based approach and offer patients the opportunity to get 6 months of medication at a time without requiring repeat appointments or visits. with alignment with other family members' visit schedule, as feasible.

2.3.1.2 ART Continuity Strategy for COP21/FY2022

OUs must craft an implementable and accountable set of site-specific standards that includes PEPFAR MPRs and addresses PEPFAR-supported Site Requirements for Client-centered Services and OU-specific site requirements, including interventions based on assessment of OU-specific challenges, assets, and opportunities.

The highest-risk group for treatment interruption or discontinuation are men under 40 and women under 35 across nearly all OUs. Given the challenges of treatment interruption in these

groups, PEPFAR teams are expected to identify and scale age- and sex-appropriate ART continuity and re-engagement strategies, including both policies and program activities, and to maximize impact for these specific age and gender groups at the commencement of COP21. Site requirements are expected to lead to efficient sites and related community services that are convenient, hospitable and welcoming, and supportive and responsive, for all patients, especially for the unique needs, preferences, and goals of younger female and male clients.

The following is a list of policies and program activities recommended to support continuous ART for clients and to identify and re-engage clients whose treatment has been interrupted or with unknown treatment status. OU teams are expected to customize these requirements to best address the social and cultural needs of clients, especially those at risk of treatment interruption or discontinuation. Both continuity of ART and re-engagement after interruptions in treatment require specific policy and programmatic activities at both the site and the community level, including national policy reforms as necessary. Finally, these site standards are expected to be supported by above-site interventions, as described below.

Minimum site (and supportive above-site) requirements are expected to establish core activities for durable linkage, retaining clients in continuous HIV treatment, and rapidly identifying and re-engaging clients who experience an interruption in ART. For more technical discussion of continuous ART and prevention of treatment interruptions, see Section 6.1.

PEPFAR-Supported Site Requirements for Client-centered Services

Below are policies, practices, and program activities demonstrated as effective in sustaining clients on continuous ART. OUs are expected to address each category at each PEPFAR-supported site and may adapt interventions to the needs, preferences, and goals of the clients and target those most at risk for interruption in treatment (IIT). Programs should identify other factors that contribute to IIT, and newer models and approaches to support continuous ART as the population ages and the size of the HIV community grows. These current best practices are categorized accordingly:

Convenient

- Multi-month drug dispensing and separation of drug dispensing from clinical care.
- Community-based treatment initiation, peer-supported linkage, navigation, and treatment continuity support services
- Measured wait times with specific interventions to reduce them, particularly for working clients (e.g., fast-tracking for those who are working), duration of clinic visits (inclusive of

viral load specimen collection and related services), and drug pick-up times must be less than one hour from patient arrival to departure

- Extended hours for working clients (including early morning, evening and weekend hours)
- More convenient places (e.g., decentralized drug distribution, facility extensions into the community) and procedures that support expedited ARV refills
- Transportation support

Hospitable and Friendly

- Creating a welcoming environment and client-centered approaches
- Regular refresher trainings and visual reminders on specifics of client-centered care
- Staff includes patient peers (e.g., patients, males, KP representatives/champions, youth, who are known by the community to provide stigma-free services) with an attempt to match patient and staff by peer group
- Rights, stigma, and discrimination policies and practices are posted, addressed specifically in trainings, and enforced
- Full funding and utilization of community CSO groups (including key populations and youth-led groups) to ensure the sites are client-centered

Supportive and Responsive

- Service referral and linkage system
- Peer outreach and/or case management for linkage and continuity with fair compensation for work
- Tracking (regular and systematic monitoring and follow-up of patient registers for interruptions in treatment) and expedited reengagement of clients with treatment interruption
- System for pre-appointment reminders - with priority to high risk/vulnerable groups (e.g., viremic clients, children).
- PrEP, prevention services and condoms and lubricants offered for those at high risk of HIV acquisition
- Client satisfaction monitored regularly and independently validated by PLWHA, Key Populations (KP) and CSO groups, and staff take action on the finding with PEPFAR support

- Tracks for urgent care and walk-ins
- System for contacting patients to return lab results or to answer questions
- System developed so 100% of clients 15 years and older, and caregivers for persons under age 14, receive VL results
- Strengthened orientation of providers to deliver team-based care to ensure services are client-centered

Accountable and Managed

- Stakeholder engagement: a community advisory board with client representatives, including KP and youth representatives
- Inclusion of customer input in service design, monitoring, and improvement.
- Regular use of data to analyze treatment interruption issues, with development of interventions to improve continuity of ART (ongoing operations research)
- Health worker standards relating to competence, workload, safety, and performance management
- Support for and assessment of staff performance, including non-stigmatizing and non-discriminatory service delivery
- Continuous Quality Improvement (see Section 3: practices at the site level that engage staff and use client input and program data for ongoing improvements in all areas of care and treatment

Return to Treatment

Return to Treatment (RTT) of clients whose treatment has been interrupted is a high priority for all treatment sites and requires coordinated facility and community efforts.

- Consistent, affirmative “Welcome Back” messaging that avoids negative consequences of interruption of care and provides positive reinforcement for re-engagement.
- Continuity of care after treatment interruption should be tailored to individual clients. Re-engagement service delivery algorithms should be developed which clearly set out an expedited timeline to access MMD and DSD models. For example, if the issue is distance to the clinic, a client should be supported with 6-month appointments and 6 months of medication with routine phone follow-up. Access to multimonth dispensing of medications should not require clients to prove they are taking their meds.

- Rapid Re-engagement services– built with robust privacy protections, patient information systems structured for the rapid identification of clients who miss appointments or drug pickup dates, outreach and contact with client by appropriate peer and community staff, assessment of client status since last recorded clinic visit including ARV use, current and active symptoms or diagnoses, sexual history for identification of high risk clients and appropriately tailored services and referral of partners to index testing, and case management to identify and address barriers to re-engagement and long term ARV use.
- Transition to Treatment – operation protocols and MOUs or agreements to link clients in a rapid manner from home/community to treatment sites, assessment of client readiness by case manager or outreach worker, transportation and accessible scheduling and appointment services, and transmission of client information to facilities to ensure appointment was made.

2.3.1.3 Non Service Delivery Activities for Continuous ART

Non-Service delivery activities including above-site services are essential in the implementation and scaling of key policies and practices at the site level. Below is a list of recognized non-service delivery activities that are to be considered and supported in order to ensure the success of the site level support for continuous ART. Countries may already be supporting these activities; if this is the case, the teams should review the IP work plans to ensure that the above-site activities are directly related to supporting efforts at the site level. This list is not meant to be exhaustive; countries may have other activities that are essential to supporting site-level services that support ART continuity.

- Electronic Medical Records: patient monitoring to ensure continued engagement in treatment: track patients, including transfers, and accurately capture patient data to improve ART continuity and facilitate appointment scheduling and reminders (e.g., by bulk SMS).
- Electronic Client Registry Infrastructure incorporated into EMRs and other health information systems where available, enabling tracking of individuals across sites and services in clinical and community settings.
- Data for decision-making: building capacity/ training of OU, district, and regional staff to synthesize routine site-level data regarding missed appointments and interruptions in care, to inform decisions to improve ART continuity (see Section 6.6.10)

- Policy and enabling environment: MOH policies and circulars that align with WHO-recommended practices that support tracking and tracing of clients for ART continuity and proscribe user fees.
- Tools: documentation of multiple phone numbers and other contact information for each patient on registers; patient tracking registers that enable facilities to track missing patients
- HRH: Capacity of district and regional staff for HR performance management, to support accountability and contribution of host-country HRH to tracking and improved ART continuity.
- Laboratory continuous quality improvement: lab CQI activities to improve viral load access, coverage, and testing quality to support the key measure of successful ART. These activities should include strengthening the fidelity of the lab/clinic interface surrounding demand creation, quality sample collection, complete test requests and documentation of viral load results in client records to inform management decisions.
- Supply chain systems: strengthening the forecasting, ordering and distribution systems to fully support MMD and to ensure there are no stock-outs of ARVs, lab reagents, OI treatment, or basic biosafety supplies through improved utilization and transparency of data at site and central levels
- Unique IDs: developing a UID system (e.g., electronic referral systems, Client Registry Infrastructure) to track patients, especially patients with treatment interruption to reengage them in care.
- Stigma reduction education for the general population and for health workers: Capitalize on community-based organizations including faith-based organizations to foster behavior change through Undetectable = Untransmittable (U = U), how to decrease stigma and support testing and treatment to support persons in living healthy with HIV

PEPFAR is at the forefront of understanding and ensuring the “universal” in Universal Health Coverage truly means universal for all clients no matter risk, poverty, disability, geography, age, gender, gender identity, sexual orientation, or substance use. Health systems that PEPFAR supports must demonstrate that everyone with need in a specific geographic area has access, is treated respectfully, is welcomed, is supported, and thrives. The community impacted by HIV is integrated into and a key stakeholder in PEPFAR planning, implementation and evaluation

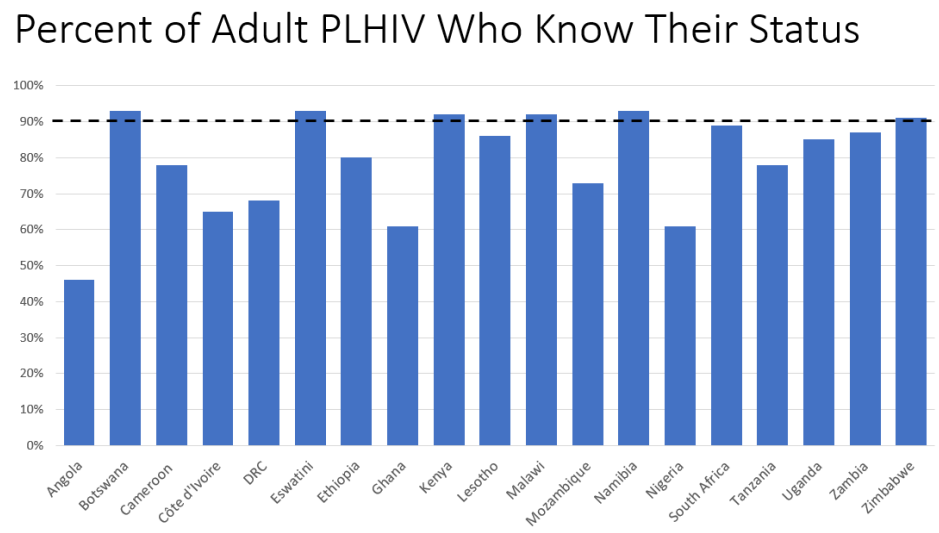
activities and programming. Together with the Global Fund, there is no U in UHC without supporting clients for sustained, continuous care, and this should be the focus of all health systems and above-site investments.

Above-site interventions should be included as part of an OU ART continuity strategy and needs to be linked to service delivery in a manner to ensure availability of services to ALL clients, regardless of affiliation with specific agency or IP, and support a vision of seamless and unfettered access to ART while protecting client confidentiality.

2.3.2 Finding PLHIV: Smart, Effective, Efficient, Confidential and Client-Centered Case Finding

Active case-finding represents the gateway to treatment, and a critical path to prevention interventions; inefficient or ineffective case-finding can also be a bottleneck to epidemic control. As countries approach epidemic control, case-finding needs to evolve to be better targeted to reach the missing population of people living with HIV. PEPFAR discourages continued funding for testing of no/low-risk individuals and populations. Country programs must develop strategies that balance case finding approaches/modalities to maximize case detection depending on the target population 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. Particular effort should be given to developing innovative and efficient ways to close those gaps, with strategic partnerships that have a presence in the communities and with the populations we are trying to reach. HIV positive individuals across many countries in sub-Saharan Africa know their status, reaching over 80% in several countries, however these achievements are not evenly distributed among all subpopulations, ages and sexes (Figure 2.3.2.1). Therefore, testing and case finding strategies must evolve and match program, and client, needs and contexts.

Figure 2.3.2.1: Percent of adult PLHIV who know their status in select countries



Source: Adjusted from John Stover, UTT UNAIDS Meeting, December 2019

While PITC remains one of the least costly case finding strategies available and remains appropriate in many contexts, in order to avoid being overly reliant on clients presenting to a facility with symptoms (e.g., advance disease), PITC programs should leverage validated risk screening tools, and programs must balance testing in this context with other targeted and active case finding approaches.

Teams must monitor the volume of HIV positive (HTS_TST_POS) individuals identified, yield, and testing volumes from each modality. Then utilize locally validated risk screening tools for that country or context (i.e., using risk screening tools that are program-evaluated, not assessed through operations research or RCTs) to ensure case-finding efforts are identifying and testing individuals and populations that are at high risk of HIV infection. To maximize impact, countries need to understand the specifics of their epidemics at a sub-national and population level, and develop tailored and focused strategies that address their case-finding gaps.

Increasing yield or positivity is not always an indicator of increasing quality of services or increasing case finding volumes. For example, during the COVID-19 pandemic, the number of patients presenting to TB Clinics, declined in several countries such as Ethiopia, Kenya, South Africa, Nigeria, and Lesotho, most markedly in FY20Q3. HIV testing within TB Clinics generally has high yields but, in several countries, yields increased even further as testing volumes declined indicating that not enough testing was being performed, as opposed to an increased efficiency in case finding. Positivity rates or yields need to be viewed holistically by assessing changes not only in testing volume but total HTS_TST_POS results.

Targeted HIV case finding of high-risk individuals is a key entry point to both ART and prevention services and programs should leverage innovative, context specific strategies such as partnering with national TB programs to leverage TB case finding and contact tracing within clinics and communities for HIV case finding as well as testing within malnutrition clinics (please see Section 6.3.1 for details).

Every person is a client in need of services, and we must apply a client-centered approach with every person who is tested. Clients should receive positive, consistent counseling on the benefits of HIV testing and treatment. HIV testing services are a crucial opportunity to provide up-to-date, fact-based information about HIV and treatment as well as accurate recommendations for retesting based on the national testing guidelines and WHO recommendations.[6] It is also an opportunity to prepare clients for ART initiation by providing a positive, respectful, and compassionate clinical experience or linkage to preventive services, if negative.

Index testing, Assisted Partner Notification, Partner Notification or Contact Tracing all represent the same approach: to find individuals who may have been exposed to an HIV positive individual (as biological children, sexual contacts or injecting contacts), and facilitate their receiving HIV testing services, in a safe and ethical manner.[7] If an individual is HIV positive, they should be linked to ART and if they are negative, they should be offered or linked to prevention services, such as PrEP, VMMC and other prevention services as part of a client-centered prevention strategy. These services must be offered in a voluntary, confidential, and respectful manner. All index testing offered at any PEPFAR-supported site must be done in accordance with WHO's 5Cs and PEPFAR Guidance on Implementing Safe and Ethical Index Testing Services (See Section 6.3.1.5). PEPFAR is committed to ensuring that (1) all PEPFAR-supported sites meet the minimum standards for safe and ethical index testing services and (2) routine monitoring and remediation practices are in place for accountability and action. PEPFAR will work collaboratively with civil society partners, government leaders, and PEPFAR Implementing Partners to ensure all voices are heard, remediation actions are taken in a timely manner, and the safety and ethical treatment of clients remains of utmost importance. More information can be found in Section 6.3.1.5 and on the PEPFAR Solutions Platform site

[6] WHO Consolidated Guidelines On HIV Testing Services for a Changing Pandemic. November 2019. Available at: https://apps.who.int/iris/rest/bitstreams/1261990/retrieve

[7] See PEPFAR Guidance on Implementing Safe and Ethical Index Testing https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

(https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services).

As the COVID-19 context has highlighted, it may be necessary to reduce exposure of patients within health facilities and offer testing services for contacts of index clients outside of facilities in a safe and ethical manner. Programs may consider accelerating plans for scaling HIV self-testing kit distribution in the following settings, if appropriate based on their epidemiological context:

- Reaching priority populations within the community or facilities
- Providing an HIVST to an index client for their partner
- Providing parents (index clients) with HIVST to screen biological children >2 years of age
- Scale of HIVST for KP and clients of FSW
- Providing HIVST for high-risk PBFW

Please see Technical Considerations (Section 6.3) for additional information on testing strategy and standards.

Figure 2.3.2.2: HIV case finding approaches supported by PEPFAR, based on ART coverage

HIV Case Finding Approaches for COP21 for PEPFAR Support								
ART Coverage (National or subnational)	Index Testing (facility or community)*	TB and STI	Key Populations	Other non-facility based testing	PMTCT	HIV Self-testing	Other facility-based testing • Symptom-based • Risk-based • Men 25 to 35 yrs old	Percentage of HTS_POS from Index Testing
80% or greater	Minimum 15% to 40% yield	Yes	Yes		Yes	Yes	Minimum 10% Yield	75%
70-79%	Minimum 15% to 40% yield	Yes	Yes	Targeted to specific populations & high burden areas	Yes	Yes	Minimum 10% Yield	50%
Less than 70%	Minimum 15% to 40% yield	Yes	Yes	Targeted to specific populations & high burden areas	Yes	Yes	Minimum 10% Yield	30%

*Index Testing Yield calculations should be disaggregated by age and sex to better understand gaps in testing coverage based on unmet need for treatment.

2.3.3 Client-Centered Prevention

An effective and accessible prevention program is essential, particularly to engage high-risk populations where there is ongoing transmission. Prevention programs must maximize their ability to provide continuous, client-centered service starting with seamlessly integrating evidence-based, efficient services as a vital part of an integrated HIV response. This will also preserve gains in reduction in transmission achieved through the expansion of test and treat services as part of Undetectable equals Untransmittable (U=U). Communities should be mobilized to support prevention and treatment activities and maximize use of virtual platforms for reaching high risk individuals for testing, treatment, and prevention.

PEPFAR must continue to tailor prevention programs for adolescents and young adults under 30 years old in sub-Saharan Africa. Prevention activities must be evidence-based, for both preventing HIV risk before it occurs and reducing ongoing risks. These include DREAMS interventions; VMMC; male and female condoms and lubricant distribution, user-focused demand creation and use promotion; post-exposure prophylaxis and PrEP for those at substantial risk of HIV; elimination of mother-to-child-transmission of HIV; harm reduction approaches and structural interventions for KPs; and immediate or rapid HIV treatment for all identified as HIV-positive. Targeted prevention plans should include as a goal routine linkage to prevention activities for those individuals testing negative in high HIV prevalence areas either by geography or risk group. Special attention must be paid to women <30 years old, including pregnant and breastfeeding women, adolescents, sex workers, and adolescents engaged in any transactional sex; discordant partners; gay, bisexual, or other men who have sex with men (MSM); transgender men and women; people who use drugs (PWUD); indigenous people, migrants, and immigrants; prisoners and others who live in closed settings when high HIV prevalence has been documented; and 18-30 year-old active-duty military personnel when HIV prevalence is over that of the general population. For 9-14 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 for this age group as well as older ages. 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. PEPFAR takes a developmental approach to HIV prevention, meaning that the primary focus is different for 9-14, 15-19, and 20-24 year-olds. For

the youngest participants (9-14), there should be more emphasis on delay and abstinence than among the other age groups, but not at the exclusion of making sure young people understand their bodies and how to protect themselves. Trauma-informed services should be provided to victims of sexual violence, with a focus on the treatment of trauma symptoms, including how to access emergency ARVs, contraception and counseling. More discussion of specific prevention interventions is described in Technical Considerations.

PrEP Targeting

PEPFAR supports the World Health Organization (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. Teams should consider developing multi-year plans that show how PrEP can contribute toward epidemic control and that incorporate new prevention modalities including injectable cabotegravir and the dapivirine vaginal ring and that allow incorporation of new agents as they are approved. PrEP should continue to be scaled up as an important intervention where risk of HIV acquisition is high, based on the best available data. Likewise, PrEP should be considered for HIV-negative partners in known serodifferent relationships where the positive partner has either unknown viral suppression status, difficulty sticking to treatment regimens, otherwise known elevated viral load, and/or other ongoing risk (such as partners outside of the relationship). In specific high-risk situations, such as the pregnancy and breastfeeding window for women in countries with high HIV prevalence, PrEP should form a significant part of national prevention efforts. Adaptations to the COVID-19 epidemic such as virtual demand creation and training, multi-month dispensation for PrEP commodities, home and community-based delivery of PrEP, and virtual/phone-based support and follow-up should be expanded. Further information is available in Technical Considerations.

2.3.4 Client-Centered Supply Chain Modernization

To support client-centered ART, Case Finding (cf), and Prevention Services (ps), PEPFAR-supported countries must drive toward more client-centered supply chains to achieve HIV epidemic control and maximize product availability, quality, and affordability as well as convenience for the client. Beginning with ARV optimization and expansion of Multi-Month Dispensing (MMD), countries must show they have a strategy for a supply chain that meets the evolving and future needs of clients.

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

- Strengthen the collection, management and use of supply chain-related data for enhanced transparency and accountability of commodity ordering, distribution, and final mile delivery.
- Strategically segment the supply chain to better reach unique patient populations more efficiently and effectively via different tailored channels based on their needs (i.e., delivering medicines to more convenient locations and pickup points).
- Make progress towards reducing long-term dependence on donor funding and refocus technical assistance to support countries assuming increasing responsibility for oversight of their supply chain as the principal stewards for commodity availability and security.
- Accelerate utilization of private sector capabilities and infrastructure where appropriate, including specifically outsourcing elements of the segmented supply chain to maximize efficiency and effectiveness. Focus for 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.
- Provide multilateral coordination for the country to receive the best prices for commodities

Country Planning Level Letters (PLL) address specific strategic opportunities in some countries to move toward modernizing the Commodity Supply Chain in a manner that maximizes client-centered service.

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 COP21. The brief and discussion should include each of the salient points addressed above and the timeline for implementation.

2.3.5 Stigma, Discrimination, Violence and Human Rights

Stigma, Discrimination, and Violence

Stigma, discrimination, and violence, as well as harmful laws, policies, and practices, reduce access to and use of essential health services, and undermine efforts toward effective responses to HIV/AIDS. PEPFAR is committed to joining others to end stigma, discrimination,

and violence and increasing access to, and uptake of, HIV prevention, treatment, and care services for all people living with HIV/AIDS and affected by HIV/AIDS; especially adolescents and young 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).

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. It can undermine human rights. To control the epidemic, it is imperative that OUs identify and understand the often complex dynamics driving 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 service-delivery cascade. Additionally, there is a need to address the structural- and policy-level barriers that perpetuate discrimination. Stigma, discrimination, and violence are most often targeted at people living with HIV and key populations, and women and girls. Yet the impact reaches beyond these populations. Other key stakeholders, including health providers, supportive community members, human rights defenders, 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 be provided taking into account WHO guidelines and should be complemented with sensitivity training to reduce violence-survivor stigma among healthcare workers. More information on PEPFAR's approach to GBV can be found in Technical Considerations (Section 6.6.3).

While each of the actions outlined in this guidance are discrete, they are all part of a framework to promote human rights and eliminate stigma, discrimination, and violence by creating an enabling environment (e.g., structural) that amplifies the successful implementation of prevention, treatment, and care services.

PLHIV Stigma Index 2.0

The PLHIV Stigma Index 2.0 is a tool to measure stigma and discrimination among PLHIV and to chart progress in reducing occurrences. 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 can begin the process of baseline data collection for evaluating the future impact of interventions on reducing stigma and should be used to inform future HIV program planning. PEPFAR teams are required to either support host 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. PLHIV Stigma Index 2.0 must be carried out in collaboration with the "PLHIV Stigma Index International Partnership," comprised of GNP+, ICW and UNAIDS. At country level, coordination should include routine meetings with all in-country stakeholders, including women living with HIV networks, key populations groups, and civil society organizations, to discuss project goals prior to implementation, assess implementation progress, and discuss findings. Completion of the PLHIV Stigma Index 2.0 should be accompanied by a response/action plan discussed and agreed upon by all stakeholders that will address findings and emphasize community leadership in needed responses and action steps. Implementation of PLHIV Stigma Index 2.0 is recommended every 3 years; during interim years, focus should be on concerted action to address findings. 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) and should be resumed as soon as local COVID conditions permit.

Human Rights

PEPFAR's human rights guiding principles include respecting, protecting, and promoting human rights, thus creating an enabling environment that promotes access to 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 COP21

strategic planning meetings and ensure they are coordinating with existing efforts of other partners and stakeholders such as the Global Fund and UNAIDS.

1. In coordination with regular CSO engagement and relevant existing working groups, including PEPFAR interagency, other U.S. Mission sections, U.S. Department of State Bureaus, and community representatives, including key populations, develop a plan, timeline, and resource allocations to measure, document, and mitigate stigma, discrimination, and violence. 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 CSOs as these relate to service provision for HIV. These PEPFAR investments should be captured in the FAST, Table 6, and other applicable tools. Additionally, teams should ensure coordination with the UNAIDS Global Partnership for Action to Elimination all forms of HIV Related Stigma and Discrimination and the Global Fund Breaking Down Barriers Initiative, where applicable. Consult with the local UNAIDS office, and also see 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
2. 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.
3. Establish or maintain an in-country, interagency point-of-contact (POC) whose responsibility will be the oversight of the USG staff Gender and Sexual Diversity (GSD) Training and ensure that a system is in place to track USG staff compliance with this training requirement. At the headquarters level, each PEPFAR implementing agency must also identify such 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 USG staff member, both field and headquarters, must complete the online version of the GSD training within two months of their hire date. USAID and Peace Corps staff should consult their agency HQ on this training. For all other agencies, the training is currently being converted to the PEPFAR Virtual Academy and a link will be provided when available. 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. 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. Instructions for the panel discussion can be found on the PEPFAR SharePoint link noted below, and teams should consult HQ for any additional guidance.

4. Ensure that legal environmental assessments (LEAs) or similar are regularly 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 and should engage 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.[8]

   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 other embassy staff/sections, such as the Political and Economic sections. The Global Fund Strategy 2017-2022 established a continued need to strengthen work on sustainability and human rights. 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: Botswana, Cameroon, Democratic Republic of Congo (province-level), Cote d'Ivoire, Ghana, Indonesia (selected cities), Jamaica, Kenya, Kyrgyzstan, Nepal, Mozambique, 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 here: https://www.theglobalfund.org/en/funding-model/throughout-the-cycle/community-

[8] https://www.unaids.org/sites/default/files/media_asset/JC2895_Fast-Track%20and%20human%20rights_Print.pdf

rights-gender/, and serve as the basis for national plans for a comprehensive response to human rights-related barriers.

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, 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.

More information about the PLHIV Stigma Index 2.0, Legal Environment Assessments, stigma and discrimination resources, and GSD Training can be found by USG staff on PEPFAR Sharepoint.[9] A country-by-country overview of various HIV related laws and policies is now available at http://lawsandpolicies.unaids.org/. In addition, the newly launched HIV Policy Lab (https://www.hivpolicylab.org/) systematically gathers and monitors laws and policies around the world, inclusive of some human rights-related laws and policies. Further information about addressing stigma, discrimination, violence and human rights specific to key populations can be found in Section 6.6.2 (Cross-cutting Key Populations Considerations).

2.4 Sustaining Epidemic Control of HIV

Effectively retaining clients in quality HIV treatment programs, as discussed at length in previous sections, through the implementation of a client-centered strategy for continuity of treatment and return to treatment at key HIV service delivery sites is pivotal to sustaining the progress made towards epidemic control. As countries advance toward epidemic control, sustainability planning is critical to defining the continued responsibility of PEPFAR and the country government while simultaneously strengthening the government's responsibility to maintain and achieve further reductions in new HIV infections and provide high quality client-centered care.

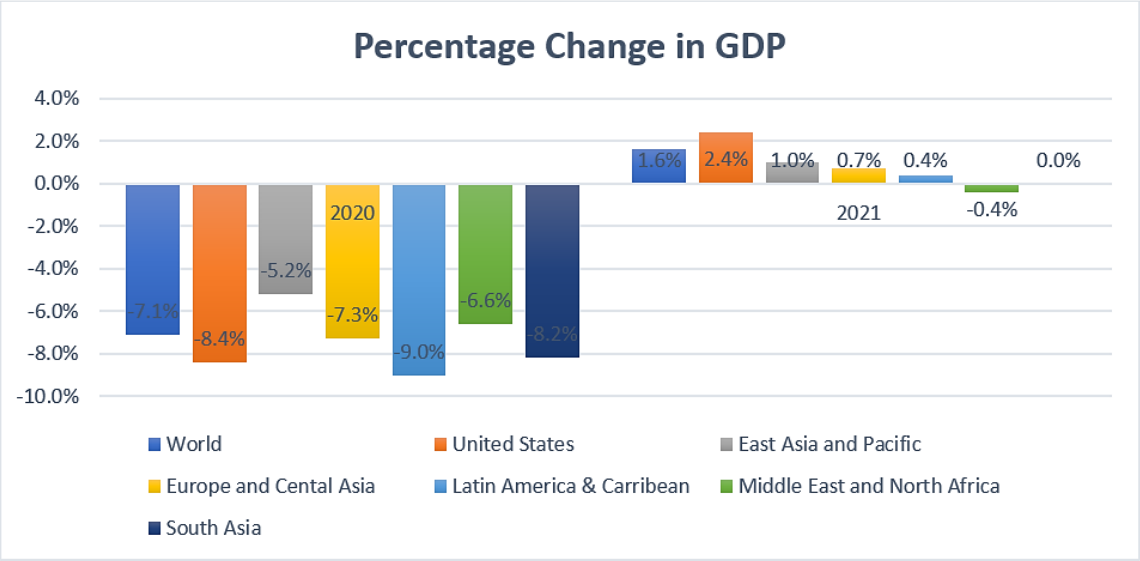
COVID-19 and Its Impact on Sustainable Financing

The COVID-19 pandemic has had severe economic repercussions. The economic downturn impacting low, middle and high-income countries will be the deepest and most severe seen in eighty years. This economic downturn is a result of both government actions to deal with the

[9] https://pepfar.sharepoint.com/sites/APCS

pandemic including lockdowns, closure of schools and travel bans as well as global factors on which individual governments have little control. These include an eighty percent drop in tourism, declines in the price of oil and other commodities, global value chain impacts and debt10. All indications are that the recovery, in many countries, will be slow and gradual and that the next two to three years will see countries experience a lot of economic stress.

Figure 2.4.1 Economic Impact of COVID-19 Pandemic



Source: Global Economic Prospect, World Bank June 2020

Since 1870 the world has experienced fourteen recessions, but this is one that will impact the largest number of countries and have a significant impact on per capita incomes of low and middle-income countries. As Kose, et.al. observe in their recent work "Global Waves of Debt: Cause and Consequences", "the past decade has seen the largest, fastest, and most broad-based increase in debt in these economies in the past 50 years. Since 2010, their total debt rose by 60 percentage points of GDP to a historic peak of more than 170 percent of GDP in 2019."11

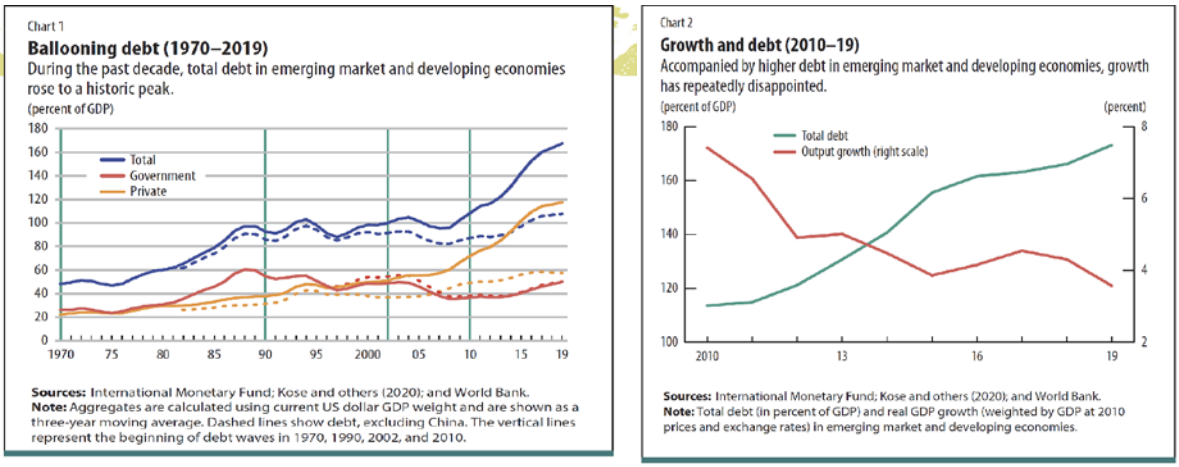
Clearly, even prior to the COVID-19 crisis debt levels (both institutional and private) rose at levels much faster than economic growth. The economic shock of COVID-19 has meant that debt to GDP ratios have increased significantly with low income countries facing the highest

[10] Global Economic Prospect, World Bank, June 2020

[11] Kose, M. A., P. Nagle, F. Ohnsorge, and N. Sugawara. 2020. *Global Waves of Debt: Causes and Consequences.* Washington, DC: World Bank.

stress. The fact that a large part of the debt is privately held means that traditional approaches taken by lender countries and other global institutions will not be as effective.

Figure 2.4.2 Change in Macro Fiscal Environment due to COVID-19



Source: IMF and World Bank

Finally, in less than nine months into the pandemic, high income countries have added 17 trillion dollars in debt which amounts to nearly $13,000 per capita. Major donor countries, including the U.S., have debt to GDP ratios that either exceed a hundred percent or are close to reaching a hundred percent12. With cases in the US continuing to increase and a second surge of COVID-19 cases impacting Europe and the United Kingdom, their economic situation will likely worsen before it gets better. Global economic recovery will likely be slow and painful.

The macro-fiscal environment shows that low and middle-income countries will have little ability to invest more of their resources into the HIV response. Given the priority to restore economic growth, their ability or willingness to invest in health will also be severely constrained and may have ramifications on key health system inputs and functions (e.g., HRH, commodities). The pandemic has also clearly shown that it is the poor, disadvantaged and marginalized populations that are impacted the most from the virus, breakdowns in routine health systems, impact on delivery of essential health services, and economic stress and downturn.

For PEPFAR to protect gains and maintain movement towards epidemic control and to ensure that needed services are available for the poor and disadvantaged populations will require an approach that leverages “All of Domestic and All of Market” approaches to finance and deliver HIV services. On the government side PEPFAR should continue ongoing work on improving

[12] Source: OECD data and FT Article by Chris Giles and Robin Harding, May 2020

public financial management systems, increasing budget execution for HIV budget allocations, and ensuring HIV services are included in social health insurance benefit packages. Routinely gathering cost information helps inform decision makers in their plans to implement a sustainable response, used to drive efficiencies and optimize allocation of scarce resources. After much consideration PEPFAR has decided to support the roll out of Activity Based Costing and Management as the preferred approach. We have built global consensus around this with UNAIDS, the Global Fund, Bill and Melinda Gates Foundation, USAID, CDC and US Treasury. The advantage of this approach is that it establishes a system that will provide cost information on a regular basis that can be then by used by PEPFAR and countries to drive decisions on optimizing resource allocation. Six countries supported by PEPFAR have started this work and UNAIDS is taking the lead in Zambia. Countries are strongly encouraged to initiate and institutionalize Activity Based Costing and Management as part of their COP planning.

While government and donor resources should target the poor and those most in need, we should find ways of leveraging the private sector to serve those that can afford to pay for care and optimize use of available resources in country to support HIV service delivery. PEPFAR and the global HIV community will need to think of new service delivery models and offerings as well as incentives that make it attractive for private players to participate in this market. Supply chains, manufacturing of commodities, leveraging pharmacies and networks of private providers to distribute ARVs, PrEP and self-test kits are all areas where the private sector can play key roles. In order to optimize the potential of the private sector, we will need the use of traditional financing mechanisms (e.g., insurance) but also the use of innovative financing mechanisms that can help unlock needed private investments. Policy interventions might be needed to help market-based solutions. Strategically leveraging partnerships with the private sector while focusing donor and public resources on those most in need will help sustain the response even in these extremely difficult fiscal times.

Refer to Section 6.6.10.4 (Financing for HIV Services) for a detailed list of traditional and innovative financing approaches, supporting an “All of Domestic and All of Market’ approach, and methods to assess the viability of these approaches based on the country context.

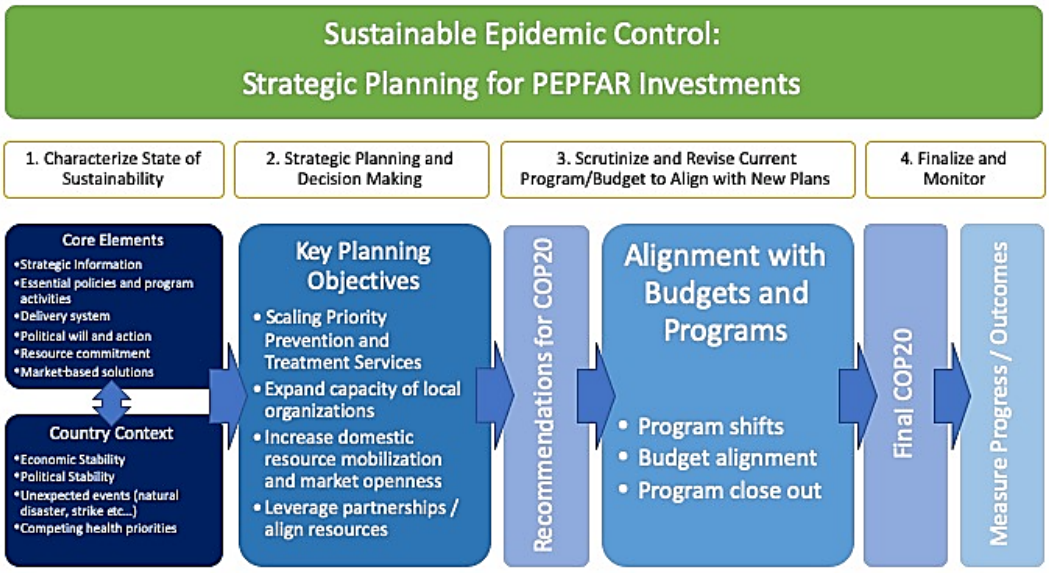
PEPFAR Sustainability Planning

In order to effectively plan and allocate resources to advance the sustainability of the national HIV response, PEPFAR teams need to continue using the planning model described below in Figure 2.4.2. The planning model includes distinct steps, beginning with an understanding of the current environment and the presence or lack of foundational policies and practices needed

for creating sustainable systems and structures that are able to maintain HIV services once epidemic control is achieved. The framework lays out essential elements in the country context area and political stability; unexpected health related events; and competing health priorities; and others. Based on the information gathered regarding country context, teams will need to evaluate the presence or absence of core components, various policies or practices currently in place related to that specific technical area. Investments are to consider both the country context and to ensure these foundational policies and practices are in place. The intent is to use this framework for each technical area separately as opposed to one comprehensive planning model for all technical areas combined.

Technical assistance with the use and application of the PEPFAR sustainability planning model can be requested from the SGAC, Office of Financial and Program Sustainability.

Figure 2.4.3: PEPFAR country framework for sustained epidemic control



Once the country context and core elements are fully understood, the team needs to establish a planning process, optimally with other stakeholders such as the MOH and the Global Fund, to ensure that the five planning objectives are met:

1. scaling priority prevention and treatment in targeted areas;
2. expanding capacity of local institutions to deliver services, including public health surveillance and other above-site interventions;
3. increasing DRM and leveraging other markets to take on donor-funded HIV programmatic inputs and functions
4. leveraging; partnerships

5. aligning resources for greater efficiency, accountability, and impact.

Countries have used similar steps to establish sustainability plans and roadmaps with MOH and Global Fund.

Refer to Section 6.6.10.1 (Essential Areas for Sustainability) for more details on the core elements and an example of applying the sustainability framework to healthcare worker issues.

Refer to Section 6.6.10.2 (Sustainability Planning for HIV Services) for a detailed step-by-step example, including an example template, of how to implement a planning process in collaboration with local governments and institutions.

Refer to Section 6.6.10.3 (HRH Sustainability Planning) for an example of how to apply the sustainability planning framework and step-by step process to HRH activities.

In addition to the general sustainability approaches described above, COP21 highlights several priority areas essential for a sustained HIV national response, specifically: (1) transitioning HIV services to local partners; and (2) addressing the sustainability of KP-led CSO through innovative financing strategies.

2.4.1 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 – regardless of current ARV coverage levels. The intent of the 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, Regional Programs, and Country Pairs. In 2018, PEPFAR set a goal that by the end of FY19, 40% of partners, by agency, must by 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%, however, the 70% benchmark has not yet been achieved when looking at the total amount of funding that is going to local partners. . Each OU must continue to contribute to

this goal based on the context of the local partner mix and types of public and private partners available to provide essential services.

COP21 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-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.

PEPFAR has continued to make progress in the transition to local partners. At the start of FY21 (COP20), 74% of the total number of PEPFAR implementing partners are now local partners. Though the number of partners that are local has surpassed 70%, the amount of funding going to local partners has not surpassed the 70% benchmark. The total funding going to local partners at the at the end of FY20 was 52%, and the amount of new funding was 55%. Among service delivery funding, 58% of total funding service delivery funding was going to local partners at the start of FY21, and 60% of new funding, though Care and Treatment service delivery was markedly better, with 71% of total funding going to local partners at the close of FY20. Thus, while there is still improvement to be made in this transition, there has been positive progress in some key areas. Prevention service delivery funding going to local partners, though lower than care and treatment service delivery in absolute percentages and well below the target of 70%, showed significant progress from FY20 to FY21, increasing by 8% from FY18 to FY19.New funding is defined as funding that is new in that COP cycle and has not been planned in a previous COP cycle and total funding is defined as the total amount of the budget-new and applied pipeline- that is planned for an operating unit. It is important to understand that FY21 results shown in this analysis represent the FY21 partners that were known at the start of FY21, 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 FY21 will not be available until all partners have been identified.

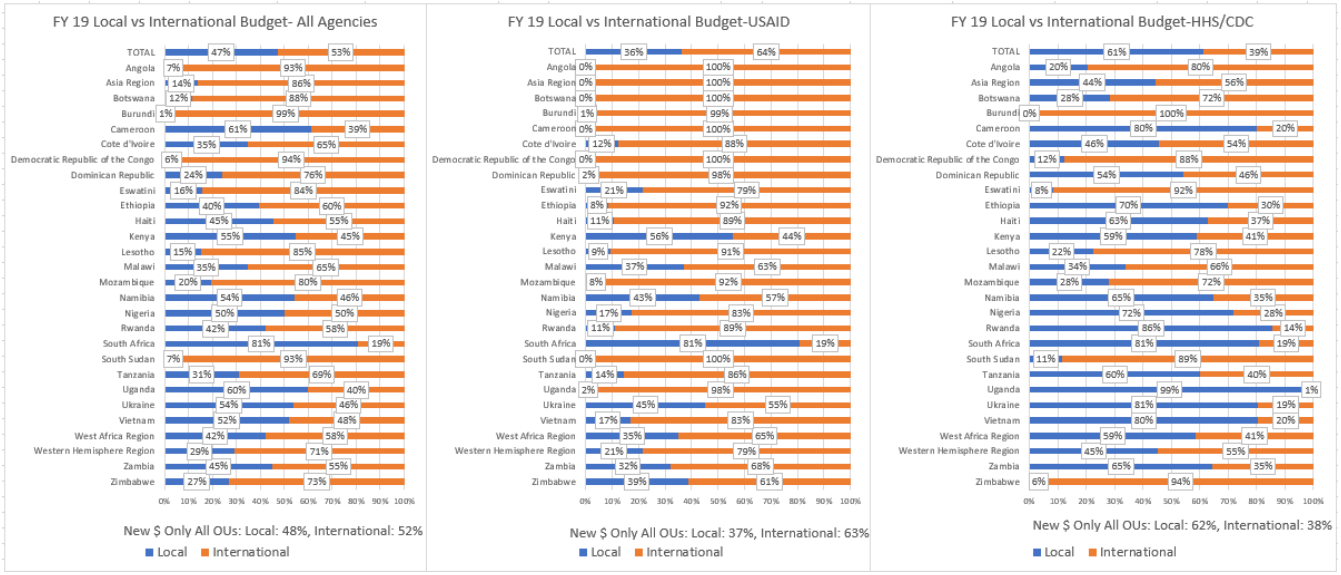
The following graphs show details of transition progress, expressed as the proportion of total and new funding going to local and international partners in the FY19, FY20, and FY21 (COP18, COP19 and COP20) cycles. The source of this data was the COP budgets as entered in the FAST (or OPU workbooks) and uploaded in Facts Info. The COP budget data for this analysis was refreshed as in November 13, 2020. These graphs show all agencies combined, then also show the progress of HHS/CDC and USAID separately. The program area detail seen in

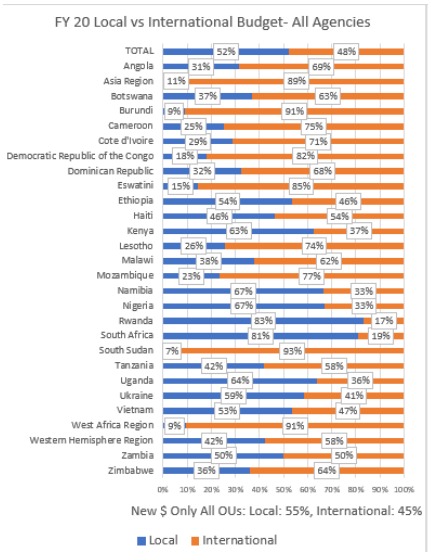
graphs 2.4.1.2, 2.4.1.3, and 2.4.1.4, is only available for FY20 and FY21 since the program area classifications shown in these graphs were not introduced into the COP budgeting process until COP19 (FY20). The following parameters are used in this local partner funding analysis:

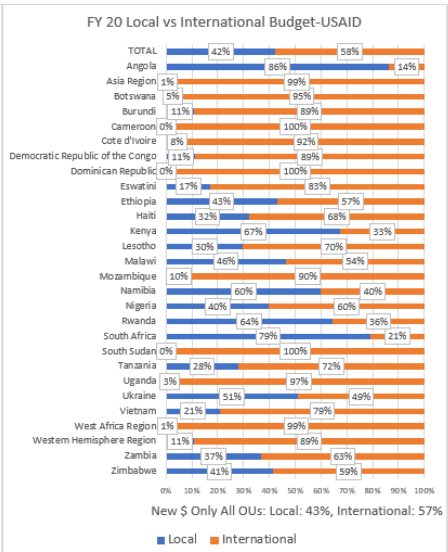
- Placeholder mechanisms whose local or international designation is unknown (because the partner has not yet been identified and named in PEPFAR systems) are excluded
- United States Government Management and Operations costs are excluded
- Major commodities procurement mechanisms are excluded (GHSC RTK and PSM mechanisms)
- Centrally managed mechanisms are included
- Total funding and new funding are both considered (COP budget amounts)
- Funding amounts are by year of implementation, not year of planning

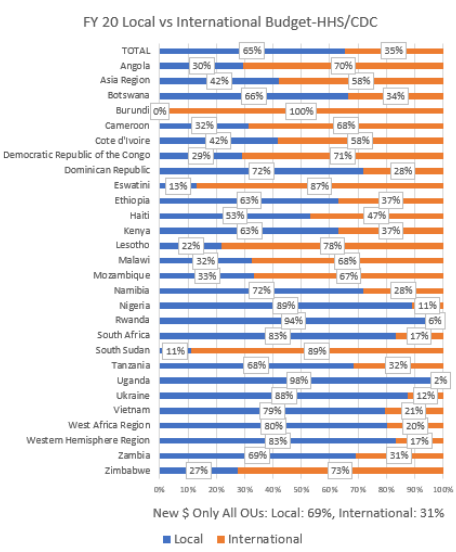
The local partner proportions shown in the graphs below may include regional partners who are not indigenous to the OU, but instead are based in the region. Please reference the definition of local partner used by PEPFAR below.

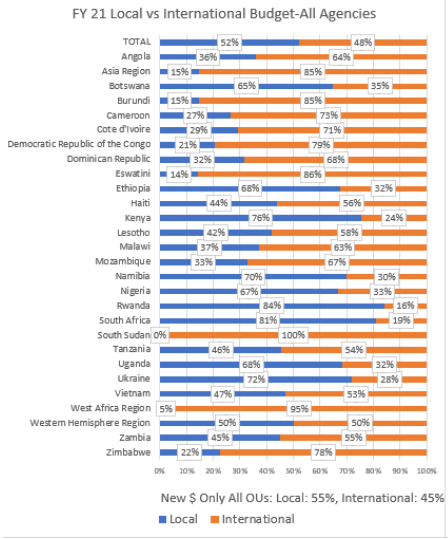
Figure 2.4.1.1: FY19-FY21Total and New Funding by Local and International Partner Charts (Total Funding Shown in Bars, New Funding at Bottom of Graph)

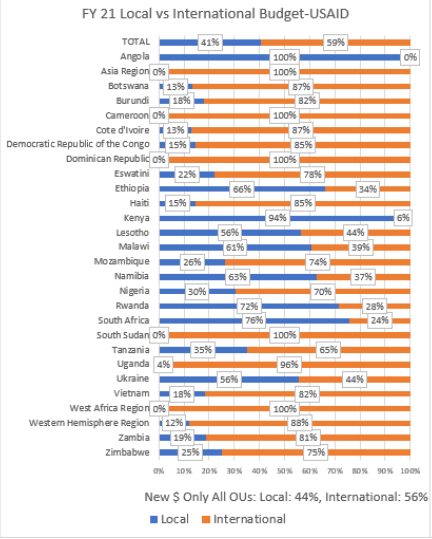



FY 20 Local vs International Budget- All Agencies
New $ Only All OUs: Local: 55%, International: 45%
Local
International


FY 20 Local vs International Budget-USAID
New $ Only All OUs: Local: 43%, International: 57%
Local
International


FY 20 Local vs International Budget-HHS/CDC
New $ Only All OUs: Local: 69%, International: 31%
Local
International


FY 21 Local vs International Budget-All Agencies
New $ Only All OUs: Local: 55%, International: 45%
Local
International


FY 21 Local vs International Budget-USAID
New $ Only All OUs: Local: 44%, International: 56%
Local
International

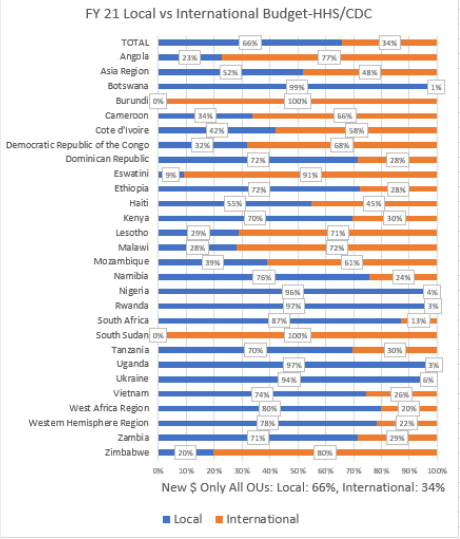
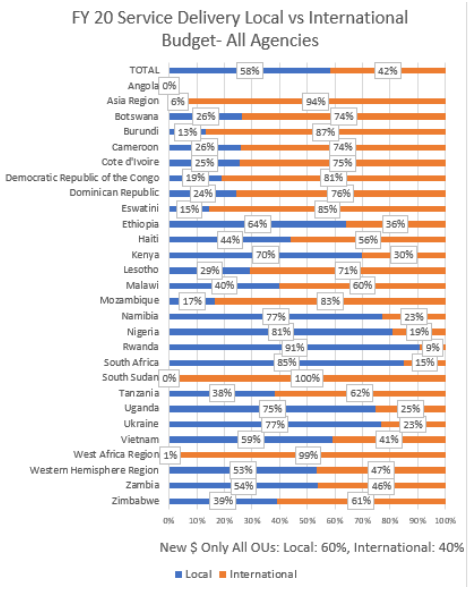
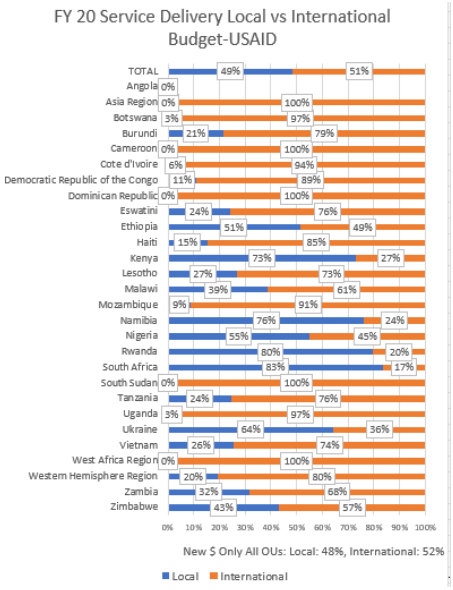
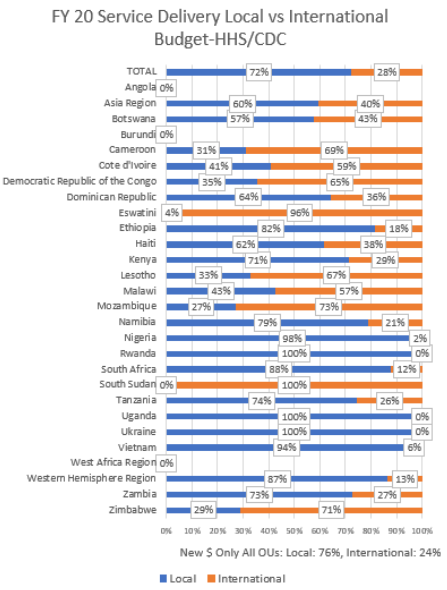
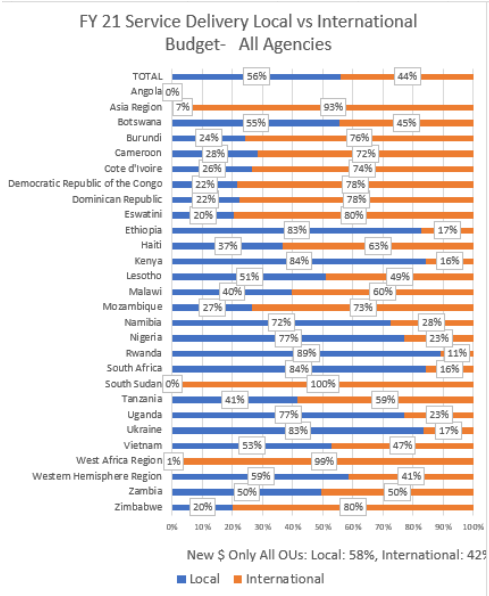

FY 21 Local vs International Budget-HHS/CDC
New $ Only All OUs: Local: 66%, International: 34%
Local
International

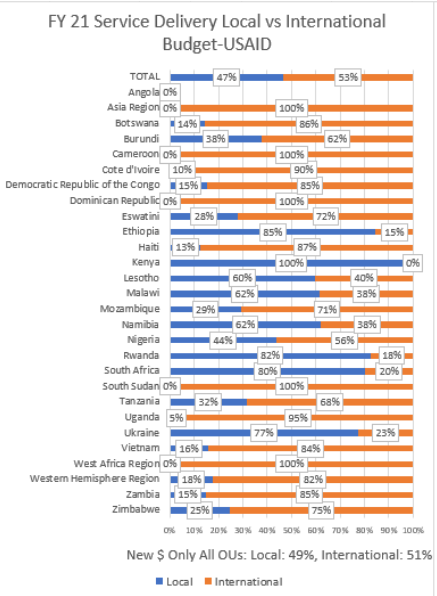
Figure 2.4.1.2: FY20-FY21 Total and New Funding for Service Delivery by Local and International Partner Charts (Total Funding Shown in Bars, New Funding at Bottom of Graph)











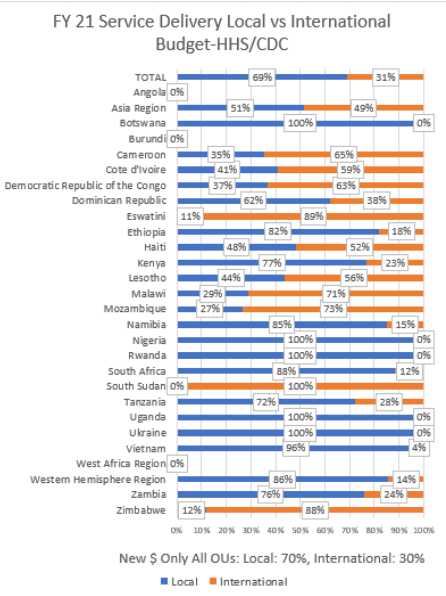


Figure 2.4.1.3: FY20-FY21 Total and New Funding for Care and Treatment Service Delivery by Local and International Partner Charts (Total Funding Shown in Bars, New Funding at Bottom of Graph)

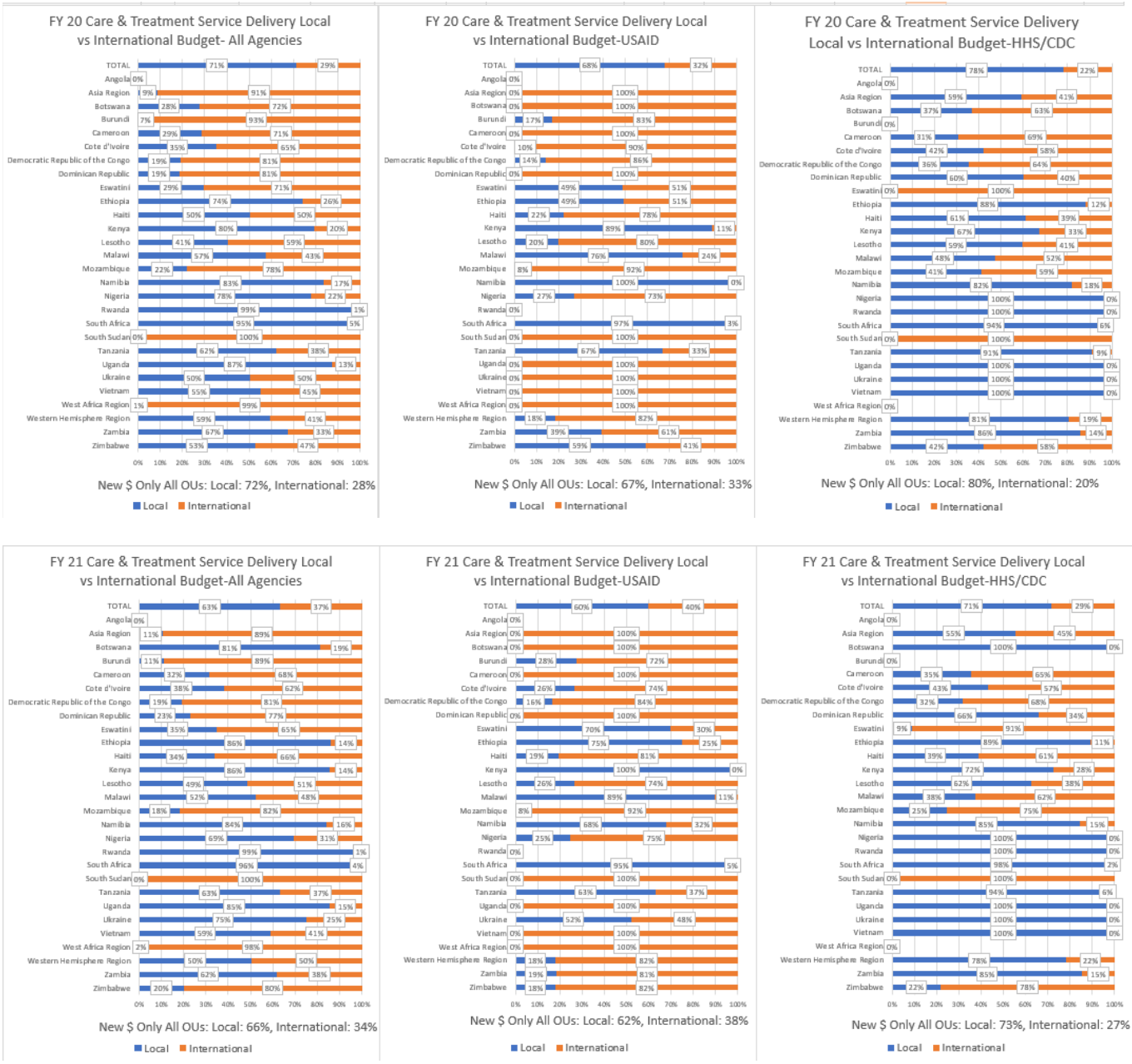
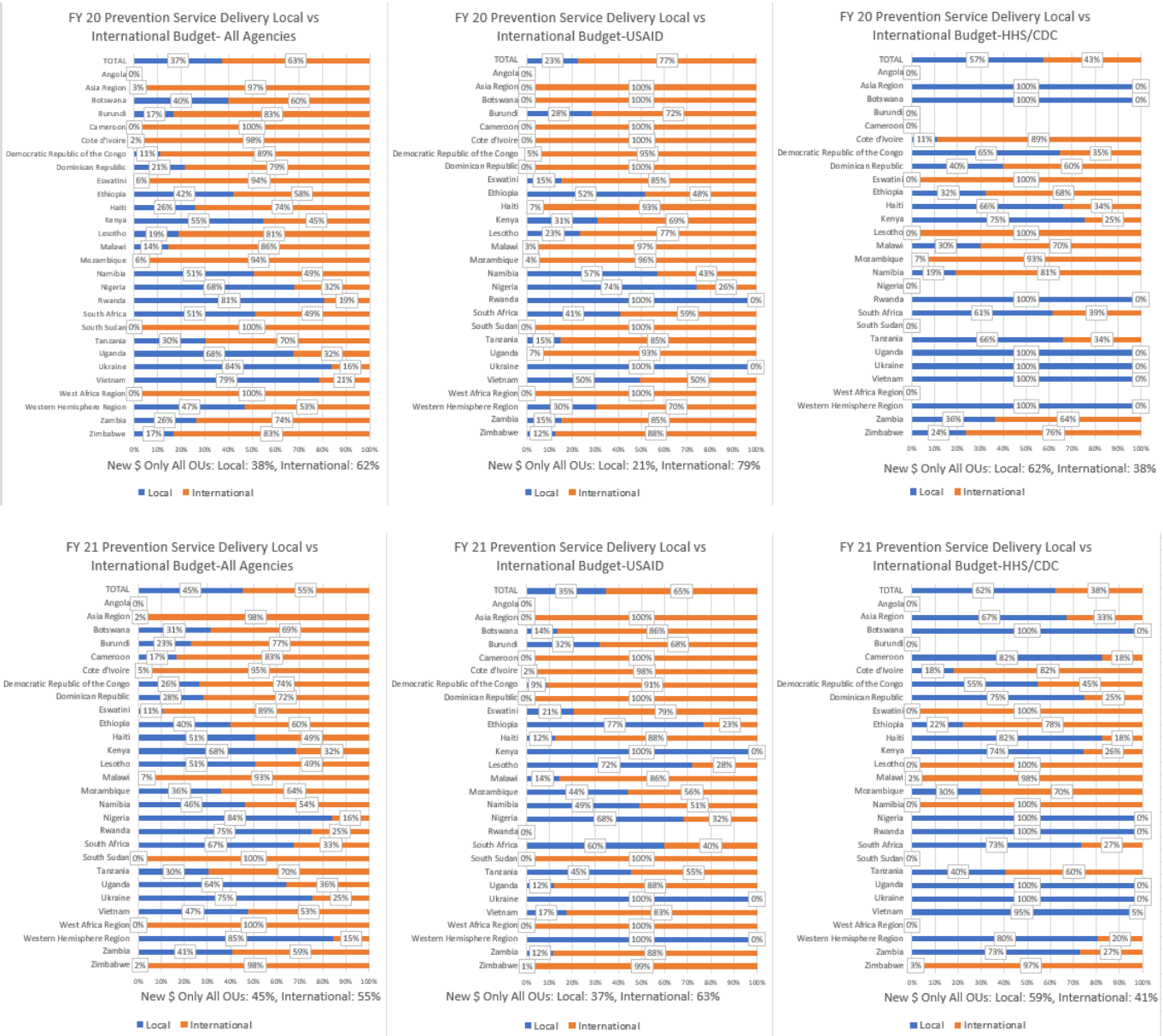
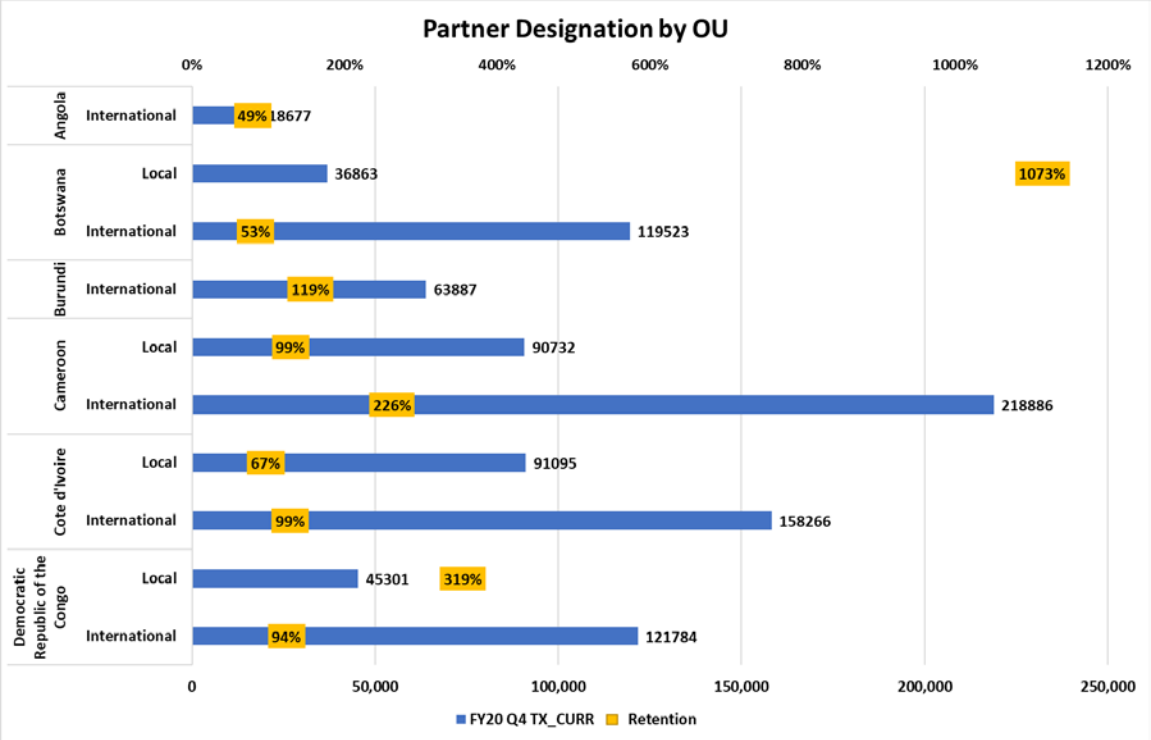


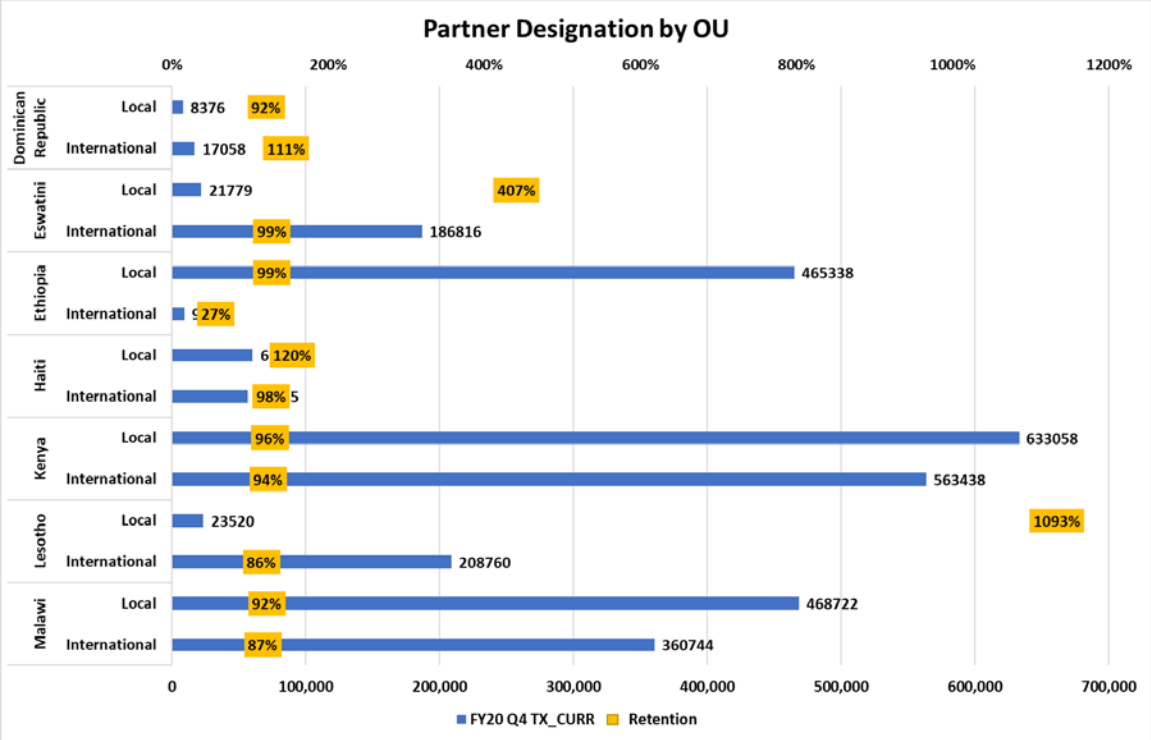
Figure 2.4.1.4: FY20-FY21Total and New Funding for Prevention Service Delivery by Local and International Partner Charts (Total Funding Shown in Bars, New Funding at Bottom of Graph)

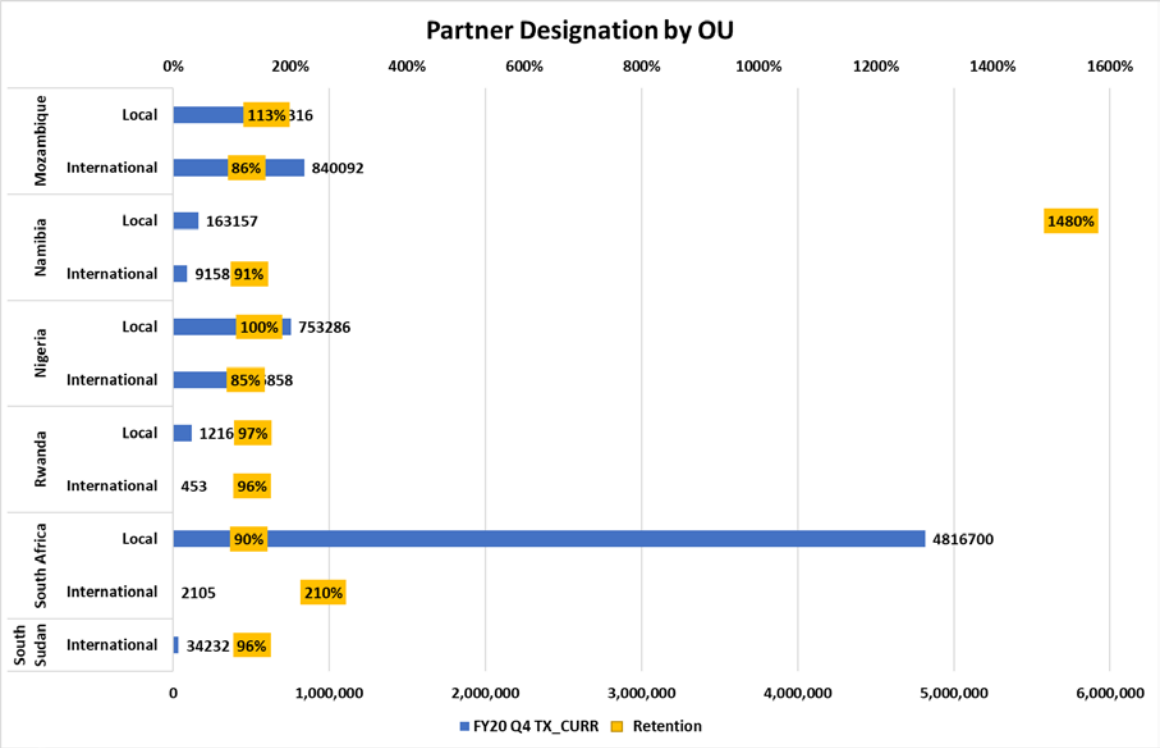


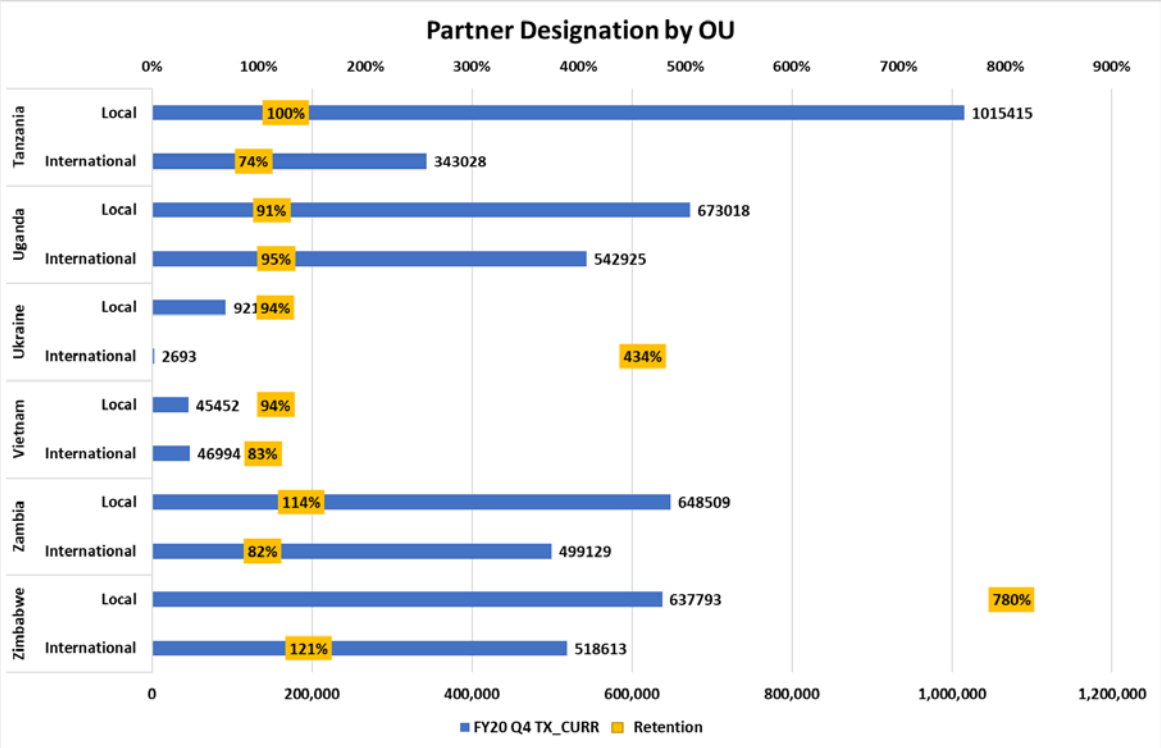
Under the challenging time of COVID-19, local partners have demonstrated their capacity to ensure that clients receive the services they need, exemplified by their results maintaining clients on continuous treatment in FY20 compared to international partners in Figure 2.4.1.5. The retention (continuity of treatment) proxy (annual calculation, in yellow) may be affected by some partners not continuing into FY20 or only starting in FY20.

Figure 2.4.1.5: Local and International Partner Results in Maintaining Clients on Continuous Treatment by OU in FY20









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.

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.

2.4.2 KP-Led Sustainability – Innovative Approaches

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 locally-led KP Key Population CSOs (KP CSOs) to provide a range of HIV services to their constituents. In doing so, locally-led KP CSOs have been shown to be valuable partners and often more effective than other public or private non-KP oriented service settings at delivering services as well as engaging in health advocacy and planning.

As a result, COP 21 introduces an optional focus on models and approaches to support the sustainability of KP-led CSOs, expanding the menu of options available to strengthen and support the long-term viability and strength of these organizations. This effort is optional; it will not be appropriate for all settings due to challenging policy environments, and does not preclude PEPFAR efforts to strengthen the broader enabling environment or address stigma and discrimination. This effort also does not substitute for PEPFAR supported KP or community service delivery. It is rather an opportunity to promote innovative models and a longer-term strategic approach to supporting KP-led service delivery.

KP CSO sustainability is highly dependent on a reliable and long-term source of financial support. Generally, there are two specific options, and one blended pathway, that CSOs use to acquire financial support. The first is obtaining direct grants and contracts from public, including government and non-government, or private institutions or organizations, including donors, and the second is 'self-financing' services using proceeds from the sales of products or services, including direct services, to clients, customers, or external organizations or institutions. A blended pathway uses a mix of both of these approaches.

Options for KP-led CSO Financing

OPTION 1 - Direct acquisition of grants and contracts

Grants and contracts, provided by a government, or other donor, are likely the most common means of financial support among KP CSOs providing HIV services in PEPFAR supported countries. 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, a much larger proportion of HIV prevention and treatment services have primary government support when they are 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.

For CSOs that are able to acquire grants and contracts, several structural elements are essential for their viability, including:

- professional management, grants support, contracting, financial and monitoring staff; payroll
- capacity to successfully submit grant applications; and
- 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 that support social contracting (or public financing of civil society service delivery);
- CSO and KP CSO formation, capacity, and ongoing operations;
- protections for KPs to access and use services; and
- capable government contract management office.

OPTION 2 - Self-Financing

The second financing option, self-financing, relies less on direct government or donor support and more on its own capacity to finance services directly. The primary condition of this option is the ability of the CSOs to raise capital for direct delivery of services, either within or outside contractual arrangements, and having a diversified portfolio of products and services.

Refer to Section 6.6.10.5 (KP-led CSO Financing) for a more detailed description of innovative financing options to promote sustainable KP-led CSO programs.

For 'Self-Financing' CSOs, the following elements are important:

- professional finance, management, operations, and accounting staff;
- business marketing and sales;
- strategic planning;
- open market opportunities to acquire capital and investments;
- regulatory compliance mechanisms; and
- protections for KPs to access and use services.

In order for these elements to be realized, several key enabling environment factors are necessary:

- a level field for competition; and

- non-discriminatory practices.

OPTION 3 – Blended Financing Models

The third, and likely optimal, option is a blending of Options 1 and 2. Many of the structural and enabling elements discussed below are essential to actualizing this option. However, challenges will exist in ensuring the organization has 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 are 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, consisting of 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 KPs.
- 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
- National policies and practices that do not support key population programming and/or legal, functioning, and transparent social contracting mechanism.

It is critical that the adoption of any or all of these approaches to innovative financing for KP-led CSOs be done ONLY when there are sufficient safe guards, including national and local policies, procedures and practices, that protect against any type of legal or non-legal acts of discrimination, including acts of violence perpetrated by government or civil society, against

KPs or CSO serving KPs. PEPFAR teams should work to ensure sufficient policies and practices are in place as a key foundational component of assuring KP-led CSOs are sustainable and contributing in an optimal manner to address the all prevention and treatment needs of targeted clients.

2.5 Leveraging Partnerships and Local Resources for Epidemic Control

To achieve sustained control of the HIV/AIDS epidemic, it is essential that PEPFAR teams actively and routinely coordinate and communicate with stakeholders and partners who can provide valuable insights that improve the impact and accountability of programs. Key stakeholders include host country governments, multilateral organizations, other bilateral donors, the private sector, and civil society, and other, including faith-based, organizations.

For COP21, teams are expected to actively engage stakeholders in all aspects of strategic planning. To this end, **each PEPFAR OU team is required to conduct an in-country strategic planning consultation with local stakeholders by the end of January 2021.** The retreat will be used to introduce and discuss all COP21 tools, guidance, results, and targets, as well as the proposed trajectory and strategy for COP21. Following COP21 submission, teams are expected to plan for continued engagement with external stakeholders through routine sharing of data from the PEPFAR Oversight and Accountability Response Team (POART).

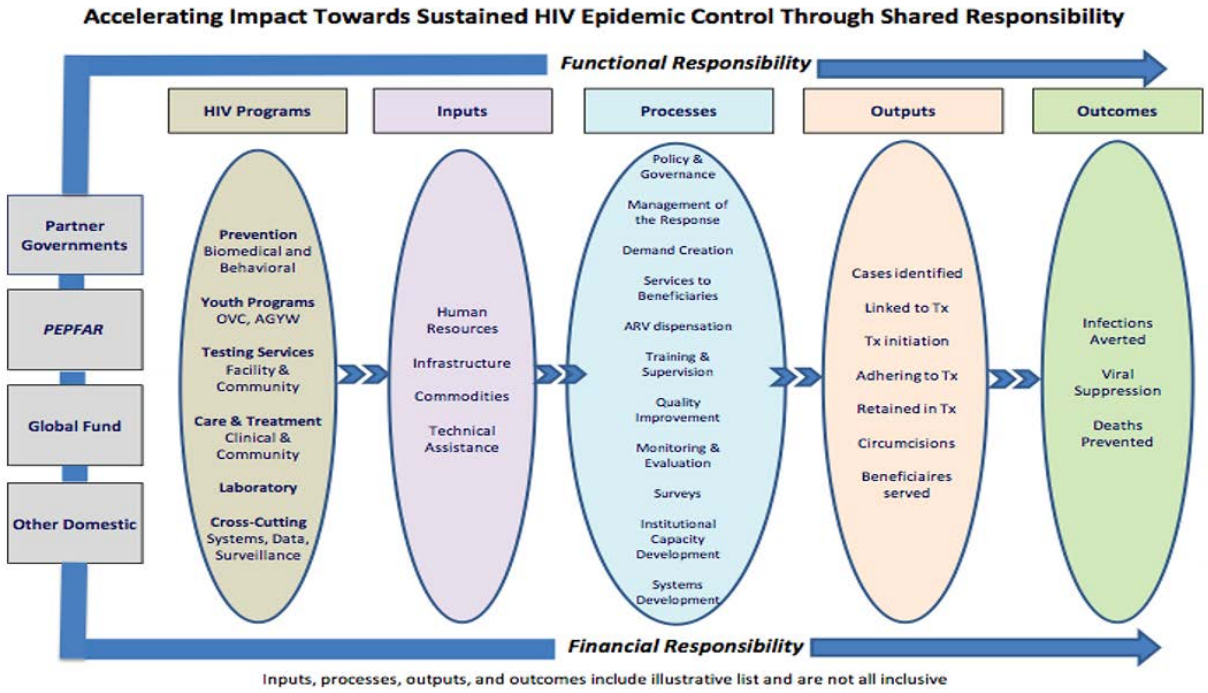
2.5.1 Host Country Governments

PEPFAR is committed to continually strengthening its partnership with host-country governments to ensure alignment between PEPFAR contributions and national priorities and investments. Collaborative planning between PEPFAR and host-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 host countries and the Global Fund—ensure that dollars strategically align to address gaps and solutions for impact while maximizing transparency, efficiency, 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, 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 COP Minimum Program Requirements 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 with the 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, the other thing to emphasize is efficiency in resource use but at the same time to ensure that budget commitments and allocations are not redirected away from supporting the HIV response.

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



Host Country Government can also serve as key PEPFAR implementing partners through our Government-to-Government (G2G) agreements. This direct funding of the Host Country

Government can provide opportunities to improve coordination of PEPFAR programs with the National response and also strengthen technical, management, and financial systems in the long term for sustained epidemic control.

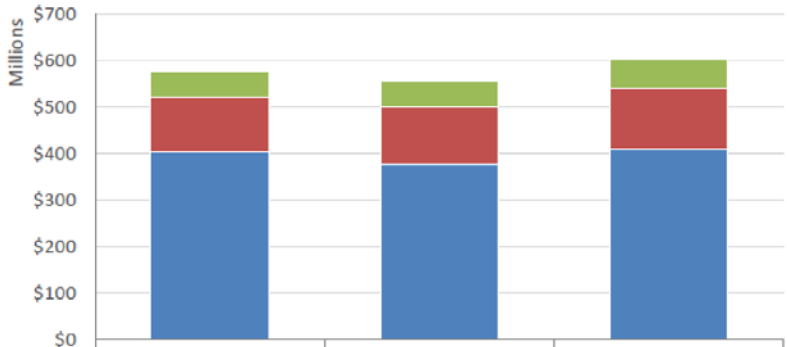
2.5.2 Multilateral and Private Sector Partner Engagement

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 host 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 has generally contributed up to one-third of all Global Fund dollars. PEPFAR teams must seek to ensure PEPFAR, host country, and Global Fund monies 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. 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. In May 2020, the Global Fund launched its grant review process for the Allocation Period 2020-2022 (implementation 2021-20230) with a target to sign the majority of Global Fund country grants by December 2021. 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, GFATM, and host country government, enhances strategic collaboration and coordination during program cycle planning, advances efforts around domestic responsibility and resource mobilization to ultimately ensure financial and programmatic sustainability of HIV programs. PEPFAR has also actively engaged in consultations around the development of the Global Fund's next strategy, including soliciting input from OU teams to inform PEPFAR priorities in this process.

Figure 2.5.2.1: Budget Trends by Stakeholder



	2018	2019	2020
Domestic Government	$54,892,751	$57,637,389	$60,519,258
Global Fund	$119,380,880	$124,064,711	$130,936,107
PEPFAR	$400,804,476	$375,122,523	$409,584,991

Using the FY20 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 COP21. 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 review technical assistance needs identified during the joint COP20 and Global Fund's new funding requests process to assess potential additional needs—in consultation with Global Fund and UNAIDS contacts—and convey these to HQ in order 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 LFTU, 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 client-centered, equitable, and efficient. Diligent and sustained attention to quality is required to reach sustained epidemic control. This expectation for COP21 should be the same as expectations for programs funded with Global Fund dollars.

PEPFAR OU teams, UNAIDS and its 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. UNAIDS and its co-sponsors can help build support for PEPFAR's approaches and its

alignment and harmonization with government-supported, Global Fund-supported, and other-supported programs. The United States assumed the chair of UNAIDS' Programme Coordinating Board in January 2020 to serve for a one-year term; in this capacity, the United States representative sought opportunities to further enhance the alignment of PEPFAR and UNAIDS efforts to achieve mutual goals during this tenure, including PEPFAR's active participation in ongoing consultations on UNAIDS' next strategy.

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 should 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 COP21 Meetings. PEPFAR teams must work with multilateral organizations to identify in-country representatives to participate in the COP21 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 the 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 often offer opportunities for pursuing innovative strategies that may later be replicated, depending on the type of partner and partnership developed. 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). As with all PEPFAR programming, partnerships should be in line with national policies and regulations set by country governments.

Private Sector Engagement (PSE) strategies and Public Private Partnerships (PPPs) are enablers that coalesce expertise, core competencies, skillsets, and/or resources (in-kind, cash, or other) 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 unites with the core business and/or competencies of the private sector to further a country's and PEPFAR's goals. For example, PEPFAR may work closely with pharmaceutical or diagnostic manufacturers to inform them of the challenges that should be considered when creating new products or technologies. In this particular illustration, PEPFAR engages the private sector not through a formal partnership, but rather through technical collaboration on the program's needs, interests, and challenges. PEPFAR Country Teams should engage 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 client-centric approach. As the needs of clients change, so should country programming, and PPPs can be utilized to ensure client-centricity in program design. Using private sector expertise such as behavior 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 client-centric and effective in reaching targets. See related Sections 6.1.3.3 and 6.4.4 on MenStar and Supply Chain for examples.

For further information on U.S. Department of State policies regarding PPPs, see 2 FAM 970.[13] The following are examples of how partnerships can support country programming to be more effective and/or client-centric:

Global Partnerships:

MenStar Coalition

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 client-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, summarized in Sections 6.1.3.3, and 6.4.4, and available at https://menstarcoalition.org/being-client-centered-2/, the MenStar Coalition 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 these barriers for men to access HIV services. To help in doing so, an Operational Guidance has been created which provides a step-by-step process on how to operationalize the MenStar approach into country programs (click here).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.

Faith and Community Initiative (FCI)

PEPFAR's success has been built in partnership with community, including faith-based organizations (FBOs) and faith-based and traditional communities. In most countries, 60-75% of the population regularly attends religious services and participates in religious communities; these communities are well-structured and have deep, intimate networks into the community. The FCI aims to utilize those community structures and networks to accomplish two objectives:

13 https://fam.state.gov/FAM/02FAM/02FAM0970.html

(1) to reach into the community in a very targeted fashion and help find people at risk for HIV and bring them into care and (2) to help address and prevent sexual violence against children. The case-finding aspects of the FCI are found in Section 6.3.1.10 and the activities to prevent sexual violence and seek justice for children are found in Section 6.2.3.1.

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 in AGYW by delivering a 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 AGYW; independent implementation science research and impact evaluation studies to measure DREAMS results; market 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. The partnership aims to reduce new cervical cancer cases by 95 percent among women living with HIV (WLHIV) in 12 African countries. In furtherance of the goals of Go Further, the partners seek to coordinate their support in select countries to integrate and scale up cervical cancer screening and treatment services for all WLHIV women on antiretroviral therapy between the ages of 25 and 49. Partners include the George W. Bush Institute, UNAIDS, and Merck. See Section 6.5.4 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 2019 WHO updated HIV guidelines and summarized in Section 6.5.1.1, all countries should prioritize rapid policy adoption and procurement of optimal pediatric ART regimens. As these pediatric regimens are available, PEPFAR looks forward to leveraging its work with private sector partners to support pediatric programs at scale.

Partnering on Client-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 client-centered supply chain, which brings our commodities to the client rather than our clients to the commodities. Specifically, PEPFAR will draw upon the private sector's insights on client 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 in order to deliver efficiently to patients by using cutting-edge technology and the latest client insights.

Differentiated service delivery is a client-centered approach to HIV care and treatment which 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.

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 client-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.

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. While the aforementioned examples are at a global level with global private sector partners, 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 into a non-binding Memorandum of Understanding (MOU) is a critical tool in which all partners are expected to outline in detail roles, responsibilities, 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 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.[14] Civil society has been a leading force in the response to HIV since the beginning of the epidemic, providing expertise and

[14]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.

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 where possible, actively participate in delivering such services. It is key to ensure that community and civil society have a voice at the decision-making table 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, identifying challenges to and gaps in health care delivery, supporting data collection and innovation, providing independent oversight of programming and processes, and promoting transparency. It is important that affected populations have a voice from the beginning in designing and implementing programs that serve them, and that PEPFAR programs set an example that encourages host governments to create a conducive enabling environment for civil society engagement. Therefore, meaningful engagement with communities and CSOs, including key populations-led organizations, remains a requirement and a critical theme of the PEPFAR program for COP21.

For COP21 and beyond, as PEPFAR continues to scale innovative, evidence-based approaches, OU teams should ensure engagement with CSOs in the planning, implementation, and scaling and evaluation of these newer approaches, such as index testing services and recency testing. OUs should note any questions/concerns raised by CSOs about index and recency testing and work together to identify measures that address concerns and challenges. Countries and stakeholders can also consider promoting the models of “People’s COP” as presented in COP20 by South Africa, Kenya, Malawi, Zimbabwe and Uganda civil society groups as a model of active engagement with civil society.

As in years past, civil society organizations will be invited to participate both in the virtual COP21 strategic planning meetings, as well as virtual approval meetings.

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 quality and accessibility of treatment services and the patient-provider experience at the facility level. Findings of Community-led Monitoring should be regularly reviewed by USG teams, and triangulated 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 beneficiaries (see Section 3.3.1.2 for more information and requirements). The focus of these activities should be for overall quality improvement, both for the users of health services and the healthcare workers providing these services. Community-led monitoring activities, though funded by PEPFAR, should be driven and implemented 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 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 youth, 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 PLHIV 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 religious 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 PLHIV; 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.

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, 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.

In 2021, external partners will be invited to participate throughout the in-country COP preparation process, during COP21 Meetings, and as COPs are being finalized. For CSO representation at the COP21 Virtual 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 COP21 Meetings and COP submission. S/GAC will also once again invite colleagues from global and regional network and advocacy organizations to participate in the COP21 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.

Ensuring Continued Meaningful Engagement

For COP21, 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 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 host-country governments. Meaningful engagement must be more than simply sharing information with community groups and civil society organizations. Various models of community engagement[15] 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 COP21.

Figure 2.5.3.1: COP21 stakeholder engagement (subject to final considerations for virtual COP meetings)

PEPFAR Team Action	**Stakeholder Action**	**Dates**
Distribute critical data and COP 21 materials to stakeholders: • COP Guidance • Planning Level Letter • COP 20 SDS and Approval Memo • Q4 results via Spotlight	Analyze materials to prepare for COP 21 discussions at Strategic Planning Retreat Identify areas of successful performance that can be leveraged going into COP 21 Develop recommendations on site level or non-service delivery activities that should not continue Global and regional CSO request information from applicable OUs	Mid-December 2020 through January 2021

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

Invite local stakeholders to Country Strategic Planning Retreat Review materials and preparations with stakeholders	Attend virtual Country Strategic Planning Retreat Provide with PEPFAR teams with recommendations for COP 21 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 January 25, 2021 Note: depending on the OU, this meeting may be virtual or in-person
Arrange for stakeholder participation in virtual COP 21 meetings Document stakeholder feedback and PEPFAR response Share meeting materials with stakeholders	Participate in S/GAC pre-meeting webinar for stakeholders Actively participate in virtual COP 21 planning meetings Provide feedback on activities, targets and approaches Include initial findings from community-led monitoring activities	Opening plenary (all OUs): February 16, 2021 Regional/Country Pair Track: February 16, 2021 - March 12, 2021 Single OU Track: • Group 1: February 22-26, 2021 • Group 2: March 1-5, 2021 • Group 3: March 8-12, 2021
Share SDS with stakeholders	Review SDS and communicate to PEPFAR coordination offices if it is not aligned with COP 21 meeting agreements/strategies	At least 48 hours prior to final submission to S/GAC: <u>Single OU Track</u> • Group 1: March 15, 2021 • Group 2: March 22, 2021 • Group 3: March 29, 2021

	Global and regional CSOs request SDS from PEPFAR Coordination offices	Regional/Country Pair OU Track • All OUs: March 29, 2021
Invite stakeholders to COP/ROP 21 Virtual In Country Approval Meetings. Share meeting materials with stakeholders.	Actively participate in COP/ROP 21 virtual approval meetings to ensure presented strategies and approaches are aligned with COP/ROP 21 planning meeting agreements	Virtual In-Country Approval Meetings Windows: 4/5-4/16/2021
Invite and engage stakeholders to meet prior to each quarterly POART call to engage their feedback and recommendations for program improvement	Participate in pre-POART stakeholder meetings; offer analysis and recommendations to remove barriers and bottlenecks	COP 21 POART schedule is not yet defined; ensure the OU calendar of events is 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 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. Since 2003, FBOs have been included among PEPFAR's essential partners and remain key partners to accelerating and sustaining epidemic control. To find persons who do not routinely intersect with medical systems (e.g., boys, men, non-pregnant women, adolescents), we must reach into communities to find them. But community case-finding efforts are often haphazard, and efforts to build community structures are expensive; it would be far more efficient and productive to access community structures already in place. In most countries, 60-75% of the population regularly attend

religious services and participate in religious communities. 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 COP21 and beyond, all countries investing funds in FCI activities, including the original 10 as well as additional countries investing core funds in COP20, are encouraged to continue core fund support for the science-based FCI activities, to accelerate reaching men and children and to strengthen justice for children (Sections 6.3.1.10 and 6.6.5). 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, 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 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 community awareness: advances in HIV care; PLHIV viral suppression; benefits of decentralized care and multi-month dispensing; and the client's ability to thrive while preventing transmission and acquisition of the virus, including through appropriate use of PrEP
- Increasing literacy in HIV prevention, care and treatment for faith and community leaders by leveraging religious and traditional 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 (Sections 6.3.1.10 and 6.6.5).
- Expanding client base of faith-engaged neighborhood community sites to increase convenient access to ARV pick-ups and MMD among index clients and contacts
- Educating PLHIV 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
- Increasing buy-in for and uptake of cervical cancer screening services among women and educating men about the importance of screening and being supportive for female partners.
- Addressing stigma among all survivors (male and female) of sexual violence across all age groups
- Preventing and responding to sexual violence among children is a shared norm or value among faith leaders; this includes building on faith leaders and faith communities' influence to change the culture around sexual violence so that faith-communities help promote post-violence clinical care, a survivor-centered response, and a culture of reporting.

- Supporting DREAMS and OVC programming

2.6 Comprehensive Services

Cervical Cancer. Cervical cancer screening must be conducted in the 12 countries participating in the Go Further partnership, selected based on high HIV prevalence among women in the 15-49 year old age group, utilizing COP funding. All countries utilizing PEPFAR resources for cervical cancer services are expected to adhere to the specific guidance and report on the indicators developed during FY18.

Viral Hepatitis and Other Services. Within PEPFAR OUs, districts (SNUs) that have demonstrated at least 80% ART coverage of all PLHIV and, importantly, 90% retention of clients in continuous ART services, 80% viral load coverage and 90% viral load suppression among all clients, may offer, as part of operational plan strategy, funding for more comprehensive services for PLHIV, such as diagnosis and treatment of hepatitis C, diabetes mellitus (DM) or hypertension (HTN). The bar for additional services is high to ensure PEPFAR HIV resources are focused on ensuring a high-quality HIV program, a platform on which additional work can be integrated. Both HTN and DM diagnosis and support will require the same attention to continuity of care to achieve disease control. This additional integration is possible once a strong client-centered approach has been documented by achieving the HIV parameters and will be key to a successful HTN and DM program. Diagnostic testing and treatment for these conditions must be affordable enough to feasibly bring to scale among PLHIV within the OU. Among these conditions, hepatitis C is particularly deleterious to PLHIV and is curable at a cost that is becoming more affordable across the globe. Country teams should work directly with their supply chain activity managers and USAID for forecasting and procuring these test kits and pricing information If these additional services are funded in the COP as PEPFAR programming, they must be offered without discrimination and user fees must not be charged. **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, coordination of resources from different sources and alignment with country government policies and funder mandates is necessary to provide optimal service.

3.0 QUALITY CLIENT SERVICES

3.1 PEPFAR's Focus on Quality and Patient-Centered Services

Quality health services are essential in order 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 client-centered, equitable, and efficient. Provision of such quality client-centered services, or minimum site standards, are tied to PEPFAR's minimum program requirements. Diligent and sustained attention to quality is required to reaching sustained epidemic control.

For COP21, all PEPFAR country programs must incorporate explicit quality management practices, including both QA and QI activities, into service delivery and partner management.

The WHO defines key principles and concepts related to quality HIV services:

Quality of care – the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[16]

Quality assurance (QA) – a range of activities related to systematic assessment and monitoring, intended to ensure that services are fulfilling stated requirements for quality. The principal tool across PEPFAR that assesses whether sites and above-site locations meet quality standards is via the Site Improvement through Monitoring System (SIMS).

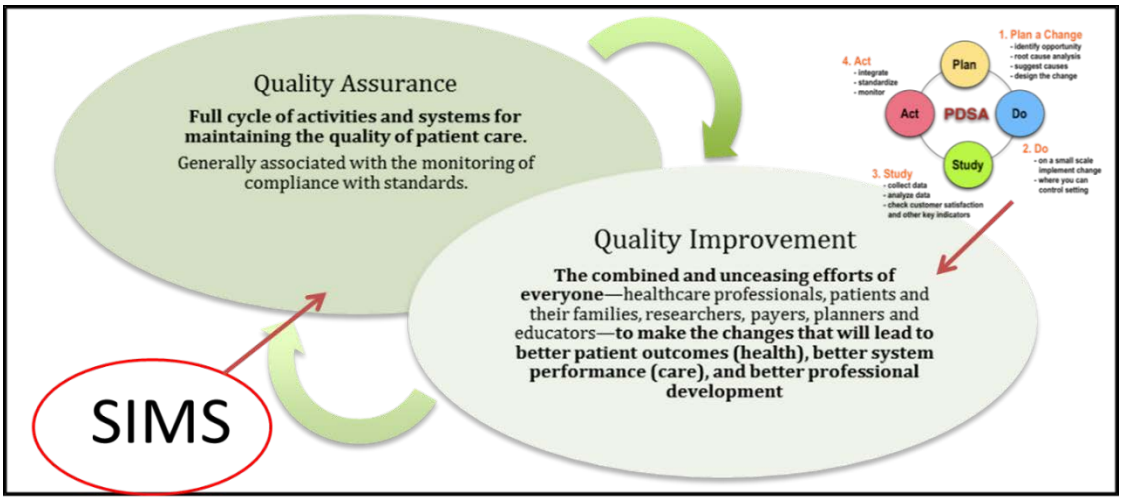
Quality improvement (QI) – a specific method designed to continually improve performance as part of a routine process, designed to test changes in program services, continually measure the effects of these changes and use data to address gaps to improve clinical performance and health outcomes over time.

[16] WHO, OECD, World Bank. Delivering quality health services: a global imperative for universal health coverage. Geneva: World Health Organization; 2018.

In short, QA assesses minimum standards, and QI—typically referred to as CQI, or Continuous Quality Improvement--is an ongoing process, best integrated into program management and implementation, designed to engage implementing teams in identifying barriers and facilitators of providing quality services, and empowering them to take action to improve results.

QA and QI are distinct but intersecting components that are important when implementing quality HIV services, and neither can be successful without the other (Figure 3.1.3).

Figure 3.1.1: Intersections between Quality Assurance and Quality Improvement as means to drive change



Quality management policies should support:

- Engagement and support of decision makers in PEPFAR service settings to support authentic CQI efforts to fully implement minimum program requirements, identify barriers to desired client outcomes, and make changes to continually improve service.
- Regularly assessing whether PEPFAR-supported sites meet standards—particularly those that support patient-centered, continuous ART and prevention services.
- Building capacity to support CQI as a routine function of quality management practices through participation and engagement from MoH and Implementing Partners, and with monitoring and support from USG staff.
- Enabling and engaging teams to use data and their first-hand understanding of operations to identify the root causes of barriers to program quality, implementing a client-centered approach and achievement of results.

- Targeted and specific site visits (including, but not limited to, SIMS) to review progress on key standards as they identify and address barriers and facilitators to quality services, especially related to the patient experience and provision of client-centered services.
- Leveraging existing indicators (MER, SIMS, SID, above-site benchmarks) and establishing new indicators to track key client-centered quality measures (e.g., wait times) and to monitor the progress of quality improvement processes.

3.2 Continuous Quality Improvement

3.2.1 Advancing CQI Culture

To advance an effective CQI program and culture, leadership and country ownership for QI are instrumental in creating the energy, professional investment and teamwork, and shared learning to design and implement QI at scale from the national to the local levels, and to sustain gains.[17] Critical to this remains the need to put the client at the center of all service delivery. This requires a sustained and active approach to implementing CQI at the site level, with integration of the CQI approach into service delivery and routine measurement of the impact of changes that are implemented. CQI must be integrated into all implementing partners' package of interventions implemented at the site level. CQI is an essential tool for USG agencies and IPs within PEPFAR and can be an important component of ensuring effective partner management and improving program performance.

PEPFAR does not prescribe a particular methodology for CQI, although acceptable CQI practices and principles, such as Plan-Do-Study-Act (PDSA) cycle models, are required for implementing PEPFAR strategy and addressing key challenges. Below are several important steps in the CQI, process such as establishing a CQI team, using standard methods to understand root causes, applying a PDSA cycle, and tracking progress in a CQI effort using run charts. These examples are from PEPFAR-supported programs where a CQI approach was successfully implemented at the site level to identify and address barriers to delivery of quality HIV services and improve performance.

[17] *Effective Leadership for Quality Improvement in Health Care: A Practical Guide*

3.2.2 Examples of Successful CQI

Establishing a CQI team to drive improvement in Rwanda

What was done?

To improve uptake and yields in index-testing, five Kigali facilities were selected as sites for intensive CQI. The PEPFAR Rwanda team conducted site visits to identify on-site challenges to service uptake and assess capacity of health facilities to implement CQI. These facilities had to have a functional Quality Improvement Committee to identify gaps and implement Small Tests of Change (STOC). This included the director of the health facility, ART clinic supervisor, ART nurses, VCT, PMTCT and ANC focal persons, social worker, data manager and District nurse mentor. Health facility QI teams were trained to implement CQI activities, including structured gap analysis (Fish bone), developing 'Change Packages', identifying and testing local solutions and using data to measure progress. After initial training and consultation, Quality Improvement Committees developed STOC projects to respond to identified gaps across the index testing cascade: 1) Number of eligible PLHIV offered index services, 2) Proportion of Index cases who accepted index testing service, 3) Number of Index case partners contacted and tested for HIV. Follow-up visits were conducted one-week after STOC model implementation. Quality Improvement Committees revised STOC components and adjusted work plans and indicator targets. Mentorship and support continued through phone calls.

What changed and how?

Intensive site-level monitoring and mentorship combined with improved CQI capacity at the site-level led to improved index-testing performance. After one month of STOC implementation, index acceptance rate increased from 21.7% to 48.2%; partner to index case ratio increased from 1.7 to 1.9, and HIV testing yields increased from 2.1% to 6.3%. Qualified and trained HIV counselors and dedicated index testing services staff were identified as successful tests of change at participating sites. The next step includes scale-up of this CQI model to the remaining 18 Kigali sites, and providing continuous mentorships, on-the job trainings and holding regular data reviews, peer learning, and experience sharing.

Reducing wait times and interruptions in treatment in the Dominican Republic

What was done?

QI teams were created at each clinical site to tackle challenges and gaps in achievement. Teams conducted root-cause analysis using the '5 whys' technique; displayed their theory of what drives the achievement of a specific goal using Driver Diagrams; prioritized interventions,

and used plan, do, study, act cycles (PDSA) to conduct small-scale tests of change. They addressed common problems like access to HIV testing through simple activities, such as analyzing patient flow at the clinic and monitoring patient wait time for HTS.

What changed and how?

After two months of implementation, all eleven PEPFAR supported sites, nine HIV clinics and two mobile clinics, had created QI teams around site-specific problems and gaps identified through root cause analysis techniques, and were testing solutions, measuring results and readjusting as needed. Resultant changes included:

- Increased HIV testing volume and yield among MSM at facility and community levels
- Reduced wait time to return of HIV test result
- Reduced number of missed appointments, or interruptions in treatment, for ARV pick-ups
- Reduction of the gap between newly diagnosed HIV positive individuals and linkage to treatment at some clinical sites
- Establishing a culture of data analysis and use for decision-making

Figure 3.2.2.1: Scaling up outreach and referral of MSM for HIV testing (CEPROSH, Puerto Plata)

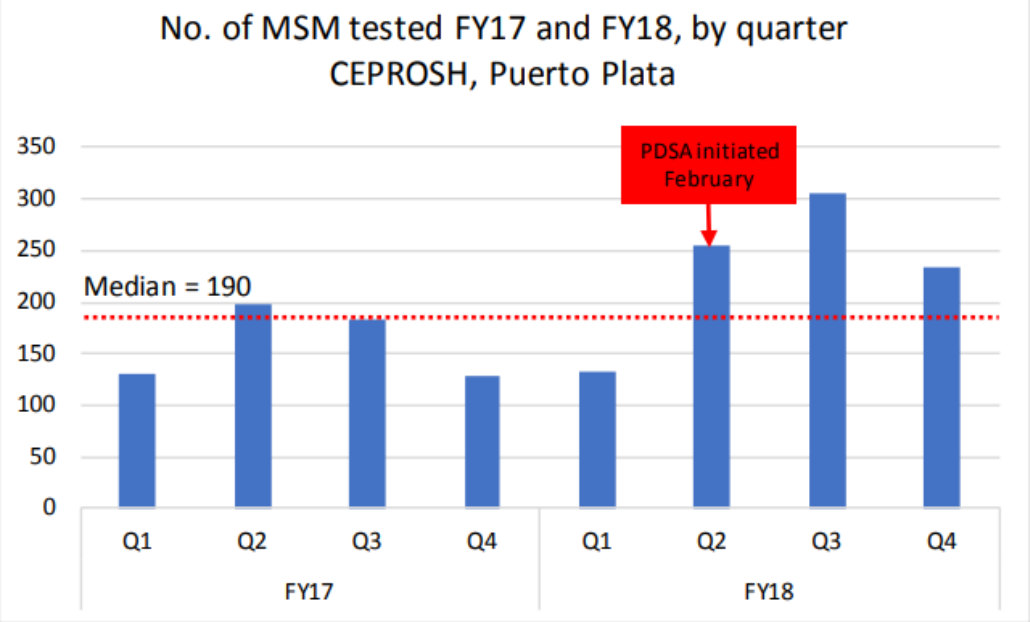


Figure 3.2.2.2: Shortening the number of days from diagnosis to initiation of treatment at the three newly supported clinical sites, FY19 Q1- Q2

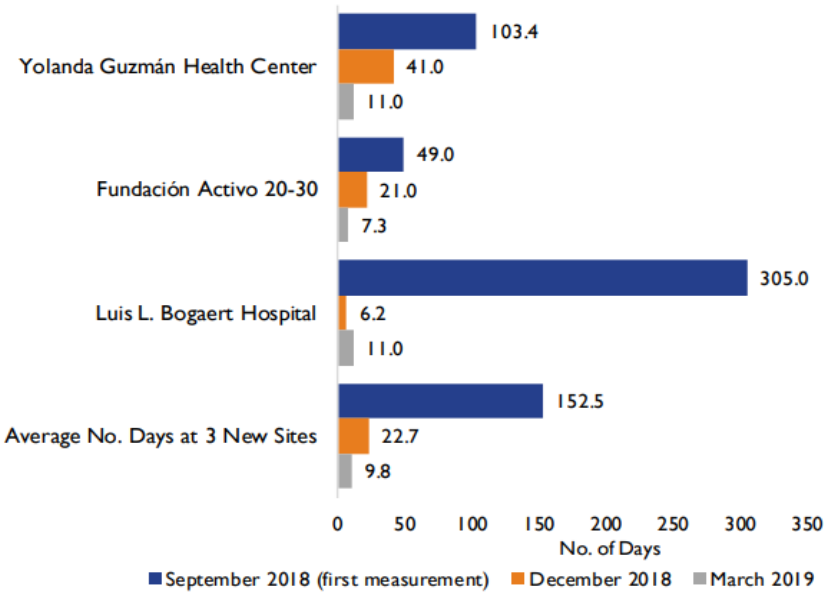
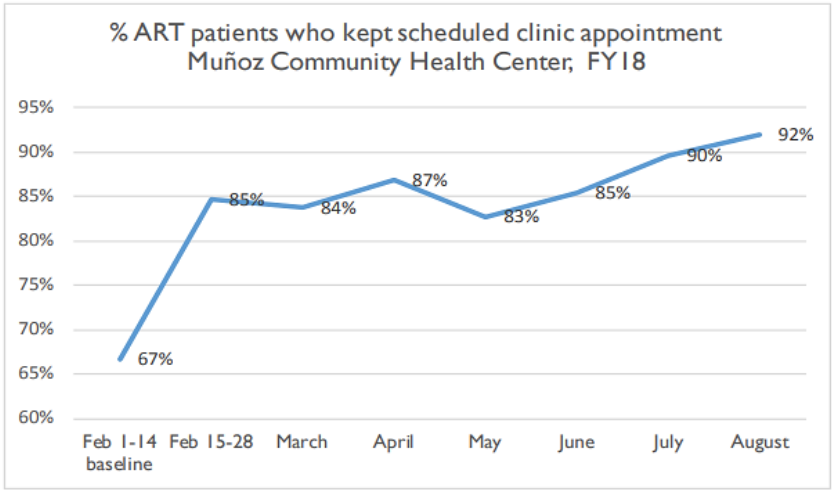


Figure 3.2.2.3: Increasing clinic attendance of Haitian migrants through reminder calls and monitoring daily appointment schedule (Muñoz Community Health Center, Puerto Plata)



Improving Data-driven Multi-month Dispensing in Nigeria

What was done?

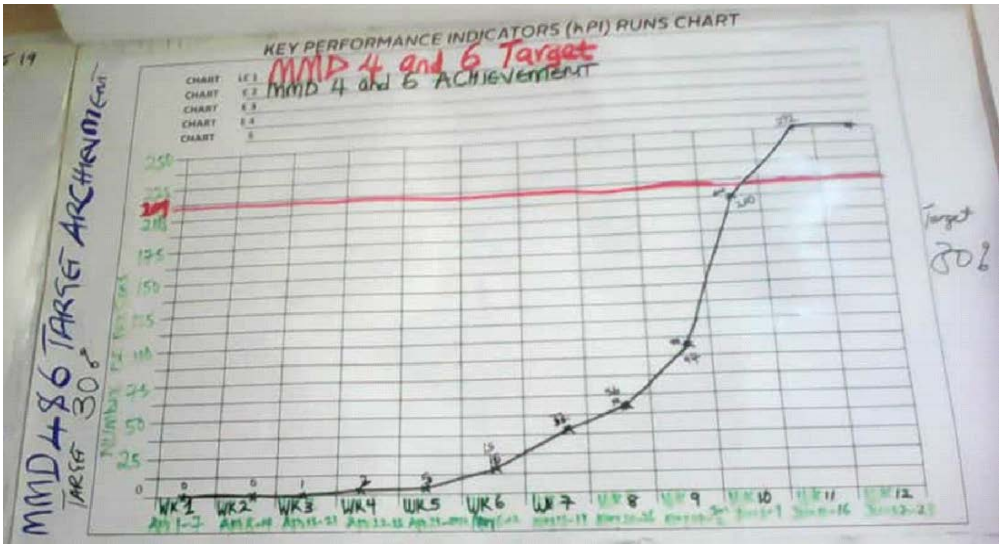
At General Hospital Ituk Mbang as of the end of FY 19 first quarter, no clients were reported on multi-month dispensing. To address this gap the facility CQI team used a fish-bone analysis to determine that insufficient stock of ARVs, non-availability of service flow, and standards of operationalization were the reasons behind zero uptake. The team developed a monitoring log on a run chart to monitor weekly MMD performance. They set an initial goal of MMD for 30% of PLHIV on ART. The performance log was reviewed weekly by the team to identify target areas

for improvements and changes. For root causes identified with the fish bone analysis, the facility implemented a reverse fish bone to address identified gaps. This included:

- Place order for sufficient stock of TLD.
- Line listing stable clients for MMD and follow up for service uptake
- Mentor triage nurses to identify eligible clients for MMD
- Mentor ART on operationalization, documentation and reporting of MMD
- Track weekly performance and make informed decisions for improvement.
- The use of entry and exit gate keepers

At the end of the quarter the team surpassed MMD targets.

Figure 3.2.2.4: Run Chart for MMD transition, General Hospital Ituk mbang (MGHIM), Akwa Ibom, Nigeria



3.3 Quality Assurance

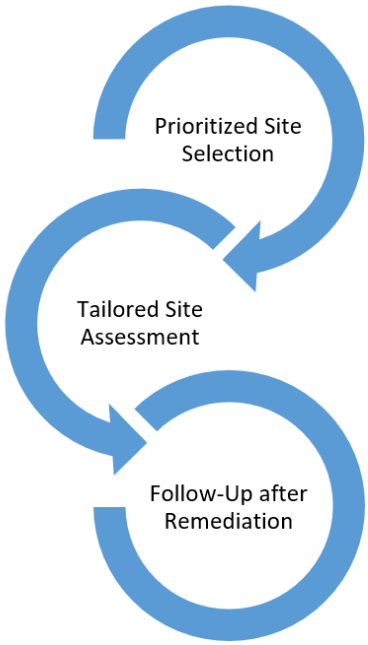
3.3.1 Site Improvement through Monitoring System

At its core, Site Improvement Through Monitoring System (SIMS) is a quality assurance method used to increase the impact of PEPFAR programs on the HIV epidemic through standardized monitoring of the quality of services at the site and above-site levels. SIMS is grounded in

quality standards against which performance can be assessed and area(s) for improvement identified.

SIMS standards cover all aspects of site and above-site 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 performance, 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 (Figure 3.3.1.1).

Figure 3.3.1.1: Main Principles of SIMS related to Prioritized Site Selection, Tailored Site Assessment and Follow-up after remediation



SIMS standards can also be used to assess whether elements of minimum program requirements have been implemented at the site level, especially in regard to patient experience and client-centered services. Some examples, that can be accessed via questions asked in SIMS standards, are:

Convenience and Access

- Multi-month dispensing
- Appointment spacing
- Extended or weekend hours
- Fast track pharmacy pickup for stable patients
- Community ARV pickup

Safe, effective and timely

- Tracking and tracing to prevent interruptions in treatment
- Adolescent friendly spaces
- Partner services
- Case managers/workers (for sites serving KP)
- Provision of non-judgmental prevention services (for PrEP), testing and treatment services
- Adherence clubs or groups
- Confidential services (for HTS)
- Psychosocial needs assessment (at community level)
- Information on Patient rights
- Information on Stigma and discrimination
- Training of providers on stigma, confidentiality, and patient rights

Safe and Ethical Index Testing[18]

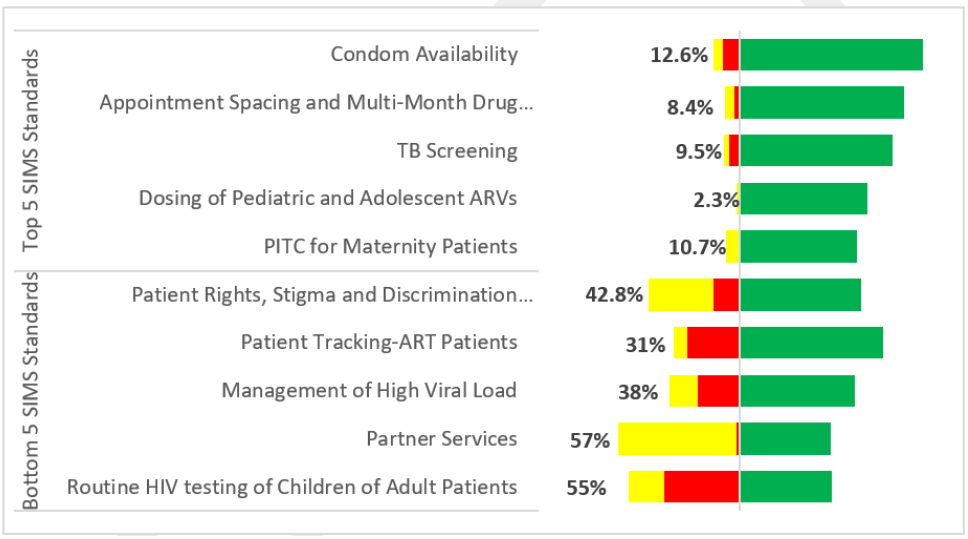
- Confidentiality of services
- Partner Services
- Patient Rights, Stigma and Discrimination
- Supportive Supervision
- Client-Centered Services (e.g., services are stigma-free)
- Post-GBV Care Provision
- Index Testing Training and Supportive Supervision
- Monitoring Adverse Events from Index Testing
- Secure Handling and Storage of Index Testing Data

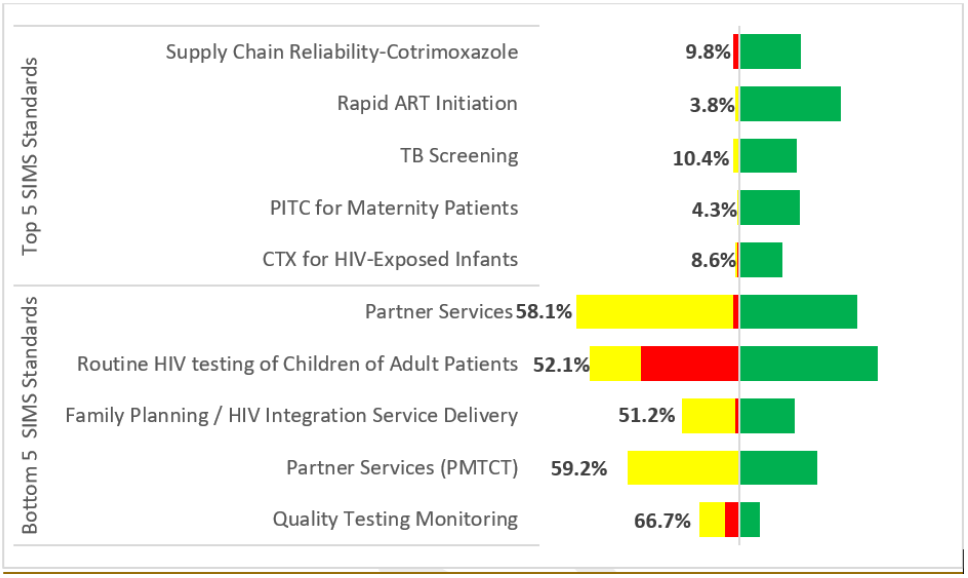
[18] See PEPFAR Guidance on Implementing Safe and Ethical Index Testing available here which includes specific guidance on using SIMS standards for on-going quality assurance and accountability: https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

- Intimate Partner Violence Risk Assessment and Support

Figure 3.3.1.2 below shows that, across PEPFAR OUs, sites continued to perform poorly on standards related to client-centered services and patient experiences (i.e., high percentage of red or yellow scores in comparison with green scores) even after a follow-up assessment was conducted. The figure highlights scores from frequently assessed SIMS Standards and shows both Top 5 performing standards and Bottom 5 performing standards at the first/comprehensive assessment (top visual) versus at the follow-up assessment (bottom visual). Percentage values show the percentage of sites that did not meet the standard denoted. Of note, standards that were in the bottom 5 in the first or comprehensive assessment were still in the bottom 5 at the follow-up assessment. Most notably standards related to client-centered services and patient experience like Partner Services, Patient tracking, Management of high Viral Load and Routine HIV testing of Children of Adult Patients remain consistent challenges for the PEPFAR program. For example, more than half (57%) of sites did not meet the standards for Partner Services during the comprehensive assessment. More than half (58%) of the sites failed to show significant improvement after a follow up assessment on Partner Services was conducted. Given these standards also align with continuing challenges in the PEPFAR program as evidenced through MER and other data analysis, it remains important to ensure SIMS and MER data are effectively used to remediate and improve programs. Analyses like these demonstrate that provision of quality client-centered services that meet standards is still a core area of improvement across the PEPFAR portfolio.

Figure 3.3.1.2: Limited improvement in percentage of sites that did not meet the standard (i.e., scored red or yellow) on most frequently assessed SIMS standards at the comprehensive assessment (top visual) versus the follow up assessment (bottom visual) (all PEPFAR OUs, October 2019 – September 2020).





MER and SIMS data can also be used to better understand elements of the patient experience as described above. When looking at MER and SIMS data related to patient tracking, multi-month dispensing and appointment spacing (which are examples of patient-centered approaches), certain patterns emerge that may inform future programming. Figure 3.3.1.3 below shows MER and SIMS data from MER indicators and SIMS Standards that are linked to multi-month dispensing, patient tracking and appointment spacing at FY20 Q1 (top visual) and FY20 Q4 (bottom visual) in deidentified Country X. In FY20 Q4 (bottom visual) in Country X, a smaller percentage of sites, out of those that assessed CEEs on patient tracking and appointment spacing for pediatrics and adults, did not meet standards (i.e., scored red or yellow) in comparison with sites assessed in FY20 Q1 (top visual). Additionally, at those same sites where a SIMS assessment occurred in Q4, fewer patients either stopped treatment (TX_ML stopped

disaggregate) or experienced interruptions in treatment after being on treatment for 3 months (TX_ML <3 months disaggregate). Finally, at those same sites, more patients were returned to treatment in Q4 versus Q1 (184 and 106, respectively), and more patients were on 6+ months of ARVs (2,455 and 922, respectively). This suggests the quality or availability of patient-centered approaches like appointment spacing and patient tracking services at those sites could have contributed to an increase in the number of patients returning to treatment and multi-month ARV dispensation.

Figure 3.3.1.3 Comparison of SIMS scores and MER indicator results related to Client-centered Approaches like Patient Tracking, Multi-month ARV dispensation, and Appointment spacing at FY20 Q1 (top visual) versus FY20 Q4 (bottom visual) in Country X.

SIMS Site and Above-site Prioritization Lists will be developed by OUs prior to the start of FY22 and can be updated (if needed) on a quarterly basis. This flexibility will facilitate timely response to emerging bottlenecks and performance challenges. The SIMS Site and Above-site

list, including a clear and detailed justification, will be submitted to S/GAC prior to the start of the fiscal year. A template will be shared by S/GAC in advance.

More information on SIMS can be found in the SIMS 4.1 Implementation Guide and through the PEPFAR Virtual Academy e-learning courses 'Introduction to SIMS' (https://learn.pepfar.net/courses/course-v1:learn-pepfar-net+PROG108SIMS100+2019_indefinite/about) and 'SIMS: Choosing Where and What to Assess' (https://learn.pepfar.net/courses/course-v1:learn-pepfar-net+PROG108SIMS101+2019_indefinite/about).

In light of the COVID-19 pandemic, SIMS assessments may be limited due to restrictions on site visits. However, virtual SIMS visits are permitted **provided certain specific conditions are met** as clearly described in the SIMS 4.1 Implementation Guide referenced above.

3.3.1.1 Examples of Using SIMS for Quality Services

Improving patient tracking, viral load suppression and reducing stockout in Cameroon

What was done?

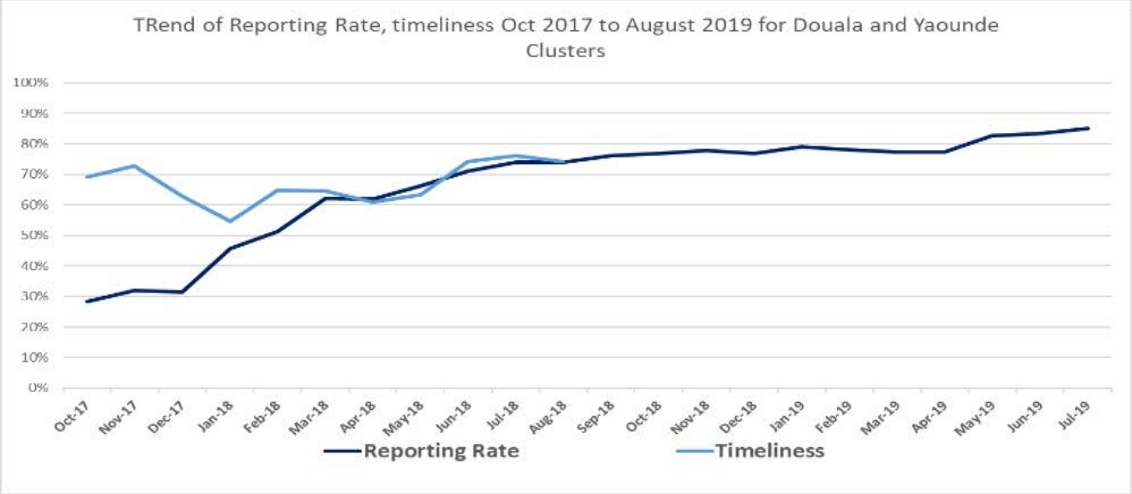
PEPFAR Cameroon has integrated SIMS into its CQI activities and triangulated SIMS data with MER to identify gaps for decision-making and program improvement.

SIMS data were used to identify gaps in low viral load (VL) coverage, poor monitoring of patients with high VL results, weak patient tracking systems, lack of written procedures and SOPs, low reporting rates of commodity data, and suboptimal Index Case Testing. Based on the scores of CEEs relevant across program areas, QI teams, IP and USG supervisors developed corrective action/remediation plans to address the gaps using QI methodologies.

What changed and how?

Best practices like extended ART clinic hours, fast tracking of stable patients, and at least 3 months of multi-month dispensing for stable patients have been replicated across sites. Poor performance on VL CEEs highlighted an issue with tracking clients with high viral load; new SOPs were developed to help community teams better monitor client eligibility for VL resulting in increased VL testing uptake. Supporting the districts to develop SOPs for commodity reporting and how to place orders resulted in improved submission of commodity reports by facilities. IPs provide supportive mentorship and USG staff provide supportive site supervision and technical assistance, with regular monitoring to ensure program quality improvements and better site performance.

Figure 3.3.1.1.1: Improved consistency in timeliness and reporting of commodities data after SIMS-based remediation at beginning of 2018



Improving implementation of cervical cancer interventions and achievement of results in Malawi

The two examples from Malawi below provide insights into two different ways that SIMS data were used to improve quality of service delivery and performance.

What was done?

In June 2019, a SIMS assessment at Nsanje District Hospital revealed gaps affecting cervical cancer screening and treatment at the site. Workforce shortages, sub-optimal client flow, and inadequate supervision of service delivery were key problems observed by the PEPFAR SIMS team. As such, the site scored red (i.e., needing urgent remediation) for the SIMS Cervical Cancer CEE. As a result of the challenges observed, the site was not on track to reach its fiscal year target.

What changed and how?

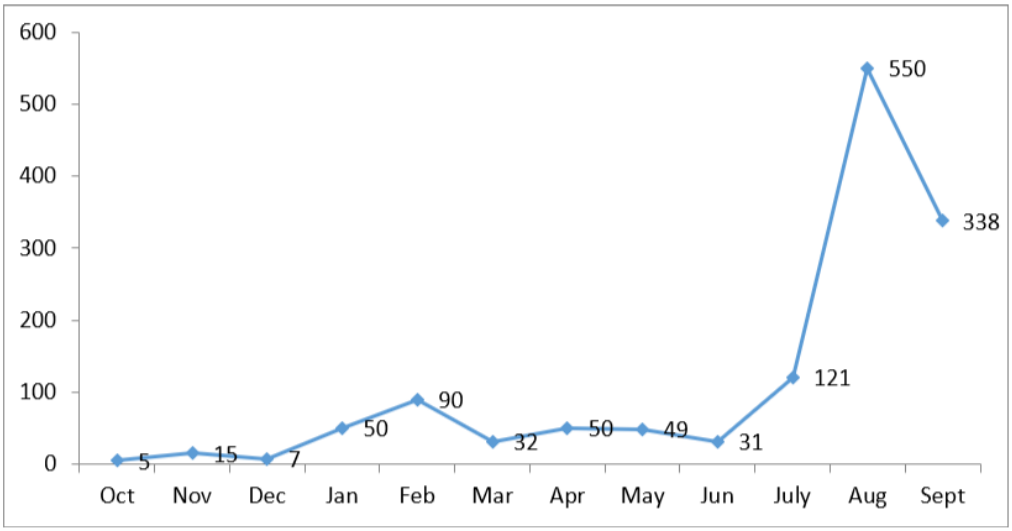
Following the SIMS assessment, the implementing partner organized a meeting with the District Health Management Team and discussed the SIMS findings. At the end of the meeting, an action plan was developed that prioritized the following key activities:

- Improve flow of clients from ART to VIA clinic
- Reduce the waiting time at the VIA clinic by having a dedicated VIA provider
- A daily target of at least 20 HIV positive clients screened for VIA per day, which translated to 100 HIV positive women per week and 400 HIV positive clients per month.

- All HIV positive women who screened VIA positive to be treated with thermocoagulator as soon as possible and referred where necessary
- PEPFAR implementing partner to consistently supervise performance on a weekly basis

The partner supporting the facility implemented these priority interventions and closely monitored progress. The interventions had immediate impact with a significantly improved performance. By the end of September 2019, the hospital managed to surpass its FY19 target by 57%.

Figure 3.3.1.1.2: Improvement in Cervical Cancer Screening Trend at Nsanje District Hospital after SIMS assessment in June 2019



What was done?

In April 2019, PEPFAR staff conducted a SIMS assessment at Nambazo Health Center in Phalombe District. While the site met the standard under the Cervical Cancer CEE, the PEPFAR

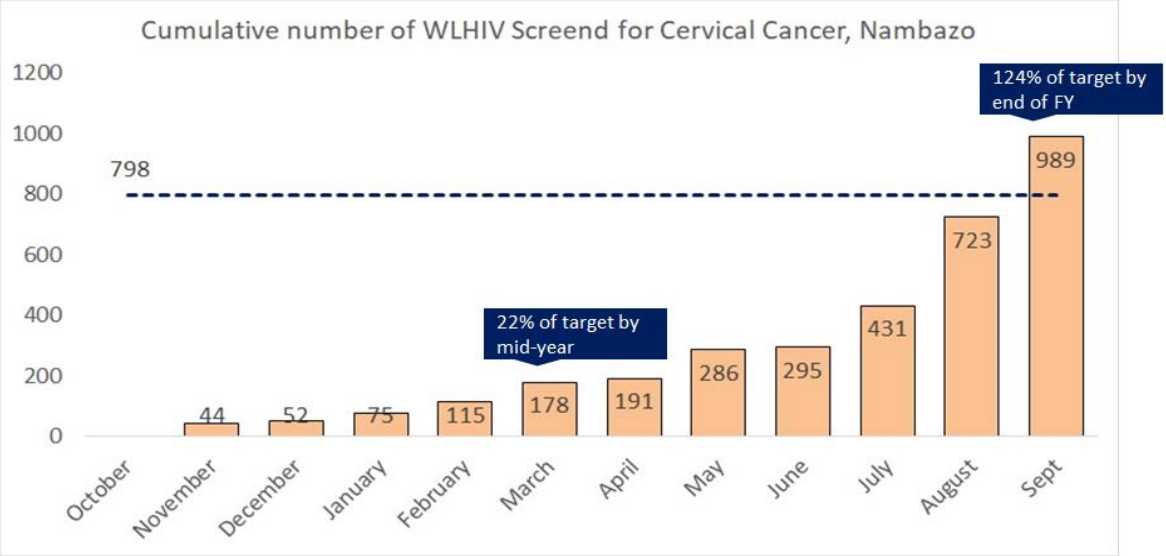
staff noted that the site was not on track to reach its fiscal year target (n=798). Although the interventions being implemented were of quality and meeting standards, it seems the volume of women screened simply needed to increase. This feedback was given to the facility providers as well as the implementing partner staff.

What changed and how?

In response, the implementing partner deployed a dedicated cervical cancer nurse to provide daily screening services (June 2019). The implementing partner also sensitized women living

with HIV (WLHIV) groups in the catchment area to raise awareness about the service and address any misconceptions. These remediation efforts resulted in a significant improvement in the number of cervical cancer screenings conducted at the facility for WLHIV. As shown in the graph below, by the end of the fiscal year, Nambazo Health Center exceeded its annual target by 24%.

Figure 3.3.1.1.3: Increase in the number of women screened with quality services after deployment of a dedicated cervical cancer nurse in June 2019 as per SIMS assessment recommendation



Improving oversight and management of Mozambique's community-level activities

What was done?

Mozambique began using a tailored assessment tool to understand barriers and challenges to delivery of quality services at the community level. This tool integrates CEEs from SIMS, while introducing elements that are unique to the Mozambique context that have been formatted into a SIMS-like manner. The assessment is conducted similar to SIMS, but the content has been tailored based on the needs and gaps of the Mozambique community program. Implementation of the tool has begun to raise the level of oversight for community level activities (often also providing clinical services) to that of the facility level activities.

What changed and how?

1. Ensuring effective facility-community linkages

- Specific changes to increase the availability of facility data to community workers conducting preventive home visits and visits to prevent interruptions in treatment.
- Linking community workers to the facility in such a way that they recognize their role as not just looking for patients who have defaulted, but also their role in preventing a patient from defaulting in the first place. This required recognizing the community worker's comparative advantage given his/her relationship with clients and ability to influence their decision making.
- CBOs sharing pertinent information with the facility as well as with the co-management committees to track performance and adjust community services, similar to what would be expected at the facility level.
- Utilizing the comparative advantage of the CBOs to ensure the "right" community players are involved in decision making.

2. Ensuring effective management and accountability structures for lay workforce
    - The tool examines the supervisory structure within CBOs with the intention of ensuring there is an adequate ratio between supervisors and lay staff. USG found a staff ratio of 1 supervisor: 40 community staff, and immediately made a change to 1 supervisor: 20 community staff in recognition of the need to increase oversight of community activities.
    - Based on USG feedback, CBOs have increased on the job training and other low-cost methods of ensuring community workers are capable of providing high quality counseling and referral services.
    - Most significantly, realization that implementing partner's reliance on low level, low cost community staff may not be the most effective and efficient way to improve ART continuity. This was confirmed by an in-depth HRH analysis conducted at the interagency level which showed that fewer, slightly higher level counselors would be more effective than a larger number of lower qualified staff in certain cases. The results of this analysis are currently being shared with implementing partners and will impact COP19 HRH plans.
    - In one case, the results of the community tool, in conjunction with meetings with the provincial government, resulted in the replacement of one CBO that was not meeting expectations.

3.3.1.2 Community-led Monitoring for Patient Experience

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 groups and civil society organizations in all aspects of COP development and presentation (see Section 2.5.3). As PEPFAR continues to confront the challenges of assuring ART continuity in patients who may not view themselves as sick, collaboration with communities and patients is urgent and critical. This collaboration can help PEPFAR programs and facilities ensure they are providing quality services that beneficiaries want to utilize. Collaboration with community groups, civil society organizations, and patients/beneficiaries can help PEPFAR programs and health institutions diagnose and pinpoint persistent problems, challenges, and barriers with service uptake at the site and facility level to effective service and client outcomes at the site. Most importantly this collaboration can identify workable solutions that overcome these barriers and ensure beneficiaries have access to these services. Therefore, beginning in COP20 and continuing in COP21, OUs are required to fund the development and implementation of community-led monitoring activities.

Community-led monitoring (CLM) is a process initiated and implemented by local community-based organizations and other civil society groups, networks of key populations (KP), people living with HIV (PLHIV), and other affected groups or other community entities that gathers quantitative and qualitative data about HIV services. 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 client-centered approach because it puts communities, their needs, and their voices at the center of the HIV response[19].

Through the use of quantitative and qualitative indicators, community monitoring initiatives have monitored a wide range of issues that are associated with effective and quality HIV service delivery. Community-led monitoring is especially important for gathering crucial information and observations regarding HIV service delivery from and about key populations and other underserved groups and empowering those groups to play a key role in advocating for

[19] See also landing page on Community-led monitoring on PEPFAR page on state.gov. https://www.state.gov/community-led-monitoring/

improvements to HIV services. It is important that beneficiary populations are directly involved in or leading the monitoring of services designed for them.

In COP21, all PEPFAR programs are required to continue to fund community-led monitoring activities in close collaboration with independent civil society organizations and host country governments. In countries where community-led monitoring may be unsafe, PEPFAR should encourage partnerships with regional and global networks to assist local beneficiaries in implementing systematic and robust 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 COP21.

Core principles of PEPFAR community-led monitoring include:

- The collective objective of community-led monitoring is to develop a shared understanding of the enablers and barriers to ART continuity in a manner that is productive, collaborative, respectful, and solutions-oriented.
- Community-led monitoring must be conducted by independent and local civil society organizations. Of note, PEPFAR Implementing partners (including those that may be civil society organizations themselves) currently working on service delivery at the site level cannot meet this requirement for community-led monitoring; this includes implementing partners who sub-contract/sub-grant to local civil society organizations. This is to help ensure the objectivity and independence of community-led monitoring is maintained. In developing or refining CLM activities, OUs should consider the level of trust CSOs have among key communities and stakeholders. 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 community-led monitoring efforts in-country.

- PEPFAR Ambassador Grants should be used as a first option in all OUs where these mechanisms are already available; OUs may propose funding for additional staff support to oversee this portfolio if they did not do so in COP20.
- PEPFAR teams must ensure a process that allows for community and host country government development of the specific metrics, measures or tools to be used for community-led monitoring. Metrics or measures should be tailored to a given context and address the needs and concerns of community members. Such CLM metrics may also consider PEPFAR-Supported Site Requirements for Client-centered Services as a starting point (Section 2.3.1.2) for an illustrative list of characteristics of client-centered services that are convenient, hospitable and welcoming, supportive and responsive, and accountable and managed.
- 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 community-led monitoring 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 patients and health workers (including ensuring stigma free service delivery) verification of the implementation of national level policies (e.g., elimination of user fees) at the facility level etc.
- Community-led monitoring can use SIMS tools as needed, though 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.

- Community-led monitoring mechanisms must be action-oriented. That is, it is not enough to simply collect patient reports or experiences, but there must be an associated follow-up process with the health facility that is overseen by USG staff, commitment to corrective public health action, and community advocacy to improve service outcomes.
- Community-led monitoring must be routine. One-off assessments are not sufficient and must be routinized to ensure follow up and continuous improvement.
- Results from community-led monitoring 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 implementing partners on a quarterly basis. Community members should not be tasked with sharing findings with service delivery partners or host governments. This requirement does not preclude community organizations from sharing their findings directly with governments or facilities where it is safe to do so. However, it does require that PEPFAR teams be directly involved in necessary follow up actions and oversight of implementing partners to strengthen the quality of service provision.
- PEPFAR teams must ensure they are triangulating community-led monitoring 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).
- As part of a commitment to transparency and accountability, community-led monitoring findings should be made as accessible as possible (while ensuring safety and confidentiality) for use by all stakeholders (within the context of PEPFAR's current Data Governance Remediation Planning policies). Where possible and relevant, this may include sharing best-practices and monitoring tools with other country teams.

4.0 PARTNER PERFORMANCE 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, as amended by the PEPFAR Extension Act of 2018. PEPFAR is building upon the PEPFAR 3.0 Strategy Controlling the Epidemic: Delivering on the Promise of an AIDS-free Generation (2015-2020) and the PEPFAR Strategy for Accelerating Epidemic Control (2017-2020). Both documents are publicly available on the website: https://www.state.gov/reports-pepfar/.

- Global policies align with WHO guidelines and policies for optimal programming and communicated through State Department transmitted cables and Country Operational Plan (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.

The PEPFAR team in country is responsible for ensuring partners implement and report applicable available funding levels in the COP consistent with the annual funding level and providing solutions to concerns raised during the COP planning process, as appropriate. The implementing agencies are fully responsible for the implementation of the PEPFAR funds allocated or transferred to them through MOAs.

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 budgets will be adjusted by S/GAC to match targets. Agencies are expected to monitor the program achievements in relation to financial data (including outlays

and partner level expenditures as available) to determine the significant areas of underperformance as described below. Once underperformance has been identified, rapid action on behalf of the agency is required in order to remediate the problem. As a consequence of underperformance, agencies are expected 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 second 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 test positive to treatment the indicator measured should be test positive to new in treatment of greater than 85%. If the issue is continuity of treatment, it should be net new on treatment equal to 90% of new on treatment. After two quarters of intensive oversight and remediation for underperformance, partners should be close to full achievement of targets expected at quarter three. 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.

Table 4.1 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

[A] The performance thresholds apply to all indicators except treatment current, OVC_SERV and AGYW_PREV. 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 carryover 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 COP21. 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.
- Effective financial monitoring to ensure 1) planned resources and spending is aligned with technical and geographic priorities as defined in the implementing partner work plan 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 COP21 budget, the COP20 budget and associated work plans and the COP19/FY2020 expenditure reporting.
- Ensuring all funding projected to be outlaid during the 12 months of FY22 must be represented in the approved COP21 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 90% of the test positives as testing will have been focused to find new clients, net new on treatment must be 90% 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 90% VLS at the site and SNU level.
    - Measures to track expenditures in alignment with PEPFAR Expenditure Reporting Reference Guide. This reporting must reflect what partners are implementing and budgeted 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
- 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 on barriers and facilitators or root cause analysis to providing client-centered services. 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, and data from surge continue to be reviewed regularly and used as an early warning system for performance trends.

More specifically, to effectively and routinely monitor performance, financials and remediation, the following programmatic and operational components should be included (in addition to the principles described above in 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 3.3.1.2)

- 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 2016-2020 reporting.
- Reporting of PEPFAR program expenditures.
- Detailed, actionable work plans, including implementing mechanism budgets by financial classification intervention and by cost category, planned interventions, expected targets and/or benchmarks, integration and use of CQI methodology. COP21 work plans will be submitted to S/GAC after COP approval starting in May.
- 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.
- Adhere to all principles of Budget Execution in Section 4.2.

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 COP21 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 annual mechanism work plan. 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 4.3 on Oversight and Accountability.

4.2 Guidance on Budget Execution

Throughout the budget cycle, beginning with the COP planning process and continuing through full execution of programming, PEPFAR operating unit interagency teams are responsible for ensuring that the planning and implementation of each COP is consistent with the budget levels approved by S/GAC and documented at the implementing partner and USG cost of doing business (CODB) budget levels within FACTS Info. The approved COP budget levels reflect the total resources – both newly appropriated funds and pipeline applied to the COP21 implementation cycle – that a country or region is approved to outlay during **the 12-month implementation period** (01 October 2021 to 30 September 2022). All partners to which the USG funding Agency expects to outlay funding during the implementation period must be included in the FACTS Info system, including outlays of prior year funding if unliquidated and outlays as part of closing out an Award.

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 disbursement of the outlays.

Upon the issuance of a signed COP Approval Memo, the final approval is given, which locks in the partner and CODB budget levels within FACTS Info. From this point, each PEPFAR implementing Agency is accountable for ensuring that they outlay to their implementing partners at no more than the approved level and do not exceed their approved COP budget without prior authorization from S/GAC. Accordingly, agencies should work closely with implementing partners to ensure that they are initiating cash drawdowns appropriately and are within their approved COP budget. Similarly, any implementing partner not documented within the system at approval should not be implementing activities and should not spend associated funding without prior authorization. Critically, agencies should be routinely monitoring site-level results against partner expenditures to ensure partners that are not performing are spending appropriately. With this guidance, the following is expected for the current implementation of COP21 and future planning cycles:

- During the COP21 implementation period, it is expected that total country or regional outlays over this period will not exceed the total funding level (inclusive of new appropriations and pipeline) stated within the COP21 cycle of FACTS Info. Consequently, agency outlays to each individual implementing partner over this period should not exceed the amounts programmed to the partner as approved and documented within the COP21 cycle of FACTS Info.
- As implementation occurs, the interagency team may identify a need for an agency to outlay to an implementing partner in excess of the approved level or need to rectify an error or omission in the original COP21 submission. In this instance, the agency (at the field or headquarters level) 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 a funding shifts table which indicates where funding is being reduced to fund the increased budget 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 PEPFAR program.

To the extent consistent with applicable legal restrictions and procedures on the fiscal year funds at issue, including any relevant or required Congressional Notifications, Agencies should fully utilize their expiring and older funds before obligating or expending any of the newest appropriated funds to ensure that all funds are obligated and expended before they expire. Due

to this budget execution approach, the actual fiscal year of funds that are outlaid in support of an approved COP activity may not match the distribution of new and applied pipeline funding that is documented in FACTS Info. This is acceptable, as long as 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 implementing partners are not allowed to accumulate pipeline greater than their award duration.

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), which 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 the 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 at a later point in time. Supplemental HOP funding for the same in-country partners will not be provided and thus all funding must be fully accounted for in the field budget.

With major programs like PEPFAR, for equipment purchased using USG funding, items should be transferred from closing mechanisms to new mechanisms where appropriate to decrease start-up and close-out costs. The final year of a mechanism's implementation (this includes cases where 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 to account for close-out costs, including NICRA costs and other costs required to close out a mechanism or end a PEPFAR activity within a broader agency mechanism. When not part of close out, the mechanism's overhead - should be budgeted accurately during COP to reflect all indirect and other program management costs. However, the level and proportion of program management costs budget compared to the overall budget may influence decisions on which mechanisms are funded during COP planning as part of analyzing efficiency in implementing for results. It is also recognized that there may be a need to overlap geographic distribution while one IM closes and another opens during a transition period. This should be evident in the implementing partner work plan. At no time should there be an interruption in service delivery of prevention, treatment, or OVC services. If this occurs, these programs will be moved to another partner to manage.

There should never be a case of an implementing partner expending funds for the sake of decreasing pipeline carried forward funds, as all partner expenditures must be in accordance with the approved COP level. In addition, the partner will appear much more costly and will jeopardize future funding and consideration.

S/GAC reiterates the crucial role financial analysis plays in accompanying performance monitoring (e.g., achieving MER targets, achieving above-site benchmarks, and achieving SIMS standards of program quality). Program managers must fully understand whether the PEPFAR program in their OU is reaching its anticipated MER targets, achieving its programmatic strategy, and if the program is in line 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 to arrive at a more comprehensive view of an IM's overall performance. Including financial analysis in POART discussions and other partner management conversations is not new guidance, but PEPFAR recognizes the need for a standardized, program-wide approach, as understanding and comparing contextualized, implementing mechanism expenditures for the same types of partners implementing the same kind of interventions allows for correcting potential inefficiencies, need for funding adjustments, and/or learning from high performers.

Planning discussions for COP21 begin from the same foundation as COP20, an incremental approach that starts by reviewing how the COP19 program was implemented – both in terms of the interventions being pursued by each implementing mechanism as well as budget levels allocated to the programs – as documented in existing contracts and work plans. Sharing this information across the full interagency is imperative to inform robust conversations and analysis to determine the COP21 direction and priorities. Also see Section 7.0 on Planning Steps.

4.3 Oversight and Accountability

Clear target setting with appropriate level of budget as well as continuous partner management and partner improvement guidance has been provided annually in the COP guidance 2016, 2017, 2018, 2019, and 2020 to ensure partner performance improves. 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, Public Law 108-25, 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[20] 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 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 community-led monitoring efforts, along with standard PEPFAR data streams such as MER, SIMS, ER, etc.

In the above-mentioned OIG inspections for PEPFAR during 2020, the OIG noted in its remarks that, ‘’In a positive development, State OIG found that the creation of the PEPFAR

[20] 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

Oversight and Accountability Response Team helped establish monitoring and evaluation activities that fostered accountability and promoted the effective use of resources toward epidemic control and the attainment of PEPFAR goals.''

5.0 COP BASICS

5.1 What is a COP/ROP?

The COP/ROP[21] 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 three organizational structures related to specific planning processes: (1) bilateral programs/operating units; (2) regional platforms; (3) and country pairs to ensure cross-border collaboration.

For COP21, all PEPFAR programs in the three organization structures will utilize the planning and submission process, including timelines, described in this document.

Bilateral Programs (Single OUs) required to complete a COP21 using the planning and submission process described in this guidance document include:

[21] 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.

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

Country Pairs are two bilateral programs that have been paired together to address the cross-border nature of the epidemic. The expectation is that these bilateral programs will bring PEPFAR financial and technical resources that are currently being implemented in both countries into one Country Operational Plan. Country Pairs are required to complete a COP21 using the planning and submission process described in this guidance document; these documents can be prepared and planned under the guidance of the participating Chiefs of Mission. The Country Pair in COP21 is Haiti and Dominican Republic

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 being implemented in the region into one Regional Operational Plan (ROP). Regional Platforms required to complete a ROP21 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: Burkina Faso, Ghana, Liberia, Mali, Senegal, Sierra Leone, and Togo

5.3 COP/ROP Timeline

The complete COP/ROP21 process will occur over approximately three months starting with the release of COP/ROP21 Guidance December 17, 2020, followed by tools and all country/region-specific guidance documents and budgets by January 13, 2021. In order to ensure the fullest engagement possible with the community and stakeholders, PEPFAR OU teams/regions are required to conduct an in-country strategic planning retreat with local stakeholders and implementing partners. This retreat should take place no later than the week of January 25, 2021 and be used to introduce and discuss all COP21 tools, guidance, results, targets, and discuss the trajectory and strategy for COP/ROP21 development.

COP21 Guidance Release Date: December 17, 2020 on both PEPFAR SharePoint and https://www.state.gov/pepfar/

COP21 Strategic Direction Summary (SDS) Template will be on the COP21 SharePoint landing page December 17, 2020. The DataPack, FAST and Commodities Supply Planning Tool will be released to OU teams January 6, 2021. Table 6 Excel Workbook with SRE Tool, and Resource Alignment Funding Landscape Table will be released to OU teams January 13, 2021.

In-country COP21 Strategic Planning Meetings: Week of January 25, 2021, at the latest.

No later than the week of January 25, 2021, all PEPFAR programs are expected to host an in-country strategic planning retreat with their local stakeholders to analyze new data, discuss performance throughout FY20, modifications that are occurring right now to improve performance, and reach consensus on the proposed COP21 direction. Programs should plan for virtual engagement as needed based on local context of COVID-19 and restrictions on in-person gatherings. Key elements of this retreat include:

1) Building on the review of FY20 Quarter 4 (Q4) and Annual Program Review (APR20) 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 FY20 Q3 Corrective Action Summary (CAS), including annual data from the Site Improvement Monitoring System (SIMS), the Sustainability Index Dashboard (SID) 2019 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 COP21 national, district, and partner level targets and budgets.

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 COP20 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 COP21, 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 COP21 direction.

Headquarters Review of Tools:

Virtual COP21 Planning Meetings (in previous years these were in-person meetings in regional locations, such as Johannesburg, South Africa and Bangkok, Thailand) will allow intensive review and refinement of COP21 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.

Also prior to the COP21 Meetings, teams will submit to headquarters for review the DataPack (targets); FAST (budgets); 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 COP21 meetings. The DataPack (targets), FAST (budgets), and Table 6 Excel Workbook (non-service delivery activities) will be submitted on a rolling basis, based on the following groupings (as defined below):

For Single OU Track

- Group 1: February 16, 2021
- Group 2: February 23, 2021
- Group 3: March 2, 2021

For Regional Platforms and Country Pair OU Track

- February 9, 2021

This submission timeline will allow headquarters to review and provide feedback so teams can make relevant adjustments prior to the COP21 Virtual Planning Meeting described below.

Building on our successes and country progress over the past several years and adapting to COVID-19 related health and safety considerations, for COP21 we will convene the headquarters and field teams, for a COP21 Virtual Meeting between February 16 - March 12, 2021. During these days, teams will review critical policy requirements, key activities and progress to reach epidemic control. PEPFAR teams, headquarters staff, host 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, and management solutions.

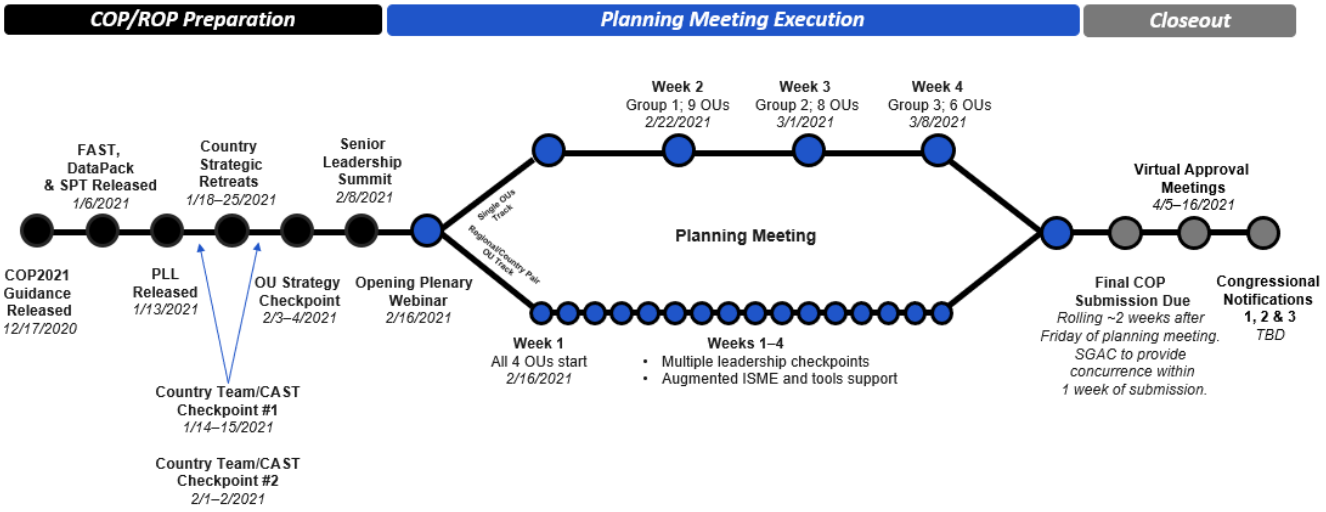
COP21 Virtual Meetings:

Virtual COP21 meeting dates have two tracks. This approach allows single OUs to have a week-long process to finalize work started before the in-country retreat in one track. Regional platforms and country pair OUs will have a longer timeline to finalize plans and tools with continuous headquarters support through approval in a second track.

The following visual represents overall timing of the two track 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 OU plus regional and country pair OU processes as each works in collaboration with subject matter experts, S/GAC focal points for tools and systems, and country leadership to finalizeCOP21 strategies, and to complete tools required for COP21 submission.

Figure 5.3.1 illustrates the Two-Track Virtual COP Planning Meeting Overview



Virtual COP Planning Meeting Dates for Single OUs

Group 1: February 22-26, 2021

- Angola, Botswana, Eswatini, Lesotho, Mozambique, Namibia, Nigeria, South Africa, Zambia

Group 2: March 1-5, 2021

- Cote d'Ivoire, Ethiopia, Kenya, Rwanda, South Sudan, Tanzania, Ukraine, Zimbabwe

Group 3: March 8-12, 2021

Burundi, Cameroon, Democratic Republic of Congo (DRC), Malawi, Uganda, Vietnam Virtual

COP Planning Meeting Dates for Regional and Country Pair OUs

- February 16-March 12, 2021
- Asia Region, Western Hemisphere Region, West Africa Region, Haiti/Dominican Republic Country Pair

Each single OU, country pair, and regional program will participate in one Virtual COP21 Planning Meeting. The COP21 Meetings will include PEPFAR field and headquarters teams,

host country leadership, global and local community and civil society representatives, private sector, and multilateral stakeholders. The COP21 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 COP21 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

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.

COP21 Submission Due Dates:

Single OU Track

- **Group 1**: March 15, 2021
- **Group 2**: March 22, 2021
- **Group 3**: March 29, 2021

Regional Platform and Country Pair OU Track

- March 29, 2020

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, country pairs, and regional platforms will submit the final COP21 in all indicated systems on a rolling basis in the two weeks following the conclusion of their Group's COP21 Meeting. The COP21 timeline is summarized in Figure 5.3.2 and the required COP21 elements checklist is found in Figure 5.4.1.

For COP21, S/GAC will manage approvals during virtual in-country meetings led by PEPFAR Country Chairs with PPMs, headquarters Agency Points of Contact, PEPFAR field program leadership, host country leadership, local community and civil society representatives, private sector and multilateral stakeholders.

COP21 Virtual In-Country Approval Meeting Dates:

All COP21 In-country Approval Meetings should take place between April 5-16, 2021

Figure 5.3.2 summarizes COP21 process, milestones, and timeline

Key Milestones	Dates
Release of COP21 Guidance	December 17, 2020
Release of COP21 Planning Level Letters	January 13, 2021
In-country Planning Retreat	No later than week of January 25, 2021
Rolling submission and review of tools (DataPack, FAST, Table 6 Excel Workbook and SRE Tool)	Single OUs • Group 1: February 16, 2021 • Group 2: February 23, 2021 • Group 2: March 2, 2021 Regional/Country Pair OUs • All: February 9, 2021
COP21 Planning Meetings	Single OUs ● Group 1: February 22-26, 2021 ● Group 2: March 1-5, 2021 ● Group 3: March 8-12, 2021 Regional/Country Pair OUs All: February 16-March 12, 2021
COP21 Submission Due	Single OUs ● Group 1: March 15, 2021 ● Group 2: March 22, 2021 ● Group 3: March 29, 2021 Regional/Country Pair OUs ● All OUs: March 29, 2021
COP21 Virtual or In-country Approval Meetings	All COP21 Approval Meetings should take place between April 5-16, 2021

5.4 Required COP Elements Checklist

Figure 5.4.1 summarizes COP21 elements and supplemental document checklist

Tool	Requirement	System of Completion / Tool / Template (location of tool/template)	Pre-COP21 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: COP21 page)*	**No**
Commodities Supply Planning Tool	**All OUs**	**Template**	**Yes**
Management and Operations: *Agency Cost-of-Doing Business, including applied pipeline* *FACTS Info Staffing Data Module* *Agency functional staff Charts*	**All OUs** **All agencies with CODB costs** **All agencies with staff** **All agencies with staff**	**FAST** **FACTS Info** **No Template**	**Yes** **No** **No**
Chief of Mission Letter	**All OUs**	**No Template**	**No**

*No site level targets are required in COP21.

*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 1.6.1. POART reviews, results reporting, SIMS, PHIAs, 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.

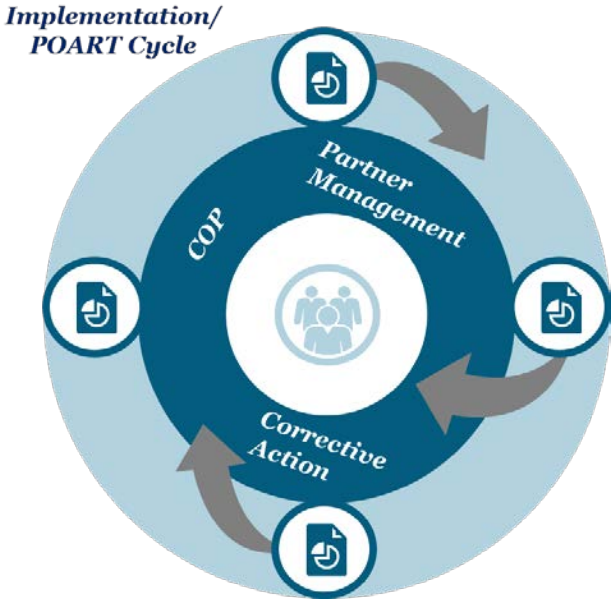
The rapid, efficient use of data has resulted in substantial progress over the past COP cycles. For example,

- 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

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



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 COP20 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 FY20 program implementation cycle (annual program results, outlays, expenditures, and costing) in reaching or

maintaining epidemic control. Information will include FY20 Q3 POART analysis and Q4 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.

COP21 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 COP21 strategic objectives, budgets, targets, solutions, innovations, and priority locations to reach agreement on the overall COP21 strategic direction.

5.6 Coordinating among U.S. Government Agencies

A key feature of PEPFAR is its collaborative and inclusive 'whole-of-government' approach that rests on a robust and productive U.S. government interagency response. 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 remotely.**

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 COP21 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, and where appropriate, try new types of partner agreements such as pay for performance, to further link achievement or impact with payments. As in prior years,

successful implementation of COP21 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 host 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 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 among the five agencies implementing the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), USAID provides support to 52 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) U.S. Centers for Disease Control and Prevention (CDC) is the U.S.'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 534,903 clients with an 85.9% virally suppression rate in 2017*. 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 in the following key areas:

- Client-centered care - medical and non-medical case management models to address the needs of populations experiencing difficulty remaining in HIV care due to factors such as mental health disorders, social determinants, and a history of trauma
- Quality Improvement (QI) – assist domestic recipients implement clinical quality management programs, advises work identifying solutions for existing gaps toward attainment of 95-95-95 goals through evidence-based and structured QI methodologies
- Retention (Treatment Continuity) – utilizing U.S. based HRSA-funded providers to provide direct onsite and virtual support for client-centered care and interventions to increase retention, as well as models employing peer support
- Viral Load Suppression (VLS) – applying QI practices for identifying and addressing process issues affecting VLS and intensive adherence counseling best practices
- Reaching high risk populations – informed domestically through research, technical assistance, and access-to-care programs to improve health outcomes for minority and special populations, which provides a lens for innovative approaches to target key populations in PEPFAR countries

- Transition to local partners – extensive experience working at the State and community level informs work to strengthen local PEPFAR stakeholders and their ongoing and expanded role in the epidemic response
- Integrating HIV services into primary care delivery – critical for both PLHIV and for health facilities. Working towards achieving better access to comprehensive health services, include HIV, through expanding the health workforce and building capacity in primary care facilities.

Additionally, HRSA's work has included a recent focus on integration of mental health screening into HIV and broad utilization of cervical cancer technologies. HRSA also continues its long-standing work to help ensure countries have an adequate supply of high-quality health workers. ***2019*** *data were released on World AIDS Day.*

The **Substance Abuse and Mental Health Services Administration (SAMHSA):** coordinates mental health and addiction treatment services for people living with HIV. SAMHSA also works at the intersection of HIV and substance-use treatment services in those countries with a high proportion of PLHIV who are injecting drug users.

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.

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 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 and civilian partners in four 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, 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 Labor: implements workplace-targeted projects that focus on prevention and reduction of HIV/AIDS-related stigma and discrimination. Additionally, Labor also builds strategic alliances with employers, unions, and Ministries of Labor to overcome discrimination and ensure continued employment of PLHIV. It also focuses on child labor, by implementing programs targeting HIV-affected children who must work to support themselves and/or their families, as well as children who have been forced into prostitution.

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 Better 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 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 Interagency Collaborative for Program Improvement (ICPI) provides 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 rates and associated results and ultimately, allow for PEPFAR to continue meeting Congressional expectations.

5.9.1.1 Orphans and Vulnerable Children

The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended, directs that 10 percent of PEPFAR's bilateral funds 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 9-14 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 6.2.2 and 6.6.4 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.

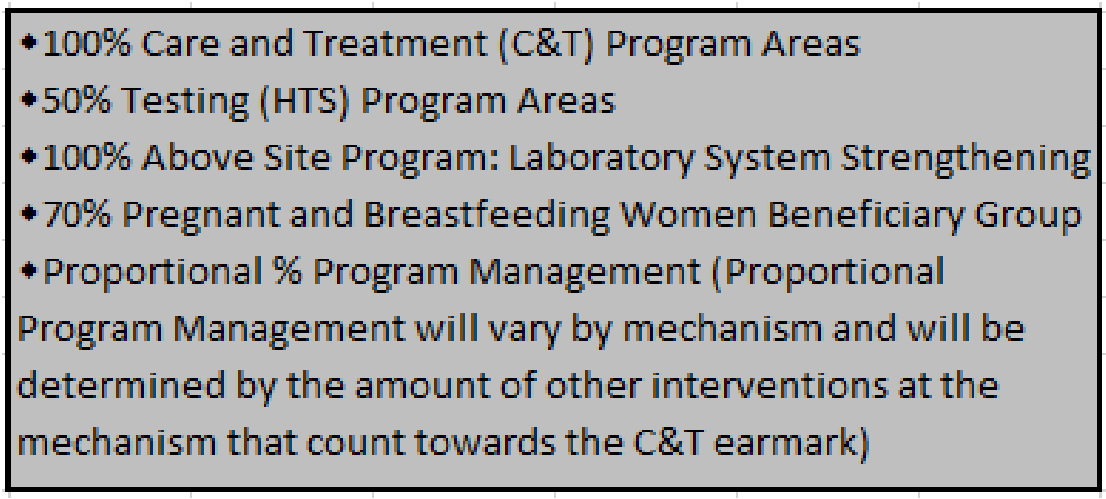
The OVC earmark during COP planning will be based on the OVC beneficiary group and the DREAMS initiative, and will subtract out commodities, testing and some care and treatment. The OVC earmark is calculated according to the following formula:

- **85% (DREAMS initiative funding — commodities planned under DREAMS initiative — Any HTS interventions planned under DREAMS initiative — Any C&T intervention planned under DREAMS initiative)**
- **100% (OVC Beneficiary group funding — commodities planned under any intervention with OVC beneficiaries — Any HTS planned under interventions with OVC beneficiaries**
- **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 OVC earmark)**

5.9.1.2 Care and Treatment Budgetary Requirements and Considerations

Globally, at least 50% of the total FY21 resources must be dedicated to treatment and care for PLHIV. To reach this global requirement, each country or region submitting a 2021 COP or ROP will be notified of their specific care and treatment requirement within the COP21 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:



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 COP21 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 the annual 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, some may fall into the category of what is sometimes referred to as “soft” earmarks. It is vitally important that implementation occur consistent with such applicable legislation, and in a manner responsive to other concerns that may be expressed in non-legally binding language. If any such provisions or language are enacted for COP21 funding in

any applicable full year appropriations act, 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.

5.9.2.1 Water and Gender-based Violence

For COP21 submissions, PEPFAR will assign control levels based on final COP20 attributions, adjusted for any changes in the total budget envelope provided for the OU as appropriate. During the COP21 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 COP21 planning level letter.

If, due to a pivotal change in COP21, a country will be unable to reach these levels of investments, please contact the appropriate PPM and/or Chair to discuss further.

5.9.2.2 Food and Nutrition

PEPFAR programs are expected to establish nutritional support programs targeted to the overall clinical and immunological profiles and based on strict nutritional assessment criteria for both adults and children. It is important to coordinate planning, budgeting and implementation of food and nutrition interventions across programs, such as PMTCT and OVC.

While the non-PEPFAR funded contributions of programs such as Feed the Future, Title II Food Programs, the World Food Program, and others cannot be counted toward PEPFAR's food and nutrition attribution, OU teams are expected to closely coordinate with these key counterpart programs to ensure maximum complementarity and synergy of our respective investments.

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.

In COP21, as we transition away from budget codes, Abstinence, Be Faithful/Youth (AB/Y) programming, formerly captured in the HVAB budget code, will now be 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 Implementation of Protecting Life in Global Health Assistance in PEPFAR Programs

The Protecting Life in Global Health Assistance (PLGHA) policy applies to global health assistance furnished by all U.S. government Departments or Agencies, including PEPFAR assistance. PLGHA applies to global health assistance to, or implemented by, foreign NGOs, including global health assistance that a U.S. NGO provides to a foreign NGO through a sub-award.

The policy requires foreign NGOs to agree, as a condition of receiving global health assistance, that they will not "perform or actively promote abortion as a method of family planning in foreign countries or provide financial support to any other foreign non-governmental organization that conducts such activities".

Relevant Departments and Agencies have been including the PLGHA standard provision in: (a) all new grants and cooperative agreements that provide global health assistance; and (b) all existing grants and cooperative agreements that provide global health assistance when such agreements are amended to add new funding.

Global health assistance to national and sub-national governments, public international organizations, and other multilateral entities in which sovereign nations participate are not subject to PLGHA.

PLGHA does not limit foreign NGOs from treating injuries or illnesses caused by illegal or legal abortions, such as emergency treatment for complications from spontaneous or induced abortion, with U.S. Government or other funds, nor does it prohibit post-abortion care as a condition for receiving U.S. Government funds. PLGHA also does not apply with respect to cases of rape, incest or endangerment of the life of the woman; as such, it does not prohibit foreign NGOs from performing or referring women for the termination of pregnancies in cases of rape, incest or endangerment of the life of the woman. In addition, under PLGHA, healthcare providers are permitted to respond to a question regarding where a safe, legal abortion may be obtained. This is not considered active promotion if a woman who is already pregnant specifically asks the question, clearly states that she has already decided to have a legal abortion, and the healthcare provider reasonably believes that the ethics of the medical profession in the host country requires a response regarding where the procedure may be obtained safely and legally. All these conditions must be met.

For more information, U.S. Government staff and implementing partners can access the publicly available eLearning course, entitled "Protecting Life in Global Health Assistance and Statutory Abortion Restrictions" available through the USAID GH E-Learning Center (https://www.globalhealthlearning.org/course/protecting-life-global-health-assistance-and-statutory) and PLGHA Frequently Asked Questions (https://www.state.gov/wp-content/uploads/2019/10/PLGHA-FAQs-September-2019.pdf).

6.0 Technical Considerations

The goals of PEPFAR are to control the AIDS pandemic and improve the lives of those already living with HIV. The global collective focus on controlling the epidemic by 2030 with clear global 2020 milestones has been challenged by COVID-19. Widespread disturbances in travel and shortages of medical supplies have adversely impacted the provision of medical care. Stay-at-home orders, staff and client illnesses, and stresses on medical care facilities and health workers have made achievement of the global goals more difficult. PEPFAR has honored its commitment to the provision of uninterrupted prevention and treatment service, as PEPFAR teams worldwide have adapted to the changing environment with resilience and creativity.

The essential goals for PEPFAR remain the same: those at highest risk for HIV must be protected by means of evidence-based primary HIV prevention, and PLHIV must be virally suppressed using the most effective medications with the least side effects. In COP2021, PEPFAR promotes the concept of the therapeutic partnership that ensures continuity of prevention and treatment interventions. Services directed at key populations (sex workers, men who have sex with men (MSM), transgender people, people who inject drugs (PWID), and people in prisons and other closed settings) that are convenient and respectful are critical to achieving PEPFAR's goals.[22] There is a strong emphasis on programming that identifies PLHIV not in care, reliably links them to treatment and ensures that their treatment remains uninterrupted. Durable viral load suppression is the ultimate measure of success, at the individual client level and at the community level. Optimizing access to medications, minimizing burdens on the clients, and providing service in a courteous and respectful manner that recognizes the therapeutic partnership between client and provider, are critical for success.

6.1 Continuity of Treatment and Ensuring Programs Work for the Clients

The goal of treatment for all PLHIV is durable viral suppression, which reduces morbidity and mortality and prevents HIV transmission. Continuity of treatment is critical to maintaining the health of PLHIV and achieving epidemic control and is attainable through a client-centered focus. Steps taken at treatment initiation may have a profound effect on treatment continuity.

[22] Unless explicitly stated, the use of the term "key populations" throughout this guidance refers to all of these groups.

Specifically identifying treatment challenges for the individual patient and addressing them in a thoughtful and caring way may go a long way to individual treatment success.

Uninterrupted treatment is critical to achieving the 95-95-95 goals. 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 PLHIV, 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 (<30kg) unable to take tenofovir disoproxil fumarate (TDF), DTG should be given with backbones that do not contain TDF (see Section 6.5.1 of ART optimization).
- Retaining patients in treatment begins the day they are diagnosed with HIV. Treatment providers should describe new treatment paradigms using hopeful language that also includes the benefits of viral suppression achieved with consistent adherence to ARVs. Positive, empowering hopeful messages that treatment is now easier and safer and PLHIV can have a long and healthy life.
- Differentiated service delivery models tailor HIV treatment by location, provider cadre, frequency of visits, and package of services d and can be adapted to subpopulations that have specific needs. These models reduce congestion at treatment facilities and have been shown to improve patient retention and viral load suppression. They also enable program staff to spend less time and resources on clients who are doing well on treatment and allocate more time and resources to clients in need of greater support.
- Multi-month dispensing (MMD) and decentralized drug distribution are interventions that have been accelerated during COVID-19, and this should continue (see Section 6.1.4). Separation of drug delivery from clinical treatment reduces the burden at clinical sites and allows more attention to the patients who need clinical evaluation. Six-month dispensing is preferred, but there may be circumstances where three-month dispensing is necessary. At a minimum, most clients at ART treatment sites should be offered prescriptions for six months of ART and a fast track refill model at the site should be adopted. In addition to adults, children, adolescents/youth, pregnant and breastfeeding women, members of key populations, and foreign nationals should all have access to 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.

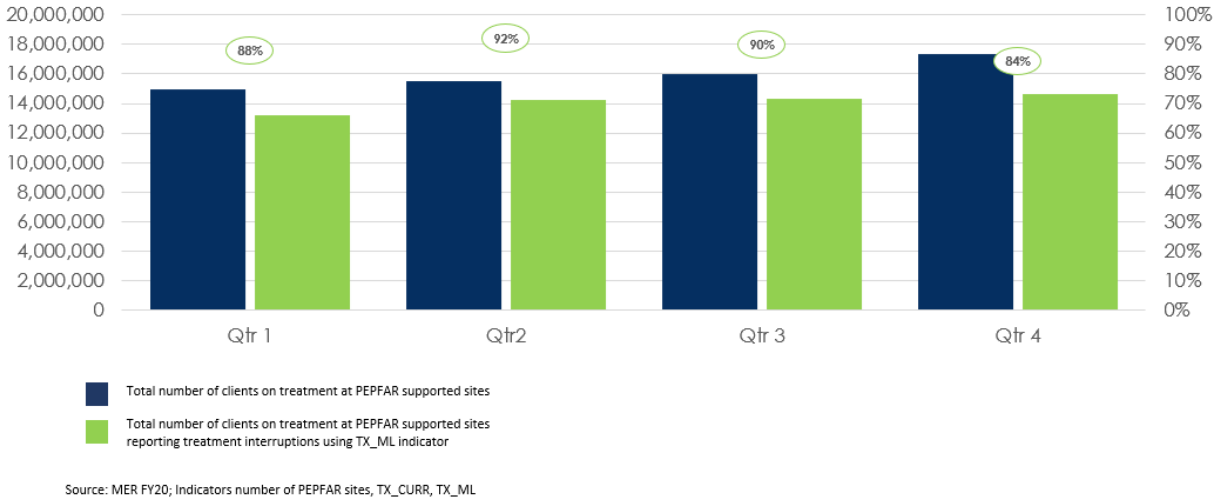
Additionally, programs should provide storage instructions for patients on multi-month 90-count and 180-count ARV bottles.

- The MER disaggregate of the TX_CURR indicator for MMD improves accountability regarding MMD for programs and partners. Facility-level partners are also be required to report two new supply chain indicators (SC_CURR and SC_ARVDISP) biannually for COP20 and beyond, underscoring the importance of implementing MMD and commodity availability.
- Programs are strongly encouraged to coordinate timing of appointments and drug pick-ups for all members of a family/household on ART in order to minimize burden on clients.
- User fees are a barrier to treatment. 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 borne by PLHIV for any health service that may serve as a barrier to access to HIV services should be addressed.
- The focus of client-centered services in COP21 will require providers to use CLM feedback to improve services and to be responsive to particular needs of each sub-population. Existing qualitative research may help clarify challenges and enablers for PLHIV to help providers to tailor interventions for the specific context.

The TX_ML indicator is helpful in identifying specific populations with challenges in treatment continuity. By FY20 Q3, 90% of PEPFAR-supported patients were receiving treatment in a site that reported on interruptions in treatment the TX_ML indicator.

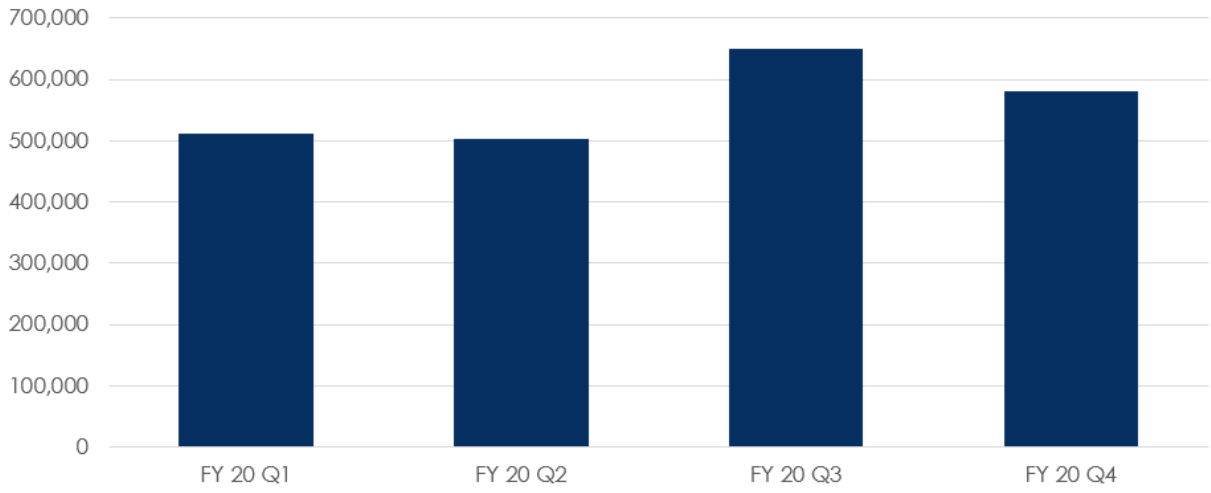
Using TX_ML, interrupted ART treatment can be further disaggregated by treatment interruption among patients recently initiated on ART (<3 months) and patients more established on ART (3+ months). Interruption for patients newly initiating treatment represents a failure to fully link the patient to treatment and programs should work to identify specific populations that may need attention. In the setting of COVID-19 many individuals are receiving 3 months of medication at initiation and the less than 3-month loss may underestimate this figure.

Figure 6.1.1 Percentage of PEPFAR supported sites reporting TX_ML by quarter



Source: MER FY20; Indicators number of PEPFAR sites, TX_CURR, TX_ML

Figure 6.1.2 Number PEPFAR clients experiencing treatment interruption, by quarter, FY20

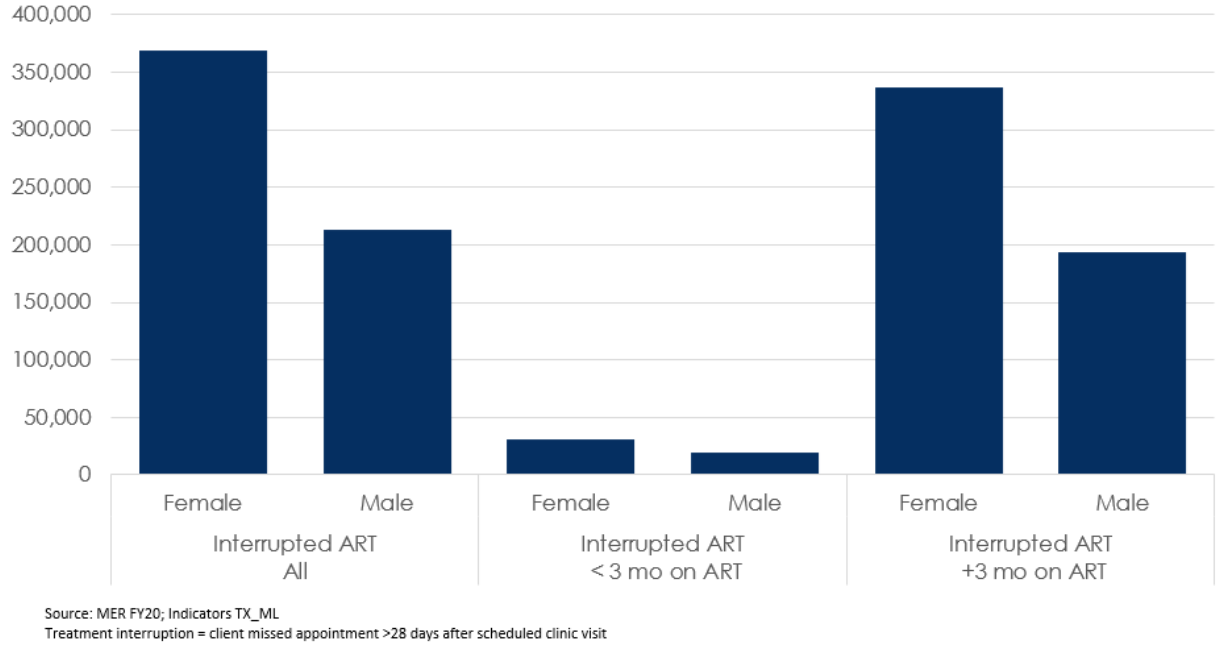


Source: MER FY20; Indicators TX_ML
Treatment interruption = client missed appointment >28 days after scheduled clinic visit

Men: Multiple data sources document that the treatment cascade for men lags behind that of women. Analysis at lower geographic levels may show wide variability in the number of overall interruptions by gender. It is a priority for PEPFAR to support services that facilitate strong linkage and continuous treatment for all populations, with a strong focus on improving the cascade for adult men.

There may be wide variability in the reasons for disengagement from treatment, which, may be patient, clinic, or structural based and will differ by age and sex.

Figure 6.1.3 Number of newly initiated and established PEPFAR clients with treatment interruption events in FY2020 Q4, by gender



Source: MER FY20; Indicators TX_ML
Treatment interruption = client missed appointment >28 days after scheduled clinic visit

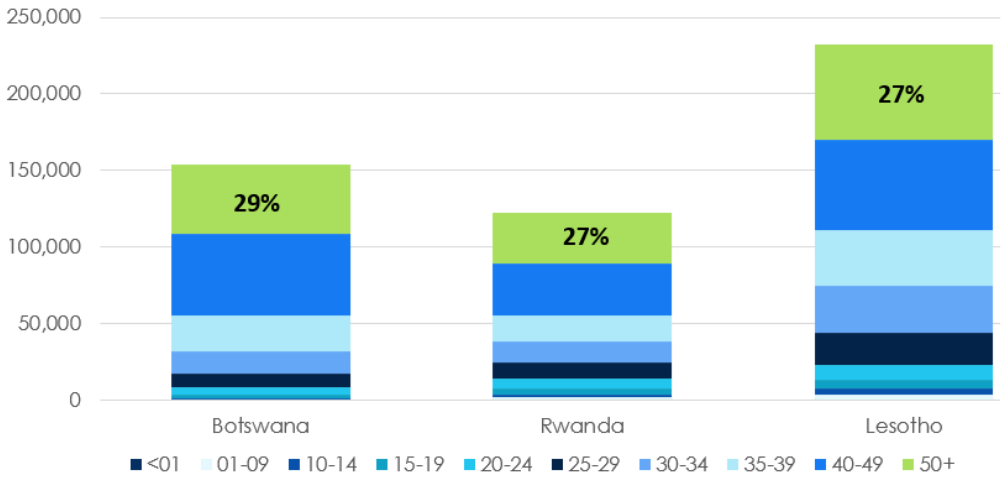
Programs need to use data to design and refine interventions with and for men using approaches that work best for them, which may include tailored messaging, appropriate clinic appointments (around work and among peers), and improving delivery using lessons from MenStar and the PEPFAR solutions database for male-friendly services. (See Section 6.4.4 for more details on men.)

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. Section 6.1.3.2 details the PEPFAR approach to this group.

Older patients. As countries reach epidemic control there will be a growing population of adults in treatment who are older than 50 years. In mature treatment programs, current data suggest that they may represent up to 1/3 of the total treatment population. Preliminary FY20Q3 data show that the average percent of TX_CURR made up by 50+ year old patients is 20% (all countries), with a range of 1% in Liberia to 34% in Burkina Faso and Jamaica. Botswana, Lesotho and Rwanda, for example, have substantial numbers of older adults in treatment. (See figure 6.1.4) The needs of older adults may be different from those of younger adults, and this

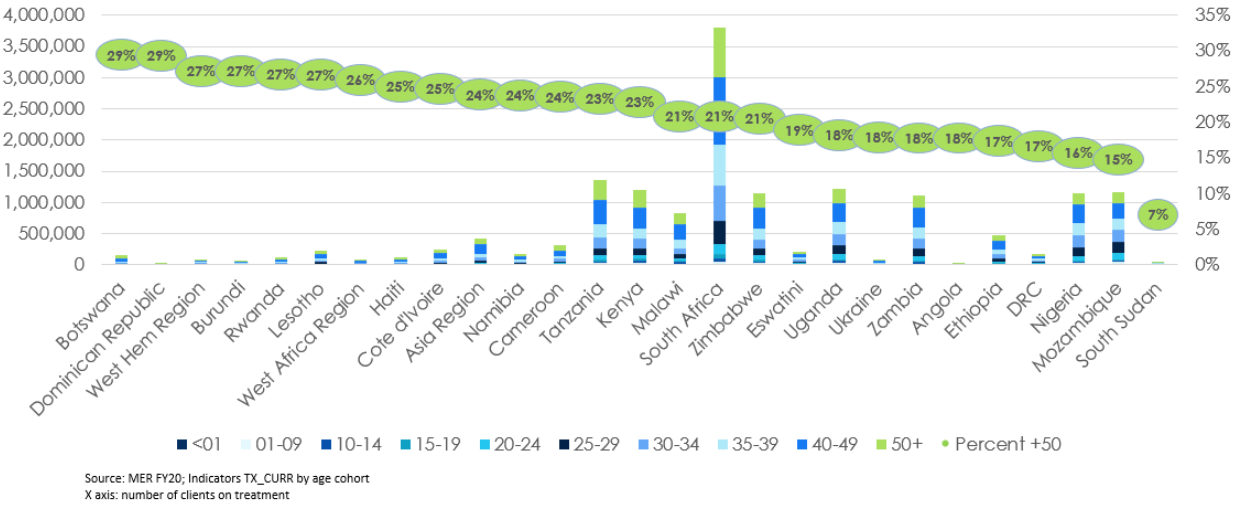
group has a higher all-cause mortality. In accordance with national guidelines other recommended screenings may be performed in this population. Older age is a significant risk factor for severe and even fatal COVID-19. Provision of other needed medications in a fast track or with ART may protect these vulnerable clients and may be lifesaving.

Figure 6.1.4 Percentage of clients aged 50+ years on treatment in FY20 Q4 from select countries



Source: MER FY20; Indicators TX_CURR by age cohort

Figure 6.1.5 Percentage of clients aged 50+ on treatment in FY20 Q4 across countries compared to number of clients on treatment by age cohort



Source: MER FY20; Indicators TX_CURR by age cohort
X axis: number of clients on treatment

6.1.1 Continuity of Treatment (Retention)

Program efforts in COP21 will investigate reasons for treatment interruption and seek to advance practices that facilitate continuous treatment. High quality programs will seek to prevent interruptions and then, if not successful, rapidly identify, locate, and support PLHIV 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.[23] After any break, clients should be warmly welcomed to re-engage in client-centered services including access to immediate or shortened-timeline DSD in order to achieve the best possible treatment outcomes.

Following case identification, 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 and sustained continuity of treatment. Collaborative partnerships with community partners including PLHIV, networks of expert patients, and support groups should be optimized to address social and structural challenges with a direct impact on adherence and retention (misinformation, stigma and discrimination). There is a growing body of information that suggests that early missed visits identify individuals who are at-risk for increased mortality. Conversely, early retention is associated with virological suppression and better patient outcomes.[24,25] Missed pharmacy pickups may be a surrogate marker that identifies individuals at risk for virological failure and interruption of treatment.[26]

All PLHIV who miss appointments or pharmacy pick-ups should be identified immediately through daily review of appointment registers, missed appointment lists, tracking logs and lists generated by electronic medical record systems (EMRs). They should be traced the next day or

[23] 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.
[24] Mugavero, M. J., et al. (2009). "Racial disparities in HIV virologic failure: do missed visits matter?" J Acquir Immune Defic Syndr 50(1): 100-108.
[25] Protopopescu, C., et al. (2017). "Brief Report: Prolonged Viral Suppression over a 12-Year Follow-up of HIV-Infected Patients: The Persistent Impact of Adherence at 4 Months After Initiation of Combined Antiretroviral Therapy in the ANRS CO8 APROCO-COPILOTE Cohort." J Acquir Immune Defic Syndr **74** (3): 293-297.
[26] El-Khatib, Z., et al (2011). "Adherence to drug-refill is a useful early warning indicator of virologic and immunologic failure among HIV patients on first-line ART in South Africa." PLoS One 6(3): e17518

as soon as possible once a missed appointment is verified by other available data sources. High risk patients, such as those who are newly diagnosed and those recently initiated on ART, those with advanced disease and, those with VL> 1000 copies/mL, especially newly diagnosed pregnant women, and children and adolescents should be prioritized. EMR reports should be updated regularly (at least twice weekly) to identify patients more than 28 days late for a clinical service (documented as LTFU or IIC in MER 2.5) to ensure all tracking and tracing efforts are being implemented to return these patients to treatment or to document their outcomes as outlined in the MER indicator TX_ML [i.e., patient transferred to another clinic, interruption in treatment (patient missed appointment >28 days and status unknown) patient refused (stopped) ART, or patient died.] The use of unique identifiers helps track patients across settings and can verify enrollment and attendance in other health facilities. An example of a loss to follow-up tool can be found on the PEPFAR Solutions Platform.[27]

The goal of tracking and tracing of PLHIV who have not initiated treatment or have failed to return/are documented lost from treatment is to help return patients to supportive treatment. At each client contact, verification of client contact details and especially mobile phone access should be done. This will allow continuity of treatment through different kinds of service disruption, including disease outbreaks, natural disasters, and political unrest. When contacted, clients should be assessed to determine their specific circumstances and the particular barriers that need to be addressed and targeted for intervention. They should not be chastised for missing appointments, but treated with respect, and welcomed back when they return to treatment with an inviting attitude from health care providers. Providers should approach patients with positive messages to take charge of their own health and support the health of their family. Solutions should be tailored to individuals' needs with a full menu of support.

There are sub-populations of PLHIV that may require modified or supplemental treatment interventions to ensure optimal health outcomes and continuity of service. These include men, children and adolescents, pregnant and breastfeeding women (including their HIV exposed infants), older patients with comorbidities, key populations, and individuals with advanced disease. Certain PLHIV subpopulations, specifically those with mental health and substance use disorders, may have more difficulty achieving consistent and long-term positive clinical outcomes associated with ART treatment. While some combined approaches, such as the

[27] https://www.pepfarsolutions.org/tools-2

Common Elements Treatment Approach (CETA), have shown promise with complex issues, continued innovations are needed.

Figure 6.1.6 Interventions that improve continuity

6.1.6 Population	Interventions that can improve continuity of treatment (retention)
Men	Male-friendly services that includes male clinical and non-clinical providers such as men living with HIV using coach and buddy approaches Promoting male patients' input in design and package of service delivery Enhanced focus on confidentiality, including HIV in multi-disease or wellness clinics Provision of clinical services closer to workplace or in community and decentralized drug delivery After hours men's clinic, such as weekends or early morning Provision of disclosure support Promoting family index testing for partner and children, highlighting the benefits of early diagnosis and treatment
Children	Child-friendly clinicians Convenient appointment times in consideration of school hours and holidays Family-centered treatment with aligned schedule for drug pick-ups and clinical appointment Age-appropriate disclosure support Parental skills and caregiver support to help with dosing, changing regimens, overall child well-being and adherence Enrollment into OVC programs
Adolescents and youth 10-24, including pregnant adolescent girls and young women	Adolescent engagement in planning/design and implementation of services Provision of screening, identification and services for STI's, pregnancy, and GBV with linkage to Child Protection Services Joint adolescent and caregiver programming to support adherence, viral load monitoring, disclosure, viral load monitoring, and transition to adult care Adolescent and youth friendly services including case management, YPLHIV support groups, convenient service hours (weekends and after school), fast tracking of youth, and use of non-clinical safe spaces for information, screening, and service delivery Professional and lay psychosocial support, including peer-led models (peer navigators, treatment supporters, expert clients, peer educators, and counsellors) Linkage to OVC programs

Pregnant and Breastfeeding women and their HIV-exposed infants	Point-of-care viral load testing Point of care early infant diagnosis Integrated and coordinated ART/PMTCT/MCH services throughout pregnancy and breastfeeding (mother-baby care) and lifelong treatment for mothers Joint appointments for women and their infants to ensure infant prophylaxis dose adjustments/refills and EID Structured peer mentor program (e.g. Mentor Mothers, Community Focal Mothers) and post-natal clubs that focus on adherence and viral load monitoring for mothers Male involvement (invitation letters, male champions) Promoting family index testing for partner and children highlighting the benefits of early diagnosis and treatment in a supportive environment
Key Populations (see section 6.4.5)	Key population-friendly services, especially peer navigation and case management Increase knowledge of HIV viral load and transmissibility (U=U) Anti-discrimination and protective laws; Enhanced focus on confidentiality, including HIV in multi-disease or wellness clinics Provision of medically assisted treatment for opioid dependence Integration of behavioral health and social support services into primary HIV treatment Inclusion of and linkage to family services for KP, especially for children of KPs Linkage to OVC programs as needed for underage KPs or KPs with children
People with advanced HIV disease and older patients with other co-morbidities	Tailored differentiated HIV treatment that streamline services Express treatment triage programs Frequent home visits and monitoring Symptom checklist review and screening for OIs during clinic/home visits For children <18 years, linkage and enrollment to OVC programs and social protection services

6.1.2 Missed Appointments, Interruptions to Treatment, and Client Tracking

Assessments of PEPFAR performance for FY 2020 revealed that retention challenges can easily be underestimated or overestimated by normal aging, (when assessing retention by age band), site shifts, and reliance on proxy indicators. While successes in retention practices and achievement are applauded, FY 2021 plans should include a focus on preventing missed appointments, preventing treatment interruptions, and tracing clients to ensure achievement of successful treatment.[28] In COP20, verification of a missed appointment or pharmacy pickup within 1 day was required, with tracking and tracing attempted within 24 hours. Figure 6.1.7 displays a sample algorithm for this activity. In COP21 further enhancements such as appointment reminders via SMS will be considered.

Tracking treatment continuity as close to real-time as possible is critical to program success. All programs need to document treatment interruptions by sex and age to develop relevant program interventions. Successful re-entry into treatment should be client-centered, seeking to understand reasons and barriers to treatment access and adherence so that their 'welcome back' care is personalized, empowering, and actively supported by services and providers (clinical and non-clinical). 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. Individuals who are experiencing tolerability issues or have recently transitioned from one regimen to another may require more intensive follow-up.

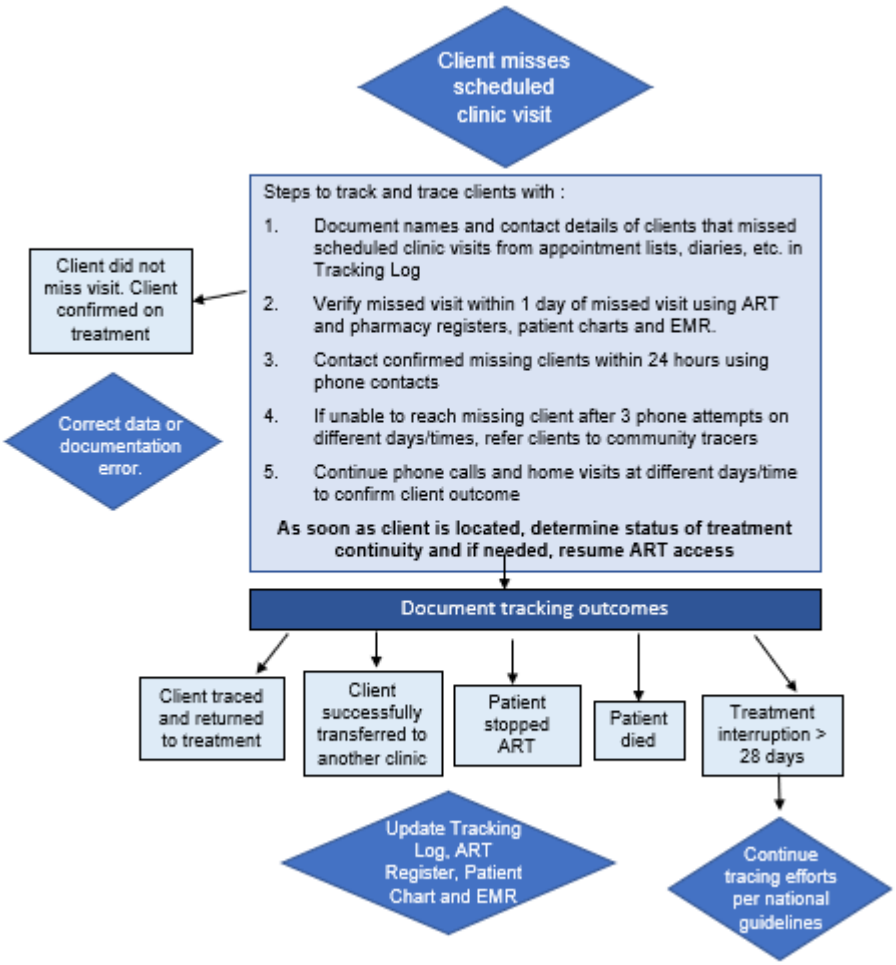
Some programs have found that a substantial proportion of patients initially identified as having interrupted treatment were in fact active on ART but had transferred or enrolled in a DSD program. As such, resources may be misallocated for tracking and tracing of patients actively engaged in care. Programs must work to strengthen and harmonize documentation and data management systems in order to more effectively capture silent transfers and DSD patients. Those clients who have been successfully contacted using phone or other virtual 'check-ins' and have sufficient medicines should not be identified for tracing.

Understanding early interruptions in treatment (under 3 months from ART initiation) and evaluating the granular data will allow the continuous growth of treatment coverage alongside

[28] https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30227-3/fulltext

sustained treatment access outcomes. Several MER indicators are designed to help with this activity.

Figure 6.1.7 Sample algorithm for tracking and tracing clients who missed scheduled appointments (Interruptions in Treatment, IIT)



TX_ML identifies outcomes for all ART patients with no clinical contact or ARV pick-up for greater than 28 days since their last expected clinical contact or ARV pick-up. Monitoring this indicator may also help to identify those PLHIV who were diagnosed and started ART in the past but have disengaged from health care services. As described above, some clients who have experienced an interruption in treatment (IIT, previously referred to as LTFU), have transferred to other clinics. Others have had significant interruptions, and upon return to treatment should be counted as TX_RTT. MER retention proxy indicators, calculated from TX_NEW and TX_CURR, provide information on retention of ART patients. Information about how to calculate and use those indicators is found in Section 7 (MER data).

All programs should regularly monitor patient retention and viral load suppression at the SNU and site levels to determine which partners and which SNUs are performing well and which are not (retention and PVLS ≥ 95%). Activities should be reviewed to document implementation of all core interventions described above, as well as additional treatment continuity support activities described in subsequent sections. Programs are expected to monitor performance closely, looking at outcome measures for especially for PVLS and IIT in HIV treatment and document clear plans for improvement.

6.1.3 Differentiated Service Delivery and the Therapeutic Alliance

Continuity of care 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 care. In COP21, these terms have been replaced by 'continuity of treatment' and 'interruption in treatment' to emphasize the therapeutic alliance that is important for successful treatment of all PLHIV. 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 treatment. Client factors such as harmful substance use and poor mental health 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 is capable of responding to these needs.

Differentiated service delivery (DSD) is a person-centered approach to HIV care and treatment that tailors services to different groups of PLHIV depending on their needs while maintaining the basis of the public health approach: simple, standardized and evidence based. When multiple DSD 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.

DSD 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 DSD models has been accelerated in response to COVID-19 and should continue when normal services resume. COVID-19 related DSD adaptation include the expansion of multi-month dispensing (MMD) and community-based drug delivery. These interventions have accelerated decongestion of health facilities, minimizing transmission of COVID-19 as well as allowing greater attention to those PLHIV requiring more intensive services.

Significant policy changes recommended by PEPFAR have been enacted in multiple OUs expanding MMD to a broader array of individuals including children, adolescents, PBFW, men, individuals with advanced disease and those who have not yet achieved viral suppression, or whose viral suppression is as yet undetermined.[29] With respect to the latter, these individuals should be prioritized for viral load testing but should still be offered MMD. Similarly, individuals starting ART should receive multiple months of treatment. Most PEPFAR countries have adopted 3 or 6-month multi-month dispensing and innovative drug delivery systems, from facility to community. Separation of clinical services and drug delivery has allowed individuals to have the supplies they need for treatment while streamlining access to care when appropriate and necessary. Most individuals should be provided with 3 or 6 month of medications, tuberculosis therapy, both preventative and treatment can be incorporated into DSD models as detailed in Section 6.5.3.3.

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[30,31,32,33]

[29] https://cquin.icap.columbia.edu/
[30] CAGs in Mozambique (paper 1, PEPFAR solutions write up), CIDRZ CAGs in Zambia, CAGs in Zimbabwe, CAGs in Lesotho
[31] 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
[32] 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**
[33] Data from Adherence Clubs in the Western Cape, South Africa (paper 1, paper 2, paper 3, PEPFAR solutions write up)

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. Multi-month dispensing 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 CAGs are non-inferior to 3-month clinical care.

Example: Community ARV Refill Group - Zimbabwe where members collect 3-monthly ART refills for the group.

2. Facility-based individual models[34]
   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 do not see clinical staff or receive adherence support; rather, they proceed directly to the pharmacy or fast track room for medication refills. These models are among the least intensive and least expensive and therefore are among the easiest to implement and scale. There are examples of this facility-based fast track model in both Ethiopia and Malawi.
3. Out-of-facility 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 and community pharmacies in Nigeria.

   Some countries have also moved the clinical consultations into communities 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. Outreach services and home delivery of treatment and services may be provided in this model. In some OUs the COVID-19

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

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 is attractive and needs further assessment

4. Health worker-managed groups[35,36]
   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, in 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: viral load clinics specifically serving those individuals (see Section 6.5.6)
- Individuals with advanced disease (see Section 6.5.2)
- Families with several individuals living with HIV: Family-centered models that recognize the needs of all family members (note adolescence is a time of growing autonomy, and teens should be able to choose whether to come with their family). Family members can be booked for joint appointments, files are kept together, couples and family counseling can be provided with treatment buddies within the same household.
- Adolescent and youth: using teen clubs to provide targeted psychosocial and clinical care. These age-specific evidence-based interventions often include the provision of directed behavioral messages (e.g., Operation Triple Zero),

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

[36] 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.

with specialized and dedicated clinic time on Saturdays or during school holidays to eliminate school absenteeism. Services could include specialized staff members and have some peer-led support for adherence, growing up with HIV, and social support (recreational activities) as well as referrals to other relevant health (sexual and reproductive) and social services.

- Pregnant and breast-feeding women, including mentor mother groups and post-natal clubs
- Older adults: many OUs have a substantial proportion of individuals who are over 50 years of age as detailed in the introduction. Some of these people have other co-morbid conditions and ensuring access to therapies directed at co-morbid conditions is a client-centered approach that in the setting of COVID-19 may reduce risk by minimizing time in health care facilities.
- Key populations (see Section 6.4.5 for details).
- Migrant populations, including those displaced by civil unrest, severe weather (flood, drought, extreme storms), or economic instability

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

Documentation of adequate patient follow-up is also important. Several methods are available: some countries like Kenya have a patient manager or social worker who follows a group of patients and reports on specific clinical aspects to a manager. DSD can be documented in a DSD register or as an add-on to the existing ART register.

Support for successful treatment

Individuals who are struggling with treatment as evidenced by missed appointments or missed pharmacy pickups require intervention tailored to their needs. Some populations of patients require nuanced interventions, and integrated services as detailed below. Patients at higher risk for disengagement, such as pregnant and breastfeeding women, individuals recently initiated on treatment, those with high viral loads, clients with advanced HIV disease, and children and adolescents should be prioritized for more intensive support to prevent interruptions.

Targeted interventions for those who need additional interventions beyond the core package (and are struggling with pill taking and clinic attendance) include:

- Ongoing case management, particularly utilizing peer mentors/HIV champions/coaches/case managers. Emerging data is showing that having a case manager or peer support from another man who is living with HIV and stable on treatment is an

effective strategy for engaging men in continuous care because it offers living proof that men can gain control over HIV and feel strong, healthy, and safe again.

- Enhanced adherence and repeat viral load testing, with treatment literacy support.
- Additional contact with health care providers and regular check-in with lay health workers, including home visits, staggered at different times, and the use of virtual forms of communication such as SMS messaging
- The use of community support personnel to work with clients facing other issues, such as mental health conditions 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
- Reminder services including digital support tools, appointment reminders and follow-ups for missed appointments.

6.1.3.1 Differentiated Service Delivery, Adherence, and Retention Support for Children

Continuity of treatment (formerly framed as “retention”) is an essential component to avert morbidity and mortality among children living with HIV (CLHIV). In addition to common barriers precluding continuity of treatment for adults, there are additional barriers for CLHIV, including dependence on caregivers, conflicts with school schedules, inconvenient clinic hours, 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 (DSD) models within a family-centered framework. For instance, children can receive community-based ART delivery and be included in other family-centered DSD models.

Furthermore, CLHIV two years of age and older are eligible for multi-month dispensing (MMD) of ART. Weight changes requiring dosing change 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.[37] As described in Section 6.1.3, 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 should be delinked from clinical consultation visits, provided outside of health facilities, and can be managed by trained lay providers (including OVC workers in cases where children face extreme challenges in accessing ART).

Programs should make every effort to supply CLHIV initiating and refilling ART with a 3-month supply (3MMD) of ARVs for children 2 - < 5 years old and a 6-month supply for children 5 years of age and older. 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, a 3-6-month supply should be provided at the same time as ART pickup. TPT should also be given in multi-month intervals at the same time as ART pickup.

For children (especially those who are younger) starting a new medication, administration of the first dose should be done before the child and caregiver leave the ART site. While children aged two years and older should receive at least a 3-month supply of ARVs, clinical follow-up should still occur (within 2-4 weeks) by phone, electronically, or in-person and include assessment of medication dosing and administration of the new or changed regimen. Limited stock of pediatric ARVs can hinder a program's ability to implement pediatric MMD; therefore, national proper supply chain planning must take into account MMD for CLHIV. In COP21, programs should further optimize pediatric ARV regimens and rapidly include DTG 10 mg dispersible tablets, simplifying the implementation of 3MMD for children 2 - < 5 years of age. Please see Section 6.5.5 for considerations regarding pediatric viral load monitoring.

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 counselled and oriented on age-appropriate disclosure processes as disclosure is associated with better clinical outcomes. However, disclosure should not be a requirement for MMD.

[37] 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.

While optimized DSD for children will improve retention, treatment interruptions may still occur. Re-engagement of children also requires focus with a welcoming and non-judgmental service approach delivered by providers. Clinical and psychosocial 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. 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 DSD models upon re-engagement.

Orphans and vulnerable children and adolescents

Clinical partners in partnership with the sites they support, should establish formal relationships with surrounding OVC 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.

In COP20, Clinical and OVC IPs should have developed formal relationships, such as a memorandum of understanding (MOU), outlining the roles and responsibilities of each member of the multi-disciplinary team and addressing key issues such as bi-directional referral protocols, case conferencing, shared confidentiality, index and other testing support, and joint case identification, and data sharing. 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 COP21, emphasis should be on improving systems and processes to facilitate 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, retention, and disclosure, ARV transitions and drug administration, viral load testing and suppression, and U=U. Likewise, OVC IPs can help train clinic staff to understand the broader factors (e.g., socioeconomic and cultural) that impact health seeking behaviors (such as EID, HTS, keeping clinic appointments, adhering to medication, returning for viral load test and results), and to help facility-based staff recognize which families and children/adolescents would benefit from OVC program support.

Solutions

Additional solutions to improve pediatric retention and adherence 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 psychosocial support for CLHIV and caregivers are key to improving retention and adherence. 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. 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. 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 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

Programs should routinely review continuity of treatment indicators by disaggregated sex and fine age bands to further identify challenges unique to specific sub-populations, including the potential impact of aging into and out of age bands. This approach can foster targeted interventions for these priority populations.

6.1.3.2 Differentiated Service Delivery and Adherence Support for Adolescents and Youth

Adolescents (ages 10-19 years) and youth (ages 15-24 years) living with HIV (AYLHIV*) have the lowest rates of continuity of treatment (formerly framed as "retention"), ART adherence, and viral suppression compared to other age groups. These poor outcomes are due to a number of barriers, faced by adolescents and youth, including lack of adolescent- and youth-friendly services, limited scale of peer support, inadequate psychosocial support, mental health challenges that often arise in adolescence[38] (see Section 6.6.7 - Mental Health), 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 perinatally-infected adolescents. Training/mentoring programs for healthcare workers (e.g., clinicians, cadres that provide psychosocial support, 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.

Adolescents may no longer receive constant caregiver oversight and frequently attend to their duties and appointments independently. 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. AYLHIV benefit from mentorship and support from peers and trusted adult figures in addition to their parents/guardians. Healthcare workers should foster relationships with AYLHIV by creating a balance between appropriate health supervision and listening to AYLHIV's voices regarding their health. 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 AYLHIV, it is important that AYLHIV have access to facility- (e.g., fast track) and community-based DSD 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

[38] https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health

psychosocial support, particularly from peer AYLHIV, 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 DSD models meet the needs of AYLHIV, 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 traits of youth cohorts, including young pregnant and/or breastfeeding mothers, young key populations, and other youth populations when linking youth to relevant support services. Additionally, countries should routinely review adolescent and youth fine age bands to identify ongoing gaps in continuity of treatment and viral load suppression in these populations.

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 DSD models targeted to youth should include new opportunities to leverage technological opportunities.[39] Such technology approaches provide an excellent opportunity to engage with AYLHIV 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 AYLHIV to peer-led service delivery models to provide peer support and motivation, strengthen problem-solving skills, and overcome adherence challenges (e.g., quality AYLHIV support programs such as Positive Connections, Teen Clubs, Operation Triple Zero, and Zvandiri)
    - Utilize targeted interventions to improve continuity of treatment amongst AYLHIV, including fast tracking (e.g., EGPAF's Red Carpet program), case management, and referrals to broader psychosocial and economic/employment support resources.
    - Ensure human resources are comprehensively trained and mentored on client-centered and -friendly care, including male-friendly, AGYW, KP, and AYLHIV services. Trainings should allow opportunities for staff to practice these skills (i.e., role-play) and partake in open discussions about possible

[39] https://www.unicef.org/publications/files/SOWC_2017_ENG_WEB.pdf

biases that may arise when caring for AYLHIV. 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.

- Ensure host 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 AYLHIV, age- and developmentally appropriate disclosure (in line with host country disclosure guidelines), adherence counseling, referrals to relevant health and social services, and transition to self-care support services for AYLHIV that includes enhanced treatment literacy, adherence interventions and messaging.
- Coordinate tracking of AYLHIV for appointment reminders/missed appointments using AYLHIV 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.
- Enroll ALHIV into OVC programs.
- Provide parenting classes for parents and caregivers of ALHIV.

- 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 AYLHIV psychological and peer support, including both individual and group peer support, which can be provided in-person or virtually.

- 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, “mystery shoppers,” and facility checklists to track the youth-friendly components of a facility, and making sure these services are advertised appropriately.
- Include youth representatives on facility advisory committees.

- At the Community Level:
  - Provide community-based peer support (groups, buddy systems, community adherence groups (CAGs).
  - Provide (peer) accompaniment to clinics.
  - Work with schools and other community platforms to decrease stigma and discrimination, and to prevent violence against AYLHIV (from school staff members and peers).
  - Conduct home-based visits, only after obtaining consent to do so.
  - Linking AYLHIV to educational support and income generation activities.

6.1.3.3 Differentiated Service Delivery and Adherence Support for Men and Women, Including Pregnant and Breastfeeding Women

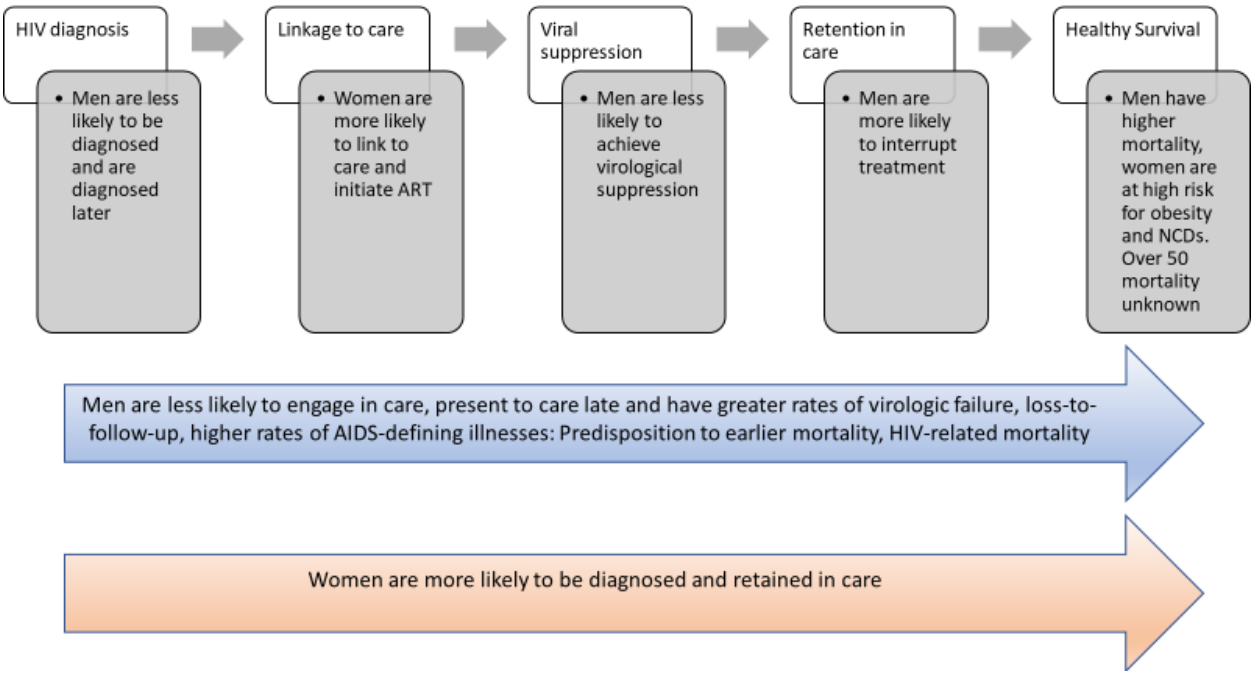
Sex differences in treatment outcomes are well described and there are challenges for men across the treatment cascade.

Research suggests that women with HIV are more likely than men to engage successfully with the healthcare system and earlier in the course of HIV disease:[40] engagement with family planning and antenatal services provides early access points. Several cohorts in sub-Saharan

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

Africa have demonstrated that men interrupt care more frequently than women and that women are more likely to be virologically suppressed.[41,42]

Figure 6.1.8 Treatment outcomes for men[43]



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. 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.

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[41] Taieb F, Madec Y, Cournil A, Delaporte E. Virological success after 12 and 24 months of antiretroviral therapy in sub-Saharan Africa: comparing results of trials, cohorts and cross-sectional studies using a systematic review and meta-analysis. PLoS One. 2017;12(4):e0174767-e.

[42] Sabapathy K, Hensen B, Varsaneux O, Floyd S, Fidler S, Hayes R. The cascade of care following community-based detection of HIV in sub-Saharan Africa - a systematic review with 90-90-90 targets in sight.

[43] (Cohn, 2020)

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

Rapid optimization of TLD

- See Section 6.5 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.

Convenience: It is critical that all clients are offered services that allow them to fulfill their obligations, with minimal disruption to their lives. Relevant strategies include:

- Multi-month drug dispensing and appointment spacing
- Decentralized drug pickup points, such as private pharmacies and hospitals, courier services, automated dispensation units or drug lockers, pop-up pharmacies, community-based dispensing, etc. (See Section 6.1.4 Multi-Month Dispensing and Decentralized Drug Delivery)
- Shortened wait times with specific interventions to reduce them to one hour, such as fast-track services and expedited clinic operations for working clients
- Extended clinic hours which meet local needs
- Transportation support

Welcoming environment responsive to men's needs

There is abundant evidence that men feel that clinics are not spaces where they receive respectful and compassionate care in a manner that caters to their unique needs as men. Insights from the focus groups suggest men feel that clinics are designed for, staffed, and attended by women, and lack confidentiality and the respect they value.

- Redesign clinics to be more welcoming to men, including male-only spaces/corners, specific male-only hours, male-to-male community outreach and support groups

- Make efforts to hire male clinical, social services and lay providers – specifically for male clients
- Enhanced focus on confidentiality and privacy
- Provide support and training to clinic staff to facilitate a more responsive environment to men's needs: empathetic, well-trained, well-supported providers
- Consistent, affirmative "Welcome Back" messaging that avoids negative consequences of interruption of care and provides positive reinforcement for re-engagement

Support the client with their journey through treatment support mechanisms

Clients should have access to responsive support structures and peer networks throughout the entire journey to help them reach and maintain viral suppression. It is especially important to help men realize early in their HIV experience that the burden of HIV care will be totally manageable and to offer differentiated service delivery early as an incentive to achieve viral suppression.

Viral load suppression should **not** be a requirement to participate in a differentiated service delivery platform; rather, clients should be given the option and then supported as needed (through peer counselor check-ins or phone calls) and prioritized for expedited assessment of viral load suppression and adherence.

Treatment Support

- Escorted linkage, ideally by another man. Data suggest that 95% of men return to care with the support of a man living with HIV serving as a coach or linkage facilitator
- Peer navigation programs can be strengthened by specific training on empathy and effective, compassionate engagement of the issues that men commonly face (e.g., fear, specific logistic challenges, disclosure, etc.).
- Case Managers, including adherence counselors or clinic coaches, to provide tools and tips for adherence to medication regime and concerns with stigma. For men, emerging data show that having a case manager or peer support from another man who is living with HIV and stable on treatment is an effective strategy for achieving continuous care, because it offers living proof that men can gain control over HIV and feel strong, healthy, and safe again.
- Adherence Clubs/support groups to create support mechanisms in the community to ensure continued adherence and viral suppression

    - Peer mentors/champions/expert clients who provide tailored support to clients
- Patient support tools to help navigate the treatment experience, including support for disclosure (especially partner disclosure)
    - Digital remote support tools, including pre-appointment reminders, supportive and informative SMS, and follow-ups for missed appointments

See Section 6.1.3 Differentiated Service Delivery and the Therapeutic Alliance.

Build coping potential with messages on the new HIV treatment narrative

COP21 focuses on the therapeutic alliance for improved health. Language that emphasizes "living with HIV" stresses adaptive responses. Viral suppression should be celebrated as success because it not only represents improved health but also has important implications for HIV transmission. The message that viral suppression means that HIV cannot be transmitted is a powerful motivator for many individuals, and counselling and messaging should emphasize this information. Reframing the treatment partnership with aspirational and achievable goals, allowing individual clients agency in these goals may go a long way to achieving therapeutic success and viral suppression. Counselling and messaging should not simply instruct men on treatment but explain the benefits of treatment, including the clinical benefits and the lifestyle benefits, and seek to connect these treatment benefits to men's own internal motivations. Some men may be motivated by the desire to eliminate new HIV transmissions; others will be motivated by a desire to improve their own well-being and reduce feelings of being a vector for infection. This new messaging has the potential to help men, and all recipients of care, reclaim a positive identity, feel like they are 'back to normal', and experience a sense of winning.

See the Solutions platform[44] for examples from PEPFAR countries on treatment support for men. In particular, a "welcome back" campaign in Uganda focused on early losses to follow-up in men and demonstrated a significant return to care in the population served.

Women and PBFW

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

[44] https://www.pepfarsolutions.org/

during breastfeeding. At particular risk are adolescents, youth and women who are newly diagnosed with HIV.[45] Poverty and low educational levels are also important contributors.[46,47]

Continuity of treatment and viral suppression are critical for mothers in ART programs. Not only does this improve the mother's health, but since approximately half of perinatally acquired HIV occurs in the breast-feeding period, viral suppression in the mother effectively prevents HIV transmission to her child. Viral suppression for women during and beyond the breastfeeding period also reduces the risk of perinatal transmission in future pregnancies.[48]

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[49,50] intimate partner violence and fear of disclosure,[51] 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,[52] "one stop shop" for maternal and infant care including dispensing medications in clinic.

[45] 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

[46] 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.

[47] 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.

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

[49] 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

[50] 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.

[51] 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.

[52] 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

- MMD to align with ANC/MCH schedule
- Access to differentiated service delivery (see below) Importantly, pregnant women who are receiving their HIV care within a differentiated service delivery model should not be referred out of this model when they become pregnant unless preferable to the woman, but rather supported to have their ANC care. Women who were not in a DSD model prior to pregnancy should also be enabled to qualify for DSD postnatally provided their infant has been tested at 6 weeks and the result received and communicated. Where culturally women travel away from their usual home to give birth and in the immediate post-natal period, MMD should be considered to align with their return date.
- Ensuring full access to TLD
- Engaging community health workers[53]
- Structured peer mentors
- Mentor Mothers,[54] M2M, or other structured peer mentoring such as community focal mothers. See the PEPFAR Solutions Platform.
- Male involvement[55]
- Family centered care
- Point-of-care viral load testing, with education and counseling
- Ante-natal and Post-natal clubs[56]
- Family centered services with integrated maternal newborn and child health HIV care

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

[53] 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

[54] 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

[55] 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

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

for mothers and infants), the use of technology driven reminders, and assistance with transportation are local solutions that may help retain these women in care. Importantly, pregnant women who are receiving their HIV care within a differentiated service delivery model should not be referred out of this model when they become pregnant, but rather supported to have their ANC care.

6.1.3.4 Differentiated Service Delivery and Adherence Support for Key Populations

In order for PEPFAR to provide effective interventions at scale and for all populations, countries must continue to prioritize client-centered approaches that meet the specific needs and address barriers that KP encounter across the entire HIV cascade. Coordination and collaboration with multilateral donors are also important. Key populations require differentiated service delivery, with support for public and private health care facilities to deliver KP-competent as well as community-based models of care which allow them to access services outside of general facilities. KP providers and facilities (e.g., KP drop-in centers) should be considered for the provision of ART and as a hub from which peer outreach/navigation operates for prevention (including PrEP) and treatment continuity support. Likewise approaches that refer KP into ART services or non KP services must ensure that KP are assigned peer navigators and/ or case managers to receive behavioral support and community care beyond the general services provided.

Please see Section 6.4.5, which describes DSD models further and the importance of a comprehensive case management system that utilizes peer navigators or other trusted individuals to facilitate KP treatment initiation and achievement of undetectable viral loads through long term treatment adherence.[57,58]

Above-site DSD activities PEPFAR supports in collaboration with the national responses include advancing enabling policies that support differentiated services and decentralization of services. These can include community initiation and dispensation of ART (i.e., at community-based organizations [CBOs] or private sector venues including pharmacies) including MMD and

[57] https://www.fhi360.org/sites/default/files/media/documents/epic-long-term-hiv-adherence-guide.pdf
Levitt D, Lillie T. Long-Term HIV Treatment Adherence for
Key Populations: Program Considerations. FHI 360; Durham (NC): 2020.
58 Levitt D, Lillie T. Long-Term HIV Treatment Adherence for
Key Populations: Program Considerations. FHI 360; Durham (NC): 2020.
https://www.fhi360.org/sites/default/files/media/documents/epic-long-term-hiv-adherence-guide.pdf

decentralized models for increasing access to VL diagnostics (i.e., transportation of blood samples drawn in the community during outreach at KP clinics or DICs).

6.1.4 Multi-Month Dispensing and Decentralized Drug Delivery

COVID-19 has accelerated MMD scale-up or initiation in the majority of PEPFAR OUs. As of October 2020, there are 33/51 OUs that have implemented 6 months dispensing and 45 OUs have implemented 3-month MMD programs. Multi-Month Scripting is a prerequisite for MMD but does not replace MMD.

Countries should continue to scale up programs for 6-month MMD for adults and a minimum of 3-month MMD for children. See Section 6.1.3.1 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 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 COP21, 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 on-time to avoid treatment disruption.

- MMD must be part of the annual quantification, forecasting, and supply planning exercise and this will be expected in COP21.
- Ensure that ARV quantity sizes (e.g.,30-, 90-, or 180-count) are accurately identified within the commodity section of the FAST No 30 ARV size bottles will be purchased after Jan 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 client 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.

- Identify safe storage requirements for larger pack sizes.
- 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, 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.

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 and enroll patients on MMD. Key considerations include:

- Creating demand for MMD by counseling patients on benefits of MMD
- 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 patients not currently enrolled on MMD or needing to transition from 3 to 6MMD, and oversee implementation of MMD for clients newly initiating treatment;
- Involving community health workers, patient navigators and psychologists to improve treatment literacy and support clients newly enrolled on MMD;
- Promoting family-centered approach to MMD by synchronizing MMD schedules and drug pick-ups for caregiver-child pairs
- Ensuring that appropriate monitoring and evaluation occurs including monitoring for adverse events, and adequate clinical follow-up

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. Similar to MMD efforts, decentralized drug distribution (DDD) is a client-centered initiative aimed at reducing ART interruptions, decongesting public facilities, and improving client-centered care, with both clinical and supply chain implications. Common DDD models include distribution through private hospitals or pharmacies, 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. To date, data from DDD implementations indicate a positive correlation between the ability to receive refills at sites devolved from a health facility, and increased satisfaction, treatment adherence, and viral suppression. See Section 6.1.3 for a further description of DSD 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 in light of the available budget, vehicles, and human resource capacity.

6.2 Primary Prevention

As countries approach epidemic control, it is imperative that we consistently find and engage individuals at highest risk of acquiring and transmitting HIV and viral hepatis infections, and as we find and engage these individuals, it is important to focus on the needs of each client for either client-centered ART, referral to hepatis C testing and treatment, or client-centered prevention services, including access to harm reduction materials and services, linkage to HBV vaccination, and viral hepatitis prevention education. Just as for other interventions, countries should maximize impact by understanding 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 already infected, AND engage and support peer-led, peer-designed prevention services that center clients and are tailored to the situation. Comprehensive prevention services including risk reduction education, condoms and lubricants, VMMC referral, harm reduction interventions, and HIV post-exposure and pre-exposure prophylaxis should be incorporated into existing services such as antenatal care, family planning, and key population venues and also provided in the community. In addition, partners identified through index testing as HIV-negative should be provided with or referred for comprehensive HIV prevention services including education, condoms and lubricants, VMMC, and pre-exposure prophylaxis as appropriate. Lessons learned on how to implement prevention interventions safely and efficiently in the setting of COVID-19 should be incorporated into all programs, and those that facilitate uptake of prevention should be continued after COVID-19 subsides.

6.2.1 Pre-Exposure Prophylaxis (PrEP)

Oral pre-exposure prophylaxis (PrEP) with oral tenofovir or tenofovir-containing regimens has been shown to reduce the risk of HIV acquisition among numerous populations.[59,60,61,62] WHO guidelines recommend offering oral PrEP to those at substantial risk of HIV infection, defined as an incidence rate of 3 per 100 persons per year or above within specific geographical areas or populations.[63] This level of risk has been seen among certain 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 (AGYW) 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), migrant populations and other epidemic-specific high-incidence populations (e.g., people in fishing communities, migrant workers, etc.). PEPFAR supports WHO guidelines on the use of oral PrEP as part of a package of comprehensive prevention services that includes condom and lubricant promotion, VMMC, and biomedical and structural interventions to reduce vulnerability to HIV infection. In COP20, PEPFAR made oral PrEP a core programmatic requirement and set an overall goal of serving one million people with PrEP in FY 2021. The global scale-up of PrEP continues as a priority in COP21. PrEP is a proven, scalable intervention, which can drastically reduce the rise in new HIV infections in many places where PEPFAR works. Data from the SEARCH study in Kenya and Uganda showed that offering PrEP at scale and prioritizing populations with higher self-assessed risk resulted in a 74% reduction in new infections.[64] It is imperative that COP21

[59] 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

[60] 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

[61] 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

[62] 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

[63] 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/

[64] Koss, C et al. Lower than expected HIV incidence among men and women at elevated HIV risk in a population-based PrEP study in rural Kenya and Uganda: Interim results from the SEARCH study. Oral presentation at the International AIDS Conference, July, 2020. Abstract OAC080. Virtual conference.

continues to take PrEP to scale, moving it to a fully realized intervention focused on getting PrEP to the people that need it. Part of ensuring PrEP is reaching the people that need it is engaging in a thoughtful, evidence-based national target-setting process to ensure that adequate coverage of the priority populations can be achieved with the resources available. The COP21 PrEP guidance also prioritizes linking the scale-up of PrEP with HIV testing in the most at-risk groups and ensuring that all HIV-negative individuals are immediately linked to the full range of prevention interventions including PrEP, in addition to other specialized services such as DREAMS for AGYW, VMMC for uncircumcised adult men, and KP specific prevention services. Through this link to testing, PrEP programs will also contribute to PEPFAR's efforts to ensure that all newly identified people living with HIV are immediately linked to treatment.

Adoption of national PrEP policies are the foundation of quality program implementation. PrEP requires trained providers, quality SOPs, HIV testing, planning and M&E systems, available and sufficient stocks of PrEP, routine inquiry for gender-based violence (GBV), including intimate partner violence (IPV) and referral for GBV services, etc., at a minimum. 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 gender-based violence (GBV) response services per WHO clinical guidelines (see Section 6.2.2.1). Screening for GBV including IPV should be happening at PrEP initiation and, of note, the experience of violence does not make one ineligible for PrEP. Resources have been developed to support the integration of IPV inquiry and referral into PrEP services available at this link: https://www.prepwatch.org/resource/sop-job-aid-ipv-prep-services/.

Scaling up PrEP targets should include scaling up demand creation and usage continuation efforts tailored to groups with increased likelihood of HIV acquisition. Prioritization of risk groups for scaling up PrEP should be evidence-based and, in addition to HIV incidence rates, can be informed by coverage estimates, recency testing, PHIAs, or other survey data. Efforts to increase awareness, health literacy, uptake, and continued use among people who may benefit from PrEP will have unique population-specific requirements. Providers will need tailored information related to PrEP, specifically those in service delivery points not previously targeted such as DREAMS programs, family planning services, post-violence clinical care, and maternal and newborn child health (MNCH) settings which increases access to PrEP for PBFW as well as their eligible partners. Clear provider education and communication with consistent messaging and information are essential to avoid community confusion, mistrust, and misuse of PrEP. Communities cannot receive conflicting messages from various service-providers and

district administrators about the eligibility for PrEP, or directions for use, especially around lead-in times for protective effectiveness and dosage, around interaction with hormones and family planning, etc. In COP21, PrEP should continue to be implemented in HIV service delivery points (including HTS, ART clinics, ANC/PMTCT clinics, DREAMS settings, and KP services) and in a client-centered manner that considers differential service delivery approaches such as decentralized dispensing, MMD, task shifting of PrEP maintenance visits to lay providers and other community and facility-based models. Client-centered approaches should also include the event driven PrEP (ED-PrEP) option for MSM (see below and Section 6.2.6.1) and include stigma reduction education for PrEP providers.

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,[65,66,67] these individuals should be offered and initiated on post-exposure prophylaxis (PEP) as early as possible, ideally within 72 hours of potential exposure. PEP is the use of ARV drugs by people without HIV, who may have been exposed to the virus to prevent HIV 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, countries should have PEP policies and programs in place which align with WHO guidance and support its access and use for all individuals from all populations who might benefit for all potential exposures to HIV. PEP should not be restricted to healthcare providers or others with potential occupational exposure and should not require anyone, including survivors of sexual assault, to file reports with law enforcement in order 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

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

start PrEP, ideally without a gap between PEP and PrEP, if the client is willing and otherwise indicated, in alignment with PrEP guidelines. Clients starting PrEP who have a recent exposure to HIV before full protection from PrEP has been achieved should be considered for PEP[68]. Additional guidance on and references to PEP can be found in Sections 6.5.8 (Integrated Women's Health), 6.6.3 (Gender-Based Violence and Post-Violence Care), 6.6.4 (Orphans and Vulnerable Children), and 6.7.1 (Infection Prevention and Control).

Finally, biomedical HIV 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 quickly progressing through regulatory approvals. A long-acting injectable cabotegravir (CAB-LA) and the Dapivirine Vaginal Ring (DVR), among other ARV-based prevention interventions, could be approved before, during, or soon after COP21. Expansion of access to oral PrEP and the monitoring and evaluation of prevention and PrEP service delivery programs and platforms will provide important context for the introduction of new biomedical prevention interventions, allowing for the availability of new options and adding to client choice. It is important that OUs explore the addition of the DVR, CAB-LA, and other upcoming biomedical prevention interventions as part of the future menu of HIV prevention options, which will lead to maximizing programmatic impact for reducing HIV incidence in vulnerable populations. For a more detailed discussion of the DVR, please see Section 6.2.4.2.

Budgeting for PrEP

As PrEP services are expanded and scaled up in an OU, the costs of demand creation, rolling out and disseminating new PrEP guidelines and training staff in screening, initiation, and maintenance of PrEP effective use should be accounted for in the budget and must be focused. However, once implemented in a country, PrEP activities should be covered within the budget of the service onto which it has been added, such as ANC, DREAMS, family planning services, or key population services. 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.

In most settings, PrEP will be integrated into existing prevention or treatment services for the target population, maximizing efficiency. For example, PrEP for serodifferent couples can be integrated into ART clinics. PrEP for key populations can be integrated into existing prevention services such as KP-friendly facilities and in drop-in centers that provide counseling, testing,

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

condoms/lubricants, STI, and other services. For AGYW, PrEP is included in DREAMS activities in most DREAMS OUs, and should be integrated into family planning, antenatal care, and HIV testing sites. For PBFW, PrEP can be integrated through PMTCT programs, ANC sites, family planning, STI clinics and primary healthcare facilities. Countries should explore private sector partnerships including pharmacies, and delivery services, as well. Targets must be fully consistent with program focus – in other words, in key population programming, no one should be reached without a full evaluation of prevention and treatment needs; thus, all reached individuals need to be tested for HIV as a gateway to 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., governments, other donors). As noted above, it will be important to leverage existing services and linkages in order to ensure efficiency within PrEP programming.

PrEP budgets, whether for PEPFAR or for the national program, should only incorporate what is new or additional. Efficiencies should be sought out where possible. As with the PrEP scale-up in COP20 and continued scale-up in COP21, the primary drivers of the OUs PrEP budget should remain the cost of commodities and the increased volume of patients receiving PrEP services. PrEP budgets may include commodities such as ARVs, 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. Teams should consider the key stakeholders they should engage with on PrEP, including community organizations, host governments, PrEP technical working groups in country, Global Fund, and other donors supporting PrEP implementation. Engagement and coordination with Global Fund on PrEP procurement and other supply chain matters (e.g., warehousing) may reduce costs and affect targeting.

More detailed examples of budget considerations are listed below:

a) Health Communication: Awareness Building and Demand Creation

Awareness building and demand creation can be incorporated into existing prevention and treatment program communications materials and approaches whenever possible. For example, information on PrEP can be incorporated into sexual and reproductive health curricula being developed for and budgeted under HIV prevention activities in AGYW or the finding-men-initiatives. Additionally, discussion of benefits of PrEP use and safety of PrEP

can be incorporated into the morning health talks at ANC/PNC and other MCH clinics to reach PBFW.

b) Laboratory Testing

HIV testing is required to initiate PrEP (must be HIV negative), and WHO recommends that PrEP users be allowed to start PrEP without creatinine testing results. PEPFAR supports initiation of PrEP without creatinine testing. Creatinine testing can be provided at a follow up visit. PEPFAR may support creatinine testing for PrEP clients in exceptional circumstances. After PrEP initiation, HIV testing should be offered every 3 months to monitor for seroconversion. Expected testing volumes for the PrEP program should be shared with the appropriate laboratory and commodity procurement planning units (see commodities below).

c) Personnel

As discussed above, in most settings, PrEP will be added to existing services, and so the amount of additional staff depends on the scale-up and size of PrEP targets and capacity of current staff. HIV testing and 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. To facilitate up-take and scale-up of the PrEP program, PEPFAR partners can consider budgeting for the costs of peer educators/navigators or other community support for effective use of PrEP. One tool for estimating site capacity and costs is PrEP-It.[69]

d) Commodities

Tenofovir, tenofovir/emtricitabine, or tenofovir/lamivudine are all acceptable regimens according to WHO guidelines. OU teams should select a regimen based on regulatory approvals and availability in-country. Monthly expected numbers of patients requiring PrEP drugs, HIV rapid 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. The WHO recommends that PrEP users be allowed to start PrEP without creatinine testing results. Forecasting should include considerations for duration of PrEP use, multi-month dispensing buffer stock, expiry, warehousing and distribution, lead time for delivery to

[69] https://www.prepwatch.org/resource/prep-it Accessed on 09/30/2020

country and delivery to point of service, stock-outs, and influence on the ART supply chain. Additionally, OU teams should confirm whether their country or region is eligible for subsidized procurement of PrEP drugs to potentially reduce procurement costs. Teams should consult commodities experts at 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. One tool for estimating commodity needs is PrEP-It.[70]

Target Setting for PrEP

For countries newly implementing PrEP, in consultation with partner governments, begin by determining which populations, identified by risk group and/or geography, are appropriate to offer PrEP. Various sources of information—including HIV testing yield data, recent survey or surveillance data, 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 in particular, when it is 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 by the use of PrEP. Further validation or modification of the tools for specific sub-populations or contexts may be needed. For MER 2.0 v2.5 the PREP_CURR indicator will help to estimate ongoing PrEP commodity needs and aid in future COP target setting. It calculates the total number of individuals, inclusive of those newly enrolled, receiving PrEP during the reporting period. To understand the impact of PrEP scale-up, OUs should look at PrEP coverage (# individuals initiating (and continuing)/people at risk). Surveillance studies such as PHIAs can provide an avenue for measuring PrEP coverage and HIV incidence at the population level.

[70] https://www.prepwatch.org/resource/prep-it Accessed on 09/30/2020

Tools to facilitate target setting for PrEP have been developed. PrEP-it (https://www.prepwatch.org/resource/prep-it/) 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. We note that a new module has been added to PrEP-it in 2020 to help identify catchment areas where PrEP may be prioritized for AGYW based on cost-effectiveness or cost savings. Population size estimates are also needed to determine denominators for measuring and understanding PrEP uptake and coverage. 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. Recency testing, if available and being implemented in the country, can also be factored in to optimize 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 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 take into account willingness and ability to use and continue PrEP, should be made according to the most recent data found in the literature (links can also be found on http://www.prepwatch.org).

Data on HIV prevalence and select risk factors at the national, sub-national, or district levels can be used with programmatic data to derive population estimates for key populations, serodifferent couples, PBFW, AGYW, and other epidemic-specific priority groups. Data on size and characteristics of vulnerable populations can be used with programmatic data on viral load suppression by sex and by age, and assumptions about PrEP coverage to derive the estimates. Country program data should be used to complete as much as possible. Rates of expected PrEP uptake would be used for a multiplier to estimate targets. The rate of uptake should be based on program results if available. If results are not available, lower rates should be used and increased if justified by results.

PrEP Tools

PrEP materials and an implementation example can be found at the following links:

- Implementation tools: http://www.who.int/hiv/pub/prep/prep-implementation-tool/en/; www.conrad.org/launchingV ; https://www.prepwatch.org/options-tools-resources/

- 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.
- Training materials and M&E tools in several languages (English, French, Spanish, and Portuguese): http://icap.columbia.edu/prep
- PrEP-it may be a useful tool in developing country targets https://www.prepwatch.org/resource/prep-it/
- In some settings, people under the age of 18 may benefit from PrEP. WHO has an implementation tool for PrEP for adolescents and young people which can be found at https://apps.who.int/iris/bitstream/handle/10665/273172/WHO-CDS-HIV-18.13-eng.pdf?ua=1
- Oral PrEP guideline template: https://www.prepwatch.org/wp-content/uploads/2020/11/TemplateLanguage_for_PrEP_Guidelines_Nov2020.docx
- HIV Prevention Ambassador Training Package and Toolkit: https://www.prepwatch.org/resource/ambassador-training-package/
- Oral PrEP eLearning Resource Package: https://hivoralprep.org/
- WHO module may be useful for implementation monitoring and evaluation: https://apps.who.int/iris/bitstream/handle/10665/279834/WHO-CDS-HIV-18.10-eng.pdf?ua=1

6.2.2 Prevention for Adolescent Girls and Young Women (AGYW)

Despite substantial declines in the number of new HIV infections, the epidemic among **females aged 15-24** in sub-Saharan African countries remains significant, though beginning to decline, especially in generalized epidemics. In 2019, adolescent girls and young women (AGYW) accounted for 73% of new infections in young people aged 15-24 years in Eastern and Southern Africa. Since 2014, the number of new infections in AGYW aged 15-24 have declined from nearly 6,000/week to 4,600/week,[71] despite the dramatic increase in 15-24-year-olds due to the youth bulge in sub-Saharan Africa. Adolescent girls and young women (AGYW) in sub-Saharan

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

Africa remain up to 14 times more likely to be infected with HIV than their male peers. The 2019 ECHO trial, enrolling women requesting contraception in Eswatini, Kenya, South Africa, and Zambia, demonstrated incidence rates over 3/100 women years despite inclusion of prevention education at each visit.[72] Incidence rates over 5/100 women years were seen in several South African sites, with the highest rate being 6.8/100 women years.[73] For many countries, comprehensive prevention and treatment programs to break the cycle of transmission from young adult men to younger women must be strategically implemented and scaled. This section will include specific discussion of the DREAMS partnership and complementary prevention interventions offered to AGYW.

6.2.2.1 Pre-Exposure Prophylaxis for Adolescent Girls and Young Women

PrEP and DREAMS. Oral pre-exposure prophylaxis (PrEP) is an essential part of the DREAMS core package as it has a direct effect on HIV acquisition for AGYW. In COP21, all DREAMS OUs should be implementing 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.

- 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 COP20 (see Section 6.2.1 on PrEP tools). 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

[72] Lancet. 2019 Jul 27;394(10195):303-313. doi: 10.1016/S0140-6736(19)31288-7. Epub 2019 Jun 13. 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.
Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial Consortium.

[73] Palanee-Phillips1, J. Baeten2, K. Heller2, K. Ahmed3, J. Batting4, I. Beesham5, R. Heffron2, J. Justman6, H. Makkan7, T. Mastro8, S. Morrison2, N. Mugo9, G. Nair10, N. Philip11, M. Pleaner1, K. Reddy1, P. Selepe7, C. Scoville2, J. Smit5, K. Thomas2, D. Donnell2, H. Rees1, ECHO Trial Consortium. High HIV incidence among young women in South Africa: data from the ECHO trial. Abstract LBPEC23, International AIDS Society Conference, Mexico City, July 2019.

regulatory approvals. OUs may wish to consider these methods which may be available for COP21 implementation and are discussed in Section 6.2.4.2.

All DREAMS OUs are required to include PrEP information and education within their primary package of services for AGYW ages 15-24, and all should include PrEP services 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. 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 whether or not AGYW access PrEP.

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. In countries where PrEP is not available beyond those populations, detailed plans are required to seek policy solutions with local governments. Field teams should also continue to advocate with local governments around lowering the age of consent for PrEP and 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 beneficiaries through community delivery in line with client-centered approaches (e.g., DREAMS on Wheels mobile units and DREAMS Safe Spaces). 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 beneficiaries. DREAMS OUs should identify those strategies that were most successful and work to strengthen and scale these up in COP21, 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. Proxy measures of substantial HIV risk (i.e., ≥ 3/100 incidence/year) in AGYW include geographic areas with highest HIV prevalence and rates

of new HIV diagnoses among pregnant women in the 15–19 and/or 20–24 age groups, high levels of early sexual debut, history of STIs, history of repeated use of PEP, high rates of adolescent pregnancy, transactional sex, history of or current report of AGYW experience of violence, and engagement in sex work. 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, new or suspected cases of intimate partner violence (IPV) must be identified and provided necessary gender-based violence (GBV) response services per WHO clinical guidelines. This must be done by integrating routine enquiry for IPV into PrEP service delivery. Because IPV is a barrier to PrEP initiation and adherence, strategies to mitigate the effects of IPV on PrEP outcomes should be explored after the initial identification within service delivery. Any service providers counseling and prescribing PrEP to AGYW and adult women should follow the guidance provided in Section 6.6.3 on GBV.

6.2.2.2 The DREAMS Partnership

Launched on World AIDS Day 2014, the DREAMS Partnership focuses on the reduction of HIV incidence in AGYW by delivering a multi-sectoral, comprehensive package of evidence-based interventions. The DREAMS core package, illustrated in Figure 6.2.2, 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 four 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. In 2017, after just thirteen months of full implementation, new HIV diagnoses among AGYW declined by more than 25% in over 60% of DREAMS geographic areas. In 2018, new HIV diagnoses among AGYW continued to decline in 85% of these geographic areas. In 2019, the majority of DREAMS geographic areas showed a decline in new HIV diagnoses among AGYW of 25% or

more. 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%. Quantitative and qualitative data analyses by PEPFAR and DREAMS partners (i.e., Population Council and London School of Hygiene and Tropical Medicine through funding from the Bill and Melinda Gates Foundation), are underway to assess best practices that should be scaled, and conversely what should be course corrected for COP21 implementation.

DREAMS IMPLEMENTATION

In COP21, all 15 DREAMS countries should follow the updated DREAMS Guidance, as well as the COP21 specific guidance in this section to refine their programming. All OUs should ensure that the following minimum requirements are met:

- Employ a dedicated DREAMS Coordinator to coordinate interagency DREAMS programming. This person should ideally sit in the PEPFAR Coordination Office.
- Employ DREAMS Ambassadors, through implementing partners, for provincial/regional/district level coordination and oversight.
- Implement evidence-based/informed curricula with fidelity that align with the DREAMS Guidance.

Figure 6.2.1: Average Percent Decline of New HIV Diagnoses in ANC in DREAMS Geographic Areas (2015-2020Q2)

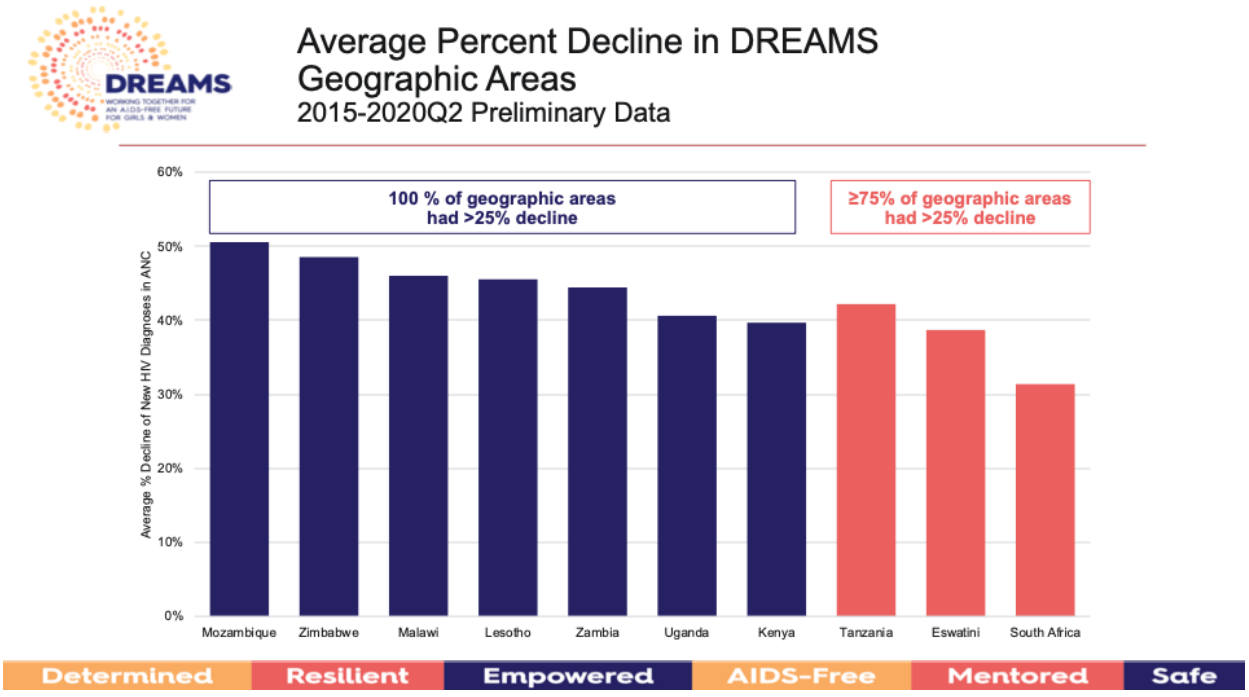
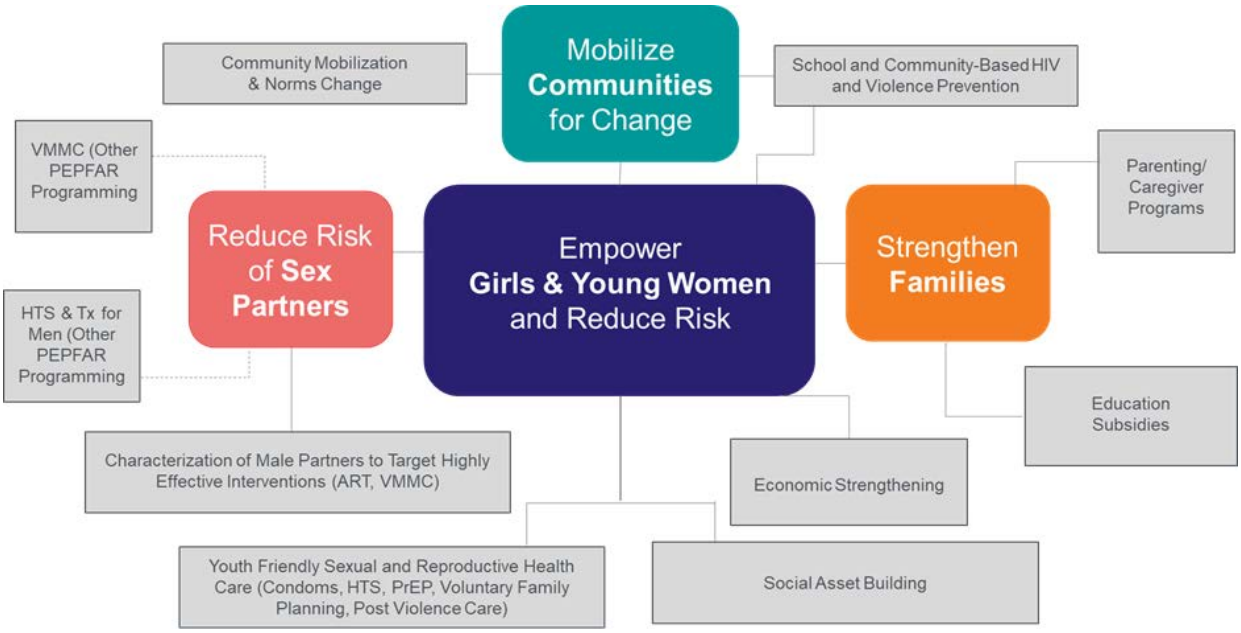


Figure 6.2.2: DREAMS Core Package



Finding and Engaging the Most Vulnerable AGYW. In DREAMS OUs, many AGYW may be vulnerable in some way. Using overly broad eligibility criteria will result in utilizing resources for AGYW who are less likely to acquire HIV, as well as targeting an inaccurately high population making it difficult to reach saturation. In order to reach the AGYW who are most vulnerable to HIV, partners should use particular entry points and eligibility criteria that are based on scientific literature and consistent across partners and SNUs. Scientific literature identifies the following risk and vulnerability factors for HIV acquisition among AGYW:[74,75,76]

- Multiple Sexual Partners

[74]Balkus JE, Brown E, Palanee T, Nair G, Gafoor Z, Zhang J, Richardson BA, Chirenje ZM, Marrazzo JM, Baeten JM. An Empiric HIV Risk Scoring Tool to Predict HIV-1 Acquisition in African Women. J Acquir Immune Defic Syndr. 2016 Jul 1;72(3):333-43. doi: 10.1097/QAI.0000000000000974. PubMed PMID: 26918545; PubMed Central PMCID: PMC4911322.

[75]Santelli JS, Edelstein ZR, Mathur S, Wei Y, Zhang W, Orr MG, Higgins JA, Nalugoda F, Gray RH, Wawer MJ, Serwadda DM. Behavioral, biological, and demographic risk and protective factors for new HIV infections among youth in Rakai, Uganda. J Acquir Immune Defic Syndr. 2013 Jul 1;63(3):393-400. doi: 10.1097/QAI.0b013e3182926795. PubMed PMID: 23535293; PubMed Central PMCID: PMC4131841.

[76] Carol R Underwood, Hilary M Schwandt, Assessing girls' HIV vulnerability: evidence from Botswana, Malawi and Mozambique, Health Policy and Planning, Volume 31, Issue 6, July 2016, Pages 729–735, https://doi.org/10.1093/heapol/czv123

- Sexually Transmitted Infection (STI)
- No or Inconsistent Condom Use
- Transactional Sex
- Experiences of Violence
- Out of School/Never Schooled
- Alcohol Use
- Orphanhood

OUs are required to assess the above factors to determine beneficiaries' eligibility for DREAMS. OUs are encouraged to continue to use additional screening questions designed to build rapport, lessen the stress of sensitive topics, and identify other risk and vulnerability factors that can help to target programming; however, these should not be used as eligibility criteria. All personnel who provide eligibility screening must be trained in establishing rapport, asking sensitive questions appropriately, and providing first-line support and linkages to services when needed (e.g., LIVES, in the case of GBV disclosure). Please review the DREAMS Risk and Vulnerability Assessment section of the DREAMS Guidance for additional detail.

It is essential to identify referral and entry points that target the most-vulnerable AGYW. OUs should map the community (including schools, clinical partners, governmental and social welfare institutions, faith and other community organizations or groups), collaborate with other service providers, use this information to identify referral pathways, and enroll AGYW who may be difficult to reach. All OUs must make active efforts to identify and engage out-of-school AGYW and must collaborate with PMTCT platforms and ANC clinics, as well as HTS, STI and FP settings, to create strong referral networks and enroll at-risk AGYW who meet the DREAMS eligibility criteria. In ANC and FP settings, all AGYW who are 10-17 years old should be linked to DREAMS and those 18-24 years old should be screened for DREAMS eligibility. In HTS and STI settings, all AGYW who are 10-24 years-old should be screened for DREAMS eligibility. IPs should also familiarize themselves with government facilities and other organizations providing services for AGYW living with disabilities and consider these entities as potential entry points for DREAMS. AGYW living with disabilities should be welcome in DREAMS and screened for eligibility. DREAMS teams should also work with KP staff to ensure that AGYW having transactional sex and young women sex workers are properly served. These two technical areas should determine which of these sub-populations are best served by the existing KP program and which should be served by the DREAMS program. Factors to consider include age, type of programming needed to best serve the AGYW, and IP capabilities to handle the

special needs of these populations. DREAMS teams should seek input from KP programs on appropriate points of entry for the sub-populations that will be served by DREAMS. Both DREAMS and KP programs should ensure active referrals between these two programs are in place.

Layering. 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. The following promising practices may be helpful in increasing layering: 1) co-locating DREAMS programs and services; 2) transporting AGYW who participate in safe space activities, as a group, to receive needed clinical services; 3) ensuring facility partners providing services to vulnerable AGYW actively refer to DREAMS community services; 4) bringing clinical services to community programming (e.g., Safe Spaces) on a regular basis; and 5) formalizing MOUs between DREAMS partners to ensure effective linkages and referrals In order to report on layering in the AGYW_PREV indicator, it is required that all DREAMS countries maintain reliable electronic databases that use unique identifiers for each AGYW to track the completion of services/interventions in line with their layering tables. Teams should budget for such a database within their COP21 DREAMS envelope. Please refer to the MER 2.5 AGYW_PREV indicator reference sheet for more information. As part of COP21 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 COP21, OUs currently implementing DREAMS should continue to assess the efficiency of their core package using the DREAMS Efficiency Questions to make this determination.

DREAMS Expansion. In COP21, some countries may want to consider broadening geographic coverage beyond the current DREAMS SNUs to other prioritized SNUs. Consideration of DREAMS geographic expansion should be made by each OU team in consultation with their Chair, PEFPAR Program Manager, AGYW ISMEs, and the S/GAC DREAMS team. Expansion decisions will be approved based on epidemiological need, not solely on the existence of saturated current DREAMS SNUs. Recent data from PHIAs, recency-based surveillance, demographic and health surveys, implementing partners, and other current sources should be used to determine areas for expansion. DREAMS geographic expansion should also take into

consideration alignment with key partner programs (e.g., host country government, Global Fund).

OUs must meet the following criteria to propose geographic expansion in COP21:

- 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 PLHIV (all ages) 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 vulnerable AGYW in a DREAMS SNU have completed the appropriate package of DREAMS interventions for their age group. In order for an SNU to be classified as saturated, this 75% or higher achievement must be reached for each of the three age categories targeted in DREAMS (i.e., ages 10-14, 15-19, and 20-24). Specific guidance on estimating DREAMS saturation is detailed in the Program Completion and Saturation section of the DREAMS Guidance and Process Resources on PEPFAR SharePoint.

DREAMS Maintenance. As DREAMS SNUs reach saturation, country teams should develop and implement maintenance plans. The goal of DREAMS maintenance is to maintain saturation levels across all DREAMS age bands to sustain DREAMS contributions to prevention and 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 **active and visible** DREAMS presence in all current SNUs
- Maintain the core package of interventions by age group, targeting smaller numbers of AGYW

- Account for epidemic control within country and/or SNU
- It is not expected that AGYW are active in the DREAMS program from age 10 to 24 years. An AGYW should exit DREAMS once she has reached program completion, however she can reenroll in the future based on new or recurring vulnerability/risk.

In order to maintain saturation in each DREAMS SNU, country teams should appropriately target to reach the most vulnerable AGYW, including those who "age-in" to DREAMS and "age-up" between DREAMS age bands in maintenance SNUs. In the event of a phased approach to saturation, country teams should target for maintenance for the appropriate age bands. Data sources used to estimate saturation (e.g., census, population size estimates, etc.) should be used to estimate how many AGYW will age up and age into DREAMS to inform targets set in maintenance districts. Please see the Program Completion and Saturation section of the DREAMS Guidance for more information.

Some cost savings in maintenance districts compared with full implementation is needed to consider geographic expansion. Targets will likely be reduced as saturation has been reached which should result in cost savings; however, it may be more costly to reach those AGYW who have yet to complete the DREAMS package because they may be among the hardest to reach. Country teams may decide to continue or expand contextual interventions in maintenance SNUs to sustain community-level changes. Country teams should continue to leverage host government, private sector, and other programs for components of the core package based on AGYW's needs and overall post-epidemic control planning.

DREAMS/OVC Collaboration. Programming using DREAMS and OVC funds should be closely coordinated in order to maximize AGYW-focused prevention activities in all DREAMS SNUs for AGYW 10-17 and young women 18-20 finishing secondary school. This requires co-planning of targets, budgets, and services between DREAMS and OVC PEPFAR staff and implementing partners to ensure that the complex prevention needs of AGYW are met, regardless of the platform in which they are initially enrolled. Based on epidemiological context and program enrollment criteria, teams should work to quantify the number of vulnerable AGYW in each SNU that should be enrolled in DREAMS, enrolled in the comprehensive OVC program as part of a household, enrolled in the OVC preventive program, or enrolled in both comprehensive OVC and DREAMS. 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 comprehensive OVC program for enrollment screening for her family. AGYW

ages 10-20 in the OVC program that need more intensive HIV prevention support should be referred to the DREAMS program for enrollment screening.

Clinical Service Providers. DREAMS partners should train service providers on the provision of client-centered and adolescent-friendly service delivery and emphasize the importance of empathetic, non-judgmental language. Facility partners should seek to establish and improve the quality of adolescent friendly-health services in PEPFAR-supported sites, especially those located in DREAMS districts (refer to WHO and UNAIDS Global Standards for Adolescents).

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 COP21 guidance. Specific examples of partner management for DREAMS include: 1) align DREAMS activities with DREAMS Guidance recommendations (e.g., work with ISMEs to review curricula used by partners and to establish implementation plans for delivering interventions to ensure fidelity); 2) ensure collaboration, coordination, and direct interaction between partners for planning and actively linking AGYW to services to verify layering takes place; and 3) ensure that all DREAMS IPs understand, report to the DREAMS layering database.

COP21 GUIDANCE ON SPECIFIC DREAMS COMPONENTS

Mentoring. Mentors are a critical component of DREAMS and provide intensive support to DREAMS beneficiaries, which enhances the ability of DREAMS OUs to deliver holistic programming that effectively responds to the needs of AGYW. DREAMS Mentors have complex roles that cover a wide variety of responsibilities and tasks, including but not limited to, delivering evidenced-based curricula and activities in Safe Spaces/Girls Clubs, actively linking beneficiaries to services, providing psychosocial support, and tracking and reporting on service completion. Mentors support AGYW both through group mentoring and individual interactions. DREAMS Mentors go beyond session facilitation to develop social networks among beneficiaries, and model supportive and healthy adult relationships for, AGYW.

Mentoring has demonstrated positive impacts on multiple youth development outcomes, including reducing vulnerability to poor reproductive health outcomes and in bridging the gap between AGYW and their communities, that are positioned to support AGYW.[77,78] Not only does

[77] Mentoring Interventions and the Impact of Protective Assets on the Reproductive Health of Adolescent Girls and Young Women. 2017. JoAH.
[78] Making the Most of Mentors Toolkit: Recruitment, Training, and Support of Mentors for Adolescent Girl Programming, 2019. The Population Council, Inc.

the literature emphasize the importance of mentors for the success of programs targeting AGYW, but DREAMS beneficiaries have further emphasized the importance of strong mentors.

In COP21, DREAMS OUs should evaluate their existing processes for mentor selection, training, onboarding and supportive supervision to ensure that DREAMS beneficiaries are being provided with the most effective, evidence-informed mentoring available. DREAMS OUs should find opportunities to enhance mentoring in DREAMS by:

1. **Selection/Recruitment:** Developing standard selection and recruitment processes (e.g., standardized job description) while recognizing the importance of community and AGYW representation to support the selection of the most qualified candidates.
2. **Training:** Ensuring that comprehensive training (i.e., technical skills, group facilitation, recognizing and responding to trauma, and specific curricula mentors will deliver) is provided at the onset and as needed throughout program implementation.
3. **Supervision/Support:**
    - Providing routine supportive supervision for DREAMS mentors that includes shared learning and peer support, and ensuring that they are equipped with standardized tools, SOPs, and referral resources to effectively support beneficiaries and empower mentors in their role; and
4. Defining a manageable mentor to mentee ratio for a cohort, mentor's total number of assigned mentees and minimum standard schedule for mentor to mentee interactions (group and individual), which is important for mentors to build relationships with mentees and provide them with the needed support in a timely and consistent manner.
   Compensation: Providing DREAMS mentors with sufficient remuneration and resources (i.e., wages, transport, airtime allowances) to support their level of effort when engaging with and delivering services to beneficiaries.
5. **Retention/Career Progression:** Creating professional development pathways for mentors to understand their career interests and grow relevant skillsets within the DREAMS program where possible, or helping mentors use their experience to transition to other career opportunities.

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. Strengthening economic interventions continues to be a priority in COP21 with the goal of decreasing AGYW's reliance on transactional sex and strengthening

AGYW's self-efficacy and decision-making power in relationships. In COP21, the following should be included for each age group:

- All 10-14 AGYW should receive financial literacy as part of the primary package. This can be covered by an entire financial literacy curriculum or financial literacy sessions integrated within another curriculum. 10-14 year olds should not receive savings group interventions.
- All 15-19 AGYW should receive basic economic strengthening including financial literacy as part of their primary package. Savings groups should be offered in the secondary package (only if AGYW are earning an income). A subset of 15-19 AGYW should receive a comprehensive package as a bridge to wage employment or self-employment as part of their secondary package. DREAMS programs should clearly define the criteria to determine which AGYW receive either the basic or comprehensive package of economic strengthening services (e.g., those who are out of school, etc.).
- All AGYW 20-24 years should receive basic economic strengthening that includes financial literacy as a part of their primary package. A subset of these AGYW should receive a comprehensive package as a bridge to wage employment or self-employment as part of their secondary package. DREAMS programs should clearly define the criteria to determine which AGYW receive either the basic or comprehensive package of economic strengthening services (e.g., those who are relying on transactional sex as their income). Savings groups should be offered in the secondary package (only if AGYW are earning an income).

For AGYW on both the self-employment and wage employment pathways, OUs should include 4 components based on emerging evidence:[79,80]

- Market assessment to guide skill development and training, with a focus on growing industries and traditionally male-dominated sectors

[79] Carranza, Eliana; Pimkina, Svetlana. 2018. Overcoming behavioral biases in job search : the value of action planning (English). Gender innovation lab policy brief; no.23. Washington, D.C. : World Bank Group. http://documents.worldbank.org/curated/en/962921524744328560/Overcoming-behavioral-biases-in-job-search-the-value-of-action-planning

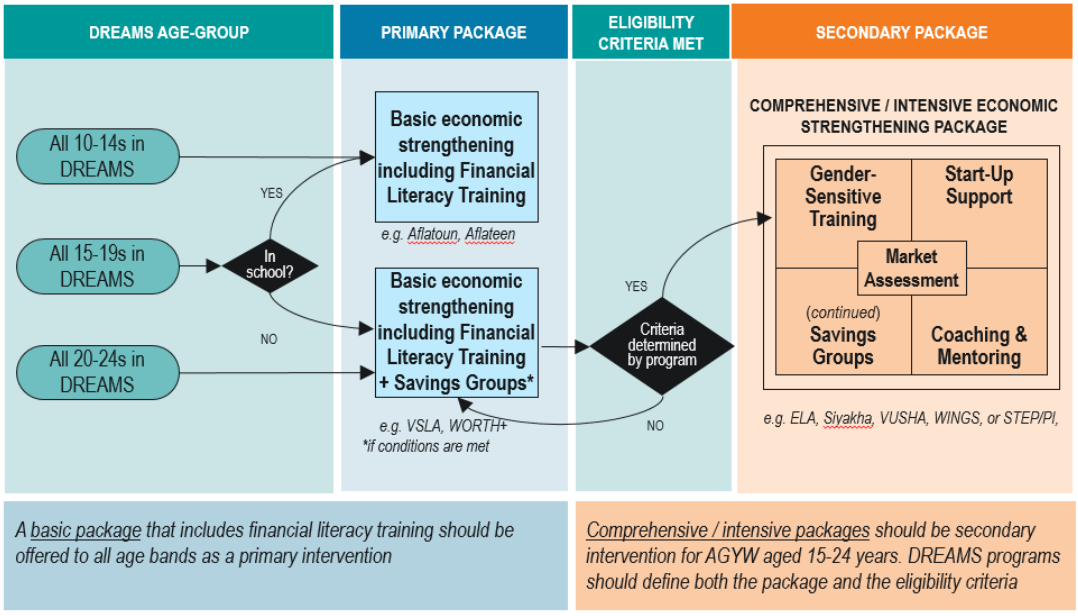
[80] Campos, Francisco Moraes Leitao; Coleman, Rachel Dawn; Conconi, Adriana; Donald, Aletheia Amalia; Gassier, Marine; Goldstein, Markus P.; Chavez, Zenaida L.; Mikulski, Joanna; Milazzo, Annamaria; Paryavi, Maliheh; Pierotti, Rachael Susan; O'Sullivan, Michael B.; Vaillant, Julia. 2019. Profiting from Parity : Unlocking the Potential of Women's Businesses in Africa : Main Report (English). Washington, D.C. : World Bank Group. http://documents.worldbank.org/curated/en/501971553025918098/Main-Report

- Gender-specific training to develop financial literacy, marketable skills (linked to the market assessment), an entrepreneurial mindset (e.g., coping strategies for resilience to setbacks) Actual bridge to employment through either wage employment (e.g., paid internships or jobs) or self-employment (e.g., starter packs or other support for small businesses) with ongoing mentorship for both wage and self-employment.
    - For DREAMS countries with weaker economies entrepreneurship training should be the priority
- Savings groups (only if AGYW are earning an income) for older AGYW (15-24)
- Facilitating access to, and acceptance in, social and business networks

In COP21, five comprehensive models are approved for DREAMS implementation to meet the bridge to wage employment/self-employment requirements — VUSHA, Siyakha, STEP/PI, WINGS, BRAC ELA. Other comprehensive models may be considered for use in DREAMS, following review from AGYW ISMEs using the following criteria:

- Alignment with 4 required components (listed above)
- Prior performance and evidence of effectiveness (e.g., study, evaluation, program data)
- Availability of training/technical assistance and approach to scale-up among DREAMS IPs

Figure 6.2.3: DREAMS Economic Strengthening Pathways



6.2.2.3 AGYW Prevention in Non-DREAMS Countries

Countries without DREAMS funding should examine HIV incidence and prevalence in AGYW ages 9-24 years before dedicating significant resources to prevention in AGYW. Countries should examine which geographic areas have the highest HIV prevalence and other indicators such as age of first sex, rates of adolescent pregnancy, rates of sexually transmitted infections, rates of GBV, and number of girls 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 to the extent possible based on budget. Countries should also focus efforts on preventing HIV and sexual violence among 9-14-year-old boys and girls using evidence-based interventions (see Section 6.2.3 for more detail).

Resources: Beyond this COP21 guidance, teams implementing prevention activities for AGYW should refer to these additional resources to guide programming (for both DREAMS and non-DREAMS countries). All resources are available on the DREAMS SharePoint page.

- Current DREAMS Guidance
- YouthPower Action AGYW Employment Slides
- MER 2.0 (v2.5) AGYW_PREV Indicator Reference Sheet

6.2.3 Primary Prevention of HIV and Sexual Violence for Vulnerable 9-14 Year Olds

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 risk starts young, given that both sexual violence and early sexual debut (occurring at the age of 15 or younger) persist at unacceptably 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 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. Over the past three years, PEPFAR has responded to these data by increasing its focus on the primary prevention of sexual violence and HIV among

9-14-year-olds, in order to try and prevent these vulnerabilities from ever occurring. Additionally, PEPFAR is reinvigorating its work with community leaders (i.e., faith, traditional, civic, etc.) to prevent and respond to sexual violence against children (SVAC) through Justice for Children, as part of the Faith and Community Initiative.

Approved Programming. In COP21, OUs should continue using the evidence-informed modules 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. For curricula being implemented across multiple countries (e.g., Sinovuyo, IMPower, etc.), S/GAC is working with curriculum developers to integrate the modules; while this process is underway, please continue to implement these curricula. All OUs must use approved curricula for program delivery. The following curricula have been approved:

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

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.

As part of the Faith and Community Initiative (FCI) Justice for Children objective, S/GAC has developed an SVAC 101 tool to support all ten OUs in providing community leaders with a standardized, basic level of education about sexual violence against children so those leaders can support the initiative in their communities. See Section 6.2.3.1 for more details on Justice for Children.

Implementation Considerations. Interventions preventing sexual violence and HIV for 9-14-year-olds should be implemented through a coordinated effort by OVC and DREAMS platforms. These interventions should be implemented in DREAMS SNUs, as well as other PEPFAR SNUs with high incidence and/or prevalence of HIV and sexual violence against children and

adolescents. Implementation should occur in school and/or community settings (e.g., community, including faith networks, youth sports clubs, community centers).

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, including efforts under Justice for Children as applicable. 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., 9-14-year-old girls not in DREAMS and 9-14-year-old boys) should be targeted and budgeted for in the OVC program. However, consideration should be 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 could benefit).

Given that primary prevention of sexual violence and HIV interventions discuss sensitive topics, facilitators must be trained in how to respond to disclosure 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 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 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 9-14-year-old boys (and 9-14-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 9-14-year-olds please see Section 6.6.4. All primary prevention of sexual violence and HIV interventions for 9-14-year-olds should be reported under the OVC_SERV indicator (see MER 2.5 guidance).

Budgeting Considerations. COP20 funding for primary prevention interventions should be budgeted under the Prevention: Primary Prevention of HIV and Sexual Violence financial classification.

6.2.3.1 Justice for Children

Justice for Children (JfC), the second priority of PEPFAR's Faith and Community Initiative (see Section 6.6.5), aims to prevent the perpetration of sexual violence against children (SVAC), and to facilitate disclosure, reporting, and appropriate system responses to cases of SVAC with a focus on holding perpetrators accountable. JfC consists of four activities: 1) education about sexual violence against children for faith, traditional and other community leaders; 2) the implementation of evidence-based interventions to complement DREAMS and OVC activities; 3) establishing child safeguarding policies for all implementing partners (primes/subs) receiving funding under this initiative; and 4) engagement of the justice sector to determine ways in which PEPFAR can support and complement efforts for responding to cases of sexual violence against children. Implementation tools, such as the Sexual Violence Against Children 101 education module for faith and community leaders, were centrally developed and tailored to local context. Country teams made progress with rolling-out these activities in COP19 and will build on this foundation in COP20. In COP21, JfC activities should be fully integrated into core COP planning. OUs are encouraged to continue successful aspects of JfC using core COP funding (e.g., DREAMS, OVC) and/or external funding. Teams should work with S/GAC and their AGYW/OVC ISMEs to inform continued JfC planning and implementation based on performance documented in semi-annual JfC narratives. For detailed information on how to implement the four activities of Justice for Children and how to monitor progress, please see the Justice for Children Implementation Guide.

6.2.3.2 Violence Against Children Surveys (VACS) and PEPFAR Programming

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 should clearly inform COP21 programming for DREAMS (Section 6.2.2.2), OVC (Section 6.6.4), primary prevention of sexual violence (Section 6.2.3), Justice for Children (6.2.3.1), and gender-based violence and post-violence care (Section 6.6.3). 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 include the conduct of a VACS survey as part of the COP21 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.

6.2.4 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 primary prevention services across the life-span 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 postpartum period). 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.

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 6.2.4.2), integrating women's health services (including family planning) (Section 6.5.8), GBV trauma-informed services (Section 6.6.3), cervical cancer screening (Section 6.5.4) 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 (AGYW), 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.

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 keep mothers healthy and alive on ART and 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 PBFW (Section 6.2.4.2)
- Prevention of unintended pregnancies among women living with HIV by providing voluntary family planning counseling and services, including integration into ART services and in the postpartum setting (Section 6.5.8)
- Identifying all pregnant and breastfeeding women (PBFW) living with HIV as early as possible, including through HTS at ANC1 and retesting as appropriate for a country's context
- 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 in pregnancy and during BF (Section 6.5.5.1)
- Longitudinal tracking and retention support for women living with HIV (WLHIV) and HIV-exposed infants (HEI)
- Intensifying maternal retesting during pregnancy and breastfeeding (as appropriate for a country's context) in maternal newborn and child health (MNCH) settings (Section 6.3.5)
- Optimizing HIV prophylaxis for HEI (Section 6.5.1.1) and early identification and treatment of HIV-infected infants with increased infant virologic testing/early infant diagnosis (Section 6.3.1.3)

To prevent new HIV infections among PBFW, who are at substantially increased risk of becoming HIV infected if exposed during late pregnancy, postpartum and breastfeeding periods, priority actions should also focus on: 1) counseling on the heightened risks of HIV infection during this period; 2) couples-based services to promote scaled-up testing and treatment of male partners; 3) expanded use of self-testing kits for both women and men; 4) greater access to voluntary medical male circumcision; and 5) use of PrEP in serodifferent couples or in regions with high HIV prevalence (Section 6.2.4.2).

Pregnant and breastfeeding adolescents and young women (AGYW) 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.[81,82] Pregnant and breastfeeding AGYW are also at increased risk of poor outcomes including mother to child transmission of HIV, maternal mortality, and stillbirth.[83] Age-appropriate interventions are needed to address these ongoing disparities. Services for pregnant and breast feeding AGYW include: 1) actively screening young mothers for HIV risk-factors and sero-conversion during pregnancy or the breastfeeding period, infant immunization visits, family planning visits, and offering PrEP to women who test negative for HIV; 2) adolescent friendly PMTCT services including peer led activities specific to young mothers (e.g., age-appropriate mentor mothers for AGYW and young mothers clubs); 3) flexible ANC schedules; 4) MCH staff who are trained to provide adolescent- and youth- friendly services; and 5) POCs/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 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, priority responses should also include: 1) 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; 2) full access to better-tolerated and more robust treatment (e.g., dolutegravir); 3) use of differentiated service delivery models to facilitate access to treatment, including assessing eligibility for 3-6 multi-

[81] Ronen K, McGrath CJ, Langat AC, *et al*. Gaps in Adolescent Engagement in Antenatal Care and Prevention of Mother-to-Child HIV Transmission Services in Kenya. *J Acquir Immune Defic Syndr*. 2017 Jan 1;74(1):30-37.
[82] Woldesenbet S, Jackson D, Lombard C, *et al*. South African PMTCT Evaluation (SAPMCTE) Team. Missed Opportunities along the Prevention of Mother-to-Child Transmission Services Cascade in South Africa: Uptake, Determinants, and Attributable Risk (the SAPMTCTE). *PLoS One*. 2015 Jul 6;10(7):e0132425.
[83] Fatti G, Shaikh N, Eley B, Jackson D, Grimwood A. 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. *S Afr Med J*. 2014 Dec;104(12):874-80

month drug (MMD) dispensing; 4) mother-to-mother mentoring, counseling, case management (including active tracing of mother-infant pair (MIPs) who miss appointments) and other community-based support for PBFW (including discussion and planning for the estimated 18-month to 2-year time period of follow-up of MIPs); 5) community mobilization to boost male involvement in partner's PMTCT services; 6) engagement of communities of women living with HIV; and 7) facilitating processes for medical record sharing between PMTCT service delivery points and ART clinics to ensure continuity of care.

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 mother-to-child 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 mother-to-child HIV transmission is extremely low.[84,85] To attain this near zero risk of MTCT for WLHIV, programs should provide client education and service delivery that focus on: (1) testing and starting WLHIV on ART prior to conception, (2) supporting pregnancy planning for WLHIV on ART, and (3) ensuring viral suppression throughout pregnancy and breastfeeding. These educational and service interventions are needed at both PMTCT service delivery points as well as in the community and general ART clinics to ensure that women know their status, start ART and are virally suppressed prior to conception or as early as possible in the pregnancy.

The WHO has introduced validation criteria for elimination of mother-to-child HIV transmission (EMTCT) 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 EMTCT case rate criterion (HIV MTCT rate of $\leq$5%; $\leq$ 50/100,000 new pediatric HIV infections due to MTCT).[86] 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 EMTCT strategies and provide technical input to the EMTCT/PTE processes, where relevant.

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[84] Mandelbrot L, Tubiana R, Chenadec Jl, Dollfus C, Faye A, Pannier E, et al. No perinatal HIV-1 transmission from women with effective antiretroviral therapy starting before conception. Clinical Infectious Diseases. 2015;61(11):1715-25

[85] Townsend CL, Byrne L, Cortina-Borja M, Thorne C, de Ruiter A, Lyall H, et al. Earlier initiation of ART and further decline in mother-to-child HIV transmission rates, 2000-2011. AIDS. 2014;28(7):1049-57

[86] WHO global guidance on criteria and processes for validation: Elimination of Mother-to-Child Transmission of HIV and syphilis, 2nd edition, November 2017. http://www.who.int/reproductivehealth/publications/emtct-hiv-syphilis/en/

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. This should also include the procurement 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 biological (i.e., altered hormonal levels, untreated 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.[87] In addition, women who are infected with HIV during pregnancy have a high risk of transmitting the HIV virus to their infants. In 2019, UNAIDS estimated that there were 160,000 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.[88] Close to one third of infant infections in SSA are estimated to occur because of acquisition of HIV during pregnancy and breastfeeding.[89] 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, and PrEP as an essential component of the PMTCT prevention toolkit for HIV-negative women.

[87] (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).
[88] https://data.unicef.org/wp-content/uploads/2019/11/HIV-snapshot-Global_2019.pdf
[89] https://www.unaids.org/en/resources/documents/2020/start-free-stay-free-aids-free-2020-progress-report

Implementing PrEP in MNCH settings is a priority in COP21 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 (population incidence rates > 3 per 100 persons per year).[90] PEPFAR programs whose country or regional PHIA data identifies HIV incidence of 1% or greater in women of reproductive potential age (15-49) are strongly encouraged to incorporate PBFW as an independent, higher-risk population to be targeted with prevention services including PrEP and not just as part of a serodifferent couple. Countries that do not meet this rate of incident infections in women of reproductive potential age, should continue to screen PBFW for risk, as done with the general population, and offer it to those who are deemed higher risk.

There are multiple identified barriers to implementation of PrEP services for PBFW. A 2019 PEPFAR survey to the field showed that only 45% of respondents (20 responses from 17 countries) noted that PBFW were included in their PrEP guidelines, with ½ of these as a stand-alone higher risk population.[91] Of those countries where PBFW are being included in PrEP programs, the major barriers to success include 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[92] noted that "pregnancy outcomes and early infant growth did not differ by PrEP exposure" thus the safety of PrEP during pregnancy should be emphasized as part of the provider training and demand creation efforts specific to this population.

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

- Training of MNCH and family planning providers and peer supporters/mentor mothers on PrEP for PBFW
- Community engagement, education, and adherence support for younger women

[90] http://www.who.int/hiv/pub/arv/arv-2016/en/

[91] PrEP in PBFW Survey to the Field https://docs.google.com/forms/d/1jH718RUwspBIYesRCVHti6T3QB9QfP4oymGbeI8oKWc/edit#responses

[92] 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.

- Demand creation for PrEP in PBFW, including addition of PrEP efficacy and safety messaging and the risk of newborn HIV infection during breast feeding in the educational morning talks provided by health care providers at MCH and family planning clinics
- 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
- PrEP service delivery and training tools that include considerations for PBFW including questions about a client's exposure to or risk of gender-based violence and intimate partner violence
- Active monitoring and surveillance of PBFW receiving PrEP, including adverse events reporting systems for information on the safety and efficacy of PrEP in PBFW

PBFW should also be included in PrEP programming in non-MCH settings, such as 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 are also AGYW, programs should consider issues unique to this vulnerable population to enhance quality and access to PrEP and other HIV prevention services, including through DREAMS platforms (see Section 6.2.2).

PrEP Initiation and Retention for 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 men whose female partners (positive or negative, AGYW or older) are pregnant and breastfeeding should be employed particularly in areas with high HIV prevalence rates. 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, which will vary by regimen type. Median time to suppression to less than 50 copies/ml was 60 days for those on integrase strand inhibitors (such as dolutegravir (DTG) and raltegravir (RAL), 137 days for those on NNRTIs (such as efavirenz

(EFV)), and 147 days for those on protease inhibitors (such as lopinavir/ritonavir). [93] Thus, if PrEP is to be discontinued after the partner obtains documented viral suppression, PrEP will likely be needed for a shorter time period for partners of those initiating Dolutegravir regimens. 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 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.

During FY20 PEPFAR operating units identified over 2 million HIV-negative people during index testing campaigns. Those 2 million HIV-negative clients are, by the nature of their connection to an HIV-positive index client, at elevated risk of acquiring HIV. This presents a population who should be screened for and offered prevention services including PrEP as an effective and immediate prevention measure. Index testing not only helps fast-track individuals 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 twofold 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. PEPFAR teams should consider how they can utilize differentiated service delivery models for initiating and retaining populations at highest risk of HIV acquisition on PrEP 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.

Injectable Cabotegravir and the Dapivirine Vaginal Ring

[93]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

A long-acting injectable cabotegravir (CAB-LA) and the Dapivirine Vaginal Ring (DVR), among other ARV-based prevention interventions, are currently progressing through regulatory approvals and could be approved before, during, or soon after COP21.

In November 2020, HPTN 084, a trial comparing long acting injectable cabotegravir (CAB-LA) to oral Truvada was stopped early because of superior efficacy in the cabotegravir arm, with an 89% reduction in HIV acquisition. CAB-LA, delivered by injections every two months, provides a discrete, woman-controlled option. Publication of more detailed results is eagerly awaited. The DVR, or "the Ring," is a woman-controlled prevention option which when placed into the vagina, slowly releases the antiretroviral agent Dapivirine over 28 days. Double-blinded, randomized trials demonstrated a 27-37% reduction of risk of HIV acquisition among women using the DVR compared to the placebo ring.[94,95] In the ASPIRE study, risk of HIV was reduced by 56% among women over age 21 but no reduction was seen among women under 21, likely related to decreased adherence to use of the ring in this younger population. In the RING study, no difference in efficacy was seen among different age groups. Both of these trials conducted open label extension studies in which all women were provided with the option of the DVR. The risk of HIV infection in the open label studies was reduced by over 50% compared to the expected background incidence in the population.[96,97] In July 2020, the European Medicines Agency (EMA) adopted a positive scientific opinion for use of the DVR to reduce the risk of HIV-1 infection, among women 18 years and older in combination with safer sex practices when oral PrEP is not used, cannot be used, or is not available. This opened the door to WHO prequalification which was granted in November 2020 and will help guide national and global procurement decisions, pending country regulatory approvals for the DVR's use. Based on current data, daily oral PrEP is expected to have at least 75% protective efficacy from HIV

[94] Baeten JM, Palanee-Phillips T, Brown ER, Schwartz K, Soto-Torres LE, … Nel A, Rosenberg Z, McGowan I, Hillier S; MTN-020–ASPIRE Study Team. Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. N Engl J Med. 2016 Dec 1;375(22):2121-2132. doi: 10.1056/NEJMoa1506110. Epub 2016 Feb 22. PMID: 26900902; PMCID: PMC4993693.

[95] Nel A, van Niekerk N, Kapiga S, Bekker LG, Gama C, Gill K, Kamali A, Kotze P, … Vangeneugden T, Van Baelen B, Rosenberg Z. New England Journal of Medicine. 2016; 375:2133-43.

[96] Baeten JM, Palanee-Phillips T, Mgodi N, et al. High uptake and reduced HIV-1 incidence in an open-lable trial of the dapivirine ring. Presented at the Conference on Retroviruses and Opportunistic Infections, 2018, Boston, MA, abstract 143LB.

[97] Nel A, van Niekerk N, van Baelen B, Rosenberg Z. HIV incidence and adherence in DREAM: an open-label trial of the dapivirine vaginal ring.

infection in women with high adherence, but women with low adherence had no benefit in several trials.[98,99]

The COP21 expansion of access to oral PrEP combined with communication within the OU as to the inclusion of CAB-LA and/or the DVR in country prevention policies will provide an important platform for the introduction of these and other new biomedical prevention intervention options. Oral PrEP, where available, should be offered to all women who are at high risk of infection. As CAB-LA and DVR products become available, like oral PrEP, they should be presented with thorough information on all available HIV prevention options, including each method's relative efficacy and safety, as well as counseling and adherence support, allowing for an informed client choice regarding a biomedical HIV prevention option. Those who prefer an alternative to oral PrEP or are unable to adhere to daily dosing, may soon have new options to consider as part of a comprehensive biomedical prevention program. Building on family planning research, it is anticipated that by expanding access to and use of a range of HIV prevention products, saturation can be more effectively achieved.[100,101] For COP21, especially in countries where CAB-LA and DVR trials occurred, OU teams are encouraged to identify implementation needs for the addition of these agents as part of the menu of HIV prevention options for women. Possible areas to consider OU engagement are regulatory approval, enabling policies, service provider education, service delivery channels, and demand generation. For more information about the DVR, refer to these sites: https://www.ipmglobal.org/our-work/our-products/dapivirine-ring or https://www.prepwatch.org/about-prep/dapivirine-ring/.

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.

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[98] Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, … Bangsberg D, Haberer JE, Stevens WS, Lingappa JR, Celum C; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med. 2012 Aug 2;367(5):399-410. doi: 10.1056/NEJMoa1108524. Epub 2012 Jul 11. PMID: 22784037; PMCID: PMC3770474.

[99] Corneli AL, Deese J, Wang M, et al. FEM-PrEP: adherence patterns and factors associated with adherence to a daily oral study product for pre-exposure prophylaxis. *J Acquir Immune Defic Syndr*. 2014;66(3):324-331. doi:10.1097/QAI.0000000000000158

[100] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4168565/pdf/203.pdf

[101] https://archives.who.int/eml/expcom/expcom15/applications/sections/ContraChoiceReview.pdf

This has been an option for accessing PrEP identified by women from many contexts.[102,103] It is important to note that there are some differences in the approaches and requirements for provision of PrEP and FP services, so field programs should carefully review service delivery protocols and capacity of health providers before initiating a new integrated activity. 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. Resources to support PrEP provision to PBFW are available on PrEPWatch: https://www.prepwatch.org/resource/prep-for-pregnant-and-breastfeeding-women/

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 8 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 relative ease of transmission from insertive to receptive partners, 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. All persons at substantially increased risk for HIV should be referred for prevention services. For men, these services include education and self-efficacy training, condom

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

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

distribution, voluntary medical male circumcision (VMMC), and pre-exposure prophylaxis (PrEP).

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.[104] PEPFAR has supported over 25 million VMMCs since the program's inception across priority countries in Eastern and Southern Africa. Recent technical and programmatic review by WHO reaffirms continued support for VMMC as a critical HIV prevention intervention.[105] In addition, recent analyses from the PEPFAR-supported Population-based HIV Impact Assessments (PHIAs) have closely looked at both male circumcision status and HIV incidence, and these data should inform VMMC prioritization to address geographic coverage gaps and maximize the impact of VMMC by targeting men in geographic areas with the lowest MC coverage and the highest HIV incidence. Additional data sources, such as military SABERS, should also inform prioritization. Countries should validate the inputs to DMPPT2 (www.vmmcipt.org/) against survey and VMMC program data to ensure that the coverage and target estimates are as accurate as possible. DMPPT2 functionalities are being transitioned into UNAIDS annual estimates process with MC coverage estimates outputs from DMMPT2 exported into the Naomi model or Spectrum. Transition work is ongoing and expected to be completed by the end of 2020, in time for the UNAIDS Estimates workshops and annual COP planning. Field support funds may be required to support additional TA beyond the COP planning period to address data issues/discrepancies identified through MC 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, STI screening as clinically indicated (with deferral of surgical circumcision until treated) and treatment/referral, and linkage to care and treatment for those testing positive in HTS, post-surgery follow-up, including adverse event

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

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

assessment and management, distribution of condoms, HIV testing prior to circumcision for men and their partner as clinically indicated.

Men with ongoing high-risk sexual behavior testing HIV negative for HIV should be offered or referred for PrEP.

Age Considerations: Since VMMC is an elective procedure, safety is the primary consideration. In COP20, PEPFAR changed the eligibility for VMMC to age 15 years and above or at least Tanner (sexual maturation) stage 3 to minimize risks. Despite standardized Tanner staging criteria, there is varying knowledge of these criteria among providers, and standard application of them is unlikely. Therefore, this same minimal age requirement of 15 remains in place for COP21 but the option of circumcising a client under age 15 if they have reached a particular Tanner stage **is no longer applicable**. Not all 15-year-olds will have reached physical maturity and any client with immature genitalia should not be circumcised. No infant circumcision activities will be supported in COP21. Health care providers should strive to postpone non-emergency invasive and irreversible interventions like VMMC until the child is sufficiently mature to provide informed consent; 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).[106] 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. Programs may continue to propose for Chair approval exceptions to the age policy for the routine use of **only** the ShangRing device in adolescents aged 13-14 years, if voluntary truly informed assent can be obtained from the adolescent, in addition to consent of the parent/guardian. Considerations for use of Shang ring in this age group should be discussed with HQ technical experts. Programs must include plans for long-term enhanced safety monitoring in this group with complete follow up within 14 days, recognizing that very large numbers of procedures may be needed to identify any increased risks. The Shang ring mechanism may protect against risks of glans injury and fistula for immature genitalia, but sufficient volumes have not yet been done in VMMC settings to rule out other injury risks in young adolescents that may be similarly uncommon, especially during the device's in situ period.

[106] 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

For districts where 80% saturation has been reached, VMMC services can continue as long as demand remains steady in adult males. Given the wide confidence bounds for estimates, services should be based on demand. For districts where 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 not lost 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 at https://www.who.int/publications/i/item/978-92-4-000854-0.

Additional measures to minimize VMMC complications and notifiable adverse events include limiting case load/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 include this suture/needle combination as standard.

Additional Considerations

- Prioritization for VMMC services should use PHIA or other recent nationally representative survey data of MC coverage as its primary basis where available, supplemented by other available tools and district level data. Age prioritization should also use incidence data from these surveys where available, including those showing higher HIV incidences in men older than 30 years, so that MC program efforts include age groups with the highest HIV incidence for rapid impact.
    - 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.
    - Programs should link with ongoing initiatives directed at finding men such as the Faith and Community Initiative 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.
- Given low prevalence of HIV infection among VMMC clients, approaches to voluntary HIV testing in VMMC programs should follow existing guidance on targeting testing

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. However, testing should remain available to any VMMC client upon request. At this point, programs should show a clear track record of or plan for decreasing testing among low-yield clients. Planning for testing in VMMC should be included in the overall COP planning to improve testing yields across modalities and should follow the yield standards applied to other modalities. VMMC sites should establish relationships with ART sites to assure that immediate linkage to treatment is available for those testing positive.

- For those presenting between age 10-14 who are not eligible for immediate VMMC, age appropriate sexual and reproductive health education and tetanus vaccine (if DPT coverage was under 70% in that birth cohort) should be provided with host country funding along with education on returning for VMMC at age 15.
- 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.[107] In addition, up to 70% of MSM in Africa also have sex with women. While more data are needed, KP programming should consider ways to integrate VMMC education and demand creation into their efforts.
- Programs are required to ensure and track linkage of those HIV+ males identified to care and treatment, following the best practices for linkage and ART initiation in use for other testing modalities in the country.
- Programs should provide quantitative evidence of substantial shifts toward reusable instruments to justify their proposed VMMC commodities budgets.
- Use of reusable instruments must be accompanied by a detailed and robust plan and budget to ensure proper instrument reprocessing.
- 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. Successful examples of VMMC demand creation can be found on the PEPFAR Solutions Platform.

[107] 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.

- Any incentives given to clients for VMMC uptake should be non-coercive in type and quantity, designed to overcome practical barriers to obtaining MC such as 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.[108]
- PEPFAR programs should continue to support host 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.** More information is available on PEPFAR SharePoint 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.
- Patient safety is 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 work within broader patient safety efforts in countries. Infection prevention standards should be maintained (see Section 6.7.1).
    - Initial VMMC training processes should include systems to readily identify and document initial training completion, and need for refresher training, at the individual provider level. The VMMC Online Training Hub (OTH) uses the learning management systems (LMS) to track trainees' completion, courses done, location and needs, and it maintains a database of trainees for future use and planning by site managers.
    - As severe AEs are rare, facility managers should provide reminder/update 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.

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

- 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 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 IP's should provide support for referral and follow up care.
- The lot number and batch of local anesthetic should be recorded on the VMMC client record so that in case of adverse events the lots 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 pursue all root and contributing causes. NAE evaluations can help to identify providers needing retraining or removal and to identify refresher training needs for all providers.
- The enhanced ShangRing safety monitoring and updated NAE reporting form which started in COP20 (active surveillance in 10-14-year-olds and reporting all device displacements as NAEs) will continue in COP21

6.2.5.2 Condoms and Lubricants

Condoms and lubricants play an important role within the context of HIV prevention, care, and treatment efforts. In an era of multiple prevention options, condom promotion and distribution are most effective when integrated with other services as part of an "informed choice" and client-centered approach to prevention. Condoms (and lubricants) should be strategically integrated into VMMC, HTS, care and treatment, PrEP, DREAMS, programs to engage men, KP service delivery interventions, and other community venues. 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. 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, and sources of funding (including from host countries) for condoms to determine specific needs for commodities and to plan for transition to government ownership.

In addition, OU teams should be aware of and ensure that the Country Coordinating Mechanism (CCM) leverages the following information from the Global Fund (GF) in the next grant writing process available at https://hivpreventioncoalition.unaids.org/resource/developing-effective-condom-programmes-technical-brief/.The GF is prioritizing investment in condom programming in the next funding cycle and recognizes that investment in condom programming needs to improve. Specifically, greater attention must be paid to both the level of investment and the nature of this investment, particularly related to host country coordination, leadership, and market stewardship.

To address these challenges, the GF introduced two strategies for the most recent funding cycle. First, it introduced a new intervention in its Modular Framework that addresses condom coordination and stewardship functions. The GF explicitly created a funding opportunity for applicants to apply for funding to address the need for greater coordination, market stewardship, and better data systems to monitor need, supply, use, preferences, and demand-side barriers to condom use. It also prioritized demand creation activities. Because this intervention area was new, applicants were supported with guidance from the Global HIV Prevention Coalition. Existing interventions that focus on last-mile condom distribution (for example through community-based outreach) also remained.

In addition to these interventions in the Modular Framework, that were open to all applicants, the GF Board approved catalytic funding (estimated at USD $5 million complemented by matching funds) for investment in condom leadership and market stewardship in four countries. This funding will catalyze stronger national leadership, support condom strategy development and improve data systems for condom programming in Uganda, Zambia, Mozambique, and Malawi. The catalytic funding will also support demand creation programs in these countries.

Effective and efficient supply solutions: USG support for procurement and supply of free condoms and lubricants should be based on realistic forecasts and quantification grounded in current use, actual demand, and realistic forecasts for growth in demand. Procurement 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 geographies. Coordination with other donors, Ministry of Health, supporting agencies (particularly UNFPA and GF), and implementing partners is necessary to align and optimize long-term forecasts and supply plans.

Tools for forecasting condom needs have recently been developed by UNAIDS and UNFPA, available at https://hivpreventioncoalition.unaids.org/resource/condom-needs-and-resource-requirement-estimation-tool/

Procured condoms and lubricants should leverage the host country's public sector supply chain to avoid the creation or support of parallel distribution systems; however, countries may realize the importance of leveraging civil society organizations to distribute condoms (and lubricants) to key and priority populations. Public health facilities are an important point to access free condoms. Community distribution should be coordinated with the public sector system with the objective of triggering demand for condoms, attracting new users, communicating the importance of condoms, and referring users to access condoms at health facilities, pharmacies, and/ community sites. Community distribution should target key and priority populations, including young people, who may face stigma in clinical settings.

PEPFAR's goal is to ensure high levels of use, equitable access to, and sustained demand for condoms and lubricants among key and priority populations and low-income groups. Overall, the vision of success for condom programming in PEPFAR includes:

- Effective and impactful host-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.
- Educational and promotional programming that emphasizes the utility of condoms in preventing pregnancy and other infectious diseases, and that addresses beliefs and norms that hinder effective condom use, such as "condoms are not acceptable in marriage" and "condoms remove pleasure"
- Adequate and sustainable supplies of free condoms and lubricants specifically targeting key and priority populations and low-income groups
- A total market approach (TMA) for each country that improves effectiveness, efficiency, and sustainability of various condom and lubricant market (e.g., public, social marketing, and commercial) by addressing the universe of need for condoms and lubricants (for HIV prevention and reproductive health, i.e., dual protection), levels of use, equity among users, and sales of condoms and lubricants in appropriate settings that decreases reliance on external funding while growing use
- Condoms and lubricants thoughtfully and effectively integrated into existing prevention, care, and treatment platforms.

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 interventions: USG support should ensure effective integration in the context of other prevention and treatment efforts (VMMC, care and treatment, PrEP, DREAMS, ANC, community programs to engage men, and KP service delivery interventions), including condom and lubricant distribution, and promotion/counseling in community and clinical settings Effective counseling will overcome specific barriers to condom use including skills for proper use, self-efficacy to negotiate condom use, and creating social and gender norms to support condom use. Free condoms should be distributed at health facilities providing prevention, care and treatment services. Self-reported condom use should be measured periodically in addition to numbers of condoms distributed.
- 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. OU's should identify a "market facilitator" to support a TMA that ensures that the following: each country has a condom programming vision, strategic framework, and supporting interventions informed by market knowledge; donor and host-country government 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 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.

  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.

- Support host country governments to assume ownership and financing of condom programming: As the economies of PEPFAR host countries expand, USG and GF programs should support host country governments to assume full ownership of condom programming utilizing a TMA. This includes forecasting, supply planning, procurement, storage, distribution, and financing of free condoms. Support for government stewardship of condoms may also include supporting the gathering, analysis, and dissemination of condom-related data and research, and coordination with all sectors including the commercial sector. Where host country governments are not ready to assume 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 countries where 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 to procure condoms throughout COP21 to assure access, but some should be ready to graduate from this activity.

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 COP21 condom needs is outlined below:

- Review the host country's GF application for condom commodities, 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 tool.

  Provide a clear justification for any central condom and lubricant requests that outlines: estimated condom and lubricant funding expected from other donors and the host country, the amount of condom and lubricant funding covered in the country's base

COP21, and the potential gap amount to be filled by central condom and lubricant funding.

6.2.5.3 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, recency, and other programmatic evidence. 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 long-haul truckers, etc.)

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

- ANC services and PMTCT should offer HIV testing including self-testing followed by linkage to treatment or other prevention services, including PrEP to PBFW (see Section 6.2.4) and their partners. Index testing or voluntary partner notification services are based on eliciting and HIV testing sexual contacts of a client living with HIV and not virally suppressed. Contacts of the index client without HIV 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 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 KPs including KP men can be found in Section 6.2.6.1.

- 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.

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 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.

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 - for example, serodifferent couples in PMTCT queues jumping ahead of single women.

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, an additional prevention strategy for MSM only (see Section 6.2.6.1).

6.2.6 Prevention for Key Populations

HIV prevention programs for key populations should employ combination HIV prevention approaches. Combination HIV prevention is the combined use of behavioral, biomedical, and structural approaches to reduce the number of new HIV infections. Biomedical interventions for key populations may include PrEP, post exposure prophylaxis (PEP), VMMC, condom and lubricant programming, and medication assisted treatment (MAT) all of which are described in this document.

6.2.6.1 PrEP for Key Populations

In September 2015, WHO recommended that oral PrEP be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention.[109] WHO has developed a series of modules to support the implementation of PrEP 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.[110] These modules are also available through a mobile device application.[111]

Long-acting injectable cabotegravir (CAB-LA), among other ARV-based prevention interventions, could be approved before, during, or soon after COP21. As CAB-LA becomes available, like oral PrEP, key populations should be presented with thorough information on all available HIV prevention options, including each method's efficacy and safety, as well as counseling and adherence support, allowing for an informed client choice. Those who prefer an alternative to oral PrEP or are unable to adhere to daily dosing, may soon have new options to consider as part of a comprehensive biomedical prevention program. For more on PrEP see Section 6.2.1.

Community Initiation, Continuation and Refills of Oral PrEP for Key Populations

DSD models for oral PrEP are essential to expand the reach of oral PrEP programs, move services closer to clients, and ultimately have a larger impact on HIV incidence. PEPFAR supported countries have explored a variety of DSD models for oral PrEP including implementation in more localized health facilities, integration into other health services (those for other STIs, family planning, gender affirming services for transgender persons, etc.), through community-based organizations, at hotspots, and through home and pharmacy-based models which include initiations, refills, and continuation visits by employing delivery services, outreach workers and pharmacists. Community models for the DSD of oral PrEP and the dispensing of oral PrEP within the community is a vital component to ensure wider access to oral PrEP and scale uptake and impact.

Implementation science research (PEPFAR's Key Populations Implementation Science

[109] https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/
[110] https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/
[111] https://www.who.int/hiv/mediacentre/news/oral-prep-app/en/

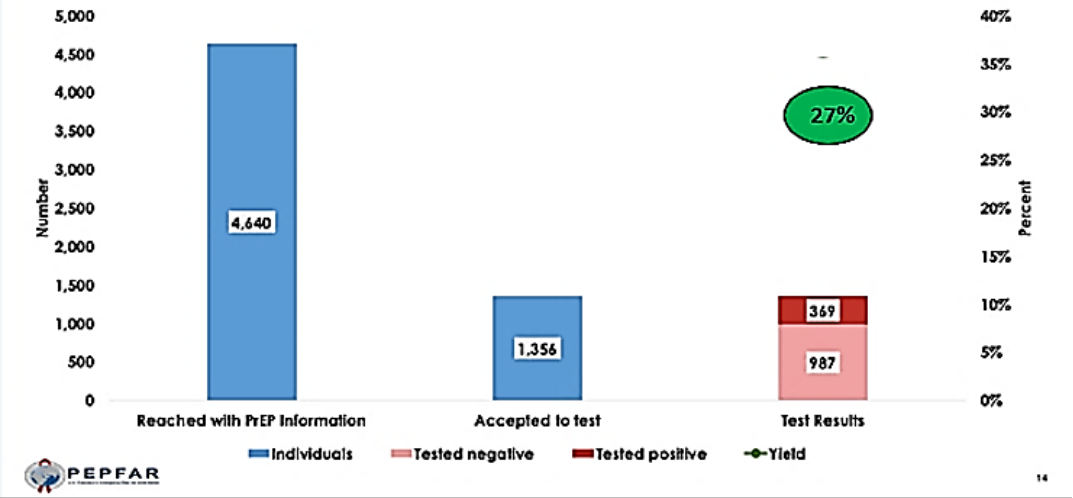
initiative) conducted in community-based and facility-based settings in Thailand has shown high uptake of and retention on oral PrEP among MSM and TG women, including through utilization of KP peer-outreach workers. In Tanzania, a model of community follow-up using outreach "backpack" workers has enabled oral PrEP clients to receive quarterly HIV testing and oral PrEP refills in their homes or in hotspot locations. This backpack mobile delivery approach has improved oral PrEP (and ART) retention among KP who may have challenges attending public facilities, especially during COVID-19, related transportation and other restrictions.

In Vietnam, innovative models from the private sector in the delivery of oral PrEP and HIVST occurred through couriers to enable oral PrEP programs to continue during COVID-19 restrictions bringing oral PrEP service delivery closer to clients. During COP20, Vietnam is exploring oral PrEP implementation through pharmacies and telehealth.

In Uganda, a community-led peer outreach and virtual strategy has enabled oral PrEP service continuity among female sex workers (FSW) and men who have sex with men (MSM) in the West Nile Region during the COVID-19 pandemic. Outreach interventions ranging from differentiated drug distribution, enhanced peer-led outreach approaches and use of virtual communications platforms were implemented. Social platforms of communication to integrate education on COVID-19 transmission and prevention, with HIV related services support for beneficiaries were created. It is important to ensure that MoH decision makers and program planners are aware of the improved effectiveness of key populations oral PrEP interventions if community initiation, multi month dispensing and continuation options are available. This could help to ensure that national guidance that authorized multi-month dispensing for oral PrEP in response to COVID remains in place. COP funds should be used to support DSD approaches for PrEP including programs where peer or lay workers conduct community-based initiation and continuation visits (community prevention case management), multi-month dispensing, delivery of oral PrEP where KP experience challenges accessing oral PrEP refills, and other decentralized and differentiated approaches.

Where PrEP has mobilized populations seeking a prevention option, it can also bring new sub-populations in for case finding. In Nigeria (2018), a PEPFAR funded oral PrEP program found that 27% of MSM seeking oral PrEP were living with undiagnosed HIV at a community One Stop Shop (see Figure 6.2.4).

Figure 6.2.4 Case finding rate among MSM seeking PrEP services in Nigeria, 2018



Event-driven oral PrEP to prevent HIV for MSM

In July 2019, WHO issued a technical update on the event-driven dosing considerations for oral PrEP containing tenofovir for MSM. The current evidence on the safety and efficacy of event-driven oral PrEP (ED-PrEP) indicates a reduction of HIV infection by 86% in clinical trials (IPERGAY) and by 97% in an open-label extension study. ED-PrEP is an additional dosing option for MSM who find this dosing strategy more convenient, have infrequent sex (less than 2 times/week), and for those who are able to plan for or delay sex for at least 2 hours after the loading dose. 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 were taken and a fourth pill 24 hours after the third pill was taken. In situations where MSM have sex on multiple days while still taking the post-sex doses, oral PrEP is continued daily until two days after the last time having sex. MSM using ED-PrEP would continue this process during each period of potential exposure to HIV, starting with a loading dose of two pills each time. MSM taking oral PrEP can switch from daily dosing to ED-PrEP (and vice-versa) depending on the frequency and predictability of sex, and their ability to effectively use the regimen.

There is insufficient evidence for ED-PrEP to be considered as a dosing strategy for women (including transgender women) and men who have sex (vaginal and/or anal) with women. Oral PrEP providers should ensure that these populations are offered daily dosing.[112] ED-PREP

[112] https://apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf?ua=1

should be implemented according to WHO recommendations. In summary, the effectiveness and safety of ED-PrEP.

ED-PrEP provides an additional dosing option for MSM, which may increase oral PrEP uptake and continuation in PEPFAR programs. There is evidence MSM can adapt daily and ED-PrEP regimens to their own needs as well as adjust their adherence to their perceived risk or exposure.[113] Policy and programmatic changes may be needed in order to effectively implement ED-PrEP in PEPFAR countries and education about ED-PrEP. is key to its implementation and effectiveness. PEPFAR created resources on ED-PrEP are available on USG SharePoint.[114] Programs planning to implement ED-PrEP should ensure that clear SOPs are in place, to address prescribing and dispensing, client education, procedures for missed/delayed dosing, and adverse event monitoring. Countries with oral PrEP programs supporting MSM and supported by PEPFAR should address the policy and programmatic changes to make ED-PrEP available for MSM. For more on prevention for men see Section 6.2.5.

Transgender Women and Oral PrEP

Given the increased exposure to HIV that transgender women face globally, oral PrEP is a critical intervention to prevent new infections that should be considered for all HIV-negative transgender women reached by PEPFAR-funded programs, with consideration for risk criteria appropriate to the program setting. As noted above, there is insufficient evidence for ED-PrEP to be considered as a dosing strategy for transgender women.

In Vietnam, 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. Where possible, PEPFAR programs should leverage provision of hormone therapy services provided through other resources to increase uptake of HIV services, including PrEP, among transgender women. Current information available suggests that there are no significant interactions between oral PrEP medicines and hormone therapy.[115] For more on prevention for transgender women see Section 6.2.6.

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[113] Vuylsteke et al. JIAS. 2019 Oct; 22(10): e25407.

[114] https://pepfar.sharepoint.com/:p:/s/PrEP/EXYHZIDYC3tDqVIeLrpgfJIBqi3UBBN22mIvKzO8mDy9rw?e=8GKA9Z

[115] 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

Female Sex Workers and PrEP

Female sex workers (FSWs) are up to 12 times more at risk of HIV infection than their general population counterparts,[116] thus, PrEP is an essential tool in the combination prevention toolkit for them, particularly in settings where they have difficulty negotiating condom use with their clients and/or non-commercial sex partners. Nevertheless, FSWs tend to be less likely than other KPs to initiate oral PrEP and to maintain good adherence to oral PrEP. Two demonstration projects (Benin[117] and Uganda found less than 50% retention in the study and relatively low pill count-based adherence in Benin, while the Uganda study also found very low plasma tenofovir levels. Some factors that contribute to low retention and adherence might be related to living conditions, mobility, as well as stigma associated to ARVs, particularly where oral PrEP is dispensed in generic versions, in packaging that is almost identical to ARVs used for treatment. In view of these findings, programs are encouraged to provide intensified adherence counseling and differentiated service delivery options to FSWs enrolled in oral PrEP and to ensure rigorous quarterly testing for those retained on oral PrEP. Clearly labeled oral PrEP packaging should also be considered, to avoid confusion with ARVs for HIV treatment. For more on prevention for women see Section 6.2.4.

Target Setting for PrEP

A key challenge when planning to implement PrEP for key populations is setting targets at national and subnational levels and estimating how many people in key populations a country or district should aim to reach and support on PrEP. UNAIDS has developed a PrEP target-setting guide to assist countries with estimating the size of key populations at various levels of exposure to HIV, which may be targeted given the amount of resources available for PrEP in a country setting. Step-by-step guidance and tools are provided, with special emphasis on defining risk and estimating the proportion at risk.[118]

As mentioned above in Section 6.2.1, tools have been developed in response to the challenge of setting targets for oral PrEP, as well as tracking the continuum of oral PrEP delivery and estimating program costs and impact. PEPFAR has developed an Excel-based tool called

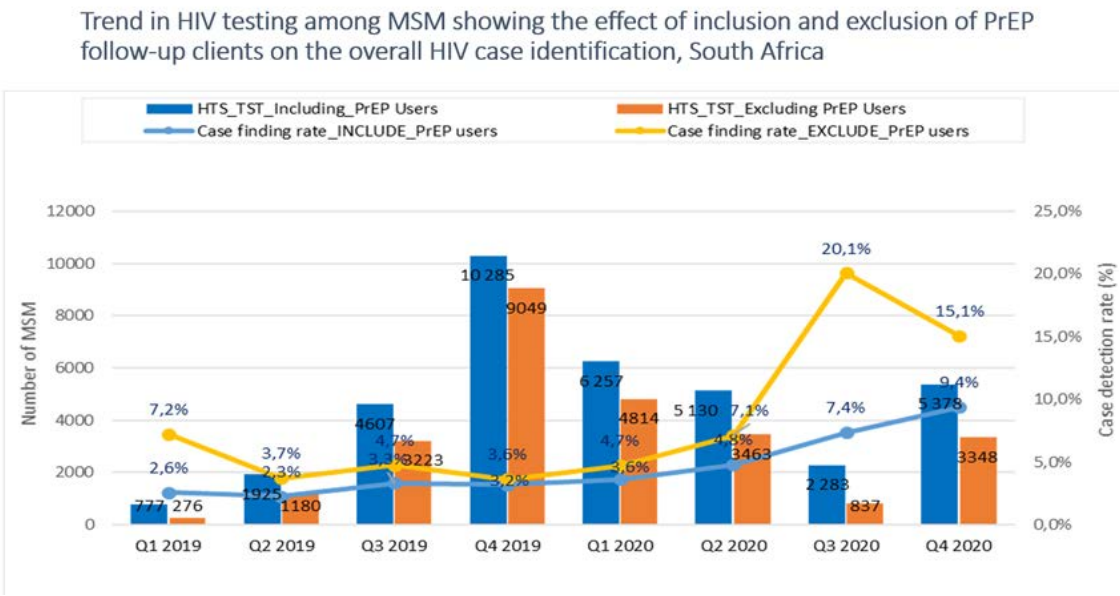
[116]Baral S, Beyrer C, Muessig K, Poteat T, Wirtz AL, Decker MR, et al. Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. Lancet Infect Dis. 2012;12(7):538–49.
[117]Mboup A, Behanzin L, Guedou FA, Geraldo N, Goma_Matse E, Giguere K, et al. Early antiretroviral therapy and daily pre-exposure prophylaxis for HIV prevention among female sex workers in Cotonou, Benin: a prospective observational demonstration study. Journal of the International AIDS Society 2018, 21:e25208
[118] https://centersfordiseasecontrol.sharefile.com/d-s7a9b860cd824cfa9

PrEP-it for oral PrEP implementation planning, monitoring and evaluation, including program monitoring, assessing site-level service delivery capacity, target setting, program cost estimation, and ARV supply forecasting.[119] As implementation of ED-PrEP for MSM is scaled, targeting and monitoring practices may need to be adjusted.

HIV Testing in PrEP Programs

PrEP programs can consider tracking HTS_TST specifically conducted for PrEP follow-up re-testing as custom indicators, and to 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.

Figure 6.2.5 HIV testing among MSM showing the effect of inclusion and exclusion of PrEP follow-up clients on the overall HIV case identification, South Africa Q1-Q4 FY20



6.2.6.2 Condoms and Lubricants for Key Populations

Effective condom and lubricant distribution, counseling and promotion ensures condoms act as a barrier to sexual transmission for every sexual encounter 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

[119] https://www.prepwatch.org/resource/prep-it/

condoms (both internal and external) and lubricants should be distributed through sites where key populations are found, i.e., in drop-in centers, anti-retroviral therapy (ART) and PrEP sites, and hotspot venues including bars and other locations key populations and their sexual partners may gather. Distribution should vary based on need. SOPs outlining the quantities and methods by which condoms and lubricants are distributed and promoted can be informed by existing implementation tools (see Section 6.6.2, Cross Cutting Key Populations Considerations). Lubricant supply and distribution deficits should be monitored and PEPFAR should intervene to ensure reliable supplies for sex workers, MSM, and TG programs.

6.2.6.3 Medication Assisted Treatment (MAT) for Key Populations

People who inject drugs are among the groups most vulnerable to HIV infection. According to WHO guidance, PWID should have access to sterile injecting equipment through needle and syringe programs and those who are dependent on opioids should be offered and have access to MAT. In addition, these services should integrate or link to HIV-specific services, including prevention, testing and treatment, and hepatitis B and C diagnosis, vaccination and/or treatment where available from non PEPFAR sources.

MAT has been shown to be a highly effective treatment for opioid dependence, reducing injecting behaviors that put PWID at risk for HIV, preventing HIV transmission and improving retention on HIV treatment. For MAT to have an impact on the overall HIV epidemic, services need to reach, provide prevention interventions for, test, treat, and retain as many PWID and their sexual partners as possible. As such, HIV testing and ART provision should be integrated into care settings that provide MAT. For countries that have recognized recent increases in HIV among PWID, or in specific subgroups such as young PWID, it is important to implement MAT service delivery models that are responsive to local conditions. MAT services, including methadone and buprenorphine where available based on national guidelines, can be delivered in primary healthcare settings or in specialized outpatient clinics offering treatment to clients. In addition, PEPFAR recommends conducting advocacy at a national level to introduce buprenorphine where not yet available.

Several PEPFAR countries currently provide MAT services – for example, India, Kenya, Kyrgyz Republic, South Africa, Tajikistan, Tanzania, Uganda, Ukraine, Vietnam – and interested OUs may want to observe their programs first-hand to learn about implementation of MAT services. Innovations in MAT services include take-away dosing (TAD) where stable MAT clients are provided with extra doses of medication to reduce the need to attend the clinic for daily

dispensing. Several countries (e.g., Tanzania, Kenya, India, Kyrgyz Republic) have implemented TAD on a small scale and early results are promising. TAD should be encouraged and explored as an important intervention for delivery of client-centered care for PWID. 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.[120]

6.3 HIV Case Finding

The gateway to epidemic control is case-finding. Timely and appropriate case-finding activities are critical to ensure focused access to prevention, treatment services for individuals to reduce HIV morbidity and mortality but it is also a critical intervention for reducing HIV transmission.

An ongoing challenge is the high volume of re-testing among "worried well" low-risk clients and among clients who are in denial about their status and also clients who believe they have been "cured" of HIV, all of which point to the need for client-centered approaches that improve linkage and retention. To develop a maximally impactful approach, countries need to understand the specifics of their epidemics at a sub-national level and develop strategies that address their case-finding gaps. In almost all countries, gaps in case-finding for men and children/adolescents are disproportionate – and particular effort should be given to developing innovative and efficient ways to close those gaps, with strategic partnerships that have a presence in the communities and populations we are trying to reach. Importantly, all HTS should be offered with in alignment with the WHO 5C's. Index testing specifically should adhere to PEPFAR's Guidance for Implementing Safe and Ethical Index Testing to ensure that (1) all PEPFAR-supported sites meet the minimum standards for safe and ethical index testing services and (2) routine monitoring and remediation practices are in place for accountability and action. PEPFAR will work collaboratively with civil society partners, government leaders, and PEPFAR Implementing partners to ensure all voices are heard, remediation actions are taken in a timely manner, and the safety and ethical treatment of clients remains of utmost importance. Also see Section 6.3.1.5.

[120] Comprehensive HIV Prevention for People Who Inject Drugs, Revised Guidance https://www.pepfar.net/OGAC-HQ/OGAC/ap-cs/Shared%20Documents/COP%20Resources/Other%20Technical%20Resources%20for%20Key%20Populations%20Programming/PEPFAR_HIV_Prevention_for_People_who_Inject_Drugs.pdf

As countries approach epidemic control, it is important that they increasingly focus testing on those at elevated risk. In countries with 80% of PLHIV on treatment, PEPFAR funding should only be allocated to index-driven testing, diagnostic testing (i.e., testing persons with signs or symptoms of HIV), highly targeted community outreaches and appropriately targeted testing of clients in VCT, ANC, TB, STI and MAT clinics and harm reduction settings. Also see Section 2.3.2.

We need to provide positive, consistent messaging on the benefits of testing and treatment to all clients and communities. We need to use smarter case finding strategies, effective screening and targeting tools that are patient-centered and context-appropriate, and we need to make treatment more attractive by providing a positive, respectful clinical experience. Lay counselors and social service providers should be engaged to work with those who seek HTS to facilitate access and use of appropriate treatment or prevention services.

6.3.1 HIV Testing Strategies for Case Finding

Programs should put together a portfolio of case finding strategies that incorporate data-driven, evidence-based and client-centered approaches, and capitalizes on new technologies. Client-centered approaches create enabling environments for successful HIV responses and affirm the dignity of people living with, or vulnerable to HIV. Each OU must develop a strategy that balances case finding approaches based on where that OU is in the first 95 of the clinical cascade, including among target populations, ART coverage, and considering any innovative adaptations in light of COVID-19. Countries should consider the following as they develop their case finding strategies:

- Review of PHIA and SPECTRUM estimates by geography, gender, and age disaggregates as well as Key Populations
- Geographic mapping of PLHIV, target populations, ART treatment gaps, testing and other services
- Linkage and enrollment in treatment
- Close examination of yield data (or HIV positivity) with a focus on new cases/diagnoses being identified, the proportional contributions and yields by different case finding approaches disaggregated by age, sex, and key population.
- Assess cost and cost-effectiveness of different testing approaches
- Community engagement with CSOs and other community organizations
- The critical role of HTS in linking HIV negative individuals to prevention services

It is essential 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). Case finding efforts should focus specifically on the gaps – and the more that programs characterize and understand the PLHIV they are missing, the better programs can target those individuals through effective and efficient case finding strategies. The most obvious and efficient way to find cases, in terms of testing yield, is to follow transmission dynamics – and all programs are required to scale-up and continually refine index testing services in a safe and ethical manner. Utilizing the privacy afforded by self-testing and in light of COVID-19 related impact on HTS delivery at facilities, HIV self-testing could extend access to individuals otherwise reluctant to test or go to a facility. Similarly, leveraging the information provided by recency testing can further refine and target case-finding efforts. Both self-testing and using recency testing results as a guide for case finding should be used strategically. For example, individuals who utilize self-test kits should be aware of what the results mean and the purpose and place for confirmation testing. Strategies that are effective at case finding among specific populations, such as social network testing in key populations, may work for other populations once they are appropriately adapted.

As mentioned in Section 2.3.2, as the COVID-19 context has highlighted, it may be necessary to reduce exposure of patients within health facilities and offer testing services for contacts of index clients outside of facilities in a safe and ethical manner. Programs may consider accelerating plans for scaling HIV self-testing kit distribution in the following settings, **if appropriate based on their epidemiological context:**

- Reaching priority populations within the community or facilities
- Providing an HIVST to an index client for their partner
- Providing parents (index clients) with HIVST to screen biological children >2 years of age
- Scale of HIVST for KP and clients of FSW
- Providing HIVST for high-risk PBFW

More information on self-testing can be found in Section 6.3.1.6.

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 by staff without any formal laboratory training and significantly increasing the number of persons who learn their HIV status at the site of testing. Several recent published and unpublished program results indicate that misdiagnosis of HIV status can occur due to poor quality HIV tests and 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%.[121] 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).[122] 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").[123]

PEPFAR teams should consider the following elements of the HIV RTCQI in COP21 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. Strengthen systems for internal quality control at testing points;
2. Develop and adhere to national testing algorithm(s);
3. Use HIV RT standardized logbooks for data capturing, monitoring, and reporting;
4. Conduct retesting for verification for all newly diagnosed individuals to verify their HIV status to ensure that individuals are not needlessly placed on life-long ART. Retesting refers to testing of a new specimen for each newly diagnosed individual, conducted by a different provider using the same testing algorithm.
5. 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;

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[121] Johnson CC, Fonner V, Sands A, Ford N, Obermeyer CM, Tsui S, Wong V, Baggaley R. To err is human, to correct is public health: a systematic review examining poor quality testing and misdiagnosis of HIV status. J Int AIDS Soc. 2017 Aug 29;20(Suppl 6):21755. doi: 10.7448/IAS.20.7.21755.
[122] https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf
[123] World Health Organization. Consolidated Guidelines on HIV Testing Services For a Changing Epidemic. November 2019. Available at: https://www.who.int/publications-detail/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

6. Develop human resources through training, certification and recruitment of in-country Quality Corp (Q-Corp) volunteers and officers to assist in the implementation of HIV RTCQI;
7. Improve and certify sites using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT/RTRI) checklist;[124]
8. Utilize RT post-marketing surveillance.
9. 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.[125] 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. In order to assure accurate test results and reduce the likelihood of HIV misdiagnosis, the WHO recommends that national programs follow validated HIV testing algorithms and recently revised their testing recommendations, including retesting for verification of all HIV-positive cases prior to ART initiation.[126]

Retesting for verification of HIV positive status provides an opportunity to reduce HIV misdiagnosis and prevent unnecessary initiation of lifelong ART. Retesting for verification should occur prior to or at ART initiation. Several factors may lead to a false-positive misdiagnosis during the initial test, including user error, poor recordkeeping, inadequate management and supervision, and over-interpretation of weak reactive results. Retesting for verification applies only to newly identified HIV positive persons and those not yet initiated on ART. HIV diagnostic tests validated for use on persons taking ART are not available therefore

[124] https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf?sequence=1
[125] Johnson CC, Dalal S, Baggaley R, Taegtmeyer M. A public health approach to addressing and preventing misdiagnosis in the scale-up of HIV rapid testing programmes. J Int AIDS Soc. 2017;20 10.7448/IAS.20.7.22190
[126] World Health Organization. Consolidated Guidelines on HIV Testing Services For a Changing Epidemic. November 2019.

individuals who have been on ART should not be retested 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.[127,128,129,130] 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 (ED): Birth Testing, Integrating POC for Early Infant Diagnosis (EID)

HIV-exposed infants face higher risk of morbidity and mortality than HIV-unexposed infants; continuity of care for the mother and infant throughout the breastfeeding period is critical to reduce morbidity and mortality among those infants and to ensure prompt diagnosis and ART initiation among those infants who acquire HIV infection during breastfeeding

Globally, most pediatric infections are due to MTCT, and 51% occur after age 2 months. While some countries have achieved reasonably high coverage of a single test by 2 months of age among known HIV-exposed infants, none have achieved high retention of these infants throughout the end of the breastfeeding period to ensure that the infant has received all the virologic tests that their national testing strategy recommends and that all transmissions occurring after 6 weeks of age are identified as early as possible. Early diagnosis is particularly

[127] World Health Organization. Consolidated Guidelines on HIV Testing Services: 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection. ANNEX 9. Available from: https://www.ncbi.nlm.nih.gov/books/NBK316036/. Geneva: World Health Organization, 2015
[128] Hsiao NY, Zerbe A, Phillips TK, Myer L, Abrams EJ. Misdiagnosed HIV infection in pregnant women initiating universal ART in South Africa. J Int AIDS Soc. 2017 Aug 29; 20(Suppl 6):21758
[129] Eaton JW, Johnson CC, Gregson S. The Cost of Not Retesting: Human Immunodeficiency Virus Misdiagnosis in the Antiretroviral Therapy "Test-and-Offer" Era. Clin Infect Dis. 2017 Aug 1; 65(3):522-525.
[130] Lasry A, Kalou MB, Young PR, Rurangirwa J, Parekh B, Behel S (2019). Cost implications of HIV retesting for verification in Africa. PLoS ONE 14(7): e0218936.

important, as up to 50% of untreated HIV-positive infants die within the first year of life, with mortality being high in the first few months of life.[131]

PEPFAR programs have improved the rate of testing of infants, but most countries have not reached the goal for all programs to achieve testing 90-95% of HIV-exposed infants by age 2 months and link 95% of infected infants promptly to treatment (Figure 6.3.1). PEPFAR teams should work with countries and other stakeholders to ensure EID testing is scaled to achieve at least 90% 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 community health workers/peer mothers, ensuring all COVID protocols are followed. Laboratories should continue to prioritize testing DBS samples given that diagnosis of HIV infection in an infant can be considered a medical emergency, requiring immediate treatment.

Recommendations from the WHO published in 2016 include consideration of a nucleic acid test (NAT) at birth ('birth testing') and introduction of point-of-care (POC)/near POC NAT tests.[132] These new 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 the risk of low-level viremia, potential contamination with maternal blood, specimen mislabeling, and laboratory contamination. The WHO recommendation to repeat testing of all indeterminate results[133] 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. While this process is ongoing and to avoid errors in current EID, PEPFAR recommends that all samples tested initially 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.

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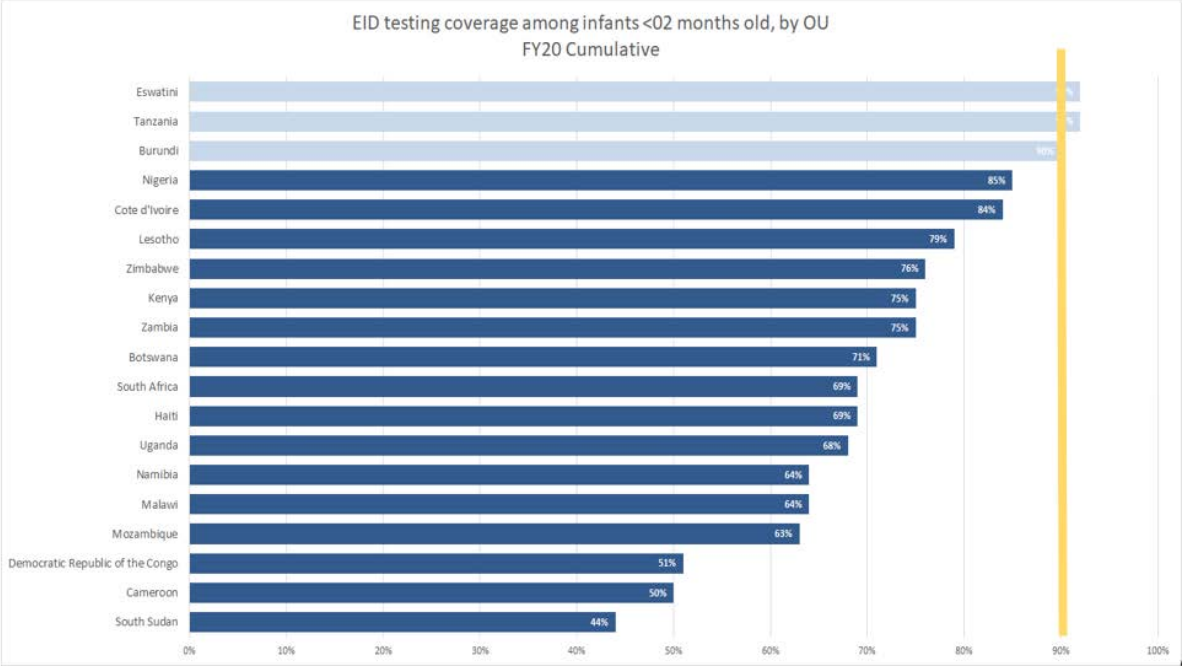
[131] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext#secd1175567e1778

[132] World Health Organization (July 2018). HIV diagnosis and ***ATV*** use in HIV-exposed infants: a programmatic update. Geneva, Switzerland (WHO/CDS/HIV/18.17)

[133] http://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf

Figure 6.3.1: FY20Q4: EID testing coverage among infants <2 months old by OU



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.

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 ≥80% 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.

- If women seroconvert while pregnant or breastfeeding, immediately initiate treatment of the mother on TLD and in accordance with client-centered counseling and treatment principles.
- Birth testing may be conducted using conventional laboratory-based or POC virologic tests.
- 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[134] 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 leads 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.

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

- 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-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.

Use of Point-of-Care Platforms for EID

PEPFAR's primary support needs to remain focused on ensuring pregnant and breastfeeding mothers are virally suppressed and all programs must recognize and support this. A positive EID result is a recognized program failure, and the priority districts with ≥5% incidence in newborns must enhance the care and support to the pregnant and breastfeeding mothers. To ensure comprehensive and timely diagnosis in newborns, programs must consider using POC testing to complement laboratory-based platforms in support of EID and VL testing in pregnant and breastfeeding women. This is especially required in countries with long turnaround time 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.[135] POC testing for EID and VL could make results available for patient management within hours of specimen collection. Recent data from Unitaid supported studies conducted in both Mozambique[136] and Malawi[137] showed that the use of POC for EID led to reduction in turn-around-times (TAT), increase in number of infants tested and placed on

[135] WHO list of prequalified in vitro diagnostic products. https://www.who.int/diagnostics_laboratory/evaluations/190918_prequalified_product_list.pdf?ua=1

[136] Jani IV, Meggi B, Loquiha O, Tobaiwa O, Mudenyanga C, Zitha A, Mutsaka D, Mabunda N, Vubil A, Bollinger T, Vojnov L, Peter TF. Effect of point-of-care early infant diagnosis on antiretroviral therapy initiation and retention of patients. AIDS. 2018 Jul 17;32(11):1453-1463. doi

[137] Mwenda R, Fong Y, Magombo T, Saka E, Midian D, Mwase C, Kandulu J, Wang M, Thomas R, Sherman J, Vojnov L. Significant Patient Impact Observed Upon Implementation of Point-Of-Care Early Infant Diagnosis Technologies in an Observational Study in Malawi. Clin Infect Dis. 2018 Feb 27. doi: 10.1093/cid/ciy169. [Epub ahead of print]

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[138] 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 especially important for country programs that are not on target to reach testing 90-95% 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, and outpatient, led to improvements in testing numbers and positivity yield.[139] Programs should consider placing POC platforms outside of PMTCT entry points as a means to increase access to timely infant HIV testing, but this must be matched with enhanced programming to support pregnant and breastfeeding women and a clear recognition that 16 years into PEPFAR, each occurrence of MTCT represents a potential PEPFAR programming failure. Priority clinical sites for consideration of placement of POC devices include TB clinics, pediatric inpatient wards, 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 6.3.1.8 on PITC), 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. The 2016 WHO guidelines recommend the use of RDT for follow up HIV diagnosis among infants at 9 months. However, substantial drug exposure for infants with implementation of the Treat All policy for mothers and enhanced postnatal prophylaxis of HIV-exposed infants may result in viral load reduction and delayed antibody development in HIV-infected infants. Also, the occurrence of maternal infection in late pregnancy or during the postnatal period may be responsible for a lack of passive HIV antibody transfer to the HIV-exposed infant. These factors increasingly jeopardize RDT accuracy at 9 months of age as a means of correctly ruling out established infection in

[138] 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

[139] HIV mother-to-child transmission in Cameroon: early infant diagnosis positivity rates by entry point and key risk factors http://www.pedaids.org/event/22nd-international-aids-conference/

HIV-exposed infants. In light of this WHO in 2018,[140] recommended the NAT for HIV diagnosis among infants at 9 months.

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 ART, 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, many countries have not yet reached the 90% target for EID coverage by 2 months of age and have lengthy turnaround time and poor linkage to ART (< 95%). As noted elsewhere in COP guidance (Section 6.3.1.3) point-of-care EID testing in selected settings has led to reduced EID turnaround time and improved linkage to ART for HIV-positive infants across multiple countries.[141,142] 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, 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 clinic, 1,025 new HIV-exposed infants (1%) were identified.[143]

(2) *Mother-baby pair tracking by peer mothers:* A household and community-based intervention by AIDSFree in Eswatini addressed loss to follow up (LTFU) and promoted retention in 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

[140] https://apps.who.int/iris/bitstream/handle/10665/273155/WHO-CDS-HIV-18.17-eng.pdf?ua=1

[141] 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

[142] https://www.thelancet.com/pdfs/journals/lanhiv/PIIS2352-3018(19)30033-5.pdf

[143] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6401209/

visits.[144] The main components of the interventions included (i) MBPs enrolled at 6-week postpartum visit, (ii) CFM created care plan with mothers during monthly home visits to proactively address challenges in attending visits up to 24 months, (iii) Care plan updated in subsequent CFM visits, (iv) CFMs issued referral forms to mothers who miss a visit, and (v) CFMs met bimonthly with facility focal person for review of MBP engagement.

(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.[145,146]

(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 their facility linkage resulted in increased DNA PCR testing, because the expert clients were accessible, appropriate, and acceptable to HIV-positive mothers.[147] 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.[148] 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.[149]

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[144] 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
[145] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5922496/
[146] https://www.praekelt.org/momconnect
[147] https://www.hindawi.com/journals/bmri/2016/5625364/
[148] https://icap.columbia.edu/wp-content/uploads/Cameroon-QICIP-Success-Story.pdf
[149] https://programme.aids2018.org/Abstract/Abstract/9780

6.3.1.5 Index Testing

For many PEPFAR countries, the main bottleneck to achieving 95-95-95 are low case-finding and retention rates among specific populations. In order to improve case-finding, countries need to use a mix of testing strategies and client-centered approaches tailored to the local epidemiology and ART coverage among specific population groups.

Index testing, historically referred to as contact tracing or partner notification or partner services, is a critical case-finding strategy that should be done routinely in all programs by closely coordinating, communicating, and sharing data between community and facility partners while adhering to PEPFAR's Guidance on Implementing Safe and Ethical Index testing. Index testing involves identifying potentially exposed contacts (i.e., sexual partners, biological children, and anyone with whom a needle was shared) of an HIV-positive person (i.e., index client), and then offering HIV testing services to those contacts. As case finding strategies evolve, staff positions and human resources will need to be aligned to these efforts. In alignment with previous guidance, PEPFAR recommends prioritizing individuals who are newly diagnosed HIV positive or virally unsuppressed as index clients.

As mentioned in Section 2.3.2 and Section 6.3, PEPFAR recognizes the importance of providing all HTS 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. This Guidance takes into account adherence to WHO's 5C minimum standards, including consent, counseling, confidentiality, correct test results, and connection to HIV prevention (for both PLHIV and HIV-negative individuals), and HIV care and treatment (often referred to as 'linkage', for HIV-positive individuals). Moreover, all PEPFAR-supported sites offering index testing services of any kind to any population group must adhere to, and maintain compliance with, PEPFAR's minimum standards for safe and ethical index testing. These minimum standards are:[150]

- Adherence to WHO's 5Cs (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- IPV risk assessment and provision of "first line" response, including safety check and referrals to clinical and non-clinical services (if not provided on site)

[150] Safe and Ethical Index Testing Services. PEPFAR Solutions: https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

- A site level adverse event monitoring and reporting system
- Providers trained and supervised on index testing procedures including 5 Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and “do no harm”)

PEPFAR is committed to ensuring that (1) all PEPFAR-supported sites meet the above minimum standards for safe and ethical index testing services AND (2) routine monitoring and remediation practices are in place for accountability and action. PEPFAR believes that working collaboratively with diverse stakeholders is essential to improve the quality and effectiveness of services we support. As such, PEPFAR will work collaboratively with civil society partners, government leaders, and PEPFAR Implementing partners to ensure all voices are heard, remediation actions are taken in a timely manner, and the safety and ethical treatment of clients remains of utmost importance. All PEPFAR-supported programs must take steps to implement safe and ethical index testing services by:

1. Monitoring site and provider-level **compliance with minimum standards** for index testing described above
2. Obtaining **informed consent** prior to the elicitation interview and before contacting partners
3. Conducting an **Intimate Partner Violence risk assessment** for each named partner and providing appropriate services for clients experiencing violence
4. Implementing a robust mechanism for detecting, monitoring, reporting, and following up on any **adverse events** associated with index testing services
5. Utilizing **quality assurance and accountability** to remediate any gaps in the provision of index testing services

Index testing remains critical to identifying HIV positive children of all HIV-positive parents, including those identified as members of Key Populations. Such an approach complements existing pediatric case finding approaches that can help close the pediatric testing gap. As a complement to index testing approaches, in order to identify HIV positive children who may have been previously missed, it is important to ensure all biological children of HIV positive individuals know their status (as per the Case Finding Minimum Program Requirement). This is a WHO minimum standard of care and should be the foundational testing strategy in all countries. SIMS standards on HIV Testing of Biological Children of HIV positive mothers is one of the poorest performing SIMS standards across PEPFAR-supported countries regardless of ART coverage.

For pediatric index testing specifically, the following considerations should be taken into account:

- Index testing is not a static one-time assessment or event. It should be offered to all newly diagnosed PLHIV, and especially among PLHIV on treatment who are not virally suppressed. Pediatric case identification remains a priority, and comprehensively understanding the index testing cascade as it affects case identification among pediatrics is critical to ensure gaps are closed and areas for improvement are identified.
- If children of male-index clients (fathers) have not been previously tested, they should be included when the biological mother is HIV-positive, deceased, or her HIV status is not known, not documented, or cannot be determined.
- If the index client is a child, his/her mother should be tested, and if the mother is HIV-positive, unknown, or deceased, then the father, all of the mother's known sexual partners, and all biologic siblings (with the same mother) of the index child should be tested.
- Index testing of biological children may be done in collaboration with OVC partners, if appropriate; OVC programs may support community and facility partners in ensuring that children of PLHIV are tested.

Overall, the following principles should be taken into account when implementing index testing services for all populations, including adherence to, and compliance with, the aforementioned PEPFAR Guidance on Implementing Safe and Ethical Index Testing.

- Contact lists must be de-linked from the index clients, and these clients must be reassured that their confidentiality will be maintained and that contacts will be offered testing as part of a broader testing strategy.[151] Processes to allow index clients to anonymously submit names and contact information of their partners should be developed.
- Facilities should consider referring all newly identified HIV positive clients to a trained lay counselor to receive index testing services; it is important to note that elicitation of partners and biological children can take up to 30 minutes per client.

[151] Building trust is key. Anecdotally, countries have noted that clients only share info about one partner at time of diagnosis, but once they see that there were no challenges with the first partner, they're willing to share information about other 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.

- Programs should offer a “menu” of options for testing as different options will be preferred by different clients and for each partner with an acknowledgment that many newly diagnosed persons may fear disclosure. Anonymous pathways to partner notification (or partner services) and index testing such as targeting HIV and other health services together with index testing should be made available.[152] Index clients must be assured of their confidentiality. Elicitation may take place over the course of multiple visits as the client builds trust with counselors and community health workers.
- Facility and community IPs must work closely and collaboratively by sharing data and information for case finding. As per the PEPFAR Guidance on Implementing Safe and Ethical Index Testing, IPs should develop systems to ensure the security and confidentiality of any information shared between partners (i.e., using anonymous IDs instead of names for index clients). Contact lists and information for index partners not returning should be provided to community IPs for follow up. MOUs articulating expectations for collaboration are recommended. Likewise, within facility settings testing providers should work closely and collaboratively with care and treatment providers who will continue to provide care for the index client.
- Sensitizing healthcare workers to deliver compassionate, rights-based, comprehensive HIV testing services is critical for success.
- Index case testing should be offered at multiple entry points, including HTS, ANC/PMTCT, VMMC, <5 clinics, pediatric nutrition clinics, OPD, TB, ART, family planning and STI clinics.

Given the availability of life-saving ART, programs have an obligation to ensure that those potentially exposed to HIV are identified, offered testing, and provided ART promptly. The proportion of HTS_TST_POS identified from index-testing varies from 30-70% based on ART coverage (see Table 6.3.4). In all cases, index testing is expected to have a yield of 15–40% in adults. Index testing yields should be disaggregated by age and sex (especially separating adult vs pediatric yields) to better understand gaps and identify areas for improvement (See Section 6.3.2.1 for further guidance on index testing in pediatrics).

Recency testing (see Section 6.3.1.7) should be used to identify geographic and demographic hot-spots (areas or groups with high rates of recent transmission), and those hot-spots should

[152] PEPFAR Index Testing Toolkit https://www.pepfarsolutions.org/tools-2/2018/4/11/index-and-partner-notification-testing-toolkit

be targeted for testing campaigns, with timely safe and ethical index testing performed for all who test positive.

Informed Consent for Index Testing

As described in detail in PEPFAR Guidance on Implementing Safe and Ethical Index Testing, informed consent (can be verbal) from the index client must be obtained, even when clients are offered the option of anonymously submitting names and contact information for contacts. Informed consent is also an opportunity to educate the client on the purpose and value of contact investigations. Each listed sexual partner and child should be contacted, informed that they may have been exposed to HIV—in a way that protects the confidentiality of the index client— and offered voluntary HTS). The PEPFAR Solutions Platform Index Partner and Family Testing Toolkit includes Job Aids, Talking points and Scripts for Index Testing Services, Tools for Documenting & Monitoring Index Testing Services, and other resources.[153] Messages should be adapted for local contexts and HIV testing may be combined with screening and testing for TB, STIs, or other diseases to increase acceptance and uptake (see PEPFAR Solutions examples).

The goal of index client testing is to break the chain of HIV transmission by offering HTS to persons who have been exposed to HIV and linking them to HIV treatment, if positive, or HIV prevention services (e.g., VMMC, PrEP, condoms), if negative. For example, if a female partner of an HIV positive man tests negative, she should be offered PrEP and other prevention services. Similarly, male partners of HIV positive women, should be referred for VMMC, provided condoms, offered PrEP, and other prevention services. Please see Sections 6.2.4 Prevention for Women and PMTCT, 6.2.5 Prevention for Men, and 6.2.6 Prevention for Key Populations which include specific guidance on prevention strategies, including PrEP.

Index Testing and other HIV Case Finding Modalities

HIV testing approaches must evolve as countries attain higher levels of ART coverage. Among adults, index testing has shown high yields across all countries and, critically, has increasingly proven to be an effective case finding strategy; in short, index testing saves lives. It is effective at finding previously undiagnosed PLHIV, identifying previously diagnosed PLHIV who are not on treatment, and linking HIV-negative individuals at risk for HIV to prevention services. Countries have made significant progress in implementing index testing; however, it has not been scaled with fidelity.

[153] PEPFAR Solutions: Index and Partner Notification Testing Toolkit, Available at https://www.pepfarsolutions.org/tools-2/2018/4/11/index-and-partner-notification-testing-toolkit

The modality, other provider-initiated testing (Other PITC) has the highest volume of tests although there have been substantial declines since FY20 Q2 due to the COVID-19 pandemic; this modality includes patients coming through outpatient departments across the facility and often has the lowest yield across all countries (See Figure 6.3.2). Other PITC should be focused on those with clear symptoms, WHO stage 3 symptoms, or use of validated risk screening protocols.

Some countries continue to over-test low risk groups at the expense of those who really need prevention and treatment services due to risk. Therefore, we need to tier HIV testing into public health case finding and more effectively target the differentiated HIV testing approaches to reach populations with the greatest gap in the first 90 (i.e., men, children, AGYW, and KPs).

In reaching and maintaining epidemic control, HIV testing approaches should be targeted to HIV case finding through index testing and optimized facility-based testing that is symptom or risk-based (e.g., testing in TB, STI clinics, or key populations). Testing through VMMC and DREAMS programs are to confirm status of an individual in order to provide relevant program interventions and are not considered case finding approaches. Figure 6.3.4 outlines HIV case finding approaches which will be supported by PEPFAR based on ART coverage.

Figure 6.3.2 HIV Testing yield across OUs FY20 Q1-Q4

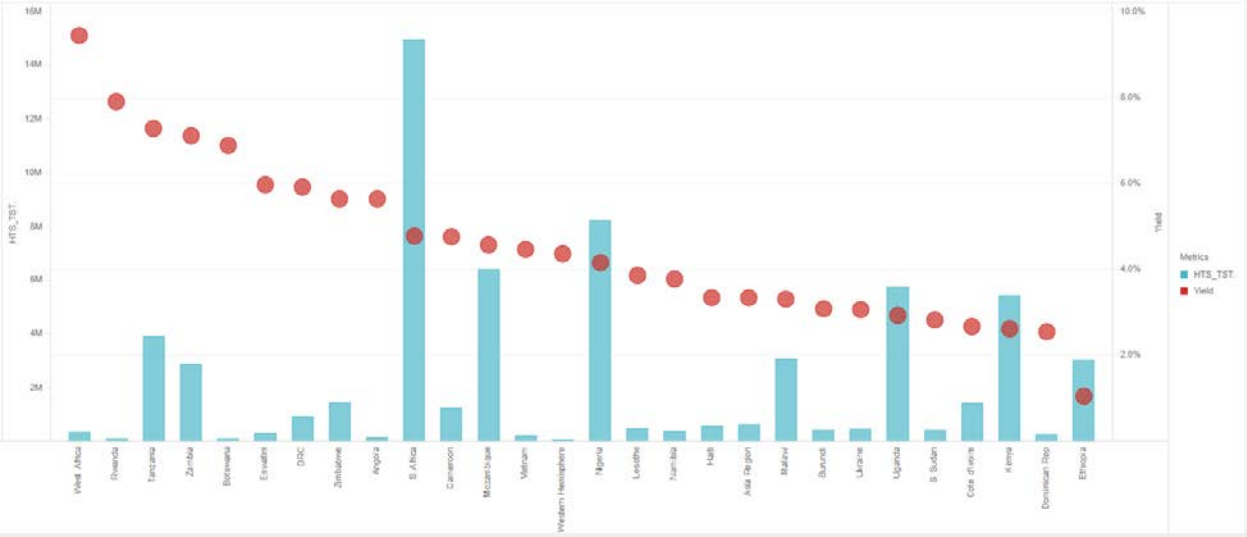

Figure 6.3.3 HIV Index Testing Yield Trends Across OUs in Africa, 2019Q2-2020Q4

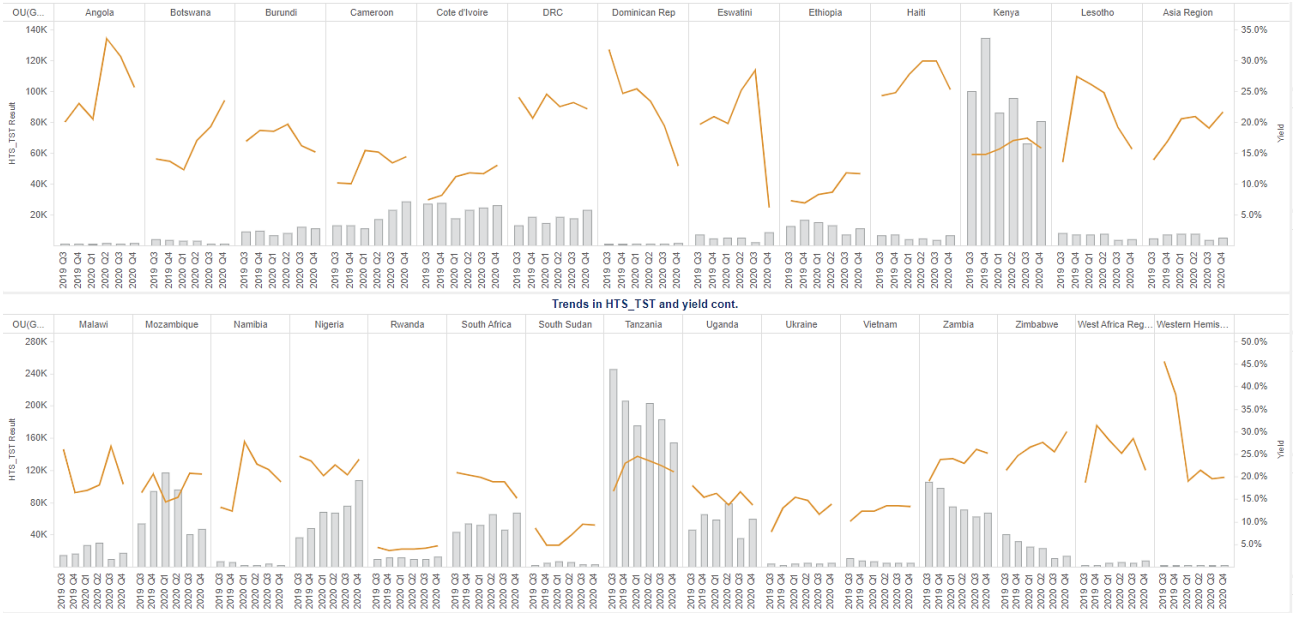

Figure 6.3.4 HIV case finding approaches supported by PEPFAR, based on ART coverage

HIV Case Finding Approaches for COP20 for PEPFAR Support								
ART Coverage (National or subnational)	**Index Testing (facility or community)***	**TB and STI**	**Key Populations**	**Other non-facility based testing**	**PMTCT**	**HIV self testing**	**Other facility-based testing** • Symptom-based • Risk-based • Men 25 to 35 years old	**Percentage of HTS_POS from index testing**
80% or greater	Minimum 15% to 40% yield	Yes	Yes		Yes	Yes	Minimum 10% yield	75%
70-79%	Minimum 15% to 40% yield	Yes	Yes	Targeted to specific populations & high burden areas	Yes	Yes	Minimum 10% yield	50%
Less than 70%	Minimum 15% to 40% yield	Yes	Yes	Targeted to specific populations & high burden areas	Yes	Yes	Minimum 5% yield	30%

*Index Testing Yield calculations should be disaggregated by age and sex to better understand gaps in testing coverage based on unmet need for treatment.

Approaches to Index Testing or Partner Notification

Typically, there are two broad approaches for voluntary notification of sexual contacts or persons with whom a needle has been shared. Regardless of the approaches utilized, the safety and ethical treatment of the index client and contacts remains of paramount importance[154]:

Traditional - Client Referral:

- The index client takes responsibility for encouraging partner(s) to seek HTS. This is often done using an invitation letter or referral slip. In addition, one approach is HIV self-test kits can be given to the index client for their sexual and /or PWID partner(s) f preferred by the index client;

Innovative - Assisted HIV partner notification testing (highly recommended):

- Provider Assisted Referral: With the consent of the HIV-positive index client, the healthcare worker (or community extender) directly contacts the client's partner(s), and either informs them that they may have been exposed to HIV, again **without naming the client**, or tells them that they are eligible for testing and healthcare services because of increased risk for HIV. The healthcare worker then offers them voluntary HTS, making sure to maintain the confidentiality of the index client. Index client testing does NOT require the index client to disclose his/her HIV status to the 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.
- Provider Assisted Delayed Referral: the index client enters into a "contract" with the counsellor and/or health care provider whereby he or she agrees to disclose their HIV status to all partner(s), provide them with an HIV Self-testing kit, and/or refer them to HTS within two weeks. If partner(s) do not access HTS within this period, counsellors/providers contact the partner(s) directly to notify them that they may have been exposed to HIV **without any disclosure of the index client**. Counsellors/providers offer voluntary HTS to partner(s) and other family members as appropriate while maintaining the confidentiality of the index client.
- Dual Referral: A trained provider sits with the HIV-positive 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. Offering HIVST for the index client and their partner (or biological children) may also be considered.

[154] PEPFAR Guidance on Implementing Safe and Ethical Index Testing
https://www.pepfarsolutions.org/tools-2/2018/4/11/index-and-partner-notification-testing-toolkit

As mentioned above, index testing should always be client-centered and focused on the needs and safety of the index client and their partner(s), needle-sharing partner(s) and children. An index client should never feel as if they are required to provide contacts in order to receive any care or services, and index clients should have the option to submit contacts anonymously.

In accordance with the PEPFAR Guidance on Implementing Safe and Ethical Index Testing services,[155] programs should continually evaluate informed consent procedures to ensure they are properly conducted and monitor the number/proportion of refusals (or discomfort) related to intimate partner violence (IPV) and occurrence of adverse events. Importantly, obtaining informed consent is one of the PEPFAR Minimum standards for Safe and Ethical index testing, and is part of the site assessments to measure compliance with these minimum standards. All index clients should be asked if they are currently experiencing or are afraid of violence from their named intimate partner(s) using a routine enquiry process (sometimes referred to as GBV or IPV screening) per WHO guidelines.[156] All sites must be able to provide, at a minimum, an immediate first line support to any person's disclosure of violence (i.e., adaptation of psychological first aid), treatment for presenting health conditions and, if possible, offer post-violence clinical care services. If it is not possible to provide post-violence clinical care at the index testing site, active referrals should be in place to ensure survivors have timely access to GBV services. If any concerns regarding IPV are identified, partner services should not be initiated until resolved. Importantly, appropriate monitoring of adverse events is critical to ensuring the safety of clients, and programs should ensure adequate monitoring for IPV-related adverse events after partner services are offered. Adverse event monitoring and response is also one of the PEPFAR minimum standards for safe and ethical index testing.

The identity of the index client should not be revealed and no information about partners should be conveyed back to the index client (unless explicit consent from all parties is obtained). For KPs, there can be additional challenges related to behavior and identities that are often hidden, hence, voluntary confidential participation is vital, and extra safety and security measures may be required.

Monitoring Index Testing Implementation and Outcomes

[155] Safe and Ethical Index Testing Services. PEPFAR Solutions: https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

[156] WHO. Responding to intimate partner violence and violence against women: WHO clinical and policy guidelines. 2013. Available at: https://apps.who.int/iris/bitstream/handle/10665/85240/9789241548595_eng.pdf?sequence=1)

Index testing of newly diagnosed patients and those with non-suppressed viral load on routine testing should be prioritized, and non-suppressed viral load registers may be used as the starting point for index testing of long-term HIV clinic clients. As described in the Guidance on Implementing Safe and Ethical Index testing, monitoring compliance and ensuring quality assurance and accountability, with the minimum standards for safe and ethical index testing requires use of multiple data sources. Importantly, no single data source can fully monitor compliance with the Guidance on Implementing Safe and Ethical index testing. Programs should use Safe and Ethical site assessment results (e.g., REDCap assessments), SIMS, MER, community-led monitoring data etc. to comprehensively understand what gaps may exist and remediation efforts that are needed. The full index testing cascade should be reviewed by age and sex to help identify and gaps and opportunities for improvement.

The Quality Assurance and Accountability section of the PEPFAR Guidance on Implementing Safe and Ethical Index testing describes these monitoring and action plans in greater detail.

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 demonstrate (with data) the capacity for reaching beyond the index's principal sexual partner to other sexual contacts by demonstrating that the average number of adult contacts elicited per adult index client exceeds one, while remaining adherent to the PEPFAR minimum standards for safe and ethical index testing.

Strategic Integration of Index Testing Approaches

Index client services should be integrated with other innovative HTS approaches that are complementary, including recency testing and social network testing. Central America Region[157] data showing how recency testing improves their yield in index testing.

In cases where the index client partner(s) is/are HIV negative, a prevention package of services including VMMC, condoms, PrEP, family planning services, and other prevention interventions should be considered and implemented as appropriate and with fidelity.

[157] PEPFAR Solutions Platform. Surveillance of Recent HIV Infections: Using Point-of-Care Recency Tests to Rapidly Detect and Respond to Recent Infections. July 13, 2018. Available at: https://www.pepfarsolutions.org/emerging-technologies-innovations/2018/7/11/surveillance-of-recent-hiv-infections-using-point-of-care-recency-tests-to-rapidly-detect-and-respond-to-recent-infections

See Figure 6.3.5 below which outlines 7 recommended steps to follow when implementing Index and Partner Notification Testing Toolkit, additional materials on index testing and partner services can be found on the PEPFAR Solutions Platform.

Figure 6.3.5: INDEX & Partner Notification/Services Testing ToolKit

INDEX & Partner Notification Testing TooLKit

7 Recommended Steps to Follow

- Step 1: Use Talking Points & Scripts for Index Testing Services to introduce partner/family testing to the index client and complete the Index Client Information Form (page 1 of Tools for Documenting & Monitoring Partner Notification Services).
- Step 2: Use the Partner/Child Elicitation Form (p. 2 Tools for Documenting & Monitoring Partner Notification Services) to record partner(s)' names and contact information.
- Step 3: Use the Partner Information Form (p. 3-4 Tools for Documenting & Monitoring Partner Notification Services) to document results of IPV screening and preferred partner notification method and/or child testing method.
- Step 4: Determine preferred method of partner notification: client referral; contact referral; provider referral; or dual referral. Additional tips and scripts for the referral processes can be found in Patient Information & Handouts.
- Step 5: Contact all named partners using the preferred approach.
- Step 6: Record partner notification outcomes on the Outcome of Testing Forms (p. 5-6 of Tools for Documenting & Monitoring Partner Notification Services).
- Step 7: Provide appropriate services for children and sero-matched & serodifferent partners based on HIV status.

6.3.1.6 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 an HIV test and interprets the result, often

in a private setting, either alone or with someone he or she trusts. HIVST continues to be an emerging approach for expanding access to HTS among men and underserved or disenfranchised populations, such as youth and adolescents. It is particularly valuable in key populations and in areas where men's awareness of their HIV status is under 60%. There has been increased evidence that HIVST increases uptake of HIV testing, is acceptable and feasible in a variety of settings and populations, and misuse and potential social harms are rare, there is no evidence that it increases sexual risk behavior, and importantly, that positivity and linkage rates are comparable to facility-based testing. In November 2019, WHO issued updated guidance that HIV self-testing should be offered as an approach to HIV testing services (strong recommendation, moderate quality evidence).[158] A positive self-testing referral can immediately lead to the established HIV diagnostic algorithm and count as the WHO recommended treatment verification test.

Scale-up of HIVST has varied by country, although targets doubled from FY19 to FY20. In line with increased HIVST targets, many countries increased their HIVST kit distribution in FY20, with some countries like South Africa, Malawi, and Eswatini surpassing their FY20 targets (Figure 6.3.6).

COVID-19 Adaptations

Within the context of COVID-19, distribution of self-testing kits may help reach individuals who otherwise would be reluctant go to a facility. Additionally, self-testing kit distribution in facilities may help decongest facilities and reduce client-provider interactions. As per the PEPFAR Guidance on COVID-19, 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 screen biological children >2 years of age for HIV.[159] Programs may need to develop alternate

[158] WHO Policy Brief. WHO recommends HIV self-testing—evidence update and considerations for success. November 2019, https://www.who.int/publications-detail/who-recommends-hiv-self-testing-evidence-update

[159] PEPFAR Technical Guidance in Context of COVID-19 Pandemic. Latest guidance available at: https://www.state.gov/pepfar/coronavirus/

workflows to ensure that patients can receive confirmatory testing per the national testing algorithm. There is some evidence that HIVST as a screening tool is highly sensitive, has lower HRH requirements, can increase testing uptake, and can catch clients missed by PITC or risk-based screening, and decrease perception of coercion.[160]

Importantly, self-testing implementation should be strategic and based on epidemiologic environment. Programs may consider accelerating plans for scaling HIV self-testing kit distribution in the following settings, if appropriate based on their epidemiological context:

- Reaching priority populations within the community or facilities
- Providing an HIVST to an index client for their partner
- Providing parents (index clients) with HIVST to screen biological children >2 years of age
- Scale of HIVST for KP and clients of FSW
- Providing HIVST for high-risk PBFW

Countries may also identify non-PEPFAR supported contexts where availability of HIVST should be increased, such as the private sector or online distribution and therefore programs must coordinate scale-up efforts with National programs and other partners.

Importantly, HIVST is a screening test and should not be used to provide a definitive HIV diagnosis. Linkage to HIV testing services through a facility or HTS provider is critical following a reactive HIVST.

Distribution and use of HIVST

Evidence from research in multiple countries indicate high accuracy of HIVST, especially when combined with the offer of direct assistance, in addition to high levels of acceptability for HIVST ranging from 74–96% among couples, young women, adolescents, key populations, and health workers.[161]

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 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

[160] Dovel K, Frackson S, Offorjebe OA, Balakasi K, Nyirenda M, Phiri K et al. Effect of facility-based self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial. Lancet Global Health. Feb 2020.vol 8(2): E276-E287.

[161] World Health Organization. Supplement to Consolidated Guidelines on HIV Self-Testing and Partner Notification. 2016. https://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1

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 and other materials found inside HIVST kits. It does not mean that the test must be performed in the presence of a provider. Unassisted HIVST refer to the distribution of HIVST kits without additional instruction or assistance.

Importantly, 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 (AGYW) and their partners, male partners of ANC clients, sex workers and their clients, KPs and their partners, and other priority populations (e.g., refugees, prisoners, young at-risk men) that face high levels of stigma and discrimination. In addition, self-testing can be incorporated into education campaigns to increase targeted testing of men. Where feasible, messages and materials should be tailored to the barriers and drivers of particular groups and it is vital to engage community groups to advocate for, design, implement, and analyze the success of HIVST. Programs should anticipate the internal and external barriers and challenges that clients may face in deciding whether to link to care and aim to address those barriers. Based on positive outcomes (e.g., linkage and initiation on ART), HIVST should be taken to scale, especially in high yield geographic locations to increase testing of young men. Index clients should also be offered self-testing kits for partners if they do not volunteer to bring them in for index client testing. It is important that individuals who receive the HIVST on from a peer or sexual partner understand how the HIVST is used and feel comfortable demonstrating this to their partners. IPs may develop and explore emerging linkage support tools (e.g., digital or community-based) for unassisted self-testing.

If the price point for HIV self-testing kits were to fall to $1 per test or less, then PEPFAR would support the targeted use of HIVST into facilities. There is preliminary evidence that at this price point, if HIVST is appropriately integrated into workstreams, it would increase testing uptake among priority populations such as men, KPs, partners of index clients, AGYW and their partners as well as be cost-effective and decrease the burden of health worker time for performing tests.

Patient-centered, stigma-free linkage support to confirmatory testing and treatment following reactive HIV self-testing remains critical. In a WHO review, linkage has been shown to be comparable to standard HTS as is linkage to prevention services for those who screen negative. When linkage support interventions are included with HIVST kit distribution, these rates can be improved. Linkage support can include but is not necessarily limited to escorts, counselling

regarding benefits of treatment, and immediate ART initiation; patient reminders were less conclusive. Pre-HIVST information on treatment options and what to do with a reactive test is critical. IPs integrating HIVST into programming should consider the overall linkage support that must be offered.

Procurement of HIVST Kits

As of October 2020, the four HIVST kits below have been WHO pre-qualified:

- In November 2019, WHO pre-qualified the Chembio Diagnostics HIV self-test (SURE CHECK HIV), a blood 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.
- WHO pre-qualified the OraQuick HIV self-test kit for children ≥2 years of age when supervised by a caregiver, which USAID is accepting for procurement.
- In July 2019, WHO also prequalified the Mylan HIV Self-test manufactured by Atomo[162] This kit can now be purchased for programmatic use, and PEPFAR distribution and programming of HIV self-test kits must occur in case-finding and index-testing settings, especially in high-burden settings. Note that country approvals and policies for HIVST and HIVST kits may still be needed.
- The INSTI HIV blood-based Self-test (bioLytical, Canada) was WHO pre-qualified on November 30, 2018.[163] An additional blood-based HIVST kit (BioSure, UK) has received interim ERP-D time-limited approvals for procurement by Global Fund while WHO pre-qualification is pending.[164]

National policies increasingly support programmatic application of HIVST; in alignment with the Minimum Program Requirement on Case Finding, countries 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 test kits to ensure that Countries can choose the optimal test(s) for their context or different settings.

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[162] WHO Prequalification of In Vitro Diagnostics. WHO PQ Public Report. July 2019. PQDx 0320-090-00 Available at: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/190708_pqdx_0320_090_00_pqpr_mylan_hiv_self_test.pdf

[163] https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

[164] Unitaid, World Health Organization. Market and technology landscape: HIV rapid diagnostic tests for self-testing, 4th edition. Geneva: Unitaid; 2018. Available at: https://unitaid.org/assets/HIV-Rapid-Diagnostic-Tests-for-Self-Testing_Landscape-Report_4th-edition_July-2018.pdf

Monitoring HIVST

PEPFAR's MER includes an HTS_SELF indicator that measures distribution of HIVST kits and, where possible, measures intended use of HIVST. Disaggregates of HTS_SELF include age/sex of recipient, point of distribution, intended use (primary or secondary distribution). HTS registers can be adapted to include reason for visit, including at HTS sites, in both community and facility settings, as well as at treatment sites. Reason for visit can include having a reactive HIV self-test and needing confirmatory testing. This is a proxy measure to assess whether individuals with a reactive HIV self-test have actually linked to HTS for confirmatory testing. HIVST indicators or metrics that indicate downstream clinical impacts (e.g., numbers and proportions linked to confirmatory testing, both in PEPFAR and non-PEPFAR-supported sites, and to ART initiation) should be developed by OU teams. Methodologies to track outcomes of HIVST may include activities such as survey questions on HIVST use at treatment and 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), return of kits to provider to estimate positivity on the same day, or drawing inferences from target HIVST population and increase in uptake of testing and treatment within that population. In addition, programs should attempt to track adverse events associated with HIVST, including instances of self-harm or intimate partner violence, and including events related to secondary distribution where possible.

6.3.1.7 Recency Testing

As of October 2020, HIV recency testing has been implemented in 18 countries, and planning and training is ongoing in 13 others.

- Implementing: Cambodia, El Salvador, Eswatini, Ethiopia, Guatemala, Honduras, Lesotho, Malawi, Namibia, Nicaragua, Nigeria, Panama, Rwanda, Tanzania, Uganda, Vietnam, Zambia, Zimbabwe
- Planning and training: Barbados, Botswana, Brazil, Burundi, DRC, Jamaica, Kenya, Kyrgyzstan, Laos, South Africa, Tajikistan, Thailand, Ukraine

In COP21, countries near or at epidemic control should have recency testing at scale across all sites, whether supported by PEPFAR or by other entities and among all newly diagnosed HIV individuals age 15 years or older who consent to the test. PEPFAR teams should consider 1) planning and development of 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) integration of recency testing into existing HIV testing services with trained/certified personnel; and 5) use of standardized site-level data collection tools (both paper-based and electronic) and a central dashboard to monitor quality and analyze aggregate data in real-time; and 6) routine monitoring of data, in as prompt of time as possible, to identify and develop a public health response.

PEPFAR OU teams should engage with the community and provide an opportunity for members of the community to voice their concerns and considerations, which should be addressed prior to and during program implementation and data use. Initial consultations should introduce the purpose of recency testing among newly diagnosed HIV-positive persons, advantages and potential harms of sharing results with clients tested, and information about the limitations of the available rapid tests for recent infection. PEPFAR OU teams should defer to countries' ethical and policy guidelines for return of recency results to individuals in accordance with WHO's 5Cs of HIV testing. OU teams should include clear information about harms and benefits (including mitigating the risk of Intimate Partner Violence and other adverse events) and avoid language suggesting causation in the informed consent and during the counseling session prior to administering the recency test. It is highly recommended that HIV recency testing include VL, as part of a recent infection testing algorithm (RITA) to improve the accuracy 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. Information below provides guidance for implementing quality-assured recency testing. Best practices from early implementers of recent infection surveillance are available on the PEPFAR Solutions Platform and the TRACE eLearning Hub.

Training

All trainings should include didactic sessions and adequate 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 improvements, and monitoring. Additional modules must include adequate hands-on training to ensure complete competency of testers and understanding of SOPs to conduct recency testing, quality assurance elements, interpretation, and RTRI 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). In settings with SARS-CoV-2 transmission, trainings will need to be adapted to be consistent with local transmission prevention regulations and OGAC guidance. This will likely include appropriate personal protective equipment (PPE), smaller class size, social distancing, symptom screening, and virtual training, if appropriate.

If a country allows return of results to individuals, testers should be trained to use appropriate language during post-test counseling. To ensure 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 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 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 task force 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.

Countries restarting recency surveillance activities after significant pause (>3 months) due to COVID-19 restrictions should consider refresher trainings and re-assessment of testing competency through QC specimen panels for staff conducting recency testing.

Monitoring

RTRI is a new point-of-care test 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 SPI-RRT checklist (refer to RT CQI section) available on the eLearning Hub. All sites should have a monitoring visit within first month of implementation. Subsequent visit may depend on indication of quality issues from aggregate data review, QC results or proficiency testing (PT) performance. However, visits should be conducted at least quarterly to ensure continuous quality of testing at sites. If any issues are identified, corrective actions, including retraining should be conducted immediately.

For countries that have paused recency activities because of the COVID-19 pandemic, a re-activation check list 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 program for HIV rapid testing should incorporate RTRI by including well-characterized specimens as part of the panels. Performance of RTRI sites should be continuously monitored internally by site supervisors through routine review of testing practices and logbook and externally by program managers/auditors through periodical site visit using the SPI-RRT checklist. During the first six months of implementation, quality of the program should be even 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 other site visits and conduct site visits at least quarterly and as soon as problems are identified and suspected. Root cause analyses should be conducted, and corrective action plans should be developed and followed up when gaps are identified. HIV recency dashboards allow for an overview and stratified view of RTRI testing, service coverage and kit performance, QC specimen performance, and testing quality at reporting sites. Ongoing review of real-time aggregate 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 data on a dashboard, disaggregated by gender, age, geography, and other key variables, can show plausibility of recent infections based on epidemiology of transmission patterns in the country, which in turn is an indicator of recency testing quality. 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. It is appropriate to include refresher of HIV testing including the national testing algorithm, specimen collection, and DBS preparation for viral load, if applicable, at recency trainings.

6.3.1.8 Optimized Provider Initiated Testing and Counseling (PITC)

There are two strategies of patient selection that may be employed in PITC: diagnostic testing and targeted testing, as defined below:

- **Diagnostic testing** is the testing of patients 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.

- **Targeted testing** is testing of subpopulations of increased risk as identified by behavioral, clinical, or demographic characteristics, or a combination of these such as STI clients, MSM, FSW, or high burden areas. All people presenting for care in the following settings are considered at risk and should be tested for HIV in Antenatal Care Clinics and family planning clinics, TB clinics, STI clinics, malnutrition clinics (for children), MAT clinics, harm reduction sites, and for hospitalized patients including children in inpatient wards.[165] In a country or SNU with ART coverage greater than or equal to 70%, targeted (risk-based) testing yield at the facility level should be at least 10% among adults and adolescents ≥15 years old. In a country or SNU with ART coverage <70%, minimum targeted (risk based) testing yield at the facility level should be at least 5% among adults and adolescents ≥15 years old. Please see Figure 6.3.5 for further details. Once a country has more than 80% ART coverage (i.e., has practically attained epidemic control), PEPFAR support for PITC will be minimal.

Considerations on when, how, and where to implement PITC

It is important to align HIV case finding and testing policies with data on ART coverage and potential gaps in testing. For example, in generalized epidemics, hospital medical wards usually have a high concentration of patients with HIV who would benefit from diagnosis, treatment, and care. If mortality is high in a country or SNU and ART coverage is less than 70% in any specific risk or age group, then testing strategies should be targeted towards that specific risk group. In areas with high ART coverage and lower gaps, PITC should be highly targeted to maintain the minimum yield.

Case finding among patients with TB symptoms

All patients who are either diagnosed with or presenting with pulmonary or extrapulmonary symptoms of tuberculosis (*presumptive TB*) should be tested for HIV (WHO, 2007). Persons with presumptive TB have been shown to have markedly higher prevalence of HIV than the general population; they are also much more numerous than TB patients and tend to be disproportionately men.

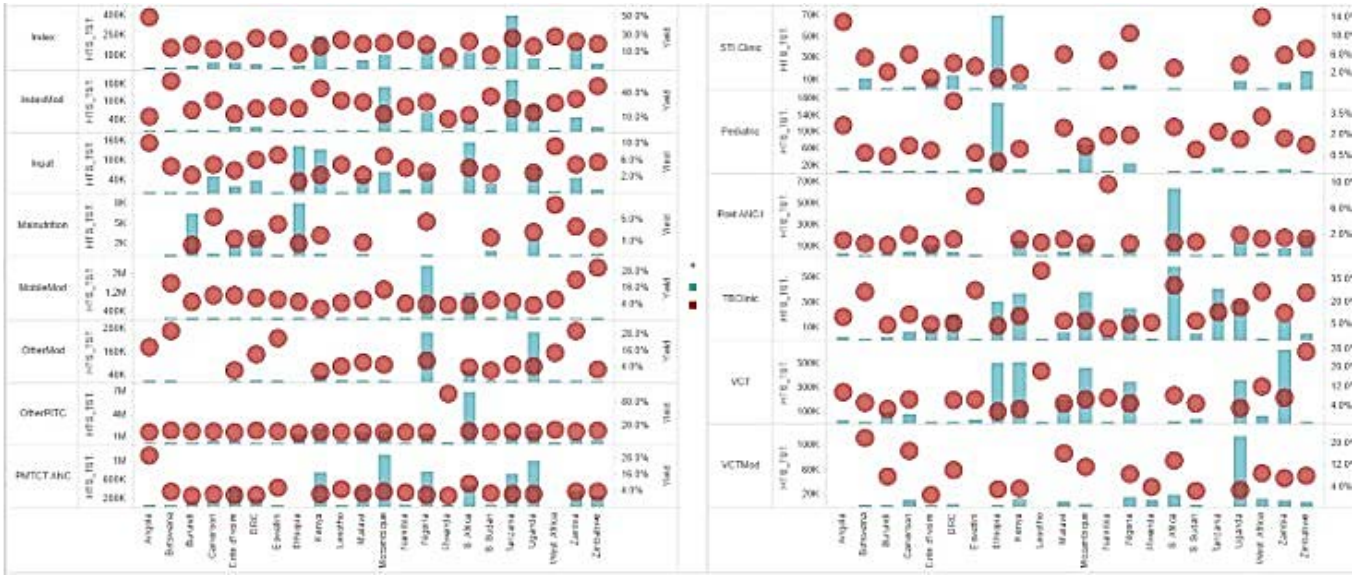
In the setting of COVID-19, countries should consider implementing universal screening algorithms for TB and COVID-19, if appropriate to their epidemiological context. All patients, including children (please see special considerations for children below) should be screened for TB symptoms and linked to TB and HIV testing services if screened positive. This should be considered as a dual infection control and case finding strategy.

[165] Cohn J et al. Pediatric HIV testing beyond the PMTCT context: A systematic review and meta-analysis. Lancet HIV. 2016. DOI: http://dx.doi.org/10.1016/S2352-3018(16)30050-9.).

All patients, including children, 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 yields among presumptive and confirmed TB patients are high ranging in many countries (up to 49%), see Figure 6.3.7, testing volumes for this group have been far below expected. PEPFAR teams 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 wards of the health facility. Countries should evaluate how well TB presumptives are being identified in both outpatient and inpatient settings with at least 5:1 presumptive: confirmed ratio as a guide.

All persons with TB symptoms should be immediately referred for additional TB diagnostic testing with WHO-approved molecular diagnostic tests and LF-LAM, if appropriate; for those deemed presumptive for TB; and TB or HIV treatment initiation, as appropriate (please see Section 6.5.3.1 on TB case finding for further detail on diagnostic testing).

Figure 6.3.6 HIV Testing Yields by Modality FY20 Q1-Q3



TB Contact Tracing as a high yield HIV case finding strategy

Tracing and screening contacts of patients with TB disease not just PLHIV with TB is an important means of increasing HIV and TB case-finding. A recent PEPFAR study in Mozambique

further emphasized the role of TB contact tracing in the community as an effective and high yield strategy for HIV case finding in countries or geographies with high TB and HIV prevalence.[166] Programs should consider collaborating with their respective National TB Programs to incorporate HIV testing into community and facility-based TB contact tracing programs. Again, all persons with TB symptoms should be immediately referred to TB diagnostic testing with a WHO-recommended molecular diagnostic assay, offered point-of-care rapid LF-LAM and TB and HIV treatment initiation. (See Section 6.5.3.1 for further guidance).

Targeted HIV Testing

Although outpatients are generally less ill than inpatients, in generalized epidemic settings, targeted HIV testing and counselling should also be implemented in medical outpatient department (OPD) facilities utilizing an HIV screening tool. Over time, the proportion of OPD patients testing positive has declined in many programs. But this trend is heterogeneous across countries and within country programs. Programs should review their OPD positivity rates by site and transition from universal OPD to targeted or diagnostic testing where positivity rates are low (below 10%). Sites that have large absolute numbers of PLHIV but low positivity rates in OPD must consider how to make OPD testing more strategic.

Programs should aim to reduce unnecessary testing using a variety of strategies, including:

- Aligning counseling messages on retesting to include retesting based on exposure and not a one size fits all 3-month window period.
- Not retesting those on ART or previously diagnosed PLHIV with a documented status.

Programs should develop screening and testing algorithms to identify individuals who need HIV testing. An HIV risk screening tool is a set of questions (behavioral, demographic, symptom-based, etc.) used to determine a client's eligibility for HIV testing. A validated HIV risk screening tool meets four conditions:

1. Decreases the number of persons needing to be tested;
2. Is non-stigmatizing (i.e., sensitive questions are asked in private spaces)
3. Has high sensitivity (i.e., does not screen out or misclassify a large % of true positives as not at risk);
4. Must be easy and quick to administer.

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

[166] 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

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, recurrent skin problems, recurrent infection,[167] swollen abdomen (enlarged liver or spleen), delayed physical and developmental growth, swollen lymph nodes, intermittent diarrhea, oral thrush,[168] history of TB or TB symptoms, pus coming from ear, discharge or sores in genital area[169,170,171,172,173]
8. For women— a child born with HIV or with unexplained illness who died before age 2

In high-prevalence areas, pregnant and breastfeeding women initially testing HIV negative should have repeat testing around delivery and during breastfeeding since risk of acquisition may be increased in PBFW and new infection during this time period is associated with increased risk of transmission to children (See Section 6.2.4.1).

In addition, in high-prevalence areas, individuals engaging in unprotected intercourse who have not been tested in the past 6 months may also have high rates of HIV infection and should be offered testing. In low-prevalence and concentrated epidemics, HIV testing and counselling is only recommended for adults, adolescents, and children who are:

- A member of key populations

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[168] WHO. Manual on Paediatric HIV Care and Treatment for District Hospitals: Addendum to the Pocket Book of Hospital Care of Children. 2011. Available at: https://apps.who.int/iris/bitstream/handle/10665/44511/9789241501026_eng.pdf?sequence=1

[169] 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;

[170] C Katureebe, JM Gross, et al. (2019) Developing a pediatric and adolescent HIV-screening tool in outpatient setting in Uganda. International Workshop on HIV Pediatrics 2019. Abstract 87: http://regist2.virology-education.com/abstractbook/2019/abstractbook_Pediatrics2019.pdf.

[171] Horwood C, Vermaak K, Rollins N, Haskins L, Nkosi P, and Qazi S. Pediatric HJIV management at primary care level: an evaluation of the integrated management of childhood illnesses (IMCI) guidelines for HIV. BMC Pediatrics. 2009;9(59). doi:10.1186/1471-2431-9-59;

[172] Moucheraud C, Chasweka D, Nyirenda M, Schooley A, Dovel K, Hoffman RM. Simple screening tool to help identify high-risk children for targeted HIV testing in Malawian inpatient wards. J Acquir Immune Defic Syndr. 2018;79(3):352-57.

[173] Ferrand RA, Weiss HA, Nathoo K, Ndhlovu CE, Mungofa S, Munyati S, et al. A primary care level algorithm for identifying HIV-infected adolescents in populations at high risk through mother-to-child transmission. Trop Med Int Health. 2011;16(3):349-55.

- Partners of people with HIV
- People with sexually transmitted infections, TB, or viral hepatitis
- Have either never been tested or not recently been tested
- Present to health facilities with signs and symptoms suggestive of underlying HIV infection (i.e., diagnostic testing), including tuberculosis and malnutrition (see above "Symptoms that should prompt an HIV test"
- Children known to have been exposed perinatally or during breastfeeding to HIV

Countries should validate HIV risk screening tools and scale up their routine use across HTS for adults, adolescents and children presenting to OPDs. HIV risk screening tools can be useful in low prevalence settings in identifying those who are at highest risk and therefore decreasing the number needed to test to identify one positive, improve testing efficiency, PITC testing yield, and ensuring that people with risk factors are tested. Countries, geographic areas, or facilities with generalized epidemics with consistently low number needed to test may be missing HIV cases and may need to re-evaluate their testing strategy.

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, timing of additional tests for PBFW (pregnancy, labor and delivery, breastfeeding) can determine how well services are covering populations in need. In settings where positivity is high, programs should consider incorporating HIV self-testing modalities 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 served. For example, in countries where yield is low in the general population (<3%), steps should be taken to focus testing on target populations. In settings where yield is high (>5%) yet 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.[174]

6.3.1.9 Community-Based Testing and Leveraging Risk-Screening Tools

Community-based testing services are those offered outside of a health facility within the broader community. WHO recommends community-based testing, especially to reach men, key populations and their partners, young people, and others who may be less likely to be seen or tested in facilities.[175] PEPFAR does not support door to door community testing unless recency tests indicate this is needed to trace individuals. All community testing should be as focused as other modalities and produce similar yields, and it should be competitive with cost for new HIV positive individuals identified. No community-based testing will be supported that does not result in immediate linkage to treatment, and countries with ART continuity challenges should prioritize fixing those issues before expanding community testing. Similarly, in light of the COVID-19 pandemic, programs should carefully consider the feasibility and safety of community testing efforts. There are several important considerations when designing these HIV testing services, including engagement of the target communities and approaches that are focused on the relevant populations and appropriate settings. It is integral that facility and community partners work closely together, share data, best practices, and collaborate on strategies to ensure that contacts to index patients are identified and brought to facilities for testing and linkage to treatment.

Given the relative expense, community-based testing should be limited to high-burden geographic areas or non-facility settings (e.g., home, bars, clubs, places of worship, cruising sites, workplaces, or mobile outreach) where selective and targeted community mobile testing may be acceptable and produce high-yields. Studies show that HIV testing uptake among key populations are highest when combined with testing for TB, STIs, and/or hepatitis but somewhat lower when combined with screening for chronic conditions.

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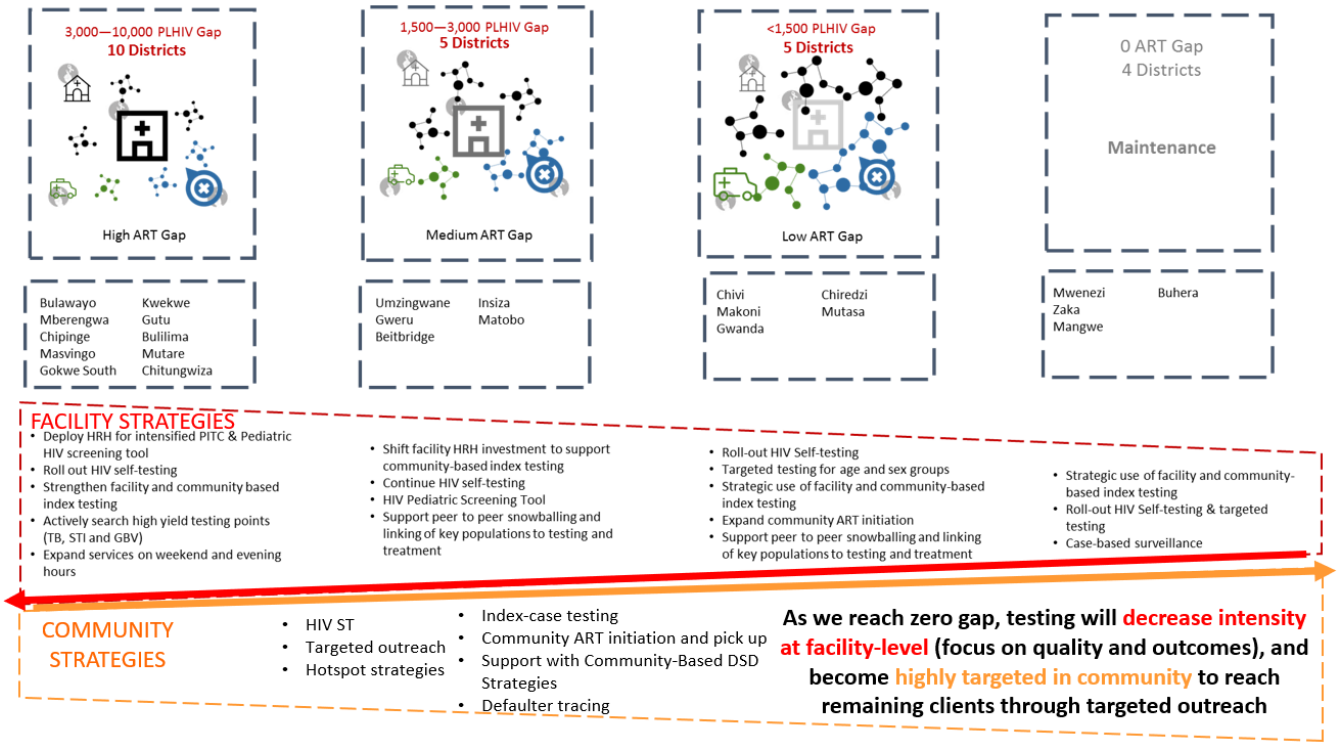
[174] Addressing the blind spot in achieving epidemic control in Malawi: Implementing “male-friendly” HIV services to increase access and uptake. December 2018. Available at: https://www.pepfarsolutions.org/solutions/2018/12/19/addressing-the-blind-spot-in-achieving-epidemic-control-in-malawi-implementing-male-friendly-hiv-services-to-increase-access-and-uptake

[175] WHO Consolidated Guidance on HIV Testing for a Changing Epidemic — https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

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 FSWs should also target their clients, and all community-based testing strategies should offer immediate linkage to care, prevention services (e.g., PrEP) for high-risk populations who test negative.

Programs should consider incorporating HIV self-testing into community-based testing strategies where appropriate. Community distribution of self-test kits may be used when targeted to high-risk individuals, notably those with risk factors or those in sexual or social networks of PLHIV or key populations with very high risk. Implementing Partners who support HIV Testing programs are responsible for both linking those who test positive to treatment and offering a variety of testing modalities including HIV self-testing. Implementing partners supporting HIV testing program must also provide facilitated linkage (e.g., peer navigation) to treatment facilities and are required to follow-up and demonstrate successful linkage to treatment. Community-based KP testing will continue to be supported in all PEPFAR settings, including high ART coverage areas. However, numbers of individuals tested, and concurrent yield should be closely monitored to inform continued use of these strategies. If the numbers or individuals tested, number identified positive or yield do not support continued efforts/expense, the specific strategies should be discontinued. Community-based testing cannot be supported unless immediate ART is available, and linkage to treatment is >90%.

Figure 6.3.7: HIV testing modalities adjustments based on ART coverage



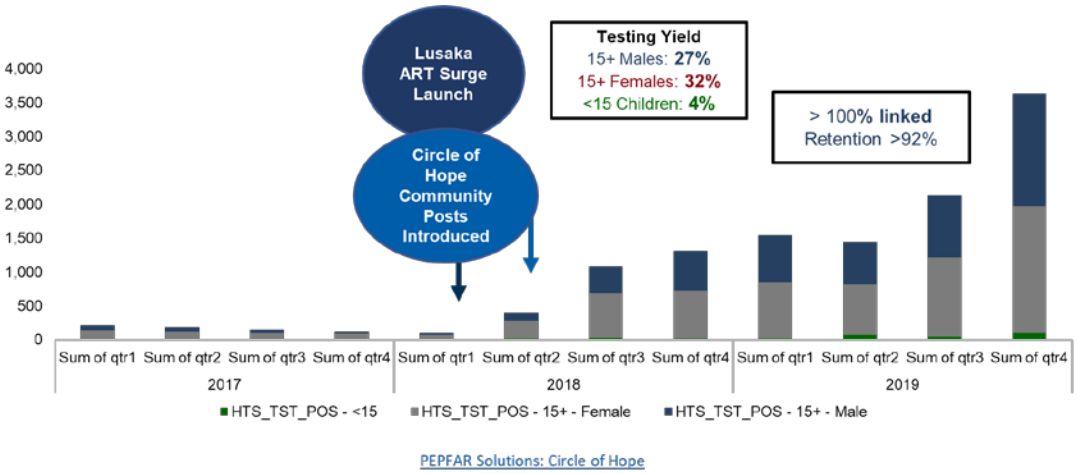
6.3.1.10 Targeted Testing in Faith Community Collaboration

Countries that support Faith Community models through Care and Treatment investments are required to use models that have an evidence base and have been shown to work. The following models are examples that may be implemented either as part of a full FCI Collaboration (See Section 6.6.5), or by incorporating them into standard HTS and treatment programming.

Faith-Engaged Community Posts, Zambia (Circle of Hope)

- To close the ART coverage gap for men and children, Circle of Hope expanded access to HIV services by introducing decentralized faith-engaged community posts (CPs).
- Multidisciplinary teams from local faith communities staff the CPs, which are not identifiable as clinic sites, and provide confidential, compassionate, comprehensive HIV services in areas of high activity that men frequently visit (e.g., markets, transport hubs, churches/mosques). Testing strategies include risk-based testing and index testing of sexual contacts and biological children.

Figure 6.3.8[176] Faith-engaged Community Posts Associated with Increases in New HIV Case Ascertainment, with High Linkage and Retention



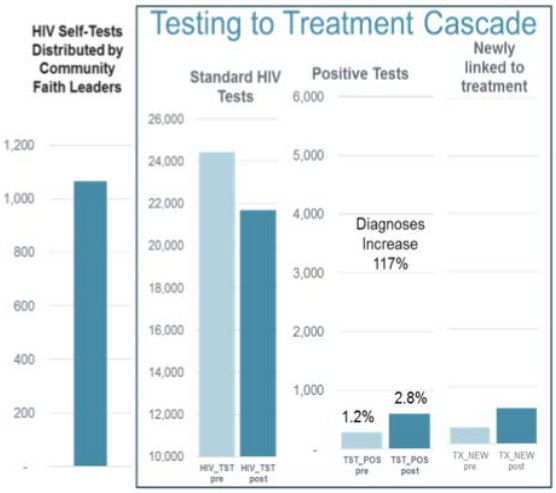
- During the 19 months following introduction of CPs (March 2018–September 2019), as compared to the 17 months before, the median number of new HIV cases identified per month increased 1087% overall, 1494% in men, and also increased for children.

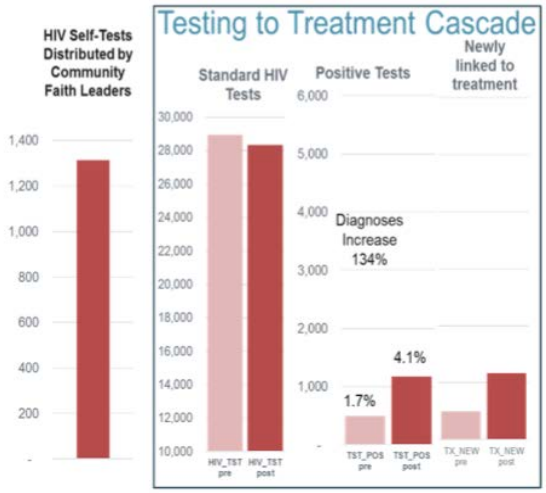
Faith-Engaged Highly Targeted HIV-Self-Testing in Urban Settlements, Kenya (EDARP)

- EDARP links clinical and community care in 14 sites in Nairobi slums. More than 1300 community health workers (CHWs) and faith leaders received tailored training to provided targeted dissemination of HIVST kits during home visits, emphasizing patient-centered partner notification services.
- In a pre-post analysis, new diagnoses increased 117% and 134% for men and women, respectively, with similar increases in linkage into treatment.

[176] G Makangila, A Mwango, M Shah, N Kancheya, K Nkwemu, I Zulu, I Essiet-Gibson, L Erickson-Mamane, S Agolory, S Hillis. Increased Case-Finding and Efficiency through Faith-Engaged Community Posts, AIDS2020Virtual

Figure 6.3.9 and 6.3.10 Increases in HIV Positive Tests, Linkages, and Testing Yield among Men and Women in Nairobi, Kenya[177]





The following FCI strategies have also been demonstrated to advance case-finding and continuity of care in faith-engaged community settings for men, youth, and children (See Section 6.6.5 and FCI Implementation Guide**,** 'Engaging communities of faith to find men and children living with HIV,' on PEPFAR SharePoint)

- Co-location of health clinics/testing sites with religious venue (Zambia *Discover project, see Section 6.6.5 for detail).*
- Community Adolescent Treatment Supporters (CATS) improve adolescent HIV care and support, Zimbabwe (*Africaid Zvandiri Program).* CATS facilitators work within and beyond faith structures to strengthen networks of social protection, create demand for HIV testing, deliver HIVST kits to at-risk youth, and support case identification, linkage, and continuing in care for children and youth.
- Baby Shower Initiative: A church congregation-based approach, Nigeria. Project demonstrated improved HIV testing among pregnant women (with 93% linkage) and their male partners, who were 12 times more likely to know their status, compared to

[177] R. Bauer, J. Motoku, C. Muriithi, C. Simbiri, A. Njoroge, H. Weyenga, A. Katana, M. Maxwell. Engagement of faith leaders in targeted HIV self-testing increased case identification and new linkages to treatment in Nairobi, Kenya, AIDS2020Virtual

partners of women giving birth who had not participated in the congregation-based events.[178]

6.3.2 Case Finding for Pediatrics

The successful scaling-up of universal 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. There have been increasing proportions of newly diagnosed children aged 5 years and older (see Figure 6.3.9), many of whom were missed by PMTCT and EID programs due to mother-infant pairs disengaging from care or treatment services. Without treatment, children living with HIV are at high risk of death, yet, in 2019, only 53% of children and young adolescents (< 15 years) living with HIV globally had access to treatment.[179]

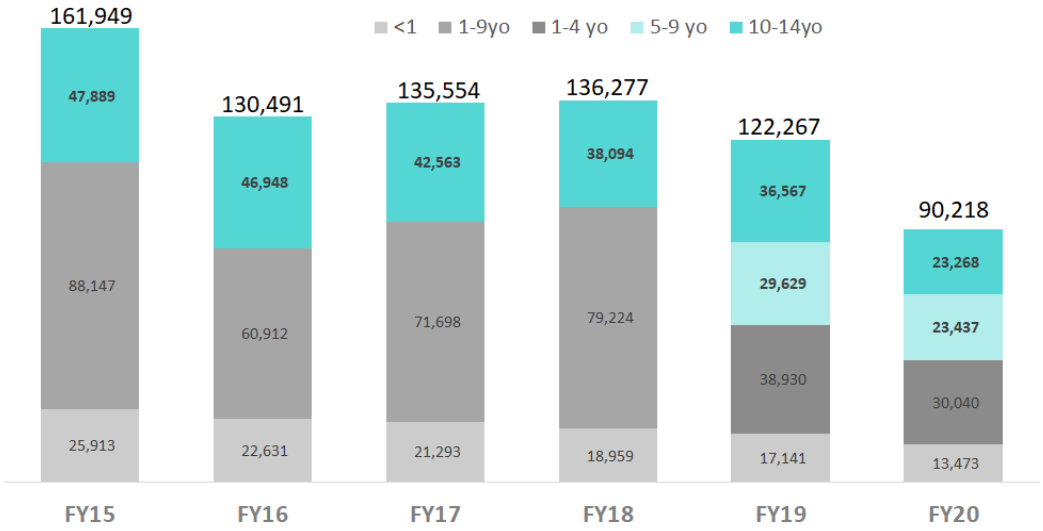
Figure 6.3.12 highlights the need to refocus case-finding and treatment efforts on school-aged children and adolescents, while also improving early infant diagnosis and identification of children in the 1-4 years age band Although children infected during breastfeeding may have slower disease progression and live beyond five years of age and into adolescence, early diagnosis is important to prevent morbidity due to HIV.[180] Furthermore, strategies to ensure that victims of childhood sexual violence are identified, receive appropriate medical care including HIV testing, and promptly referred to local child welfare authorities, psychosocial support services and the OVC program are critical when designing programs that target case finding for children.

[178] Ezeanolue, E.E., et al., Effect of a congregation-based intervention on uptake of HIV testing and linkage to care in pregnant women in Nigeria (Baby Shower): a cluster randomised trial. Lancet Glob Health, 2015. 3(11): p. e692-700.

[179] UNICEF, 2019AIDSinfo I UNAIDS, Coverage of people receiving ART – by age (Global AIDS Monitoring 2020; UNAID estimates, 2020: https://aidsinfo.unaids.org/

[180] 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).

Figure 6.3.12: Number of children (<15) newly diagnosed in PEPFAR programs by age band[181]



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.

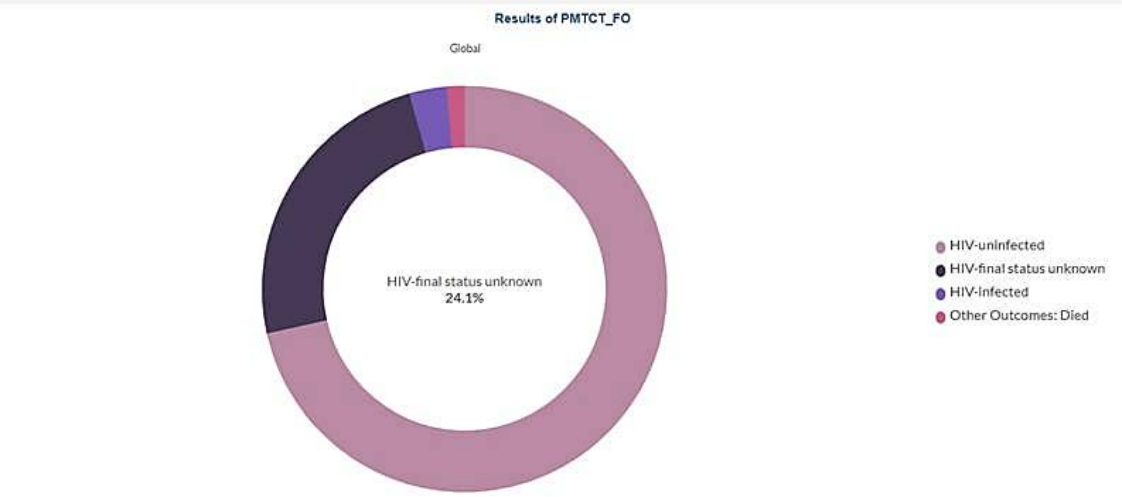
Early Infant Diagnosis (EID)

Early infant diagnosis (EID) is a critical approach to test HIV-exposed infants (HEI) and promptly link infants living with HIV to treatment. It is important to test infants of women with HIV periodically during breastfeeding and after the end of breastfeeding (final outcome, PMTCT_FO), per WHO guidelines. Undiagnosed infants living with HIV are at high risk for mortality due to HIV. Up to 50% of untreated infants living with perinatally transmitted HIV die

[181] Source: Panorama, Age and Sex Disaggregates from November 20, 2020: All PEPFAR OUs Dashboard; HTS_TST_POS 1-9; (<1) FY15-18 Cum Results PMTCT_EID_POS and FY18-FY19 Cum Results PMTCT_HEI_POS; FY19–FY20 data by fine age band.

within the first year of life, with mortality being especially high in the first months of life.[182,183,184] FY20 data showed that nearly 25% of HEI had an unknown final outcome (see Figure 6.3.12); this is concerning given the above-mentioned high rates of mortality among infants living with HIV who do not receive effective treatment.

Figure 6.3.13: Nearly 25% of known HEIs had an unknown HIV status, FY20[185]



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 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

[182] 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. [Available from: https://academic.oup.com/ije/article/40/2/385/733186]

[183] 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. [Available from: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext#articleInformation]

[184] 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/

[185] Source: Panorama, *PMTCT-HEI Global* Dossier, *Overall Results of PMTCT_FO*, November 20, 2020 FY20 data

uptake of timely EID services. (Please see Section 6.3.1.3 for guidance on EID.) Mother-infant pairs 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 of breastfeeding women occurs judiciously (please see Section 6.3.5), with immediate testing of infants of newly diagnosed women with HIV.

Children and adolescents (≤ 19 years old)

An optimal mix of testing strategies is needed to maximize the identification of C/ALHIV, while ensuring index testing of pediatric contacts is prioritized. Each program should identify an overall testing strategy that reduces the number needed to test (NNT) to identify one C/ALHIV, while increasing the absolute number of HIV-positive children identified, and utilize other analyses such as contribution of new diagnoses by testing modality, fine age and sex band analyses, etc. 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).

Routine, universal testing of children in OPD is no longer strategic and thus not warranted. Figure 6.3.14 illustrates that Other PITC and Index testing account for the largest volume of newly diagnosed HIV-positive children, with Other PITC having a higher NNT compared to most other testing modalities. 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 an HIV positive biological parent are offered HIV testing services. Programs must optimize the use of risk screening tools with fidelity in OPD settings to reduce the NNT, while improving yield and increasing the absolute number of HIV-positive children identified. Risk screening tools should be evaluated to ensure they 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 do not miss undiagnosed CLHIV.

Ensuring coverage of routine HIV testing 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 PLHIV with TB can be high yield for CLHIV case-finding and provide an opportunity for TB prevention and pediatric case-finding.

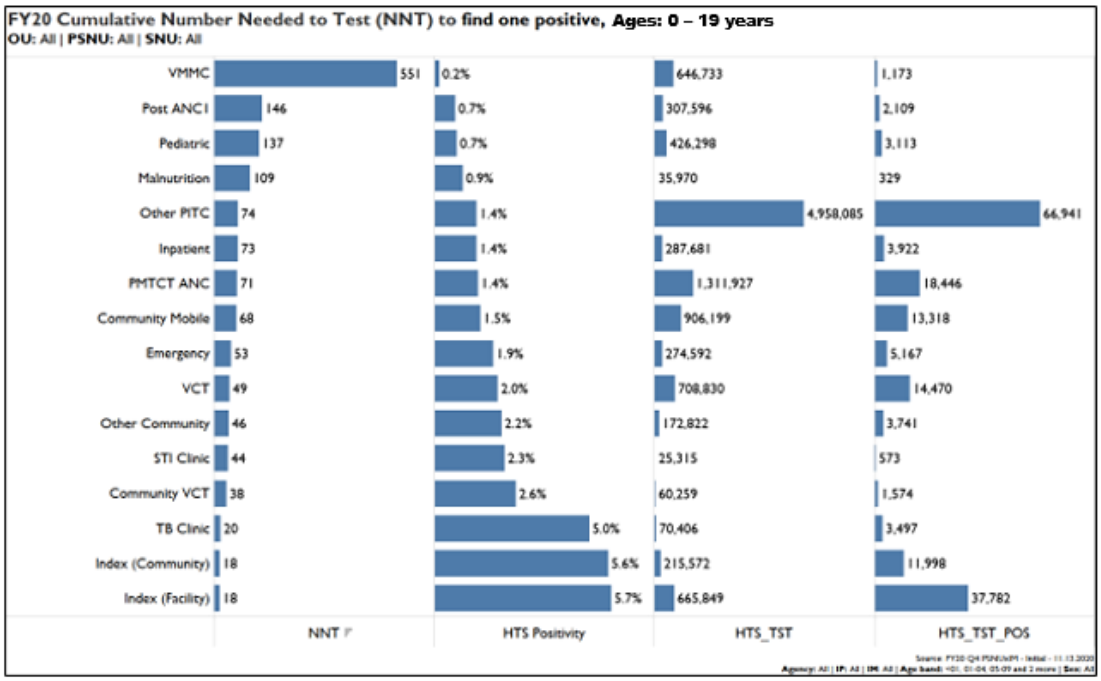
Testing analyses, including but not limited to NNT, for these sick entry points should be re-evaluated routinely to ensure that they remain prioritized, effective, and efficient modalities from

which to identify CLHIV. Testing modalities with higher NNT require additional analyses as they may still offer essential standard of care testing services (like for VMMC). Similarly, testing modalities with lower NNT necessitate further review to ensure testing coverage is appropriate for the population served. Routine inpatient department (IPD) testing may still be appropriate in many high HIV burden areas, and programs should systematically evaluate IPD testing compared to other modalities to ascertain efficiency and effectiveness of testing strategies. It is important to determine the limitations of this data in order to assess whether pediatric inpatient testing should be limited to diagnostic and HIV risk-based testing, or if implementation of a standardized HIV risk screening tool would be more appropriate.

Pediatric testing strategies should include:

1. Index testing services to all individuals newly diagnosed with HIV (and virally non-suppressed PLHIV on ART) 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. Targeted OPD testing (Other PITC, MCH/pediatric (< 5 years of age) well child clinic) using 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) in order to lower the NNT to identify one CLHIV, while still ensuring the high volume of undiagnosed CLHIV presenting to OPD are identified and absolute numbers are maintained.
4. Routine HIV testing for sick-entry points (malnutrition, TB, inpatient, STI clinic).

Figure 6.3.14: Cumulative Number Needed to Test (NNT) to Find One C/ALHIV (0 – 19 years) across HIV Testing Modalities, FY20[186]



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 old) of a parent diagnosed with HIV are offered safe and ethical HIV testing services if the biological child/adolescent has an unknown HIV status.** It is important for HTS, Clinical and OVC 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 the per the Case Finding Minimum Program Requirement, while also optimizing testing at all facility and community entry points to identify at-risk children, including biological pediatric and adolescent siblings of C/ALHIV (see Section

[186] Source: MER Structured Database, November 20, 2020 FY20 APR data

6.3.2.2 on OVC case finding). Additional implementation resources, such as SOPs, to improve coverage of safe and ethical index testing for children will soon be available. Programs must ensure index testing service 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 laws of consent) must never be coerced in any way to receive HIV testing services for their dependents or themselves, or denied any relevant services.*

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). Trainings and messaging on index testing should increase awareness among healthcare workers and PLHIV 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 coverage (percent of elicited children tested, including reporting on those with known HIV status) and yield (as one of the measures of fidelity and impact) for this essential pediatric case-finding strategy.

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[187] approaches to engage with and reach in a safe and ethical manner, further detailed here.

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.[188]

[187] 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.
[188] 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.

PEPFAR Technical Guidance in Context of COVID-19 Pandemic recommends programs collaborate with Ministries of Health to consider temporary 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 partners) is recommended. This may include creation or modification of a memorandum of understanding among all parties.

6.3.2.2 Case Finding in OVC

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 for referral and follow-up by OVC partners to ensure that children who are elicited or identified as part of index testing are tested. Clinical and OVC IPs should have developed formal relationships, such as a memorandum of understanding (MOU), outlining the roles and responsibilities of each member of the multi-disciplinary team and addressing key issues such as bi-directional referral protocols, case conferencing, shared confidentiality, index and other testing support, and joint case identification, and data sharing. All women living with HIV with biological children of unknown HIV status need to have an OVC case worker assessment, and the OVC team in coordination with HTS providers and other clinic staff must 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 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, 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).

6.3.3 Case Finding for Adolescents and Youth

This section will provide guidance on case-finding in adolescents (10 – 19 years of age) and youth (15 – 24 years of age) with sexual HIV exposure. For guidance on case finding for adolescents with perinatal HIV exposure please see Section 6.3.2.

Adolescents and youth living with HIV (AYLHIV) 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 access HIV testing services (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 negative attitudes towards HIV, and limited access to youth-friendly, non-judgmental health services..

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, Other PITC of youth presenting for sexual and reproductive services, and HIV self-testing (HIVST). Adolescents and youth engaging in sex work, injecting drugs as well as young MSM and transgender individuals should be prioritized for testing given increased risk of acquiring HIV. 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. 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.

HIVST has a high acceptance rate among youth.[189] Although HIVST holds the potential to increase HTS coverage among adolescents and youth, programs will need to ensure that individuals screening reactive are linked to confirmatory testing, as per the national testing

[189] https://www.who.int/features/2015/hiv-self-testing/en/

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 AYLHIV than older adults, national programs and implementing partners should ensure that prior to commencement of HIVST kit distribution to AYLHIV, procedures 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. This strategy may be effective among targeted 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, programs should include known adolescent and youth HIV risk factors on adult risk screening tools, and ensure adult tools are validated and used for older adolescents (15-19 years old). Adolescent risk factors include ≥ 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 a STI. Anyone who is identified at risk for or is the survivor of maltreatment (negligence or abuse, including violence against children or intimate partner violence) should be provided with first line support aligned with the LIVES framework and referred to the appropriate medical, psychosocial, legal, and child welfare support services.

Younger adolescents (10-14 years old) should be screened using validated 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 and youth 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.

6.3.4 Key Populations: Optimizing Testing and Case-Finding Strategies

PEPFAR teams should consider how they can access undiagnosed HIV-positive sub-populations of key populations 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 technology (ICT) platforms to complement venue testing. 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 evolves and becomes more client-centered, both physical and online mobilization and referral are needed.

6.3.4.1 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, their partners and children to ensure their safety and security. All sites serving key populations living with HIV (KPLHIV) must ensure implementation of:

- PEPFAR has issued guidance on safe and ethical index testing for index testing provided at any PEPFAR-supported site (See Section 6.3.1.5). This Guidance includes PEPFAR Minimum Standards that are referenced below. Some specific points of emphasis regarding these minimum standards for key populations in particular are:
    - Adherence to 5Cs (consent, confidentiality, counseling, correct test results, and connections to treatment and prevention services:
    - An emphasis must be placed on participation in index testing and partner elicitation as voluntary and that establishment of trust between KP clients and service providers is paramount.
    - Confidentiality, privacy, informed consent and their implications for index testing including in country-specific contexts needs to be stressed. Service providers must be aware of the legal and cultural environment where they operate and how KP may be adversely impacted from disclosure of their KP "status."
        - For example, index testing programs must avoid practices that may out gay, bisexual, and other men who have sex with men as they might face the risk of

violence, losing their livelihoods or being expelled from their homes, which is a particular concern for youth.

  - Personal identity and other information about key populations must be protected and kept confidential. The Minimum Program Requirements (MPRs) require use of unique identifier codes (UICs) with all populations. In particular, programs working with key 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.

- Intimate partner violence (IPV) risk assessment and provision of "first line" response, including safety check and referrals to clinical and non-clinical services (if not provided on site)
  - 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.
- A site level Adverse Event Monitoring and Reporting system
  - A mechanism should be in place for patients/beneficiaries to anonymously report any adverse event or other risk experienced as a result of participating in index testing.
  - Providers trained and supervised on index testing procedures including 5Cs, IPV screening, adverse event monitoring, and ethics (respect for the rights of clients, informed consent and 'do no harm')
  - 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)

For detailed guidance on providing safe and ethical index testing, see Section 6.3.1.5. All index testing for all populations should be provided in alignment with the Guidance on Implementing Safe and Ethical Index testing. 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.

In addition to the above, other KP considerations for index testing include:

- A good counsellor or motivational interviewer can impact the number of partners elicited considerably. Investing in training counsellors is critical.
- Considerations for partner elicitation should be practiced (e.g., prioritize eliciting non-paying partners, "sweethearts" or "special boyfriends" of female and male sex workers; MSM and transgender women must be asked about both male and/or female sex partners; PWID must be asked about both needle-sharing and sexual partners).
- 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 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.
- Under-19 years old biological children should be elicited from key populations living with HIV, and a strong referral, treatment linkage, and retention system with trusted providers (i.e., programs for orphans and vulnerable children (OVC)) should be in place to ensure services for these children. Programs for children of key populations have informed specific guidance to ensure appropriate care and demonstrated the need for services as the case finding rates for children of key populations KP were double that of other children when data was compared across 9 countries. 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 home due to authorities' perceptions of abuse or neglect due to parenting by adults from a KP group. KP and OVC partners should coordinate to ensure that children of key populations are not lost from referral, and that HIV-positive children of KP are linked to treatment and retained, while ensuring safeguards to protect the HIV status of key populations and their children. (For more guidance on Safe and Ethical Index Testing, please see Section 6.3.1.5, and 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 6.6.2.2 Structural Interventions for Key Populations.

In Tanzania, index testing implementation has shown an increase in the contribution of newly diagnosed HIV positive individuals from FY19Q1 (27%) to FY20Q3 (85%) from one KP implementing partner. Data from FY20 Q3, shows over 17,000 contacts elicited from index clients with an index-to-contact ratio of 1:4. This index-to-contact ratio has been accomplished through prioritization of FSW with multiple sexual partners, active mentoring of community outreach volunteers and healthcare workers, and respectful, non-coercive re-elicitation at ART follow-up visits conducted in community settings. Of the contacts elicited during this period, 80% were tested with 32% newly diagnosed positive individuals among 15 and older and 11.7% for contacts less than 15 years.

6.3.4.2 Social Network Testing

Focused KP testing through sexual, drug-using, and other social networks of key populations to improve HIV case-finding 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, 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 model, link HIV-positive key populations to rapid ART initiation, and connect HIV-negative key populations to services that will help them remain HIV-negative.

These approaches have been used since 2014 to supplement peer venue-based outreach in favor of using KP mobilizers (also known as “seeds”) who are HIV-positive or high-risk HIV-negative (depending on the strategy) to promote and refer testing among members of their

sexual, drug-using, and social networks. It is understood that these networks are important given the greater likelihood of positive status among social and sexual networks of KP members, particularly key populations living with HIV). In addition, social network testing can especially be utilized to reach hidden and harder to reach specific sub-populations like key populations who use drugs, such as amphetamine-type stimulants (ATS), during sex, often referred to as ChemSex, which may facilitate high risk group sex activity for long periods. There are documented associations between stimulant drug use (injecting and non-injecting) during sex and decreased condom use, sex with multiple partners, other high risk sexual behaviors, and sharing of needle equipment, which lead to increased risk for HIV and other STIs.[190] Network strategies can be utilized to ensure hard-to-reach key populations, such as those engaged in ChemSex or group sex, access needed HIV prevention, testing and treatment services.

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 well monitored or non-monetary incentives, for example, must be in line with ethical testing policies and a sustainable national approach.

Evidence of the impact of social and risk network approaches can be found in many contexts. Thirteen implementing partners in Kenya launched SNS with non-monetary incentives for their KP programs in 2020. Early results demonstrate 329 (18.2%) new cases among 1,805 MSM, FSW, and PWID sexual and social network members tested. This testing yield far exceeds the 1.9% yield from their combined other KP testing approaches and SNS new cases represent 17% of all new KP diagnoses over the four-month period. Refinements of the program include further scale-up and building acceptance among MSM. In Côte d'Ivoire, similarly, EPOA resulted in consistently higher HIV case finding among FSW and MSM (19%-23% compared to 8% through venue based traditional outreach testing). When testing yields declined, approaches were adapted, and sustained high levels of case finding were achieved. Once identified through this approach, index testing methods are a natural complement to identify other sexual and needle-sharing partners of key populations living with HIV.

[190] UNODC. HIV Prevention, Treatment, Care and Support for People Who Use Stimulant Drugs: Technical Guide https://www.unodc.org/documents/hiv-aids/publications/People_who_use_drugs/19-04568_HIV_Prevention_Guide_ebook.pdf

6.3.4.3 Blended Index and Social Network Strategies

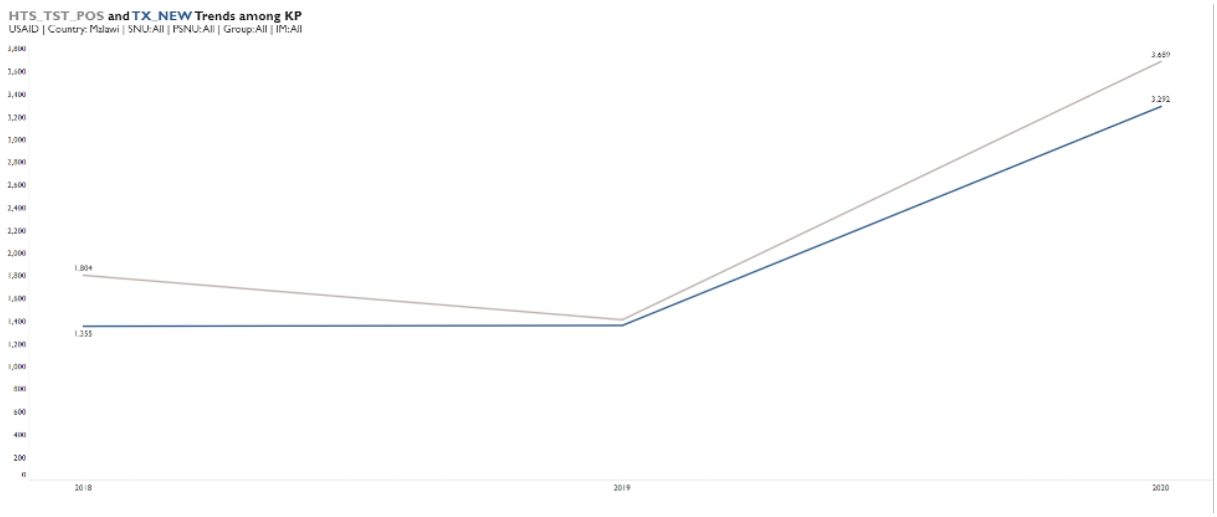
In FY20 most PEPFAR OU's are on track to achieve their KP HIV case-finding targets. Where this has been the case OUs have built upon a core foundation of community, facility and complementary index testing and social network strategies (SNS) to expand their case-finding options for key populations. Index and social network testing can be used in concert to ensure that all high-risk, direct exposure contacts and social network members are tested, and that HTS extends into harder-to-reach networks of undiagnosed PLHIV, especially among key populations. In addition, complementary index testing strategies 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 6.3.4.1 (index testing) and 6.3.4.2 (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 elicitation of exposed contacts from an HIV-positive individual (index client). SNS is a complementary case-finding activity that involves the 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 cards. SNS referral cards may be offered to KP clients who, for whatever reason, are unwilling to provide names or contact information of all direct-transmission partners during index partner elicitation but would be willing to give that partner the SNS referral card. Another illustrative example of blending index and SNS testing could be with female sex workers. These KP members may give names of sexual partners during index testing elicitation and may also be provided with SNS cards to refer other social network members, for example other female sex workers or males (sexual or non-sexual partners) at sex worker hotspots. 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 to share KP contacts, for example, allows for even greater anonymity 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 6.3.4.4 for more information about self-testing for key populations.

During the COVID-19 lockdown, Malawi combined a blended approach to social network testing with scale-up of HIV self-testing and an online and mobile phone outreach approach promoting and escorting clients for testing referrals, this blended approach led to KP FY20 case finding results that exceeded targets by over 200%.

Figure 6.3.15 HTS_TST_POS and TX_NEW Trends among KP in Malawi



6.3.4.4 HIV Self-Testing for Key Populations

HIV self-testing (HIVST) plays an important role in increasing access to and frequency of testing, while deliberately working to promote linkage to treatment for those who screen HIV positive as a best practice. 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 self-test kit distribution. Primary HIVST kit distribution strategies for key populations include drop-in centers, hotspot distribution, home delivery, online orders, automatic dispensers, community-based mobile units, and private pharmacies. WHO recommends secondary distribution of test kits via index testing and social network strategy approaches (WHO recommends HIV self-testing-evidence update and considerations for success.[191] The first efficacy trials for HIVST were with sex workers who successfully distributed tests to their clients. Many countries use HIVST to reach partners of newly diagnosed KP who may not feel comfortable providing partner information during index testing partner elicitation. Likewise, HIVST can be used in cases where routine testing doesn't effectively reach hidden KP networks, for example, clients of sex

[191] WHO/CDS/HIV/19.36 Nov 2019 Policy Briefs

workers, men who have sex with men but do not identify as gay or are closeted, or key populations who will only order a HIVST online or pick one up but who won't visit a testing site.

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. One KP implementing partner distributed HIVST kits through peer-led activities that achieved 19,529 (62%) beneficiaries receiving assisted HIVST services and 11,842 (38%) receiving unassisted HIVST. Through active follow-up, end users update the IP staff and peers via SMS or calls through phone numbers given on HIVST kits resulting in FY20 results return for 90% of HIVST beneficiaries. An innovation of secondary distribution to key populations involved a collaboration with community volunteers (Peer Maids) who distributed HIVST kits in Tanzania. In FY20 Q3, HIVST kits were distributed to female housekeeping staff in 135 hotels for a period of three months in Dar es Salaam and three weeks in Mwanza. This demonstration project in Dar es Salaam and Mwanza reached 1,138 FSW, provided HIVST to 1,021, and identified 129 newly diagnosed HIV positive individuals for a 13% testing yield and immediate linkage to ART. Scale-up to other regions is being planned in FY20 Q4. Implementation science research (PEPFAR's KPIS initiative) conducted in Kenya and Brazil showed successful examples of HIVST among female sex workers and MSM. Brazil's HIVST kit distribution to MSM has been expanded through online orders and automated dispensers installed in generic locations such as transport hubs. Self-testing has been introduced and scaled up in Zimbabwe through PEPFAR programming, and over 55,000 self-test kits were distributed to key populations by F20 Q2. The program has been successful in reaching key populations, in particular MSM, through community-based kit distribution, follow-up for diagnostic testing and linkage to treatment (where needed) and prevention services. The HIVST roll out in Zimbabwe is widespread across all program areas with high levels of acceptability. Through support from peer outreach, a KPLHIV who performs a HIVST and gets positive result, can get access to diagnostic HIV testing and ensure they are linked to the appropriate HIV services. In Burundi, the KP program distributed over 700 self-test kits, achieved an 11% case finding rate and successfully linked 98% of those found positive to treatment. The HIVST approach, like index testing requires strong motivational counselling to ensure that after the test is performed the key populations PLHIV discloses to a trusted provider so that diagnostic HIV testing can occur, and if needed, the individual is linked to treatment.

6.3.4.5 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, and those unable to access community platforms due to COVID-19. ICT platforms (e.g., Facebook, WhatsApp, dating apps such as Grindr or Hornet, online reservation apps) provide KP programs additional strategies to reach and engage key populations to HIV services including risk screening, and general education, and linkage to essential health and HIV services in a way that meets key populations needs in confidential and client-centered way. Program data from countries, including Brazil, Botswana, Burma, Burundi, Cameroon, Côte d'Ivoire, Ghana, Indonesia, Kenya, Jamaica, Nepal, Thailand, and Vietnam show that ICT platforms bring in many first-time testers and some older MSM, or harder to reach men who have sex with men (e.g., men who have sex with men but who do not identify as gay or bisexual and are not part of gay social networks, women who do not identify as SWs but trade sex, and other subpopulations not always found in peer-to-peer approaches conducted in physical/venue-based outreach). These approaches have also been associated with higher HIV-positive testing yields. A successful example of ICT implemented in Vietnam can be found on the PEPFAR Solutions Platform.

Once key populations are reached through these various platforms, programs can use different methods for linking and referring clients to appropriate services, e.g., online 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. A KP-led clinic in Kenya, created a country specific online reservation app named Step1 which provides those reached online (mainly MSM) to book and link to offline services. Virtual outreach workers utilized to support linkage to services, in FY20 313 appointments were booked online via the app and 50% attended the clinic for services, including 64 tested for HIV with 25% case finding rate. This was a considerable achievement as it resulted in a case finding rate 10-fold greater than other modalities, much higher than their average testing yield and reached MSM that otherwise would not have tested and was implemented by a KP-led organization.

KP programs across multiple countries have also utilized ICT platforms to integrate EPOA approaches through online peer referrals and also provide the opportunity for client led anonymous partner notification services.

In addition, virtual approaches and ICT platforms can be utilized by peer workers, case managers and other program 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. In Ghana, the KP program was able to increase in its MSM testing yield from 4% FY18Q1 to 15% (HTS_POS 1,678) in FY19Q4, primarily via its "Health Living Platform", a virtual strategy integrating social media apps, hotline/WhatsApp counseling and KP champions in facilities. The program maintained strong linkage rates and was most successful in enrolling older and harder to reach MSM via these virtual strategies. Lastly, KP programs across PEPFAR have also integrated electronic client feedback systems[192] into ICT platforms and data management systems as part of the program's quality assurance efforts so services can be improved and evolved to meet client's needs. For example, in Thailand an electronic client feedback system was integrated into partners' existing program data monitoring system where an automated message is sent to clients who accessed services via SMS message with a link to an electronic survey asking for feedback on the quality of services they received. The results are then visualized via web-based dashboards down to the site level which are used during project performance meetings.

Tracking and reporting services like online outreach, engagement, reach and referral to services and actual linkage and delivery of services is essential to assess impact of these approaches use for decision making, and to ensure key populations reached virtually are linked to a full range of quality HIV services. Custom indicators can be utilized to distinctly track these online and virtual efforts and link them to service delivery outcomes like key populations reached with a standardized and comprehensive set of prevention interventions and risk assessment, documented linkage to HIV services, and efforts around continuous engagement and support in prevention and treatment.

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 example,

[192] https://www.fhi360.org/sites/default/files/media/documents/resource-linkages-electronic-client-feedback-systems.pdf)

gay men and other men who have sex with men but do not identify as gay. If these men are outed, they can face a variety of risks including violence, homelessness, being disowned by family, and losing jobs or being expelled from school and in some context, prison time or even a death sentence. For additional program resources on how various ICT platforms can be utilized for KP programming, please reference PEPFAR supported Going Online tools.[193]

6.3.5 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, and HIV seroconversion during this critical time can result in high maternal viral loads, placing their fetus/infants at extremely high risk for mother-to-child HIV transmission (MTCT). According to 2019 UNAIDS estimates, there were 160,000 new HIV infections among children aged 0-9 years, with almost all occurring between the ages of 0-4 years during pregnancy, birth, or the breastfeeding period.[194]

The World Health Organization (WHO) currently recommends that "lactating mothers in high HIV prevalence settings who are HIV negative should be retested periodically throughout the period of breastfeeding.[195] Maternal retesting is increasingly important to help reach targets on elimination of MTCT (eMTCT) and the UNAIDS 95-95-95 goals.[196]

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 MTCT rates at 6 weeks to below 5% in some countries. However, in 2020 UNAIDS estimates, 27% of new infection in children were linked to acute infection in pregnancy and breastfeeding.[197]

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[193] FHI360 Going Online to Accelerate the Impact of HIV Programs. https://www.fhi360.org/resource/going-online-accelerate-impact-hiv-programs

[194] https://data.unicef.org/wp-content/uploads/2019/11/HIV-snapshot-Global_2019.pdf

[195] World Health Organization (WHO) Technical Brief: Preventing HIV During Breastfeeding and in the Context of PrEP. July 2017. Accessed 10/4/19 at: https://apps.who.int/iris/bitstream/handle/10665/255866/WHO-HIV-2017.09-eng.pdf

[196] 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

[197] UNAIDS epidemiological estimates 2020. http://aidsinfo.unaids.org/

Evidence shows that:

1. Pregnancy, itself, may be a risk factor for HIV acquisition.[198]
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.[199]
3. Acute HIV infection is associated with elevated viral loads that increase risk of transmission.[200] In African cohorts, MTCT 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).[201]
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 2.7 million post-ANC1 tests reported across PEPFAR in FY19 with a trend toward increasing the number of women tested each quarter. Trends in the data collected and reported in the post ANC1 modality, PMTCT_STAT_POS and HEI_POS from FY19 and FY20 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 in early pregnancy (first ANC visit) and/or the third trimester ANC visit/late pregnancy, (if care delayed) with the option of adding an additional retest at either 14wks, six-months or nine-months post-partum in SNUs with high HIV prevalence and among key populations or women at high risk of HIV acquisition

[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 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] Thomson KA et al. Conference on Retroviruses and Opportunistic Infections (CROI), 2018; Boston; Abs. 45
[200] Lehman DA, Farquhar C. Biological mechanisms of vertical human immunodeficiency virus (HIV-1) transmission. Rev Med Virol. 2007;17(6):381–403T
[201] 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)

from their partner[202]. Some low HIV prevalence countries with a high MTCT rate may benefit from retesting in high prevalence SNU's at high volume ANC sites or those offering postnatal care or under-5 visits. Countries, regions, and/or facilities with a high number of HIV-positive women or HIV-positive infants should introduce more opportunities to provide repeat HIV tests for PBFW and, if found positive, appropriately and immediately provide linkage to treatment for the mother and testing for infant.

Maternal retesting can be focused based on geographic considerations such as where high numbers of mothers and infants are present. For example, immunization (EPI) clinics are a practical location for infant/pediatric case finding and HIV testing for high-risk postpartum mothers who previously tested HIV negative. In addition, it may be efficient to integrate maternal retesting in family planning (FP) settings, since most women routinely access these services in 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 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., MCHN, EPI, FP);
- examination of the physical space and clinic flow to allow for confidential HTS;
- ensuring linkage and retention of newly diagnosed mothers and HEI, for example using mentor mothers; and,
- 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

[202] Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020.

level.[203] These questions can be assessed alongside SIMS or incorporated in granular site management or used as a standalone assessment.

In high-volume facilities, even when the requirements for successful retesting are addressed, there may be limited resources for retesting all eligible at-risk mothers. Universal retesting may not be feasible given human resources, commodity, and clinic space constraints. In addition, universal retesting may not be necessary, as all pregnant and breastfeeding women do not experience the same level of risk of HIV acquisition; some at higher risk (e.g., those in a serodifferent relationship, or sex workers) may require more frequent testing.

Programs should prioritize retesting women at increased risk of incident HIV infection (ex. age <30 y/o, serodifferent couple, multiple sexual partners, condomless sex with partner with high-risk behaviors, partner with unknown HIV status, history of STI) and should pursue retesting any time that a pregnant or breastfeeding woman presents with potential symptoms of acute HIV infection. In addition, as countries implement recency testing, facilities or geographies with high rates of recent infections and high HIV prevalence, should be prioritized for retesting in PBFW.

Risk screening tools for maternal retesting are not widely available; however, programs may adapt or use existing PITC/outpatient screening tools already available. Teams may consider drawing from existing risk screening tools that were developed to predict HIV acquisition in women[204] and target PrEP in high-risk pregnancy and in postpartum/breastfeeding women.[205] Such tools, once adapted and validated, can be incorporated into the HIV prevention package during pregnancy and post-partum visits. Risk screening for maternal retesting will also require improved documentation approaches to track women who have previously screened negative and need to be re-screened for eligibility, such as a mother-baby cards and electronic medical records systems.

6.3.6 HIV Recency Surveillance and Response Using a Rapid Test for Recent Infection among Newly Diagnosed PLHIV

Routine assessment of the direction of the HIV epidemic through ongoing surveillance of newly diagnosed PLHIV remains essential to ensure that prevention interventions are efficiently and

[203] For more details on facility assessment checklists, refer to Maternal retesting resource document on PEPFAR SharePoint
[204] Balkus, et.al. An Empiric HIV Risk Scoring Tool to Predict HIV-1 Acquisition in African Women, JAIDS 2016
[205] Pintye et al. A Risk Assessment Tool for Identifying Pregnant and Postpartum Women Who May Benefit From Preexposure Prophylaxis. Clin Infect Dis 2017

effectively targeted to those at highest risk of acquiring or transmitting HIV infection. RTRI has paved the way for the establishment of a HIV recent infection surveillance system in routine HIV testing services to rapidly detect, monitor, characterize, and intervene on recent HIV infection among newly diagnosed HIV cases. While these tests are not meant to be used clinically or on an individual basis, the data are useful for targeting prevention interventions. Epidemiologically, data from a recent infection surveillance system serve as signals of new or recent transmission and acquisition. Routine epidemiological analysis of these data can be used to monitor trends in recent infection and identify subgroups and geographic locations (i.e., time-space clusters) associated with recent HIV transmission. Programmatically, these data can be used to identify gaps and enhance prevention and treatment programs to prevent transmission to HIV-negative contacts, without altering routine services (Figure 6.3.16). Country teams should implement index testing strategies for all those identified as HIV positive with priority given to those who are newly diagnosed, and on ART but not virally suppressed. In particular, index testing strategies should be provided to recently- or newly infected individuals, while adhering to the minimum standards in the PEPFAR Guidance on Implementing Safe and Ethical index testing[206].For additional details on Index Testing, see Section 6.3.1. As countries achieve epidemic control and 95-95-95 targets, we anticipate fewer undiagnosed HIV-positive contacts and fewer known HIV-positive contacts who are not virally suppressed. Best practices from early implementers of recent infection surveillance are available on the PEPFAR Solutions Platform and on the TRACE eLearning Hub.

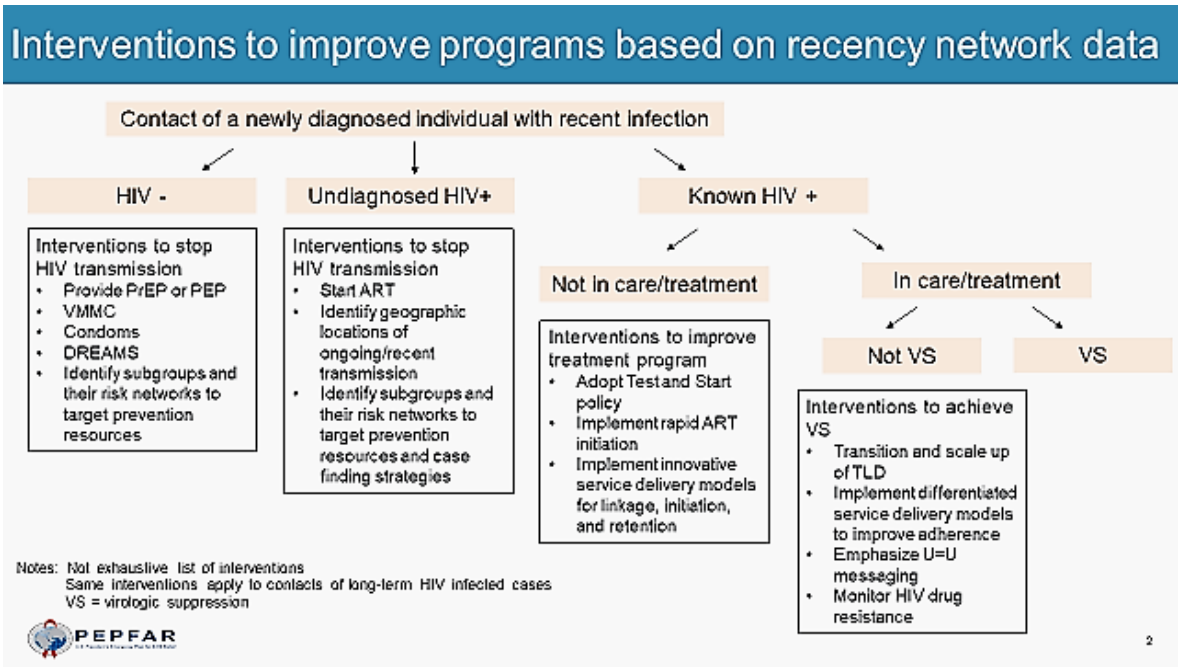
In COP21, country teams should consider the following elements in building a real-time surveillance system of new infections: 1) engagement of multiple expertise from laboratory, surveillance, prevention, treatment, testing, M&E, key populations, data management, and informatics; 2) collaboration with Ministry of Health officials to develop and implement policies that endorse the use of RTRI testing in routine HIV testing services; 3) strategies for transitioning from phased to full-scale implementation for countries that have started recent infection surveillance; 4) integration of RTRI test kit procurement in national supply chain; 5) 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); 6) integration into a national HIV case surveillance system where one exists; and 7) continuous quality improvement plan to ensure

[206] PEPFAR Guidance on Implementing Safe and Ethical Index Testing is available here: https://www.pepfarsolutions.org/tools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

testing and surveillance data quality. Results from HIV recency testing will be reported through the MER indicator HTS_Recent. Country teams should reach out to the interagency task force responsible for HIV recency data use for public health response guidance.

Information below provides recommendations on building a 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.

Figure 6.3.16: Interventions to improve programs based on network data from recently infected individuals



Role of site level staff and implementing partners in recent HIV infection surveillance and response

- Ensure high quality recency testing for all newly diagnosed HIV-positive persons by well-trained, certified testers
    - Collect, transport, and track blood sample (as plasma or dried blood spot specimens) for viral load testing in laboratory for cases identified as recently infected by RTRI
    - Include use of barcodes or other electronic tracking systems to ensure linkage and prevent transcription/completion errors

    - Ensure testing is performed by trained and certified testers that were trained using the TRACE format of 3 QCs and 10 TPs (Refer to Section 6.3.1.7)
    - 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 recency testing results and appropriate socio-demographic and behavioral data through appropriate data systems (paper or electronic) in real-time.
    - Securely store all data to protect client privacy and confidentiality
    - Support reporting of MER indicator (HTS_Recent) and narratives
    - Screen for and document previous HIV diagnoses and ART use
- Ensure that all new HIV diagnoses receive appropriate package of HIV prevention and treatment services
    - Monitor uptake and outcomes of index testing (e.g., index testing coverage and yield among contacts from recent and long-term cases) and referrals for ART initiation, PrEP, VMMC, and other prevention services
    - Monitor and report any adverse events or social harm related to recency testing, especially those associated with return of results
    - Identify major barriers to recency testing and implement activities on overcoming them
- Consider recent HIV cases for triage or enhanced follow-up services (e.g., provision of index testing services while ensuing compliance with PEPFAR Guidance on Implementing Safe and Ethical Index Testing as mentioned above)
- Collaborate with above-site partners in case detection, investigation, and response at site, subnational, and national levels

Informatics

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. Depending on whether countries are collecting and returning VL for RITA, interoperability with the lab information system, or a process in place of this, is essential to connect these test results back to the patient file. 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 is needed.

Data Collection

- Refer to the principles for digital development available at https://digitalprinciples.org
- 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

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 integrated with HIV case surveillance. Countries should engage in discussions around data ownership, data governance, and data sharing as early as possible.
- 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

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. The 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 eLearning Hub. It is important that countries share aggregate data in dashboard form with HIV recency leads at HQ and key stakeholders, particularly during the early phase of implementation, to assist with data quality, review, and analysis. This will help guide the public health response. Electronic medical records system, if present in countries, can be tweaked to enhance recency data collection.

6.4 Linkage to Treatment

Successful linkage is the first step in a lifelong therapeutic partnership between the client and the health care system. How this is accomplished is critical to sustained treatment success. All eligible individuals with newly diagnosed HIV should be offered same-day 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 within 7 days of diagnosis and actively but sensitively tracked and supported to prevent interruptions in care, particularly within the first three months. Few comorbidities contraindicate the use of ARVs, waiting for completion of a workup is a barrier to same day start. See Section 6.5.2 (advanced HIV disease) for additional guidance. The primary responsibility for linkage to treatment services rests with the testing partner regardless of where the testing was done. Coordination between testing and treatment services is critical to therapeutic and programmatic success.

The updated WHO guidance prioritizes three essential messages to begin care: the personal health benefits of early ART, that PLHIV with a suppressed viral load cannot transmit HIV to their partner(s), and the benefits of voluntary provider-assisted referrals to treatment for PLHIV. In addition, WHO reviewed evidence and identified that effective linkage packages ensure that clients arrive at each service delivery point (often facilitated by lay cadres), provide safe and

confidential services to reducing stigma and COVID-19 risk, and are responsive to client's context and adherence support needs.[207] These benefits should be integrated overall into counseling messaging related to HTS. Understanding how treatment is delivered may facilitate linkage to care and providing an understanding of DSD options available and timelines for access to these options, including MMD and drug dispensation through decentralized drug distribution is critical to this endeavor.

Data from countries implementing same-day and rapid ART initiation have shown successful increases in ART uptake and fewer treatment interruptions. Monitoring to ensure that this trend continues and to identify and address gaps can be done with continued analysis of linkage to treatment by sex, age cohort, and key populations. It is also critical to continue collecting quality data to help better understand disruptions to linkage to and initiation of treatment, this includes TX_ML (interruption in treatment, IIT).

Different HIV testing modalities: (e.g., clinic-based, community-based, index testing and self-testing) may require tailored linkage strategies to ensure continuity of care and start of treatment. The treatment partner is responsible for early retention (< 3 months) and reducing events reported as lost to follow-up (IIT). Please see Section 6.1 which describes the process for triangulating data sources to ensure that individuals have actually interrupted services before attempting follow-up. To continue with advances made in COP20, services should ensure that welcome back to care packages are accessible. Welcome back packages are built on the principles of expediting care (with drop-in clinic visits and fast track services), appreciating the client's efforts to re-engage (without reprimand), reducing health effects of interruptions, and finding practical solutions to continuing care in this period. COVID-19 adaptations have permitted MMD for this group of clients in many OUs.

A range of evidence-based program approaches to improve linkage to treatment are on the PEPFAR Solutions portal[208] and across agencies.[209]

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[207] Consolidated Guidance for HIV Testing Services in an Evolving Epidemic, WHO November 2019

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

[209] https://www.cdc.gov/hiv/research/interventionresearch/compendium/lrc/index.html
https://www.hiv.gov/topics/linkagetocare
https://www.iapac.org/files/2018/05/JIAPAC-IAPAC-Guidelines-for-Optimizing-the-HIV-Care-Continuum-Supplement-Nov-Dec-2015.pdf

6.4.1 Linkage Models to Enhance the Therapeutic Alliance

The therapeutic alliance is a vital relationship between the health care system, the health care providers and the recipients of care. In linkage to treatment, this alliance is the means of initial and early engagement with each other to effect beneficial outcomes including better health and reduced HIV transmission. When working together, providers can facilitate client's voices, inputs, and support decisions in care and adherence responsibilities. Linkage provides the foundation for ART access and can drive demand and use of services and trust in optimized ARVs. One area that can be especially challenging is the linkage from the inpatient service to treatment facilities. (See Section 6.5.2 on advanced disease). Linkage officers physically based in the hospital were able to successfully ensure that PLH were initiated on ART.[210]

A recent review of linkage evidence highlighted the following areas that enhance relationships between providers and clients.[211]

Facility

- Congested facilities with difficult to navigate service flow create challenges for new client appointment-keeping and client-provider relationships during linkage to treatment and early care. Patient navigators including peer navigators may be helpful in ensuring that PLHIV receive the care they need.
- Many clients entering HIV treatment have other appointments and are bound to other clinic schedules that address other health needs. Integrated care, especially with immunization services, TB and family planning may address some of these issues.

Community

- Social barriers reduce successful case identification and linkage to treatment especially when linked to stigma and misinformation,
- Community resource/peer/expert clients/HIV champions are credible stakeholders that can support successful linkage to treatment.
- With clusters of clients (greater than 5), linkage to treatment and refills in community settings can be safe, efficient, and convenient. (See Section 6.3.1 for description of DSD models)

Vulnerable populations

[210] AIDS 2020. Bisnauth et al. Abstract OAE0404.

[211] Bunda BA, Bassett IV. Reaching the second 90: the strategies for linkage to care and antiretroviral therapy initiation. *Curr Opin HIV AIDS*. 2019;14(6):494-502. doi:10.1097/COH.0000000000000579 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6798739/

- Aggregate data can hide lagging subpopulations in need of additional program elements for linkage success (e.g., peer navigation and treatment literacy programs)
- As case identification evolves so should linkage to treatment approaches that respond to client's needs, overcome known barriers to engagement, and bolster motivation to start and stay on treatment.
- Continued rapid learning with innovation for populations with remaining gaps in linkage to treatment (children, youth, men, PBFW) are needed.

Comprehensive community case-management can help resolve ambivalence and provide logistical support to successful therapy. Lay cadres, such as CHWs/peer navigators/counselors can assist with support group discussions, contacting patients, supporting referrals for integrated services, and tracking and tracing should there be a missed appointment or refill. This approach is of demonstrated success and PEPFAR supports the use of this model of care to achieve results. To that end, linkage relationships should be formalized and remunerated fairly. COVID-19 adaptations have included the redeployment and repurposing of multiple community health workers, training in linkage activities of these cadres across multiple partners may be of value.

At the above-site level, PEPFAR should work with partners to monitor and evaluate the implementation and scale-up of rapid ART initiation and effective linkage-to-care interventions in defined geographic units or populations. Memoranda of understanding or other legal agreements may be needed between community and facility partners to assure linkage to care without duplicated counting and efficient index case testing. Continuity of treatment and viral load suppression should also be closely monitored to ensure that patients initiated on ART are kept in care and achieve optimal treatment outcomes.

6.4.2 Linkage for Children and Families

Children living with HIV have historically suffered from particularly poor linkage to treatment and early treatment interruption (formerly framed as loss to follow-up),[212] thus requiring greater attention to ensure that they promptly register in care and initiate and continue treatment. Efforts to improve linkage for infants and young children, especially infants tested under EID within

[212] Phelps BR, Ahmed S, Amzel A, et al. Linkage, initiation and retention of children in the antiretroviral therapy cascade: an overview. *AIDS*. 2013;27 Suppl 2(0 2):S207-S213. doi:10.1097/QAD.0000000000000095. [Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4124132/pdf/nihms607454.pdf]

PMTCT programs, 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 can also increase linkage to care and shorten time to treatment initiation and should be made available as appropriate (see Section 6.3.1.3). General linkage recommendations described in Section 6.4.1 should be utilized, with peer navigation focused on caregivers and provided by caregivers who are able to navigate family- and child-friendly clinics.

Clinic spaces should be made welcoming to families and children, and psychosocial support, including peer groups and age-appropriate disclosure support, should be made available to both caregivers and children. 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. Many of the interventions that support children and family linkage have similarities to the interventions that promote adherence and continuity of treatment. Please see Section 6.1.3.1 for a comprehensive description of these interventions.

6.4.3 Linkage for Adolescents and Youth

Adolescents and youth have historically encountered challenges with linkage to and continuity of treatment, and therefore require specific interventions to ensure that a positive therapeutic alliance is initiated at the time they enroll in testing and treatment services. Prompt linkage to ART can be supported most impactfully with a suite of services that cater to the needs of adolescents and youth and that center on peer-drive, peer-engaged interventions (see WHO's November 2019 Adolescent-friendly health services for adolescents living with HIV: from theory to *practice* publication). Pre- and post-test counseling are vitally important, and care should be taken to ensure that all education is presented in an age- and developmentally-appropriate way that is non-threatening, non-judgmental and clear.

Adolescents and youth benefit from support and guidance to successfully navigate the healthcare system, making it important for peer navigators to orient adolescents and youth to the clinic processes and foster a level of independence within the health system. For example, (peer) linkage officers stationed at treatment sites can enhance prompt linkage to ART. Many of the interventions that support adolescent and youth linkage are similar to the interventions that support continuity of treatment and adherence. Please see Section 6.1.3.2 for a comprehensive

description of these interventions. Programs are encouraged to strengthen bidirectional facility-community referral systems to ensure all adolescents and youth newly diagnosed with HIV are swiftly linked to optimal treatment.

Health facilities must provide immediate, same-day linkages to adolescent/youth (if available) or adult ART services for adolescents and youth living with HIV (AYLHIV). This should include linkages to AYLHIV support groups, sexual and reproductive health (SRH) services and referrals to OVC programs. Youth-friendly HIV testing and treatment services should include mental health and substance use support to help improve linkage among youth and referrals to appropriate services should be made, as necessary. Working with community structures - particularly communities of faith, with built-in support structures - and increasingly addressing adolescent- and youth-specific health components, including mental health and SRH, can support achievements across the HIV prevention, testing and treatment cascades. Additionally, programs are encouraged to use evidence-based technologies to reach young people.

Consent requirements can complicate or restrict access to treatment. Research has shown that a lower legal age of consent for independent HTS services is associated with an increase HIV testing uptake among adolescents in high-HIV burden countries.[213] 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, PEPFAR programs should follow client-centered, safe, and ethical protocols.

6.4.4 Linkage for Men

Men continue to have less access to HTS services and are more reluctant to enter care immediately as described in Section 6.1.3.3. As such programs need prepare for successful linkage before men are tested. Preparation for successful linkage may aid successful therapy including specialized messaging so that men are fully educated on the benefits, male-friendly ART services, and return to normalcy when virologically suppressed. See Section 6.3.3 on pre-test counseling and messages for men.

[213] https://www.who.int/bulletin/volumes/97/1/18-212993.pdf

Evidence shows many barriers to initiating treatment are unique to men including loss of identity, loss of respect and status/social death, disclosure, loss of fun and pleasure, loss of support and connection, loneliness, and loss of control/autonomy. Initiating treatment makes the diagnosis real to them, and men often lack the coping potential to deal with that. They may be ignorant of the benefits of treatment to themselves, their partners and their community. They may feel like they are a danger to their loved ones and because they cannot accept that, they are in denial.

The global MenStar Coalition recommends development of context specific, engaging marketing to advertise new clinic standards and new medicines. These communications should take a consumer marketing approach to demand generation, including staying with overarching brand guidelines and targeted messages to engage men who have tested positive but not started treatment or those who have discontinued care. Media selection should be guided by effective reach amongst men in the local context. Identification and promotion of HIV Champions who can address stigma by advocating for acceptance/normalization of HIV among men.

In addition, programs can support client linkage support with:

- Availability of immediate ART, offered as multi-month starter pack upon testing
- Escorted linkage, ideally with a male escort
- Peer navigation programs with specific training on empathy and effective, compassionate engagement of the issues that men commonly face (e.g., fear, specific logistic challenges, disclosure, etc.).
- Men-friendly clinic services, including trained/sensitized staff, male-only clinics, expedited services (fast-tracking) for working men, after-hours and community-based ART distribution
- Early access to differentiated service delivery models, with supportive remote service tools like SMS and scheduled phone calls, and community peer counselors - both face-to-face and virtual.
- Case Managers or Clinic Coaches to orient men to the clinic experience both within the community and within the clinic. For men, emerging data is showing that having a case manager or peer support from another man who is living with HIV and stable on treatment is an effective strategy for engaging men in continuous care because it offers living proof that men can gain control over HIV and feel strong, healthy, and safe again.
- Counseling and (including virtual) support tools to enhance coping potential

- A comprehensive service referral and linkage system that seeks to identify and address clients' personal challenges and is supportive rather than insistent/coercive
- Specific support for disclosure, particularly partner disclosure

See 6.1.3.3 for discussion of improving ART service delivery to men and PEPFAR Solutions for examples of interventions to improve service delivery to men.

The MenStar Strategy and program examples are available online.[214] In addition, below are summarized insights for action.

Figure 6.4.1: MenStar table of key functional and emotional needs of male clients

Who are they?	Key Functional Need	Key Emotional Need
Unaware of status/undiagnosed	Confidential and convenient testing options	Increase risk internalization and coping potential
Aware but never engaged in treatment/not linked	Confidence that the clinic experience and medicine will be manageable in their lives	Increase coping potential Feeling of getting back to normalcy
Newly initiated on treatment. First 90 days are critical. Skeptical of treatment	A positive experience from day 1	Support to stick with it
Lost to follow up: Has initiated treatment and has rejected due to poor experience with clinic or medicine or inability to cope with social and psychological barriers	Belief that the medicine and the clinic have **changed** and will now meet his needs	Increased confidence that it's "worth it" to give it another try
Engaged in treatment and virally suppressed	Convenient differentiated service delivery options	Continued access to support and a move toward feeling that HIV doesn't define him

[214] https://www.menstarcoalition.org/strategy/

Figure 6.4.2: MenStar core package of services

Unaware of status/undiagnosed	Aware but never engaged in treatment/not linked	Newly initiated on treatment	Lost to follow up:	Engaged in treatment and virally suppressed
Build coping potential with messages on the new HIV treatment narrative (A reclaiming of normalcy for men through modern treatment options)				
Improve experience and outcomes of testing	Drive demand for treatment services with emphasis on emotional benefits (e.g., "prove that it will meet my needs."). The package here includes education, counseling and emotional support.	The package here includes strengthened service delivery with client participation to improve the client experience and make it more convenient, private, and welcoming.	Drive demand for return to treatment services with emphasis on functional benefits. The package includes outreach, demonstrable changes to HIV care and treatment (e.g, Try me again.")	Support the client throughout the journey with linkage and initiation, treatment, and adherence support mechanisms
		Support the client throughout the journey with linkage and initiation, treatment, and adherence support mechanisms		Rapid optimization of ART by offering TLD
		Rapid optimization of ART by offering TLD		Differentiated Service Delivery

6.4.5 Key Populations Continuum of Care and Case Management

Comprehensive Case Management from Initiation to Undetectable

Rapid ART initiation (within 7 days of testing positive but ideally on the same day) results in improved outcomes across the HIV treatment cascade, including greater ART adherence and viral suppression.[215] Rapid ART initiation for key populations should be offered at various points of entry, meeting the client where they can best be served, including at community testing sites, drop-in centers, STI clinics, private clinics, primary care clinics, and hospitals.

Comprehensive case management teams should support rapid ART initiation for newly diagnosed key populations members and KP-PLHIV that have been lost to follow-up. 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 KP-PLHIV themselves. In settings where KP members are newly diagnosed with HIV in a community setting, an integrated case management approach can facilitate

[215] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012962.pub2/full

linkage from the community to public health systems for rapid ART initiation and continuity of care or to a KP community clinic. Peer navigation and case management ensure continuity of care.

Differentiated key populations case management is important to ensure a client-centered approach; some clients require a more intensive package of services than others. These can also be progressive where an unstable client enters the program with intensive needs, stabilizes and later, after ensuring viral suppression, needs less care. The client requiring intensive case-management needs frequent, personalized client support and counseling from the time they enter the program until sustained viral suppression is achieved. 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 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 could 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, complaints of mistreatment at clinics, etc.), and for those who have fallen out of care previously, continuation of intensive follow-up is recommended. Zimbabwe is a country that is defining models of services for key populations living with HIV based on intensive or maintenance models as an important step to determining sustainability for scaling KP programs nationally. For example, in Zimbabwe, PEPFAR is supporting the development of government guidelines whereby stable key populations are referred into government ART sites and newly initiated key populations with a specific risk profile access KP clinical services and treatment initiation and dispensation along with more regular peer navigation.

To ensure continuous follow up and support for stable clients, online portals are being scaled up. In Namibia, many key populations ART clients will be supported across 73 sites using peer navigation assisted by an online case management system. Clients without internet access can still be supported by phone. Those with internet will have their case manager or peer set up appointments and receive SMS reminders automatically. Case managers also benefit from automatic reminders as the client's ART number and visit status is linked through the clinical system.

Peer navigators play a critical role in case management. Navigators are often KP PLHIV 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 patient protections, and violence reduction and prevention. Navigators can assist newly diagnosed or out-of-care KP PLHIV 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 KP PLHIV 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 by strengthening the relationship between facility staff and key populations community members. Facility-based health care workers should receive regular training on client-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.

Differentiated Service Delivery for Key Populations

PEPFAR teams should consider how they can utilize client-centered differentiated service delivery models for initiating key populations and ensuring continuity in life-saving treatment. Differentiated services are intended to expand ART access to community-based settings, inform the models that work for different groups of key populations and ensure an integrated and scaled national approach by increasing KP competency of facilities and utilizing referral to dedicated KP drop-in centers (DICs).

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, GBV services and legal services. DICs can also play a fundamental role in reaching children of key populations and their partners, mainly through index or social network testing.[216] 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-competent 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 retention on treatment for KPs 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).[217] 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

[216] https://www.fhi360.org/sites/default/files/media/documents/epic-long-term-hiv-adherence-guide.pdf
[217] https://www.who.int/hiv/pub/toolkits/keypopulations-2016-update/en/

Populations.[218] The online publication features a number of PEPFAR-supported interventions, and considers the Who, What, Where, and When of key populations ART services.

Viral Load Coverage for Key Populations

Globally, PEPFAR program viral load coverage among key populations, for FY20 Q3, is 65%, with VLS being 95% for all KP groups. Differentiated service delivery points that facilitate viral load testing are essential components of KP programs delivering client-centered services. DIC collection points are often not prioritized for collection and transportation within the national lab systems leading to long processing times and delayed return of results to key populations clients. Clinical and KP partners across agencies need to collaborate and work together to ensure the KP program is integrated within the national lab collection and transport systems and KP partners have access to the VL testing and results in a timely manner. 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 KPs who otherwise would be missing their VLT. For further guidance on community-based VL sample collection, see Section 6.5.5. In addition, at the start of FY20, KP disaggregates are required reporting within the VL indicators. 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.

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. 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.

218 http://www.differentiatedcare.org/Portals/0/adam/Content/2a0WxWUHfUKtul1mKWdmGQ/File/Decision%20Framework%20Key%20Population%20Web3.pdf

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.[219]

6.5 Optimizing HIV Care and Treatment

Successful antiretroviral therapy reduces or eliminates HIV-related morbidity and mortality at all stages of HIV infection and reduces HIV transmission. The goal of therapy for all PLHIV should be maximal and durable suppression of plasma viremia. Guided by an overarching objective to lower mortality and improve the lives of PLHIV and the communities in which they live, OU teams and implementing partners should develop comprehensive, accessible, client-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 patients presenting with advanced disease, and patients at risk for HIV-related comorbidities such as cervical cancer and TB. Finally, interventions that focus on those at risk of treatment interruption and that, to help them attain and maintain viral load suppression are, critical to ensure community and national-level epidemic control.

6.5.1 ART Optimization Best Practices, Drug Interactions, and Regimen Sequencing

All PLHIV 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 care and viral load suppression. This is the cornerstone of the PEPFAR program. The World Health Organization (WHO) released updated normative and derivative guidance documents in July at the 2019 International AIDS Society (IAS) meeting.[220] PEPFAR continues to recommend TLD as the preferred option for ART for both first and second line treatment (for PLHIV >=30kg), and further recommends that countries continue with their transition to DTG based regimens from both first and second line regimens as evidence supports DTG transition in individuals virologically suppressed on PI and NNRTI based treatment. See Section 6.5.6 for the approach to individuals who are not virologically suppressed.

[219] www.preventionaccess.org
[220] https://www.who.int/hiv/pub/guidelines/ARV_Guidelines-2018-Annex3a.pdf?ua=1

6.5.1.1 Optimization of Newborn HIV Prophylaxis for HIV-exposed Infants

Identification and testing of HIV exposed infants (HEI) is 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, and 52% by their second year.[221] Implementation of Option B+ ("treat all") policy (now fully included within the recommendation for immediate lifelong ART for all PLHIV, including PBFW) has significantly reduced mother to child transmission of HIV; however, despite significant improvements in maternal testing and ART initiation prior to delivery, in 2018 there were 160,000 new HIV infections among children aged 0-9 years, with almost all occurring between the ages of 0-4 years during pregnancy, birth, or the breastfeeding period.[222] Shift in the timing of incident HIV infections in infants 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. As of 2018, global coverage of early infant diagnosis (EID) was 59%, which is a slight improvement from 43% in 2012.[223] PEPFAR supported programs have remained steady at a proxy < 2-month EID coverage of approximately 71% in FY19 and FY20[224]; however, although these numbers are higher compared to global data, they still fall short of the 90% global EID target. Optimization of newborn HIV prophylaxis for HEI is reliant upon: 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.

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 mother to child

[221] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17140-7/fulltext
[222] Data source: 2019 UNAIDS Estimates
[223] https://data.unicef.org/wp-content/uploads/2019/11/HIV-snapshot-Global_2019.pdf
[224] Panorama. *PMTCT-HEI Global* Dossier. *PMTCT and HEI Cascade* Chapter. [Accessed 30 November 2020.]

transmission (MTCT) during breastfeeding.[225] An infant at high risk of acquiring HIV is one *whose mother* meets the following criteria:[226]

- 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*[227] outlines formulations that can be used for 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 and timing of maternal infections on the HIV status of the infant, strengthening of maternal (re)testing (See Section 6.3.5) and treatment efforts, considerations for PrEP (see Section 6.2.4.2), and increased achievement of maternal viral suppression at the time of delivery, is a necessary component in reducing morbidity, and optimizing the management and survival of HEI.

6.5.1.2 Pediatric ART Optimization

There continue to be robust efforts to make optimal ARV drugs available for infants and children in a timely fashion. The US government (USG), through PEPFAR and together with global partners, continues to work on accelerating the entire life cycle of pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security and program uptake.[228] Building upon the momentum from meetings convened at the Vatican in 2016, 2017,[229] 2018,[230,231] and virtually in 2020,[232] all global partners continue to demonstrate commitment to advance robust, child-friendly pediatric HIV treatment options.

[225] 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.
[226] 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
[227] https://apps.who.int/iris/bitstream/handle/10665/273155/WHO-CDS-HIV-18.17-eng.pdf?ua=1
[228] http://www.gap-f.org/
[229] https://www.paediatrichivactionplan.org/2017-hiv-treatment
[230] https://www.who.int/hiv/mediacentre/news/scaleup-diagnostic-treatment-paediatric-HIV/en/
[231] https://www.paediatrichivactionplan.org/2018-hiv-treatment-1
[232] https://www.paediatrichivactionplan.org/2020-hiv-treatment

In 2018, WHO updated the consolidated HIV guidelines[233] to ensure children were not left behind in the recommendations to optimize ART for PLHIV, including a shift away from NNRTIs to integrase-strand transfer inhibitor (INSTI)-based regimens, especially DTG-based regimens; this recommendation was reiterated in 2019[234] and 2020[235] (see Figures 6.5.1 and 6.5.2). 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, and allowance for once-daily dosing.[236,237,238] In July 2020, WHO released pediatric DTG dosing recommendations[239] for pediatric DTG formulations (DTG 5 mg dispersible tablet* [DT] and DTG 10 mg [scored DT] anticipated to be available in 2020 and 2021, respectively) and PEPFAR headquarter implementation subject matter experts will keep OUs updated regarding the availability of pediatric DTG and programmatic considerations.

Rapid policy adoption and procurement of optimal pediatric ART regimens must continue to be a priority for all countries. Programs should have already transitioned all infants, children and adolescents off NNRTI-based (NVP and EFV) ART regimens to LPV/r- or DTG-based regimens

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 – 19.9 kg; TLD is preferred beginning at 30 kg. Further, USG, through PEPFAR, expects that all countries will transition all CLHIV onto a DTG-based regimen as quickly as possible; full implementation should occur during early COP21 and within 12 months upon receipt of the first shipment of DTG 10 mg DT. Therefore, careful supply planning must begin in COP20 and should leverage DTG 10 mg transitions tools available in COP20, including DTG 10 mg Readiness Questionnaires. OUs must work with their respective Ministry of Health to specify concrete 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 roll out of DTG is not hindered by

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[233] https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf
[234] https://apps.who.int/iris/bitstream/handle/10665/325892/WHO-CDS-HIV-19.15-eng.pdf?ua=1
[235] https://www.who.int/publications/i/item/9789240007888
[236] https://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf;jsessionid=B47A6C09B860030A59EBA3B29195AD30?sequence=1
[237] https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf
[238] https://www.who.int/publications/i/item/9789240007888
[239] WHO. *Considerations for introducing new antiretroviral drug formulations for children.* July 2020. [Available from: https://www.who.int/publications/i/item/9789240007888]

over-supply 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 a prompt transition to pediatric DTG. Programs are encouraged to work with respective stakeholders to ensure context-specific demand creation activities are in place to accelerate pediatric ART optimization efforts.

Figures 6.5.1 and 6.5.2: DTG is a component of the preferred first line and second line ARV regimens in WHO guidance.

Table 1. Preferred and alternative first-line antiretroviral therapy regimens

Population	Preferred first-line regimen	Alternative first-line regimen
Children	ABC + 3TC + DTG[a]	ABC + 3TC + LPV/r or RAL[b] TAF + 3TC (or FTC) + DTG[c]
Neonates	AZT + 3TC + RAL[d]	AZT + 3TC + NVP

[a] For age and weight groups with approved DTG dosing.
[b] RAL should be used as an alternative regimen only if LPV/r solid formulations are not available.
[c] For age and weight groups with approved TAF dosing.
[d] Neonates starting antiretroviral therapy with an RAL-based regimen should transition to an LPV/r solid formulation as soon as possible.

NB: In respect to footnote (d) above, the WHO July 2020 Policy Brief was released prior to the November 2020 US FDA tentative approval of DTG 10 mg DT. PEPFAR programs should transition neonates on a RAL-based regiment to a pediatric DTG-based regimen as soon as the infant reaches the pediatric DTG weight and *age threshold (≥ 3 kilograms and ≥ 4 weeks, respectively).*

Figure 6.5.2

Table 2. Preferred and alternative second-line antiretroviral therapy regimens

Population	Failing first-line regimen	Preferred second-line regimen	Alternative second-line regimens
Children and infants	ABC + 3TC + DTG[a]	AZT+ 3TC + LPV/r (or ATV/r[b])	AZT + 3TC + DRV/r[c]
	ABC (or AZT) + 3TC + LPV/r	AZT (or ABC) + 3TC + DTG[a]	AZT (or ABC) + 3TC + RAL
	ABC (or AZT) + 3TC + EFV	AZT (or ABC) + 3TC + DTG[a]	AZT (or ABC) + 3TC + LPV/r (or ATV/r[b])
	AZT + 3TC + NVP	ABC + 3TC + DTG[a]	ABC + 3TC + LPV/r (or ATV/r[b] or DRV/r[c])

[a] For age and weight groups with approved DTG dosing.
[b] ATV/r can be used as an alternative to LPV/r for children older than three months, but the limited availability of suitable formulations for children younger than six years, the lack of a fixed-dose formulation and the need for separate administration of the ritonavir booster should be considered when choosing this regimen.
[c] DRV should not be used for children younger than three years and should be combined with appropriate dosing of ritonavir.

Figure 6.5.3: Current and Expected DTG formulations with FDA approval status available for PEPFAR[240]

Dolutegravir Product	Formulation	US FDA approval or tentative approval?	Globally available?	Lowest weight or age approved for:	Can tablet be split?
DTG	Film Coated tablet 50 mg	Tentative approval	Yes	20 kg	No
Tenofovir disoproxil/ Lamivudine/ Dolutegravir	Fixed Dose Combination 300/300/50 mg	Tentative approval	Yes	30 kg	No
DTG Dispersible Tablet	Dispersible, Scored Tablet 10 mg	Tentative approval (Granted in November 2020)	Anticipated global availability in early – mid 2021	3 kg and 4 weeks	Yes
Abacavir/ Lamivudine/ Dolutegravir Dispersible Tablet	Fixed Dose Combination 60/30/5 mg	Tentative approval is not currently anticipated before 2022	No, but expected after FDA tentative approval	To be determined	To be determined

Figure 6.5.3 depicts the current and expected DTG products that are or will be available for PEPFAR countries. Starting in COP20 (FY21), programs are expected to provide DTG-based ART to all PLHIV (≥ 4 weeks of age and who weigh ≥ 3 kg).

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 2021 or 2022, PEPFAR does not anticipate procuring this product until **after** OUs have successfully adopted DTG 10 mg DT and have exhausted their pediatric LPV/r "2-in-1" stock. Programs may consider the use of raltegravir 100mg granules for suspension in combination with AZT/3TC for neonates (0 – 4 weeks of age) in programs that are implementing at- or near-birth testing, and should use this regimen for the shortest period possible until the infant can safely be administered pediatric DTG (or pediatric LPV/r if pediatric DTG is not available in country).

The administration of DTG dispersible formulations will resemble the administration of ABC/3TC dispersible formulations, and the dispersible formulations are easier for caregivers to administer than LPV/r granules or pellets. Still, healthcare workers will require guidance and training on appropriate dosing and administration of pediatric DTG formulations and approaches for counseling and educating caregivers. It is critical that frontline providers receive intensified

[240] 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.

support to effectively prescribe, administer and monitor infants and children on ART. 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 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.

Country programs must monitor the uptake, scale-up and outcomes of pediatric ART. Programs should report the number of CLHIV on ART, stratified by ART regimen (including specific LPV/r and DTG formulation), WHO dosing weight bands, and if feasible, PEPFAR finer age bands. PEPFAR host 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. M&E tools should be adjusted to capture this required data. It is imperative that PEPFAR programs ensure children reach and maintain ≥ 90% 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 and any individual with a persistent elevated viral load after enhanced adherence counseling must be promptly switched to appropriate regimens as indicated. Please see Section 6.5.6.2 on recommendations to mitigate and address viral non-suppression in children.

6.5.1.3 Adolescent and Adult ART Optimization

Dolutegravir (DTG)-containing regimens are the preferred first-line and (following non-DTG first-line ART failure) second-line ART for all PLHIV ≥3kg and >=4 weeks old, due to superior efficacy, more rapid viral suppression, improved tolerability, and higher threshold for resistance as compared to efavirenz (EFV)-containing regimens. The fixed dose combination (FDC) of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) is affordable for low- and middle-income countries and minimizes pill burden; it is the WHO preferred ART regimen for all

adolescents and adults ≥ 30 kg and other DTG containing regimens are preferred for those <30kg. 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 by the start of COP21.

TLD should be provided to all adults and adolescents (>=30kg) 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)

In the rare instance in which a patient does not tolerate dolutegravir, TLE (300/300/400 mg) may be offered as an alternative. 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 optimal regimens. 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. In addition, if individuals are in a differentiated service delivery model, they should remain in that model of care 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.[241] 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[242] and in one study not greater than the background risk.[243] These data led the WHO to recommend DTG for all populations as first and second line therapy

[241] 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

[242] Zash R et al. Tsepamo: Evolution of NTD Prevalence with Preconception DTG IAS Virtual July 2020 Abs. OAXLB0102

[243] 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

including during pregnancy.[244] US Department of Health and Human Services HIV Guidelines were updated in April 2020 and DTG is now a preferred ARV drug throughout pregnancy and an alternative ARV drug for women who are trying to conceive.[245]

Programs should therefore plan to include pregnant and breastfeeding women in their TLD transition plan. Programs are encouraged to follow data on uptake and outcomes of TLD amongst men and women across different age groups closely. Specifically, they should report ARV exposures during pregnancy to The Antiretroviral Pregnancy Registry at www.APRegistry.com. This data reporting procedure should be incorporated in a standardized fashion into HCW trainings.

Concerns have been raised about the risk of weight gain including the development of obesity with DTG: important because of the association 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.[246,247] In the AFRICOS cohort, individuals switching to dolutegravir were evaluated. A clinically small but statistically significant rise in weight was noted, 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 C/PLHIV treated in PEPFAR-supported programs should have been transitioned to either DTG-based treatment, or if < 20 kg, or an alternative optimal regimen and formulation . Countries should include in their budget for the destruction of excess NVP-based formulations. Note: PEPFAR will continue to procure NVP

[244] https://www.who.int/hiv/pub/arv/arv-update-2019-policy/en/
[245] https://clinicalinfo.hiv.gov/en/guidelines/perinatal/table-5-situation-specific-recommendations-use-antiretroviral-drugs-pregnant
[246] Sokhela S et al. ADVANCE: ADVANCE Trial: DTG + TDF or TAF vs EFV 1st Line ART Excess Weight Gain with DTG-TAFI AS Virtual July 2020 Abs OAXLB0104
[247] Kouanfack C et al NAMSAL Trial, 96 Weeks: DTG vs Low Dose EFV400 1st Line ART Similar Viral Efficacy, Weight Gain More with DTG. IAS Virtual July 2020 Abs. OAB0402

oral solution and NVP dispersible tablets for infant prophylaxis until a more optimal regimen becomes available.

Note: PEPFAR will continue to procure NVP oral solution and NVP dispersible tablets for infant prophylaxis. Meetings to update the 2018 WHO Paediatric ARV Formulary and Limited Use List, which includes information on ARVs for infant prophylaxis and treatment, will be convened in 2020.

Available evidence indicates that patients receiving treatment for TB (with rifampin-containing regimens) require an additional DTG 50 mg administered 12 hours after TLD; therefore, TLD planning should include planning for procurement of adequate DTG 50 mg tablets for management of patients above 20 kg with TB coinfection for the duration of rifampin therapy.

PEPFAR currently recommends the use of tenofovir alafenamide fumarate (TAF) containing regimens in individuals with renal insufficiency or bony disease. Widespread procurement is not recommended until more data are available for use in pregnant women and patients with TB co-infection.

6.5.2 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 PLHIV with advanced disease at 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.[248] All children under 5 who are not on effective ART are considered to have advanced disease because of high viremia and rapid disease progression with high mortality. PHIA data suggest a prevalence of advanced disease at ART initiation between 10-20%. In the AFRICOS cohort, the proportion of individuals with advanced disease remained near 20% until 2019.[249] 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

[248] https://www.who.int/publications/i/item/9789240008045
[249] Oboho et al. Advanced HIV Disease among Adults in the African Cohort Study (AFRICOS) ID Week 2020

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.[250]

People with advanced HIV disease in PEPFAR programs include those who are initiating ART and those who are treatment experienced, many of whom have interrupted therapy. The Zimbabwe 2016 PHIA showed that 17% of PLHIV 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.

The WHO has identified a package of interventions[251] 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 CNS infection); (2) co-trimoxazole prophylaxis; (3) screening for active TB disease with a WHO-recommended rapid molecular diagnostic test (e.g., Xpert MTB/RIF Ultra) and urinary TB-lipoarabinomannan (LAM) with rapid return of results and prompt initiation of anti-TB treatment or TB preventive treatment as indicated. These interventions should happen in parallel, not sequentially. Initiation of TB therapy in individuals who are presumed to have TB, or have a positive Urinary Lam should never be delayed. (4) screening for cryptococcal disease with cryptococcal antigen (CrAg) testing and either preemptive therapy with fluconazole or treatment of meningitis (for children 10 and older, and adults only); (5) intensive follow-up for IRIS events. In places where Histoplasmosis is endemic (e.g., Central America), the Pan American Health Organization has 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 DSD 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. See http://www.differentiatedcare.org/Resources/Resource-Library/DSD-for-advanced-HIV-disease-toolkit for more detail and resources for implementation

Patients with advanced HIV disease who have been discharged from a hospital are at high risk of mortality, and linkage to follow-up care is critical to successful therapy therapy—intensified follow-up approaches appropriate to the local context should be implemented (e.g., phone calls, community follow up). At hospital discharge, linkage is needed to an agreed OPD or PHC with

[250] Zaniewski E et al, JAIDS, 2020) http://www.ncbi.nlm.nih.gov/pmc/articles/pmc7343336/
[251] https://apps.who.int/iris/bitstream/handle/10665/255884/9789241550062-eng.pdf

adequate information and planning so that OI treatment and prophylaxis may be continued. ART should be initiated as an inpatient. Delays in ART initiation should occur for only for meningitis, (tuberculous or cryptococcal) or other CNS infections. Pending evaluations for tuberculosis should not delay ART initiation.

Immune Reconstitution Inflammatory Syndrome (IRIS) events, are more common in in individuals with extremely low CD4 counts (e.g., <50 cells/mm^3). Concerns about IRIS, should not delay ART start; except in the setting of CNS infections, particularly tuberculous and cryptococcal meningitis. If ART has been delayed, clear referral information regarding when to start ART must be made. Intensified follow-up should also be considered for advanced disease patients who are managed in the outpatient setting alone. Community support may be helpful to counsel PLHIV through the early stage of ART, monitor for IRIS, and support adherence in the first few months following ART initiation."

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 (ages 5 years and older) who will benefit from the package of care.

Cotrimoxazole prophylaxis for *Pneumocystis jirovecii* pneumonia, severe bacterial infections and (in endemic areas) malaria as well as treatment for TB infection (for those who do not have evidence of TB disease) are of demonstrated value in appropriate individuals. Shorter course tuberculosis preventive therapy and the use of fixed-dose formulations that contain INH/cotrimoxazole/Vit B6 may facilitate more widespread use of these lifesaving therapies (See Section 6.5.3.3). 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).[252] No PLHIV in PEPFAR programs should pay for cotrimoxazole, TB preventive treatment, or the diagnostics and medicines required fluconazole for secondary prophylaxis or pre-emptive treatment of cryptococcal meningitis.

The diagnostic approach to TB for individuals with advanced disease includes screening for TB with a symptom screen at every clinical encounter (see Section 6.5.3). For individuals who screen positive for TB symptoms, a WHO-recommended rapid molecular diagnostic test (e.g., Xpert MTB/RIF Ultra, Truenat MTB Plus and Truenat MTB-Rif) should be used in conjunction

[252] https://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_dec2014/en/

with LF-LAM, if appropriate. Urinary LF-LAM is helpful for those who cannot produce sputum, but sputum testing with sensitive WHO-recommended rapid molecular diagnostic tests should always be attempted. LF-LAM should be performed in parallel to molecular diagnostic tests. **However, 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 6.5.3.1.

Evaluation for TB disease should not delay the initiation of antiretroviral therapy, and enhanced linkage and tracking interventions should be in place to follow-up pending TB diagnostic results to ensure appropriate anti-tuberculous treatment. When more sensitive urinary assays for TB become available, PEPFAR will support their use if they are recommended by the WHO TB Program and prices are competitive. In the meantime, programs should scale-up and implement the currently available LF-LAM test. Procurement quantities of LF-LAM should exceed the number of people living with HIV who present to care with signs and symptoms of TB or advanced HIV disease in inpatient and outpatient settings, and sufficient budget should be allocated accordingly.

PEPFAR supports cryptococcal antigen testing, preemptive therapy with fluconazole and management of cryptococcal meningitis according to the WHO 2018[253] (or later, should they be revised). Individuals older than 10 with advanced HIV disease (CD4 <200 cells/mm^3 or stage 3 or 4 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. Fluconazole in different doses is recommended for consolidation and maintenance. Countries should plan for adequate treatment according to their needs.

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.

[253] http://www.who.int/hiv/pub/guidelines/cryptococcal-disease/en/

6.5.2.1 Approach to CD4 Testing

Viral load testing remains the primary method used to monitor the effect of therapy. CD4 testing is supported by PEPFAR in select settings to identify individuals with advanced HIV disease. It is **not** to be used for determining eligibility for ART or monitoring response to ART. Individuals who have been out of care for more than a year, or who have documented viremia should have a CD4 performed to determine eligibility for the advanced disease package.

Patients initiating care in geographic regions or populations where the suspected or documented prevalence of patients presenting or re-presenting with advanced disease is >15% either overall or in specific age or risk group may also have a CD4 at initiation of therapy. Finally, if surveillance or public health investigation indicates disproportionately high morbidity or mortality among PLHIV in specific SNUs or populations, or for sites meeting the above criteria of >15% of the population presenting with advanced HIV disease, CD4 testing may be warranted. OU teams should budget for CD4 testing support at high volume facilities implementing advanced disease treatment models.

All programs should consider options for low-cost, quality-assured CD4 testing approaches whether existing laboratory-based or existing or new POC based to support patients with advanced HIV diseases. For example, WHO recently prequalified the Omega Diagnostics VISITECT CD4 Advanced Disease test.[254] The test is a rapid, semi-quantitative lateral flow assay that estimates CD4 protein on the surface of CD4+ T cells in human whole blood. It is inexpensive ($3.98 per test),[255] and able to differentiate CD4 values above and below 200 cells/mm^3. This and other CD4 point of care approaches with similar characteristics and implementation considerations should be given highest priority. The approach to achieving optimal CD4 testing[256] will be for the Ministry of Health to review current HIV advanced disease facility access to CD4 testing services. The review should include: an inventory of facilities identifying and/or providing care for HIV advance disease patients, determination of each inventoried facility's access to existing CD4 testing services and, where possible, optimization of existing, CD4 testing services. HIV facilities that remain without sufficient CD4 testing access

[254] https://www.medicaldevice-network.com/news/omega-who-prequalification-visitect-test/
[255] https://www.clintonhealthaccess.org/unitaid-and-chai-announce-agreement-with-omega-diagnostics-to-increase-access-to-new-portable-cd4-testing-device-for-people-living-with-hiv-in-over-130-low-and-middle-income-countries
[256] 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

after the review and initial optimization exercise should be prioritized for placement of CD4 testing technology that is able to meet facility-specific testing demand. CD4 testing technology selection and procurement planning should be guided by the health facility and CD4 service inventory review, patient and testing volumes, geospatial maps and/ or calculations of national and subnational test demand versus existing and/ or projected capacity.

6.5.2.2 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) 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. Additionally, supportive, client-centered counselling for both the caregiver and the child should be provided to reinforce the importance of continuity of treatment.

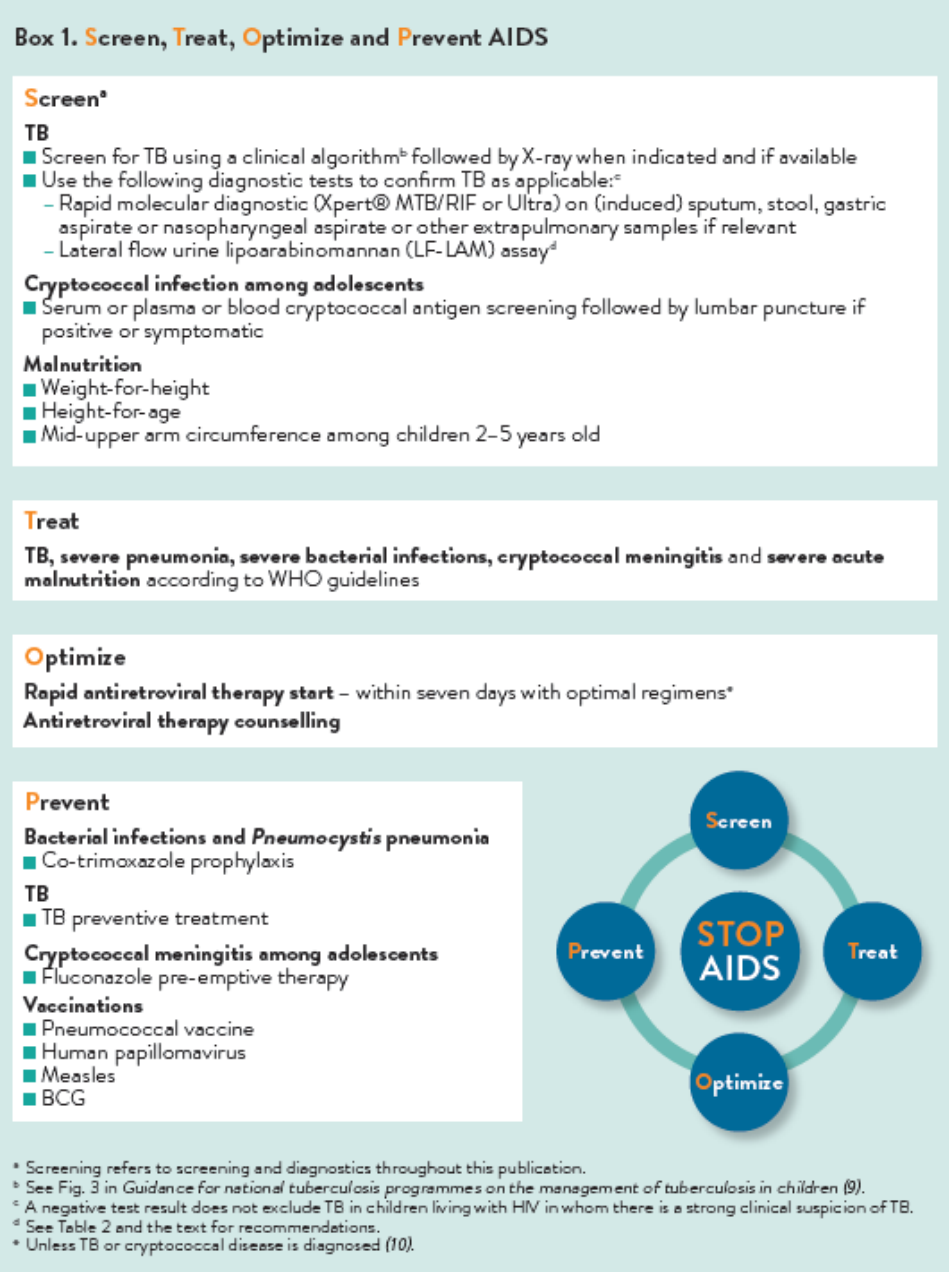
In July 2020, WHO released a technical brief[257] that outlines a package of interventions to STOP AIDS among C/ALHIV (see Figure 6.5.4). PEPFAR programs must incorporate this package of AHD interventions into PEPFAR-supported pediatric HIV programs. Although many components of the package addressing pediatric AHD is 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 deworming, malaria prophylaxis, and iron and vitamin A supplementation. 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 6.5.3).

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

[257] WHO. *Package of care for children and adolescents with advanced HIV disease: stop AIDS.* 1 July 2020. Available from: https://www.who.int/publications/i/item/9789240008045

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.

Figure 6.5.4: WHO's Package of Care for Children and Adolescents with Advanced HIV Disease: STOP AIDS[258]



[258] WHO. *Package of care for children and adolescents with advanced HIV disease: stop AIDS.* 1 July 2020. Available from: https://www.who.int/publications/i/item/9789240008045

6.5.2.3 Reducing Mortality

The “fourth 90” refers to living with HIV and having a good health-related quality of life as people age. Mortality among PLHIV is an independent measure of program quality and successful implementation across the HIV prevention and treatment cascade.

In practical terms for PEPFAR, this refers to identifying associated causes of death among PLHIV and taking action to mitigate them. One of the TX_ML disaggregates is death, and when available, programs are asked to record cause of death.

Individuals with advanced disease have a significant mortality, and early identification, linkage, and treatment initiation are critical to reducing mortality. (see Section 6.5.1.3). TB is and is the leading cause of death among PLHIV[259]; therefore, regular TB screening rapid TB diagnosis with LF-LAM in combination with a sensitive molecular assay, rapid treatment initiation, and TPT are critical for reducing mortality (see Sections 6.5.3.3.and 6.5.3).

The other group with excess mortality is older individuals, and in some programs, there is a growing proportion of older adults (see Section 6.1). These individuals may develop age-associated co-morbidities that can affect life expectancy and mortality, yet routine data on comorbidities might not be routinely collected.[260] The COVID-19 pandemic has highlighted the importance of data on chronic diseases and comorbidities to guide programmatic and policy actions. Programmatic adaptations that include the identification and treatment of comorbid conditions and alignment of multi-month dispensing of ARVs with other medications may be helpful in mitigating excess morbidity in this important group of individuals.

6.5.3 TB/HIV (Overview)

Globally, TB is the leading cause of death from a single infectious disease and it remains the most common cause of death among PLHIV, responsible for an estimated 208,000 deaths among PLHIV in 2019—approximately one-third of all HIV-related deaths.

Implementation of the package of evidenced-based TB/HIV interventions is a crucial and high-impact investment of resources and is a priority for PEPFAR programming. In the context of SARS-CoV-2, TB prevention, diagnosis, treatment and care services are even more important and should be provided in tandem and coordination with the COVID-19 response in a way that

[259] https://www.who.int/hiv/mediacentre/news/hiv-tb-patient-centred-care/en/
[260] Harris TG, Rabkin M, El-Sadr WM. Achieving the fourth 90: healthy aging for people living with HIV. AIDS (London, England). 2018;32(12):1563-9.

maintains and augments routine TB services rather than seen as competitive with COVID-19 response.

Ending HIV-associated TB among PLHIV is possible through a combination of strategies: high index of clinical suspicion, early detection and treatment of TB, comprehensive HIV testing among patients with TB symptoms, widespread ART coverage, TB preventive treatment (TPT), and effective prevention and infection control (IPC). The PEPFAR TB/HIV strategy is based on three key objectives and designed to reduce morbidity and mortality among PLHIV, CLHIV, and contacts of PLHIV with TB:

1. **Intensified TB case-finding** is an important and effective HIV case finding strategy
    - Consistent, high quality, and appropriate TB screening should be conducted at all facilities for all ages
    - TB screening should also be conducted within all PEPFAR-supported community settings (e.g., ANC, OVC, KP, and DSD) and for all age groups
    - 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 PLHIV must be screened at every clinical encounter for TB symptoms and using available technologies consistent with international guidelines. Of note, updated WHO Guidelines on TB screening are expected in early 2021 and "A Rapid Communication: Key updates to the WHO guidelines for systematic screening of TB" is also expected in December 2020 which may provide more options for TB screening among PLHIV.
    - All PLHIV with TB symptoms should be referred promptly for clinical evaluation and have quality specimens collected for diagnostic testing with a point-of care diagnostic test such as LF-LAM and WHO-recommended molecular diagnostic test with rapid patient results returned.
    - Completion of TB treatment and TPT should be assured for those who are started through provision of psychosocial, nutritional, and adherence support, as needed.
    - TB/HIV clinical services should be fully integrated to ensure that ART and TB treatment are optimized and harmonized, including differentiated service delivery (DSD)
3. TB Prevention
    - Scale-up of TB prevention interventions TPT for all eligible PLHIV, including children and adolescents

- Integrating provision of TPT through differentiated service delivery models (DSD)
- Screening and TPT for all eligible children and adults who are household contacts of PLHIV with TB
- Implementation of routine and effective infection prevention and control activities at all facilities and community settings.

6.5.3.1 Effective TB Case-Finding among PLHIV/CLHIV and Integration of TB and HIV Case-Finding Efforts

It is essential to detect and treat TB promptly and prevent TB morbidity and mortality among PLHIV, especially among CLHIV who can progress rapidly to severe TB disease. Screening and testing for TB is also a highly effective and critical HIV case finding strategy with HIV testing yields among confirmed and presumptive TB patients ranging from 3 to 49% across countries (FY2019 program data). Similarly, regular and high-quality TB screening of PLHIV, followed by prompt diagnostic testing and treatment for TB, if positive and treatment with TPT, if screen negative, are critical programmatic interventions that have been demonstrated to decrease mortality. TB screening is done by administering a simple symptoms screening tool to all individuals at every encounter, whether they are presenting at a facility, are enrolled in a Differentiated Service Delivery (DSD) model of care, being seen in the community, or being assessed remotely via innovative digital platforms, by phone, or SMS.

HIV positive adults and adolescents should be screened at every encounter or at least once every six months, for any of the following symptoms regardless of duration: fever, cough, night sweats, or weight loss. PLHIV positive for ANY of these symptoms should be evaluated and tested for active TB. For PLHIV enrolled in DSD models, screening should be done routinely as part of DSD services. Please see below for special considerations for TB Screening for children.

If available, programs may consider use of technologies such as chest x-ray and computer aided detection (CAD) software to screen for TB and to identify TB among people presenting with non-specific respiratory symptoms and therefore identify cases of TB early among PLHIV, including CLHIV.[261] Updated WHO Guidelines on TB screening are expected in early 2021. Programs need to ensure that there are no user fees associated with TB diagnosis or treatment, this includes molecular

[261] World Health Organization End TB Strategy. Chest Radiography in Tuberculosis Detection: Summary of current WHO recommendations and guidance on programmatic approaches. 2016. Available at: https://apps.who.int/iris/bitstream/handle/10665/252424/9789241511506-eng.pdf;jsessionid=A942759BB9F07BFAB023670C95035E92?sequence=1

diagnostic testing, services for sample collection, and chest x-rays, if they are part of the National algorithm.

TB screening should be administered by lay counselors and HIV testing providers as part of HIV case-finding and index testing efforts, for Key Populations, and by OVC/DREAMS case managers when they conduct home or community visits or meetings. In addition, in settings with high rates of TB and HIV transmission such as prisons, TB/HIV screening should be performed for prisoners at entry, annually, and at exit; consideration should be given to incorporating molecular diagnostic or radiographic screening for TB at entry.

TB and COVID-19 symptoms may overlap, and patients may be co-infected. Therefore, it's critical that TB and COVID-19 symptom screening algorithms and infection prevention and control procedures be implemented at all facilities and community settings. COVID-19 and TB screening algorithms and evaluation pathways should be bi-directional.

PLHIV should be routinely evaluated for TB & COVID-19 symptoms, even if they are being seen in the community. PLHIV screened for COVID-19 should be screened for TB. Similarly, PLHIV 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 to ensure systematic symptom screening, appropriate triage of patients presenting with respiratory symptoms, and infection control practices.

The proportion of PLHIV expected to screen positive 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.[262] 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 symptom screening among PLHIV is done poorly and results in missed opportunities to prevent TB morbidity and mortality. Poor quality screening in that study was associated with PLHIV on ARVs who have more frequent clinical encounters or attend high volume clinics are more likely to have poor quality TB screening.[263]

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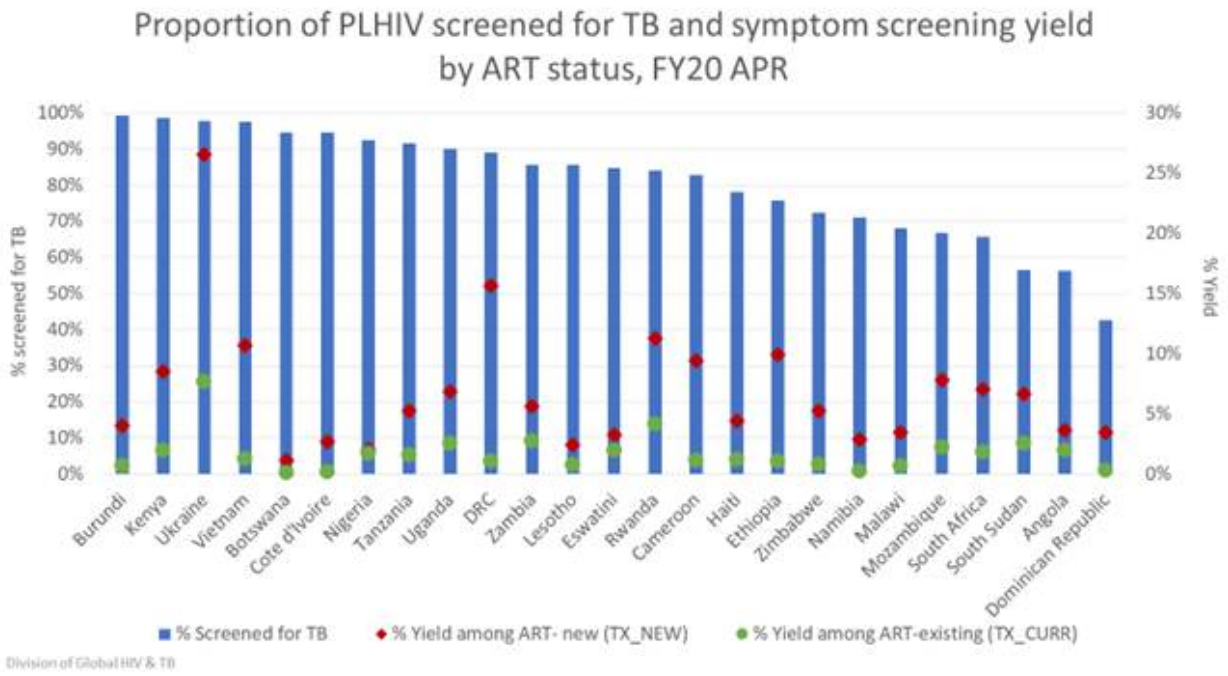
[263] Owiti P, Onyango D, Momanyi R, Harries AD. Screening and testing for tuberculosis among the HIV-infected: outcomes from a large HIV programme in western Kenya. BMC Public Health (2019): 19:29. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6323798/pdf/12889_2018_Article_6334.pdf

PEPFAR data among 14 priority countries reporting data in FY20 Q2 are consistent with these findings (see Figure 6.5.5). The screening yield for TB among PLHIV newly enrolled in care was <10% for 10 countries, while only one country had a yield above 15% (range 2-28%). The screening yield for TB among PLHIV already on ART ranged from 0.1% (suggesting poor screening quality) to 9%.

Another study in Tanzania demonstrated that while there was high yield of TB symptom screening among PLHIV presenting to clinics, more than 30% of PLHIV 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.[264] 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.[265]

Figure 6.5.5 Screening Yield for TB by ART status in FY20 Q4



[264] 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. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7015871/pdf/fpubh-07-00404.pdf

[265] 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; 9

Special considerations for TB diagnosis for infants and children

There are some specific challenges related to TB screening and diagnosis among children, especially young children and it's imperative that programs ensure that there is specific training and considerations for TB diagnosis among CLHIV.

CLHIV with any symptom of any duration should be evaluated for TB and other diseases with similar symptoms.[266] It is critical that C/ALHIV are screened for TB at each clinical and community visit/encounter. Similarly, all CLHIV enrolled in OVC programs must also be regularly screened for TB symptoms.

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 unfortunately limited data on the best screening tools for TB among children, who can present with more subtle or vague symptoms than adults and more likely to present with extrapulmonary TB. The WHO recommends that CLHIV and HIV negative children who are household contacts of PLHIV with TB be screened for the following symptoms: poor weight gain, fever, fatigue (reduced playfulness or energy), or cough.[267]

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 C/ALHIV.[268] Furthermore, there is some evidence that the symptom screen has even lower sensitivity (51%) for detecting TB disease among CLHIV on ART.[269] Another recent study evaluating TB screening in several Southern and East African countries highlighted significant variation in uptake and documentation of TB symptom screens for clinical visits among

[266] According to WHO, "poor weight gain is defined as reported weight loss, very low weight-for-age (<-3 z-score), underweight (weight-for-age <-2 z-score), confirmed weight loss (>5%) since the last visit or growth curve flattening." Available at: https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en/

[267] WHO. Systematic Screening for Active Tuberculosis: Principles and Recommendations. 2013. https://www.who.int/tb/publications/Final_TB_Screening_guidelines.pdf

[268] 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

[269] 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.

C/ALHIV and poor sensitivity of TB symptom screening to detect TB on the day of diagnosis and in the preceding 30 days.[270] Despite the limitations of these tools, these studies all 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 C/ALHIV with TB are diagnosed and placed on treatment promptly. All CLHIV positive for any of these symptoms during routine screening or CLHIV who are household contacts to TB patients should be evaluated for active TB disease immediately.

Active TB is among the top ten killers of children less than 5 years of age making it imperative to also ensure that child household contacts of PLHIV diagnosed with TB are screened and evaluated for TB and treated for TB or provided with TB preventive treatment if TB is ruled out.[271] Clinicians and programs should have a low threshold to pursue TB testing using WHO approved molecular diagnostic tests in children with a known contact with TB disease. Clinicians and programs should also 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.

National TB, HIV and TB/HIV guidelines should specifically address TB screening, diagnosis, treatment and TPT for CLHIV.

In addition to the below guidance on TB testing, special considerations are needed to improve TB diagnosis for CLHIV including special considerations for evaluating children for extrapulmonary TB and specimen collection and processing for child-friendly specimens. As young children are generally unable to produce quality sputum specimens, implementation of procedures for collection of alternative sample types (i.e., gastric aspirates, nasopharyngeal aspirates, stool) for molecular diagnostic testing should be supported according to WHO guidance. In addition, urine LF-LAM should be routinely available for diagnostic testing of children presenting with TB symptoms.[272] Where appropriate, programs should ensure WHO-recommended rapid molecular TB diagnostic testing for children is done using both sputum and non-sputum specimen types (including stool) according to the WHO policy guidance for each test type. Reagents and supplies required for testing of non-sputum specimens should be treated as essential commodities and budgeted accordingly. Should standardized stool processing solutions

[270] Haq H, Vonasek B, Dhillon D., et al. Predictive utility of tuberculosis symptom screening for children and adolescents living with HIV in six high HIV/TB burden countries in eastern and southern Africa. Pediatrics 2020, 146 (1 Meeting Abstract) 282-283

[271] 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.

[272] 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.

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.

TB Contact Tracing has a high yield for HIV and active TB

Tracing and screening contacts of patients with TB disease can be an effective for HIV and TB case-finding. A recent PEPFAR study in Mozambique further emphasized the role of TB contact tracing in the community as an effective and high yield strategy for HIV case finding in countries or geographies with high TB and HIV prevalence.[273]

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 PLHIV who are found to have TB disease and community-based, patient-centered approaches should be prioritized. All contacts of PLHIV with active TB should be screened for TB and sexual partners and biologic 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 WHO-recommended molecular diagnostic test with rapid patient result return; and TB or HIV treatment initiation, as appropriate.

All contacts who screen negative and have no contraindications should be offered TPT, if they have no other contraindication.

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 Ministries of Health, to ensure that the instruments/ tests that are selected meet their specific patient demand/ needs and build upon their current infrastructure, lab systems and geographic variability.

TB specimen collection should adhere to national guidelines. Individuals should be provided with materials and instructions for sample self-collection in an outdoor or well-ventilated space. All PLHIV with TB symptoms should be referred promptly for clinical evaluation and have quality specimens collected for diagnostic testing with a WHO-recommended molecular test ((such as Xpert MTB/RIF Ultra, Truenat MTB Plus, or MTB-RIF Dx) and with LF-LAM, if appropriate. In addition, all PLHIV determined to be resistant to rifampicin by molecular diagnostic testing

[273] 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

should be linked to TB culture and drug susceptibility testing services to ensure the full spectrum of drug resistance is quickly identified and the most effective TB treatment regimen is provided.

Use of sputum smear for acid-fast bacilli (AFB) is known to have unacceptably low sensitivity (in PLHIV and HIV-negative people) and should not be used as the initial diagnostic test. In areas where low or no access to approved WHO-recommended molecular diagnostic testing exists, smear microscopy may be used as a last resort. These areas/sites should be prioritized for support through diagnostic network expansion and/or improved linkage to existing testing services through enhanced specimen referral networks.

In addition, PEPFAR IPs should procure and utilize the urine lipoarabinomannan (LF-LAM) assay as a rapid point-of-care diagnostic test. 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 PLHIV in a randomized controlled trial. The WHO released updated guidance on the use of LF-LAM in November 2019 with a strengthening of their recommendations for the use of LF-LAM in both in-patient and outpatient diagnosis.[274,275] Programs should work with their respective ministry of health to incorporate LF-LAM in the national algorithm along-side WHO recommended molecular diagnostic tests and ensure appropriate procurement quantities and implementation. LF-LAM is not intended to replace initial WHO-recommended molecular diagnostic tests however, it should be used in combination with these molecular diagnostic tests, for adults, adolescents, and children living with HIV and TB treatment initiated immediately following a positive result while waiting for confirmatory molecular test results. Procurement quantities of LF-LAM should exceed 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, and sufficient budget should be allocated accordingly. The recommendations for use of LF-LAM are differentiated based on whether a client is presenting to an inpatient or outpatient setting:

Inpatient settings, use LF-LAM in the following clinical scenarios:

[274] 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 3.0 IGO Available at: https://www.who.int/tb/publications/2019/LAMPolicyUpdate2019/en/

[275] WHO Operational Handbook on tuberculosis: Module 3: Diagnosis. June 2020. https://www.who.int/publications/i/item/who-operational-handbook-on-tuberculosis-module-3-diagnosis---rapid-diagnostics-for-tuberculosis-detection

- **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
- **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)

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 <100, regardless of signs and symptoms of TB. WHO recommends urine LAM testing for anyone with CD4 below 200 in the inpatient setting or below 100 in the outpatient setting, for ease of administration, PEPFAR recommends urine LAM testing for anyone with CD4 below 200.

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 and local epidemiology.

OU teams should make urine LAM test 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 should be initiated, regardless of a negative urine LF-LAM or rapid molecular diagnostic test result.

PEPFAR implementing partners should collaborate with Ministries of Health and other stakeholders to ensure policies, algorithms, laboratory and clinical training materials, and quality assurance programs are developed and implemented to support quality-assured LF-LAM testing. 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. The WHO SPI-POCT checklist and CDC HIV RT-CQI program may be adapted for use with LF-LAM as a POC rapid test.[276] A newer, more sensitive version of the test may become commercially available in the next few years; however, teams should not wait for this newer assay to be available and should procure the available LF-LAM assay immediately.

Delays in TB diagnostic workup and therefore TB treatment and ART initiation result in significant morbidity and mortality; countries should make implementation and increased access to LF-LAM, WHO-approved molecular TB diagnostics, optimization of specimen transport systems for required TB culture and drug susceptibility testing services and results reporting processes a priority.

Testing for HIV among those with TB symptoms 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 presumptives"). Most countries are currently facing gaps in diagnosing and/or reporting of all individuals with TB disease, and this has been particularly exacerbated by decline in health facility visits in the setting of COVID-19 and may result in significant increases in TB burden and transmission. 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 presumptives or in TB clinic settings is also among the highest yield modalities across all OUs.

6.5.3.2 Optimizing Treatment for Patients with TB and HIV

Delay in diagnosing TB disease or initiating TB treatment prevents PLHIV on ART from attaining viral suppression, can increase non-adherence to ART, and can thereby contribute to morbidity, mortality and ongoing HIV and TB transmission. Accordingly, 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. Delays in initiating ART result in excess morbidity and mortality (See Section 6.5.2 Identification and Treatment of Advanced Disease). A forthcoming update to WHO guidance on the exact timing of ART initiation for newly diagnosed PLHIV on TB treatment is expected in early 2021. Patients should be treated in the same clinic for both TB and HIV to optimize their treatment regimens

[276] 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

and minimize potential for drug-drug interactions, streamline monitoring, and avoid confusion for both patients and providers. 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. If PLHIV are enrolled in a DSD program for ART, TB treatment or TPT should also be integrated into DSD. To ensure TB prevention and treatment services continuity in the context of COVID19, many countries moved into implementation of 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

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.[277] While there is some field experience showing that patients on TLD and standard TB therapy without a second dose of DTG did well, PEPFAR supports the WHO recommendations for a second dose of DTG for patients taking RIF concomitantly. PLHIV on TLD and the shorter TB Preventive Treatment (TPT) regimen 3HP do not need an extra dose of DTG.

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. Unfortunately, data are extremely limited on the use of TLE400 in TB patients who are receiving treatment with rifampin-containing regimens (i.e., first-line TB treatment that includes rifampin, along with isoniazid, pyrazinamide and ethambutol). WHO currently endorses the coadministration of EFV400 and RIF; however, larger studies of PLHIV with TB disease who are on TLE400 are needed.

Appropriate care of patients with TB and HIV aims to support adherence by minimizing the burdens placed on the patient. This can be best accomplished through the spectrum of collaborative and integrated models of TB/HIV care to provide ART and TB treatment in the

[277] 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

same clinic and providing adherence support. Adherence support may include addressing barriers to treatment adherence and include but not be limited to peer or other treatment support, identifying and addressing food insecurity or transportation barriers, or using electronic or mobile devices for additional support. Close monitoring via community visits, 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. Provision of refills should be adapted to align with MMD for ART. Adherence support also includes procurement of pediatric-friendly fixed dose combinations for TB disease treatment when available.

TB/HIV integration should be planned in all settings, including PMTCT/maternal child health settings and programs for Key Populations. Patients with HIV and TB disease should never be made to visit different clinics for treatment; rather, they should be treated by a single provider in a single clinic. Similarly, if patients are enrolled in a differentiated service delivery (DSD) model, efforts should be made to align TB treatment or TB preventive treatment, when appropriate, with that patient's chosen or assigned model for minimal disruption. PLHIV with TB disease should be considered for differentiated service delivery models for PLHIV with advanced disease.

A successful example of optimizing TB and HIV activities in Eswatini can be found on the PEPFAR Solutions Platform. 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. 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 or community workers, or by remote telephonic or video communication.[278] As above, teams should also ensure access to both HIV and TB diagnostic testing at current HIV service sites for all household contacts. 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.

[278] 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.
WHO. Digital Health for the End TB Strategy: an Agenda for Action. 2015, Available at: https://www.who.int/tb/areas-of-work/digital-health/Digital_health_EndTBstrategy.pdf

Please see Section 6.5.3.3 below for examples of differentiated service delivery models that integrate HIV care and TPT.

6.5.3.3 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, scale-up of TPT for all PLHIV (including eligible household contacts of PLHIV with TB disease) is an integral part of the clinical care package and a PEPFAR priority. Broader awareness is crucial to reduce stigma and discrimination around TB-HIV, increasing knowledge about benefits of TPT among both providers (within clinical facilities and community settings), and patients, and creating 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 have been set accordingly; therefore, all PEPFAR-supported care and treatment programs should be fully engaged in aggressive TPT scale-up with clear timelines to 100% coverage. In many countries, TPT initiations slowed or were delayed in the wake of COVID-19; these countries will need to implement aggressive TB "catch-up" plans in order to achieve full TPT coverage. At entry into care, and at each subsequent encounter--whether at a facility or community or remotely; e.g., every three or six months at a DSD or standard clinical encounter--all PLHIV including C/ALHIV should be screened for symptoms of TB disease using standard WHO screening tools and algorithms, with clear results captured in medical charts or, preferably, a TB screening register. Patients and caregivers of C/ALHIV should also be educated to recognize TB symptoms, including child-specific symptoms such that they report to care promptly if detected.

In order to facilitate rapid scale-up, partners and facilities should ensure that clear policies and/or guidelines for the use of TPT are in place, including integration with DSD models, and that they have adequate plans (and budgeting) for programmatic and clinical trainings (as needed), patient literacy/education, procurement and supply management, adequate diagnostic capacity (including specimen transportation and laboratory results reporting) development of appropriate data collection and data alignment systems (see Figure 6.5.7).

An efficient and effective TPT implementation progress monitoring system (i.e., TPT initiation and adherence, TPT outcomes, including adverse events) should also be established to ensure

continuous program quality improvement. Programs should also have a mechanism to assess and track on an individual level as well as across their OU, who has already completed a course of TPT, and if possible, which TPT regimen they received, within the last three years. 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.

TPT Regimens

Historically, the preferred treatment regimen has been 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 (Module 1: Prevention) preventive treatment 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). All PEPFAR-supported care and treatment programs should be fully engaged in aggressive TPT scale-up with clear timelines to 100% coverage, focusing on rifapentine-based regimens. Presently, shorter, rifapentine-based TPT regimens are the preferred PEPFAR regimen for TPT for adults and adolescents. PEPFAR recognizes that supply of rifapentine has been limited due manufacturing disruptions related to COVID-19, delays in ERP approval, as well as recent nitrosamine related alerts requiring additional quality control measures. While COVID related disruptions have been mostly resolved, manufacturers and regulatory agencies continue to work closely together to put in place nitrosamine impurity mitigation strategies and resolve any pending QC requirement as soon as possible.[279] It is anticipated and we are hopeful that supply capacity will improve in FY2021.

It is important to note that when efavirenz and DTG are co-administered there is a reduction in DTG trough levels. Once efavirenz is stopped, these effects may linger for a couple of weeks. It is unknown whether the lingering effects of efavirenz and rifapentine may compromise DTG effectiveness among patients switching from an efavirenz-based regimen to TLD and starting 3HP. Therefore, for PLHIV in the midst of transitioning from efavirenz to TLD, it is reasonable to wait 2-4 weeks before starting 3HP. 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

[279] FDA. "FDA works to mitigate shortages of rifampin and rifapentine after manufacturers and nitrosamine impurities." October 29, 2020. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-works-mitigate-shortages-rifampin-and-rifapentine-after-manufacturers-find-nitrosamine

patients however this is ultimately determined by Country level policies.[280] 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 C/ALHIV are screened for TB symptoms routinely (See Section 6.5.3.1) and if active TB disease is ruled out initiated on TPT. TPT is a lifesaving intervention for children with HIV however the choice of regimen requires special consideration including ARV regimen, 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 pending availability of 3HP in child-friendly formulations at an affordable price.[281,282,283] Special attention needs to be given to the forecasting of pediatric formulations of INH (INH 100 mg dispersible formulations). Erroneous forecasting of pediatric formulations of INH often results in its stockouts which in turn results in low TPT initiation among children. Three months daily isoniazid and rifampin is an alternative regimen and has been demonstrated to be non-inferior to 6 to 12 months of INH for TB prevention however, providers must be aware and adjust dosing where appropriate because of the drug-drug interactions between rifampin and different ARV regimens for children. The DOLPHIN KIDS Study to assess for drug-drug interactions between 3HP and DTG is planned for 2021 with results in early 2022.

[280] 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. http://www.croiconference.org/sessions/safety-pk-weekly-rifapentineisoniazid-3hp-adults-hiv-dolutegravir (abstract); http://www.croiwebcasts.org/console/player/41177 (webcast)
[281] Hsu KH. Isoniazid in the prevention and treatment of tuberculosis. A 20-year study of the effectiveness in children. *JAMA*.1974; 229: 528-533
[282] 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
[283] 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

Figure 6.5.6 Comparison of TPT Regimens for CLHIV and drug-drug interactions with ARVs[284]

	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 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 and 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.[285] While there are still some uncertainties around the safety, efficacy, and appropriate timing of TPT in pregnant women with HIV, treatment guidelines generally recommend the same regimens and dosing for pregnant and breastfeeding women. Country programs should consider the benefits and risks of deferring TPT initiation for pregnant women based on their epidemiologic context, national guidelines, and in conversation with pregnant women. 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.[286] A recently reported, randomized controlled trial of IPT during pregnancy

[284] 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.

[285] Mathad JS, Gupta A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. *Clin Infect Dis*. 2012;55:1532–49

[286] IMPAACT 2001. CROI

compared with IPT deferred until after 12 weeks postpartum reported no difference in maternal serious adverse events or rates of maternal or infant TB; however, the study reported a higher incidence of treatment-related adverse events, and excess adverse pregnancy outcomes in the immediate IPT arm. The study did not demonstrate higher incidence of these adverse outcomes when analyzed separately and other retrospective and prospective studies have not found adverse maternal or infant outcomes associated with IPT use. 6H or 9H remain the preferred regimens in pregnant and breastfeeding women with HIV or are contacts of TB patients. Treatment literacy and counseling should be provided to empower pregnant women to decide when and whether to initiate TPT, this may include review of hepatoxicity risks by ARV regimen based on immediate or deferred IPT.

Additional considerations

Per WHO guidelines, for populations with a markedly elevated burden of TB, programs may consider use of continuous INH, which has been shown to lower the risk for TB more than six months of treatment alone in areas with high TB prevalence. 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 >14-24.9kg.[287]

WHO recommends the consideration of vitamin B6 (pyridoxine) coadministration to PLHIV receiving INH to prevent peripheral neuropathy, although no randomized placebo-controlled study has assessed the effect of vitamin B6 on side effects.[288] 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 malnutritional and alcohol use should be considered. Forecasting and supply management of vitamin B6 should mirror that for INH if not in FDC. Lack of availability or delays in procurement of Vit B6 alone should never be a reason to discontinue or prevent initiating TPT in otherwise eligible PLHIV.

There are many important considerations in the implementation and scale-up of TPT from commodity planning to clinician education to monitoring for adverse events and reporting (see Figure 6.5.7). A full suite of tools to assist with program implementation and scale-up is available on PEPFAR Solutions,

[287] 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

[288] WHO. Latent TB Infection: Updated and consolidated guidelines for programmatic management. 2018 Available at: https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en

see TB Preventive Treatment Implementation Tools on PEPFAR Solutions.[289] Commodity agents from GHSC-PSM are available to assist with forecasting and procurement and supply management. An effective supply chain management technique called "kitting" has been implemented by Nigeria and other OUs to ensure that PLHIV initiated on TB TPT do not have interruptions in treatment due to supply chain delays. Kitting refers to mechanism to ensure that a patient has a dedicated complete course or sufficient quantity of drugs available at the point of care to avoid treatment interruption.

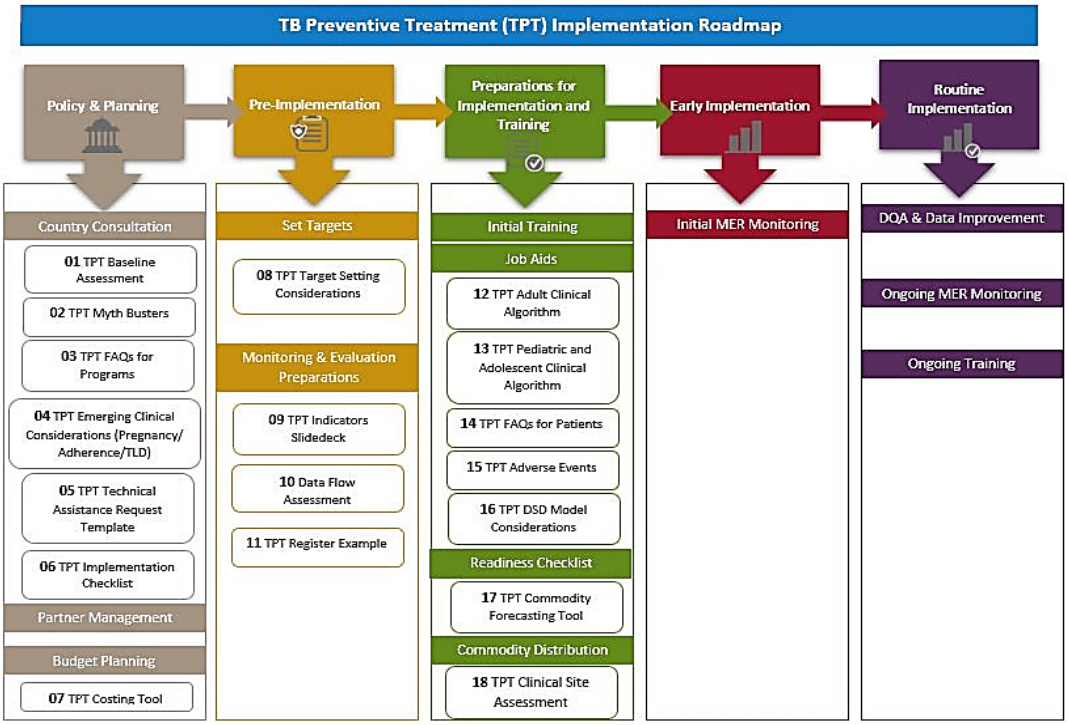
There is a need for quality data on TPT implementation, especially in the midst of a concomitant TLD transition if 3HP is being used as TPT regimen. With such a rapid scale-up of activity, it is crucial to effectively monitor implementation and rigorously monitor for adverse events. Programs should consider 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, as programs scale-up TPT, regardless regimen, they are expected to develop or strengthen pharmacovigilance and adverse event monitoring. 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.

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 and TB preventive treatment (TPT). Differentiated service delivery models for delivery of TB services can be modified to accommodate children and adolescents living with HIV and adapted to national COVID19 response. PLHIV with TB disease should be prioritized for differentiated service delivery models adapted specifically to PLHIV with advanced disease.

[289] PEPFAR Solutions: TB Preventive Treatment Implementation Tools Available at https://www.pepfarsolutions.org/tools-2/2018/9/25/tpt-implementation-tools

Figure 6.5.7: TB Preventive Treatment Implementation Tools



In most countries, targets for TPT will not be met by only providing a course of TPT to newly-diagnosed PLHIV. Therefore, 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 multi-month dispensing, community commodities distribution, 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 must be considered to ensure PLHIV already in these differentiated service delivery models complete a course of TPT.

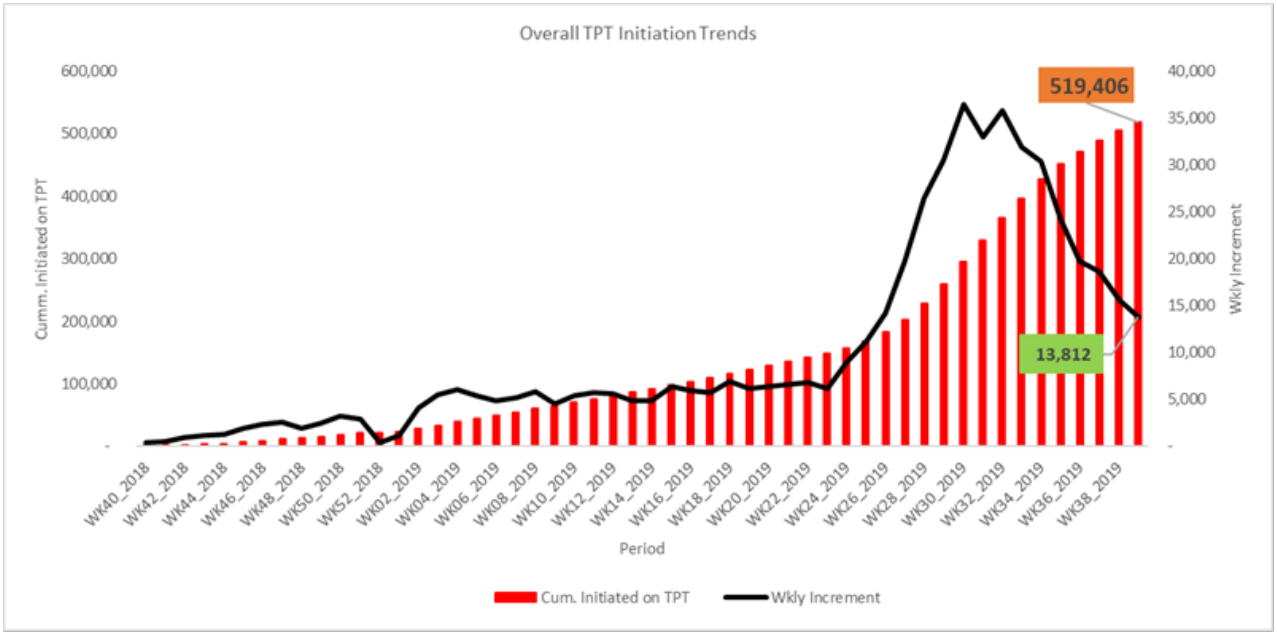
General programmatic considerations for TPT in differentiated service delivery

A critical part of integrating TPT into DSD models is ensuring that there is sufficient investment in client treatment literacy around TB symptoms and TPT safety and side effects to facilitate adherence, avoid adverse events and ensure TPT completion. DSD 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 DSD for TPT, especially if their parent, guardian or caregiver is also receiving ARVs and/or TPT through DSD (aligning their model to their caregiver). DSD models should account for potential weight changes and needed dose adjustments for young children.

Figure 6.5.8: Uganda Successfully Launched and Implemented a 100-day Campaign to treat 100,000 people with TB Prevention Treatment



Examples of DSD models for TPT delivery

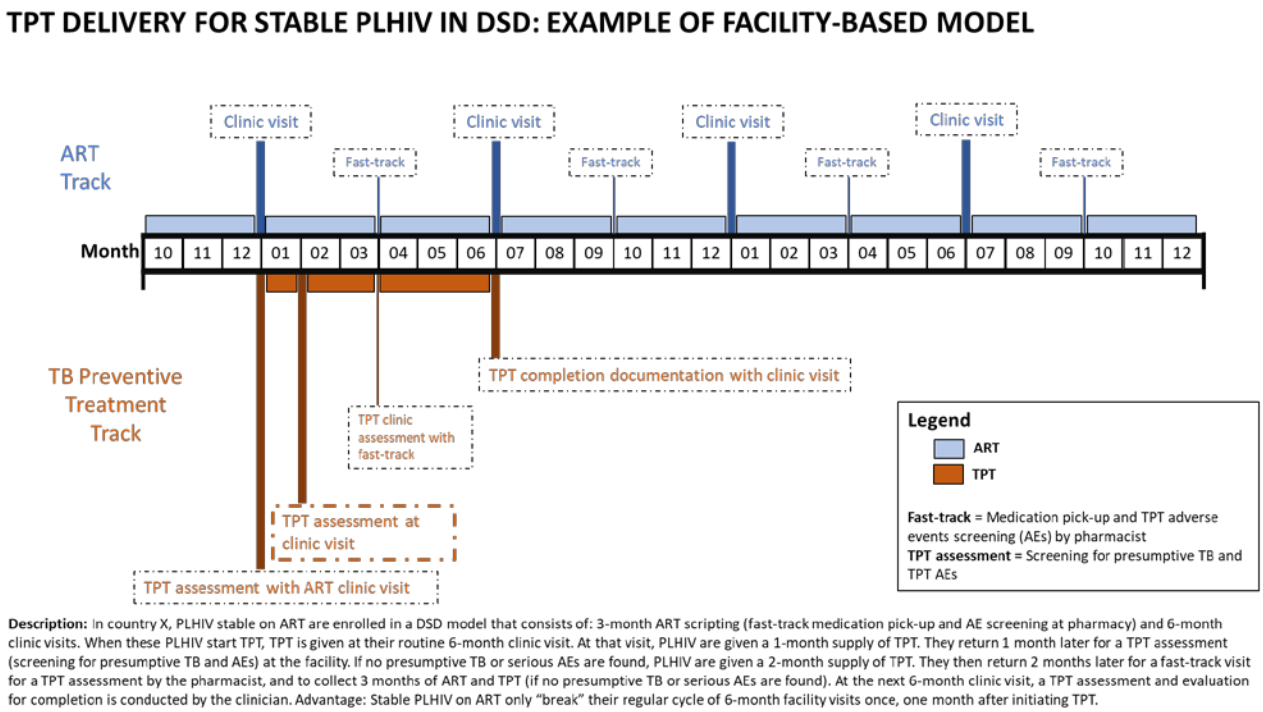
The following figures provide operational examples of differentiated service delivery models for TPT delivery. The first figure depicts an operational example of a facility-based model, and the second depicts a community-based model. The final figure is a blank program worksheet for

adaptation of differentiated service delivery for TPT delivery, intended to provide program managers the opportunity to construct differentiated service delivery models for TPT delivery, considering important elements of *what, when, where,* and *by whom.*

Preventing TB Transmission

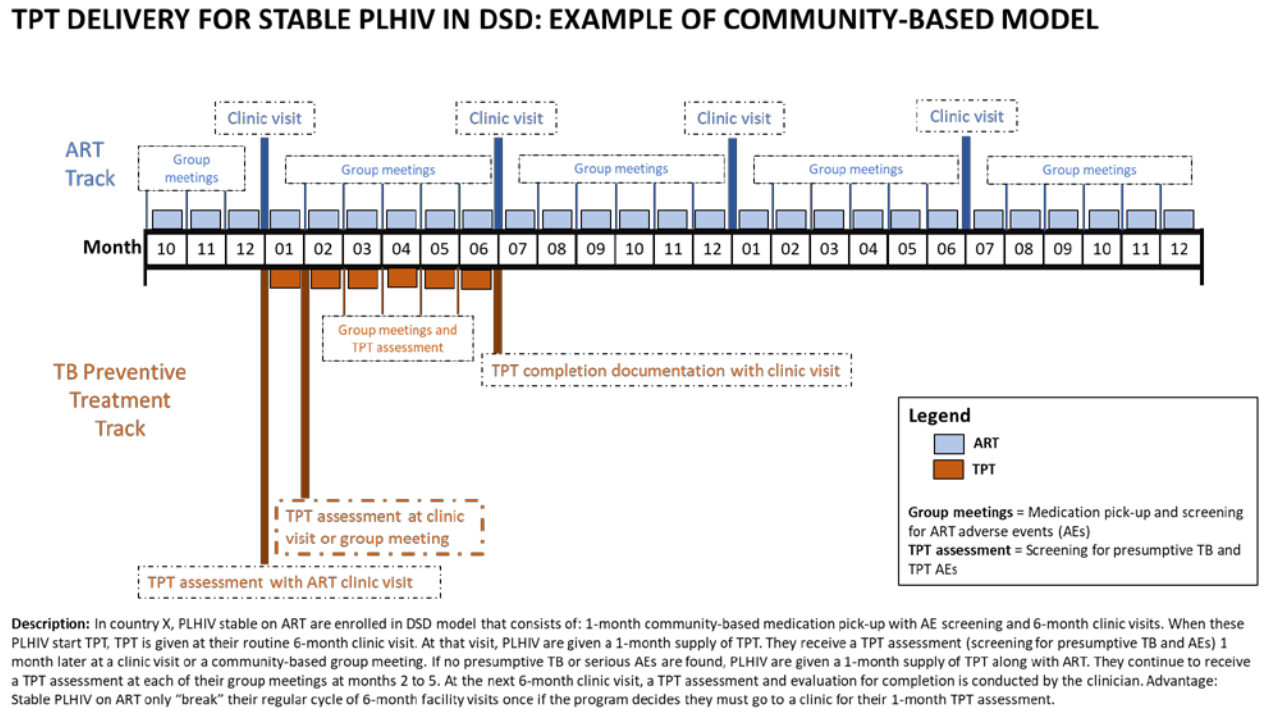
Preventing TB disease requires focused efforts to reduce transmission as well as efforts to diminish the risk of developing active disease among PLHIV through TB preventive treatment (discussed in more detail in Section 6.5.3.3). All program systems investments should include facility-level and administrative measures for TB infection prevention and control. Please see Section 6.7.1 for further detail.

Figure 6.5.9: TPT Delivery for Stable PLHIV: Example of Facility-Based Model



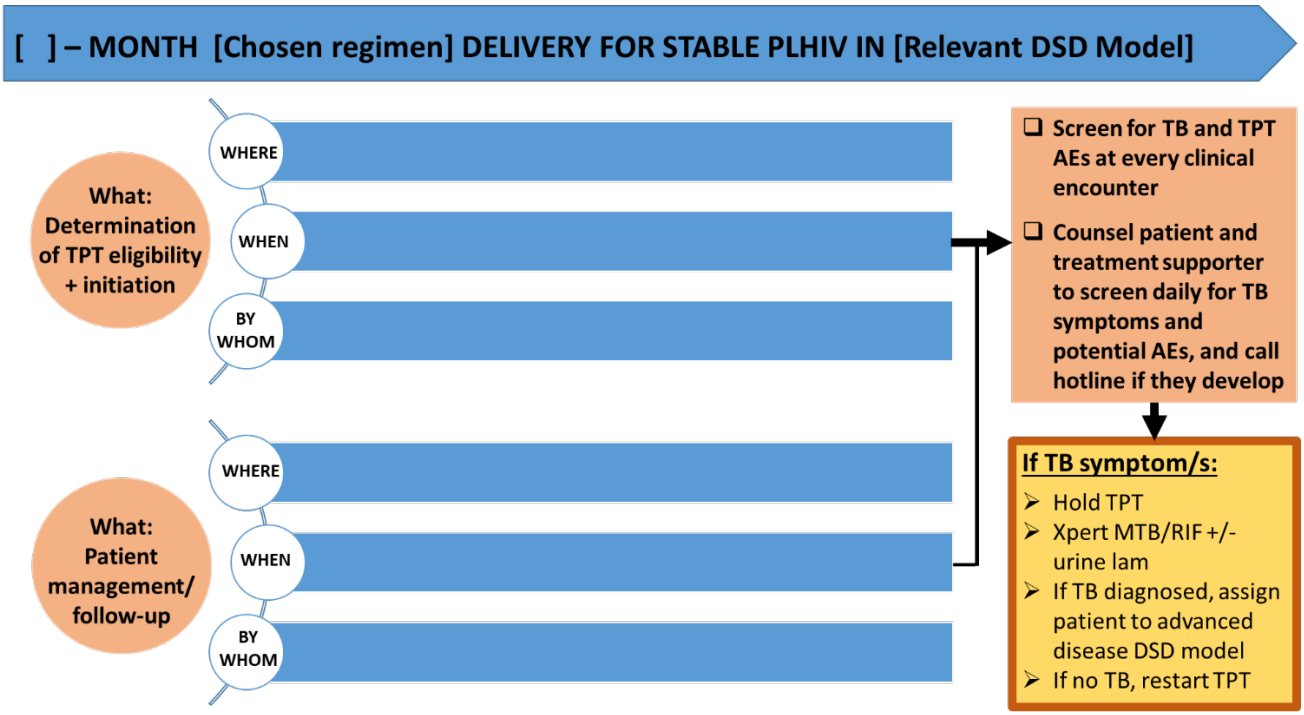
Description: In country X, PLHIV stable on ART are enrolled in a DSD model that consists of: 3-month ART scripting (fast-track medication pick-up and AE screening at pharmacy) and 6-month clinic visits. When these PLHIV start TPT, TPT is given at their routine 6-month clinic visit. At that visit, PLHIV are given a 1-month supply of TPT. They return 1 month later for a TPT assessment (screening for presumptive TB and AEs) at the facility. If no presumptive TB or serious AEs are found, PLHIV are given a 2-month supply of TPT. They then return 2 months later for a fast-track visit for a TPT assessment by the pharmacist, and to collect 3 months of ART and TPT (if no presumptive TB or serious AEs are found). At the next 6-month clinic visit, a TPT assessment and evaluation for completion is conducted by the clinician. Advantage: Stable PLHIV on ART only "break" their regular cycle of 6-month facility visits once, one month after initiating TPT.

Figure 6.5.10: TPT Delivery for Stable PLHIV in DSD: Example of Community-Based Model

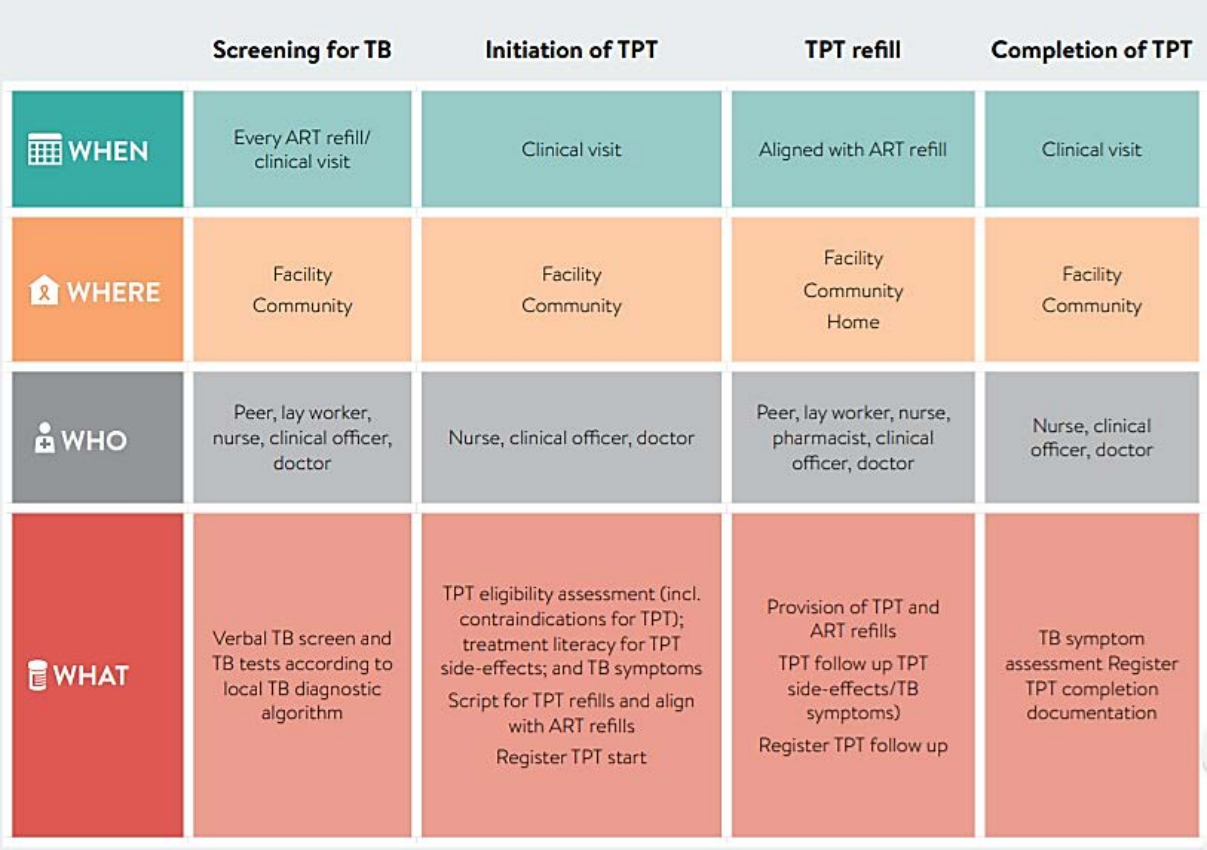


Description: In country X, PLHIV stable on ART are enrolled in DSD model that consists of: 1-month community-based medication pick-up with AE screening and 6-month clinic visits. When these PLHIV start TPT, TPT is given at their routine 6-month clinic visit. At that visit, PLHIV are given a 1-month supply of TPT. They receive a TPT assessment (screening for presumptive TB and AEs) 1 month later at a clinic visit or a community-based group meeting. If no presumptive TB or serious AEs are found, PLHIV are given a 1-month supply of TPT along with ART. They continue to receive a TPT assessment at each of their group meetings at months 2 to 5. At the next 6-month clinic visit, a TPT assessment and evaluation for completion is conducted by the clinician. Advantage: Stable PLHIV on ART only "break" their regular cycle of 6-month facility visits once if the program decides they must go to a clinic for their 1-month TPT assessment.

Figure 6.5.11: Program worksheet for adaptation of DSD for TPT delivery



6.5.12: The Building blocks of Tuberculosis Preventive Therapy Integration into Differentiated Service Delivery Models[290]



	Screening for TB	Initiation of TPT	TPT refill	Completion of TPT
WHEN	Every ART refill/ clinical visit	Clinical visit	Aligned with ART refill	Clinical visit
WHERE	Facility Community	Facility Community	Facility Community Home	Facility Community
WHO	Peer, lay worker, nurse, clinical officer, doctor	Nurse, clinical officer, doctor	Peer, lay worker, nurse, pharmacist, clinical officer, doctor	Nurse, clinical officer, doctor
WHAT	Verbal TB screen and TB tests according to local TB diagnostic algorithm	TPT eligibility assessment (incl. contraindications for TPT); treatment literacy for TPT side-effects; and TB symptoms Script for TPT refills and align with ART refills Register TPT start	Provision of TPT and ART refills TPT follow up TPT side-effects/TB symptoms) Register TPT follow up	TB symptom assessment Register TPT completion documentation

6.5.4 Cervical Cancer Screening and Treatment

Cervical cancer is an important public health problem worldwide. In 2018, approximately 311,000 women died from cervical cancer; and more than 90% of those deaths occurred in low- and middle-income countries.[291] Cervical cancer is the number one cancer killer of women in sub-Saharan Africa (SSA). Roughly 110,000 women in SSA are diagnosed annually with cervical cancer, and of these about 68% will die from the disease.[292] We also know that women living with HIV (WLHIV) are six times[293] more likely to develop persistent precancerous lesions and progress to cervical cancer, often with more aggressive forms and with higher mortality. For these reasons, since 2018, PEPFAR has

[290] Adapted from DifferentiatedCare.org "Leveraging differentiated ART delivery models for stable clients to scale up TPT"; Available at: http://www.differentiatedcare.org/Portals/0/adam/Content/3qTmUzah5kWCdeEogdiJ5A/File/IAS%20TPT%20supplement%208-Pager%20DIGITAL.pdf

[291] Global Cancer Observatory: https://gco.iarc.fr

[292] WHO/International Agency for Research on Cancer: http://gco.iarc.fr/

[293] https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30459-9/fulltext

focused its effort to provide cervical cancer screening and treatment for pre-invasive lesions to WLHIV in areas of high HIV prevalence through utilizing ART and other service delivery platforms. In addition, recognizing the preventable and curable nature of the disease, in 2020, WHO and global partners launched the *Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem.*[294]

Starting in FY18, PEPFAR refocused its support for the implementation of cervical cancer screening and treatment of precancerous cervical lesions in ART clinics among women with HIV on ART. The Go Further Partnership was launched in May 2018, building on the earlier success of Pink Ribbon Red Ribbon. It brings together PEPFAR, UNAIDS, the George W. Bush Institute, and Merck by leveraging strengths of each institution. In COP 18/19, PEPFAR committed funding to eight sub-Saharan African countries (Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, Zambia, and Zimbabwe) to catalyze screening and pre-invasive treatment services for HIV-positive women. In COP20 four additional countries (Tanzania, Uganda, Kenya, and Ethiopia) were added to the Go Further Partnership. All countries with HIV prevalence above 5.0% among women in the 15-49-year-old age group are expected to provide cervical cancer screening for women living with HIV receiving ART. In addition, programs utilizing PEPFAR resources (regardless of whether or not they are a Go Further country) for cervical cancer services are expected to adhere to the specific guidance and report on the indicators developed during FY18.

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. Subsequent screening should be every two years (recommendation based on PEPFAR modeling) up until age 49 years. 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.

The primary method of screening should be visual inspection with acetic acid (VIA) with immediate treatment of pre-cancerous lesions (Figure 6.5.13) VIA with 5% acetic acid is a single-visit 'point-of-care' clinical screening test for early detection of cervical cancer and has been extensively evaluated globally in low- and middle-income countries. VIA is simple, low-cost, easy to implement, and may be

[294] Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health
Organization; 2020.

performed by well-trained healthcare workers of different cadres (physicians, nurses, midwives, lay health workers), with appropriate quality assurance measures. VIA has an overall sensitivity ranging between 60-80% and a specificity of 70-90% although these metrics can vary substantially.

If platforms and capacity exist in country, quality-assured HPV DNA testing with timely follow-up/referral of WLHIV with positive results can be utilized for screening WLHIV (Figure 6.5.14) and may be prioritized for the initial screening of postmenopausal women in whom pelvic exam and visualization of the transformation zone may be difficult. In addition, HPV DNA testing may be an option for sites that are not able to offer quality-assured VIA to allow for timely referral and management of only those WLHIV testing positive for high-risk HPV types. Currently, PEPFAR does not support prophylactic treatment for women who are HPV positive but have no lesions seen on VIA. HPV DNA sample collection should be conducted in accordance with national guidelines and SOPs.

A "screen-and-treat" approach is recommended to maximize opportunities for immediate cryotherapy or thermal ablation treatment for eligible women without the need for diagnostic pathology confirmation and to reduce loss to follow-up. 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 women during pregnancy or for two months post-partum.

Management of a Positive Cervical Screen: 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 should be linked to treatment.[295] 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. The PEPFAR program should aim to include provision of cryotherapy or thermal

[295] Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization 2020

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 4-6 months. Women with suspected invasive cervical cancer should either receive additional evaluation and treatment at the same facility or referred to established treatment referral sites that were identified during the planning process. All sites providing cervical cancer screening that do not provide cryotherapy, thermal ablation, or LEEP, should establish a relationship with a site that performs these procedures to allow referral of women needing treatment, LEEP, or more definitive diagnosis. Women should be given specific appointments and assisted with logistical planning and resources to reach the referral site and monitored to assure follow up. Referral sites should also have the capacity to track patients and report on outcomes.

Figure 6.5.13: VIA-based Screening Algorithm

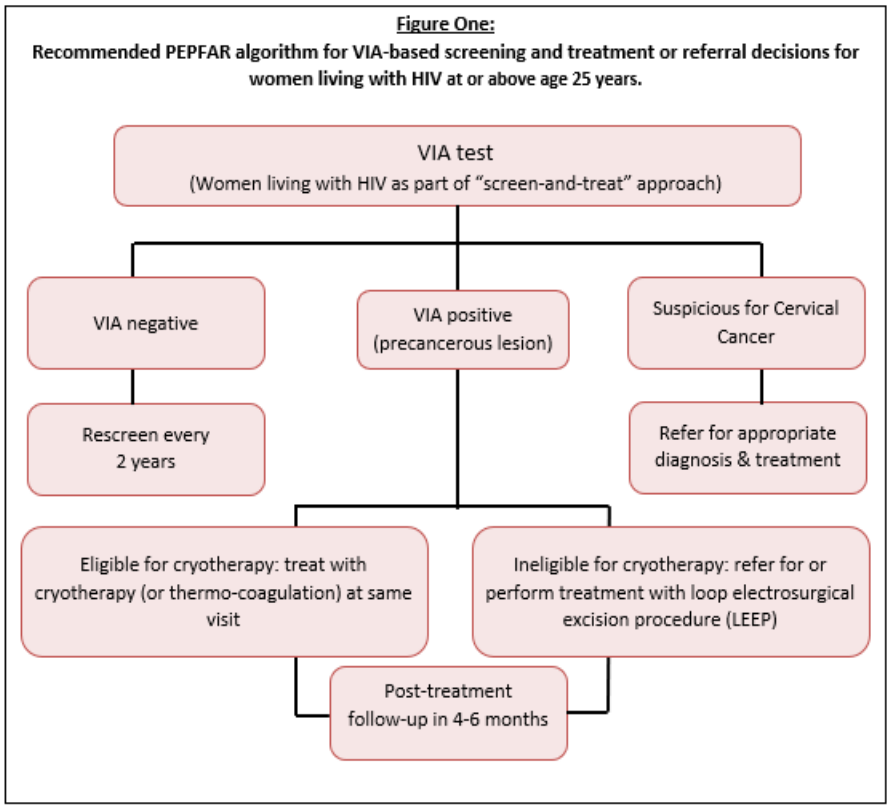
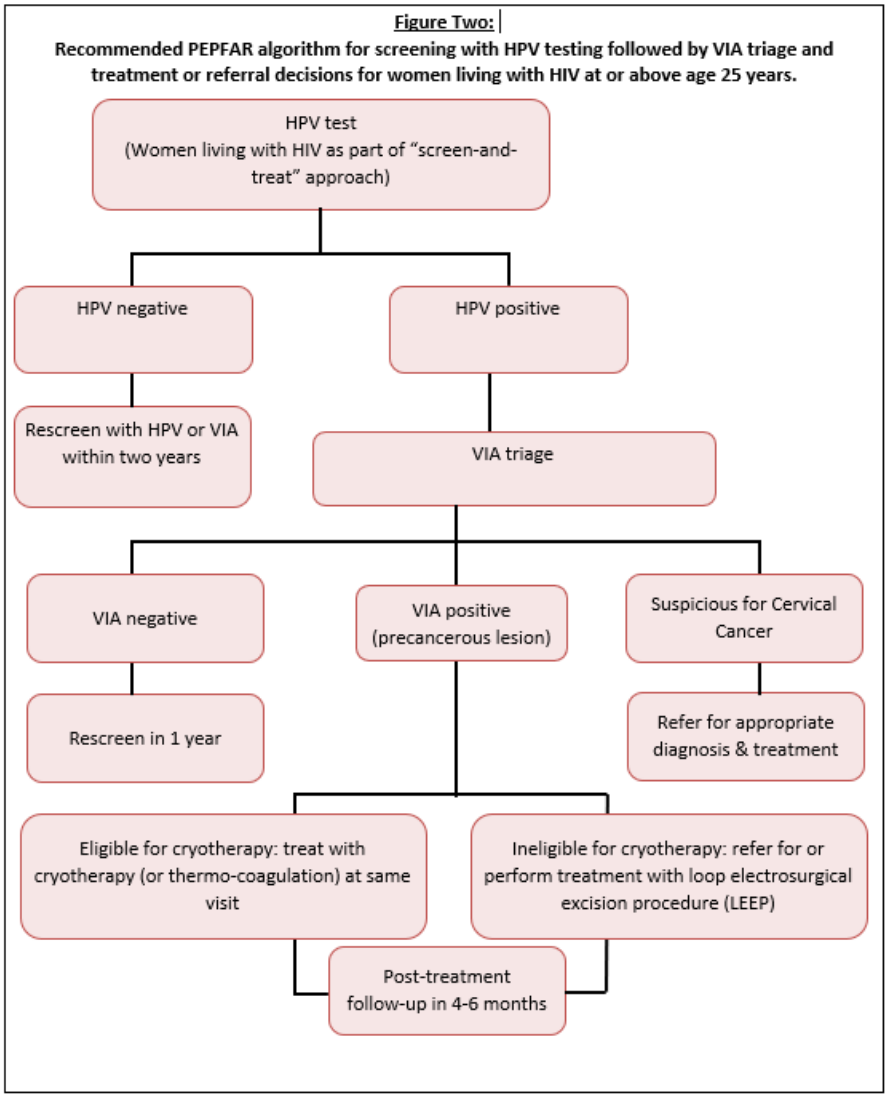


Figure 6.5.14: Screening with HPV testing followed by VIA triage algorithm



Demand Creation

Offering of services, provides an educational opportunity to address the lack of awareness and persistent stigma about cervical cancer screening procedures that persist in many communities. In addition, in some places inappropriate messaging is leading women to be screened multiple times in the same year.

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 and the

meaning of screening results, and 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, 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 FY20 Q4, over 1.5 million screenings have been done for cervical cancer, of which over 1.3 million were first-time screenings. Of those screened, 7% (111,320) had been 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, adequate equipment and sufficient HR support, dedicated HWs 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, either with cryotherapy, thermal ablation and LEEP should be a priority in COP21.

For more specific detail on the PEPFAR cervical cancer screening and treatment program, please see the clinical guidance developed June 2018, available on PEPFAR SharePoint.

6.5.5 Approach to Viral Load Testing (overview)

The goal of antiretroviral therapy is virological suppression, and this should be achievable by all PLHIV. A viral load should be assessed at six months after initiating ART and if virologically suppressed then yearly thereafter. Though many PEPFAR supported programs have made

significant progress in achieving between 85% and 95% viral suppression, some of these countries are below 80% viral load testing coverage (Figure 6.5.15). 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. 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 6.5.16 shows decrease in VLC from FY20Q1-Q3 as a result of this. PEPFAR teams should work with countries and other stakeholders to ensure viral load testing is scaled for 100% national coverage. 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. More use of DBS for sample collection outside of the facility to avoid many patients coming to the facility for sample collection should be encouraged.

Creating demand for VL remain a challenge in many national HIV programs. 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. National HIV treatment guidelines or algorithms should be shared with healthcare workers, explaining the importance of VL and management of high VL results. Importantly, results should be provided directly to the clients, this will enhance record keeping and client engagement in their care. Engagement of community-based organizations to increase patient demand by promoting awareness and education of VL testing and utilization of results for patient management is needed. Significant treatment literacy efforts may be an important part of making viral load effective as both a clinical and prevention intervention and teams should consider including high-quality treatment literacy training as part of their treatment and laboratory strategies. This should include sharing information on opportunities to participate in less intense model of care, particularly for patients who are virologically suppressed.

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$\geq$1000copies/ml should be considered a critical lab value and communicated to the clinical staff and the patient in an expedited fashion. Enhanced adherence VL 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. As one of the key client-centered approaches in this COP21, while patient results go to the charts, there should be a method either through SMS or other electronic systems[296] to ensure every client is also immediately alerted of his or her results being available. 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.

Undetectable Equals Untransmittable U = U

Recent studies have provided evidence of near zero risk of HIV sexual transmission from an HIV-positive to an HIV-negative primary partner during condomless anal and vaginal sex with the use of suppressive ART.[297,298] These studies built on the landmark HPTN 052 phase III randomized clinical trial, which showed the personal and public health benefits of early treatment.[299] It was the largest study to date that showed no linked HIV transmissions within serodifferent couples having unprotected sex when the HIV-positive partner had durable viral suppression less than 200 copies/ml.[300] This evidence- based information will be critical to achieving the UNAIDS targets of 90-90-90. Importantly, continued dissemination and incorporation of this data may reduce HIV stigma, encourage individuals to seek and adhere to ART, and achieve and maintain viral suppression. Critical caveats about the message are important: clinical trial participants had repeated virologic measures and were continuously undetectable over time. In addition, undetectable was defined in most cases as a VL<200c/ml. Considerations and implications for public health implementation (e.g., policy decisions, messaging for specific populations, laboratory testing, clinical and programmatic strategies) need to be further explored as U=U gains momentum in PEPFAR-supported countries. This inference is based on data from Vietnam and from the AFRICOS cohort. Information on the benefits of ART should be provided to PLHIV and U=U should be emphasized when counseling people for HIV testing. The need to ensure rapid viral suppression to prevent further

[296] https://www.senaite.com/
[297] Bavinton BR, Jin F, Prestage G, Zablotska I, Koelsch KK, Phanuphak N, et al. The Opposites Attract Study of viral load, HIV treatment and HIV transmission in serodiscordant homosexual male couples: design and methods. BMC Public Health. 2014;14(1):917.
[298] Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, Van Lunzen J, et al. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. JAMA. 2016;316(2):171–81.
[299] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med. 2016;375(9):830–9.
[300] Eshleman SH, Hudelson SE, Redd AD, Swanstrom R, Ou S-S, Zhang XC, et al. Treatment as prevention: characterization of partner infections in the HIV prevention trials network 052 trial. J Acquir Immune Defic Syndr. 2017;74(1):112–6.

transmission underscores the rationale for rapid linkage and initiation of ART with regimens such as TLD that rapidly suppress viral load. While U=U protects individuals from HIV transmission, it offers no protection from other STIs. Countries should adapt health promotion materials accordingly.

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.

Figure 6.5.15 FY20Q4: Only four OUs have achieved both ≥80% VL Coverage & ≥95% Viral Suppression

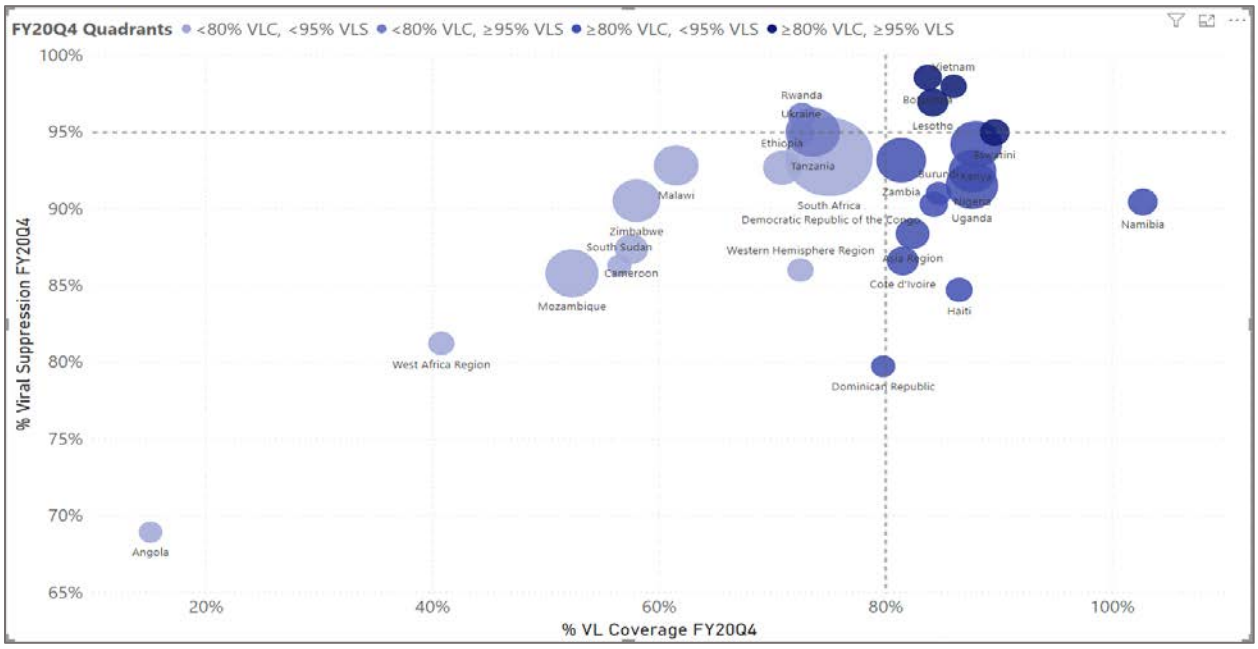
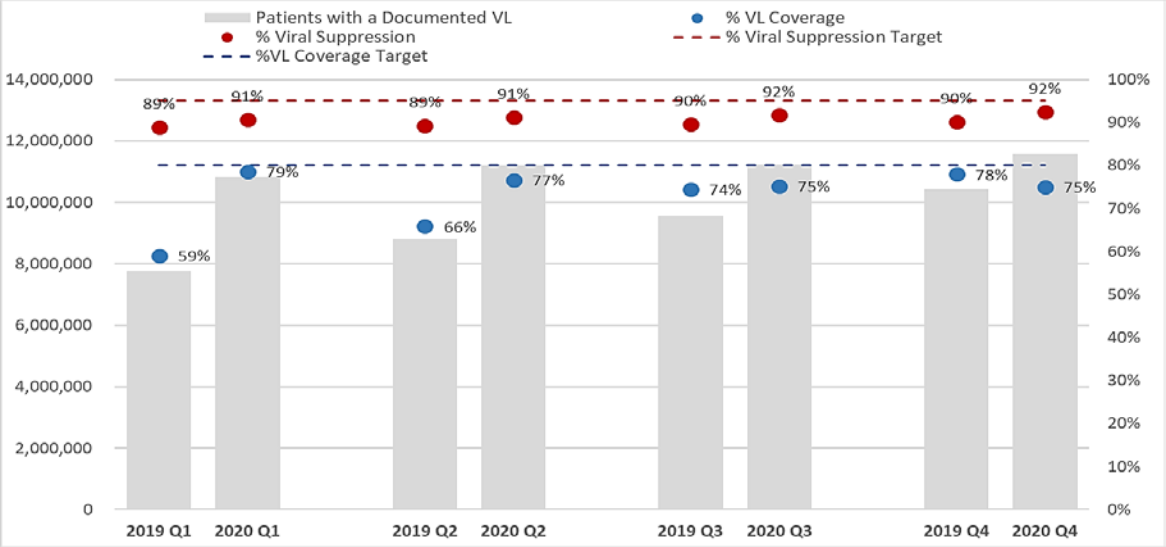


Figure 6.5.16: Decrease in VLC from FY20Q1-Q4 in all PEPFAR OUs during COVID-19 outbreak



Use of Dried Blood Spot (DBS)

Viral load, a complex molecular test is primarily performed at centralized laboratories located at the national or regional levels of the tiered laboratory network. This requires robust laboratory systems including an efficient sample referral network for transportation of specimens from various clinics or treatment sites. Transporting whole blood and/or plasma for processing within manufacturer's recommended time for reliable viral load testing is challenging and poses a barrier to successful viral load testing for remote or peripheral treatment sites. WHO has prequalified the suitability of DBS for viral load testing for some of the platforms. Dried blood spots (DBS) can be used as an alternative specimen type to plasma to increase access to routine viral load monitoring. 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. In light of 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 6.5.5.1. The use of DBS should be considered only in situations where POC testing capacities do not exist.

6.5.5.1 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 HIV-infected individuals on ART is widely recognized, VL testing coverage among pregnant and breastfeeding women (PBFW), infants, children and adolescents has been low in most PEPFAR-supported countries. Data from IAS 2019 that characterized VL burden among HIV-positive pregnant women around the time of delivery in South Africa using POC platforms showed that 20% of these women were virally non-suppressed.[301] Viral non-suppression is a medical urgency in 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 within PBFW, there is the ability to provide intensified adherence counseling and potential alternate ARV regimens for the mother and an intensified prophylaxis regimen for exposed infants whose mothers have elevated viral load at delivery. Hence, POC testing should be used to address 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. Past suggestion to address this has been to use fingerstick or heel stick methods to collection blood on to DBS and transport to the central laboratory for VL testing; an approach that is more time consuming, cumbersome and may further compound these challenges. The use of fingerstick or heel stick approach for sample collection and direct transfer to the POC instrument cartridge for immediate testing and release of results should address this. 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 serve as an aspect of family centered testing as well as improved optimization and effective use of these instruments. Considering this, it is recommended that in COP21, POC should be used for VL testing among PBFW and infants and children. Programs should, however, 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.

[301] Moyo F. Characterizing viral load burden among HIV-infected women at time of delivery: Findings from four tertiary obstetric units in Gauteng, South Africa. IAS 2019

6.5.5.2 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. Persistent virologic non-suppressed patients: A comparison of FY18, 19 and 20 showed tremendous improvement in viral load testing coverage among PEPFAR supported countries, however, this did not result in similar increases in viral suppression (Figure 6.5.17). Hence, few of these countries have attained the 95% viral suppression target. This may partly be due to less attention paid to the continued 15-20% of the virologic non-suppressed population. Developing targeted interventions to improve viral suppression among the virologic non-suppressed population will eventually decrease the non-suppressed gap and increase the overall population viral load suppression to meet the 95% target. These interventions are sometime challenging because of lack of evidence of precise gaps. An innovative snapshot to identify these gaps among programs is the construction of high viral load cascades, establishment and use of high VL registers, enhanced adherence counselling (EAC) flip charts.[302] Figure 6.5.18 is an example of high viral load cascade from one of the facilities in South Sudan. This cascade shows that poor retention within the EAC portion is significantly affecting follow up interventions among this population and should be the primary focus. Country programs should construct facility specific high viral load cascade to determine and address specific gaps.

2. Low VL testing coverage and suppression among infants, children and adolescents: Continued low VL testing coverage and suppression among infants, children and adolescents compared to adults has been another area of concern that warrants targeted innovations (Figure 6.5.19). Sub-optimal VL testing coverage has been associated with a combination of issues including weak demand creation, inconsistent verification/utilization of VL at clinic level and use of venipuncture/phlebotomy rather than DBS for pediatric sample collection. On the other hand, low VL suppression is related to limited optimal pediatric formulations, difficulty in

[302] https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium

dosing and administration challenges, lack of /or incomplete age-appropriate enhanced adherence counselling (EAC), delayed repeat VL testing after EAC as well as provider and caregiver-associated challenges. Some best practices to address these challenges include; mapping of infants, children, and adolescents non-suppressed and those with low VL results by areas of residence, home visits and community VL sample collection by team, and assigning them to community-based volunteers (CBVs) for quality EAC and repeat VL testing. Additionally, identification of caregivers and adolescents to join support groups on voluntary basis, monthly support group meetings covering specific topics e.g., adherence, health literacy and positive living have been very helpful (https://pepfar.sharepoint.com/sites/VL-EID). New in COP21 (Section 6.5.5.1) is the recommendation to use point of care (POC) testing platforms to support VL testing among infants and children to address the venipuncture blood collection challenges and increase testing coverage.

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. For example, in FY20, pregnant women had lower VL coverage documented in MER than any other sub population (Figure 6.5.20). 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. 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, and 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[303]. 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

[303] 2020 WHO-UNAIDS-PEPFAR-Global Fund Joint Data Quality module for assessing and strengthening viral load testing data. September 2020

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 6.5.5.1, 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 located in the best practice manual at the following link: https://pepfar.sharepoint.com/sites/VL-EID.

4. Delivery of test results to patients: As one of the key client-centered approaches in COP20, there was a recommendation that while patient results go to the charts, 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 provide 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, results alert systems to include use of SMS are feasible and possible. For example, Zimbabwe has developed an SMS system that could send notification to patients that their results are ready. If the VL is suppressed, they will be advised to go to the clinic on 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. This will be incorporated for HIV VL and EID results reporting.[304] Similarly, through PEPFAR support in Eswatini, an implementing partner has collaborated with a cell phone company to pilot and roll out an approach for communicating high VL results to patients. Through this VL notification system, the patient receives an SMS alert as soon as a result is authorized in the Laboratory Information System (LIS) while the actual results are transmitted to the clinician. The SMS will advise the patient to visit their health facility to get the results. Country programs should be more innovative and consider incorporating patient result alert systems that fit into their local context. Additionally, the Joint Data Quality Module for Assessing and Strengthening Viral Load Testing Data provides information on how to enhance quality and use of data, including accuracy, timeliness, completeness and return to the facility and patient records.

[304] https://www.senaite.com/

Figure 6.5.17: Significant improvement in VL testing coverage compared to viral suppression

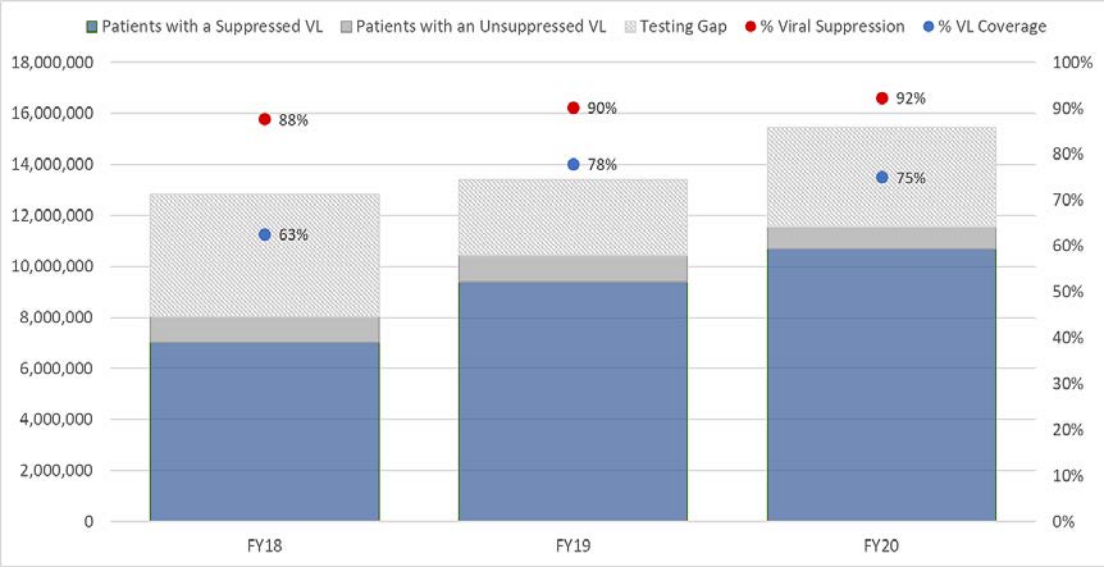


Figure 6.5.18: High Viral Load Cascade from South Sudan

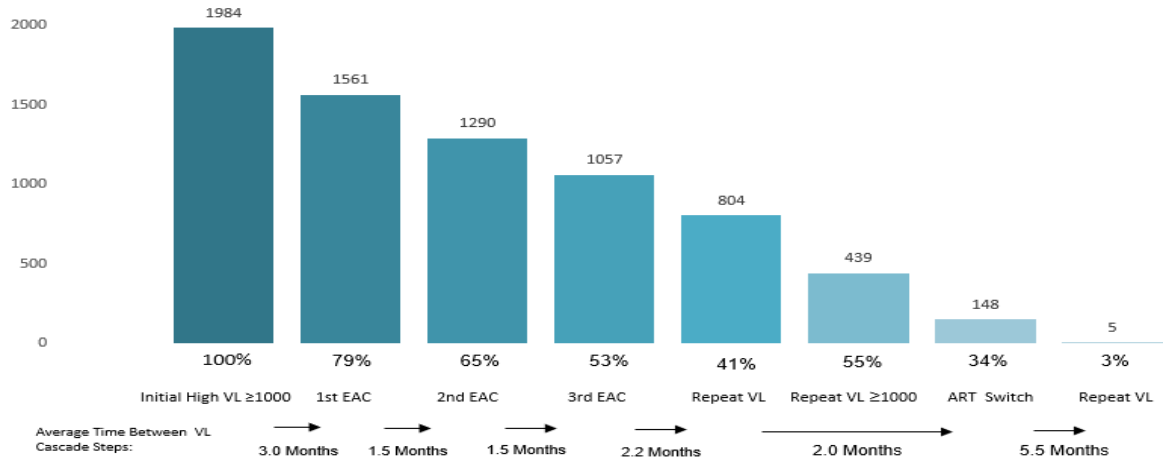


Figure 6.5.19: FY20Q4: Low VL testing coverage and suppression among infants, children and adolescents

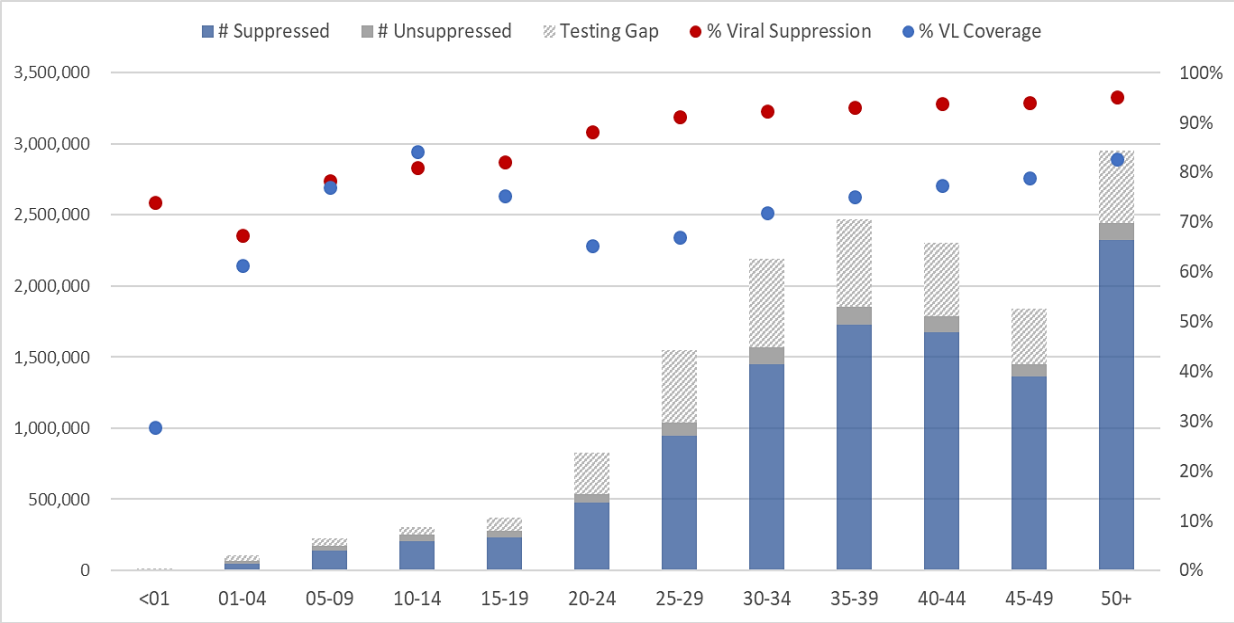
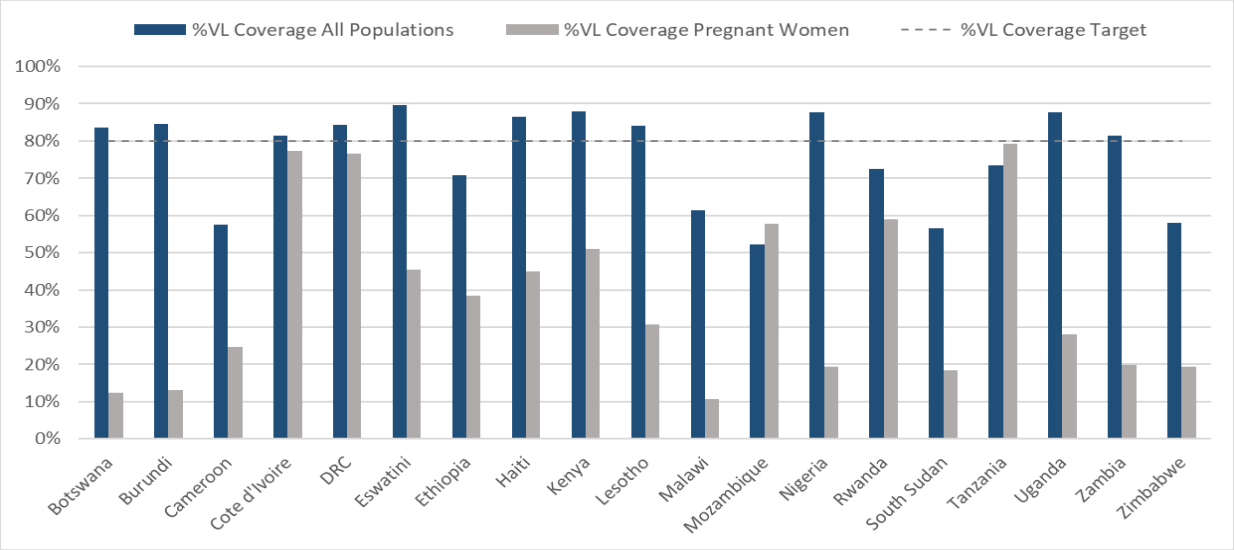


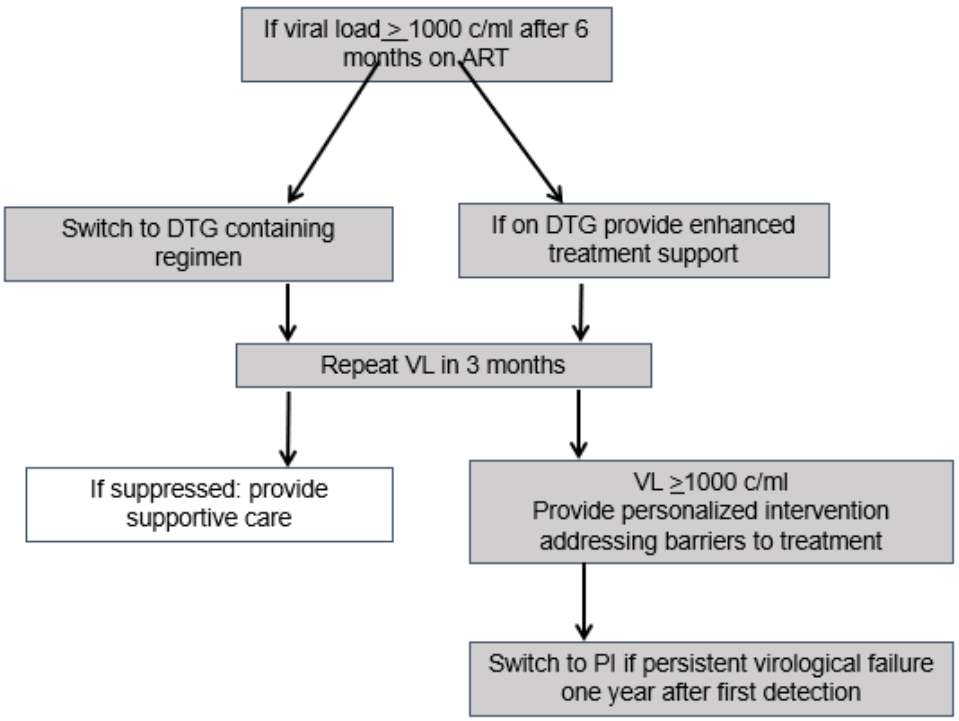
Figure 6.5.20: FY20Q4: Pregnant Women VLC vs. All Population



6.5.6 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. A VL≥1000cps/ml is the threshold for considering switching therapies. When non-suppression is detected, all efforts should be made to ascertain barriers to treatment; and provide support for the struggling patient including individual case management as available, enhanced adherence counselling, and repeat viral load testing. Structural barriers to treatment such as frequency of visits and location of clinic may be addressed with DSD models and MMD. Enhanced adherence interventions may be delivered over the phone and by adherence clubs. The use of high VL registers may be helpful and designated clinical staff need to regularly review these registers and track clients with high VL, looking for interruptions in care and delays in repeat VL testing (Figure 6.5.21). In all cases viral load should be repeated after an intervention; point of care tests, discussed below, may facilitate repeat testing.

Figure 6.5.21: Approach to virological non-suppression



6.5.6.1 Virologic Failure among Adults and Adolescents

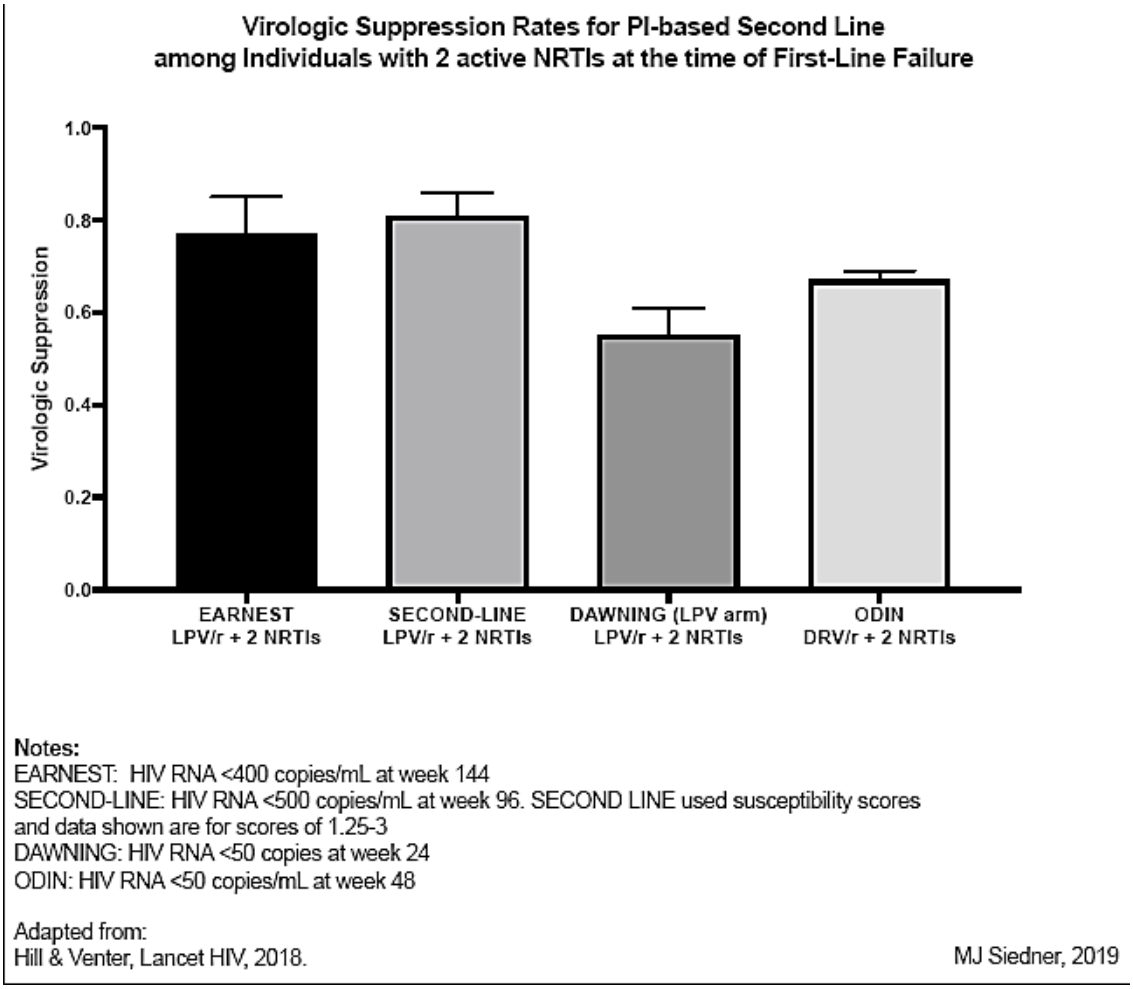
DTG in combination with tenofovir and lamivudine is the preferred **second-line** regimen for PLHIV (who weigh at least 30 kg) for whom **non**-DTG-based regimens are failing. Evidence from Haiti supports continuing tenofovir and lamivudine in second line therapy even in settings where there are concerns about drug resistance.[305] Individuals on a PI-based second-line regimen who are suppressed may be confidently switched to TLD, a regimen that is better tolerated, has fewer drug-drug interactions, and is less expensive.[306] PEPFAR does not support resistance testing for clinical care, and individuals on a PI-based therapy who are experiencing virological failure present a dilemma. Data from the AIDS Clinical Trial Group suggest that a large proportion of individuals with first-line ARV failure will have a genotype suggesting that the PI-based therapy will retain activity.[307,308] For this reason, PEPFAR supports a TLD switch for this group as well.

The goal is to preserve TLD therapy as long as possible, and individuals with a viral load ≥ 1000/copies/ml need to be evaluated promptly and provided with enhanced adherence counseling. Please see Section 6.5.6 for the approach to treatment failure. In addition to incomplete adherence, virological failure may be due to issues of tolerability or, rarely, resistance. There are no clear data to direct second-line therapy for individuals failing TLD. These individuals should not remain on a failing regimen, and many patients in this circumstance may suppress on a PI-based regimen. Individuals should not remain on a failing DTG-based regimen for more than one year. after non-suppression was first detected. See Figure 6.5.22.

In all cases, individuals switching therapy need a viral load 3 months after switch to confirm response to the new regimen.

[305] Pierre 2020 https://cattendee.abstractsonline.com/meeting/9289/presentation/793
[306] Sangaré MNd, Baril J-G, de Pokomandy A, et al. Treatment switch to dolutegravir with 2 nucleoside reverse transcriptase inhibitors (NRTI) in comparison to continuation with protease inhibitor/ritonavir among patient with HIV at risk for prior NRTI resistance: a cohort analysis of real-world data. Open Forum Infectious Diseases 2020 doi: 10.1093/ofid/ofaa404[published Online First: Epub Date]|.
[307] Wallis CL, Hughes MD, Ritz J, Viana R, Silva de Jesus C, Saravanan S et al. Diverse HIV-1 Drug Resistance Profiles at Screening for ACTG A5288: A Study of People Experiencing Virologic Failure on Second-line ART in Resource Limited Settings. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2019. doi:10.1093/cid/ciz1116.
308 Grinsztejn B, Hughes MD, Ritz J, et al. Third-line antiretroviral therapy in low-income and middle-income countries (ACTG A5288): a prospective strategy study. The lancet. HIV 2019;6(9):e588-e600 doi: 10.1016/s2352-3018(19)30146-8[published Online First: Epub Date]|.

Figure 6.5.22: Virologic Suppression Rates (Courtesy MJ Seidner)



6.5.6.2 Virological Non-Suppression among Children

Children have lower rates of viral suppression (see Figure 6.5.19) and any child with known virologic failure requires urgent attention. Programs must immediately ensure all infants and children have access to optimal treatment (NVP-based ART was to be phased out in 2019 and EFV-based ART was to be phased out in FY20). **DTG is the preferred anchor ARV for infants and children ≥ 4 weeks of age and weighing ≥ 3 kg,** as shown in the July 2020 WHO policy brief[309] that outlines preferred and alternative first line and second line ART regimens (see Figures 6.5.1 and 6.5.2 in Section 6.5.1.2).

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

[309] https://www.who.int/publications/i/item/9789240007888

specimen collection materials. Proxy VL coverage is particularly low in children < 5 years of age (Figure 6.5.20), urgently needs to be addressed, and family/household-centered interventions should be implemented. 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, repeat viral load testing, and timely switching of ART regimens in accordance with national HIV treatment guidelines. High VL registers should include the age of individuals to tailor client-centered support and management services for infants and children. 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 and support 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 need to adhere to the treatment regimen (including appropriate timing and ART dose), the importance of routine VL testing, and providing anticipatory guidance on the formulation/dose required as infants and children grow.

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[310] and *Zvandiri*[311] in PEPFAR Solutions[312]). See Section 6.1.3.1 on adherence support for children and families.

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 with high VL should be prioritized.

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[310] 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
[311] https://www.pepfarsolutions.org/adolescents/2018/1/13/zvandiri-peer-counseling-to-improve-adolescent-hiv-care-and-support
[312] https://www.pepfarsolutions.org/solutions

6.5.6.3 Interventions to Improve Virologic Suppression: Viremia Clinics and Wrap-Around Community Services

The literature describes several common features associated with viral non-suppression. Younger age, distance from clinic, poverty and non-disclosure are all associated with poorer virological outcomes. For a given patient, the specific factors associated with non-adherence should be determined. Demand creation for viral loads is an important activity and ensuring timely return of results to both the providers and the clients may drive increased uptake. Programs should consider the use of POC platforms to increase viral load testing coverage, particularly among PBFW, infants and children as mentioned in Section 6.5.5.1.

All PLHIV should know their most recent viral load result and understand the algorithm in Section 6.5.6. Strategies include enhanced adherence counseling, digital reminders, peer support and mental health services.[313] In the setting of COVID-19 mitigation efforts, virtual platforms may be used for enhanced adherence counselling. The use of social media may also add value in certain populations as described in the "My future my life" solution in Vietnam. Of particular interest are differentiated service delivery models (see Section 6.1.3) specifically designed for a particular population. Viremia clinics, a DSD model described in Section 6.1.3 are of particular interest and can support family adherence. These platforms can offer specific targeted support to individuals with virological failure and include wraparound community services and may facilitate rapid re-suppression while addressing specific barriers to continuity of care.

6.5.6.4 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.[314] 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

[313] Kanters S, Park JJH, Chan K, Socias ME, Ford N, Forrest JI et al. Interventions to improve adherence to antiretroviral therapy: a systematic review and network meta-analysis. The Lancet HIV. 2017;4(1):e31-e40.
[314] Making viral load routine: successes and challenges in the implementation of routine HIV viral load monitoring. Geneva: Médecins Sans Frontières; 2016.

counselling and received the recommended follow-up viral load test.[315] Some individuals may be experiencing a prolonged period of viremia with its attendant health challenges.

Point of care (POC) viral load tests or improved transport and communication of results is critical to ensuring access to VL re-testing in non- suppressed individuals or in settings where prompt identification of viremia is critical, such as in pregnant and breastfeeding women. The first randomized, controlled implementation trial of POC HIV viral load testing in South Africa demonstrated an increase in viral suppression and retention in care after a year in those who received the test.[316] 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 virological failure is detected.

6.5.7 Monitoring for HIV Drug Resistance

Data support transition to TLD regardless of viral load (VL) suppression or baseline rate of dual NRTI resistance.[317] Data from the AFRICOS cohort confirm that the rates of suppression on DTG are very high, and resistance is uncommon. DTG has a very high barrier to HIV drug resistance (HIVDR) and virologic failure with HIV drug resistance mutations among ART naïve patients is vanishingly rare. In addition, failure with HIVDR among patients not virologically suppressed on a DTG-based regimen has been reported in the literature but at very low rates and usually in the setting of inadequate dosing of DTG with TB treatment or after exposure to raltegravir.[318]

Given that TLD is used for first- and second-line regimens in PEPFAR-supported countries for individuals >30kg, PEPFAR HIVDR resistance monitoring focuses on patients failing TLD. This HIVDR strategy aims to ensure the durability of TLD, inform ART regimen switch algorithms,

[315] WHO 2019: HIV Molecular Diagnostics Toolkit to Improve Access to Viral Load Testing and Infant Diagnosis.https://www.who.int/hiv/pub/vct/hiv-molecular-diagnostic/en/

[316] Paul KD, Jienchi D, Lauren V, Justice Q, Katherine T, Natasha S, Hope N, Koleka M, Pravi M, Deborah JD, Ruanne VB, Kogieleum N, Salim AK, Connie LC, Nigel G. Point of care viral load testing improves HIV viral suppression and retention in care. http://www.croiconference.org/sessions/point-care-viral-load-testing-improves-hiv-viral-suppression-and-retention-care

[317] J da Silva SP, G Siberry, C Godfrey, A Phillips, E Raizes. 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 Africa2019

[318] 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.

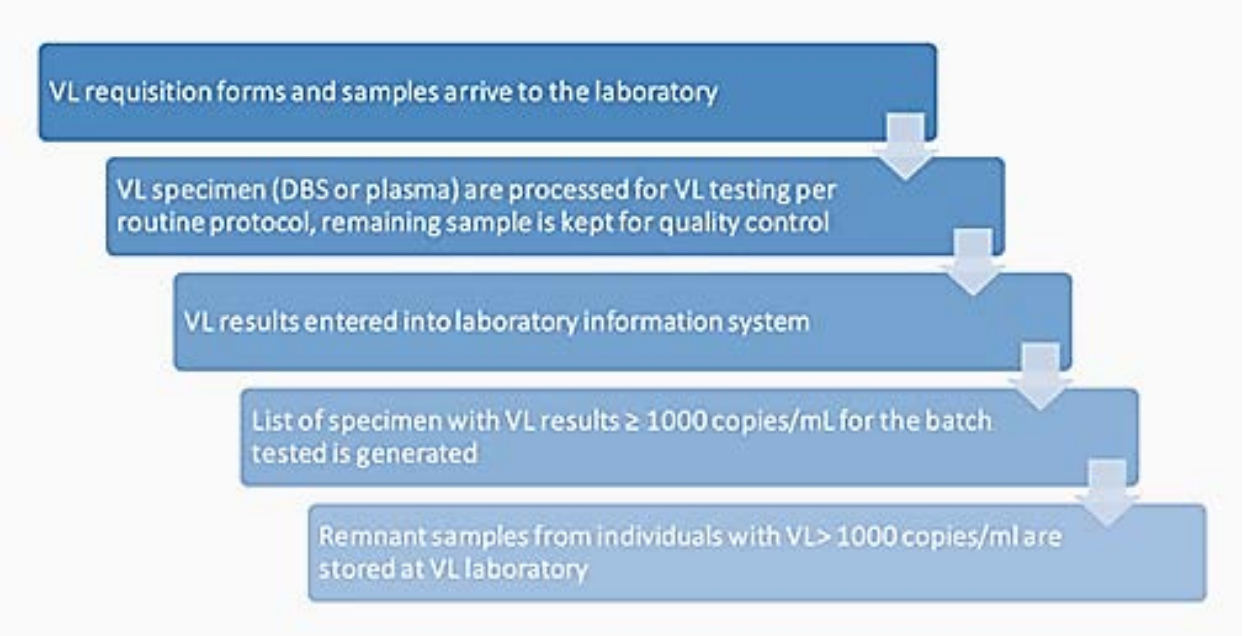
and provide guidance for the clinical management of the anticipated small proportion of patients who may not achieve virologic suppression on TLD

HIVDR 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 (Figure 6.5.23). Specifically, the methodology should
    a. Focus on sampling individuals with virological failure after at least 9 months on TLD or other dolutegravir-based regimen
    b. Randomly select laboratories from a framework of all laboratories conducting viral load in country
    c. Collect a set of minimal epidemiologic data that allow programs to understand who is being affected by emerging drug resistance (age, gender, ARV regimen, time on ARVs)
3) Limit monitoring to persons with VL non-suppression 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) Incur minimal additional data collection or other burden to programs

Pre-treatment and transmitted drug resistance (PDR and TDR) surveys are not supported except if utilizing residual specimens from other activities such as the Tracking with Recency Assays to Control the Epidemic (TRACE) initiative or the Population-based HIV Impact Assessments (PHIAs). Data from these surveys can inform decisions on optimal regimen in special situations such as for persons with breakthrough HIV infection after use of PrEP or in the setting of an HIV outbreak. 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 6.5.23: Cyclical Acquired Drug Resistance Patient Monitoring Approach



6.5.8 Integrated Women's Health

The 2019 ECHO trial data demonstrated persistently high rates of HIV acquisition among AGYW in South Africa, Kenya, Eswatini, and Zambia, although the rates did not vary significantly by contraceptive assignment, namely the intramuscular injectable depot medroxyprogesterone acetate (DMPA-IM), levonorgestrel (LNG) implant, and copper intrauterine device (IUD). High rates of other STIs were also noted, especially among women <25, which may independently increase risk of HIV acquisition.

Based on ECHO trial results, the WHO released New Recommendations for Contraception for Women at High Risk of HIV.[319] The key messages include:

- 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 progestogen-only contraceptive methods without restriction (MEC Category 1), including progestogen-only pills (POPs), DMPA-IM, subcutaneous depot medroxyprogesterone acetate (DMPA-SC), norethisterone enanthate (NET-EN), LNG implants, and etonogestrel (ETG) implants.

[319] https://apps.who.int/iris/bitstream/handle/10665/326653/9789241550574-eng.pdf;jsessionid=F75B2DA4E583E94BE029D931C7FCE755?ua=1

- Women at a high risk of HIV infection are eligible to use copper-IUDs and LNG-IUDs without restriction (MEC Category 1). In considering the use of IUDs, many women at a high risk of HIV are also at risk of other STIs; for these women, providers should refer to the MEC recommendations for women at an increased risk of STIs, and the *Selected Practice Recommendations for Contraceptive Use* (3rd edition) on STI screening before IUD insertion.
- Women at a high risk of HIV infection are eligible to use all combined hormonal contraceptive methods without restriction (MEC Category 1), including combined oral contraceptives (COCs), combined injectable contraceptives (CICs), combined contraceptive patches and combined vaginal rings.
- Efforts to expand contraceptive method options and ensure full and equitable access to voluntary family planning services must continue.
- A renewed emphasis on HIV/STI testing and treatment, given the lack of sensitivity and specificity of syndromic management in women, and prevention services is urgently needed, including the integration of family planning and HIV/STI services as appropriate, along with sexual and reproductive health packages.

PEPFAR HIV programs should look for innovative approaches to expanding HIV prevention options for women at high risk of HIV, including integration of HTS within FP settings and scale up women's access to FP and HIV prevention services, including PrEP, with a focus on reaching AGYW, in high HIV prevalence settings. Programs should also review Section 6.6.3 (Gender-Based Violence and Post-Violence Care) of COP21 guidance 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.

Depending on the country context, PEPFAR programs need supportive tools and guidance to operationalize standardized national, facility and patient-level messages that will help PEPFAR country teams provide informed and evidence-based HIV, safer conception, and voluntary FP messages and services to all women living with HIV (WLHIV) of reproductive potential. Although PEPFAR funds cannot be used to procure contraceptive commodities,[320] they are often integrated into PEPFAR service delivery platforms through other donors. As such, client-

[320] PEPFAR funds may purchase condoms for HIV prevention purposes.

centered programming must consider both sets of needs. Programs should ensure all WLHIV have 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 push the client to use contraception even when she does not want to. 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. All WLHIV who do not currently want to be pregnant should be counseled on their FP options, including the full range and voluntary use of contraception.

The WHO 2019 HIV guidelines recommend TLD as the preferred first-line regimen for all people living with HIV, including women of childbearing potential. This recommendation is not linked to the use of contraception, but the WHO guidelines emphasize the principles of providing women with choice and access to effective family planning for those who desire it and ensuring clear information about potential benefits and potential risks of any medication, including ART is provided. Women should be counseled on the benefits of TLD, including more rapid viral suppression and improved tolerability, and risks/side effects of all available ART and contraceptive options, including the small potential risk (less than 1% of all women; 3/1,000 compared to background risk of 1/1,000[321]) of neural tube defects (NTD) associated with TLD/DTG use, to ensure they are able to make an informed decision. Women should also be supported to choose the ART regimen that works best for them and contraceptive services should be tailored to meet individual client needs.

If women participate in a differentiated service delivery (DSD) model of receiving their ARVs that results in less frequent visits to a health care setting than had been common, they should also discuss a potentially modified schedule for receiving their family planning method. For women who have chosen a long-acting reversible contraceptive, 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

[321] Zash, R. , Holmes, L. , Diseko, M. , Jacobson, D. L. , Brummel, S. , Mayondi, G. , Isaacson, A. , Davey, S. , Mabuta, J. , Mmalane, M. , Gaolathe, T. , Essex, M. , Lockman, S. , Makhema, J. & Shapiro, R. L. (2019). Neural-Tube Defects and Antiretroviral Treatment Regimens in Botswana. The New England Journal of Medicine, 381(9), 827–840. doi: 10.1056/NEJMoa1905230

client-centered goal would ideally be to align their method refills to their ART visits or leverage multi-month dispensing regimens, where available and feasible in each OU.

All women living with HIV who wish to delay, space, or limit pregnancies should have access to a range of contraceptive methods that suit their specific needs and health situations. These include short-acting methods, condoms, oral contraceptive pills, injectables, long-acting reversible contraceptives (implants and IUDs) and permanent methods (tubal ligation/occlusion). These methods should be available and provided based on voluntarism and client preference.

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. Ideally, 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, or have a dedicated FP provider routinely offer services on-site
- 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 where possible.

6.6 Cross-Cutting

This section is important to our guidance because it includes cross cutting innovations designed to address issues pertinent to all PEPFAR programs. Laboratory systems, human resources for health and data systems impact all PEPFAR programs. Key populations, individuals with mental health issues and OVC require both prevention and treatment services. We work in partnership with civil society and faith communities, these relationships are critical to our success. This section includes information on all these groups.

6.6.1 Laboratory

Laboratory interventions, at the site and above-site levels, 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. In COP21, PEPFAR laboratory support will be limited only to viral load, HIV diagnosis for adults, infants and children, HIV recency testing, limited 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.

New for the FAST Commodities Tab in COP21

To accommodate laboratory commodity procurements, services, and budgets for COP21, the FAST commodities tab has been modified. 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. Countries are expected to transition all chemistry and hematology commodity needs to host governments, or additional donors in COP21; except creatinine to support PrEP only. These products can no longer be budgeted for in the COP21 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 COP21 budget and FAST reviews.

6.6.1.1 Diagnostic Network Optimization (DNO)

Past lack of coordination among laboratory stakeholders has resulted in the procurement of more (point of care and centralized) instruments than needed to meet current and projected HIV-related access and demand needs, stock-outs of reagents to run instruments, poor instrument service and maintenance, suboptimal testing coverage, suboptimal instrument utilization, and fragmented data and quality systems. WHO has prequalified the use of two platforms (Cepheid GeneXpert® and Abbott mPIMA) for early infant diagnosis and viral load testing. As part of a strategically tiered national diagnostic network, POC instruments can be used to facilitate more rapid, actionable virologic testing, especially for infants and pregnant/breast-feeding women and those with non-suppressed viral load. The integration of POC into the centralized HIV diagnostic network has to be done according to an evidence-informed and patient-centered strategy.

In COP20, there were recommendations for countries to conduct diagnostic network optimization. Though some countries have engaged this process, progress has been generally slow in many PEPFAR OUs. As PEPFAR country teams consider the use of both laboratory-based and POC instruments as part of optimal networks for EID and VL, there is need to conduct diagnostic network optimization exercises (if not yet done) to ensure appropriate procurement and placement of these instruments; ensuring complementarity of these platforms. Countries with investments in DNO are better prepared to respond to pandemics as exemplified during the 2019 COVID-19 outbreak. During COVID-19 outbreak, DNO investment capacities such as multiplex instruments, supply chain, waste management, sample transportation, and data systems in Cameroon, Nigeria and Zimbabwe, some of the countries that have completed this exercise, were leveraged to quickly scale up testing.[322] Hence, country programs should accelerate completion of the DNO activities. A diagnostic network optimization could be achieved using a step-wise approach, beginning with assessing the current network structure, laboratory capacity, and testing coverage and efficiency by laboratory catchment area to identify gaps. Countries should immediately begin to address gaps identified in this first step and repeat the assessment routinely to facilitate continuous quality improvement of the network. If this review

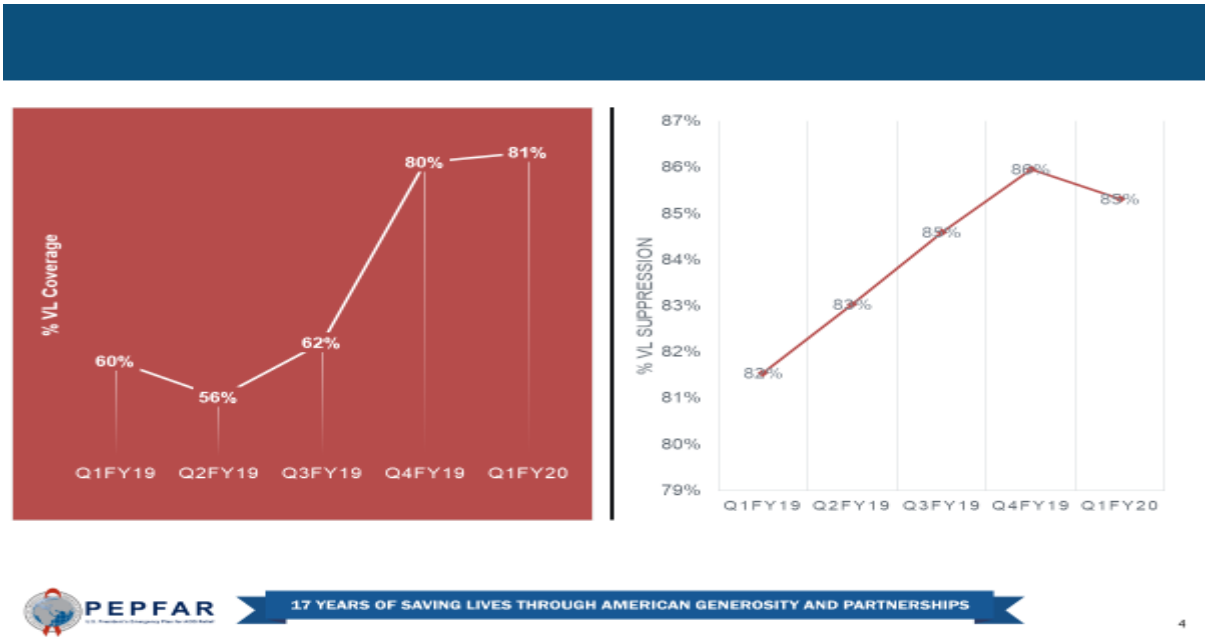
[322] https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium

identifies numerous and widespread gaps that indicate the need to modify or significantly change the network structure, then an expanded optimization exercise should be performed. The diagnostic network optimization should review and address the following indicators to ensure appropriate access, coverage, and testing efficiency: 1) number and location of laboratories, 2) instrument type (conventional/POC), 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. For example, a recently completed first phase of diagnostic network optimization in Nigeria led to reduction of centralized VL laboratories, introduction of Mega laboratories, and significant increase in VL testing coverage from 60% to 81% and VL suppression from 82-85% between Q1FY19 and Q1FY20 (Figure 6.6.1).

Operationalization of this new structure will also include complementary incorporation of POC platforms, strengthening sample transport, data dashboard, and supply chain systems; with a resultant reduction in turnaround time and overall improvement in VL/EID testing coverage. However, in country verifications should be conducted to ensure that appropriate training has been offered and that instruments are performing in country as expected. Continued data collection and analysis using available tools to include the viral load scorecard, quarterly monitoring tool or viral load implementation monitoring tool and clinical facility readiness tool[323], to identify and fill any programmatic gaps real-time is encouraged. Lastly, country programs should ensure appropriate and efficient patient access to HIV, TB, HPV and other diseases testing services across the clinic-lab interface (e.g., patient presentation to sample collection and testing and laboratory testing to result return and clinical action) to maximize the effect of the optimized laboratory network on patient identification, diagnosis, and treatment.

[323] PEPFAR latest results. https://www.pepfar.gov/funding/results/index.htm

Figure 6.6.1: Nigeria PEPFAR supported network optimization leads to reduction in number of HIV molecular laboratories, introduction of Mega labs, and increase in VL testing coverage and suppression

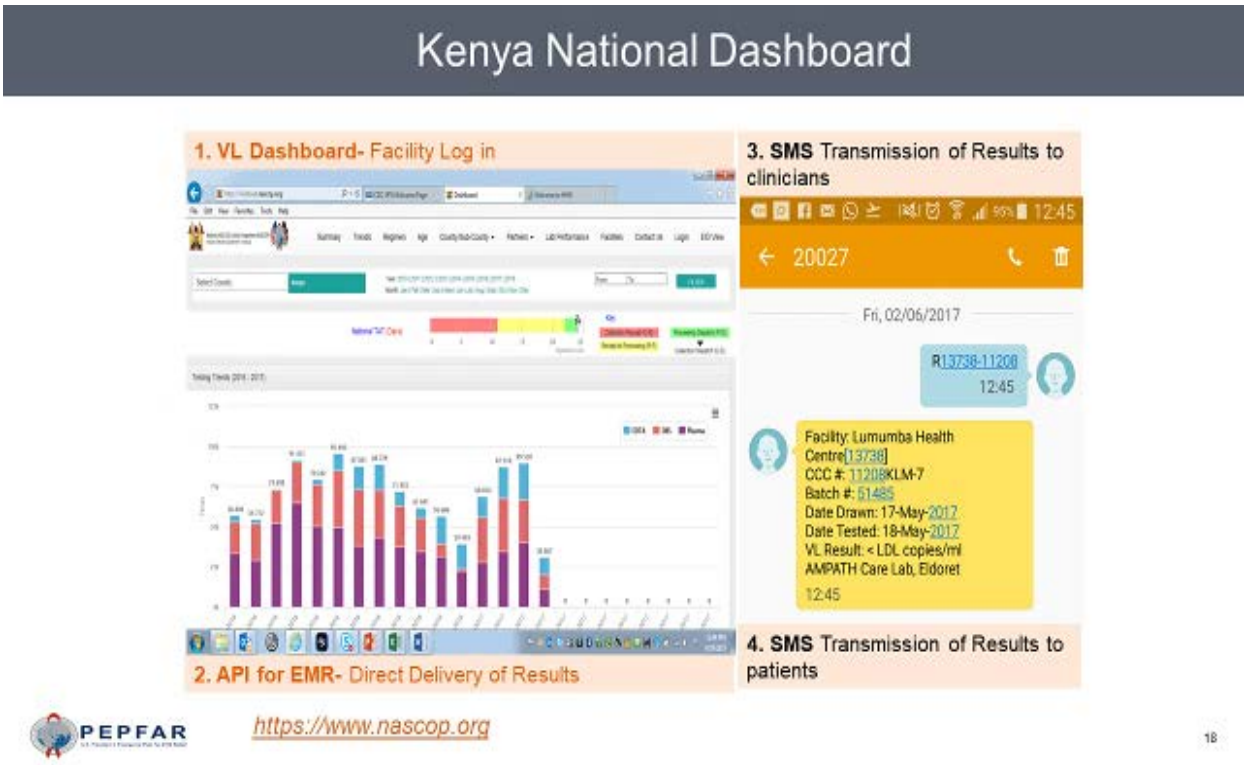


Laboratory Data Systems and Dashboards

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 (Figure 6.6.2). These dashboards also

have the possibilities to track supply chain data, ensuring proper forecasting, planning and avoiding stock-outs. 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/HIV 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.

Figure 6.6.2: Kenya national dashboard provides opportunity for real-time data analysis and visualization



6.6.1.2 Laboratory Global Purchasing and Service Level Agreements to Streamline Supply Chain

In FY2020, PEPFAR through its USAID Global Health Supply Chain Program–Procurement and Supply Management (GHSC-PSM) project – implemented global purchasing and service level agreements (SLAs) by leveraging PEPFARs purchasing influence with diagnostic manufacturers for VL and EID reagents, consumables and services. These SLAs are designed to shift laboratory programs to an all-inclusive reagent rental model. These agreements have been negotiated to achieve specific strategic PEPFAR goals: improved system performance

through greater data visibility and standardized SLAs across countries, reduced cost and transparent pricing, and enhanced supply chain security. It is expected that through these awards the total savings across all PEPFAR-supported countries will reach $20 million or more annually. Each supplier's SLA establishes rigorous key performance indicators to improve maintenance response times, machine uptime, reduced error rates, on-time delivery of reagents, increased frequency of end-user training, and establishing instrument connectivity and reporting solutions. The data and connectivity provisions of the global SLAs are expected to provide operational and strategic benefits, enhanced forecasting and reagent re-supply through the provision of near real-time information. Direct reporting from instruments will also improve operational data availability for diagnostic network optimization efforts and network management strategies. This initiative was fully supported by country ministries of health, GF and other stakeholders during COP20 review and approval processes. To address issues around instrument breakdown/sample backlog due to poor service and maintenance contracts, stock-outs, discrepant/volume commitment pricing, and high unit-cost-per-test for reagents, all countries should stop outright instrument procurement and pursue the PEPFAR supported Global Purchasing and Service Level Agreements that incorporate the all-inclusive pricing approaches. This should be applied to both centralized and POC instruments, including procurement and use of cartridges. This should be done in collaboration with country Ministry of Health stakeholders to ensure a single country efficient pulled procurement approach. Also, countries should conduct complete diagnostic network optimization exercises to ensure full benefits of this innovative initiative.

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, UNITAID, Ministry of Heath) have been involved in strengthening laboratory systems to support efficient and sustained program implementation. With the 90/90/90 targets, PEPFAR support for laboratory continuous quality improvement (LCQI), defined as the process of routine implementation of lab quality systems 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[324] 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.
- Train and certify laboratory technologists competencies for performing different tests
- Support for laboratories to enroll into external quality assessment programs to monitor quality of various tests (EID, viral load, TB, CD4, CrAg, creatinine etc.), routinely evaluate program performance, and implement corrective actions, if needed.
- It is recommended that countries should use only instruments/assays prequalified by WHO or approved by PEPFAR and they should avoid repeated in-country evaluations

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. Similar country mapping should be developed for RT/POC testing sites to ensure sustainability of PEPFAR investments, to support transition to ownership and country-led dedicated resources.

6.6.1.4 Multiplex use of Diagnostic Testing Platforms for HIV and TB

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.[325] Multiplexing and diagnostic integration has the following potential advantages: provide diagnosis in a one-stop-shop, help respond to global co-infection crisis, improve test efficiency and TAT,

[324] https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf?sequence=1
[325] UNITAID 2918: Multi-Disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB and Other Coinfections. https://unitaid.org/assets/multi-disease-diagnostics-landscape-for-integrated-management-of-HIV-HCV-TB-and-other-coinfections-january-2018.pdf

lower testing cost, provide an opportunity to diagnose and monitor treatment for patients with advanced HIV disease, as well as fits in WHO recommendation for use of multi-disease testing devices in integrated laboratory networks.[326] 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 time, safe and secure specimen referral and transport, and rapid expansion of COVID testing in these countries.[327] Furthermore, a multiplexing HIV and TB testing evaluation in Zimbabwe that used the GeneXpert near POC instrument to simultaneously test for TB, VL and EID, 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.[328] It should be noted that in situations where instrument testing capacity is less than the capacity needed (for example POC instrument with less testing capacity), there should be testing prioritization to ensure that key programs are not overwhelmed or neglected. The drive towards multi-diseases 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.[329] In PEPFAR-supported countries, there may be opportunities to multiplex diagnostic platforms for both HIV and TB. For example, many countries have networks of GeneXpert instruments that are used by national TB programs for initial detection of TB and rifampicin-resistant TB. These same networks may also be used by the national AIDS program for detection of TB among PLHIV. In addition, recent evidence from a WHO technical expert consultation showed that there could be utility in multiplexing existing Roche and Abbott instruments used for VL testing for detection of TB and drug-resistant TB. 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 HIV and TB testing networks (e.g., instrument multiplexing, combined specimen transport)

[326] Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks. https://apps.who.int/iris/handle/10665/255693
[327] https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium
[328] Ndlovu Z, Fajardo E, Mbofana E, MaparoT, Garone D, Metcalf C, et al. (2018) Multidisease testing for HIV and TB using the GeneXpert platform: A feasibility study in rural Zimbabwe. PLoS ONE 13(3): e0193577. https://doi.org/10.1371/journal.pone.0193577
[329] http://africacdc.org/press-centre/news/103-africa-hiv-viral-load-movement-launched-in-addis-ababa

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, CHAI, etc.) within the Integrated Diagnostic Consortium (IDC) is necessary to ensure a coordinated and efficient approach.

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.[330] 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. Proper disposal of waste containing this chemical requires high temperature incineration, up to about 1000 ^{o} 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. At this point, some countries are collaborating with cement factories or other in country institutions with incinerators with such capacity to manage this waste product. The most recent recommendation is for diagnostic platform manufacturers utilizing GTC to be responsible for the management of this waste and could include 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 point and support to transportation of waste. PEPFAR OU teams should work closely with Ministry of Heath, diagnostic manufacturers and other stakeholders to ensure safe disposal of guanidinium thiocyanate and other laboratory waste.

[330] WHO 2014: Safe management of wastes from health-care activities, 2014. http://www.who.int/water_sanitation_health/publications/safe-management-of-waste-summary/en/

Global Health Security

The Global Health Security Agenda (GHSA) encourages countries to set up national tiered laboratory systems able to reliably conduct test 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 US 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.[331]

6.6.2 Cross-Cutting Key Populations Considerations

An effective key populations program should consider cross-cutting dimensions that strengthen the prevention and treatment cascades. According to the UNAIDS 2020 Global AIDS Update,[332] at the end of 2019, key populations and their sexual partners were estimated to account for the majority (62%) of new HIV infections globally. In order to advance epidemic control, PEPFAR teams should reach, provide prevention interventions for, test, treat and ensure treatment continuity for key populations to achieve durable, undetectable viral load (VL). Important considerations for all KP programs include: (1) partnering with community and civil society groups to improve the quality of existing KP programs and service delivery organizations; (2) mentoring and building capacity of nascent KP-led service delivery organizations; (3) reducing stigma and discrimination present in public and private HIV and other service settings; (4) addressing and preventing violence and various forms of abuse against key populations; (5) ensuring safe and accurate data collection and use to better inform programming through KP surveys and ongoing case-based surveillance; (6) promoting UICs and other means and tools to document key populations HIV and service-related outcomes ; and (7) ensuring strong coordination with other PEPFAR program areas, including DREAMS, OVC and pediatrics. 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

[331] https://events.ugovirtual.com/event/AIDS2020/en-us#!/SatelliteAuditorium
[332] https://www.unaids.org/en/resources/documents/2019/2019-UNAIDS-data

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.

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

Key populations are often subject to not only stigma, discrimination and violence, but also criminalization of their behavior, which complicates their access to needed HIV prevention and treatment services. Many of these challenges have been exacerbated by COVID-19. The hidden nature of many key populations hampers our ability to monitor their true access to HIV services due to lack of disclosure of stigmatized identities and behaviors, and the lack of completeness of data collection systems to track KP disaggregates at various steps along the HIV services cascade.

6.6.2.1 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."[333] For key populations, this community is even more impactful. Highly marginalized and often living in criminalized settings, many key populations are challenged to access health services for fear of stigma, discrimination and violence.

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 service KP communities. Fundamentally, these competencies value the insight and leadership of KP community members in designing, implementing and evaluating KP programs. Services offered are non-judgmental and non-stigmatizing, meeting the unique needs of KP clients, and implemented by trained and capable service providers, many of whom may come from KP

333 https://www.unaids.org/sites/default/files/media_asset/JC2236_guidance_partnership_civilsociety_en_0.pdf

communities themselves. KP competency entails ensuring cultural, geographical, linguistic, financial and procedural accessibility to those services and should be determined in consultation with local KP communities. These competencies are based on the WHO (2016) Consolidated Guidelines on HIV Prevention Diagnosis, Treatment and Care for Key Populations.[334] "KP-led" organizations have similar aspirational goals, yet the majority of staff and board leadership are members of the KP communities they serve. 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 client-centered services for key populations. By engaging these CSOs as implementing partners, trust in health services is somewhat gained automatically, as these CSOs often are known to KP communities. Furthermore, KP leaders are often extremely motivated to engage in efforts, recognizing the life of their own community is at stake. Investments in these CSOs should build infrastructures with a vision towards enabling social contracting schemes between KP-led CSOs and national and local governments and other financing mechanisms.

6.6.2.2 Structural Interventions for Key Populations

With a focus on client-centered services, PEPFAR acknowledges structural barriers that may restrict key populations' access to HIV services, thus inhibiting an OU's ability to reach epidemic control. Often referred to as structural interventions, these programs seek to address factors that are not under an individual's control but can affect risk and behavioral choices.[335] Structural interventions work by changing the context or environment to promote health; they locate the source of public health problems and their related factors in the social, economic, and political environments that can determine individual, community, and social health outcomes.[336]

A useful taxonomy and framework of structural interventions has been developed in the context of the U.S. HIV epidemic, and it addresses the following areas: access, capacity strengthening,

[334] https://apps.who.int/iris/bitstream/handle/10665/246200/9789241511124-annexes-eng.pdf;sequence=5

[335] *Structural Interventions in HIV Prevention: A Taxonomy and Descriptive Systematic Review* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5824620/

[336] https://www.who.int/social_determinants/knowledge_networks/phconditions/structural_interventions.pdf

policy/procedure, mass media, physical structure, community mobilization, and social determinants of health.[337,338]

In the global context, WHO 2016 Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care For Key Populations HIV epidemics[339] 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." These critical enablers include:

- Reviewing law and policy
- Reducing stigma and discrimination
- Empowering the community
- Preventing violence

A series of implementation toolkits for KP programming have been developed to address both service delivery and critical enablers for specific key populations:

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/

Looking at the intersection of these two frameworks, PEPFAR recommends the following structural interventions for KP programs:

Access and physical structures: Structural interventions addressing access intend to make a product or service more readily available to its intended user. Physical structures affect HIV risk directly or the ease with which healthy behaviors can be performed. For key populations, these structural interventions might include the following:

- Expanding operating hours of health facilities, and expanding services to more KP-led, KP-managed or KP-competent drop-in centers

[337] https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/si/cdc-hiv-si-review-methods.pdf
[338] https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/si/cdc-hiv-si-review-methods.pdf
[339] https://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

- Integrating related services in one location and/or ensuring strong referral systems. Where PEPFAR cannot directly provide services (e.g., hormone therapy), leverage the work of other providers and donors.
- Increased provision of HIV prevention supplies and equipment (i.e., condoms (both internal and external),[340] lubricants, secondary distribution of sterile injection equipment, PrEP, HIV self-testing kits, etc.)
- Using a mobile van to deliver other services

Social determinants of health: Structural interventions addressing social determinants of health 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 due to societal stigma, discrimination and violence, 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:

- connecting or referring KP to legal literacy or legal services—e.g., FSW harassed through colonial vagrancy laws or MSM in criminalized settings. This can impact whether PEPFAR-funded program staff can carry out their regular duties.
- Safe space and shelter for highly marginalized KPs and their children. Programming should recognize the precarious living conditions of some key populations. PEPFAR funding cannot support the provision of housing for clients, but instead recommends referring to existing resources (see also more information below on emergency response grants)
- Addressing gender-based violence, including intimate partner violence, prevention and response programs that focus on the lived realities of key populations.
- Addressing stigma and discrimination (see Additional Considerations)

Capacity-strengthening: Structural interventions that aim to strengthen capacity should strive for change that improves an agency's or large-scale system's ability to provide services or programs. Capacity-strengthening structural interventions for key populations might include the following:

[340] Condom distribution counts as access only if condoms are available widely and the intervention does not require enrollment into a program to procure

- Health worker KP competency training[341] to improve health workers' understanding of KP-specific issues and increase identification and classification of key populations for the provision of appropriate services (see below).
- Increase direct funding to KP-led and KP-competent organizations
- Strengthening leadership and administrative competencies of KP-led CSOs, such as 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 (see also Section 6.6.10.5 Planning for Sustainability of KP-led CSOs).
- Technical assistance (above-site) to support Ministries' ability to monitor KP performance data
- Electronic tracking/monitoring of HIV care and treatment outcomes among key populations (in a way that is not personally identifying) to prevent duplication and mitigate loss to follow-up
- Training for healthcare workers on index case testing, complemented by training on inquiring about and responding to disclosures of violence according to the WHO LIVES approach.

Policy/Procedure: 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

[341] ICAP. "Final Dissemination Meeting on Implementation and Evaluation of Key Population (KP) Friendly HIV Services at AIDS/STD Facilities in Yangon Region, Myanmar", July 15, 2018.

- 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 2.3.5)
- Preventing stigma and discrimination against health workers attending to KP clients

KP Community mobilization: Community mobilization is a process of change involving multiple stakeholders within a community including people who live in the community. For key populations, this might include the following:

- Engaging KP communities in the design, development, implementation and evaluation of HIV programming. This engagement may be formal by funding KP-led organizations as implementing partners 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).[342]
- Convening groups of KPLHIV or young or older key populations in group sessions led by a counsellor to discuss risk, risk negotiation, violence and other personal issues thereby strengthening their collective agency to work together
- Engaging KP peer navigators or peer educators to provide information and linkage to services for KP-peer groups.
- Ensuring an explicit focus on key populations in PEPFAR-supported community led monitoring (CLM) activities (see Section 3.3.1.2)

Additional Considerations

Addressing Stigma, Discrimination and Violence

Stigma, discrimination and violence are firmly established as key barriers that impede scale-up of HIV prevention, treatment and support services, impacting all stages of the HIV cascade. 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

[342] "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

stigma, which creates fear of denial and rejection at many levels, deters key populations from seeking access to appropriate HIV services and health care. To achieve PEPFAR's ambitious targets for epidemic control, barriers like stigma, discrimination and violence must be addressed.

Effective KP programs address stigma, discrimination and violence by engaging KP leaders and building KP-competency in the program (e.g., hiring experienced and empathetic staff and training them to address the unique needs of key populations). Various virtual and in-person training curricula exist to strengthen KP-competency at healthcare facilities and in community settings. Because key populations 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 including 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 client-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.

PEPFAR and other funders support routine data collection utilizing a standardized methodology 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 2.3.5).

Safety and security approaches

KP task forces or fora are an important platform for communities to interface with PEPFAR and government stakeholders to monitor and track progress on issues pertaining to safety and security. PEPFAR OUs should consult with key population-led organizations, UNAIDS, and other stakeholders to determine the best strategies to provide support in preventing and addressing instances of violence and harassment against individuals and community-based organizations. Support to mitigate safety and security concerns facing key populations could include:

- Convening with government and non-governmental stakeholders to discuss safety and security strategies.

- Building core knowledge and skills among implementing partners on the connections between violence and HIV, and best practices for preventing and responding to violence. The PEPFAR-funded project LINKAGES created a brief to provide guidance and a checklist to implementing partners on addressing violence available online.
- Emergency funding to cover incidents, including but not limited to emergency shelter, legal fees (bail, lawyer fees, etc.), 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 (https://frontlineaids.org/our-workincludes/rapid-response-fund/), which will continue with other donor support. OUs should also be aware of the Dignity for All LGBTI Assistance Fund (https://freedomhouse.org/programs/LGBTI-assistance).

6.6.2.3 KP Surveys and Surveillance

Demographic and health surveys, such as PHIAs, rarely capture reliable information on key populations. Bio-behavioral surveys (BBSs) use sampling designs and methodologies for "hidden populations" and generate population level estimates on HIV prevalence and progress toward 95-95-95 targets among key populations. WHO and UNAIDS recommend that BBSs of key populations be conducted every two-to-three[343] years. OUs that have not conducted a 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 COP21. BBSs 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 KPLHIV, i.e., viral load suppression.[344] Specific and detailed guidance on calculating sample sizes are found in the WHO Blue Book. As BBSs are conducted in locations with the highest HIV prevalence and among KP populations, results cannot be generalized for the general population or the whole country. BBSs should also estimate the size of each key population group in relevant locations including rural districts where no previous population size estimates exist, through the use of multiple-source capture-recapture method or other empirical population size estimation (PSE) methods. PSEs are needed to inform policymaking and resource allocation. Many countries lack robust size estimates and instead rely heavily on

[343] https://apps.who.int/iris/bitstream/handle/10665/258924/9789241513012-eng.pdf

[344] https://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en/

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 hard to reach, and not likely to be counted via hotspot mapping and enumeration. As key populations increasingly embrace the Internet and mobile applications in some settings, they may have shifted away from physical venues. Hence, virtual hot spots or sampling should be considered in population size estimation exercises, as appropriate. Robust methods should (1) include methodologies that scientifically and robustly 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 and virtual size estimate data (e.g., multiplier method).

Country teams planning to conduct PSE should include in COP21 a plan to obtain robust estimates of key and vulnerable populations with reasonable upper and lower bounds. Stand-alone population size estimation activities may be appropriate when a BBS has been conducted in the past two to three years. Otherwise, population size estimation activities should be conducted in conjunction with a BBS, or SABERS for military populations, if appropriate.

Engagement of KP community members is vital for the success of BBSs and PSEs, including survey design, implementation, results validation, and development 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. Key populations involvement 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, in order 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 co-author reports and publications. 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.

6.6.2.4 Unique Identifier Codes & Special Considerations for KP

There are a number of models working to follow key populations across the cascade including:

a) The program model where a PEPFAR-funded program registers all key populations and tracks them with a unique identifier code (UIC) across services, from outreach to PrEP continuation for key populations who are HIV negative or from outreach to 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.

b) An integrated KP program and clinical tracking model where the KP program assigns key populations a UIC and through collaboration with referral clinics matches that KP 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 key populations 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.

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 patients. 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: i) confidential and secure, ii) non- stigmatizing; iii) client generated; iv) easy to recall; v) unique for each client i.e., cannot be replicated for another client; and vi) allow mobility within the region without duplication of services. 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.

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 Zambia, KP clients are tracked via model (b). Community-based KP implementing partners that provide initial outreach, prevention, and testing assign a UIC at the first service encounter. This UIC is used to track HIV-negative key populations through the prevention continuum, as well as HIV-positive KP clients receiving ART through community-based services. For HIV-positive KP clients wishing to receive ART from government facilities, the government ART number is shared with the KP implementing partner. KP case managers continue to check in with the clients on a quarterly basis and track treatment retention, viral load testing and viral load suppression. On a quarterly basis, the KP implementing partners share KP disaggregates with the governmental implementing partners responsible for facility-based treatment. Through this system, governmental implementing partners can continue to monitor and report on KP-disaggregated treatment indicators, while maintaining confidentiality, data safety, and security of KP clients.

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 patient 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.

6.6.2.5 KP Client-level Information Tools and Customized Indicators

Key populations receive services for HIV prevention, treatment and care through different service delivery mechanisms. Key populations commonly access prevention and testing services though 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, they do not necessarily

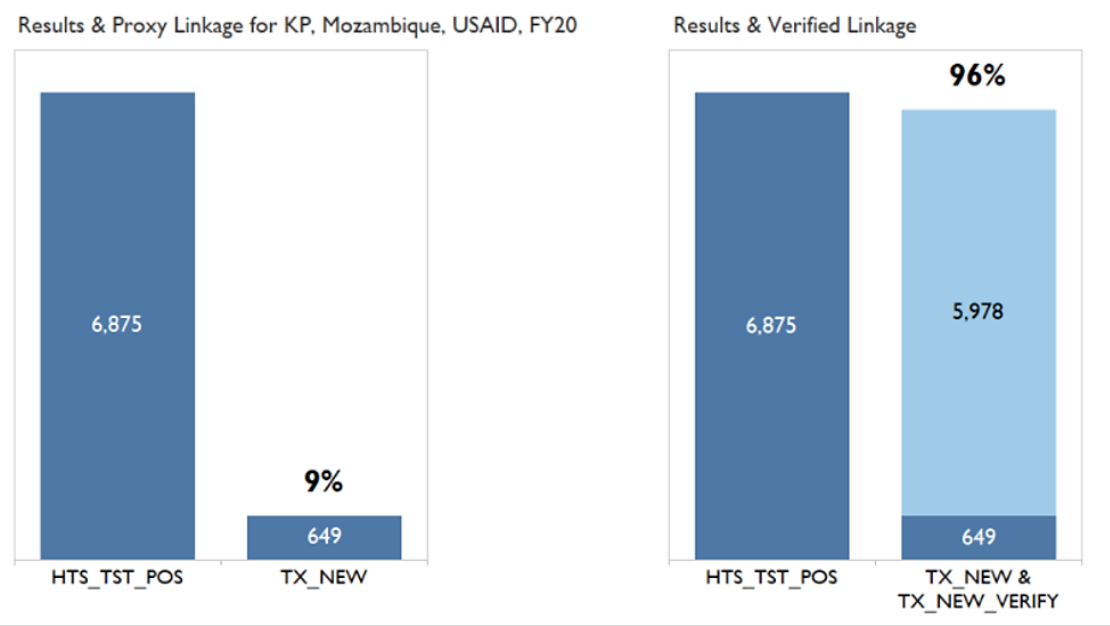
capture the comprehensive set of interventions and linkages that are implemented among key populations. Supplemental KP program monitoring using customized indicators is not required in MER but recommended by USAID and CDC for program improvement and to accurately demonstrate results for KP across the entire cascade. As with all health data collection, but especially in regard to KP, precautions should be made to protect identifying information of key populations and must be approached from a "do no harm" standpoint.
The example below from Mozambique (FY20 Q4) on their cascade outcomes demonstrates that while a treatment linkage rate could be calculated as 9% using MER indicators, the use of the customized indicator TX_NEW_VERIFY can effectively indicate that actually 96% of the newly diagnosed key populations were successfully linked and initiated into 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. These are supplemental indicators, and notably utilization of customized indicators does not substitute for complete and accurate MER indicator reporting.

A number of countries are also adopting the use of electronic individual-level monitoring systems (e.g., electronic case management systems or case surveillance platforms) for key populations through the use of mobile data applications to provide real-time data collection and referrals tracking for the HIV cascade for program improvement. The range of such applications includes, but is not limited to: 1) documentation and follow-up of key populations from diagnosis to viral suppression; 2) PrEP initiation and PrEP continuation; 3) determining the modality of testing among those testing positive; 4) unique patient identifier code generation; 5) service linkage monitoring; and 6) geo-data mapping (i.e., KP hotspots and high testing yield areas). Information collated through these types of electronic data systems can be easily generated and analyzed in near real-time down to the sub-national unit (SNU) and site level and is an efficient way for immediate programmatic course correction. In aggregating data across countries through these systems trends can be better understood and data is more rapidly available for course correction across countries.

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.

Figure 6.6.3: FY20 Q4 Linkage Cascade in Mozambique



6.6.2.6 The Key Populations Investment Fund (KPIF)

In 2018 PEPFAR reaffirmed its deep commitment to expanding key populations' non-discriminatory access to quality, lifesaving HIV prevention and treatment services through the $100 million Key Populations Investment Fund (KPIF), which has been distributed to local partners through CDC and USAID.

KPIF, following guidance from the Office of the Global AIDS Coordinator, extended the ability of local KP-led, trusted and competent implementing partners (IPs) to contribute to PEPFAR's key populations scale-up of differentiated HIV/AIDS prevention, care, and treatment services. By supporting greater involvement of local organizations at the community and national level, the funding contributed to innovative, evidence-based strategies to achieve epidemic control for key populations. The KPIF is operated as a complementary but distinct set of funding in 20 countries. Countries should aim to build upon KPIF's successes within their COP21 programming.

KPIF has accelerated KP program innovations and best practices, and help strengthen the capacities of KP-led community organizations in HIV service delivery, program management, financial management, human resources, data collection and use and governance. CDC

committed about 3% of their funding to build capacity and generate baseline data as a benchmark for KP-led organizations' ability to secure and manage funds, and to deliver KP prevention and treatment service delivery, among other functions. Likewise, USAID expanded funds provided to KP-led and competent organizations, giving grants to organizations that have never been funded by PEPFAR and for those that were only sub partners, putting them in a position to deliver clinical services and take on independent awards. Upon the completion of the KPIF awards, the agencies can provide data among participating KP-led and competent organizations to identify new strengths and remaining gaps for focus on future capacity-strengthening efforts.

6.6.2.7 Children of Key Populations

High levels of mobility as well as stigma and discrimination experienced by key populations can negatively impact their children's essential access to health, education, and child protection services. Due to limited access to HIV services care, 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.

A KP-friendly, 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), HIV testing including index testing (see Section 6.3.2.1 Index Testing and Section 6.3.4.1 Index Testing for Key Populations), linkage to ART, and retention in care to achieve viral suppression, as well as other critical health, psychosocial and economic strengthening interventions.[345] 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 (as appropriate), and Orphans and Vulnerable Children (OVC) services using a family-centered approach for service delivery. For example, in female key populations who are pregnant or breastfeeding, PMTCT services should be prioritized for female key populations living with HIV (KPLHIV) who are pregnant or breastfeeding. All programs will need to be implemented by trusted providers

[345] Srivastava M, Dastur S, Ficht A, Wheeler T. Addressing service delivery needs of children of key populations. Child Survival Working Group, Approaching 2020: Scaling up key interventions for children and adolescents living with HIV, July 2018. Accessible at: http://www.childrenandaids.org/sites/default/files/2018-07/01-Addressing-the-service-delivery-CSWG.pdf

within a carefully designed system that maintains confidentiality of HIV status of key populations and their children.

Considerations for identifying biological children of key populations living with HIV (KPLHIV) should be prioritized in case finding programs, with a focus on biological children (< 19 years of age) FSWs living with HIV, female PWID, and/or biological mothers with unknown HIV status (see Section 6.3.2.1 Index Testing and Section 6.3.4.1 Index Testing for Key Populations). KP, OVC and Clinical Implementing partners must coordinate to ensure that children of key populations are included in the referral process, and that all HIV exposed and HIV-positive children of key populations are linked to appropriate testing or treatment services, ensure treatment continuity, and offered enrollment in comprehensive OVC programs (see Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic), while ensuring safeguards to protect the confidentiality of the parent and child's HIV status as well as the parent's status as part of a KP group. Similarly, HIV-negative children of key populations should be assessed for eligibility for the OVC program and offered enrollment, if appropriate (and if new enrollment slots are available). It is important to consider how the needs of children of KP may differ from those of other vulnerable, HIV-affected children, given children of key populations may not be living with their parents, but with a relative/caregiver in a different locality (e.g., Case Finding in OVC).[346] 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 6.6.4 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic), while ensuring safeguards to protect the confidentiality of the parent and child's HIV status as well as the parent's status as part of a KP group. Similarly, HIV-negative children of KPLHIVs should also be assessed for eligibility for the OVC program and offered enrollment, if appropriate (and if new enrollment slots are available). It is important to consider how the needs of children of KP may differ from those of other vulnerable, HIV-affected children, given children of KP may not be living with their parents, but with a relative/caregiver in a different locality (e.g., a child may be in a rural setting as opposed to with the biological parent in an urban setting; a student may be attending a boarding school, etc.) or the household may be unaware of the parent as part of a KP group.[347] KP, OVC and Clinical implementing partners (IPs) should

establish strong bidirectional referral systems and data sharing agreements. , while respecting the ethical considerations needed relating to consent and confidentiality.[348] .

Where services for key populations are primarily provided, such as in drop-in centers (or one-stop shops), these sites should ensure child-friendly, safe spaces and services for the children of key populations or if preferred, strong referral mechanisms to health facilities. In general, providers in facilities that serve key populations should be trained to provide safe and non-judgmental services not only to key populations and their children, should KP prefer to bring their children to the 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 available at both KP drop-in-centers and other sites serving the general population. As children of key populations are at greater risk of abuse, in particular sexual abuse,[349] further considerations must be made regarding 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. It is important for local and national governments as well as in-country KP, OVC, and, Clinical and OVC staff 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. Enumerating the number of children of key populations and supporting data collection and analysis for Clinical, KP and OVC partners across the clinical cascade (including HIV testing, linkage to ART, retention in care and achievement of viral load suppression) should be prioritized.

PEPFAR programs have demonstrated that innovative and integrated approaches can successfully reach children of key populations. For example, program models that coordinate KP, pediatric and OVC partners utilize program strategies such as using bidirectional referrals, where KP programs refer vulnerable children and HIV-exposed infants of HIV-positive FSW for OVC optimal service delivery. Once enrolled, children receive protection, psychosocial support, nutrition supplement for malnourished ones and education. Other program elements include using a Peer-to-Peer approach to provide targeted need-based services for children of key populations and their households. Additionally, KP members should be trained and engaged as Community Case Workers to provide services to their fellow key populations. An important

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[349] Beard J, Biemba G, Brooks MI, et al. 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. 2010;13(Suppl 2):S6. doi:10.1186/1758-2652-13-S2-S6.

program component includes offering escort services for drug refill and viral load testing for children of KPLHIV and counselling FSW caregivers if their children are not virally suppressed. Moreover, KP caregivers and adolescents living with HIV can be provided business support to improve household resilience.

For example, the USAID Kizazi Kipya OVC program in Tanzania designed a differentiated service delivery approach tailored to children of FSW and their mothers/caregivers living with HIV. The service package tailored to children of FSW (beneficiaries of the OVC program) includes:

a) Linkage of at-risk children to HIV testing, treatment and care services
b) Tracing children living with HIV who missed appointments
c) Providing community health fund cards, disclosure support, linkage to support groups and services such as child protection, early childhood development, and nutrition assessment, counseling, and support.

The service package tailored to mothers/caregivers who are FSWs included economic strengthening services and positive parenting education. As of FY20Q3 the program reached 3,976 KP and their children (2,548 children of FSW and 1,428 FSWs) and determined that 5% of children of FSW and 14% of FSW caregivers were HIV-positive. 99% of all enrolled children of FSWs have a known HIV status as per OVC program requirements (OVC_HIVSTAT).

Given their highly vulnerable status, mobility, and elevated risks of marginalization and criminalization, protection of children of key populations and their families must be the utmost priority. Offering key populations and their families access to safe clinical and community PEPFAR-supported programs will significantly advance efforts to reduce the pediatric treatment gap and ensure these families are reached with life-saving HIV services as well as critical protection and socio-economic services.

6.6.3 Gender-Based Violence and Post-Violence Care

Violence can negatively impact the lives of all and reduce 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 some members of KP groups (e.g., transgender people) 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. Intimate partner violence (IPV) is the most common form of violence experienced by women globally.[350,351,352] While GBV encompasses a wide range of behaviors, PEPFAR is predominantly focused on prevention and response to physical and sexual violence; including marital rape, sexual assault or rape, female genital cutting/mutilation, sexual violence against children and adolescents; and child marriage, because of their inextricable links to HIV.

A strengthened continuum of response between GBV 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 and DREAMS), HIV testing (particularly index testing, recency testing, and partner notification), HIV care and treatment, PMTCT, ANC, and OVC services.

Prevention. For more information on evidence-based GBV prevention activities, please see Section 6.2.2.2 on DREAMS, Section 6.2.3 on primary prevention of HIV and sexual violence for 9-14 year-olds, Section 6.2.3.1 on Justice for Children, or consult the DREAMS Guidance. Additional resources tailored to key populations programming are available through the PEPFAR-funded LINKAGES project, which developed a guide and training manuals to support the integration of violence prevention and response activities with HIV prevention, care and treatment services.

Routine Enquiry. Routine enquiry for intimate partner violence (IPV) may be warranted in some HIV service settings to avoid exacerbating a harmful situation and to ensure sensitive delivery of those same services to clients experiencing IPV. Routine enquiry (also referred to as the IPV risk assessment) should always be conducted as part of safe and ethical index testing and partner notification, as well as counseling and initiation of PrEP, and eligibility screening for DREAMS and OVC programs. In addition, identifying PLHIV in HIV clinical services who are

[350] 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.
[351] Pulerwitz, J. et. al. Unpacking the Influence of Gender on HIV Testing and Treatment Uptake: Evidence from Mpumalanga, South Africa. Project SOAR. 2017.
[352] 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.

survivors of violence helps to ensure post violence care services are provided in a timely manner, supporting improved adherence, retention, and ultimately viral suppression. To ensure the effective provision of these HIV services for AGYW and adult women, new or suspected cases of IPV must be identified and survivors must be provided or referred to necessary GBV response services per WHO clinical guidelines and per the GEND_GBV indicator (link to MER Guidance). Providers in these settings should be trained on the following using LIVES or a similar training:

- Asking about violence in a sensitive and non-judgmental manner; using a standard set of questions where they can document responses
- Ensuring privacy and confidentiality
- Following a simple standard operating procedure, job aid, or algorithm that outlines the steps that counselors/clinicians take if a client discloses experience or fear of violence
- Providing age-appropriate first-line support when violence is suspected or disclosed
- Providing 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
- Incorporating violence-informed HIV service delivery, following GBV identification, to mitigate the effects of violence on core HIV clinical outcomes (e.g., tailored adherence counseling, disclosure support, other strategies that mitigate risks while enabling service access)

Post-violence Care. Implementing partners who provide post-GBV care services must:

- Provide training and supportive supervision to both providers and IPs on first-line counseling for trauma-informed care (empathetic listening, inquiring about needs and concerns, validating their experience, enhancing safety, and connection to other support, which may include referrals to additional services) to provide immediate, client-centered support and meet the overall emotional, physical, safety, and support needs of survivors.
- 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 and the GEND_GBV MER indicator definition and meet the expressed needs of survivors. These services must be client-centered and trauma-informed.
- 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. Improving quality of

clinical post-GBV care through routine program monitoring and quality improvement processes.

- 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.).

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. 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).

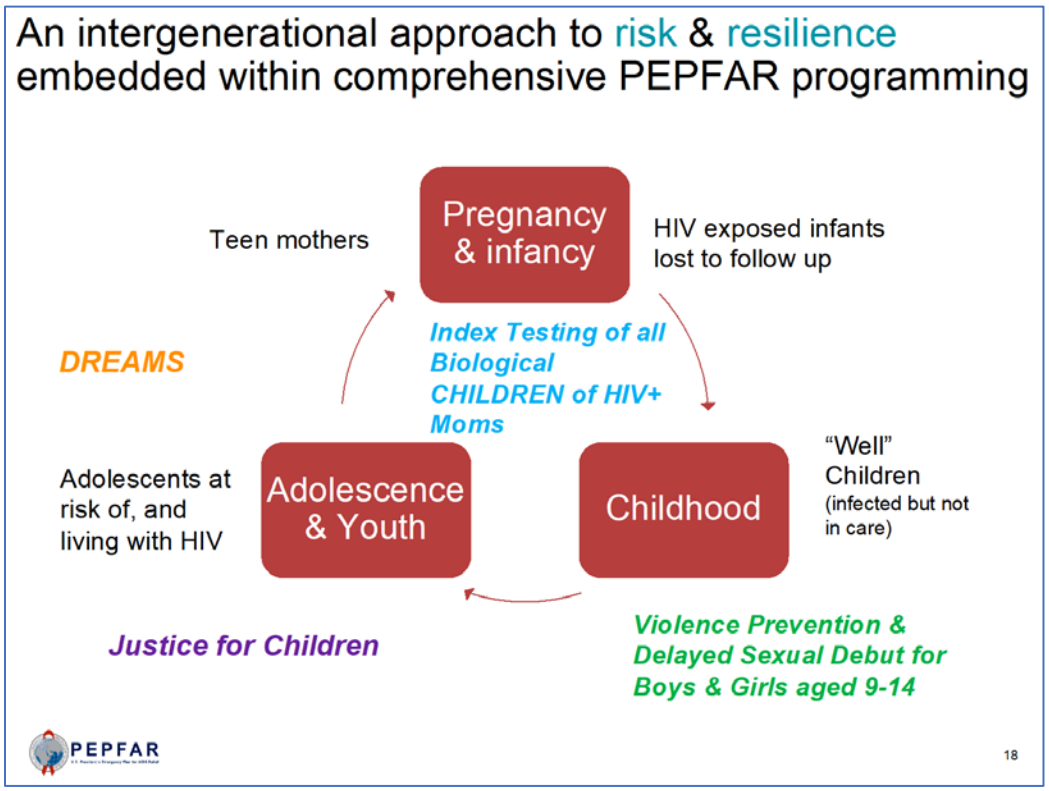
6.6.4 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic

Although the rate of orphaning continues to decline with the expansion of treatment, significant risks remain for children and adolescents as a result of HIV/AIDS. In COP21, OVC programs must continue to evolve and to focus on the key challenges for children in the epidemic, specifically the pediatric treatment gap, 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.

An Intergenerational Response to Key Challenges for Children

The framework in Figure 6.6.4 depicts the range of risks children face from the perinatal period through late adolescence and young adulthood and underscores the cyclic nature of intergenerational risk. Each stage impacts on the next, until the cycle regenerates, and today's adolescents mature and become the parents of tomorrow's infants. Eliminating intergenerational risk requires strategies that target critical junctures in the lifecycle while also addressing the unique needs of diverse subpopulations.

Figure 6.6.4: OVC Intergenerational Approach Framework



Many more children are now on treatment thanks to PEPFAR, but treatment coverage and viral suppression among young children and adolescents remain a challenge, as does finding "well" or asymptomatic children living with HIV who remain undiagnosed. As of 2019, UNAIDS estimates global treatment coverage for children under the age of fifteen at only 53%,[353] indicating that almost half of children living with HIV remain unidentified, and in grave danger. Supporting continuity of treatment of children and adolescents is the leading priority for OVC partners in COP21. Additionally, OVC community networks 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 modalities. In COP21, PEPFAR is prioritizing the scale-up of index testing of biological children (<19yo, with unknown HIV status) of current adults and siblings diagnosed with HIV. Through household visits and support, OVC frontline providers are key to identifying children of index clients, facilitating their access to testing, and ensuring linkage to and continuation on treatment for those living with HIV.

[353] UNAIDS 2020 Report

To that end, OVC implementing partners/sub-partners and all PEPFAR testing and treatment partners/sites must establish formalized partnerships to rapidly increase the number of "well" children found, tested, linked, and supported on treatment. Where OVC and pediatric treatment programs geographically overlap, children living with HIV should be offered enrollment in area OVC programs. In high volume clinics within high burden SNUs, at least 90% of children (<age 19) in PEPFAR supported treatment sites should be offered enrollment in OVC programs. OVC staff placed in clinics (e.g., as linkage coordinators, case managers, etc.) should have the capacity to assess child and family needs and to offer appropriate referrals.

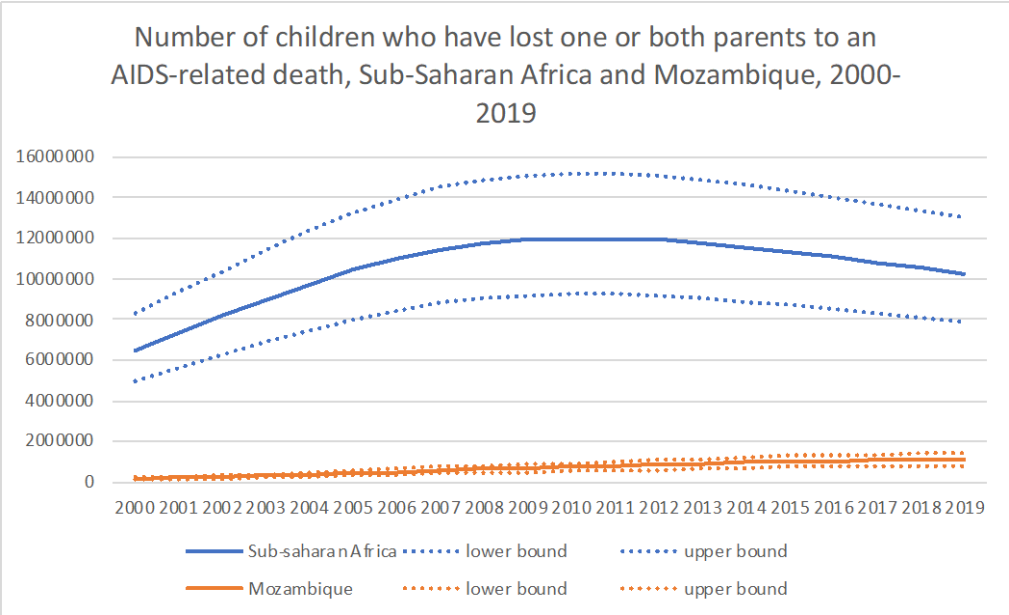
While the focus of OVC programs is children, safeguarding children's futures also entails supporting adult continuity of treatment. As seen in Figure 6.6.5, where adult continuity of treatment is suboptimal in places such as Mozambique, orphaning rates are not declining at the same rate as in other Sub-Saharan African countries. In addition to preventing HIV transmission and ensuring that children living with HIV live a long and healthy life, keeping children's parents alive and healthy will always have the greatest lifelong impact on vulnerable children in the pandemic. OVC IPs, with their wide community reach and social protection expertise, must play a key role in ensuring that HIV-positive or HIV-affected children and their parents are retained in care through routine engagement and support, including home visits that promote adherence to ART, accompaniment to clinics, case conferencing, psychosocial support, and provision of socioeconomic assistance.

Supporting children on treatment can be challenging, especially as they enter adolescence and become keenly sensitive to real or perceived stigma and seek to establish their independence.

In addition to parents, adolescents living with HIV also benefit from the added comprehensive support available through the OVC platform. Adolescents on ART in South Africa, for example, who had access to multicomponent interventions, including parental monitoring, support groups, and social transfers such as cash and food provisions, had greater adherence than those who did not.[354] For the OVC platform, the focus for adolescents is two-fold: continuity of treatment and living a productive, healthy, AIDS-free life.

[354] Cluver, et al. (2016). Achieving Equity in HIV-treatment Outcomes: Can Social Protection Improve Adolescent ART-adherence in South Africa? *AIDS Care*, *28* (sup2), 73–82.

Figure 6.6.5: Trends in Orphaning Due to HIV/AIDS[355]



As children become young adults, their risk for acquiring HIV through sexual transmission increases sharply. OVC programs are uniquely poised to address the myriad factors that put adolescents at risk. Pregnant adolescents are a particularly vulnerable group, with HIV-negative adolescents at high risk of HIV acquisition and adolescents living with HIV at high risk of loss to follow up from PMTCT services, with resulting high risk of mother-to-child HIV transmission. OVC programs can provide client-centered support through the PMTCT platform to pregnant women living with HIV and their infants most at risk for interruption in treatment or missing EID such as pregnant adolescents. Adolescent girls who have lost a parent, for example, have an earlier sexual debut than their male counterparts do (both those who have and have not lost a parent). 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.[356] 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 invest in primary prevention of sexual violence and HIV in pre-and young adolescent girls and boys aged 9-14**.**

[355] UNAIDS 2020 estimates
[356] Birdthistle, et al. (2008). From Affected to Infected? Orphanhood and HIV Risk among Female Adolescents in Urban Zimbabwe. *AIDS, 22(6),* 759-66.

To implement the intergenerational framework described above, two distinct but complementary OVC program strategies are required to address children's vulnerabilities across the lifecycle. As described in Figure 6.6.6, the OVC Comprehensive program, is a time and resource intensive strategy that should be reserved for 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 during the critical window between ages nine to fourteen.

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 recruitment through clinical services to identify children already in HIV treatment (especially those newly enrolled), infants of mothers at risk of interruption in treatment in the PMTCT cascade or missing EID (especially adolescent mothers during and after pregnancy), and biological children of female adult index cases. Other targeted groups with known risk factors include children who are survivors of sexual violence, children who have lost parents due to AIDS, and children of key populations such as female sex workers (prioritizing children of FSWs living with HIV), all of whom may be identified through child welfare and community referrals. Children and family members in the comprehensive group should be formally assessed and regularly monitored through case management. Case files for each family should include 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 2.5 OVC_SERV reference sheet.

In order to ensure client-centered care that bridges clinical and community resources, OVC programs should work with clinics and child welfare services as part of multi-disciplinary teams.

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 be stationed at the highest volume clinics to ensure smooth coordination and referrals between clinicians and community case workers.

So that roles and responsibilities between health and community services are clear, PEPFAR supported clinics and OVC IPs should establish Memoranda of Understanding (MOUs). The MOUs should address key issues such as bi-directional referral protocols, pediatric case finding, case conferencing, shared confidentiality, joint case identification and data sharing (related to ART status, VLS, and index testing). In addition, PEPFAR-supported clinical staff 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 U=U messaging. Likewise, OVC IPs can help train clinic staff to understand the factors (e.g., socioeconomic and cultural) that impact health-seeking behaviors (e.g., HIV and EID testing, keeping clinic appointments, adhering to medication, and returning for viral load test and results); and to recognize which families and children would benefit from OVC program support.

OVC Preventive Program

The Preventive Program focuses on children aged nine to fourteen years in high burden SNUs. For boys and girls, the developmental period of pre and young adolescence 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 and community members, including faith and traditional leaders, in protecting adolescents from violence, and that supports 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. As shown in Figure 6.6.6, monitoring of this target population is distinctly different from the comprehensive program, and does not involve providing case management or monitoring against graduation benchmarks.

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 COP21 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. Additionally, 9-14-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.

Figure 6.6.6: OVC Comprehensive & Preventive Program Areas

Program Area	Target Population	Recruitment Modality	Program Approach	Relevant COP20 Guidance Sections
OVC Comprehensive	• Children and adolescents living with HIV • Children of adults living with HIV at risk of interruption in treatment; children who have lost parents to AIDS • HEI at high risk of interruption in treatment (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 & 6.3.3 Case Finding for Pediatrics, Adolescents and Youth • 6.3.2.2 Case Finding in OVC • 6.1.3.1 & 6.1.3.2 DSD and Adherence Support for Children, Adolescents and Youth • 6.6.2.7 Children of Key Populations
OVC Preventive	• Boys and girls aged 9-14 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 9-14 Year Olds • 6.2.3.1 Justice for Children • 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 6.6.7 are currently represented in the OU's OVC cohort. Where transitions may need to be made to accommodate a greater proportion of children living with HIV, teams should work with local partners to conduct a planned and responsible transition.

Data Sources:

- Prevalence and incidence by age/sex and SNU for persons < age 15 and 10-19 [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]
- FY20Q4 MER results, particularly:
    - OVC_SERV<18, by age/sex and participation status, graduation rate
    - OVC_HIVSTAT by age/sex
    - Comparison of OVC_HIVSTAT_POS with TX_CURR <15 and <20 for proxy OVC program coverage of PEPFAR-supported C/ALHIV by SNU
    - <15 and 15-19 results for clinical cascade indicators, including HTS_TST, HTS_TST_POS, TX_NEW, TX_CURR, TX_PVLS, TX_ML and TX_RTT
    - 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 <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 those services offered where possible. These OUs include Burundi, Cameroon, DRC, Dominican Republic, India, South Sudan, and Ukraine.

Budgeting for the different program areas should incorporate findings from program data, recent analyses of case management costs[357,358] as well as costs of the different prevention interventions.[359] Given the greater intensity of resources required for the Comprehensive

[357] Gobin, Foley. (2019). The Cost of Case Management in Orphans and Vulnerable Children Programs: Results from a Mixed-Methods, Six-country Study. *MEASURE Evaluation.*
[358] MEASURE Evaluation (2019). An Assessment of the Actionable Drivers of HIV Outcomes: A Study of the COVID Case Management System in Three Provinces in Mozambique.
[359] World Health Organization (2018). INSPIRE Handbook: Action for Implementing the Seven Strategies for Ending Violence Against Children.

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 and Preventive interventions 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.

6.6.5 Faith and Community Initiative

Along with other community organizations, faith communities often have a deeply established and trusted community presence in the countries where PEPFAR works, where 60-75% of the country-populations regularly attend religious services. As such, they are often ideally suited to help find men and other individuals living with HIV who are less likely to interact with the medical system. Faith communities often seek to improve the lives of their congregants and others in their communities and have expressed renewed interest in addressing the epidemics of HIV and sexual violence in their communities. On World AIDS day 2018, PEPFAR formalized and launched the Faith and Community Initiative (FCI), to enhance PEPFAR's engagement with faith communities and other traditional community structures. Ten high-burden countries were selected to receive funding for COP19 (Botswana, Eswatini, Haiti, Kenya, Lesotho, Malawi, Uganda, Tanzania, Uganda, Zambia, Zimbabwe), and programming to facilitate partnership with faith communities and other traditional community organizations in these countries was developed. In 2019, FCI technical assistance visits were conducted in 9 of the 10 countries by S/GAC, HQ Agency, and field staff, and engagement with the field teams helped the FCI cohere around two over-arching priorities: 1). to help find men, youth, and children living with HIV and link them into continuing care, and 2) to prevent sexual violence among children and accelerate justice for children who have suffered from it (see Section 6.2.3.1 for information on Justice for Children). Programs are encouraged to leverage synergies with existing programs, including OVC and DREAMS platforms (Sections 6.6.4 and 6.2.2.2). The goal of the first priority 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. FCI priorities include evidence-based treatment and biomedical prevention interventions. PEPFAR continues to collaborate with faith and community leaders to increase the acceptance and uptake of behavioral interventions such as condoms and lubricants through complementary sources of

core programming. This priority also directly supports the aims of MenStar (Section 2.5. Leveraging Partnerships and Local Resources for Epidemic Control). Engagement with faith and other communities will advance PEPFAR's ability to leverage social capital in support of epidemic control.

In light of delays in FCI programming associated with delayed arrival of funds for FCI and/or new subs for FCI funding received in COP19, FCI funds from COPO19 were protected and could be outlaid in COP20, (in excess of the new COP20 total budget envelope, without being considered an over-outlay); this carryover does not impact pipeline. Additional COP20 activities and investments were incorporated by 9 OUs, to support engaging FBOs and faith communities to help reach and continue care for well men and children. For COP21, OUs are encouraged to support Strategic Religious Engagement of FBOs and Faith Communities (including Religious Parent Bodies), to advance and sustain FCI activities, as described below.

There are three activities under this FCI priority aiming to reach and retain men which focus on engaging communities of faith and other traditional communities to understand the epidemic, raise community awareness, and increase uptake of critical treatment and prevention interventions for men and children through relevant organizations, including faith-based organizations, and other faith and community partners. High level engagement by host country governments in the FCI confirm that continued strategic religious engagement is an operational imperative for maintaining and extending the gains in HIV epidemic control, particularly in the context of COVID-19.

The FCI must have a coordinating structure to achieve rapid results. The Steering Committee (SC) is established to serve as the country's coordinating body with defined roles and responsibilities to ensure that selected IPs fulfill PEPFAR's FCI priorities. The following key tasks are essential for the SC to successfully engage faith communities to reach men and children:

1. Work with PEPFAR technical team to review current health and HIV messages for men, youth, and children, to revise them accordingly to reflect current PEPFAR FCI strategy;
2. Disseminate new 'Messages of Hope' across parent body infrastructures;
3. Coordinate and facilitate HQ–led and in-country trainings for FCI IPs and host country governments to achieve identified priorities in each country;
4. Coordinate procurement, distribution and monitoring of self-test kits for FCI partners.

The Steering Committee members and their collaborators act together to oppose all discrimination based on race, sex, gender, sexual orientation, religion, ethnicity, or occupation; and they uphold PEPFAR's commitments to serve all people living with HIV or at risk of HIV.

Implementation Guide and Tools

A full implementation guide for 'Engaging communities of faith to find men and children living with HIV is available to USG OU teams on PEPFAR SharePoint. This Guide outlines how engaging communities--including communities of faith--to find men and children will be implemented through the three principal activities described below. MER and DATIM indicators and narratives outlined in the FCI section of the MER Guidance are used to monitor these activities.

Activity 1: Train leaders and disseminate Messages of Hope through community, including faith-based community structures.

Purpose: To expand community awareness of modern approaches to HIV (such as U=U), and to enhance highly targeted demand creation for HIV testing.

Every OU develops an **Inter-Faith Steering Committee,** or builds upon existing religious forums or steering committees, to drive contextualized and expansive dissemination of Messages of Hope, through in-person, virtual, and digital channels, including radio/TV, WhatsApp, Facebook live.

Materials/Training for USG OU teams:

- HQ Messages of Hope for Men and Children Tool at PEPFAR SharePoint.
- HIV Educational Update at PEPFAR SharePoint.
- HQ Messages of Hope for HIV prototypes (https://www.faithandcommunityinitiative.org)
- *To maintain the gains for HIV prevention and control, global faith leaders also developed Messages of Hope for COVID-19.* (https://www.faithandcommunityinitiative.org)
- *Faith Matters* is a training for faith and community leaders that builds their knowledge, confidence, and skills to effectively disseminate the new messages of hope surrounding testing and treatment. Information and strategies to address sexual violence prevention and response, stigma and discrimination, and healing in their communities are also a part of the 2-day programming. Adaptations are in progress that allow virtual delivery of training for *Faith Matters (*possible in countries with trained facilitators for Families Matter Program).

Activity 2: Expand HIV Testing, including targeted self-testing; improve linkage to treatment; and promote continuing in care

Purpose: to leverage the trust, access, compassion, and social networks of faith communities to identify those at risk for HIV, get them tested and quickly linked to HIV treatment, and support continuing in care. Countries are required to either: 1) adapt one or more of the 'Best Practices' models for testing and/or treatment models, supported by strong data (See Section 6.1.3.1 for expanded descriptions and impact data); or 2) adapt and evaluate 'Promising Practices' models supported by emerging COP19 data from Q1-Q3.

'Best Practices' for advancing case-finding by engaging faith & community leaders and FBOs.

- *Faith-Engaged Community Posts, Zambia* – Utilization of non-descript community health posts for comprehensive decentralized HIV service delivery (prevention, testing, treatment, retention, VLS). Continuous engagement of leaders, including faith leaders, and the use of expert clients to build community trust, at Faith and Community Initiative and Circle of Hope, PEPFAR Solutions Faith-Engaged Community Posts
- *Faith-Engaged Highly Targeted HIV-Self-Testing in Urban Settlements, Kenya –* After training in MINISTRY OF HEATH 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, with a comprehensive system for promoting high linkage at Faith and Community Initiative.
- *Maximizing Same-Day Antiretroviral Treatment (ART) Initiations, Eswatini -* Providing immediate access to senior-level staff for late adopters significantly increased ART initiation, at Faith and Community Initiative,
- *Co-location of Testing Sites on Premises of Religious Venues, Zambia –* As the latter are places where many people congregate and 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. Adaptation of Circle of Hope, PEPFAR Solutions Faith-Engaged Community Posts *Community Adolescent Treatment Program (CATS), Zimbabwe* – 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.

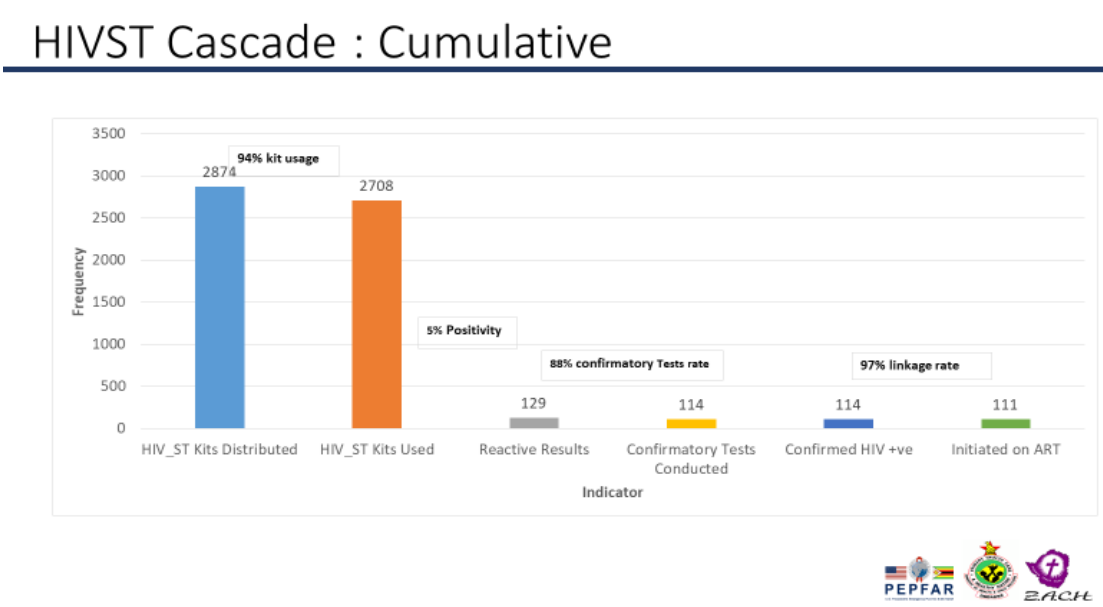
- *Baby Shower Initiative: A church congregation-based approach, Nigeria -* A congregation-based initiative shown in randomized trials supported programmatically by HQ, improves HIV case-finding with linkage among pregnant women and significantly improves case-finding among healthy male partners of pregnant women, as reported here, and shown in video clip here.

'Promising Practices' for advancing case-finding by engaging faith & community leaders, FBOs.

Making highly targeted distribution of HIV self-tests or standard HTS available through active outreach of trained faith-engaged leaders who, through trusted relationships with families in their communities, know and can offer HIVSTs to many with markers of HIV risk (e.g., relationship conflict or violence, death/serious illness in family, attendance at healing services while avoiding health services, substance abuse). COP19 MER/DATIM measures for the FCI show early successes and challenges for Q2-Q3.

- Early Successes: Trained, faith-engaged leaders from churches and mosques, when working in collaboration with facility partners, were able to reach many with HIV risk, as shown by the percent of HIVST's and/or standard HTSs that were reactive or positive, and early successes at increasing uptake of PrEP by the general population of PLHIV. Many of those newly identified as positive through the FCI were persons considered unlikely to seek care in facilities due to cost of travel, poor customer care, distance, time spent in facilities, and stigma. Examples of early successes follow.
- Zimbabwe, Q3, 5% reactive HIVSTs across 9 districts, 88% confirmed, 97% linked

Figure 6.6.7 HIVST Cascade: Cumulative



- Zimbabwe, Q3, 16% reactive HIVSTs when integrated into CATS adolescent programming, offering HIVSTs to youth with risk; initial linkage 75% due to resistance to seeking care, but ongoing engagement is supports continued efforts to link.
- Botswana, 20%, when faith leaders offered one-on-one testing to men with risk; this approach was a course correction after widely offering HIVSTs to men in faith venues led to low yield.
- Kenya, 8.3% yield, when faith leaders used the RASP (PrEP risk assessment tool) in informal settlements to actively reach out to those in their congregations and combine this tool with further dialogues with individuals and families, which clarified risk.
- Kenya, HIV testing yield increased from 1.2% (294/24,429) to 2.8% (604/21,703 p<00001) among men, with 100% linkage; and from 1.7% (491/28,952) to 4.1% (1169/28,321 p<00001) among women, with 100% linkage.[360]
- Zambia, 18% yield with 100% linkage, Q2, as faith-engaged Community Posts expanded
- Zambia, co-location of testing sites on premises of churches in informal settlements led to high yield in children under age 15 (9%), males 15-34 (20%), and males 35+ (13%), as well as showing success with identifying positive index clients and positive contacts for these same age bands, including a 38% indexing yield rate for children.

[360] Bauer, Motoku, Muriithi et al. Engagement of faith leaders in targeted HIV self-testing increased case identification and new linkages to treatment in Nairobi, Kenya, AIDS2020Virtual

Figure 6.6.8: Number of individuals with positive test results (through faith setting) linked to a facility in FY20 Q2

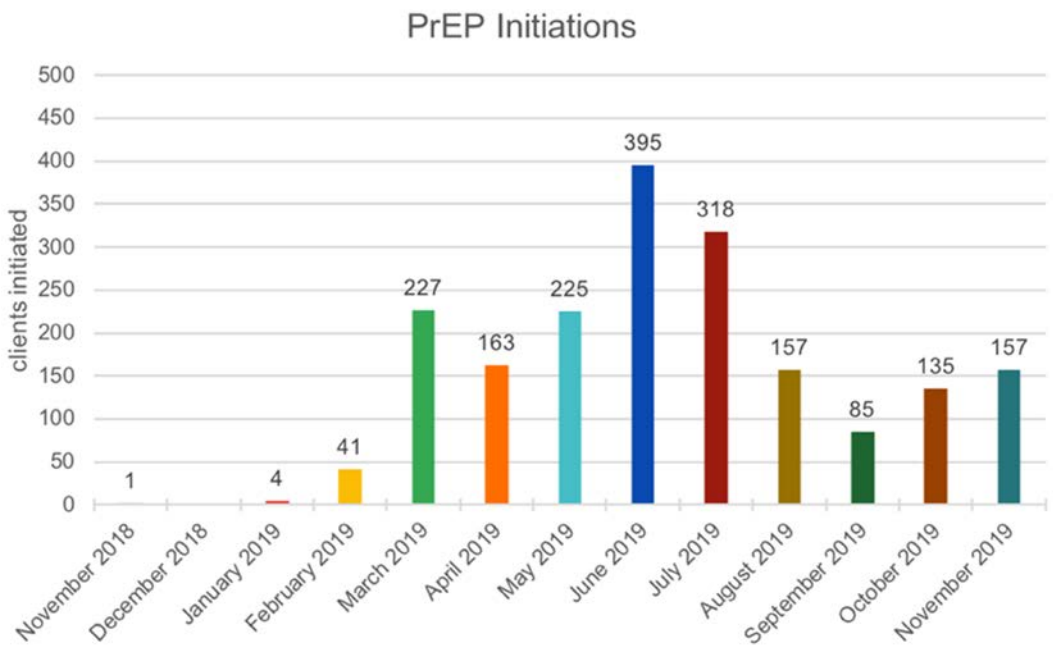
FY20 Q2	Children <15 Yrs	Males 15-34 Yrs	Males 35+ Yrs
Tested (HTS_TST)	2273	1283	3553
Tested HIV+ (HTS_TST_POS)	209	256	465
Yield rate	9%	20%	13%
Initiated on ART (TX_NEW)	210	284	494
Linkage rate	100%	111%	106%

Figure 6.6.9 Number of positive index clients and number of positive contacts identified through faith community or congregation in FY20 Q2

FY20 Q2	Children <15 Yrs	Males 15-34 Yrs	Males 35+ Yrs
INDEX Tested	148	174	322
INDEX_Tested_POS	56	89	145
Indexing yield rate	38%	51%	45%
% HIV+ from indexing	27%	35%	31%
INDEX_Known_POS	19	61	82
HTS_SELF_TEST	263	134	397

- Eswatini, increases in uptake of PrEP were observed after implementation of an uptake plan that a) positioned PrEP as a prevention resource for the general population of those testing negative via HIVSTs or HTS, and b) integrated PrEP into a comprehensive health care platform. Numbers of clients rose from 4 in February 2019, to 1862 during March-November 2019 (Q2-early Q4).

Figure 6.6.10 PrEP Initiations[361]



- Factors influencing early successes for the models above included the following (1) faith and community leaders frequently disseminated messages of hope about HIV in congregations and to surrounding communities/SNUs, to create demand for targeted testing and to reduce stigma; (2) partners mapped locations of congregations and identified for faith leaders which facilities were closest to their congregations, to facilitate confirmatory testing and linkage; and (3) partners made course corrections for challenges faith leaders faced with partner elicitation and improved performance of risk factor screening tools by combining them with risk markers often known by faith leaders (e.g., relationship problems, bereavement counseling, substance use, or attending healing services).
- Early Challenges: While successes above are promising, there were several OUs/IPs with low yield in Q2/Q3, and those are in the process of course corrections by south-to-south learning from models that work, so they may effectively target testing.

Activity 3: Decrease stigma and non-adherence to treatment

Purpose: to decrease loss-to-follow up, treatment failure, progression to AIDS, and death, that are associated with stigma and related non-adherence to treatments in various communities.

[361] VanderWal, Mirira, Munamato; Lukhele, Increasing PrEP Uptake through HTS Counselor Sensitization, Integrated Screening, and Client Education, AIDS2020Virtual**.)**

Materials/Training for USG OU teams:

- All the materials/training listed in Activity #1 above also include some information on reducing stigma and related non-adherence to treatments in various communities, particularly in the context of exclusive reliance on faith-healing in congregations or communities.
- "Treatment Adherence in the Context of HIV and AIDS in Africa: Training Manual for Religious Leaders," from World Council of Churches (English, French, Swahili, Kinyarwanda; Core modules: 6, 7, 8, 11, 13).

Of note, all countries participating in the FCI in COP19 have leveraged these platforms, particularly the Coordination through the Steering Committee, to rapidly and nimbly advance pandemic risk communication, referral, contact tracing, and mitigation of second order impacts such as sexual and domestic violence, for those populations at risk of HIV.

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 global financial uncertainty, evolution in global treatment guidelines, and continued interdependence of donor funding, subject to applicable law and to policy and legal approval. Although the ECF use has been limited, it is not intended to be a parallel solution that provides a bypass for criteria of accountability and efficient grants management or effective procurement and supply chain practices. PEPFAR will no longer replenish the ECF. All remaining 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 will be expected to reimburse use of the ECF in full. Use of the ECF requires the Ambassador's approval authority with a commitment from the country to pay back funds expended.

6.6.7 Mental Health

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 and psychotic illness are common in individuals living with

HIV.[362,363] Mental health disorders and psychiatric illness can[364] be a risk factor for HIV exposure that complicates the disease course and treatment. These disorders have been associated with decreased testing for HIV,[365] reduced likelihood of initiating ART and being retained in care,[366,367,368,369] poor ART adherence, and lower likelihood of virological suppression.[370,371] In addition, psychosocial factors that commonly[372] co-occur with both mental disorders and HIV, such as violence, trauma, stigma, and other social determinants, may additionally impact HIV treatment outcomes.[373]

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[362] 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. Epub 2019/09/21. doi: 10.1136/bmjspcare-2019-001952. PubMed PMID: 31537580.

[363] 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.

[364] 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.

[365] 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. Epub 2008/07/09. doi: 10.1017/s0033291708003930. PubMed PMID: 18606051; PubMed Central PMCID: PMCPMC2640447.

[366] 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. doi:10.1007/s10461-017-1776-8.

[367] 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

[368] 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. doi: 10.1007/s10461-016-1442-6. PubMed PMID: 27251436.

[369] 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. doi:10.1037/hea0000606.

[370] 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. Epub 2011/08/23. doi: 10.1097/QAI.0b013e31822d490a. PubMed PMID: 21857529; PubMed Central PMCID: PMCPMC3858003.

[371] 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. Epub 2018/02/22. doi: 10.1001/jamapsychiatry.2017.4726. PubMed PMID: 29466531; PubMed Central PMCID: PMCP 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.MC5875308.

[372] 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.

[373] 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.

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. Research has strongly linked depression to poor adherence to ART. 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.[374] Interventions that address both adherence and depression have been shown to improve virological suppression.[375] 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.[376]

[374] 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. doi:10.1007/s12160-013-9559-6.

[375] 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. Epub 2009/02/13. doi: 10.1037/a0012715. PubMed PMID: 19210012; PubMed Central PMCID: PMCPMC2643364.

[376] Effect of Depression on Adherence to Oral PrEP Among Men and Women in East Africa Jennifer Velloza 1, Jared M Baeten 1 2, Jessica Haberer 3, Kenneth Ngure 4 5, Elizabeth Irungu 5, Nelly R Mugo 6, Connie Celum 1 2, Renee Heffron 1, Partners Demonstration Project TeamJ Acquir Immune Defic Syndr 2018 Nov 1;79(3):330-338.

Figure 6.6.11 High rates of psychiatric comorbidities[377,378,379,380]

Psychiatric comorbidity	Literature based prevalence
Substance use	40-74%
Depression	22-61%
Anxiety disorders	2-40%
PTSD	30%
Sleep disturbance	10-50%
Neurocognitive impairment	~50%
Severe mental illness/psychotic illness	0.2-15%

Given the linkage between mental health and poorer HIV-related outcomes, screening for and treatment of mental health and substance use disorders for people accessing HIV prevention or treatment services is warranted Mental health issues are prevalent in key populations and attention to these populations is critical to prevention and treatment success. [381,382,383,384]

A review of screening tools validated for use in low-and-middle income countries identified specific tools for common mental health symptoms, depression, anxiety, PTSD and substance use.[358] Several challenges exist: mental health stigma is a challenge for patients, providers and

[377] Wang et al., 2020. Global prevalence of HIV-associated neurocognitive disorders: a meta-analysis. Neurology, e-pub ahead of print,

[378] Glynn TR, Safren SA, Carrico AW, Mendez NA, Duthely LM, Dale SK, et al. High Levels of Syndemics and Their Association with Adherence, Viral Non-suppression, and Biobehavioral Transmission Risk in Miami, a U.S. City with an HIV/AIDS Epidemic. AIDS and Behavior. 2019;23(11):2956-65. doi: 10.1007/s10461-019-02619-0.

[379] Nedelcovych MT, Manning AA, Semenova S, Gamaldo C, Haughey NJ, Slusher BS. The Psychiatric Impact of HIV. ACS chemical neuroscience. 2017;8(7):1432-4. Epub 2017/05/24. doi: 10.1021/acschemneuro.7b00169. PubMed PMID: 28537385.

[380] Remien RH, Stirratt MJ, Nguyen N, Robbins RN, Pala AN, Mellins CA. Mental health and HIV/AIDS: the need for an integrated response. AIDS (London, England). 2019;33(9):1411-20. Epub 2019/04/06. doi: 10.1097/qad.0000000000002227. PubMed PMID: 30950883; PubMed Central PMCID: PMCPMC6635049.

[381] 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.

[382] 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.

[383] 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. doi: 10.2471/blt.10.082784. PubMed PMID: 21379414; PubMed Central PMCID: PMCPMC3044251.

[384] 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. Epub 2004/06/03. doi: 10.1001/jama.291.21.2581. PubMed PMID: 15173149.

policy makers. Another important barrier is diagnostic: many HIV care settings do not include mental health screening,[359] and therefore clients remain undiagnosed. Other challenges include the fact that there is a global shortage of trained mental health workers,[360] and treatments for mental health often include multiple components and vary based on symptom presentation. The result is that a majority of mental health concerns are untreated in low-and-middle income countries.[361] Mental health training resources in the prevention setting such as within the dreams portfolio and in programming for other vulnerable subpopulations, evidence-based components to promote mental health and quality of life can be integrated into the program to promote engagement and help prevent any deleterious impacts of mental health disorders and help to establish skills for life-long coping and resilience. Peer-delivered mental health services have been shown to be highly effective. Dreams Ambassadors, case managers and other mentors can be trained as mental health coaches to provide support, encouragement, and advocacy to peers for improved mental health.

Testing settings can serve as an entry point to screening for mental health and substance use, to address stigma and ensure that people with mental health conditions have access to voluntary services. Psychosocial interventions should be offered as part of an integrated package of services at the facility and community level in both HIV treatment and prevention settings. HIV prevention, testing, and/or linkage to treatment should be integrated into drug and alcohol treatment settings. Campaigns to increase mental health knowledge and HIV awareness should be implemented to address stigma and discrimination.

To meet the challenge of mental health diagnosis in HIV treatment settings, programs must consider who, when, and how to conduct screenings.[385] Due to the broad prevalence of mental health issues, there may be value to 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 in the resource limited setting by professionals or paraprofessionals.[386] Training on screening and symptom recognition should be provided, these resources may be helpful:

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[385] Reynolds CFR, Patel V. Screening for depression: the global mental health context. World Psychiatry. 2017;16(3):316-7. doi:10.1002/wps.20459.

[386] 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):e0156939-e. doi: 10.1371/journal.pone.0156939. PubMed PMID: 27310297

https://apps.who.int/iris/bitstream/handle/10665/259161/WHO-MSD-MER-17.6-eng.pdf?sequence=1

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, at a minimum, 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;[387,388] further, evidence also suggests that some mental health interventions can also lead to improvements in HIV-related outcomes.[389,390,391] However, scaling up mental health interventions, particularly in resource-limited settings, has proved challenging. Opportunities to leverage faith and other community-based partners, including traditional structures as partners for mental health should be explored, as these structures could provide low-cost models that are accessible within potentially non-stigmatizing, culturally sensitive, and safe environments. 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 specialist, especially general clinicians, social workers, case managers, and community health workers including adherence counselors. 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:

[387] 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.
[388] 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.
[389] 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.
[390] 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.
[391] Sin & DiMatteo. 2014. Depression treatment enhances adherence to antiretroviral therapy: A meta-analysis. Annals of Behavioral Medicine, 47, 259-269.

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 care interventions, where patients receive a different "dose" or type of intervention, depending on their mental health care needs. Alternatively, 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. Trans-diagnostic approaches in which it is recognized that mental health disorders often co-occur and may have a shared underlying pathology. An intervention can be deployed which addresses symptoms across multiple mental health diagnoses (e.g., Common Elements Treatment Approach (CETA).[392] Transdiagnostic approaches may also be extended to address co-occurring psychosocial and structural factors, such as stigma, substance use, and violence.[393]
4. Technology: Telephone and computer-delivered interventions are growing in popularity and can help scale mental health care and support lay counselor interventions. There is strong evidence in high-income countries that telemedicine for mental health is effective,[394,395] evidence for mental health apps more mixed.[396] 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. 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.[397]

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[392] 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

[393] 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.

[394] Bashshur, Shannon, Bashshur, & Yellowlees. (2016). The empirical evidence for telemedicine interventions in mental disorders. *Telemedicine journal and e-Health, 22*, 87-113.

[395] 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.

[396] Weisel, Fuhrmann, Berking, Baumeister, Cuijpers, & Ebert. 2019. Standalone smartphone apps for mental health—A systematic review and meta-analysis. *NPJ Digital Medicine*, 2, 118.

[397] Acharibasam & Wynn. (2018). Telemental health in low- and middle-income countries: A systematic review. *International Journal of Telemedicine and Applications*, 2018, 9602821.

5. Collaborative care: Collaborative care is a model where mental health care is integrated into health care, such as HIV care, and involves collaboration between the HIV care specialist and the individual providing mental health treatment. Measurement-based care may be incorporated into collaborative care models. The model of mental health collaborative care may include a more intensive case management model for PLHIV with significant mental health needs.

Age-appropriate services across the life-span are required. Consideration should be given for subpopulations who present a special challenge including:

1. Adolescents and youth present a special challenge. The first presentation of psychiatric illness often occurs in adolescence and is commonly undetected. This age cohort is at high risk for HIV and for poor adherence to recommended therapy. The services required for this group are different than those needed by older individuals. Service providers, both lay and professional, in the facility and the community should be trained to screen for and provide low-intensity psychological interventions and adherence support should include screening and treatment for mental health conditions 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). OVC programs and youth care and treatment programs are in the unique position to provide screening and referrals for MH services for children, adolescents, and older caregivers through the comprehensive case management services approach and youth case management programs respectively provided in the facilities, community and home-based settings.
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

[37]Naslund, Aschbrenner, Araya, Marsch, Unutzer, Patel, & Bartels. (2017). Digital technology for treating and preventing mental disorders in low-income and middle-income countries: A narrative review of the literature. *Lancet Psychiatry, 4*, 486-500.

[38]Fu, Burger, Arjadi, & Bockting. (2020). Effectiveness of digital psychological interventions for mental health problems in low-income and middle-income countries: A systematic review and meta analysis. *Lancet Psychiatry,* 7, 851-64.

primary partner, depression and anxiety.[398,399,400] Support for disclosure, screening for depression may be helpful and the perinatal period may be an important window for screening for psycho-social issues.

3. Older Adults: Older adults comprise a growing proportion of individuals in HIV treatment programs and may have more difficulty especially if they are sheltered or alone. As with all clients, emotional support can be provided through informal networks (families) and mental health professionals. Simple facts and clear information that can be understood easily by people with and without cognitive impairment are key to improved mental health. Information in clear language with large fonts from multiple trusted sources (family, health care providers, media) with frequent repetition may be necessary. Use of online platforms and messaging apps may not be the preferred method of communication for this group. Personal contact may be needed.
4. PLHIV with comorbidities: Specific circumstances may require mental health interventions. For example: as PEPFAR continues to scale up cervical cancer screening and treatment, more women living with HIV will be found bearing the dual burden of a pre-cancer or cancer diagnosis. Women facing the prospect of treatment (for either removal of a pre-cancerous lesion or advanced cancer care) may experience distress that can become overpowering to their daily lives. Community networks of women living with HIV and cancer support groups can provide support and counseling, usually from peers who can relate directly to the issues these women are facing. When these groups are empowered and connected with agencies like UNAIDS for education and training, it is possible to help change the narrative. In Eswatini, a group of young women living with HIV who have been trained on cervical cancer move through the Kingdom to raise awareness and foster community support for women dealing with cancer diagnoses. Peer networks can help facilitate palliative care modalities to improve mental health outcomes in some settings.

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[398] 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.

[399] 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.

[400] 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.

5. Other psychosocial and structural factors that commonly occur with HIV, such as violence, trauma, and stigma, may also be addressed through mental health interventions. These issues may be disclosed during the course of counseling; however, some recent interventions have directly screened for and addressed these factors, with initial promising results.[401,402]

6.6.8 Optimizing HRH Staffing for Maximum Impact and Sustainability

PEPFAR has long invested in the health and social service workforce in order to rapidly scale up HIV services. The fiscal environments of many countries, particularly constraints imposed by policies, budget decisions, wage bills and hiring freezes that impact the filling of health and social service worker position vacancies, contribute to staffing deficits that limit countries' ability to meet program targets. In addition, PEPFAR's supported models for testing, linking and retaining patients on lifelong ART rely heavily on lay cadres, such as lay counselors, expert clients and community health workers—cadres which are not formally recognized by most countries' Ministry of Health and Public Service Commission (or equivalent). To address these constraints, PEPFAR has heavily invested in hiring large numbers of health, social welfare, community and lay cadres to support provision of HIV services, as well as staff who provide technical assistance across sites to support improved quality and performance of service provision.

Currently, HRH is a significant annual cost driver of PEPFAR's programs, at nearly two billion dollars in COP20. Optimizing this investment can have a significant impact on achieving countries' HIV epidemic control goals. As many countries begin to near epidemic control, PEPFAR must further streamline the HIV health workforce investments, with an eye for efficiency, effectiveness, and sustainability. COVID-19 has exacerbated health and social service workforce challenges and created opportunities for innovation in delivering quality services. Countries should build upon the innovations identified to establish new models of using the health and social service workforce effectively. Countries should also consider what additional HRH requirements and supplies may be needed to continue to safely resume HIV

[401] 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.

[402] Ongeri, Bukusi, Cohen, Neylan, Oyaro, Rota, Otewa, Delucchi, & Meffert. 2016. Interpersonal psychotehrapy for depression and posttraumatic stress disorder among HIV-positive women in Kisumu, Kenya: Study protocol for a randomized controlled trial. Trials, 17, 64.

services in a prolonged COVID response environment. Continued success in achieving, and then maintaining, epidemic control requires that PEPFAR work closely with countries' Ministry of Health, Public Service Commission or equivalent, Ministry of Finance, private sector, and other stakeholders, to address continuing gaps in HRH availability, optimize the use of available HRH for maximum impact, and plan for sustaining the workforce required for maintaining epidemic control.

In planning for COP21, countries should prioritize: 1) ensuring the safety and well-being of the health and social service workforce; 2) further optimizing the health and social service workforce to efficiently and effectively achieve epidemic control; and 3) advancing the sustainability of the health and social service workforce for maintaining epidemic control under local leadership through institutionalized policies and procedures to finance, develop, protect, support and retain the workforce.

Caring for the Caretaker: The COVID 19 pandemic has brought additional challenges to the health and social service workforce in PEPFAR-supported countries. PEPFAR-programs must prioritize the safety and well-being of the workforce, and revive some of the 'care for the caretaker' practices that were essential to supporting the workforce in the early days of the HIV pandemic to support the resilience of the workforce as they face twin pandemics. PEPFAR programs should invest in building health and social service worker resilience to reduce the risk of burnout and preempt longer term mental health effects. Steps to increase resilience can include ensuring a safe working environment to support health care worker physical and mental health. PEPFAR programs should conduct routine wellness checks on the health and social service workers they support, to determine their emotional and physical well-being to maintain responsive services, and should teach skills to increase resilience. Programs should also work to ensure that staff have access to mental health services and encourage staff to utilize the support.

Optimizing HRH: Optimizing the health and social welfare workforce to efficiently and effectively achieve epidemic control requires a data driven approach to health and social service workforce decision-making and management. Two key questions that guide optimization are (1) are health and social service workers appropriately trained to provide equitable and competent care; and (2) is the right skill-mix of workers at the right locations? Countries should actively advance monitoring and realignment of the workforce to meet programmatic objectives. This can be done through the establishment and use of health workforce datasets, and through strong human resource management systems, including:

- *HRH Inventory and HRH Data Use:* HRH Inventories provide a comprehensive dataset to guide HRH analytics to inform requirements and allocation of HRH. HRH Inventories will be a reporting requirement in FY21 Q4 and will be used to understand the entire footprint of PEPFAR-supported staff (including not only service delivery staff, but also those that support non-service delivery activities and technical assistance), their cadre composition, roles and expense, and distribution across SNUs, PSNUs and above-site. In the interim, countries should use available data sources (HODA, WAOT, HRH Needs and Optimization analysis, key MER indicators analyzed against available responsible PEPFAR and other source HRH, other Inventories) to capture current and planned staffing levels, and show how they are optimizing the PEPFAR-supported workforce through redistribution and repurposing to align with program targets, and potentially redistributing budgets and scopes of work where possible/required. Analyses of PEPFAR staffing should include comparison of key MER indicators to the staff responsible for meeting those program targets to assess program priorities and assess impact. For example: addition of expert clients should demonstrate an increase in "net positives" at the site level, and addition of NIMART-trained nurses at a site should demonstrate an increase in TX_NEW and TX_CURR at that particular site.

- *Human Resource Information Systems (HRIS):* National HRH data from Human Resource Information Systems (HRIS) or the equivalent are critical to 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 on both the health and social service workforces 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 the sustainability framework in Section 2.4, investments in HRIS or equivalent are a Core Element critical to ensure the sustainability and transition of PEPFAR-supported HRH.

- *Team-based Care:* Countries should further define and optimize multidisciplinary team-based approaches for case management to support client-specific needs, including retention. Facility-based teams should work closely with CHWs to strengthen linkages to care and to better plan and execute community-based services for KPs, adolescents, men, children and those at risk for defaulting. Lay workers play an important role in differentiated service delivery and should be recognized and sufficiently funded in order to scale DSD models. Further opportunities to provide integrated HIV services should be identified and pursued where they have the potential to yield further efficiency gains and advance client-centered care. 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 and clear referral procedures. Provider workflow and handoff must be monitored over time and regularly realigned for greater efficiency and client-centered care.

- *Quality Service Provision:* Countries should continue to support improvements in the quality of services delivered by health and social service 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. In particular, programs should invest in the capacity of and partner with institutions of higher education for training, and work with professional councils to ensure that pre-service curricula and entry-to-practice exams include HIV competencies and continuing professional development requirements include opportunities for building and maintaining HIV skills.

- *Performance management:* Routine use of HRH data is essential to drive improvements in HRH performance and productivity, including addressing challenges that may have become more problematic during COVID-19. Countries should strengthen approaches for monitoring staff performance and seek to measure the impact of HRH's work on outcomes related to the clinical cascade and provision of quality, client-centered care. Processes for attributing service outcomes to the facility and community-based HRH responsible for delivering the services should be

regularly used for HRH management and decision-making. This is critical for driving improvements and improving accountability.

Sustainability: As described in Sections 2.4 and 6.6.10, sustainability planning is an important priority for all PEPFAR-supported programs, particularly those nearing epidemic control. The health and social service workforce, as a key cost driver of PEPFAR's programs and a critical element of sustained service delivery for maintaining epidemic control, must be an integral consideration when planning for sustainability. The steps for defining and establishing a health and social service workforce that meets workload requirements for HIV services and that host country governments are willing and able to sustain can take several years to complete. Many countries will need to involve other actors, particularly the private sector health workforce, to ensure a comprehensive approach to sustaining the workforce necessary for epidemic control. In addition, the ability for a country to absorb any additional workload or HRH personnel requires availability of financing. COVID-19 has already affected the resource envelope available within countries, with several countries already reporting resource constraints for paying HRH wages, risk allowances, and hiring. Therefore, an understanding of anticipated HRH financing needs is critical for HRH sustainability planning.

- *Institutionalizing Efficient Models:* Optimizing the health workforce, as described above, is a vital component of sustainability planning. Countries nearing epidemic control should conduct a rigorous analysis of workforce requirements to support the essential 'maintenance package' of HIV services. In addition, countries must ensure any training provided is effective and efficient, and equitably distributed so that the right health workers receive the training. Any off-site trainings must be fully justified with clear reasons for the need and associated costs and be evaluated to demonstrate impact. Training programs should be synchronized with GFATM and other donor investments to the maximum extent. Countries should build upon flexible training modalities and technologies that can be rapidly and inexpensively redeployed to address emerging issues, as was done from the onset of the COVID pandemic.
- *Alignment to Host Government Systems:* Alignment of HRH support to host country government systems is key for facilitating the absorption of workers into public sector payrolls that is required for sustained epidemic control. PEPFAR-supported health and social service workers should be employed under terms that are aligned with government-recognized cadres, pay scales and qualifications. PEPFAR should work with IPs to rationalize the roles, responsibilities, pay scales, and qualifications across IPs

and with the government. Plans for HRH absorption should be connected to broader domestic resource mobilization efforts to advance greater shared responsibility for HIV. Alternative types of hiring and remuneration of HRH should be considered (e.g., contracting) to yield a more flexible and resilient workforce and greater efficiencies.

- *Host Government HR Management Capacity:* Strengthened local government human resource management capacity, especially at sub-national levels, is critical to building a more accountable, responsive and resilient workforce for maintaining HIV services and future response needs.
- *Community Health Workers and Lay Cadres:* The critical role of community health workers and lay cadres has been further highlighted during COVID. PEPFAR teams should work with host country governments to identify opportunities for cadres not formally recognized by the government to be formally integrated into countries' employment systems and recognized in accordance with the 2018 "WHO guideline on health policy and system support to optimize community health worker programmes."[1] PEPFAR-supported programs should work with host governments to develop a plan for a rationalized and integrated (including fair remuneration, supervision, training and growth opportunities) community and lay health workforce that can be sustainably maintained once epidemic control is reached.
- *Resource Mobilization and Market Openness:* In addition to working with host country governments on issues pertaining to the public sector workforce, countries should advance use of the private sector workforce through further introduction of market-based solutions and decentralization to expand access to client-centered HIV services (e.g., HIV testing, ART distribution). Investments to improve the quality of services delivered through the private sector should focus on accreditation, accountability and oversight over individual level investments, such as health worker training, in order to maximize the impact of PEPFAR's investment. Countries should also prioritize HRH for co-financing investment to complement PEPFAR investments in country. Countrywide health labor market analyses and linkages to National Health Workforce Accounts can be used as data points to guide investments and policies.
- *Local Organizations:* Strengthening local organizations should be an essential component of developing a sustainable HRH plan. Countries should seek to expand the capacity of local organizations for key HRH responsibilities. HRH training is a prime role for local institutions, particularly institutions of higher learning, to take on. Professional Councils can take on a larger role in in-service training through continuing professional

development tied to re-licensing and can use their regulatory powers over pre-service curricula and entry-to-practice exams to drive the inclusion of HIV training material in pre-service training programs.

6.6.9 Impact-Driven Information Systems and Data Management Investments

Problem Statement

- Disparate data formats and systems in each country are barriers to using data to drive programmatic impact. Data linked from multiple sources are required for improved on-the-ground patient care, and they provide a standardized foundation for surveillance and health care monitoring.
- Most national-scale data in PEPFAR-supported countries are programmatic aggregates and periodic HIV surveys. Where other types of data are available, they are often in disparate systems and formats affecting the overall data quality. The lack of consistently-applied data standards often limits primary and secondary data use.
- The current data and systems environment is a complicated landscape of existing investments/systems. Major investments in data management and information systems remain siloed and that approach increases the challenges of data fragmentation, poor data flow solution duplication, and lack of interoperability leading to challenges in effectively using data.
- There is a need to provide context-specific pathways to enhance data use and system capabilities that document and address issues of data availability, sharing, and governance in country and across a variety of stakeholders with shared interests around improving patient monitoring and program performance.
- PEPFAR and other global stakeholders from donor, technical assistance, and global health initiative organizations, in conjunction with host governments, must collaborate and promote common solutions, standards and principles for data use. Standards will align digital health investments with costed national digital health strategies. Shared principles promote the use of digital global goods and sustainable country capacity.[403]

These problems can best be addressed by fostering information sharing via *peer-learning community approaches*.

[403] Digital Investment Principles. https://digitalinvestmentprinciples.org/

Data Impact Vision

- Where feasible, data should be collected, processed, and analyzed at the individual level to effectively monitor clinical HIV care and treatment outcomes and community-based program performance using a patient-centered or client-centered approach. Above-site information systems investments and clinical service delivery approaches that do not effectively enable person-centered HIV monitoring should be reviewed and revised to reflect this vision. Managing Interruptions in Treatment (IIT, previously Loss to Follow Up), ART continuity, and returning patients to care are critical use cases to support a patient-centered approach to care delivery.
- Working with the broader PEPFAR data use communities, there are opportunities for country teams to make steady and incremental changes around data access and use within and throughout national HIV programs. OU teams should work to foster a culture of secure data sharing across the OU team, inclusive of all USG agencies, relevant ministries, implementing partners, civil society, and beneficiaries as appropriate. OU teams should consider the entire *Data Value Chain* (Figure 6.6.12)[404] and also plan to ensure uptake and impact. Data should be viewed holistically. *Triangulating* data sources provides insight into the current challenges observed in the global HIV epidemic. The use of deduplicated, linked, individual-level client data allows more accurate identification of silent transfers and metrics calculation compared to aggregated, non-deduplicated data. USG OU teams must share all data in the interagency space. This includes *facility-level data* and *individual-level* data from medical records and registries, community health information systems, and other relevant data available in any repository supported directly or indirectly with PEPFAR resources, including but not limited to commodity/supply chain, and human resources for health data. Barriers preventing this level of sharing should be identified and overcome, including potential changes to USG and/or host country government policies and guidelines that ensure data can be linked and shared while maintaining or strengthening *patient confidentiality*, *data security* and *ethical safeguards*. Proper metadata management and curation of local terminologies across the referenced domains (e.g., clinical, community-based programs, supply chain) are integral to the data sharing process.

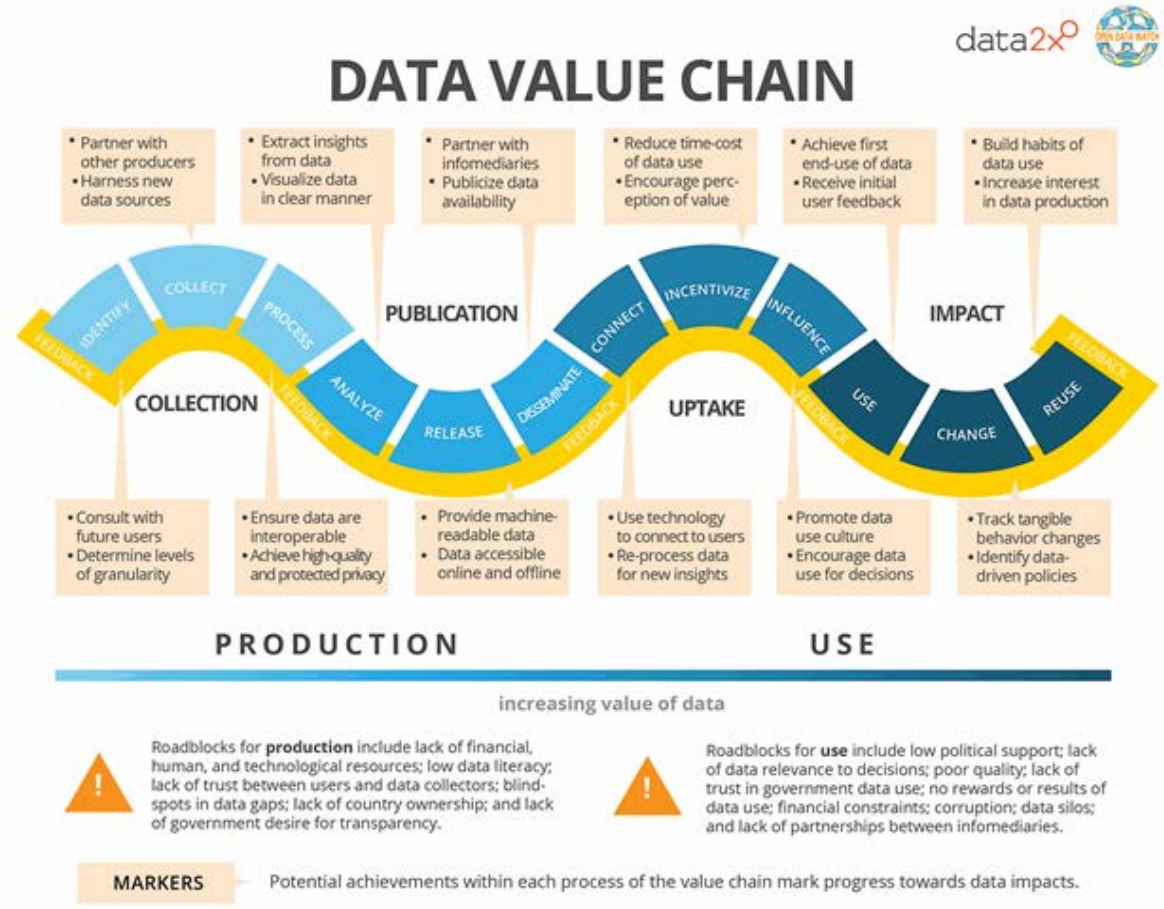
[404] The Data Value Chain: Moving from Production to Impact. https://opendatawatch.com/publications/the-data-value-chain-moving-from-production-to-impact/

- Developing scalable, sustainable, and context-appropriate processes and systems that deliver data that drive impact requires regular engagement of an interdisciplinary group of stakeholders who consider the entire *Data Value Chain* as data management and information systems investments are planned, implemented, and iteratively improved.
- Increasingly sophisticated programmatic questions and other emerging data needs place greater demands on existing data and systems infrastructure and associated support staff. OU teams need to capacitate and/or recruit staff that can manage and guide adoption or adaption of interoperable data or health information exchange concepts across the OU team,[405] promote adoption of the Principles for Digital Development[406] across all data- and systems-related activities, and participate regularly in relevant peer-to-peer learning networks (e.g., Data Use Community). Teams should orient themselves to relevant frameworks[407] available to assist with planning for capacity of various aspects of their digital health infrastructure. Teams should allocate support to the *PEPFAR/Ministry of Health Data Alignment activity*[408] and ensure that lessons learned throughout the activity inform data and systems investment plans. Strategic investments should align with the *Data Value Chain*; continue to track investments in data management and information systems. The World Health Organization's soon-to-be-released (October 7, 2020) *Digital Intervention Implementation Guide* serves as a resource for those considering digital interventions.

[405] Data Interoperability: A Practitioner's Guide to Joining Up Data in the Development Sector: https://unstats.un.org/wiki/display/InteropGuide/Home
[406] Principles for Digital Development: https://digitalprinciples.org
[407] Early Stage Digital Health Assessment Tool: http://www.katicollective.com/what-were-thinking/introducing-the-early-stage-digital-health-assessment-tool
[408] PEPFAR/Ministry of Heath Alignment Activity Overview: https://datim.zendesk.com/hc/en-us/articles/360035139192-PEPFAR-Ministry of Heath-Data-Alignment-Activity-Overview

Figure 6.6.12: Data Value Chain

Supporting and Solving Data and Systems Issues



<u>Peer-to-Peer Learning through a Community of Practice Approach</u>

- Health is an information-centric enterprise. As such, many of the most challenging health issues have embedded complex data management/use challenges that are solved only by those with a firm grasp of the local care delivery context. Within HIV for example, understanding continuity of treatment requires coordination between processes for ongoing appointment management, with others that identify and trace treatment defaulters in clinical and community-based settings, and others that reconcile what actually happened to that patient. Viable data solutions in this complex ecosystem first serve the care delivery process and the coordination between various workers. These solutions can often secondarily generate the information needed to accurately surveil programmatic progress. As a result, in-country, frontline health workers often hold the

best vantage point in effective data system design. If these end-user centric designs can be *coordinated* and *standardized* into best practices, PEPFAR has the potential to accelerate epidemic control.

- 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. A community of practice is a group of people who "share a concern or a passion for something they do and learn how to do it better as they interact regularly."[409] 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.[410] These best practices can be used as the collective voice and wisdom of field experience to influence standards of HIV care and treatment. Decades of experience have shown repeated examples of success of such networks when appropriately supported.[411]
- In 2020, the Data Use Community (DUC) was established as an open community of practice comprising global health field practitioners, researchers, and data systems experts who all come together to share experiences and coalesce best practices around complex health delivery issues such as continuity of ART and interruptions in treatment. This community is endorsed by PEPFAR and a growing number of organizations with the hope of learning from and adapting data systems standards of practice within the global health sphere.

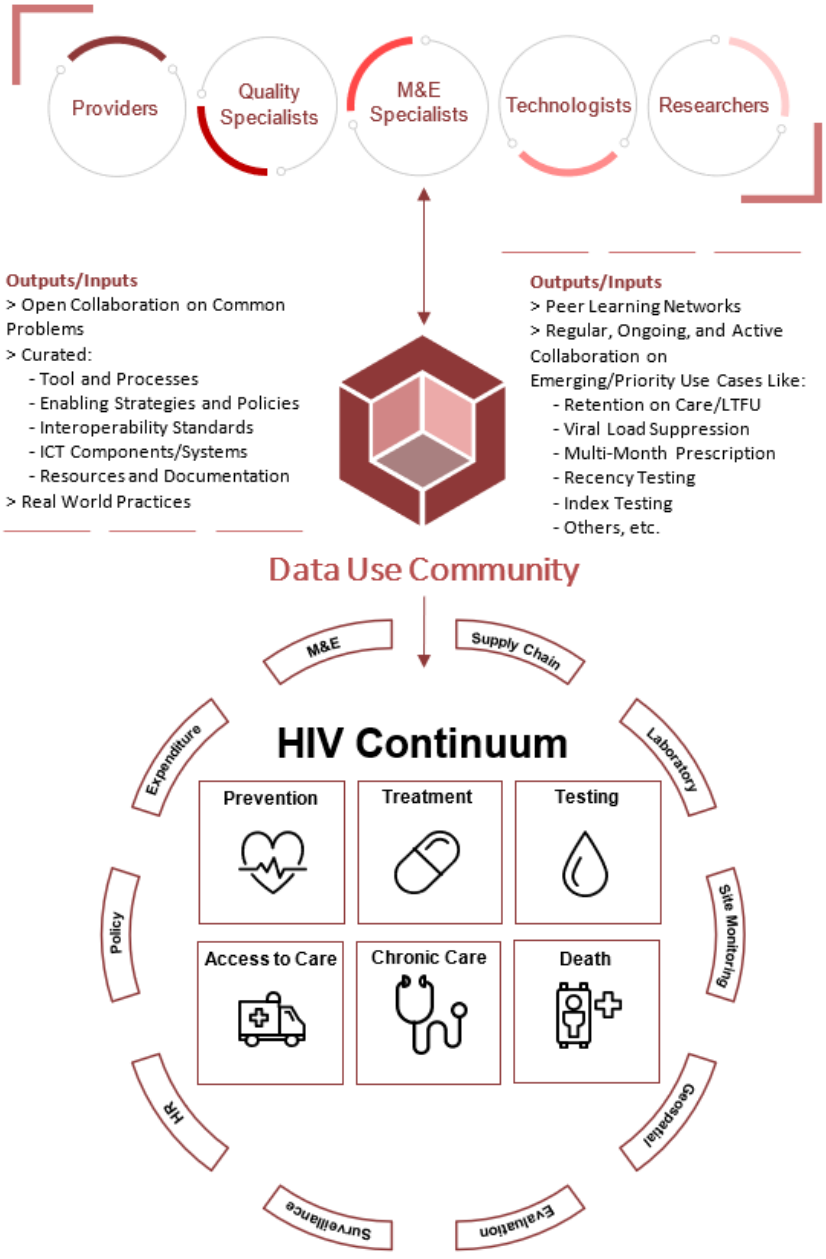
Collaborative Identification of Solutions

- Country teams should establish and/or support multi-stakeholder (Ministry of Health, inter-agency, implementing partners) communities of practice and HIS governance approaches to address PEPFAR programmatic priorities that enable sharing and refining best practices for developing and implementing context-specific solutions that maximize data impact. The DUC will consolidate best practices, drawn from country experience, to a generally applicable and context-specific approach to the priority data use cases

[409] https://hbr.org/2000/01/communities-of-practice-the-organizational-frontier
[410] Wenger, E., Trayner, B., and 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.
[411] Anderson-Carpenter, KD, 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.

identified by the DUC. The DUC complements existing PEPFAR Solutions Platform, providing an opportunity to share and explore data impact solutions in much greater detail from field, programmatic, technical, policy, and integrated perspectives.

Figure 6.6.13: Data Use Community Model



- The initial DUC focus use case is to work with OU teams and field experts to identify data challenges around the management and use of systems to capture individualized data in efforts to improve ART continuity. These priorities will continue to drive the development

of technical approaches to address these challenges. This community approach seeks to maximize peer learning opportunities for those interested in addressing program data impact challenges, like ART Continuity, by using and reusing data more effectively and efficiently. These technical approaches will be provided within a data use and systems maturity framework that OU teams will be able to use to readily understand the applicability of a particular approach in their setting. As depicted in Figure 6.6.13, additional focus use cases along the HIV Continuum will be subsequently incorporated.

The DUC utilizes a three-pronged approach leveraging a) **Communities of Practice:** To develop repeatable community processes with a user-centered perspective to address complex problems by collaborating with subject matter experts, country teams, and other stakeholders; b) **Identifying Solutions:** To collate, document, and develop a reusable methodology with ART continuity and interruption as our first problem statement; and c) A **Strategic Data Vision**: To put the power of data in the hands of every member of the global PEPFAR community, and to enable them to put this data to work in our united effort to reach epidemic control.

- The DUC is supported by a secretariat that facilitates the community in synthesizing findings and developing and sharing actionable technical artifacts. The activities for the DUC secretariat include:
    - Socializing community concepts and on-board and building sub teams, *Impact Squads*, that can take a deep look at specific data collection and management practices and tools that support ART continuity
    - Develop and vet the data systems and use maturity framework, based on the Data Value Chain, with DUC members
    - Harmonize data analytic approaches to address our problem statements
    - Engage exemplar countries and implementers, at different levels within the maturity framework, whose priorities will drive the needs for identification of existing or the development of new technical artifacts
    - Coordinate and contribute to the development of reusable technical artifacts to accelerate digital transformations through routine “Technical Exchange Calls”
    - Orient OU teams to relevant technical artifacts and other digital health assets that can be used to address ART Continuity issues as well as to highlight successful approaches by national programs through Data Use Community meetings

- Maintain shared meeting schedules and minutes and curate relevant tools on a public web-portal

Data Use Community's Future Vision

The Data Use Community will benefit from the shareable- and peer-learning experience in the following ways:

Short-Term Outcomes

- Build out repository of best practices
- Understand the current challenges from in-country colleagues
- Focus activities on strategic priorities
- Reduce operational and architectural silos

Mid-Term Outcomes

- Develop and share new tools and knowledge
- Increase data accuracy and quality
- Improve interoperability
- Increase data reuse

Long-Term Outcomes

- Recommendations for COP planning
- Develop policy recommendations
- Create repeatable problem-solving methodology
- Drive sustainable, cost-effective technical solutions
- Facilitate data use for patient clinical care at point of service

Data Use and Impact Spotlight: Zambia's Innovative Use of Individual Level Data

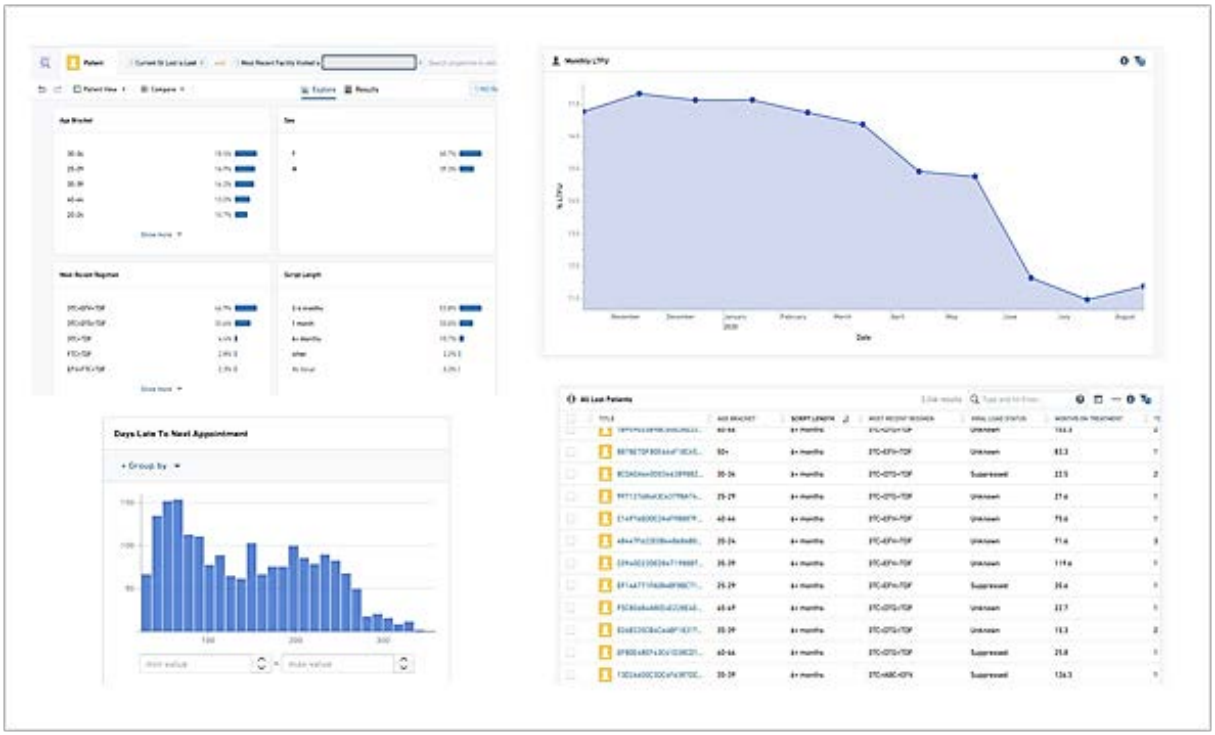
In 2020, the PEPFAR Zambia Interagency team began to use a data management and interoperability platform to monitor and evaluate programmatic decisions. The platform allows Zambia to drill down into many areas of interest including the ability to monitor the scale-up of MMD, compare stock level of TLD 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 quickly and accurately analyze the behavior and clinical outcomes of different patient cohorts, including:

- Accurately track patients lost to follow up by using their missed appointment dates instead of retention 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 LTFU 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 retention rates at more granular levels. They can now accurately categorize patients into buckets and differentiate between new, transfers, late, and many other categories.

Figure 6.6.14: LTFU Patient Cohort Analysis



This level of insight has enabled the Zambia team to confidently assess and improve retention each month at the site level. In the example below (Figure 1), Zambia began transitioning more patients to 6-month MMD in February 2020. see the drop in LTFU % the next month and continued advancing the program. These insights at the patient-level have led to substantial

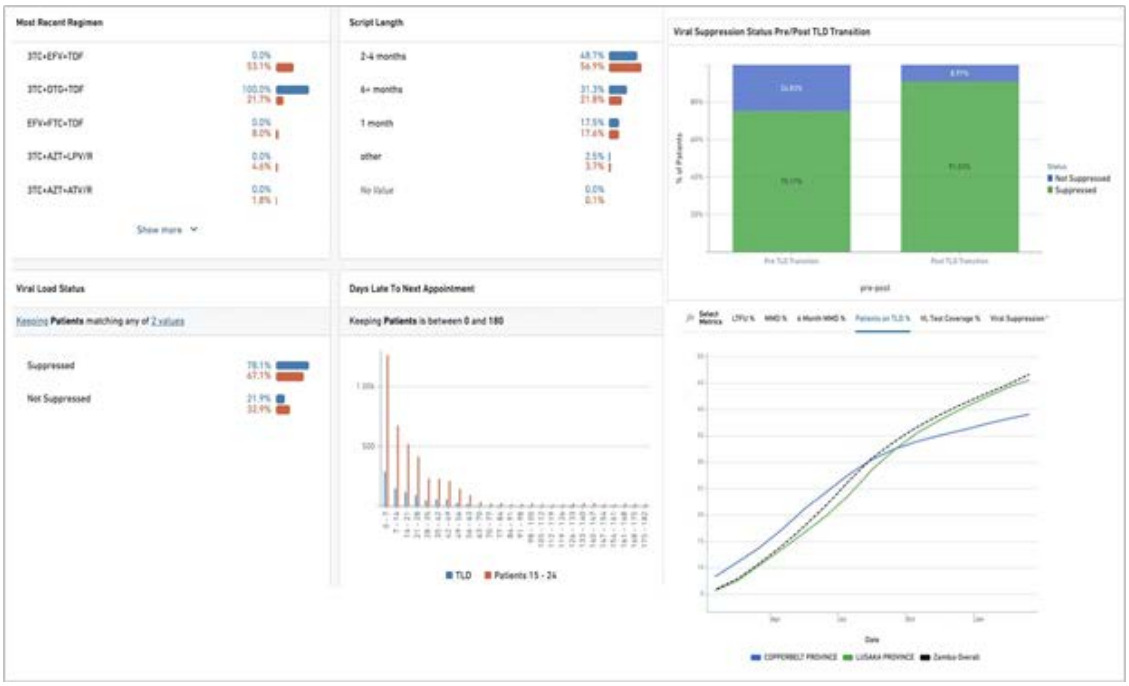
improvements in retention rates every month in 2020, going from 17% in January 2020 to under 11% in July 2020, at this key site.

Cohort analysis allowed for evaluation of TLD regimen transition for pediatrics

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 6.6.15: Cohort Comparison, Pre and Post TLD Regimen Transition



Technical Considerations for Success

- 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.

New in COP21: OU-Specific Data Use Community Work Plans

In FY21, each PEPFAR-supported OU will develop a work plan with their PEPFAR Country Chair and Program Manager that describes the priority areas the country team intends to address through the Data Use Community process. These work plans will align to country needs and to the initial focus areas of the Data Use Community. The minimum work plan requirement for each OU will be to complete an inventory of all USG-supported digital health investments aligned with summary entries of digital health investments entered in the Funding Allocation to Strategy Tool (FAST). These data will be made available broadly within the program and to the maximum extent possible outside of the program via the Digital Health Atlas. Additional details on this requirement will be shared with country teams in forthcoming FAST guidance and later in detailed digital health investment inventory guidance.

The DUC provides the opportunity for capturing in-country learning and experiences to define problems and build standards-based technical approaches that will address interruption in care, bring together community and clinical program data, and advance governance/systems development more holistically. Visit http://ohie.org/duc to engage in the DUC.

Additional References:

- Draft Global Strategy on Digital Health 2020– 2025
- Digital Strategy 2020-2024 [Internet]. Washington DC: U.S. Agency for International Development; 2020 Jun. Available from: https://www.usaid.gov/usaid-digital-strategy
- Guide to developing a national cybersecurity strategy – Strategic engagement in cybersecurity [Internet]. Switzerland: International Telecommunications Union; 2018. Available from: https://www.itu.int/en/myitu/Publications/2020/02/28/15/28/Guide-to-developing-a-national-cybersecurity-strategy---Strategic-engagement-in-cybersecurity

- Health Information Systems Interoperability Maturity Toolkit [Internet]. MEASURE Evaluation; 2019. Available from: https://www.measureevaluation.org/resources/publications/cl-19-034
- Recommendations on Digital Interventions for Health System Strengthening [Internet]. Geneva: World Health Organization; 2019.
- Person-centered HIV Patient Monitoring
- Software Global Goods Valuation Framework [Internet]. Washington (DC): U.S. Agency for International Development; 2019 Dec. Available from: https://www.usaid.gov/cii/software-global-goods-valuation-framework

6.6.9.1 HIV Case Surveillance

HIV case surveillance (CS) is the systematic reporting of diagnosed HIV cases 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 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 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. As countries reach epidemic control, national HIV CS data will become essential for sustaining epidemic control by monitoring trends of new infections, 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 that may be contributing to transmission, 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 Training: Botswana, Burma, Cambodia, DRC, Namibia, Senegal, South Africa, Tanzania, Uganda, Ukraine, Vietnam, Zambia
- Implementation: Ethiopia, Guatemala, Haiti, Honduras, Kenya, Malawi, Rwanda, Vietnam, Zimbabwe

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 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 public health and programmatic response.

In COP21, countries should consider 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 the time of diagnosis (e.g., description of person, time, and place of new HIV diagnoses, clinical status, linkage to ART, 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 when initial name-based reports will be transitioned to more secure unique identifiers and de-identified data, and how this can work with the security and use case needs of the country, need to be made early on in the planning phase.

PEPFAR has supported host-country governments to strengthen routine client-level health information systems (HIS) including electronic medical record systems (EMRs) for effective implementation of HIV prevention, care and treatment programs. An EMR is only one data source pulled into a CS system and should be combined with testing and laboratory data via a national health information exchange architecture aligned with broader use cases such as clinical-community systems data exchange and patient identity management and tracking of services across health service delivery points. These data, which are primarily used at the facility-level to guide clinical management of patients, may be used at the above-site level to establish a CS system. Having client-level HIS infrastructure and health information exchange systems with the ability to uniquely, securely, and confidentially link individual-level patient data to track sentinel events across points of testing, care, clinical monitoring, and treatment sites and deduplicate data is critical to support data collection for CS. This should all be part of the holistic landscape of the Data Impact Vision, Data Value Chain, and Data Use Community workplan as outlined in overarching Section 6.6.9. As OUs invest in these systems, they should not only consider current use and policy, but look forward to envision future uses and possible policies, and make sure they invest in systems that will support sustainable CS now and in the future.

6.6.10 Planning for Sustainable Epidemic Control

6.6.10.1 Essential Areas for Sustainability

Programmatic Components for Sustained Epidemic Control include:

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. All PEPFAR programs are expected to use program data as a surrogate for surveillance and

establish national and subnational surveillance systems as a critical component of long term sustained control. CS includes as well as subsequent report of follow-up sentinel events for that case. As they occur, sentinel events for HIV cases are transmitted nationally as an update to an initial case report, hence allowing the tracking of the individual in the continuum of HIV care. Recent infections surveillance establishes a signal for the first 95, to identify where and among whom recent transmission is occurring, to target the public health and programmatic response.

Information systems need to be robust and implemented across health facilities. As countries move toward sustainable HIV epidemic control, it is critical that host 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 will also be 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 scaled in order to track clients across sites, outcomes, and over time. A need for a comprehensive data linkage system in Botswana led to the development of a comprehensive tool, which can be found on the PEPFAR Solutions Platform. 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. Ability to monitor status of these indicators and respond quickly will form the foundation of epidemic control. In addition, 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 even academic courses should be present in country to ensure skills can be acquired and updated. There should also be laws 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.

Critical above-site programmatic elements include HIV surveillance, supply chain, laboratory, and information systems. Advancing domestic resource mobilization and a total market approach 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.

Supply chain is critical. A functional and effectively governed supply chain system is central to sustainable epidemic control. However, PEPFAR needs to weigh the ongoing comprehensive investment in lab and supply chain (except for commodities) over the past 15 years and the reality of the investment to date versus progress to date. 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. There is need for better inventory management systems to avoid stock outs and interrupted testing. Only countries willing to integrate supply chain and procurement data down to the site with site-level results will be eligible for supply chain funds outside of commodities.

Good governance and leadership are prerequisites for effective and efficient, country-led HIV responses. Good governance is demonstrated by political decisions to align domestic resources, Global Fund, and PEPFAR to advance critical policies and ensure high performance and efficiency of services, in collaboration with UNAIDS. A country that is able to sustainably control its epidemic has appropriate laws, regulations policies and strategic planning processes, based on a culture of decision-making that is informed by data and by 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. See Appendix 10.3 for more guidance on the legal and policy environment.

Orienting service delivery toward patient-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 retain newly diagnosed PLHIV. 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, co-morbidities, 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) and host country governments' 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 host country government systems is key for facilitating absorption of workers required for sustained epidemic control. To advance integrated patient-centered care, HRH staffing will need to be reconfigured toward integrated team-based care and case management.

- **Domestic Resource Mobilization and Total Market Approaches** are key to ensuring programmatic sustainability. As countries move toward epidemic control and long-term maintenance of epidemic control, there will be a greater focus on ensuring domestic resources are available for the HIV response. Domestic resource mobilization (DRM) should include both 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 addition to greater and more efficient use of domestic public resources, the private sector has an important role to play in financing the HIV response (e.g., employee-based health insurance). 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 also 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, adolescent, or key population groups. PEPFAR programs typically do not provide funding to deliver services through the private sector but these can be considered if they are the preferred option and PEPFAR should facilitate communications and partnerships with host governments. 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. In particular, 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. An example of the Total Market Approach from Vietnam can be found on the PEPFAR Solution Platform. 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.

Greater engagement of local partners in implementation of HIV services and above-site functions will facilitate greater shared responsibility for sustainable epidemic control. Building capacity of local partners, including local governments, community, religious, and civil society organizations, is a first step to ensuring that these entities are ready to manage funds directly and deliver quality and high-impact services. Direct funding of community and civil society organizations, initially by donors and ultimately by national governments through formal, transparent, and regular processes for HIV service delivery (sometimes called social contracting), 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 indigenous organizations is a complementary critical step in increasing country capacity for local implementation and ensuring services can be sustained without external partners.

6.6.10.2 Sustainability Planning for HIV Services

Working toward sustainability of PEFPAR funded activities by the countries is not new. Aspects of the program, like blood safety and HIV planning, were successfully transferred to national and local governments over the past several years. More recently, OUs have programmed above-site investments, as included in Table 6 of the SDS, to strengthen and fill the gaps in 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. A short period of transition to domestic responsibility is a risk to sustaining the gains and maintaining epidemic control. While countries may be able to create the form and structure of a modern HIV response, developing a functional system that is adapted to local context and program needs takes much longer.

In order to effectively achieve and sustain epidemic control, country teams will need to use a systematic, multi-year plan to identify a select number of programmatic areas that, over time, can be transitioned, both functionally and fiscally, to governments and other institutions. It is critical that such plans are established and agreed upon in partnership with governments and other institutions to ensure a clear set of roles and responsibilities during the expected time period of capacity building and transition.

This technical consideration lays out the primary goals, planning objectives, and components for a step-by-step process in developing and implementing a sustainability planning roadmap.

The goals of sustainable planning include:

(1) establish a highly functional partnership between PEPFAR and national/local government and institutions to establish an agreed upon pathway to sustainability;

(2) build strong, resilient foundations to support the implementation and management of new activities within the country context, such areas of legal/policy reforms, domestic investments including direct grant/contract funding, social contracting, and others, and establishing an ‘all domestic, total market’ approach to delivering a range of services to diverse communities; and

(3) build capacities of local governments and institutions to begin the transition of PEPFAR supported services including strengthening the management, operations, and contracting capacity; improving the collection and use of strategic information for monitoring and planning; human resource management; identifying innovative financing solutions to support; and utilizing a regulated private sector to maximize the overall efficiency gains on service delivery and related operational activities.

The specific objectives for sustainability planning include:

(1) increase the capacity of host 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 from COP16-20;

(2) create a systematic planning process with specific activities and budgets to operationalize the transition of specific programmatic areas, at the regional and/or national level, based on current levels of ARV coverage and epidemic control;

(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 and intervene when unexpected challenges, barriers or unexpected events arise, and a safety net to protect against losses.

Components and Steps for Developing a Sustainability Planning Roadmap

The process for sustainability planning includes four key elements:

(1) identifying specific PEPFAR supported activities to begin transition, functional and financial, to the host country governments;

(2) understanding the country context in order to identify conditions that either facilitate or impede the successful transition, adoption and execution of the activity;

(3) securing core elements, such as policies or practices, that are necessary to support the activities; and

(4) establishing a high level, multi-year plan with specific activities, roles and responsibilities, and related monitoring procedures.

STEP 1 - Establishing a Sustainability Plan with Governments and Local Institutions

Determine activities and/or technical areas to be included in the multi-year sustainability plan. This step is done in partnership with key government agencies and non-government institutions to gain agreement on types of activities, 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 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 in the near future.

STEP 2 - Understanding the Country Context

An understanding of the country context is essential for informing and influencing decisions related to types of activities to transition, timelines, vulnerabilities in the capacities of the existing public and private health systems, and roles and responsibilities of the key stakeholders for the sustainability plan. The purpose is to identify those conditions that either facilitate or impede the successful transition, adoption and execution of the activity within the existing country health care system. The goal is to ensure that services can be integrated into the existing health system based on the specific characteristics of the country in an efficient and effective manner, as opposed to the adoption of PEPFAR supported activities writ large. What can be adopted and how can these activities be implemented in an effective, efficient and sustainable manner?

Important national and subnational issues to consider include:

1. economic stability and current health budget levels, national and local;
2. political stability and political will to assume responsibility across key ministries, such as the MOH, MOF, and others;
3. likelihood of occurrence of unexpected natural disasters or social events such as environment catastrophes, emerging epidemics, labor strikes, and others;
4. competing health priorities such as NCDs or other infectious diseases; and
5. strengths and weaknesses of the existing health care infrastructure, including service delivery sites, laboratory and pharmaceutical capacity, and human resources – and capacity of non-government actors (including private sector) to support the epidemic control response.

STEP 3 - Securing Core Elements

Prior COP Table 6 investments and SID findings should be used to inform this choice. To ensure effective transition and management of these by local institutions, several ‘core elements’ need to be examined. These elements need to be firmly in place and enduring. For example, host governments are unlikely to assume responsibility for index testing without the necessary guidance/policies, testing capacity, ability to sufficiently stock supplies and test kits, and a sufficient number of adequately trained contract tracers and other human resources. In order to capacitate governments to assume responsibility for testing, PEPFAR teams need to invest in putting in place essential core elements as needed.

An analysis of gaps or weaknesses for each activity or technical area considered for transition to domestic support is needed to determine COP21 areas of investment and capacity building. Previous program reviews, SID and Responsibility Matrix findings, and other reports or

documents on the national or local HIV programs need to be viewed to assess for weaknesses and strength. Additional analysis at the local level may be further needed to justify investments.

Minimum areas of 'Core Elements' for each 'transitioning' activity includes:

1. strategic information for monitoring, managing, and reporting;
2. political will and action to view service/s as an important component of national or local HIV service package;
3. legal and policy frameworks to allow for the delivery of quality services by government and non-government actors and ensure access to such services by the general population and KPs;
4. resource commitments, public and/or private financial and human resource commitments, to allow for an 'all domestic, total market' approach, including the importance of innovative financing strategies; leveraging private sector and other non-government capacity for direct delivery of HIV services, commodity warehousing and distribution, and other epidemic control efforts; and effective public financial management practices.
5. responsible and accountable governance and operations structures and capabilities; and
6. an accessible and functional delivery systems/platform at either the facility and/or community level integrated INTO the existing healthcare delivery system and structures.

The review of core elements should be specific to the activity/technical area that will be transitioned to domestic support. The outcome of the analysis is used to establish the initial year.

STEP 4 - Establishing a Sustainability Planning Roadmap with Annual Activities and Benchmarks

This final step is critical in guiding future resource investments to prepare to shift the mix of programmatic activities and providers from direct to non-direct service delivery and case finding according to the effectiveness in reaching and attaining sustained epidemic control. Optimally, PEPFAR investments to support a fully sustained HIV epidemic should focus on strengthening national and local systems and structures and, most importantly, establishing a national case-based surveillance system, a robust public health response to identify and respond to outbreaks, quality assurance practices to manage clinical and prevention services, and ongoing efforts to increase domestic resources.

Recommendations for sustainability planning roadmaps include:

1. A narrative, with accompanying worksheet or Gantt Chart, of the types of activities that will be transitioned to the government and/or local institutions, roles and responsibilities of key stakeholders, timeline, benchmarks with indicators, and outputs and outcomes. The information can be included in the Appendix of the COP21 SDS and can be used as a monitoring tool by OUs and during POART reviews.
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.
3. A list of policy/regulatory actions that need to be taken to ensure the successful transition, adoption and implementation of these activities. These are likely to be identified as a 'Core Element', as described in Step 3, and provided sufficient support to enact.

6.6.10.3 Human Resources for Health Sustainability Planning

As described in Section 2.4, COP21 provides an opportunity for country teams to establish a systematic, plan to identify a select number of programmatic areas that, over time, can be transitioned, both functionally and fiscally, to governments and other institutions. One programmatic area which may be considered for transitioning over time is health and social service workforce staffing support. The health and social service workforce are a significant PEPFAR investment, and changes due to COVID have presented both opportunities and challenges for sustaining the workforce. This technical consideration presents an example of how a country might use the sustainability process to plan for sustaining the health workforce programmatic element.

STEP 1 - Establishing a Sustainability Plan with Governments and Local Institutions
The first step in sustainability planning is determining the technical areas to be included in a multi-year sustainability plan in partnership with key government agencies and non-governmental institutions. In preparation for stakeholder engagement meetings, countries should evaluate the available data to determine appropriate areas of transition. To evaluate whether human resources is an appropriate programmatic area to focus, countries should look at:

- Several years of health workforce data from the MER indicators (HRH_PRE, HRH_CURR and HRH_STAFF_NAT) and HRH Inventories coupled with host-country data from HRIS and National Health Workforce Accounts. Additional information from

other sources, such as professional councils, may be required. Query the data to determine:

  - What proportion of the workforce is supported through PEPFAR? Are PEPFAR-supported healthcare workers and HIV trained health care workers distributed according to the high risk or prevalence of HIV?
  - Are the workload requirements for an HIV maintenance service delivery package known? Will this workload need to be integrated into broader health worker SOPs? Do provider teams need to be reconfigured?
  - What are the national health workforce gaps? Are workers optimally allocated? Is the private sector being leveraged? Does the government contract providers or services?
  - How has COVID impacted HRH? What are the financial implications of COVID that might affect long-term sustainability planning for HRH? How have HRH configuration changed, and what might be maintained for the long-term?
  - Is the number of health workers produced within the country sufficient, or increasing, to meet demand?
  - Are health workers entering the workforce with the required competencies for HIV service delivery? Are there mechanisms in place, such as professional council requirements for continuing professional development, that will continue to build health worker competencies while they are in practice

- Are health workers given pathways for advancement and does such advancement promote equity and gender equality in practice?
- SID and Responsibility Matrix assessments. When evaluating the SID, pay attention not only to the overall score, but changes in the score over time and the individual elements reflected in the answers to the questions—where is the country's response to the health workforce strong, and what are the critical weaknesses? When evaluating the Responsibility Matrix, consider what proportion of support PEPFAR is providing for the various types of health workers versus other funding sources, as well as who is investing in above-site HRH.
- Several years of Table 6 of the SDS. What HRH investments have been made above-site? How have they addressed gaps impeding service delivery? Which investments have been completed, and how have efforts been sustained by host countries? What investments have been discontinued? What gaps have not been addressed? What is the above-site staffing compared to site level staffing? What proportion of HRH, and

which cadres, have been transitioned to the MOH? Are the Table 6 elements focusing on the key weaknesses identified through analyzing the other data sources?

- Several years of ER and Inventory data. What is the level of health worker investment? What is the ratio of service delivery to above-site staff investment? Triangulate with HRH Inventory data to determine the types of health workers supported and the level of investment for each type and level. (Note that the ER data will incompletely show the HRH investments, as HRH investments are also captured in the subrecipient cost category, which is an aggregate of all sub spending).

After developing a picture of the current state of HRH in the country, convene stakeholder meetings with key government and non-governmental representatives to discuss the findings, alongside the findings from other programmatic areas, to determine whether HRH is an appropriate programmatic area for focusing transition efforts in the near term. The country may still have considerable work to do in order to make transition feasible, but, given that HRH is one of PEPFAR's largest investments, developing a long-term plan for building capacity for sustaining the health workforce response may be a priority for most countries.

If HRH is selected as an area of focus for sustainability planning, agree with the government on priorities and specific areas for domestic transition. In this example, we will assume that government and non-governmental agencies agreed that HRH was a priority for transition, and of specific concern was the large numbers of lay health workers that PEPFAR relies upon to deliver services. In discussion about this issue, the government agreed that the role of many of the lay health workers was critical to sustaining epidemic control, but was unsure of how many would be required, cost implications, and also how the lay workers could be incorporated into the country's staffing structure. The government and non-governmental organizations agreed to work closely with PEPFAR to further define the issue, develop activities and divide roles and responsibilities, and establish a system for monitoring progress.

- Action Point: Having agreed with the government and non-governmental organizations that HRH, and specifically planning for the lay health workforce, was a priority focus area, the PEPFAR country team included a short narrative in the COP21 proposal describing how external stakeholders and host government staff were engaged in the discussion; salient findings in the data about the lay workforce (such as the number; roles; cost; and ratio supported by PEPFAR to those supported through the government,

other donors, or the private sector); and a description of the government and non-governmental organizations' commitment and reservations.

STEP 2 – Further Understanding the Country Context

With an initial agreement to focus on absorption of the role and workload supported by lay workers reached, the next step is to further understand the country context for this issue. In addition to the general data identified in Step 1, the PEPFAR team, in close collaboration with the host government and non-governmental stakeholders, should conduct an in-depth analysis of the country's context in order to determine the conditions that will either facilitate or impede the successful transition and adoption of the lay workforce. Some questions to consider include:

- How stable is the host country's economy, and what are the current health budget levels and resource envelope for HRH? What factors are playing a role in the wage bill—for example, has the IMF imposed constraints on the wage bill? Complement this with a side-by-side analysis of PEPFAR's level of investment in lay workers, broken down by type and function of lay worker, and the host government's lay workers to examine commonalities and gaps.
- What other non-HIV roles and health priorities do country government lay workers support? Will these competing priorities decrease the number of workers available for HIV, or reduce effectiveness? Has the country looked at ways to integrate services delivered by lay workers effectively for efficiency?
- What is the political stability and political will to assume responsibility for any additional lay workers across key ministries? Does the country have policies that recognize the lay workforce? Are lay workers or community health workers recognized as a cadre in the register? Is there an appetite within the Ministry of Finance and Ministry of Public Service to take on additional workers, especially if the number is in the thousands? What standards are in place for their qualifications, remuneration, and capacity building? Are health workers given pathways for advancement, and is advancement gender-equal in practice?
- What is the likelihood of unexpected shocks that may affect the lay workforce, such as natural disasters, emerging epidemics, or labor strikes? How has COVID impacted these workers and their roles?
- What are the strengths and weaknesses of the existing health care infrastructure that the lay workers operate within? Are there mechanisms in place to integrate lay workers into health facilities, including standardized linkages to care? Are lay workers provided

opportunities to continue to improve their skills? What management and monitoring structures are in place to support the quality of services delivered by lay worker?

Questions specific to the programmatic area to transition should be considered as well, particularly those that help ascertain how to best integrate the required HIV workload into the existing health system in an efficient and effective manner based on the specific characteristics of the country. For example:

- Which of the roles and responsibilities that the lay workers support is still needed once epidemic control is reached? Is there a way to streamline the roles and responsibilities in order to reduce the number of lay workers needed? Which roles and responsibilities could conceivably be taken on by other health worker cadres? Is it possible to integrate the key HIV services with other prevention and treatment services?
- Is there opportunity to transition some of the lay workforce to the private-for-profit or not-for-profit sectors rather than entirely to the government? How are private-for-profit and not-for-profit sectors financing their health workforces, and is there opportunity to expand their payrolls to include lay workers, if they are not yet utilizing them?

STEP 3 - Securing Core Elements

With a deeper understanding of the factors affecting the transition the role of lay workers, the country is ready to make a plan for securing the core elements that are necessary for successful transition of the lay workforce. At minimum, the following core elements should be in place based on the needs and requirements outlined in Step 2:

- Strategic information for monitoring, managing and reporting to ensure sustained achievements and quality service delivery (i.e., HRIS, national health workforce accounts, government payroll in place and capturing lay workers, and used for workforce decision-making)
- Political will and action (i.e., Essential policies in place for guiding task-sharing and community health workers)
- Legal and policy frameworks (i.e., legal framework to support utilizing lay workers to deliver quality services in both public and private sector; policy that allows lay workers to deliver services to KPs)
- Resource commitments (i.e., position on compensation of lay/community workers determined; innovative financing strategies in place to fund the required workforce; mechanism for private sector financing and/or employing lay workers)
- Responsible and accountable governance and operations structure

- Appropriate integration of lay workers into its structures (e.g., lay workers operating at the facility and community levels in a way that yields further HIV efficiencies and client-centered HIV services)

An analysis of gaps and weaknesses for each area will help determine areas for investment and capacity building. The country should also analyze what changes PEPFAR can consider in order to prepare for transition. For example, PEPFAR IPs may need to first standardize roles and responsibilities, pay scale and qualification requirements for lay workers to be uniform across IPs and to reflect government and/or private sector's terms.

STEP 4 - Establishing a Planning Roadmap with Annual Activities and Benchmarks

The final step is developing a roadmap that pulls together the analyses and planning from the previous steps to define:

- Which core elements and issues identified in the country context analysis will be addressed through PEPFAR or government investments
- Activities to address the priorities, and roles and responsibilities of key stakeholders. For example, PEPFAR may support the drafting of a policy to allow absorption of lay workers into the government payroll, and the government would take responsibility for ensuring the policy is approved.
- A multi-year timeline for the key activities
- Benchmarks with indicators, outputs and outcomes. For example, first year benchmarks may include drafting and adopting a lay worker policy; and rationalizing PEPFAR's investments in lay workers to ensure uniform roles, responsibilities, remuneration and hiring standards; establishing a MOU with host-country government stakeholders with transition plan terms.

In addition, the PEPFAR team should include the COP21 investments in sustainability in the Table 6 and incorporate any policy or regulatory requirements. Monitoring progress and revising the plan based upon developments on the ground should occur quarterly as part of the POART review. The PEPFAR team should make the data on HRH available to the government and other institutions for health workforce planning and also make the data available to the public and civil society for advocacy purposes.

6.6.10.4 Financing for HIV Services

COVID-19 has resulted 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 be severely constrained. Ensuring the sustainability of programs will need a renewed focus on how PEPFAR can assist governments not just mobilize more resources but how to use these more efficiently and effectively. It is 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 financing approaches and instruments while not losing sight of the traditional health financing support we have always provided to countries.

Traditional Health Financing Approaches

In this section we will address the traditional health financing instruments that we should consider using to increase domestic resource mobilization and optimize resource use

1. **Public Financial Management**

   A starting point is to figure out what percentage of the HIV budget is coming from government contributions and whether this has increased over the years. While doing this assess the percentage of resource available for HIV/AIDS from donors. Governments, private sources, pre-payment schemes and out-of-pocket spending. The Resource alignment work should provide information on government and donor spending and sources such as National Health Accounts of National AIDS Spending Assessments should be a source for information on other sources of financing. Given the data are 2-3 years old or older, country teams should consult with governments to assess the validity of the information. If government budget allocations continue to be low, then we should think of ways in which we can engage with government to increase their spending on HIV. In the post COVID-19 environment it might be equally important to ensure that cuts are not made to current levels of government spending on HIV. Think of specific activities or actions we can support to ensure current levels of government spending 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 and has this improved from previous years. If budget execution is low, then would activities to focus on what support and activities will support improving budget execution. This might be overcoming bottlenecks in things such as commodity procurement, better management of resources.

   Finally, are there specific domestic budget line items for HIV-related commodities, especially ARVs, and/or program interventions (prevention, testing, care and treatment)? Guidance: Review HIV/AIDS government budgets to identify if any specific line items for

HIV commodities and/or programs. If yes, assess the historical and present amount of government contribution to assess the trend and percentage of the budget expended. If no, then focus on activities that would add specific budget line items to ensure greater sustainability of the HIV response.

2. **Improved Collection and Use of Cost Data to drive efficiencies and improve resource allocation**

   S/GAC has made a major commitment to Activity Based Costing and Management as an approach that produces cost data on a routine basis that can be used by managers and policy makers to drive efficiencies and improve resource allocation. The work is currently underway in six countries and we have been able to get UNAIDS, Global Fund, USAID, CDC and others to back this. Consider initiating and institutionalizing ABC/M work in your country.

- Beginning ABC/M approach
    - Has the idea of activity-based costing or cost studies been raised at a country level? Does the mission understand the potential value-add on activity-based costing or cost studies? If more information is needed, reach out to either Michael Ruffner (RuffnerME@state.gov) or Allyala Nandakumar (Nandakumarak@state.gov)
    - Have conversations with government been held to get their buy-in for conducting cost studies and better use of cost data? Is there any support from HQ that can be provided for the dialogue with government?
    - Is there a local partner that can, with support, carry out this activity in country?
    - Develop a plan to initiative and implement ABC/M
- For countries that have already collected cost data of critical services and completed Phase I of the work focus should be on the following for Phase II:
    - Building a more effective data system architecture:
        - What data systems are in place, what are the critical gaps to capture more routine HIV cost data? What is the capacity needs of the data users of the data system architecture to effectively use the data generated from more routine HIV cost data that will improve budgeting, allocation, use, drive efficiencies, and ultimately improve HIV outcomes?

- *Guidance: Identify the critical areas that need to be addressed and develop a plan to carry out capacity building needs/mentoring and any data systems changes that are needed.*

- Using HIV cost data produced:
  - What is the kind of technical support that will be needed to create the capacity within governments to use this data for decision making on how to improve efficiencies?
  - What programmatic shifts within the PEPFAR program are needed that will provide a more efficient HIV program in-country (linked to outcomes)? An analysis of the results from ABC/M cost studies provides a historical context and can help inform the discussion on funding gaps and resource projections.
  - What financial commitments in the short and medium-term can the government make in taking on more fiscal responsibility of their HIV response?
  - What are the non-HIV and HIV cross-subsidies that are occurring with PEPFAR funding? What are the subsidies, how they interact, and what do countries need to be prepared for when PEPFAR transitions or shifts away from supporting the system? For this above-site costs and facility level costs will provide the insights on support PEPFAR investments provide beyond HIV. This information should be available from cost studies such as ABC/M and other studies as well as the Expenditure Alignment work.
  - Where are improvements in quality and efficiencies in service delivery that can be made and how does this influence outcomes? Process maps indicate key areas of quality gaps in HIV service delivery. The information provided in the process maps should be unpacked further and this used to see where quality gaps exist and how to fill these gaps to improve outcomes.

3. Risk pooling/social 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

4. Contracting with private sector

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 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.

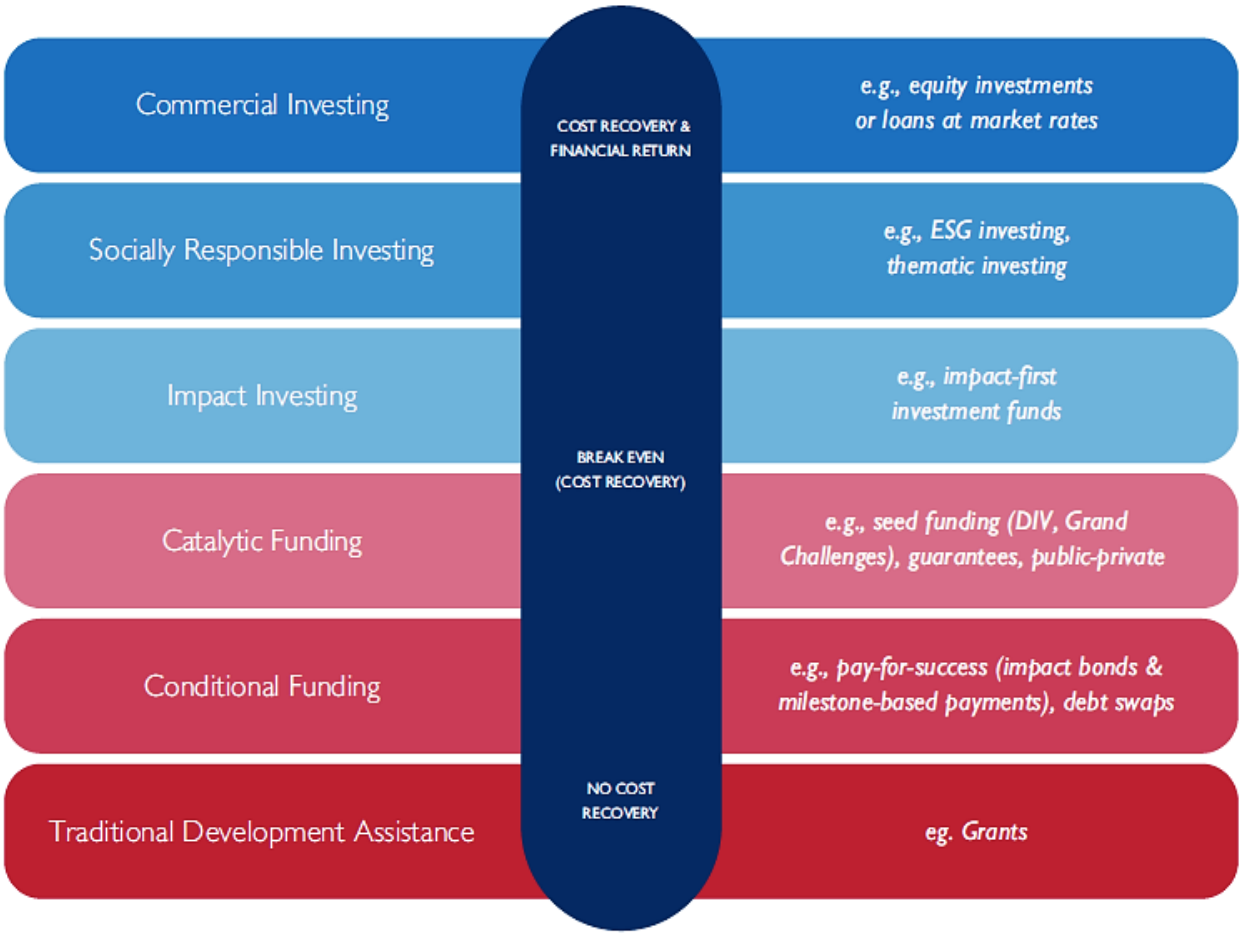
Blended and Innovative Financing Approaches

Innovative financing focuses on OU 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 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

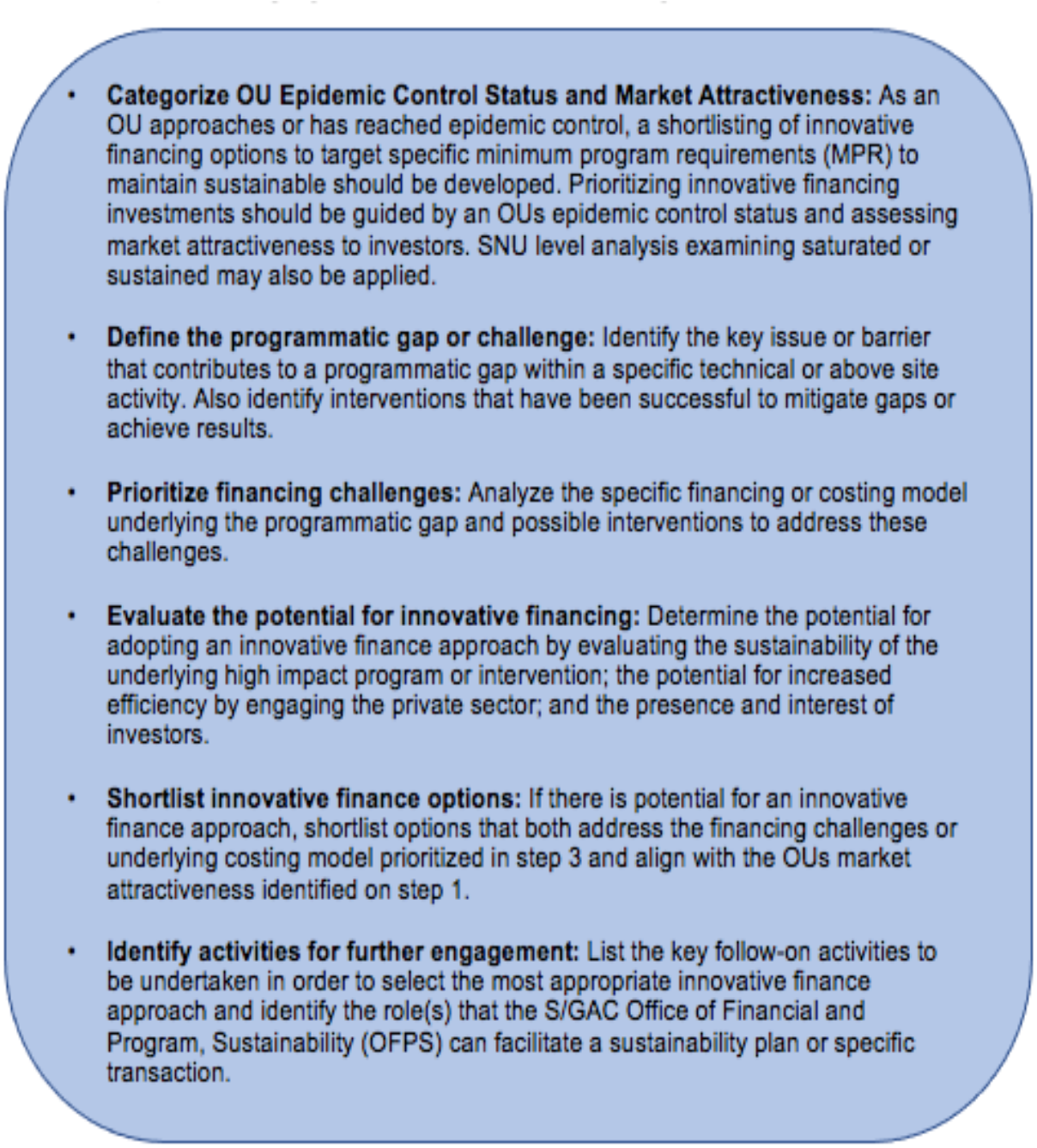
These new resources can catalyze the growth of small and medium-sized enterprises (SME's) in health at the frontlines of the HIV/AIDS response. Furthermore, innovative financing approaches can help incentivize local government partners to address institutional and policy barriers that limit access to affordable capital to expand successful 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 6.6.17). While considering innovative financing mechanisms it will be important to ensure that they conform to existing PEPFAR guidance on their permissibility.

Figure 6.6.16: Portfolio of innovative financing tools & spectrum of cost recovery/return[412]



[412] Referenced from Unleashing Private Capital for Global Heath Innovation, USAID Center for Innovation and Impact

Figure 6.6.17 SNU Roadmap to Engage Innovative Financing to Maintain HIV/AIDS Epidemic Control.[413]



[413] Referenced from Unleashing Private Capital for Global Heath Innovation, USAID Center for Innovation and Impact

Leveraging Innovative Financing to Cultivate New Ideas to Achieve Sustainability

Transitioning an OU 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. OU 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 compliment minimize risk of stockouts. OUs must determine the types of interventions, incremental or breakthrough, where innovative financing investments are feasible and should to 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 base line 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 polices, 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.

Please contact SGAC_Sustainability@state.gov if your team has a specific innovative financing opportunity and would like analytic or negotiation support with potential collaborators.

6.6.10.5 Key Population-Led Civil Society Organizations (KP CSOs) Financing

Introduction

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 locally-led KP 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 and often more effective than other public or private non-KP oriented service settings as well as engagement in health advocacy and planning.

Evidence has shown that the provision of funding resources to CSO initiatives improves the reach and the quality of services provided while enhancing linkages with government services, achieving greater results with fewer financial resources, 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 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*. This document (UNAIDS 2019b) notes that many lessons have been learned since HIV was first recognized as a global public health threat: “One of the common lessons learned in a diversity of geographic, epidemic and cultural settings is that providing a comprehensive set of services tailored by and for the people in greatest need—and removing gender- and human rights-related barriers to service access—is a winning formula that alters HIV epidemics. Reaching large percentages of the people in greatest need requires a community-based and community-led approach.”

Numerous challenges, however, threaten the long-term sustainability of KP CSOs. For example, while donor assistance is expected to be available in the short term, there's a significant probability that donors will reduce their levels of investments in the HIV response in the coming years. Concurrently, as country incomes grow, donor expectation will be for countries to take on more of the financing responsibilities. Additionally, 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.

The purpose of this document is to outline a set of recommendations to guide country teams in planning for a more sustainable KP CSO response. **The goal is to shift from overreliance on donor sources to primarily local public and private sources for the financial and managerial resources necessary for KP CSO operations.**

Financial Sustainability

KP CSO sustainability is highly dependent on a reliable and long-term source of financial support. Generally, there are two specific options, and one blended pathway, that CSOs use to acquire financial support. The first is obtaining direct grants and contracts from public, including government and non-government, or private institutions or organizations, including donors, and the second is 'self-financing' 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 grants and contracts

Grants and contracts, sourced from the government, donor and others, are likely the most common means of financial support among KP CSOs providing HIV services in PEPFAR supported countries. 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, a much larger proportion of HIV prevention and treatment services have primary government support when they are 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.

For CSOs that are able to acquire grants and contracts, several structural elements are essential for their viability, including:

- professional management, grants support, contracting, financial and monitoring staff;
- capacity to successfully submit grant applications; and
- 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 effecting social contracting;
- CSO and KP CSO formation and ongoing operations;
- protections for KPs to access and use services; and
- capable government contract management office.

OPTION 2 - Self-Financing

The second financing option, Self-Financing, relies less on direct government or donor support and more directly on its own capacity to finance services directly. The primary condition of this option is 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' CSOs, the following elements are important:

- professional finance, management, operations, and accounting staff;
- business marketing and sales;
- strategic planning;
- open market opportunities to acquire capital and investments;
- regulatory compliance mechanisms; and
- protections for KPs to access and use services.

In order for these elements to be realized, several key enabling environment factors are necessary:

- a level field for competition; and
- non-discriminatory practices.

OPTION 3 – Blended Financing

The third, and likely optimal, option is a blending of Options 1 and 2. Many of the structural and enabling elements discussed below are essential to actualizing this option. However, challenges

will exist in ensuring the organization has 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 KPs.
- 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.

Building a Sustainable KP CSO

The remainder of this document will describe in greater detail the financial, legal/policy, and organizational capacity considerations essential for the long-term sustainability of KP CSOs.

I. Leveraging Innovative 'Self -Financing' Mechanisms

When donors exit, there is typically no sustainability plan and, instead, there may exist an assumption, or even plan, for governments to assume responsibility for KP programming. Often these efforts fail to materialize. In some cases, however, efforts have been made to establish means for **social contracting or direct reimbursement of services through health insurance mechanisms**. Social contracting is where the government, using public funds,

contracts with a non-governmental organization to deliver specific services. Getting reimbursed for services can be considered a mode of self-financing. Health insurance reimbursements is one method of tapping into national health insurance schemes. However, in general, governments often lack the political will to continue direct contracting for most services, especially those delivered through KP CSO's, and the use of social contracting and health insurance reimbursements relies heavily on political will to serve marginalized groups.

This guidance recommends two alternative financing options, **social enterprises** and **Blended Financing Facility**. Both options reflect a 'Self-Financing' Approach to sustainable financing. As mentioned in the introduction, these can be blended with other financing approaches, such as private or public grants.

Social Enterprises

Social Enterprises are organizations that generate revenue from their activity and services, and as non-profits, reinvest in the enterprise in order to subsidize members of their community who need but cannot afford their services. Social enterprises tap into a community's ability and willingness to pay for services.

There are many variants of social enterprises, from those that purely do HIV prevention and treatment services for members of a distinct community group (e.g., MSM or FSW) using a sliding scale model, to organizations that funds the community's HIV services through providing other goods and services for non-community members. Hybrid models may engage in social contracting or light subsidization from government sources or may partner with private sector businesses. Strategic partnerships with private sector entities or foundations can be used to form win-win joint ventures. For example, a private clinic may be able to supply medical personnel and regulatory clearance while the community provides paying patients and the infrastructure for a KP friendly clinic.

For example, in recent years, many non-profit organizations (NPO's) in the countries of Central and Eastern Europe and Central Asia (CEECA) have witnessed significant changes in the structure of their revenues; the volume of grant financing provided by charitable foundations has been gradually decreasing. Such a development has forced NPO's to search for alternative sources of funding for their programs and projects. NPO's are moving towards significantly more complex financing models, such as crowd-funding, involvement of businesses in charitable projects, and the establishment of social enterprises, amongst others. These activities are reaching a new level and becoming more mature and professional; they are now taking into consideration the interests and particularities of all stakeholders involved in the process.

Information on these programs can be found in web link to the attached report, Alternative Financing: Eurasian Harm Reduction Organization.

https://harmreductioneurasia.org/alternative-financing/

Social enterprises, like any private business, require starting capital in the form of shared community funds, donor grants, outside debt finance, or equity investments. Normal capital markets can be tapped for resources, or CSOs can receive seed capital (as well as technical assistance and training) from donors, international foundations or governments.

Social Enterprises require different skills and training than what most CSOs currently possess. These organizations will need professional management including financial, marketing and legal expertise. Astute market research is required to find and maintain a product that people value.

An enabling environment is also required to allow enterprises to form and deliver services. A basic legal and regulatory open competition framework that does not create artificial or additional barriers to competition is the foundation for development of social enterprises.

To facilitate CSOs to become social enterprises, OUs should consider supporting market analyses, willingness to pay studies, business and strategic planning, and capacity building to CSO staff on financial and strategic management and marketing. These interventions can also be paired with innovative financing that help CSOs access low-interest loans to secure needed capital to build out new service lines or revenue generating ventures.

Blended Financing Facility

A second option is to move away from a singular approach to taking a more holistic portfolio approach. This option reinforces the ability to leverage market-based solutions to support services for KP populations, as well as ensure KP CSO sustainability. While pressure should continue to be put on governments to increase its financing of KP services, it is abundantly clear that a diversification and spreading of risk is essential.

A BFM (Blended Finance Model) is one way to address the problem. A BFM is a single organizational entity created to facilitate the distribution of KP funding to local KP CSOs service providers. The entity combines grant and loan components to leverage donor investments to attract investments from the market in order to design solutions for market failures. In one case from India, an investment of $5 million from donors has led to a commitment of $150 million from various lenders.

Implementing BFM requires:

- Conducting analyses to understand what is impacting the sustainability of KP CSOs, including constraints to market-based solutions.
- Based on the assessment, designing a portfolio of investments that will address the critical HIV prevention and treatment needs of KPs, that can be delivered through KP CSOs.
- Finding ways in which to leverage market-based solutions to address both KP needs as well as KP CSO sustainability.
- Providing technical assistance to KP CSOs to develop and implement sustainability plans and deliver a range of quality services.
- Leveraging market-based financing instruments to make capital at preferential terms available to KP CSOs. The financing instruments will be tailored to address specific problems but can include:
    - Use of donor funds to mitigate risk;
    - Advance market commitments;
    - DCAs;
    - Accounts receivable guarantees;
    - Low-collateral loans;
    - Blended loans;
    - Loan buy downs; and
    - Development Impact Bonds.
- The BFM can also support:
    - Analyses needed to integrate KP services into existing social or private insurance programs;
    - Analyses needed to support payers to decide on options to purchase services; and
    - Design of online platforms to support distribution of commodities such as self-test kits or ARVs.

Finally, it is critical to put in place a governance structure that engenders confidence amongst private investors that the operations will be transparent, focused on achieving results, and that their investments will be well used. While each country will make its own determination of the actual governance structure, it is required that this include representatives from the KP community, government, donor representatives, the lending institutions and others who, due to their standing, will bring credibility to this effort.

Refer to Appendix A for an overview and explanation of the USAID India COVID BFF.

II. Legal/Policy Considerations

Creating sustainable KP CSOs requires a range of laws and policies at various levels – national/local, service delivery, and client level – meant to establish access and use of essential quality HIV services in a timely and efficient manner. The goal is to promote the establishment and ongoing operations of the KP CSO by reducing barriers to the establishment of essential service delivery organizations, providing an even playing field with other government and non-government organizations in the acquisition of public and private financing and human resources and the ongoing operations of the organization, and protecting client's rights to access and use of quality HIV services.

Below, specific questions are highlighted to enhance access to 'Self-Financing' of HIV services. These policies are identified at three levels: national, service delivery, and client, to assist policy makers in addressing potential barriers to the successful establishment and operations of KP-led CSOs, and the effectiveness of these services for addressing KPs HIV-related health and well-being. This is not an exhaustive list and numerous other laws and policies are likely to be identified as part of this review. These are meant to be used as a guide for broad stakeholder discussions, which will include national and local governments and donors such as PEPFAR and GF and KP CSOs, on how to reduce barriers and promote use of effective and efficient service delivery sites.

National and Local Government Laws and Policies

- Does the country or donor laws or policies grant exclusive rights for the government or another local provider to provide HIV services and potentially restricting the provision of any one aspect of HIV prevention, testing, social service, or treatment to KP CSOs?
- Does the country or donor laws or policies establish a license, permit, credentialing, or authorization process as a requirement of operation that restricts KP CSOs from delivering HIV services as either prime contractors or subprime contractors of services?
- Are there country or donor laws, policies, and/or regulations in place which permit KP CSOs to be funded from a government budget for HIV services at the national and local level?
- Does the country or donor have formal channels or opportunities for KP CSOs and groups to engage and provide feedback on its HIV/AIDS policies, programs, and services?

Service Delivery Level Laws and Policies

- Does the country or donor have laws and/or policies that present barriers for KP CSOs to the delivery of HIV prevention, testing, social services, and treatments services?
- Does the country or donor laws or policies limit the ability of specific licensed HIV service providers, or otherwise recognized health care workers such as community health workers, to provide certain HIV services by KP CSOs?
- Do KP CSOs face higher start up or ongoing maintenance costs compared to government or non KP CSOs facilities to funds such as lack of access to funds, higher accreditation or licensing fees or requirements, prohibitive contracting costs or accounting measures, and others?
- Does the country or donor policies create geographic barriers for KP CSOs to supply goods, services or labor, or invest in capital?
- Does the country or donor policies limit the freedom of KP CSOs to advertise or promote HIV services either online, over TV or radio, or in public spaces?

Client Level Laws and Policies

- Does the country or donor have laws in place that specify protections for Key Populations for accessing health services, including HIV services.
- Does the country or donor have laws and/or policies that present barriers to the delivery of HIV prevention, testing and treatments services by KPs such a criminalization of certain KP groups or specific types of sexual or HIV risk related practices?
- Does the country or donor policies, and the enforcement of those polices, ensure access to the same quality standards of services as delivered by the KP CSOs, and are KP specific related services included in these standards of care?
- Recognizing the right to nondiscriminatory access to HIV services and support, does the country or donor have efforts in place to educate and ensure that the rights of KPs and those that need to access HIV services about their rights?
- Does the country or donor policies raise the cost-of-service provision for clients of KP CSOs, either as direct out of pocket payment or lack of coverage through social contracting and insurance mechanisms, as compared to government and/or non KP CSO providers?

III. Organizational Capacity - Management, Governance & Operations

Civil Society Organizations (CSO) have been demonstrated to be highly effective at providing targeted health services to key populations (KP), but their sustained success depends upon having effective leadership and governance. With poor leadership and governance, CSOs will fail

to meet the expectations of their constituents and other stakeholders, and will struggle to maintain long-term sustainability. How the organization functions and is managed, especially in response to change, the level of financial sustainability, and the ability to consistently deliver quality services will determine both how effective the CSO is at achieving its mission, and its longevity.

The following subsections, Governance and Management and Operations, highlight essential organizational capacities or structures necessary for the success of an organization in meeting its goals in delivering quality HIV prevention and treatment services. Although these areas are general to all CSOs, there will be a need to customize them to ensure sensitivity and accountability to the KP clients.

Governance

Strategy and Mission: Does the CSO have a strategic plan that clearly describes how it serves KPs? A clear and cohesive strategic plan facilitates success in both activities and mission, and helps the CSO focus on core competencies to avoid mission creep even as the CSO diversifies funding sources and mechanism. A clear Mission statement which describes the long-term development vision, coupled with objectives and role Missions and strategic plans should be informed by careful research.

Governing Body: Does the CSO have a board of directors composed of individuals with a clear understanding of the idiosyncrasies of sustaining a CSO focused on KPs? Establishing a governing body is foundational to transparency. CSOs should have a board of directors, with a charter and clearly communicated organizational structure and process for exercising oversight.

Legal Status: Is the CSO legally established and following regulations for provision of services to KPs? Formal structures, including ensuring the CSO is legally established, registered and in compliance with legal or regulatory requirements establishes credibility and ensures CSOs can access diverse funding sources.

Constituency: Has the CSO clearly identified the KPs that they serve, and established mechanisms for involving KPs? CSOs should have a clearly identified constituency, and have formalized mechanisms to allow constituents to participate in planning for service provision, feedback and evaluation.

Coordination: Poor or disorganized networking can cause duplicated efforts, time inefficiencies, conflicting strategies and an inability to learn from experience. CSOs should build strong links within the KP CSO community, and belong to associations, networks or umbrella

groups. Organizing across CSOs allows greater advocacy around KPs and can help in creating an enabling environment to allow better representation of KPs.

Credibility: Is the CSO seen as a credible service provider for KPs? Building the credibility of the CSO supports steady growth and sustainability. Subscribing to a code of conduct or ethics code, as well as being transparent about funding sources and reporting decisions made by the governing board builds the confidence of stakeholders.

Accountability for Quality Services: CSOs delivering services to KPs must make quality one of the cornerstones of their strategy. CSOs should set up structures to monitor quality of service delivery to ensure that services are delivered in line with national guidelines and standards, as well as local and international best practices. At minimum, KP CSOs should have:

- Data driven Continuous Quality Improvement (CQI) approach
- Client confidentiality strictly required for all services
- Clear, defined system of accountability to ensure patients can report problems
- Mechanism for regular anonymous feedback

Management and Operations

Leadership and Staffing: CSOs should establish accountable, adaptable leadership, and ensure that all staff and volunteers have clarity around their roles in the organization.

Administration: To support service delivery, CSOs require adequate physical and logistical infrastructure. CSOs should establish standard procurement processes, and plan for regular maintenance.

Financial Management: Long-term sustainability requires strong financial systems, including:

- A regular budget cycle
- Written procedures for the authority and responsibility, monitoring and accountability of handling funds
- Operating budgets and financial reports
- A competent accounting system
- Bank account with regular statements and system for physical security of advances, cash and records
- Audited financial statements

Planning and Reporting: Regardless of the funding source, KP CSOs should have structures for planning and reporting, including a process for translating strategic planning into operational

activities, a regular review process for programs, and a mechanism for including the viewpoint of beneficiaries in design and review of programming. Indicators and benchmarks should be used for objective measurement of progress.

Marketing: For KP CSOs seeking to diversify their funding sources, a strong marketing protocol is essential. Effective business and social marketing plans should incorporate research, market analysis, market segmentation, marketing mix, brand positioning, communication and monitoring and evaluation.

For an example of a KP CSO organizational capacity assessment, please visit: https://www.healthpolicyproject.com/pubs/462_SIDChecklistfillableinreader.pdf

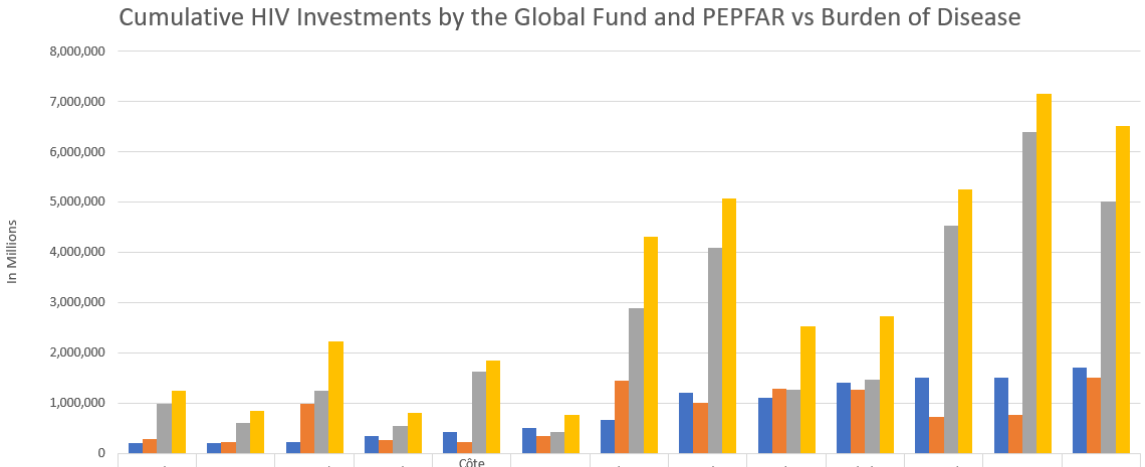
Summary

KP CSO sustainability is highly dependent on a reliable and long-term source of financial support. The document includes several key elements to promote the sustainability of CSOs through innovative financing approaches and describes the various governance and law/policy conditions that are required to support the sustainable application of such financing approaches.

6.6.11 Analysis of Country Performance

Trends in Investment

Figure 6.6.18: Cumulative HIV Investments by Global Fund and PEPFAR vs Burden of Disease



	Namibia	Eswatini	Rwanda	Lesotho	Côte d'Ivoire	Cameroon	Ethiopia	Zambia	Malawi	Zimbabwe	Uganda	Kenya	Tanzania
PLHIV	210,000	200,000	230,000	340,000	430,000	510,000	670,000	1,200,000	1,100,000	1,400,000	1,500,000	1,500,000	1,700,000
GF x $1000	$273,113	$223,244	$987,463	$265,480	$222,218	$344,811	$1,435,000	$996,961	$1,276,246	$1,263,897	$716,011	$760,138	$1,506,117
PEPFAR x $1000	$978,070	$611,316	$1,243,798	$544,033	$1,627,255	$417,676	$2,883,487	$4,081,294	$1,259,040	$1,462,948	$4,539,238	$6,393,931	$5,013,046
Total x $1000	$1,251,183	$834,560	$2,231,261	$809,513	$1,849,472	$762,487	$4,318,487	$5,078,255	$2,535,286	$2,726,845	$5,255,249	$7,154,069	$6,519,162

Figure 6.6.19: GDP Growth (Pre- and Post-COVID-19) and HIV Prevalence

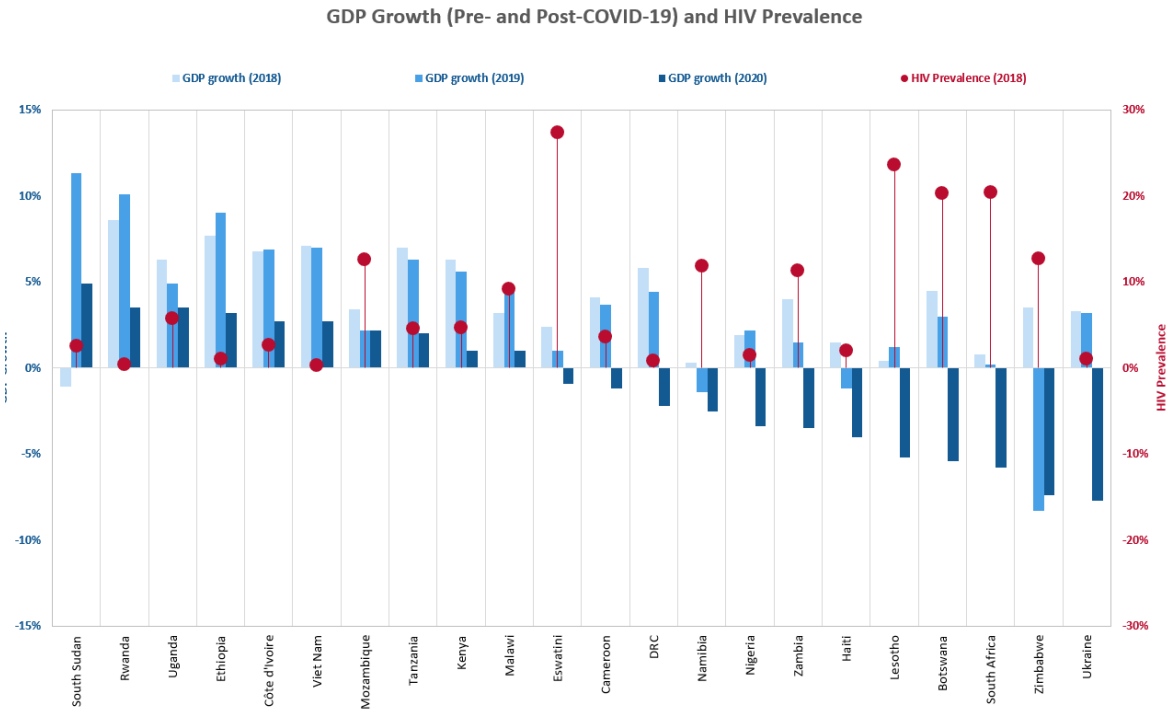
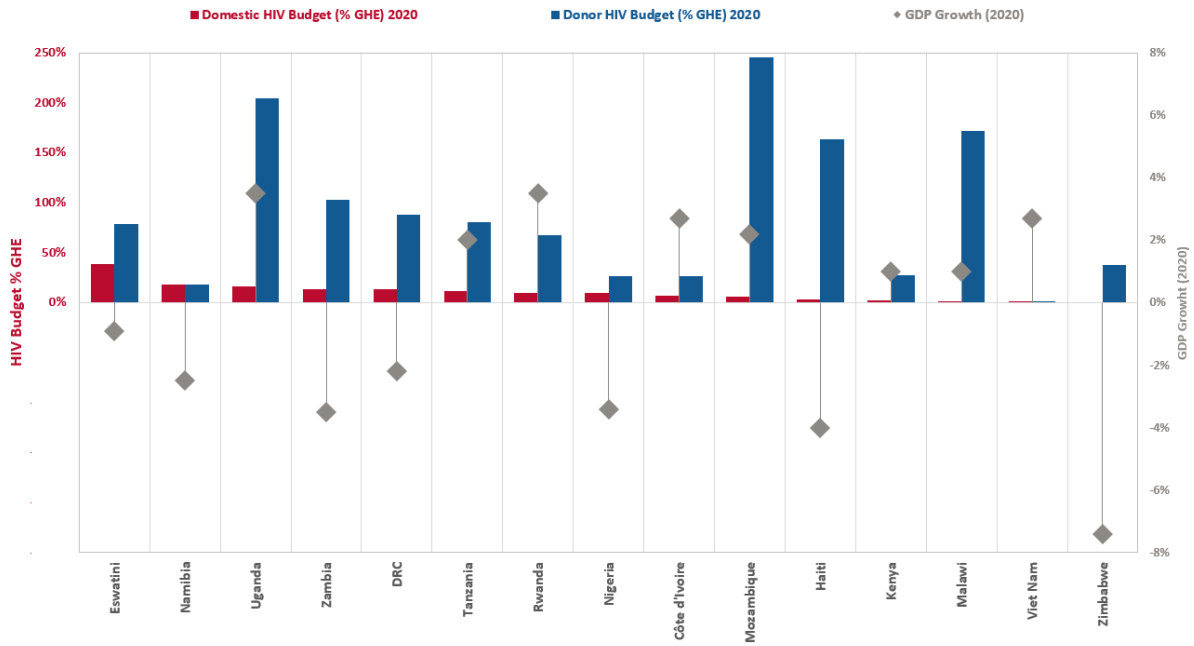


Figure 6.6.20: Domestic Govt and International Donor HIV Investments as % of Govt Health Expenditure and Projected GDP Growth



Trends in Epidemiology

Figure 6.6.21: Index Testing Cascade for Adults over 15 years of age – Countries A-I

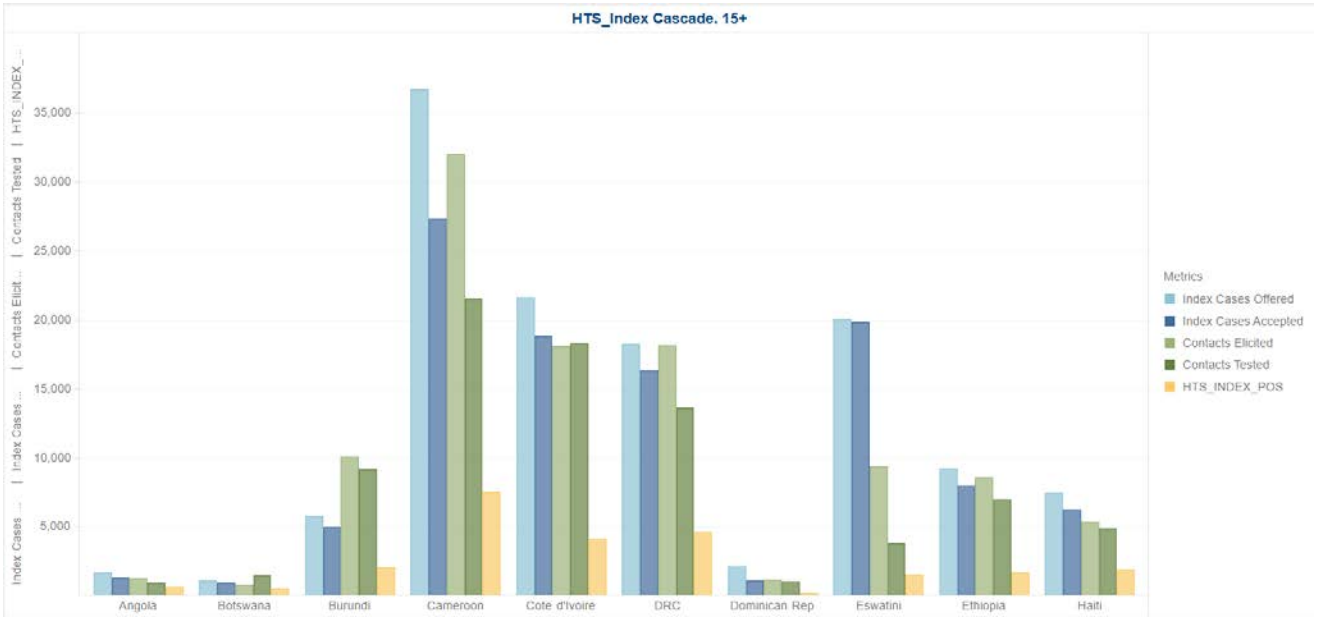


Figure 6.6.22: Index Testing Cascade for Adults over 15 years of age – Countries K-Z

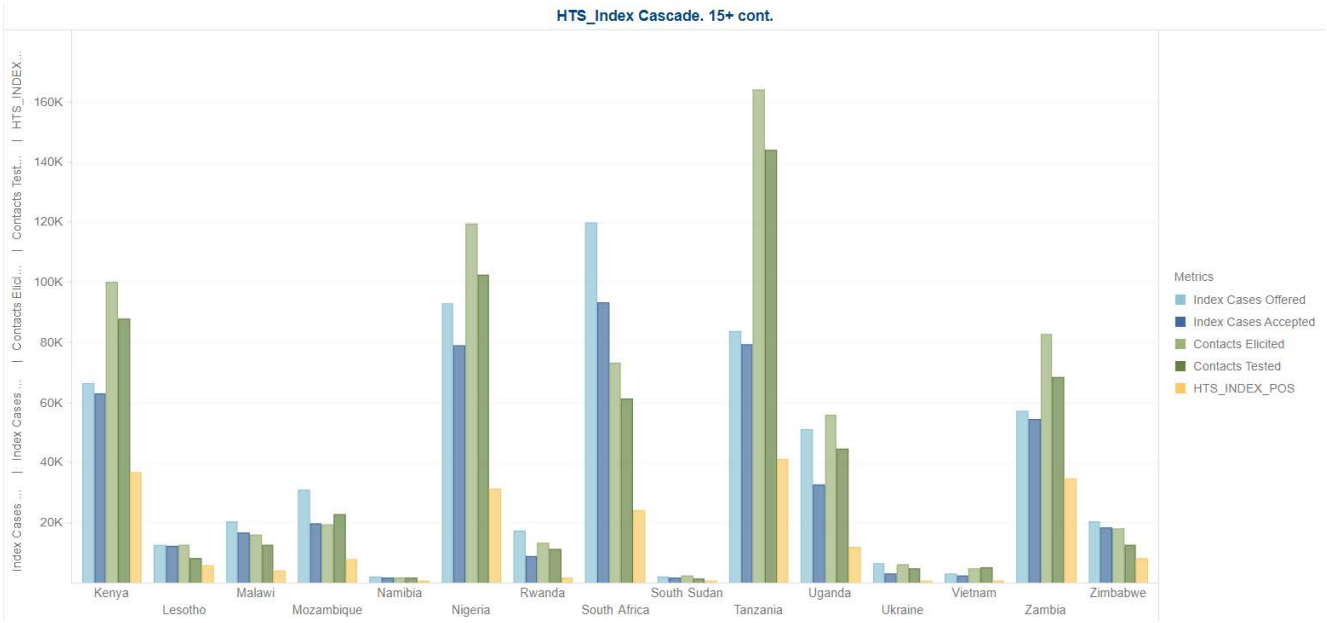
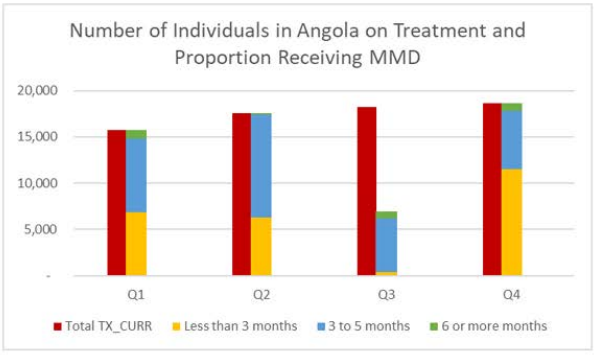


Figure 6.6.23: Individuals in Angola and Asia Region on ART and Proportion Receiving MMD



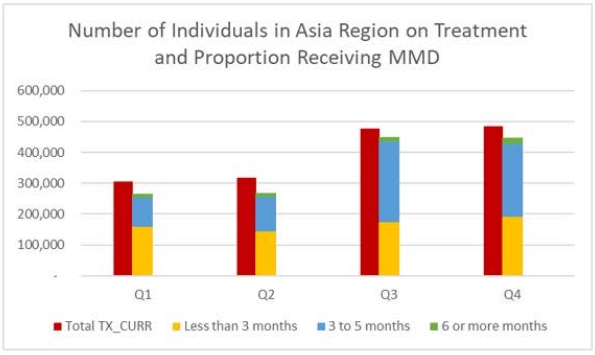
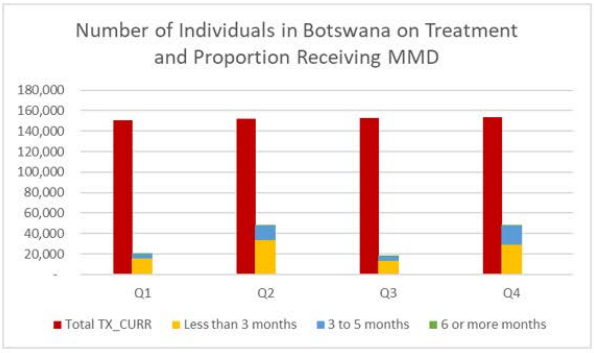


Figure 6.6.24: Individuals in Botswana and Burundi on ART and Proportion Receiving MMD



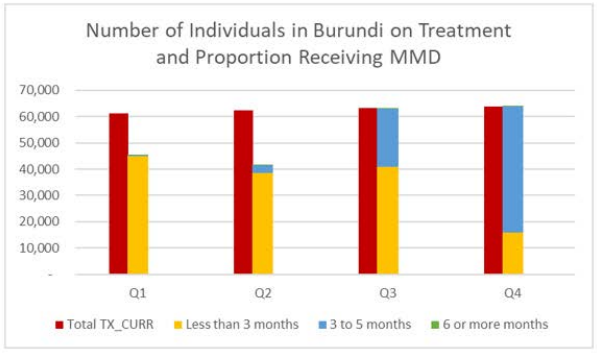
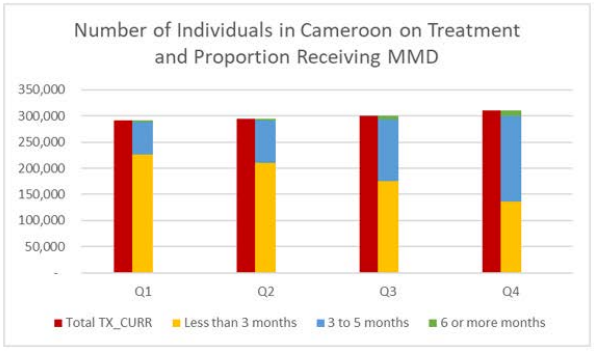


Figure 6.6.25: Individuals in Cameroon and Cote d'Ivoire on ART and Proportion Receiving MMD



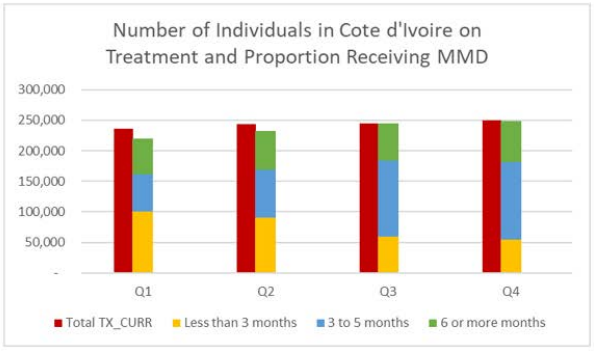
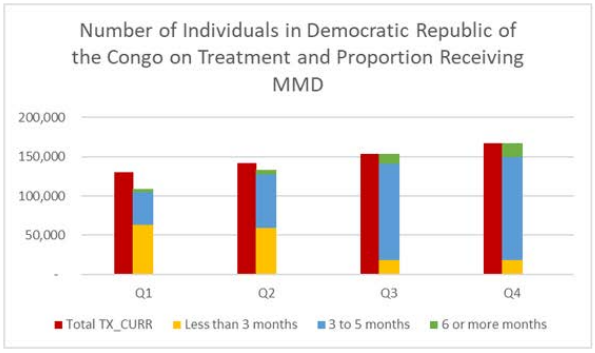


Figure 6.6.26: Individuals in DRC and Dominican Republic on ART and Proportion Receiving MMD



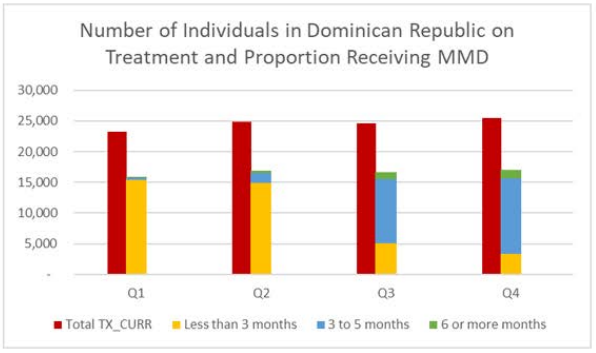
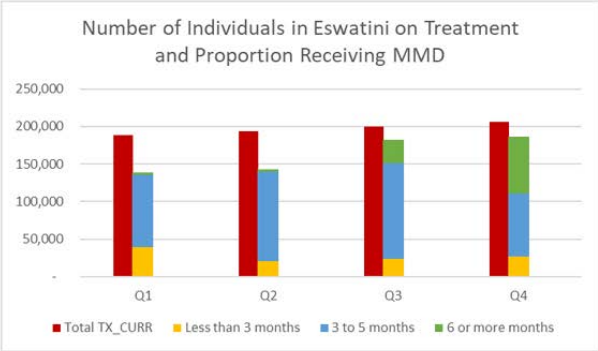


Figure 6.6.27: Individuals in Eswatini and Ethiopia on ART and Proportion Receiving MMD



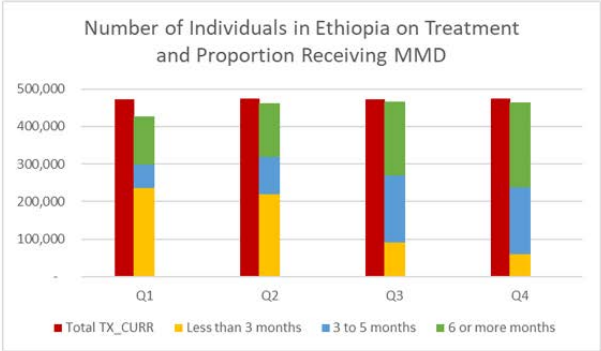
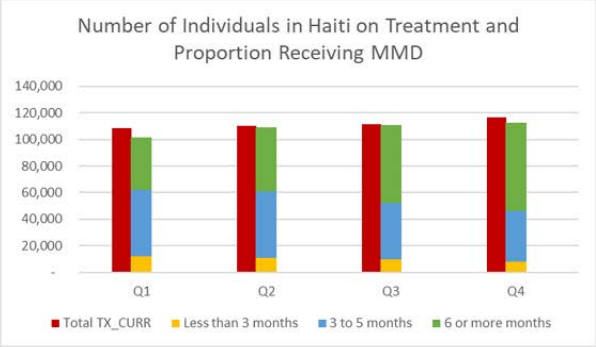


Figure 6.6.28: Individuals in Haiti and Kenya on ART and Proportion Receiving MMD



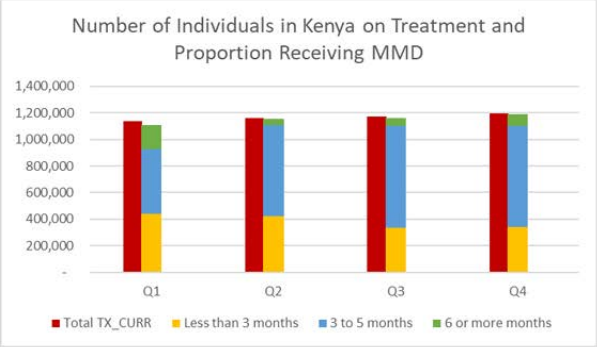
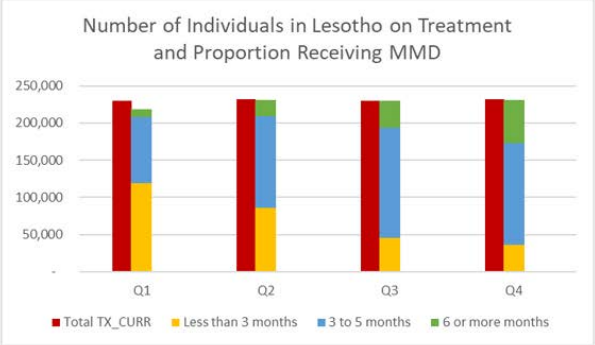


Figure 6.6.29: Individuals in Lesotho and Malawi on ART and Proportion Receiving MMD



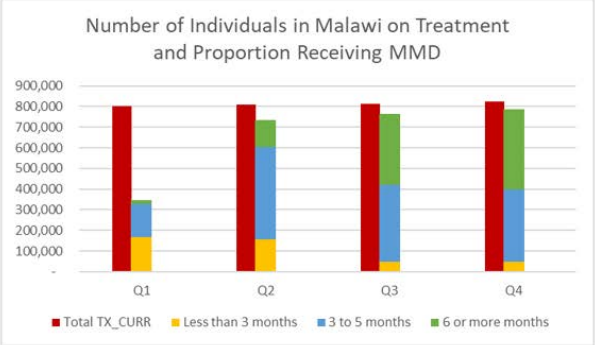
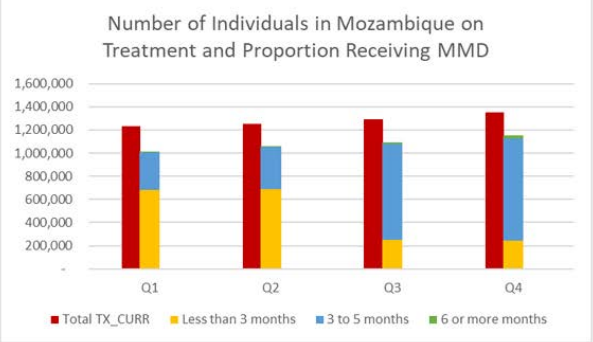


Figure 6.6.30: Individuals in Mozambique and Namibia on ART and Proportion Receiving MMD



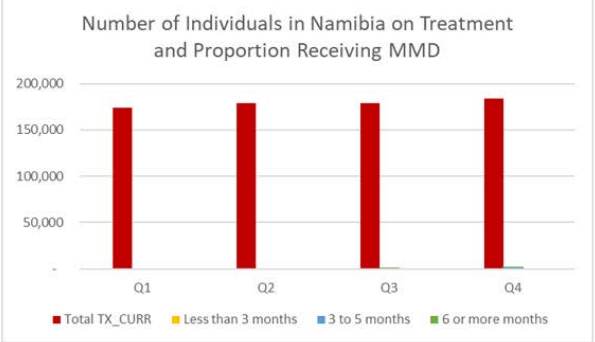
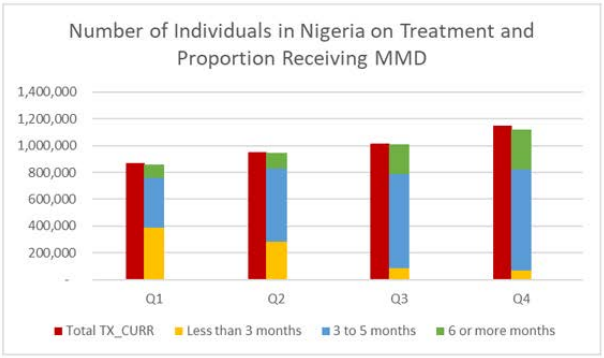


Figure 6.6.31: Individuals in Nigeria and Rwanda on ART and Proportion Receiving MMD



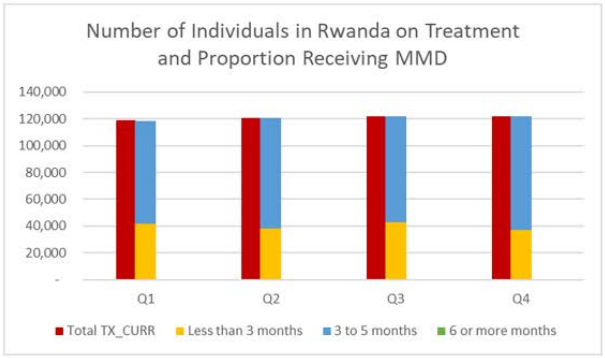
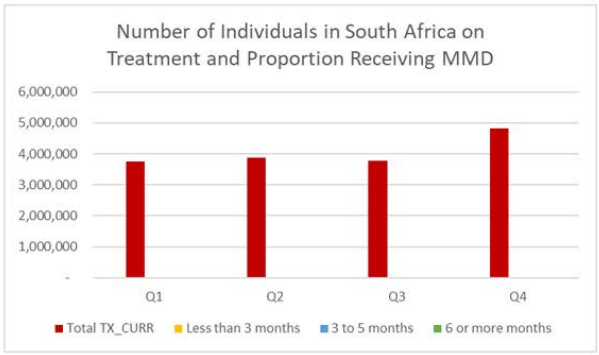


Figure 6.6.32: Individuals in South Africa and South Sudan on ART and Proportion Receiving MMD



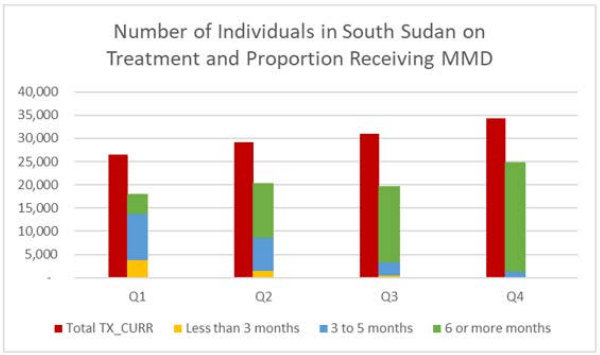
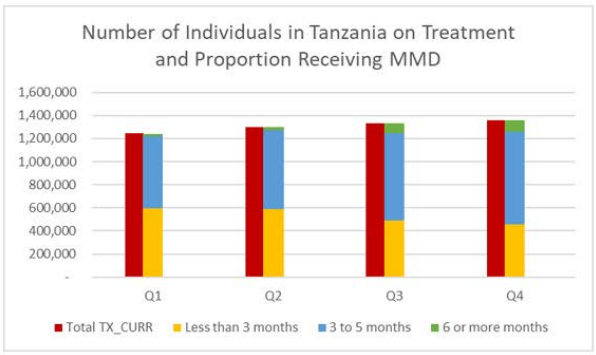


Figure 6.6.33: Individuals in Tanzania and Uganda on ART and Proportion Receiving MMD



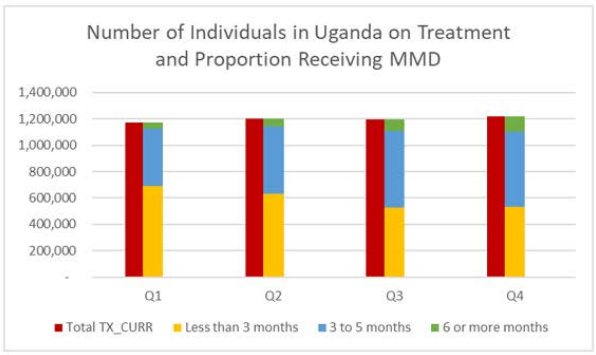
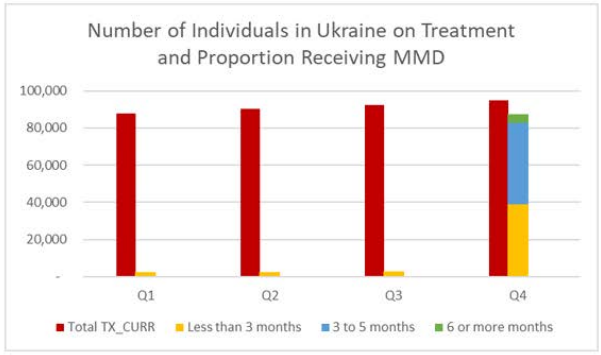


Figure 6.6.34: Individuals in Ukraine and Vietnam on ART and Proportion Receiving MMD



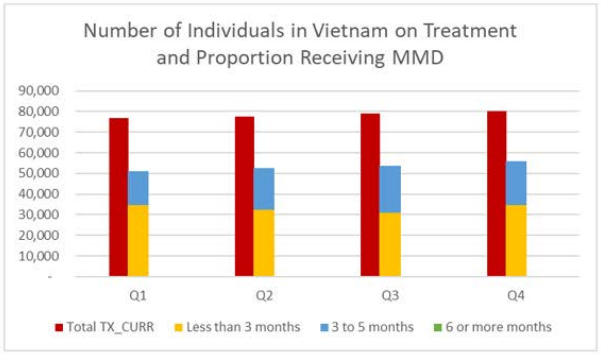
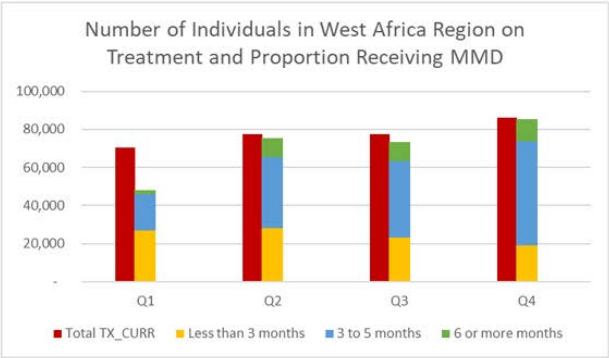


Figure 6.6.35: Individuals in West Africa Region and Western Hemisphere Region on ART and Proportion Receiving MMD



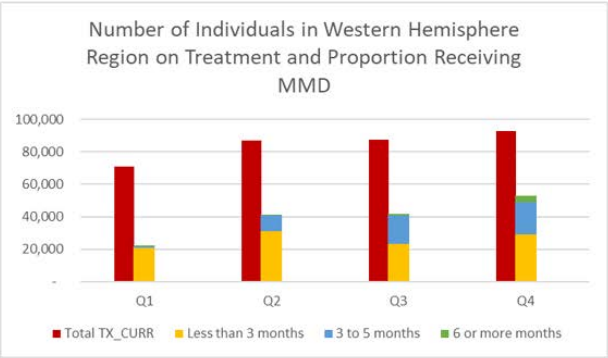
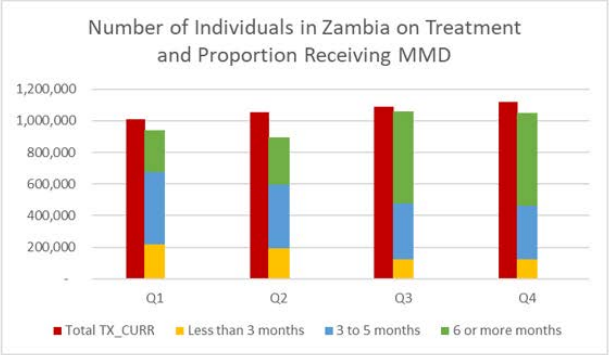
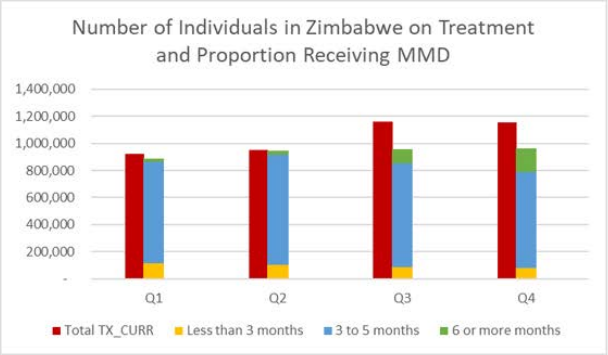


Figure 6.6.36: Individuals in Zambia and Zimbabwe on ART and Proportion Receiving MMD





6.7 Site Safety

PEPFAR is committed to providing prevention and treatment services safely, and the COVID-19 pandemic has highlighted the need to focus attention on site safety. Transmission of COVID-19 in the health care setting is preventable and the following expanded section on infection prevention and control has information on the prevention of all respiratory diseases. VMMC and cervical cancer screening programs have expanded, and this section consolidates guidance on cleaning, disinfection and sterilization. Finally, health care workers are at risk of contracting infectious diseases as well as transmitting them, the new section on occupational health provides some information on best practices.

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. All program systems investments should include provisions for infection prevention including administrative, environmental and personal IPC

protections. Well-conceived and carefully implemented infection prevention programs reduce illness, prevent death, improve continuity of services, and save money. Active support of infection prevention and control activities fosters a culture of safety in the health care setting.

WHO has outlined the minimum IPC requirements for facilities and national levels.[414] 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). Functions of the IPC Focal Person or Committee include regularly reviewing and implementing national IPC guidelines; 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; monitoring key IPC indicators such as hand hygiene compliance, injection safety, and respiratory hygiene for TB and COVID-19; and ensuring safe waste management.

Other essential minimum requirements include the presence of standard operating procedures (SOPs), IPC training for frontline staff, and multimodal prevention strategies such as continuous quality improvement (CQI) for priority IPC issues. Maintenance of proper staffing, bed occupancy, and physical environment are also critical components to enable effective IPC in a facility. 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. All programs are encouraged to review or assess facility level progress toward meeting these minimum requirements, and to identify key areas for improvement.

The following are definitions and descriptions of key IPC terms:

Administrative and environmental controls: 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.

Environmental controls are the physical modifications that may be used to reduce risk. Examples include open window policies, conduction of some activities outside, and a transparent glass or plastic barrier at triage stations.

[414] WHO 2019 https://www.who.int/infection-prevention/publications/core-components/en/

Facility-level administrative and environmental control measures should be prioritized.

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 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. 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 infection control (IC) including dedicated personnel, were unlikely to have established policies and procedures for isolation, hand hygiene, respiratory hygiene and injection safety.[415] Monitoring IPC activities, prevention of infection in health workers (HW), specific policies regarding hand and respiratory hygiene, safe injection practices and ongoing education of IC practitioners, have all been shown to be important in reducing health care-associated infections.[416]

In all settings and environments, administrative control measures have a significant impact in reducing the spread of infectious disease. 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.

Standard precautions: Standard precautions are the minimum level of infection prevention activities and should be used in the care of all patients. [417] 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 refers to both hand-washing and the use of alcohol- based hand rub (ABHR). Hand hygiene is a critical intervention for the prevention of COVID-19

[415] 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.
[416] 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.
[417] https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html

infections and prevents many healthcare-associated infections. A recent review documented more than 20 studies in the acute care setting in which improved hand hygiene was associated with measurable reductions in carefully defined hospital-associated infections.[418] Good hand hygiene reduces surgical site infections and is an important measure in preventing VMMC- associated infections. A large review of circumcisions in rural Ghana demonstrated significantly increased morbidity associated with poor adherence to key health care associated hygiene practices including hand hygiene and appropriate disinfection.[419]

The WHO has defined 5 moments for hand hygiene: before touching a patient, before aseptic procedures, after body fluid exposure/risk, after touching a patient, and after touching patient surroundings.[420]

In addition to these moments, hand hygiene should be performed after glove removal. Unless hands are visibly soiled, an alcohol-based hand rub is preferred over soap and water in most clinical situations due to evidence of better compliance compared to soap and water. WHO and UNICEF are sponsoring “Hand Hygiene for all Global Initiative” and resources, including an inexpensive method for local manufacture of an ABHR. WHO “clean hands” campaign materials are available online.[421] Products should be accessible at the point of care and hand washing supplies such as soap and single use towels should be readily available. Community health workers should have access to materials for hand hygiene and should be instructed in their use.

Personal Protective Equipment (PPE): PPE is used to protect healthcare personnel and patients when providing care. 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

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[418] Allegranzi, B. and D. Pittet (2009). "Role of hand hygiene in healthcare-associated infection prevention." J Hosp Infect 73(4): 305-315.

[419] 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.

[420] https://www.who.int/infection-prevention/campaigns/clean-hands/5moments/en/

[421] 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/

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.[422]

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.

Blood and injection safety: Re-use of injection equipment is associated with the transmission of bloodborne viruses such as HIV, HBV, HCV and bacterial infections such as abscesses and is prohibited in PEPFAR facilities. Re-use includes the reintroduction of injection equipment into multi-dose vials, re-use of syringe barrels or of the whole syringe.[423]

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. Hepatitis B is a greater risk than HIV to the health care provider and vaccination should be available to non-immune individuals with a needle stick injury.

Transmission- based precautions: Some infectious diseases require additional precautions beyond standard precautions because of the specific mode of transmission that might be present.[424] Types of transmission-based precautions include contact precautions, droplet precautions and airborne precautions. Contact Precautions are intended to prevent transmission

[422] https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/medical-waste.html
[423] https://aidsfree.usaid.gov/resources/pepfars-best-practices-vmmc-site-operations-0
[424] https://www.cdc.gov/infectioncontrol/basics/transmission-based-precautions.html

of infectious agents which are spread by direct or indirect contact such as on environmental surfaces or intact skin. Droplets are relatively large respiratory particles and droplet precautions are used to prevent the spread of respiratory pathogens through coughing, sneezing and talking. Droplets are propelled a short distance (usually considered one to two meters through the air and are deposited on the nasal, oral or conjunctival mucosa of the new host or fall onto surfaces. Large droplets do not remain suspended in the air. Airborne spread refers to disease that are spread by smaller particles that remain suspended in the air for some time. See for further information. https://www.cdc.gov/infectioncontrol/basics/transmission-based-precautions.html for further information. Different diseases require different types of precautions.

Universal source control in which all visitors and clients of a facility wear face coverings, together with continuous medical masking in which health care workers wear a medical mask from the beginning of their shift to the end (without exceptions), has been shown to reduce infections in health care workers and transmission of SARS CoV2 in facilities. In the outpatient environment, source control most commonly refers to respiratory illnesses such as tuberculosis and COVID-19. In **every** health care encounter, individuals with cough should be given a medical mask and separated from other patients.

With respect to COVID-19, contact and droplet precautions are recommended for COVID-19 protection. Airborne precautions are recommended for staff performing aerosol generating procedures. 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.[425]

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

[425] https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/index.html

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.[426]

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 contains several CEEs that relate to infection prevention (see below). Facility level review of SIMS data is a good starting point for infection prevention practice audits. Work is underway that may help guide other continuous quality management efforts.

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]

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.[427]

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. Furthermore, HCW quarantine, testing, and return to work policies must be effectively implemented in response to COVID-19 facility outbreaks. PEPFAR supports

[426] WHO Guidelines on Tuberculosis Prevention and Control (update 2019) https://www.who.int/publications/i/item/9789241550512
[427] Reuters, COVID-19 in Health Care workers 17 Sept 2020

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.

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.

It is now incontrovertible that universal source control and continuous medical masking prevent transmission of COVID-19 to health care workers.[428] Continuous medical masking refers to the practice of 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.

With respect to workplace exposures, the CDC guidance on the definition of exposure may be found here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/public-health-management-hcw-exposed.html and the WHO tool for assessing exposure may be found here https://apps.who.int/iris/bitstream/handle/10665/331496/WHO-2019-nCov-HCW_risk_assessment-2020.2-eng.pdf?sequence=1&isAllowed=y

Both the WHO and the CDC have recommended time-based criteria for terminating isolation in individuals who test positive for COVID-19. 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.

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

[428] 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.

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.

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 drugs and vaccines, and laboratory waste. Policies and procedures should be in place for the appropriate management of each of these categories. Pharmacies should have clearly documented policies and procedures, and individuals delivering ART should understand the basic principles of expiry dates, and appropriate disposal of ART.

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.[429]

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.

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

[429] 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/

may result in inadequate cleaning and contaminated environmental surfaces that could facilitate transmission of pathogens, including viruses (e.g., SARS-CoV-2), bloodborne pathogens, and resistant bacteria. As such, review of environmental cleaning programs is encouraged. The details of best practices are available online.[430]

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 done correctly every time, clients are at risk for infectious complications. Complete reviews of this topic are available in materials from CDC[431] and WHO.[432] (https://www.who.int/infection-prevention/publications/decontamination/en/1).

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, disinfection, and sterilization are the basic steps 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

[430] 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/

[431] CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (updated May 2019) https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

[432] Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO and PAHO (2016) https://www.who.int/infection-prevention/publications/decontamination/en/

manufacturer's instructions including type of disinfectant and how long it must remain in contact with the item.

High level disinfection (HLD) is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. After a semi-critical item has been cleaned, it is disinfected by an appropriate HLD method as detailed by the manufacturer. Chemical disinfectants appropriate for HLD, and processes for their use, can be found in the WHO and CDC references above.

Sterilization is a process that eliminates all forms of microbial life, including spores that cause tetanus. 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, 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.

It is important to recognize the complexity of instrument reprocessing and how each step in the pathway from dirty instrument at the end of one procedure, to sterilize an instrument at the beginning of the next procedure, is absolutely essential for client safety. Dedicated, well-trained individuals overseeing the process, SOPs, frequent quality assurance activities, CQI, and surgical checklists are critical to assist sites in carrying out this process correctly every time.

PART B: COP/ROP21 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 – including MER, financial data, Table 6 and SRE reporting, the SID, PLHIV estimates, the responsibility matrix, resource alignment, community-led monitoring data, and program quality as measured within SIMS – to assess the quality, impact and efficiency of the current program and to align resources to further prevention interventions, ARV coverage, and viral suppression for all age groups to reach and sustain epidemic control. 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.

Section 7 is designed to **demonstrate a clear link among analysis, planning, and operationalizing of the COP process through each U.S. implementing agency and its respective implementing partners**. To strengthen the PEPFAR implementing agencies' transparency, monitoring, and use of financial data, together we are establishing clear linkages between COP planning budgets and targets with implementing partner budget execution and results. We also need to link above-site- level technical assistance support costs, and direct service delivery and site-level technical assistance costs, to quality service delivery costs so that we can (1) understand the full investment and allow (2) a transparent dialogue with governments as a country reaches and maintains epidemic control through focused prevention and sustaining viral load suppression.

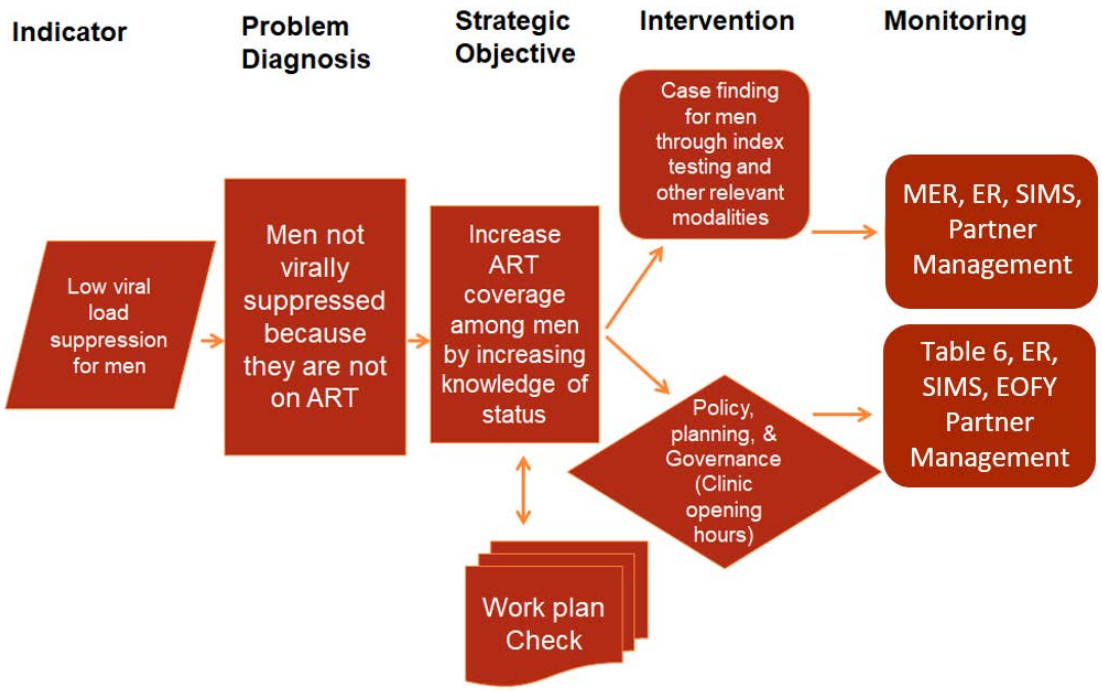
We will need to continually refine and evolve interventions to address the needs of specific populations to reach each 95-95-95 (critical to ensuring focused prevention interventions with the first 95), while maintaining a laser focus on ART continuity for all clients across sex and age bands; as such, ensuring everyone remains virally suppressed for their health and the health of the community remains a key priority. We also need to ensure programmatic prevention and treatment activities and funding clearly link with targets and outcomes for impact. This not only ensures that U.S. taxpayer dollars are impactful, but also provides an early warning signal of fraud, waste and abuse. We expect that clear outcomes of all prevention programming will also be measured while noting that "reaching" an individual without directly linking them to prevention or treatment services is a measure of program failure, not success.

We thought it might be helpful to walk through an analysis example to determine if PEPFAR investments are in the right places for impact. A framework for these planning discussions is presented below, using the example of increasing ART coverage for men to increase viral load suppression (illustrated in Figure 7.0.1). This framework is meant as one illustrative example of the process of analysis/COP planning decision tree for country teams to utilize.

- **Problem Statement/Indicator:** In country X, through our quarterly monitoring and triangulation with PHIA data, we identify that men have low viral load suppression (VLS), due to low ART uptake, which is in turn, in this scenario, is due to low knowledge of HIV status. Thus, for epidemic impact, clinical services for men need to be scaled to 90% VLS directly through the first 90.
- **Problem Diagnosis:** First, all site level data were reviewed to determine 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, and discussions were held with partners and site health staff and peer navigators to understand what was happening and how this could be brought to scale. If there aren't clear examples of excellence, then it is key to determine why men are not being tested, linked and virally suppressed. For example, conducting focus group interviews, soliciting client feedback, and conducting demonstration projects. 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? When will the MoH adjust policies and distribute circulars? In parallel, agencies evaluated partners/ work plans to ensure they include the new, fully-costed interventions.
- **Monitoring and Partner Management:** Relevant targets and outcomes were 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 7.0.1: Example COP planning decision tree



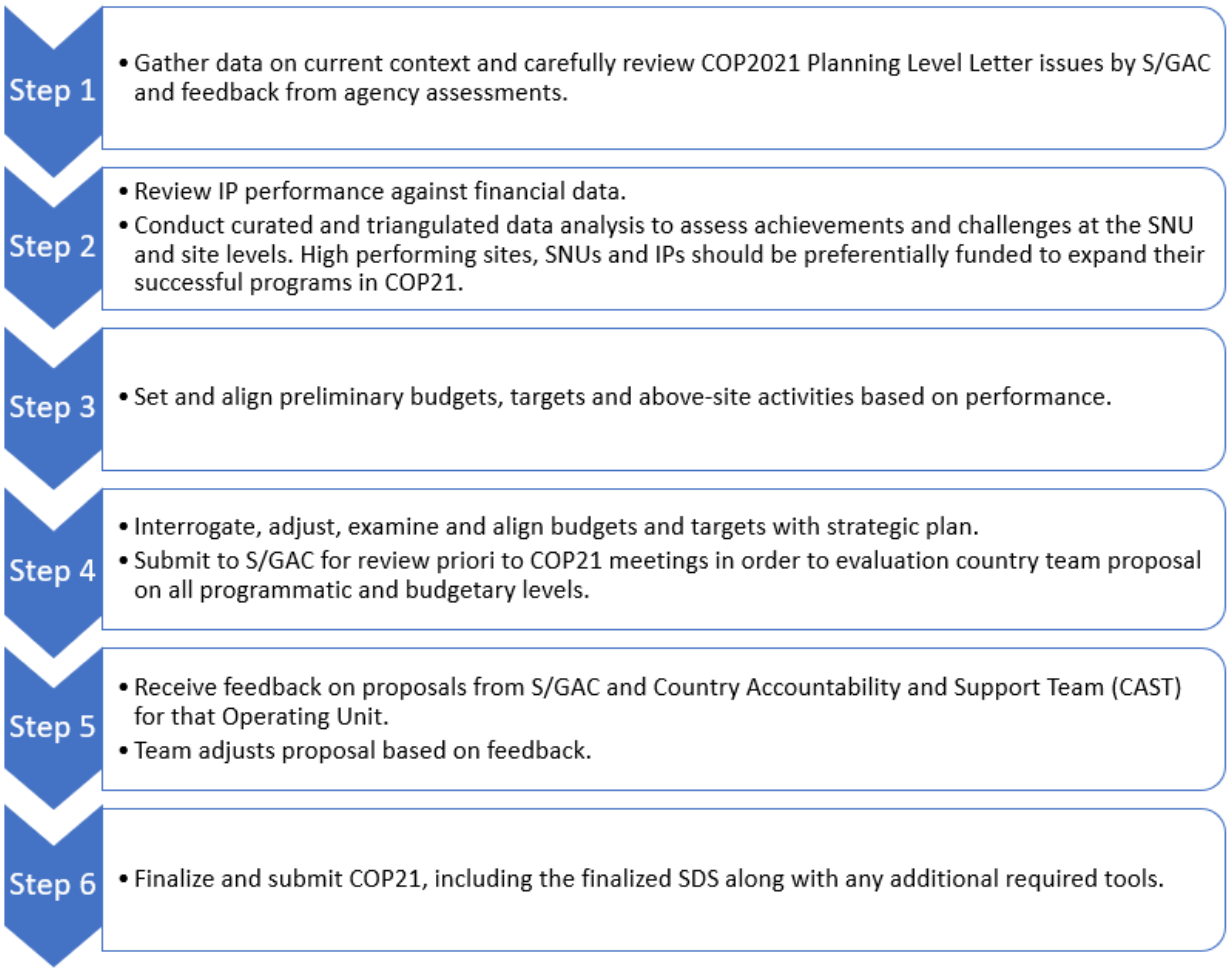
COP21 Guidance uses modular planning steps, like those used for COP17-20, for completing the COP21 process. Like COP20, the COP21 planning steps emphasize using integrated data analysis to refine programming, target setting, and budgeting and to ensure quality partner performance for increased impact.

Modular Planning Steps

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 COP21 planning are a continuation of the program and partner performance routinely discussed during the quarterly POART process. This section offers guidance to countries 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 prevention and treatment programmatic gaps, how the difference will be monitored and how the OU will course correct.

The COP21 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. The recommended order for these steps is illustrated in Figure 7.0.2 below.

Figure 7.0.2: COP21 process planning steps



As noted elsewhere in the COP21 guidance, country teams are required to engage civil society, host government and communities inclusive of vulnerable and key populations – discussions must reflect all communities and community generated solutions, host governments, and external partners early and often in the development, implementation, and monitoring of the COP, as doing so will help to ensure a collaborative process as defined by meaningful partner engagement.

7.1 Planning Step 1: Review Data on Current Program Context, Program Performance and Financials

COP21 Planning Step 1 should seamlessly flow from the quarterly POART process, during which country teams review program and partner performance to assess country progress toward sustainable epidemic control while analyzing down to the site levels and up to the district level. These analyses should be focused on who is missing from prevention and treatment and how they will be found and supported to access prevention and treatment services. In turn, these analyses and findings should be tied to effective partner management practices.

Planning discussions for COP21 will begin from this foundation, reviewing how previous COPs were implemented and COP20 is 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 this information across the full interagency, where feasible, is imperative to inform robust conversations and analyses to establish COP21 direction and priorities and COP21 Implementing Partner work plans.**

Planning Step 1 requires that country teams, with their stakeholders, compile the analyses, decisions, key outcomes, and recommendations from the POART. A proposed structure, with data sources, is as follows (note: this structure is used throughout the planning steps):

- **Understanding the full funding envelope**: Using ODA (Other Donor Assistance) data, the team will meet with bilateral donors who are invested in women and girl's health and/or education to ensure synergies with critical programs to prevent or treat HIV. DREAMS teams should meet with bilateral donors invested in aspects of the DREAMS programming to ensure maximal synergies as this will be a component of the COP21 discussions.
- **Understanding the full multilateral investments**. Teams should be able to understand current and future Global Fund concept note development and investments. Joint development of both the Global Fund concept notes and COP execution must be demonstrated at all levels for both communities and governments.
- **Understanding underlying epidemiology and program performance:** Demographic, epidemiologic data, national/regional program data to the lowest SNU possible, by age and sex (see Figure 3.1.1). Source: PHIA, Biobehavioral Surveys, SABERS, DHS,

National/Subnational MER data, SIMS site and above-site data, MOH Data Alignment, and other sources.

- 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 client-centered services. Source: MER, SIMS, CQI, 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. Source: Table 6 and Above-site Tool for SIMS, POART recommendations and any post-POART Corrective Action Summaries (CAS).
- COP21 Planning Level Letters and HQ feedback.
- Financial Performance (budgets, outlays, expenditures): Information on how financial resources are budgeted, outlaid and spent by IM. Source: 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 OU level. Source: SID, and country-specific sustainability framework.
- Donor and Government responsibility: Information on who is responsible for which aspect of the HIV response at the OU level. Source: Responsibility Matrix, Resource Alignment, and other multilateral resources.
- Supply chain (including all commodities): Information on flow and procurement of commodities at the OU level. Source: Commodities budgets and Supply Plan tools.
- HRH and IP staff supporting services: Information on current IP staffing footprint and distribution/alignment across sites, HRH needs, and programming. Source: HRH inventories, Health Workforce Registries, or 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. Source: 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 programmatic context and HIV data and
- The data available to comprehensively:
    - assess partner and program performance, quality and progress,
    - assess financial performance
    - identify programmatic gaps and barriers,
    - identify program facilitators
    - assess progress toward epidemic control
    - multilateral and bilateral investments and how these will be integrated to advance HIV prevention and treatment

7.2 Planning Step 2: Identify Specific Barriers and Program Gaps Based on Curated In-Country Analysis of Data on Performance

COP21 starts with the premise that, after over seven years of interpreting data and focusing on the populations and geographies with the highest burden of HIV, the country PEPFAR team and all stakeholders understand the path to epidemic control. The focus of COP21, therefore, is on continuing to use the data to refine approaches to sustain epidemic control and high ensure quality program performance.

Each COP cycle, teams worked together to identify SNUs for scale-up. Reviewing key epidemiologic and program data is important to understand if course corrections are needed, to determine whether acceleration to program saturation is happening at a faster or slower pace than anticipated. The primary treatment focus must be sustaining clients on treatment at all sites, in saturated districts moving away from all stand-alone testing counselors to equipping Community Health Workers (CHW) that can support ART continuity and scale effective prevention efforts. All sites with substantial patient losses (identified through treatment current change year to year) should suspend HIV testing, with exceptions for testing in inpatient wards and TB clinics, until ART continuity is improved. Continuing to add clients to programs that are failing clients cannot continue, so these sites must receive special attention to improve. If there are geographically close sites that are doing well and assuring ART continuity for clients, additional investments should be made to high-performing sites and encourage clients to move to these sites if logistically possible. To determine which sites fall into this category, country teams should assess which sites are outliers when reviewing sites on a bell-curve. Teams

should give attention to program results by age and sex bands and subgroups (e.g., key or priority populations) that may be falling behind in reaching epidemic control, identify the next set of SNUs for program scale-up, and move resources that are freed up to these opportunities.

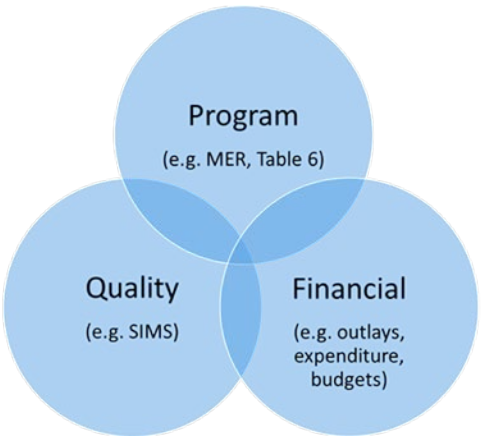
Reviewing the most granular disaggregated data is critical as evidence continues to mount regarding age, sex, and other population-related disparities in accessing HIV prevention and treatment services.[433] Country teams must continue focusing HIV activities towards the populations with the highest HIV burden and unmet need, and therefore the highest likelihood of transmitting or acquiring HIV. Creating and supporting a health system that is welcoming and client-centered will be key to reaching this population. Of note, PEPFAR's contribution to Universal Health Coverage (UHC) is the same as that of the Global Fund.

Triangulated data analysis, including financial data, plays an essential role in accompanying performance monitoring. Country teams must fully understand whether the PEPFAR program in their respective OU is reaching its anticipated impact by reviewing MER achievements, in conjunction with other key data sources, including measures of program quality. Country teams must also analyze financial data at the implementing mechanism level to arrive at a more comprehensive view of an IM's overall performance. PEPFAR recognizes the need for a standardized, program-wide approach, as understanding and comparing implementing partner expenditures for the same types of services and interventions may allow for correcting inefficiencies and learning from high performers, while considering PEPFAR contributions versus financial contributions from others.

As illustrated in Figure 7.2.1, country teams should step back to look holistically at country context and program performance to confirm that the overall PEPFAR program is having the intended impact. That is, are all parts of the strategic approach leading to epidemic control? Analyses should triangulate program, financial, and quality data to provide a holistic view of programmatic progress and this must be overlaid with the epidemiologic data to ensure impact. Such analyses should begin at the OU level, and then overlay SNU level data from program, quality, and epidemiology. Then, teams should align future resources by performance.

[433] UNAIDS. (2014, September). *The Gap Report*. Retrieved from http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport

Figure 7.2.1: Triangulation of data to provide a holistic view of progress (first at the OU level, then at the SNU level, where possible)



Based on the data and local and program context information, 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 client-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 epidemic control.

Based on these analyses and recommendations from S/GAC, through this COP21 planning process, **all country teams are expected to adjust the COP20 activities and Implementing Partner mix and associated budgets accordingly for COP21. Including expanding funding and geographic reach of high performing partners and limiting funding to the poorer performers. These changes should be evident in the COP21 plan.**

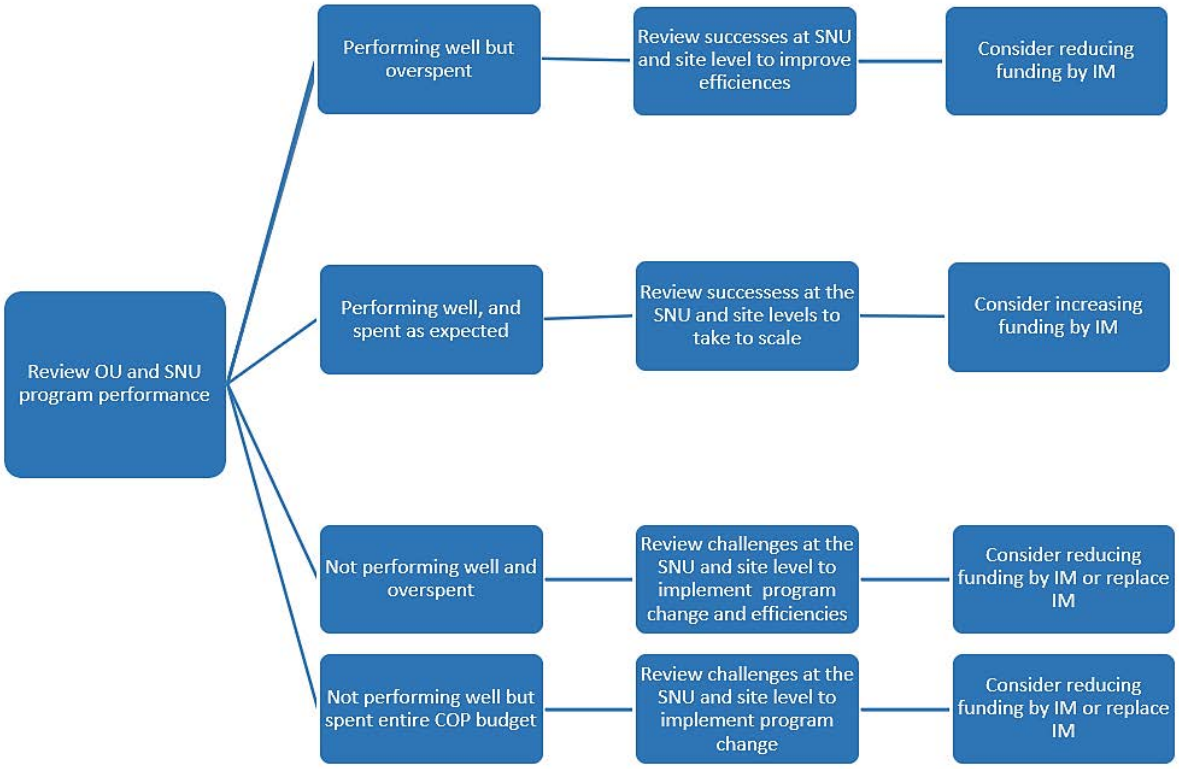
Planning Step 2 builds on Planning Step 1 by:

- Understanding progress toward epidemic control 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 Global Fund resources and all other bilateral and host government funding using Resource Alignment data
- Aligning future programming and investments with performance

- Understanding gaps in programming and potential barriers and facilitators to achieving or reaching sustainable epidemic control at quality at both the site and above-site levels
- Understanding gaps and barriers in developing a patient-centered approach to service delivery at the site level

The overall flow/decision tree to accomplish these goals is shown in the visual below. That is, ultimately, teams should align resources based on performance.

Figure 7.2.2: Overall flow or decision tree of assessing performance by geographic area and IM



Keeping the above decision tree in mind, the below analyses offer a step-by-step guide to comprehensively and holistically understand historical program achievement, implementation, gaps and barriers, to inform COP21 planning.

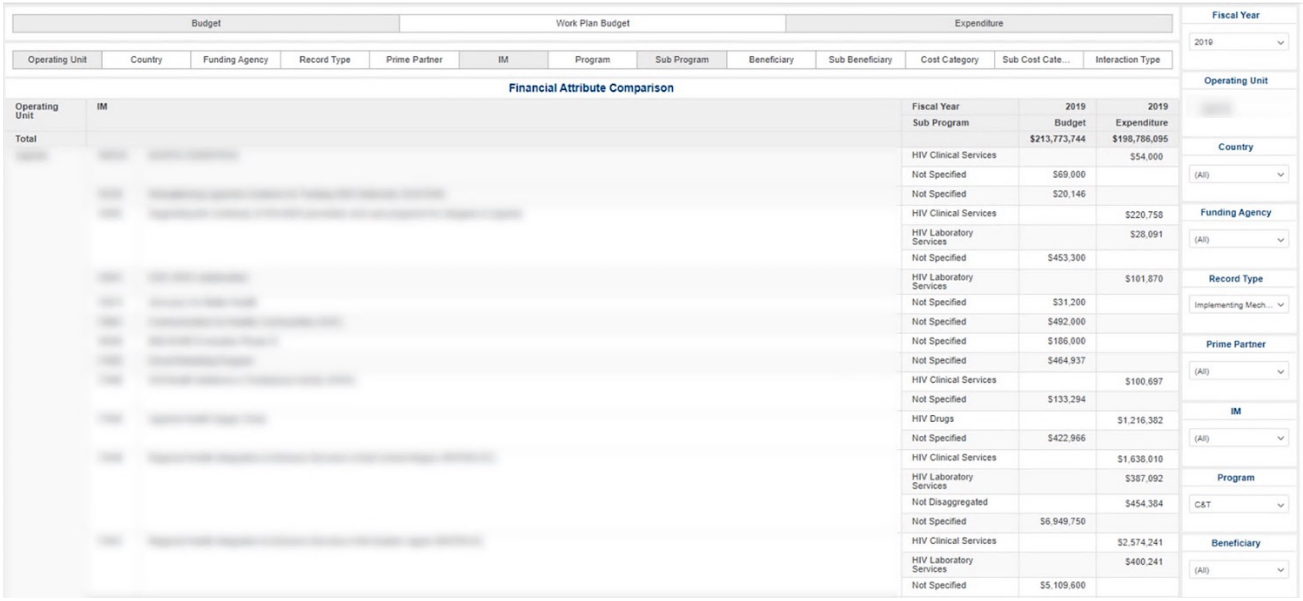
IMPORTANT NOTE: the below steps use a de-identified country example with illustrative data from FY19 to outline how one might approach an analytic question of interest. Our analytic example dives into viral load suppression by highlighting the core questions that should be answered to analyze partner viral load suppression performance and identifying programmatic changes needed by the partner, SNU and/or site(s) to improve viral load suppression performance in COP21. Following steps A-I, a “deep dive” sub-section provides additional

analytic questions to further drill down and identify root causes of partner-, SNU- and/or site-level performance successes and challenges.

A. Who is being funded? What and how much was budgeted and spent? What was accomplished?

We will start with looking at viral load suppression. Since viral load suppression is a Care & Treatment activity, the financial classifications aligned to viral load suppression are the Care & Treatment program area and HIV Laboratory Services sub-program area. The Financial Management: OU dossier in Panorama provides funding agency, partner and implementing mechanism detail down to the program and sub-program areas of interest. Figure 7.2.7a identifies mechanisms with greatest budget and expenditure by program area; in this instance, filtered for the Care & Treatment program area. Figure 7.2.7b identifies mechanisms with greatest budget and expenditure by sub-program area; in this instance, HIV Laboratory Services. These figures provide us with a base understanding of the mechanisms working in viral load suppression area in Country X. Please keep in mind that the transition to the new financial classification system began for budget data in COP19. Some prior year budget data has been mapped to major program areas; however, mapping is unavailable for many sub-programs, including HIV Laboratory Services and beneficiaries

Table 7.2.7a: Budget and Expenditure by Care & Treatment Program Area in Country X



Budget | Work Plan Budget | Expenditure

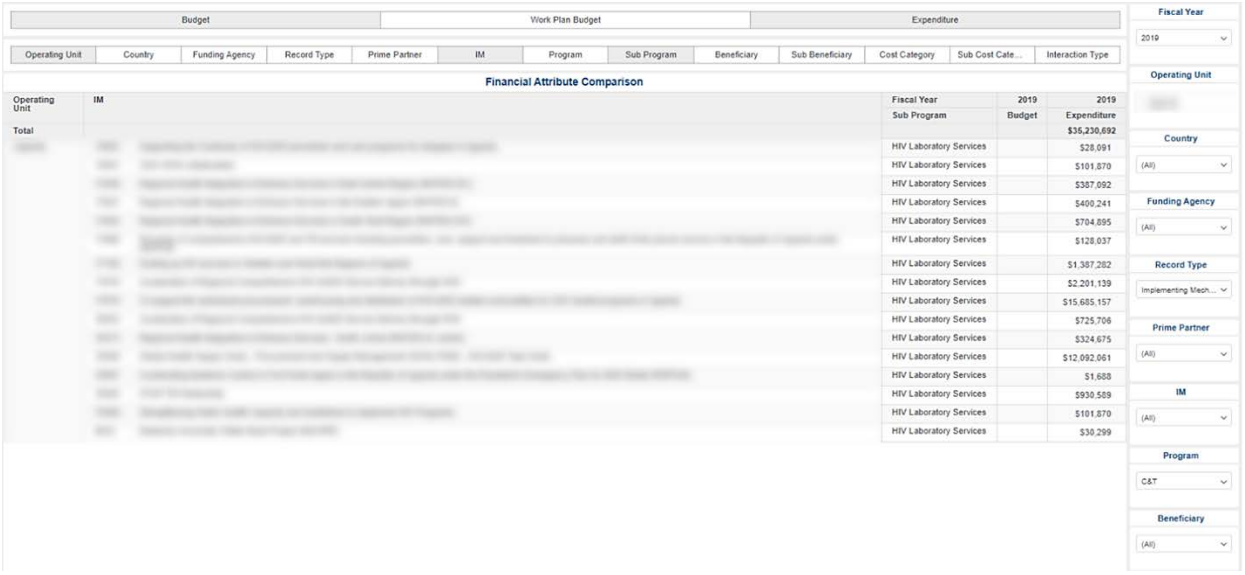
Operating Unit | Country | Funding Agency | Record Type | Prime Partner | IM | Program | Sub Program | Beneficiary | Sub Beneficiary | Cost Category | Sub Cost Cate... | Interaction Type

Financial Attribute Comparison

Operating Unit	IM	Fiscal Year / Sub Program	2019 Budget	2019 Expenditure
Total			$213,773,744	$198,786,095
[redacted]	[redacted]	HIV Clinical Services		$54,000
		Not Specified	$69,000	
		Not Specified	$20,146	
		HIV Clinical Services		$220,758
		HIV Laboratory Services		$28,091
		Not Specified	$453,300	
		HIV Laboratory Services		$101,870
		Not Specified	$31,200	
		Not Specified	$492,000	
		Not Specified	$186,000	
		Not Specified	$464,937	
		HIV Clinical Services		$100,697
		Not Specified	$133,294	
		HIV Drugs		$1,216,382
		Not Specified	$422,966	
		HIV Clinical Services		$1,638,010
		HIV Laboratory Services		$387,092
		Not Disaggregated		$454,384
		Not Specified	$6,949,750	
		HIV Clinical Services		$2,574,241
		HIV Laboratory Services		$400,241
		Not Specified	$5,109,600	

Fiscal Year: 2019 | Operating Unit | Country: (All) | Funding Agency: (All) | Record Type: Implementing Mech... | Prime Partner: (All) | IM: (All) | Program: C&T | Beneficiary: (All)

Table 7.2.7b Expenditure by Care & Treatment: HIV Laboratory Services Sub-Program Area in Country X



B. What is the underlying epidemiology in Country X?

It is critical to understand shifts in disease burden across Country X and by population, who is need of ART by fine age/sex disaggregates and rates of viral load suppression (Figure 7.2.8). Teams should triangulate the PHIA results (PLHIV estimate or other SRE data) with program data; i.e., map program data against current PHIA results by region to identify areas/populations that are underserved, according to community-level PHIA data. If PHIA data are not available, program data, PLHIV estimates or other SRE data can be used, as shown below. In Country X, program data was used in lieu of PHIA data, which were unavailable, revealing clear gaps in ART coverage, viral coverage, and viral suppression by age and sex. Poor treatment and viral suppression indicates an increased focus on young people and men is needed.

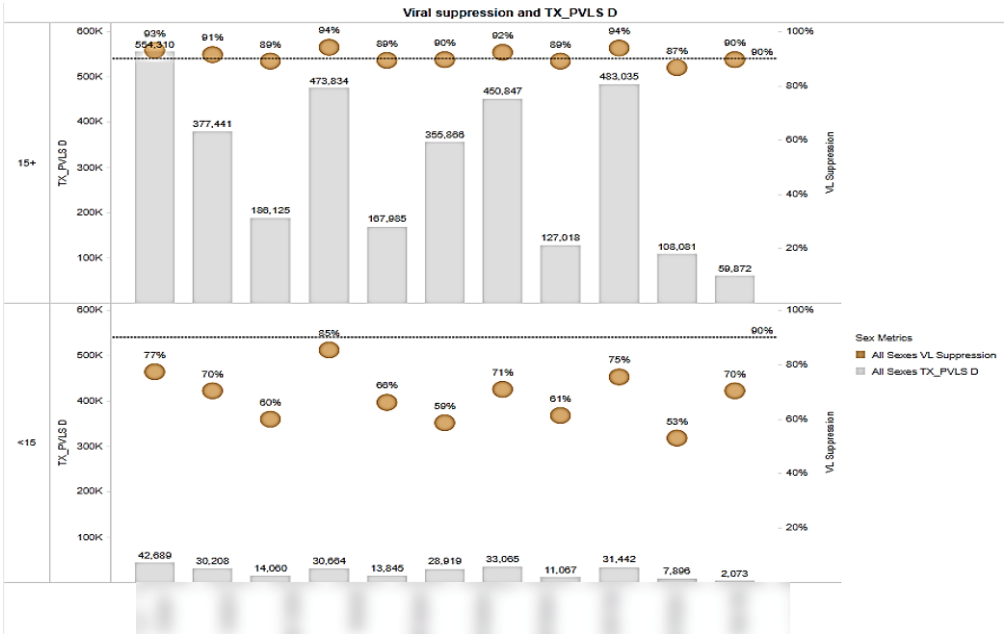
Table 7.2.8: Country X Disease Burden and Clinical Outcomes Highlighting Gaps in Treatment and Viral Suppression among Young People and Men

Age	Sex	PLHIV	On Treatment	VL Suppressed	On Treatment	VL Suppressed
<10	Female	33,845	17,980	12,941	53.1%	38.2%
<10	Male	34,899	16,479	10,824	47.2%	31.0%
10-19	Female	55,863	34,121	24,874	61.1%	44.5%
10-19	Male	37,938	22,074	16,429	58.2%	43.3%
20-29	Female	191,563	168,757	128,631	88.1%	67.1%
20-29	Male	84,177	49,018	27,248	58.2%	32.4%
30-39	Female	244,765	230,577	191,611	94.2%	78.3%
30-39	Male	157,202	115,968	82,486	73.8%	52.5%
40-49	Female	173,370	160,644	135,448	92.7%	78.1%
40-49	Male	138,140	110,162	87,588	79.7%	63.4%
50+	Female	119,007	101,664	94,549	85.4%	79.4%
50+	Male	107,315	79,980	70,298	74.5%	65.5%
Overall		**1,378,085**	**1,107,424**	**882,927**	**80.4%**	**64.1%**

C. What is performance of the program and IPs by SNU and sites in relation to viral suppression?

Overall, viral load suppression varies in Country X by SNU and age groups (see Figure 7.2.8). Many SNUs are not performing above the 90% suppression level, variability also still exists across age levels when comparing adults against pediatrics. Viral load suppression across age and sex groups within an SNU depends on the ecosystem of IMs within that region. The balance between IMs and their respective activities should be carefully considered to ensure the right interventions are being implemented to achieve viral load suppression.

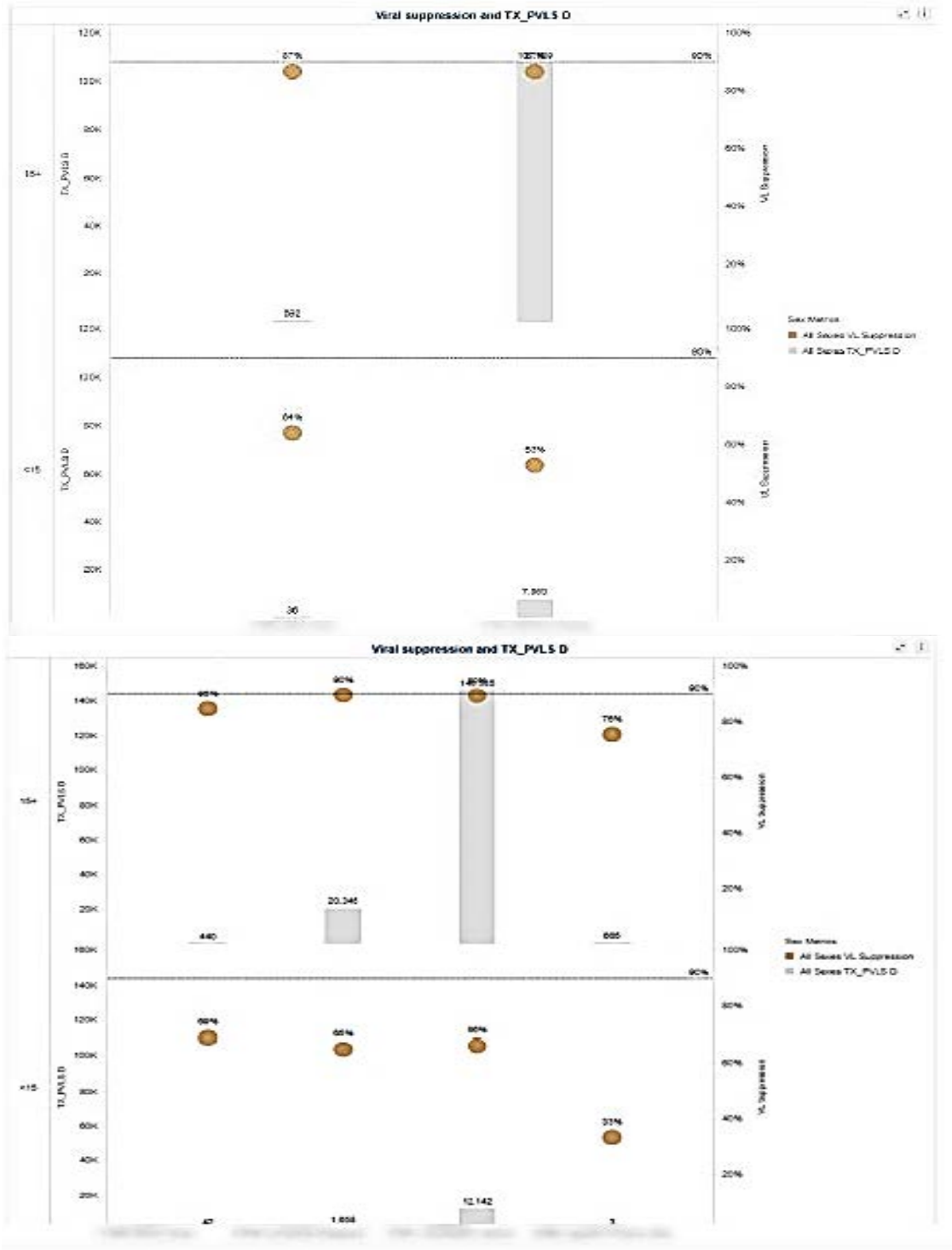
Figure 7.2.9: Viral Load Suppression at the SNU Level for Adults vs. Pediatrics Highlights Disparities by SNU and Age Group in Country X



When these results are reviewed by SNU and IM, several IMs do not meet the 90% suppression mark by SNU, and viral load coverage remains low. If performance is a persistent problem, begin constricting the geography of low performing IMs and expanding the geographical footprint of top performing IMs, after a deeper dive analysis with the implicated IM(s). .

Highlighting two different high burden SNUs (SNU X and SNU Y) reveals that IMs have **differential viral load suppression performance both within and across SNUs**.

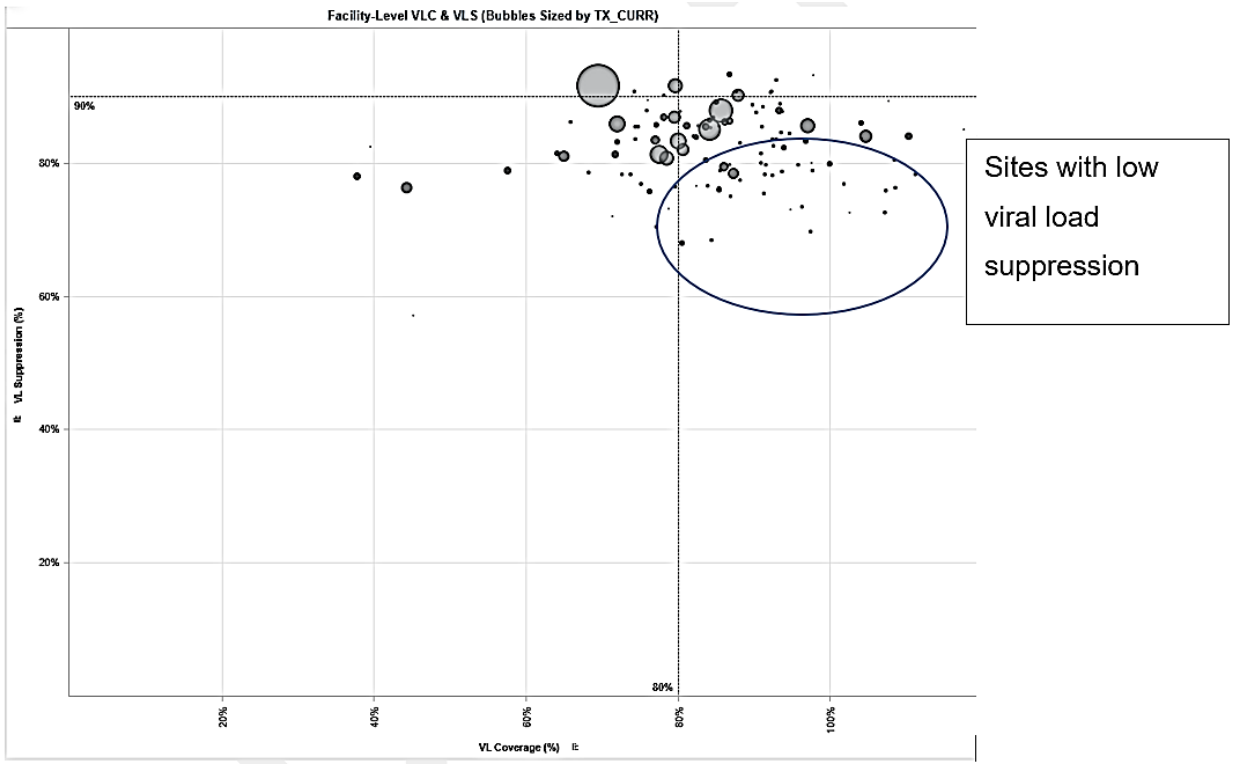
Figure 7.2.10: Differential Performance in Viral Load Suppression across IMs Implementing Clinical Programs in SNU X (top) and SNU Y (bottom)



It is critical to assess the performance of potentially under-performing IMs at the site level. Below, Figure 7.2.11 shows that although viral suppression in some high-volume sites (as denoted by the size of the bubble) lies above the 80% coverage and 90% suppression marks, there are many smaller sites with low levels of both viral load coverage and suppression (as

denoted by small bubbles and the sites falling below the 90% suppression and 80% coverage marks). Immediate questions around the quality of services, and whether targeted viral load testing due to treatment failure is being conducted at these smaller sites, should be considered. Additional analyses may involve determining whether viral suppression rates were maintained quarter over quarter as viral load coverage increased.

Figure 7.2.11: Identifying Small Volume Sites with Low Viral Load Coverage for IM Y in SNU X.



Analyzing SIMS data (in the SIMS-MER Integrated and Patient Experience dossiers in Panorama) for seemingly poor-performing IM Y at the site level, showed that several smaller sites had challenges delivering quality services (i.e., those sites scored either ‘red’ or ‘yellow’ via SIMS). Furthermore, looking at SIMS performance over time at those sites demonstrated that those sites consistently did not meet standards. Additional questions may include whether remediation occurred at the sites, which should lead to improved achievement of quality standards; or, whether IM Y consistently performs poorly in terms of quality of services all along the clinical cascade.

Figure 7.2.12: Number of Times Viral Load Related SIMS Standard Scored “Red” or “Yellow” (i.e., needing remediation) for Poor-Performing IM Y

Evaluating Site CEE Score Trends

SIMS Universal CEE ID	SIMS Universal CEE Title	Count of CEEs Scoring Red	Count of CEEs Scoring Yellow	Count of CEEs Scoring Light Green	Count of CEEs Scoring Dark Green
S_02_21	Dosing of Pediatric and Adolescent ARVs	0	0	0	162
S_02_22	Viral Load Access and Monitoring	10	14	36	100
S_02_25	Routine HIV Testing for Children and Adolescents	6	20	53	83
S_02_26	TB Screening	0	0	15	146
S_02_28	Cotrimoxazole (CTX)	1	1	3	157

With the **'shortlist of IMs' identified above, return to the financial data** (in the Financial Management: OU Dossier) to glean a better understanding of how IMs implemented their activities by understanding **how they spent their budget**. First, understand how much of the budget a mechanism spent, as measured by expenditures. Below, Figure 7.2.13a shows how to compare budget vs. expenditure at the total Operating Unit, partner, IM, or program area level. Figure 7.2.13b shows the same information included in Figure 7.2.13a, but in grid instead of graph format. Beginning with COP 19/FY 20, budget execution grids and graphs are also available for sub-program area, beneficiary, sub-beneficiary, site level and interaction type comparisons.

If a shortlisted mechanism only expended a small portion of the budget, this may indicate that the mechanism budget was overestimated during planning or that the mechanism was simply not operational for some of the period of performance, potentially due to a delay in funds outlaid to the partner. Consult the Obligations & Outlays (O&O) report and the End of Fiscal Year (EOFY) tool to identify if the partner under-outlaid their budget, noting the explanation provided for that under-outlay. Depending on the findings in these reports, 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 possibly reduce or reallocate the IM's budget. It may also be helpful 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 expenditures in commensurate fiscal years.

Next, it is important to understand what the mechanism purchased. This includes both the interventions (i.e., combination of a program area and beneficiary) that the mechanism spent their money on and what the mechanism actually purchased (i.e., cost categories).

Figure 7.2.13a Budget Execution by IM

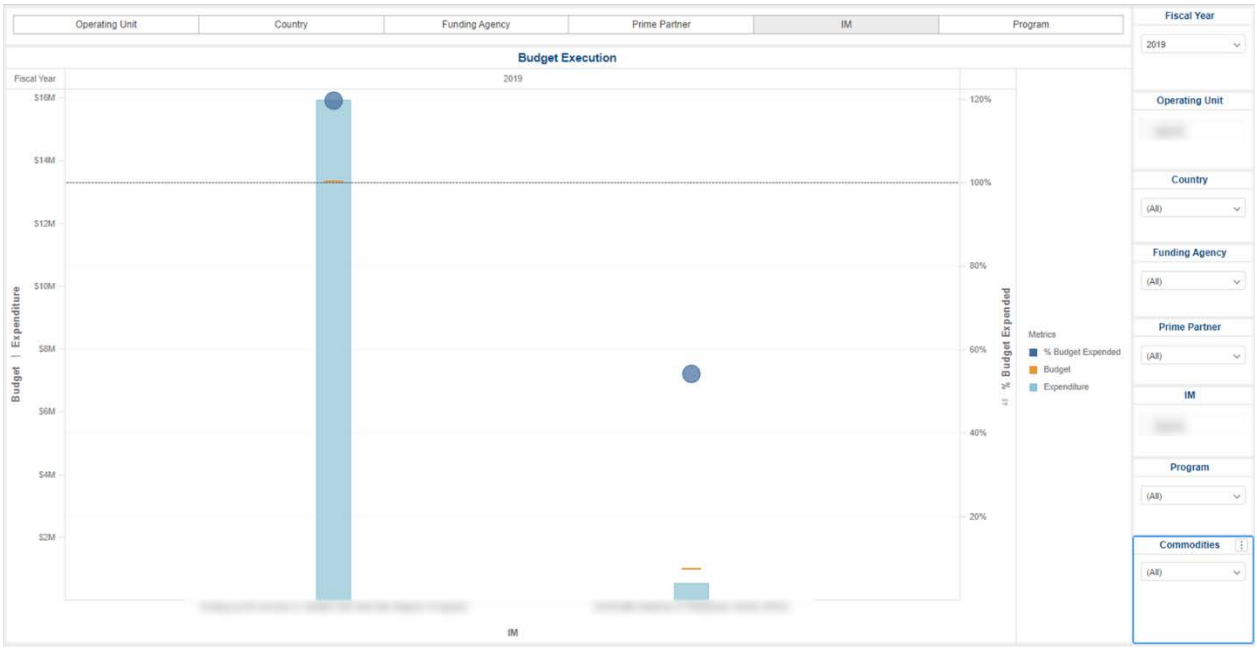


Figure 7.2.13b Budget Execution by IM Grid

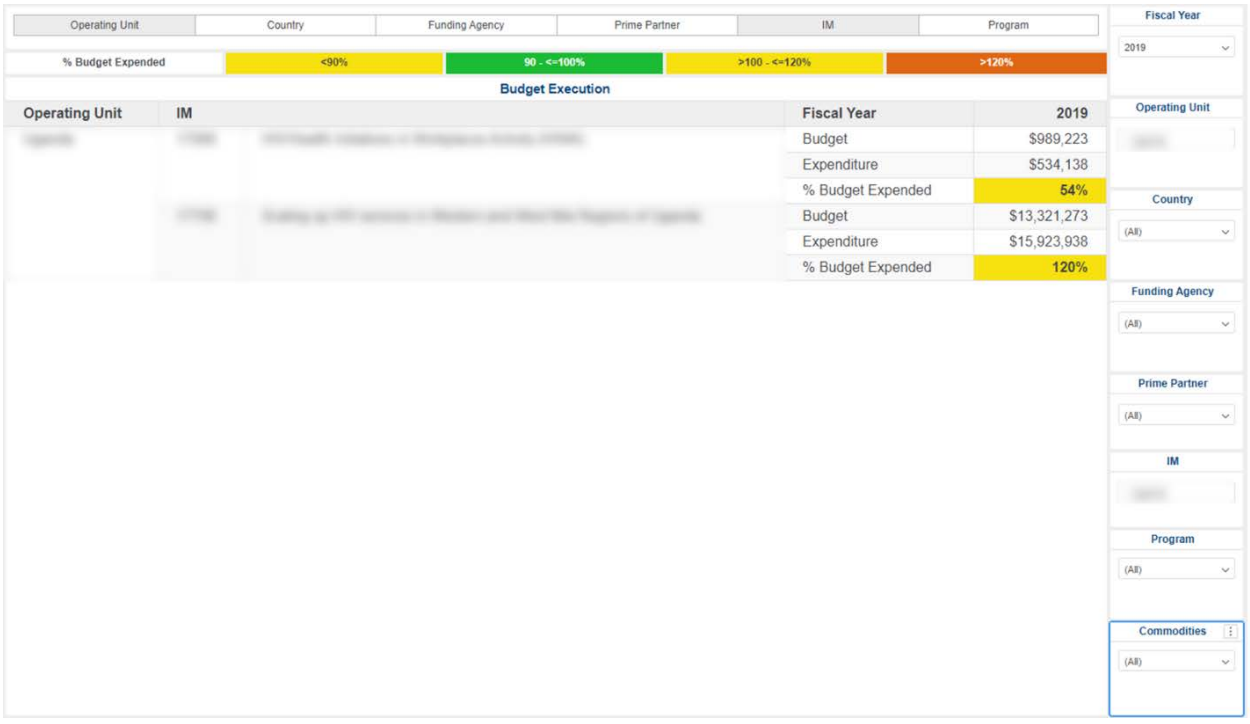
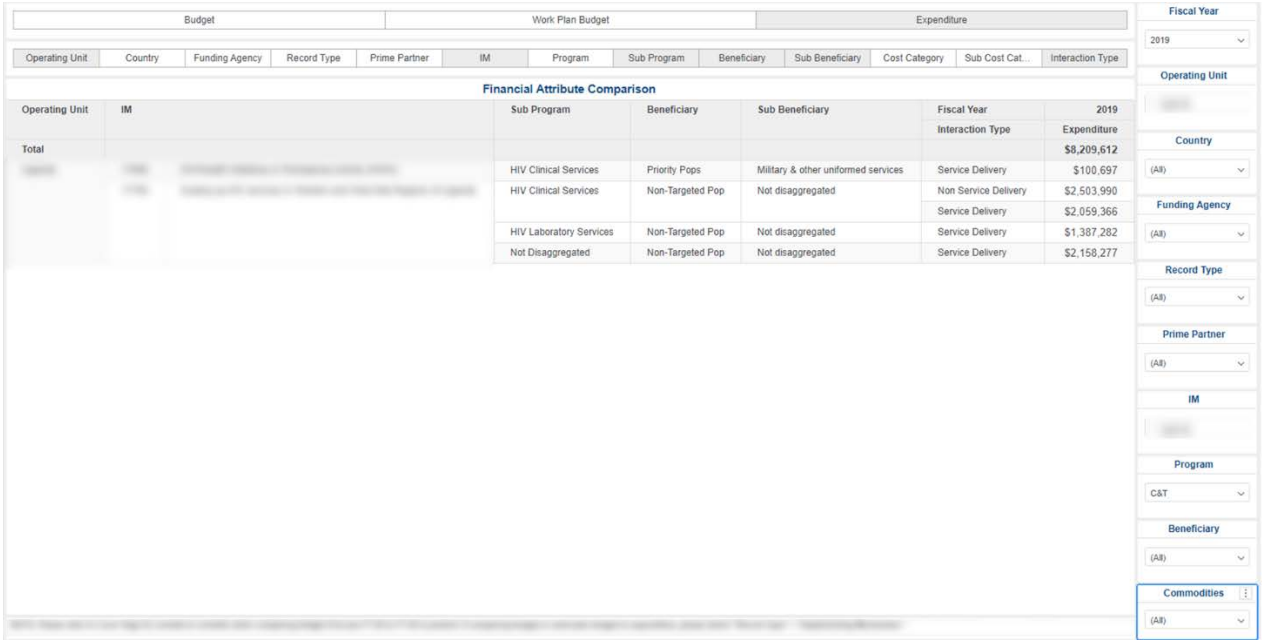


Figure 7.2.14 Expenditures by Program, Sub-Program, Beneficiary, Sub-Beneficiary, and Interaction Type



Looking at the above figures, we learn a lot about what each shortlisted mechanism is spending with its budget. Figure 7.2.13a shows which mechanisms spent within 100% of their allocated fiscal year budget in FY19. The reference line at 100% budget execution, as well as the "% Expended" row in Figure 7.2.13b, allows us to easily identify which mechanisms spent >=100% of their fiscal year budget.

Drilling down to individual mechanisms, Figure 7.2.14 shows that the short-listed mechanisms offer a mix of interventions within the Care & Treatment program area. Please recall that the HIV Laboratory Services sub-program area, at both service delivery and non-service delivery levels, is the most relevant financial classification match to viral load suppression, but does not represent viral load activities exclusively and will include additional and broader lab-related expenditures at the site level. While we see that several mechanisms work in the HIV Laboratory Services sub-program area, most mechanisms spend more on HIV Clinical Services than HIV Laboratory Services. Of mechanisms that do spend on HIV Laboratory Services, the majority of the spend is at the service delivery level. This makes sense because while non-service delivery interventions are critically important in some contexts, if we're focusing on mechanisms with low performance in viral load suppression and see that a mechanism is only spending a small subset of their budget on HIV Laboratory Services, of which a majority is tagged to non-service delivery, it may make sense to redirect the mechanism's budget to HIV

Laboratory Services: Service Delivery interventions. Additionally, the interventions denoted in Figure 7.2.14 indicate that almost all work at Care & Treatment partners is serving non-targeted populations. Since age and sex gaps in viral load suppression were revealed in earlier analyses, it may be advisable to redirect partners to fund interventions that are specifically targeted to disaggregated age and sex beneficiaries that have known viral load performance gaps in the OU or region.

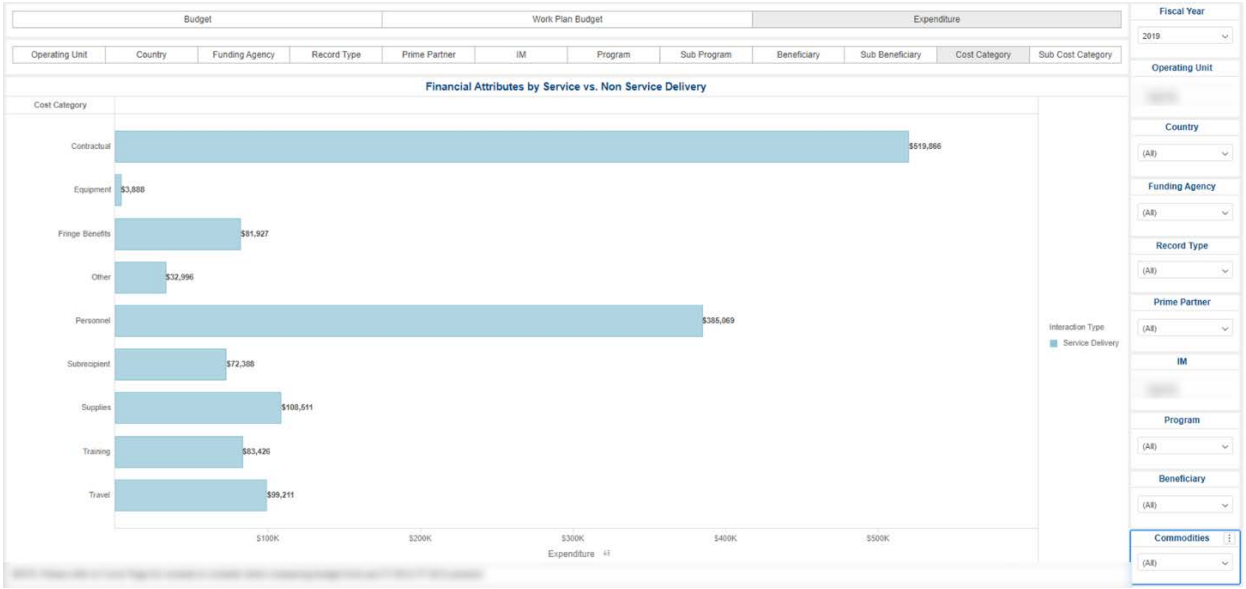
Note that, in Expenditure Reporting, the implementing partner may choose to aggregate certain interventions because smaller interventions are not significant enough to be reported separately. Thus, looking at reported sub-program areas may suggest that a partner is not working in a program area for which they have results; when in reality, the partner just lumped small expenditures into a Not Disaggregated intervention in the same program area. For example, in the case of viral load, a partner with TX_PVLS results may not report expenditures in the HIV Laboratory Services sub-program area because they lumped those expenditures into Care & Treatment: Not Disaggregated or even Care & Treatment: HIV Clinical Services, if the viral load portion of their work was much less substantial or indistinct from the HIV Clinical Services work. Thus, it is important to examine expenditures both at the sub-program area of interest, but also at the Not Disaggregated and total program area level as well in case the partner chose to aggregate their interventions. If a partner severely underperforms on viral load, while aggregating all Care & Treatment sub-program areas to Not Disaggregated, it may make sense to request that the partner disaggregates their Care & Treatment interventions going forward, particularly at the HIV Laboratory Services sub-program area level. While a disaggregation showing HIV laboratory services is not a perfect proxy for viral load programming, it is a closer approximation than Care & Treatment: Not Disaggregated, and thus would be much better to inform an analysis of the viral load programming and expenditure.

Next, it is important to understand, via cost and sub-cost categories, what each mechanism is actually buying. Cost and sub-cost categories are available for COP 17-19 expenditure reporting; and, for COP20, cost and sub-cost categories will also be available for PEPFAR Budget and Projected Expenditures. When examining mechanisms with low viral load suppression performance, it may be helpful to filter cost categories by the HIV Laboratory Services sub-program area. If treatment coverage is also of interest, consider filtering to the C&T: HIV Clinical Services and C&T: Not Disaggregated sub-program areas to compare how cost category spend differs across sub-program areas. Figure 7.2.15, below, reveals that a large portion of HIV Laboratory Services expenditures was made to contracts, most likely

contracted interventions related either to viral load tests or stipends to staff on site who take samples for viral load testing. If this approach is correlated with poor viral load suppression performance, it may be wise for partners to redirect their expenditures 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. The partner may also need to re-evaluate their contracts if certain contracted interventions are underperforming. Other large cost categories seen below are travel and fringe benefits, both of which may be secondary priorities for an underperforming partner.

Cost categories also 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. The limitation of cost category expenditures is that they do not provide an overview of how many individuals are being supported or where the personnel are working. Importantly, healthcare workers are often included in the “Subrecipient” cost category. Since it is currently not possible to disaggregate Subrecipients by other cost categories in standard work plan budget and expenditure reporting, please consult the mechanism work plan or communicate with the mechanism directly to gain a better understanding of subrecipient spend by cost category.

Figure 7.2.15: HIV Laboratory Services Expenditures by Cost Category and Interaction Type

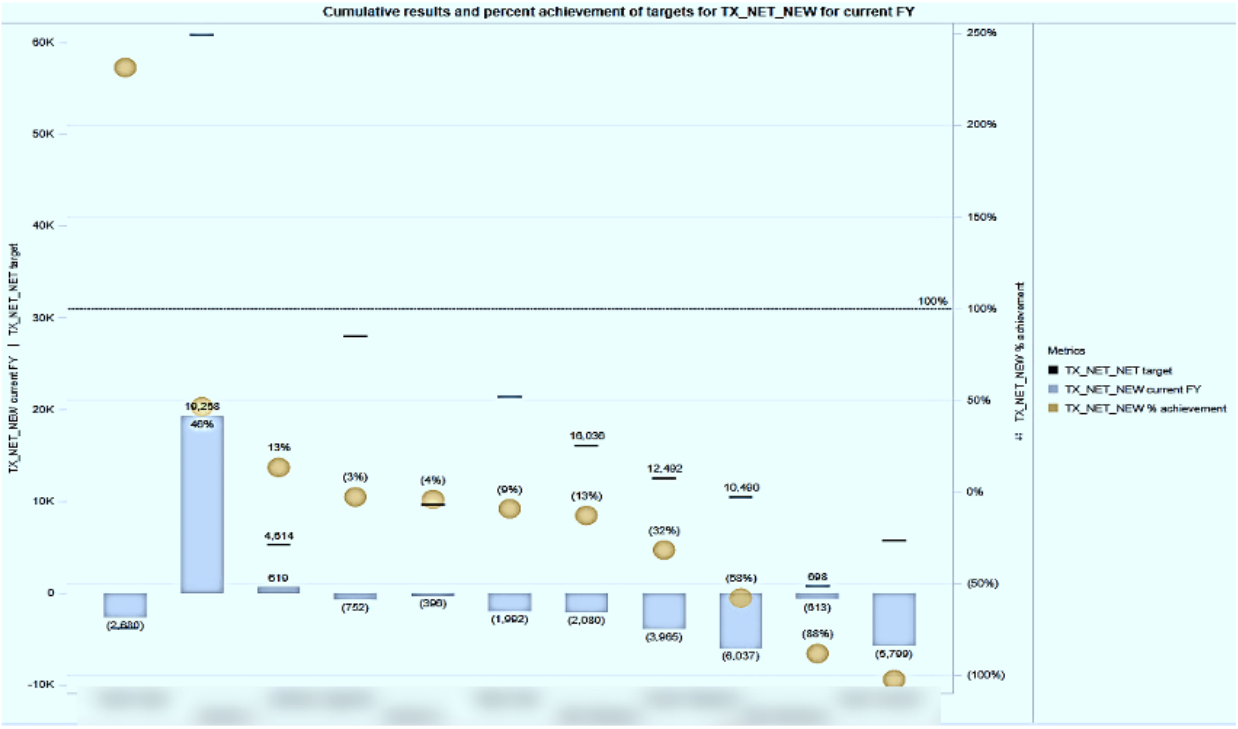


Lastly, it may be helpful to look at total cost categories for the shortlisted IMs, to see if their cost category selection is unique to the HIV Laboratory Services sub-program area, or if the mechanisms spend their budget differently across interventions.

D. What is performance of the program and IPs by SNU and sites in relation to ART continuity and treatment growth?

For these two IMs selected we know that additional questions remain about how these IMs are performing in relation to treatment growth and ART continuity of clients on treatment. In Figure 7.2.16 below, we can see that SNUs overall struggle with increasing the number of patients on treatment as evidenced by the negative NET NEW numbers across several SNUs. In this example, this difference could not be explained by data quality issues at sites within those SNUs.

Figure 7.2.16: Net Change in the treatment cohort (TX_CURR) across SNUs

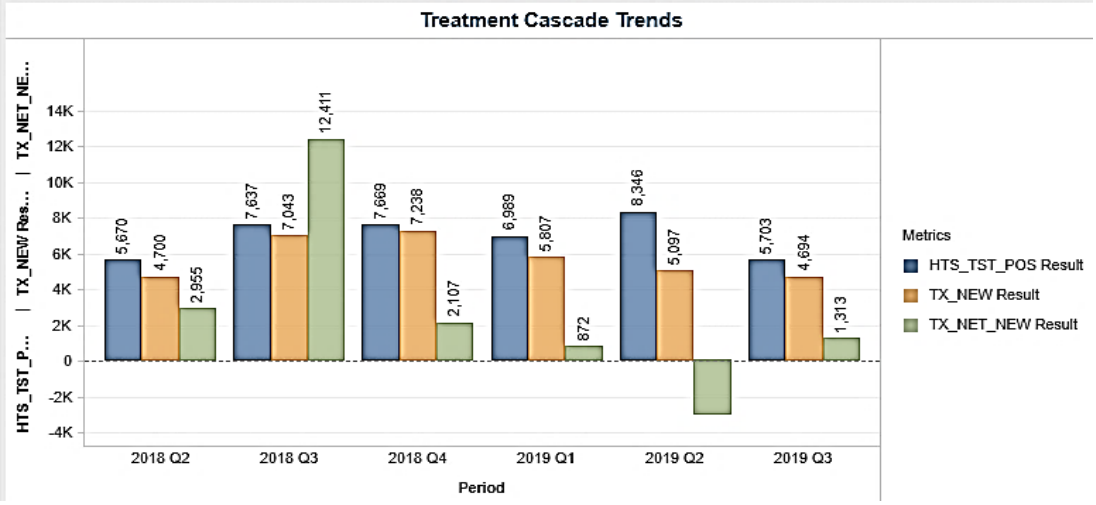


These results were also apparent at the site level (data not shown).

Looking at whether these results are the same quarter over quarter, we continue to see the same challenges in which TX_CURR growth is not keeping pace with TX_NEW. Specifically looking at IM X from the viral suppression analysis, we see that this pattern holds true overall,

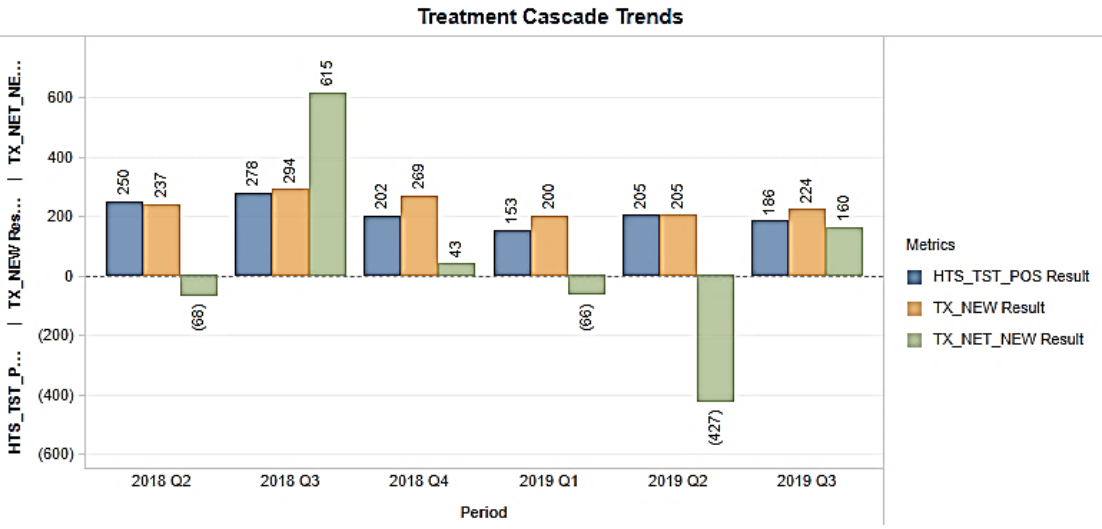
even when comparing under 15 years to over 15 years (Figure 7.2.17 and 7.2.18) across all SNUs.

Figure 7.2.17: Treatment growth in all SNUs supported by IM X by over 15 years



Finally, the disparities in IM X's treatment performance in a single SNU by age also hold when looking at ART continuity by sex over time. ART continuity declined among women over time, suggesting the bulk of the recent losses are from women. Although ART continuity among men has recently improved in this SNU, trends over time suggest challenges in ART continuity among men also exist.

Figure 7.2.18: Treatment growth in all SNUs supported by IM X by under 15 years



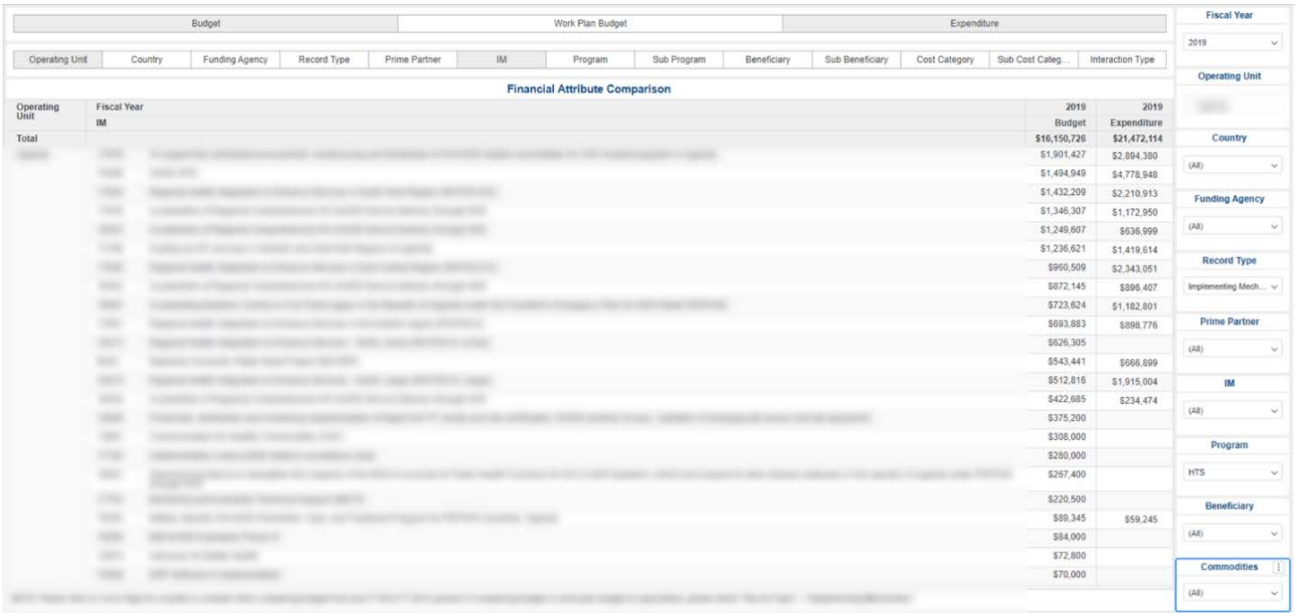
In all these cases, it will be important to understand the number and proportion of patients at the site level who are (1) accessing 3- or 6-month ARV dispensation options (2) taking the optimal

drug regimen of TLD (3) utilizing differentiated service delivery models. Furthermore, knowing whether ARVs are consistently available at the site level (through triangulation with supply plan data and SIMS stockout data) may shed light on site level structural or operational challenges which may be affecting access and delivery of treatment services. Similarly, quality of services or access to services could also be affecting overall ART continuity at sites (see Section 3 on Quality). Looking for more closely at SIMS CEE scores and question level responses (in the Patient Experience and SIMS-MER Integrated dossiers in Panorama) reveal that IM X did not consistently meet standards related to Patient Tracking and Multi-month drug dispensation. Collectively such information from MER, SIMS and ER could help us better understand the factors that may be contributing to this IM's ART continuity and treatment growth challenges.

E. What is performance of the program and IPs by SNU and sites in relation to case finding?

The financial analysis described in Step 2A regarding viral load can be replicated across other program areas. In sub-section E, Testing is the corresponding program area of interest for case finding. The largest testing partners, as measured by budget and expenditure, can again be identified using the Financial Management: OU Dossier, filtering to only show Testing budget and expenditure in Figure 7.2.19, below.

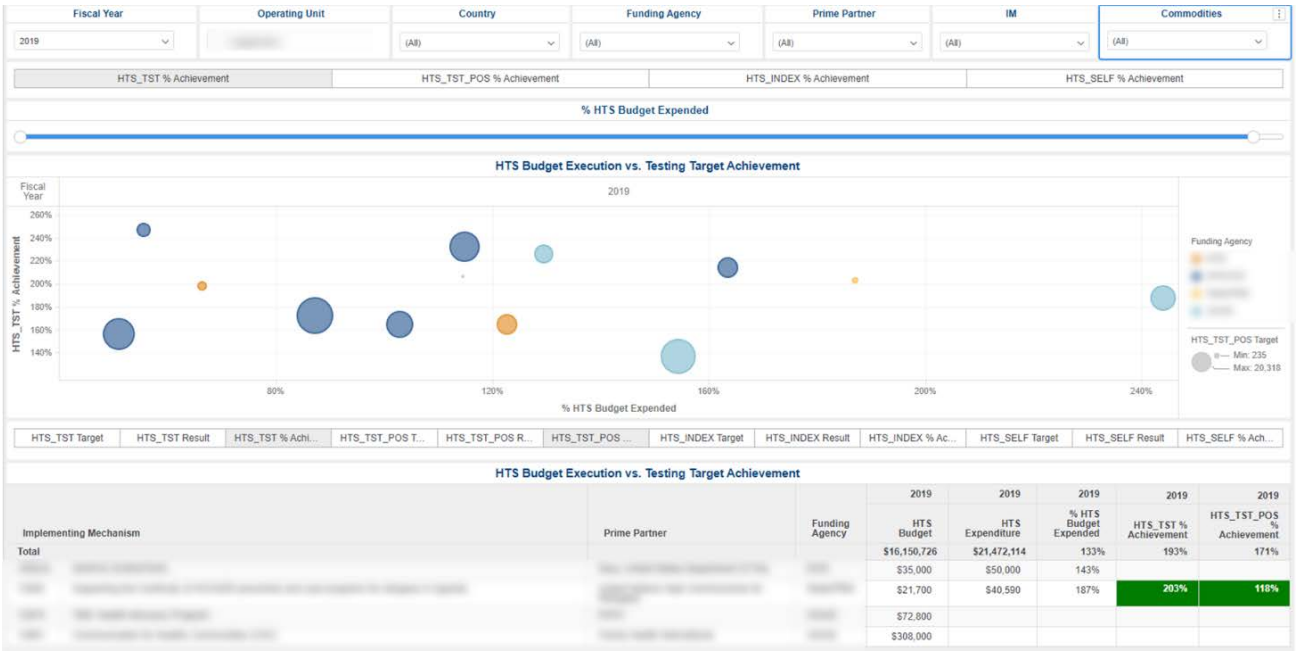
Figure 7.2.19: Testing Budgets and Expenditures by IM



As low performing case finding partners are identified through MER and SIMS analysis for further review, the mechanisms should also be investigated using the Financial Management:

OU dossier to determine mechanism financial performance down to the program area, sub-program area, beneficiary, sub-beneficiary and interaction type (service delivery vs. non-service delivery) levels, as well as the EOFY and O&O report to understand mechanism outlays. The Financial Management: OU dossier will also reveal mechanism cost category purchases. Additionally, the Integrated Analytics dossier, displayed in Figure 7.2.20, below, is useful to evaluate HTS budget execution vs. HTS_TST, HTS_TST_POS, HTS_SELF, and HTS_INDEX target achievement to quickly identify high-performing and inefficient mechanisms.

Figure 7.2.20: HTS Budget Execution vs. HTS_TST Achievement by IM

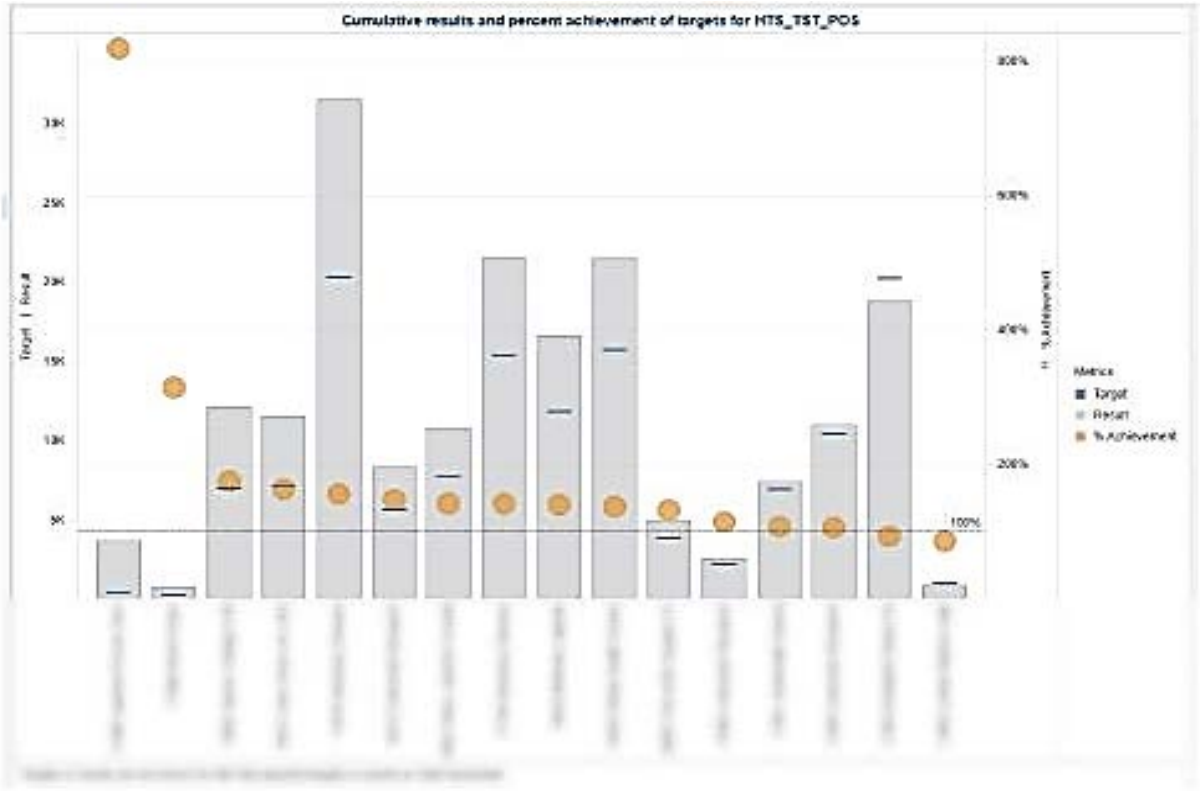


Partner performance at the OU by IM level clearly demonstrates that all IMs are over-testing to achieve their HTS_TST targets (Figure 7.2.21 below). These results do not vary considerably by SNU, suggesting the need for efficiencies in case finding across the board. Moreover, the majority of partners tested above the target by at least 40%, causing programs to potentially spend more on a less effective approach than orient towards a more effective approach.

Figure 7.2.21: IM level Testing performance against targets shows all IMs over-tested by FY19Q3

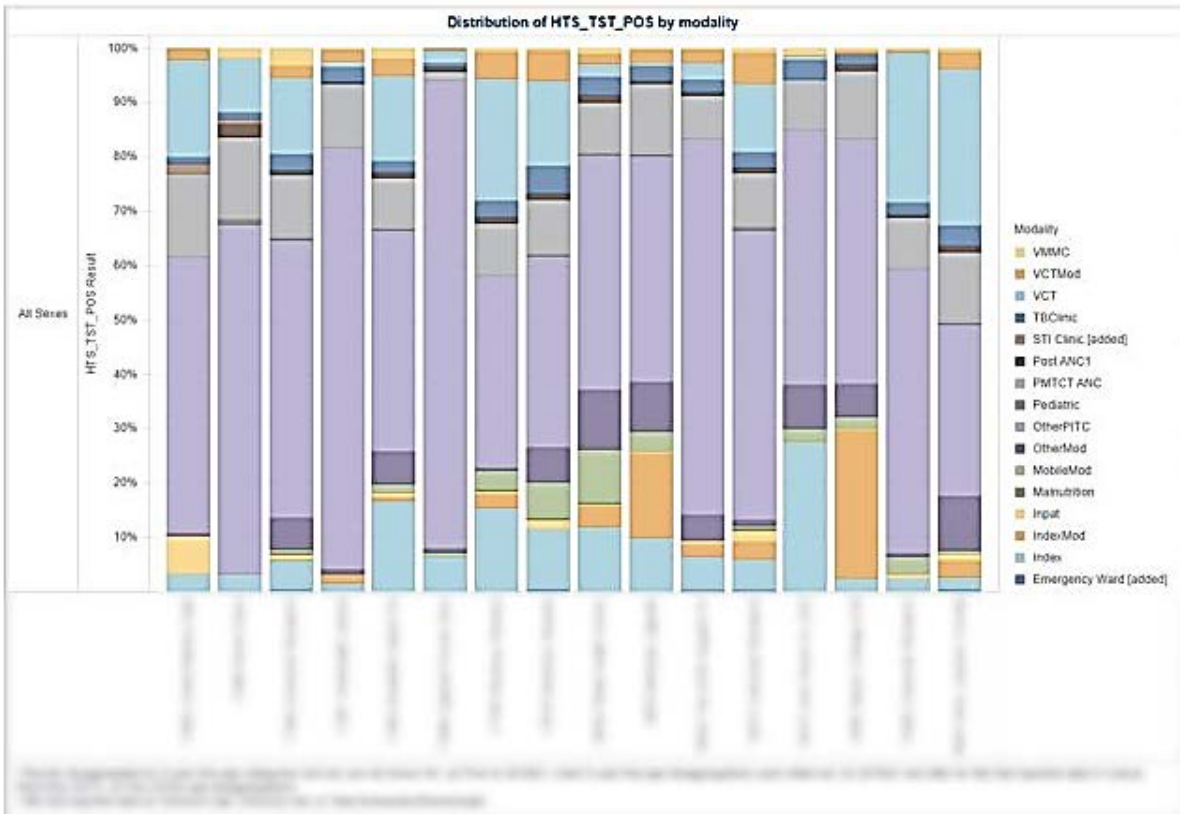
	Uganda		
	FY19 Cum. Results	FY19 Target	FY19 %
	6,171,413	4,165,870	148.1%
	93,871	8,265	1135.8%
	306,669	157,905	194.2%
	967,053	512,981	188.5%
	459,294	262,450	175.0%
	442,589	266,992	165.8%
	257,508	163,389	157.6%
	45,229	29,352	154.1%
	30,026	19,518	153.8%
	80,689	54,465	148.1%
	539,585	373,541	144.5%
	747,271	526,259	142.0%
	318,073	229,261	138.7%
	446,677	326,531	136.8%
	505,712	391,485	129.2%
	290,027	241,209	120.2%
	641,140	602,267	106.5%

Figure 7.2.22: Achievement of HTS_TST_POS targets by IM only possible through high volume of testing



Of these IMs only three IMs had over 20% of their POS results from index testing, further suggesting the need for effective and efficient testing modalities scale up with fidelity (Figure 7.2.23).

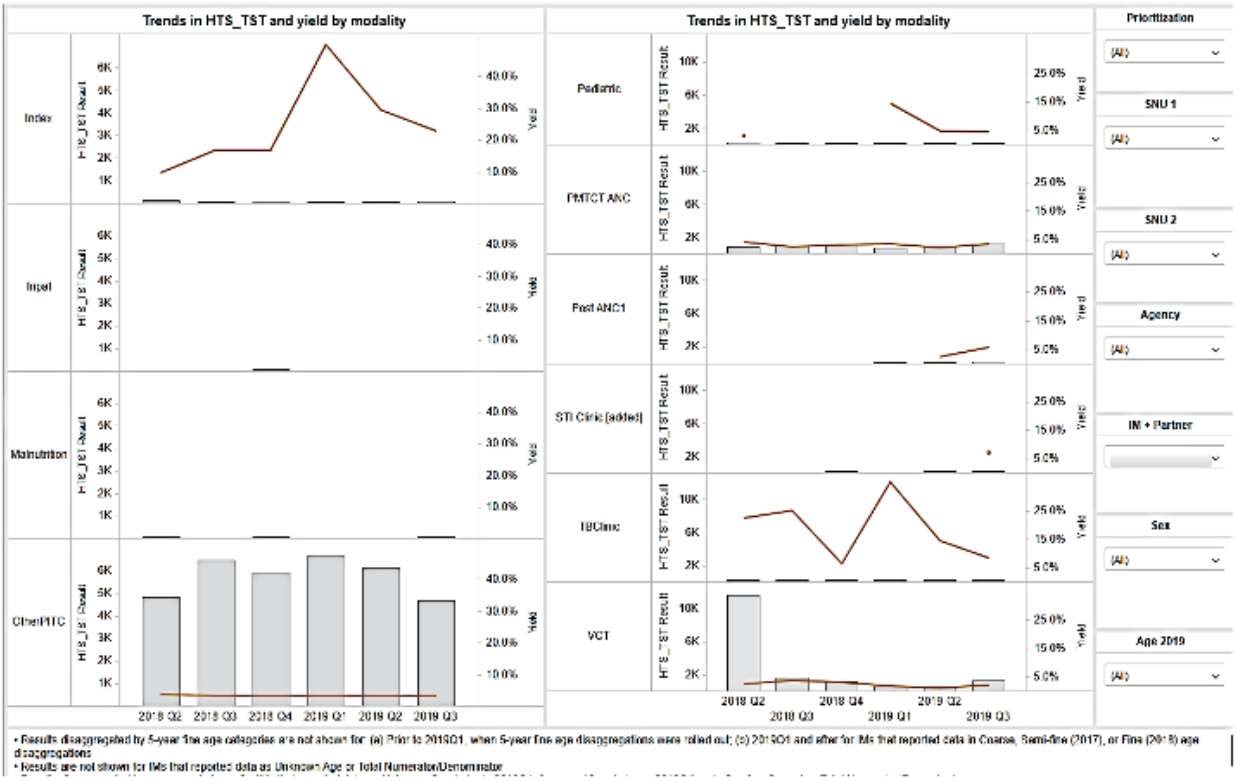
Figure 7.2.23: Distribution of POS from testing modalities demonstrates lower than expected scale up of index testing by modality



A deeper analysis of IM Y identified in the previous viral load suppression and ART continuity analysis showed that overall this IM tested 174,438 persons using PITC while only finding 586 newly diagnosed HIV positive individuals (0.3% yield) compromising cost and human resource time while index testing, although demonstrating a high yield of 27.6%, only identified 16 POS (Figure 7.2.24 below). This program review demonstrates the need to optimize case finding with highly focused PITC and rapidly scale up index testing as means to identify PLHIV.

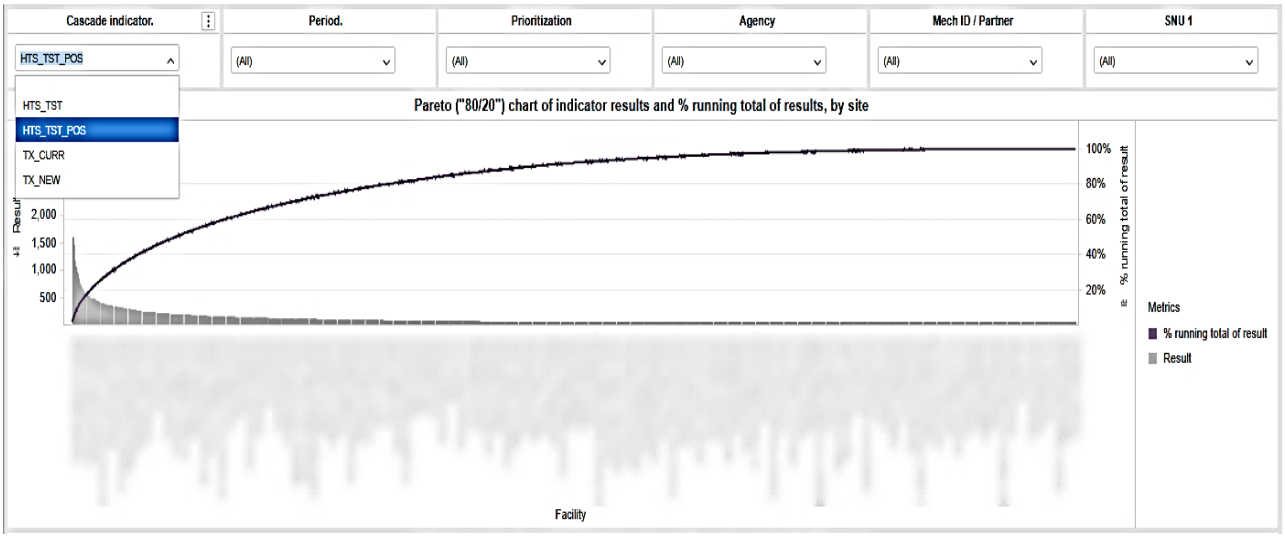
Triangulating against SIMS data, analysis of standards related to routine testing of children of HIV positive mothers demonstrated that 37% of sites assessed do not meet the basic standard of offering this service – leaving many children with HIV undiagnosed and without access to life saving services. Even after remediation and follow-up assessment, 39% of sites assessed still did not meet this standard. Moreover, closer analysis of SIMS data against MER results for this IM, revealed that high volume sites did not meet the SIMS standard most frequently, and rates of contact elicitation at those sites remained low. This suggests there are opportunities for improvement and scale-up of index testing at those specific sites that are being missed.

Figure 7.2.24: Comparison of testing modalities implemented by IM Y demonstrates limited scale-up of index testing



Furthermore, a critical question here is overall performance of this IM at the site level. An analysis of the number of newly diagnosed HIV positive individuals being identified at the site level should be conducted (Figure 7.2.25). Importantly, if 20% of the sites are identifying 80% of the newly diagnosed individuals, then resources need to be refocused to optimize investment.

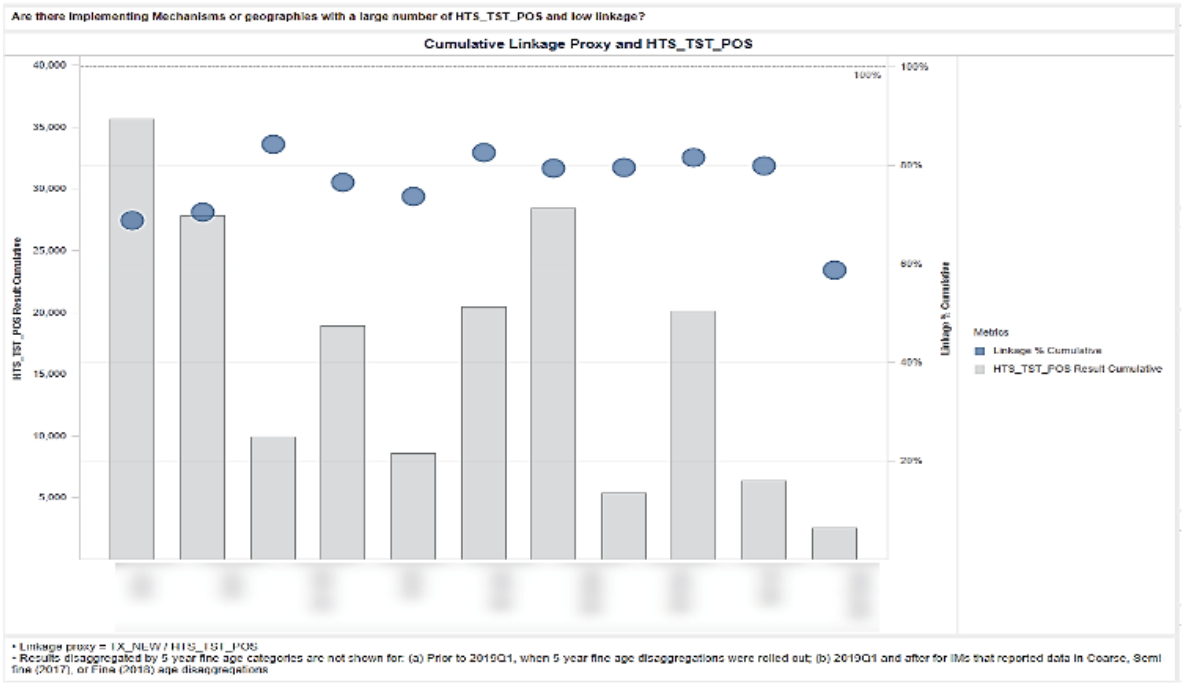
Figure 7.2.25: Site level analysis of HTS_TST demonstrating that a small number of sites are identifying 80% of the POS



F. How is the program performing in terms of linkage and access to treatment services?

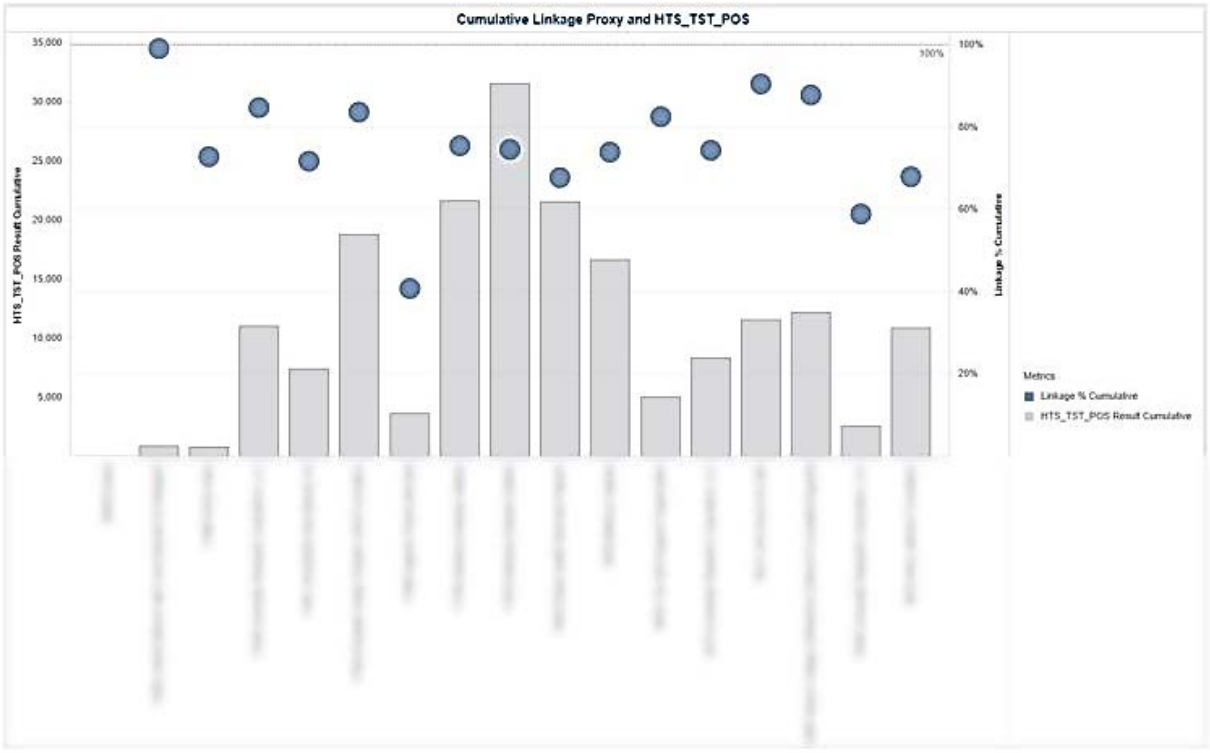
Much like treatment growth and ART continuity, linkage to treatment is also variable by SNU (Figure 7.2.26). Here we see that many SNUs are below even the 80% linkage to treatment threshold, leaving large numbers of persons unlinked to treatment services.

Figure 7.2.26: Variable rates of Linkage to Treatment by SNU in Country X



When exploring this pattern by IM, we see that IMs identifying large and/or small numbers of POS have variable linkage to treatment rates. IM X from our previous analysis has a linkage to treatment rate of under 80%, demonstrating (as mentioned above) that diagnosed PLHIV are not accessing lifesaving treatment services. It thus becomes even more important to understand the root causes of both the variability and the overall lower than expected linkage rates.

Figure 7.2.27: Highly variable rates of Linkage to treatment by IM in Country X

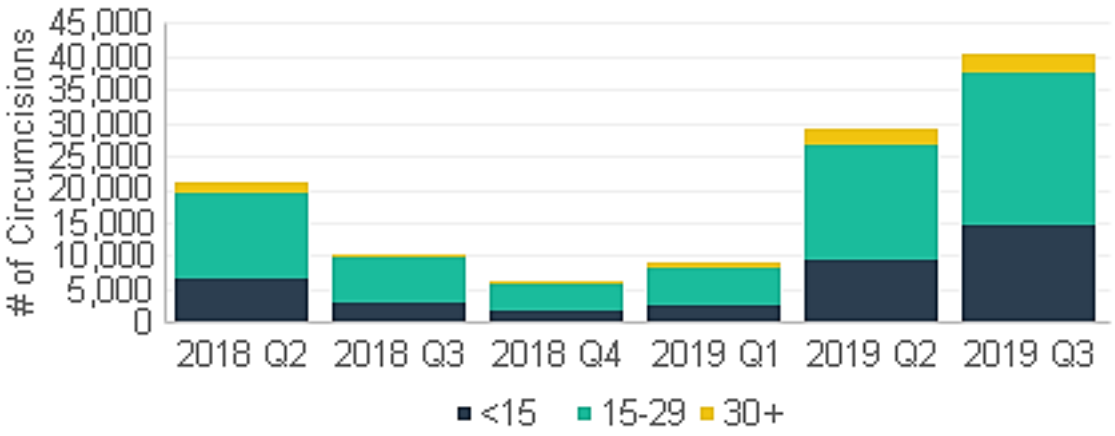


G. How are programs performing in terms of other Prevention interventions?

a. VMMC

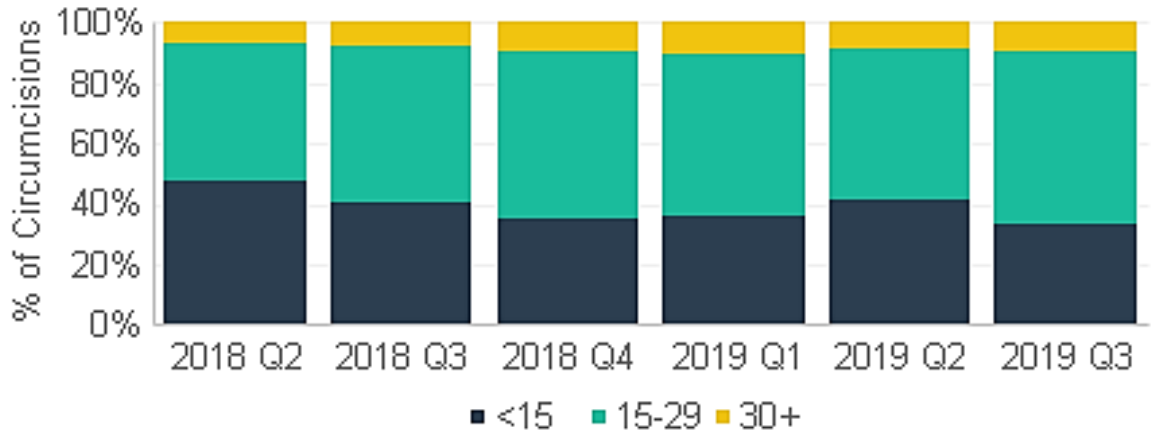
Critical questions for VMMC programs include whether the program is reaching saturation overall, and by SNU in the priority groups. In Figure 7.2.28, we see that country X has been increasing the volume of VMMC quarter over quarter for the last six quarters.

Figure 7.2.28: VMMC volume in quarterly trends of circumcisions by priority age bands increasing over time in Country X



We also see that the relative proportion of circumcisions in the priority age bands has remained steady quarter over quarter (Figure 7.2.29). These patterns hold true for the largest VMMC IMs (data not shown). Triangulating against SIMS data, we see that this IM consistently meets the standards related to VMMC service provision at relevant sites, suggesting the quality of services remains good.

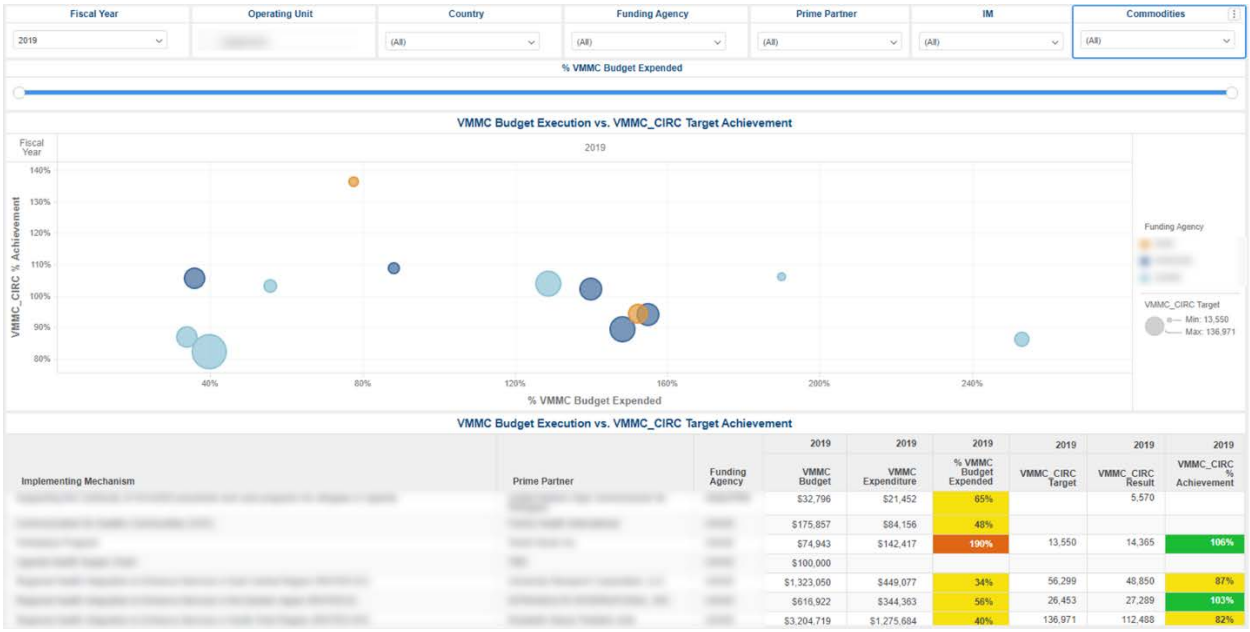
Figure 7.2.29: Proportion of circumcisions in priority age bands remained steady over time



Finally, using expenditure data, we recommend comparing IM level budget execution against target achievement to determine if all IMs are using resources in an effective and efficient manner. In Figure 7.2.30, below, we see that some IMs had low VMMC_CIRC target achievement; however, all but one IM had VMMC budget execution (as measured by the VMMC sub-program area) fall <=100%. In this case, it would be helpful to look at the entire mechanism to investigate achievement and budget execution across other program areas. If the mechanism performed well with responsible budget execution in all other program areas, the mechanism

could be encouraged to dedicate more financial resources to the VMMC sub-program to meet at least 100% of their targets. Conversely, in the case of mechanisms that had >=100% target achievement with very low budget execution, these mechanisms would be good candidates to either reduce COP21 budget while maintaining the same targets since the mechanisms have proven their ability to do more with less; or, these mechanisms would be good candidates to shift targets towards away from low performing mechanisms.

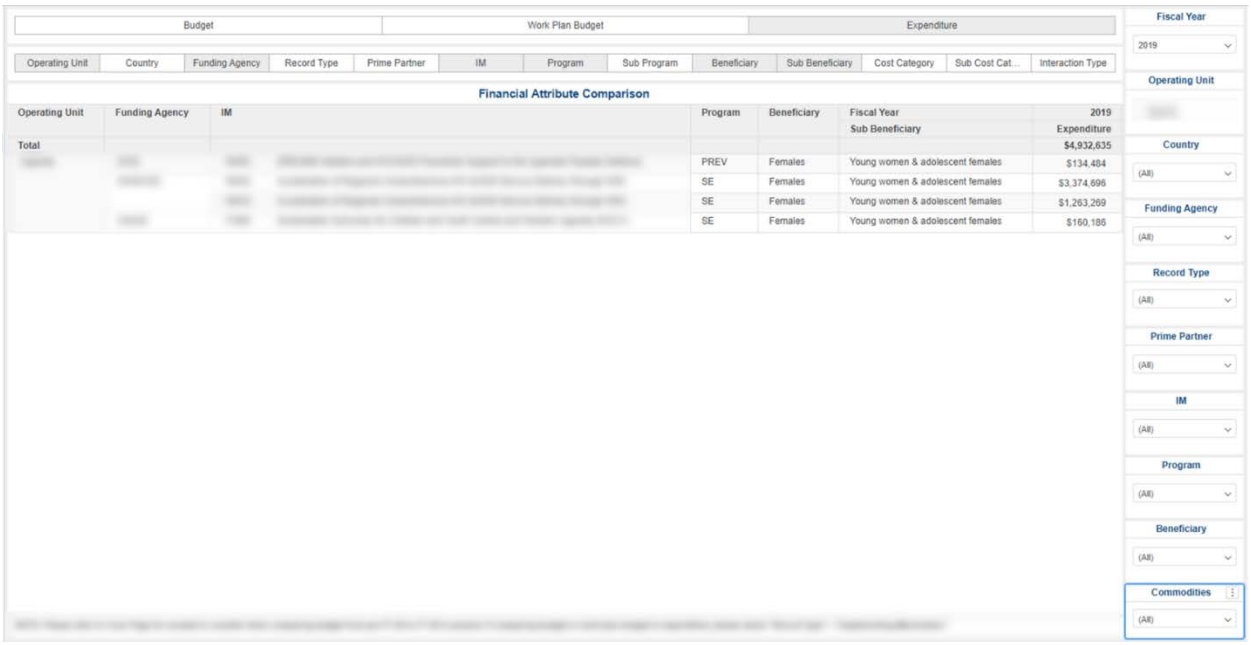
Figure 7.2.30: VMMC Budget Execution vs. Target Achievement in Country X



b. DREAMS

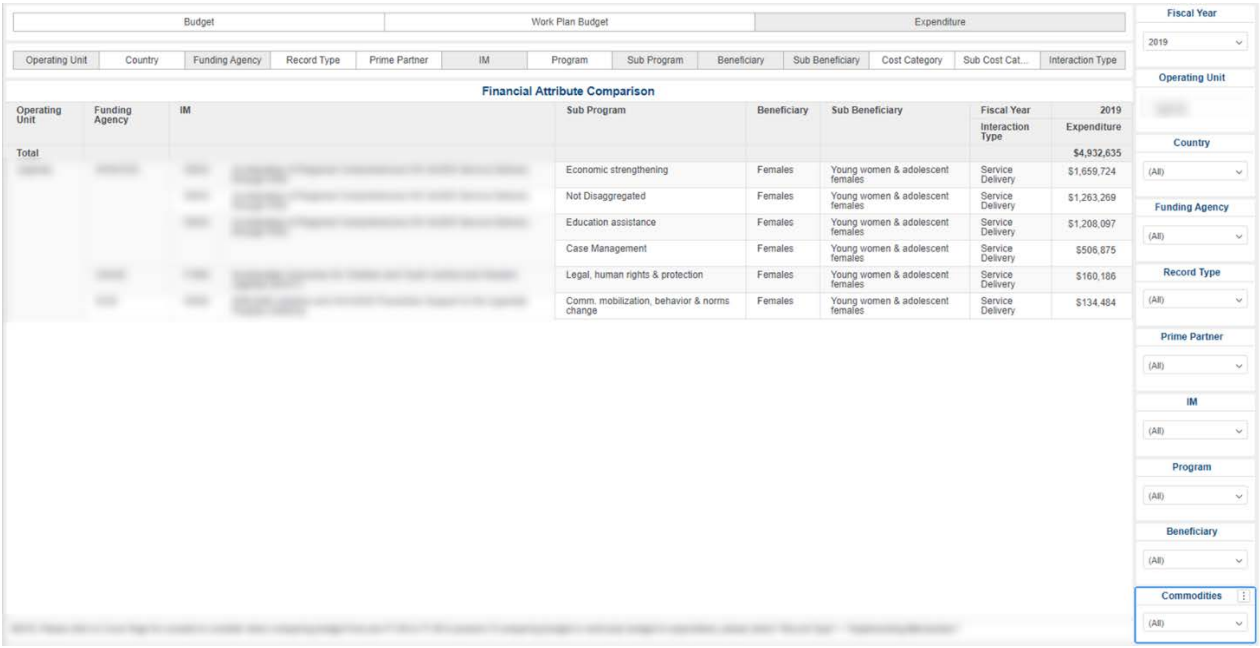
Using expenditure data, we can select the “Females: Young Women & Adolescent Females” sub-beneficiary in the Financial Management: Operating Unit Dossier to identify the partners working with the Adolescent Girls & Young Women (AGYW) population and determine the program areas partners work in to serve AGYW. In Figure 7.2.31, below, we see that the four IMs working in DREAMS primarily spent their budget on Socioeconomic interventions, while also spending a small amount on Prevention activities. This provides useful context when triangulating MER and SIMS data, below.

Figure 7.2.31: Young Women & Adolescent Female Expenditures by Program Area



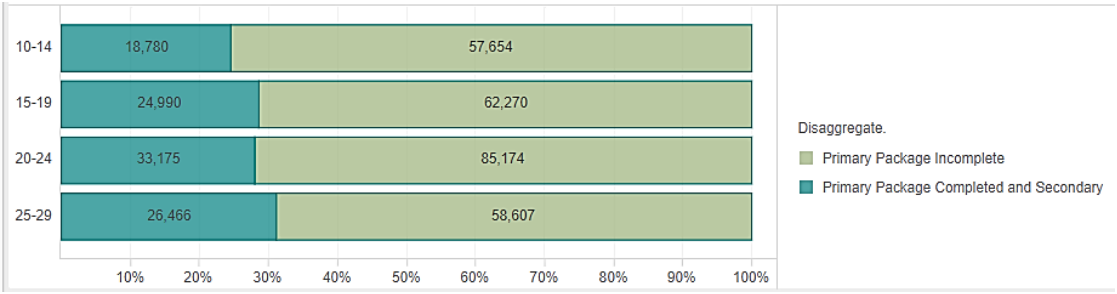
As expected, in Figure 7.2.32, below, most expenditures impacting Young Women & Adolescent Females in Country X are spent on service delivery activities covering Legal, Human Rights and Protection, Education Assistance, Case Management, etc. Knowing how AGYW resources were spent can inform how we view MER and SIMS results from DREAMS IMs and SNUs in Country X.

Figure 7.2.32: Young Women & Adolescent Females Expenditures by Program Area, Sub-Program Area, and Interaction Type in Country X



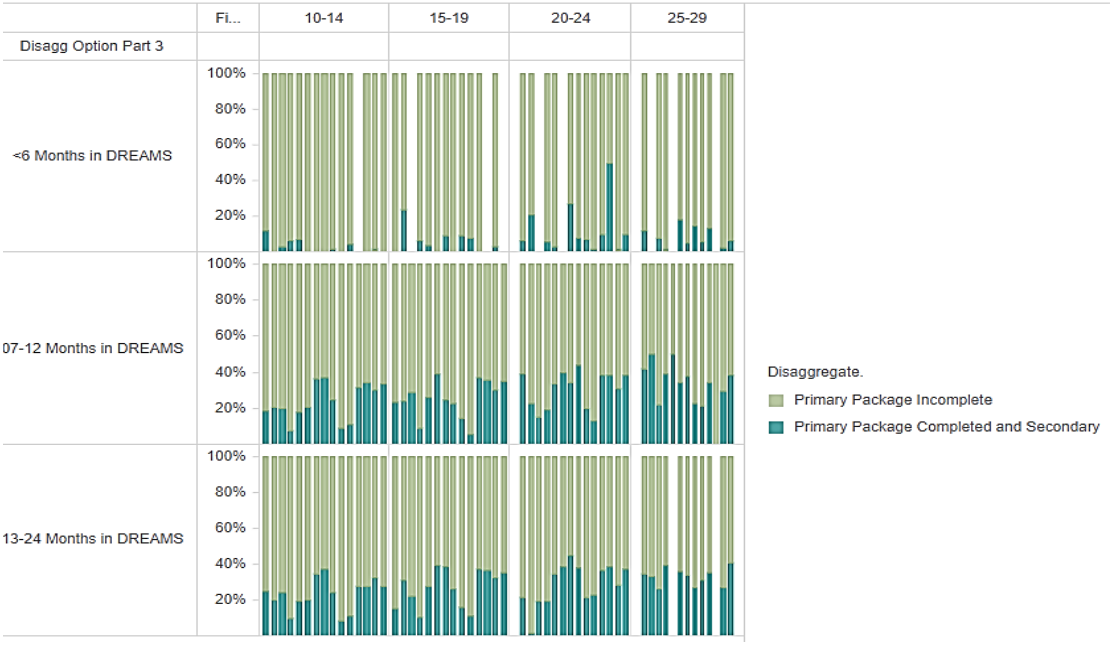
From our MER data, we know that 205,609 out of 367,116 AGYW (or 56%) are in the age group of 15-24 yrs in Country X (Figure 7.2.33). These results do not vary considerably by SNU in Country X (data not shown). Country teams should consider what may be needed to ensure DREAMS programming is increasing targeting the priority age group of 10-14 year olds who make up the smallest age group in Country X.

Figure 7.2.33: Proportion of AGWY who are within the age band 15-24 yrs in Country X versus the priority age band of 10-14 yrs



Similarly, the proportion of AGYW who do not complete even the primary intervention package remains high across SNUs, regardless of how long the DREAMS beneficiary has been in the program (Figure 7.2.34). This suggests there may be broader challenges or barriers to completing the DREAMS primary package that are independent of time in the program.

Figure 7.2.34: Rates of completion of Primary Package of services by SNU do not increase with time in DREAMS, in Country X



Our SIMS analysis in Country X demonstrated that standards related AGWY programming scored a ‘red’ or ‘yellow’ at least the following percentage of the time these standards were assessed: Preventing HIV amongst AGYW (25%), Case Management (38%) and Gender Norms (53%). These results show standards of service quality are not being met consistently, which compromises the overall quality of the DREAMS package available. Note also that expenditure data review above revealed that IMs were spending resources in these specific areas of programming that were also assessed through SIMS, suggesting that a closer look is needed to understand how resources are being spent. Triangulated analysis such as this among MER, SIMS and ER results may help shed light on what may be contributing to the lower-than-expected rates of completion of the primary package.

c. OVC

Critical questions for OVC programming include whether we are increasingly serving beneficiaries aged 10-17, and if the distribution of beneficiaries by age/sex and program status and rates of exiting without graduation vary across IMs. From the figures below (7.2.35 and 7.2.36), we see that the two main IMs (IM A and IM B) are serving a large group of 10-14 yr olds, although the relative proportion of this group is smaller than others (such as 18+). Although, in the first example IM A, almost all beneficiaries were active in the fiscal year, but 10,917 beneficiaries exited without graduation. This suggests that populations reached with services may not be staying in the program.

Figure 7.2.35: Distribution of OVC_SERV results for IM A by program status and age/sex demonstrate potential for improvement in reaching 10-14 year olds may be needed

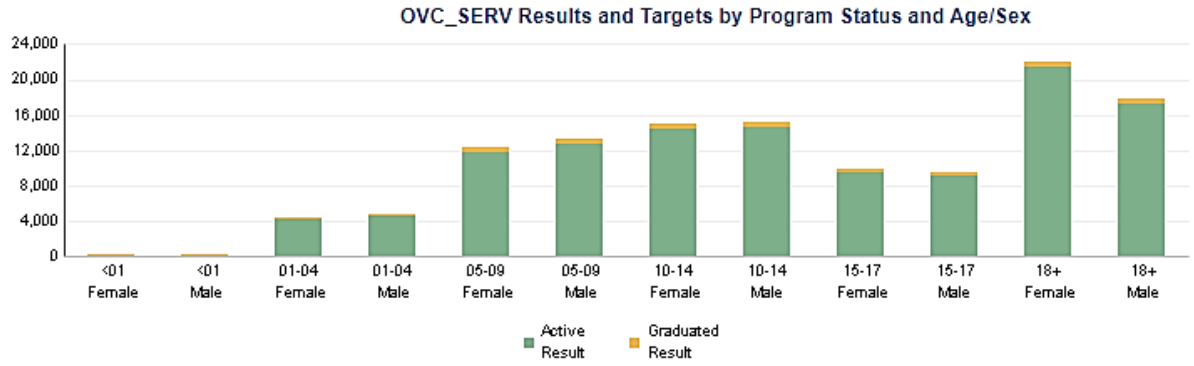
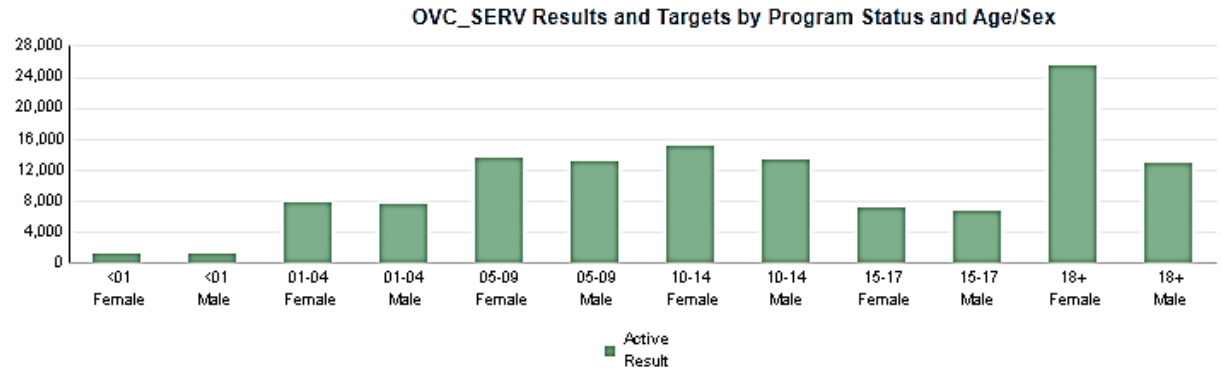


Figure 7.2.36: Distribution of OVC_SERV results IM B by program status and age/sex demonstrate potential for improvement in reaching 10-14 year olds may be needed

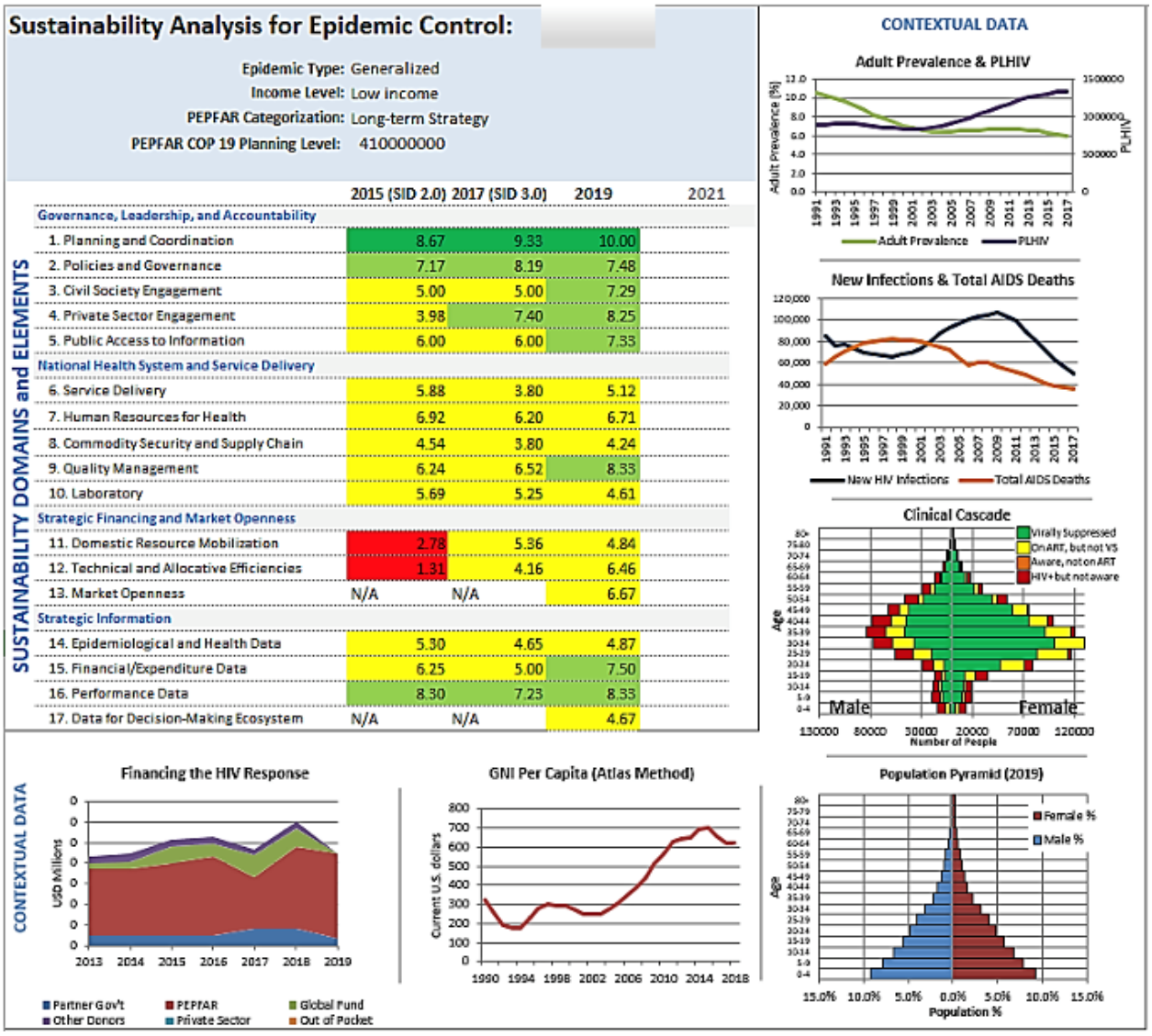


Triangulation with SIMS data demonstrates that both IMs scored a 'red' or 'yellow' at least 20% of the time, at sites where standards related to OVC were assessed (including Case Management standards). This also suggests that a need may exist to understand the quality of services being provided to understand the high rates of exiting without graduation.

H. How sustainable is the HIV response? And who is responsible among donors and host governments? What are the above-site investments tied to performance and achievement of epidemic control? What remains to be funded at the above-site level?

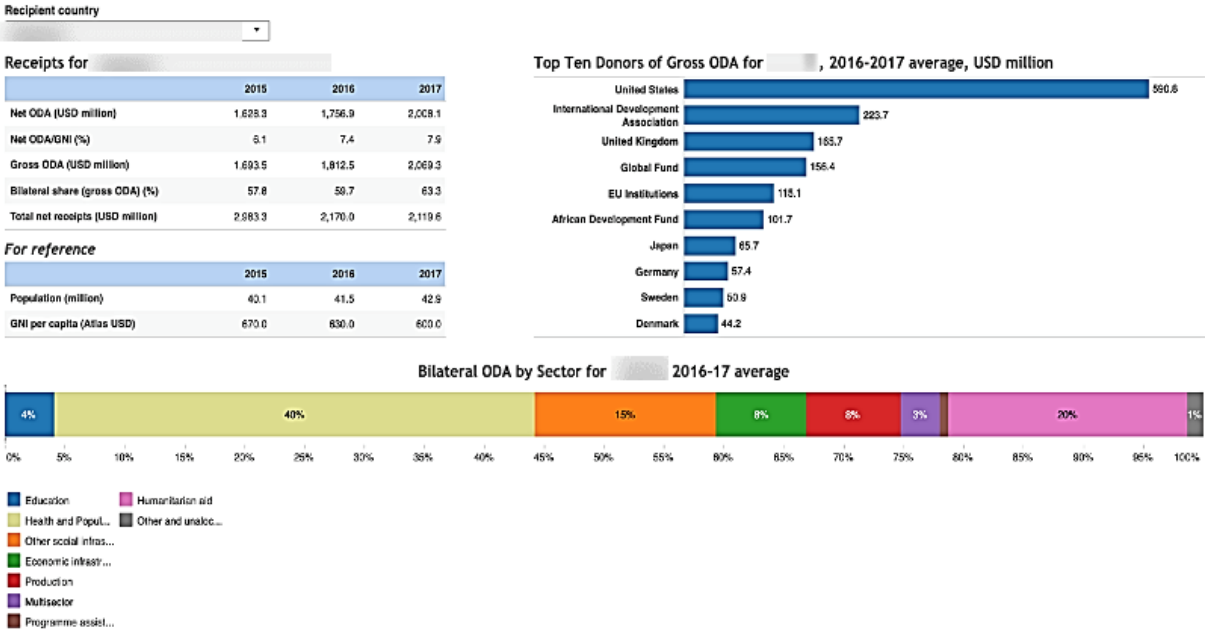
In Figure 7.2.37 of Country X's SID, we see that the national response has persistent gaps in service delivery and strategic financing over time. It will be important to understand why such problems persist, who the responsible parties may be, and what needs to change to see improvement in these areas. In light of the COVID-19 pandemic, it will also be important to understand any resultant effects on the national response.

Figure 7.2.37: SID results demonstrate persistent gaps over time in Service Delivery and Strategic Financing in Country X



To this end, it's important to know the financial investments by donor and program area/sector in-country. For country X, you can see that several different parties are engaged in funding the epidemic across multiple sectors (Figure 7.2.38). Efforts to leverage and maximize all investments and programming are key to achieving epidemic control.

Figure 7.2.38: Summary of donors and investments in Country X by Sector, 2016-2017

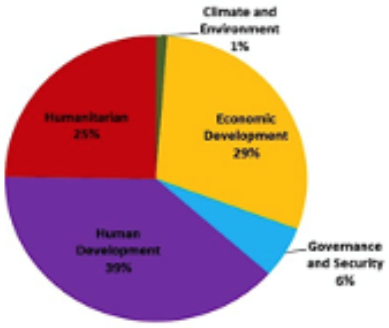


Similarly, it is important to consider what other bilateral partners are investing in health or AGYW programs, and what is the scope of their work? From Figure 7.2.39 below, we see that other bilateral partners have substantial investments in the health and AGYW programs with the aim of achieving the Global Goals. For example, 40% of bilateral funds are used for Health and Population programming. As with the analysis above, understanding and leveraging these investments and donor activities (while avoiding duplication) towards collective goals is key, and should be considered when planning for COP21 activities and setting COP21 budgets by IM.

Figure 7.2.39 Planned bilateral budget for one donor in Country X

Planned budget for 2018/19	**£100m**
Planned budget for 2019/20	**£96m**

Sector breakdown of 2018/19 bilateral plans



Top 3 planned spending programmes in 2018/19 (as at 9th May 2018)

Building Resilience and an Effective Emergency Refugee Response	£35m
Strengthenin Response to Malaria	£10.3m
Transforming the Economy through Climate Smart Agribusiness	£8.8m

Contribution to the Global Goals and other government commitments (achieved as at March 2018)*

248 thousand children under five years old, women and adolescent girls reached through nutrition related interventions

572 thousand additional women and girls provided with modern methods of family planning

56 thousand children supported to gain a decent education

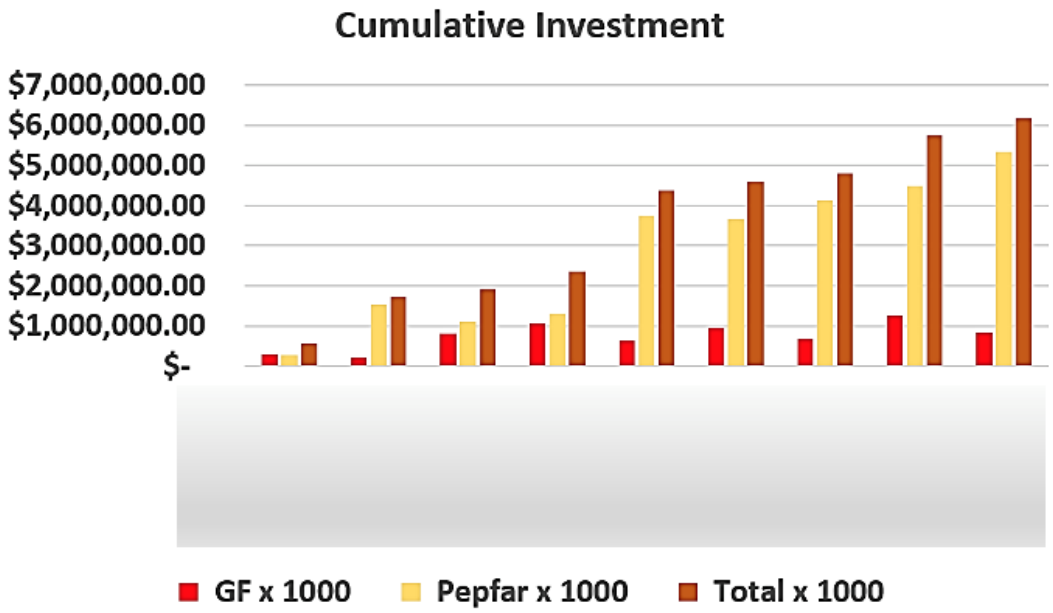
130 thousand people with sustainable access to clean water and/or sanitation

Headline deliverables

- **Economic development:** UK support has led to a 62% average time reduction at targeted border crossings, a 50% reduction in customs clearance times from 3 days to 1.5 days and a reduction in cargo transit time from 8 days to 2 days to provide goods to the market serving over 200 million people. We will continue to unlock opportunities for the UK and other businesses to bid for US $24 billion of public private partnerships projects and support increased incomes for 331,000 people. This will help Uganda create jobs for its people and become a greater trading partner for the UK in the future.
- **Women and girls:** We focus on strengthening health and education systems nationally in order to help manage population growth rate. We are also helping to bring positive social change by increasing choices for women and girls, tackling violence against women and girls and managing high birth rates. Over the next five years we will support over 360,000 women and girls with modern methods of family planning; and help 200,000 women and girls receive an education. Young people and the disabled, often marginalised because of cultural and structural barriers, are at the core of our work.
- **Humanitarian:** Between December 2016 and February 2018, we provided food for over 1,000,000 people; supported 64,000 women and 146,000 under-fives with immunisation and food supplements;

Similarly, it is key to know how Global Fund and PEPFAR resources synergized or aligned to achieve epidemic control, as shown in Figure 7.2.40. In addition, it will be important to know what are PEPFAR, Global Fund and Host Country Government's planned investments, whether we have a complete view of HIV funding in country and how these stakeholders are aligned towards the goals of achieving epidemic control.

Figure 7.2.40: Cumulative investment of PEPFAR and Global Fund in select countries



PEPFAR, the Global Fund and host country governments are the primary financiers of the HIV response. To improve efficiency and impact of these investments, it is important to understand the distribution of resources across the three stakeholders and other contributors where possible. Timing of PEPFAR's COP21 and Global Fund's grant planning cycles along with availability of 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.

The following figures provide trends in planned investments across the three stakeholders and planned 2020 HIV investments across PEPFAR, Global Fund, and host country government by program areas (incl. commodities). This information is helpful in prioritizing resource allocation in some areas instead of others and identifying funding gaps in important PEPFAR focus program areas that may not have enough funding from other sources.

Figure 7.2.41: Trends in total budget by stakeholder in Country X

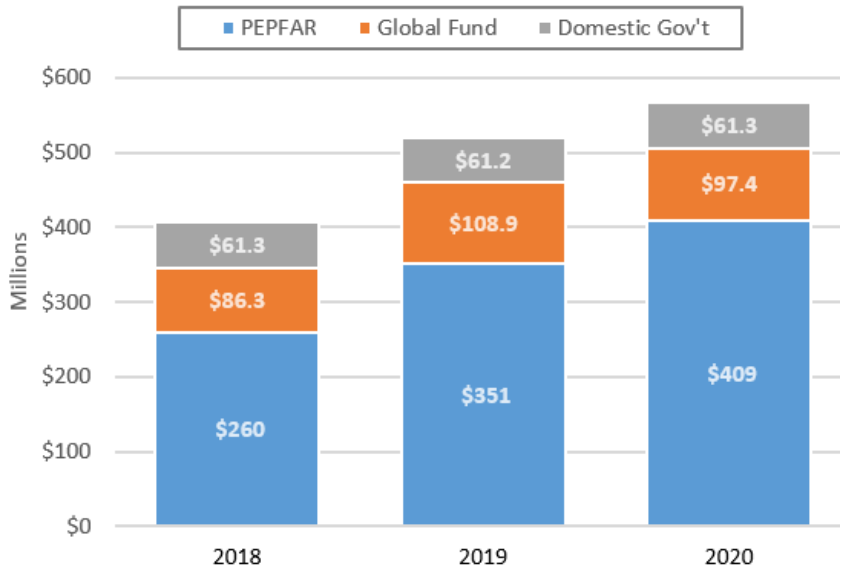
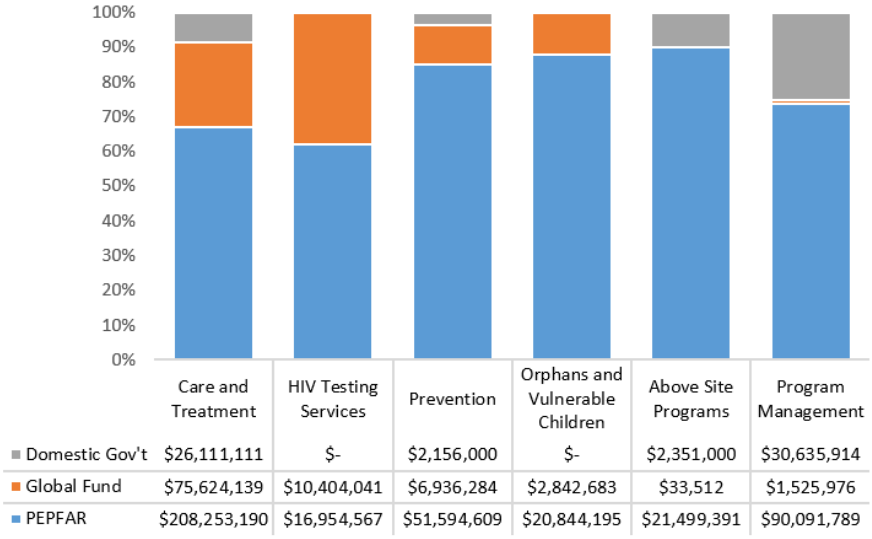


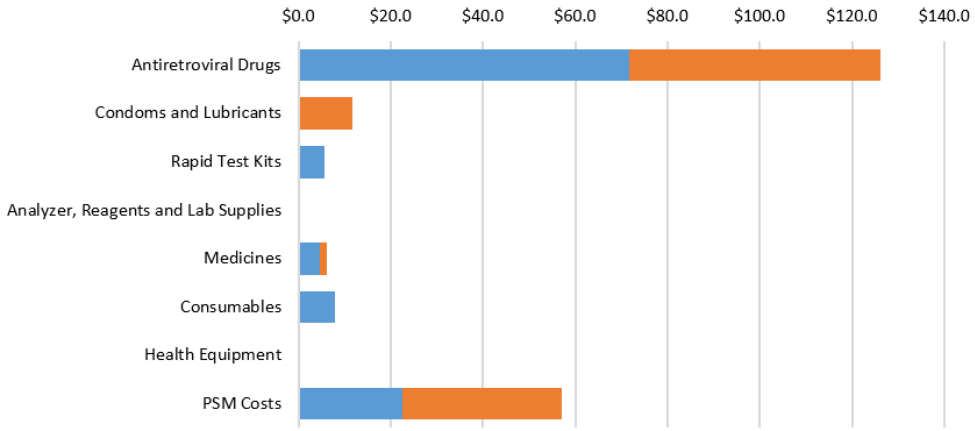
Figure 7.2.42: Budget Proportions by Program Area, 2020, in Country X



	Care and Treatment	HIV Testing Services	Prevention	Orphans and Vulnerable Children	Above Site Programs	Program Management
Domestic Gov't	$26,111,111	$-	$2,156,000	$-	$2,351,000	$30,635,914
Global Fund	$75,624,139	$10,404,041	$6,936,284	$2,842,683	$33,512	$1,525,976
PEPFAR	$208,253,190	$16,954,567	$51,594,609	$20,844,195	$21,499,391	$90,091,789

The following visual and table provide planned 2020 HIV commodity investments by type across PEPFAR, Global Fund, and host country government.

Figure 7.2.43: Country X Commodity Budgets by Stakeholder, 2020



	PSM Costs	Health Equipment	Consumables	Medicines	Analyzer, Reagents and Lab Supplies	Rapid Test Kits	Condoms and Lubricants	Antiretroviral Drugs
PEPFAR	$22,587,618	$-	$7,784,775	$4,520,758		$5,696,934	$-	$71,789,477
Global Fund	$34,497,862	$162,614	$-	$1,541,247		$-	$11,589,307	$54,327,965
Domestic Gov't								

In COP19 in Country X, the following Table 6 investments were prioritized: case-based surveillance, scale-up of PrEP, HRH investments and supply chain. Given the challenges identified in earlier Steps 2A-H, and the known gaps in national service delivery, should these remain to be the main investments at the above-site level? It may be important to consider, what above-site investments would be needed to address known site and SNU level challenges in service delivery around ART continuity of patients on ART and delivery of client-centered services and that are key to sustaining HIV control. Other factors to consider based on the donor profiles above for Country X would include improving ways to leverage other bilateral funds in a complementary manner to achieve Global Goals and epidemic control.

I. 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 2H, country teams should:

(1) Cross-check the IMs they shortlisted (as performing well or poorly) as they completed the sub-steps, against the COP Matrix and Figure 7.2.3 from Step 2A. That is, teams should 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 in order to achieve epidemic control, with a focus on retaining patients in client-centered services

Teams will use this cross-check and detail of program areas 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 be then be determined.

In general, well-performing SNUs and IMs should be preferentially funded while those under-performing should consider have funding decreased. Similarly, sites within SNUs that continue to perform and grow should also be preferentially funded in a manner commensurate with SNU-level targets although site level target setting is not required to be submitted. Where relevant, new SNUs should be assessed based on PLHIV burden. Additional details about targets for such SNUs and IMs can be found in Section 7.5.

'Deep Dive' Questions: TO BE COMPLETED AS NEEDED

As mentioned above, these additional analytic questions are provided to help understand what the root causes or implementation challenges may be. As such, while these 'Deep Dives' should be answered as needed.

- Underlying Epidemiology: What is the demographic, epidemiologic, and national/regional program data to the lowest SNU possible as well as age and sex disaggregated data?
    - If PHIA data are available, teams should triangulate the PHIA results with program data - map program data along PHIA results by region to identify areas/populations that are underserved by community-level PHIA data and address programmatic data and targeting. Overall, this type of analysis identifies those in need of ART by age/sex. PHIA data should also guide the need for program data audits, i.e., program data treatment over-reporting compared to PHIA data on treatment.
    - What does MOH data alignment data demonstrate about the PEPFAR vs. national response? Are there any discrepancies, and why?
        - Are certain sites or PSNUs performing better than others?
        - Are MOH sites with linkage rates over 100% in similar geographies to PEPFAR sites with linkage rates below 90%? And vice-versa?
- Program Performance via MER: Who are we missing?
    - Case Finding:

- What is the quality and scale of implementing of index testing?
  - What proportion of newly identified HIV positive individuals are offered and accept index testing services?
  - How many contacts are elicited and tested (by age/sex)?
  - How many new HIV positive individuals were identified and what was the yield?
  - What algorithm is used?
  - What is the status of recency testing across districts and sites, as it may pertain to case finding?
  - What is the right strategic mix of testing modalities, given your epidemic and current ART coverage by SNU, age/sex with a special focus on number of POS and yields from Other PITC and Index testing modalities?
  - Using FY19 data at a minimum, develop ART coverage and testing tables (i.e., at a minimum, ART coverage and testing data by modality and age/sex) by SNU – either PSNU-level or grouping SNUs depending on your context.
  - Refer to your OU's planning level letter for HTS-specific guidance on prioritized testing modalities depending on ART coverage.
  - Using the data and conclusions from above, map out the following by SNU:
    - ART Coverage
    - Recommended testing modalities and expected yields (for example, expectation of 20-40% yield from index testing)
    - Any age/sex focus populations as per COP Guidance or other data supporting unmet need (for example, if ART coverage amongst men or children remains low, those populations should be prioritized for index testing approaches)
  - Reconcile the tables you developed with the 'mapping' above. That is, determine what shifts are needed in terms of contribution of newly diagnosed HIV positive individuals and expected yields to align with your 'mapping'. Use these inputs to understand the 'right strategic

mix' of testing modalities to be implemented AND expected outcomes from those modalities (such as, contribution of positives and yields by modality and age/sex)

- Were there any documented instances of test kit stockouts and/or challenges with distribution of kits?

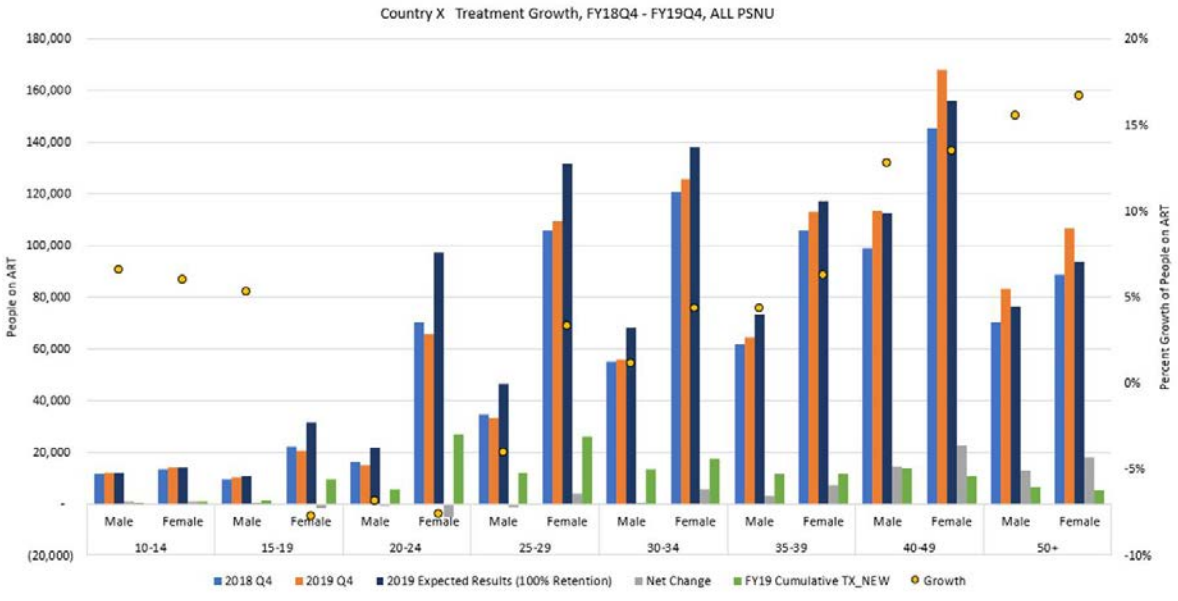
o Treatment: Who are we missing in terms of linkage to treatment?

- What is linkage by age, sex, and geographic location and testing modality? 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 is the linkage rate at sites with the highest number of un-initiated newly diagnosed PLHIV?
- Do initiation rates differ by sex? By age? By SNU?

o Treatment: Who are we not retaining on treatment?

- Who are losing from treatment by age/sex and SNU? How does this loss compare with the rate of treatment growth? How many people are being lost for each person gained? Figure 7.2.44 which continues use of Country X from the above Steps A-I.

Figure 7.2.44: Treatment growth by age and sex, FY18Q4 to FY19Q4 for Country X



- 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)?
- Are all patients eligible for multi-month dispensing accessing and using MMD options? Are all patients eligible for TLD on TLD? How many sites meet these criteria, and what is the volume of patients at those sites?
- 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 and/or challenges with distribution of ARVs?

o Viral Suppression: Who are we missing?

- What is coverage of viral-load testing by age/sex/geography? What are the barriers to 100% coverage?
- What is VLS by age/sex/geography?
- Are those eligible for annual viral load tests getting annual viral load tests? Are results being returned to the client record?

o Tuberculosis:

- What is TB screening coverage of PLHIV by age/sex? Who is missing?
- What is the progress on scale-up of TPT? IPT? What are the barriers?
- What is the HIV testing and ART coverage of TB+ patients? What are the barriers to full coverage?
- What are TB treatment completion rates for HIV/TB co-infected patients? What are the barriers to 100% completion rates?

o Prevention:

- What is the coverage of prevention interventions, including VMMC, condoms (and lubricants), PrEP, and DREAMS interventions (especially among relevant target populations)? Modeling tools can assist countries to estimate unmet need for VMMC for adolescent boys and men, particularly for those aged 15-29 years. Where available, incidence data from surveys, including those showing higher HIV incidences in men older than 30 years, should be

considered in age targeting, so that MC program efforts include age groups with the highest HIV incidence.

- Is PrEP available for pregnant and breastfeeding women, serodiscordant couples, or other high risk populations?
- Are we reaching saturation in high-burden districts for VMMC?

o 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)?

o Key Populations

- What is the performance of the overall clinical cascade? What are the HIV testing modalities, volume, and yield? What are rates of linkage to treatment, ART continuity and viral load suppression?
- What is the proportion of prevention (KP_PREV) reach versus testing reach?
- What is the uptake of PrEP among relevant target populations? What are the barriers?
- How are MAT programs performing (where implemented)?

o OVC

- Country teams should pay careful attention to risk trends across the age span, noting for example high risk of morbidity and mortality among adolescent girls in East and Southern Africa, reductions in numbers of children orphaned, and reductions in the number of children infected via PMTCT. Countries should also look at trend data as the number of children orphaned by AIDS continues to decline with advanced ART coverage. Important MER results data from FY20 Q4 to take into consideration include the following:
  - OVC_SERV<18, disaggregated by age and sex for age 10-17
  - OVC with known HIV status (OVC_HIVSTAT) and also paying 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 exposed children (PMTCT_HEI_POS), pregnant women PW who are newly positive, adolescent pregnant women PW (10-19)
        - 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 via DHS and MICS. 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.
  - Cervical Cancer (if relevant):
    - What is the progress by sex against the target, and along the screening to treatment cascade? What are the gaps in linking from screen positive to treatment?
- Program Performance via Quality (SIMS, CQI, community-led monitoring, completion of assessments required through PEPFAR Guidance on Safe and Ethical Index Testing):
  - What do SIMS results show about overall achievement of quality standards for key interventions? Does these vary by partner or geography?
  - What do SIMS results show about barriers and facilitators to implementing or scaling patient-centered approaches at the site level, especially in sites with challenges in retaining patients? See Section 3.
  - What CQI steps have been implemented to improve site level service delivery, and tailor services to the needs of urban, well, young and/or male clients?
  - What did you learn from any community-led service quality monitoring activities at sites? See Community-led Monitoring section in Section 3.
  - What do we learn about patient-provider barriers, motivations, facilitators to accessing and/or providing quality client-centered services?

- Does elicitation of contacts under 15 years and identification of new HIV positive individuals under 15 years remain low despite clear WHO guidelines and unacceptable high risk of morbidity and mortality among the missing children? Using MER data, we know that the number of HIV positive children identified even through index testing remains low. In particular, the number of contacts who are under 15 elicited from women is lower than expected. This suggests that there may be incomplete coverage of routine testing of children of mothers who are HIV positive. Using SIMS data, we see that performance of the SIMS Standard on Routine Testing of HIV positive mothers performs poorly across all OU (See Section 3 on Quality Assurance). Using these data together, this suggests improvements are needed to ensure all HIV positive mothers are offered HIV testing of their biological children.
- What did the findings from the site-level assessments demonstrate about adherence to PEPFAR minimum standards on Safe and Ethical Index Testing? What improvements and remediations are needed to ensure improved outcomes?

- Financial Performance: Budgets, Outlays, and Expenditures
  - What were the major interventions by planned and actual spending? Were these aligned to strategy?
  - Did what IPs purchase align to what was the stated purpose, e.g., if the budget was for HIV clinical service delivery, did IPs procure health care workers, commodities, or how else did they directly interact with beneficiaries?
  - Using the budgets and outlays as reported through the End of Fiscal Year (EOFY) tool:
    - What are, by agency, approved spend versus actual outlays (as per EOFY)?
    - What is the approach to obligating and approving outlays for an IP that has performance shortfalls?
    - Which mechanisms have had delays in their drawdown of funds, resulting in OPUs or in requests to over outlay?
    - Which mechanisms have unliquidated obligations? What are they related to and will be liquidated in COP20 or will they need to be included in the COP21 budget and outlays?
- Planned interventions and IP work plans

- For each of the IP work plan elements below, teams should review the details about what IPs planned to achieve against the COP strategy and results.
    - Program narrative: Explains how the IP will comply with partner improvement plans and management directives and achieve the targets (categorized as service delivery and non-service delivery activities), above-site benchmarks, and SRE outputs in line with the approved COP/ROP20.
    - Work Plan budget: Shows the cost categories planned for the coming COP cycle. The work plan budget is submitted by implementing partners and follows the COP budget.
    - Targets set against MER indicators.
    - Budget by program area, beneficiary, and cost category as well as budget narrative

- Human Resources for Health (HRH):
    - 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?
    - Is there a functioning information system or inventory to monitor the allocation, deployment, and productivity of host-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? Are PEPFAR-supported workers having an additive impact on workload?
- 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)?

- SID:
  - What were the major findings for each domain? Which elements represented particular 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 COP21, 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.)

- Resource Alignment and HIV Funding Landscape:

- Using the Resource Alignment country profile, what is the strategic alignment of investments across PEPFAR and the Global Fund?
- Does the allocation of funds match program priorities and needs?
- Is there a potential for duplication in the current resource allocation?
- Are they specific areas or types of funds with low absorptive capacities? If yes, what are the possible reasons? How can that be addressed?
- Resource Alignment and SID, MER -- to see if the systems investments are adequately targeted to address issues in the clinical cascade;
- Resource Alignment and MER -- to assess possible duplication, gaps in funding and pockets of inefficiencies
- Resource Alignment and Responsibility Matrix, MER -- to identify areas where agency/host government can prioritize resources based on program need and advance domestic responsibility

- Donor and Government responsibility:
  - The Responsibility Matrix (RM) serves as a baseline assessment of the functional responsibilities of the three major funding components of the HIV response: PEPFAR, the Global Fund, and Host Government.
  - 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?

- Above-site interventions: Efficient and effective above-site investments 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.
  - Are above-site barriers and activities aligned to address barriers to advancing and sustaining epidemic control and improve site-level performance? How is the progress measured?

- Teams should review expenditures and budgets against the Table 6 activities. Is the funding for above-site investments aligned to the gaps identified? Are high priority gaps receiving sufficient funding? Low priority activities have 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 COP19 benchmarks, what is the rationale for continuing in COP21? How many additional years of support is needed?
- For activities that have partially achieved COP19 benchmarks and continuing in COP21, what is the course correction?
- For activities that are not initiated or have not achieved any of the COP19 benchmarks and continuing into COP21, what is the rationale for continuation?
- Where relevant (especially for countries close to epidemic control), are investments in place to support systems for recency and case-based surveillance?

- Surveys, Research and Evaluation:
  - Are previously funded SREs providing data for program action to address known gaps and barriers in achieving epidemic control?
  - Are data from SREs disseminated and widely shared for use by stakeholders?
  - What evaluation activities are occurring in a given OU? (Note that you will only be able to see evaluations in the OU(s) associated with your DATIM account.)
  - What questions are being answered?
  - For these evaluations, what was the level of adherence to PEPFAR's publicly available Evaluation Standard of Practices?

7.3 Planning Step 3: Set Preliminary Budgets, Targets, and Above-Site Activities

By the end of Planning Step 3, PEPFAR teams and stakeholders should have consensus on:

- Balanced IM intervention-level budget for COP21 in the FAST

- Proposed IM by SNU-level targets for COP21 in the DataPack
- Proposed above-site, non-service delivery activities for COP21 in Table 6
- Proposed surveys, surveillance, research, and evaluation activities for COP21 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 COP21, 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 COP21 budgeting approach is the same as for COP18-20. First, COP21 focuses on the intended program outputs and outcomes of the budget. A program is a set of activities that results in a common group of outputs or outcome. These programs are defined as either having a service delivery or non-service delivery approach and are implemented at either the site or above-site levels. Programs are targeted toward an intended beneficiary group. Interventions are the unique combination of program and beneficiary population. The PEPFAR Financial Classifications Reference Guide provides comprehensive definitions for PEPFAR program areas and beneficiaries that are used in both allocating budget and reporting expenditures.

Program budgeting questions:

- 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?
    - Are HIV services being provided by local partners and, if not, what are the plans to increase coverage by local partners?
- Is current investment achieving the intended objective?
    - Is this approach an appropriate intervention for the context, for the epidemic, and for the IM?
    - What are the opportunities to shift services to local partners?

Second, COP21 budgeting builds directly on what was executed in COP19 and planned in COP20. This practice of starting from the previous execution and budget is also known as *incremental budgeting* and focuses on what is incremental or different for the future.

Incremental budgeting looks at the following questions, assuming decisions from Steps 1-3 indicate similar program approaches:

- What needs to go up? For example:
    - Rapid scale-up or expansion to a new geographic area or population
    - 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.
    - Macroeconomic issues such as inflation or nurse or doctor strikes
- 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
    - Underperforming/overspending activities
- 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.

PEPFAR country teams must work during this phase to draft an initial budget in the FAST to use as a starting point for budget adjustment and to identify strategic gaps that need to be closed to align to your country's strategic plan and planning envelope. The FAST is prepopulated with FY20/COP19 IM expenditure reporting and COP20 budgets by intervention and to facilitate the incremental changes for COP21. 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. As in previous years, all outlays that are projected to be during the 12 months of COP21 should be included in the COP21 budgets as either new funding or applied pipeline. It is important to include any outstanding IM close-out costs that may need to be disbursed during COP21, even if it is not clear at this time if they will take place in COP21 or a future COP. Having these close-out costs accounted for in the budget ensures that budget levels are sufficient to meet obligations and outlays.

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. While some program management costs are negotiable and will change as part of the COP budget finalization, others may be less flexible. 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 COP21 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 provide as much detail when selecting and planning the interventions of their mechanisms as is possible for each mechanism to provide and report on.

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.

Budgeting for commodity procurement

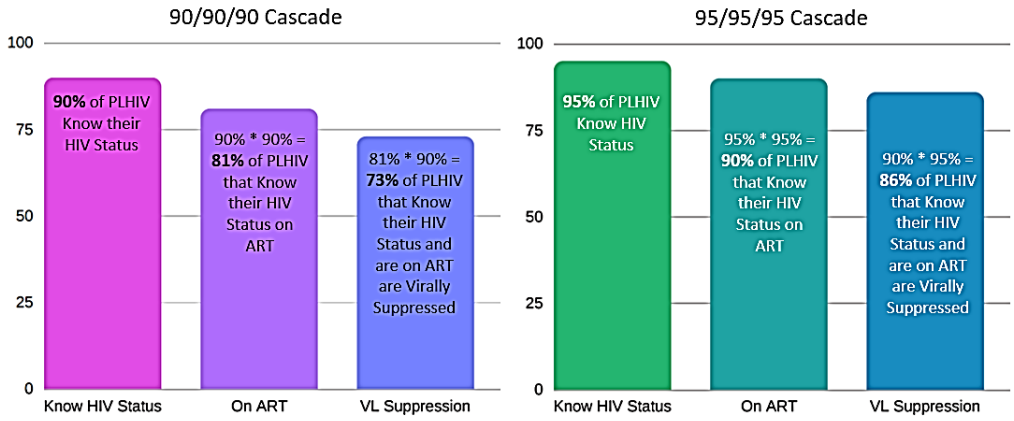
In addition to the overall budget represented by IM-level interventions, additional entry is required when commodities are procured. The commodity tab entry is similar to the process for COP17-20 and is required for all IMs procuring commodities (i.e., ARVs, essential medicines, HIV rapid test kits, 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 chain 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 host-country government and the Global Fund.

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 2021 stakeholder strategic planning retreat. 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. Targets should be set to MER 2.5 indicators. Be sure to review MER 2.5 indicator definitions and DataPack User Guide to guide target setting.

Figure 7.3.2.1: Reaching 95/95/95 at the country level



Attained SNUs: Geographic areas that have achieved ≥90% 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 >90% 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 90% 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 90% of people at all ages, gender and risk groups, PLHIV on ART by 2021 and 2022.
- 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 90% of PLHIV by 2021 or 2022.

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.

As described above, the COP21 development process provides a platform for OUs to review progress toward the COP20 goals and reevaluate which SNUs will be designated for saturation or aggressive scale-up in COP21 (Figure 7.3.2.2). Figure 7.3.2.3 shows the continuous nature of prioritization at the SNU level.

Figure 7.3.2.2: SNU prioritization for epidemic control COP20-21

Refreshing SNU Prioritization for Epidemic Control

COP20 SNU Prioritization	Potential COP21 SNU Prioritization
Attained	**Attained** by default
Scale-Up: Saturation	**Attained** (if >81% ART coverage is expected to be achieved among both adult and pediatric males and females living with HIV by APR 21) **Scale-UP: Saturation** (if ART coverage >81% is not expected to be reached for adult and pediatric males and females living with HIV by APR 21)
Scale-Up: Aggressive	**Scale-Up: Saturation** (if 81% target is achievable by APR 22) **Scale-Up: Aggressive** (if 81% target is not achievable by APR 22)
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 APR 22) **Scale-Up: Aggressive** (if the SNU is prioritized based on PLHIV for the next tranche of scale-up, but a target of 81% is not achievable by APR 22)
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 support based on HIV burden)

Figure 7.3.2.3: 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 15	Scale-Up: Saturation	APR 16	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 16	Scale-Up: Saturation	APR 17	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 17	Scale-Up: Saturation	APR 18	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 18	Attained	APR 19	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 19	Attained	APR 20	86%	84%	85%	89%	83%	94%	88%	87%	94%	89%	95%	88%	95%	87%	89%	86%	95%	89%	97%	91%	95%	83%	94%	90%	92%
SNU 2	COP 15	Scale-Up: Aggressive	APR 16	27%	33%	47%	46%	73%	68%	35%	48%	58%	43%	55%	40%	68%	44%	67%	43%	70%	61%	66%	73%	77%	74%	57%	71%	47%
	COP 16	Scale-Up: Aggressive	APR 17	51%	60%	53%	59%	75%	77%	60%	48%	66%	51%	64%	42%	77%	50%	73%	45%	83%	66%	78%	75%	83%	80%	76%	89%	63%
	COP 17	Scale-Up: Saturation	APR 18	72%	71%	81%	77%	89%	88%	81%	63%	82%	79%	89%	65%	88%	77%	87%	81%	92%	77%	89%	89%	87%	83%	91%	93%	84%
	COP 18	Attained	APR 19	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 19	Attained	APR 20	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 15	Sustained	APR 16	22%	26%	20%	21%	71%	39%	35%	37%	53%	25%	50%	39%	59%	36%	71%	49%	77%	55%	71%	60%	71%	68%	72%	68%	39%
	COP 16	Scale-Up: Aggressive	APR 17	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 17	Scale-Up: Saturation	APR 18	45%	44%	38%	42%	84%	56%	46%	55%	56%	45%	70%	56%	66%	71%	84%	72%	88%	75%	91%	70%	84%	88%	81%	76%	63%
	COP 18	Scale-Up: Saturation	APR 19	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 18	Attained	APR 19	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 15	Sustained	APR 16	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 16	Sustained	APR 17	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 17	Scale-Up: Aggressive	APR 18	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 18	Scale-Up: Saturation	APR 19	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 19	Scale-Up: Saturation	APR 20	67%	63%	79%	70%	75%	90%	88%	65%	89%	75%	93%	79%	94%	65%	75%	64%	85%	74%	89%	81%	87%	82%	94%	80%	85%
SNU 5	COP 15	Central Support	APR 16	N/A: no target required																								55%
	COP 16	Central Support	APR 17	N/A: no target required																								58%
	COP 17	Central Support	APR 18	N/A: no target required																								59%
	COP 18	Central Support	APR 19	N/A: no target required																								61%
	COP 19	Central Support	APR 20	N/A: no target required																								72%

In this example, SNU 1 was prioritized in COP15 to get 90% ART coverage (or saturation) by APR 17. The SNU did not reach saturation of 90% coverage at the SNU level by APR 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 APR 19. In COP19 and COP20, SNU 1 then remains at attained. In COP21, 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 APR 22.

In COP22, the next districts should be identified for saturation by APR 2023. SNUs that were identified as scale-up: aggressive in previous COP cycles should be revisited to see which ones can become saturated by APR 2022 or APR 2023.

Process for Prioritizing Locations and Populations for COP21

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 7.3.3.4, and the analysis 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 7.3.2.4: 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 COP21. **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:

1. 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?)
2. Calculate the percentage of total (national) PLHIV in each SNU
3. Calculate the cumulative burden by SNU by summing and recording the percent of total PLHIV for each SNU entry.
4. Sort SNUs largest to smallest by current ART coverage as of APR 18. 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.
5. 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

Country teams should calculate the **net new patients** required to achieve at least 90% ART coverage for PLHIV (by age/sex) by SNU by end of APR 2022. In determining these targets, PEPFAR teams should adjust for scale-rate, mortality, and changes in program to ensure ART continuity for individuals on treatment.

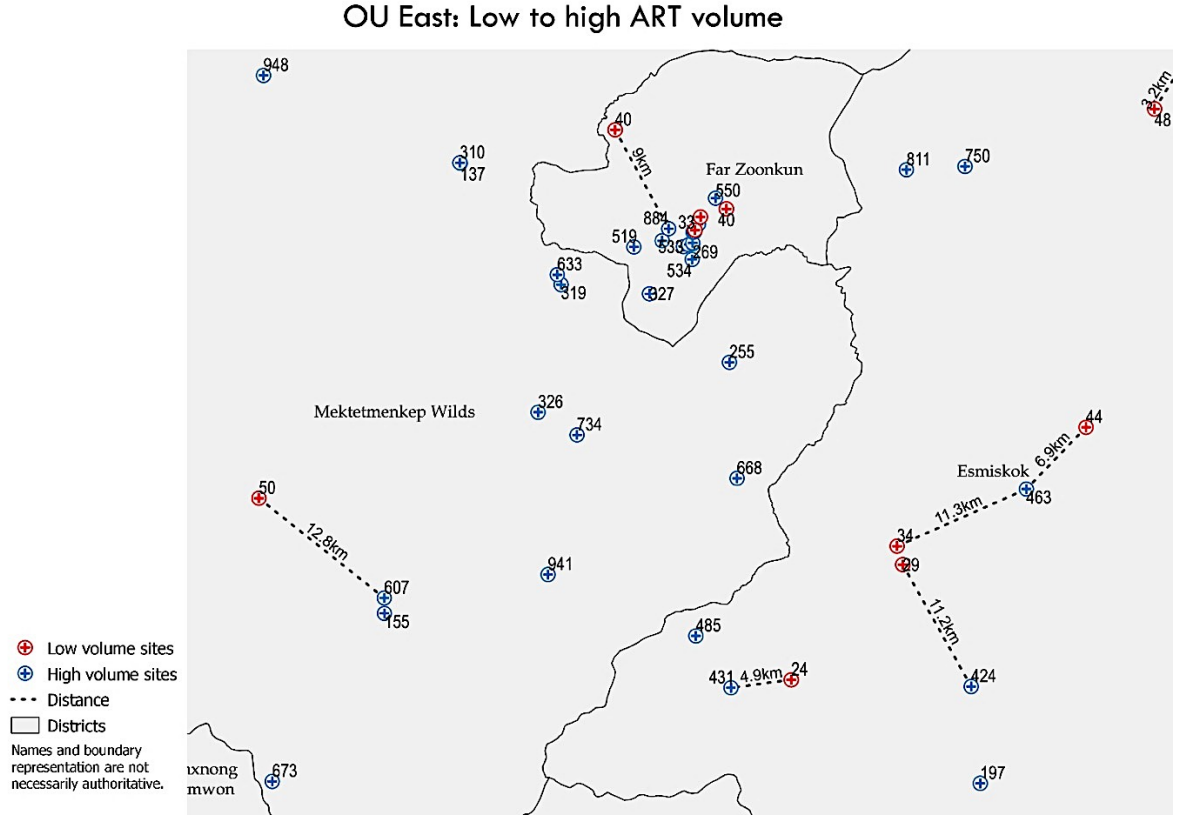
Each country context will be different and one method or standard selection criteria should not be applied across the board; however, there are key considerations PEPFAR teams should take into account when prioritizing SNUs:

1. 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 area 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).

2. Prioritize within high-prevalence SNUs to focus resources on the highest prevalence areas, highest volume facilities, and highest prevalence population groups at the local level, with the highest performing SNUs. Note that definitions of high volume, highest prevalence and highest performing SNUs may different 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 7.3.2.5: Example map illustrating SNUs with potential to consolidate sites based on volume



3. 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 90% ART coverage and accelerated coverage of combination prevention in the hotspot(s) within the SNU.

4. Ensure that gaps in treatment coverage are understood by age/sex to ensure SNUs will high rates of interruptions in treatment or low treatment program growth (and high PLHIV burden) are appropriately prioritized.
5. Ensure that gaps in quality of client-centered services is understood to ensure SNUs and populations with high unmet are appropriately prioritized.
6. Ensure that **local partners** are funded accordingly
7. 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 90% 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 >90%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:

1. 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.

2. Target timeframe should be framed by goals beyond implementation in COP21.

   Strategic planning requires PEPFAR teams to think beyond the implementation year associated with COP21 (FY22). In this COP, the DataPack will support calculating two-year strategic targets (e.g., APR 2022 and APR 2023), however teams are *not* expected to submit site-level targets.

   In COP15, for ART coverage specifically, teams were requested to select priority locations and populations in which coverage of 81 percent is possible by the end of FY17 and then FY18 and FY19. Since areas have already been identified for saturation in FY20, in COP21 teams should identify the areas for saturation by FY 2022. 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.

3. 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 COP20 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 host 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:

1. **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.

2. **TB-HIV patients**

   Teams should initiate ART in TB patients diagnosed with HIV.PEPFAR teams should estimate how many individuals currently receiving TB treatment and TPT at TB sites will receive HIV testing and be linked effectively to ART sites as newly initiating ART patients.

3. **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 (EID) of HIV-exposed infants is another important opportunity for case finding and pediatric ART initiation.

4. **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.

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.

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_CURR. 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 2.5 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.

While setting OVC targets, teams should focus on providing a comprehensive package of prevention and treatment services and supports to OVC ages 0-17 years, with particular focus on adolescent girls in high HIV burden areas, 9-14 year-old girls and boys in regard to primary prevention of sexual violence and HIV, and children and adolescents living with HIV who require

socioeconomic support, offering OVC program enrollment to at least 90% of children and adolescents living with HIV (TX_CURR<15 and <20, to cover OVC_HIVSTAT_POS<18). 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.

7.3.3 Client-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, decreased manufacturing workforces causing decreased supply capacity, 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 COP21.

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 COP21. 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. 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
- Stakeholder engagement
- Quantification and forecasting
- 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. 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 COP21, S/GAC will lead a preliminary review and feedback process of all proposed surveys-surveillance, research, and evaluations (SRE) during the COP21 Strategic Planning Meetings. Section 8.4 of the COP2021 Guidance describes the SRE COP elements and submission process in greater detail.

7.3.4.1 Prioritize Activities in Table 6

Accelerating progress toward epidemic control and ensuring that the program's achievements and gains are consolidated and sustained remain major areas of focus. Thus, sustainability remains 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 operationalize the sustainability framework (Section 2.4) that sustains the gains made towards achieving epidemic control.

In COP21, 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 COP21 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 host 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, 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 has further highlighted system strengths /weaknesses and changed priorities?
- Focus on gaps
    - SID 2019 – Does SID 2019 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 host country?
- Teams should review expenditures and budgets against the Table 6 activities. In COP21, for the first time, country teams will have access to complete COP19 budget and expenditure data for all IPs.
    - 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 COP19 benchmarks, what is the rationale for continuing in COP20? How many additional years of support is needed?
- For activities that have partially achieved COP20 benchmarks and continuing in COP21, what is the course correction?
- For activities that are not initiated or have not achieved any of the COP20 benchmarks and continuing into COP21, what is the rationale for continuation?

7.3.4.2 Review and Revise Resource Alignment Table

The Resource Alignment collaboration between PEPFAR and the Global Fund has enabled the availability of routine financial data to get a more complete picture of the HIV funding landscape across countries. This information is key to efforts to make strategically aligned resource allocation decisions, avoid duplication, drive efficiency, improve the cost analysis and resource estimations of HIV treatment and prevention programming and advance greater domestic responsibility, resource mobilization, 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. However, domestic government and other funders data are less widely available and need to be verified during the COP planning process.
- Country teams will receive pre-populated resource alignment data verification sheets that will include domestic government and other funders HIV funding data as currently available from PEPFAR's COP20 and the Global Fund's grant making processes.
- In collaboration with host country counterparts and other stakeholders, country teams will facilitate the verification of HIV funding data for domestic government and other funders (i.e., non-PEPFAR and non-Global Fund). Country teams are not expected to verify PEPFAR and Global Fund data since this will be retrieved directly from the respective HQ systems to populate the resource alignment country profiles.
- Once the verified templates are received from the country teams, pre-populated country profiles reflecting HIV funding data across PEPFAR, the Global Fund, domestic government, and other funders where applicable will be available to country teams.
- These country profiles are intended to facilitate a collaborative planning process, inform guided discussions around strategic alignment of investments across entities, get a fuller understanding of the HIV funding landscape, and assist country teams in completing the "Investment Profile" section of 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 chain planning and forecasting for the OU, for all key HIV commodities, even if the procurement is not using PEPFAR funding.

Aligning the budgets and targets with the strategic direction from the completion of Step 2 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 FY21 and what improvements are being done in FY22.
- Did planned budgets and targets shift based on partner performance?
- 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 COP21 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 chain 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 COP21 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 90/90/90 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. Additionally, visibility should be extended to current orders and forecast for when deliveries of ARVs will arrive in-country, across all donors (PEPFAR, Global Fund, etc.) and procurement by the host-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).
- 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 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 18 out of 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.

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 COP21 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 COP21 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 COP21 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 COP21 Meeting.

Step 5 is to complete the COP21 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 COP21 Planning Meetings.

As in COP20, 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 COP21 Planning Meeting.

7.6 Planning Step 6: Finalize and Submit COP

To finalize COP21, country teams must finalize the budget, targets, SDS, and all supplemental materials in advance of the COP21 approval meetings.

To complete the COP submission:

- 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
- Final FAST with budget balanced to planning levels, required applied pipeline, and mandatory earmarks
- Submit age and sex disaggregated targets by IM in DATIM
- Submit the SDS and supplemental documents

7.6.1 Develop Annual Work Plans and Targets

Keeping to the COP21 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 COP21 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[434] 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 COP/ROP21. 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 COP21 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 COP21.

PEPFAR teams should use the guiding questions and adhere to the required tables and figures in the SDS templates to successfully meet this COP21 requirement.

The SDS templates may be downloaded on the PEPFAR SharePoint COP21 website.

Note: The COP21 SDS is a public document, to be shared with stakeholders during development and prior to submission and published on pepfar.gov 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

434 Ambassador, Chargé, or Deputy Chief of Mission

distributed outside of PEPFAR implementing agencies/partners and released into public domain. Elements that may be useful for internal program planning, but not yet cleared by external owners (e.g., unpublished data provided by host 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.

8.3 Funding Allocation to Strategy Tool (FAST)

The COP21 FAST is a refinement and simplification of the COP20 tool, with the major change being the elimination of budget codes from the tool. 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. Budgeting will continue to take place at the intervention-level, which was also done in COP19's and COP20's FASTs.

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 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 COP21 planning to implementing partner management is clear. IM-level budgets 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 COP21 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 COP21 Strategic Planning Meeting and will provide a final review at the COP21 Approval Meeting. Prior to COP21 Meetings, Table 6 must also be disseminated to in-country CSOs and CSO COP21 Meeting participants.

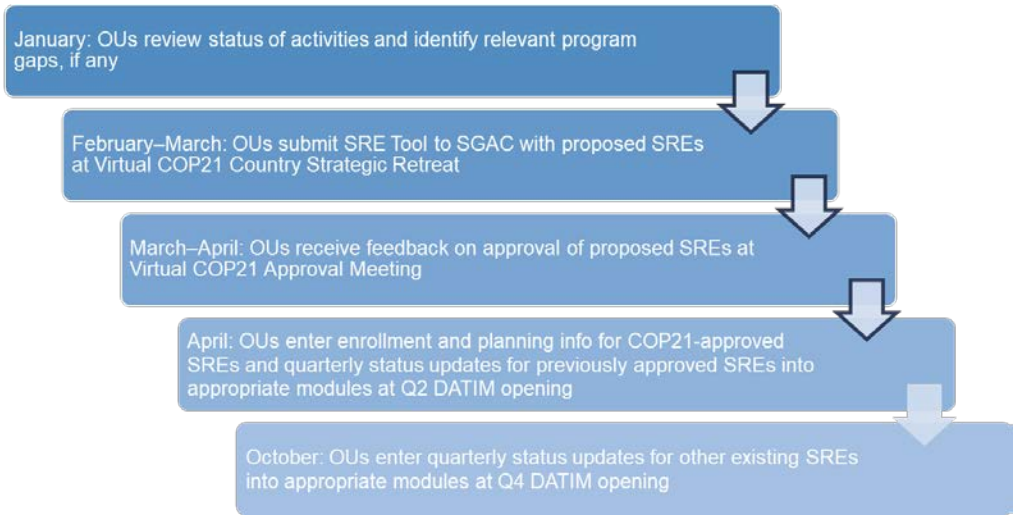
Table 6 should draw on the results of SID 2019 and previous year's performance as described in Section 7. Teams should use the tool to propose continued or new activities for COP21, providing details on the timeline, proposed budget, benchmarks, and gaps the proposed activity will address. This information will be used at the COP21 meetings to provide a view of countries' past ASP and assist in determining needed ASP for COP21.

The SRE Tool should draw on Table 6 and the previous year's SRE Tool. 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 COP21 meetings to provide a view of countries' past SRE activities and assist in determining SRE activities needed for COP21.

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 COP21 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.

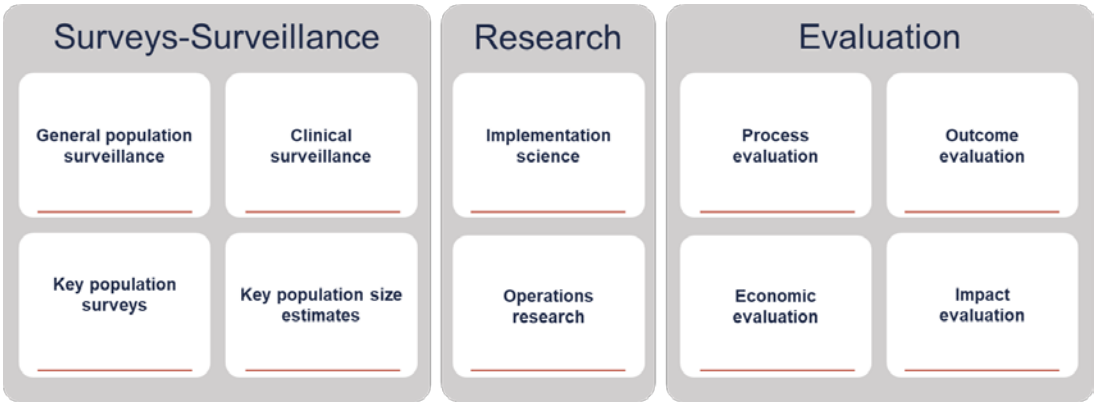
Figure 8.4.1: SRE process and timeline for COP21



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.[435] 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 COP21 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.

[435] 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 COP21 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.[436]

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.

[436] 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).[437]

PEPFAR supports four types of evaluation activities: process, outcome, impact,[438] 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 COP21 SRE Tool.

Evaluation requirements for COP21 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

[437] Foreign Aid Transparency and Accountability Act (2016). https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf

[438] 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. S/GAC will provide additional guidance on criteria for conducting impact evaluations during the COP21 planning process.

ESoP responds to recommendations by the Government Accountability Office (GAO) and the Institute of Medicine (IOM), as well as stipulations within the congressional reauthorization and requirements established under the Foreign Aid Transparency and Accountability Act of 2016, to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. PEPFAR ensures compliance with 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.

8.5 Commodities Supply Planning Tool

The PEPFAR Commodities Supply Planning Tool will again be required to be completed by the twenty-four standard OU teams. This tool can be found on PEPFAR SharePoint under the guidance, tools, and resources folder. PEPFAR Coordinators should share this tool with their respective Ministry of Health commodities planners. This tool 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 host-country government, the Global Fund, or other entities). Planning for COP21 logistical requirements must include participation and collaboration from the PrEP and 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 18 months of all ARVs (adult, pediatric, infant prophylaxis, PMTCT, and PrEP) that countries will use for ART. The tool will require countries to map out current stock on-hand of each ARV, condoms and lubricant, laboratory product, rapid test kit, tuberculosis, and VMMC product. 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.). 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 multi-month dispensing.

The Commodities Supply Planning Tool has undergone numerous changes for COP21 that should facilitate its completion. New this year, the tool will allow for the auto-population of supply plan data from Pipeline and will also enable 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. A

user guide will also be available along with the tool on PEPFAR SharePoint. Members from USAID/SCH and SGAC will be available to provide assistance and support to countries completing this tool.

The Commodities Supply Planning Tool should be completed before 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 (which can be done via automated link within the tools), 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 COP21 implementation period.

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 COP21. 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 OU Collaboration page.

8.7 Resource Alignment

The Resource Alignment collaboration between PEPFAR and the Global Fund has enabled the availability of routine financial data to get a more complete understanding of the HIV funding landscape across all sources of funding. This data supports country teams making strategically aligned resource allocation decisions, avoid duplication, drive efficiency, and ensure spending is in line with program priorities and gaps. HIV Resource Alignment country profiles will be available to country teams to inform joint coordination and strategic planning for sustained epidemic control, validating information where necessary, and for inclusion in their SDS investment profile section. More details are in Part A and Section 7.3.4.2.

Country teams will receive pre-populated data tables which, in close coordination with host country counterparts and other stakeholders, they are expected to verify/revise and fill in data gaps specifically

for domestic government and other funders where available. Country teams will send the updated table to their S/GAC Chair and PPM prior to their COP strategic planning retreats (date TBD). This will enable generation of the Resource Alignment Country Profile which will be made available to country teams for their planning retreats. PEPFAR and the Global Fund data will be added to the country profiles directly from their respective HQ systems and therefore, country teams will not need to perform specific verification for these data.

The Resource Alignment country profiles, with standardized format, transparent and rigorous methodology, particularly harmonizing data from 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.

Illustrative questions for country teams to consider when reviewing Resource Alignment Country Profiles:

- Does the funding data across PEPFAR, the Global Fund, and national government reflect alignment with the country's HIV response?
- Does the funding allocation match program priorities and needs?
- Are allocated resources duplicative and is there a need for better alignment between funders?
- Are above-site program investments adequately targeted to address issues in the clinical cascade?
- Are there areas where the agency/host government can prioritize resources based on programmatic gaps and needs?
- Examining actual expenditures against planned investments by specific program areas will help identify areas of low absorptive capacities, investigate possible causes, and develop strategies to address it.

Please contact the S/GAC Office of Financial and Programmatic Sustainability (OFPS) team with any questions: Elan Reuben ereuben@usaid.gov; Michael Ruffner ruffnerme@state.gov; or Matthew Wollmers wollmersm@state.gov.

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 COP20, placeholder new mechanisms were created for each implementing Agency in each of the OUs. These placeholder mechanism IDs will be included in the prepopulated COP21 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 COP21.

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 2.4.1. 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 host 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.
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

All fields on the Construction/Renovation Project Plan form must be completed. There is no minimum or maximum limit on the amount of funds allocated to a construction/renovation project for it to be subject to inclusion in the COP21 submission, i.e., 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.

8.8.2 Motor Vehicles, Including All Transport Vehicles

This tick box is used to identify mechanisms that have purchased and/or leased motor vehicles over the timeframe of the IM/agreement. The main section of the tab requires OUs to provide specific information on each motor vehicle request. Upon clicking the “add” button, you will be required to provide:

- The type of vehicle requested (boat, truck, car, ambulance, motorcycle, etc.)
- The acquisition method for the requested vehicle (leased or purchased)
- The total number/amount of this particular type of vehicle being requested
- The new COP21 funding being requested for the group of vehicles that are batched in this entry.
- NOTE: 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 FY 2021 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 and in the planning level letter.

Applied Pipeline Resources: OU teams must enter the amount of "**Applied Pipeline Funding**," that each mechanism will utilize in COP21 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 COP21 implementation. The applied pipeline is the amount of money not spent in COP19 as well as COP20 funding you project will not be expended by September 30, 2021, and therefore can be used as a part of COP21 (i.e., during FY22). The FAST will auto-sum the applied pipeline with the new COP21 funding requested, by funding account, to indicate the total funding (new + applied pipeline) allocated to each mechanism

In COP21, the applied pipeline field 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.

COP21 Funding Sources

Funding sources and accounts for implementing mechanism records by IM for COP21 funding will be entered in FAST and imported into FACTS Info. Within the FAST, OU teams will provide details of the breakdown across funding accounts and new vs. available pipeline being applied towards COP21 implementation. OU teams are encouraged to think about the new planned COP21 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 COP21 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. 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).

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 COP21 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 COP21 implementation period. The initiatives that are planned for COP21 may vary by OU and will be indicated in the planning levels.

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 agreements 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 COP21 and is posted on the COP21 site of PEPFAR SharePoint. We continue to encourage all agencies to advance agreements with Ministries and greatly expand and strengthen agreements with Ministries of Social Welfare, Women and Girls, Youth and Sports as well as Gender. These are critical to the long-term success of PEPFAR and there is currently only a handful of agreements with these mission essential Ministries.

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". Pending the completion of the COP planning process, agencies with approved funding for G2G mechanisms will provide S/GAC with the information necessary to notify funds for G2G 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 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.[439] 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

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

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.

For example, the MenStar Coalition, launched in 2018, is a global partnership to address the unique needs of at-risk men in the HIV epidemic and expand the diagnosis and treatment of HIV infections in men. The partnership combines private sector expertise in consumer marketing with PEPFAR's existing service delivery infrastructure, to increase the uptake of HIV testing, treatment, and continuity of ART among this target population. This partnership provides an opportunity for countries to leverage the consumer marketing approaches of the private sector to increase the impact of their service delivery to men along different parts of the client-centered cascade. The performance of PPPs should be monitored and evaluated on a regular basis at the OU team level and as part of the country program's regular performance evaluation process. While each PPP may have its customized metrics and/or indicators, it is important for OU teams to monitor PPP performance towards stated goals on a regular basis. Global PPP performance should be reported on a regular basis to headquarters.

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.

- OU Teams are encouraged to make use of the Public Private Partnership Toolkit at https://pepfar.sharepoint.com/:f:/s/PSE/EqTWXDdmbyhGrIKqjvb4D5IBE41TwlgYR3AhHxdfjNNuEA?e=m2n3hX 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 referenced below, as well as the State Department Office of Global Partnerships for additional information at https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/office-of-global-partnerships/.

Figure 8.8.5.1: Community of practice toolkit

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 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.***

Please contact the PSE Team if you have any questions with regards to completing the PPP portion of the COP: Lauren Marks: marksla@state.gov, Neeta Bhandari: bhandarin@state.gov, Kenise Hill: hillkd@state.gov, Gary Kraiss: kraissgp@state.gov, and Laurie Batschi: batschilk@state.gov.

9.0 COP PLANNING LEVELS AND APPLIED PIPELINE

9.1. COP21 Planning

Countries or regions should fund their program based on the COP21 planning level letter, finalizing the notional S/GAC provided budget to the level of in country ambition and final budgets and earmark requirements. COP21 should be planned to the stated level in the letter, which equals the sum of new resources (FY21 and prior fiscal year funds) and prior year available pipeline applied in support of COP21 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 COP21 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 COP21 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 COP21 implementation period in FY 2022.

The COP planning level is the sum of new resources and pipeline applied to COP21 implementation (COP Planning Level = New Funding + Total Applied Pipeline). All outlays anticipated to occur during the COP21 implementation period must be included within the COP21 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. If your OU team determines that there is more pipeline to apply to the implementation of COP21, the budget controls for both the applied pipeline and the new funding account must be updated. Contact your PEPFAR Program Manager prior to final COP21 submission to ensure new funding and applied pipeline control levels are updated within FACTS Info, such that the complete COP submission balances against the budget control figures. 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 COP21 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. Underperforming partners are expected to under-outlay.

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 "excessive pipeline" during the EOFY process should be reflected as applied pipeline and therefore available for implementation

within COP21 to the extent consistent with applicable law and regulations. COP submissions that do not sufficiently allocate excessive 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 COP21 cycle (i.e., construction funding programmed in a previous year that continues to outlay during COP21), as well as the application of prior year funding deemed in excess**.** All agencies within all countries or regions must monitor, analyze, and manage their pipeline throughout the year and ensure that they use are consistent with applicable law and regulations.

Every PEPFAR 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 (Burkina Faso, Ghana, Liberia, Mali, Senegal, Sierra Leone, and Togo); 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 (Burma, Cambodia, India, Indonesia, Kazakhstan, Kyrgyz Republic, Laos, Nepal, Papua New Guinea, Philippines, Republic of Tajikistan, and Thailand); Western Hemisphere Regional Program (, Brazil, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, and Trinidad & Tobago); Country Pair Regional Program: Haiti and Dominican Republic (funding will be notified separately); Ethiopia; South Sudan; and Zimbabwe.

Pipeline above the acceptable level of 3 months (or 4 months for those OUs specified above) is considered "excessive."

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 COP21 mechanism or CODB category (i.e., "applied pipeline") in cases where the threshold for acceptable pipeline (3 or 4 months) has already been achieved.

The funding type field within COP21 is categorized as new or applied pipeline. 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 COP21 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 COP21, i.e., to the COP21 planning level. Applied pipeline will be tracked in both the FAST and in Facts Info at the implementing mechanism, initiative and intervention level.

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 FY21 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 COP21 activity may not match the approved COP21 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 decreased to any mandatory earmark levels.*

9.2 Phase Out of Budget Codes

Beginning in COP21, budget codes will be replaced by interventions. In COP19 a combination of budget codes and interventions were used in the planning process, with both fields requiring manual data entry in the FAST. In COP20, interventions and budget codes were both used again, however in COP20 formulas were used to translate interventions into budget codes with no manual data entry for the budget codes. Beginning in COP21, budget codes will no longer be used as part of the COP process; planning will be based on interventions. Interventions are defined as the unique combination of program area and beneficiary classifications. The six major program areas-care and treatment, prevention, testing, socioeconomic, above-site programs and program management- encompass everything PEPFAR does to achieve and sustain control of the HIV/AIDS epidemic. Each program is disaggregated into subprograms, which are unique to the program. When the activities cannot be disaggregated, funds may be classified under the major program, not disaggregated. The goal is to capture a group of activities with a common outcome; not to capture each discreet work plan activity. The beneficiary populations are the intended recipients of the PEPFAR programs. The seven major beneficiary groups are non-targeted, males, females, key populations, pregnant and breastfeeding women, orphans and vulnerable children, and priority populations. Each

beneficiary is disaggregated into sub-beneficiaries, which are unique to the beneficiary. When the beneficiaries cannot be disaggregated, funds may be classified under the major beneficiary, not disaggregated. The identification of the beneficiary population quantifies the resources specifically allocated to a population. This represents an outcome linked to the resources budgeted or spent, regardless of its effectiveness or effective coverage. Individuals might belong to more than one category. In these cases what needs to be classified is the budget according to the primary objective or intent of the program. Definitions and a full list of all program areas and beneficiaries can be found in the PEPFAR Financial Classifications Reference Guide.

Examples of interventions are:

- Care and Treatment: HIV Clinical Services-Service Delivery—Males: Boys (<15 years)
- Prevention: Condom and Lubricant Programming- Non-Service Delivery—Key Populations: Sex workers
- Program Management: Not Disaggregated—Non-Targeted Population: Not Disaggregated

Interventions will be budgeted in the FAST at the implementing mechanism level. The total number of interventions at each implementing mechanism will depend on several factors, including but not limited to: total budget and size of the IM; whether the IM has specific activities targeting specific beneficiary groups or to achieve program outcomes; total spending of each intervention; and ability to allocate shared costs across program areas. It is recommended that each mechanism plan no more than 20 interventions for the COP cycle. For COP21 planning, USG field teams should be particularly cognizant that the level of detail and disaggregation of the interventions allow for adequate and appropriate budget tracking of all priority technical and programmatic areas.

Planning budgets at the intervention level, rather than the budget code level provides much greater detail on the nature and beneficiary of each PEPFAR program activity. Additionally, since interventions are also the way that expenditures are reported, planning at the intervention level allows funding for each intervention to be tracked all the way through from planning to expenditure reporting. Elimination of budget codes will also significantly simplify data entry in the FAST tool and should simplify the processing of the FAST.

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 COP21, 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.

COP21 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 COP21, 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 COP21. 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 COP21 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 COP21 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, 2021) 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 COP21 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 COP21, 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.

5) Outline any major scopes of work for which ISME assistance is requested during COP21 implementation.

10.2 Staffing and Level-of-Effort Data

OUs **must** update their staffing data within the FACTS NextGen (pre-populated with COP21 staffing data).

10.2.1 Who to Include in the Database

All fully or partially PEPFAR-funded (i.e., GHP, GAP, or other PEPFAR fund accounts) current, vacant (as of March 1, 2021), and proposed positions working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities. Note that **all** PEPFAR-funded staff must be included in the staffing data.

Any non-PEPFAR-funded current, vacant (as of March 1, 2021), and proposed positions that are involved in decision making for PEPFAR planning, management, procurement, and/or programmatic oversight activities.

Any non-PEPFAR funded current, vacant (as of March 1, 2021 and proposed positions that will spend at least 30 percent of their time working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities.

Include all:

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, GH Pro, ITOPPS) and provides full-time, permanent support to field operations and sits imbedded with U.S. government staff should be included in the staffing data if they are partially or fully funded by PEPFAR and/or otherwise 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 COP20. A complete and correct staffing matrix is needed for successful COP21 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 COP21, 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 COP21.

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 FACTS Info. 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 in the M&O section, 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.

If there is any funding requested for the following CODB categories, then you must complete the "Item Description" field associated with the category and planned amount.

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). The narrative should be no more than 500 characters.

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. The narrative should be no more than 500 characters.

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 1000 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 host 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 does NOT include required relocation and R&R travel (those are included in U.S. government Salaries and Benefits).

This category includes the costs associated with technical staff travel and travel costs associated with the provision of technical assistance. All costs associated with technical staff time should be reflected within M&O; 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 COP20, in COP21, technical assistance-related travel costs of HHS/CDC HQ staff for trips of less than 3 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 shared common administrative support services and

Equitably distribute 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 http://www.state.gov/m/a/dir/regs/fah/c23257.htm.

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 FY 2022 anticipated ICASS costs. This FY 2022 ICASS cost estimate, by agency, should then be included as the planned ICASS funding.

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 FY 2022 with new COP21 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 FY22, 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 COP20) 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 FACTS Info PEPFAR Module.

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, 2021** and **September 30, 2022**.

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 **2022** will have expenses in **FY 2022 (four months), FY 2023 and FY 2024 (eleven months)**.

Volunteers arriving in September **2022** will have expenses in **FY 2022 (one month), FY 2023, FY 2024, and FY 2025 (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., adds on a new structure or expands the outside walls).
>
> **Renovation** – refers to projects with existing facilities intended to accommodate a change in use, square footage, technical capacity, and or other infrastructure improvements.
>
> **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.

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, and 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 and implementing mechanisms may contribute to the ESCM account through the Capital Security Cost Sharing program.

PEPFAR Funding May Be Used to Lease U.S. Government-Use Facilities

Where essential office space or living quarters cannot be obtained through the Embassy or USAID Mission, a request to use PEPFAR funds may be made 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" that is 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 support from the Ambassador that justifies the renovation project. 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 may require the clearance of the State/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, 2021;
- Projected Volunteer Extensions on board as of October 1, 2021;
- Projected Peace Corps Response Volunteers on board as of October 1, 2021;
- New Volunteers proposed in COP21;
- Volunteer Extensions proposed in COP21; and
- New Peace Corps Response Volunteers proposed in COP21.
- Peace Corps Washington will obtain this information from Peace Corps country programs.

11.0 OTHER ELEMENTS

11.1 Small Grants Program

Beginning in FY 2005, program funds were made available for all PEPFAR countries and regional programs to support the development of small, local partners. The program is known as the PEPFAR Small Grants Program and replaced the Ambassador's Self-Help Funds program for those activities addressing HIV/AIDS. These grants provide an opportunity for OU teams to address diverse issues specific to each country context. In prior years, grants have supported a wide range of activities, including but not limited to:

- Training for local press to effectively cover HIV/AIDS
- Building capacity within civil society organizations to combat LGBTQ stigma and discrimination
- Developing education and cultural programs for HIV prevention and awareness, including for PLHV and key populations (MSM, PWID, TG, SW, and prisoners)
- Providing job skills training for women and girls living with HIV
- Developing networks of PLHIV to increase retention in care
- Beginning in COP20, this is the preferred mechanism for Community-led Monitoring (see Section 3.3.1.2)

Country and regional programs should submit an entry for the PEPFAR Small Grants Program as part of their yearly COP. The total dollar amount should include all costs associated with the program, including support and overhead to an institutional contract to oversee grant management if that is the preferred implementing mechanism. As described in previous sections, all PEPFAR programs will need to provide evidence of increased engagement of local partners across the entire spectrum of HIV services, and consideration should be given to FBOs and other groups to either establish or expand HIV service delivery to local communities. A program can have limited funding for a CSO technical assistance mechanism in addition to small grants, which should not supplant direct funding to CSOs for CLM.

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

PROTECTING LIFE IN GLOBAL HEALTH ASSISTANCE AWARD PROVISION — A required provision in all grants and cooperative agreements that provide global health assistance using U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funding. The requirements apply to such assistance provided to, or implemented by, foreign non-governmental organizations or that U.S. NGOs provide to foreign NGOs through sub-awards. For more information, see Section 5.9.4 and go to https://www.state.gov/protecting-life-in-global-health-assistance-award-provision/

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 of the newest on-line training course: PY478 - Federal Assistance: Closeout. This completes the series of online courses that 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 will replace PY220, PY220, and PY224.

In-person Course	**Total Hours**
PY260/Federal Assistance Management	40 hours
Total In-Person Course Hours	**40 hours**
Online Courses	**Total Hours**
PY472/Federal Assistance: Pre-Award	16 hours
PY474/Federal Assistance: Award	4 hours
PY476/Federal Assistance: Post-Award	16 hours
PY478/Federal Assistance: Closeout	4 hours
Total Online Course Hours	**40 hours**

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.

Additional Requirements for Construction/Renovation

OU teams that have small grant applications for construction/renovation need to submit a ***Small Grants Program - Construction/Renovation Project Plan*** form for each construction/ renovation project (under an already approved COP implementing mechanism) for

review/approval throughout the year (there is no set time for submission but is as needed based on the country's small grants award timeline).

Please send the project plan form applications directly to your PEPFAR Program Manager (copy the Management and Budget team at PEPFAR-Construction-Renovation@state.gov) throughout the year during your small grant proposal review periods. Note, all form fields need to be completed.

The form(s) will be uploaded into the **FACTS Info – PEPFAR Module Document Library** as part of the COP Submission after it is reviewed and approved.

Once the OU receives confirmation from S/GAC that the small grant applications have been approved, the OU team needs to the upload the approved application forms (for construction/renovation only) into the **FACTS Info – PEPFAR Module Document Library** under the approved COP cycle (e.g., if the 'small grants program' implementing mechanism was approved in the COP16, then the S/GAC approved small grant applications need to be uploaded in the Facts Info Document Library under the COP16 cycle).

The ***Small Grants Program - Construction/Renovation Project Plan*** form template is located at the PEPFAR SharePoint within the COP19 Planning and Reporting cycle folder.

11.2 Construction and Renovation of Laboratories

This supplemental document is required for all biosafety level (BSL)-3 and BSL-2 enhanced laboratory construction or renovation projects. To submit, upload the completed template to the FACTS Info COP21 document library as part of the COP submission. Please provide the following as a supplement to your project proposal:

Receiving institution information:

- Name of receiving institution
- Address of receiving institution
- A point of contact at the institution

Purpose of proposed lab:

- Expected containment level (BSL-2 enhanced or BSL-3)
- If enhanced BSL-2, what specific enhancements are planned?
- Rationale for why that containment level is required

Presentation of an analysis of alternatives, if appropriate, or plans to conduct one

List of Select Agents (if any) and toxins (if any) that the lab anticipates handling

Proposed timeline:

Including additional planning, funding, design and construction

Proposed construction end date/building delivery

For transition to host country oversight, sustainability:

What Ministry/organization/institution will be responsible for long-term sustainability of the lab?

Involvement of other domestic/international partners

11.3 Technical Assistance Available for Global Fund Activities

Since 2005, the U.S. government (USG) has been permitted to withhold up to five percent of its annual contributions to the Global Fund to provide technical assistance (TA) to assist countries in overcoming bottlenecks in performance and improving Global Fund grant implementation. These funds are programmed on an annual basis in prioritized countries and technical areas to achieve outcomes in ending the three diseases of HIV/AIDS, Tuberculosis (TB), and Malaria. Through PEPFAR, the President's Malaria Initiative (PMI), and USAID TB programs, technical assistance is coordinated with U.S. bilateral programs to augment desired disease outcomes.

While some countries have U.S. Mission staff and partners already working closely with Principal Recipients (PRs) and Sub Recipients (SRs), Country Coordinating Mechanisms (CCMs) and committees within CCMs on the ground, other countries do not have this presence and may have insufficient resources to be able to provide support. For these reasons, the USG has some resources set aside for technical assistance in "non-presence" countries to address key program issues in Global Fund grant implementation. Countries at risk of not achieving results and therefore not having the needed impact on controlling the three diseases are also prioritized.

The Global Fund's 2020-2022 Allocation Period will begin in 2021 and countries eligible have been submitting new funding requests (NFRs) during calendar year 2020, which aligned well with the COP20 submission process. For HIV, PEPFAR OU teams are encouraged to review needs that were identified through the joint planning process for COP20 and the Global Fund's

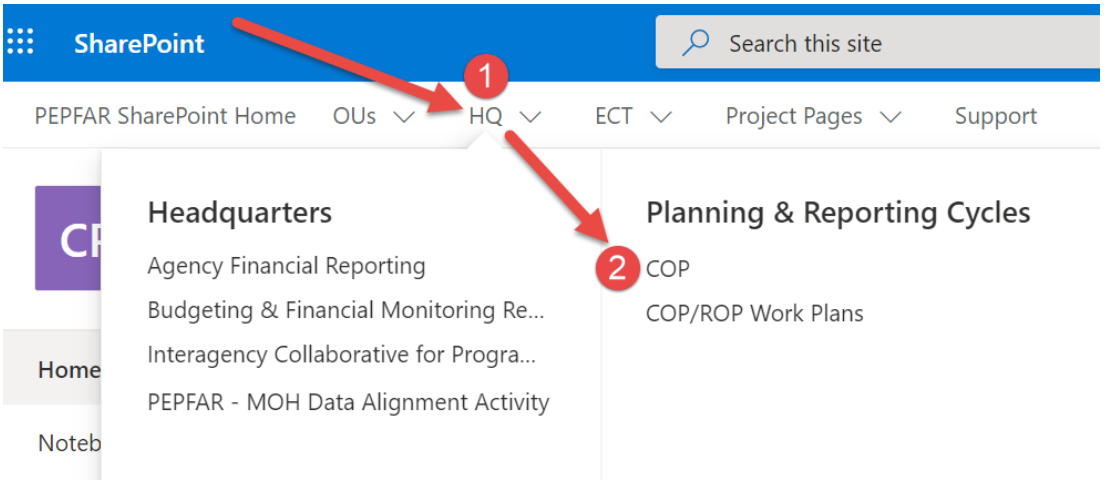
NFR process to assess potential additional needs—in consultation with Global Fund and UNAIDS contacts—and convey these needs to HQ to inform allocation of Global Fund technical assistance resources.

11.4 PEPFAR SharePoint Contacts and Help Information

COP21 Resources on PEPFAR SharePoint:

Templates and guidance documents for COP21 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 in the main menu from the PEPFAR Homepage as shown in Figure 11.4.1. (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.

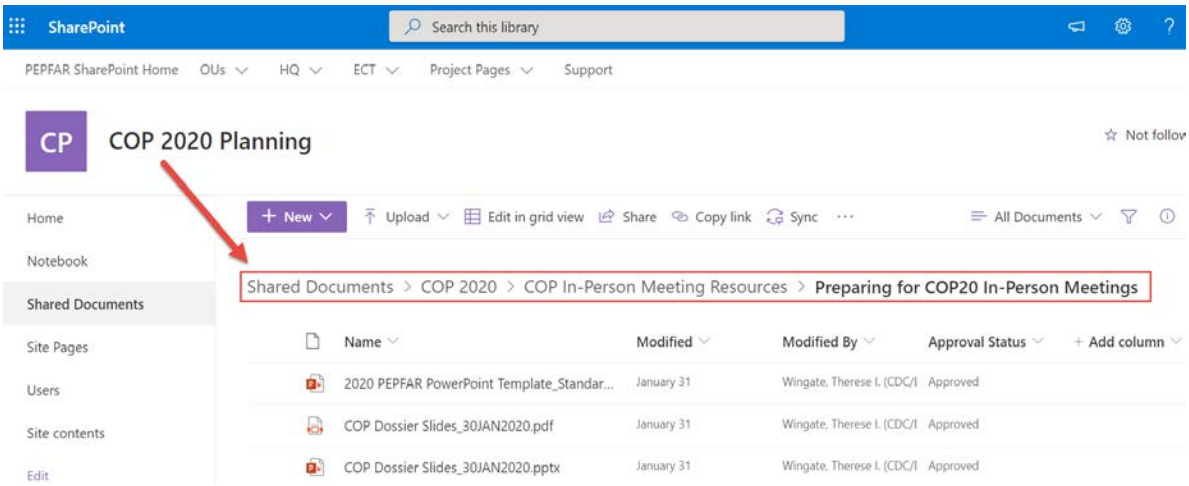
Figure 11.4.1 How to find the COP page on PEPFAR SharePoint



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".

Figure 11.4.2 An example document path in SharePoint Online.



Logging in to PEPFAR SharePoint (users *with* existing access to Pepfar.net):

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 access to Pepfar.net):

PEPFAR SharePoint invitations should be requested by submitting a New Account Request 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.*

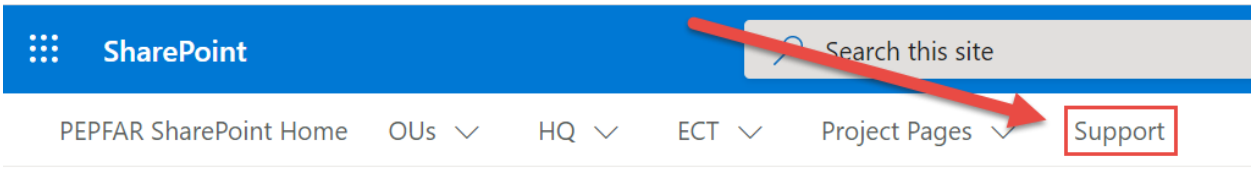
Obtaining access to specific pages within PEPFAR SharePoint:

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 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 11.4.3 How to access support in SharePoint Online



11.5 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

ACT – Accelerating Children's HIV/AIDS Treatment

AFG – AIDS-free Generation

AGYW – Adolescent girls and young women

AIDS – Acquired Immune Deficiency Syndrome

ANC – Antenatal clinic

A/OPE – Administration /Office of the Procurement Executive

AOR – Agreement Officer's Representative

AOTR – Agreement Officer Technical Representative

APR – Annual Program Results

APS – Annual Program Statement

ART – Antiretroviral Therapy

ARV – Antiretroviral

ASLM – African Society for Laboratory Medicine

B+ – Option B+

BSL – Biosafety level

CAS – Corrective Action Summary

CAST – Country Accountability Support Team

CBO – Community-based organization

CCM – Country coordinating mechanism

CDC – Centers for Disease Control and Prevention (part of HHS)

CEE – Core essential element

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.

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

CQI – Continuous Quality Improvement

CQM – Continuous Quality Management

CrAg – Cryptococcal Antigen

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

CTO/CTOR – Cognizant Technical Officer/Cognizant Technical Officer Representative

CTX – Cotrimoxazole

DATIM – Data for Accountability, Transparency, and Impact Monitoring

DBS – Dried blood spots

DCMM – DC Management Meetings

DFID – Department for International Development (UK)

DHS – Demographic and Health Surveys program

DOD – U.S. Department of Defense

DOL – U.S. Department of Labor

DOS – U.S. Department of State

DP – Deputy Principal

DREAMS – Determined, Resilient, Empowered, AIDS-free, Mentored, Safe partnership

DRM – Domestic resource mobilization

DSD – Direct Service delivery

DTG – Dolutegravir

DTS – Dried tube specimen

EAP – East Asian and Pacific Affairs (State Department Bureau)

ECT – Epidemic Control Team

EFV – Efavirenz

EID – Early-infant diagnosis

EOFY – End of Fiscal Year

EQA – External quality assessment

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

FBO – Faith-based organization

FDA – Food and Drug Administration (part of HHS)

FDC – Fixed dose combination

FJD – Framework Job Description

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

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”)

GHAI – Global HIV/AIDS Initiative (funding account; replaced by GHCS-State)

GHCS – Global Health Child Survival funds (funding account)

GHI – Global Health Initiative

GHP – Global Health Programs

GHSC-PSM – Global Health Supply Chain Program - Procurement and Supply Management

GHSC-RTK – Global Health Supply Chain Program - Rapid Test Kits

GOR – Grant Officer Representative

GSD – Gender and Sexual Diversity Training

HCD – Human capacity development

HCN – Host Country National

HW – Health Workers

HEI – HIV-exposed infants

HHS – U.S. Department of Health and Human Services

HIV – Human Immunodeficiency Virus

HIVDR – HIV Drug Resistant (surveys)

HIVRTCQI – HIV Rapid Testing Continuous Quality Improvement

HIVST – HIV self-testing

HMIS – Health Management Information System

HOP – Headquarters Operational Plan

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)

HTS – HIV Testing Services (formerly HIV Testing and Counseling – HTC)

IAA – Inter-agency Agreement

IAPAC – International Association of Providers of AIDS Care

IBBS – Integrated Bio-Behavioral Survey

IC – Institutional Contractor

ICASS – International Cooperative Administrative Support Services

ICF – Intensified Case Finding

ICPI – Interagency Cooperative for Program Improvement

IIT – Interruption in Treatment

IM – Implementing mechanism

INH – Isoniazid

INR – Intelligence and Research (State Department Bureau)

IPT – Isoniazid preventive therapy

IQC – Indefinite quantity contract

IRM – Information resources management

IS – Implementation science

ISME – Implementation Subject Matter Expert

ITSO – IT support

IVT – Infant virologic testing

KENAS – Kenya Accreditation Service

KP – Key populations

LAM – Lipoarabinomannan

LCI – Local Capacity Initiative

LCP – Local Compensation Plan

LCQI – Laboratory continuous quality improvement

LE – Locally Employed (Staff)

LEA – Legal Environment Assessment

LEEP – Loop electrosurgical excision procedure

LGBTI – Lesbian, gay, bisexual, transgender, and intersex

LIS – Lab Information Systems

LMIS – Lab Management Information Systems

LOE – Level of effort

LTFU – Lost to follow up: The term interruption in treatment is being used in the guidance.

LZN – Lamivudine/Zidovudine/Nevirapine

M&E – Monitoring and evaluation

M&O – Management and Operations

MAT – Medication Assisted Treatment

MER – Monitoring, Evaluation, and Reporting

MMD – Multi-Month Dispensing

MMS – Multi-Month Scripting

MMT – Methadone Maintenance Treatment

MOA – Memorandum of Agreement

MOH – Ministries of Health

MOU – Memorandum of Understanding

MSM – Men who have sex with men

MTCT – Mother-to-child-transmission

MUAC – Mid-upper arm circumference

NACS – Nutrition Assessment Counseling and Support

NAE – Notifiable Adverse Event

NAT – Nucleic acid test

NTD – Neural Tube Defect

NEA – Near Eastern Affairs (State)

NFR – New funding requests

NGO – Non-governmental organization

NIH – National Institutes of Health (part of HHS)

NVP – Nevirapine

OE – Operating expense

OGA – Office of Global Affairs (part of HHS)

OR – Operations research

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

PCRV – Peace Corps Response Volunteer

PCV – Peace Corps Volunteer

PEM – Preventative equipment maintenance

PEP – Post-exposure prophylaxis

PEPFAR – President's Emergency Plan for AIDS Relief

PEPFAR SharePoint – the website, available to U.S. government staff only, which houses COP19 templates and guidance

PHDP – Positive Health, Dignity, and Prevention

PHIA – Population-based HIV Impact Assessment

PI – Protease inhibitor

PITC – Provider-initiated testing and counseling

PLGHA – Protecting Life in Global Health Assistance

PLHIV/PLWHA/PLWA – People Living with HIV/AIDS or People Living with AIDS

PM – Political-Military Affairs (State Department Bureau)

PMTCT – Prevention of mother-to-child HIV transmission

POART – PEPFAR Oversight and Accountability Response Team

POC – Point of care

PPM – PEPFAR Program Manager

PPP – Public-Private Partnership

PR – Principal recipient

PrEP – Pre-exposure prophylaxis

PSA – Personal Services Agreements

PSC – Personal Services Contract

PSE – Private Sector Engagement

PSNU – Priority sub-national unit

PWID – People who inject drugs

QA – Quality assurance

QI – Quality improvement

QMEC – Quality management for epidemic control

RCNF – Robert Carr civil society Networks Fund

RM – Responsibility Matrix

ROP – Regional Operational Plan

RPM – Regional Planning Meeting

RPSO – Regional Procurement Support Offices

RSSH – Resilient and Sustainable Systems for Health

RT – Rapid testing

RTK – Rapid test kit

SABERS – HIV Seroprevalence and Behavioral Epidemiology Risk Survey (DOD)

SAMHSA – Substance Abuse and Mental Health Services Administration (part of HHS)

SAPR – Semi-Annual Program Results

SCA – South and Central Asian Affairs (State Department Bureau)

SCMS –Supply Chain Management System

SDS – Strategic Direction Summary

S/GAC – Office of the U.S. Global AIDS Coordinator (part of State)

SI – Strategic Information

SID – Sustainability Index and Dashboard

SIMS – Site Improvement through Monitoring System

SNU – Sub-national unit

SPI-RT – Stepwise Process for Improving the Quality of HIV Rapid Testing

SRE – Surveillance, Research, and Evaluation

STAR – Strategic and Technical Alignment for Results process for completing COP

STI – Sexually transmitted infection

SW – Sex workers

TA – Technical assistance

TB – Tuberculosis

TBD – To Be Determined

TBT – TB preventative treatment

TCN – Third Country National

TEE – Tenofovir/efavirenz/emtricitabine

TG – Transgender people

TLD – Tenofovir/lamivudine/dolutegravir

TLE – Tenofovir/lamivudine/efavirenz

TPT – TB preventive treatment

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

UNAIDS – Joint United Nations Program on HIV/AIDS

UNDP – United Nations Development Program

UNICEF – United Nations Children's Fund

U.S. – United States

USAID – U.S. Agency for International Development

USDA – U.S. Department of Agriculture

USDH – U.S. direct hire

USPSC – U.S. personal services contractor

UTAP – University Technical Assistance Project

VAST – Volunteer Activities Support and Training

VCT – Voluntary counseling and testing

VL – Viral load

VLS – Viral load suppression

VMMC – Voluntary medical male circumcision

WHA -– Western Hemisphere Affairs (State Department Bureau)

WHO – World Health Organization

WISN – Workload indicator of staffing need